

## Cleanup Levels for CERCLA Remedial Actions

By David M. Buxbaum

Changes in standards used to develop cleanup levels may call into question the protectiveness of a remedy at a Superfund site. Under CERCLA Section 121(d) remedial actions selected at Superfund sites must be protective of human health and the environment as well as comply with applicable or relevant and appropriate requirements (ARARs). Prior to remedy selection, a remedial investigation is conducted which includes a baseline risk assessment to identify the contaminants of concern, affected media and establish acceptable exposure levels. The Feasibility Study involves developing remedial action objectives, remedial alternatives and preliminary remediation goals (PRGs). Per the NCP, PRGs are developed based on readily available information, such as chemical-specific ARARs or To-be-considered (“TBC”) guidance. Final cleanup levels are determined when the remedy is selected in the Record of Decision (ROD). When ARARs or TBCs are not available, cleanup levels that are protective of human health and the environment should be developed based upon a risk assessment. At sites where remedy leaves hazardous substances above levels suitable for unrestricted use and unlimited exposure, a five-year review (FYR) is required to ensure remedy protectiveness. As part of the FYR, the EPA evaluates whether the cleanup levels remain valid and reviews changes in ARARs and TBCs identified in the ROD.

### **I. Overview of the CERCLA Remedy Selection Process**

#### ***Compliance with CERCLA, the NCP and Agency Guidance***

The CERCLA statute, at 42 U.S.C. § 9601 et seq., provides the legal requirements for the Superfund Program, and the National Oil and Hazardous Substances Pollution Contingency Plan (“NCP”), at 40 C.F.R. Part 300 et. seq., reflects these requirements and contains the regulations for the Environmental Protection Agency (“EPA”) to follow in investigating releases, selecting remedies, and conducting cleanup activities. EPA also issues guidance and policy documents on nearly every aspect of CERCLA and the NCP to foster consistency across the Agency in carrying out the Agency’s Superfund Program.<sup>1</sup> In addition, preambles to the NCP and other Agency regulations provide valuable insight into the Agency’s reasoning and intent, and often serve as further guides during the remedial action selection process.

CERCLA Section 121(a) (*Selection of remedial action*), provides that remedial action under Sections 104 or 106 of CERCLA shall be carried out in accordance with Section 121 (*Cleanup standards*) and, to the extent practicable, the NCP.<sup>2</sup> Whether performed as a PRP-lead or Fund-lead cleanup, EPA requires CERCLA remedial actions to adhere to the NCP the extent practicable, as well as to follow Agency policy and guidance where appropriate.<sup>3</sup>

Pursuant to CERCLA Section 121(d) (*Degree of cleanup*), any remedial action selected by EPA must meet two threshold requirements. The remedy: (1) must attain a degree of cleanup which, at a minimum, assures protection of human health and the environment;<sup>4</sup> and (2) shall require a level or standard of control, at the completion of the action, which at least attains (or justifies a waiver of) all ARARs with respect to any hazardous substance, pollutant or contaminant that will

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<sup>1</sup> While guidance and policy documents are not legally binding, they represent the Agency’s interpretations of CERCLA and the NCP, and outline the Agency’s preferred methodologies and approaches.

<sup>2</sup> 42 U.S.C. § 9621(a).

<sup>3</sup> See EPA OSRE and U.S. DOJ 2009 Revised CERCLA Model RD/RA Consent Decree Section I.B. which in part states that “...the performance of the work shall be consistent with the NCP.”

<sup>4</sup> 42 U.S.C. § 9621(d)(1) states, “Remedial actions . . . shall attain a degree of cleanup of hazardous substances, pollutants, and contaminants released into the environment and of control of future release at a minimum which assures protection of human health and the environment. See also 40 C.F.R. §§ 300.430(f)(1)(i)(A), 300.430(f)(5)(ii)(A) & (B).

remain onsite.<sup>5</sup> Remedial actions must also be cost-effective, utilize permanent solutions and alternative treatment or resource recovery technologies to the maximum extent practicable, as well address the preference for treatment of wastes that pose a principal threat.<sup>6</sup> The overarching mandate of the Superfund program is to protect human health and the environment from current and potential threats posed by uncontrolled hazardous waste sites and it cannot be waived.<sup>7</sup>

### ***Summary of RI and Baseline Risk Assessment***

In order to select a remedial action, a Remedial Investigation (“RI”) is conducted, which characterizes the site through field investigations to determine the nature and extent of contamination and assesses the risks (human health and/or ecological) posed by the contamination.<sup>8</sup> Specifically, the NCP states that the baseline risk assessment should characterize the current and potential threats to human health and the environment that may be posed by contaminants migrating to ground water or surface water, releasing to air, leaching through soil, remaining in the soil, and bioaccumulating in the food chain.<sup>9</sup> The baseline risk assessment identifies contaminants of concern<sup>10</sup>, exposure pathways and evaluates whether the site poses a current or potential risk to human health and the environment in the absence of any remedial action.<sup>11</sup> It provides the basis for determining whether or not remedial action is necessary and justification for performing remedial actions.<sup>12</sup> Generally, where the baseline risk assessment indicates that a cumulative site risk to an individual using reasonable maximum exposure (“RME”)<sup>13</sup> assumptions for either current or future land use exceeds the 10<sup>(-4)</sup> lifetime excess cancer risk end of the risk range, action under CERCLA is generally warranted at the site.<sup>14</sup> For sites where the cumulative site risk to an individual based upon RME for both current and future land use is less than 10<sup>(-4)</sup>, action is generally not warranted, but may be warranted if a chemical-specific standard that defines acceptable risk is violated or unless there are noncarcinogenic effects or an adverse environmental impact warrants action.<sup>15</sup>

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<sup>5</sup> 42 U.S.C. § 9621(d)(2)(A); *see also* 40 C.F.R. §§ 300.430(f)(1)(i)(A), 300.430(f)(5)(ii)(A)&(B); Preamble to Final NCP, 55 Fed. Reg. 8666, 8726 (Mar. 8, 1990).

<sup>6</sup> 42 U.S.C. § 9621(b)(1).

<sup>7</sup> 55 Fed. Reg. 8666, 8725 (Mar. 8, 1990).

<sup>8</sup> 40 C.F.R. § 300.430(d)(1) and (2) *Remedial investigation*.

<sup>9</sup> 40 C.F.R. § 300.430(d)(4).

<sup>10</sup> Chemicals (or contaminants) of concern (COCs) are the hazardous substances, pollutants, and contaminants that at the end of the risk assessment are found to be the risk driver or may actually pose unacceptable human health or ecological risks.

<sup>11</sup> In considering land use, Superfund exposure assessments most often classify land into one of three categories: (1) Residential, (2) commercial/industrial, and (3) recreational. EPA also considers the ecological use of the property and, as appropriate, agricultural use. In general, the baseline risk assessment will look at a future land use that is both reasonable, from land use development patterns, and may be associated with the highest (most significant) risk, in order to be protective. 55 Fed. Reg. 8666, 8710 (Mar. 8, 1990). *See also* EPA, OSWER Dir. 9355.7-04, *Land Use in the CERCLA Remedy Selection Process*, May 25, 1995. Guidance on EPA consideration of reasonably anticipated future use in the remedy selection process.

<sup>12</sup> Preamble to Proposed NCP, 53 Fed. Reg. 51394, 51425 (Dec. 21, 1988).

<sup>13</sup> EPA/540/1-89/002, *Risk Assessment Guidance for Superfund Volume I Human Health Evaluation Manual (Part A)*, December 1989, (*Chapter 6 Exposure Assessment*, § 6.1.2.) The reasonable maximum exposure is defined as the highest exposure that is reasonably expected to occur at a site under both current and future land-use conditions. The intent of the RME is to estimate a conservative exposure case (i.e., well above the average case) that is still within the range of possible exposures.

<sup>14</sup> EPA, OSWER Dir. 9355.0-30, *Role of the Baseline Risk Assessment in Superfund Remedy Section Decisions*, April 22, 1991.

<sup>15</sup> *Id.* Chemical-specific standards that define acceptable risk levels (e.g., non-zero MCLGs, MCLs) also may be used to determine whether exposure is associated with unacceptable risk to human health or the environment and whether remedial action under CERCLA Section 104 or 106 is warranted.

A second major objective of risk assessment in Superfund is to use the risks and exposure pathways developed in the baseline risk assessment to determine chemical concentrations associated with levels of risk that will be adequately protective of human health for a particular site (i.e., remediation goals).<sup>16</sup> The results of the baseline risk assessment conducted as part of the RI (which includes exposure assessment, toxicity assessment, and risk characterization components) help establish acceptable exposure levels in the FS for use in developing remedial alternatives.<sup>17</sup> EPA's "Risk Assessment Guidance for Superfund Volume I Human Health Evaluation Manual (Part A)", [RAGS, EPA/540/1-89/002 December 1989] provides detailed guidance on how to conduct the human health portion of the risk assessment. Other pertinent guidance includes the, "Guidance for Conducting Remedial Investigations and Feasibility Studies Under CERCLA", [EPA OSWER Dir. 9355.3-01, Interim Final October 1988] which describes how the baseline risk assessment fits into the overall RI/FS process.

EPA's RAGs includes several Parts (A through F) as well as supplemental bulletins that can be accessed from <http://www.epa.gov/oswer/riskassessment/ragsa/index.htm>. RAGS Part B provides guidance on using EPA toxicity values and exposure information to derive risk-based preliminary remediation goals ("PRGs") for a Superfund site. These PRGs may be modified based upon the results of a baseline risk assessment, which clarifies exposure pathways and may identify situations where cumulative risk of multiple contaminants or multiple exposure pathways at the site indicate the need for more or less stringent cleanup levels than those initially developed as PRGs.<sup>18</sup> In addition to being modified based on the baseline risk assessment, PRGs and the corresponding cleanup levels may also be modified based on the given waste management strategy selected at the time of remedy selection that is based on the balancing of the nine criteria used for remedy selection.<sup>19</sup>

Contamination at a CERCLA site may originate from releases attributable to the site in question, as well as contamination that originated from other sources, including natural and/or anthropogenic (i.e., man-made) sources not attributable to the specific site releases under investigation. In some cases, the same hazardous substance, pollutant or contaminant associated with a release is also a background constituent.<sup>20</sup> These constituents should be included in the risk assessment, particularly when their concentrations exceed risk-based concentrations.<sup>21</sup> Background information is important to risk managers because the CERCLA program, generally, does not clean up to concentrations below natural or anthropogenic background levels.<sup>22</sup> However, where anthropogenic background levels exceed acceptable risk-based levels, and EPA has determined that a response action is appropriate, EPA's goal is to develop a comprehensive response to address area-wide contamination.<sup>23</sup>

#### ***ARARs and TBC Identification during RI/FS***

Prior to the RI, EPA and support agencies conduct "scoping" which includes for example: evaluation of existing data on the site; developing a conceptual understanding of the site; identifying type and quantity and quality of data to be collected; and developing sampling and

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<sup>16</sup> 55 Fed. Reg. 8666, 8709 (Mar. 8, 1990).

<sup>17</sup> *Id.* at 8708.

<sup>18</sup> EPA OSWER Dir. 9355.0-30, *Role of the Baseline Risk Assessment in Superfund Remedy Section Decisions*, April 22, 1991.

<sup>19</sup> *Id.*

<sup>20</sup> EPA OSWER 9285.6-07P, *Role of Background in the CERCLA Cleanup Program*, May 1, 2002.

Background refers to constituents or locations that are not influenced by the releases from a site, and is usually described as naturally occurring or anthropogenic.

<sup>21</sup> *Id.*

<sup>22</sup> *Id.*

<sup>23</sup> EPA, OSWER 9355.0-69, *Rules of Thumb for Remedy Selection*, August 1997.

analysis plans.<sup>24</sup> During scoping of the RI, the lead agency shall initiate identification of potential federal and state ARARs and, as appropriate other criteria, advisories, or guidance to be considered.<sup>25</sup> Identification of chemical-specific ARARs is particularly important during the scoping phase because the preliminary remediation goals, which are typically formulated during project scoping, are initially based on readily available environmental or health-based ARARs [e.g., maximum contaminant levels (“MCLs”), ambient water quality criteria (“AWQC”)] and other criteria, advisories, or guidance (e.g., reference doses (“RfDs”).<sup>26</sup> As new information and data are collected during the RI, including the baseline risk assessment, and as additional ARARs are identified during the RI, these preliminary remediation goals may be modified as appropriate to ensure that remedies comply with CERCLA's mandate to be protective of human health and the environment and comply with ARARs.<sup>27</sup> Under 40 C.F.R. § 300.400(g)(3), both lead and support agencies may, as appropriate identify other advisories, criteria, or guidance “to be considered” (“TBC”) for a particular release. The TBC category consists of advisories, criteria, or guidance that were developed by EPA, other federal agencies, or states that may be useful in developing CERCLA remedies.<sup>28</sup> In many circumstances TBCs will be considered along with ARARs and may be used in determining the necessary level of cleanup for protection of human health and the environment.<sup>29</sup>

### ***Establishment of PRGs during the FS***

Following the RI, a Feasibility Study (“FS”) is conducted, which develops and evaluates remedial alternatives to address the contamination along with other information such that the remedial action options can be presented to a decision-maker and an appropriate remedy be selected.<sup>30</sup> The first step in the FS process involves developing remedial action objectives for protecting human health and the environment which should specify contaminants and media of concern, potential exposure pathways, and preliminary remediation goals.<sup>31</sup> The preliminary remediation goals (“PRGs”) are concentrations of contaminants for each exposure route that are believed to provide adequate protection of human health and the environment based on preliminary site information.<sup>32</sup> The PRGs consist of medium specific or operable unit specific chemical concentrations that are protective of human health and the environment.<sup>33</sup>

Preliminary remediation goals are developed based on readily available information such as chemical-specific ARARs or other information.<sup>34</sup> For all classes of chemicals, EPA uses health-based ARARs to set remediation goals, when they are available.<sup>35</sup> However, ARARs do not exist for all exposure media (e.g., certain types of contaminated soil) or for all chemicals, and therefore EPA must use other information to set remediation goals that will ensure protection of human health and the environment.<sup>36</sup> For systemic toxicants (e.g., noncarcinogenic chemicals) acceptable exposure levels shall represent concentrations levels to which the human population,

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<sup>24</sup> 40 C.F.R. § 300.430(b) *Scoping*.

<sup>25</sup> *Id.* § 300.430(b)(9).

<sup>26</sup> 53 Fed. Reg. 51394, 51425 (Dec. 21, 1988); *see also* 55 Fed. Reg. 8666, 8712 (Mar. 8, 1990).

<sup>27</sup> *Id.*

<sup>28</sup> 40 C.F.R. § 300.400(g)(3). Examples of TBCs include health advisories, reference doses or recommended PRGs from EPA guidance documents such as EPA, OSWER 9355.4-01FS, *A Guide on Remedial Actions at Superfund Sites with PCB Contamination*, August 1990.

<sup>29</sup> EPA, OSWER Dir. 9234.1-01, *Compliance with Other Laws Manual Part I*, (August 8, 1988), (*Executive Summary*).

<sup>30</sup> 40 C.F.R. § 300.430(e)(1).

<sup>31</sup> 55 Fed. Reg. 8666, 8712 (Mar. 8, 1990); *see also* 40 C.F.R. § 300.430(e)(2)(i).

<sup>32</sup> *Id.* at 8712.

<sup>33</sup> *Id.* at 8713.

<sup>34</sup> 40 C.F.R. § 300.430(e)(2)(i).

<sup>35</sup> 55 Fed. Reg. 8666, 8712 (Mar. 8, 1990).

<sup>36</sup> *Id.* at 8713.

including sensitive subgroups, may be exposed without adverse effect during or part of a lifetime, incorporating an adequate margin of safety (i.e., a hazard index at or below one).<sup>37</sup> For known or suspected carcinogens, acceptable exposure levels are generally concentrations that represent an excess upper bound lifetime cancer risk to an individual of between  $10^{-4}$  to  $10^{-6}$  using information on the relationship between dose and response.<sup>38</sup> The  $10^{-6}$  level shall be used as the point-of departure for determining remediation goals for alternatives when ARARs are not available or are not sufficiently protective because of the presence of multiple contaminants at a site or multiple pathways of exposure.<sup>39</sup> Remediation goals shall also be developed by considering factors related to technical limitations such as detection/quantification limits for contaminants, factors related to uncertainty and other pertinent information.<sup>40</sup> For remedial actions of contaminated groundwater that is a current or potential drinking water source, non-zero MCLGs or MCLs shall be attained where relevant and appropriate.<sup>41</sup> For remedial actions addressing impacted surface water, AWQC under Sections 303 or 304 of the Clean Water Act shall be attained where relevant and appropriate.<sup>42</sup> In addition, EPA will set remediation goals for ecological and environmental effects based on environmental ARARs, where they exist, and levels based on site-specific determination to be protective of the environment.<sup>43</sup> Assessment of ecological risk is conducted as part of the baseline risk assessment.<sup>44</sup>

It has been EPA's policy that compliance with a chemical-specific ARAR generally will be considered protective even if it is outside the [cancer] risk range (unless there are extenuating circumstances such as exposures to multiple contaminants or pathways of exposure).<sup>45</sup> Many ARARs, which Congress specifically intended be used as cleanup standards at Superfund sites are set at risk levels less stringent than  $10^{-6}$ .<sup>46</sup> However, EPA has clarified that in rare situations PRGs may be established by EPA at levels more protective than required by a given ARAR, even absent multiple pathways or contaminants, where application of the ARAR would not be protective of human health or the environment.<sup>47</sup> This decision should be made based upon a

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<sup>37</sup> 40 C.F.R. 300.430(e)(2)(i)(A)(1). The potential for noncarcinogenic effects is evaluated by comparing an exposure level over a specified time period (e.g., lifetime) with a reference dose derived for a similar exposure period. This ratio of exposure to toxicity is called a hazard quotient and generally should not exceed unity or 1. See EPA/540/1-89/002, RAGs Part A, Chapter 8 (*Risk Characterization*).

<sup>38</sup> *Id.* § 300.430(e)(2)(i)(A)(2).

<sup>39</sup> *Id.* See also 55 Fed. Reg. 8666, 8716 - 8718 (Mar. 8, 1990). While the  $10^{-6}$  starting point expresses EPA's preference for setting cleanup levels at the more protective end of the risk range, it is not a presumption that the final Superfund cleanup will attain that risk level. PRGs for carcinogens are set at a  $10^{-6}$  excess cancer risk as a point of departure, but may be revised to a different risk level within the acceptable risk range based on the consideration of appropriate factors including, but not limited to: exposure factors, uncertainty factors, and technical factors. The final selection of appropriate risk level is made when the remedy is selected based on the balancing of criteria.

<sup>40</sup> 40 C.F.R. § 300.430(e)(2)(i)(A)(3)-(5).

<sup>41</sup> *Id.* § 300.430(e)(2)(i)(B) and (C).

<sup>42</sup> *Id.* § 300.430(e)(2)(i)(E).

<sup>43</sup> 55 Fed. Reg. 8666, 8712 (Mar. 8, 1990).

<sup>44</sup> See EPA, OSWER Dir.9285.7-17, *Role of the Ecological Risk Assessment in the Baseline Risk Assessment*, August 12, 1994. See also <http://www.epa.gov/oswer/riskassessment/tooleco.htm>.

<sup>45</sup> EPA, OSWER Dir. 9355.0-30, *Role of the Baseline Risk Assessment in Superfund Remedy Section Decisions*, April 22, 1991. See 40 C.F.R. 300.430(e)(2)(i)(D) (authorizing consideration of the cancer risk range where attainment of ARARs will result in cumulative cancer risk of greater than  $10^{-4}$  due to multiple pathways or contaminants).

<sup>46</sup> 55 Fed. Reg. 8666, 8717 (Mar. 8, 1990). For example, the SDWA directs the Agency to consider science, treatment techniques and feasibility, cost of compliance, in addition to protection of human health when promulgating MCLs.

<sup>47</sup> EPA, OSWER Dir. 9200.4-23, *Clarification of the Role of Applicable, or Relevant and Appropriate Requirements in Establishing Preliminary Remediation Goals*, August 22, 1997.

review of the level of risk associated with the ARARs; the soundness of the technical basis for the ARAR; and other factors relating to the ARAR or to its application at an individual site.<sup>48</sup>

### ***ARARs Identification and Evaluation during FS***

The primary objective of the FS is to “ensure that appropriate remedial alternatives are developed and evaluated such that relevant information concerning the remedial action options can be presented to a decision-maker and an appropriate remedy selected.”<sup>49</sup> At this point, EPA and states must identify action-specific and location-specific ARARs that are applicable or relevant and appropriate to the remedial alternatives evaluated in the FS.<sup>50</sup> Pursuant to 40 C.F.R. § 300.430(e)(8), the lead agency shall notify the support agency of the alternatives that will be evaluated in detail to facilitate the identification of ARARs and, as appropriate, pertinent advisories, criteria, or guidance to be considered. The lead and support agencies must identify their ARARs related to specific actions in a timely manner and no later than the early stages of the comparative analysis.<sup>51</sup> As more information is learned about the site and as remedial alternatives are considered, Federal and State requirements can be narrowed to those which are potential ARARs for each alternative.<sup>52</sup>

The remedial alternatives are assessed to determine whether they are protective, and whether they attain ARARs under federal environmental laws and state environmental or facility siting laws or provide grounds for invoking a waiver.<sup>53</sup> During the detailed analysis and selection of remedy phases, the decision-maker must compare the potential ARARs to the known information regarding conditions at the site and the remedial alternatives to determine if the potential ARARs are, in fact, actually applicable or relevant and appropriate to the response action.<sup>54</sup> Remedial alternatives that do not comply with ARARs (or for which a statutory waiver is not justified) are not eligible for selection as the remedy.<sup>55</sup> Using the evaluation of remedial alternatives presented in the FS, EPA presents its proposed remedial action (*i.e.*, Preferred Alternative) to the public in the Proposed Plan.<sup>56</sup> Following an opportunity for public comment on the Proposed Plan, EPA then selects its remedy and documents the remedy, including site-specific ARARs, in a Record of Decision.<sup>57</sup>

### ***Decision Documents***

Section 117 of CERCLA requires the issuance of decision documents for remedial actions taken pursuant to §§104, 106, 120, and 122. In particular, CERCLA Section 117(b) requires that EPA provide notice of the final remedial action plan (*i.e.*, the “Record of Decision” or “ROD”), and that the ROD be made available to the public before commencement of any remedial action. Sections 300.430(f)(2), 300.430(f)(4), and 300.435(c)(2) of the NCP establish the regulatory requirements for these decision documents including the ROD, Proposed Plan, Explanation of

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<sup>48</sup> *Id.*

<sup>49</sup> 40 C.F.R. § 300.430(e)(1).

<sup>50</sup> *Location-specific* ARARs are restrictions on hazardous substances or the conduct of response activities solely based on their location in a special geographic area (*e.g.* wetlands, watersheds, floodplains, sensitive habitats, coastal zones, historic places). *Action-specific* ARARs are technology- or activity-based requirements or limits on actions taken with respect to particular hazardous substance or waste type (*e.g.*, RCRA hazardous waste or TSCA PCB waste). These requirements are triggered by a particular remedial activity (*e.g.*, excavate soil, stage waste in pile or containers, treat, dispose, emit, discharge, cap with waste in place, etc.).

<sup>51</sup> 40 C.F.R. § 300.430(e)(9).

<sup>52</sup> 53 Fed. Reg. 51394, 51438 (Dec. 21, 1988).

<sup>53</sup> 40 C.F.R. § 300.430(e)(9)(iii)(B).

<sup>54</sup> 53 Fed. Reg. 51394, 51438 (Dec. 21, 1988).

<sup>55</sup> 55 Fed. Reg. 8666, 8724 (Mar. 8, 1990); 53 Fed. Reg. at 51429 (Dec. 21, 1988).

<sup>56</sup> See 40 C.F.R. § 300.430(f)(2) *The proposed plan.*

<sup>57</sup> See 40 C.F.R. § 300.430(f)(4) *Final remedy selection.*

Significant Differences, and ROD Amendment. The EPA's *Guide to Preparing Superfund Proposed Plans, Records of Decision, and Other Remedy Selection Decision Documents*, [hereinafter *ROD Guidance*] provides recommended formats and content for Superfund decision documents to ensure that all statutory and regulatory documentation requirements are met.<sup>58</sup>

### ***ROD Requirements***

Following receipt of public comments and any final comments from the support agency (usually the State), the lead agency (usually EPA) selects and documents the remedy selection for a site or operable unit ("OU") in a ROD.<sup>59</sup> EPA retains the final authority for remedy selection for all response actions which are federally-funded or are to be carried out by a PRP pursuant to a CERCLA enforcement action.<sup>60</sup> Pursuant to the NCP, remedies described in a ROD must: 1) protect human health and the environment, 2) comply with ARARs unless a waiver is justified; 3) be cost-effective; 4) utilize permanent solutions and alternative treatment technologies or resource recovery technologies to the maximum extent practicable; and 5) satisfy a preference for treatment as a principal element or explain why this preference was not met.<sup>61</sup>

The ROD shall also indicate the remediation goals, as discussed in 40 C.F.R. 300.430(e)(2)(i) that the remedy is expected to achieve.<sup>62</sup> In addition to specifying the final cleanup levels for each medium (i.e., contaminant specific remediation goals), the ROD should identify the basis for cleanup levels (ARARs, TBC or risk-based).<sup>63</sup> The ROD serves as a legal document in that it certifies that the remedy selection process was carried out in accordance with CERCLA and, to the extent practicable, in accordance with the NCP and that explains the rationale for the selected remedy.<sup>64</sup> It is also a technical document that provides information necessary for determining the conceptual engineering components, and which outlines the remedial action objectives, and cleanup levels for the Selected Remedy.<sup>65</sup>

## **II. Compliance with ARARs**

### ***Remedial Actions***

Section 121(d)(2) of CERCLA, added by SARA in 1986, states that remedial actions must comply with federal and more stringent state environmental laws that are legally "applicable" or "relevant and appropriate" (commonly referred to as "ARARs") under the circumstances of the release or threatened release of such hazardous substance or pollutant or contaminant. Further, the NCP requires remedies to attain, or waive under CERCLA Section 121(d)(4), ARARs during the

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<sup>58</sup> EPA OSWER 9200.1-23P, July 1999.

<sup>59</sup> See 40 C.F.R. § 300.430(f)(4). Under 40 C.F.R. § 300.5, an 'Operable Unit' or "OU" means a discrete action that comprises an incremental step toward comprehensively addressing site problems. The cleanup of a site can be divided into a number of OUs, depending on the complexity of problems associated with a site. Per 40 C.F.R. § 300.515(2)(ii), state concurrence on a ROD is not a prerequisite to EPA's selecting a remedy, i.e., signing a ROD.

<sup>60</sup> 40 C.F.R. § 300.515(e)(2)(ii). Under 40 C.F.R. § 300.430(f)(4)(iii), the process for selection of a remedial action at a federal facility on the NPL shall entail a joint selection by the head of the relevant department or agency and EPA. If mutual agreement on the remedy is not reached, selection of the remedy is made by EPA.

<sup>61</sup> 40 C.F.R. § 300.430(f)(5)(ii).

<sup>62</sup> 40 C.F.R. § 300.430(f)(5)(iii)(A).

<sup>63</sup> See *ROD Guidance*, § 6.3.12 (*Selected Remedy*), at p. 6-45. Final cleanup levels are not formally determined until the remedy is ready to be selected and are established in the ROD. In the ROD it is preferable to use the term "remediation level" or "cleanup level" rather than "remediation goal" in order to make clear that the Selected Remedy establishes binding requirements.

<sup>64</sup> 53 Fed. Reg. 51394, 51430 (Dec.21, 1988).

<sup>65</sup> *Id.*; See also *ROD Guidance*, § 6.1.1 (*Purpose of the ROD*), at p. 6-1. .

course of a remedial action.<sup>66</sup> ARARs are any promulgated standards, requirements, criteria, or limitations under federal environmental laws, or any promulgated standards, requirements, criteria, or limitations under state environmental or siting laws that are more stringent than federal requirements, that are either legally applicable or relevant and appropriate under the circumstances.<sup>67</sup> EPA has issued numerous guidance documents to assist agencies in understanding the statutory and NCP requirements related to identifying, documenting and complying with ARARs, most of which can be found on EPA's website.<sup>68</sup>

Pursuant to 40 C.F.R. § 300.5 (*Definitions*), "Applicable requirements" means those promulgated cleanup standards, standards of control, and other substantive requirements, criteria, or limitations that specifically address a hazardous substance, pollutant, contaminant, remedial action, location, or other circumstance found at a CERCLA site. "Relevant and appropriate" requirements means those promulgated cleanup standards, standards of control, and other substantive requirements, criteria or limitations that, while not "applicable" to a hazardous substance, pollutant, contaminant, remedial action, location, or other circumstance found at a CERCLA site, address problems or situations sufficiently similar to those encountered that their use is well suited to the particular site. Only those state standards that are identified by a state in a timely manner and that are more stringent than federal requirements may ARARs.

### ***More Stringent State ARARs***

CERCLA Section 121(d)(2)(A) requires attainment of a state standard, requirement, criteria, or limitation (including any siting standard) when the state requirement is promulgated, more stringent than federal law(s), and it is identified by the State in a timely manner.<sup>69</sup> In general, EPA considers state regulations under federally-authorized programs to be federal requirements.<sup>70</sup> Where no federal ARAR exists for a chemical, location, or action, but a state ARAR does exist, or where a state ARAR is broader in scope than the federal ARAR, the state ARAR is considered more stringent.<sup>71</sup> For purposes of identification and notification of promulgated State standards, the term "promulgated" means that the standards are of general applicability and are legally-enforceable.<sup>72</sup> In addition, a state standard must be consistently applied or it may be waived under CERCLA Section 121(d)(4).<sup>73</sup>

### ***Types of ARARs***

For ease of identification, EPA has classified ARARs into three categories, chemical-, action-, and location-specific. *Chemical-specific* ARARs are health- or risk-based numerical values or methodologies which, when applied to site-specific conditions, result in the establishment of numeric values. These values establish an acceptable amount or concentration of a chemical that may remain in, or be discharged to, the ambient environment.<sup>74</sup> If a chemical has more than one requirement that is ARAR, the most stringent generally should be complied with.<sup>75</sup> It is

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<sup>66</sup> 40 C.F.R. § 300.435(b)(2). *See also* Preamble to the Proposed NCP, 53 Fed. Reg. 51394, 51435 (Dec.21, 1988).

<sup>67</sup> 42 U.S.C. § 9621(d)(2)(A).

<sup>68</sup> *See* <http://www.epa.gov/superfund/policy/remedy/sfremedy/arars.htm>.

<sup>69</sup> *See also* 40 C.F.R. § 300.400(g)(4). "Only state standards that are promulgated, are identified by the state in a timely manner, and are more stringent than federal requirements may be applicable or relevant and appropriate."

<sup>70</sup> 55 Fed. Reg. 8666, 8742 (Mar. 8, 1990).

<sup>71</sup> 53 Fed. Reg. 51394, 51435 (Dec. 21, 1988).

<sup>72</sup> *See also* EPA, OSWER Pub. 9234.2-05/FS, *CERCLA Compliance with State Requirements*, Dec. 1989.

<sup>73</sup> *See* 40 C.F.R. § 300.430(f)(1)(ii)(C)(5).

<sup>74</sup> 52 Fed. Reg. 32496, 32497 (August 27, 1987) Notice of Guidance: Interim Guidance on Compliance with Applicable or Relevant and Appropriate Requirements.

<sup>75</sup> EPA, OSWER Dir. 9234.1-01, *Compliance with Other Laws Manual Part I*, (August 8, 1988), § 1.2.3.1 (*Chemical-Specific Requirements*)(p. 1-13).

important to recognize that ARARs that are used to determine final remediation levels apply only at the completion of the action.<sup>76</sup> Examples of common chemical-specific ARARs include maximum contaminant levels (“MCLs”) under the Safe Drinking Water Act (or “SDWA”) and ambient water quality criteria (“AWQC”) under the Clean Water Act (or “CWA”). Federal standards, criteria, or requirements that might be considered ARARs for cleanup of contaminated soil are very limited. Some States however, have promulgated soil cleanup levels that mostly apply in their brownfields program but occasionally apply to RCRA corrective action or other State remediation programs. Often the State regulations include cleanup levels for industrial and residential land uses. Depending on site circumstances, and after careful analysis of the regulations, EPA may consider the State cleanup levels as relevant and appropriate standards for addressing soil contamination at a Superfund site.

### ***Determining ARARs***

Identification of ARARs is done on a site-specific basis and depends on the specific chemical at a site, the particular actions proposed as a remedy, and the site characteristics.<sup>77</sup> It involves a two-part analysis. First, the lead and support agencies shall identify any requirements that are legally applicable to the release or remedial action contemplated based upon an objective determination of whether the requirement specifically addresses a hazardous substance, pollutant, contaminant, remedial action, location, or other circumstance found at a CERCLA site.<sup>78</sup> Second, if it is determined that a requirement(s) is not applicable, the requirement(s) may nevertheless be relevant and appropriate to the circumstances of the release.<sup>79</sup> In evaluating relevant and appropriateness, the agency should examine the factors in 40 C.F.R. § 300.400(g)(2)(i) through (viii) to determine whether the requirement is both relevant and appropriate and, thus, well-suited for the site.<sup>80</sup> In some cases, a requirement may be relevant but not appropriate, given the site-specific circumstances: such a requirement would not be ARAR for a site.<sup>81</sup> In addition, there is more discretion in the determination of relevant and appropriate: it is possible for only part of a requirement to be considered relevant and appropriate in a given case.<sup>82</sup> Only those requirements that are determined to be both relevant and appropriate must be complied with.<sup>83</sup>

### ***ARARs Frozen at ROD***

An on-site remedial action must attain those ARARs identified at the time of the ROD signature or provide grounds for invoking a waiver under CERCLA Section 121(d)(4).<sup>84</sup> Once a ROD is signed and a remedy chosen, EPA will not reopen that decision based on modified or newly promulgated ARARs unless the new or modified ARARs call into question the protectiveness of the remedy.<sup>85</sup> EPA believes it is necessary to “freeze ARARs” when the ROD is signed rather than upon initiation of the remedial action because continually changing remedies to

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<sup>76</sup> 55 Fed. Reg. 8666, 8755 (Mar. 8, 1990).

<sup>77</sup> 52 Fed. Reg. 32496, 32497 (August 27, 1987) Notice of Guidance: Interim Guidance on Compliance with Applicable or Relevant and Appropriate Requirements.

<sup>78</sup> 40 C.F.R. § 300.400(g)(1) (*Identification of applicable or relevant and appropriate requirements*).

<sup>79</sup> *Id.* § 300.400(g)(2)

<sup>80</sup> *Id.* See also EPA, OSWER Dir. 9234.1-01, *Compliance with Other Laws Manual Part I*, (August 8, 1988), § 1.2.4.3 (*General Procedures for Determining if a Requirement is Relevant and Appropriate*) (pp. 1-65 thru 1-71). The determination that a requirement is relevant and appropriate is site-specific and must rely on professional judgment.

<sup>81</sup> *Id.* at § 1.2.2 (*Definitions of Applicable and Relevant and Appropriate*) at p. 1-10.

<sup>82</sup> *Id.*

<sup>83</sup> *Id.* at § 1.2.4.3 at p. 1-67.

<sup>84</sup> 40 C.F.R. § 300.430(f)(1)(ii)(B) and (C). See also EPA, OSWER Pub. 9234.2-03/FS, *Overview of ARARs Focus on ARAR Waivers*, Dec. 1989.

<sup>85</sup> 55 Fed. Reg. 8666, 8757-8758 (Mar. 8, 1990).

accommodate new or modified requirements would disrupt CERCLA cleanups, whether the remedy is in design, construction, or in remedial action.<sup>86</sup>

It is possible that more ARARs may need to be identified during the remedial design as the specific details of the remedy are developed. However, identification of ARARs that significantly affect the remedy in terms of protectiveness, scope, cost, performance etc. would require an ESD or ROD Amendment depending on the extent of the post ROD changes to the remedy.<sup>87</sup> For example, if an ESD results in the addition of any new components to the remedy, then any ARARs that apply to the change the ESD describes must be discussed and met or waived.<sup>88</sup>

### **III. Summary of Five Year Review Process**

CERCLA Section 121(c) requires periodic reviews (at least every five years) at sites where the remedial action leaves hazardous substances, pollutants or contaminants on-site. The EPA interprets this requirement to mean a review is required at those sites where such substances remain on-site above levels that allow for unrestricted use and unlimited exposure for human and environmental receptors.<sup>89</sup> Unlimited use and unrestricted exposure (“UU/UE”) means the selected remedy will place no restrictions on the potential use of land or other resources.<sup>90</sup> In addition, a review will be conducted at sites where substances remain on-site if the standards initially used to define protective exposure levels are subsequently changed.<sup>91</sup> The purpose of a five-year review is to evaluate the implementation and performance of a remedy in order to determine if the remedy is or will be protective of human health and the environment.

When determining the protectiveness of the remedy the following questions should be examined: 1) Is the remedy functioning as intended by the decision documents?; 2) Are the exposure assumptions, toxicity data, cleanup levels, and RAOs used at the time of the remedy selection still valid?; and 3) Has any other information come to light that could call into question the protectiveness of the remedy.<sup>92</sup> In evaluating question #2, EPA considers for example, whether changes in ARARs in the ROD, newly promulgated standards, and/or changes in TBCs identified in the ROD, changes in land use or anticipated land use on or near the site, new human health or ecological exposure pathways of receptors have been identified, new contaminants or contaminant sources have been identified, changes in the physical site conditions, and changes in toxicity factors for COCs that could call into question the protectiveness of the remedy.<sup>93</sup> If the periodic review shows that a remedy is no longer protective of human health and the environment, additional action will be evaluated and taken to mitigate the threat.<sup>94</sup>

Generally, EPA only considers changes in standards that were identified as ARARs in the ROD, newly promulgated standards for chemicals of potential concern, and TBCs identified in the ROD

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<sup>86</sup> *Id.*

<sup>87</sup> See *ROD Guidance § 7.0 (Documenting Post-ROD Changes: Minor Changes, Explanations of Significant Differences, and ROD Amendments)*.

<sup>88</sup> *Id.*

<sup>89</sup> 40 C.F.R § 300.430(f)(1)(ii). See also 53 Fed. Reg. 51394, 51430 (Dec. 21, 1988).

<sup>90</sup> EPA, OSWER No. 9355.7-03B-P, *Comprehensive Five-Year Review Guidance*, June 2001. [hereinafter *Five-Year Review Guidance*]

<sup>91</sup> 53 Fed. Reg. 51394, 51430 (Dec. 21, 1988).

<sup>92</sup> See *Five-Year Review Guidance*, June 2001, § 4.0 (*Assessing the Protectiveness of the Remedy*)(p. 4-1).

<sup>93</sup> *Id.* at § 4.2 (*Question B: Are the exposure assumptions, toxicity data, cleanup levels, and RAOs used at the time of the remedy selection still valid?*)(p. 4-4 thru 4-8).

<sup>94</sup> 53 Fed. Reg. 51394, 51430 (Dec. 21, 1988).

that bear on protectiveness of the remedy.<sup>95</sup> Thus, EPA reviews any newly promulgated standards, including revised chemical-specific requirements (such as MCLs, AWQC), revised action-and location-specific requirements, and State standards if they were considered ARARs in the ROD.<sup>96</sup> For example, based on revised risk information for a specific chemical, a new standard (e.g., more stringent MCL for a chemical) may result in a situation where the cleanup level to be achieved by the original remedy would pose a  $10^{-3}$  cancer risk. In that circumstance, the five-year review could recommend that a new cleanup level based on the new standard be adopted and, if necessary that the remedy be modified.<sup>97</sup> However, a change in a standard may not necessarily result in a change in the resulting risk and therefore may not always impact protectiveness.<sup>98</sup>

***Author note***

*David M. Buxbaum is a Senior Attorney with the U.S. EPA Region 4 Office of Regional Counsel and he provides counseling on matters related to implementation of cleanups conducted under CERCLA. The information provided in the paper is based upon CERCLA, the NCP, and available EPA policy and guidance. Statements provided in the paper do not represent any official Agency position with respect to the matters covered.*

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<sup>95</sup> *Five-Year Review Guidance*, June 2001, § 4.2.1 (*How should I check the impact of changes in standards and TBCs?*)(pp. 4-6 and 4-7).

<sup>96</sup> *Id.*

<sup>97</sup> *Id.*

<sup>98</sup> *Id.*