CHAPTER 2
Background and Authorities

2.1 Lead in the Environment

Lead is present in the environment from both naturally occurring sources and anthropogenic activities and can present an unacceptable risk to human health primarily via ingestion. Young children (<7 years of age) are particularly susceptible to health impacts from lead exposures.

Throughout human history, lead has been mined, smelted, refined, and used in many products (*e.g.*, as an additive in paint, gasoline, pottery, water pipes, solder, crystal, and ceramics). These activities have resulted in substantial increases in lead levels in individuals and in the environment, especially near mining and smelting sites (Patterson et al. 1991, Chaney et al. 1984, Shacklette and Boerngen 1984).

Lead in the environment does not decompose. Lead compounds may be transformed in the environment to other lead compounds; however, lead is an element and cannot be destroyed. Because lead does not decompose, these former uses leave their legacy as higher concentrations of lead in the environment.

Lead particles in the environment can be a substantial constituent of dust and can travel long distances in the air. These lead-containing dust particles may also be removed from the air by rain and then deposited on surface soil, where they may remain for many years and where they can further migrate to surface water. In addition, heavy rains may cause lead in surface soil to migrate into groundwater and eventually into water systems.

Since the 1970s, lead concentrations in exposure media and national BLLs have decreased as a result of efforts to reduce the use of lead in fuel, reduced emissions associated with smelters, reduced mining, banned use of LBP in households, and decreased use of lead-based printing inks in food packaging materials[5] (Egan et al. 2021).

Residential lead site characterization and cleanup procedures are unique from a risk assessment standpoint as the principal effect of lead exposure is neurologic impairment of young children (including impacts to intelligence quotient [IQ]). There is no known threshold level of lead exposure that is not harmful to the neurological system (U.S. EPA 2024, CDC 2012). See Section 8.7 for more information.

[5] https://www.cdc.gov/nchs/nhanes/index.htm.

In general, lead risks to young children are characterized by predicting blood lead concentrations with computer models and are also based on guidance developed by EPA that is available at http://www.epa.gov/superfund/lead-superfund-sites-guidance. See Sections 8.5 and 8.6 for more information.

2.2 Overview of Policies, Laws, and Regulations

This section is designed to provide EPA RPMs and OSCs with a description of important authorities to help better understand EPA directives, policies, and regulations related to lead risk assessment and remediation. Additional information regarding federal laws is available online at http://www.epa.gov/lead/lead-laws-and-regulations. For state and tribal considerations, OSCs and RPMs are encouraged to refer to appropriate state and tribal sources of information related to site-specific exposure assumptions, regulations, and guidance that may inform the response decision.

2.2.1 Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA)

Enacted in 1980, CERCLA has provided response authority for site assessments and cleanups at numerous releases across the United States.[6] CERCLA authorities have been used for responses ranging from the removal of drums of hazardous substances, pollutants, and/or contaminants at long-abandoned sites to large-scale responses at sites on the National Priorities List (NPL) (NRC 2005, SARA 1986,[7] CERCLA 1980[8]). Depending on site-specific circumstances, CERCLA response authority allows EPA to address a wide variety of releases to air, surface water, sediment, groundwater, and soil.

CERCLA authorities address a release or threatened release of a hazardous substance or pollutant or contaminant into the environment (U.S. EPA 2000a, SARA 1986, CERCLA 1980). "Release" may include spilling, discharging, emitting, or leaking into the environment, and may also include the abandonment of closed containers containing hazardous substances, pollutants, or contaminants.[9] "Hazardous substance" and "pollutant or contaminant" are defined at CERCLA Section 101(14) and 101(33), respectively.[10] CERCLA's broad response

[6] http://www.epa.gov/superfund/superfund-cercla-overview.
[7] Superfund Amendments and Reauthorization Act of 1986, Pub. L. No. 99-499, 100 Stat. 1613-1782 (1986).
[8] Comprehensive Environmental Response, Compensation and Liability Act of 1980, Pub. L. No. 96-510, 94 Stat. 2767 (1980).
[9] See CERCLA 101(22) for full definition of "release."
[10] http://www.epa.gov/laws-regulations/summary-comprehensive-environmental-response-compensation-and-liability-act.

authorities make it possible to conduct environmental assessments and site cleanups utilizing CERCLA response authorities.

CERCLA provides EPA with the authority to perform "removal" and "remedial" actions. Removal Site Evaluations evaluate risk for contaminants of concern, exposure pathways, and potential receptors. If a site meets the criteria in 40 Code of Federal Regulations (CFR) 300.415(b)(2), a removal action may be appropriate. Removal actions can be performed on mining and mineral processing (primary lead and other metal smelters) sites, and other sites with lead releases to the environment, of any size. Removal actions, both time-critical and non-time critical, can be performed on lead releases to the environment.[11] Once a determination is made to conduct a removal action, there are two types of removal actions that are commonly performed at residential lead properties/sites: Time Critical Removal Actions (TCRA) or Non-Time Critical Removal Actions (NTCRA). The primary difference is the time sensitivity of the action and the associated evaluation and community relations requirements. All fund-lead removals, TCRAs and NTCRAs alike, are subject to $2 million or 12-month statutory limitations, though the National Oil and Hazardous Substances Pollution Contingency Plan (National Contingency Plan or NCP) outlines two exemptions to the $2 million/12-month limitations.[12] Both TCRA and NTCRA authorities may be utilized regardless of the NPL site status.[13] Additionally, both TCRAs and NTCRAs can be used in conjunction with remedial action. For example, removal authority may be appropriately used to address areas that pose significant risks or act as contamination sources while remedial authority would be used to select a final, comprehensive response.

Remedial actions are typically long-term responses performed at those sites placed on the NPL or being addressed through remedial authorities on non-NPL sites (such as Superfund Alternative Approach sites). Remedial actions are not subject to the time or dollar limitations imposed on removal actions but require a more detailed and formal decision process. Under these conditions, EPA's cleanup decisions are generally based upon a risk assessment, risk management decisions, and consideration of Applicable or Relevant and Appropriate Requirements (ARARs). CERCLA response actions can be conducted by EPA, states, tribes, or other federal agencies (Section 104), or federal agencies may enter into agreements with private parties (Section 122) or require private parties (Section 106) to perform such cleanup activities. CERCLA provides the flexibility to assess and clean up releases based upon site-

[11] NCP 300.415.
[12] NCP 300.415(b)(5).
[13] NCP 300.425(b)(1).

specific circumstances. There are also limitations to CERCLA response actions as discussed in the next section.

2.2.1.1 CERCLA Limitations

There are potential limitations in CERCLA that may be relevant to lead-contaminated sites. For example, Section 104(a)(3) limits EPA's ability to respond to releases within residential structures as follows:

> "Limitations on Response. The President shall not provide for removal or remedial action under this section in response to a release or threat of release from products which are part of the structure of, and result in exposure within, residential buildings or business or community structures..."

The above cited section of CERCLA generally limits the authority of EPA/Office of Land and Emergency Management (OLEM) to respond to LBP inside a structure or house. However, as noted in Chapter 6, EPA may have the authority to conduct response actions addressing soils contaminated by a release of lead-contaminated paint chips from the exterior of homes to prevent recontamination of soils that have been remediated. In addition, Section 104(a)(4) provides an exception to the limitations in Section 104(a)(3) and states, "notwithstanding 104(a)(3)…, to the extent authorized by this section, the President may respond to any release or threat of release if in the President's discretion, it constitutes a public health or environmental emergency and no other person with the authority and capability to respond to the emergency will do so in a timely manner." Refer to to EPA's guidance, *Response Actions at Sites with Contamination Inside Buildings*,[14] for additional information (U.S. EPA 1993).

2.2.2 Applicable or Relevant and Appropriate Requirements (ARARs) and To Be Considered (TBC) Criteria

Under Section 121(d) of CERCLA, remedial actions must comply with substantive provisions of federal environmental laws and more stringent, timely-identified, state environmental or facility siting laws. Removal actions should comply with ARARs to the extent practicable considering the exigencies of the situation, while remedial actions must comply with ARARs unless waived. "Applicable" requirements are those federal or state laws or regulations that specifically address a hazardous substance, pollutant, contaminant, remedial action, location, or other circumstance found at a CERCLA release. "Relevant and appropriate" requirements are not "applicable," but address problems or situations similar enough to those at the CERCLA

[14] https://semspub.epa.gov/work/HQ/123627.pdf.

release that their use is well suited at the release (refer to EPA's guidance on ARAR requirements).[15] Whether a law or regulation is an ARAR for a particular site is a site-specific decision.

The Toxic Substances Control Act (TSCA) Section 403 Soil-Lead Hazard Rule from 2001 establishes a soil-lead hazard of 400 parts per million (ppm) for bare soil in play areas and 1,200 ppm for bare soil in non-play areas of the yard. Section 403 standards provide generic levels that can be used at thousands of widely varying sites across the nation. The site-specific characterization of releases that are conducted at CERCLA and RCRA sites allow for development of action levels that are tailored to the individual release, exposure, and risk. Therefore, while TSCA Section 403 may be identified as an ARAR for some CERCLA response actions where it would help inform a CERCLA acceptable risk level, for protectiveness purposes on a site-specific basis, response actions may go further than the Section 403 rule.

State requirements may be ARARs if they meet several criteria including that they be health based, applied consistently, promulgated and enforceable, identified in a timely manner, and more stringent than federal requirements.[16] See also 40 CFR 300.5 and CERCLA 121(d)(2) for the NCP definitions of "applicable" and "relevant and appropriate." States may have carcinogenic and toxicity values for lead that could be considered when assessing lead sites. Such values may constitute a to-be-considered (TBC) guidance under 40 CFR 300.400(g)(3). A state might also have laws or promulgated regulations that establish a protective value for lead that could constitute an ARAR that under CERCLA would either need to be met or waived in accordance with the NCP. This information is evaluated on a site-specific basis.

More information on ARARs is provided in the *CERCLA Compliance with Other Laws Manual*, Part I, August 1988, and Part II, August 1989 (U.S. EPA 1989a, 1988a) and in U.S. EPA (2023a). Consultations with appropriate program offices and the Office of Regional Counsel (ORC) will help ensure that the most current regulations are considered.

In addition to ARARs, the lead and support agencies involved in assessing and addressing Superfund sites may identify other advisories, criteria, or guidance that were developed by EPA, other federal agencies, or states to be considered relevant for a particular release. These

[15] https://www.epa.gov/superfund/applicable-or-relevant-and-appropriate-requirements-arars.
[16] See U.S. EPA (2023a), OLEM Directive 9234.0-07 *Documenting Applicable, or Relevant and Appropriate Requirements in Comprehensive Environmental Response, Compensation, and Liability Act Response Action Decisions* at https://semspub.epa.gov/work/HQ/100003232.pdf.

comprise the TBC category, which may be used to inform remedy selection (U.S. EPA 2017a). For more information, see 40 CFR § 300.400(g)(3).

2.2.3 Superfund Lead Directives

EPA has developed the following lead directives for addressing lead contamination in soils at CERCLA and RCRA sites.

EPA Directive 9355.4-12, *Revised Interim Soil Lead Guidance for CERCLA Sites and RCRA Corrective Action Facilities* (Office of Solid Waste and Emergency Response [OSWER]) (U.S. EPA 1994a), established EPA's approach for addressing lead in soil at CERCLA and RCRA sites. The 1994 Directive states that, "OSWER (OLEM) will attempt to limit exposure to soil lead levels such that a typical (or hypothetical) child or group of similarly exposed young children would have an estimated risk of no more than 5% probability of exceeding a 10 microgram per deciliter (µg/dL) blood-lead level" (U.S. EPA 1994a). Refer to Appendix B for the 1994 Directive.

In 1998, EPA clarified the 1994 Directive through Directive 9200.4-27P ("Clarification") (U.S. EPA 1998), recommending that the Integrated Exposure Uptake Biokinetic (IEUBK) model be used as the primary tool to generate risk-based soil cleanup levels at lead sites for current and future residential use. Additionally, the 1998 clarification states that response actions can be taken using the IEUBK predictions alone, and that blood lead studies, while providing useful information, should not be used alone either to assess risk from lead exposure or to develop soil lead cleanup levels (U.S. EPA 1998). EPA recommends that risk assessments conducted at lead-contaminated residential sites use the individual residence as the primary exposure unit (EU) of concern. Refer to Appendix C for the 1998 Directive.

In 2024, EPA updated the residential soil screening levels and EPA's approach for reducing lead exposures at CERCLA sites and RCRA Corrective Action Facilities in a manner consistent with the best available science (Breen 2024).

2.3 Other Acts, Rules, and Regulations Regarding Lead Contamination

The substantive portions of federal statutes that may constitute ARARs on a site-specific basis include, but are not limited to:

- Resource Conservation and Recovery Act (RCRA);[17]
- Clean Air Act (CAA);[18]
- Clean Water Act (CWA);[19]
- Safe Drinking Water Act (SDWA);[20]
- Reduction of Lead in Drinking Water Act;[21]
- Lead and Copper Rule;[22] and
- TSCA Subchapter IV Lead Program.[23]

2.4 Other Superfund Resources on Lead

In addition, supplemental guidance and technical support are available through the Technical Review Workgroup (TRW) Lead Committee website at: https://www.epa.gov/superfund/lead-superfund-sites.

[17] http://www.epa.gov/rcra.
[18] http://www.epa.gov/air/caa/.
[19] http://www.epa.gov/laws-regulations/summary-clean-water-act.
[20] http://www.epa.gov/laws-regulations/summary-safe-drinking-water-act.
[21] https://www.gpo.gov/fdsys/pkg/BILLS-111s3874enr/pdf/BILLS-111s3874enr.pdf.
[22] http://water.epa.gov/lawsregs/rulesregs/sdwa/lcr/.
[23] http://www.epa.gov/enforcement/toxic-substances-control-act-tsca-and-federal-facilities.