
EPA GUIDANCE ON
RISK MANAGEMENT PROGRAMS
GENERAL DUTY

Prepared by
Peter S. Puglionesi, P.E., DEE
610-449-3430
peter.puglionesi@appliedehs.com

Copyright © 2008 Applied EHS Management, Inc.

APPLIED EHS MANAGEMENT, INC.

www.appliedehs.com

EPA GUIDANCE ON RISK MANAGEMENT PROGRAMS GENERAL DUTY

Peter S. Puglionesi, P.E., DEE
Applied EHS Management, Inc.
654 Lawson Avenue
Havertown, PA 19083
610-449-3430
peter.puglionesi@appliedehs.com

Environmental Protection Agency (EPA) regulations on Risk Management Programs (RMPs) have been in effect for almost 10 years now (40 CFR Part 68). Since the rule became effective there have been a number of developments that have resulted in some fundamental and major changes, including:

- What chemicals and processes are regulated;
- How information is accessed and disseminated; and
- What EPA's expectations are for users of other chemicals subject to the General Duty Clause.

This article focuses on the EPA's General Duty Clause guidance that has far reaching effects on all chemical manufacturers and users. All chemical users should be aware of this guidance and how it could affect your operations.

General Duty Clause Grows Teeth - EPA Issues Guidelines

What is the General Duty Clause?

The General Duty Clause—Section 112(r)(1) of the Clean Air Act (CAA)—is a performance based authority making owners and operators of facilities responsible for preventing accidental chemical releases. It requires owners and operators to:

1. Identify hazards which may result from accidental releases of extremely hazardous substances using appropriate hazard assessment techniques,
2. Design and maintain a safe facility taking such steps as are necessary to prevent releases, and
3. Minimize the consequences of accidental releases which do occur.

Who is Subject to General Duty?

The General Duty Clause applies to any stationary source producing, processing, handling, or storing any extremely hazardous substance. EPA has indicated that general duty applies to RMP regulated chemicals present under Threshold Quantity and extremely hazardous substances identified under the Emergency Planning and Community Right-to-Know Act (EPCRA).

In its EPA's *Guidance for Implementation of the General Duty Clause Clean Air Act Section 113(r)(1)* (EPA 550-B00-002, May 2000, <http://www.epa.gov/emergencies/docs/chem/gdcregionalguidance.pdf>), EPA indicates that extremely hazardous substances "are not limited to the list of regulated substances listed under Section 112(r) nor the extremely hazardous substances under EPCRA". EPA suggests that the legislative history provides further guidance that they include any agent "which may as a result of short-term exposures associated with releases to the air cause death, injury or property damage due to its toxicity, reactivity, flammability, volatility, or corrosivity". A release "of any hazardous substance which causes death or serious injury because of its acute toxic effect or as a result of an explosion or fire or which causes substantial property damage by blast, fire, corrosion or other reaction would create a presumption that such substance is extremely toxic.

At first glance, this definition appears so broad as to potentially cover almost every chemical; however, a careful reading suggests that it would apply to chemicals that can result in injury via release to the air or cause a fire or explosion. EPA references other sources, such as OSHA, ACGIH and NFPA, but offers no further clarification in its guidance on specific criteria that would suggest a chemical is "extremely" hazardous.

How will EPA Enforce the General Duty Clause?

EPA's general duty guidance (EPA 550-B00-002) was intended to provide guidance to EPA Regions who will enforce this clause, but also provides the most comprehensive guidance to date for facilities. The EPA Regions may:

- Require you to provide information to determine if you are in compliance with the general duty clause.
- Pursue enforcement by seeking penalties and/or injunctive relief.
- Bring civil judicial actions for violations.
- Bring criminal actions for knowing violations.

What Do You Need to Do to Comply?

In the introduction to its general duty guidance, EPA makes comforting references to adhering to recognized industry standards and practices as well as any government regulations but does not stop there. The introduction also states that additional measures may be warranted for site-specific conditions, if there are no relevant industry standards or government regulations, or an existing standard or practice is inadequate.

These "additional measures", rather than codes and standards, appear to be what is called for by the focus of most of the specific advice provided by EPA in its guidance. Sections 2 and 3 of the general duty guidelines go on to explain what EPA inspectors should look for in facility investigations to determine if the three general duties have been met. Herein lies the surprise! Inspectors are advised that almost every aspect of an RMP Program 3 Prevention Program and Offsite Consequence Analysis *should* be performed.

Table 1 compares the general duty guidelines with RMP Prevention Programs 2 and 3. Note that the guidelines generally say "should" rather than "must" or "shall" and it is not clear how EPA will apply "should" in this case.

The comparison suggests that EPA's concept of a general duty Risk Management Program falls somewhere between Prevention Program 2 and 3. For example, Program 2 does not require Management of Change. Of course, EPA does not suggest a formal management system or RMP submittal (both are Program 2 and Program 3 requirements).

There are some EPA concepts of a general duty program (indicated in italics in Table 1) that appear to go beyond the regulatory requirements. These include a third party audit, including all PHA release scenarios in Emergency Plans, and indicating that employees must perform active emergency response.

Generally Confusing Duty

Many in the regulated community were looking forward to guidance on how to meet their general duty. The current guidance seems a bit confusing, however, because of:

- The lack of guidance on what chemicals and processes to develop a general duty program to.
- The departure from EPA's own Risk Management Programs regulations approach of scaling down requirements for lower risk substances and processes.

While some were advising applying a Program 2 approach to meet general duty before the guidance, some interesting questions arise. For example:

- Does a Program 1 facility now need to develop a full prevention program to meet general duty?
- Do all facilities need to upgrade where the general duty guidance suggests going beyond the regulatory requirements?

Some Practical Advice

A prudent approach at this juncture is to:

- Identify all other bulk hazardous substances in use at your facilities.
- Evaluate them to determine whether any have the capability to cause fire or explosion or can become airborne to cause injury. Consider both normal processing conditions and potential mishaps (e.g., accidental mixing of incompatible chemicals, incidents in adjacent exposures, etc.).
- Perform thorough review of the processes and operation against codes, standards and accepted industry practices and correct any deficiencies.
- Finally, organizations and facilities will have to decide if they believe the current guidance has overstepped the Clean Air Act Amendment provisions, or if they believe this approach will stand. To ensure that you meet general duty, develop the prevention programs called for in the guidance. Pattern these programs after those required in the RMP, as discussed above.

Recommendations for EPA

This guidance created for EPA's enforcement staff may lead EPA to make inappropriate citations and may make some industries take unnecessary actions to comply. It is recommended that EPA revise the guidance to:

- Refine and clarify the criteria defining an extremely hazardous substance.
- Modify the recommendations for prevention programs by either scaling them back to reflect the language of the statute or tier them (like the regulations do) based on some surrogate measure of degree of risk.

About the author: Peter S. Puglionesi, founder and President of Applied EHS Management, Inc., led the development of AwwaRF's *Compliance Guidance and Model Risk Management Program for WTPs* and participated in writing the Center for Chemical Process Safety's *Technical Planning for On-Site Emergencies* book. He has provided PSM/RMP development and audit services, conducted hazard analyses, assisted in implementing other PSM/RMP requirements and provided workshops and training for over 100 facilities.

Table 1 Comparison of RMP General Duty and Program 2 and 3 Requirements

RMP/PSM Element	EPA General Duty Guidelines	EPA RMP Program	
		2	3
Hazard Assessment:			
Worst-Case Analysis	"...include type, rate and duration of potential releases. Modeling or an applicable dispersion analytical technique should be used ... effect of the release on affected populations..."	•	•
Alternative Release Analysis		•	•
5-Year Accident History	"The experience of the specific process can be developed from the accident history of the facility."	•	•
Management System (Documented)	Not addressed	•	•
Prevention Program:			
Employee Participation Plan	Not addressed		•
Process Safety Information	<ul style="list-style-type: none"> "...review the safety information...based design...upon...codes...industry practices. ...assess whether...obligation to exceed." "...consider risks from adjacent processes..." "...must update equipment to current codes and standards, as appropriate..." "...try to substitute less hazardous chemicals..." No mention of P&IDs, PFDs, mass balance, etc. 	•	•
Process Hazard Analysis	<ul style="list-style-type: none"> Two of the three types of Hazard Assessment scenario identification methods cited are also PHA methods (HAZOP and What-If Analysis). If the third type ("collective experience") is used, then PHA apparently need not be done, but there is later mention (in Incident Investigation of "periodic PHA reviews", implying that both initial and periodic PHA updates are called for. 	•	•
Operating Procedures	<ul style="list-style-type: none"> "SOPs should be written for every aspect of the processes...safe upper and lower limits...corrective measures...include the various phases of operation..." No mention of annual review (this is also true of Program 2). 	•	•
Training	<ul style="list-style-type: none"> "...implement and evaluate programs for training employees on...hazards...operations...receiving, storing, transferring and shipping...clear and concise objectives..." "...ensure that evaluation of training competence is included in the program." 	•	•
Contractors	Not addressed		•
Management of Change	<ul style="list-style-type: none"> "When changes...are planned...evaluate how those changes affect the hazards identified..." "These changes should be evaluated to determine if hazards, materials of construction, operating and maintenance procedures, and prevention programs need to be updated." 		•

Table 1 (Continued)

RMP/PSM Element	EPA General Duty Guidelines	EPA RMP Program	
Mechanical Integrity	<ul style="list-style-type: none"> • Preventive maintenance programs "should, at a minimum, meet guidelines from industry sources..." • "At a minimum...include schedules for replacement, repairs, or regular maintenance ... " • "...quality control program to ensure that components...meet design specifications and to construct the process equipment as designed." • "...should apply the same ... quality requirements for spare parts, installation and repair procedures, testing, quality controls, replacement in kind controls and maintenance enforcement procedures." • "... training employees on ... proper maintenance procedures..." 	•	•
Hot Work Permit	Not addressed		•
Prestartup Review	Not addressed		•
Incident Investigation	<ul style="list-style-type: none"> • For an incident or near miss, "owners and operators should investigate the cause..." • "... should result in recommendations...to prevent similar occurrences." • "... document how these recommendations were evaluated and implemented or why recommendations were not implemented." • "... ensure that any new information is included in periodic PHA reviews, changes in procedures, and changes in operation and maintenance programs." 	•	•
Compliance Audit	<ul style="list-style-type: none"> • "... should practice self auditing of the facility's prevention programs." • "<i>Generally a self audit would involve a third party</i> evaluating the effectiveness of a facility's prevention and mitigation program." 	•	•
Emergency Response Program:	<ul style="list-style-type: none"> • "... should develop an emergency response program <i>that specifically addresses release scenarios developed from the PHAs and historical information.</i>" • "Planning ... includes identifying populations, systems and environments that may be impacted, and specific procedures for <i>employees to stop further chemical releases and/or mitigate the effects of the substances released.</i>" 	•	•
Risk Management Plan Submittal:	Not addressed	•	•

* Some Program 2 elements are defined differently from Program 3 or OSHA PSM.

** Items in italics appear to go beyond RMP regulatory requirements for any program.