Comprehensive Default Methodology for the Analysis of Exposures to Mixtures of Chemicals Accidentally Released to the Atmosphere

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Introduction

Safety analysis of Department of Energy (DOE) facilities requires consideration of potential exposures to mixtures of chemicals released to the atmosphere. Exposure to chemical mixtures may lead to additive, synergistic, or antagonistic health effects. In the past, the consequences of each chemical have been analyzed separately. This approach may not adequately protect the health of persons exposed to mixtures. However, considerable time would be required to evaluate all possible mixtures. The objective of this paper is to present reasonable default methodology developed by the EFCOG Safety Analysis Working Group Nonradiological Hazardous Material Subgroup (NHMS)[a] for use in safety analysis within the DOE Complex. This default methodology is applicable to exposures to mixtures of chemicals, and is needed because there is seldom enough toxicity information available for a sophisticated analysis of the effects of exposure to mixtures of materials likely to be involved in accidental releases from DOE facilities. To facilitate application of this methodology, toxic consequences of exposure to individual chemicals is described in terms of health code numbers (HCNs). These methodologies have been applied to several release scenarios of chemicals from DOE facilities to compare the resulting hazard indices (HIs) of a chemical mixture with those obtained when each chemical is treated independently. This paper demonstrates how HCNs can be used to sum HIs only for those chemicals that have the same toxic consequence. The methodology used and results obtained from analysis of one example mixture are presented.

Recommendations

Exposure to Multiple Chemicals with Noncarcinogenic Independent Effects

Calculate the peak 15-minute TWA concentration (C_i) for each chemical component "i" at each receptor point, and when necessary for chemicals with dose-dependent effects only (i.e., the peak 15-minute TWA value is too restrictive, or HI > 1.00), the peak 60-minute TWA concentrations. If the release duration is less than 15 minutes and the substance is known to cause severe concentration-dependent consequences, then the peak concentration may be averaged over a shorter time period (not less than 1 minute). Calculate the ratio of concentration (C_i) to the relevant concentration-limit guideline (L_i) for each chemical to obtain the hazard index for that chemical (i.e., $HI_i = C_i / L_i$ for chemical "i"). Relevant L_is at the receptor point(s) of interest are

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[a] Similar methodology, focused on emergency planning and exposures, was developed for DOE's Emergency Management Advisory Committee Subcommittee on Consequence Assessment and Protective Actions (SCAPA)

the applicable Emergency Response Planning Guidelines (ERPGs)[1]. ERPG values have been approved for seventy-three (73) chemicals to date (January 1997). Since there are no ERPGs for many chemicals, DOE-SCAPA has developed a hierarchy of concentration-limit parameters for deriving TEELs[2,b].

For noncarcinogenic chemicals, toxic effects are both chemical-specific and exposure-level specific. In addition, exposure to the same chemical at different concentrations, and/or for different exposure durations, can result in a range of toxicologic consequences. When simultaneous or consecutive exposure to more than one chemical occurs, the toxicological consequences will depend upon the target organ(s) of each chemical at the concentration or exposure-dose (concentration x exposure time) of interest, and any interactive effects among these chemicals. If it can be shown that (a) there are no interactive effects (e.g., superadditivity, subadditivity, synergism, antagonism), (b) the target organ(s) are not the same, and (c) the modes of toxicologic action are not the same, then the consequences of exposure to multiple chemicals with noncarcinogenic effects may be considered independent rather than additive.

Chemical guidelines have been developed by a Westinghouse committee[3] for conduct of hazard assessments. These recommend use of ERPGs as the primary concentration guideline values, and are compatible with the DOE Emergency Management Guides[4]. Guidelines depend upon the specific application (e.g., hazard classification, safety analysis). The exposure concentration (C_i) should be compared with the appropriate ERPGs to evaluate acceptability of that exposure as in equation (1). The ratio of concentration to guideline gives HI_i for chemical "i":

$$HI_i = \frac{C_i}{ERPG_i} \quad\text{...} \quad (1)$$

where $\quad HI_i \leq 1 \quad$ is considered acceptable.

Recommended Methodology for Assessment of Exposures to Chemical Mixtures

In the absence of data, the conservative approach (considering the consequences of exposure to be additive) should be taken and, unless chemicals are known to display significant interactive effects, HIs for chemicals exerting combined effects should be added, i.e.,

$$\sum_{i=1}^{n} HI_i = HI_1 + HI_2 + \ldots + HI_n \quad\text{..} \quad (2)$$

As a first approximation, this sum of HIs for chemicals exerting combined effects must be less than or equal to one to be acceptable,

i.e., $\quad \sum_{i=1}^{n} HI_i \leq 1 \quad\text{..}\quad (3)$

The rationale for this conservative approach is that treatment of simultaneous exposure to multiple chemicals as independent potentially allows a greater exposure to occur. Consequently, the burden of proof should lie with the decision to treat these kinds of exposures as independent, rather than with the decision to conservatively treat them as additive. This is consistent with the approach for evaluation of exposure to mixtures recommended by both the EPA[5] and ACGIH[6].

For carcinogens, calculate and sum the incremental cancer risks (ICR)[5], i.e.,

$$(\sum_{i=1}^{n} ICR_i) = ICR_1 + ICR_2 + \ldots + ICR_n \quad\text{...}\quad (4)$$

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[b] The acronym "TEEL", for Temporary Emergency Exposure Limit, was adopted by SCAPA in April 1996.

for each component at each receptor point. Compare this sum with the applicable guidelines. For example, the DOE safety goal of cancer fatalities from DOE facilities or operations is less than 0.1% of the sum of all cancer fatality risks resulting from all other causes[7].

When exposure to more than one chemical is involved, if assuming additivity of all the chemicals involved produces an unacceptable analytical result (i.e., $\Sigma HI > 1.0$), a matrix of chemicals, their target organs and/or mode of action should be prepared. Methodology for the preparation of a toxic effects matrix and its application is presented in the next section.

Application of the Mixtures Methodology

Introduction

Additional methodology has been developed to assist the analyst in evaluating exposures to mixtures. This involves preparation of a matrix of the chemicals in a mixture and their toxicologic classification using HCNs (Table 1)[8] established for each chemical. This allows for evaluation of consequences in terms of modes of action (e.g., acute effects versus cumulative or chronic effects) and toxic endpoints for each chemical (Table 2, in which some HCNs have been expanded to facilitate classification of chemicals by target organ when this information is available). The NHMS recommends that these HCNs be used to determine those chemicals for which HIs must be added and those which can be treated independently. Concentrations at two receptor points of interest, the applicable ERPGs or TEELs, and calculated HIs are presented for one mixture of chemicals (Table 3). By using the very conservative approach of summing the HIs for all chemicals in the mixture, conditions would be unacceptable in both cases evaluated.

Preparation of the Health Effects Matrix

Required input includes a list of all chemicals in the mixture, with Chemical Abstract Services (CAS) number for positive identification, as well as the airborne concentration (C_i) and concentration-limit (L_i) for each receptor point of interest. Requirements for implementation of the mixture methodology include the toxicologic classification of each chemical in the mixture, starting with the health code numbers in Patty (pp. 158-185)[8]. Health code numbers for chemicals not listed in Patty are derived from the "Safety Profile" in SAX[9], three or more HCNs being determined for each chemical. It is necessary to know whether the toxicologic consequences of exposure to a chemical are concentration-dependent, dose-dependent, or both[3].

The HIs are summed for those chemicals having the same toxic consequences (i.e., the same series HCN). For irritants, HIs are adjusted based upon whether irritation is severe, moderate, or mild. Patty[8] gives a table of these codes for approximately 600 chemicals, and codes have been derived from the safety profiles in SAX[9] for about 100 additional chemicals. A few concentration-limit classifications given in Patty were changed, based on SAX safety profile indications that a chemical was an irritant. If the SAX safety profile does not list a target organ, toxicity is assumed to be systemic (i.e., HCNs 3.00 for chronic, or 4.00 for acute, from Table 2).

This additional methodology has been applied to several specific mixtures of chemicals likely to be released in accidents at DOE facilities. The HCNs for health effects caused by exposure to each chemical are entered in the matrix. These HCNs determine those chemical-specific HIs that should be added and those that can be treated independently. Chemicals in a fourteen-component mixture (Table 3), their CAS numbers and HCNs are presented in Table 4. This is performed for all relevant toxic endpoints. Results are presented for reproductive effects (Table 5), narcosis (Table 6), and respiratory irritation (Table 7). Using the developed methodology, all

HIs greater than unity (bold print), whether for individual chemicals or for those summed according to toxic consequence, represent unacceptable conditions.

Unless chemicals are known to display significant interactive effects (superadditivity or subadditivity), HIs for chemicals exerting combined effects should be added for each specific target organ and/or mode of action (i.e., $\sum HI_{i(p)}$, where "p" represents a specific target organ and/or mode of action). A non-specific or systemic health code for a chemical should be included in summation of consequences for the primary HCN (e.g., HIs for chemicals having HCN 3.00 should be added to the HIs for chemicals having HCNs 3.10, 3.11, etc.). To be acceptable, the sum of the HIs should be less than or equal to unity (i.e., $\sum HI_{i(p)} \leq 1.0$). The HCNs for chemicals whose HIs should be added for a particular toxic endpoint are shown in bold print in Tables 5, 6, and 7.

Results

Concentrations, concentration limits and HIs at two receptor points are given in Table 3 for all chemicals in the mixture. These concentration limits are ERPG or TEEL levels 2 and 3. Chemical concentrations are determined at receptor distances of 30 meters (within facility) and 100 meters (outside the facility). The sums of the HIs calculated for each receptor point are also presented. These represent the opposite extreme from consideration of each HI separately.

HCNs for these fourteen chemicals are given in Table 4. Tables 5, 6, and 7 present sample results for summation of HIs for chemicals with the same toxic consequences: reproductive effects (Table 5), narcosis (Table 6), and finally, respiratory irritation (Table 7). The HIs, when irritation is the toxic endpoint, are multiplied by an arbitrary adjustment factor depending upon whether irritation is marked (severe = 1.0), moderate (0.5), or mild (0.25). These target-organ- or mode-of-action-specific HI summations represent analyses that are more realistic than either of the two extremes; namely, treating all the chemicals in the mixture as independent, or summing the HIs for them all.

Discussion

Examination of the individual HIs (Table 3) shows that there are several values that exceed unity (e.g., benzene, ethylene glycol and toluene). These indicate unacceptable conditions, irrespective of how mixtures are being treated, and would demand mitigative action such as inventory reduction or engineering controls. Clearly, whenever the HI at a receptor location exceeds unity for any chemical involved in assessment of the hazards of exposure to a mixture, that exposure condition will be unacceptable.

These data indicate that concentration limits are exceeded for three chemicals at 30 meters, since HI > 1.00 for each of benzene, ethylene glycol, and toluene. Only the HI for benzene exceeds unity at 100 meters. However, the sum of the HIs at 100 meters exceeds unity even if benzene is excluded. Table 5, 6, and 7 give results of applying the mixture methodology for three different toxic endpoints. It is of interest to note that, even though the individual HIs at 100 meters for chemicals causing narcosis are less than unity, their sum is greater than unity. Consequently, some mitigative action to reduce the potential downwind concentration of one or more of these chemicals would be required. Since HI = 0.75 for toluene in this case, reduction of its inventory by a factor of ten would solve the problem.

Conclusions

Default methodology has been recommended for use in hazard assessments, safety analysis, and other applications within the DOE complex. This methodology conservatively addresses gaps in the field of exposure to multiple chemical sources. It is recommended that HIs (equation 1) be calculated for each chemical, and unless contraindicated by experimental data or empirical toxicologic knowledge for each chemical, that these HIs be summed (equation 2). This sum is compared to unity (equation 3) to determine acceptability of the scenario being evaluated, protective actions to be implemented, or administrative controls to be applied. For all carcinogens, including those for which HIs have been calculated, ICRs must be calculated and summed (equation 4). This total value is compared with appropriate guidelines. The more conservative of the toxic risk (equation 2) or the carcinogenic risk (equation 4) calculations should be used.

To facilitate application of methodology developed for the analysis of potential exposures to mixtures of materials, a matrix of chemicals and target-organ toxicities, in terms of HCNs, has been presented for a fourteen-chemical mixture. This matrix has been used to decide which chemical-specific hazard indices must be added, and which can be treated separately. To be acceptable, individual HIs and, where appropriate, sums of HI_js, must be less than or equal to unity. There are several instances in the example for which this is not the case. If individual chemical HIs are greater than unity, mitigative action must be taken. If all individual HIs for chemicals in a mixture are < 1.00 then this methodology will facilitate a more in-depth look at additivity and aid the analyst in determining possible hazardous combinations of mixtures and also not burden the analyst with an over conservative method of summing all HIs for chemicals in a mixture.

References

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Table 1: Health Code Number Key for Toxicologic Classification of Chemicals

Health Code Number	Health Effect
1	Cancer - currently regulated by OSHA as carcinogens
2	Chronic (cumulative) toxicity - Suspect carcinogen or mutagen
3	Chronic (cumulative) toxicity - long-term organ toxicity other than nervous, respiratory, hematologic or reproductive
4	Acute toxicity - Short-term high hazards effects
5	Reproductive hazards - Fertility impairment or teratogenesis
6	Nervous system disturbances - Cholinesterase inhibition
7	Nervous system disturbances - Nervous system effects except narcosis
8	Nervous system disturbances - Narcosis
9	Respiratory effects other than irritation - Respiratory sensitization (asthma)
10	Respiratory effects other than irritation - Cumulative lung damage
11	Respiratory effects - Acute lung damage/edema
12	Hematologic (blood) disturbances - Anemias
13	Hematologic (blood) disturbances - Methemoglobinemia
14	Irritation - eye, nose, throat, skin - Marked
15	Irritation - eye, nose, throat, skin - Moderate
16	Irritation - eye, nose, throat, skin - Mild
17	Asphyxiants, anoxiants
18	Explosive, flammable, safety (No adverse effects encountered when good housekeeping practices are followed)
19	Generally low risk health effects - Nuisance particulates, vapors or gases
20	Generally low risk health effects - Odor

Table 2: Health Code Number Detail to Classify Toxic Effects by Target Organ

Health Code Number	Target Organ	Health Code Number	Target Organ	Health Code Number	Target Organ
1.00	OSHA carcinogen	3.09	heart	8.01	central nervous system
1.01	bladder carcinogen	3.10	kidney	9.00	respiratory sensitizor
1.02	liver carcinogen	3.11	liver	10.00	chronic respiratory toxin
2.00	suspect carcinogen or mutagen	3.12	see health code number 10	11.00	acute respiratory toxin
2.01	kidney carcinogen	3.13	ocular	12.00	blood toxin- anemia
2.02	liver carcinogen	3.14	skin	13.00	blood toxin- methemoglobinemia
3.00	chronic systemic toxin	3.15	skin perforation	14.00	severe irritant
3.01	bladder	4.00	acute systemic toxin	14.01	eye
3.02	see health code numbers 12 and 13	4.01	eye	14.02	skin
3.03	bone	4.02	nose	15.00	moderate irritant
3.04	bone marrow	5.00	reproductive toxin	15.01	eye
3.05	brain	6.00	cholinesterase toxin	15.02	skin
3.06	see health code number 7	7.00	nervous system toxin	16.00	mild irritant
3.07	eye	7.01	central nervous system	16.01	eye
3.08	gastrointestinal tract	8.00	narcotic	16.02	skin

Table 3: Concentrations, Concentration-Limits, and Hazard Indices for Chemicals in Fourteen-component Mixture

No	Chemical Name	C@30m mg/m^3	C@100m mg/m^3	TEEL-2 mg/m^3	TEEL-3 mg/m^3	HI (T-3) @ 30 m	HI (T-2) @ 100 m
1	Acetone	5.77E+03	5.44E+02	2.01E+4	2.01E+4	2.87E-01	2.70E-02
2	Benzene	9.17E+03	8.63E+02	4.79E+2	3.19E+3	**2.87E+00**	**1.80E+00**
3	Biphenyl	5.01E+01	4.72E+00	7.00E+0	1.00E+2	5.01E-01	6.74E-01
4	Carbon Tetrachloride	6.98E+01	6.57E+00	6.29E+2	4.72E+3	1.48E-02	1.04E-02
5	Chlorobenzene	2.06E+02	1.94E+01	9.20E+2	4.60E+3	4.49E-02	2.11E-02
6	Diphenylamine	3.41E+01	3.21E+00	5.00E+1	5.00E+2	6.82E-02	6.42E-02
7	Ethylene glycol	2.48E+02	2.34E+01	1.02E+2	1.52E+2	**1.63E+00**	2.29E-01
8	Methyl ethyl ketone	3.78E+03	3.56E+02	2.95E+3	8.85E+3	4.27E-01	1.21E-01
9	Methylene chloride	1.22E+03	1.15E+02	2.60E+3	1.39E+4	8.75E-02	4.40E-02
10	Phenol	7.37E+00	6.93E-01	1.93E+2	7.70E+2	9.57E-03	3.59E-03
11	Tetrachloroethylene	1.22E+02	1.15E+01	1.36E+3	6.78E+3	1.79E-02	8.42E-03
12	Toluene	9.01E+03	8.48E+02	1.13E+3	3.76E+3	**2.40E+00**	7.51E-01
13	Trichloroethane, 1,1,1-	8.87E+02	8.35E+01	5.45E+3	1.64E+4	5.41E-02	1.53E-02
14	Xylene	5.20E+02	4.89E+01	8.68E+2	3.91E+3	1.33E-01	5.64E-02
Summation of hazard Indices for all Chemicals						8.55E+00	3.83E+00

Table 4: Target Organ Toxicity by Health Code Numbers for Chemicals in Mixture

No	Chemical Name	CAS number	Health Code Numbers				
			1	2	3	4	5
1	Acetone	67-64-1	16.00	8.00			
2	Benzene	71-43-2	2.00	12.00	3.00	14.01	14.02
3	Biphenyl (Diphenyl)	92-52-4	15.00				
4	Carbon tetrachloride	56-23-5	3.11	2.00	5.00		
5	Chlorobenzene	108-90-7	3.00	8.00	5.00		
6	Diphenylamine	122-39-4	3.11	3.10	3.01	5.00	
7	Ethylene glycol	107-21-1	15.00	3.00	7.00		
8	Methyl ethyl ketone (Butanone, 2-)	78-93-3	15.00	8.00	3.00		
9	Methylene chloride	75-09-2	17.00	3.11	8.00		
10	Phenol	108-95-2	14.00	4.00	2.00		
11	Tetrachloroethylene (Perchloroethylene)	127-18-4	3.11	7.01	8.00	2.00	
12	Toluene	108-88-3	15.00	8.00	7.01		
13	Trichloroethane, 1,1,1- (Methyl chloroform)	71-55-6	16.00	8.00	3.00		
14	Xylene	1330-20-7	15.00	8.00	5.00		

Table 5: Summation of Hazard Indices for Chemicals in Mixture having the same Toxic Consequences: Reproductive Effects (i.e., health code number 5.00)

No.	Chemical Name	Health Code Numbers					HI for T-3 @ 30 m	HI for T-2 @ 100 m
		1	2	3	4	5		
4	Carbon Tetrachloride	3.11	2.00	5.00			1.48E-2	1.04E-2
5	Chlorobenzene	3.00	8.00	5.00			4.49E-2	2.11E-2
6	Diphenylamine	3.11	3.10	3.01	5.00		6.82E-2	6.42E-2
14	Xylene	15.00	8.00	5.00			1.33E-1	5.64E-2
Summation of HIs for Reproductive Effects							1.33E-1	5.64E-2

Table 6: Summation of Hazard Indices for Chemicals in Mixture having the same Toxic Consequences: Narcosis (i.e., health code number 8.00)

No.	Chemical Name	Health Code Numbers					HI for T-3 @ 30 m	HI for T-2 @ 100 m
		1	2	3	4	5		
1	Acetone	16.00	8.00				2.87E-1	2.70E-2
5	Chlorobenzene	3.00	8.00	5.00			4.49E-2	2.11E-2
8	Methyl ethyl ketone	15.00	8.00	3.00			4.27E-1	1.21E-1
9	Methylene chloride	17.00	3.11	8.00			8.75E-2	4.40E-2
11	Tetrachloroethylene	3.11	7.01	8.00	2.00		1.79E-2	8.42E-3
12	Toluene	15.00	8.00				2.40E+0	7.51E-1
13	Trichloroethane, 1,1,1-	16.00	8.00	3.00			5.41E-2	1.53E-2
14	Xylene	15.00	8.00	5.00			1.33E-1	5.64E-2
Summation of HIs for Chemicals causing Narcosis							3.45E+0	1.04E+0

Table 7: Summation of Hazard Indices for Chemicals in Mixture having the same Toxic Consequences: Respiratory Irritation (i.e., health code numbers 14.xy, 15.xy, and 16.xy)

No.	Chemical Name	Health Code Numbers					Adj. factor	HI for T-3 @ 30 m	HI for T-2 @ 100 m
		1	2	3	4	5			
1	Acetone	16.00	8.00				0.25	7.18E-2	6.76E-3
2	Benzene	2.00	12.00	3.00	14.01	14.02	1.00	2.87E+0	1.80E+0
3	Biphenyl	15.00					0.50	2.51E-1	3.37E-1
7	Ethylene glycol	15.00	3.16	7.00			0.50	8.17E-1	1.15E-1
8	Methyl ethyl ketone	15.00	8.00	3.00			0.50	2.13E-1	6.03E-2
10	Phenol	14.00	4.00	2.00			1.00	9.57E-3	3.59E-3
12	Toluene	15.00	8.00				0.50	1.20E+0	3.75E-1
13	Trichloroethane, 1,1,1-	16.00	8.00	3.00			0.25	1.35E-2	3.83E-3
14	Xylene	15.00	8.00	5.00			0.50	6.65E-2	2.82E-2
Summation of Hazard Indices for Respiratory Irritants								5.52E+00	2.73E+00

Note: Adjustment factors (Adj. factor) of 1.0 for "severe" (code 14), 0.5 for "moderate" (code 15), and 0.25 for "mild" (code 16), have been applied to the hazard indices.