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Proposed Risk Evaluation Guidelines for Use By the DOE-AL Nuclear Explosive Safety Division in Evaluating Proposed Shipments of Nuclear Components

October 1997

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**Proposed Risk Evaluation Guidelines
for use by the DOE-AL Nuclear Explosive Safety Division
in Evaluating Proposed Shipments of Nuclear Components**

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A. F. Love

October 20, 1997

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Y-12 Nuclear Packaging Systems

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LOCKHEED MARTIN ENERGY SYSTEMS, INC.
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ACRONYM LIST

ACGIH	American Conference of Governmental Industrial Hygienists
ACL	administrative control level
AIHA	American Industrial Hygiene Association
ALARA	as low as reasonably achievable
CFR	U.S. Code of Federal Regulations
CTEDE	cumulative Total Effective Dose Equivalent
DBA	design basis accidents
DOE	U.S. Department of Energy
DP	Office of Defense Programs (U.S. Department of Energy)
EBA	evaluation basis audit
EG	Evaluation Guideline
EHS	extremely hazardous substance
EMAC	Emergency Management Advisory Committee
EPA	U.S. Environmental Protection Agency
ERPG	Emergency Response Planning Guideline
FEMA	Federal Emergency Management Agency
IAEA	International Atomic Energy Agency (Vienna, Austria)
IDLH	immediately dangerous to life or health
LOC	level of concern
LSA	Low specific activity
NAS	National Academy of Sciences
NESD	Nuclear Explosive Safety Division
NII	Nuclear Installation Inspectorate (United Kingdom)
NIOSH	National Institute for Occupational Safety and Health
NRC	U.S. Nuclear Regulatory Commission
OSHA	U.S. Occupational Safety & Health Administration
PEL	Permissible Exposure Limit
RAM	radioactive material
REL	Recommended Exposure Limit
SAR	safety analysis report
SCAPA	Subcommittee on Consequence Assessment and Protective Actions
SCO	surface contaminated objects
SER	Safety Evaluation Report
SPEGL	Short-term Public Emergency Guidance Level
SSC	structure, system, or component
SST	safe-secure transport
STEL	Short-term Exposure Level
TEDE	Total Effective Dose Equivalent
TSRA	Transportation System Risk Assessment
TLV	Threshold Limit Value
USDOT	U.S. Department of Transportation
WEEL	Workplace Environmental Exposure Level

SPECIAL TERMS

ERPG-2	Emergency Response Planning Guideline 2: "The maximum airborne concentration below which it is believed that 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 their abilities to take protective action."
EEGL	Emergency Exposure Guidance Level: "A concentration of a substance in air (as a gas, vapor, or aerosol) that may be judged by DOD to be acceptable for the performance of specific tasks during rare emergency conditions lasting for periods of 1-24 h. Exposure at an EEGL might produce reversible effects that do not impair judgement and do not interfere with proper responses to the emergency". The EEGL is "a ceiling guidance level for a single emergency exposure, usually lasting from 1 h to 24 h—an occurrence expected to be infrequent In the lifetime of a person."
PEL-C Ceiling:	"The employee's exposure which shall not be exceeded during any part of the work day." If necessary from a monitoring point of view, C may be assessed as a 15-minute time weighted average.
LOC	Level of Concern: "The concentration of an extremely hazardous substance in air above which there may be serious Irreversible health effects or death as a result of a single exposure for a relatively short period of time." (Also used by FEMA and USDOT)
TLV-TWA	Threshold Limit Value Time Weighted Average: "The time weighted average concentration for a normal 8-hour workday and a 40-hour workweek, to which nearly all workers may be repeatedly exposed, day after day, without adverse effect."
TLV-C	Threshold Limit Value - Ceiling: "The concentration that should not be exceeded during any part of the working exposure." "... if instantaneous monitoring is not feasible, then the TLV-C can be assessed by sampling over a 15-minute period except for those substances that may cause immediate irritation when exposures are short."

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1. INTRODUCTION

The licensing requirements of 10 CFR 71 (U.S. Code of Federal Regulations) are the primary criteria used to license proposed U. S. Department of Energy (DOE) shipments of nuclear components. However, if a shipment cannot meet 10 CFR 71 requirements, a Transportation System Risk Assessment (TSRA) is prepared to document: (1) the degree of compliance of proposed DOE shipments of nuclear components with applicable federal regulations and (2) the risk associated with the proposed shipments. The Nuclear Explosive Safety Division (NESD) of the Department of Energy, Albuquerque Area Office (DOE-AL) is responsible for evaluating TSRA's and for preparing Safety Evaluation Reports (SERs) to authorize the off-site transport.

Hazards associated with the transport may include the presence of fissile material, chemically and radiologically toxic uranium, and ionizing radiation. The Nuclear Regulatory Commission (NRC) has historically considered only radiological hazards in licensing the transport of radiological material because the U.S. Department of Transportation considers licensing requirements of nonradiological (i.e., chemically toxic) hazards. The requirements of 10 CFR 71 are based primarily on consideration of radiological hazards. For completeness, this report provides information for assessing the effects of chemical toxicity.

Evaluating the degree of compliance with the requirements of 10 CFR 71 is relatively straightforward. However, there are few precedents associated with developing TSRA risk assessments for packages that do not comply with all of the requirements of 10 CFR 71.

The objective of our task is to develop Risk Evaluation Guidelines for DOE-AL to use when evaluating a TSRA. If the TSRA shows that the Risk Evaluation Guidelines are not exceeded, then **from a risk perspective** the TSRA should be approved if there is evidence that the ALARA (as low as reasonably achievable) principle has been applied. If the TSRA shows that the Risk Evaluation Guidelines are exceeded, DOE-AL should closely examine shipment options before authorizing the proposed off-site transport.

The proposed Risk Evaluation Guidelines were developed by examining existing information applicable to the development of Risk Evaluation Guidelines for DOE Shipments of Nuclear Components. The results of the literature search are documented in Attachment A, *Literature Search for Information Applicable to the Development of Risk Evaluation Guidelines for DOE Shipments of Nuclear Components*.

Development of the Risk Evaluation Guidelines required the resolution of issues that involve both technical and "political" decisions. The more important issues and considerations used to generate the approach used in developing the Risk Evaluation Guidelines are presented in Attachment B.

Recommended Risk Evaluation Guidelines were developed in late 1995 by first asking two senior risk analysts (R. A. Just and A. F. Love) to independently develop proposed Risk Evaluation Guidelines based on the information presented in Attachment A. The preliminary recommendations by Just and Love are presented in Attachments C and D. These recommendations were then refined by comparing the preliminary recommendations and obtaining input from

additional safety/risk analysts who reviewed a consensus recommendation prepared by Just and Love. The "consensus" recommendation is presented below.

2. APPLICATION OF RISK EVALUATION GUIDELINES

The Risk Evaluation Guidelines are used to determine if the risk is acceptably low. However, the application of Risk Evaluation Guidelines is not necessary if the risk can be determined to be acceptably low using an alternate approach. The risk can be determined to be acceptably low if:

- a. no credible accidents result in significant consequences, or
- b. all consequences are negligible, or
- c. if DOE guidance indicates a formal safety analysis report (SAR) is not required.

An event is considered incredible if the annual frequency of occurrence of the event is less than 10^{-6} per year. Consequences may be considered negligible if all radiological exposures are less than the 0.5 rem to whole body dose criteria presented below for accidents with an annual frequency of 10^{-2} .

A formal safety analysis report is not required if a facility Hazard Classification based on DOE Order 5480.1B is less than Low and the hazard categorization based on DOE-STD-1027-92 is less than Category 3. Therefore, based on consideration of only the radiological hazards, if the hazard categorization based on DOE-STD-1027-92 is less than Category 3, a SAR will not be required based on the presence of a radiological hazard and consequently, the risk can be considered acceptably low.

3. RADIOLOGICAL RISK EVALUATION GUIDELINE

The recommended radiological Risk Evaluation Guideline is shown in the following table. The Risk Evaluation Guideline is based on straight line interpolations on a log-log plot for annual frequencies between 10^{-6} and 10^{-4} and between 10^{-4} and 10^{-2} , and an assumed constant value for frequencies greater than 10^{-2} .

**50-year Committed Effective Dose
Equivalents (C.E.D.E.)**

Annual Frequency	Whole Body
10^{-6}	25 rem
10^{-4}	2.5 rem
$\geq 10^{-2}$	0.5 rem

The following graph shows the relationship between the Risk Evaluation Guideline for the whole body dose and the frequency of the accident(s) being evaluated.

4. CHEMICAL EVALUATION GUIDELINE

If chemical effects are considered, it is recommended that the consequence criterion be based on not exceeding reversible effects; i.e., exposed individuals would not experience or develop irreversible or other serious health effects or symptoms that could impair their abilities to take protective action. It is proposed that either the Short-Term Public Emergency Guidance Level (SPEGL), the Emergency Response Planning Guideline 2 (ERPG-2), or an ERPG-2 alternative in decreasing order of preference be used as an Evaluation Guideline for credible accidents.

If information is available on the toxicity of a material other than a SPEGL, ERPG-2, or an ERPG-2 alternative, this information can be used if the information is a more appropriate basis or the best information available for determining if the health effect can be considered reversible.

For example, Chemical Risk Evaluation Guidelines for uranium could be based on an ingestion intake of 15 mg of uranium and on an inhalation intake of 10 mg of soluble uranium because these intakes have no long-term health effects. This is based on information contained in NUREG-1391, *Chemical Toxicity of Uranium Hexafluoride Compared to Acute Effects of Radiation*, and in the *Health Physics Manual of Good Practices for Uranium Facilities*, EGG-2530. NUREG-1391 concluded that an inhalation intake of approximately 10 mg of soluble uranium would have no long-term health effects, and EGG-2530 indicates that about a 15-mg intake of Class D very soluble material would not be considered toxicologically harmful.

ERPGs only currently exist for relatively few chemicals. Therefore, ERPG alternatives must be used for many chemicals. The Subcommittee on Consequence Assessment and Protective Actions (SCAPA) of the DOE-HQ Emergency Management Advisory Committee (EMAC) has developed the following hierarchy of alternative criteria if ERPGs are not available. The alternative guidelines are documented in *Alternative Guideline Limits for Chemicals Without Environmental Response Planning Guidelines* [D. K. Craig, et al., American Industrial Hygiene Association Journal 56:919-925 (1995)]. Craig's recommended hierarchy of alternative criteria for ERPG-2 values is:

	<u>Source</u>
EEGL (60-min)	NAS
LOC	EPA/FEMA/DOT
PEL-C	OSHA
TLV-C	ACGIH
TLV-TWA•5	ACGIH

EPA has defined "levels of concern" (LOCs) as the concentrations of an extremely hazardous substance in air above which there may be serious irreversible health effects or death from a single exposure for a relatively short time. The LOC may be estimated by using 0.1 of the immediately dangerous to life or health (IDLH) level or as the Threshold Limit Value (TLV), the Short-term Exposure Level (STEL), the Permissible Exposure Limit (PEL), or the Recommended Exposure Limit (REL).

ERPG-2 values and alternatives are based on a one-hour exposure period. If the exposure duration significantly exceeds one hour, then the criterion should be either the ERPG-2 or ERPG-2 alternative divided by the exposure duration in hours. If the duration is significantly less than one hour, the ERPG-2 or ERPG-2 alternative **SHOULD NOT** be divided by the exposure duration if the health effect is concentration dependent.

Concentration-dependent chemicals are fast-acting chemicals whose toxic effects are immediate and correlate more closely to concentration than the dose. Included in this category are sensory irritants and chemicals that are corrosive or vesicant (inducing blistering) in their action. Any chemical assigned an OSHA PEL-STEL or PEL-C, or an ACGIH TLV-STEL or TLV-C value must be considered to have concentration-dependant health effects. In contrast, the effects of dose-dependent chemicals depend on both concentration and duration of exposure.

When two or more toxic substances are present, their combined effect should be considered. Without information to the contrary, the effects of the different hazards should be considered as additive. That is, if the sum of the fractions, $C_1/T_1 + C_2/T_2 + \dots + C_n/T_n$ is greater than 1, the limit of the mixture should be considered as exceeded. C is the observed atmospheric concentration, and T, the corresponding limit.

Exceptions to the above rule may be made when there is a good reason to believe that the chief effects of the different harmful substances are not in fact additive, but *independent* as when purely local effects on different organs of the body are produced by the various components of the mixture. In such cases, the limit ordinarily is exceeded only when at least one member of the series (C_1/T_1 , C_2/T_2 , etc.) itself has a value exceeding 1.

Consideration of synergistic action would normally not be considered. However, if a mixture of hazardous chemicals has known synergistic chemicals that can be identified and characterized by inspection by an Industrial Hygiene staff member, synergism should be considered.

5. EVALUATION OF TOTAL RISK

To decide if the risk of a proposed shipment or shipments is acceptable, all accident scenarios must be considered and compared with the Risk Evaluation Guidelines. For each accident scenario, the frequency and consequence should be evaluated to determine the value of

$$\sum_{i=1}^n \frac{(Consequence)_i}{(Criterion)_i}, \text{ where } n \text{ is the number of credible scenarios.}$$

If $\sum_{i=1}^n \frac{(Consequence)_i}{(Criterion)_i} < 1$ for **both** chemical **and** radiological effects, the risk is

acceptable. If $\sum_{i=1}^n \frac{(Consequence)_i}{(Criterion)_i} \geq 1$ for either chemical or radiological effects, a management

decision is required to accept the risk.

6. DEFINITION OF ACCIDENT FREQUENCY

If the TSRA addresses a single shipment of material, using the frequencies of accidents associated with that shipment is appropriate. However, if multiple shipments are addressed in a TSRA, then the entire campaign should be considered.

Currently the criterion for an incredible event is accepted throughout the DOE community to be an event whose annual frequency of occurrence is less than 10^{-6} per year. This number is applicable to a fixed installation with operations ranging from continuous operations to a number of batch activities.

Therefore, considering only one shipment would be equivalent to only considering a duration less than one year (e.g., that associated with a batch process) and would "underestimate" the perceived risk.

The TSRA should calculate the risk associated with an individual shipment, the annual risk based on the maximum expected shipments in a one-year period, and the risk over the entire campaign. The frequency definition of accidents will be based on the annual risk.

7. LOCATIONS FOR EVALUATING PUBLIC IMPACTS

To evaluate the consequences of an accident, determining the appropriate location for evaluating the impact is necessary. For example, consequences could be evaluated at all locations or only a certain distance. Because worst case consequence at "ground zero" will usually be significant, and using this position as a basis would be too conservative, it is recommended that consequences only be evaluated beyond a certain finite distance from the accident.

If a safe secure transport (SST) is involved in a significant accident, a 500-ft radius security zone will be established to keep the public at least 500 ft from the SST. Therefore, the TSRA should consider the impact on the public for distances less than 500 ft only for the time required to establish the security zone. The TSRA should consider the impact on the public for distances 500 ft and beyond for the duration of the postulated accident.

8. NEW INFORMATION

On February 1, 1995 a proposed appendix to DOE-STD-3009-94 was issued for comment. This draft proposes a 25-rem Evaluation Guideline independent of frequency and using the ERPG-2 as a Chemical Evaluation Guideline. If this proposal gains acceptance, then the Risk Evaluation Guidelines used to evaluate proposed shipments will need to be modified.

As of mid January 1996, the latest information indicates that a frequency independent 25-rem whole body dose is likely to be specified by DOE-HQ either in an update to DOE-STD-3009-94 for the Radiological Evaluation Guideline, in the final version of 10 CFR 930.110, or in guidance for implementation of 10 CFR 930.110. It is unclear whether a Chemical Evaluation Guideline will be issued by DOE-HQ.

DOE has recently canceled a number of directives (DOE N 251.1 through DOE N 251.8) and issued new orders. In January 1996, the changes to the DOE command media were examined to determine whether there were any changes that would impact the previous recommendations. Although no modifications to the original recommendation were found to be appropriate based on the changes to the command media, two changes are worth noting:

- (1) Section 6 (a) of DOE N 441.1, *Radiological Protection for DOE Activities*, indicates that a system of administrative control levels (ACLs) shall be implemented to control radiological worker doses at levels below the occupational exposure limits provided in 10 CFR 835.202.
 - (a) A DOE ACL of 2 rem (0.02 Sv) Total Effective Dose Equivalent (TEDE) per year shall be implemented.
 - (b) A cumulative Total Effective Dose Equivalent (CTEDE) ACL of 1 rem (0.01 Sv) TEDE per year of age shall be implemented.
- (2) DOE O 430.1, *Life Cycle Asset Management*, indicates that after 10 CFR 830.340, *Maintenance Management*, and DOE O 420, *Facility Safety*, for defense nuclear facilities are issued as finals, DOE 6430.1A should be considered as deleted or consolidated into DOE O 430.1 and shall be phased out.

Because DOE guidance is still evolving, future changes to the command media should be considered when implementing risk acceptance guidance for TSRAs.

9. EXAMPLE APPLICATION

The following example is provided to illustrate the application of the proposed risk acceptance criteria. Consider a shipment campaign that has the following characteristics:

- The package and contents do not comply with the requirements of 10 CFR 71;
- Twenty-one identical shipments are planned, with 7 convoys of 3 SSTs;
- A maximum of 4 convoys of 3 SSTs will be conducted in any 12-month time period (this may span across a calendar year boundary);
- The frequency of accidents for tractor semi-trailers that could result in a need to tow away the vehicle and cause a driver fatality is $\sim 4.8 \cdot 10^{-7} \cdot 0.28$ or $\sim 1.3 \cdot 10^{-7}$ accidents per mile (this is assumed to be appropriate as a conservative upper bound for an accident involving the release of SST contents or a potential for a significant radiation exposure);
- Influence factors are also used to modify a generic accident frequency to reflect the influence of road conditions. Typical influence factors for the type of road are as follows:

Road Influence Factors

Limited Urban	Limited Rural	Other Urban	Other Rural
0.63	0.93	3.91	3.83

- Each SST shipment will involve 500 miles of travel, including 200 miles of limited urban roads, 200 miles of limited rural roads, 50 miles of other urban roads, and 50 miles of other rural roads.

Road Type	Influence Factor	Mileage	Accident Rate per mile	Contribution to Probability
Limited Urban	0.63	200	1.3E-7	1.64E-5
Limited Rural	0.93	200	1.3E-7	2.42E-5
Other Urban	3.91	50	1.3E-7	2.54E-5
Other Rural	3.83	50	1.3E-7	2.49E-5
Probability of an SST Accident ~ 9.1E-5				

The following information should be provided:

- The probability of an SST accident = 9.1E-5;
- The probability of a accident involving any one convoy ($3 \cdot 9.1E-4$) = 2.7E-4;
- The maximum annual frequency of an accident ($4 \cdot 3 \cdot 9.1E-5$) = 1.1E-3;
- The probability of an accident for the entire campaign ($21 \cdot 9.1E-5$) = 1.9E-3;
- The Risk Evaluation Guidelines associated with any one SST, any one convoy, the annual shipments, and for the entire campaign:

Risk Evaluation Guidelines for the Campaign

Basis	Frequency	Evaluation Guideline
1 SST	9.1E-5	3.1 rem
1 convoy	2.7E-4	2.4 rem
The maximum number of annual shipments	1.1E-3	2.1 rem
Entire campaign	1.9E-3	1.9 rem

- Comparison of the predicted consequences to the Risk Evaluation Guidelines.

It should be noted that the proposed Risk Evaluation Guidelines are intended to be compared to reasonable estimates of potential consequences. For example, if very conservative consequence estimates are used (e.g., those evaluated in *Effects of a Postulated Uranium Transportation Accident*, Y/LF-504, October 1997) the probability calculations should be appropriately revised. Given the robust nature of an SST, it is probably reasonable to conclude that the accident frequencies sited above

for tow-away accident for tractor semi-trailers that could result in a driver fatality ($\sim 1.3 \cdot 10^{-7}$ accidents per mile) is conservative by at least a factor of 10.

If the frequency estimates shown above are reduced by a factor of 10, the Risk Evaluation Guidelines become as follows:

Risk Evaluation Guidelines for the Campaign

Basis	Frequency	Evaluation Guideline
1 SST	9.1E-6	20.7 rem
1 convoy	2.7E-5	13.6 rem
The maximum number of annual shipments	1.1E-4	2.5 rem
Entire campaign	1.9E-4	2.5 rem

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Attachment A:

**Literature Search for Information
Applicable to the Development of Risk Evaluation Guidelines
for DOE Shipments of Nuclear Components**

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Attachment A:

Literature Search for Information Applicable to the Development of Risk Evaluation Guidelines for DOE Shipments of Nuclear Components

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Radiological Evaluation Guidelines:

1. Section 0200-1.3 of the General Design Criteria, DOE Order 6430.1A (Ref. 12), specifies a 25-rem whole body radiological dose siting guideline for new or modified DOE facilities. It should be noted that the use of these guideline doses is not intended to imply that these doses are acceptable limits for emergency doses to the public under accident conditions. Rather, these values are reference values to be used in the evaluation of facility sites with respect to potential accidents of exceedingly low probability of occurrence and low risk of public exposure to radiation. They do not apply to facility operations under normal or emergency status, nor to emergency dose guidelines that might be appropriate for the general public should an accident occur.
2. Radiation guidelines published in 10 CFR Part 100 of the *Federal Register* establish an exclusion area around a commercial nuclear reactor. 10 CFR Part 100 indicates that a single whole body dose of 25 rem would not lead to significant acute health effects.
- 2a. From Ref. 3, 10 CFR 100 states a public siting criterion of 25 rem for design-basis accidents, which are defined to be exceedingly low probability accidents. Generally, a very low probability accident has been interpreted as having a frequency lower than 10^{-4} per year and is sometimes characterized as having a frequency of 10^{-6} per year. Although 10 CFR 100 does not explicitly discuss risk values, a dose of 25 rem at a frequency between 10^{-4} and 10^{-6} per year can be translated into a fatality frequency of $2.5 \cdot 10^{-8}$ to $2.5 \cdot 10^{-6}$ per year.

The conversion factors used to convert dose to fatality probabilities are 10^{-3} fatalities per rem for both workers and the public for a dose greater than or equal to 10 rem; $4 \cdot 10^{-4}$ fatalities per

rem for workers for a dose less than 10 rem; and $5 \cdot 10^{-4}$ fatalities per rem for the public for a dose less than 10 rem. This is in contrast to the NRC/DOE public safety goals, which use an annual risk of fatal cancer of $2 \cdot 10^{-6}$. Prior DOE Office of Defense Programs (DP) proposed offsite guidelines used a criterion of 25 rem for accident frequencies between 10^{-6} and 10^{-4} per year. Again, this can be translated into a fatality frequency between $2.5 \cdot 10^{-8}$ and $2.5 \cdot 10^{-6}$ per year for the range of accident frequencies.

4. CSET-15 (Ref.2) establishes frequency dependent Evaluation Guidelines (EGs) for potential candidate Safety-class structure, system, or component (SSC). As indicated in the following table, safety-class SSCs may be required for any event that could result in a dose of 0.5 rem or higher.

Reference EGs for the identification of Safety Class SSCs are:

Scenario Frequency	Consequences
$< 10^{-5}/\text{year}$	25 rem
10^{-3} to $10^{-5}/\text{year}$	5.0 rem
$> 10^{-3}/\text{year}$	0.5 rem

The scenario frequencies are assumed to be "best estimate" values. For situations in which estimated scenario frequency values are substantially and dependably conservative, the scenario frequency range values for a particular consequence in the above table may be increased by an order of magnitude.

3. CSET-15 (Ref.2) established reference safety-significant EGs to aid in the Safety SSCs analysis. EGs based on on-site consequences for co-located workers are the same as those presented above for safety class SSCs. The reference EG for facility workers is 100 rem.
5. DOE Order 6430.1A refers to DOE Order 5400.5, "Radiation Protection of the Public and the Environment," for off-site accidental dose limits. Chapter II of DOE Order 5400.5 notes a design limit of 100 mrem/year (note: this is a cumulative dose over a period of one year and not a one-time accidental dose) for off-site releases due to **normal operation** (i.e., frequency greater than or equal to $10^{-2}/\text{year}$). DOE Order 5400.5 only applies to normal operations, not accident conditions. However, DOE Order 6430.1A invokes it for accidental releases. The upper limit for normal operation is therefore 100 mrem/year with the exception that a 500 mrem/year limit may apply to short-term activities with DOE approval.
6. From Ref. 3, a qualitative worker safety goal was presented which states that the risk of fatality from radiological accidents should be a small contributor to a worker's overall occupational risk. Using statistics for other industries, this qualitative goal was translated into (1) a threshold-for-action risk value and (2) a quantitative risk goal to **aspire to**. The team recommended a threshold frequency of 1 fatality in 10,000 per year and a quantitative risk goal of 1 fatality in 100,000 per year. This goal applies to either prompt or latent cancer fatalities. The 10^{-4} threshold fatality value for accidents, if translated to a yearly occupational exposure, corresponds to an

annual dose of 250 mrem. This threshold value also corresponds to approximately the average yearly background dose for an individual in the United States.

Basis: In 1989, the average annual risk of accident fatalities in American industries was $0.9 \cdot 10^{-4}$ fatalities per year, or approximately 1 fatality in 10,000 fatalities per year.

7. From Ref. 3, since 1980, OSHA has employed quantitative risk assessment and used a benchmark for the threshold of significant lifetime risk of 1 in 1000, which is equivalent to $3 \cdot 10^{-5}$ per year for an assumed 30-year work life.
8. From Ref. 16, Public risk goals for DOE are defined. These public risk goals are considered aiming points and translate into annual fatality risks from radiological accidents of $5 \cdot 10^{-7}$ per year for prompt fatalities and $2 \cdot 10^{-6}$ per year for latent fatalities.
9. From Ref. 3, Prior DOE DP proposed offsite guidelines [i.e., DOE-STD-3005-YR (draft)] used a dose criterion of 5 rem for accident frequencies between 10^{-4} and 10^{-2} per year and a criterion of 0.5 rem for accident frequencies higher than 10^{-2} per year (to approximately 10^{-1} per year). For a 5-rem exposure, for frequencies between 10^{-4} and 10^{-2} per year, the average annual dose is between $5 \cdot 10^{-4}$ and $5 \cdot 10^{-2}$ rem, which can be interpreted as consistent with the average annual dose of 0.5 rem in DOE Order 5400.5. The 5-rem criterion translates into fatality frequencies between $2.5 \cdot 10^{-7}$ and $2.5 \cdot 10^{-5}$ per year. The 0.5-rem criterion translates into fatality probabilities between $2.5 \cdot 10^{-6}$ and $2.5 \cdot 10^{-5}$ per year.
10. From Ref. 18, the Nuclear Installation Inspectorate (NII) of the United Kingdom (UK) has issued two public guidelines for licensing requirements of nuclear facilities. The objective guideline serves as a goal, and the limit guideline serves as an upper limit. See guidelines in following table:

NII Off-Site Guideline Summary

Public Exposure (Rem)	Total Annual Frequency for all accidents that could result in associated consequence	
	Limit	Objective
0.01-0.1	1	10^{-2}
0.1-1	10^{-1}	10^{-3}
1-10	10^{-2}	10^{-4}
10-100	10^{-3}	10^{-5}
> 100	10^{-4}	10^{-6}

These guidelines are basically equal risk (iso-risk) guidelines, giving a constant fatality probability per year (other than a factor of 2 difference in the conversion from rem to fatality probability at approximately 10 rem). The guidelines are defined as part of the Safety Assessment

Principles issued by the Health and Safety Executive. As seen below from the fatality probabilities, the guidelines are similar to NRC's Safety Goals and those defined in DOE-SEN-35-91.

Public Exposure (Rem)	Total Annual Frequency for all accidents which could result in associated consequence		Fatality Probability (per year)	
	Limit	Objective	Limit	Objective
0.01-0.1	1	10^{-2}	$5 \cdot 10^{-6} - 5 \cdot 10^{-5}$	$5 \cdot 10^{-8} - 5 \cdot 10^{-7}$
0.1-1	10^{-1}	10^{-3}	$5 \cdot 10^{-6} - 5 \cdot 10^{-5}$	$5 \cdot 10^{-8} - 5 \cdot 10^{-7}$
1-10	10^{-2}	10^{-4}	$5 \cdot 10^{-6} - 5 \cdot 10^{-5}$	$5 \cdot 10^{-8} - 5 \cdot 10^{-7}$
10-100	10^{-3}	10^{-5}	$10^{-5} - 10^{-4}$	$10^{-7} - 10^{-6}$
> 100	10^{-4}	10^{-6}	10^{-5}	10^{-7}

The guidelines are used to assess the total frequency of accidents within a given consequence range. The frequency guidelines for individual accident scenarios are one-tenth of the total frequency specified by the guidelines, although this is only a recommendation. Therefore, guidelines for a single accident scenario are one-tenth the values listed in the table.

11. From Ref. 11, radiological consequence guidelines are established to ensure that nuclear facilities are designed so that they can be operated without an undue risk to the general public or to workers at the facility. This is accomplished by requiring that (1) doses resulting from normal facility operation be maintained as low as reasonably achievable (ALARA), and (2) allowable doses from abnormal and accident conditions to be scaled as a function of the likelihood of occurrence of the initiating event. Doses in the guidelines are based on 50-year Committed Effective Dose Equivalent (C.E.D.E.) values.

Probability of Occurrence	Radiological Consequence Guidelines for Public Exposure	References
$P \geq 10^{-2}$	25 mrem/year to the whole body and 75 mrem/year to any organ	40 CFR 61, Subpart H 40 CFR 190.10(a)
$10^{-2} > P \geq 10^{-4}$	2.5 rem to the whole body, 30 rem thyroid, 30 rem bone surface, 7.5 rem lung, and 7.5 rem to other organs	10 CFR 100
$P < 10^{-4}$	25 rem to whole body, 300 rem to thyroid, 300 rem to bone surface, 75 rem to lung, and 75 rem to any other organ	10 CFR 100

12. From Ref. 27, the following radiological consequence guidelines are proposed:

Probability of Occurrence	Radiological Consequence Guidelines for Public Exposure	References
$P \geq 1$	25 mrem C.E.D.E.	10 CFR 20.105(c) 40 CFR 190.10(a)
$1 > P \geq 10^{-2}$	0.5 rem C.E.D.E.	DOE 5400.5, Section 3 10 CFR 20.105(e)
$10^{-2} > P \geq 10^{-4}$	2.5 rem C.E.D.E.	10% of 10 CFR 100 DOE/TIC-11603
$10^{-4} > P \geq 10^{-6}$	25 rem C.E.D.E.	10 CFR 100

13. From Ref. 24, the following radiological dose guidelines for accident evaluation are presented:

Annual Probability of Occurrence	Radiological Dose Guidelines for Accident Evaluation	References
$P \geq 10^{-2}$	< 10 mrem whole body, < 30 mrem to lungs, < 120 mrem to thyroid, < 120 mrem to bone surface, and < than 60 mrem to other organs	10 CFR 20.105(c) 40 CFR 190.10(a)
$10^{-2} > P \geq 10^{-4}$	10-500 mrem whole body, 30-1500 mrem to lungs, 120-6000 mrem to thyroid, 120-6000 mrem to bone surface, and 60-3000 mrem to other organs	10% of 10 CFR 100 DOE/TIC-11603
$10^{-4} > P \geq 10^{-6}$	0.5-25 rem whole body, 1.5-75 rem to lungs, 6-300 rem to thyroid, 6-300 rem to bone surface, and 3-150 rem to other organs	
$P < 10^{-6}$	> 25 rem whole body, > 75 rem to lungs, > 300 rem to thyroid, > 300 rem to bone surface, > 150 rem to other organs	10 CFR 100

14. From Ref. 30, approval requirements have been graded according to the hazards posed by the radioactive material to be transported. For example, most shipments of radioactive material are of small quantities for which routing controls are adequately specified in the Regulations, and therefore minimum review/approval requirements apply. Such shipments and the associated packages, usually Excepted, Industrial Type or Type A (except for fissile shipments), require no special approvals by the competent authorities of the countries through which the shipments must pass. When the quantities of radioactive materials in a single package are greater than the Type A limits, the package must be designed to withstand accident conditions in transport. For this type package, regulations require that the competent authority of the country of origin of a Type B(U) package design independently review that design to ensure its adequacy. Should a Type B package not satisfy all regulatory requirements, multilateral approval of the package design is imposed, and this package is denoted as a Type B(M) package. When the quantity of radioactive material in a single Type B(M) package becomes very large, for example 3000 times the Type A limits, the potential consequence of the loss of package integrity become sufficiently large for the regulations to require a review/approval of the shipment itself.
15. From Ref. 31, the types of radioactive material packages are described below.

Excepted packages - permitted to contain small quantities of radioactive materials and are excepted from various specific packaging and labeling requirements, provided they meet the general requirements specified in the Regulations with respect to radiation and contamination levels and to packaging.

Consequences of transport accidents - consequences of accidents, if any, involving excepted packages are minor, and there are no radiological reasons for taking special protective actions.

Industrial packages - Low specific activity (LSA) materials and surface contaminated objects (SCOs) often carried in large quantities in industrial packages. Industrial packages are required to meet general package requirements. Type 2 and Type 3 industrial packages are required to withstand normal conditions of transport without loss or dispersal of their contents or loss of adequate radiation shielding integrity.

Consequences of transport accidents - The quantities of LSA material and SCO in a package, which is usually an industrial package, are limited so that the external radiation level at 3 m from the unshielded material or object, or collection of objects, does not exceed 10 mSv/h (1000 mrem/h). Although the total activity in a consignment of LSA material or SCO may be significant, the nature of the contents is such that should containment be lost in an accident, the potential radiological hazard would be relatively low.

Type A packages - total activity of radioactive material in a Type A package is limited. The activity limits are determined from the maximum acceptable radiological consequences following failure of the package as a result of an assumed accident. These limits for "special form" (nondispersible) and other than special form radioactive materials are known as the A_1 and A_2 values, respectively. Type A packages are required to withstand the normal conditions of transport without loss or dispersal of their contents or loss of

adequate shielding integrity. Experience has shown that only a small fraction of packages shipped have suffered loss of contents or a change in external radiation levels when they have been involved in a transport accident.

Consequences of transport accidents - the activity limits prescribed for Type A packages limit the immediate hazard near these packages such that the effective (or committed effective) dose equivalent to a person near a single package following an accident should not exceed the annual dose limit for radiation workers, namely 50 mSv (5 rem). It is assumed that a person does not remain for more than 30 min within 1 m of the damaged package.

Type B packages - contain radioactive materials in quantities greater than those allowed in Type A packages. Type B packages must be designed to withstand both normal and accident conditions of transport. Experience to date has confirmed the suitability of this package design concept and has shown that the probability of loss of shielding or containment for such packages is very low.

Packages containing fissile materials - Regulations include specific provisions for packages containing fissile materials. Criticality safety in the transport of fissile material is ensured by limiting the quantity and geometric configuration of the fissile material, by package design features, and by controlling the number of packages allowed to be carried on a single conveyance or to be stowed together in transit.

16. From Ref. 17, the following radiological EGs were proposed for the public: Doses shall not exceed (1) 0.5 rem for accidents with estimated frequency less than 0.1 event per year but greater than or equal to 0.01 event per year; (**note:** reference actually indicates this limit as 5 vs 0.5 due to a typographical error) (2) 5 rem for accidents with estimated frequencies less than 0.01 event per year, but greater than or equal to 0.0001 event per year, and (3) 25 rem for accidents with estimated frequencies less than 0.0001 event per year, but greater than or equal to 0.000001 event per year.
17. From Ref. 33, examples of a consequence classification mechanism using qualitative and quantitative measures for scenario binning are provided for both radiological and chemical accidents.

The examples are provided below:

Category	Radiological Consequence	Chemical Consequences
HIGH	> 5 rem at site boundary	> ERPG-2 at site boundary
MODERATE	> 0.1 rem at site boundary	Not applicable
LOW	< Moderate	< High

Chemical Consequence Guidelines:

1. Ref. 14 examined the radiation guidelines published in 10 CFR Part 100 of the *Federal Register* and uranium chemical toxicity data. Ref. 14 concluded that an inhalation intake of approximately 10 mg of soluble uranium would have no long-term health effects and have a consequence roughly comparable to a 25 rem exposure.
2. Human ingestion studies have shown that an acute uptake of 0.1 mg of U per kg of body weight would not be considered toxicologically harmful (p. 2-26 of EGG-2530). For a 72-kg standard man, this represents a 7.2 mg uptake, or about a 15 mg intake of Class D very soluble material. The corresponding no effect levels for intakes of Class W slightly soluble or Class Y relatively insoluble material would require a significantly larger intake of uranium than the 15 mg associated with Class D material.
3. From Ref. 26, nonnuclear facilities (with radioactive material inventory below 40 CFR 302, Table 302.4, Appendix B) with hazardous material inventories at or above 20 CFR 1910.119 threshold or the levels specified in 40 CFR 255, *Emergency Planning and Notification* (only if chemicals are **not** listed in 29 CFR 1910.119), shall develop a safety analysis in accordance with DOE 5481.1B. Nonnuclear facilities with hazardous material inventories between process safety management thresholds and potentially reportable 40 CFR 302 levels, shall develop an Auditable Safety Analysis.
4. From Ref. 19, EPA specifies toxicity criteria that were used to identify the chemicals on the list of extremely hazardous substances required by Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA; i.e., Emergency Planning and Community Right-To-Know Act). For the inhalation route of exposure, the acute toxicity measure was specified as the LC50 (i.e., the concentration of the chemical in air at which 50 percent of the test animals died). If a chemical's LC50 was less than or equal to 0.5 mg/L air for exposure time of 8 hours or less, the chemical was identified as an extremely hazardous substance. Some chemicals that do not meet the above-mentioned criteria for acute toxicity were also included on the EPA list of extremely hazardous substances (EHSs). Criteria for designating these other chemicals included the following factors: large volume production, acute lethality values, and known risk as indicated by the fact that some chemicals have caused death and injury in accidents.
5. From Ref. 19, EPA also defined "levels of concern" (LOCs) as the concentrations of an EHS in air above which there may be serious irreversible health effects or death from a single exposure for a relatively short time. The LOC for an EHS has been estimated by using 0.1 of the IDLH level published by the National Institute for Occupational Safety and Health (NIOSH) or an approximation of the IDLH from animal toxicity data. For those chemicals that do not have IDLHs, the following estimates are proposed:

$$\text{Estimated IDLH} = \text{LC}_{50} \cdot 0.1$$

$$\text{Estimated IDLH} = \text{LC}_{\text{Lo}}$$

$$\text{Estimated IDLH} = \text{LD}_{50} \cdot 0.01$$

$$\text{Estimated IDLH} = \text{LD}_{\text{Lo}} \cdot 0.1$$

6. From Ref. 19, the EPA also states that some organizations may want to use any one of the following as definitions of LOCs: Threshold Limit Values (TLVs) as defined by American Conference of Governmental Industrial Hygienists (ACGIH), Short-term Exposure Levels (STELs) as defined by National Academy of Sciences, Emergency Response Planning Guidelines (ERPGs) as defined by the American Industrial Hygiene Association (AIHA), OSHA Permissible Exposure Limits (PELs), or NIOSH Recommended Exposure Limits (RELs).

7. From Ref. 21, the following statements are extracted:

"The use of a TLV, PEL, or WEEL (Workplace Environmental Exposure Level) value, although decidedly safe in the vast majority of cases, could conceivably result in major over prediction of downwind evacuation or hazard zones in many situations. These values are often (but not always) much lower than what they need to be to protect the public from exposures associated with rare or infrequent spills of brief duration."

"The NAS/NRC SPEGLs and AIHA ERPG-2 values are possibly the best choice among currently available guidelines for protection of the public during relatively short-term events given the objectives of their respective developers."

"Overall, there is no widely accepted method available for selection of an appropriate exposure limit for general populations subjected to toxic vapors or gases, particularly where the exposure limit is to be used for public emergency planning purposes. Some options, in order of decreasing preference, and by no means mandatory for use, are as follows:

- Use the NAS/NRC SPEGL or the AIHA ERPG-2 value for the material if available;
- Consult a toxicologist or similarly qualified individual for advice based on a formal review of the toxicity of the material of concern;
- Use the highest value among the following:
 - IDLH value divided by 10 (with 10 being a safety factor)
 - TLV-STEL
 - TLV-TWA multiplied by 3 (if a TLV-STEL does not exist)
 - TLV-C
- If the evacuation of additional areas is not a problem or the exposure may be prolonged beyond one hour, use the TLV-TWA or the TLV-C value or apply an additional safety factor to other selections.

NOTE: It is necessary for government and industry to consider cases involving carcinogens carefully and on a case-by-case basis."

8. From Ref. 17, the following toxicological EGs were proposed for the public: Dosages shall not exceed the ERPG-2 dosage. If ERPG information is not available for a toxicological hazard, the

EG shall be either (1) one-tenth of the IDLH concentration, or (2) any better toxicological information available to show estimated dosages do not represent a potential health threat in excess of the ERPG-2 definition.

Notes:

1. The U.S. Department of Transportation (DOT), EPA, and to some extent, DOE have various responsibilities for regulating hazardous cargo transport.
2. From Ref. 4, "One of the major problems encountered in regulating hazardous material transport is the plethora of regulations that, as a whole, appear to make little or no sense. Each individual rule making has been based on its own set of criteria, which is usually different from all others. Federal regulators, states, localities, shippers, and industry have all complained of this problem. It has been suggested that the use of risk assessment, as a basis for rule making, might result in a more logical and flexible rationale for establishing regulations. As far as can be ascertained, no rule making in the hazardous transport area, to date, has formally used risk criteria in its establishment."
3. Strategy for establishing Evaluation Guidelines—Review existing rules and regulations to determine the levels of risk revealed by each rule making. Those cases that are significantly higher or lower than the average levels might then provide insight as to how Risk Evaluation Guidelines might be formulated.
4. From Ref. 29, there are two basic types of packagings for radioactive material (RAM): Type A and Type B. Type A packaging must withstand normal conditions of transport without loss or dispersal of its radioactive contents as demonstrated by the tests set forth in 49 CFR 173.465 or 173.466. Type B packaging must withstand both normal and accident test conditions set forth in 10 CFR 71.71 and 10 CFR 71.73. Type B packagings are subjected to the leak-rate criteria of the NRC's Regulatory Guide 7.4.
5. From Ref. 29, LSA materials, such as uranium ores and concentrates, that present a relatively low hazard because of their limited radioactive concentration, may be transported by conveyances assigned for the exclusive use of the consignor in packages called strong, tight packages (49 CFR 173.24) of less rigorous construction than Type A packages. LSA materials may also be transported in nonexclusive-use shipments in what are essentially Type A packages that meet the requirements of 49 CFR 173.465. LSA material is defined in 49 CFR 173.403(n) and 10 CFR 71.4.
6. From Ref. 29, RAM may be shipped in either special form or normal form. The special form (49 CFR 173.403(z) and 173.469(a) or 10 CFR 71.4 may be caused by a material characteristic (e.g., massive solid metal); or the special form may be acquired through high-integrity encapsulation. Special form material may present a direct radiation hazard if released from its package, but normally it will present relatively little hazard as a result of dispersal or external surface contamination. Special form RAM must satisfy the test requirements of 49 CFR 173.469 or 10 CFR 71.75. Normal form materials (173.403(s)) include any materials not qualifying as special form.

7. From Ref. 29, the regulatory standards for packaging and transport of RAM are designed to achieve four primary objectives:
- To protect persons and property from radiation emitted from packages during transportation, by specific limitations on the allowable radiation levels.
 - To provide proper containment of the radioactive material in the package under the normal rigors of transportation for Type A quantities or under normal and accident conditions for Type B quantities. This is achieved by packaging design requirements based on performance oriented packaging integrity tests and environmental criteria.
 - To prevent nuclear criticality.
 - To provide physical protection against theft and sabotage during transit of strategic quantities of special nuclear materials.
8. From Ref. 29, each radionuclide is assigned two values A_1 and A_2 , that represent the maximum number of curies permitted in Type A packages in special form and normal form. Type B quantities are quantities exceeding the appropriate A_1 and A_2 value for the radionuclide of interest. IAEA (International Atomic Energy Agency) Safety Series No. 37, "Advisory Material for the Application of IAEA Transport Regulations."
9. From Ref. 29, all packagings except those that contain a limited quantity of RAM, or excepted articles or devices (those excepted from the specification packaging, marking, and labeling requirements of Subpart I) under 49 CFR 173.421 through 173.424, must meet the general design requirements of 49 CFR 173.411. Additional design requirements for Type A packagings are described in 49 CFR 173.412.
10. Quantities of RAM exceeding Type A packaging limits may be transported only in strong, accident-resistant Type B packagings. In addition to meeting design requirements for Type A packagings, a Type B packaging must survive certain severe hypothetical accident conditions that demonstrate resistance to impact, puncture, fire, and water submersion (10 CFR Part 71.73). To be judged as surviving, a Type B packaging must not exceed the allowable releases defined in 10 CFR 71.51. Further, the radiation-dose rate outside a Type B packaging must not exceed 1 rem/hr at a distance of 1 m (10 CFR 71.51) from the package surface after the tests specified under 10 CFR 71.73.
11. The level of nonfixed (i.e., removable) radioactive contamination on the external surfaces of each package offered for shipment shall be kept as low as practical. This level is limited as specified in 49 CFR 173.443 and 10 CFR 71.87.
12. From Ref. 29, general requirements for packages containing fissile materials are found in 49 CFR 173.451 through 173.459 and in 10 CFR 71.55. A packaging used to ship fissile material must be designed so that it is subcritical in the most reactive configuration that is credible for the form of the material and for optimal conditions of neutron moderation and reflection by water.

13. From Ref. 29, "From incident-free transport, the exposure of the public and workers to radiation arises only from the radiation allowed by the standards to penetrate the package."
14. From Ref. 30, the thresholds for nuclear facilities are defined in DOE 5480.23 as Category 1, Category 2, or Category 3 based strictly on the inventory of radiological material in the facility.
15. From Ref. 30, the threshold for non-nuclear facility designation is "radioactive material inventory is less than 40 CFR 302 levels."
16. From Ref. 30, the upper threshold for a "radiological facility" is radiological inventory less than Category 3 quantities as defined in DOE-STD-1027-92, and the lower threshold for a radiological facility is radiological inventory greater than levels defined in 40 CFR 302.
17. From 49 CFR Part 171, which prescribes the requirements of the DOT governing the transportation of hazardous material:

hazard class - category of hazard assigned to a hazardous material under the definitional criteria of Part 173 of this subchapter and provisions of 172.101 Table.

hazard zone - one of four levels of hazard (Hazard zones A through D) assigned to gases, as specified in 173.116(a), and one of two levels of hazard (Hazard zones A and B) assigned to liquids that are poisonous by inhalation as specified in 173.133. A hazard zone is based on the LC50 value for acute inhalation toxicity of gases and vapors as specified in 173.133.

hazardous material - substance or material, which has been determined by the Secretary of Transportation to be capable of posing an unreasonable risk to health, safety, and property when transported in commerce, and which has been so designated. Term includes hazardous substances, hazardous wastes, marine pollutants, and elevated temperature materials as defined in this section, material designated as hazardous under the provisions of 172.101 and 172.102 and materials that meet the defining criteria for hazard classes and division in part 173 of this subchapter.

packing group - grouping according to the degree of danger presented by the hazardous material; Packing group I indicates great danger; Packing group II, medium danger; packing group III, minor damage (172.101)

See attachments from 49 CFR Part 173 regarding hazard class and hazard zone.

18. ERPGs have been developed by the American Industrial Hygiene Association for emergency response applications. ERPGs are widely accepted endpoints for evaluating the consequences of accidental chemical exposures. ERPGs only currently exist for relatively few chemicals. Therefore, ERPG alternatives must be used for many chemicals. The Subcommittee on Consequence Assessment and Protective Actions (SCAPA) of the DOE-HQ Emergency Management Advisory Committee (EMAC) has developed the following hierarchy of alternative criteria if ERPGs are not available. The alternative guidelines are documented in *Alternative Guideline Limits for Chemicals Without Environmental Response Planning Guidelines*, D. K. Craig, et al., American Industrial

Hygiene Association Journal 56:919-925 (1995). Craig's recommended hierarchy of alternative criteria for ERPG-2 values is:

	<u>Source</u>
EEGL (60-min)	NAS
LOC	EPA/FEMA/DOT
PEL-C	OSHA
TLV-C	ACGIH
TLV-TWA•5	ACGIH

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Attachment B:

Issues Associated with Risk Evaluation Guidelines

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Attachment B:

Issues Associated with Risk Evaluation Guidelines

Issue 1 Should transportation Risk Evaluation Guidelines be more or less stringent than Evaluation Guidelines for facilities?

More stringent:

Publicity and public relations impact will probably be more severe for a transportation accident. People can choose not to live near a hazardous facility, while they have little option about using public roadways.

Less stringent:

Hazard "containment" may be less feasible or much more costly for transportation than for facility activities.

Recommendation: Without any precedent and the conflicting drivers, the Evaluation Guideline for facilities and transportation should be assumed to be equivalent.

Issue 2 Should radiological and chemical risks have the same criteria? (e.g. not exceeding a "no effect level")

More stringent criteria for radiological:

Various regulatory agencies and the public have required a higher level of protection for the radiological hazards.

The same criteria:

From a risk perspective, the nature of the hazard is irrelevant: The issue is the severity of impact.

Recommendation: Because most regulatory agencies have more stringent criteria for radiological hazards, and because the public expects a higher level of protection from radiological hazards, the radiological Evaluation Guideline should be more stringent.

Issue 3 What is the appropriate location for evaluating the impact? Should the risk analysis consider impacts only beyond a certain distance or at all locations?

The worst case consequence at ground zero will almost always be significant, and using this position as a basis would be overly conservative. Therefore, the risk should be evaluated at some finite distance from the accident.

Recommendation: If an SST is involved in a significant accident, a 500-ft radius security zone will be established to keep the public at least 500 ft from the SST. Therefore, the TSRA will consider the impact on the public for distances less than 500 ft only for the time required to establish the security zone. The TSRA will consider the impact on the public for distances 500 ft and beyond for the duration of the postulated accident.

Issue 4 Risk is acceptable if consequence•probability is acceptably low. Should it be concluded that the risk is acceptable if (a) Frequency is incredible (e.g., 10^{-6} /yr) or consequence < Evaluation Guideline (e.g., < 25 rem) or (b) if DOE guidance would indicate a SAR is not required (e.g., < STD-1027 and < Low hazard).

Recommendation: The risk should be considered acceptably low if either (a) frequency < Evaluation Guideline (e.g., 10^{-6} /yr) or consequence < Evaluation Guideline (e.g., < 25 rem or < ERPG-2) or (b) if DOE guidance would indicate a SAR not required (e.g., < STD-1027 criteria and < Low hazard criteria).

Issue 5 Should the number of people impacted be considered? The risk and consequence associated with an accident includes the severity of the consequence and the number of people impacted.

Recommendation: The number of people impacted should probably not be considered. Most of the DOE criteria have been associated with the maximally exposed individual. Although some criteria consider the average impact (e.g., within a 5-mile radius) the complexity, cost, and minimal benefit of considering demographics does not appear to be justified.

Issue 6 Should a credible criticality incident be considered unacceptable independent of consequences?

Recommendation: Based on the potential for extremely adverse public relations, programmatic impact, etc., a credible criticality incident should be considered an unacceptable risk.

Issue 7 What is meant by frequency and incredible event for a shipment? If the Evaluation Guideline has frequency-dependent thresholds or if the criteria include the concept of an incredible event, then the identification of the appropriate frequency is required.

Recommendation: If the TSRA is addressing a single shipment of material, it is reasonable to use the probabilities of accidents associated with that shipment. However, if multiple shipments are addressed in a TSRA, then the entire campaign should be considered.

Currently the criterion for an incredible event is accepted throughout the DOE community to be an event whose annual frequency of occurrence is less than 10^{-6} per year. This number is based on considering a fixed installation with operations ranging from continuous operations to a number of batch activities. Therefore, considering only one shipment would be equivalent to only considering a duration less than one year (e.g., that associated with a batch process) and would "underestimate" the perceived risk.

The TSRA should calculate the risk associated with an individual shipment, the annual risk based on the maximum expected shipments in a 1 year period, and the risk over the entire campaign.

The frequency definition of accidents will be based on the risk of the entire campaign if the campaign duration is less than one year, or on the annual risk if the campaign lasts more than one year.

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Attachment C:
R. A. Just's Recommendation

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Attachment C:
R. A. Just's Recommendation

Table 1.2-1 of DOE/TIC-11603, Rev. 1 provides the following definitions:

	Estimated Probability of Occurrence
<u>Incredible Events:</u> Events of extremely low probability of occurrence or nonmechanistic hypothetical events.	$< 10^{-6}$ per year
<u>Extremely Unlikely</u> Events which . . . are not expected to occur in the life of a facility . . .	$10^{-6} \leq P < 10^{-4}$
<u>Unlikely Events</u> Incidents or events which are not expected, but which may occur during the lifetime of a facility.	$10^{-4} \leq P < 10^{-2}$
<u>Anticipated Events</u> Incidents or events of moderate frequency, but which may occur once or more during the life of a facility.	$10^{-2} \leq P \leq 1$

Many sources equate annual probability of occurrence with the annual frequency of occurrence although they have different definitions. However, for most applications the two are approximately equal for low probabilities/frequencies. Risk Evaluation Guidelines will be developed based on the following accident categories:

	Estimated Frequency of Occurrence
Incredible Events	$< 10^{-6}$ per year
Extremely Unlikely	$10^{-6} \leq \text{Frequency} < 10^{-4}$
Unlikely Events	$10^{-4} \leq \text{Frequency} < 10^{-2}$
Anticipated Events	$10^{-2} \leq \text{Frequency}$

Initially Risk Evaluation Guidelines criteria will be developed for events with an annual frequency of occurrence of 10^{-6} , 10^{-4} , 10^{-2} , and $> 10^{-2}$ and then an interpolation scheme(s) will be proposed.

Radiological Evaluation Guideline:

1. Evaluation Guideline for an Accident Frequency of 10^{-6} per Year

A number of sources give a 25 rem criterion for design basis accidents (DBAs) or evaluation basis audits (EBAs):

- (a) Section 0200-1.3 of the General Design Criteria, DOE Order 6430.1A (Ref. 12), specifies a 25-rem whole body dose radiological siting guideline for new or modified DOE facilities.
- (b) 10 CFR 100 states a public siting criterion of 25 rem to whole body, 300 rem to thyroid, 300 rem to bone surfaces, 75 rem to lung, and 75 rem to any other organ for DBAs (e.g., 10^{-4} to 10^{-6} per year)
- (c) Proposed Standard DOE-STD-3005-YR provides a public Evaluation Guideline of 25 rem for accident frequencies between 10^{-6} and 10^{-4} per year.
- (d) DOE/TIC-11603 for $10^{-4} > P \geq 10^{-6}$ and $P \leq 10^{-6}$.
- (e) LA-10294-MS, for $P \leq 10^{-6}$, > 25 rem whole body, > 75 rem to lungs, > 300 rem to thyroid, > 300 rem to bone surface, > 150 rem to other organs.
- (f) Section 0200-1.3 of 6430.1A indicates

"The maximum calculated dose shall not exceed 25 rem to the whole body, 300 rem to the thyroid, 300 rem to the bone surface, 75 rem to the lung, or 150 rem to any other organ."

DOE-STD-3011-94 indicates that consequences exceeding 5 rem at the site boundary should be placed in the High Consequence bin. However, it seems overly conservative to use 5 rem as a criterion. Therefore, it is concluded that for credible events the criterion should be:

The maximum calculated dose shall not exceed 25 rem to the whole body, 300 rem to the thyroid, 300 rem to the bone surface, 75 rem to the lung, or 150 rem to any other organ.

This is consistent with DOE/TIC-11603 and LA-10294-MS, and the DOE-STD-3005-YR.

2. Evaluation Guideline for an Accident Frequency of 10^{-4} per Year

10 CFR 100, TIC-11603 and LA-10294 show guidelines equal to 10% of the above values at frequency of 10^{-4} per year. Use 0.1 times the above criterion for a frequency of 10^{-4} per year or the maximum calculated dose shall not exceed 2.5 rem to the whole body, 30 rem to the thyroid, 30 rem to the bone surface, 7.5 rem to the lung, or 15 rem to any other organ.

3. Evaluation Guideline for an Accident Frequency of 10^{-2} per Year

DOE Order 6430.1A refers to DOE Order 5400.5, which applies to normal operations and not accident conditions. However, DOE Order 6430.1A invokes it for accidental releases. Order 5400.5 indicates the upper limit for normal operation is therefore 100 mrem/year (with the exception that a 500 mrem/year limit may apply to short-term activities with DOE approval).

A single whole body dose of 100 mrem corresponds to no significant acute health effects, and based on a conversion factor $5 \cdot 10^{-4}$ fatalities per rem for the public for a dose less than 10 rem, the long term consequences of a 100 mrem exposure corresponds to a fatality probability of $5 \cdot 10^{-5}$.

DOE-STD-3011-94 indicates that consequences exceeding 0.1 rem at the site boundary should be placed in the Moderate Consequence bin.

Based on the very low consequences of a 100 mrem exposure, it does not appear to be appropriate to consider a lower consequence for annual frequencies less than 0.01 per year.

4. Interpolation of Proposed Radiological Risk Evaluation Guidelines

Several approaches were considered for interpolating between 10^{-6} and 10^{-4} , between 10^{-4} and 10^{-2} , and above 10^{-2} :

- (a) linear interpolation
- (b) assuming a straight line on a log-log plot, which is equivalent to assuming the Evaluation Guideline = $a(\text{Radiation Dose in Rems})^b$, where a and b are constants;
- (c) assuming a straight line on a semi-log plot, which is equivalent to assuming the Evaluation Guideline = $ae^{b(\text{Radiation Dose in Rems})}$, where a and b are constants.

It is recommended that the Evaluation Guideline be interpolated assuming a straight line on a log-log plot.

Originally the following radiological Evaluation Guideline were recommended:

Annual Frequency	Radiation Exposure Level				
	Whole Body	Thyroid	Bone Surface	Lung	Any Other Organ
10^{-6}	25 rem	300 rem	300 rem	75 rem	150 rem
10^{-4}	2.5 rem	30 rem	30 rem	7.5 rem	15 rem
$\geq 10^{-2}$	0.5 rem	6 rem	6 rem	1.5 rem	3 rem

On February 1, 1995 a proposed appendix to DOE-STD-3009-94 was issued for comment. This draft proposes a 25 rem whole body radiological Evaluation Guideline independent of frequency. As of mid January 1996, the latest information indicates that a frequency independent 25 rem whole body radiological Evaluation Guideline is likely to be specified by DOE-HQ either in an update to DOE-STD-3009-94, in the final version of 10 CFR 830.110, or in guidance for implementation for the 10 CFR 830.110. Based on consideration of the most recent guidance from DOE-HQ, it seems appropriate to consider only whole body doses. Consequently, the recommended radiological Risk Evaluation Guidelines are those shown in the following table.

**50-year Committed Effective Dose
Equivalents (C.E.D.E.)**

Annual Frequency	Whole Body
10^{-6}	25 rem
10^{-4}	2.5 rem
$\geq 10^{-2}$	0.5 rem

Chemical Evaluation Guideline

1. Evaluation Guideline for an Accident Frequency of 10^{-6} per Year

- (a) The *Handbook of Chemical Hazard Analysis Procedures*, Federal Emergency Management Agency, U.S. Department of Transportation, and U.S. Environmental Protection Agency indicates that :

“The NAS/NRC SPEGLs and AIHA ERPG-2 values are possibly the best choice among currently available guidelines for protection of the public during relatively short-term events given the objectives of their respective developers.”

The SPEGL or Short-Term Public Emergency Guidance Level is defined as:

“a suitable concentration for unpredicted, single, short-term, emergency exposure of the general public. In contrast to the EEGL, the SPEGL takes into account the wide range of susceptibility of the general public. This includes sensitive populations -- such as children, the aged, and persons with serious debilitating diseases.”

The ERPG-2 or Emergency Response Planning Guideline 2 is defined as:

“The maximum airborne concentration below which it is believed that nearly all individuals could be exposed for up to 1 hour without experiencing or developing irreversible or other serious health affects or symptoms that could impair their abilities to take protective action.”

- (b) DOE-STD-3011-94 indicates that consequences exceeding ERPG-2 at the site boundary should be placed in the High Consequence bin.

Therefore, it is recommended that the consequence Evaluation Guideline should be either the SPEGL, ERPG-2, or an ERPG-2 alternative in decreasing order of preference for accidents with a frequency of occurrence of 10^{-6} per year. If information is available on the toxicity of a material other than a SPEGL, ERPG-2 or an ERPG-2 alternative, this information can be used if the information is a more appropriate basis or the best information available for determining if the health effect can be considered reversible. For example, Chemical Risk Evaluation Guidelines for uranium could be based on an ingestion intake of 15 mg of uranium and on an

inhalation intake of 10 mg of soluble uranium because these intakes have no long-term health effects.

ERPGs only currently exist for relatively few chemicals. Therefore, ERPG alternatives must be used for many chemicals. The Subcommittee on Consequence Assessment and Protective Actions (SCAPA) of the DOE-HQ Emergency Management Advisory Committee (EMAC) has developed a following hierarchy of alternative criteria if ERPGs are not available. The alternative guidelines are documented in *Alternative Guideline Limits for Chemicals Without Environmental Response Planning Guidelines*, D. K. Craig, et al., American Industrial Hygiene Association Journal 56:919-925 (1995). Craig's recommended hierarchy of alternative criteria for ERPG-2 values is:

	<u>Source</u>
EEGL (60-min)	NAS
LOC	EPA/FEMA/DOT
PEL-C	OSHA
TLV-C	ACGIH
TLV-TWA•5	ACGIH

The above Evaluation Guideline is equivalent to a criterion that the effects would be considered reversible; i.e., exposed individuals would not experience or develop irreversible or other serious health effects or symptoms that could impair their abilities to take protective action. If there is information on the toxicity of a material other than an SPEGL, ERPG-2 or an ERPG-2 alternative, this information can be used if the information is a more appropriate basis for determining if the health effect can be considered reversible.

EPA has defined the level of concern (LOC) as the concentration of an extremely hazardous substance in air above which there may be serious irreversible health effects or death from a single exposure for a relatively short time. The LOC may be estimated by using 0.1 of the IDLH level or as the Threshold Limit Value (TLV), the Short-term Exposure Level (STEL), the Permissible Exposure Limit (PEL), or the Recommended Exposure Limit (REL).

ERPG-2 values and alternatives are based on an 1 hour exposure period. If the exposure duration significantly exceeds 1 hour, then the Evaluation Guideline should be either the ERPG-2 or ERPG-2 alternative divided by the exposure duration in hours. If the duration is significantly less than 1 hour, the ERPG-2 or ERPG-2 alternative **SHOULD NOT** be divided by the exposure duration if the material is concentration dependent.

Concentration-dependent chemicals are fast-acting chemicals whose toxic effects are immediate, and correlate more closely to concentration than dose. Included in this category are sensory irritants and chemicals that are corrosive or vesicant in their action. Any chemical assigned an OSHA PEL-STEL or PEL-C, or an ACGIH TLV-STEL or TLV-C value must be considered concentration-dependant. In contrast, the effects of dose-dependent chemicals depend on both concentration and duration of exposure.

2. Evaluation Guideline for an Accident Frequency $> 10^{-6}$ per Year

As indicated above, a baseline assumption was that Evaluation Guideline should be developed for events with an annual frequency of occurrence of 10^{-6} , 10^{-4} , 10^{-2} , and $> 10^{-2}$. However, it seems appropriate to reexamine this assumption.

Although initially it would appear to be appropriate to have a frequency dependent chemical Evaluation Guideline similar to that proposed for radiation effects, this may result in an overly stringent chemical Evaluation Guideline. The radiation Evaluation Guideline proposed corresponds to no significant acute effects for all frequencies of occurrence and for a probability of fatality (delayed from cancer), given that the accident occurs, ranging from 0.005 to 0.025 fatalities. Normal industry routinely ships hazardous materials, for which the DBAs and EBA would be expected to have significant acute and/or long-term consequences (e.g., irreversible health effects or fatalities). It does not appear to be appropriate to have more stringent criteria for accidental chemical exposures than the onset of possible irreversible effects recommended above for an annual accident frequency of 10^{-6} .

Therefore, it is recommended that the consequence Evaluation Guideline should be either the SPEGL, ERPG-2 or an ERPG-2 alternative in decreasing order of preference for all credible accidents (e.g., accidents with a frequency of occurrence $\geq 10^{-6}$ per year. Alternatively, if a more stringent Evaluation Guideline is required, it is recommended that ERPG-3 or ERPG-3 alternatives be used in decreasing order of preference as the Evaluation Guideline for $p \geq 10^{-4}$ and that the Evaluation Guideline be interpolated between 10^{-6} and 10^{-4} by assuming Evaluation Guideline = $a(\text{Radiation in Rems})^b$, where a and b are constants.

ERPG-3 **Emergency Response Planning Guideline 3:** "The maximum airborne concentration below which it is believed nearly all individuals could be exposed for up to 1 hour without experiencing or developing life-threatening health effects."

ERPGs only currently exist for relatively few chemicals. Therefore, ERPG alternatives must be used for many chemicals. The Subcommittee on Consequence Assessment and Protective Actions (SCAPA) of the DOE-HQ Emergency Management Advisory Committee (EMAC) has developed a following hierarchy of alternative criteria if ERPGs are not available. The alternative guidelines are documented in *Alternative Guideline Limits for Chemicals Without Environmental Response Planning Guidelines*, D. K. Craig, et al., American Industrial Hygiene Association Journal 56:919-925 (1995).

Craig's recommended hierarchy of alternative criteria for ERPG-3 values is:

ERPG-3	Source
EEGL (30 min)	NAS
IDLH	NIOSH

3. Mixtures

When two or more toxic substances are present, their combined effect should be considered. Lacking information to the contrary, the effects of the different hazards should be considered as additive.

That is, if the sum of the following fractions, $C_1/T_1 + C_2/T_2 + \dots + C_n/T_n$ exceeds 1, then the limit of the mixture should be considered as exceeded. C indicates the observed atmospheric concentration, and T the corresponding limit.

Exceptions to the above rule may be made when there is a good reason to believe that the chief effects of the different harmful substances are not in fact additive, but *independent* as when purely local effects on different organs of the body are produced by the various components of the mixture. In such cases, the limit ordinarily is exceeded only when at least one member of the series (C_1/T_1 or C_2/T_2 , etc.) itself has a value exceeding 1.

4. Evaluation of Total Risk

To decide if the risk of a proposed shipment or shipments is acceptable, all accident scenarios must be considered and compared with the Risk Evaluation Guidelines. For each accident scenario, the

frequency and consequence should be evaluated to determine the value of $\sum_{i=1}^n \frac{(Consequence)_i}{(Criterion)_i}$,

where n is the number of credible scenarios.

If $\sum_{i=1}^n \frac{(Consequence)_i}{(Criterion)_i} < 1$ for both chemical and radiological effects, the risk is acceptable. If

$\sum_{i=1}^n \frac{(Consequence)_i}{(Criterion)_i} \geq 1$ for either chemical or radiological effects, a management decision is

required to accept the risk.

Attachment D:

A. F. Love's Recommendation

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Attachment D

A. F. Love's Recommendation

Radiological Risk Criteria

Frequency of Occurrence	Radiological Consequence Guidelines for Public Exposure	References
$P \geq 0.1$	25 mrem C.E.D.E.	10 CFR 20.1301(c) ¹ 40 CFR 190.10(a) ⁴
$0.1 > P > 10^{-2}$	0.5 rem C.E.D.E.	DOE 5400.5, Section 2 ⁵ 10 CFR 20.1301(c) ³ DOE STD-3005-YR (Draft)
$10^{-2} > P \geq 10^{-4}$	2.5 rem C.E.D.E.	10% of 10 CFR 100 ¹ DOE/TIC-11603
$10^{-4} > P \geq 10^{-6}$	25 rem C.E.D.E.	10 CFR 100 ¹ DOE Order 6430.1A, Sect. 0200-1.3 ² DOE/TIC-11603

¹10 CFR Part 100 states a public siting criterion of 25 rem for design basis accidents, which are defined to be exceedingly low probability accidents. Generally, a very low probability accident has been interpreted as having a frequency lower than 10^{-4} per year and is sometimes characterized as being of a frequency of 10^{-6} per year.

²DOE Order 6430.1A specifies a 25 rem whole body dose radiological siting guideline for new or modified DOE facilities. The order notes that this value is a reference value to be used in the evaluation of facility sites with respect to potential accidents of exceedingly low probability of occurrence.

³From 10 CFR 20.1301, Dose Limits for individual members of public, A license or license applicant may apply for prior NRC authorization to operate up to an annual dose limit for an individual member of public of 0.5 rem. Otherwise, the dose limit for individual members of public is 25 mrem.

⁴From 40 CFR Part 190.10, Subpart B, Environmental Standards for the Uranium Fuel Cycle, the annual dose equivalent does not exceed 25 mrem to whole body, 75 mrem to thyroid, 25 mrem to any other organ of any member of public as the result of exposures to planned discharges of radioactive material.

⁵From Section 2 of DOE Order 5400.5, item (4) Exceptions. Unusual circumstances could affect a DOE activity in such a manner that the potential public dose could exceed an effective dose equivalent of 100 mrem in a year. If avoidance of the higher exposures is impractical, the Manager of the DOE Field Office, in coordination with their Program Office, may request, from EH-1, specific authorization for a temporary public dose limit higher than 100 mrem, but not to exceed 500 mrem, for the year.

Chemical Risk Criteria

Recommendation: All credible (i.e., frequency $\geq 10^{-6}$ per year) accidents should result in concentrations less than the ERPG-2 or ERPG-2 equivalent value.

ERPGs have been developed by the American Industrial Hygiene Association for emergency response applications. ERPGs are widely accepted endpoints for evaluating the consequences of accidental chemical exposures. ERPGs only currently exist for relatively few chemicals. Therefore, ERPG alternatives must be used for many chemicals. The Subcommittee on Consequence Assessment and Protective Actions (SCAPA) of the DOE-HQ Emergency Management Advisory Committee (EMAC) has developed a following hierarchy of alternative criteria if ERPGs are not available. The alternative guidelines are documented in *Alternative Guideline Limits for Chemicals Without Environmental Response Planning Guidelines*, D. K. Craig, et al., American Industrial Hygiene Association Journal 56:919-925 (1995). Craig's recommended hierarchy of alternative criteria for ERPG-2 values is:

<u>ERPG-2</u>	<u>Source</u>
EEGL (60 min)	NAS
LOC	EPA/FEMA/DOT
PEL-C	OSHA
TLV-C	ACGIH
TLV-TWA•5	ACGIH

References:

1. From Ref. 19, "The NAS/NRC SPEGLs and AIHA ERPG-2 values are possibly the best choice among currently available guidelines for protection of the public during relatively short-term events given the objectives of their respective developers.

"Overall, there is no widely accepted method available for selection of an appropriate exposure limit for general populations subjected to toxic vapors or gases, particularly where the exposure limit is to be used for public emergency planning purposes. Some options, in order of decreasing preference, and by no means mandatory for use, are as follows:

- Use the NAS/NRC SPEGL or the AIHA ERPG-2 value for the material if available
- Consult a toxicologist or similarly qualified individual for advice based on a formal review of the toxicity of the material of concern
- Use the highest value among the following:

- IDLH value divided by 10 (with '10' being a safety factor)
- TLV-STEL
- TLV-TWA multiplied by 3 (if a TLV-STEL does not exist)
- TLV-C
- If the evacuation of additional areas is not a problem or the exposure may be prolonged beyond one hour, use the TLV-TWA or the TLV-C value or apply an additional safety factor to other selections.

NOTE: It is necessary for government and industry to consider cases involving carcinogens carefully and on a case-by-case basis."

EPA also defined levels of concern (LOCs) as the concentrations of an extremely hazardous substance (EHS) in air above which there may be serious irreversible health effects or death from a single exposure for a relatively short time. The LOC for an EHS has been estimated by using 0.1 of the IDLH level published by the National Institute for Occupational Safety and Health or an approximation of the IDLH from animal toxicity data. For those chemicals that do not have IDLHs, the following estimates are proposed:

Estimated IDLH = $LC50 \cdot 0.1$

Estimated IDLH = LCLO

Estimated IDLH = $LD50 \cdot 0.01$

Estimated IDLH = $LDLO \cdot 0.1$

2. From DOE-STD-3005-YR (Draft), the following toxicological Evaluation Guidelines were proposed for the public: Dosages shall not exceed the ERPG-2 dosage. If ERPG information is not available for a toxicological hazard, the EG shall be either (1) one-tenth of the IDLH concentration; or (2) any better toxicological information available to indicate estimated dosages do not represent a potential health threat more than the ERPG-2 definition.

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