Interim Draft Outline:

Sampling and Analysis Plan for Environmental Samples Potentially Containing Pathogens

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U.S. Environmental Protection Agency
Cincinnati, Ohio 45268

Disclaimer for Interim Draft

The U.S. Environmental Protection Agency (EPA), through its Office of Research and Development, funded and managed the interim draft document described here under Contract No. EP-C-14-001, WA 1-14 with ICF Incorporated and along with the Microbial Data Usability Workgroup. It has been subjected to the Agency's review and has been approved as an interim draft. 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, endorsement, or recommendation. ***Please note that this interim draft is subject to change following beta testing of the corresponding online tool for which this outline was developed***.

This interim draft is meant to provide an outline to assist in generation of a microbiological sampling and analysis plan (SAP), which could be used for a contamination incident and could be amended to be used for exercises and research studies. This document is an outline of the tool which will be used by environmental unit leaders to develop SAPs for site characterization, verification sampling, and post decontamination sampling stages of sampling and analysis activities for environmental samples potentially containing pathogens in which the EPA would be responsible for conducting sampling. It is assumed that a separate committee will make decisions regarding clearing a site. The SAP outline does not include considerations for the initial response phase of an event, as it is assumed that the initial response would have been previously completed by another agency during the clearance phase of the response. However, the SAP outline could be modified to include clearance and initial response phases as appropriate. A statistician or sample planning tool should be utilized for generation of sampling numbers and locations.

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

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Acronyms

CDC	Centers for Disease Control and Prevention
DQA	Data quality attribute
DQI	Data quality indicator
DQO	Data quality objectives
EPA	United States Environmental Protection Agency
ERLN	Environmental Response Laboratory Network
FBI	Federal Bureau of Investigation
FEM	Forum on Environmental Measurement
FEMA	Federal Emergency Management Agency
FN	False negative
FP	False positive
GPS	Global Positioning System
HASP	Health and safety plan
HSEEP	Homeland Security Exercise and Evaluation Program
ICLN	Integrated Consortium of Laboratory Networks
LRN	Laboratory Response Network
MicroSAP	Name of the tool for developing microbiological sampling and analysis plans
NHSRC	National Homeland Security Research Center
OSHA	Occupational Safety and Health Administration
PPE	Personal protective equipment
QA	Quality Assurance
QC	Quality Control
SAP	Sampling and Analysis Plan
SOP	Standard Operating Procedure
TN	True negative
TP	True positive
QA	Quality assurance
QC	Quality control

User Instructions

The U.S. Environmental Protection Agency has developed a user-friendly, on-line tool called the MicroSAP. The goal of the MicroSAP tool is to assist users with development of SAPs needed for site characterization, verification sampling, and post decontamination sampling stages of microbiological sampling and analysis activities in which the EPA would be responsible for conducting sampling. These activities could include sampling and analysis for a contamination incident, a research study, or an exercise involving a pathogen of interest. This interim sampling and analysis plan (SAP) outline presented herein was produced as a companion to the MicroSAP tool. This SAP outline provides a general description of the sections that would be present in a SAP generated using the MicroSAP tool. The SAP outline does not include considerations for the initial response of an incident, as it is assumed that the initial response would have been previously completed by another agency during the response, or the clearance phase, as it is assumed that separate committee would be established to make decisions regarding clearing a site. This outline does include considerations for capturing the associated data quality objectives in the SAP.

While this document was developed specifically to be an outline of the output for the MicroSAP tool, it could also be used as a "ready to go" outline for creating a SAP for other microbiological incidents, research activities, and exercises that have not utilized the MicroSAP tool. The outline provides a general description of the essential features that should be included in a SAP. The main numbered headings represent major sections of the outline. Underneath each heading, a brief description of information that would be included in that section is provided. These descriptions should be deleted and replaced with the appropriate text for that section. Example forms such as chain-of-custody and sample collection forms are provided as examples only. This outline does not establish the number or locations of where samples should be collected and a statistician or sampling planning tool should be consulted to determine this information.

Please note that this interim draft is subject to change following beta testing of the MicroSAP tool for which this outline was developed. In addition, this SAP outline does not replace SAP requirements that might already be in place for a particular EPA region or office. Prior to using this outline, please check to ensure that there are not established contractor or Agency requirements for using a specified format for data collection and reporting.

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Sampling and Analysis Plan for Environmental Samples Potentially Containing Pathogens Outline

[Name of Data Collection Activity]

[Type of Data Collection (Incident, Research, Exercise)]

Prepared by:

[Address]

[Date]

Sampling and Analysis Plan Approval

[Name of Data Collection Activity]

[Insert Date]

Fill-out the name(s) and agencies of the required approvers on the lines below. Please note that signature(s) will be obtained when the Sampling and Analysis Plan (SAP) is routed for approval following review.

Approved by: _____ Date: _____

Title: _____ Agency: _____

Print Name: _____

Approved by: _____ Date: _____

Title: _____ Agency: _____

Print Name: _____

Disclaimer

Insert required disclaimer

Send questions to:

[Insert Contact Name]

[Insert Contact Address]

[Insert Contact Phone Number]

[Insert Contact Email]

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Acronym List

[Provide a list of acronyms that are used in the SAP]

1.0 Introduction

The following narrative provides information on the type of data input which will be needed to develop microbiological sampling and analysis plans (SAPs) for use during site characterization, verification sampling, post decontamination sampling and/or waste characterization phases of an incident, research study, or exercise involving a pathogen of interest. While this SAP outline did not specifically consider clearance phase, which might be handled by an clearance committee, this SAP could be adapted to address clearance phase sampling. It is also assumed that post-decontamination sampling might be used to inform a separate committee in charge of decisions regarding clearance. Post-decontamination sampling depending upon the type of SAP chosen (incident, research, exercise) specific input data will be required.

1.1 Sampling Phase and Pathogen

SAPs provide a reference document for sampling and analysis during an environmental incident, research study, or simulation exercise. A SAP describes a specific pathogen or multiple pathogens, quality assurance/quality control (QA/QC) measures, and data quality objectives. SAPs need to include the phase of the incident; type of pathogen(s); and type of media to be collected and analyzed, at specific location(s).

One of the following choices will be selected:

- Incident
- Research
- Exercise

1.2 Personnel

Key personnel involved in the planning and/or technical activities performed for this data collection activity will be provided in Table 1.1 below. The name of the individual, their position, the agency they are affiliated with, their cell phone number, and email address should be entered into the table.

Table 1.1 List of Key Personnel Involved in Planning and Technical Activities

Name	Position/Role	Agency/Office/Division	Cell Phone #	Qualifications*	Email

*Qualifications might include information on education, training, experience and/or knowledge of the project.

1.3 Background

This section defines and organizes information about the current understanding of the problem, and identifies key questions and expected outcomes, along with alternative actions or outcomes. This section also summarizes the extent of the known and unknown of the pathogen contamination and organizes the current understanding of the problem. It also includes a description of the relevant resources for the data collection activity (incident, research, exercise).

1.3.1 Problem Description

This section should include a general explanation of exposure routes, environmental sampling that could be conducted, and potential cleanup goals. This section also characterizes the pathogen(s) of interest targeted for this data collection activity in Table 1.2 below. Please note that in the MicroSAP tool, the pathogen is selected in step 1.1 and the tool pre-populates the first column of this table. Pathogen type options include bacteria, virus, protozoa, helminth or biotoxin. The third column states if the pathogen is a CDC select agent (yes or no). Matrix refers to the type of sample media the pathogen is contained in (example soil, water). Persistence/stability information and fate and transport information is filled in to the last two columns of the table for the pathogen and matrix combination.

Table 1.2 Pathogen Characterization

Pathogen	Pathogen Type	CDC Select Agent (Y/N)	Matrix	Persistence/ Stability*	Fate and Transport*

*For the pathogen/matrix combination

1.3.2 Intended Use [Decision or estimate]

The intended use of the data will be selected in this step. There are two primary types of intended uses of the data collected, decision-making or estimation. Decision-making is defined as making a choice between alternative conditions and usually occurs during regulatory activities, emergency responses, and other contexts where action is taken. Estimation evaluates the magnitude of an environmental parameter or characteristic and usually supports longer term Agency activities, such as scientific background for rulemaking. An example of data being collected for estimation purposes is determining the density of fecal indicator organisms in water. The resulting estimate might be used in further research, as input to a model, or to support decision making.

1.3.3 Goal

A statement describing how the environmental data will be used in meeting objectives and solving the problem, identifying key study questions, and defining alternative outcomes will be formulated. Table 1.3 below is used to establish the goal(s) of the study. First, the principal study question(s) are identified. Then alternative outcomes are defined. Finally, a decision statement(s) (choices to be made among alternative actions for decision-making uses of the data) or an estimation statement (statement of what needs to be estimated along with key assumptions for estimation type uses of the data) is developed. Two examples (one for decision-making and one for estimation) are provided in the Table 1.3 below.

Table 1.3 Defining Goals for the Study

Intended Use of the Data	Principal Study Questions	Alternative Outcomes	Decision Statement(s) or Estimation Statement(s)

Example: Decision	What locations have been contaminated with the pathogen(s) in the specified sampling area (site characterization)?	Pathogen is (confirmed/not confirmed) to be located at a sampled location	Determine the locations that the pathogen can be detected in a specified sampling area
Example: Estimation	What is the quantity of contamination present in the sampling area (site characterization)?	Pathogen quantity (is/is not) estimated	Determine the concentration of contamination associated with the pathogen in the specified sampling area

1.3.4 Site Condition

Information on what is known about the location of the contamination is included. At a minimum, the following information, where available is needed:

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

1.3.5 Conceptual Site Model

A conceptual site model for the data collection activity is provided in this section.

1.4 History and Available Information

This section describes what is known about the data collection activity (incident, research, exercise) including the any known history, site conditions, and any data that has been previously collected (for example, data collected during the initial response to identify the pathogen).

1.4.1 History

This information describes what is known regarding the data collection activity history, background, the location, and prior actions taken at the site.

1.4.2 Previously Collected Data

During an incident, this section describes the data that has already been collected that might aid in decisions regarding further sampling and analysis needed. Some of the possible sources of previously collected data are law enforcement, clinicians, and public health personnel. When being used for research or an exercise this information can be historic (research) or simulated to support the exercise.

1.4.3 Lines of Evidence

Lines of evidence used to support decision making during the data collection activity will be discussed in this section. Several different types of information or data might be needed to understand and support decision making related to complex issues, issues such as those related to QC and determination of the need for additional remediation. Lines of evidence might include environmental sampling results, epidemiology data, environmental monitoring, animal monitoring data, and pathogen fate and modeling.

1.5 Operation Schedule

The general operation schedule for the phase of the data collection activity (incident, research, exercise) will be described. This schedule might include information such as sampler personnel training, actual sample activities, documentation of when decontamination might occur or occurred, etc.

1.5.1 Operation Period

The operation schedule will be described or a file with this information in the format of a calendar or Gantt chart will be included. The start and end dates for all activities (where available) are noted in this section.

1.6 Relevant Deadlines

Important deadlines related to the sampling and analysis activities should be described. Examples of important deadlines include tentative sampling and analysis dates.

1.7 Budget

Information on the budget for activities related to the data collection activity (incident, research, exercise) is provided in this section.

1.8 Available Equipment

Information on the available equipment for the data collection activity is provided in this section. Information regarding calibration and maintenance of any equipment or instruments used in collecting measurement data should also be included. All equipment is uniquely identified and labeled. Defective equipment should be isolated to prevent mistaken use.

1.9 Other General Resources

Information on other general resources available during the data collection activity is provided in this section.

1.10 Other General Schedule Information

Other general schedule information is provided in this section.

2.0 Management and Agency Coordination

This section focuses on the management of the data collection activity (incident, research, exercise) and the coordination of all agencies involved. An organization chart that illustrates agency responsibilities and collaboration will be the output of this section.

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

The roles of each of the agencies participating in the data collection activity and the coordination between the agencies are described in this section (Sections 2.1.1 through 2.1.9). If an agency listed in Sections 2.1.1 to 2.1.9 is not participating in the sampling and analysis activities, "Not applicable" or "N/A" is entered. The following is a listing of agencies who normally respond to an incident:

2.1.1 Federal Bureau of Investigation (FBI)

2.1.2 State and Local Public Health

2.1.3 Department of Health and Human Services (HHS)/Centers of Disease Control and Prevention (CDC)

2.1.4 United States Environmental Protection Agency (EPA)

2.1.5 Integrated Consortium of Laboratory Networks (ICLN)

Please note that the ICLN is made up of six established laboratory response networks, including the CDC Laboratory Response Network (LRN) and the EPA Environmental Response Laboratory Network (ERLN).

2.1.5.1 Laboratory Response Network (LRN)

2.1.5.2 Environmental Response Laboratory Network (ERLN)

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2.1.6 Other Federal Agencies

2.1.7 Other State Agencies

2.1.8 Other Local Agencies

2.1.9 Civil Support Teams

2.2 Summary of Data Collection Management and Resources

The available personnel for this data collection activity (incident, research, exercise) including management personnel, technical experts, and laboratory resources are described in this section.

A summary of the personnel responsible for data collection activity management are input using Table 2.1 below. Include the name of the individual or organization, number of personnel from the organization, the affiliation, the role in the data collection activity, the relevant expertise, and a contact phone number and email. If available, an organizational chart that illustrates the available personnel should be included.

Table 2.1. Summary of Personnel Responsible for Data Collection Management

Name/Organization	Number of Participants Involved	Affiliation	Role	Expertise	Phone Number	Email

Provide a summary of the individuals who will be consulted for their expertise during the data collection activities in Table 2.2. Include the name of the individual, their affiliation, their role in the data collection activity, their relevant expertise, a contact phone number and email, who referred this individual as an excerpt for this data collection activity (if applicable), and the purpose of contacting the individual.

Table 2.2. Available Technical Expertise Teams

Name	Affiliation	Role	Expertise	Phone Number	Email	Referred by	Purpose of Contact

A summary of the available laboratory resources is provided in Table 2.3 below. Important information can include the laboratory contact name, the laboratory address (and shipping address if different), if EPA currently has a contract with the laboratory, names of important contacts at the laboratory, whether the laboratory is a member of the ERLN or LRN network, the laboratory capabilities (sample types the laboratory is willing to accept and the type of analysis methods the laboratory can perform), and the highest biosafety level the laboratory can operate at.

Table 2.3. Laboratory Resources Available

Laboratory Name	Laboratory Address	Shipping Address	Contract on File	Laboratory Contacts	ERLN Lab Or LRN Lab	Analysis Capacity	Sample Types the Lab Can Analyze	Biosafety Level

3.0 Boundaries of the Data Collection Activities

In this section the target population and spatial and temporal features of the data collection activity (incident, research, exercise) are described. The input needed for this section includes regulatory and jurisdictional boundaries, building priority zones, hazard characteristics, spatial and temporal considerations for the site itself, and logistical and practical constraints. This section does not cover sample locations or the sampling design which are addressed in Section 5.

3.1 Regulatory/Jurisdictional Boundaries

In this section the regulatory and or jurisdictional boundaries and facility permits are described. This description should include if there are action levels for the pathogen sampled for in this collection activity. In addition, existing quality management plans and/or standard operating procedures can be mentioned.

3.2 Hazard Characteristics

The hazard characteristics (conditions or physical parameters that might affect quality of measurements/samples) are described for the data collection activity. This type of information might include data on temperature of the site, sunlight intensity, smoke, wind, rain, and dust.

3.3 Location: Spatial and Contextual

The spatial and contextual boundaries of the data collection activities are described, mapped and sketched in this section. If available, a site map should be included as an input file.

3.3.1 Building Priority Zones

The current designation of building priority zones are described in this section. If available, a file that illustrates all sampled priority zones should be included as input.

3.3.2 Potential for Pathogen to Spread

The transmission routes relevant for the collection activity are described in this section.

3.4 Logistical Considerations

The logistical issues to be considered for the collection activity are described in this section. These might include, but are not limited to, laboratory capability and/or capacity and maintenance practices.

3.5 Practical Constraints

The practical constraints (physical and civil) that might interfere with data collection to be considered for the activity are described in this section. Include conditions that may adversely impact the quality of measurements/samples, if applicable e.g. rain, wind, smoke, dust etc.

3.6 Waste Facility Capacity and Considerations

Waste facility capacity and other related issues to be considered for the collection activity are described in this section.

3.7 Appropriate Scale for the [decision or estimate]

The scale for the decision or estimate to be considered for this collection activity is described in this section.

4.0 Phase-based Project Planning

This section includes descriptions of the types and sources of information needed to address the data collection activity (incident, research, exercise) goal(s) described in 1.3.3. The information collected includes: describing the phase of the sampling; identifying the appropriate sampling and laboratory methods exist to properly address the intended use of the data; identifying sample types; and identifying the laboratory reporting requirements. This step may be re-evaluated after initial data collection during an incident.

4.1 Phase Sampling

A general discussion of the sampling phase, the type of data needing to be collected, and any other kind of relevant descriptors should be discussed in this section. Specific details are provided in the subsequent fields within this section. Note that there will be different considerations for the input step, data interpretation step, and sampling information based on the selected sampling phase.

4.2 Information Inputs

The types and sources of information needed to address the goals of the collection activity are described in this section. The information includes whether appropriate sampling and laboratory methods exist to properly support collection and analysis activities. This step may be re-evaluated after initial data collection during an incident.

4.2.1 Other Target Analytes

Additional target analytes considered during the collection activity are described in this section. Examples of other target analytes include: decontamination byproducts, oxygen levels, or decontamination constituents such as chlorine.

4.2.2 Sampling Standard Operating Procedures

This section describes the sample types and sampling standing operating procedures (SOPs) to be used during the collection activity. It is preferred that users select sample media for which validated analytical methods with supporting data have been published. However, analytical methods for media that have not yet been validated can be presented as a choice in instances where their use is beneficial. While these sampling methods might yield information that is more qualitative than quantitative in nature, their application can provide important indicators of the state of a potentially contaminated space. The laboratory that will be used for sample processing should be consulted to determine which sample types can be accepted for processing. If available, the sampling SOP can be included in the Appendices.

4.2.3 Sample Types

The general sample types that will be used during the collection activity are described as text or using Table 4.1 below. The pathogen should be carried over from what was entered in section 1.1. The matrix is the sample media the pathogen is contained in (ex. surface), while sub-matrix refers to a specific type of matrix being sampled. For example, if the matrix being sampled is a surface, the user should also identify the specific type of surface (laminate, wood, glass, etc.) to be sampled under sub-matrix. Another example would be if water is selected as the matrix, the user should identify it the water is drinking water, surface water, recreational water, etc., under sub-matrix. Specific sample type would describe the sample collection tools being used such as a sponge-stick, swab, vacuum sample, etc. Select if a wetting solution will be used (yes or no). Verify that the laboratory that has been selected to analyze the samples can handle the selected sample type. List the sampling SOP that will be used to collect the samples and include the SOP in the appendices.

Table 4.1. Sample Protocols to be Used

Pathogen	Matrix	Sub-Matrix	Specific Sample Type	Wetting Solution Used (Y/N)?	Sample Type Accepted by Lab Performing the Analysis (Y/N)?	Sampling SOP

4.2.4 Processing and Analysis

The processing and analysis protocols that will be used are described in this section as text or in Table 4.2 below. The pathogen should be carried over from what was entered in section 1.1. The matrix is the sample media the pathogen is contained in (ex. surface), while sub-matrix refers to a specific type of matrix being sampled (ex. laminate, wood, glass). Specific sample type would describe the sample collection tools being used such as a sponge-stick, swab, vacuum sample, etc. Maximum storage holding time refers to the maximum time the sample can be held after collection, before it is analyzed. Results required refers whether presence/absence data (ex. PCR data outputting cycle threshold time) is need or if quantitative data is needed (ex. CFU). List the sample processing protocol and analytical protocols that will be used and include the protocols in the appendices. The sample processing protocol and the analysis protocol can be included in the Appendices. The EPA's Selected Analytical Methods for Environmental Remediation and Recovery (U.S. EPA 2012) may be consulted for more information on protocol selection. Include any relevant quantitation or detection limits for the protocols if known. Verify the laboratory that will be doing the analysis.

Table 4.2. Analysis Protocols to be Used

Pathogen	Matrix	Sub-Matrix	Sample Type	Maximum Storage Holding Time	Maximum Storage Temperature	Results Required	Sample Processing Protocol	Analytical Protocol	Quantitation and/ Or Detection Limit	Laboratory Selected for Analysis

4.2.5 Laboratory Reporting Requirements

The agreed upon format for reporting out laboratory results are described in this section. Alternatively, a copy of the results format can be included in the Appendices. A check should be performed to determine if there are any contractor or Agency requirements for using a specified format for data collection and reporting. Reports include information such as environmental conditions that may affect the interpretation of the results.

5.0 Sampling Design

This section will provide information about the sampling strategy to develop the sample design for the data collection activity (incident, research, exercise).

5.1 Sampling Approach

The sampling approach (i.e., judgmental/targeted, probabilistic, combined targeted and probabilistic) are described in this section. Note that the description of the sampling approach is unique and site-specific.

5.2 Sampling Locations

A general description of the locations that are to be sampled during the collection activity are provided as input to this section.

5.2.1 Outside Sampling Locations

Outside locations that are to be sampled during the collection activity are to be described in this section.

5.2.2 Interior Sampling Locations

Interior locations that are to be sampled during the collection activity are to be described in this section.

5.3 Plan for Obtaining the Sample

The planning process including a description of software, the use of technical expertise teams, and the use of processes from previous plans is described in this section. For example, Scribe® is a software tool that is often used for data collection.

5.4 Sample Collection Tools

The tools that will be used during sample collection are described in this section. Tools that could be used might include:

- Global Positioning System (GPS) device
- Laser measuring device

- Tablet with electronic data sheets
- Bar coded sample labels and label reader

5.5 Sample Forms

Sample forms to be used as part of the planning process should be described or included in this section. Sample and analysis forms should include information on how many samples will be collected for each tactic or mission. The forms will be completed in order to prepare the necessary sample kits, ensure adequate supplies are available, and plan for laboratory capacity for analysis. An example SAP form is provided below. This form collects information on the type of sampling location (provide the name or location type), the identification numbers for the samples to be collected, and if the samples are being taken indoors or outdoors. It also collects information on the type of matrices to be sampled, the name of the sampling SOP to be used, and the total number of samples to be collected. Finally, the type of sampling container the samples will be collected in, any requirements for preserving the sample prior to shipping, and the maximum holding time allowed between sample collection and shipping should be included.

Form 5.1 EXAMPLE Sampling and Analysis Planning Form

Name of Data Collection Activity:

Pathogen:

Sampling Location (this could be outside or inside, and includes sample orientation)	Location ID Numbers (indicate range of numbers)	Indoor or Outdoor	Collected Sample Matrices	Sampling SOP	Total Number of Collected Samples	Containers (number, size and type)	Preservation Requirements	Holding Time*

5.6 Sample Supply, Equipment, and Personal Protective Equipment (PPE) List

Supplies, equipment, and PPE will be used during the collection activity are described in this section.

5.7 Sampling Diagrams

A sampling diagram is included in this section. This diagram should illustrate where samples will be collected.

5.8 Sample Collection Considerations

Contamination control activities are described in this section. This might include use of aseptic techniques and pre-assembled sample kits to control the spread of contamination during sampling from areas of high contamination and in areas with no or low contamination.

5.8.1 Aseptic Techniques
Aseptic techniques that will be used during the sampling activity are described in this section.

5.8.2 Use of Pre-Assembled Sample Kits
Pre-assembled sample kits that will be used during the sampling activity are described in this section.

5.8.3 Sample Decontamination
Sample decontamination approaches that will be used during the sampling activity are described in this section.

5.9 Sampling Team Personnel
The sample team configuration is described in this section. A list of available sampling personnel or companies used for sampling can also be included in place of a description.

5.10 Safety and Health Considerations
Information on medical monitoring, training, and appropriate selection and use of PPE are contained in a site specific health and safety plan (HASP). The name or project number for the HASP is entered as an input for this section. If available, the site specific HASP can be included as an attachment in the appendices.

5.10.1 Certification and Training
A list of required certifications and training are provided in this section.

6.0 Analytical Data Display and Statistical Approach for Results
The summary statistics and the approach to how the data will be displayed or analyzed are described in this section. If needed, a statistician or planning tool for additional input should be consulted before completing this section.

6.1 Possible Summary Statistics
The summary statistics will be used to present analytical data for the collection activity (incident, research, exercise) are described in this section. The decision rule table (Table 6.1) is completed as appropriate.

Table 6.1. Decision Rule Table

Qualitative (presence or absence)	Quantitative
If the [pathogen] is detected, then [user should identify what decision is made]	If [user should enter their parameter (e.g. pathogen concentration)] are above the threshold [user should insert the threshold value here], then [user should identify what decision is made]
If the [pathogen] is not detected, then [user should identify what decision is made]	If [user should enter their parameter (e.g. pathogen concentration)] are below the threshold [user should

	insert the threshold value here], then [user should identify what decision is made]
If the results are inconclusive and include detects and non-detects, then [user should identify what decision is made]	If [user should enter their parameter (e.g. pathogen concentration)] are inconclusive, then [user should identify what decision is made].

6.2 Analytic Approach – Decision Making

This section is applicable to decision making only. The null hypothesis, consequences of the decision, false acceptance, and false rejection for the data collection activity (incident, research, exercise) will be described in this section.

6.2.1 Null Hypothesis

In this section the null hypothesis is described.

6.2.2. False Acceptance

In this section the probability limits for false acceptance decision errors are described.

6.2.3. False Rejection

In this section the probability limits for false rejection decision errors are described.

6.2.4. Consequences

In this section the impact of decision errors for the collection activity is described.

6.3 Analytic Approach – Estimation

This section is applicable to estimations only. The estimation rule, confidence or tolerance intervals and consequences are described in this section.

6.3.1. Confidence Interval or Tolerance Interval

Confidence intervals or tolerance intervals used to indicate uncertainty around the estimation parameter are described in this section.

6.3.2. Consequences

The impact of decision errors for the estimation problem (magnitude of misestimating a parameter) are described in this section.

7.0 Quality Control Activities

This section will provide information about the data quality indicators (DQIs), sampling method controls, analysis method controls, sample processing timeline, and data review procedures used during the data collection activity (incident, research, exercise).

7.1 Data Quality Indicators (DQIs)

The DQIs for critical measurements and data completeness are listed in Table 7.1. Examples of DQIs that might be considered include measurement of precision, accuracy, bias,

representativeness, comparability, completeness, sensitivity, specificity, and recovery. The method for measuring each DQI should be recorded. Include information on the accuracy and/or target value of the method that is needed. Include information on what values or completeness of the measurement will be accepted. This table should be repeated for each sampling matrix to be collected.

Table 7.1. DQIs for Critical Measurements and Data Completeness Criteria

Measurement Parameter	Method	Accuracy	Target Value	Acceptance Criteria	Completeness

7.2 Instrument Calibration Frequency

Describe the equipment calibration to be employed during sampling in Table 7.2 below. Include information on the type of equipment being used and any calibration or certifications associated with that equipment. Tolerance refers to the range of values that will be accepted. Frequency refers to how often the equipment must be calibrated or re-certified.

Table 7.2. Instrument Calibration Frequency

Equipment	Calibration/Certification	Tolerance	Frequency

7.3 Field Quality Controls

The following sections should discuss any field quality control samples not previously discussed that are being collected to support the sampling activity. This could include, but is not limited to, field blanks, field replicates, field splits, co-located samples, field matrix spikes, trip blanks, etc. 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**.**

7.4. Collection and Processing Timeline

A Gantt chart that describes the collection and processing timeline is developed in this section.

7.5 Data Review Procedures

The data review procedures to be used as part of QC during the data collection activities are described in this section.

7.6 Other [User enters title]

Additional QC activities not described in other sections above are described in this section.

8.0 Sample Transportation and Storage

Specific packaging and shipping considerations that will be used, including any regulations or applicable Select Agent requirements, for shipping are described in this section. Specific sample shipment considerations are described in the Table 8.1. The pathogen should be carried over from what was entered in section 1.1. The matrix is the sample media the pathogen is contained in (ex. surface), while sub-matrix refers to a specific type of matrix being sampled (ex. laminate, wood, glass). Specific sample type would describe the sample collection tools being used such as a sponge-stick, swab, vacuum sample, etc. The temperature at which the samples should be shipped and the type of sample packaging required are described. In addition, the method for transporting the package (air, car, etc.) and any shipping regulations and methods to prevent tampering should be included under Sample Transport. The maximum holding time before sample analysis should be included.

Table 8.1. Sample Shipment Considerations

Pathogen	Matrix	Sub-Matrix	Sample Type	Shipping Temperature	Sample Packaging	Sample Transport*	Maximum Holding Time

9.0 Documentation, Forms, and Data Management

This section will provide information on documentation, forms and data management for the sampling and analysis activities. This information might include: written or electronic documentation; forms used to document sample collection, chain of custody, field photographs, and evidence; the data management plan to be used; and the waste management plan to be used.

9.1 Written Documentation

Describe in this section how written documentation will be handled. Written documentation typically consists of transcribing information into a bound logbook with sequentially numbered pages, and completing standard sampling forms, as appropriate. Back up electronic data to another media at least daily. Records are sufficiently detailed to document that personnel performing particular tasks have been properly trained and that their subsequent ability to perform these tasks has been formally evaluated (EPA 2017 QA Field Activities Procedure).

9.2 Sample Collection Field Form

A copy of the form that will be used to document sample collection activities is provided in this section. The form below can be included as an option.

Form 9.1. EXAMPLE Sample Collection Field Form

Location: GPS Coordinates:
Date: Samplers:

Sample Collection Field Form							
Sample ID	**Sample Location and Description (include orientation and matrix of location)**	**Sample Matrix and Type**	**Area or Volume Collected**	**Wetting Solution Used (if any) and Amount**	**Date and Time Sample Collected**	**Photograph Reference**	**Sampler's Initials**

9.3 Chain of Custody Form

The chain of custody form used for the collection activity is included as part of this section. Contractor or agency requirements should be checked to determine if a specified format for chain of custody reporting is required. Note that the form provided here is only to be considered as an example and might not meet all of the necessary requirements of your contractor or agency.

Form 9.2 EXAMPLE Chain-of-Custody Record No._____ Page ____of ____

Chain of Custody Form						
Lab Address:	**LAB:**				**Sample Location (e.g. address, GPS Coordinates)**	
Project Name:	**Technical Contact:**				**Field Samplers:**	**Field Sampler Signatures:**
Project No.:	**Project Manager:**					
Sample ID	**Lab ID**	**Date**	**Time**	**Matrix**	**Analysis**	**Comments**

	Name (print)	Company Name	Date	Time
Relinquished by:				
Received by:				
Relinquished by:				
Received by:				
Comments:				

9.4 Photographic and Video Documentation

The field photograph log form provided in this section should be completed or a comparable form that document times and locations of photographs and video documentation during the collection activity should be included, if applicable.

Form 9.3 EXAMPLE Field Photograph Log Form

Field Photograph Log Form					
Name:				**Date:**	
Type of Camera:			**Photographer's Name(s):**		
Date /Time	**Picture Number (from camera)**	**Location of Picture**	**Subject of Picture**	**Direction of Photo (N, NE, S, etc.)**	**Photographer's Initials**

9.5 Evidence Documentation

Evidence documentation associated with the collection activity is included in this section. The purpose of this documentation is briefly described in this section. Describe the appropriate EPA records retention schedule.

9.6 Data Management Plan

The processes for establishing data retention, storage, and retrieval are described in this section. The use of any electronic data management tools, such as Scribe is also noted. A data management plan can be included and provided as an attachment in the appendix, if appropriate. Include data review procedures.

9.7 Sample Collection Waste Management Plan

The processes for managing waste generated during sample collection are described in this section. A sample collection waste management plan can be included and provided as an attachment in the Appendices, if appropriate.

10.0 References

[The references listed below have been included as references for this SAP outline. Include references relevant to the SAP being developed in this section].

Brown E, Caraco D, Pitt R, and CWP (Center for Watershed Protection). 2004. Illicit Discharge Detection and Elimination: A Guidance Manual for Program Development and Technical Assessments. Washington DC: Office of Water and Wastewater, U.S. Environmental Protection Agency. Accessed April 12, 2017 at: https://www3.epa.gov/npdes/pubs/idde_manualwithappendices.pdf

DHS (Department of Homeland Security). 2009. Draft Planning Guidance for Recovery Following Biological Incidents. Washington DC: Biological Decontamination Standards Working Group, National Science and Technology Council, Department of Homeland Security .

FEM (Forum on Environmental Measurement). 2010. Agency Policy Directive FEM-2010-01, Ensuring the Validity of Agency Methods Validation and Peer Review Guidelines: Methods of Analysis Developed for Emergency Response Situations. Washington DC: U.S. Environmental Protection Agency. Accessed April 12, 2017 at: https://www.epa.gov/sites/production/files/2015-01/documents/emergency_response_validity_policy.pdf

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. Washington DC: U.S. Environmental Protection Agency.

FEMA (Federal Emergency Management Agency). 2010. Developing and Maintaining Emergency Operations Plans. Comprehensive Preparedness Guide, Version 2.0. Washington DC: Federal Emergency Management Agency. Accessed April 12, 2017 at: http://www.fema.gov/pdf/about/divisions/npd/CPG_101_V2.pdf

HSEEP (Homeland Security Exercise and Evaluation Program). 2011. “What is the difference between a tabletop exercise, a drill, a functional exercise, and a full-scale exercise?” Accessed April 12, 2017 at: http://www.calhospitalprepare.org/post/what-difference-between-tabletop-exercise-drill-functional-exercise-and-full-scale-exercise

OSHA (Occupational Safety and Health Administration). 2002. Anthrax eTool. Washington DC.: Occupational Safety and Health Administration. Accessed April 12, 2017 at: http://www.osha.gov/SLTC/etools/anthrax/sampling.html#sampling_objectives

U.S. EPA. 2002. RCRA Waste Sampling Draft Technical Guidance: Planning, Implementation, and Assessment. Washington, DC: U.S. Environmental Protection Agency, Office of Solid Waste and Emergency Response. EPA530/D/02/002.

U.S. EPA. 2004. Quality Assurance/Quality Control Guidance for Laboratories Performing PCR Analyses on Environmental Samples. Washington, DC: U.S. Environmental Protection Agency. Washington, D.C. EPA 815-B-04-001.

U.S. EPA. 2010. Sample Collection Information Document for Pathogens and Biotoxins: Companion to Standardized Analytical Methods for Environmental Restoration Following Homeland Security Events (SAM) Revision 5.0. Washington DC: U.S. Environmental Protection Agency. EPA/600/R-09/074.

U.S. EPA. 2012. Selected Analytical Methods for Environmental Remediation and Recovery (SAM). U.S. Environmental Protection Agency, Washington, DC: U.S. Environmental Protection Agency. EPA/600/R-12/555.

U.S. EPA. 2014. SW-846 Compendium: Project Quality Assurance and Quality Control: Chapter 1. Washington, DC: U.S. Environmental Protection Agency. SW846 Update V. Accessed April 12, 2017 at: https://www.epa.gov/sites/production/files/2015-10/documents/chap1_1.pdf

U.S. EPA. 2017. Information Directive Procedure: EPA QA Field Activities Procedure. U.S. Environmental Protection Agency. EPA No CIO 2105-P-02.0.

USGS (United States Geological Survey). 2009. Instructions for Field Use of Spike Solutions for Organic-Analyte Samples, Chapter A5. Section 5.3.2. in: National Field Manual for the Collection of Water-Quality Data: U.S. Geological Survey Techniques of Water-Resources Investigations, book 9. Washington DC: U.S. Geological Survey. Accessed April 12, 2017 at: https://water.usgs.gov/owq/FieldManual/chapter5/pdf/5.3.2.pdf

Attachment 1: Sampling and Analytical Protocols

Protocols would be inserted here.

Attachment 2: Data Quality Objective Summary Table

This optional table is meant to be a summary of the data quality objectives identified while filling out SAP with the purpose of providing a summary for quality assurance project plan review.

Data Quality Objective Summary Table

STEP 1. State the Problem	
Members of the planning team	
STEP 2. Identify the Goal of the Sampling and Analysis Activities (estimation statement)	
STEP 3. Identify the Information Inputs	
STEP 4. Define the Boundaries of the Sampling and Analysis Activities	
Define the regulatory and jurisdictional boundaries for the sampling and analysis activities	
Define the spatial boundaries or geographical are for the sampling and analysis activities	
Define the temporal boundaries for the sampling and analysis activities.	
Identify the logistical considerations	
Identify practical constraints on data collection	
Specify the scale of the decision or estimates to be made	
STEP 5. Develop the Analytic Approach	
Specify the summary statistics used	
Specify the estimation or decision rule	
Specify the hypothesis testing parameters (decision making)	
Acceptable levels of uncertainty (estimation)	
STEP 6. Specify the Performance and Acceptance Criteria	
STEP 7. Optimize the Design	
Develop the general sampling and analysis design	

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Glossary

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 (U.S. EPA 2004).

Bias: The measure of disagreement between the concentration of an analyte as measured by a method and the true concentration in the environmental sample that was tested (U.S. EPA 2004).

Characterization: Phase of the response which expands on the initial assessment findings to identify other contaminated locations and determine the contamination footprint at the affected locations, in order to better define the boundaries. The 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

Cleanup Goal: the clean-up goal is set in order to determine whether remediation is successful and the treated area may be returned to normal use. There is no formula available for biological agents for setting the cleanup goal and will be dependent on site-specific circumstances (DHS 2009).

Clearance: The process of determining that a cleanup goal has been met for a specific contaminant in or on a specific site or item. Generally, clearance occurs after decontamination and before re-occupancy.

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 document the precision of a sampling process (U.S. EPA 2014).

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 (U.S. EPA 2014).

Decontamination: The processes used to reduce, remove, inactivate, or neutralize contamination. Decontamination processes could include physical, chemical, or other processes to meet a cleanup goal.

Decontamination Verification: Phase of the response which involves monitoring decontamination processes to confirm decontamination has been conducted according to the specified parameters. Examples include use of biological indicators used during fumigation, monitoring decontaminant concentrations, and documentation of process parameters.

Data 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 (U.S. EPA 2014).

Data Quality Indicators (DQIs): Indicators of an underlying data quality attribute.

Data Quality Objectives (DQOs) Process: Qualitative and quantitative statements derived from the DQO Process that clarify study technical and quality objectives, define the appropriate type of data, and specify tolerable levels of potential *decision error*s that will be used as the basis for establishing the quality and quantity of data needed to support decisions (U.S. EPA 2002).

Exercise: There are seven types of exercises according to the Homeland Security Exercise and Evaluation Program (HSEEP 2011). The exercises that would be most likely to use this tool include:

- **Full-Scale Exercise:** A full-scale exercise is a multi-agency, multi-jurisdictional, multi-discipline exercise involving functional (e.g., joint field office, emergency operation centers) and "boots on the ground" response (e.g., firefighters decontaminating mock victims).
- **Functional Exercise:** A functional exercise examines and/or validates the coordination, command, and control between various multi-agency coordination centers (e.g., emergency operation center, joint field office). A functional exercise does not involve any "boots on the ground" (i.e., first responders or emergency officials responding to an incident in real time).
- **Tabletop Exercise:** A tabletop exercise involves key personnel discussing simulated scenarios in an informal setting. Tabletop exercises can be used to assess plans, policies, and procedures.
- **Operations-based Exercise: An operations-based exercise** validates plans, policies, agreements and procedures, clarify roles and responsibilities, and identify resource gaps in an operational environment. Types of operations-based exercises include:
    - **Drill:** A drill is a coordinated, supervised activity usually employed to test a single, specific operation or function within a single entity (e.g., a fire department conducts a decontamination drill).

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 2002).

Field Replicates/duplicates: Two or more samples collected at the same time and location to be considered identical. Also referred to as "collocated samples" (U.S. EPA 2002).

Field Matrix Splits: A quality control matrix spike sample prepared at the sample site to evaluate bias from analyte degradation related to shipping and storage from the field site to the laboratory, and potential bias from the sample matrix (USGS 2009).

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 2014).

Incident: An occurrence, caused by either human action or natural phenomena, that might cause harm and might require action. Incidents can include major disasters, emergencies, terrorist attacks, terrorist threats, wild and urban fires, floods, hazardous material spills, nuclear accidents, aircraft accidents, earthquakes, hurricanes, tornadoes, tropical storms, war-related disasters, public health and medical emergencies, and other occurrences requiring an emergency response (FEMA 2010).

Initial Response: Actions taken immediately following notification of a contamination incident or release. In addition to search and rescue, scene control, and law enforcement activities, initial response might include initial site containment, environmental sampling and analysis, and public health activities, such as treatment of potentially exposed persons.

Inhibition Positive Control: A sample used to verify that interfering constituents from an environmental matrix carried over from the isolation of the organism or nucleic acids do not inhibit the PCR (U.S. EPA 2004).

Internal Positive Control: The internal positive control of a known concentration consists of a simple DNA template material for the assay target added to its own dedicated PCR reaction run in parallel with the samples on a test. A positive test result in this reaction validates the function not only of the shared master mix components tested by an internal control, but also uniquely shows the function of target-specific primers and probes. These controls may form the basis for a standard curve for quantitative assays by allowing the quantitation standard to take into direct account possible variations in extraction efficiency across a range of target concentrations (U.S. EPA 2004).

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 2002).

Matrix: The principal material in which the analyte of interest is contained (e.g., waste water, storm water; U.S. EPA, 2010).

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 2002).

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 2002).

Post-Decontamination Sampling: Post-Decontamination Sampling is required to ensure decontamination procedures reached cleanup endpoints. As part of this sampling, a body of data of adequate quantity and quality is developed to enable Incident Command/Unified Command to verify that the originally contaminated environment has been sufficiently decontaminated to allow re-occupancy of the area without the use of personal protective equipment (PPE) or other protective measures (OSHA 2002).

Precision: A measure of how closely values from replicate measurements of a sample agree with each other (U.S. EPA 2004).

Reagent Blank: A sample used for quality control in order 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 2014.

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

Representativeness: A measure of the degree to which data accurately represent a characteristic of a population, a parameter variation at a sampling point, a process condition, or an environmental condition (U.S. EPA 2014).

Sample: A portion of material collected from a larger quantity for the purpose of estimating the properties and/or composition of the larger quantity (U.S. EPA 2002).

Sampling Protocol: A procedure for sample collection that considers the following basic elements: (1) where to collect samples; (2) when to collect samples; (3) sample preparation; (4) sample collection technique; (5) storage and preservation of samples; (6) sample labeling and chain of custody plan; (7) quality assurance/control samples; (8) safety considerations (Brown et al. 2004).

Sensitivity: 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) × 100% (U.S. EPA 2004).

Specificity: The specificity of a test can be described as the proportion of all negatives it detects that truly were negative. All negatives are the sum of (detected) true negatives (TN) and false positives (FP). Specificity is therefore: TN / (TN + FP) × 100% (U.S. EPA 2004).

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 (FEM 2012).

Validation: For the purposes of this guidance, the term is to be used as described by the EPA's Forum on Environmental Measurement (FEM) Policy Directive FEM-2010-01 "Ensuring the Validity of Agency Methods Validated and Peer Review Guidelines: Methods of Analysis Developed for Emergency Response Situations" (FEM 2010). More specifically, "…validation is the confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use are fulfilled" (FEM 2010).

Waste Characterization: Waste characterization is required for off-site disposal of any and all contaminated items and debris. If a single object or debris requires disposal, the waste must be profiled in order for the disposal facility to accept it and to determine the appropriate method of disposal.