

Environmental Hazards: A Framework for Risk-Informed Decision-Making

GAO-24-107595

Q&A Report to Committee on Energy and Commerce, House of Representatives

September 23, 2024

Why This Matters

Across the federal government, agencies are tasked with making decisions about how best to use taxpayer resources to reduce risks to human health and the environment posed by environmental hazards such as polluted soil and water. For example, federal agencies must decide how to best clean up legacy contamination at sites across the country and how to address the presence of chemicals and other hazards in the environment. These decisions range in scale and complexity, but involve balancing the benefits of reducing human health and environmental risks with the costs of doing so. The U.S. government's environmental liability—the estimated cost to the federal government of cleaning up environmental contamination from past activities—was \$645 billion in fiscal year 2023 and is expected to continue to grow.

Decisions about how to address human health and environmental risks posed by environmental hazards are informed by—but not solely based on—risks and costs. Agencies must also weigh and balance other factors, such as legal and regulatory requirements and the diverse values and perspectives of those interested in or affected by the decision. Data limitations and other sources of uncertainty also influence these decisions. To help agencies make effective and credible decisions when faced with trade-offs among risks, costs, and other factors, we issued a framework for risk-informed decision-making in September 2019. This report presents an updated version of the risk-informed decision-making framework with new information about its application and scope.

We prepared this report under the authority of the Comptroller General in light of congressional interest in the effective and efficient use of taxpayer dollars in addressing environmental hazards. This report describes GAO's risk-informed decision-making framework for human health and environmental risks posed by environmental hazards, describes why and how federal agencies can use a risk-informed decision-making framework, and examines the phases and steps in the framework.

Key Takeaways

- We developed the risk-informed decision-making framework to serve as a guide for managing and overseeing federal decision-making processes regarding environmental hazards. We designed the framework for any federal decision-making process that involves limited resources, risks to human health and the environment posed by environmental hazards, diverse values and perspectives of those interested in and affected by the decision, and uncertainty.
- The framework consists of four phases. Each phase consists of multiple steps that describe what should occur in each phase.
- The framework can be applied to all scales and types of decisions, from selecting the best option at a single site, to prioritizing projects across a

portfolio, to setting agency-wide policy. When applied, the depth and extent of the framework’s phases and steps should be tailored to the nature and significance of the decision being made.

What is risk-informed decision-making?

Risk-informed decision-making is a decision-making approach that helps agencies consider trade-offs among risks to human health and the environment, costs, and other factors in the face of uncertainty and diverse stakeholder and government perspectives. “Risk-informed” decision-making is different from “risk-based” decision-making in that risk-informed decision-making considers risk alongside other factors that are important to stakeholders and governments. “Risk-based” decision-making, on the other hand, considers risk alone.

What is risk?

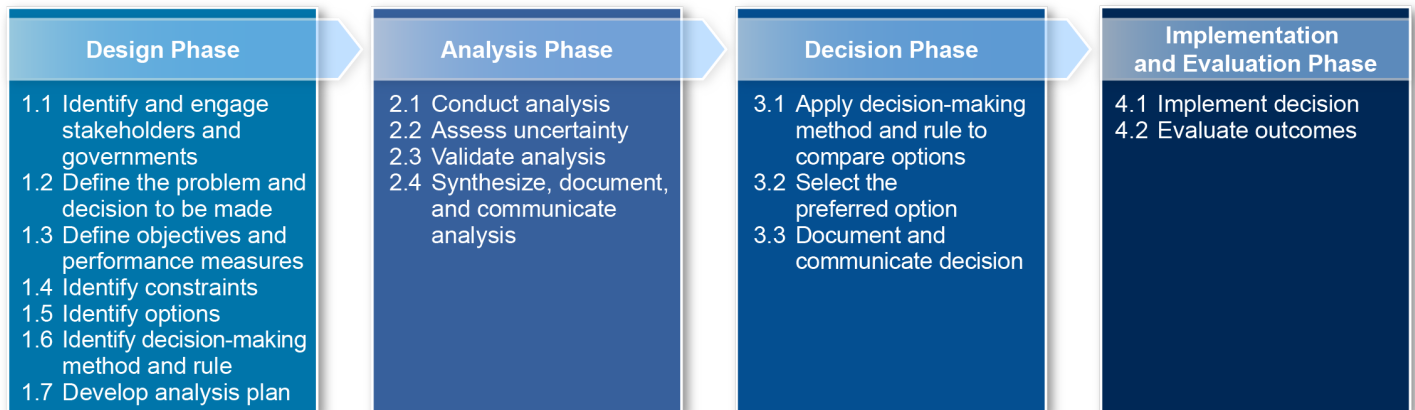
We define “risk” in this context as the probability of adverse consequences to human health or the environment from exposure to an environmental hazard. Environmental hazards include substances in the environment—such as toxic chemicals, radioactive and hazardous waste, and other contaminants and pollutants—that have the potential to cause harmful effects, including cancer and other illnesses or injuries. Environmental hazards also include situations—such as exposure to stressors—that have the potential to negatively affect humans or the environment.¹

Decisions about air and water pollution, nuclear and hazardous waste management, workplace exposure to toxic materials, natural resource management, and chemical substances in consumer products are examples of issues that pose potential environmental hazards that are the focus of this report. While other types of risks, such as project management and security risks, may influence agency decision-making, these types of risks are not the focus of this report.

What is a framework for risk-informed decision-making?

We developed a framework for making risk-informed decisions about human health and environmental risks posed by environmental hazards. The framework consists of four broad phases: (1) designing the decision-making process by, for example, defining objectives and identifying potential options; (2) analyzing the performance of each option against the established objectives; (3) deciding which option is preferred; and (4) implementing and evaluating the preferred option.² Each phase comprises several steps (see fig. 1).

Figure 1: Phases and Steps of the Risk-Informed Decision-Making Framework for Environmental Hazards



Source: GAO. | GAO-24-107595

This report updates a version of the framework we issued in our 2019 report related to nuclear waste cleanup decisions.³ To develop the framework for the 2019 report, we reviewed key concepts from the literature on risk and decision-making and obtained input from experts who participated in a meeting convened by the National Academies of Sciences, Engineering, and Medicine (National Academies). The information from that work is relevant not only to nuclear waste cleanup but also to other environmental hazards. As a result, we have updated the framework to reflect this broader application to risks to human health and the environment posed by a wider array of environmental hazards. We based the statements in the framework on literature we reviewed and expert input we obtained for the 2019 report.

Why should agencies use the framework?

Using the risk-informed decision-making framework may be especially important given the federal government's broad-ranging efforts to address contamination at sites across the country. Agencies like the Departments of Energy and Defense are working to address environmental hazards at sites contaminated by federal activities such as nuclear weapons production and military operations. The estimated cost of these efforts—\$645 billion in fiscal year 2023—continues to grow even as the government spends billions each year on cleanup efforts. Accordingly, we have included the U.S. government's environmental liability on our High Risk List since 2017.⁴ In addition to agency efforts to clean up contamination from prior federal activities, the Environmental Protection Agency uses the Superfund Program established by the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended, to carry out or oversee cleanup activities at seriously contaminated nonfederal sites. As of September 2019, the Environmental Protection Agency's list of the most seriously contaminated sites contained 1,336 active sites, about 90 percent of which were nonfederal. For fiscal year 2025, the agency has requested approximately \$661 million for the Superfund Program to continue cleanup of these sites.

Agencies that manage or oversee federal decision-making processes related to human health and environmental risks posed by environmental hazards at such sites can use the framework as a guide for ensuring these processes result in risk-informed decisions that are effective and credible.⁵ Agencies may likewise find the framework useful in other efforts, such as in prioritizing research and development for addressing environmental hazards and as a means for analyzing natural resource management plans.⁶

By applying the framework, agencies may be better positioned to effectively set priorities and direct their limited resources to address those priorities. The framework can help agencies apply a defensible method for weighing numerous inputs, comparing options, and implementing decisions. Such formal decision-making methods provide a rigorous, transparent way for agencies to evaluate trade-offs and ultimately identify cost-effective approaches for addressing risks to human health and the environment posed by environmental hazards.

How should agencies use the framework?

Agencies can apply the risk-informed decision-making framework to all scales and types of decisions, from selecting the best option at a single site, to prioritizing projects across a portfolio, to setting agency-wide policy. Agencies implementing the framework should ensure that their decision-making process is participatory, logical, transparent, traceable, and that it uses current scientific knowledge and practice to produce technically credible results. These are characteristics of an effective and credible risk-informed decision-making process identified in 2005 by the National Academies.⁷

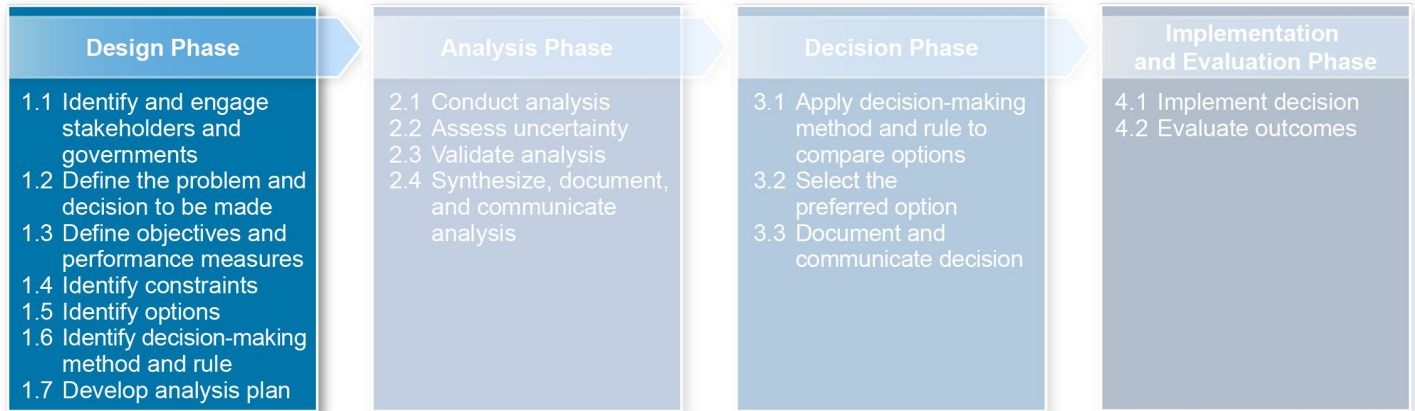
Considerations when using the framework include the following:

- **All phases and steps are essential to achieving a risk-informed decision.** Because the results of the phases and steps feed into subsequent phases and steps, using any one portion of the framework in isolation from the others does not ensure that a risk-informed decision will be reached. In our work to develop the framework, we found that all of the phases and steps are essential, though the extent and sequence of the phases and steps will differ, as described below.
- **The framework describes required and suggested practices.** The steps in the framework consist of required and suggested practices. Required practices are denoted using language such as “should” (required practices are numbered and lettered below). The required practices must be in place for a risk-informed decision to be reached. Suggested practices are denoted using language such as “may” and “for example.” The suggested practices are presented along with additional information that further describes what a step means and how an agency may implement it.
- **The depth and extent of the phases and steps should be tailored to the needs of the decision.** Resources invested into implementing each phase and step of the framework should be tailored to the needs of the decision, with highly complex, high-stakes decisions warranting greater resource investment than simpler, less consequential decisions.⁸ Users of the framework should exercise their professional judgement when determining how the phases and steps should be tailored to a given decision.
- **Iteration among steps may be needed.** We present the framework as a sequential series of steps; however, in practice, the results of one step may lead to revisiting a previous step, or some steps may occur at the same time. In addition, the exact ordering and grouping of the steps under these four phases is less important than the substance of the steps.⁹
- **The framework does not replace existing laws, regulations, guidelines, or agreements.** The framework is not intended to replace or supersede the processes required under applicable laws, regulations, guidelines, or agreements. Rather, it is intended to highlight essential elements of risk-informed decision-making that should be applied when making decisions in general.

What is the Design Phase of the framework?

The Design Phase of the framework lays the groundwork for decision-making. The purpose of this phase is to define the scope and goals of the decision-making process, and to specify who will be involved in informing and making the decision and the analytical methods to be used. This phase emphasizes deliberation in that it involves collective and intentional consideration of the values and preferences driving the decision. The Design Phase consists of seven steps (see fig. 2).

Figure 2: Design Phase Steps of the Risk-Informed Decision-Making Framework for Environmental Hazards



Source: GAO. | GAO-24-107595

1.1 Identify and Engage Stakeholders and Governments

This step involves identifying stakeholders and governments—individuals, groups, organizations, and agencies that can influence the decision or that will be affected by the decision—and engaging them in the decision-making process. Meaningful stakeholder and government engagement is critical to sound decision-making.¹⁰

Table 1: Risk-Informed Decision-Making Framework: Required and Suggested Practices for Step 1.1 Identify and Engage Stakeholders and Governments

Required practices for the framework	Additional description and suggested practices
<p>1.1A The agency should identify stakeholders such as local communities and nonprofit organizations, and governments such as regulatory agencies and Tribal Nations, that can influence the decision or that will be affected by the decision.^a</p>	<p>Various methods may be used to identify stakeholders and governments, including analyzing the distribution of social and economic impacts to identify populations that may be affected by a decision and analyzing relevant laws to identify who is legally required to participate in the decision-making process.</p>
<p>1.1B The agency should define different stakeholders' and governments' authorities and interests and, based on this information, define the roles they will play throughout the decision-making process.</p>	<p>For a risk-informed decision, stakeholders and governments are likely to include ones external to the federal department or agency in charge of making the decision, such as tribal, state, and local governments; industry groups; nonprofit organizations; and community members.</p> <p>Considering federal taxpayers as a stakeholder group in a risk-informed decision about a project or activity funded by a federal agency can be useful, to the extent taxpayers bear the cost of the selected project or activity.</p> <p>Stakeholders' and governments' roles may include informing the decision, helping make the decision, approving the decision, or performing other functions, such as reviewing analyses.</p> <p>The most appropriate role for stakeholder groups representing members of the public, such as nonprofit organizations and community groups, is likely to be one of helping to inform the decision, rather than of ultimately making it. For example, such stakeholders may help define the issue or problem, define objectives, or identify options.</p>

Source: GAO. | GAO-24-107595

^aExecutive Order 13175, *Consultation and Coordination With Indian Tribal Governments*, directs federal agencies to have an accountable process to ensure meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications. 65 Fed. Reg. 67249 (Nov. 9, 2000). In November 2022, a Presidential Memorandum established uniform minimum standards for tribal consultation to be implemented across all federal agencies. 87 Fed. Reg. 74479 (Dec. 5, 2022). In addition, some federal laws and regulations require federal agencies to consult with Tribes in specific circumstances.

1.2 Define the Problem and Decision To Be Made

This step involves specifying the problem or issue that exists, including its context, and then defining the decision that is to be made about the problem. Because stakeholders and governments may have differing views about the nature and extent of a problem and the scope of the decision that should be made to address it, their input during this step can help build confidence that the right problem is being addressed. Further, this step can help to build transparency and objectivity into the process so that it is clear what an agency is looking to decide, and so that an agency does not go into the process with a pre-determined solution.

Table 2: Risk-Informed Decision-Making Framework: Required and Suggested Practices for Step 1.2 Define the Problem and Decision to Be Made

Required practices for the framework	Additional description and suggested practices
<p>1.2A The agency should collect new or existing information to specify the problem that exists, including its context.</p>	<p>Relevant context for an issue or problem could include the regulatory, social, and environmental settings in which the issue or problem occurs.</p>
<p>1.2B The agency should define the decision that is to be made about the problem. It should articulate the scope and boundaries of the specific decision to be made.</p>	<p>Questions an agency may consider when defining the decision to be made include:</p> <ul style="list-style-type: none"> • Will the decision aim to address all of the problem, or a part of it? • Will the decision involve selecting a single preferred option from a set of candidates, or does it entail another type of decision, such as ranking projects by priority, differentiating between acceptable and unacceptable options, or developing a consistent system for making decisions that are likely to be repeated? • What other decisions affect or will be affected by this one?
<p>1.2C The agency should involve stakeholders and governments in this step because they may provide important information and insights that could affect how a problem or issue is characterized.</p>	<p>None identified.</p>

Source: GAO | GAO-24-107595

1.3 Define Objectives and Performance Measures

This step involves defining agency objectives for the decision and identifying performance measures to compare options. Objectives and performance measures are important because they provide a basis for consistently and transparently comparing options during the Decision Phase and can be used in the final phase of the framework—the Implementation and Evaluation Phase—to assess the performance of the implemented decision.

Table 3: Risk-Informed Decision-Making Framework: Required and Suggested Practices for Step 1.3 Define Objectives and Performance Measures

Required practices for the framework	Additional description and suggested practices
<p>1.3A The agency should define the objectives—the important outcomes or consequences that could be affected by a decision—using input from stakeholders and governments.</p>	<p>None identified.</p>
<p>1.3B Objectives should capture what matters in a decision. Each definition of an objective should identify the topic that matters and include a verb indicating whether more or less is preferred, all else being equal.</p>	<p>Objectives may reflect expectations from different levels within an agency, such as an agency’s mission or strategic planning goals, as well as concerns significant to some or all of the stakeholders and governments. For example, an agency’s goal to protect worker safety could result in an objective to increase worker safety, while different stakeholder groups’ concerns about local economic impacts could result in an objective to promote job opportunities.</p> <p>Fairness and equity considerations may also be included as objectives, as well as concerns about administrative feasibility, such as the time required to obtain any necessary approvals or permits from other agencies.</p>
<p>1.3C To be considered risk-informed, a decision should include objectives to: (1) reduce risks to human health and the environment and (2) reduce cost, among any other objectives required by law or identified by the agency and stakeholders and governments.</p>	<p>None identified.</p>
<p>1.3D To be useful for decision-making, the set of objectives identified for a decision should be both complete and concise, in that it should capture the key things that matter to the agency, stakeholders, and governments in the context of the decision.</p>	<p>None identified.</p>
<p>1.3E Objectives should represent the outcomes that matter to the agency, stakeholders, and governments, rather than any particular method of accomplishing those outcomes, to help ensure that the decision-making process stays open to a range of potential options.</p>	<p>None identified.</p>
<p>1.3F The agency should also identify performance measures, or the measures that will be used to estimate and report on the extent to which objectives are achieved by the options. While objectives may be broad, performance measures should be specific, since they define how the achievement of an objective is to be quantified.</p>	<p>Multiple performance measures may be needed to evaluate achievement of an objective.</p>

Source: GAO. | GAO-24-107595

1.4 Identify Constraints

This step involves identifying any constraints for decision-making, some of which may be fixed and some of which may be flexible. Agencies may use constraints early in the decision-making process to screen out options. This allows more time and resources to be directed toward evaluating options that align with constraints. Agencies may also use constraints later, during the Decision Phase, to eliminate options or to pursue waivers to constraints that may be flexible.

Table 4: Risk-Informed Decision-Making Framework: Required and Suggested Practices for Step 1.4 Identify Constraints

Required practices for the framework	Additional description and suggested practices
<p>1.4A The agency should identify any constraints for decision-making, including those that are fixed and those that are flexible.</p>	<p>Fixed constraints are those that are widely accepted as absolute, non-negotiable thresholds, or standards that an option must meet to be considered for selection.</p> <ul style="list-style-type: none"> • Such constraints may result from statutory, regulatory, or budgetary requirements. For example, requirements in existing agreements between an agency and a regulator may serve as fixed constraints. • Agencies can use fixed constraints early in the decision-making process to screen out options that do not meet them, thus allowing more time and resources to be directed toward evaluating better options, or they may help eliminate options later on during the Decision Phase. • A required level of human health protectiveness and an agency's overall budget for a project or activity are examples of fixed constraints for risk-informed decision-making. <p>Flexible constraints are those that are less well-defined at this stage because of scientific uncertainty or because they may be open to negotiation or changes.</p> <ul style="list-style-type: none"> • In some cases, a constraint related to human health risk may be difficult to specify early in the decision-making process because of uncertainty in the science linking a given hazard with negative health effects. In addition, regulatory or statutory constraints, such as federal or state requirements, may not be fixed because an agency can seek waivers or statutory changes.
<p>1.4B The agency should consider opportunities to negotiate or pursue waivers or changes to flexible constraints where appropriate, so that the decision-making process stays as open as possible to creative solutions. In addition, the agency should avoid using these types of flexible constraints to limit or screen out options from consideration early in the decision-making process.</p>	<p>None identified.</p>

Source: GAO. | GAO-24-107595

1.5 Identify Options

This step involves identifying options for the decision. Broad stakeholder and government involvement can help create a list of options for achieving the established objectives. Their involvement ensures that the list is guided by the values that are driving the decision instead of simply reflecting readily apparent options or the favored option of a vocal few. The degree to which the options are estimated to perform with respect to the objectives will be studied during the Analysis Phase.

Table 5: Risk-Informed Decision-Making Framework: Required and Suggested Practices for Step 1.5 Identify Options

Required practices for the framework	Additional description and suggested practices
1.5A The agency should generate a set of options for the decision that 1) are responsive to the established objectives, 2) represent a range of potential actions or changes, including the status quo, and 3) are broad enough to be expected to offer distinct differences with respect to human health and environmental risks and cost.	None identified.
1.5B Stakeholders, including public stakeholder groups, governments, and subject-matter experts should play a role in identifying options that would be useful to analyze.	None identified.

Source: GAO. | GAO-24-107595

1.6 Identify Decision-Making Method and Rule

This step involves identifying a decision-making method and rule that will be used to integrate information from the analyses into a basis for decision-making. Formal decision-making methods provide a rigorous, transparent way to evaluate trade-offs between objectives. They help make explicit and manage any subjectivity or personal preference that may enter the decision-making process, such as a decision-maker's or stakeholder's views about the relative importance of various objectives or subconscious cognitive biases. Identifying a decision-making method early in the process helps enhance accountability and transparency by outlining how a decision will be reached. The decision-making method and decision rule will be applied in the Decision Phase, and the results should aid (though not dictate) the decision.

Table 6: Risk-Informed Decision-Making Framework: Required and Suggested Practices for Step 1.6 Identify Decision-Making Method and Rule

Required practices for the framework	Additional description and suggested practices
<p>1.6A The agency should identify a formal, systematic method that will be used to integrate information from the analyses into a basis for decision-making, along with an associated decision rule that specifies which option should be considered "best" under that method.</p>	<p>The choice of decision-making method may depend on a number of factors. Examples of these factors include: the time and resources available for implementing it; the number of stakeholders and governments and extent of their expected involvement in providing input to the decision; the extent to which objectives can be quantified or monetized; and whether any relevant statutes or regulations require or explicitly exclude certain types of methods.</p> <hr/> <p>For a risk-informed decision, examples of potentially appropriate decision-making methods, along with each method's associated decision rule, including benefit-cost analysis, cost-effectiveness analysis, and multiattribute utility theory (see fig. 3).</p> <hr/> <p>For a risk-informed decision, decision rules that could be informed by such decision-making methods include selecting the option that minimizes either: (1) human health and environmental risks subject to constraints on cost and any other factors, or (2) cost subject to constraints on human health and environmental risks and any other factors.</p> <hr/> <p>Identifying the decision-making method before analyses are conducted helps ensure that the analysis results can be formatted in a way that can be used by that method.</p>

Source: GAO. | GAO-24-107595

Figure 3: Risk-Informed Decision-Making Framework: Examples of Potentially Appropriate Decision-making Methods and Associated Decision Rules



Source: GAO; GAO (icons). | GAO-24-107595

^aOffice of Management and Budget, *Guidelines and Discount Rates for Benefit-Cost Analysis of Federal Programs*, OMB Circular No. A-94 (Washington, D.C.: Nov. 9, 2023). For additional information about the application of benefit-cost analysis, see: Office of Management and Budget, *Regulatory Analysis*, OMB Circular No. A-4 (Washington, D.C.: Nov. 9, 2023).

^bOffice of Management and Budget, *Guidelines and Discount Rates for Benefit-Cost Analysis of Federal Programs*.

^cMultiattribute utility theory is also known as multiattribute value theory. It is one of many methods under the larger umbrella of multicriteria decision analysis, all of which seek to help decision-makers explicitly account for multiple, conflicting objectives. For a detailed description of multicriteria decision analysis methods and their relative strengths and weaknesses, see: Valerie Belton and Theodor J. Stewart, *Multiple Criteria Decision Analysis: An Integrated Approach* (Boston: Kluwer Academic Publishers, 2002).

1.7 Develop Analysis Plan

This step involves developing a plan for analyses to be conducted in the Analysis Phase. Obtaining stakeholders' and governments' input on the types of analyses to be conducted and how results will be used can help improve the likelihood that they will view the decision-making process as fair and legitimate. Further, this step can help to build transparency and objectivity into the process.

Table 7: Risk-Informed Decision-Making Framework: Required and Suggested Practices for Step 1.7 Develop Analysis Plan

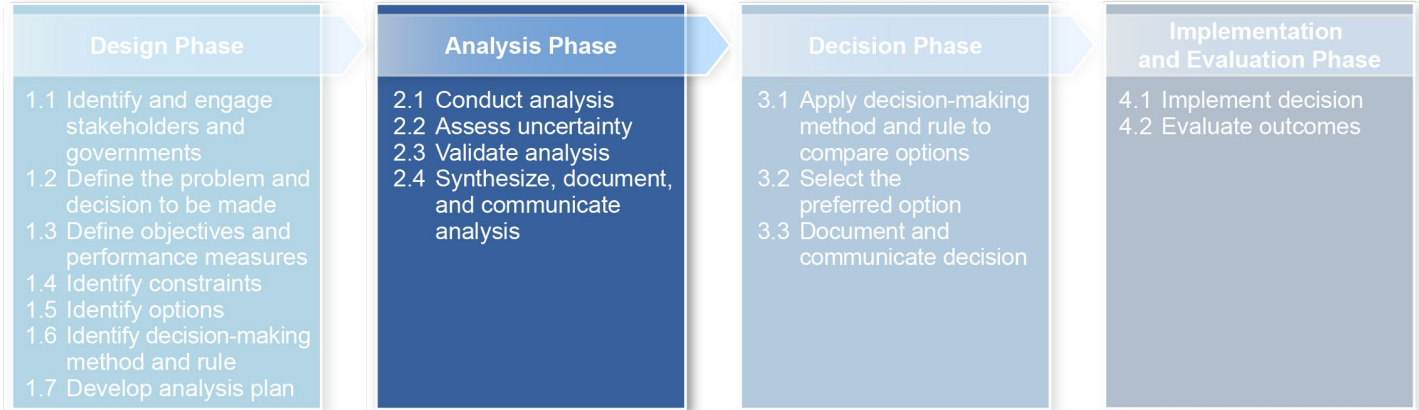
Required practices for the framework	Additional description and suggested practices
<p>1.7A The agency should develop a plan that identifies the types of analyses that need to be conducted to assess how well each option performs with respect to the objectives, along with a timeline for completing the analyses.</p>	None identified.
<p>1.7B For a decision to be risk-informed, the types of analyses to be conducted should include quantitative or qualitative human health risk assessments and life cycle cost estimates (described in the Analysis Phase below), including estimates of costs to the private sector and individuals, along with any other analyses needed to assess performance of each option with respect to the objectives.</p>	None identified.
<p>1.7C The analysis plan should include information about:</p> <ul style="list-style-type: none"> • The resources needed to conduct the analyses, including the data and expertise needed, along with an assignment of tasks. • The budget and time frame within which analyses should occur. • The depth and rigor of the selected analytical methodologies, which should depend on the complexity and stakes of the decision. • Data gaps and uncertainties associated with the analyses, including plans for how uncertainty will be assessed. • Intended outputs of the analyses. • The approaches that will be used to validate or peer-review the analyses. • Any existing analyses that can be updated or modified in lieu of conducting new analyses. • Provisions to facilitate coordination and consistency among the different entities within an agency that may be responsible for conducting the analyses. 	None identified.
<p>1.7D Stakeholders and governments should have a role in reviewing the analysis plan.</p>	None identified.

Source: GAO. | GAO-24-107595

What is the Analysis Phase of the framework?

The purpose of the Analysis Phase is to determine how the options perform with respect to the objectives for the decision. This phase provides a factual, analytic basis for decision-making and is to be carried out by subject matter experts. The Analysis Phase consists of four steps (see fig. 4).

Figure 4: Analysis Phase Steps of the Risk-Informed Decision-Making Framework for Environmental Hazards



Source: GAO. | GAO-24-107595

2.1 Conduct Analysis

This step involves implementing the analysis plan developed in the previous phase. Conducting the planned analyses allows the agency to estimate the performance of each identified option with respect to each objective.

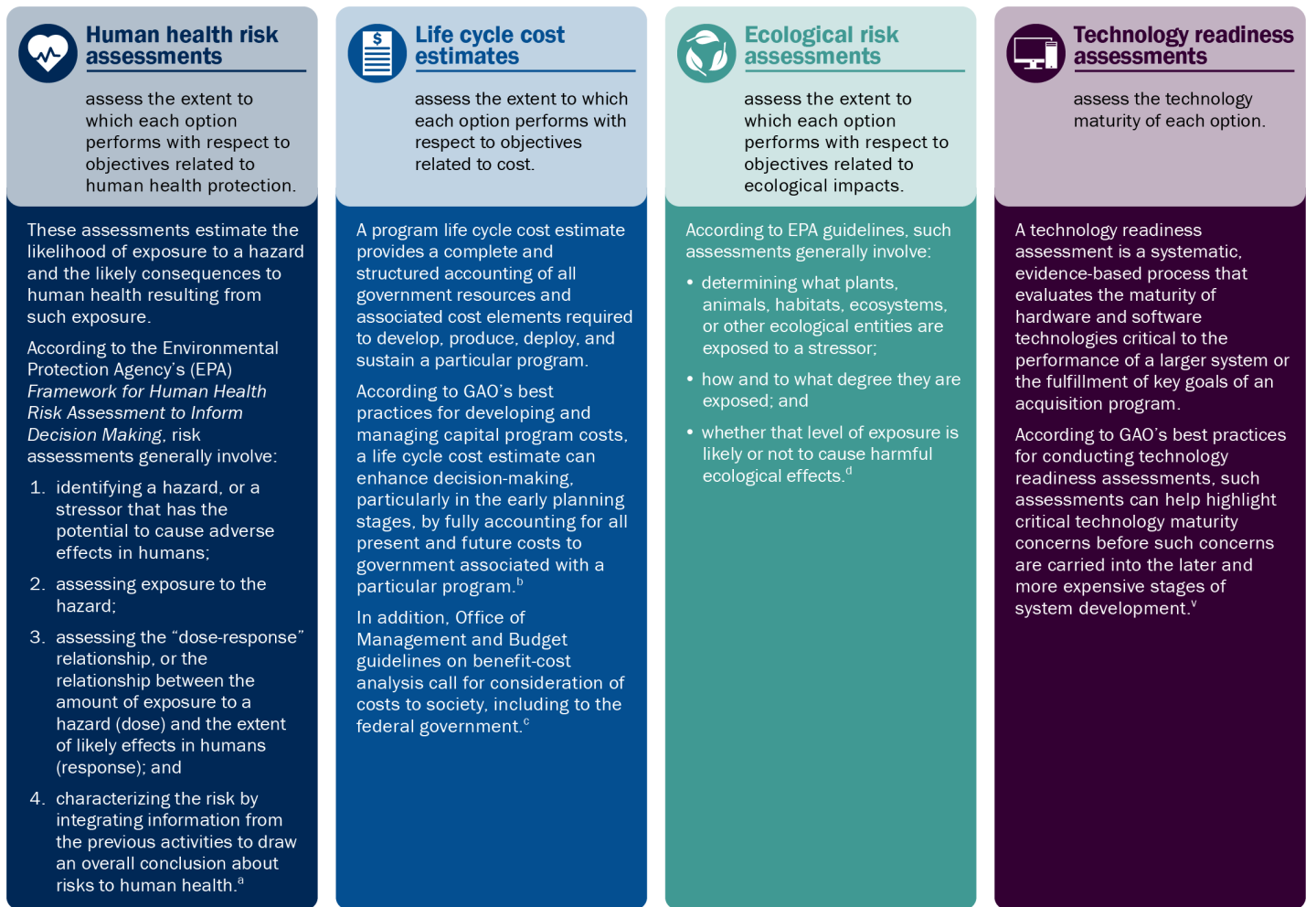
Table 8: Risk-Informed Decision-Making Framework: Required and Suggested Practices for Step 2.1 Conduct Analysis

Required practices for the framework	Additional description and suggested practices
2.1A The agency should implement the analysis plan by collecting quantitative or qualitative data and developing and conducting analyses that estimate the performance of each option with respect to each objective.	Many analyses involve developing statistical or computational models to predict such performance.
2.1B The agency's analyses should be conducted in accordance with generally accepted standards and guidelines that apply to that field of study and should use the most up-to-date data.	Data may be drawn from a variety of sources, including scientific field data, information from the literature, Indigenous Knowledge, and expert opinion obtained using expert elicitation methods. ^a
2.1C For a risk-informed decision, the agency's analyses should include human health risk assessments and life cycle cost estimates, including estimates of costs to the private sector and individuals, as applicable.	Depending on the specific decision and objectives, other analyses may include assessments of ecological risk and technology readiness. It may also be appropriate to conduct an analysis of whether each option may be viewed as acceptable to different stakeholder groups, or to examine the equity or environmental justice implications of each option. See figure 5 for examples.

Source: GAO. | GAO-24-107595

^aAccording to a 2022 memorandum from the Office of Science and Technology Policy and Council on Environmental Quality, Indigenous Knowledge is a body of observations, oral and written knowledge, innovations, practices, and beliefs developed by Tribes and Indigenous Peoples through interactions and experience with the environment. This memorandum provides guidance on how federal agencies should recognize and include Indigenous Knowledge in research, policy, and decision-making. Office of Science and Technology Policy and Council on Environmental Quality, *Implementation of Guidance for Federal Departments and Agencies on Indigenous Knowledge* (Washington, D.C.: Nov. 30, 2022).

Figure 5: Examples of Types of Analyses Conducted in Risk-Informed Decision-Making



Source: GAO; GAO (icons). | GAO-24-107595

^aU.S. Environmental Protection Agency, *Framework for Human Health Risk Assessment to Inform Decision-Making*, EPA/100/R-13/001 (Washington, D.C.: April 5, 2014). The Environmental Protection Agency's guidance reflects the longstanding, basic approach to risk assessment first outlined by the National Academies in its 1983 report, *Risk Assessment in the Federal Government: Managing the Process*. See: National Research Council of the National Academies, Committee on the Institutional Means for Assessment of Risks to Public Health, *Risk Assessment in the Federal Government: Managing the Process* (Washington, D.C.: The National Academies Press, 1983).

^bGAO, *GAO Cost Estimating and Assessment Guide: Best Practices for Developing and Managing Capital Program Costs*, GAO-09-3SP (Washington, D.C.: March 2009).

^cOffice of Management and Budget, *Guidelines and Discount Rates for Benefit-Cost Analysis of Federal Program*, OMB Circular No. A-94 (Washington, D.C.: Nov. 9, 2023).

^dU.S. Environmental Protection Agency, *Guidelines for Ecological Risk Assessment*, EPA/630/R-95/002F (Washington, D.C.: April 1998).

^eGAO, *Technology Readiness Assessment Guide: Best Practices for Evaluating the Readiness of Technology for Use in Acquisition Programs and Projects*, GAO-16-410G (Washington, D.C.: August 2016).

2.2 Assess Uncertainty

This step involves identifying the sources of uncertainty in any analyses conducted, assessing the amount of uncertainty, and taking steps to reduce uncertainty when reasonably feasible. Uncertainty exists in decisions that involve predicting impacts over time, since it is not possible to obtain perfect information or to precisely anticipate the future consequences of an action. It also exists when one makes an assumption or judgement call in the course of conducting an analysis.

The purpose of this step is to characterize uncertainty and take appropriate measures to reduce it so that an agency can make the best possible decisions in the face of whatever uncertainty remains. Specifically, improving the accuracy of data and modeling can help reduce uncertainty and avoid unduly conservative or liberal estimates of risks to human health and the environment. In addition, reducing uncertainty can help avoid unnecessary efforts and excessive costs.

Table 9: Risk-Informed Decision-Making Framework: Required and Suggested Practices for Step 2.2 Assess Uncertainty

Required practices for the framework	Additional description and suggested practices
<p>2.2A The agency should explicitly characterize—and quantify, where possible—uncertainty as it relates to predicting the performance of each option, and it should take appropriate measures to reduce uncertainty.</p>	<p>Quantifiable uncertainty. Some types of uncertainty, such as random variability that is inherent to natural systems, may be reasonably quantified. Depending on the timeline and resources available for the decision, and depending on the type and extent of information needed to inform the decision, methods to assess or reduce quantifiable uncertainty include: collecting additional data or information; improving the quality of data, modeling, and research; eliciting judgements from experts about the range and likelihood of potential outcomes; and developing assessment tools that use statistical methods to estimate a probability distribution of potential outcomes.^a</p> <p>Non-quantifiable uncertainty. Other types of uncertainty, such as that related to major unanticipated future events, cannot be reasonably quantified due to an absence of data or scientific understanding that is unlikely to be addressed within a time frame relevant to the decision. One method to qualitatively assess this type of uncertainty is to identify which options would meet objectives under a range of plausible scenarios.</p>
<p>2.2B The agency should place particular emphasis on understanding and reducing uncertainty associated with objectives that will most influence the decision so that the individual or group making the decision can be confident that the selected option is optimal given the information available.^b</p>	<p>Sensitivity analysis and value-of-information analysis are types of analyses that help determine whether collecting new or additional data or taking other steps to reduce uncertainty would change the results of the analyses to a degree that affects which option is preferred. For example, value-of-information analysis can help clarify the level of effort required to obtain more precise information on any uncertain variable. It can also clarify whether reducing uncertainty could materially affect the decision. Decision-makers—with input from stakeholders and governments, as appropriate—can then weigh whether that level of effort is worth the reduced level of uncertainty.</p>

Source: GAO. | GAO-24-107595

^aFor example, a predictive model associated with a cost estimate could show a range of estimated total costs for various options, as well as the probability associated with the values within that range. For instance, in estimating costs associated with environmental cleanup options, a predictive model could show that the estimated cost of one cleanup option is \$41 to \$67 billion, with a mean of \$53 billion, while the estimated cost of another cleanup option is \$27 to \$39 billion, with a mean of \$32 billion. For additional information and an example of a cost estimate we developed using Monte Carlo simulation to account for uncertainties, see GAO, *Nuclear Waste Management: Key Attributes, Challenges, and Costs for the Yucca Mountain Repository and Two Potential Alternatives*, GAO-10-48 (Washington, D.C.: Nov. 2009).

^bFor a risk-informed decision, efforts to reduce uncertainty related to human health risk assessments and cost estimates may be beneficial in clarifying distinctions between contending options. For example, assume that a human health risk assessment shows that option A is slightly better, on average, at protecting human health than option B, but that there is some chance that option B is actually better due to uncertainty in outcomes. In such a case, steps to reduce uncertainty related to human health outcomes may help clarify the distinction between the options.

2.3 Validate Analysis

This step involves evaluating the analyses and addressing any issues or problems that may be detected. Such review can help ensure the credibility and quality of the analyses.

Table 10: Risk-Informed Decision-Making Framework: Required and Suggested Practices for Step 2.3 Validate Analysis

Required practices for the framework	Additional description and suggested practices
2.3A The agency should thoroughly validate the analysis by evaluating the data, models, and results from the analyses and addressing any detected issues or problems.	This step may include peer review by an independent panel of individuals who have expertise in the data and analytical approaches used.

Source: GAO. | GAO-24-107595

2.4 Synthesize, Document, and Communicate Analysis

This step involves synthesizing, documenting, and communicating results from the analyses. Doing so helps facilitate comparison of the options with consideration of key trade-offs and uncertainties.

Table 11: Risk-Informed Decision-Making Framework: Required and Suggested Practices for Step 2.4 Synthesize, Document, and Communicate Analysis

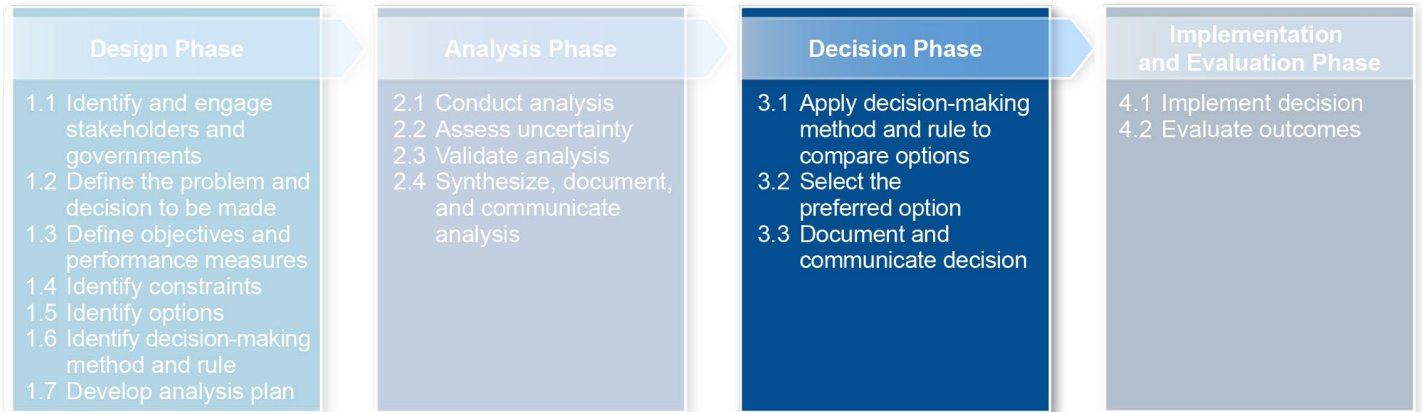
Required practices for the framework	Additional description and suggested practices
2.4A The agency should synthesize results from the analyses showing the estimated performance of each option with respect to each objective and any constraints, and then document and communicate these results in writing.	None identified.
2.4B To be useful for decision-making, these results should be presented in a way that facilitates consistent comparison of the relative performance of the options and exposes key trade-offs and uncertainties.	For example, the results may show whether some of the options are less well understood or certain than others.
2.4C Documentation of the analyses should describe the data inputs and assumptions used to characterize the options, the modeling methodology, the methods used to consider uncertainty, and any caveats relevant to the methodology and results.	None identified.
2.4D This information should be communicated in a way that is accurate, thorough, and that can be understood and accessed by decision-makers and various stakeholders and governments.	None identified.

Source: GAO. | GAO-24-107595

What is the Decision Phase of the framework?

The goal of the Decision Phase is to choose an option (or set of options) that meets constraints and achieves an acceptable balance of performance across the objectives. This phase involves making judgments about the worth of one objective, such as reducing risk, against that of another. In the Decision Phase, such judgments are made by applying the decision-making method and decision rule identified in the Design Phase to the credible technical information developed in the Analysis Phase. The Decision Phase consists of three steps (see fig. 6).

Figure 6: Decision Phase Steps of the Risk-Informed Decision-Making Framework for Environmental Hazards



Source: GAO. | GAO-24-107595

3.1 Apply Decision-making Method and Rule to Compare Options

This step involves carrying out the decision-making method identified during the earlier Design Phase. This allows the agency to apply the identified decision-making method to compare how the identified options each offer a different balance to achieving the objectives. The agency can systematically evaluate trade-offs—make judgments about how much of one objective to give up in exchange for gains in another.

Table 12: Risk-Informed Decision-Making Framework: Required and Suggested Practices for Step 3.1 Apply Decision-Making Method and Rule to Compare Options

Required practices for the framework	Additional description and suggested practices
<p>3.1A Using results of analyses, the agency should carry out the decision-making method to compare how well each option performs with respect to the objectives and to evaluate trade-offs among competing objectives.</p>	<p>In some decisions, an option may perform well with respect to one objective without coming at the expense of other objectives. However, for many decisions, the options will each offer a different balance across the objectives, requiring judgments to be made about how much of one objective to give up in exchange for gains in another. For example, judgments may need to be made about whether it is worth giving up the incremental human health protection offered by one option to achieve the reduced costs offered by another option.</p> <p>For some decision-making methods, such as multiattribute utility theory, this step may involve assigning weights to objectives as a way to incorporate decision-maker or stakeholder and governments preferences about the relative importance of the objectives. Surveys, workshops, and other structured tools and methods may be used to elicit an individual's or group's preferences and assign weights to objectives. To be useful and defensible, the weights should be assigned by considering concrete information about how well each option performs with respect to the objectives.^a</p>
<p>3.1B The decision-making method and decision rule should provide a basis for making such judgments and for identifying an option that provides the best balance across objectives.</p>	<p>None identified.</p>
<p>3.1C Some uncertainty will remain in the Decision Phase, because it is neither possible nor practical to reduce all uncertainty. Decision-making will likely need to proceed despite incomplete information about the exact way any of the options—if selected and implemented—would perform. To compare options under this remaining uncertainty, decision-makers should consider their willingness to accept the chance that an option will fail to perform as expected for any given objective.</p>	<p>Depending on the circumstances, decision-makers could also opt to revisit the value of obtaining more precise information before selecting an option, as described in the Analysis Phase. An agency's stance on risk; the potential consequences of an option failing to perform as expected; and any relevant regulatory, statutory, or budget constraints will likely influence which option is preferred.</p>

Source: GAO. | GAO-24-107595

^aAccording to Keeney (2002), weighting or prioritizing objectives in the abstract—without concrete information about how well each option performs with respect to the objectives—may not provide meaningful insight. Keeney provides an example of asking people to rank in importance: (1) economic costs of cleaning up a hazardous waste site, (2) potential human life loss or sickness due to the hazard, and (3) potential damage to the environment. He reports that almost everyone ranks (2), loss of life or sickness, as the most important. He then asks them to rank the importance of: (1) spending \$3 billion to clean up the site, (2) avoiding a mild 2-day illness to 30 people, and (3) destroying 10 square miles of mature forest. Almost everyone then ranks (1), cost, as most important. Keeney's example illustrates that people need to understand the specific amounts of gains and losses for each objective in order to make informed evaluations of trade-offs. Information about these specific amounts is not known until analyses have been conducted. See Ralph L. Keeney, "Common Mistakes in Making Value Trade-Offs," *Operations Research*, vol. 50, no. 6 (2002).

3.2 Select the Preferred Option

This step involves applying the decision-making method and decision rule to select the preferred option. By doing so, the agency should have strong support for its decisions.

Table 13: Risk-Informed Decision-Making Framework: Required and Suggested Practices for Step 3.2 Select the Preferred Option

Required practices for the framework	Additional description and suggested practices
<p>3.2A The agency should select an option to implement or, if necessary, return to an earlier phase or step within the framework to consider or gather additional information prior to making a final decision. The results of applying the decision-making method and decision rule should provide strong support for selecting an option.</p>	<p>If multiple decision-makers must agree on the final decision, then negotiation, mediation, or other conflict resolution methods may be necessary to achieve consensus. For example, a neutral, informed mediator can facilitate discussion among individuals about areas of and reasons for agreement and disagreement, thus increasing the possibility of consensus. In addition, formal, quantitative methods for evaluating trade-offs, as described above, can be useful in situations with multiple decision-makers because they produce results that readily identify areas of agreement and disagreement.</p>

Source: GAO. | GAO-24-107595

3.3 Document and Communicate Decision

This step involves documenting and communicating the decision. Doing so can help promote accountability by sharing information with stakeholders and governments on why and how the agency made the decision.

Table 14: Risk-Informed Decision-Making Framework: Required and Suggested Practices for Step 3.3 Document and Communicate Decision

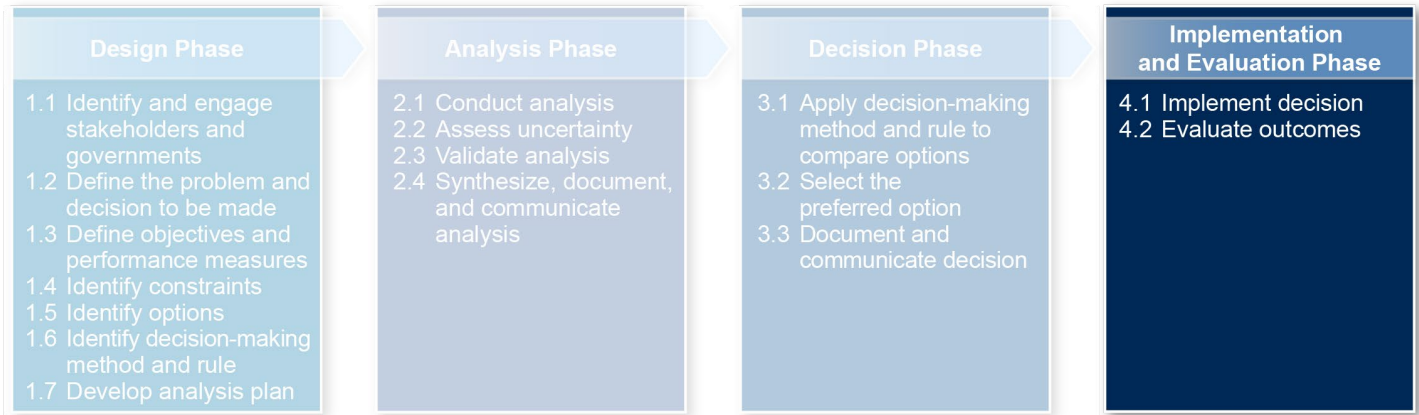
Required practices for the framework	Additional description and suggested practices
<p>3.3A The agency should communicate the decision and the rationale—including any trade-offs that were considered—to stakeholders and governments.</p>	None identified.
<p>3.3B This step should include communicating information about how uncertainty affected the decision.</p>	None identified.
<p>3.3C This step should include communicating about how and to what extent the results of the decision-making method and decision rule were used in making the decision.</p>	<p>For example, if the decision is inconsistent with the results of the decision-making method, then a discussion providing the justification would help ensure accountability.</p>

Source: GAO. | GAO-24-107595

What is the Implementation and Evaluation Phase of the framework?

The Implementation and Evaluation Phase is the final phase of the framework. This phase involves taking action to implement the selected option and then monitoring and evaluating the outcomes of the implemented decision to learn from the results (see fig. 7).

Figure 7: Implementation and Evaluation Phase Steps of the Risk-Informed Decision-Making Framework for Environmental Hazards



Source: GAO. | GAO-24-107595

4.1 Implement Decision

This step involves taking action to implement the decision—the option selected during previous phases of the framework.

Table 15: Risk-Informed Decision-Making Framework: Required and Suggested Practices for Step 4.1 Implement Decision

Required practices for the framework	Additional description and suggested practices
4.1A The agency should take action to implement the selected option.	None identified.
4.1B In implementing a decision, an agency should follow applicable leading practices, such as program and project management leading practices related to scope, cost, schedule performance, and use of independent reviews.	None identified.

Source: GAO. | GAO-24-107595

4.2 Evaluate Outcomes

This step involves monitoring and evaluating the outcomes of the implemented decision. Evaluating the decision using adaptive management methods can help promote learning and build capacity to make better decisions in the future.

Table 16: Risk-Informed Decision-Making Framework: Required and Suggested Practices for Step 4.2 Evaluate Outcomes

Required practices for the framework	Additional description and suggested practices
4.2A The agency should establish and follow a timeline to monitor and evaluate the outcomes of the implemented decision.	None identified.
4.2B The objectives used to assess the options in the Analysis and Decision Phases should also be used to evaluate the success of the selected option once it has been implemented.	None identified.
4.2C If evaluation results show that the implemented option is not performing as expected and is outside the bounds of acceptable outcomes, or if new information exists, then it is important to revisit the decision rather than continuing to invest resources in an option that is not working.	None identified.

Source: GAO. | GAO-24-107595

How GAO Did This Study

We developed the original risk-informed decision-making framework for [GAO-19-339, *Environmental Liabilities: DOE Would Benefit from Incorporating Risk-Informed Decision-Making into its Cleanup Policy*](#). To develop the original framework, we conducted a literature review of reports and studies on risk and decision-making in the context of environmental cleanup. The literature review included our prior reports on environmental cleanup, risk, and decision-making; reports from the National Academies; reports and studies from government agencies; and academic research. We gathered information from our literature review about essential steps within a risk-informed decision-making process, including information about why each step is important and who should perform each step. Based on the results of our literature review, we developed a draft framework of essential elements for making risk-informed cleanup decisions.

We then obtained expert input on the draft framework. We worked with the National Academies to select 15 experts and convene a 2-day meeting with those experts. We asked the experts to discuss topic areas including (1) whether the draft framework was logical, reasonable, and a valid representation of risk-informed decision-making; and (2) the applicability of the draft framework to actual cleanup decisions. Throughout the 2-day meeting, we summarized key points and themes, and we recorded and transcribed the experts' meeting to ensure that we accurately captured the experts' statements. Following the experts' meeting, we analyzed the transcript to characterize the experts' responses and to identify major themes related to the framework. We then revised the draft framework to incorporate themes from the literature and the experts' views.

To update the framework for this report, we clarified the application and scope of the framework. Because the literature we reviewed and expert input we obtained for the 2019 report was relevant not only to nuclear waste cleanup but also to other environmental hazards, we determined that the framework applies to risks posed by a wider array of environmental hazards. In addition, we updated terminology in the framework to align with relevant GAO work issued since 2019, such as [GAO-24-106014](#) on stakeholder and government engagement in the

context of environmental cleanup. We also added statements to help the reader understand the potential effects of implementing or not implementing the phases and steps in the framework.

Finally, we reformatted the content to distinguish between practices that are requirements for risk-informed decision-making and those that are suggestions for implementation. We defined required practices as those presented in the original framework using language such as “should” or “must.” We defined suggested practices as those presented in the original framework using language such as “may” or “for example.”

We conducted our work from June 2024 to September 2024 in accordance with all sections of GAO’s Quality Assurance Framework that are relevant to our objectives. The framework requires that we plan and perform the engagement to obtain sufficient and appropriate evidence to meet our stated objectives and to discuss any limitations in our work. We believe that the information and data obtained, and the analysis conducted, provide a reasonable basis for any findings and conclusions in this product.

List of Addressees

The Honorable Cathy McMorris Rodgers
Chair
The Honorable Frank Pallone, Jr.
Ranking Member
Committee on Energy and Commerce
House of Representatives

We are sending copies of this report to the appropriate congressional committees and other interested parties. In addition, the report is available at no charge on the GAO website at <https://www.gao.gov>.

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Endnotes

¹For a guide on analyzing federal actions to facilitate and promote resilience to natural disasters, see GAO’s Disaster Resilience Framework: GAO, *Disaster Resilience Framework: Principles for Analyzing Federal Efforts to Facilitate and Promote Resilience to Natural Disasters*, [GAO-20-100SP](#) (Washington, D.C.: Oct. 23, 2019).

²In this context, we define “objective” as an important outcome or consequence that could be affected by a decision.

³GAO, *Environmental Liabilities: DOE Would Benefit from Incorporating Risk-Informed Decision-Making into its Cleanup Policy*, [GAO-19-339](#) (Washington, D.C.: Sept. 18, 2019).

⁴GAO, *High-Risk Series: Efforts Made to Achieve Progress Need to Be Maintained and Expanded to Fully Address All Areas*, [GAO-23-106203](#) (Washington, D.C.: April 20, 2023). Our High-Risk List identifies government operations that are vulnerable to fraud, waste, abuse, and mismanagement or that need transformation to address economy, efficiency, or effectiveness challenges.

⁵Prior GAO reports that have used the risk-informed decision-making framework as a guide for evaluating federal decision-making processes include: GAO, *Federal Real Property: More Consistent Monitoring of Asbestos Could Improve Oversight*, [GAO-24-106324](#) (Washington, D.C.: Mar. 4, 2024); GAO, *Nuclear Waste Cleanup: DOE Needs to Address Weaknesses in Program and Contractor Management at Los Alamos*, [GAO-23-105665](#) (Washington, D.C.: July 19, 2023); GAO, *Hanford Cleanup: DOE Should Validate Its Analysis of High-Level Waste Treatment Alternatives*, [GAO-23-106093](#) (Washington, D.C.: May 24, 2023); GAO, *Nuclear Waste Cleanup: DOE Needs to Better Coordinate and Prioritize Its Research and Development Efforts*, [GAO-22-104490](#) (Washington, D.C.: Oct. 28, 2021); GAO, *Nuclear Waste Disposal: Actions Needed to Enable DOE Decision That Could Save Billions of Dollars*, [GAO-22-104365](#) (Washington, D.C.: Dec. 9, 2021); and GAO, *Lake Ontario-St. Lawrence River Plan: Improved Communication and Adaptive Management Strategy Could Help Address Stakeholder Concerns*, [GAO-20-529](#) (Washington, D.C.: July 23, 2020).

⁶For example, in 2020 we reported on the extent to which the process to develop a plan that sets regulatory rules and criteria for water releases from Lake Ontario into the St. Lawrence River was consistent with our framework for risk-informed decision-making. Water releases have the potential to cause environmental hazard situations, such as flooding and erosion. For more information, see [GAO-20-529](#).

⁷National Research Council of the National Academies, Committee on Risk-Based Approaches for Disposition of Transuranic and High-Level Radioactive Waste, *Risk and Decisions About Disposition of Transuranic and High-Level Radioactive Waste* (Washington, D.C.: The National Academies Press, 2005).

⁸For example, a decision that will affect a large geographic area over a long period of time likely calls for substantial efforts to involve stakeholders and use of sophisticated techniques to assess and quantify data uncertainty. Conversely, for a less consequential decision, a light approach to stakeholder involvement and use of existing datasets may be more practical and in the taxpayer's interest.

⁹The rationale for our presentation of the phases and steps in our framework is that it reflects the analytic-deliberative paradigm set forth by the National Academies in its 1996 report, *Understanding Risk: Informing Decisions in a Democratic Society*. This report concluded that defensible decisions involving risk require the effective and ongoing integration of analysis and deliberation. In our framework, the Design Phase emphasizes collective and intentional consideration of the values driving a decision, the Analysis Phase emphasizes analysis of empirical evidence, and the Decision Phase involves combining deliberation with analytical results to arrive at a decision. See National Research Council of the National Academies, Committee on Risk Characterization, *Understanding Risk: Informing Decisions in a Democratic Society* (Washington, D.C.: The National Academies Press, 1996).

¹⁰In September 2024, we reported on leading practices for engaging stakeholders and governments in the context of environmental cleanup. The leading practices are consistent with the requirements described in "1.1 Identify and Engage Stakeholders and Governments" and provide additional information about how agencies can meaningfully engage stakeholders and governments on environmental cleanup issues, decisions, and actions. See: GAO, *Nuclear Waste Cleanup: Adopting Leading Practices Could Strengthen DOE's Engagement with Stakeholders and Governments*, [GAO-24-106014](#) (Washington, D.C.: Sept. 9, 2024).