



Sampling and Analysis Plan Template Tool for Addressing Environmental Contamination by Pathogens

User Guide

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U.S. Environmental Protection Agency
Cincinnati, Ohio 45268

Disclaimer

The U.S. Environmental Protection Agency (EPA), through its Office of Research and Development, funded and managed the content for the document described here under Contract No. EP-C-17-024 with General Dynamics Information Technology (GDIT). It has undergone the Agency's review process prior to approval for publication. Note that approval does not necessarily signify that the contents reflect the views of the Agency. Mention of trade names, products, or services does not convey official EPA approval or endorsement.

Questions concerning this document or its application should be addressed to:

Erin Silvestri, MPH
U.S. Environmental Protection Agency
National Homeland Security Research Center
26 W. Martin Luther King Drive, MS NG16
Cincinnati, OH 45268
513-569-7619
Silvestri.Erin@epa.gov

Foreword

EPA is charged by Congress with protecting the Nation's land, air and water resources. Under a mandate of national environmental laws, the Agency strives to formulate and implement actions leading to a compatible balance between human activities and the ability of natural systems to support and nurture life. To meet this mandate, EPA's research program is providing data and technical support for solving environmental problems today and building a science knowledge base necessary to manage our ecological resources wisely, understand how pollutants affect our health, and prevent or reduce environmental risks in the future.

The Center for Environmental Solutions and Emergency Response (CESER) within the Office of Research and Development (ORD) conducts applied stakeholder-driven research and provides responsive technical support to help solve the Nation's environmental challenges. The Center's research focuses on innovative approaches to address environmental challenges associated with the built environment. We develop technologies and decision-support tools to help safeguard public water systems and groundwater, guide sustainable materials management, remediate sites from traditional contamination sources and emerging environmental stressors, and address potential threats from terrorism and natural disasters. CESER collaborates with both public and private sector partners to foster technologies that improve the effectiveness and reduce the cost of compliance, while anticipating emerging problems. We provide technical support to EPA regions and programs, states, tribal nations and federal partners, and serve as the interagency liaison for EPA in homeland security research and technology. The Center is a leader in providing scientific solutions to protect human health and the environment.

The User Guide and corresponding Template Tool are provided to facilitate generation of an outline that can be used to develop sampling and analysis plans (SAPs) in support of exercises, research studies or remediation activities following a contamination incident involving pathogens in environmental matrices. The guide and template are applicable for phases of a contamination incident in which EPA is responsible for conducting sampling and analysis activities, and provide a general description of the types of information and sections that would be included in a SAP for sampling and analysis activities associated with environmental matrices potentially containing pathogens. The fillable Template Tool is meant to be used as a "ready-to-go" outline for creating a SAP in EPA-report format. The template also facilitates capturing information associated with the data quality objective (DQO) process, including generation of a DQO summary.

Gregory Sayles, Director
Center for Environmental Solutions and Emergency Response

Acronyms

APHL	Association of Public Health Laboratories
BSL	biosafety level
CDC	U.S. Centers for Disease Control and Prevention
CFU	colony forming unit
COC	chain of custody
DMP	data management plan
DOT	U.S. Department of Transportation
DQI	data quality indicator
DQO	data quality objective
EPA	U.S. Environmental Protection Agency
ERLN	Environmental Response Laboratory Network
FBI	Federal Bureau of Investigation
FEM	Forum on Environmental Measurement
FEMA	Federal Emergency Management Agency
FERN	Food Emergency Response Network
GDIT	General Dynamics Information Technology
GPS	Global Positioning System
HASP	Health and Safety Plan
HSMMMD	Homeland Security and Materials Management Division
IATA	International Air Transport Association
ICLN	Integrated Consortium of Laboratory Networks
ID	identification
LRN	Laboratory Response Network
NRF	National Response Framework
OSHA	Occupational Safety and Health Administration
PPE	personal protective equipment
QA	quality assurance
QAPP	Quality Assurance Project Plan
QC	quality control
RCRA	Resource Conservation and Recovery Act
SAP	Sampling and Analysis Plan
SOP	Standard Operating Procedure
WLA	Water Laboratory Alliance
WMP	Waste Management Plan

Executive Summary

This User Guide is intended to supplement and provide general best practices for using the U.S. Environmental Protection Agency's (EPA's) [Sampling and Analysis Plan Template Tool for Addressing Environmental Contamination by Pathogens](#) ("Template Tool").

The User Guide and corresponding Template Tool are provided to facilitate generation of an outline that can be used to develop sampling and analysis plans (SAPs) in support of exercises, research studies or remediation activities following a contamination incident involving pathogens in environmental matrices. The guide and template are applicable for phases of a contamination incident in which EPA is responsible for conducting sampling and analysis activities, and provide a general description of the types of information and sections that would be included in a SAP for sampling and analysis activities associated with environmental matrices potentially containing pathogens. The fillable Template Tool is meant to be used as a "ready-to-go" outline for creating a SAP in EPA-report format. The template also facilitates capturing information associated with the data quality objective (DQO) process, including generation of a DQO summary.

Please note that the Template Tool does not replace a detailed incident-specific SAP or SAP requirements that might be in place for a particular EPA region, EPA office, or State or Local agency. Prior to its use, please check to ensure that there are not established contractor or Agency requirements for using a specified format for data collection and reporting.

Product Development Quality Assurance

The information in this document is based on secondary sources, including peer reviewed scientific manuals; federal agency websites; peer reviewed publications and regulations; and nationally-recognized scientific, technical or response organizations. Citations are provided throughout the document. Full citations and/or access to each source used are provided in the references section.

The document completed several review cycles prior to publication including EPA project lead review, internal EPA technical review, Homeland Security and Materials Management Division (HSMMD) quality assurance and technical edit reviews, external technical review, and HSMMD management reviews. All comments from reviewers have been tracked and are maintained by EPA and General Dynamics Information Technology (GDIT), along with the revisions and adjustments made to address the comments.

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Introduction

Following an intentional or unintentional wide-area release of an environmentally persistent pathogen, remediation of contaminated areas might be required to protect human health and the environment. Remediation can include efforts to determine the extent and location of contamination (site-characterization) and whether decontamination efforts were effective. A well-defined and thorough sampling and analysis plan (SAP) needs to be developed and implemented to collect data that are suitable for decision-making and/or determinations of existing conditions. The SAP defines sample collection and analysis, resulting in data that can be used by the Incident Command, local health departments, decontamination teams, decision-makers and attorneys. The decisions and actions taken rely on the quality of the data, and the SAP should include consideration of data quality objectives (DQOs), which are used to ensure that collected environmental data are of known and documented quality for the intended use.

This User Guide is intended to supplement and provide general best practices for using EPA's [Sampling and Analysis Plan Template Tool for Addressing Environmental Contamination by Pathogens](#) (referred to as the "Template Tool").

This document is divided into the following major sections supporting the U.S. Environmental Protection Agency's (EPA's) Template Tool:

- Part I:** Instructions for **General Use** of the Template Tool
- Part II:** **Section-by-Section Instructions** for use of the Template Tool

This User Guide and its corresponding Template Tool are applicable to phases of a contamination incident in which EPA is responsible for conducting sampling and analysis activities. Together, they provide a general description of the types of information and sections that would be present in a SAP that supports activities involving sampling and analysis of environmental matrices potentially containing pathogens. The fillable Template Tool is meant to be used as a "ready-to-go" outline for creating a SAP in EPA-report format. The template also facilitates capturing information associated with DQOs, including generation of a DQO summary.

Please note that the Template Tool requires site or incident-specific information and does not replace a detailed incident-specific SAP or SAP requirements that might be in place for a particular EPA region, EPA office, or state or local agency. Prior to its use, please check to ensure that there are not established contractor or Agency requirements for using a specified format for data collection and reporting.

The User Guide and Template Tool are not intended to establish the detailed information that would be included in the following:

- Quality Assurance Project Plan (QAPP)
- Health and Safety Plan (HASP)
- Data Management Plan (DMP)
- Waste Management Plan (WMP)

I. General Use Instructions




[Adobe Acrobat Reader DC](#) software is needed for viewing and use of this template.

Viewing the document can be improved by the following:

- Go to Edit > Preferences.
- Select Page Display on the left.
- Clear the check box for **Enhance thin lines** (if it is checked by default, turn it off).
- Save your settings (Click “OK”).
- Now view the **PDF** – the **table borders** should display.

Viewing the navigation bar:

When initially opened, the template defaults to a view of the Table of Contents (TOC)/Bookmarks on the left-hand side of the screen. Clicking on the TOC/Bookmarks sections allows users to navigate to different sections of the template. Clickable icons are also available on the far left, to allow users access to:

- Table of Contents (TOC)/Bookmarks tab 
- Page-by-page view 
- List of files that have been attached by the user 

Entering text:

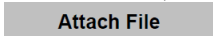
The template is set to a specific size, number of pages and Table of Contents that cannot be changed.


- As a result of the fixed size, all fields and pages will print out in a final report, including those that are blank. To avoid confusion, users are encouraged to select or enter “N/A” in text fields rather than leaving fields blank.
- The text fields in the template are also a fixed size. In cases where a user enters more text than the allotted space, the font size will automatically decrease to accommodate.

Drop-down lists:

All drop-down lists in the template include an option to select “N/A.” Users are encouraged to select this option rather than leaving a field without a selection. This will provide an indication that the field was not missed unintentionally.


Attaching/Deleting files:

The template includes several sections that allow users to attach a file in addition to, or instead of, adding text. Files are attached by clicking on an “Attach File” button  located below the text field. Clicking this button will allow a user to browse their hard drive to find and attach a file.

- Once attached, the name of the file will appear in the list of files that can be viewed by selecting the paper clip icon  in the navigation bar on the left-hand side of the screen. Files can be accessed using this listing.
- A text field is provided under each “Attach File” button, in which the user should provide the name of the file(s) attached to that location. This will allow users to associate and access attached files that correspond to a particular section of the document.

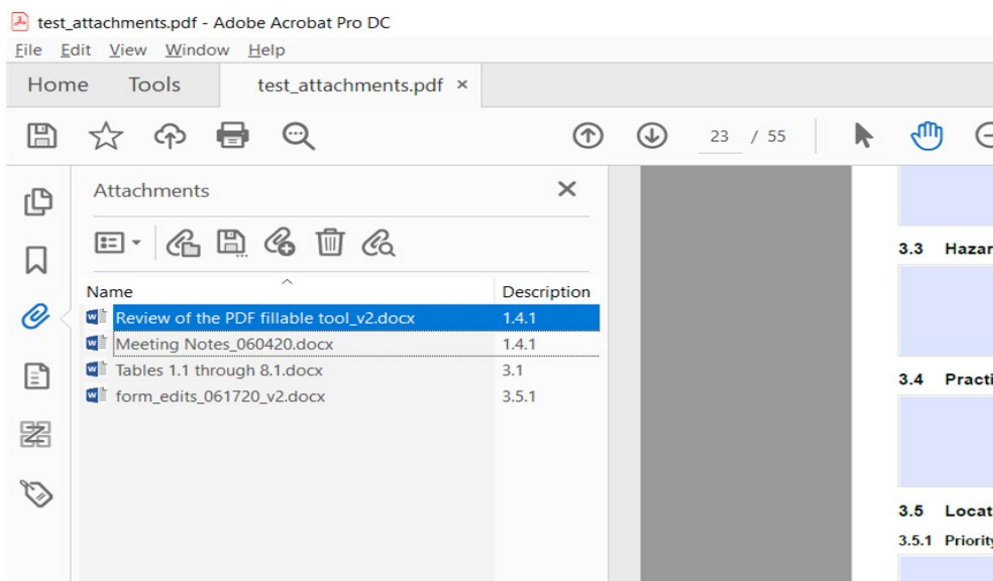
To delete a file, click on “Comment” at the top of the navigation bar that appears on the right-hand side of the screen. Once opened, select the file to be deleted and right click on the ellipse (●●●) that appears to the upper right. Select “Delete.”

Viewing and navigating attached files:

A list of files that have been attached by a user can be viewed by selecting the paper clip icon  in the navigation bar. Hovering over a file name will provide a description that can be edited to provide a page or section number location to which the file was attached.

A user can do the following to sort and arrange their attachments:

- In the attachments panel, right-click on the attachment in question.
- Select “Edit Description.”
- Type in the chapter number (or page number) of the corresponding attachment.
- With this option, you can also sort by description, so if the user attaches a document out of order, the template will automatically arrange them in numerical order in the attachments pane:



II. Section-by-Section Instructions

NOTE: All tables and fields that are unused (blank) in this document will be retained and printed out in the final report. Users are encouraged to enter “N/A” in text fields or select “N/A” in drop-down bars rather than leaving fields blank.

Cover Page

Text Entry: Click in the fields to enter text for the following:

- The title of your Sampling and Analysis Plan (SAP)
- The name of the individual(s) who will be the Technical Lead
- The name of the individual(s) or party responsible for preparing the template report

Date: Click on the date field to select date of preparation from pop-up calendar.

Sampling and Analysis Plan Approvals (page i)

Text Entry: Click in the fields to enter text for the following:

- SAP Title
- Project Numbers (Enter Project Number, Task Number and/or Research Effort Number)
- Other Tracking IDs (Enter other identification (ID) numbers associated with the SAP)

EPA Approvals (page i)

Text Entry: If you are tasked to approve a plan:

- Click on the appropriate field to type your Name and Title.
- Click on the corresponding Signature/Date field:
 - If you have an existing Digital ID, follow the steps to enter your digital signature
 - If you do NOT have an existing Digital ID, click “Configure New Digital ID” and follow the steps to create your digital signature

Extramural / Contractor Approvals (page i)

Text Entry: If you are tasked to approve a plan:

- Click on the appropriate field to type your Name and Title.
- Click on the corresponding Signature/Date field:
 - If you have an existing Digital ID, follow the steps to enter your digital signature
 - If you do NOT have an existing Digital ID, click on “Configure New Digital ID” and follow the steps to create your digital signature

Distribution List (page ii)

Text Entry: Click in the fields to enter the following information for individuals who should receive a copy of the template report:

- Name
- Email
- Organization

Revision History (page iii)

Text Entry: Click in the fields to enter text for the following:

- Status: Provide the status of the template report (e.g., in progress; awaiting information regarding pathogen(s); awaiting approval; approved).
- Revision #: Provide the revision number of the current report.
- Date: Click on the date field to select date of preparation from pop-up calendar.
- Point of Contact: Provide the name and contact information for the individual(s) responsible for the template report.
- Revision: Provide an explanation of the current revision.

Acronym List (page iv)

Text Entry: Click in the fields to enter text for the following:

- Acronym: List the acronyms that are used in the template report.
- Meaning: Provide the definition or meaning associated with each acronym used.

Table of Contents

The Table of Contents cannot be changed and acts no differently than the Bookmarks for the document. Clicking on the text allows the user to navigate to different sections of the PDF.

1.0 Background

The background section provides overarching information for the data collection effort, including a general description of the types of data to be collected, the sampling phase, what is currently known about the pathogen(s), and the history of the incident including site condition and lines of evidence. Use this section to define and organize information about the current understanding of the problem, and to identify key questions and expected outcomes.

1.1 General Data Collection Activity Description

Provide a description of the data collection activity, including a brief discussion of the contamination incident and the type of environmental sampling to be conducted.

1.2 Sampling Phase and Pathogen

Provide a brief description of the purpose of the sampling and analysis activities, the applicable sampling phase(s), pathogen(s) of interest, and type of media to be collected. For example:

- **Exercise:** This SAP is intended to provide associated Quality Assurance/Quality Control (QA/QC) measures and data quality objectives (DQOs) for an agency exercise simulating [*User inserts Sampling Phase*] environmental sampling and analysis activities to be conducted in response to a simulated contamination incident involving [*User inserts pathogen name*] in [*User inserts applicable matrices*].
- **Research Study:** This SAP is intended to provide associated quality assurance/quality control (QA/QC) measures and DQOs for field research involving environmental sampling and analysis activities for [*User inserts pathogen name*] in [*User inserts applicable matrices*] that could be used for [*User inserts Sampling Phase*] of a contamination incident.
- **Contamination Incident:** This SAP is intended to provide associated QA/QC measures and DQOs for collection of environmental samples and sample analysis activities during the [*User inserts Sampling Phase*] of a contamination incident involving [*insert pathogen name*] in [*inserts applicable matrices*].

Table 1.1 is used to characterize each pathogen targeted for the data collection effort. Two tables are provided to allow users to enter information for multiple pathogens. The table provides drop-down selection items for pathogen, pathogen type, and potential exposure pathway fields, and a yes-or-no selection option to indicate whether a pathogen is a U.S. Centers for Disease Control and Prevention (CDC) Select Agent. Users enter text to provide information related to pathogen persistence/stability and fate and transport.

Table 1.1
Pathogen Characterization

Pathogen	Pathogen Type	CDC Select Agent?	Potential Exposure Pathways	Fate and Transport	Persistence/ Stability
<i>Select from drop down</i>	<i>Select from drop down</i>	<i>Select Yes or No</i>	<i>Fill in</i>	<i>Fill in</i>	<i>Fill in</i>

- Pathogen: Select the pathogen(s) of concern from the items in the two drop-down bars provided. Each drop-down bar provides access to a list of the pathogens that are included in EPA's [Selected Analytical Methods for Environmental Remediation and Recovery \(SAM\)](#) (U.S. EPA 2017). Viruses are included in the first drop-down list; bacteria, protozoa and helminths are included in the second (italicized) drop-down list.

Adenoviruses	<i>Bacillus anthracis</i>
Astroviruses	<i>Baylisascaris procyonis</i>
Caliciviruses: Noroviruses	<i>Brucella</i> spp.
Caliciviruses: Sapovirus	<i>Burkholderia mallei</i>
Coronaviruses	<i>Burkholderia pseudomallei</i>
Hepatitis E virus	<i>Campylobacter jejuni</i>
Influenza H5N1 virus	<i>Chlamydomytila psittaci</i>
Picornaviruses: Enteroviruses	<i>Coxiella burnetii</i>
Picornaviruses: Hepatitis A virus	<i>Cryptosporidium</i> spp.
Reoviruses: Rotavirus (Group A)	<i>Entamoeba histolytica</i>
Other (with option to fill in)	<i>Escherichia coli</i>
	<i>Francisella tularensis</i>
	<i>Giardia</i> spp.
	<i>Legionella</i>
	<i>Leptospira</i>
	<i>Listeria monocytogenes</i>
	<i>Naegleria fowleri</i>
	<i>Salmonella</i> (non-typhoidal)
	<i>Salmonella</i> Typhi
	<i>Shigella</i> spp.
	<i>Staphylococcus aureus</i>
	<i>Toxoplasma gondii</i>
	<i>Vibrio cholerae</i>
	<i>Yersinia pestis</i>
	Other (with option to fill in)

- Pathogen Type: Select the pathogen type from the following items in the drop-down bar provided (Note: Pathogen types for the pathogens included in the template are identified in EPA's [SAM](#); accessed July 27, 2021):
 - Bacteria
 - Virus
 - Protozoa
 - Helminth
- CDC Select Agent: Click on either the Yes or No radio button to indicate whether the pathogen(s) of concern is a Select Agent. A [List of Select Agents](#) is available through the U.S. Centers for Disease Control and Prevention (CDC)_(accessed July 27, 2021).
- Fate and Transport: Provide information, if known, regarding the anticipated or the potential fate and transport of the pathogen at the site. Consider site conditions and the potential for the pathogen to transport (whether in viable, non-viable, or spore form) through air, surface water, groundwater, soil, surfaces and vegetation.

- Potential Exposure Pathway: Select the potential exposure pathway(s) from the following items in the drop-down bar:
 - N/A (Note: If no information is available, select N/A to avoid leaving the field blank)
 - Direct contact
 - Ingestion
 - Inhalation
 - N/A

- Persistence/Stability: Provide information regarding the known or the potential persistence and stability of the pathogen (in both viable and non-viable forms) in the environmental conditions and sample matrices at the site.

1.3 Goal

Details regarding the goal(s) of the data collection effort should be provided in the QAPP. Use this section of the Template Tool to identify and describe the overall goal(s) and a summary of the associated DQOs. Include a description of the corresponding decision unit(s) (see Section 3.6) and any available action levels and/or clearance goals for the target pathogen(s). Use Table 1.2 to link the goal(s) to the intended uses of the data that will be collected and to the corresponding outcomes and determination statement(s). [Note: The appendix of the Template Tool is designed to provide an automatically generated summary table to access information that has been entered into the template and has been organized to address project DQOs.]

Table 1.2 provides four identical rows, each containing a drop-down box for users to select between intended uses of the collected data for decision-making or estimation purposes. In each case, users provide text to identify principal questions and decision or estimation statements. Example principal study questions, and decision or estimation statements, are provided below. Users should focus on this information and consider the decision unit(s) (described in Section 3.6) to which they apply.

Table 1.2
Defining Intended Use, Outcomes, and Determination Statements

Intended Use of the Data	Principal Questions	Decision Statement(s) or Estimation Statement(s)
<i>Select from drop down</i>	<i>Fill in</i>	<i>Fill in</i>
Example: Decision	What locations have been contaminated in the decision unit(s)?	Determine whether [<i>pathogen</i>] is detected in and requires removal from the decision unit(s).
Example: Decision	What sample matrices have been contaminated in the decision unit(s)?	Determine whether [<i>pathogen</i>] is detected in and requires removal from soil in the decision unit(s).
Example: Estimation	What is the quantity of contamination present in the water and soil sample matrices in the decision unit(s)?	Determine the average concentrations of contamination in each matrix, including confidence limits and accounting for non-detects.
Example: Estimation	What is the concentration of [<i>pathogen</i>] within the first 5-cm depth of soil?	Estimate the average measure of [<i>pathogen</i>] concentrations within the first 5-cm depth of soil over time, including confidence limits and accounting for non-detects.

- Intended Use of the Data: Identify the intended use of the data from the following options provided in the drop-down bar:
 - N/A (Note: If information is not available, select N/A to avoid leaving this field blank)
 - Decision-making
 - Estimation

Note: Whether or not data are generated during environmental surveys/screening assessments, during preliminary analyses, or during confirmatory identification and quantification of contamination, there are two primary types of intended uses of collected data: decision-making and estimation. Use of data for decision-making usually occurs during regulatory monitoring, emergency response, and other contexts where decisions will be made regarding action(s) that will be taken (e.g., site clearance versus continued decontamination and/or sampling activities). Uses of data for estimation purposes include supporting the development of regulatory levels or decision criteria, and other determinations that provide a quantitative result (e.g., pathogen concentration or specific location of contamination) on which a decision could be based. Estimation results, for example, can be used to support “limits” against which a decision can or will be made (e.g., site cleanup goal that can be used to determine whether additional remediation and/or sampling is needed).

The following guidance for determining the intended use of collected data is adapted from EPA’s [Guidance on Systematic Planning Using the Data Quality Objectives Process, EPA QA/G-4 \(U.S. EPA 2006b\)](#):

- Are there specific actions that will be guided or determined based on the results of data collection efforts? If so, this is likely to be a decision problem.
- Is this a research study that is trying to advance the state of knowledge by characterizing environmental conditions or trends? If so, this is likely to be an estimation problem.

- Is this a study that will provide information about environmental conditions or trends to support the framing of regulations? If so, this is likely to be an estimation problem, although care should be taken to identify potential decisions that the study will directly support.
 - Is this an environmental survey that is attempting to characterize levels of exposure for specific populations or areas? If so, and there are no existing statutes or regulations that will be applied to the results, then this is likely to be an estimation problem. However, if the exposure levels will be compared to acceptable risk-based thresholds, then this could be a decision problem.
- Principal Questions: Identify the principal questions you plan to answer with the results of the SAP activities. These questions should support and inform the efforts to meet the goal(s).
 - Decision Statement(s) or Estimation Statement(s): Provide decision statements (decisions to be made that will inform the selection of an alternative action) and/or estimation statements (what it is that needs to be estimated along with key assumptions).

1.4 Site Information and History

Use this section to provide information about the history of the site, site conditions, and any data that have been collected previously (e.g., data collected during the initial response to identify the pathogen).

1.4.1 Site Condition

Provide the address or location of the contaminated site, along with information regarding the areas known to be impacted and what surrounds the impacted area/location. At a minimum, the following information, where available, should be included:

- Site location and address
- Description of indoor and outdoor locations
- Existing hazards
- Known impacted surrounding areas/locations
- Impacted or potentially impacted populations
- Boundaries that have been set up around the contamination
- Relevant weather information

This section also includes a database field that allows users to attach files that contain pertinent information, such as site maps, datasets and contamination plumes. (See Part I for instructions on attaching files.)

1.4.2 Prior Actions Taken on the Site

Provide information regarding what is known about any prior actions taken at the site, such as site mitigation efforts, and impact and/or hazard assessments.

1.4.3 Lines of Evidence

Describe any lines of evidence that might be used to support decision-making during data collection. Several different types of information or data might be needed to understand and support decisions related to issues, such as quality control (QC), determination of the need for additional remediation, or assessing site-specific conditions. Lines of evidence might include pathogen fate and transport modeling and/or previously collected data such as environmental sampling results, epidemiology data, animal monitoring data, data collected during the initial response phase by first responders or law enforcement, and clinical data collected for public

health assessments. When being used for research or as an exercise, this information can be either historic (e.g., published research) or simulated for the purposes of the exercise.

This section also includes a field that allows users to attach files that contain pertinent information, such as datasets, contamination plumes and/or toxicological impacts. (See Part I for instruction on attaching files.)

2.0 Agency Coordination and Key Personnel

Section 2.0 focuses on information needed to facilitate the coordination of agencies, advisory groups and individuals involved in the data collection effort. This section allows users to identify key personnel and laboratory resources. It also allows users to import an organizational chart, if available, to illustrate communication and activity responsibilities. (See Part I for instructions on attaching files.) Note: Agencies, organizations and personnel involved in data collection will be identified in the QAPP.

2.1 Roles and Responsibilities of Key Agencies, Advisory Groups, and Laboratories

Use Sections 2.1.1 through 2.1.7 to describe the roles of and coordination between each of the agencies, advisory groups and laboratories that will be participating in the data collection effort. Note: If an organization listed in Sections 2.1.1 to 2.1.7 is not participating in the sampling and analysis activities, “Not applicable” or “N/A” should be entered to avoid leaving a blank space in your report.

The U.S. Department of Homeland Security and U.S. EPA [Draft Planning Guidance for Recovery Following Biological Incidents](#) (U.S. DHS and U.S. EPA 2009) describes a general risk management framework for decision-makers in planning and executing activities required for response and recovery from a biological contamination incident. Appendix 3 of the U.S. DHS and U.S. EPA document outlines federal agency roles and responsibilities in response to biological contamination (U.S. DHS 2017).

2.1.1 Federal Bureau of Investigation (FBI)

If applicable, describe the role the Federal Bureau of Investigation (FBI) will play in the data collection and analysis effort. According to the National Response Framework (NRF) (U.S. DHS 2019), the FBI is the lead federal agency for criminal investigation of a suspected intentional (e.g., criminal or terrorist-related) contamination incident, and local law enforcement usually notifies the FBI of potential such incidents. Other methods of notification can be through local or state public health departments, fire department hazardous material responders, local search warrants where "questionable items" are observed by local law enforcement officers, and the FBI Joint Terrorism Task Force officers.

If initial laboratory results indicate a presumptive positive presence of the pathogen and/or the circumstances of the incident suggest that a credible threat exists, the FBI will commence an investigation, including the collection of evidence. The main objectives for evidence collection are to: 1) obtain biological material for further microbiological, chemical, physical and forensic analysis for attribution purposes, 2) locate a dissemination device, and 3) obtain other traditional forensic evidence. If it is a known or suspected biological incident, the FBI will coordinate with the Incident Command (IC) and other entities having jurisdiction but will be the lead agency for the criminal investigative response. As part of their investigation, the FBI might work with response partners to: collect information on the biological agent, including specific genetic, physical, and chemical properties; search for additional items of evidence; establish a possible source of the contamination; and determine the perpetrator(s).

2.1.2 Centers for Disease Control and Prevention (CDC)

Describe the role the Centers for Disease Control and Prevention (CDC) will play in data collection and analysis. Under the National Response Framework (NRF) (U.S. DHS 2019), the U.S. Department of Health and Human Services, which includes CDC and other human health service agencies, has the responsibility for public health and medical services. This responsibility provides the mechanism for coordinated federal assistance to supplement state, local, tribal, and territorial resources in response to a public health and medical emergency. The CDC engages in all phases of a biological incident. The CDC's involvement might include:

- Conducting epidemiologic assessments and surveillance to identify individual cases and the populations at risk, and to determine the source of exposure
- Providing laboratory support for the identification, confirmation, characterization, and drug susceptibility of the biological agent
- Conducting environmental evaluations to support epidemiological and surveillance activities and to estimate the extent of contamination
- Providing guidance on identification, diagnosis, and clinical management of human cases
- Providing technical assistance to state, local, tribal, territorial, federal and international partners
- Disseminating key public health and safety messages to the public to provide timely, accurate, clear, consistent, credible, and easily accessible information relevant to the information needs of all stakeholders

2.1.3 State and Local Public Health Agencies

Describe the role state and local public health agencies will play in data collection and analysis. State public health programs have primary responsibility for protecting the health and welfare of the public under their jurisdiction. These programs vary considerably in the nature and scope of the public health services they provide. State governments are responsible for responding to a public health emergency and play certain key roles in preparedness and response. Except for the largest metropolitan public health departments, local public health officials tend to rely on state personnel and capacity for a number of key functions, including providing advanced laboratory capabilities and capacity, providing epidemiological expertise, and serving as a conduit for federal assistance. When the resources of state and local authorities are overwhelmed, federal assistance can be requested by the affected state.

2.1.4 Other Federal, State or Local Agencies

Describe the role other federal, state or local agencies will play in the data collection effort.

2.1.5 Laboratory Response Network (LRN)

Describe the role the CDC Laboratory Response Network (LRN) will play in data collection and analysis. The CDC LRN is an integrated network of laboratories that can respond quickly to biological, chemical, and radiological threats through training, rapid testing and timely notification. It is comprised of approximately 160 laboratories across the United States and several foreign countries, and includes over 100 biological laboratories. It is important to consider that, depending on the incident of contamination, LRN laboratories might be committed to prioritizing analysis of clinical samples and have limited availability to handle environmental samples. The LRN can be contacted via email at LRN@cdc.gov (accessed July 27, 2021). LRN member laboratories and their contact information can be obtained from the LRN Program Office, accessible through the [CDC Emergency Operations Center](#) (accessed July 27, 2021). Use of multiple LRN laboratories can provide sample surge capacity when dealing with many samples, and the LRN Program Office will work with the Incident Commander to coordinate sample distribution throughout the LRN. Each LRN laboratory is designated as either a national,

reference or sentinel laboratory, depending on the types of tests the laboratory can perform and how it handles infectious agents to protect workers and the public.

- LRN national laboratories have resources to handle highly infectious agents and the ability to identify specific agent strains. They are responsible for specialized strain characterizations, bioforensics, select agent activity, and handling highly infectious biological agents.
- LRN reference laboratories can perform tests to detect and confirm the presence of certain biological agents. Reference laboratories are limited in the types of sample that can be accepted and are responsible for investigation and/or referral of specimens. This allows local authorities to respond quickly to emergencies.
- LRN sentinel laboratories provide routine diagnostic services, rule-out, and referral steps in agent identification. If unable to rule out the presence of a biological threat agent, sentinel labs can package and refer specimens to an LRN reference laboratory.

2.1.6 Environmental Response Laboratory Network (ERLN)

Describe the role the Environmental Response Laboratory Network (ERLN) will play in data collection and analysis. EPA's [ERLN](#) (accessed July 27, 2021) network is part of the Interagency Contract Laboratory Network (ICLN). The ERLN consists of federal government, state government, water utilities, and commercial laboratories capable of performing environmental sample analyses for chemical, biological, and radiochemical contaminants to support EPA's homeland security responsibilities. The ERLN's mission is to provide reliable analytical data for environmental samples of known and documented quality to federal, state, and local decision-makers. Such data can then be used to mitigate and recover from releases of toxic industrial chemicals, chemical warfare agents, biological agents, and radiochemical contaminants in environmental matrices collected in support of homeland security incidents. In addition to its own resources, the ERLN leverages other networks' capabilities to support responses related to a biological threat release. In the case of the ERLN, it is important to consider that many of the laboratories handling biological samples are also in the CDC LRN and, depending on the incident, might be committed to prioritizing analysis of clinical samples.

2.1.7 Other Laboratories

Describe the role other laboratories will play in the data collection and analysis effort. In addition to the laboratory networks noted in Section 2.1.5 and 2.1.6, laboratories might include those in one or more of the following:

- [The Integrated Consortium of Laboratory Networks](#) (ICLN; accessed July 27, 2021): The ICLN is a partnership between nine federal agencies (Department of Defense, Department of Agriculture, Department of Energy, Department of Health and Human Services, Department of Homeland Security, Department of Interior, Department of Justice, Department of State, and the EPA) to provide a federally coordinated system of laboratory networks for obtaining timely, credible, and interpretable data in support of surveillance, early detection, and effective consequence management for acts of terrorism and other major incidents requiring laboratory response capabilities. Examples of laboratory networks included in the ICLN and discussed in this User Guide are the ERLN, LRN and Food Emergency Response Network (FERN).
- EPA's [Water Laboratory Alliance](#) (WLA; accessed July 27, 2021): EPA's WLA is part of the ERLN and is focused on providing the nation's water sector with an integrated nationwide network of laboratories with the analytical capability and capacity to respond to intentional and unintentional drinking water contamination incidents. The WLA structure consists of three tiers of laboratories: sentinel, confirmatory and reference. Sentinel laboratories perform

routine monitoring and surveillance to rule out or refer samples to confirmatory laboratories for further analysis. Confirmatory laboratories perform rapid, high-confidence presumptive and confirmatory identification analyses, and generally have facilities with a biosafety level (BSL) of either 2 or 3. Reference laboratories provide definitive characterization of agents and attribution of the source. These laboratories have facilities with a BSL of either 3 or 4.

- [Food Emergency Response Network](#) (FERN; accessed July 27, 2021): FERN integrates the nation's food-testing laboratories at the local, state and federal levels into a network that can respond to emergencies involving contamination of food. The FERN structure is organized to ensure federal and state interagency participation and cooperation in its formation, development and operation. The FERN plays critical roles related to food security and defense, including prevention, preparedness, response and recovery; and provides training, proficiency testing, method development validation, surveillance, electronic communication, and laboratory outreach/cooperative agreements.
- [Association of Public Health Laboratories](#) (APHL; accessed July 27, 2021): The APHL supports the role of public health laboratories in shaping national and global health objectives. It promotes policies, programs and technologies that assure continuous improvement in the quality of laboratory practice and health outcomes. A membership must be purchased to access most APHL publications and services.

2.2 Key Personnel

Section 2.2 provides a database field that allows users to insert an image of the data collection effort's organizational chart, table or other documentation showing lines of reporting and communication between individuals and organizations. By clicking in the field, users can browse their files to select and insert an image. If preferred, this section also includes a field that allows users to attach a file containing an organizational chart and/or other documentation of the organization. (See Part I for instructions on attaching files.)

Contact information for key personnel that will be involved in planning and data collection is provided in Sections 2.2.1 through 2.2.3, below. This includes information for personnel involved in oversight, management and planning activities; technical experts; and laboratory resources. Tables are provided for entering information for individuals involved in planning activities (Table 2.1), data collection and management (Table 2.2), technical expertise (Table 2.3) and laboratory resources (Table 2.4).

2.2.1 List of Key Personnel Involved in Planning Activities

Use Section 2.2.1 to identify and provide contact information for personnel involved in planning. This section allows for entry of information for up to ten individuals. Include the name of the individual, the individual's organization or affiliation, their role in planning (e.g., Incident Command, quality assurance, SAP development, laboratory procurement, subject matter expert, data management, data review, reporting), and a contact phone number and email address.

Name:	<i>Fill in</i>	Role:	<i>Fill in</i>
Organization/Affiliation:	<i>Fill in</i>	Phone:	<i>Fill in</i>
Email:	<i>Fill in</i>		

2.2.2 List of Key Personnel Responsible for Data Collection and Management

Use Section 2.2.2 to identify and provide contact information for the individuals who will be responsible for data collection and management. This section allows for entry of information for up to eleven individuals. Include the name of the individual, the individual's organization or affiliation,

their role in collecting and/or managing the data (e.g., sample collection; data recording, reporting, entry, assessment; data management), and a contact phone number and email.

Name:	<i>Fill in</i>	Role:	<i>Fill in</i>
Organization/Affiliation:	<i>Fill in</i>	Phone:	<i>Fill in</i>
Email:	<i>Fill in</i>		

2.2.3 Available Technical Expertise Teams

Use Section 2.2.3 to identify and provide contact information for individuals who will be consulted for their expertise. This section allows for entry of information for up to six individuals. Include the name of the individual, the individual’s organization or affiliation, their role (e.g., planning advisement, SAP development, method development), their relevant expertise (e.g., statistical assessment, SAP development, sample analysis, pathogen fate and transport evaluation, microbial analysis), and a contact phone number and email. Users should also enter the name of the person who referred or recommended the individual’s involvement.

Name:	<i>Fill in</i>	Role:	<i>Fill in</i>
Organization/Affiliation:	<i>Fill in</i>	Expertise:	<i>Fill in</i>
Email:	<i>Fill in</i>	Phone:	<i>Fill in</i>
Referred by:	<i>Fill in</i>		

2.2.4 Available Laboratory Resources

Table 2.1 is used to provide summary and contact information for the laboratories that will be involved in sample analysis. It allows for entry of information for up to up to four laboratories. Include the laboratory name, the laboratory address and phone number (both mailing and shipping addresses and phone numbers, if different), and the name of at least one individual as the laboratory contact. The table also includes information regarding laboratory capabilities.

Note: Each laboratory should be contacted and evaluated to confirm it has the necessary equipment and personnel, can perform the required analyses, can provide appropriate contact information, and will report data results in accordance with DMP and/or QAPP requirements.

Table 2.1
Available Laboratory Resources

Laboratory Name	Laboratory Address/Phone	Shipping Address/Phone	Laboratory Contacts	Contract on file?
<i>Fill in</i>	<i>Fill in</i>	<i>Fill in</i>	<i>Fill in</i>	<i>Select Yes or No</i>
	Sample Type Capability	Analysis Capability	ERLN or LRN Member Lab	Biosafety Level
	<i>Select from drop down</i>	<i>Fill in</i>	<i>Select from drop down</i>	<i>Select from drop down</i>

Click on the fields to enter text for the following:

- Laboratory Name
 - Laboratory Address/Phone
 - Shipping Address/Phone
 - Laboratory Contacts
 - Analysis Capability: Describe the capability of the laboratory in terms of sample types, pathogen types, and/or analytical methods expertise
- Contract on File? Select either the Yes or No radio button to indicate whether there is a contract in place and on file with the laboratory.
 - Sample Type Capability: Select the sample type the laboratory can analyze from the following options:
 - 37-mm vacuum cassette
 - Air filter
 - Grab
 - Impactor
 - Impinger
 - Sponge-stick
 - Swab
 - Wipe
 - Other (with option to fill in)
 - ERLN of LRN Member Lab? Select the laboratory's membership status from the following options:
 - ERLN
 - LRN
 - Both
 - Neither
 - Biosafety Level: Select the laboratory's biosafety level (BSL) from the following options:
 - N/A
 - BSL-1
 - BSL-2
 - BSL-3

3.0 Boundaries of the Data Collection Activities

Information in this section should describe the schedule and relevant deadlines, regulatory/jurisdictional boundaries, hazard characteristics, practical constraints, sampling locations, priority zones, conceptual model, budget and other resources (e.g., waste facilities, on-site trailers) supporting the data collection and analysis effort.

3.1 Operation Schedule and Relevant Deadlines

Provide the schedule of activities supporting the data collection, including milestones for planning, personnel training and certification, decontamination activities, sampling phases and associated sampling activities, laboratory analysis, and data assessment and reporting. Note the start and end date for each activity (where available). This section also includes a field that allows users to attach a file containing the schedule and deadlines (e.g., in the form of a calendar or Gantt chart). (See Part I for instructions on attaching files.)

3.2 Regulatory/Jurisdictional Requirements

Provide information regarding any pertinent regulatory and/or jurisdictional boundaries and permits. This description should include any action levels associated with the target pathogen(s), as well as existing permits, documented compliance with regulations, and documented approval of site access from landowners and local authorities.

3.3 Hazard Characteristics

Describe any known hazardous characteristics of the site, such as conditions or physical parameters that might impact personnel safety and/or affect sample collection and the quality of resulting data. This type of information might include, for example, data on anticipated temperatures, steepness of terrain, an abundance of rocks and/or debris, sunlight intensity, smoke, weather conditions, and dust or other particulates.

3.4 Practical Constraints

Describe any known practical constraints that might interfere with data collection that should be considered. Practical constraints refer to hindrances or obstacles that might interfere with collecting a complete data set. Examples of these constraints would be fences, property access, water bodies, water elevation and/or stream flow rates, snowpack, density of undergrowth, access to personal protective equipment (PPE), or problems that might impact the technical quality of the measurements. Include any existing access agreements to conduct work on private property and/or indicate areas where a property owner has denied access.

3.5 Location: Spatial and Contextual

Use this section to describe the spatial and contextual boundaries of where sample collection activities will occur. The introductory portion of this section includes a field for written text, as well as a field that allows users to attach a file containing a sketch and/or site map that demonstrates site boundaries and conditions, if available. (See Part I for instructions on attaching files.)

3.5.1 Priority and Exclusion Zones

A description of contamination zones and designated sampling priority zones is included in this section. This section also includes a field that allows users to attach a file to illustrate zone boundaries. (See Part I for instructions on attaching files.)

Examples include:

- Hot Zone (Exclusion Zone): Contains actual or potential contamination with the highest potential for exposure
- Warm Zone (Reduction Zone): Transition area between the hot zone and the support zone; used for decontamination and entry into and egress from the hot zone
- Cold Zone (Support Zone): Free from contamination; used for planning and staging
- Priority Zones: Priority zones within the hot zone, that are targeted for sampling

Appendix 4 of the *Draft Planning Guidance for Recovery Following Biological Incidents* document (U.S. DHS and U.S. EPA 2009) includes additional information regarding these work zones.

3.5.2 Conceptual Model

Provide a conceptual model that includes a written description and/or illustrative representation of relationships (actual or predicted) between the pathogen(s) and potentially impacted populations. The model should represent any conditions and processes (physical, chemical and biological) that could affect the migration and impacts of the contamination. The complexity of the conceptual model is dependent on factors such as the number of pathogens, the anticipated or known fate and transport of the pathogen(s) in the site conditions, and the number and proximity of human or animal populations. The model should include considerations regarding:

- Known or potential sources of contamination – where the source of the contamination is located and whether it is a point source, non-point source or natural source
- Known or expected locations of contamination
- Exposure pathways – environmental media that have the potential to become contaminated and transport the pathogen(s) (e.g., air, groundwater, soil, vegetation)
- Exposure scenarios (location of human health or zoonotic receptors)

This section includes a field that allows users to attach a file to further describe and/or illustrate the conceptual model associated with the SAP activities. (See Part I for instructions on attaching files.)

EPA resources containing information and guidance on conceptual models include:

- [Framework for Human Health Risk Assessment to Inform Decision Making](#) (U.S. EPA 2014a)
- [U.S. EPA Risk Assessment website](#) (accessed July 27, 2021)

3.6 Scale for the Decision or Estimate

Describe the scale of the unit(s) on which the decision and/or estimate statements listed in Table 1.2 will be based. The scale should describe the units, for example, first floor of building, playground within fencing, or city block. When defining these units, consider that it is possible to have multiple subunits within a single larger unit; in this case, each subunit should be described. Each unit and subunit will be evaluated and assessed individually and/or in combination to inform remediation and clearance decisions or to establish estimation statements, depending on the intended use of the collected data.

This section also includes a field that allows users to attach a file to further describe and/or illustrate the decision units. (See Part I for instructions on attaching files.)

3.7 Budget Constraints

If available, provide information regarding any limitations or constraints placed on the sampling and analysis activities based on the source(s) and anticipated amount of the project budget. Include any information regarding Mission Assignment funding (i.e., funding for Federal Emergency Management Agency [FEMA] work order to another federal agency directing completion of a specified task) if funding is to be provided under the Stafford Act. Include the specific activities that will be covered by the budget, as well as those that could be performed if additional resources were available. Provide, for example, any specifics regarding limitations to the sampling locations, number and/or types of samples, number and/or type of laboratories, analytical methods that will be used, and scheduling of activities. If available, provide itemized details that address the activities described in Sections 3.0 through 9.0.

3.8 Other General Resources

Provide information on other general resources that will be or might be available and used in support of SAP activities. Examples of other resources might include command and communication centers; training facilities; contracted support; and trailers or facilities used for equipment storage, decontamination, on-site sample processing, sample packaging and shipping.

3.9 Waste Facility Capacity and Considerations

Waste facility capacity and other related issues to be considered regarding handling and disposal of waste generated during the collection activity are described in this section. Waste generation and management begin as soon as the response to a contamination incident is initiated. Used PPE, used and disposable sampling materials, and liquids from equipment decontamination, for example, can be generated by sampling personnel, and generation of these waste streams will continue throughout the response and recovery phases. Provide summary information regarding the types of waste that are anticipated and how the waste will be handled, packaged and transported for disposal. Identify the waste treatment, storage and disposal facility(ies) (TSDf) that can accept the waste and that will be used, along with their contact information. Information provided in this section should consider that waste characterization is required for off-site disposal of contaminated items and debris. If a single object or debris requires disposal, the waste must be profiled for the disposal facility to accept it and to determine the appropriate method of disposal.

The following resources provide information regarding TSDf's and their capabilities and capacity:

- [EPA's Hazardous Waste Management Facilities and Units website](#) (accessed July 27, 2021)
- [EPA Assessment of National Capacity for Hazardous Waste Management reports](#) (accessed July 27, 2021)

The following resources provide EPA information and guidance regarding waste treatment and disposal:

- [EPA's Waste Management Options for Homeland Security Incidents website](#) (accessed July 27, 2021) – provides information regarding waste management options to assist in planning and cost-effective decisions – beginning with reduction and reuse – and continuing through recycling and composting, energy recover, and treatment and disposal as a final option.
- EPA's [Incident Waste Decision Support Tool](#) (I-WASTE DST; accessed June 9, 2021) – a decision support tool that organizes information related to waste management. The tool also provides access to technical information, regulations and guidance to work through waste management issues to facilitate safe and efficient removal, and transport and management of waste materials.

4.0 Documentation and Forms

4.1 Sample Documentation

Sample documentation typically consists of information that will be used to identify and describe each individual sample, and to attach each sample to its corresponding information, such as the type of sample collected, where and when the sample was collected, and the analytical results. Details regarding this documentation are often included in the QAPP and/or DMP. Use this section of the template to provide text and/or to attach a file to describe how sample documentation will be prepared and handled. (See Part I for instructions on attaching files.) Include information such as how the information will be documented on sample collection field. Provide information about sample labels (Section 4.1.1) and chain-of-custody (COC) forms (Section 4.1.2) in the sections below.

- EPA's Scribe is a software tool that has been developed by EPA's Environmental Response Team (ERT) to manage environmental data, and includes functionality to support sample documentation, including sample labels and COC forms. For additional information regarding this tool see <https://www.epa.gov/ert/environmental-response-team-information-management> (accessed July 27, 2021)
- Esri's [ArcGIS](#) (accessed July 27, 2021) Survey 123 provides a means for gathering and capturing data using various devices and forms that can be completed, submitted and shared using a web browser.

4.1.1 *Sample Labels*

Provide information to describe how samples will be labeled, and what information will be included on each sample label. Consider that a unique sample label must be applied to each individual sample container, with information that identifies and describes the sample. Sample container labels are incident- and site-specific and typically must, at a minimum, include the sample identification (ID) number. Additional information that can be provided on these labels includes:

- Time and date sample collected
- Sample matrix (e.g., particulate)
- Sample volume (flow rate and collection time)
- Preservation, if applicable
- Sample collection location (Global Positioning System [GPS] coordinates or brief description)
- Signature or initials of the sample collector

This section includes a field that allows users to attach a file detailing or depicting a template of the sample labels that will be used. (See Part I for instructions on attaching files.)

4.1.2 *Chain-of-Custody (COC) Forms*

Provide text and/or attach a file in this section to describe the COC form that will be used. (See Part I for instructions on attaching files.)

COC forms create a written record that can be used to trace the creation, possession and handling of a sample from the moment of its collection through analysis. A COC form accompanies each sample or group of samples as custody is transferred from one custodian to another. Sample progress should be tracked and recorded at each step of sample handling, from collection through processing, packaging and shipment. The individual(s) performing each step of sample transfer is required to record their initials or signature on the COC form to qualify the condition of the sample at that point of sample progression. Although COC forms vary in style, format and detail,

the forms should contain the same minimal information required to identify the sample and document custody. ***Note: Please check if there are any contractor or Agency requirements to use a specified format for COC reporting.***

4.2 Photographic and Video Documentation

If photograph or video documentation will be generated during data collection activities, provide a description or insert an illustration of the form that will be used to document the times and locations the photographs and/or videos are taken. In addition to times and locations, these forms should, at a minimum, include fields for documenting the date, the name of the photographer, and a description of the subject of the photograph or video.

4.3 Evidence Documentation

Site conditions should be documented at all sites (see Section 1.4), including those conditions that involve or might involve criminal investigations. Documentation of these conditions is essential for informing and developing a strategy for subsequent sampling activities. In cases where there is an active criminal investigation, lead law enforcement agencies should be consulted when planning for SAP activities, and chain-of-custody requirements and procedures will need to be adapted to meet law enforcement needs. For example, in some cases, specific conditions and areas of a site are required to be preserved and/or documented prior to initiating any sampling activities, including preserving the scene while collecting detailed written and photographic/video documentation. The planning team may also need to consider split sampling with law enforcement entities, as appropriate. Use this section to describe suspected crime scene(s), their location(s) and any requirements or potential requirements for documentation.

This section includes a field that allows users to attach a file describing or depicting locations of the site areas in which evidence documentation will be required. (See Part I for instructions on attaching files.)

5.0 Sample Collection

This section includes information that describes the resources, protocols and strategies that will be used to collect samples. The information provided should include:

- Description of the sample collection activities to be conducted
- Identification of the sample matrices (e.g., soil, drinking water, surface, air) and sample types (e.g., bulk/grab, filter, swab, sponge-stick, vacuum filter cassette) that will be collected
- Identification of the sampling supplies and equipment that will be required
- Sampling design
- Sample locations
- Description of the plan for obtaining field data
- Identification of the sampling team organization

The sampling approach should consider all aspects needed to address the goals described in Section 1.3, including the analytical data needs (e.g., presence/absence, viability), as well as the characteristics of the decision unit(s) and sample matrices to be sampled. Note: This section of the SAP is often re-evaluated after initial data collection has occurred. Sampling designs and strategies and the protocols selected for use are often influenced as data collection proceeds, as well as by the phase of the sampling effort and the specific goals and needs of the data collection effort.

- EPA's [RCRA Waste Sampling Draft Technical Guidance: Planning, Implementation, and Assessment](#) (U.S. EPA 2002c) – steps users through systematic planning for sample collection and analysis addressing RCRA waste (i.e., waste regulated under the federal Resource Conservation and Recovery Act) in accordance with the DQO process. The detailed guidance and information can be applied to a variety of efforts requiring the collection of samples for identification and assessment of contamination.
- [EPA's Environmental Sampling and Analysis Program website](#) (accessed July 27, 2021) – provides information in support of a comprehensive program to facilitate a coordinated response following a homeland security-related contamination incident (intentional or accidental), including information that supports field and laboratory efforts to characterize contaminated sites
- [EPA's Homeland Security Research Program Sample Collection Procedures and Strategies website](#) (accessed July 27, 2021) – provides documents and tools developed by EPA to provide information regarding sample collection following a biological contamination incident, as well as a framework to assist decision-makers in developing and implementing an approach for sample collection.

5.1 General Description of Sample Collection Activities to be Conducted

Provide a general description of the sample collection activities to be conducted under the SAP. Include the matrices that will be collected, the number and type(s) of samples to be collected in each matrix, sampling locations, and the sample collection protocols (e.g., standard operating procedures [SOPs]) that will be used. **Table 5.1** provides fields for entering information specific for each sample type.

The sample matrix is the contaminated media (e.g., air, soil, water, surface type); sample type refers to the specific type of sample that will be provided to the laboratory. For example, if the matrix being sampled is a surface (e.g., glass, laminate, plastic), the user should identify the sample type as the specific type of sampling equipment or material used, which will be provided to the laboratory (e.g., swab, wipe). Another example would be when water is the sample matrix. In this case, the user should specify the matrix as drinking water, source water, recreational water or wastewater; the corresponding sample type to these matrices would be either grab or other (e.g., filter).

Note: Analytical methods specify the sample types that they have been designed to process. The use of sample types that are specified in the selected analytical methods is preferred. However, sample types that have not yet been evaluated for use in an analytical method can be selected as in instances where their use might be beneficial. In these cases, the laboratory should be consulted, and additional field and analytical QC is recommended.

- EPA’s [Sample Collection Information Document \(SCID\) for Pathogens - Companion to Selected Analytical Methods for Environmental Remediation and Recovery \(SAM\) 2017](#) (Chattopadhyay 2017) and [corresponding query](#) (accessed July 26, 2021) – provide information and guidance regarding collection of samples to be analyzed for pathogens, including appropriate sample containers, sample sizes, and preservation.

Table 5.1
Sample Collection Planning Form

Sample Type:	Sample Matrix:	Sample Collection Protocol to be Used:	Wetting Solution Used:
<i>Select from drop down</i>	<i>Select from drop down</i>	<i>Fill in</i>	<i>Select from drop down</i>
	Specific Location(s):	Location ID Numbers (individual or range of numbers)	
	<i>Fill in</i>	<i>Fill in</i>	
	Preservation Required:	Collection Containers (number, size, type):	Samples Accepted by Laboratory?
	<i>Select from drop down</i>	<i>Fill in</i>	<i>Select Yes or No</i>

- Sample Type: Select the sample type from the following options:
 - 37-mm vacuum cassette
 - Air filter
 - Grab
 - Impactor
 - Impinger
 - Sponge-stick
 - Swab
 - Wipe
 - Other (with option to fill in)
- Sample Matrix: Select one or more (up to six) sample matrices from following options (Note: Only one item can be selected from each drop-down list):
 - Air
 - Ballast rock
 - Carpet
 - Ceramic tile
 - Drinking water
 - Fabric
 - Glass
 - Gravel
 - Laminate
 - Plastic
 - Recreational water
 - Sediment
 - Soil
 - Source water
 - Stainless steel
 - Vegetation
 - Vinyl tile
 - Wastewater
 - Wood
 - Other (with option to fill in)
- Sample Collection Protocol to be Used: Provide information that identifies the sample collection protocol that will be used (e.g., title, author, version number, publication date, journal citation).

Consider that the protocol should include, at a minimum, sample collection equipment, collection techniques, appropriate quality control, sample packaging, and safety protocols.

- **Wetting Solution Used:** Wetting solutions are often used when collecting samples using wipes, swabs or sponge sticks. Select from the following options:
 - None
 - Neutralizing buffer
 - Phosphate buffered saline
 - Sterile water
 - Other (with option to fill in)

- **Specific Location(s):** Identify the sampling location(s) associated with the sample type and matrix. Detailed descriptions or identification of these locations can be provided in Section 5.4.
- **Location ID Numbers:** Provide the individual numbers or range of numbers for the sampling location(s) associated with the sample type and matrix.
- **Preservation Required:** Select the required sample preservation from the following options:
 - None
 - $\leq 10^{\circ}\text{C}$; do not freeze
 - Room temperature
 - Other (with option to fill in)

- **Collection Containers:** Describe the containers that will be used to contain the sample(s). Include the primary containers (those that will come into direct contact with the collected sample(s)), as well as any secondary and tertiary containers that will be used.
- **Samples Accepted by Laboratory:** Verify that the laboratory selected to analyze the samples can accept the samples and perform the appropriate analyses. Select “Yes” or “No” to indicate whether the collected samples can be accepted and analyzed by the designated laboratory.

5.2 Sampling Supplies and Equipment

Samples collected in response to a biological contamination incident should be collected using dedicated and sterile – or sufficiently clean equipment – to minimize interferences and cross-contamination. Use this section of the template to provide information describing the supplies and equipment that will be used during the sample collection activity. Include pre-packaged equipment (e.g., wetted wipes, sponge sticks, filter cassettes), laboratory-prepared equipment (e.g., clean grab samplers), and supplies included in pre-assembled sampling kits. This information should include manufacturer identifiers (e.g., part numbers), equipment specifications (e.g., sizes of wipes, swabs, augers; type of impinger fluid), and certification of equipment cleanliness. The information also should include procedures that will be used to calibrate and/or maintain equipment that will be used to document and measure site conditions (e.g., soil pH meters, photography equipment).

This section includes a field that allows users to attach a file to provide additional details regarding the sampling equipment. (See Part I for instructions on attaching files.)

5.3 Sampling Approach

Identify and describe the approach that will be used to design the sample collection effort in terms of the number of samples and their locations. Sampling approaches should be designed to maximize the representativeness and usability of the collected data with respect to the data collection goals, such as scientifically based decision-making. In your description, indicate and identify the resources that will be used, such as any software or technical support, to develop the approach. This section also includes a field

that allows users to attach a file describing or depicting the approach and/or design. (See Part I for instructions on attaching files.)

Some of the common approaches to designing environmental sampling include:

- Judgmental or targeted
- Simple random
- Stratified
- Systematic (grid and transect)
- Composite
- Combined targeted and probabilistic sampling

contamination incidents and is intended as an information companion to this User Guide and the SAP. Refer to EPA's [Guidance on Choosing a Sampling Design for Environmental Data Collection for Use in Developing a Quality Assurance Project Plan](#), EPA QA/G-5S (U.S. EPA 2002b), which provides a toolbox and descriptions of statistical designs for sample collection that can be consulted during development of the SCP.

[EPA's Sampling, Laboratory and Data Considerations for Microbial Data Collected in the Field](#) (U.S. EPA 2018) – provides a summary of elements that should be considered in planning sampling approaches involving microbiological Template Tool.

The [Visual Sample Plan \(VSP\) Tool](#) (accessed July 26, 2021) – developed by Pacific Northwest National Laboratory; is intended to facilitate development of a sampling plan based on statistical sampling theory and the statistical analysis of resulting data to support confident decision-making.

5.4 Sampling Locations

Provide a description of the locations where samples will be collected. In general, sampling locations are determined based on the sampling design (Section 5.3) and are dependent upon the data collection phase, the pathogen and sample matrices, lines of evidence, as well as other study boundaries (e.g., designated decision units and sub-units, physical barriers, dynamic site conditions). The choice of specific sample locations should target areas that maximize the likelihood of pathogen detection and/or viability, and should support the evaluation of pathogen spatial distribution or concentration. Examples include:

- Impaction surfaces such as HVAC air intakes or air inlets/intakes
- Surfaces that have not been recently disturbed
- Surfaces that would promote stability and survivability of the organism
- Areas that have reduced ultraviolet light exposure or areas that are shaded and moist, which could decrease environmental decay

This section includes a field that allows users to attach a file describing the sampling areas and specific locations. (See Part I for instructions on attaching files.)

5.5 Plan for Obtaining Data

Describe the process that will be used to obtain and document information in the field, including a description of the sample collection tools, software or sampling forms used to document the information, and sampling diagrams.

5.5.1 Sample Documentation Information

Provide a description or attach a file depicting the form(s) to be used to document information pertaining to each sample in the field. (See Part I for instructions on attaching files.) During

sample collection, information associated with each sampling event is recorded and maintained in logbooks, on sample tracking forms, or in other means of documenting information associated with the samples. These field records should be completed at the time each sample is collected, and copies should accompany samples during shipment. The information recorded is essential to data assessment, is extremely useful to laboratories and data users, and includes, at a minimum:

- Unique sample ID number
- Date and time of sample collection
- Sampling location (including GPS coordinates, if appropriate)
- Sample matrix and type
- Collection equipment settings (e.g., flow rate)
- Name of sample collector

Note: Sample collection field forms should include fields for documenting any additional information that might be needed to support the assessment of data results. For example, documentation associated with collection of air samples should include the start and stop times of collection, as well as the collection flow rate. Documentation associated with collection of soil samples should include the depth at which the soil was collected. Additional information that might be requested and recorded could include site conditions at the time of collection, field measurements (e.g., water temperature, soil pH and moisture), and other pertinent observations such as weather conditions.

Electronic devices can also be used as a means of recording information in the field. If used, these devices should be selected based on durability, accuracy, backup capability and ease of decontamination.

It is EPA policy (Stanislaus 2016) to use [Scribe](#) (accessed July 26, 2021) when practical to collect, store and report sampling and analytical data in support of response to a contamination incident. Scribe was designed to capture sampling data, observational information, monitoring field data and analytical data.

5.5.2 *Sampling Diagrams*

Provide a description and/or attach a file depicting a diagram of the sampling approach. (See Part I for instructions on attaching files.) The information should describe or illustrate where samples will be collected. It should detail the number and type of field and QC samples to be collected at each location. Include exact locations (e.g., GPS coordinates), along with distances from charted physical boundaries or landmarks. Additional helpful details include sample depths, surface area sizes, and types of collection devices

5.6 Sample Container and Equipment Decontamination

Decontamination information and procedures should be detailed in the HASP. Use this section of the template to describe the approaches that will be used to decontaminate sample containers and sampling equipment to control contamination during sample collection, packaging and transport. Consider that, in all cases, sample containers and used sampling equipment should be decontaminated before reuse or before leaving a contaminated area. Approaches to decontamination should also consider site egress procedures, which address decontamination and transfer of sample containers and contained waste in accordance with the HASP. Contamination of samples from external sources and cross contamination between samples can be avoided by careful planning, appropriate use of PPE, training and adherence to clean techniques, and adherence to documented decontamination procedures.

Equipment used for collection of samples following a biological contamination incident is often available prepackaged and free of contamination from the manufacturer. The following examples might be considered and implemented in cases where sampling equipment is to be reused and decontaminated in the field:

- Equipment that is contaminated in the field can be cleaned with disinfectant wipes and either reused or bagged for transport to a facility that can clean the equipment for reuse.
- Unless determined to be free of contamination, materials used for decontamination are collected as waste and removed from the sampling site for proper disposal. Five- or 20-gallon buckets with lids can be used for containment.
- Drums or large garbage cans can be used to contain contaminated PPE, accumulated wastes, containers or equipment.

Additional information is provided in EPA's [Decontamination Line Protocol Evaluation for Biological Contamination Incidents, Assessment and Evaluation Report](#) (U.S. EPA 2015).

5.7 Sampling Team Configuration

The sample team organization is described in this section. This section also includes a field that allows users to attach a file depicting the organization. (See Part I for instructions on attaching files.) Any sampling effort requiring the collection of multiple samples, particularly those involving hazardous conditions, should involve a sampling team consisting of at least two personnel. Additional personnel may be required for large-scale sampling efforts or when site-specific hazards may be encountered. For example, a sampling team might utilize one person to collect samples while others coordinate the supply of materials and are responsible for sample containment, inspection and documentation. Depending on the size of the sampling event and the number of samples required, a three-person sampling team is recommended, consisting of a *collector*, a *supplier* and a *support person*. For example:

- **Collector** - responsible for operating the sampling equipment and collecting the sample
- **Supplier** - provides collector with equipment and materials needed to collect the sample, helps with assembly and disassembly of equipment, and decontaminates sample containers
- **Support Person** - responsible for sample documentation, documenting flow rate and sampling duration, radio communication

This team approach can reduce the time required for sample collection and adds additional layer of quality assurance to the overall process. Sampling teams also provide an additional level of safety.

5.8 Other Sample Collection Considerations

Other sample collection considerations not mentioned above can be discussed here.

6.0 Quality Control Activities

All aspects of quality control (QC) related to the data collection efforts should be detailed in the QAPP. Use this section of the template to provide information about the QC activities that will be used during the data collection activities, including data quality indicators (DQIs) and corresponding acceptance criteria, instrument calibration, field QC samples, and other QC activities (e.g., documentation review, laboratory QC samples). Planners should consider that although sufficient QA/QC procedures can increase the cost of a sampling program substantially, they are often less costly than having to discard data because of questionable outcomes.

6.1 Data Quality Indicators (DQIs)

Identify and provide information regarding the DQIs that will be applied to critical measurements represented by the data that will be collected. For the purposes of the SAP template tool, DQIs are defined generally, as quantitative measures of the identified DQOs. DQIs are used to assess data accuracy (precision and bias), comparability, completeness, and representativeness. DQIs that will be assessed and the method that will be used to measure each DQI should be recorded. The recorded information should include the criteria that will be associated with each DQI and how the data will be assessed based on the criteria.

Table 6.1 provides examples of DQIs and subsequent corrective actions that might be applied when considering data generated to assess pathogen viability as measured by colony forming units (CFUs). The table includes 13 rows for capturing DQI information; if needed, please use the larger field provided in Section 6.1 to include additional information.

Table 6.1
Data Quality Indicators

Parameter	Measurement Method	QA/QC Check	Frequency
<u>Example:</u> Comparability	Culture Plate Colony Counts	Agreement of ≥ 3 replicates by statistical analysis	Per batch of [#] samples
	Acceptance Criteria	Corrective Action	
	Within 10% for 1000 or more CFUs/mL; within 30% for <1000 CFUs/mL	Check adherence to analytical protocol for sufficient mixing of extracts and proper calibration and use of pipettors, preparation of dilution series, and/or late spreading	
Parameter	Measurement Method	QA/QC Check	Frequency
<u>Example:</u> Accuracy	Culture Plate Colony Counts	% recovery in duplicate spiked samples	Per batch of [#] samples
	Acceptance Criteria	Corrective Action	
	\geq [#] % recovery \leq [#] relative standard deviation between duplicates	Check adherence to analytical protocol for sufficient mixing of extracts and proper calibration and use of pipettors, preparation of dilution series, and/or late spreading	
Parameter	Measurement Method	QA/QC Check	
<u>Example:</u> Completeness	Culture Plate Colony Counts	Analytical results	
	Acceptance Criteria	Corrective Action	
	95% = valid results/planned results	Determine and correct cause(s) of missing or invalid data	

The following resource is recommended for information regarding DQIs and their application:

- U.S. EPA [Guidance for Data Quality Objectives Process: EPA QA/G-4](#) (U.S. EPA 2006b) – Provides a standard working tool for project managers and planners to develop DQO for determining the type, quantity, and quality of data needed to reach defensible decisions or make credible estimates.

Table 6.2 provides fields for entering information regarding calibration of the equipment that will be used during sample collection and analysis. Include information on the type of equipment used and any calibration or certifications that are associated with that equipment. Tolerance refers to the range of values that will be considered acceptable to indicate appropriate calibration and is typically expressed in terms \pm a percentage (%) of a specific measurement. In this case, frequency refers to how often the equipment must be calibrated or re-certified. **Note:** Equipment manufacturer instructions, and best professional judgement depending on the intended use of the equipment, should be considered for guidance regarding equipment calibration and its frequency.

Table 6.2
Instrument Calibration

Equipment:	Calibration/Certification:	Tolerance:	Frequency of Calibration:
<i>Fill in</i>	<i>Fill in</i>	<i>Fill in</i>	<i>Fill in</i>

- **Equipment:** Provide the type of equipment that will require calibration (e.g., balances, pipettors, pH meters, incubators, spectrophotometers, flow cytometers) or certification (e.g., microscopes, autoclaves, thermometers, biological safety cabinets) for use in supporting both sample collection and analysis activities. Include the identifying information, such as the manufacturer and serial number.
- **Calibration/Certification:** If equipment is to be calibrated, provide information regarding how calibration will be performed (e.g., using NIST-certified thermometer; pH standards of 4.0, 7.0 and/or 10.0; ASTM Class S reference weights). Provide information regarding equipment certification, including the certification type, technician, date and number.
- **Tolerance:** Provide the “window” or range of values that will be considered acceptable to indicate appropriate calibration. For example, \pm a percentage (%) of a specific measurement at each calibration standard used.
- **Frequency:** Provide the frequency that will be required for the calibration and/or certification of the equipment (e.g., daily, monthly, annually, prior to and/or after each use). For example, temperatures of refrigerators, freezers and incubators are typically checked and recorded daily; pH meters are typically calibrated prior to each use; balances are typically calibrated once per month and certified annually.

6.2 Field Quality Controls

This section should provide information regarding field quality control samples not previously discussed that will be collected to support the sampling activity. This could include, but is not limited to, co-located samples, field blanks, field replicates/duplicates, field matrix splits, field matrix spikes, and trip blanks. Wherever possible, the locations at which the samples will be collected should be identified and a rationale provided for the choice of location. Frequency of collection should also be described.

- **Co-Located Samples** A type of field duplicate where independent samples are collected as close as possible to the sample point in space and time. They are two separate samples taken from the

same source, stored in separate containers, and analyzed independently by the same protocol and laboratory. These are useful in documenting the precision of a sampling process.

- **Field Blank:** A blank used to provide information about contaminants that may be introduced during sample collection, storage, and transport. The clean sample is carried to the sampling site, exposed to sampling conditions, returned to the laboratory, and treated as an environmental sample. (U.S. EPA 2002b).
- **Field Replicate/Duplicate:** Two or more samples collected at the same time and location to be considered identical. Also referred to as “co-located samples” (U.S. EPA 2002b).
- **Field Splits:** A type of field duplicate where the sample is homogenized and then divided into two or more aliquots so that variability can be evaluated (U.S. EPA 2018).
- **Trip Blank/Media Blank:** A sample of analyte-free media taken from the laboratory to the sampling site and returned to the laboratory unopened. The sample is used to document contamination attributable to shipping and field handling procedures (U.S. EPA 2012).

6.3 Other QC Activities

Describe any other QC activities that will be implemented and are not described above. Possible examples include:

- **Laboratory QC samples** – The type(s) of laboratory QC samples that are appropriate is highly dependent on the type of sample(s) that will be analyzed and analytical method(s) that will be used. Examples include:
 - **Positive Control:** A sample containing a known quantity of the target pathogen or surrogate (in some cases, the concentration is known only to be above the analytical protocol’s detection limit). Analytical results of a positive control should fall within a specified range of the known quantity or exhibit characteristics typical of the target pathogen (U.S. EPA 2018).
 - **Negative Control:** A sample that contains a non-target organism (e.g., does not grow on the medium or produces colonies with different morphology) and does not contain the target pathogen or surrogate. Negative culture controls should produce either no growth or atypical growth (e.g., colony morphology is different from the target pathogen). Negative PCR controls (no template controls) should not exhibit amplification (U.S. EPA 2018).
 - **Internal Standards:** A standard added to a test portion of a sample in a known amount and carried through the entire determination procedure as a reference for calibrating and assessing the *precision* and *bias* of the applied analytical method (U.S. EPA 2004).
 - **Matrix Spike** (for culture methods): A sample used for quality control in which a known amount of the target analyte is added to a specified amount of matrix. These samples can be used to evaluate the effect of the matrix on the recovery efficiency and performance of a method (U.S. EPA 2018).
 - **Method Blank:** A blank prepared to represent the sample matrix as closely as possible and analyzed exactly like the calibration standards, samples, and QC samples. Results of method blanks provide an estimate of the within-batch variability of the blank response and an indication of bias introduced by the analytical procedure (U.S. EPA 2018).
 - **Reagent Blank:** A sample used for quality control to assess background interference or contamination in the analytical system. This blank sample is prepared without the analyte of interest and is intended to detect any contamination originating from the reagents (U.S. EPA 2014b).

- Recovery: The total amount of the analyte found in the sample, corrected for background, divided by the amount of the analyte added into the sample (U.S. EPA 2004).
- Replicates: An additional sample that allows for averaging two or more samples to ensure the most accurate results and to improve quality assurance.

Additional information regarding laboratory QC practices and sample recommendations and requirements can be found in the following resources:

- The analytical methods listed in EPA's [Selected Analytical Methods for Environmental Remediation and Recovery \(SAM\) 2017](#) (U.S. EPA 2017)
 - EPA's [Quality Assurance/Quality Control Guidance for Laboratories Performing PCR Analyses on Environmental Samples](#) (U.S. EPA 2004)
- **Documentation review** – Review of field records and laboratory reporting forms prior to submission and use is a critical component of ensuring the quality of the collected data and information. Describe how this documentation will be reviewed, including when, who will perform the review, and how the review will be documented. Field records, for example, should be reviewed prior to leaving the collection site to ensure the sample ID number and all its corresponding information, along with pertinent site conditions, are documented correctly. Laboratory data should be reviewed along with corresponding laboratory QC records (e.g., solution and equipment checks), prior to submission for use.

7.0 Sample Transportation and Storage

Proper packaging and transport of samples is essential to prevent cross contamination and to protect sample transporters and laboratory personnel. Provide a summary description of the sample packaging and shipment procedures and conditions. Include the types of transport containers, the name and contact information for the individual or company responsible for shipment, as well as for any individuals who will be involved in each step of transport (i.e., transfer of samples into the transport container or vehicle, transfer of samples between containers/vehicles, and receipt of samples at the laboratory). Include pertinent shipping regulations and labeling requirements, particularly any regulations associated with transport of select agents, and methods to prevent tampering (e.g., custody seals). Refer to:

- International Air Transport Association (IATA). 2009. “Guidance Document – Infectious Substances.” International Civil Aviation Organization Dangerous Goods Panel. http://www.icao.int/publications/Documents/guidance_doc_infectious_substances.pdf (accessed July 27, 2021).
- U.S. Department of Transportation (DOT). 49 CFR 172. “Hazardous Materials Table, Special Provisions, Hazardous Materials Communications, Emergency Response Information, Training Requirements, and Security Plans.” <https://ecfr.io/Title-49/Part-172> (accessed July 27, 2021).
- U.S. Department of Transportation. 49 CFR 173. “Shippers – General Requirements for Shipments and Packagings.” <https://ecfr.io/Title-49/Part-173> (accessed July 27, 2021).
- U.S. Department of Transportation. October 2006. “Transporting Infectious Substances Safely.” Federal Register, Hazardous Materials: Infectious Substances; Harmonization with the United Nations Recommendations. Pipeline and Hazardous Materials Safety Administration. Washington DC. <https://www.phmsa.dot.gov/transporting-infectious-substances/transporting-infectious-substances-safely> (accessed July 27, 2021)

Specific sample packaging and shipment considerations are provided in **Table 7.1**. The temperature at which the samples will be shipped and the type of sample packaging required are included, as well as information regarding sample transport container labels. In addition, the method for transporting the package (air, car, etc.) should be recorded here.

Table 7.1
Sample Shipment Considerations

Sample Type:	Shipping Temperature:	Sample Packaging:	Transport Container Labels:	Mode of Sample Transport:
<i>Select from drop down</i>	<i>Select from drop down</i>	<i>Fill in</i>	<i>Fill in</i>	<i>Fill in</i>

- **Sample Type:** Select the sample type from the following options:
 - 37-mm vacuum cassette
 - Air filter
 - Grab
 - Impactor
 - Impinger
 - Sponge-stick
 - Swab
 - Wipe
 - Other (with option to fill in)
- **Shipping Temperature:** Select the sample shipping temperature from the following options:
 - None
 - $\leq 10^{\circ}\text{C}$; do not freeze
 - Room temperature
 - Other (with option to fill in)

- Sample Packaging: Describe the packaging and packaging materials that will be used to prepare samples for shipment.
- Transport Container Labels: Consult with the IATA and DOT requirements cited above, and describe the information that will be included on the sample transport container labels. Note: In most cases, transport packages will be marked as “Biological Substance, Category B” with an attached diamond shaped United Nations (UN) label. Packages containing samples that are known or suspect of containing a select agent, are marked as “Infectious Substance, Category A,” with a diamond shaped UN 2814 (Select Agents) label. If shipping by commercial air carrier, an airway bill is used, and the “Nature and Quantity of Goods” box should indicate “Biological Substance, Category B” and “UN 3373” (Category B). On the airbill, the name of the agent is provided if known, along with its UN number and the name, address and telephone number of the responsible person.
- Mode of Sample Transport: Identify how the samples will be transported (e.g., air freight, car) and the responsible party.

8.0 Processing and Analysis Protocols

Describe the sample processing and analysis protocols that will be used in this text field and in Table 8.1. A variety of methods are available for processing and analyzing samples. The method(s) that will be used are selected based on the pathogen, the type of analysis needed (e.g., detection, viability assessment), the purpose for sampling (e.g., site characterization, post decontamination assessment) and the turnaround time needed for the results. Depending on data needs, single or multiple methods might be used to analyze a single sample or sample type.

- U.S. EPA’s [Selected Analytical Methods for Environmental Remediation and Recovery](#) (SAM) website and corresponding SAM [pathogen methods query](#) (both accessed July 27, 2021) – provide guidance in determining appropriate sample preparation and analytical methods during site characterization and post-remediation phases of site cleanup. Methods have been selected by multi-agency technical workgroups, with emphasis given to the pathogens listed in Section 1.0 and the following environmental sample types: air, particulates (wipes or swabs), soil, drinking water and post decontamination wastewater.

Table 8.1
Analytical Protocols to Be Used

Sample Type:	Laboratory Selected for Analysis:	Sample Processing Procedure:	Analytical Procedure:	
<i>Select from drop down</i>	<i>Fill in</i>	<i>Fill in</i>	<i>Fill in</i>	
		Maximum Holding Time and Storage Temperature:	Quantification and/or Detection Limit:	Reporting Units:
		<i>Select from drop downs</i>	<i>Fill in</i>	<i>Fill in</i>
		<i>Fill in</i>		

- Sample Type:** Select the sample type from the following options:
 - 37-mm vacuum cassette
 - Air filter
 - Grab
 - Impactor
 - Impinger
 - Sponge-stick
 - Swab
 - Wipe
 - Other (with option to fill in)
- Laboratory Selected for Analysis:** Identify the laboratory that will be performing the analysis. Note: Consult with the laboratory to verify and confirm the accuracy of the information included in the table.
- Sample Processing Procedure:** Provide information to identify the sample processing protocol that will be used. Identifying information should include, at a minimum, the title, author, revision number and date.
- Analytical Procedure:** Provide information to identify the analytical protocol that will be used. Identifying information should include, at a minimum, the title, author, revision number and date.

- Maximum Storage Holding Time and Storage Temperature: (Note: In most cases, samples to be analyzed for pathogens should be transported to the laboratory as quickly as possible.) Select the maximum allowable sample storage holding time from the following options:
 - Analyze as soon as possible (ASAP)
 - 24 – 72 hours
 - 24 hours
 - 48 hours
 - 72 hours
 - 96 hours

Provide the temperature that will be required to maintain the integrity of the samples prior to analysis. Note: In some cases, sample storage temperatures are provided in the analytical protocol. In general, samples to be analyzed for pathogens are stored at ≤ 10 °C, without freezing. Samples to be analyzed for *Vibrio cholera* are an exception; these samples should be stored at room temperature.

- Results Required: Identify the type(s) of analytical results that are required, including corresponding supporting information. Examples include presence/absence determinations (PCR data outputting cycle threshold time) or quantitative data (e.g., colony forming units [CFU]).
- Quantification and/or Detection Limit: Include any relevant quantitation or detection limits for the pathogen that are associated with the analytical protocol, if known. Note: If the analytical protocol includes limits for a pathogen other than the pathogen of interest, identify the pathogen along with the pathogen-specific limit(s).
- Reporting Units: Indicate the units in which the data will be reported. Reporting units depend on how the data will be used and are specific to the analytical procedure used.

8.1 Laboratory Reporting Requirements

Describe the format that will be used to report laboratory results, including the file type, all data reporting fields (e.g., pathogen, sample type, analytical method used, date/time of analysis, results, QC checks, and approval of results), the type of results and corresponding units (e.g., colony forming units [CFU], most probably number (MPN), presence/absence, and statistical estimates [percent recovery, percent difference]). Include specifications regarding how results of QC samples will be reported (e.g., analytical result, percent recovery, identifier for association with a sample or sample batch). In some cases, these reports also might include information reported during sample collection, such as field conditions that may affect the interpretation of the results. Alternatively, or in addition, attach a file showing the data reporting format. Note: A check should be performed to determine if there are any contractor or Agency requirements. For example, if [Scribe](#) (accessed July 27, 2021) is used, a specific format for reporting might be required.

This section also includes a field that allows users to attach a file depicting the data reporting format that will be used by the laboratory(ies). (See Part I for instructions on attaching files.)

9.0 Data Reduction, Statistical Analysis, and Visualization

Use this section of the template to describe the procedures that will be used to review and assess the collected data, as well as how the resulting data will be applied to support decision-making and subsequent actions. Note: Details regarding data review and data assessment procedures will be included in the incident-specific QAPP (see Section 10.1).

9.1 Data Review and Reduction

Data review involves the evaluation of the quality of the collected data and documentation of associated limitations. It is performed to ensure that the collected data, and the subsequent computations based on those data, are appropriate for their intended use. Procedures used to review the collected data will be detailed in the incident QAPP. Use this section of the template to provide a summary description of how the collected data will be reviewed, including the data review process and the QC checks that will be applied. This information should include, for example:

- What data will be reviewed – Identify the dataset(s) that will be reviewed, including both field and laboratory data.
- How the data will be assessed – Include field and laboratory data and information that might impact data interpretation (e.g., site conditions, condition of samples upon receipt in the laboratory, and/or QC sample results can affect how the analytical results of a field sample might be interpreted).
- Who will review the data – Identify reviewers with the appropriate knowledge, skills, experience and objectivity.
- What documentation will be used to support data review activities – Identify the DMP, data review standard operating procedures (SOPs), data review forms or databases, as well as data reporting forms and supporting guidance (e.g., QAPP).
- How the data will be reviewed (including variable-specific strategies and criteria) – Describe the strategies and criteria that will be applied during data review (e.g., were samples analyzed within the required maximum holding time, were acceptance criteria for field and laboratory QC samples met).
- How issues such as data discrepancies and potential errors will be documented and handled – For example, indicate how data will be “flagged” or corrected in situations such as the following:
 - Analytical results of corresponding field QC samples do not meet QC criteria
 - Analytical results of corresponding laboratory QC samples do not meet QC criteria
 - Sample analyzed outside maximum holding time requirement
 - Sample preservation conditions questionable or outside requirements
 - Potential data entry errors or ineligibility
 - Potential impacts of site conditions (e.g., weather, wind)
 - Results that appear to be impossible, illogical, or outside the anticipated range

U.S. EPA [Data Quality Assessment: A Reviewer’s Guide](#), EPA QA/G-9R (U.S. EPA 2006c) – provides general guidance on determining whether the type, quantity and quality of data needed to support the intended use have been achieved.

9.2 Data Assessment and Summary Statistics

Use this section to describe the approach that will be used to analyze the data. Describe how the results of the data review will be assessed and presented (e.g., detailed reports, summary statistics, graphical displays) for use in informing decisions and supporting conclusions. Include a description of how the collected data will be organized and applied to support decisions. For example:

- Will data that have been “flagged” during the data review process be included in the assessment?
- Will results from multiple datasets be combined to represent contamination in each sample matrix?
- Will multiple datasets be combined to represent contamination in each decision unit and/or subunit?
- Will subunits be assessed separately as well as in combination to represent a decision unit?

The resources below provide useful guidance regarding assessments of environmental data that can facilitate decision-making and conclusions. Statistical assessment of the collected data might include, for example, determining the mean, median, percentiles, interquartile ranges, standard deviations and/or coefficients of variation for each data variable, as well as correlations between primary or calculated variables. Graphical representations of the data, such as histograms, frequency plots, box and whisker plots, or plots of spatial or temporal data can also be helpful in illustrating tendencies, variability and trends. **(Please note: It is highly recommended that a statistician or planning tool be consulted to determine and apply any statistical approach to data assessment that will be used.)** The guidance cited considers and explains application of these and other approaches to applying statistical assessments to data sets depending on the purpose and intended use of the collected data:

- U.S. EPA [Data Quality Assessment: Statistical Methods for Practitioners](#), EPA QA/G-9S (U.S. EPA 2006a) – provides general guidance to EPA program managers and planning teams regarding statistical methods that can be applied in assessing environmental datasets to determine whether they meet project objectives.
- EPA’s [RCRA Waste Sampling Draft Technical Guidance: Planning, Implementation, and Assessment](#) (U.S. EPA 2002b) – describes the application and use of statistical evaluations to evaluate data collected for characterization of waste. The detailed guidance and information can be applied to a variety of efforts requiring the collection of samples for identification and assessment of contamination.

9.3 Application of Results

Once the data review and evaluation activities described in Sections 9.1 and 9.2 have been completed, the resulting data are considered for application to their intended use. Use this section of the template to describe how the data will be applied to inform decisions or estimations, along with the resulting actions that will or might be taken. Include a description of the actions that will be taken in cases where the results of data review and assessment indicate the data might be considered unacceptable for the intended use, as well as the actions that will be taken assuming the data are sufficient.

For example, application should consider questions such as the following, at a minimum, to address the DQIs of completeness, representativeness and sensitivity:

- Were samples collected and analyzed as required (i.e., as described in the sample collection and analysis protocols identified in Sections 5.0 and 8.0, respectively)?
- Are datasets complete and have data been reported and documented as described in Sections 4 and 8, and in the QAPP and the DMP?

- Have the QC acceptance criteria identified in Section 6.0, Table 6.1 been met?
- Have the data been reviewed as described in Section 9.1 and the QAPP?
- Do the results of the data review and assessment indicate the data are acceptable for their intended use?

If the answer to any of these questions is no, there are risks associated with data use and you should consider and describe the types of decision errors that could occur, along with their impact and related consequences. For example:

- **False Positives** – Incorrectly concluding that contamination is present or that a change in contamination has occurred. False positives are also known as Type I Errors and are represented by the Greek letter alpha (α).
- **False Negatives** – Failing to detect contamination or recognize that a change in contamination has occurred. False negatives are also known as a Type 2 Errors and are represented by the Greek letter beta (β).

If the answer to all questions you consider is yes, describe the action(s) that will be taken (decision-making purpose) or how the results will be used (estimation purpose). As a reminder, the intended use(s) of the collected data were defined in Table 1.2, as supporting either decision-making or estimation purposes, along with corresponding principal questions, and decision or estimation statements. The examples that were provided for this table are shown below (**Table 9.1**), along with examples of alternative actions that might be taken based on the results (i.e., how the results will be applied).

Table 9.1
Defining Alternative Actions

Intended Use of the Data: Decision		
Principal Questions / Decision Statement(s)	Results of Data Collection	Alternative Actions
<u>Question:</u> What locations have been contaminated in the decision unit(s)? <u>Statement:</u> Determine whether [pathogen] is detected in and requires removal from the decision unit(s).	[Pathogen] detected	<ul style="list-style-type: none"> - Continue remediation activities - Continue and/or increase sampling focused on [specific locations]
	[Pathogen] not detected	<ul style="list-style-type: none"> - Take no action - Clear the unit for [intended use]
	DQOs not met	<ul style="list-style-type: none"> - Continue and/or increase sampling focused on [specific locations] - Revise sampling design
<u>Question:</u> What sample matrices have been contaminated in the decision unit(s)? <u>Statement:</u> Determine whether [pathogen] is detected in and requires removal from soil in the decision unit(s).	[Pathogen] detected	<ul style="list-style-type: none"> - Continue and/or increase decontamination of soil - Increase sampling of [matrix] - Take no action - Pathogen detection in soil will result in use of [decontamination procedures]
	[Pathogen] not detected	<ul style="list-style-type: none"> - Increase sampling of [matrix]
	DQOs not met	<ul style="list-style-type: none"> - Increase sampling of [matrix] - Revise sampling design

Intended Use of the Data: Estimation		
Principal Questions / Estimation Statement(s)	Results of Data Collection	Alternative Actions
<p><u>Question:</u> What is the quantity of contamination present in the water and soil sample matrices in the decision unit(s)?</p> <p><u>Statement:</u> Determine the average concentrations of contamination in each matrix, including confidence limits and accounting for non-detects.</p>	[<i>Pathogen concentration</i>] present in water	N/A (Results used to inform remediation, sampling and/or study approach)
	[<i>Pathogen concentration</i>] present in soil	N/A (Results used to inform remediation, sampling and/or study approach)
	DQOs not met	<ul style="list-style-type: none"> - Increase sampling of [<i>matrix</i>] - Revise sampling design
<p><u>Question:</u> What is the concentration of [<i>pathogen</i>] within the first 5-cm depth of soil.</p> <p><u>Statement:</u> Estimate the average [<i>pathogen</i>] concentrations within the first 5-cm depth of soil over time, including confidence limits and accounting for non-detects.</p>	[<i>Result for pathogen</i>]	N/A (Results used to inform remediation, sampling and/or study approach)
	DQOs not met	<ul style="list-style-type: none"> - Increase sampling of [<i>matrix</i>] - Revise sampling design

10.0 Supplemental Plans

10.1 Quality Assurance Project Plan (QAPP)

Provide the name of the QAPP (or equivalent document, e.g., Quality Management Plan, Quality Control Plan) associated with this data collection and analysis activity, along with an outline or brief description. This section also provides a field for attaching the QAPP document. (See Part I for instructions on attaching a file.) The QAPP is a comprehensive document describing in detail the activities that must be implemented to ensure that the results of the collected data and information satisfy the project performance criteria. For a specific incident, it is possible that an overall QAPP will be developed for the overall incident, and then a more detailed SAP could be developed for each specific sampling activity to be conducted. The elements of a QAPP address aspects of project management; quality assurance (QA) and quality control (QC); and data collection, production and use. Guidance on the technical requirements of a QAPP is provided in *Requirements for Quality Assurance Project Plans* EPA QA/R-5 (U.S. EPA 2001) and [Guidance on for Quality Assurance Project Plans](#) EPA QA/G-5 (U.S. EPA 2002a), which present advice intended to help prepare a QAPP. At a minimum, QAPPs should address the following elements:

- Project Management – key personnel and their roles; organization chart; project description and background; data quality objectives and criteria for measurement data; documentation and records
- Data Generation and Acquisition – sample design, methods, and handling; analytical methods; quality control; instrument and equipment inspection, maintenance, and calibration; data management
- Assessment and Oversight – assessments and response actions; reports to management
- Data Validation and Usability – data review, verification, and validation; verification and validation methods

[U.S. EPA Guidance for Quality Assurance Project Plans \(U.S. EPA 2002a\)](#) – provides detailed guidance regarding development of QAPPs to address EPA requirements.

[Federal Policy for Quality Assurance Project Plans](#) (U.S. EPA, U.S. DoD and U.S. DOE 2012) – was developed by an Intergovernmental Data Quality Task Force, consisting of the U.S. EPA, the U.S. Department of Defense, and the U.S. Department of Energy. The document provides guidance and worksheets to facilitate consistency in planning for, collecting and using environmental data.

10.2 Data Management Plan (DMP)

Provide the name of the DMP associated with the data collection and analysis activity, along with an outline or brief description of how the data will be reported, documented, stored and handled. This section also provides a field for attaching the DMP document. (See Part I for instructions on attaching a file.) If a DMP is not available, describe the processes that will be used to report, document, handle, store and retrieve the collected data. If collected, data that should be addressed include:

- Field observations
- Field measurements
- Field logs and sample documentation forms and labels
- Autonomous instruments (e.g., remote data-loggers)
- Results of laboratory sample analysis
- Global positioning system (GPS) sample/sample-unit location coordinates
- Photos and videos

10.3 Waste Management Plan (WMP)

Provide the name of the WMP associated with this data collection and analysis activity, along with a brief outline describing the procedures that will be used. This section also provides a field for attaching the WMP document. (See Part I for instructions on attaching a file.) If a WMP is not available, provide a description of the processes that will be used for managing waste generated during sample collection. It is recommended that a WMP should be in place prior to initiation of any sample collection activities associated with site characterization and/or remediation activities following a contamination incident. The WMP should outline waste management requirements, procedures, strategies, and processes from the point of generation to final deposition. Ideally, a general WMP will be in place that can be used to prepare an incident-specific WMP. This incident-specific plan should address federal, state and local waste management requirements for the different waste streams. The plan should address waste characterization and waste acceptance sampling and analysis, identification of waste management facilities, on-site waste management and minimization strategies and tactics, off-site waste management, and waste transportation, health and safety. In addition, it should address tracking and reporting of waste sampling results. State and local waste management officials should be contacted as early in the development process as possible.

For more information on WMPs, see EPA's Waste Management Benefits, Planning and Mitigation Activities for Homeland Security Incidents website (available at: <https://www.epa.gov/homeland-security-waste/waste-management-benefits-planning-and-mitigation-activities-homeland>; accessed July 27, 2021). Information on tools and other resources for managing sample collection waste can be found online at <https://www.epa.gov/homeland-security-waste> (accessed July 27, 2021).

10.4 Health and Safety Plan (HASP)

Provide the name of the HASP associated with the data collection and analysis effort, along with a description of its components and associated requirements (e.g., medical monitoring, training, selection and use of PPE). This section also provides a field for attaching the HASP document. (See Part I for instructions on attaching a file.) Each pathogen and contamination incident poses specific health hazards, and an incident-specific HASP should be available to sample collectors. HASPs will vary depending on the site, the sampling phase (site assessment, remediation or post decontamination) and the responsible organization. The purpose of these plans is to ensure maximum protection to workers, the environment and surrounding communities, in a way that is consistent with requirements needed to perform operational activities. HASPs should follow guidelines provided by the U.S. Department of Labor Occupational Safety and Health Administration (OSHA). At a minimum, HASPs should include instructions and guidelines regarding:

- Names, positions, and contact information of key personnel and health and safety personnel
- Site- or incident-specific risk assessment addressing sample collection activities
- Training requirements
- Personal protective equipment (PPE) on site and usage requirements
- Medical screening requirements (maintain confidential documents properly and securely)
- Site or incident control
- Emergency response plan, containing off-site emergency contact information such as local hazardous materials response teams or additional trained rescue personnel
- Entry and egress procedures
- Spill containment
- Personnel decontamination procedures

11.0 References

This section of the template allows users to provide citations for references and sources of information that were used to prepare the SAP outline. [Note: The references listed below were used in developing this User Guide.]

- Chattopadhyay, S. 2017. Sample Collection Information Document for Pathogens: Companion to Selected Analytical Methods for Environmental Remediation and Recovery (SAM) 2017. EPA/600/R-17/374. U.S. Environmental Protection Agency, Washington, D.C. https://cfpub.epa.gov/si/si_public_record_report.cfm?Lab=NHSRC&dirEntryId=339261 (accessed September 22, 2021)
- U.S. Department of Homeland Security (DHS). 2017. Biological Incident Annex to the Response and Recovery Federal Interagency Operational Plans. Final – January 2017. <https://asprtracie.hhs.gov/technical-resources/resource/6103/biological-incident-annex-to-the-response-and-recovery-federal-interagency-operational-plans> (accessed September 22, 2021)
- U.S. DHS. 2019. National Response Framework, Fourth Edition. <https://www.fema.gov/emergency-managers/national-preparedness/frameworks/response> (accessed September 22, 2021)
- U.S. DHS and U.S. EPA. 2009. Draft Planning Guidance for Recovery Following Biological Incidents. Biological Decontamination Standards Working Group, National Science and Technology Council, Department of Homeland Security, Washington, D.C.
- U.S. EPA. 2001. EPA Requirements for Quality Assurance Project Plans: EPA QA/R-5, EPA/240-B-01/003. U.S. Environmental Protection Agency, Office of Environmental Information, Washington, D.C. https://www.epa.gov/sites/default/files/2016-06/documents/r5-final_0.pdf (accessed September 22, 2021)
- U.S. EPA. 2002a. Guidance for Quality Assurance Project Plans: EPA QA/G-5, EPA/240/R-02/009. U.S. Environmental Protection Agency, Office of Environmental Information, Washington, D.C. <https://www.epa.gov/quality/guidance-quality-assurance-project-plans-epa-qag-5> (accessed September 22, 2021)
- U.S. EPA. 2002b. Guidance on Choosing a Sampling Design for Environmental Data Collection for Use in Developing a Quality Assurance Project Plan, EPA QA/G-5S, EPA/240/R-02/005 <https://www.epa.gov/quality/guidance-choosing-sampling-design-environmental-data-collection-use-developing-quality> (accessed September 22, 2021).
- U.S. EPA. 2002c. RCRA. Waste Sampling Draft Technical Guidance: Planning, Implementation, and Assessment, EPA530/D/02/002. U.S. Environmental Protection Agency, Office of Solid Waste and Emergency Response, Washington, D.C. <https://www.epa.gov/hw-sw846/draft-technical-guidance-about-waste-sampling-under-resource-conservation-and-recovery-act> (accessed September 22, 2021)
- U.S. EPA. 2004. Quality Assurance/Quality Control Guidance for Laboratories Performing PCR Analyses on Environmental Samples, EPA 815-B-04-001. U.S. Environmental Protection Agency, Washington, D.C. <https://www.epa.gov/esam/quality-assurancequality-control-guidance-laboratories-performing-pcr-analyses-environmental> (accessed September 22, 2021)
- U.S. EPA. 2006a. [Data Quality Assessment: Statistical Methods for Practitioners](#), EPA QA/G-9S. EPA/240/B-06/003. U.S. Environmental Protection Agency, Office of Environmental Information, Washington, D.C. (accessed September 22, 2021)

- U.S. EPA. 2006b. Guidance for Data Quality Objectives Process: EPA QA/G4, EPA/240/B-06/001. U.S. Environmental Protection Agency, Office of Environmental Information, Washington, D.C. <https://www.epa.gov/quality/guidance-data-quality-objectives-process-epa-qag-4-august-2000> (accessed September 20, 2021)
- U.S. EPA. 2006c. Data Quality Assessment: A Reviewer’s Guide, QA/G-9R. EPA/240/B-06/002. U.S. Environmental Protection Agency, Office of Environmental Information, Washington, D.C. <https://www.epa.gov/sites/default/files/2015-08/documents/g9r-final.pdf> (accessed September 20, 2021)
- U.S. EPA, U.S. Department of Defense, and U.S. Department of Energy. 2012. Uniform Federal Policy for Quality Assurance Project Plans. https://www.epa.gov/sites/production/files/documents/ufp_qapp_worksheets.pdf (accessed September 22, 2021)
- U.S. EPA. Forum on Environmental Measurements (FEM). 2012. Validation of U.S. Environmental Protection Agency Environmental Sampling Techniques that Support the Detection and Recovery of Microorganisms. FEM Document Number 2012-01. U.S. Environmental Protection Agency, Washington, D.C.
- U.S. EPA. 2014a. Framework for Human Health Risk Assessment to Inform Decision Making, EPA/100/R-14/001. U.S. EPA, Office of the Science Advisor, Risk Assessment Forum. <https://www.epa.gov/risk/framework-human-health-risk-assessment-inform-decision-making> (accessed September 22, 2021)
- U.S. EPA. 2014b. SW-846 Compendium: Project Quality Assurance and Quality Control: Chapter 1. SW-846 Update V. U.S. Environmental Protection Agency, Washington, D.C. <https://www.epa.gov/hw-sw846/chapter-one-sw-846-compendium-project-quality-assurance-and-quality-control> (accessed September 22, 2021)
- U.S. EPA. 2015. Decontamination Line Protocol Evaluation for Biological Contamination Incidents, Assessment and Evaluation Report. EPA 600/R-14/476. U.S. Environmental Protection Agency, Washington D.C. https://cfpub.epa.gov/si/si_public_record_Report.cfm?Lab=NHSRC&dirEntryId=307093 (accessed September 22, 2021)
- U.S. EPA. 2017. Selected Analytical Methods for Environmental Remediation and Recovery (SAM) 2017, EPA/600/R-17/356. U.S. Environmental Protection Agency, Washington, D.C. <https://www.epa.gov/esam/selected-analytical-methods-environmental-remediation-and-recovery-sam> (accessed September 22, 2021)
- U.S. EPA. 2018. Sampling, Laboratory and Data Considerations for Microbial Data Collected in the Field, EPA/600/R-18/164. U.S. Environmental Protection Agency, Office of Research and Development, Cincinnati, Ohio. https://cfpub.epa.gov/si/si_public_record_report.cfm?dirEntryId=341832 (accessed September 22, 2021)
- Stanislaus, M. 2016. Memorandum from Mathy Stanislaus, Office of Land and Emergency Management, U.S. Environmental Protection Agency to Office of Land and Emergency Management Employees regarding subject “Scribe – Exclusive Agency Database during a National Response,” March 8, 2016. U.S. Environmental Protection Agency, Washington, D.C.

Appendix. Data Quality Objective Summary

The data quality objective (DQO) process is discussed in detail in EPA’s *Guidance on Systematic Planning Using the Data Quality Objectives Process*, EPA QA/G4. The process is designed to produce scientific and resource effective data collection designs that will support decision-making with a defined level of confidence. This section of the Template Tool provides an automatically generated summary table containing information that has been entered into the template, organized to address project DQOs.

Note: Use “Ctrl + Click” on the sections identified in the right-hand column to navigate to the corresponding section in this User Guide. The same navigation capability is included in the template.

Data Quality Objective Summary Table	
STEP 1. State the Problem	
General Description	<u>1.1 General Data Collection Activity Description</u>
Sampling Phase and Pathogen	<u>1.2 Sampling Phase and Pathogen</u>
History	<u>1.4 Site Information and History</u>
STEP 2. Identify the Goal of the Sampling and Analysis Activities (estimation statement)	
Goals	<u>1.3 Goal</u> <u>Table 9.1 Defining Alternative Actions</u>
STEP 3. Identify the Information Inputs	
Sampling Protocols	<u>Table 5.1 Sample Collection Planning Form</u>
Plan for Obtaining Data	<u>5.5 Plan for Obtaining Data</u>
Analytical Protocols	<u>Table 8.1 Analytical Protocols to be Used</u>
STEP 4. Define the Boundaries of the Sampling and Analysis Activities	
Regulatory and Jurisdictional Boundaries	<u>3.2 Regulatory/Jurisdictional Boundaries</u>
Practical Constraints on Data Collection	<u>3.4 Practical Constraints</u>
Spatial and Geographical Boundaries	<u>3.5 Location: Spatial and Contextual</u> <u>3.5.1 Priority and Exclusion Zones</u> <u>3.5.2 Conceptual Model</u>
Scale for the Decision or Estimate	<u>3.6 Scale for the Decision or Estimate</u>
STEP 5. Develop the Analytical Approach	
Data Review and Reduction	<u>9.1 Data Review and Reduction</u>
Summary Statistics	<u>9.2 Data Assessment and Summary Statistics</u>
Analytical Approach	<u>9.3 Application of Results</u>
STEP 6. Specify the Performance and Acceptance Criteria	
Data Quality Indicators	<u>6.1 Data Quality Indicators</u>
Instrument Calibration	<u>Table 6.2 Instrument Calibration</u>
Field Controls	<u>6.2 Field Quality Controls</u>
STEP 7. Optimize the Design	
Sampling Approach	<u>5.3 Sampling Approach</u>
General Sampling and Analysis Design	<u>5.5.1 Sample Documentation Information</u>
Sample Collection Planning Form	<u>Table 5.1 Sample Collection Planning Form</u>

Attachment. Glossary

The definitions provided below reflect the intended use of each term for the purpose of EPA's SAP Template Tool and this corresponding User Guide.

Term	Definition	Reference
Accuracy	The degree of agreement between an observed value and an accepted reference value. Accuracy includes random error (precision) and systematic error (bias or recovery) that are caused by sampling and analysis. A data quality indicator.	U.S. EPA 1992 U.S. EPA 2004
Bias	The systematic or persistent distortion of a measurement process which deprives the result of representativeness (i.e., the expected sample measurement is different than the sample's true value.) A data quality indicator.	U.S. EPA 2016
Chain of Custody	Provides a chronological record of who has possessed the sample(s) from the moment of collection through receipt in the laboratory, to the eventual destruction or disposal. Also documents all analyses that were performed on the samples.	U.S. EPA 2018c
Site Characterization	Assessment of the extent, location, and magnitude of contamination. Characterization systematically expands on the initial assessment findings to identify contaminated locations and determine the contamination footprint at the affected locations, to better define the boundaries. Sampling information, specifics of the incident, and the data collected during the initial assessment might take on many forms and might come from several different groups involved in the initial response and assessment activities. The data will be evaluated and reviewed, and used to assist in formulating the objectives, strategy, and approach for the characterization phase. The information that results from the characterization affects and shapes the planning and implementation of the remediation phase.	Carlsen <i>et al.</i> 2012 U.S. EPA 2017 U.S. EPA 2018c
Co-located Samples	Field duplicates collected as close as possible to the sample point in space and time. They are two separate samples taken from the same source, stored in separate containers, and analyzed independently by the same protocol and laboratory. These are useful in documenting the precision of a sampling process.	U.S. EPA 2014
Combined Targeted and Probabilistic Sampling	Uses Bayesian statistical methodology to combine results from targeted and probabilistic samples to make statistical confidence statements. This sampling approach ensures that samples are collected from locations perceived as most likely to be contaminated (through targeted samples) while protecting against the possibility that contamination may exist in less likely areas (through probabilistic samples).	Sego <i>et al.</i> 2007 Sego <i>et al.</i> 2010 U.S. EPA 2018c

Term	Definition	Reference
Comparability	The degree to which different methods or data agree or can be represented as similar. Comparability describes the confidence that two data sets can contribute to a common analysis and interpolation. Comparability for sampling primarily involves sampling designs and time periods, while analytical comparability focuses on whether different laboratories were used, the units of measure, and sample preparation procedures. A data quality indicator.	U.S. EPA 1992 U.S. EPA 2014 U.S. EPA 2016
Completeness	A measure of the amount of valid data obtained from a measurement system compared with the amount that was expected to be obtained under correct, normal conditions. A data quality indicator.	U.S. EPA 2014 U.S. EPA 2016
Composite Sampling	Sampling method used where several samples are physically mixed into a larger composite sample. The entire composite sample may be measured for desired information, or one or more random sub-samples may be measured individually. In general, individual samples which are composited must be the same size or volume and the composite sample must be completely mixed. Composite sampling can be useful for estimating mean concentration of a substance, and if appropriate, compositing can result in substantial savings where the cost of analyzing individual samples is high.	U.S. EPA 2002b
Confidence Limit	A value above or below a measured parameter that is likely to be observed at a specified level of confidence.	U.S. EPA 2002b
Culture (method)	Preferred and definitive method (gold standard) to assess the viability of a target organism, in addition to determining its presence. Common culture-based protocols include: (1) bacterial assays that use either selective growth (preferential growth of a bacteria) or non-selective growth (general or non-specific growth) media and colony formation or turbidity as an indicator of bacterial growth and (2) viral assays that use cultured mammalian host cells (e.g., total culturable virus assay [TCVA]) and either cytopathic effects or plaque formation as an indicator of virus growth or replication. Less common, but important for viability assessment, are culture-based protocols for protozoa and helminths.	U.S. EPA 2018c
Data Quality Assessment	The evaluation of environmental data to determine if they meet the quality criteria required for a specific application.	U.S. EPA 2016
Data Quality Indicators	A performance measure for sampling and analytical procedures; a quantitative measure of the achievement of data quality objectives; qualitative statistics and quantitative descriptors that are used to interpret the degree of acceptability or utility of data to the user. The principal data quality indicators are precision, accuracy, comparability, completeness, and representativeness.	U.S. EPA 2002a U.S. EPA 2016
Data Quality Objectives	Qualitative and quantitative statements of the overall level of uncertainty that a decision maker is willing to accept in results or decisions derived from environmental data. DQOs provide the statistical framework for planning and managing environmental data operations consistent with the data user's needs.	U.S. EPA 2002a U.S. EPA 2006c U.S. EPA 2016

Term	Definition	Reference
Data Review	The evaluation process that determines the quality of reported analytical results. It involves examination of raw data (e.g., instrument output), quality control and method parameters, and statistical analyses by a professional with knowledge of the tests performed.	U.S. EPA 2006a
Data Reduction	Data reduction is the process of converting raw analytical data to final results in proper reporting units. In most cases, data reduction will be primarily concerned with the equation used to calibrate results.	Ohio EPA 1998
Data Usability	The process of determining and ensuring that the quality of the data produced meets the intended use of the data and the criteria set forth in the QAPP.	U.S. EPA 2018b
Data Validation	The process of determining that the data satisfy the requirements as defined by the data user.	U.S. EPA 2016
Decision Criteria	Quantitative or qualitative criteria to support decision making (e.g., determining when, where, and how many samples or measurements to collect and a desired level of confidence).	adapted from EPA 2006a
Decision Statement	Statements regarding decisions to be made that will inform the selection of an alternative actions.	adapted from U.S. EPA 2006c
Decision Unit	Decision units represent each area/volume for which a decision will be made.	Michigan DEQ 2018
Defensible	The ability to withstand any reasonable challenge related to the veracity of integrity of laboratory documents and derived data.	U.S. EPA 2016
Detection Limit	A measure of the capability of an analytical method of distinguished samples that do not contain a specific analyte from a sample that contains a low concentration of the analyte; the level of target analyte that can be determined to be different from zero by a single measurement at a stated level of probability DLs are analyte- and matrix-specific and may be laboratory dependent.	U.S. EPA 2002b
Documentation	Description of the data collection activities sufficient to be able to evaluate the completeness, comparability, representativeness, precision, and accuracy of the analytical data sets; types of documentation can include sampling and analysis plan, standard operating procedures, field and analytical records, and chain-of-custody records.	U.S. EPA 2006a
Direct Contact Transmission	Direct contact transmission requires physical contact between an infected person and a susceptible person, and the physical transfer of microorganisms. This type of transmission requires close contact with an infected individual and will usually occur between members of the same household or close friends and family.	CDC 2012
Environmental Data	Any measurements or information that describe environmental processes, location, or conditions; ecological or health effects consequences; or the performance of environmental technologies. For EPA, environmental data include information collected directly from measurements, produced from models, and compiled from other sources such as data bases or the literature.	U.S. EPA 2002b

Term	Definition	Reference
Environmental Sample	A sample of any material that is collected from an environmental source.	U.S. EPA 2016
Estimation Statement	Statements regarding what it is that will need to be estimated, along with key assumptions.	adapted from U.S. EPA 2006c
Exposure Pathway	Exposure pathways refer to the ways a person can come into contact with a hazardous substance. There are three basic exposure pathways: inhalation, ingestion, or direct contact.	U.S. EPA Emergency Response (accessed September 2021)
False Negative	Determination that an analyte is not present when it actually is present. Also called a Type II (beta) error or false acceptance decision error.	U.S. EPA 2002b U.S. EPA 2016
False Positive	Estimation that an analyte is present when it is actually not present. Also called a Type I (alpha) error or false rejection decision error.	U.S. EPA 2002b U.S. EPA 2016
Field Blank	A blank used to provide information about contaminants that may be introduced during sample collection, storage and transport. The clean sample is carried to the sampling site, exposed to sampling conditions, returned to the laboratory, and treated as an environmental sample.	U.S. EPA 2002b
Field Replicates/ Duplicate	Two or more samples collected at the same time and location to be considered identical. Also referred to as “co-located samples”.	U.S. EPA 2002b
Field Splits	A type of field duplicate where the sample is homogenized and then divided into two or more aliquots so that variability can be evaluated.	U.S. EPA 2018c
Hazard	Represents the pathogens potential to generally cause adverse effects in normally healthy humans.	U.S. EPA 2007
Intended Use of Data Collection: Decision-making	Use of data for decision-making usually occurs during regulatory monitoring, emergency response, and other contexts where decisions will be made regarding action(s) that will be taken (e.g., site clearance versus continued decontamination and/or sampling activities).	adapted from U.S. EPA 2006c
Intended Use of Data Collection: Estimation	Uses of data for estimation purposes include supporting the development of regulatory levels or decision criteria, and other determinations that provide a quantitative result (e.g., pathogen concentration or specific location of contamination) on which a decision could be based. Estimation results, for example, can be used to support “limits” against which a decision can or will be made (e.g., site cleanup goal that can be used to determine whether additional remediation and/or sampling is needed).	adapted from U.S. EPA 2006c
Matrix	The type of media in which the analyte of interest is contained (e.g., wastewater, storm water).	U.S. EPA 2004
Matrix Spike	A sample in which a known amount of the target analyte is added to a specified amount of matrix. These samples can be used to evaluate the effect of the matrix on the recovery efficiency and performance of a method.	U.S. EPA 2004

Term	Definition	Reference
Media Blank/ Trip Blank	A sample of analyte-free media taken from the laboratory to the sampling site and returned to the laboratory unopened. The sample is used to document contamination attributable to shipping and field handling procedures.	FEM 2012
Method Blank	A sample used to simulate the sample matrix conditions and analyzed using the exact same calibration standards, samples, and quality control samples. Intended to discover any bias in the analysis and detect within-batch variability of the blank response.	U.S. EPA 2004
Most Probable Number (MPN)	A statistically derived estimate of the presence of microorganisms based on the presence or absence of growth in serially diluted samples.	U.S. EPA 2012a
Media Blank	Unexposed samples not taken to the field or shipped. Media blank results are used for background correction of sample readings and for recovery studies.	U.S. EPA 2018c
Negative Control	A sample that contains a non-target organism (e.g., does not grow on the medium or produces colonies with different morphology) and does not contain the target pathogen or surrogate. Negative culture controls should produce either no growth or atypical growth (e.g., colony morphology is different from the target pathogen). Negative PCR controls (no template controls) should not exhibit amplification.	U.S. EPA 2018c
Non-detect	Data generated from analysis that fall below the detection limit of the analytical procedure.	U.S. EPA 2006b
Pathogen	Microorganisms (e.g., bacteria, viruses, or parasites) that can cause disease in humans, animals and plants.	U.S. EPA 2007
Persistence	The ability of the microorganism to survive in the environment of host.	U.S. EPA 2007
Performance or Acceptance Criteria	Statements of the type and content of deliverables and results that are necessary to assess the usability of data for risk assessment. Specific limits placed on the characteristic of an item, process, or service.	U.S. EPA 2002b U.S. EPA 2006c
Polymerase Chain Reaction (PCR)	Laboratory technique used to make multiple copies of a segment of DNA. PCR is very precise and can be used to amplify, or copy, a specific DNA target from a mixture of DNA molecules.	U.S. EPA 2004 U.S. EPA 2018c
Positive Control	Ideally, positive controls contain a known quantity of the target pathogen or surrogate (in some cases, the concentration is known only to be above the analytical protocol's detection limit). Analytical results of a positive control should fall within a specified range of the known quantity or exhibit characteristics typical of the target pathogen.	U.S. EPA 2018c
Precision	A measure of how closely values from replicate measurements of a sample agree with each other. Usually expressed as standard deviation, variance, or range in either absolute or relative terms. A data quality indicator.	U.S. EPA 2004 U.S. EPA 2016
Quality Assurance (QA)	An integrated system of activities involving planning, quality control, quality assessment, reporting, and quality improvement to ensure that a product or service meets defined standards of quality with a stated level of confidence.	U.S. EPA 2016

Term	Definition	Reference
Quality Assurance Project Plan (QAPP)	A document describing in comprehensive detail the necessary QA, QC, and other technical activities that must be implemented to ensure that the results of the work performed will satisfy the stated performance objectives and criteria.	U.S. EPA 2014 U.S. EPA 2016
Quality Control (QC)	The overall system of technical activities that measures the attributes and performance of a process, item, or service against defined standards to verify that they meet the stated requirements established by the customer; operational techniques and activities that are used to fulfill requirements for quality.	U.S. EPA 2001a U.S. EPA 2001b U.S. EPA 2016
Quantitative	An observation that has a meaningful numerical value. It can be either a direct observation or a count.	Dytham 2011
Recovery	The total amount of the analyte found in the sample, corrected for background, divided by the amount of the analyte added into the sample.	U.S. EPA 2004
Recovery Efficiency	The recovery of an analyte in an assay is the detector response obtained from an amount of the analyte added to and extracted from the biological matrix, compared to the detector response obtained for the true concentration of the pure authentic standard.	U.S. EPA 2012b U.S. EPA 2018c
Replicate	An additional sample that allows for averaging two or more samples to ensure the most accurate results and improves quality assurance.	U.S. EPA 2012b
Representativeness	The degree to which data accurately and precisely represent a characteristic of a population, a parameter variation at a sampling point, a process condition, or an environmental condition. A data quality indicator.	U.S. EPA 2002b U.S. EPA 2016
Sample Integrity	The maintenance of the sample in the same condition as when sampled.	U.S. EPA 2018c
Sample Preservation	Techniques that stabilize parameters of interest by retarding chemical or biological changes.	U.S. EPA 2012b
Sample Processing	The processing of biologically contaminated environmental samples prior to sample analysis to remove debris, chemical components, and biological impurities.	Silvestri <i>et al.</i> 2014/ Silvestri <i>et al.</i> 2016/ U.S. EPA 2018c
Select Agent	Biological agents and toxins that have been determined to have the potential to pose a severe threat to public health and safety, to animal and plant health, or to animal or plant products.	CDC Center for Environmental Preparedness and Response website (accessed 2021)
Sensitivity	(1) The capability of a method or instrument to discriminate between small differences in analyte concentration; (2) A qualitative description of an instrument's or analytical method's detection limit. The sensitivity of a test can be described as the proportion of all positive results detected that were truly positive. All positives are the sum of (detected) true positives (TP) and (undetected) false negatives (FN). Sensitivity is therefore: $TP / (TP + FN) \times 100\%$.	U.S. EPA 2004 U.S. EPA 2012b
Spiked Sample	Known amounts of analyte are added to a sample and the percent recovery is calculated. Used to test an analytical method at varying concentrations of analyte.	U.S. EPA 2018c

Term	Definition	Reference
Relative Standard Deviation (RSD)	Used to compare the variance between results obtained by repeated measurements on the same sample, expressed as a percentage of the mean recovery. %RSD (also known as the coefficient of variation) is calculated by first obtaining the SD of a set of measurements, or the differences between repeated measurements, dividing that result by the average of those measurements or their differences, and then multiplying by 100 to represent it as a percentage.	U.S. EPA 2016 U.S. EPA 2019
Standard Operating Procedures (SOPs)	A written document that details the method for an operation, analysis, or action with thoroughly prescribed techniques and step. Some SOPs are officially approved as the method for performing certain routine or repetitive tasks.	U.S. EPA 2001 U.S. EPA 2014
Trip Blank/ Media Blank	A sample of analyte-free media taken from the laboratory to the sampling site and returned to the laboratory unopened. The sample is used to document contamination attributable to shipping and field handling procedures.	U.S. EPA 2012b
Variability	This refers to the observed differences attributable to true heterogeneity or diversity in a parameter. Examples include human physiological variation (e.g., natural variation in body weight, height, breathing rate, drinking water intake rate), weather variability, variation in soil types, and differences in contaminant concentrations in the environment. Variability is usually not reducible by further measurements of study, but it can be better characterized. NRC Definition: Variability refers to true differences in attributes due to heterogeneity or diversity. Variability is usually not reducible by further measurements of study, although it can be better characterized.	USDA and EPA 2012
Waste Characterization	Assessment of the waste based on all available information [e.g., sampling results] to document that the waste meets regulatory requirements and any additional requirements of waste receivers prior to off-site disposal.	U.S. EPA 2018a

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