APPENDIX C

SHORT-TERM TOXICITY VALUES

The short-term effectiveness criterion for evaluating remedial alternatives includes an evaluation of the risks due to the short-term exposure of populations to contaminants during remedy implementation. Such short-term risks generally include both baseline risks from existing site contamination and new risks that would occur during the implementation of a remedy. In some cases, potential exposures and risks due to short-term exposures should be quantitatively assessed; however, there is no simple or widely accepted method for estimating such risks. Therefore, in all cases where short-term toxicity values are needed, TSC should be consulted. EPA's Environmental Criteria and Assessment Office (ECAO; where TSC is located) will maintain the data files for the most appropriate short-term toxicity values for evaluating risks from remedial alternatives. To obtain the most up-to-date information, regional EPA CERCLA staff must contact:

Superfund Health Risk Technical
Support Center
Environmental Criteria and Assessment Office
U.S. Environmental Protection Agency
Mail Stop 114
26 West Martin Luther King Drive
Cincinnati, OH 45268
Phone: 513-569-7300 (FTS-684-7300)
FAX: 513-569-7159 (FTS-684-7159)

Requests from others must be submitted to the TSC in writing and must contain the following information for consideration:

- CERCLA site name, site location, and 12-digit site number;
- name and phone number of the RPM; and
- detailed description of the risk assessment related question.

The remainder of this appendix provides some general background on exposure duration issues and an overview of some of the existing methods for deriving short-term human health toxicity values.

C.1 BACKGROUND ON EXPOSURE DURATION

In assessing short-term risks of remedial alternatives, the time frame (e.g., hours, days, weeks up to seven years) is generally of a much shorter duration than that identified in the baseline risk assessment. Nevertheless, there are a number of types of toxicity values that have been developed to characterize risk due to these short-term exposures. Some of these types depend on concentration- or dose-based threshold limits that are used as guidance levels for protection of specific populations from specific exposures (e.g., guidance levels intended to protect healthy workers from daily occupational exposure to chemicals in the workplace). In this section, the types of exposure durations commonly suggested or implied by the toxicity value types (discussed later) are presented.

Releases that may occur during remedy implementation could last for varying durations but are expected, in most if not all cases, to give rise to less-than-lifetime exposures. Furthermore, releases that occur during remediation may result in exposure levels much higher than those preceding remediation. Different risk levels may be associated with these different exposure durations (assuming the same dose rate) and with various exposure concentrations. Therefore, it is important that the dose- or concentration-based toxicity values that are chosen to characterize the short-term risks be based on appropriate exposure durations. Exposure durations associated with existing methods for characterizing short-term risks include hours, days, weeks, months, and years (generally up to seven years).

Currently, RAGS/HHEM Part A defines three exposure durations, apart from long-term exposure, that may be of concern at CERCLA sites: single

exposure event, very short-term exposure, and short-term (subchronic) exposure.

- **Single Exposure Event.** The majority of chemicals are capable of producing an adverse health effect after a single exposure event, depending on the intensity of exposure. For developmental toxicants, irritants, and neurological poisons, a single, low level exposure event can result in effects after minutes, hours, or a day.

- **Very Short-term Exposure.** For some acute toxicants, multiple exposures over several days could result in an adverse effect. For these chemicals, the exposure is assessed over days or weeks (up to two weeks).

- **Short-term (Subchronic) Exposure.** Exposure lasting anywhere from two weeks to seven years to low concentrations of a chemical can also produce adverse effects; this exposure is assessed by averaging it over the specific duration.

During evaluations of remedial alternatives, it may be important to assess exposure (and risk or hazard) for all relevant exposure durations. Both the shortest time period of exposure, from peak or accidental releases, to the cumulative exposure over the entire time period of the remedy implementation, may need to be considered. Quantitative assessment is contingent, however, upon the availability of adequate exposure characterization. Exposure models used to predict concentrations have not for the most part been validated over the short durations considered for single exposure events (e.g., minutes to hours). At best, meteorological data are collected on an hourly basis at a site removed from the location of interest; using these data to derive a model to predict exposure concentrations for durations shorter than those for the meteorological data may produce results that could not be supported scientifically. In addition, the need to evaluate peak exposures as well as longer-term average exposures during remedy implementation depends on a number of considerations, including the degree of risk or hazard associated with the longer-term exposure and the difference between the predicted peak and average exposure concentrations.

A review of the types of (duration-specific) toxicity values that are available (discussed later in this appendix) indicates that a number of the types correspond to various durations that are relevant to releases during remedy implementation. Because a toxicity value generally is specific to a certain duration, however, risk may need to be characterized separately for the three short-term exposure durations.

C.2 EXISTING SHORT-TERM TOXICITY VALUES

In this section, commonly encountered short-term toxicity values are summarized. These values are: (1) concentration and dose threshold values primarily for noncarcinogenic effects; and (2) specific short-term carcinogenic risk values. A section is provided on each of these toxicity value categories.

C.2.1 TOXICITY VALUES FOR ASSESSING RISK OF NONCARCINOGENIC EFFECTS FOR SHORT-TERM EXPOSURE

Toxicity values designed to characterize the risk of noncarcinogenic effects are summarized in the following subsections. Further information on the suitability of these values for various CERCLA exposure scenarios can be obtained from the TSC.

C.2.1.1 Developmental Toxicant Reference Dose (RfD_{dt}) and Reference Concentration (RfC_{dt})

RfD_{dt}s and RfC_{dt}s are developed for chemicals that have been shown to cause adverse effects in a developing organism. EPA's Human Health Assessment Group of the Office of Health and Environmental Assessment is in the process of developing RfD_{dt} and RfC_{dt} values and the methodology for their derivation. As proposed by EPA (EPA 1989b), these values will likely be derived from the no-observed-adverse-effect-level (NOAEL) or lowest-observed-adverse-effect-level (LOAEL) in a manner consistent with the derivation of reference doses (RfDs) and reference concentrations (RfCs), and without adjustment for short exposure duration. RfD_{dt}s are expressed in terms of dose and RfC_{dt}s are expressed as an air concentration. Additional information on these criteria is available in EPA's Proposed Amendments to the Guidelines for the Health Assessment of Suspected Developmental Toxicants (EPA 1989b), or by contacting the Reproductive

and Developmental Toxicology Branch of the Office of Health and Environmental Assessment at 202-260-7331 (FTS-260-7331).

Currently (i.e., at the date of publication of this guidance), developmental toxicity is considered in the derivation of EPA criteria for noncarcinogenic effects (including RfDs and RfCs for subchronic and chronic exposure and drinking water Health Advisories [HAs]). That is, these criteria are set at levels considered protective for developmental effects as well as for other noncarcinogenic effects.

C.2.1.2 Subchronic Reference Dose (RfD_s) and Reference Concentration (RfC_s)

RfD_ss and RfC_ss are developed by ECAO and are used to characterize potential noncarcinogenic effects associated with short-term exposures (two weeks to seven years as defined in RAGS/HHEM Part A). To date, approximately 305 RfD_ss and 60 RfC_ss have been published. These RfDs and RfCs are developed based on NOAELs or LOAELs identified from subchronic (i.e., usually $\geq$90 days but less-than-chronic) toxicity studies. RfD_ss are expressed in terms of dose and RfC_ss are expressed as air concentrations. Subchronic RfDs and RfCs are available in HEAST. The derivation of RfD_ss is described in more detail in RAGS/HHEM Part A.

C.2.1.3 One-day, Ten-day, and Longer-term Drinking Water Health Advisories (HAs)

Drinking water HAs developed by EPA provide guidance to assist state and local officials responsible for public health protection during emergency situations involving drinking water contamination. HAs are derived in a manner reasonably consistent with oral RfD methodology. Accordingly, these HA values constitute suitable criteria for evaluating short-term oral exposure. The HA concentrations include a margin of safety to protect sensitive members of the population (e.g., children, the elderly, pregnant women). "One-day HA" is the term used to describe the concentration of a chemical in drinking water that is not expected to cause any adverse noncarcinogenic effects for one day of exposure, with a margin of safety. The "Ten-day HA" describes the concentration of a chemical in drinking water that is not expected to cause any adverse noncarcinogenic health effects for two to ten consecutive days of exposure, with a margin of safety. The "Longer-term HA" is the concentration of a chemical in drinking water that is not expected to cause any adverse noncarcinogenic effects up to approximately seven years of exposure. ("Lifetime HAs" that are protective for exposure over a lifetime are also developed based on chronic RfDs.)

In general, the HAs described here are protective of only noncarcinogenic effects. These values are expressed as concentrations in drinking water but can be converted to mg/kg/day doses by using the assumptions that were applied in their calculation: consumption of 1 L/day by a 10 kg child (one-, ten-, and longer-term HAs) and 2 L/day by a 70-kg adult (lifetime HA). Approximately 140 HAs have been developed by EPA for each exposure duration. (HAs are briefly described in RAGS/HHEM Part A.)

C.2.1.4 Acute Inhalation Criteria (AIC)

A report describing the derivation of AICs for benzene and beryllium is available through the TSC. AICs are derived as criteria for single, short-duration (up to an hour or a few hours) inhalation exposures, as may occur from releases during remediation. The AICs are based on noncancer endpoints and are expressed as air concentrations. AICs have been derived for a limited number of chemicals using EPA RfC methodology, modified as required for this acute exposure scenario. The modification consists of using the NOAEL (or LOAEL) as reported in the study without adjustment for exposure duration (hours/24 hours). Because these criteria are conceptually consistent with inhalation RfCs, they are a good basis for assessing short-term risks from single, very short exposures. The TSC should be contacted for additional AIC values.

C.2.1.5 Minimal Risk Levels (MRLs)

MRLs are derived by the Agency for Toxic Substances and Disease Registry (ATSDR) from human or animal studies for threshold effects on chemicals found at CERCLA hazardous waste sites. MRLs are developed for both inhalation and oral exposures; oral MRLs are expressed as doses and inhalation MRLs are expressed as concentrations in air. Estimates of exposure posing minimal risk to humans are made for the most sensitive noncarcinogenic endpoint (including developmental and reproductive endpoints) for three different exposure durations (i.e., acute,

intermediate, and chronic). These exposure durations for which MRLs are derived are as follows: acute MRL — 1 to 14 days; intermediate MRL — 15 to 364 days; chronic MRL — ≥365 days. MRLs are developed using an approach that is consistent with EPA RfD methodology (i.e., identification of a NOAEL or LOAEL and application of uncertainty factors to reflect human variability and, where appropriate, the uncertainty of extrapolating from laboratory animal data to humans).

Acute inhalation MRLs differ from AIC in regard to adjustment for exposure duration. The guidance for derivation of acute inhalation MRLs specifies that "exposure periods of less than 24 hours in the toxicity study from which the MRL is derived, can be adjusted to one day" (ATSDR 1991); this adjustment is commonly carried out. No such adjustment is carried out in the derivation of AICs, which are intended to serve as guidance for acute, very short, and single exposures (e.g., ranging from less than an hour to a few hours, perhaps as inadvertent releases during remediation).

MRLs can be found in the ATSDR Toxicological Profile documents in the Health Effects Summary section, on the Levels of Significant Exposure figure (graph). The bottom of the dotted line on the graph represents the MRL. Except in the earliest ATSDR Toxicological Profiles, MRL values and the endpoints on which they are based are also identified in the text accompanying the figure. To date, approximately 62 acute MRLs (38 oral, 24 inhalation) have been derived by ATSDR. As with other short-term toxicity values, guidance regarding use of the MRL must be sought from the TSC.

C.2.1.6 Emergency Exposure Guidance Level (EEGL), Short-term Public Emergency Guidance Level (SPEGL), and Continuous Exposure Guidance Level (CEGL)

EEGLs and CEGLs are exposure guidance levels developed by the National Research Council (NRC 1986) specifically for military personnel operating under emergency conditions. Therefore, setting of these levels involves consideration of various factors (such as age distribution, length of exposure, and susceptibility) that are different from those related to the general population. These guidance levels are published in the NRC (1984-1988) *Emergency and Continuous Exposure Guidance Levels for Selected Airborne Contaminants*. To date, 43 chemicals have been evaluated by NRC.

The EEGL is defined as the air concentration of a substance that is acceptable for the performance of specific tasks during rare emergencies usually lasting from 1 to 24 hours (i.e., it is a ceiling guidance level for a single emergency exposure) (NRC 1986). EEGLs are intended to prevent irreversible harm or serious impairment of judgment or performance. Exposure at an EEGL might produce reversible effects, and therefore should not be considered hygienic or safe. Acute toxicity is the primary basis for establishing an EEGL. However, even brief exposure to some substances might have the potential to increase the risk of cancer or other delayed effects. Derivation of an EEGL may involve application of an uncertainty factor of ten to extrapolate from animal data to humans, but no other species adjustments are applied. Some EEGLs are based on extrapolation of oral data. EEGLs are based on the most sensitive or most important noncarcinogenic health effects known. Because EEGLs are derived for healthy military personnel during rare emergencies, and are not intended to protect against reversible effects, they should not be applied directly to the general population (NRC 1986).

The SPEGL is defined as a suitable concentration for unpredicted, single, short-term emergency exposure of 1 to 24 hours of the general public. SPEGLs take into account the wide range of susceptibility of the general public. The SPEGL is generally estimated by applying an uncertainty factor of two to ten to the EEGL, to account for sensitive groups — such as children, the elderly, and persons with serious debilitating diseases. NRC (1986) suggests that a safety factor of two (i.e., EEGL x 0.5) is appropriate to protect more sensitive groups, such as children or the elderly, and that a safety factor of ten (i.e., EEGL x 0.1) is appropriate for fetuses or newborns. Because the SPEGL is derived from the EEGL, the considerations discussed above with regard to the EEGL also apply to SPEGLs.

The CEGL is defined as a ceiling concentration of a chemical in air to which military personnel can be exposed for up to 90 days without immediate or delayed adverse effects or degradation of performance (NRC 1986). CEGLs

are not derived for carcinogens. When data from chronic studies are available, they can be used to derive CEGLs. A CEGL is generally estimated, however, by applying an uncertainty factor of 10 to 100 to the EEGL (i.e., EEGL x 0.01 to 0.1), depending on the evidence for detoxification or accumulation of the substance in the body. Where there is evidence of substantial detoxification, a safety factor of ten is recommended by NRC (1986). If there is no evidence of detoxification or detoxification is slow, a safety factor of 100 might be more appropriate. If the substance accumulates in tissues, such as halogenated biphenyls and metals, even higher factors are recommended by NRC (1986). Other considerations discussed with regard to the EEGL also apply to CEGLs derived from EEGLs.

C.2.1.7 Threshold Limit Values — Short-term Exposure Limits (TLV-STELs), Threshold Limit Values — Time-weighted Averages (TLV-TWA), and Threshold Limit Values — Ceiling (TLV-C)

TLVs are concentrations developed by the American Conference of Governmental Industrial Hygienists (ACGIH) to protect workers from adverse effects of occupational exposure to airborne chemicals. However, because occupational exposure limits are not intended to protect sensitive workers or other populations, are not intended for the assessment of community air pollution or continuous exposure, may not incorporate the most recent toxicological data, may be based on unpublished documentation that is not available for review, and may differ from EPA derivations with respect to weight-of-evidence considerations and use of uncertainty factors, EPA does not endorse the general use of occupational exposure limits in deriving EPA criteria. In addition, it should be noted that the TLVs for a fair number of chemicals are derived by analogy to other chemicals because health effects data are inadequate or lacking.

The TLV-STELs are 15-minute time-weighted average (TWA) exposures that should not be exceeded at any time during the eight-hour work day/40-hour work week and should not occur more than four times a day, with at least 60 minutes between successive exposures in the STEL range (ACGIH 1990). The TLV-STEL is established to prevent workers from suffering irritation, chronic or irreversible tissue damage, or narcosis of sufficient degree to increase the likelihood of accidental injury. Use of the TLV-STEL should be limited to very short, single exposure events. STELs are recommended for substances with acute effects recognized from high short-term exposures in either humans or animals (ACGIH 1990). Approximately 115 TLV-STELs have been published by ACGIH.

The TLV-TWA is the time-weighted average concentration for a normal eight-hour workday/40-hour workweek to which nearly all workers may be exposed, day after day, without adverse effects. The TLV-C is a concentration that should not be exceeded during any part of the working exposure. The ACGIH uses the TLV-C for substances that are particularly fast acting and hence are best controlled by a ceiling limit. In excess of 500 TLV-TWAs and fewer than 50 TLV-Cs have been published by ACGIH.

C.2.1.8 Permissible Exposure Levels (PELs) and Recommended Exposure Limits (RELs)

PELs are enforceable occupational exposure standards developed by the Occupational Safety and Health Administration (OSHA). They are meant to protect workers against catastrophic effects (such as cancer; cardiovascular, liver, and kidney damage; and lung diseases) as well as more subtle effects resulting in central nervous system damage, narcosis, respiratory effects, and sensory irritation. The PELs are generally adopted from (existing) secondary guidance levels (e.g., ACGIH's TLV-TWAs and TLV-STELs and the recommended exposure limits [RELs] developed by the National Institute for Occupational Safety and Health [NIOSH]), and nearly 400 are available from OSHA. EPA's reservations concerning the use of TLVs as the basis for criteria to protect the general population (see Section C.2.1.7) apply also to PELs and RELs.

C.2.1.9 Other Miscellaneous Methods

The following are some other methods that risk assessors or RPMs may encounter.

- **Immediately Dangerous to Life and Health (IDLH) Guidelines.** IDLH guidelines are developed by NIOSH. These air concentration limits are for 30-minute exposures under what are essentially emergency conditions, and generally far exceed corresponding TLV-TWA, TLV-STELs or PELs. IDLH guidelines were

determined only for the purpose of respirator selection. These guidelines are intended to be the maximum air concentration from which, in the event of respirator failure, a worker could escape within 30 minutes without experiencing any escape-impairing or irreversible health effects (NIOSH 1985). Many of the IDLH exposure levels are so high that they define levels at which severe toxic effects (unconsciousness, incapacitation, intolerable irritation or death) would be likely (Alexeef *et al.* 1989). Therefore, the IDLH guidelines are not suitable as benchmark guidelines for acute exposure and may be higher than would be useful even as a guideline for immediate evacuation.

- **CERCLA Section 102(a) Reportable Quantities (RQs).** RQs are developed by EPA based on, among other factors, acute toxicity, chronic noncarcinogenic toxicity, and carcinogenicity. RQs define the quantity in pounds above which a release is considered potentially hazardous (or, at least, warrants reporting) under CERCLA section 102(a). The documentation for RQs may contain health effects information that would be useful in determining criteria for short-term exposure but are not by themselves useful in characterizing risks from releases that might occur at a CERCLA site.

C.2.2 SPECIFIC CARCINOGENIC RISK VALUES FOR SHORT-TERM EXPOSURES

There is relatively little guidance available on characterizing risks from short-term exposure to carcinogens. For cancer endpoints, most of the currently available values are specific to lifetime exposure. Many experimental investigations of carcinogenicity involve high-dose, long-duration exposure to compensate for the small number of animals that are used. Carcinogenicity data on short-term or single exposures are virtually nonexistent for most chemicals. For most chemicals, the current scientific view is that any exposure, no matter how short in duration, can result in a carcinogenic risk. Characterizing this risk is complicated, however, because of factors such as age at first exposure and mechanism of the carcinogen's action. Consistent with RAGS/HHEM Part A and the Guidelines for Carcinogen Risk Assessment (EPA 1986a), the preferred approach would be to consider cumulative dose, averaged over a lifetime. This method is discussed in Section C.2.2.1.

Several investigators have reported additional methods to characterize the effects from short-term exposure to carcinogens. Some of these methods are currently being investigated by EPA but are not recommended for short-term carcinogenic assessments at this time. However, brief summaries of these methods are provided below with documentation for the interested reader to pursue.

C.2.2.1 RAGS/HHEM Part A Method

RAGS/HHEM Part A currently recommends that lifetime average exposures always be used to estimate carcinogenic risks. That is, because the cancer toxicity values (i.e., SFs) are based on lifetime average exposures, Part A recommends that less-than-lifetime exposures be converted to equivalent lifetime values for the assessment of risk. (This is also the recommended approach in EPA's Guidelines for Carcinogenic Risk Assessment [EPA 1986].) In this manner, risks from short-term exposures would be averaged over a 70-year lifetime, with modifications for specific chemicals if appropriate, and, therefore, may appear to be relatively minor in comparison to risks from longer-term exposures. While adjusting less-than-lifetime exposure to an equivalent lifetime exposure may be valid for relatively long exposure durations, this adjustment for short-term exposures may underestimate the risk for "early-stage" carcinogens (i.e., DNA-damaging agents).

C.2.2.2 Office of Research and Development (ORD) Interim Method for Vinyl Chloride

EPA's ORD (EPA 1989a) used a study by Drew *et al.* (1983) to determine that the lifetime carcinogenic risk from vinyl chloride inhalation increases when exposure occurs early in life. Drew *et al.* showed that the effects from exposure to vinyl chloride depend on both age at initial exposure and duration of exposure. His data showed that children face higher risks than adults for exposures of a given duration. Cogliano stated that if risk for partial lifetime exposures is estimated by ignoring the age at initial exposure and considering only the duration, the risk will be underestimated for children and overestimated for adults over 30. He proposed that risk for partial

lifetime exposure to vinyl chloride be: (1) estimated as being proportional to the remaining lifetime of the exposed individual, and (2) adjusted depending on the length of exposure. The author also stated that, at this time, this analytical technique is applicable only to vinyl chloride and should not be applied to any other substances. The TSC should be contacted for further guidance on assessing risks from vinyl chloride.

C.2.2.3 EEGLs for Carcinogens

The NRC (1986) has developed a method for deriving EEGLs (1 to 24-hour exposure guidelines) for inhaled carcinogens when the computed cancer risk associated with the toxicity-based EEGL (see Section C.2.1.6) is more than one in 10,000. In these cases, the EEGL is lowered so that the risk is not more than one in 10,000 ($1x10^{-4}$). The NRC method draws on the analysis of Crump and Howe (1984) and appears to employ a higher level of acceptable lifetime risk (i.e., $1x10^{-4}$) than the RAGS/HHEM Part A method. This method is discussed in further detail in *Criteria and Methods for Preparing Emergency Guidance Level (EEGL), Short-term Public Emergency Guidance Level (SPEGL), and Continuous Exposure Guidance Level (CEGL) Documents* (NRC 1986). The 24-hour EEGL for a carcinogen is estimated as follows:

$$EEGL = \frac{d \times 25{,}600}{2.8} \times \frac{R}{\text{level of risk at } d}$$

where:

d = lifetime exposure level (air concentration), as computed by a regulatory agency or by the NRC Committee on Toxicology in accordance with procedures used by regulatory agencies (multistage model) associated with "acceptable" level of cancer risk, e.g., $1x10^{-6}$ level of risk,

25,600 = number of days in a lifetime (25,600 days = 70 years); application of this duration factor assumes that carcinogenic effects are a linear function of the total (cumulative) dose,

2.8 = a factor to account for uncertainties regarding which stage of carcinogenesis is affected by the substance and for the likely youth of military personnel; the NRC (1986) states that "the maximal additional risk that these considerations contribute is a factor of 2.8," based on the "data of Crump and Howe (1984)," and

R = target acceptable risk level (e.g., $1x10^{-4}$) for one day of exposure.

The reservations with this method concern the choice of a higher target risk level ($1x10^{-4}$) in combination with other assumptions of this method, and the origin of the above uncertainty factor of 2.8. The origin of this uncertainty factor is not explained adequately by NRC (1986), nor is it apparent in the cited paper (Howe and Crump 1986).

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