7 Regulatory Perspective

The process of how to conduct optimization and identify technical risks to successful optimization have been presented in Sections 2 through 6. In addition to the technical challenges encountered during the design and implementation of optimization of P&T systems, environmental statutes, their implementing regulations, and the changing regulatory environment may also pose obstacles to optimization. Conversely, statutes and regulations may provide opportunities to begin the optimization process. The goals of this section are to identify statutory and regulatory challenges and opportunities and to suggest ways to address them and to improve the chance of successful optimization (ITRC 2020[SKNUVGR8] ITRC. 2020. "Optimizing Injection Strategies and In Situ Remediation Performance." Washington, D.C.: Interstate Technology & Regulatory Council, OIS-ISRP Team. https://ois-isrp-1.itrcweb.org/.). Section 7.1 presents the regulatory frameworks that optimization must work within, Section 7.2 explains why optimization is not a do nothing alternative, Section 7.3 examines how changes to regulatory standards can be addressed in optimization, Section 7.4 looks at optimization and remedy change and alternatives, Section 7.5 examines how controlling documents need to be reviewed and considered during optimization, Section 7.6 looks at optimization and the regulatory aspects of the closeout process, and Section 7.7 presents regulatory-related resources.

Optimization Life Cycle Navigation Diagram
Source: E. Madden, ITRC. Used with Permission.

7.1 Understanding Federal and State Regulatory Frameworks and Optimization

Optimization of P&T systems should be part of engineering and operations best practices. Optimization itself is not a regulatory matter, it is based on the scientifically defined conditions of sites, as represented by a current CSM, and the execution of a well-designed site implementation or project management plan. The P&T system changes resulting from optimization reviews may trigger regulatory actions, such as permit modifications, but not all optimization recommendations rise to the level of a regulatory matter (e.g., changing the choice of power for a site from fossil fuel–based to renewable energy). Regulatory frameworks may create opportunities for optimization to occur; this section will identify such opportunities, discuss potential regulatory barriers to optimization, and provide example(s) of optimization within a regulatory framework.

7.1.1 Regulatory Frameworks

State and federal agencies have several regulatory frameworks for regulating hazardous site remediation programs. Some programs regulate underground storage tank (UST) releases, some regulate abandoned industrial facilities or brownfields, and yet others regulate landfills. Any of these regulatory framework sites may have P&T systems associated with the remediation.

7.1.1.1 State Programs

While there are no known barriers to optimization, some states have guidance or regulations that address aspects of optimization. Even states that make no specific references to optimization may have regulations that create obligations that may be addressed by optimization such as requiring periodic performance certifications or review. States have an interest in the results of optimization as demonstrated by the Survey of State Interest conducted for this document. Three questions on the survey have direct state regulatory tie-ins. For more details about the Survey of State Interest see Appendix E . Four questions in the survey asked states about assuming responsibility for P&T systems during the O&M phase.

Question 10 was this open-ended question: "How does your state approach the prospect of taking over P&T responsibility at Superfund sites after long-term response action is completed?" The responses lacked a common theme, but several expressed varying degrees of concern. An example response was, "We hope that the call for optimization during the LTRA period will help [the] state prepare for the transition and be assured that the site is in as good an operating condition as possible upon transition." The LTRA is the period of operations and monitoring after construction when the system is determined to be operational and functional. LTRA is important to the state as this phase is still paid for by the USEPA; more on the LTRA period can be found in Section 7.6.

Question 11 was, "What criteria [are] used by your agency to determine if your project is approaching an exit window to complete the remedy or transition to a new remedial approach?" The full results can be found in the appendix, but the top four results can be found here:

ANSWER CHOICES	RESPONSES
Meeting Regulatory Endpoints	80%
Concentration Trends (asymptotic recovery, etc.)	79%
Risk to Receptors (i.e., lack of receptors or additional receptors)	55%
Technical Impracticability	39%

Question 12 was, "Does your state have regulations for any of the following concepts that apply to Pump and Treat Systems?" The full results can be found in the appendix, but the top four answers are as follows:

ANSWER CHOICES	RESPONSES
Risk to Receptors	86%
Remedial Endpoints	77%
Alternate Remedies	36%
Technical Impracticability	36%

Question 13 was, "Does your state have guidance materials for any of the following concepts that apply to Pump and Treat Systems?" Here are the top four responses:

ANSWER CHOICES	RESPONSES
Risk to Receptors	71%
Remedial Endpoints	63%
Technical Impracticability	38%
Alternative Remedies	29%

In summary, nine states reported regulations (Question 12) or guidance (Question 13) pertaining to "Periodic system evaluations" and "Periodic process optimization." Arkansas, Georgia, Michigan, Mississippi, Rhode Island, Texas, and Wisconsin reported having guidance. Delaware and Pennsylvania reported having both guidance and regulations. ITRC's State Engagement Team Points of Contacts may be able to help you find state-specific information regarding these responses.

Other states may have regulations that create opportunities for optimization or create obligations that may be resolved by the optimization process. New Jersey has an example of regulatory language that creates opportunities for optimization. An example of a regulatory framework that presents optimization opportunities is presented below.

The New Jersey Department of Environmental Protection's (NJDEP) "Technical Requirements for Site Remediation, N.J.A.C. 7:26 E, aka the "Tech Rule" (NJDEP 2018[Z3Y7HTV4] NJDEP. 2018. "Technical Requirements for Site Remediation." New Jersey Department of Environmental Protection 7 (26). https://www.nj.gov/dep/rules/rules/njac7_26e.pdf.), recognizes that "continuous effectiveness monitoring" and "periodic site condition reviews" may occur. The definition of "remedial action costs" is provided below:

"Remedial action costs" means all costs associated with the development and implementation of a remedial action including all direct and indirect capital costs, engineering costs, and annual operation, maintenance and monitoring costs. Such costs, when applicable, shall include, without limitation, costs for construction of all facilities and process equipment, labor, materials, construction equipment and services, natural resource damages, land purchase, land preparation/development, relocation expenses, systems start up and testing, facility operation, maintenance and repair, **continuous effectiveness monitoring, periodic site condition reviews…**

In addition to NJDEP's Tech Rules and their equivalents in other states, ICs such as classification exception areas (CEAs) for groundwater contamination and deed notices or declarations of environmental restriction (DERs) for soil contamination require periodic reviews. CEAs and DERs also have periodic review requirements, biennial certifications (Remedial Action Protectiveness / Biennial Certification Form) in New Jersey, and review requirements for modifications and termination (Remedial Action Permit Modification and Termination Applications). The forms and associated guidance ask for the reasons for the modification or termination of remedial activities, and optimization reviews can support these decisions. Likewise, optimization reviews can propose remediation paths that would require these forms to document the change in or termination of remedial activities at a site. These reviews of site conditions prior to submitting these forms are good opportunities to conduct optimization activities—particularly evaluations and/or proposals for work to improve the remediation effectiveness or time frames. The reviews are instituted to ensure that the site cleanups remain protective of human health and the environment. As conditions change, optimization is one method to ensure protectiveness in the long-term (ITRC 2004[JKA62F2T] ITRC. 2004. "Remediation Process Optimization: Identifying Opportunities for Enhanced and More Efficient Site Remediation." Washington, D.C.: Interstate Technology & Regulatory Council, Remediation Process Optimization Team. https://itrcweb.org/teams/projects/remediation-process-optimization.).

Some states have established licensing programs for remediation professionals and have granted certain responsibilities for the remediation process to these professionals; most establish guidance or regulations to guide or limit what these professionals can do on sites. Massachusetts has a five-year requirement for documenting compliance with the Massachusetts Contingency Plan (MCP) (MassDEP 2008[XGW8RNHH] MassDEP. 2008. "Site Cleanup - Fact Sheets." https://www.mass.gov/lists/site-cleanup-fact-sheets.); depending on the nature of the cleanup, the party conducting the remediation has up to five years to submit documents showing a site meets MCP requirements. Ongoing remediation projects in *Remedy Operation Status (ROS)* are assessed an annual fee with reporting requirements. Optimization efforts can be used to ensure that the ROS is effective and targeted at meeting the requirements of the MCP.

7.1.1.2 Federal Programs

The USEPA has officially encouraged optimization at Superfund sites, and the USEPA website for Cleanup Optimization at Superfund Sites explains the strategy:

In September 2012, the Superfund program released a *National Strategy to Expand Superfund Optimization Practices from Site Assessment to Site Completion*. The goals of the Strategy are to expand and formalize optimization practices as an operating business model for the Superfund remedial program. The Strategy envisions the application of optimization concepts throughout all phases of the remedial pipeline as a normal part of remedial program activities (USEPA 2022[ZHVKLCQP] USEPA. 2022. "Cleanup Optimization at Superfund Sites." U.S. Environmental Protection Agency. https://www.epa.gov/superfund/cleanup-optimization-superfund-sites.).

The USEPA issued a follow-up progress report in 2020 (USEPA 2020[RLVPF7D5] USEPA. 2020. "Superfund Optimization Progress Report." U.S. Environmental Protection Agency, Office of Land and Emergency Management. https://semspub.epa.gov/work/HQ/100002585.pdf.) on optimization of P&T systems. The report focuses on technical reasons for optimization. The report and the process that it supports can be used to educate regulators about the advantages of optimization. The report can be found here: https://www.epa.gov/superfund/cleanup-optimization-superfund-sites

The USEPA issued the Guidance on Management of Superfund Remedies in Post Construction (USEPA 2017[LW4KL27N] USEPA. 2017. "Guidance for Management of Superfund Remedies in Post Construction." Office of Superfund Remediation and Technology Innovation (OSRTI), U.S. Environmental Protection Agency, OLEM 9200.3-105, February 2017. https://semspub.epa.gov/work/HQ/196829.pdf.), https://www.epa.gov/superfund/superfund-post-construction-completion, which specifically highlights optimization efforts during the long-term remediation period and states:

In general, optimization reviews to verify remedy effectiveness and identify opportunities for cost savings normally should be conducted early enough in the LTRA period (generally by year six or seven) to allow sufficient time for 1) implementation of the recommendations that are deemed appropriate and necessary; and 2) operation and monitoring of an optimized system prior to transfer (USEPA 2017[LW4KL27N] USEPA. 2017. "Guidance for Management of Superfund Remedies in Post Construction." Office of Superfund Remediation and Technology Innovation (OSRTI), U.S. Environmental Protection Agency, OLEM 9200.3-105, February 2017. https://semspub.epa.gov/work/HQ/196829.pdf.).

Superfund is not the only program that can benefit from P&T optimization. Although standardized Superfund terminology is used in this document, many users may work in other programs. Table 7-1 from the USEPA provides a useful guide for comparing terminology among programs (USEPA 2011[B5FVZMT4] USEPA. 2011. "Environmental Cleanup Best Management

Practices: Effective Use of the Project Life Cycle Conceptual Site Model." Office of Solid Waste and Emergency Response. EPA 542-F-11-011. https://www.epa.gov/sites/default/files/2015-04/documents/csm-life-cycle-fact-sheet-final.pdf.). Whatever the name for the work effort, the message is clear: Optimization can benefit a remediation project at any phase of the work.

Table 7-1. Crosswalk of regulatory program stages and CSM life cycle phases

General Environmental Cleanup Steps	CSM Life Cycle	Best Management Practices: SPP	Best Management Practices: DWS/ RTMT	CERCLA - Superfund	RCRA	Brownfields	UST	VCUP Varies by State	IRP/ERP	MMRP
Site Assessment	Conceptual Preliminary CSM Baseline CSM			Preliminary Assessment (PA) Site Inspection (SI) National Priorities List (NPL) No Further Remedial Action Planned (NFRAP)	Facility Assessment (RFA)	Phase I Environmental Site Assessment (ESA)	Initial Site Characterization Initial Response	PA SI	PA SI	PA SI MR Site Prioritization Protocol (MRSPP)
Site Investigation and Alternatives Evaluation	Characterization CSM Stage			Remedial Investigation/ Feasibility Study (RI/FS) Removal Actions - Emergency/ Time Critical/Non-Time-Critical	Facility Investigation (RFI) Corrective Measures Study (CMS)	Phase II ESA	SI Corrective Action Plan (CAP)	RI/FS	RI/FS NFRAP	RI/FS
Remedy Selection	Design CSM Stage			Proposed Plan Record of Decision (ROD)	Statement of Basis (SB) Final Decision and Response to Comments	Remedial Action Plan (RAP)	Cleanup Selection	ROD	Proposed Plan ROD	Remedy Selection
Remedy Implementation	Remediation/ Mitigation CSM Stage			Remedial Design (RD) Remedial Action (RA) – Interim and Final	Corrective Measure Implementation (CMI)	Cleanup and Development	Corrective Action - Low-impact site cleanup - Risk-based remediation - Generic remedies - Soil matrix cleanup	RD RA	RD RA – Interim and Final Remedy in Place (RIP)	RD Time Critical Removal Action (TCRA) RA RIP
Post-Construction Activities	Post-Remedy CSM Stage			Operational & Functional Period Operation & Maintenance (O&M) Long term monitoring (LTM) Optimization Long Term Response Action (Fund-lead groundwater/surface water restoration)	O&M On-site inspections and oversight	Property Management Long-term O&M Redevelopment Activities (Private- and Public-led)	LTM	O&M LTM	Shakedown period Operating Properly and Successfully O&M LTM	Shakedown period Long Term Management
Site Completion	Quantitative			Construction Complete (CC) Preliminary or Final Close Out Report (PCOR/FCOR) Site Completion - FCOR Site Deletion O&M as appropriate	Certification of Completion Corrective Action Complete with Controls or without Controls	CC Property Management	No Further Action (NFA)	CC	Response Complete (RC) NFA	RC NFA

Abbreviations:
SPP = Systematic Project Planning
DWS = Dynamic Work Strategies
RTMT = Real Time Measurement Technologies
CERCLA = Comprehensive Environmental Response, Compensation and Liability Act
RCRA = Resource Conservation and Recovery Act
UST = Underground Storage Tanks
VCUP = Voluntarily Clean Up Programs
IRP/ERP = Installation Restoration Program/ Environmental Restoration Program
MMRP = Military Munitions Response Program

Source: Adapted from USEPA's "Environmental Cleanup Best Management Practices: Effective Use of the Project Life Cycle Conceptual Site Model," EPA 542-F-11-011, July 2011 (USEPA 2011[B5FVZMT4] USEPA. 2011. "Environmental Cleanup Best Management Practices: Effective Use of the Project Life Cycle Conceptual Site Model." Office of Solid Waste and Emergency Response. EPA 542-F-11-011. https://www.epa.gov/sites/default/files/2015-04/documents/csm-life-cycle-fact-sheet-final.pdf.).

7.1.1.2.1 The National Contingency Plan and Climate Resiliency

Optimization should take into consideration the NCP criteria (USEPA 2019[MPMSNKHM] USEPA. 2019. "Climate Resilience Technical Fact Sheet: Groundwater Remediation Systems." U.S. Environmental Protection Agency, Office of Superfund Remediation and Technology Innovation. https://www.epa.gov/sites/default/files/2019-12/documents/cr_groundwater_systems_fact_sheet_2019_update.pdf.). Climate resilience is an example of what the optimization reviewer can consider. The NCP provides nine criteria to evaluate remedial action alternatives prior to issuing a proposed plan for a given site (see 40 CFR §300.430(e)(9)(iii)). According to a USEPA Office of Land and Energy Management (OLEM) memorandum on "Consideration of Climate Resilience in the Superfund Cleanup Process for Non-Federal National Priorities List Sites," which refers to National Priority List (NPL) sites where USEPA generally carries out or oversees the cleanup conducted by one or more PRPs, "consideration of climate resilience should not be treated as a new criterion; however, some or all of the following five criteria may be relevant to evaluating a remedial action alternative's climate resilience" (USEPA, OLEM Directive 9355.1-120, 2021).

- (A) Threshold criteria: overall protection of human health and the environment
- (B) Primary balancing criteria:
    - long-term effectiveness and permanence
    - reduction of toxicity, mobility, or volume through treatment
    - short-term effectiveness
    - implementability

In instances where remedial actions have been selected but not yet implemented, the remedial design phase may provide an opportunity to consider potential site and remediation system vulnerabilities and identify adaptation measures to help maximize climate resilience.

For remedial actions under construction or those already in place, five-year reviews may provide opportunities to evaluate, or optimize, remedy protectiveness in the context of new information, such as changes in intensity, frequency, or duration of extreme weather events. As discussed in the 2001 Comprehensive Five-year Review Guidance and the 2016 Five-year Review Recommended Template, site changes or vulnerabilities that may not have been apparent during remedy selection, implementation, or O&M should be considered when assessing the protectiveness of a remedy. Site changes and vulnerabilities also may concern climate-related changes that are gradual, such as rising sea level, changing seasonal precipitation or temperatures, increasing risk of floods, increasing intensity and frequency of hurricanes and wildfires, and melting of permafrost in northern regions. If the original remedial action selected in a record of decision (ROD) requires climate resilience-related changes, they should be documented appropriately. This may require an ESD or ROD amendment consistent with the provisions in CERCLA (e.g., § 117) and the NCP (e.g., 40 CFR §300.435). Section 7.7 provides additional information on ROD amendments.

7.1.1.2.2 Climate Adaptation and Optimization

Consistent with CERCLA, the NCP and associated USEPA Superfund guidance encourages USEPA regions to consider the following recommendations during remedy selection and remedy implementation for nonfederal-lead NPL sites (USEPA 2019[MPMSNKHM] USEPA. 2019. “Climate Resilience Technical Fact Sheet: Groundwater Remediation Systems.” U.S. Environmental Protection Agency, Office of Superfund Remediation and Technology Innovation. https://www.epa.gov/sites/default/files/2019-12/documents/cr_groundwater_systems_fact_sheet_2019_update.pdf.). The recommended approach may involve program or site activities intended to assure or build, where needed, resilience of the long-term integrity of remedial actions in the face of potential extreme weather events. Specific adaptation measures may be identified through an optimization evaluation.

Regions generally should assess the vulnerability of a remedial action’s components, including its associated site infrastructure, and evaluate whether the long-term integrity of a selected remedy may be impaired by adverse effects of climate change. A site-specific analysis of the remedial action in light of current, forward-looking information on local or regional climate and weather regimes may be useful. For example, the assessment may include predictive information on future climate conditions, such as the intensities and frequencies of extreme weather events over a time frame corresponding to a remedy’s anticipated duration, including long-term monitoring.

Based on any potential vulnerabilities identified, regions should evaluate adaptation measures that increase the system’s resilience to a changing climate and ensure continued protectiveness of human health and the environment. Examples of climate resilience measures may include adapting a system’s operating parameters, such as installing equipment that enables off-site workers to remotely adjust or suspend operations during extreme weather events. Other measures may involve installing engineered structures that address vulnerabilities, such as elevation of on-site power supplies and enhanced erosion controls. Engineered structures also may help prevent transport of contaminated material across a site or to off-site areas during heavy or prolonged precipitation, thereby avoiding site recontamination due to stormwater runoff from off-site sources.

Regions should consider implementing adaptation measures, as needed, to ensure the long-term integrity of CERCLA remedial actions and their protectiveness of human health and the environment. Multiple adaptation measures may be appropriate based on the site evaluation; in such cases, the site team typically should prioritize the resilience measures to maximize return on limited resources, based on best professional judgment regarding factors such as cost and impact on site operations.

Climate resilience planning for a remedy generally involves three phases: (1) assessing the vulnerability of the remedy’s elements and site’s infrastructure, (2) evaluating measures that could potentially increase the remedy’s resilience to a changing climate, and (3) assuring the remedy’s capacity to adapt to a changing climate, which helps the remedy continue to be protective of human health and the environment (Figure 7-1:).

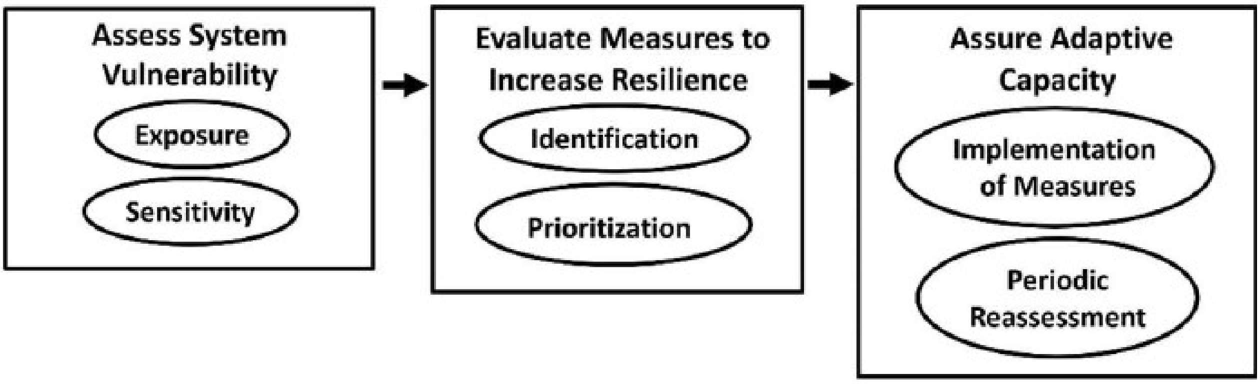

Figure 7-1. Climate resilience planning.
Source: Adapted from USEPA, October 2019, Climate Resilience Technical Fact Sheet: Groundwater Remediation Systems EPA 542-F-19-005 (USEPA 2019[MPMSNKHM] USEPA. 2019. "Climate Resilience Technical Fact Sheet: Groundwater Remediation Systems." U.S. Environmental Protection Agency, Office of Superfund Remediation and Technology Innovation. https://www.epa.gov/sites/default/files/2019-12/documents/cr_groundwater_systems_fact_sheet_2019_update.pdf.).

7.1.2 Regulatory Barriers

There are no known specific regulatory barriers to conducting optimization. As identified in ITRC RPO-1, "Remediation Process Optimization: Identifying Opportunities for Enhanced and More Efficient Site Remediation," regulatory matters may impact optimization in direct and indirect ways:

…Different regulatory programs may cover a single facility or site, and often state, local, and federal agencies are each involved. Disagreement among and within agencies may inhibit the ratification or implementation of a proposed RPO plan, particularly when the parties consider overturning agreed-upon decisions. Regulations may change over time, such as new contaminants being added to the regulated list or MCLs being revised upward or downward. In addition, while regulatory standards are commonly used to establish cleanup goals, more recently, risk-based goals have gained greater acceptance from the regulatory community. Room for flexibility by regulatory stakeholders while keeping within the governing environmental regulations will facilitate the optimization process. (ITRC 2004[JKA62F2T] ITRC. 2004. "Remediation Process Optimization: Identifying Opportunities for Enhanced and More Efficient Site Remediation." Washington, D.C.: Interstate Technology & Regulatory Council, Remediation Process Optimization Team. https://itrcweb.org/teams/projects/remediation-process-optimization., 37)

The site-specific regulatory environment may limit what can be done regarding optimization. For example, if the updated CSM identifies the need to increase the amount of water to be pumped to capture the existing plume, or the plume of a newly identified emerging contaminant, water use regulation may come into play. There may be strict regulatory groundwater extraction caps, new or existing, that may limit the volume of water that can be pumped or where it can be discharged. If the limits cannot be addressed by the permit modification process, alternate remediation technologies (e.g., installing reactive barrier walls), modified pumping strategies (e.g., pulse pumping), or increased treatment to achieve alternate water use standards may be needed.

Optimization reviews are a good time to evaluate power sources and consumption. A recommendation may be made to install solar panels to supply power to the site and perhaps send some power into the grid to provide a cost offset for the budget. A regulatory hurdle that might be encountered in this scenario might be grid capacity. Grid capacity may limit the number of panels in the proposed array. "Capacity amounts can also vary with regard to utility type, customer type, technology and system type" (NCSL 2017[73FMXMA5] NCSL. 2017. "State Net Metering Policy." National Conference of State Legislatures. https://www.ncsl.org/research/energy/net-metering-policy-overview-and-state-legislative-updates.aspx.). These considerations may limit the number of panels that can be installed and, in turn, impact the financial viability of this option; without the cost offset can the optimization budget pay for the panels? Potential regulatory barriers are listed below:

- new regulations
    - newly regulated contaminants, aka CECs
    - new MCLs, discharge levels, points of compliance, etc.

- reporting requirements
    - frequency
    - who can make the report (e.g., licensed site professional programs)
    - how reports are made (e.g., change to electronic deliverables)

- regulatory requirements
    - the site might have multiple regulatory authorities
    - lack of regulatory authority to conduct an action
    - limitations to regulatory actions based on regulation language

- project management challenges
    - consultants and engineers, maintaining institutional knowledge
    - change in regulator review process over time
    - loss of institutional memory as regulators retire or change jobs

- transition of agency leads
    - CERCLA Fund Lead sites transfer to State Lead
    - delegation or loss of delegation of regulatory authority (e.g., CERCLA, RCRA, UST)
    - change in regulatory lead (e.g., federal to state lead or within agencies)

- time
    - permit modifications may require review and approval
    - public hearings may be required or recommended
    - stakeholder objections may arise at any time

7.1.3 Strategies to Address Potential or Actual Regulatory Barriers

The potential or actual barriers identified in Section 7.1.2 can act to stop or delay implementation of optimization recommendations. There are opportunities to help establish a successful optimization program by anticipating barriers and developing strategies to overcome objections to optimization. The list below provides strategies to help deal with potential objections to optimization:

> ***Technical Consult***
> Some states or agencies offer technical consultations. These are informal information sessions to present information prior to a formal submission. These "tech consults" (click here for a NJDEP example) can be a good way to educate the regulators about optimization, solicit feedback, or get advice. (See also: EPA Technical Experts.)

Be ready to make changes to your plans based on input from these strategies. Stakeholders, regulators, and site operations staff all have valuable information to provide to optimization practitioners. Communication is most effective when it is two-way: you provide the information the stakeholder needs to understand your proposal, and you receive feedback from a properly briefed stakeholder. Key to this process is making sure the stakeholder understands you have received and evaluated their feedback. Addressing each comment and suggestion is important to build goodwill and close potentially endless loop-backs on specific topics. Each loop-back is a delay, and each delay prevents the implementation of needed optimization. Giving credit to stakeholders who provide input into the process that makes a change or adds value is another way of building goodwill.

Communication is important in shifting regulatory environments. From the turnover of regulatory personnel due to retirements or other staffing turnover to formal process changes, regulators need the facts to make informed reviews and decisions. It is quickly becoming a thing of the past that a regulator has a long, sometimes decades-long, relationship with a project. More commonly, a regulator is called upon when needed for review or approval of a specific action and may never, or only occasionally, see work related to one project again. Some federal government agencies and some states have a method for organizing site records to aid these reviews (NJDEP 2020[GGC6X8PJ] NJDEP. 2020. "A New Site Remediation DataMiner Report: Case Inventory Document and Associated Areas of Concerns." October 2020. https://www.nj.gov/dep/srp/srra/listserv_archives/2020/20201008_srra.html.); others do not. Even at the agencies that do have organized records, the practices may vary by region, office or individual. Presenting a synopsis of the history of the site and what is being proposed with every submittal is recommended. This will help the regulator understand how the proposed or actual optimization action is an improvement to the site remediation process.

7.2 Communicating Optimization to Regulators

Regulators might have a perception that optimization is a method to simply save money or do less. Optimization assessments and implementation are performed to improve the efficiency and effectiveness of the remediation underway at a particular site; they are not a way to undermine the remedial objectives or protectiveness built into the regulatory and technical processes established for a site. Efficiency can include identifying greener or more resilient energy sources that will limit the impact of the remediation (green) or allow the system to continue to operate under the pressure of outside factors, such as climate change impacts (resiliency). Effectiveness is the ability to achieve the remediation goals of the site, including protecting human health and the environment, in a better way (e.g., new technology may be able to achieve the remedial goals in a reduced amount of time). All optimization activities should be conducted within a regulatory oversight framework. As a result, regulators have the opportunity to review or audit the work. Clearly communicating this message and providing sufficient supporting information to the regulatory reviewers is important to the success of the optimization effort. Failure to communicate the benefits of optimization to the regulators may result in delays until the reasoning is made clear or, a worse outcome, denial of an application to improve the remediation.

7.3 Changes to Regulatory Standards

Examples of Changes to Regulatory Standards:
• emerging COC
o chemical identification
o concentration limit(s)
o effective date of regulation
• changes in groundwater cleanup criteria
o lowering of MCLs
o ARARs
o groundwater classification
• discharge limitations
o flow
o contaminant concentration
o discharge monitoring
• groundwater or other environmental monitoring
o frequency
o sampling methodology
o analytical methodology
• reporting
o frequency
o method
o authority (who must report)

Changes in regulatory standards that impact P&T operations periodically occur. Examples of these changes range from the addition of newly regulated chemicals and changes in discharge limitations to new or revised reporting requirements and more. Owners and operators need to address these changes to remain in compliance with permits and permit equivalencies. Most changes involve deadlines to achieve compliance with technical and/or regulatory time frames established in the enabling statutes or regulations. These changes can be triggers, or be opportunities, for optimization of P&T systems.

Take the case of CECs, which can include newly regulated chemicals that may be found in the groundwater already being treated by a remediation system. Review of the system analytical data or, potentially, new sampling and analysis, will determine whether the COC is being treated to the new or proposed standards by the existing system. If it is not, then using the optimization tools and resources found in this document or referenced elsewhere can assist in determining the best course of action.

Continuing with the newly regulated chemical example, the optimization study may determine that a new treatment train or unit operation should be installed to address the chemical. Considerations for determining the proper treatment may include the following:

- Has the overall water quality changed during the years of treatment? As an example, saline intrusion may be occurring due to climate change conditions.
- Have groundwater conditions changed that impact flow rates and needs? Does the system need to be pumped at the same rate as it has been to achieve the needed capture zone? Can it do the job with a lower rate if the contaminant plume has been reduced over time? Will flow rates impact the treatability of the waste stream? Plants are designed to operate at specific rates, and changing those rates may impact treatment of the contamination.
- What are the characteristics of the chemicals, and will they impact the need for continuous operation? Will uptime calculations need to be considered? Will components have to be upsized or downsized for proper retention? Will resins work or can activated carbon do the job?

An example of a monitoring change could include a new requirement for continuous discharge monitoring. Adding the instrumentation, flow sensors, and telemetry to achieve continuous monitoring might be an optimization opportunity. The addition of continuous sampling or analysis of other parameters may reduce the need for personnel to conduct sampling. The addition of instrumentation or telemetry to other parts of the system at the same time may allow for lowered technician or operator on-site and travel time by allowing diagnosis of certain issues remotely rather than by traveling to the site. Conversely, if the monitoring is a new requirement, then there will be additional costs for technician or operator time; if so, automation of the monitoring system may lessen that impact.

Reporting requirement changes do occur. A common change is in the frequency that reporting is needed. These changes can be initiated by the regulator or the regulated entity. An example of a change initiated by the regulated entity can be a request to reduce sampling frequency and reporting. If a site has a long history of consistent, favorable (declining concentration trend), sampling results, the regulated entity or their representative may request a reduction in the sampling frequency. New Jersey, for example, has recommended sampling frequencies as part of the Ground Water Remedial Action Permit Guidance (Table 7-2). This is just an example; other states may require or recommend different frequencies. New York, for example, allows the use of a 15-month sampling cycle to minimize seasonal effects (NYDEC 2022[QEW2ZSSF] NYDEC. 2022. “Technical Guidance for Site Investigation and Remediation.” New York State Department of Environmental Conservation. https://www.dec.ny.gov/regulations/67386.html.).

Table 7-2. Recommended monitoring well sampling frequency

Situation	Performance Well Sampling Frequency	Sentinel Well Sampling Frequency
Permit Issued	Annual years 1-4 *	½ travel time to nearest receptor or annually, whichever is more frequent
After 4 Years	Biennial years 5-8 *	½ travel time to nearest receptor or biennially, whichever is more frequent
After 8 Years	**BTEX:** Every 8 years for the remainder of the permit. **Contaminants other than BTEX greater than 10 times GWQS:** every 4 years **Contaminants other than BTEX less than 10 times GWQS:** every 8 years for remainder of the permit	½ travel time to nearest receptor or the same frequency as the performance wells, whichever is more frequent

Source: Adapted from the NJDEP Ground Water Remedial Action Permit Guidance, Version 1.0, Issued 10/19/2017, Posted 10/20/2017.

Notes: BTEX = benzene, toluene, ethylbenzene, and xylene; GWQS = groundwater quality standard

* Progression through this sampling schedule is appropriate only if contaminant degradation is occurring as predicted during

each monitoring event and the remedy remains protective of receptors. If contaminant degradation is not occurring as predicted, the applicability of the MNA remedy must be reevaluated in accordance with the MNA guidance.

Point to Consider:
Optimization reviewers should be alert for special situations such as differing regulatory standards—different agencies may have different standards for contamination. In a New Jersey example, the State of New Jersey and the USEPA had different standards for the COCs at two nearly adjacent former dry-cleaning facilities that were both Superfund Sites. The contaminant plumes were comingled. Both sites shared recovery wells and the same treatment plant. These were USEPA Fund Lead sites. USEPA achieved federal standards for one site during the remedial action phase. In this case, the New Jersey standards required lower concentrations than the USEPA standards. New Jersey then entered into an agreement to pay a portion of the P&T system operating costs to continue treating the groundwater contaminants at the first site to New Jersey standards. The second site went beyond the LTRA period, and New Jersey is now performing long-term O&M and monitoring for both sites.

Other examples of regulatory changes involve the relationship between laboratory analysis and the ability of site operators of monitoring teams to adapt to changing regulations:

- A change in a regulatory standard may change the implementation strategy at a P&T system if existing effluent data show what would be an exceedance of the new standard or if the existing method detection limit (MDL) for the laboratory analysis is above the proposed standard.
- If the proposed regulatory standard is below the MDL, then the contract laboratory should be made aware of the proposed change, and new sampling and analysis protocols may be required. The regulatory agency proposing the standard can be contacted to advise on which laboratory methods can be used to reach the proposed standard.
- If a review of the existing effluent data shows what would be an exceedance of the new standard, process modifications will need to be made to reach regulatory compliance prior to the new standard taking effect.

7.4 Optimization and Remedy Change—How to Transition Away from Pump and Treat

There are times when optimization analysis determines that P&T may no longer be the preferred remedial action alternative. This section looks at what happens from a regulatory standpoint when the decision is made to shift away from P&T to another technology, long-term monitoring, or site closeout.

7.4.1 Technical Impracticability

Optimization studies usually do not necessarily result in a TI determination (USEPA frequently refers to “TI waivers”) (USEPA 2022[78KSY939] USEPA. 2022. “Technical Impracticability Waivers.” U.S. Environmental Protection Agency. https://www.epa.gov/superfund/selecting-groundwater-remedy#technical.), but TI determinations can be supported by optimization efforts (NJDEP 2013[69XQA5B2] NJDEP. 2013. “Technical Impracticability Guidance for Ground Water.” New Jersey Department of Environmental Protection, Site Remediation Program. https://nj.gov/dep/srp/guidance/srra/ti_guidance_gw.pdf.). Before a TI determination on an existing P&T system is considered by regulators, they will want to know whether optimization efforts have been conducted. They will want to know what these efforts were, when they were conducted, and what was done to implement the optimization. They will want to know the results of the optimization and whether the optimization recommendations were successful. Were they partially successful? How long were they attempted? If optimization recommendations were rejected or not implemented, the regulators will want to know why. Additionally, proposed TI waivers for Superfund sites must be provided for public comment as part of a CERCLA proposed plan for remedial action before they can be approved by USEPA.

The NCP recognizes that technical or engineering cleanup limitations may exist. The USEPA issued guidance on how to evaluate TI which can be found here: https://www.epa.gov/superfund/selecting-groundwater-remedy#technical. A series of USEPA directives and guidance are found at the TI website. USEPA states that “in situations where, from an engineering perspective, it is not possible to restore all or part of a groundwater plume, USEPA may waive applicable or relevant and appropriate requirements (ARARs) and establish alternative, protective remedial strategies.”

TI determinations or waivers are limited and only apply to the portion of the site impacted by the TI; it is not a blanket exemption for all issues or areas of concern at the site. The 2016 USEPA guidance titled Clarification of the Consultation Process for Evaluating the Technical Impracticability of Groundwater Restoration at CERCLA Sites includes a checklist of what components are expected in a TI evaluation; it is modified from the Groundwater Road Map (USEPA 2011[IYZAA8Z6] USEPA. 2011. "Groundwater Road Map." U.S. Environmental Protection Agency, Office of Solid Waste and Emergency Response. http://semspub.epa.gov/src/document/HQ/174480.), and associated guidance (USEPA 2016[YFTLSB2L] USEPA. 2016. "Clarification of the Consultation Process for Evaluating the Technical Impracticability of Groundwater Restoration at CERCLA Sites." U.S. Environmental Protection Agency, Office of Land and Emergency Management. https://semspub.epa.gov/work/HQ/198193.pdf.). The USEPA 2011 Groundwater Road Map identifies that a TI proposal should include the following:

- specific ARARs (e.g., media cleanup levels) for which TI waiver determinations are sought
- spatial area over which the TI waiver decision will apply
- current CSM
- results of the evaluation of restoration potential of the site
- estimates of the costs of the existing remedy and proposed alternative remedial strategy
- any additional information USEPA deems necessary (USEPA 2011[IYZAA8Z6] USEPA. 2011. "Groundwater Road Map." U.S. Environmental Protection Agency, Office of Solid Waste and Emergency Response. http://semspub.epa.gov/src/document/HQ/174480.)

7.4.2 Alternative Remedies

Optimization evaluations may very well determine that P&T systems are no longer the preferred remedial alternative. New technologies may be developed that are better suited to address groundwater contamination. Land-use pressures may force a change in the time frame for the remediation. Development, residential or commercial, may be encroaching on the site, or the site itself may have become desirable for redevelopment. These are just some of the changing conditions that might force a recommendation for a change in remedial technology.

Again, alternative remedies are not without their costs. Alternative remedies recommended by an optimization study may require a feasibility study, engineering evaluation, schedule analysis, and a cost assessment (NAVFAC 2012[WSLI4CNQ] NAVFAC, U.S. 2012. "US Navy NAVFAC Optimization UG-NAVFAC EXWC-EV-1301." U.S. Department of Defense. https://www.navfac.navy.mil/navfac_worldwide/specialty_centers/exwc/products_and_services/ev/go_erb/program-support/optimization.html.).

For additional discussion of alternative technologies see Section 5.4.2 Reevaluation of Remedial Alternatives and the Case Studies in Appendix B.

7.4.3 Alternative Endpoints

Alternative endpoints may be considered if an alternative remedial strategy cannot improve the remedial effectiveness or achieve the regulatory goals for the remediations (ITRC 2017[GMA6VGKV] ITRC. 2017. "Remediation Management of Complex Sites." Washington D.C.: Interstate Technology & Regulatory Council, Remediation Management of Complex Sites Team. https://rmcs-1.itrcweb.org/., NAVFAC 2012[WSLI4CNQ] NAVFAC, U.S. 2012. "US Navy NAVFAC Optimization UG-NAVFAC EXWC-EV-1301." U.S. Department of Defense. https://www.navfac.navy.mil/navfac_worldwide/specialty_centers/exwc/products_and_services/ev/go_erb/program-support/optimization.html.). While alternative endpoints may be applicable under CERCLA, RCRA, and several state cleanup programs, the process to implement those endpoints must be followed according to the appropriate regulatory authority. Alternative endpoints may be considered during the optimization process as long as the evaluation includes the current state of the contamination (an updated CSM), current exposure pathways are evaluated, and impacts to current and future receptors are addressed (NAVFAC 2012[WSLI4CNQ] NAVFAC, U.S. 2012. "US Navy NAVFAC Optimization UG-NAVFAC EXWC-EV-1301." U.S. Department of Defense. https://www.navfac.navy.mil/navfac_worldwide/specialty_centers/exwc/products_and_services/ev/go_erb/program-support/optimization.html.). Much work should be done to establish alternative endpoints, such as ARARs or a state equivalent. Even if an alternative endpoint can be established, there will still be work to be done: additional remediation, long-term monitoring, and establishment of land-use controls or groundwater classifications, to name a few.

Some types of alternative endpoints include the following:

- ARARs
- alternate concentration limits
- risk-based cleanup values
- groundwater management or CEAs
- groundwater reclassification
- land-use controls

ASM is one tool that can be used to do the work necessary to ensure that alternative endpoints are the appropriate remedial pathway to take for a site. See ITRC's 2017, Remediation Management of Complex Sites, RMCS-1, for an in-depth look at how to conduct ASM and for additional details regarding the application of alternative endpoints. RMCS-1 also has an extensive list of resources and references on ASM.

7.5 Changes to Controlling Documents

Site remediation is often controlled by statutory, administrative, or judicial documents. Optimization evaluations must examine the control documents associated with the site being evaluated. While not all optimization activities rise to regulatory levels, the terms of the control documents must be understood by the optimization evaluators. If changes to the control documents are necessary to implement the optimization recommendation, it would be helpful for the optimization team to understand what limitations this may have on recommendations. The process for making changes to control documents depends on the type of document and controlling authority. The optimization implementation schedule must include time to address changes to control documents (ITRC 2004[JKA62F2T] ITRC. 2004. "Remediation Process Optimization: Identifying Opportunities for Enhanced and More Efficient Site Remediation." Washington, D.C.: Interstate Technology & Regulatory Council, Remediation Process Optimization Team. https://itrcweb.org/teams/projects/remediation-process-optimization.). Optimization considerations associated with the major types of control documents are presented in this section.

7.5.1 Record of Decision and Other Control Documents

RODs document the selected remedial action for a site or operable unit(s) and serve as a legal document that certifies the remedy selection process was carried out in accordance with CERCLA and, to the extent practicable, the NCP. The NCP directs the lead agency to produce a ROD documenting all facts, analysis of facts, and site-specific policy determinations considered in the course of selecting a remedial action and explaining how the nine remedy selection criteria were used to select the remedy (NCP 300.430(f)(5)(i)). The lead agency prepares the ROD in consultation with the support agency (USEPA 2022[WLTW29HD] USEPA. 2022. "Superfund: CERCLA Overview." U.S. Environmental Protection Agency. https://www.epa.gov/superfund/superfund-cercla-overview.USEPA 2022[BE94AAZQ] USEPA. 2022. "Record of Decision (ROD) Guidance." U.S. Environmental Protection Agency. https://www.epa.gov/superfund/record-decision-rod-guidance.). The ROD identifies the selected remedy and explains how the remedy fulfills statutory and regulatory requirements. The selected remedy may include reference to the incorporation of optimization; however, if this is not done, there are opportunities to consider optimization later in the Superfund process. The USEPA guidance on decision documents provides more detailed information (USEPA 2022[BE94AAZQ] USEPA. 2022. "Record of Decision (ROD) Guidance." U.S. Environmental Protection Agency. https://www.epa.gov/superfund/record-decision-rod-guidance., https://www.epa.gov/superfund/record-decision-rod-guidance). When optimization analysis is conducted and identifies an opportunity for optimization of the remedy, the lead agency and support agencies need to collaborate to determine whether the optimization will be implemented. If the lead agency and support agencies agree to move forward with optimization activities, they must decide whether the change rises to the level of a significant change or a fundamental change to the remedy. This will determine whether an ESD or a ROD amendment is required.

An ESD is used when documenting significant changes to a remedy. An ESD must describe to the public the nature of the significant changes, summarize the information that led to making the changes, and affirm that the revised remedy complies with the NCP and statutory requirement of CERCLA. ESDs do not require a public comment period as a public involvement requirement; however, the lead agency may decide to hold a public comment period and/or a public meeting. The lead agency must publish a notice of availability and a brief description of the ESD as required (NCP 300.430(c)(2)(i)(B)). ESDs may happen after actions are taken in the field to document such changes. When possible, ESD level changes should be documented before the significant changes to the remedy are completed. Remediation process optimization analysis provides the opportunity to develop this documentation and engage the appropriate stakeholders in a timely manner before changes are made. An example of an ESD-level change might be reducing or increasing the number of pumping wells in a capture zone array or significantly changing the pumping rates.

The ROD amendment process is used when a fundamental change is made to the basic features of the remedy selected in a ROD with respect to scope, performance, or cost. The lead agency is required to develop and document the change consistent with the NCP (NCP 300.430(c)(2)(ii)(A–H)). This entails the issuance of a revised proposed plan that highlights the proposed changes, followed by issuance of the ROD amendment. When fundamental changes are proposed to the ROD, the lead agency must conduct the required public participation and documentation procedures such as a public comment period on the proposed plan. The final decision to amend the ROD is not made until after consideration of public comment. An example of a fundamental change to a remedy that would require a ROD amendment would be eliminating P&T entirely from a remedy and installing a reactive barrier wall in place of pumping. Time is a consideration for the optimization team. If they are recommending a change that will require a ROD amendment, the team must build that time into the optimization plan. Guidance on RODs and ROD amendments can be found in the resources section.

Consent decrees, or CDs, are U.S. federal or state, legal documents that are approved by a judge and signed by the parties to a remediation. They range in scope but can specify the remediation technologies, down to pumping rates and monitoring protocols, that the parties have agreed to use at a site. A judicial CD is the only settlement type that USEPA can use for the final phase (remedial action) at a Superfund Site. The USEPA Enforcement website, Negotiating Superfund Settlements, provides further information on this topic including example documents. (USEPA 2022[UF527LFM] USEPA. 2022. "Negotiating Superfund Settlements." https://www.epa.gov/enforcement/negotiating-superfund-settlements.) A CD is also subject to a public comment period. Should an optimization review determine that the terms and conditions of the CD need to be changed due to changes in, or a new understanding of, site conditions then the CD may need to be modified in addition to other site decision documents. CD modification requires negotiation among the parties to the CD—typically all the consenting PRPs, the state and federal regulators, and the judge responsible for the CD. Optimization changes to CDs can be initiated by any party to the CD, but it is typically one of the regulatory authorities or the lead responsible party or committee. Time is also a consideration for CD modifications; even if all parties agree to the changes, scheduling time before a federal judge must be considered in the schedule. If all parties do not agree on the changes, then the optimization team must build in time for negotiations or litigation.

State Equivalents
States have a range of control documents that they use to document site remediation activities. A common term used in the states is an Administrative Consent Order or ACO; this should not be confused with the RCRA ACO, which is an enforcement tool used in the RCRA program. State ACOs, or equivalents, come in a range of names and forms. For example, New Jersey uses a term, Administrative Order/Notice of Civil Administrative Penalty Assessment (AO/NOCAPA), for one of their enforcement tools. Permits are also used as control documents by the states.

7.5.2 Permits and Permit Equivalencies

This section deals with the remedial action permits and reporting. Optimization practitioners are advised that sites (including federal Superfund sites operating under permit equivalents) are subject to a wide range of permits. Optimization process recommendations may impact any number of permits held at a site, from air pollution control to NPDES permits (wastewater discharge); therefore, the optimization report needs to identify all permits, local through federal, and determine whether the recommendations impact those permits. The site record should have all permits identified that are needed for a site. If the record is incomplete or it is a new site, it is necessary to conduct research to identify which permits are needed. See the NJDEP Permit Readiness Checklist for the types of permits and information that might be needed by the optimization review team.

Once a change is deemed necessary or desirable by the optimization review process, changes to the remediation system must be established by permit modification or during the permit reporting period, depending on the state framework. If a major change is proposed, a permit modification is usually required in advance of the change. Examples of two types of modifications are presented below. Both are hypothetical; check with your regulatory agency to see whether they apply to your site-specific conditions:

The first example has an active P&T system on the site, and the optimization process recommends that MNA would be the most appropriate option under current site conditions. Typically, a permit modification would be needed in advance of the change in most jurisdictions. Changing the remedial activity or method is usually considered a major change for most state remedial action permits.

The second example is a proposed modification of the pumping regimen, such as a site where the site groundwater recovery rate was pumping 100 gpm from one recovery well out of three existing recovery wells. Optimization now recommends splitting the pumping rate among all three wells. Typically, that type of change would only be required during the periodic reporting required for the site. Alternately, the optimization process could recommend alternating pumping for a specified period for each of the wells. Typically, this does not require a remedial action permit modification as no change in remediation method was required. Normally changes in operation, not method, are reported in periodic reporting associated with the remedial action permit or discharge permit, as appropriate. Such a change may require a change to well permits (e.g., the Water Resources Control Board in California or the Water Allocation Permit in New Jersey) if the wells were not installed with such alternatives identified up front.

7.6 Site Closeout

Optimization efforts support site closeout efforts. One of the main goals of remediation is to complete the cleanup as quickly as possible. Time is a major component of risk (ITRC 2015[BW2ACV73] ITRC. 2015. “Decision Making at Contaminated Sites: Issues and Options in Human Health Risk Assessment.” Washington D.C.: Interstate Technology & Regulatory Council, Risk Assessment Team. https://projects.itrcweb.org/risk-3.); the longer that hazardous materials remain in the environment, the longer the risk of damage to human health and the environment exists. The longer a remediation system is in place, the longer it is exposed to outside risks such as flood and wildfires, raising resiliency issues. Time also impacts the ability of the site to reenter productive use, which is an element of sustainability. Like other elements of the site remediation process, site closeout is usually not a direct optimization evaluation recommendation, but optimization evaluations can support site closeout decisions.

Site closeout decisions need to be based on current site conditions, and the decision logic should be accurately and comprehensively documented (USEPA 2011[FWQWTQM8] USEPA. 2011. “Close Out Procedures for National Priorities List Sites.” U.S. Environmental Protection Agency. https://www.epa.gov/superfund/close-out-procedures-national-priorities-list-superfund-sites.ITRC 2021[MVXSX8BV] ITRC. 2021. “Sustainable Resilient Remediation.” Washington, D.C.: Interstate Technology & Regulatory Council, Sustainable, Resilient Remediation Team. https://srr-1.itrcweb.org/.). As an example, one of the key pieces of site documentation that should be updated as part of the closeout determination is the CSM. Optimization evaluations can update the CSM. An updated CSM can be used to clearly communicate to all stakeholders the conditions remaining at the site. By accurately and transparently documenting the decision process, in a way that all stakeholders can understand, the implementation process has a better opportunity for success.

Site closeout terminology can be confusing to a range of stakeholders. For example, the USEPA uses the term “site completion” (USEPA 2011[FWQWTQM8] USEPA. 2011. “Close Out Procedures for National Priorities List Sites.” U.S. Environmental Protection Agency. https://www.epa.gov/superfund/close-out-procedures-national-priorities-list-superfund-sites.) for the period when “no further Superfund response is necessary to protect human health and the environment.” Any site with O&M activities being conducted in a continued effort to attain RAOs or cleanup levels typically does not qualify for site completion until these objectives and levels are met. These activities typically include actions related to groundwater or surface water restoration. For Fund-financed remedies, the opening section of the O&M plan normally describes the transfer of O&M responsibilities, including the organizational unit of the state government responsible for O&M, state funding mechanisms for O&M activities, and milestone dates for state assumption of O&M.

Another term USEPA uses is Remedial Action Completion (USEPA 2011[FWQWTQM8] USEPA. 2011. “Close Out Procedures for National Priorities List Sites.” U.S. Environmental Protection Agency. https://www.epa.gov/superfund/close-out-procedures-national-priorities-list-superfund-sites.). Remedial Action Completion refers to the actual construction or implementation of a discrete scope of activities supporting a Superfund site cleanup. O&M measures are initiated after the remedy has achieved the RAOs and remediation goals in the ROD and is determined to be operational and functional, except for groundwater or surface water restoration under §300.435(f)(4). A state must provide its assurance to assume responsibility for O&M, including, where appropriate, requirements for maintaining ICs under §300.510(c). Generally, O&M is the responsibility of the PRPs, states, or federal agencies other than the USEPA.

The USEPA term LTRA refers to remedial actions at a site involving treatment or other measures to clean up groundwater or surface water quality to a level that assures protection of human health and the environment. The operation of such treatment or other measures for a period of up to 10 years after the remedy becomes operational and functional is considered an LTRA. In other words, the 10-year period between the operational and functional determination and the start of O&M is defined as an LTRA. "Operational and functional" is described in the NCP, 40 CFR 300.435(f)(2) as follows: "A remedy becomes 'operational and functional' either one year after construction is complete, or when the remedy is determined concurrently by EPA and the state to be functioning properly and is performing as designed, whichever is earlier." USEPA generally intends to transfer groundwater and surface water restoration systems to states when those systems are operating effectively and efficiently. As such, optimization reviews by an independent party often are an important tool used to evaluate operating systems (see the (USEPA 2017[LW4KL27N] USEPA. 2017. "Guidance for Management of Superfund Remedies in Post Construction." Office of Superfund Remediation and Technology Innovation (OSRTI), U.S. Environmental Protection Agency, OLEM 9200.3-105, February 2017. https://semspub.epa.gov/work/HQ/196829.pdf.) guidance at https://semspub.epa.gov/work/HQ/196829.pdf for more information). In certain site-specific circumstances, the USEPA may determine that it is appropriate to pay or partially pay for repairs to or modifications of Fund-financed operating remedies even though a state has already assumed responsibility for O&M. Because the state is responsible for O&M of the remedy, coordination and discussions with the state about the need for and financing of modifications or repair of a remedy are crucial.

For Fund-financed remedies, the USEPA Region conducting the remediation may choose to conduct optimization efforts during the LTRA period (USEPA 2022[A8L2DUR6] USEPA. 2022. "Superfund: Operation and Maintenance and Long-Term Response Actions." https://www.epa.gov/superfund/superfund-operation-and-maintenance-and-long-term-response-actions.). Optimization during the LTRA can verify remedy effectiveness and identify opportunities for cost savings and will help create the conditions for a smooth transition to state responsibility at the end of the LTRA period (USEPA 2022[ZHVKLCQP] USEPA. 2022. "Cleanup Optimization at Superfund Sites." U.S. Environmental Protection Agency. https://www.epa.gov/superfund/cleanup-optimization-superfund-sites.). USEPA regions can seek assistance in performing optimization from the USEPA Headquarters Technology Integration and Information Branch (USEPA 2022[AZTQDXPW] USEPA. 2022. "Optimizing Site Cleanups." https://clu-in.org/Optimization/index.cfm.). States should discuss optimization options with the site remedial project manager. Conducting optimization as early in the LTRA period as practical (although this varies from site to site) can allow for implementation of optimization recommendations before the LTRA period ends.

7.7 Regulatory Challenges and Opportunities Resources

This section provides selected references and resources to help navigate the regulatory challenges and opportunities faced by optimization practitioners and regulators evaluating optimization proposals.

7.7.1 Interstate Technology Regulatory Council

Optimizing Injection Strategies and In Situ Remediation Performance. OIS-ISRP-1, ITRC February 2020, https://ois-isrp-1.itrcweb.org/. This document has developed a regulatory perspective section that can be applied to optimization of P&T systems (https://ois-isrp-1.itrcweb.org/5-regulatory-perspectives/). Notably, it cites the USEPA Memorandum "Use of Early Actions at Superfund National Priorities List Sites and Sites with Superfund Alternative Approach Agreements," from August 23, 2019.

Project Risk Management for Site Remediation, RRM-1, March 2011, and *Using Remediation Risk Management to Address Groundwater Cleanup Challenges at Complex Sites*, RRM-2, January 2012, ITRC, https://itrcweb.org/teams/projects/remediation-risk-management. RRM-1 and RRM-2 identify regulatory and statutory changes as a project risk. The RRM-1 document provides guidance on how to manage project risk specifically for site remediation. P&T sites are specifically identified as sites subject to project risk. Areas of P&T project risk, including regulatory, are included in this document. RRM-2, Section 3, has a discussion of regulatory issues that is applicable to both risk management and optimization.

7.7.2 United States Environmental Protection Agency

The USEPA's Superfund Optimization page is at https://www.epa.gov/superfund/cleanup-optimization-superfund-sites. The page focuses mainly on the technical and process aspects of optimization, and it provides many resources for P&T optimization. Use of these resources can help underpin formal or regulatory site recommendations at any phase of the remediation.

The USEPA's optimization landing page at Clu-In.org is here: https://clu-in.org/Optimization/index.cfm. This page includes an array of optimization resources.

The USEPA's Clu-in.org page dedicated to information on, and training for, the National Optimization Strategy is here: https://clu-in.org/Optimization/strategy.cfm. As above, an understating of the National Optimization Strategy is important to be able to explain to regulatory reviewers or auditors the value of optimization.

The USEPA webpage on "Record of Decision (ROD) Guidance," https://www.epa.gov/superfund/record-decision-rod-guidance, includes the link to preparing RODs, https://www.epa.gov/sites/default/files/2015-02/documents/rod_guidance.pdf.

The USEPA link on ARARs is here: https://www.epa.gov/superfund/applicable-or-relevant-and-appropriate-requirements-arars. This webpage includes numerous refences and guidance, including http://semspub.epa.gov/src/document/HQ/174423, "Permits and Permit 'Equivalency' Processes for CERCLA On-site Response Actions," which clarifies how and when permit equivalencies are used.

7.7.3 Other Federal Agencies

The United States Department of the Navy, Navy Facilities Engineering Command's optimization website is a good resource, and a number of optimization resources can be found here, including the NAVFAC Guidance for Optimizing Remedial Action Operation (RA-O), UG-NAVFAC EXWC-EV-1301, November 2012. This document addresses the need to identify the current regulatory environment, including state regulations when evaluating a site for optimization. The document provides recommendations for regulatory review under several optimization scenarios.

The USACE, Remediation System Evaluations is helpful. Checklists related to P&T systems can be found here; the Above Ground Treatment System Performance Checklist contains suggested questions for interviewing regulators.

The Federal Remediation Technologies Round Table (USEPA 2020[PFJY3BQ6] USEPA. 2020. "Sustainable and Healthy Communities: Strategic Research Action Plan 2019-2022." U.S. Environmental Protection Agency, Office of Research and Development.
https://www.epa.gov/research/sustainable-and-healthy-communities-strategic-research-action-plan-2019-2022.) optimization website has a number of resources including case studies that can be used to learn about regulatory issues associated with optimization.

Key Takeaways

Regulator involvement with a particular site varies from agency to agency, within agencies, from region to region, and within regions of the USEPA. Communication is critical; reach out to the agencies when planning an optimization and seek to get the regulators involved with the process up front.

TI is not a blanket do nothing alternative; contamination remains in the groundwater or soils and remains a threat to human health and the environment. TI will require periodic reevaluation of remedial technologies to determine whether new means or methods have been developed to address the issue, ongoing monitoring will be required to ensure conditions do not deteriorate, or periodic reevaluation of threat pathways (e.g., vapor intrusion) will continue.

Sites may have a control document, or even multiple control documents, in place impacting all or portions of a site. Some might be documentary in nature (a ROD), others may be enforcement generated (an ACO), others may be enforced by a state or federal court (a CD), and some control documents may be permits. Optimization teams need to identify what control documents exist and make sure recommendation are evaluated against the terms of these documents. Time to modify these documents must be factored into the optimization implementation schedule.

Optimization during the LTRA period at Fund Lead superfund sites is beneficial to both the federal and state governments. The federal government benefits by ensuring a smooth transition to state lead. The states benefit in that the remediation system has been optimized, or recommendations for optimization are established before the transition to state lead occurs.