Federal Environmental and Occupational Toxicology Regulations and Reporting Requirements: a Practical Approach to What the Medical Toxicologist Needs to Know, Part 2

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Abstract Toxicologists are often called upon to assist in environmental, industrial, occupational and public health assessments. Accordingly, medical toxicologists may find it prudent to be aware of applicable federal toxicological regulations and reporting requirements and of the roles of relevant federal agencies. These regulations are numerous, complex, and have evolved and expanded over time, making it difficult for toxicologists to sustain a current knowledge base. This article reviews the pertinent federal toxicological reporting requirements with regards to the Toxic Substances Control Act (TSCA), the Atomic Energy Act (AEA), the Federal Insecticide, Fungicide, and

Rodenticide Act (FIFRA), the Resource Conservation and Recovery Act (RCRA), the Clean Air Act, the Clean Water Act, the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), the Emergency Planning and Community Right to Know Act (EPCRA), the Occupational Safety and Health Act, the Department of Transportation, and information about the National Response Center. We reference internet-based government resources and offer direct links to applicable websites in an attempt to offer rapid and current sources of practical information. The format of the article is a series of hypothetical scenarios followed by commentary. Discussions of the Safe Drinking Water Act and the Food, Drug, and Cosmetic Act and the Dietary Supplement Health and Education Act are beyond the scope of this paper. For those desiring a more in depth discussion of the relevant federal environmental laws and statutes, and applicable case law, the reader is directed to resources such as the Environmental Law Handbook, the websites of individual laws found at www.epa.gov and the decisions of individual courts of appeal. It is our hope that this article provides not only useful practical information for the practicing toxicologist, but also serves as a key reference for Medical Toxicology core content on environmental laws and regulations.

Keywords Environmental toxicology · Occupational toxicology · Federal regulations · Reporting requirements

Scenario 5: You are the medical director of your local poison center and you have been asked by your state health department to assist in developing local public health emergency plans. As a medical toxicologist, you have been specifically tasked with developing the emergency response plans as they relate to the potential release of toxic substances from industrial facilities in your area. You would want to know how you can determine exactly which chemicals are

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present at each facility and in what quantity, what emergency plans and provisions may already be in place at each facility, what are the potential public health consequences of an uncontrolled release, what types of accidental chemical releases need to be reported, any background on actual accidents or releases which may have already occurred, and what local emergency response plans may already be in place.

The environmental release or potential release of substances known to be harmful or potentially harmful to human health or the environment are regulated by the Environmental Protection Agency (EPA) through the Clean Air Act of 1970 (CAA), the Federal Water Pollution Control Act of 1972 which is better known as the Clean Water Act (CWA), the Comprehensive Environmental Response, Compensation, and Liability Act enacted on 11 December 1980 (CERCLA), CERCLA's amendment known as the Superfund Amendments and Reauthorization Act of 1986 (SARA), and the Emergency Planning and Community Right to Know Act (EPCRA), also known as SARA Title III.

The CAA and CWA allow the EPA to set air and water quality standards and to regulate the release of specific pollutants into the atmosphere and into navigable “waters of the United States,” respectively. Neither the CAA nor CWA are “pre-emptive” laws; states can set their own rules and standards.

CAA

The term “Clean Air Act” is a misnomer, as the current form of the statute is the 1990 Amendment to the CAA, upon which current air quality standards, requirements for pollution control measures on sources, and permitting programs for polluters, are based. The original 1955 Air Pollution Control Act was not regulatory but provided funds for research on sources and types of air pollution. The 1963 Clean Air Act funded research on monitoring and controlling air pollution. Not until the CAA of 1970 did significant

regulations take effect. An additional 1990 CAA Amendment added important provisions for control of acid rain, control of ozone-depleting agents such as chlorofluorocarbons (CFCs), and new permitting requirements for fixed source polluters. Ambient air quality standards for specific pollutants are continuously reviewed based on science, litigation, or at least every 5 years [1].

CAA of 1970

The CAA—which was amended in 1990—deals with both Air Pollution Prevention and Control (Title I) and Emission Standards for Moving Sources (Title II). (Title II of the CAA is responsible for the annual emissions test most motor vehicles' owners must demonstrate each year.) Under Title I of the CAA, the central regulatory provision is the National Ambient Air Quality Standards (NAAQS) program. NAAQS is a set of air quality measures for six “criteria air pollutants”: sulfur dioxide, nitrogen dioxide, particulate matter (PM), carbon monoxide, ozone, and airborne lead [2]. The six criteria pollutants were chosen based on the ubiquitous nature of these chemicals; levels are set to protect the public from known (primary standard) and anticipated (secondary standard) adverse health effects (Table 1).

States are responsible for maintaining NAAQS-based regulation of fixed sources of air pollution within its borders. A State Implementation Plan (SIP) is the primary regulatory instrument; states develop plans, which are ultimately submitted to the EPA for final approval (thus giving the provisions of the SIP the authority of federal law). A SIP contains many requirements, including how a state will permit and approve the construction of new sources of air pollution, how a state will monitor their air quality, how they will enforce emissions standards for polluters (through economic incentives and technology requirements), and how they will deal with interstate air pollution.

In addition to the NAAQS criteria pollutants, the Clean Air Act Amendment of 1990 (Title III, Sect. 112) added regulations for 189 less ubiquitous hazardous air pollutants

Table 1 NAAQS Criteria Air Pollutants and Limits

Criteria air pollutant	Limit	Amended/most recent review	Litigant (or case law)
NO ₂	0.053 ppm	1996	
SO ₂	0.03 ppm (annual standard), 0.14 ppm (24 h), and 0.5 ppm (3 h standard)	1996+	American Lung Association petition to the US Court of Appeals (DC)
PM 2.5	35 µg/m ³ (primary and secondary 24 h standard) and 15 µg/m ³ (primary and secondary annual standard)	2006	Whitman v American Trucking Association
Ozone	0.08 ppm	1999	
Pb	1.5 µg/m ³ quarterly mean	2008	
CO	9 ppm (primary 8 h) and 35 ppm (primary 1 h)		

known as “air toxics” [3]. The original list of 189 (currently 187) regulated “hazardous air pollutants” can be found at the EPA’s Website [4]. Any source which has the potential to emit more than 10 tons of a substance (or 25 tons of any combination of air toxics) falls under the regulatory program of the 1990 CAA (Sect. 112). Sections 107 and 110 of Title 1 of the 1970 CAA authorize the states to regulate emissions from sources to insure compliance with the NAAQS. Title V of the CAA of 1990 sets out the process for SIP, including which polluters are to be regulated, and the process of state filing of a SIP. Once final approval from EPA is obtained for a SIP, the state is responsible for enforcing the provisions, maintaining an up to date plan, and ensuring that their airshed is in compliance with NAAQS. A state which does not meet NAAQS compliance for 18 months can have its federal highway funds frozen at the discretion of the EPA Administrator [5].

Title VI of the 1990 CAA called for a phase out of ozone depleting chemicals (chlorofluorocarbons).

CAA Reporting Requirements

Section 112(r) of the Clean Air Act (CAA) requires that fixed facilities producing, storing, or using regulated toxic substances at or above their regulated threshold quantities (TQ) must develop a documented risk management program (RMP). A list of the regulated materials and their respective threshold quantities can be found at the referenced Website [6]. RMPs typically include an executive summary describing the overall RMP at the facility, contact information of the organization and responsible personnel submitting the RMP, an accidental hazardous substance release off-site consequence analysis that includes a “worst-case scenario,” and one alternative release scenario, an accident prevention plan, an emergency response plan, and a 5-year facility accident history [7]. The EPA’s complete RMP user’s manual containing detailed instructions on how to complete an RMP, and the required data elements for an RMP. How and Where to schedule an appointment at a Federal Reading Room to review RMPs can be found at the RMP resource page [8]. RMPs are not routinely available to the public and must be read in a Federal Reading Room because of security concerns over the worst-case scenarios potentially offering a roadmap to a terrorist on how to carry out an attack using a chemical agent of opportunity. To gain access, you need to go through the Local Emergency Planning Committee (LEPC) or local Emergency Management Agency (EMA) director to explain who you are and why you require access to the information. Your ability to further disseminate RMP information with others may be limited as well. RMPs must be filed with the EPA and updated every 5 years [9]. There are also requirements under both the CWA and Oil Pollution

Act of 1990 for facility plans similar to RMPs. These include operations, contingency, and response plans. These may be more accessible than the RMP and yield some of the same information.

Clean Water Act

The initial intent of the CWA of 1972 was to set limits on industrial wastewater discharges, to set water quality requirements for navigable waters impacted by industrial effluent discharges, and to institute a permit program to control industrial pollution discharges. Though these steps began the process of regulating wastewater pollution of the waterways, they were initially intended to address biosolid municipal waste discharge and not necessarily “hazardous” chemical pollutants. All three provisions—the municipal wastewater treatment program, the dredging permit program, and the pollution control program termed the National Pollutant Discharge Elimination System (NPDES)—were embodied in the original 1972 Federal Water Pollution Control Act (FWPCA) amendment of 1977 which became known as the “Clean Water Act”. Section 301 of the 1977 CWA prohibits discharges except those in compliance with the provisions of the CWA. The NPDES permitting program for polluters (Sect. 402) is administered by the EPA or by 46 states under authority of the EPA (Sect. 402(b)) [10]. Facilities which plan to discharge into the nation’s “navigable waterways” must file an NPDES application (Forms 1, 2C, 2D, 2E, and 2 F) and await state or EPA approval. Permits must be renewed every 5 years. Facilities must also submit discharge monitoring reports. A facility may gain a waiver for testing of its effluent, as long as it follows provisions of the NPDES program such as use of best possible pollution control technology, testing of its waste stream prior to discharge to demonstrate no more than background levels of contaminants, etc. States are required under the CWA to define all waters within their borders with respect to use (drinking water source, fishing, recreation); minimum criteria for 150 pollutants have been set by EPA. Not all “discharges” are regulated by the CWA; for example, water discharged over a dam is not covered by the NPDES program. Similarly, while the definition of “navigable waters of the USA” has been interpreted broadly to include almost all surface waters including small streams these waters end at the borders. Beyond the borders, discharge of pollutants (including dredged sediment) into international waters is prohibited by the Ocean Dumping Ban Act of 1988; enforcement is performed by the Coast Guard.

Initial reaction to the original 1972 FWPCA was that the program was essentially a permitting vehicle to limit the amount of pollution a fixed source could emit; there was a concern that pollutions’ impact on the environment, or more

importantly health, was not being considered. Thus, in 1976, as a result of a lawsuit filed by environmental groups against the EPA, the “Flannery Decree” created strict new guidelines for the pretreatment and discharge of 65 toxic “priority pollutants” [11]. (The decree is named for presiding US District Court Judge Thomas A. Flannery who heard the case *National Resources Defense Council et al. vs Train*, 6 ELR 20588, D.D.C., 9 June 1976.) The current list of now 126 CWA Priority Pollutants can be found at the following CWA Website [12].

Another important element of the original 1977 CWA was Sect. 311(b)(5), which specifically dealt with the reporting, prevention, and response to oil spills. This section requires the responsible person at a facility to report the accidental release or spill of one of 300 hazardous substances identified by the EPA to the National Response Center. (This reporting of releases which are out of compliance with NPDES is in addition to CERCLA or EPCRA reporting we will examine below.)

More specifically, oil spill reporting took on a whole new meaning after the 1989 Exxon Valdez spill. The subsequent Oil Pollution Act of 1990 (OPA 90) created a new regulatory program for oil spill response under the CWA, including higher limits on liability; Title I of OPA 90 broadened the scope of damages polluters must pay (including compensation for damage to natural resources).

Synergy of CAA and CWA

Both the CAA and CWA allow the EPA or other designated state or local environmental agencies to provide permits to organizations that discharge pollutants into the environment (air or waterways) on a regular basis, in an effort to control the total quantity of pollutants released. “State Program Status” for the 46 states which act under EPA authority in NPDES permitting, regulating, and enforcement can be found at the following Website [13]. Alternately, information on specific facilities holding NPDES permits can be found at the following Website and is searchable by zip code [14].

Similarly, for CAA Sect. 112 permitting requirements, a list of local permitting agencies by EPA region with their respective contact information, filed permit applications, and a list of published, granted permits can be found at the following site [15].

CERCLA

Hazardous waste sites that were either abandoned or have an uncontrolled hazardous waste release have come under the jurisdiction of CERCLA. This law establishes guidelines for

the cleanup requirements of sites associated with past unregulated disposal of hazardous substances and has authorized the EPA to create a national priorities list (NPL) to determine the order in which these sites are remediated [16]. In a previous section, we saw how RCRA is designed to regulate current or ongoing hazardous waste disposal where the responsible party is known. CERCLA is synonymous with the Hazardous Substances Superfund (or “Superfund”) formerly a tax on chemical and petroleum industries which was used to pay for cleanup, natural resources restoration, and private damage claims. The Agency for Toxic Substances and Disease Registry (ATSDR) was created under CERCLA to periodically survey for human health effects related to Superfund sites. CERCLA Sect. 104(i)(6)(A) [42 U.S.C.9604(i)(6)(A)] requires that ATSDR conduct a Health Assessment within 1 year of the listing of any site on the NPL [17].

SARA

On 17 October 1986, the Superfund Amendments and Reauthorization Act was passed to expand the CERCLA statute by stressing more permanent remediation technologies, greater state involvement in the site listing and remediation process, greater citizen participation in the Superfund process, and expansion of the fund ceiling to \$8.5 billion. The Hazard Ranking System (HRS) was developed during SARA passage to “score” the degree of risk to human health each NPL site poses (however, HRS score does not factor in to the order of clean-up or level of funding each site gets for remediation). Instead, scoring may inform more frequent monitoring of the exposed population, or alternate temporizing measures aimed at preventing human exposure (such as connecting city water to all potentially exposed households).

On the 2nd and 3rd of December 1984, a catastrophic release of methyl isocyanate from the Union Carbide plant in Bhopal, India, killed over 5,000 victims and injured over 20,000. One of the legacies of that accident was the effort to better inform communities in the USA of the type and scope of chemical hazards in their midst. This intent established SARA Title III, known as the Emergency Planning and Community Right-to-Know Act (EPCRA Sect. 301 and 303), which provides for the creation of local emergency response plans and the existence of state emergency response commissions (SERC) and local emergency planning committees (LEPC) to whom possession and release of toxic chemicals must be reported [18]. Subchapter I (Sect. 301–304) of SARA Title III establishes both LEPC and SEPC membership, authority, planning process, and areas of responsibility.

The purpose of Subchapter II (Sect. 311–313) establishes the reporting requirements for several different classes of hazardous substances. “Hazardous substance” reporting under SARA Sect. 302, 304, and 311–313 becomes rather confusing: there are five separate reporting requirements, lists of chemicals subject to reporting, and threshold amounts which trigger notification and reporting (summarized in Table 2). At its simplest, one trigger for reporting under SARA requires notification to the LEPC when possession, use, or inventory of a specific hazard exceeds a specified threshold quantity (Sect. 302, 311–313), while a second set of requirements are invoked when an unintentional release occurs over a reportable quantity of a hazardous chemical. In addition, there are two types of chemical hazards which must be reported when possession of a substance or an unanticipated release occurs: hazardous substances (HS) and extremely hazardous substances (EHS).

EPA’s EHS list (Sect. 302(a)(2)) was established in November, 1985, and the current list of 356 chemicals can be found in Appendix A of the Chemical Emergency Preparedness Program Interim Guidance (40 CFR Part 355 Appendix A) [19]. Emergency planning for possession of an EHS is only required under EPCRA Section 302 if the amount on site at any time exceeds a Threshold Planning Quantity (TPQ). The TPQ is defined (also in Part 355 Appendix A) as greater than 500 lb of a solid powder (with particle size <100 µm or in solution) or 10,000 lb if NOT a solid, molten, or in solution. Thus, facilities that produce, store, use, or dispose of any EHS substance must report the production, storage, use, or disposal of any quantities exceeding either 10,000 lb or the lower TPQ under EPCRA Sect. 302 requirements to the SEPC within 60 days and provide contact information for the facilities’ emergency coordinator to the LEPC within 30 days. A list of EHS

substances and their TPQ can be found at the referenced site [20].

Release of an EHS triggers a second reporting requirement (under Sect. 304 of EPCRA) when the release exceeds an EHS’s “Reportable Quantity” or RQ. As many EPCRA EHS are also CERCLA HS, many EHS have CERCLA Reportable Quantities (RQ) which triggers reporting if exceeded in a release. If there is no RQ for an EHS release, then EPCRA Sect. 304 mandates that the RQ is equal to the TPQ. Thus, an EHS’s RQ may be the same as the TPQ, but oftentimes is different; EHS CERCLA RQ’s are also found at 40 C.F.R. Part 355 Appendix A along with the TPQ [20]. The definition of a release which meets the EPCRA Sect. 304 reporting requirement is a release which exceeds the threshold for reporting over a 24-h period. Release reports are made to the SEPC and the LEPC each time a release occurs.

The second category of hazards which require reporting for possession or unintentional release under EPCRA are HS. HS’s are defined under the CERCLA statute, Sect. 101(14) and includes the specific hazard lists from several other environmental regulations. Thus, CERCLA/SARA Hazardous substances include:

1. “Hazardous wastes” defined by RCRA (all F-, K- P-, and U- wastes);
 - a. 359 U-list wastes,
 - b. 123 P-list wastes,
 - c. 151 K-list wastes,
 - d. 39 F-list wastes,
2. “Hazardous substances” defined by Sect. 311(b)(5) of the CWA (40 CFR 116.4)—approximately 300 chemicals listed on Table 116.4A/116.4B [21];
3. “Toxic pollutants” defined by Sect. 307(a)(1) of the CWA—129 pollutants;
4. “Hazardous Air Pollutants” under Sect. 112 of the CAA—189 (now 187) air toxics;

Table 2 SARA Hazardous/extremely hazardous substance reporting requirements

Category (#)	When	Threshold (lb)	Report form	To whom	Deadline	Section
EHS (356)	Possession	Lower of TPQ or 10,000 (500 if solid)		SEPC LEPC	60 days 30 days	EPCRA 302
EHS (356)	Release	RQ; if none then RQ=TPQ		SEPC LEPC	Immediate followed by written	EPCRA 304
HS	Possession	TPQ (10,000)		SEPC LEPC	60 days 60 days	EPCRA 311
HS	Release	CERCLA 103 RQ or 1 lb		SEPC LEPC	Immediate followed by written	CERCLA 103(a)
HS EHS	Annual Inventory	RQ (10,000) TPQ (1–10,000)	EPA tier I or II	SEPC LEPC	1 March	EPCRA 312
TRI (>650)	Any “release”	25,000 (new) and 10,000 (used) Low for PBTs	EPA form R or A	EPA	1 July	EPCRA 313

5. CERCLA Sect. 102 substances which threaten public health—approximately 800 chemicals (40 CFR 302.4 “List of Hazardous Substances and RQs”);
6. RCRA Section 3001 D-list “characteristic” wastes (i.e., those with physical or chemical “characteristics” that classify them as hazards)—43 wastes;
7. “Imminently hazardous” chemicals under Sect. 7 of TSCA (i.e., any TSCA chemical which due to the situation or circumstances represents an unreasonable hazard to human health or the environment) [22].

EPCRA reporting of possession of a HS covers well over 500,000 entities, and facilities must report their quantities of CERCLA HS exceeding a TPQ of 10,000 lb to the SEPC and LEPC under EPCRA Sect. 311. The litmus test for whether a facility may have a reporting requirement under Sect. 311 is if the facility is required to have material safety data sheets (MSDS) available to its workforce under the Occupational Safety and Health Act (OSHA; discussed below). If a facility must maintain MSDSs for hazardous chemicals it keeps on site, EPCRA Sect. 311 reporting will be triggered if the substance exceeds the TPQ (10,000 lb) and meets the OSHA definition of a “hazardous substance” (29 C.F.R. Sect. 1910.1200(c)) [23]. The OSHA definition covers a broad spectrum of potential hazards defined as any “element, chemical, or compound that is a physical or health hazard”. EPCRA Sect. 311 reports must be sent to both the LEPC and SERC within 60 days following the receipt of—or production of—the substance in question [24]. Reports must include a copy of the MSDS for each reported substance, and the reporting is done using a standard chemical inventory form found at EPCRA’s Tier II Website [25].

Furthermore, facilities must submit an additional annual inventory of HS to the appropriate SERC, LEPC, and local fire department [24]. These annual inventory updates are required under EPCRA Sect. 312 and cover the hazardous materials on site for the prior calendar year; reporting occurs 1 March. The thresholds for annual reporting of HS possession/use/storage are the same as for EPCRA Sect. 311: the RQ of 10,000 lb for HS and 500 lb or the TPQ of 1–10,000 lb (whichever is less) for an EHS. Section 312 reports are submitted on EPA or state inventory forms called Tier I or II. Tier I reports are general, do not name specific chemicals, provide maximum and daily inventories, and do not provide information on location of storage within a facility. A Tier II report is much more detailed, includes chemical-specifics, and the exact location in which a chemical is stored [25].

As with EHS, EPCRA Sect. 304 requires reporting of unintentional releases of HS. Just as EHS reporting is triggered if the release exceeds the EHS’s Reportable Quantity (RQ), a HS release requires reporting if the amount exceeds the HS’s RQ. EPCRA Sect. 304 does not specify the RQ for

HS the way Sect. 302 does the RQs for EHS. Instead, EPCRA 304 relies on the HS’s RQ from CERCLA Sect. 103(a) which can be found at 40 C.F.R Part 302, Table 302.4 [26]. If no CERCLA RQ exists for a HS, then EPCRA reporting is required if the release exceeds 1 lb. Note that it is very likely that a release of a HS requires reporting both under CERCLA as well as under EPCRA (Sect. 304); the difference is that CERCLA reporting is to the federal government through the National Response Center (discussed below) while EPCRA reporting is through state and local agencies. Though reporting may be required under both laws, there is also an economy of scale—a CERCLA “release” could, and often does mean an ongoing release into the environment over decades at an abandoned hazardous waste site. An EPCRA “release” on the other hand is the more acute “spill” that toxicologists may think of in terms of a chemical incident. A list of reportable quantities of EPCRA Sect. 302 EHS, CERCLA Hazardous Substances, EPCRA Sect. 313 Toxic Chemicals, and CAA112(r) hazardous air pollutants, can be found on the EPA consolidated “List of Lists” [27]. Exceptions to the EPCRA Sect. 304 reporting rule include (i) the release of substances already regulated under other laws and by other federal or local agencies (such as permitted under the CAA and the appropriate application of pesticides), (ii) the proper application of fertilizers, (iii) engine exhaust, and (iv) certain radionuclide releases that only expose individuals within the facility itself or federally permitted releases.

Accidental releases of any EHS or HS require that two separate reports be made to the appropriate local and state emergency planning commissions and to the National Response Center at (800) 424-8802. The first report is an immediate oral notification by telephone that identifies the substance released, whether that substance is considered to be extremely hazardous, the estimated timing, duration, quantity, and medium of release, known health hazards, required precautions such as evacuation, and contact information of the individual making the report. The second is a written report to be made as soon as practicable and must include a description of release containment and response activities, a description of anticipated health risks to the community, and advice regarding public health intervention. Written reports are required only for fixed facility incidents and are usually limited to chronic releases like landfill leachates rather than transient releases. As written report requirements stipulate fixed facilities, transportation accidents (which will be covered further down) require notification of the LEPC or the local fire service chief if an LEPC is not locally available; telephone reporting to the National Response Center is also required [24].

Toxic Release Inventory

There is a fifth and final type of report which must be made under EPCRA Sect. 313. In addition to the EPCRA reporting requirements for possession of an EHS (Sect. 302) or HS (Sect. 311–312), and for the release of an EHS (EPCRA Sect. 304) or HS (CERCLA Sect. 103(a)), certain facilities are also required to report annually all toxic releases—unintentional and intentional (permitted, fugitive emissions, waste management that involves discharge to the environment)—to the EPA's Toxics Release Inventory (TRI). TRI reports are made using EPA Form R by 1 July of each year. TRI reporting is required if: (i) certain facility characteristics are met (has >10 full time employees), (ii) the chemical appears on the TRI list of >650 chemicals (40 C.F.R. 372.65), and (iii) manufactures or processes more than 25,000 lb or uses >10,000 lb except for some bioaccumulative toxins with lower threshold quantities [28]. TRI chemicals include those chemicals which are likely to cause adverse human health effects in concentrations presumed to extend beyond the boundaries of the facility, are reasonably thought to cause cancer, teratogenic effects, reproductive dysfunction, neurological disorders, genotoxicity, or chronic health effects. Section 313(f)(1) describes the TRI reporting threshold quantities—typically 25,000 lb (manufactured) or 10,000 (used or otherwise processed)—however, several classes of persistent

bioaccumulative toxins (PBT) have been revised much lower [29]. PBTs and their thresholds are listed in Table 3.

For facilities with very low annual reportable amounts (<2,000 lb) and no PBT releases to the environment (may appropriately dispose of 500 lb/year), an abbreviated TRI report Form A is required annually. Further details regarding TRI eligible facility characteristics and reporting requirements can be found at the Website [30].

A final and perhaps most significant element of EPCRA reporting that directly impacts clinicians is found under Subchapter III (Sect. 321–330). Sections 322–323 permits a company to withhold the identity of a chemical from any EPCRA reporting under Sect. 302, 311, 312, and 313 in order to protect trade secrets [31]. The one exception to this trade secrets withholding is when the identification of a chemical is necessary to diagnose or treat an individual [32]. Facilities which make unsubstantiated trade secret claims in an effort to avoid EPCRA reporting face stiff civil and—if willful—criminal penalties (Table 3).

OPA 90

The Oil Pollution Act of 1990 followed the Exxon Valdez disaster in Prince William Sound, Alaska, on 24 March 1989. The Act is mentioned briefly here as a corollary to the sections on land-based releases (CERCLA and EPCRA) discussed above and due to the recent oil spill of national significance in the Gulf of Mexico (Deepwater Horizon) in 2010. CERCLA has a petroleum exclusion: the release of petrochemicals into the environment does not fall under CERCLA (or SARA/EPCRA). This exclusion has been debated since the establishment of CERCLA in 1980—even a Memorandum in 1987 sought to establish whether the “contaminants” present in used oil could be subject to CERCLA and thus would eliminate the exclusion for the oil itself. OPA established a substantial environmental regulation for petrochemical releases, OPA carefully defines oil as petroleum in order to avoid any overlap with CERCLA 9601(14)(A) thru (F) by excluding cooking oils and animal fats from OPA regulations [33].

OPA 90 includes nine titles; Title I describes the liability for oil spills, and following the damage to Prince William Sound, specifically included damage to natural resources as part of the liability incurred by the responsible party. Compensatory damages do not only include restoration of natural resources themselves but also damage to real property, loss of subsistence use of oiled resources (such as tribal fishing areas), loss of government revenue from oiled areas (protected wetlands, federal parks), loss of profits and earnings capacity (commercial fisherman), and loss of public service (beaches). It should be noted that all such losses occurred following the Gulf Spill in 2010.

Table 3 Persistent bioaccumulative toxins and reporting limits

Chemical or category	Reporting threshold (lb)
Aldrin	100
Benzo(g,h,i)perylene	10
Chlordane	10
Dioxin and 17 related dioxin-like polychlorinated dibenzo-p-dioxins and dibenzofurans	0.1 g
Heptachlor	10
Hexachlorobenzene	10
Isodrin	10
Lead	100
Mercury	10
Mercury compounds	10
Methoxychlor	100
Octachlorostyrene	10
Pendimethalin	100
Pentachlorobenzene	10
Polycyclic aromatic compounds	100
PCBs	10
Tetrabromobisphenol A	100
Toxaphene	10
Trifluralin	100

The cornerstone of OPA 90 is the Oil Spill Liability Trust Fund (OSLTF) established by a 5 cent a barrel tax on oil. The OSLTF was renewed in 2005 but is set to expire without action in 2014; the fund maintains a level of \$2.7 billion to be used if spill costs exceed a responsible party's insurance cap [33]. Title IV of OPA establishes numerous preparedness and prevention measures and sets out responsibilities in the event of a spill. Title IV requires that companies have detailed response plans for spill cleanup, allows the federal government to take over big spills (such as the Deepwater Horizon of 9 April 2010). Preventive measures include new rules on safe shipping and navigation (use of tugs and “experienced” harbor pilots), as well as the conversion to double hulled freighters. (Exxon Valdez was not double hulled and leaked oil when it grounded on Bligh Reef in Prince William Sound.)

The remaining Titles of OPA deal with references and overlap to other environmental regulations or simply apply only to Alaska and the Valdez spill; for example, Title VIII is specific to operation of the Trans-Alaska Pipeline, while Title V is about ongoing recovery in Prince William Sound [33].

In terms of Scenario 5 described above, the toxicologist has at least three and as many as five sources of information related to the presence (or release) of hazardous chemicals from facilities in the area. CAA provisions require the filing of SIPs with the EPA (1990 CAA, Sect. 112) for any fixed facility that has the potential to emit more than 10 tons of 189 regulated air pollutants. The SIP for facilities in your area would identify the facilities and which air pollutants have the potential for release and can be found at <http://www.epa.gov/air/oaqps/permits/whereyoulive.html#stato-cal>. Second, Section 112(r) of the CAA required facilities to file RMPs with the EPA; through contact with the LEPC or SERC, the toxicologist could request an appointment at a Federal Reading Room to view the RMPs for specific facilities. Through the CWA (Sect. 402) the EPA—or 46 states given authority by the EPA—administers the NPDES permitting program where information on facilities' discharge of 126 priority pollutants can be found (information on specific facilities holding NPDES permits maybe available [14]. In addition, facilities with accidental discharges of one or more of 300 hazardous substances which are out of compliance with NPDES, must report the release to the National Response Center (see Scenario 8 below). In terms of facilities' possession and/or release of an EHS or HS, reports under EPCRA for possession of an EHS (Sect. 302) or HS (Sect. 311–312) or for the release of an EHS (Sect. 304) or under CERCLA for the release of a HS (Sect. 103(a)) must be made to the LEPC or SERC where the toxicologist would most likely find the information related to the potential (or actual) release of toxic substances from industrial facilities in the area.

OSHA

Scenario 6: You are a medical toxicologist specializing in occupational health. You work for a major chemical manufacturer and were just notified that an accidental release of nitric acid under pressure within one of the manufacturing facilities sent five employees to the hospital with respiratory complaints. The release has been contained and no other workers are in danger. You would likely want to know if there is a quick reference on-site to which employees may refer regarding their safety around nitric acid and proper release containment procedures. In addition, you would also like to know what reports need to be made to government agencies and kept on file, what types of information needs to be included in the reports, and to which agency the reports need to be made.

Human exposures and potential exposures to hazardous materials within the workplace are regulated by the US Occupational Safety and Health Administration (OSHA) of the Department of Labor the under the authority of the Occupational Health and Safety Act of December, 1970. OSHA has authority over most workplaces with a few exceptions (workplaces with fewer than 10 workers; federal workplaces). OSHA has developed workplace hazard communication standards, which include the provision of proper hazardous chemical container and pipe labeling, current workplace hazardous chemical standards, medical record-keeping requirements, workplace accident reporting requirements, and the provision or availability of MSDS for all hazardous materials in the workplace. OSHA does have procedures for the establishment of health standards for approximately 500 toxic chemicals in the workplace. The process of reaching a Final Rule on a workplace standard relies on recommendations for standards from the National Institute of Occupational Safety and Health (NIOSH) which provides the pivotal documentation (scientific studies and research) used by OSHA (which assesses feasibility) in establishing a health standard.

OSHA 1970 is composed of Subparts A thru Z. Each Subpart deals with a particular workplace hazard (for example, Subpart P—Hand and Portable Power Tools; Subpart D—Walking and Working Surfaces; Subpart M—Compressed Gas and Air Equipment). Subpart Z covers Toxic and Hazardous Substances and Table Z-1 lists the current Final Rule air concentration standards (permissible exposure limits (PELs)) in parts per million or milligrams per cubic meter for an 8-h time-weighted average (TWA). Despite the sheer volume of chemicals present in the workplace, fewer than 500 have Final Health Standards. The origins of standards in Table Z-1 come from one of three processes—termed Sect. 6(a), 6(b), or 6(c) rules [34]. The vast majority of the standards on the list fall under the 6(a) process: in its first 2 years of standard setting OSHA adopted thresholds for chemicals, which were developed in the 1960s by private

industrial hygiene organizations. Thus, most Z-1 PELs date from 1971 or earlier, have not gone through the NIOSH recommendation and Administrative Procedures process (Fed Register notice, public comment period), and reflect 1960s science and consensus. Several final standards have been established using the formal NIOSH nomination and scientific study procedure described under OSHA Subpart Z, Sect. 6(b) [34]. Finally, Sect. 6(c) allows OSHA to establish an Emergency Temporary Standard (ETS; good for 6 months) to address an immediate hazard without the lengthy administrative procedures and review necessary under 6(b). For example, in November, 1983, OSHA enacted an ETS for asbestos which attempted to reduce the PEL from 2 fibers/cm³ air as science advanced and the cancer risk from asbestos exposure became clear. A reversal of the asbestos ETS by the US Fifth Circuit Court of Appeals struck down the ETS resulting in the establishment of several temporary standards. Following a number of labor lawsuits, the Final Standard for asbestos of 0.1 fiber/cm³ air went into effect in August, 1994 [35]. Some of the more notable chemicals on the OSHA Table Z-1 list with final health standards are the historically important chemical hazards toxicologist will recognize based on their association with particular toxidromes: lead, hexavalent chromium, vinyl chloride, and benzene.

A second and important element of the OSH Act, for toxicologists who work in occupational health, is the requirement for medical monitoring and recordkeeping. General safety standards (for example, noise) or under Subpart Z for a toxic chemical have, as part of the standard itself, required medical monitoring such as blood lead levels under the lead standard. In the case of the asbestos standard described above, Table 1 in Sect. 1910.1001(l)(3)(ii) sets forth the frequency of chest X-ray (from 1 to 5 years based on age of employee and years since first exposure) required as part of medical surveillance for the employer to remain in compliance with the standard. Medical records must be preserved for 30 years, must remain available at the request of an employee/retiree, and must be transferred to NIOSH if a company goes out of business.

By and large, OSHA provisions for workplace medical surveillance and screening are mainly preventative measures designed to detect hazards or exposures that may ultimately lead to poor employee health outcomes. Specific regulations describing occupational medical surveillance and screening methods for particular hazardous agents are listed in 29 CFR 1910, subpart Z [36].

The vast majority of OSHA's current effort is geared towards inspections of workplaces, including investigations and follow-up of workplace accidents and employee claims of unsafe working conditions. OSHA conducts over 25,000 inspections (and even more workplace-initiated

“consultations”) each year. Fines are levied if violations of any provision of OSHA are found—exceeding PEL standards, failure in medical record keeping, improper safety and engineering controls, unavailability of hazard communication like MSDS. Normally OSHA conducts inspections without advanced notice—although in *Marshall v Barlow's, Inc.* (436 US 307 (1978) the US Supreme Court upheld the Fourth Amendment rights against search and seizure and ruled that OSHA required probable cause and a search warrant to enter a premise to inspect [37].

The OSHA Hazard Communication Standard (HAZCOM) enacted on 25 November 1983 is considered successful in promoting a safer workplace and preventing unnecessary risk of exposure by regulating the labeling of chemical hazards, education of workers on chemical hazards in the workplace, requiring the producers of chemicals in the workplace to provide an MSDS, and manufacturers to assess the toxicity of chemicals they produce [38]. All chemicals undergo a hazard evaluation by the producer if the chemical appears on any one of:

- OSHA's subpart Z-1 list;
- An IARC monograph;
- The Annual Report on Carcinogens from the National Toxicology Program; and
- A list of TLVs for chemicals in the work environment from the ACGIH.

Provision of an MSDS, and appropriate education and training is provided to workers if a toxic chemical is present as more than 1 % of any mixture or preparation (0.1 % if the chemical is a carcinogen). A producer may claim a “trade secret” when refusing to list an ingredient or chemical on an MSDS, but just as with EPCRA, this trade secret protection is surrendered if needed for a physician treating an exposed patient. There are several limitations of an MSDS which include the fact they are: (1) prepared with no review, (2) may be prepared by anyone who supplies the materials, (3) are often formula specific, and (4) must only contain and list those ingredients that constitute more than 1 % (or if in excess of 0.1 % for a carcinogen) of an OSHA substance listed in subpart Z. MSDSs must include the substance name, hazardous ingredients, physical properties, fire hazards, reactivity, health hazards, handling precautions, appropriate spill containment, transportation classifications, and any specific regulations to use of the substance, including OSHA PELs [38]. OSHA requires that all employees using such hazardous materials be properly trained in the use of these agents, be provided with appropriate personal protective equipment, and be trained in the use of that equipment. Worksites must also have an on-site safety officer who has all appropriate MSDS paperwork in their possession.

To date there are no OSHA reporting requirements that specifically address workplace hazardous materials

exposure as opposed to any other injury. All workplace injury reporting requirements: traumatic, ergonomic, and toxicological, fall under the same regulation. All employers are required to report to OSHA, within 8 h of the occurrence, any workplace fatalities or workplace events causing injuries to three or more people and requiring hospitalization. Such reports must be made by telephone to either the local OSHA office or the central OSHA call center at (800) 321-6742, and must include the time and location of the incident, the name of the responsible organization, the number of casualties and their names, the reporting individual's contact information, and a description of the incident [39]. Employers must also keep records of all work-related injuries and adverse health effects, and these records must be accessible to employees or their designees [40]. OSHA provides three standard, work-related injury report forms (OSHA Form 300, Form 300-A, and Form 301) and requires that either these or equivalent forms be used for injury recording. The forms can be found at the referenced link [41].

Any workplace accident requiring treatment (or resulting in lost work time) must be reported on OSHA Form 300 within 6 days. This basic form describes accidents by type and must be maintained for 5 years. Knowingly failing to report or falsifying information invokes criminal penalties.

OSHA Form 300-A is a second form which provides greater detail and specificity and allows better tracking of types and rates of accidents related to specific activities.

OSHA Form 301 (Supplementary Record of Occupational Injuries and Illness) is a detail description of an accident.

The logs of workplace injuries (generated from Form 300-A) must be reported annually with access available to all employees, may be reviewed by OSHA workplace inspectors during periodic site visits, and must be sent to OSHA and the US Bureau of Labor Statistics upon request [42].

A final type of reporting occurs for workplace fatalities and fall under the authority of NIOSH: the Fatality Assessment and Control Evaluation (FACE) Program [43]. The FACE program concentrates on investigations of fatal occupational injuries. NIOSH FACE is currently targeting investigations of deaths associated with machinery, deaths of foreign born workers, energy production, and falls in construction. As second area of focus started in 1989 in which 9 State health or labor departments have cooperative agreements with NIOSH for conducting surveillance, targeted investigations, and prevention activities at the State level using the FACE model. The primary intent of the FACE program is to provide interested users with access to the full text of hundreds of fatality investigation reports.

Thus, in terms of the scenario described at the beginning of this section, the fact that more than 3 workers were involved and required treatment requires immediate (within

8 hour) reporting to OSHA. In addition, OSHA Forms 300, 300-A, and possible 301 will need to be submitted (Form 300 within 6 days) owing to the need for treatment, and they must be maintained for 5 years. In addition, this accident will appear in the workplaces' Annual Report.

DOT Office of Hazardous Materials Safety

Scenario 7: You are a medical toxicologist providing medical control and consultation to a local hazardous materials response team (HAZMAT team). You have just been notified of a tanker truck accident and subsequent release of anhydrous ammonia on a major highway near a residential area. You learn that so far there are no fatalities or injuries. The HAZMAT team has contained the ammonia leak. In accordance with DOT Manual standards, residents within a one mile radius of the accident have been evacuated and the local highway has been closed for the last several hours. Does this incident need to be reported to any federal agencies, as no injuries or fatalities have occurred? If a report needs to be made, you need to know who should report, how, when, and to what agency it must be made and what information must be included.

The transportation of hazardous materials, including all aspects of loading, unloading, transit, or temporary storage is regulated by the United States Department of Transportation (DOT) Office of Hazardous Material Safety (OHMS). All modes of transportation fall within the DOT's purview, including road, rail, air, marine intermodal containers, and pipeline. Marine Bulk transport is a Coast Guard function and they no longer fall under DOT.

The accidental release of any hazardous material as a result of the failure of a DOT container that leads to a human death, a human injury requiring hospitalization, public evacuation for more than 1 h, closure of a major transportation route or facility for more than an hour, or disruption of major flight corridors must be reported by the responsible party to the National Response Center by telephone as soon as possible but no more than 12 h after the incident. Telephone reports are also required if there is a release of radioactive or infectious materials, a release of greater than 450 L of a liquid marine pollutant (or greater than 400 kg of a solid marine pollutant), or the release of a material that poses an ongoing threat to human health. Telephone reports can either be made to the National Response Center at (800) 424-8802, or, if the hazardous material is an infectious agent, the Centers for Disease Control and Prevention's Emergency Operations Center at (770) 488-7100. Reports must include: the date and time of the incident, the incident location, the class and proper shipping name of the hazardous material, the quantity of material released, the extent of any injuries incurred, the nature of the incident, any ongoing

immediate health threats, and the name and contact information of the individual making the report [44].

All incidents involving the release of a hazardous material as a result of the failure of a DOT container, regardless of any injury or environmental or transportation disruption must be reported to the DOT OHMS in writing within 30 days of the incident. These reports can be made electronically or paper forms can be downloaded [45]. Details of what information must be included in these written reports can be found on the report site links themselves. Incidents involving aircraft transportation must also be reported to the nearest Federal Aviation Administration Security Field Office. Thus, in terms of the scenario, if the release is more than the RQ for anhydrous ammonia, then it must first be reported to the National Response Center within 12 hours. A written report will need to be made to the DOT OHMS within 30 days as a result of the spill involving a DOT container (the tanker truck).

Federal Response Elements

Scenario 8: You are on-call as your regional poison center's medical toxicologist and are notified that a freight train carrying several tanker cars containing hydrochloric acid, petroleum, an organophosphate insecticide, and chlorine gas, and several flat cars carrying casks of radioactive medical waste destined for a waste isolation pilot plant in New Mexico, has derailed; several cars have wound up on the river bank below. There are initial reports of a fire and possible chlorine gas release but it is unclear if any radioactive material has breached its containment. Local police, fire fighters, emergency medical services, and HAZMAT specialists are on the scene. There appear to be several casualties among the train's crew. Considering the multiple types of hazardous materials present and the different regulatory jurisdictions and agencies to be involved, you would likely want to know who should be contacted, how such a complicated report is to be made properly, and who should make the report.

Any accidental environmental release of a petroleum product or radiological, chemical, or biological substance, as well as terrorist suspicious activities and maritime security breaches anywhere within the United States, can be reported by anyone to the National Response Center 24 h a day at (800) 424-8802. The center is operated by the US Coast Guard and serves as the initial federal point of contact for all incidents in which federal agencies have jurisdiction [46]. Reporting incidents to the National Response Center by the responsible parties fulfills many of the reporting requirements to the EPA under RCRA and CERCLA, as well as DOT hazardous substance spill reporting requirements [47]. Once an incident is reported, a Federal On-Scene Coordinator (FOSC) from either the EPA (for land based releases) or the United States Coast Guard and/or EPA (for waterway releases) is

or may be activated and, along with national and local response teams, coordinates the response between all federal and local agencies with jurisdiction. FOSCs maintain a 2-h response time to anywhere in the USA. Many other federal resources are at the disposal of the FOSC to assist the FOSC, including Coast Guard Strike Teams with special training and equipment to contain oil and chemical spills, the EPA's Environmental Response Teams that can offer scientific monitoring and clean-up technical support, specialized public affairs personnel, and National Oceanic and Atmospheric Administration (NOAA) scientific support specialists in instances when weather may factor into response, containment, or mitigation planning [48]. Information conveyed to the National Response Center can be routed directly to the White House, the Department of Homeland Security, the DOT, the EPA, the Federal Emergency Management Agency (FEMA), the Department of Energy, the Nuclear Regulatory Commission (NRC), the Department of the Interior, the Department of Defense, the Federal Railroad Administration, the Department of Health and Human Services, the Centers for Disease Control and Prevention, and the Federal Bureau of Investigation (FBI) as appropriate, thus streamlining much of the federal reporting in an emergency [49].

In the above scenario, reporting by the responsible party to the National Response Center as soon as possible, and within 12 h, not only fulfills reporting requirements under RCRA, but will also bring considerable resources in terms of a FOSC. Within 30 days, report to the EPA's OHMS must be made as a result of a DOT container failure resulting in injury (to the train crew).

In conclusion, toxicologists may benefit from an understanding of the federal environmental and occupational toxicological regulations and hazardous materials reporting requirements as well as sources of toxicological information contained in the laws and regulations. As a greater number of toxicological agents are introduced into industry and more is learned about the environmental and health effects of these substances, toxicologists may benefit from an understanding of federal and local laws and regulations and the sources of information on hazardous substances and chemicals they contain. The use of the internet and other centralized resources such as the National Response Center can hopefully alleviate some of these information access difficulties.

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