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ER PROJECT WORKSHOP

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Sampling and Analysis Plans

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In order of presenter (Johnnye Lewis, Kathy Campbell, Bart Vanden Plas, and Larry Souza)

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E. Earth Sciences Directory

F. Decision Support Directory

G. EPA Criteria

A

Objectives of SAP Training

- Provide training for use of SAP outline
- Establish consistency in the development of SAPs
- Communicate project/regulator expectations for SAP development

ER Project Requirements

- Quality Management Plan (QMP)
  - master document, management approach to QA planning
- Quality Assurance Project Plan (QAPP)
  - programmatic document
  - specifies elements to be addressed in site-specific SAPs
- Sampling and Analysis Plans (SAPs)
  - site-specific document
  - includes former field sampling plan, site-specific QAPP, portions of field implementation plan

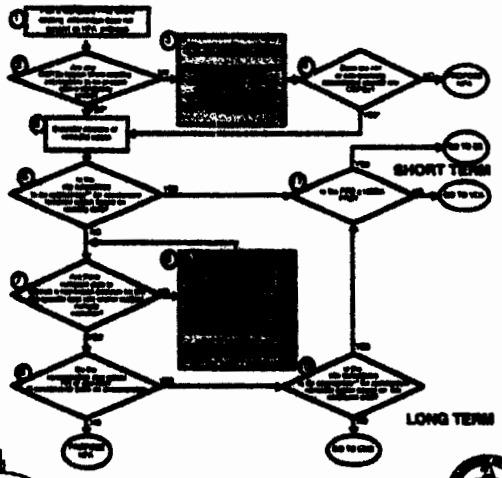
SAP Within ER Project Framework

- Major deficiency noted to date in NODs
  - several issues in last NODs related to SAP deficiencies
- Expands on November training
  - SAPs as part of RFI work plans, RFI reports, VCAs, and ECs
  - can also stand alone
- Driven by accelerated decision logic to
  - support risk-based decisions
  - determine appropriate interim actions
  - verify cleanup

SAP

- Documents the result of the planning process
- Details site-specific QAPP elements
- Is third-party implementable

Accelerated Decision Logic



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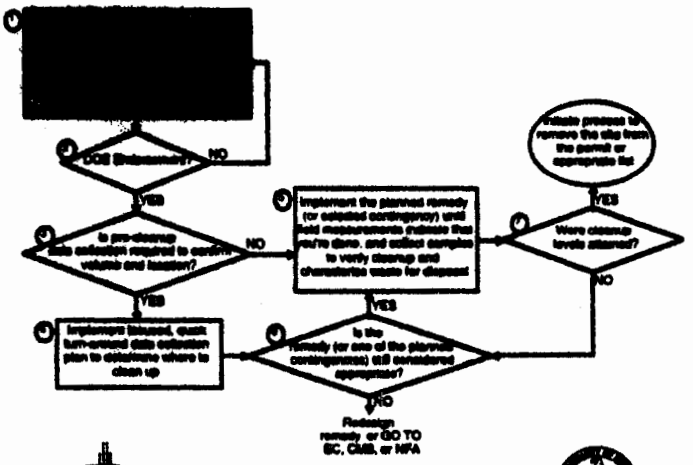
Voluntary Corrective Action



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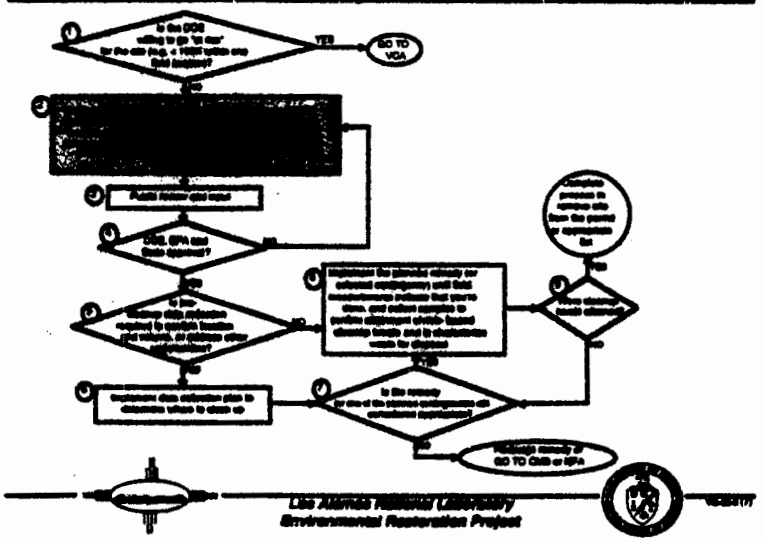
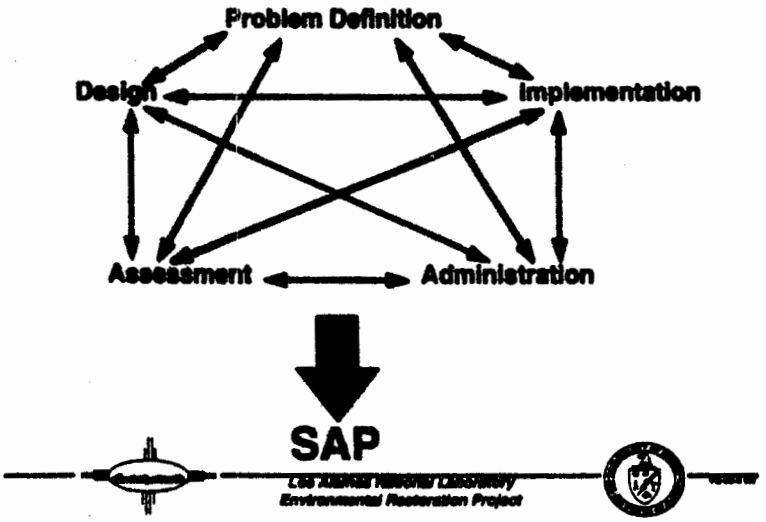
Expedited Cleanup Approach



SAP Development Process (Iterative)



SAP Product (Linear)

Problem Definition

↓

Design

↓

Implementation

↓

Assessment

↓

Administration

↓

SAP

Potential Participants

LANL

- Chemists, geochemists, geologists, hydrologists, risk assessors (human health and ecological), statisticians, field team members, FPLs, budget analysts, community involvement representative, regulatory compliance specialists, FPCs

Other

- Facility Manager, D&D, Pueblos, County representatives, regulators, laboratory analysts

Sampling and Analysis Plan
Section 1
Problem Definition

Kelly-Campbell
EPS

Contents

- What question(s) are the data intended to answer?
- Why is the answer to each question required? (What decision about what type of action requires this information?)

Question + Context: Guaje Pines

- Questions:
  - Must berm material be treated as hazardous waste?
  - (After berm material is removed) Does residual contamination pose a risk to human health?
- Context:
  - If material is not hazardous, a satisfactory and relatively inexpensive disposal option is available.
  - The site is to be released for residential use.

Design Implications: Guaje Pines

- **Must berm material be treated as hazardous waste?**
  - **Measurements for classifying waste as hazardous (specifically, TCLP lead) are needed.**
  - **A relatively large number of samples is justifiable because the alternative disposal options are very expensive. A sequential design may be used to minimize actual sample sizes.**

Design Implications: Guaje Pines (continued)

- **Does residual contamination pose a risk to human health?**
  - **Verification sampling design must permit estimation of means within lots of size comparable to surrounding development (these are larger than the default 1/8 acre).**

Multiple Questions vs. Mulitple SAPs

- More than one SAP should be prepared when different questions are to be answered by sampling at different times (e.g., Guaje Pines)
  - Two or more SAPs may be written at the same time by the same team
- Multiple questions can be addressed by one SAP when all sampling will be done at approximately the same time by the same team (e.g., OWR site)
  - It is necessary to go through the design process for each question, to ensure that data will be adequate to address each question individually

Question + Context: HE Resampling

- Questions:
  - Are undetected HE or HE products present at previously sampled locations? (Can the "rejected" data be used qualitatively?)
  - Do the concentrations of detected HE exceed 10 times the levels estimated using "rejected" data? (Can the "rejected" data be used semiquantitatively, to bound levels of HE contamination at South Site?)
- Context:
  - Confirm (or refute) tentative conclusion that HE is not of concern at this site without resampling all locations.

Design Implications: HE Resampling

- Large number of samples not justifiable
- Analyses need to be done by the standard SW-846 method for HE or equivalent
- All holding times and other QC requirements must be met
- Resamples should include
  - locations where nothing was detected originally
  - locations where original data indicated presence of HE

Questions + Context: OWR Tanks and Pit

- Questions:
  - How much additional soil should be removed during D&D?
  - At conclusion of D&D (if we think we're done) have cleanup standards been met?
  - (If not done) Where do we go from here?
- Context:
  - Exploit the opportunity during D&D to complete remediation of this site using already mobilized equipment and personnel.

Questions + Context: OWR Tanks and Pit (continued)

- Water table rises to within about six feet of surface during wet periods. NM surface and ground water regulations may apply.

Design Implications: OWR Tanks and Pit

- How much additional soil should be removed during D&D?
  - Use field methods where possible.
  - Confirmatory (off-site) analyses to supplement field observations must have very short turnaround.
  - Given the uncertainty and potential for plume of mobile contaminants, stopping rules and contingency planning are essential.
    - Consider also, what measurements could be made during D&D to help design further investigation or remediation?

Regulatory Drivers: Guaje Pines

- Must berm material be treated as hazardous waste?
  - RCRA—for definition of "hazardous"
  - WACs—for potential alternative treatment/disposal options
- Does residual contamination pose a risk to human health?
  - Risk Assessment Guidance—for PRG development and evaluation of verification data

Regulatory Drivers: OWR Tanks and Pit

- How much additional soil should be removed during D&D?
  - PRGs—which may depend on risk guidance or NM regulations
  - WACs—for D&D-selected disposal site
- Have cleanup standards been met?
  - NM surface and ground water regulations
  - Risk Assessment Guidance—for PRG development and evaluation of verification data

Checks and Feedback

- **Are existing data already adequate to answer the question?**
  - **If so, there is no need to collect new data**
- **Might additional data support NFA?**
  - **If so, collecting additional data might be more cost effective than starting to plan EC/VCA**
- **Is the remedy obvious or should we be investigating several potential remedies?**
  - **If the latter, then CMS may be the correct regulatory framework, which could imply some additional objectives for SAPs**

Contents

- Overview of the design
  - What data will be collected?
- Data use
  - Exactly how will these data be used to answer the questions?
- Basis for design
  - Assumptions ("conceptual model"), data quality requirements, contingency plans/stopping rules
- N.B.: "design" also includes
  - QA/QC design to verify assumptions and data quality
  - Observations to trigger contingency plans or stopping rules

Overview

- Summarize, using figures and tables as appropriate
  - locations to be sampled
  - frequency of sampling
  - media to be sampled
  - measurements (both field and lab) to be reported

Data Use

- Summary statistic(s) to be computed
- Levels or data sets for comparison

Basis for Design

- What assumptions about site conditions must hold for proposed approach to succeed?
- What quality requirements must be met for data to be usable as intended?
- What provisions have been made for verifying critical assumptions and data quality requirements?
- What contingency plans are proposed if one or more of the assumptions fail?

Design and Data Use: Guaje Pines

- How much additional soil should be removed during D&D?
  - twenty surface samples, composited using a stratified grid design
  - two composites per grid to capture local variability
  - TCLP analysis
  - compute 90% UCL for mean leachable Pb
    (later, decided also to compute 90% UCLs for means within subareas)
  - compare UCLs with TCLP level for Pb (5 mg/L)

Assumptions Underlying Guaje Pines Design

- TCLP Pb (mg/L) will not be more than 1% total lead (ppm)
  - samples to be collected will be similar to most recently collected grab samples from the back of the berm (measured values below 1000 ppm)
    - this assumption will be evaluated as part of data quality assessment, based on results themselves
  - composite samples representative of bulk material
    - two composites per grid will be used to evaluate variability on that scale

Design and Data Use: HE Resampling

- **Are undetected HE or HE products present at previously sampled locations? Do the concentrations of detected HE exceed 10 times the levels estimated using "rejected" data?**
  - eight locations to be resampled, judgmentally selected based on initial results
  - collocated samples at two locations
  - analysis by SW-846 procedure 8330 or equivalent

Design and Data Use: HE Resampling (continued)

- estimate
  - (a) fraction of mismatches between new and original samples
    (mismatch = new analyte or analyte at more than 10 times original observation)
  - (b) 90% UCL for fraction of mismatches in collocated samples
- compare (a) with larger of 0.05 or (b)

Assumptions for HE Resampling Design

- Phase I sampling locations can be relocated and enough undisturbed surface material can be found to collect a new sample collocated with original sample
  - contingency plan is provided if this is not the case
- Concentrations in new sample are similar to concentrations in original sample
  - two collocated samples included to test this assumption if found to be not true; criteria for matching new and original data will be adjusted accordingly

Assumptions for HE Resampling Design (continued)

- Good laboratory practices will be followed
  - arrangements guaranteeing prompt analysis to be confirmed before samples are collected

Design and Data Use: OWR Tanks and Pit

- How much additional soil should be removed during D&D?
  - initial calibration sampling required to determine comparison level to use for field gamma instrument (corresponding to 1/2 PRG)
  - field gamma plus rapid turnaround confirmatory samples (gamma spec, tritium, Cr), both biased by field observations and unbiased
  - compare field observations with predetermined levels
  - compare individual observations with stopping criteria

Assumptions for OWR Tanks and Pit

- D&D will be carried out in a dry (low water level) season.
  - If not guaranteed, then alternative field methods may be needed.
- D&D will remove all physical barriers to sampling (tanks, concrete pit, connecting lines, other utilities). Excavation can be left open for 10 days.
  - These requirements will be negotiated with D&D team.
- Appropriate field methods and/or fast turnaround methods exist for the principal COPCs.

Assumptions for OWR Tanks and Pit (continued)

- Adequacy of SOPs will be evaluated, and special training in their use will be provided for the field team. Field pilot planned (see design).
- Contract with local analytical laboratory will be in place prior to start of sampling activities.

Checks and Feedback

- Does an analytical method that can provide both the required turnaround and the required sensitivity or specificity exist?
  - may have to relax time constraints, use a more costly method, or proceed at risk using a less than ideal method
- Is the number of samples required to control false positives at the desired level prohibitive?
  - may have to rethink basis for defining the desired level

Team Participation Depends on the Question and Context

NATURE OF PROBLEM	SOME KEY PARTICIPANTS
Identification of release Identify COPCs Determine whether off-site migration is occurring	Site manager or historian Process chemist Hydrologist or geochemist
Risk-based decisions Develop baseline Support NFA Evaluate corrective action	Risk assessor --human health --ecological

Team Participation Depends on the Question and Context (continued)

NATURE OF PROBLEM	SOME KEY PARTICIPANTS
Preparing for or concurrent with corrective action Waste characterization, segregation Real-time determination of extent Budget estimation	Project engineer Waste management expert Analytical chemist
Compliance monitoring (air, water, sediments, biota) During remediation Post-closure	Geologist Hydrologist Ecologist

Team Participation Depends on the Question and Context (continued)

ALWAYS: -FPL, FPC.

CONSULT: -Regulatory specialists. For high-profile sites, the regulators themselves.

INVOLVE: -Those who will be writing later parts of the SAP.
-Those who will be using the data to make decisions.
-Those who will execute the SAP.

INFORM: -Possibly, members of the public.

Team Tasks

- Develop one or more plausible, site-specific scenarios ("conceptual models") compatible with existing knowledge: What constituents are potentially present at levels of concern?
  - Where are the highest concentrations now?
  - Where are they most likely to migrate in the future?
  - What range of concentration levels is likely?

Team Tasks (continued)

- Identify the potentially most significant consequences of wrong decisions that could result from inadequate data: unnecessary expenditure of resources on remedial action
  - Risk to human health under one of the appropriate scenarios
  - Generating mixed waste during corrective action
  - Mercury in surface water above NM regulatory levels
  - Migration of contaminants beyond Laboratory boundaries

Team Tasks (continued)

  - Unnecessary destruction of habitat by corrective action
- How much more sampling would be needed to avoid these errors with satisfactory degree of certainty?
- What might go wrong during the field activities?
  - What contingency plans can be devised to handle such situations?

Team Tasks (continued)

- What flaws would disqualify the data for the intended use?
  - What precautions can be taken to ensure that these problems do not occur?
- What measurements can be made to detect these problems if they do occur?

Alternative Models for OWR Tanks and Pit

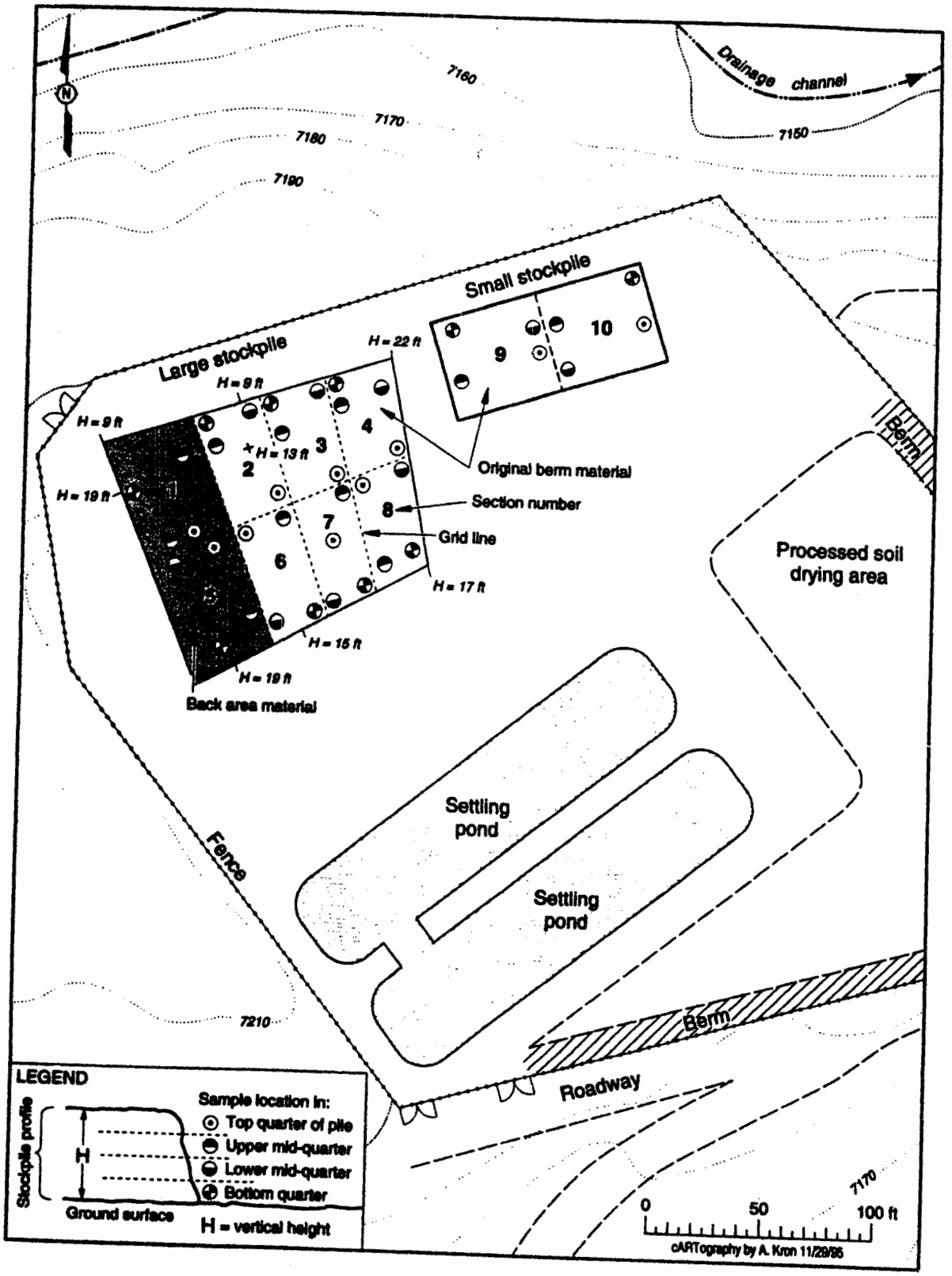
- No release beyond volume to be excavated by D&D
- Bounded release, not more than 5 or 10 feet beyond volume to be excavated by D&D
- Extensive release, into alluvial aquifer, commingled with releases from other PRSs

Section 1: Problem Definition

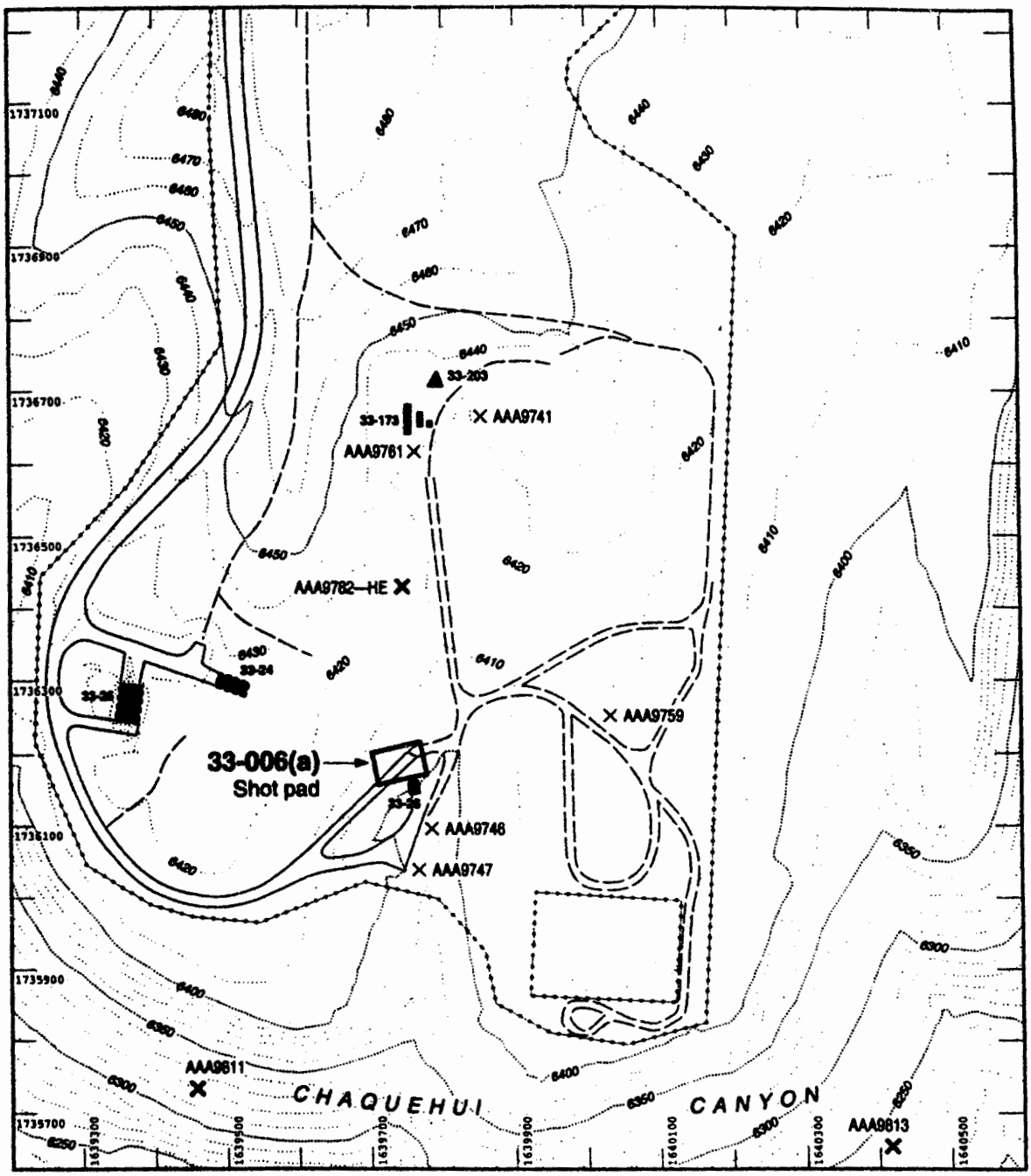
- What question(s) are the data intended to answer?
- Why is the answer to each question required?

Section 2. SAP Design

- Overview of the design:
  - What data will be collected?
- Data use:
  - Exactly how will these data be used to answer the questions?
- Basis for design:
  - Assumptions ("conceptual model")
  - Data quality requirements
  - Contingency plans/stopping rules



Soil stockpile characterization sample locations, SWMU 0-016.



Permanent structure
Temporary structure
Underground structure
Shot pad
Sampling location—no elevated levels
Sampling location—analytes listed above LANL UTLs
AAA9813 Sample number
Paved road
Unimproved road/trail
Fence
Contour interval 10 ft

0 100 200 ft

Source: FIMAD 12/10/94, G102851
Modified by: cARTography by A. Kron 12/18/95

South Site: PRS 33-006(a), shot pad. Resampling locations for high explosives.

02-004(d)
02-004(e)
02-004(c)
02-004(b

Sampling and Analysis Plan
Section 3
SAP Implementation

Bart Vanden Plas
Los Alamos Technical Associates

Contents

- How will samples be collected?
- How will sample parameters be measured?
- How will samples be handled?
- How will samples/data be tracked and managed?
- What is the schedule for each activity?

Considerations

- Consider third-party implementation of the SAP as a priority
  - Client requires that SAPs can be implemented by a third-party.
  - Ask, "what information and detail do I need to provide so that a third party can implement this SAP?"

Planning Personnel

- All personnel from SAP design, plus
  - Field team leader
  - Sample management representative
  - Data manager
  - Health and safety specialist

Checks and Feedback

- Sample collection
  - Is access adequate for the selected techniques? Are there site-specific constraints that preclude using particular sampling methods?
    - If not, then provide this feedback to the design
  - Are there regulatory considerations (site disturbance, waste generation, or specific methods required)?
    - If so, then provide this feedback to the design if it was not considered
  - Is the selected sampling technique compatible with all analytes and analytical techniques required for the sample?
    - If not, then provide this feedback to the design for consideration

SAP Implementation Process: Checks and Feedback (continued)

- **Measurement Methods**
  - Are there site, sampling, or matrix constraints that preclude using particular measurement methods? Can on-site measurements by used?
    - If not, then provide this feedback to the design for consideration
  - Are methods available for providing the needed data? If a new method is required, can it be developed in a timely and affordable manner?
    - If method development schedules and costs are not acceptable, then provide this feedback to the design for consideration

Checks and Feedback (continued)

  - Is the selected sampling technique compatible with all analytes and analytical techniques required for the sample?
    - If not, then provide this feedback to the design for consideration
- **Sample handling and sample/data tracking**
  - Are there site, sampling, or matrix constraints that preclude using routine sample handling methods?
    - If so, then provide this feedback to the design for consideration and document the non-routine method used for sample handling

Checks and Feedback (continued)

- Do you need to provide radioactivity screening prior to removing samples from the site (or to ship off-site)?
  - If so, then provide this feedback to the design for consideration so that all scheduling and other impacts can be addressed
- Do the data users require quick turnaround on the data for decision-making purposes? What data format will be used?
  - If so, then provide this feedback to the design
- How will the data be organized and delivered to users for decision-making purposes? Will the data be handled electronically and put into FIMAD, will it require manual entry, or will hardcopy reports be sufficient?

Checks and Feedback (continued)

- Provide feedback to the design on how data will be reported,what the data reports will contain, and who will receive them (at a minimum).

- **Schedule**
  - Are there temporal constraints on the sample collection activities (such as water level changes, method development/validation required, or required infrastructure not available)?
    - If so, then provide this feedback to the design
  - Are there regulatory constraints on the schedule? Can the schedule be coordinated with D&D? How about budgetary constraints?
    - If so, then provide this feedback to the design

Checks and Feedback (continued)

- Do the data users require quick turnaround on the data for decision-making purposes? Are the critical path items on the schedule identified properly and can they be incorporated into the schedule constraints?
  - If so, then provide this feedback to the design

- **Questions to be asked, maybe more than once:**
  - Can the selected techniques for sampling, analysis, and data handling be combined as planned?
  - Will the planned activities truly add to the information already available for the site?

Checks and Feedback (continued)

- Can the sample information collected, both in the laboratory and in the field, be combined electronically in an efficient manner and be available for use when needed?
- Does the plan make sense as a whole?

Sampling and Analysis Plan
Section 4
Data Assessment

Larry Souza
ER Project

Data Assessment

Specify how to evaluate adequacy and usability of data for intended purpose

- **Verification and Validation**
  - for routine analytical service, reference the contract task for Contract Compliance Screening and Routine Validation
  - for data generated as a result of implementing ER SOPs, reference the SOP if the SOP addresses the data evaluation or SOP 1.04

Data Assessment (continued)

- **For nonroutine analytical services and on-site measurement activities, describe how you are addressing the following:**
  - completeness
  - compliance
  - consistency
  - correctness

Data Assessment (continued)

- **Data Quality Assessment**
  - identify how you are going to reconcile your data with your DQO's
  - identify problems that would trigger in-depth validation
  - state how you are going to compare achieved bias and precision with levels originally prescribed
  - state how you are going to evaluate the validity of the assumptions that were made for planning purposes

B

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Sampling and Analysis Plan
Section 5
Administration

Larry Souza
ER Project

Administration

- **Project Task Organization**
  - identify functional roles and responsibilities for the task; include a task organization chart
- **Training**
  - identify special training needed for the task
- **Records**
  - identify what records are going to result from the task, how they are organized, and how they are going to be managed

Administration (continued)

- **Oversight**
  - identify planned oversight, e.g., peer reviews, readiness review, field audits
- **Inspection/acceptance**
  - identify how supplies and consumables are going to be inspected and accepted
- **Reports to management**
  - identify expected reports, their content, and how frequently they are required

B

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Typographical conventions used in this outline:

Bold: **Required contents**
Italics: *Interpretation and guidance*
Normal: Details or examples, to be included only as appropriate. Omit anything that is not integral to planned investigation.

OUTLINE FOR SAMPLING AND ANALYSIS PLANS

If this is a part of an RFI report all the numbers are prefixed by 5.xx.11. For example, "Problem Definition" is Section 5.xx.11.1. If it is part of some other report outline, numbers have other prefixes as appropriate.

1 Problem Definition

Question(s) To Be Answered By The Data
Formulation of questions must be concrete and specific, not open-ended.

Purpose For Which This Information Is Needed
What decisions depend on the answers to these questions?

Include only as much of the following types of information as is necessary to clarify the questions and purposes of the proposed investigation or help the reader to understand the site.

Site Description
- Figure showing the salient site features and indicating the areas of interest.
- Summary of physical features and site history pertinent to this SAP.
  - *If this is part of a larger report in which the site has already been adequately described (e.g., an RFI report), reference the appropriate section(s).*

Historical Data
- Summarize the most pertinent existing data; a short table may be appropriate.
  - *Reference earlier sections of an RFI report, an attachment, or another report, for detailed information and lengthy data tables.*
- Reference sources of historical data.
  - *If numerous, reference another document (e.g., the RFI Work Plan) in which a comprehensive list or references can be found.*

Regulatory Drivers
- Identify pertinent legislation, permits, guidance, etc.

2 SAP Design

Present an overview of "what" and "why." The details of "how" belong in Section 3.

Overview Of Information To Be Collected

- Identify locations and media to be sampled, and frequency if more than once.
- Identify target analytes.
- List all measurements (both field and laboratory) to be reported.
  - *Explain, if appropriate, how selection of samples for laboratory analysis will be based on results of field tests or surveys.*
- Include as appropriate figure(s) identifying sampling locations, and table(s) listing sample matrices, locations, depths, and proposed analyses.
- Describe contingency plans, if any.

How Will These Data Be Used To Answer The Questions?

- Specify the summary statistics to be calculated.
- Specify target levels with which summary statistics will be compared.
- Identify sources of other information for statistical or other comparisons as appropriate, such as:
  - background data sets
  - previously collected baseline data
  - data from an upgradient well

Assumptions Underlying the Design

- Identify the assumptions underlying the design, for example:
  - Expectations about the spatial distribution and levels of contamination
  - Availability and use of field data, historical data, or other auxiliary information for biasing or stratifying samples.
  - Availability and performance of field kits and other on-site analytical tools.
  - Anticipated bias and precision of individual measurements.
  - Physical and temporal constraints affecting the design.
- Discuss the constraints on data quality implied by the intended use of the data.
  - *Consider foreseeable problems that could render the data unusable for its intended purpose.*

Requirements For Data Quality Implied By Intended Data Use

- Define critical range of concentrations (e.g., within an order of magnitude of the PRG or WAC).
- Determine acceptable levels of precision and bias for summary statistics within this critical range.

Measurements To Verify These Assumptions and Requirements

- Identify data quality assessment information to be collected to verify critical assumptions.
- Identify observations that will permit problems affecting usability of data to be detected.
- Identify measurements or observations that will be used to trigger implementation of any contingency plan.
- Describe data acceptance criteria that will be used for review, verification and validation of the data.

3 SAP Implementation

Provide a level of detail that makes the design outlined in Section 2 "third-party implementable." Cite SOPs when available and appropriate. (Develop or modify SOPs if necessary.) Provide details not included in the SOPs.

Field Methods

Include all methods for surveying and sampling that will affect data to answer question.

- Describe surveying and permanent marking of survey and sample locations.
- Describe site preparation for surveys and sampling.
- Describe sampling methods to be used.
  - *Include any special field sample preparation not covered in SOPs.*
- Specify when and how to collect QC samples, calibrate field instruments, etc.
- Identify all sampling information that must be recorded on the sampling logs, in logbooks, and/or in the field data base.

Measurement Methods

Include field, mobile laboratory, and offsite laboratory methods. Exclude measurements for H&S, DOT, etc. Cite SOPs wherever possible.

- Identify screening instruments to be used.
  - *Supplement SOPs with sufficient QC/calibration/testing to meet requirements.*
- Describe use of field test kits.
  - *Supplement SOPs or manufacturer's instructions with sufficient QC/calibration/testing to meet requirements.*
- Describe auxiliary field measurements to be made.
  - E.g., dry sieving to determine particle size fractions, soil type characterization
- Specify which field measurements are to be recorded in sampling logs, logbooks and/or the field data base.
- Describe mobile van analyses.
  - *Negotiate modifications to mobile van procedures if needed to assure sufficient level of QC and documentation to meet requirements.*
- Describe off-site analytical methods to be used.
  - *If nonroutine, detailed SOWs including QC requirements will need to be developed.*
  - *Specify any special requirements such as rapid turnaround, sample cleanup expectations.*

Field Decisions

- Provide clear instructions on the use of field measurements to select samples for further analysis.
  - *Specify what information is to be recorded both for these locations/samples and for other candidate locations/samples.*
- Provide criteria (i.e., "stopping rules") to be used by field team to determine when a contingency plan should be invoked.

Sample Handling

- Describe how offsite samples are to be packaged, shipped, and tracked.
  - -- *SMO procedures may be cited where applicable.*

Data Tracking

- Describe how field information will be prepared for and transmitted to a central data management system.
  - -- *If using a standard field electronic data base system such as ACCESS or 4D-based system, ascertain that it captures the required information or provide for alternative reporting.*
- Describe how mobile laboratory data will be reported to field crews and how it will be uploaded to the central data management system.
- Describe forms of data (electronic, hard copy) expected from offsite laboratories, and how it will be uploaded to the central data management system.
  - -- *SMO procedures may be cited where applicable.*

Schedule

- Anticipate the length of time each activity will require.

  If contingency plans need to be invoked, how will that modify the schedule?

  Include time for analysis of samples, data assessment, and preparation of reports.

4 Data Assessment

Describe the process by which the usability of all data for its intended purpose will be evaluated vis-a-vis the assumptions and requirements specified in Section 2.

Verification and Routine Data Validation

- Discuss data verification and routine validation process.
  - -- *Standard procedures may be cited if available and appropriate.*
- Describe how results will be communicated to data users, for example
  - -- By application of standard qualifiers to results
  - -- By uploading QC results to the central data management system
  - -- *Standard procedures may be cited if available and appropriate.*
- Describe how field data will be reviewed and verified
  - -- How will timely evaluation of data used to make decisions in the field be accomplished?
  - -- How will handwritten sources be used to complete/verify information in field data bases?

Data Quality Assessment

- Describe additional activities planned to complete reconciliation of results with data quality objectives, such as
  - -- Focused validation of analytical data packages

    Identify problems that would trigger in-depth validation
  - -- Comparison of achieved bias and precision with levels originally prescribed

-- Evaluation of validity of the assumptions that were made for planning purposes

5 Administration

Summarize the nontechnical aspects of the SAP essential to maintain quality and to achieve third-party implementability.

Project Task Organization

- Functional roles and responsibilities
  - -- *Include those for which names, phone numbers and addresses will need to be supplied before SAP is executed.*

Training

- Identify special training needed for this investigation, such as:
  - -- use of field kits
  - -- nonstandard field sample prep
  - -- special field documentation requirements

Records

- What they are [e.g., handwritten field records (sample logs, logbooks), electronic data files, and formal reports] and who is to receive them

Oversight

- What is planned, e.g., readiness review, peer reviews, field audits.
  - -- *Mention special concerns, if any, such as completion of SOPs or SOWs.*

Inspection/Acceptance Policies

- -- *Cite SOPs if available and appropriate.*

Reports to Management

- Expected frequency and content.

C

SITE-SPECIFIC QAPP REQUIREMENTS

In late 94 early 95, a decision was made by ER Project Management to incorporate the Site-Specific QAPP requirements into the Sampling and Analysis Plans (SAPs) rather than having a separate document. To satisfy this requirement, the items that must be addressed in the SAPs (as required by EPA Region 6 QA/R-5) are addressed in the SAP outline as follows:

The applicable elements from Section A that must be addressed and the corresponding elements in the SAP outline are:

EPA Region 6 QA/R5 Requirement	**Location in ER Project SAP Outline**
A4: Project Task Organization	Section 5: Administration requires: **Project Task Organization** • Functional roles and responsibilities.
A5: Problem definition/background	Section 1: Problem Definition requires: **Question(s) to be answered by the data.** **Purpose for which this information is needed.** **Site description** • Figure showing the salient site features and indicating the areas of interest. • Summary of physical features and site history pertinent to this SAP. **Historical Data** • Summarize the most pertinent existing data; a short table may be appropriate. • Reference sources of historical data.
A6: Project/task description	Section 2: SAP Design Requires: **How will these data be used to answer the questions?** • Specify the summary statistics to be calculated. • Specify target levels with which summary statistics will be compared. • Identify sources of other information for statistical or other comparisons as appropriate. **Assumptions underlying the design .** • Identify the assumptions underlying the design. • Discuss the constraints on data quality implied by the intended use of the data.

A7: Quality Objectives and Criteria for Measurement Data	Section 2: SAP Design Requires: **Requirements for data quality implied by intended data use** • Define critical range of concentrations (e.g., within an order of magnitude of the PRG or WAC). • Determine acceptable levels of precision and bias for summary statistics within this critical range. **Measurements to verify these assumptions and requirements.** • Identify data quality assessment information to be collected to verify critical assumptions. • Identify observations that will permit problems affecting usability of data to be detected. • Identify measurements or observations that will be used to trigger implementation of any contingency plan. • Describe data acceptance criteria that will be used for review, verification, and validation of the data.
A8: Project Narrative	Required only for research projects conducted by the EPA Office of Research and Development.
A9: Special Training Requirements/-Certification	Section 5: Administration Requires: **Training** • Identify special training needed for this investigation.
A10: Documentation and Records	Section 5: Administration Requires: **Records** • What they are (e.g., handwritten field records (sample logs, logbooks), electronic data files, and formal reports) and who is to receive them.

The applicable elements from Section B that must be addressed and the corresponding elements in the SAP outline are:

EPA Region 6 QA/R5 Requirement	**Location in ER Project SAP Outline**
B1: Sample Process Design	Section 2: SAP Design Requires: **Overview of information to be collected.** • Identify locations and media to be sampled, and frequency if more than once. • Identify target analytes. • List all measurements (both field and laboratory) to be reported. • Include as appropriate figure(s) identifying sampling locations, and table(s) listing sample matrices, locations, depths, and proposed analyses. • Describe contingency plans, if any.

B2: Sampling Methods Requirements	Section 3: SAP Implementation Requires: **Field Methods** • Describe surveying and permanent marking of survey and sample locations. • Describe site preparation for surveys and sampling. • Describe sampling methods to be used. • Specify when and how to collect QC samples, calibrate field instruments, etc. • Identify all sampling information that must be recorded on the sampling logs, in logbooks, and/or in the field data base.
B3: Sample Handling and Custody Requirements	Section 3: SAP Implementation Requires: **Sample Handling** • Describe how offsite samples are to be packaged, shipped, and tracked.
B4: Analytical Methods Requirements	Section 3: SAP Implementation Requires: **Measurement Methods** • Identify screening instruments to be used. • Describe use of field test kits. • Describe auxiliary field measurements to be made. • Specify which field measurements are to be recorded in sampling logs, logbooks and/or the field data base. • Describe mobile van analyses. • Describe off-site analytical methods to be used.
B5: Quality Control Requirements	Quality control requirements are defined in Sections 2 (SAP Design) and implemented in Section 3 (SAP Implementation) for the sampling, analysis, and measurement techniques. The QC requirements are incorporated either into the SAP or the SOPs associated with a SAP only as they relate to the data collection activities. There is no distinct QC section to the SAP.
B6: Instrument/Equipment Testing, Inspection and Maintenance Requirements	Section 5: Administration Requires: **Inspection/Acceptance Policies**
B7: Instrument Calibration and Frequency	Instrument calibration and frequency are considered part of the SOPs in place for the ER Project. This requirement is met through incorporation of instrument calibration requirements into SOPs for each instruments use (see element B2).
B8: Inspection/Acceptance Requirements for Supplies and Consumable	Section 5: Administration Requires: **Inspection/Acceptance Policies**
B9: Data Acquisition Requirements (Non-direct Measurements)	The data acquisition requirements are mainly handled by the Data Management scheme outlined in the table element that immediately follows this one. Since the SAP is usually part of a larger document, non-direct measurement data are usually handled by the larger document.

B10: Data Management	Section 3: SAP Implementation Requires: **Data Tracking** • Describe how field information will be prepared for and transmitted to a central data management system. • Describe how mobile laboratory data will be reported to field crews and how it will be uploaded to the central data management system. • Describe forms of data (electronic, hard copy) expected from offsite laboratories, and how it will be uploaded to the central data management system.

The applicable elements from Section C that must be addressed and the corresponding elements in the SAP outline are:

EPA Region 6 QA/R5 Requirement	Location in ER Project SAP Outline
C1: Assessments and Response Actions	Section 5: Adm ation Requires: **Oversight** • What is planned, e.g., readiness review, field audits.
C2: Reports to management	Section 5: Administration Requires: **Reports to Management** • Expected frequency and content.

The applicable elements from Section D that must be addressed and the corresponding elements in the SAP outline are:

EPA Region 6 QA/R5 Requirement	Location in ER Project SAP Outline
D1: Data Review, Validation, and Verification Requirements	Section 4: Data Assessment Requires: **Verification and Baseline Data Validation** • Discuss data verification and routine validation process. • Describe how results will be communicated to data users. • Describe how field data will be reviewed and verified.
D2: Validation and Verification Methods	See above for verification and baseline validation and below for focused validation. These procedures are standardized across the ER Project except as stated in the discussions above and below.
D3: Reconciliation with Data Quality Objectives	Section 4: Data Assessment Requires: **Data Quality Assessment** • Describe additional activities planned to complete reconciliation of results with data quality objectives

D

DRAFT

To: Distribution

SUBJECT: RECONSIDERING AND/OR STOPPING WORK ON EXPEDITED CLEANUPS (ECs)/VOLUNTARY CORRECTIVE ACTIONS (VCAs)

STATEMENT OF ISSUE

The Los Alamos National Laboratory's Environmental Restoration (ER) Project has issued a common sense method for evaluating ECs and VCAs while in progress. Unforeseen circumstances often surface during the implementation of ECs or VCAs. A framework for assessing whether to continue with an EC or VCA follows.

SUMMARY OF POLICY

During the conduct of ECs or VCAs, it is important to plan a framework for assessing whether a potential release site (PRS) conceptual model is flawed to the extent that continuing the EC or VCA should be reconsidered. This determination may be complicated by factors that are not readily apparent. It is important to ER Project success that, when implementing an EC or VCA, we carefully ensure that the pursuit of a "bean" does not tempt us to ignore emerging problems during field work. Any time information becomes available that indicates the site conceptual model may be off target, the Field Project Leader should evaluate whether to continue. If the additional information warrants it, work will be stopped.

DISCUSSION

We must maximize the opportunity to reconsider or stop work before it becomes a safety hazard, a professional embarrassment, or a bottomless pit for scarce resources, such as budget dollars or site disposal capacity.

If one or more factors change the prevailing site conceptual model, then consider the consequences of the change(s) and stop work if the change warrants it. When stopping work is determined to be the appropriate action, it is crucial to have a plan that describes safe shutdown for the site EC or VCA operation. One should consider the safety of workers and trespassers, the safe storage of wastes generated to date, and a shutdown configuration that ensures that existing site conditions do not further mobilize contaminants or provide enhanced pathways for off site migration.

The following criteria is a framework; it is not a prescriptive solution to the problem of determining whether to stop work on ECs or VCAs. The examples provided are not intended to be an exhaustive listing of all possible changes, only an indication of changes that have been frequently encountered.

1) **WASTE** - Changes in type, volume, disposal capacity, disposal location, etc.

- If the composition of waste changes and there is limited capacity for the site waste, such as mixed wastes,
- If the volume of waste begins to grow by more than 50%[1] of the initial estimate, or
- If the disposal or treatment capacity for the site waste changes and would require waste storage for more than 90 days.

2) **COST** - Changes in available budget, total cost of project, etc.

- If the budget for site EC or VCA grows by more than 50%[1] of the initial estimate,
- If sites are prioritized similarly, those with increasing costs may go down in project priority due to added costs, because the project would accomplish fewer EC/VCAs, or
- If continuation will affect the program's ability to take action at sites of equal or greater urgency.

3) **LEVEL OF PROBLEM UNDERSTANDING** - Changes in contamination type or level, job difficulty, etc.

- If the waste constituents change and impact the selected treatment/disposal alternatives,
- If changes to the extent of contaminant movement or changes to the contaminant transport mechanism affects the overall job difficulty, or
- If the impact of continuing the action creates a greater problem (e.g., regulatory, public relations, ecological, etc.) than stopping work.

4) **RESOURCES** - Changes in knowledge, expertise, equipment, services, etc.

- If new or additional site data causes the site problem to change from understood/ documented site historical and/or characterization data,
- If the remediation equipment needed for the changed site problem is unavailable,

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[1] Initial estimates of engineering costs are typically only good within a range of + or - 50%. The relationship of waste management volume to waste management cost is usually linear, so that if volume increases 50% then so do costs.

- If the expertise of available staff does not match the changed site problem, or

- If the sensitivity or analytical detection limits of available analytical methods for the changed site problem do not meet the revised site cleanup requirements.

5) **SAFETY** - Changes in engineering plan or risk to remedial site worker, Laboratory worker, or off-site citizen, etc.

- If additional site findings suggest a new or greatly increased risk of an acute or chronic nature to remedial site worker, Laboratory worker, or off-site citizen,

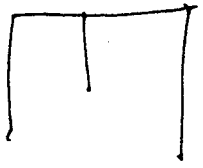
- If a change to the remedial engineering plan, such as the depth of excavation, differs from the site safety plan, or

- If getting a "bean" by end of the fiscal year appears to compromise safety.

6) **"LAUGH" TEST** - Question the appropriateness of what is being done.

- If you doubt that your actions are consistent with common sense, or

- If you think you are being asked to do something off-target.



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INTERIM DRAFT
EPA REQUIREMENTS FOR QUALITY ASSURANCE PROJECT PLANS

EPA QA/R-5

Region 6 U.S. EPA
Office of Quality Assurance

Dallas, Texas 75202

MAY 1994

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Call us for any assistance we can give you on QA matters, such as finding out about the status of your QA Plans, advice on writing your QA Plans, or attending one of our QA Courses.

QUALITY ASSURANCE PROJECT PLANS

Introduction

This document incorporates the national U.S. Environmental Protection Agency (EPA) requirements for Quality Assurance Project Plans (QAPP) and the Region 6 policy requirements into one document for ease of use by our customers.

It is both a Regulatory requirement and policy of EPA that all projects and tasks involving environmentally related measurements shall have a QAPP developed and approved by the Agency prior to any such activities being accomplished. This chapter presents detailed instructions on what information must be contained in a QAPP for environmental data operations performed by or on behalf of EPA Region 6 and on the procedures for its review and approval. While there is diversity in the various programs, it is Region 6 policy that all elements applicable to the QAPP Use Category. to be discussed in detail further on in this document, will be addressed in each QAPP. To do otherwise would be to deviate from the national standard and could dilute EPA's goal of national consistency for Quality Assurance requirements.

The complexity of environmental data operations demands that a systematic process and structure be established to provide decision makers with the necessary confidence in the quality of data produced for the decisions to be made, as well as with the means to determine when the data are not fully usable and what to do about the situation. This process and structure is provided by the quality system for the organization conducting the environmental data operations. EPA policy requires that the collection of environmental data by and on behalf of the Agency be supported by a mandatory Quality System, documented in a Quality Management Plan (QMP).

An area that must be addressed in each QMP is the systematic planning process used for each project or task such as the Data Quality Objective process. All projects involving the generation, acquisition and use of environmental data shall be planned using a systematic planning process such as the Data Quality Objective process as defined by the current revision of Guidance for Planning for Data Collection in Support of Environmental Decision Making Using the Data Quality Objectives Process, EPA QA/G-4, or acceptable alternate. The use of the Data Quality Objectives process leads to definition of many of the specific elements required in a QAPP.

It is EPA policy that all decisions and work involving the use of environmental data be supported by a *Quality Assurance Project Plan*. The QAPP is the principal product of the planning process inasmuch as it integrates all technical and quality aspects for the life-cycle of the project, including planning, implementation, and assessment. The QAPP provides a project- or task-specific blueprint of how Quality Assurance (QA) and Quality Control (QC) are applied to an environmental data operation to assure that the results obtained are of the type and quality needed and expected. Effective implementation of the QAPP should provide the best opportunity to achieve the technical and quality goals of a project.

The ultimate success of an environmental program or project depends on the quality of the environmental data collected and used in decision-making, and this may depend significantly on the adequacy of the QAPP and its effective implementation. Quality planning is an absolutely essential component of project management and the QAPP provides the mechanism for documenting the results of the planning process. In the sections to follow, the elements of the QAPP are discussed in detail. These elements represent the information that EPA believes to be necessary for data operations involving the characterization of environmental processes and conditions.

Quality Assurance Project Plan Requirements

QAPP Policy

All work performed by or on behalf of EPA that involves the collection and use of environmental data[1] shall be supported by an Agency-approved QAPP. No work performed under contract, work assignment, technical directive, delivery order, assistance agreement, or interagency agreement involving the environmental data generated from direct measurement activities, collected from other sources, or compiled from computerized data bases and information systems shall be implemented without an approved QAPP or without a condition stating that the actual collection of data shall not occur until after the QAPP is approved. Region 6 has implemented this requirement by establishing a process that requires a joint certification of the presence and approval status of QMPs and QAPPs by the Region 6 Office of Quality Assurance and the Region 6 Program Office that has management responsibilities for the particular project.

QAPP Purpose

The QAPP is a critical planning document for any environmental data operation. The QAPP documents how QA and QC activities will be *planned, implemented, and assessed* during the life cycle of a program, project, or task. The QAPP is the "road map" or blueprint for how a particular project is integrated with the QA program of the organization performing the work and how the specific QA and QC activities will be applied during a particular project.

Applicability of QAPPs

These QAPP requirements apply to all (intramural and extramural) environmental data operations that acquire, generate, or compile environmentally-related data and that are performed by or on behalf of EPA. These operations include work performed through contracts, interagency agreements, and financial assistance agreements (e.g cooperative agreements, grants).

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[1]Environmental data include any information collected, produced, or derived from measurements analyses, or models of environmental processes and conditions, or from experimental systems representing such processes and conditions, including results from laboratory analyses.

Environmental data operations encompass diverse and complex activities, and represent efforts pertaining to rulemaking, compliance with regulations, and research. Consequently, any requirements developed to define how QA/QC should be applied to environmental activities **must contain considerable flexibility**. This may mean, for example, that some environmental data operations, perhaps involving research projects, may only require a qualitative discussion of the experimental process and its objectives, such as a project narrative statement. Others may require extensive documentation in order to adequately describe a complex environmental program. ***This means that the content and level of detail in each QAPP will vary according to the nature of the work being performed and the intended use of the data.*** For QAPPs submitted to EPA Region 6 the decision on the content and level of detail is to be consistent with national EPA requirements, as defined by the current revision of EPA Requirements for Quality Assurance Project Plans for Environmental Data Operations, EPA QA/R-5. It is EPA policy that the type and quality of environmental data needed for their intended use shall be defined and documented using the EPA Data Quality Objectives (DQO) Process, or its equivalent, to the extent possible or practicable. The results of the DQO Process provide key inputs to the QAPP and will largely determine the level of detail required in the QAPP. These inputs from the DQO Process are identified later.

QAPP Use Categories

Because of the diversity and variability in the mission requirements of the organizations (e.g., state program offices, EPA regions, research laboratories, municipal organizations) comprising the environmental community, it is not always possible to define a single checklist of elements and details needed for all QAPPs. To provide some of the needed flexibility, several EPA organizations, including Region 6, have been categorizing QAPP requirements according to the type of work being performed and the intended use of the data. Four categories have been defined that vary the level of detail and rigor prescribed for particular QAPPs.

These Use Categories are mandatory for QAPPs prepared and submitted for approval to U.S. EPA Region 6. They are presented as an aid to determining the level of detail that may be needed in a QAPP for a particular type of work. This approach recognizes that not all environmental data operations require QAPPs with the same level of detail. For example, data collected for compliance or enforcement decisions in a Region will require a more comprehensive QAPP than an exploratory research project conducted for an ORD R&D laboratory. The categories are:

- **Category I** – Direct Support to Rulemaking, Enforcement, Regulatory, or Policy Decisions

  These projects include environmental data operations that **directly support** rulemaking, enforcement, regulatory, or policy decisions. They also include research projects of significant national interest, such as those typically monitored by the Administrator. Category I projects require the most detailed and rigorous QA and QC for legal and scientific defensibility. Category I projects are typically stand-alone; that is, the results from such projects are sufficient to make the needed decision without input from other projects.

- **Category II** – Complementary Support to Rulemaking, Regulatory, or Policy Decisions

  These projects include environmental data operations that **complement** other projects in support of rulemaking, regulatory, or policy decisions. Such projects are of sufficient scope and substance that their results could be combined with those from other projects of similar scope to provide the necessary information for decisions. Category II projects may also include certain high-visibility projects as defined by EPA management.

- **Category III** – Interim Studies

  These projects include environmental data operations performed as interim steps in a larger group of operations. Such projects include testing research hypotheses, estimating effects, developing methods, and other work producing results that are used to evaluate and select options for interim decisions or to perform feasibility studies or preliminary assessments of unexplored areas for possible future work.

- **Category IV** – Basic Studies

  These are projects involving environmental data operations to study basic phenomena or issues, including proof of concept and qualitative screening for particular analytical species.

The final determination of a project's category is made by the EPA Region 6 Program Office[2] responsible for the work. Where no category is defined, the preparer of the QAPP shall assume that it is a Category I project. It should be noted that projects may contain specific tasks or subtasks that vary in the level of QA/QC requirements. Such conditions should be considered when deciding on the Use Category for a particular project.

[2]Organization refers to the EPA Program Office, Region, or ORD Laboratory having an approved Quality Management Plan that describes its quality system for planning, implementing, and assessing environmental programs.

Special Requirements

In some cases, it may be necessary for special requirements to be added to the QAPP that are not included in this document. When this occurs, such additional elements must also be addressed by the QAPP in the same manner as the elements listed in this document. The EPA Region 6 program office sponsoring the work shall delineate any specific requirements beyond those listed in this manual. If none are specified, the QAPP shall address all elements required, as specified by their particular Use Category. Attached documentation, such as an approved Work Plan, Standard Operating Procedures (SOPs), etc., may be referenced in response to a particular QAPP element. This is, in fact, encouraged to reduce the time required to prepare the QAPP. The QAPP shall also address related QA planning documentation (e.g., Quality Management Plans, QA Project Plans) from subcontractors or suppliers of services critical to the technical and quality objectives of the project or task. In any case, all referenced documents must be attached to the QAPP itself or be placed on file with the appropriate EPA office for routine referencing when needed. Such references must be kept current by the submitter.

QAPP Process Responsibilities and Approvals

The QAPP may be prepared by different groups. The QAPP may be prepared by the EPA principal investigator for an in-house project and may be reviewed by the principal investigator's immediate supervisor before it goes to the QA manager or coordinator for final approval. The QAPP may be prepared by a contractor or an assistance agreement holder. In addition, the QAPP may be prepared by another Federal agency under an interagency agreement. These specific situations must be addressed in the organization's QMP to establish how, when, and by whom review, approval, and effective oversight of QAPPs occurs. **Except where specifically delegated, all QAPPs prepared by non-EPA organizations must be approved by EPA for implementation.** Region 6 policy allows for the development of a QAPP to occur **only** after a QMP has been approved, and specifically precludes approval of a QAPP until the applicable QMP has been approved.

EPA believes that the necessary flexibility in content and level of detail in the QAPP may be best achieved by having the QAPP requirements reviewed and confirmed by the EPA project manager (or officer)[3] with the assistance and concurrence of the EPA QA Manager. In the case of Region 6, the authority to review and approve QAPPs has been delegated to the Region 6 Program Offices, and is covered and defined by the Quality Management Plans of the various divisions.

None of the environmental work addressed by the QAPP should be started until the initial QAPP has been approved and distributed to project personnel. It is Region 6 policy that sixty days prior to the initiation of any environmental measurements or data generation, the recipient (of any EPA funding) shall submit to the EPA Project Officer.

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[3]This term refers to the responsible EPA official for the project and includes such descriptors as project officer, work assignment manager, and principal investigator.

for review and approval, a written Quality Assurance Project Plan for the project. **Any costs for environmental measurements or data generation incurred prior to approval of the QAPP by the EPA Project Officer will be ineligible for reimbursement.** The Region 6 Policy does not authorize granting **conditional approval** to a QAPP. There are only two recognized statuses of a QAPP are **approved**, and **not approved.** It is the responsibility of the organization performing the work to assure that no environmental data are acquired before the QAPP is **approved** and **received** by project personnel.

QAPP Implementation and Revision

It is EPA policy that all approved QAPPs shall be implemented for the intended work. It is the responsibility of the group performing the work to implement the approved QAPP and to ensure that all personnel involved in the work have copies of the **approved** QAPP and all other necessary planning documents and understand their requirements prior to the start of data generation activities.

Because of the complex and diverse nature of environmental data operations, changes to original plans are often needed. When such changes occur, it is the responsibility of the Project Manager for whom the work is being performed to determine if the change significantly impacts the technical and quality objectives of the project. This determination should be done in consultation with the QA Manager. When substantive change is contemplated, the originator of the QAPP shall modify the QAPP as necessary to document the change and submit the revision for approval by the same parties as for the original review. Only after the revision has been approved and receipt of the change (at least verbally with written follow-up) by the project personnel performing the work, shall the change be implemented.

It is absolutely essential that the QAPP be kept current and that all personnel involved in the work effort have a current version of the QAPP available. For programs or projects of long duration, such as multi-year monitoring programs, the QAPPs shall be reviewed at least annually by the Project Manager, revised if necessary to reflect current needs, and resubmitted for review and approval. If the entire QAPP is current valid and accurately reflects the project goals and the organization's policy, at a minimum, each year the organization will submit to EPA Region 6 a certification that the plan is current, to include a copy of new, signed approval pages for the QAPP.

QAPP Elements

General Content

All projects involving the generation, acquisition, and use of environmental data shall be planned and documented. The QAPP is the logical product of the planning process and must provide sufficient detail to demonstrate that:

- the project technical and quality objectives (e.g., DQOs, or equivalent) are identified and agreed upon;

- the intended measurements or data acquisition methods are appropriate for achieving project objectives;

- assessment procedures (including QA and QC) are sufficient for obtaining data of the type and quality needed and expected; and

- any limitations on the use of the data can be identified and documented.

Environmental data operations require the coordinated efforts of many individuals, including managers, engineers, scientists, chemists, statisticians, and others. The QAPP must integrate the contributions and requirements of everyone involved into a clear, concise "blueprint" of what is to be accomplished, how it will be done, and by whom. This means it must provide understandable instructions to those who must implement all parts of the QAPP, including the field sampling team, the analytical laboratory, and the data reviewers. In all aspects of the QAPP, the use of national standards and practices, and inclusion of standard operating procedures is encouraged.

The QAPP elements that follow are presented in an order corresponding to planning, implementation, and assessment. They have been grouped for convenience into four types of elements. The individual QAPP elements are numbered sequentially within each group. The four types of elements and their intent are summarized as follows:

A. Project Management - This group of QAPP elements covers the basic area of project management, including the project history and objectives, roles and responsibilities of the participants, etc. These elements ensure that the project has a goal, that the participants understand the goal and the approach to be used, and that project planning is documented.

B. Measurement/Data Acquisition - This group of QAPP elements covers all of aspects of measurement systems design and implementation, ensuring that appropriate methods for sampling , analysis, data handling, and QC are employed and will be thoroughly documented.

C. Assessment/Oversight - This group of QAPP elements addresses the activities for assessing the effectiveness of the implementation of the project and associated QA/QC. The purpose of assessment is to ensure that the QAPP is implemented as prescribed.

D. Data Validation and Usability - This group of QAPP elements covers the QA activities that occur after the data collection phase of the project is completed. They ensure that the individual data elements conform to the specified criteria thus enabling reconciliation with the project objectives.

The optional Use Categories and elements are summarized in Table 4-1. As stated earlier, the decision to use this approach and the determination of a project's category and the actual QAPP elements required is made by the EPA organization. The term *DQO* after the QAPP Element title indicates that the information needed to address this element in the QAPP is usually identified in the DQO process.

TABLE 4-1 USE CATEGORY CHART

CATEGORY	ELEMENT	DESCRIPTION
Project Management		
I, II, III, IV	A1	Title and Approval Sheet
I, II, III	A2	Table of Contents
I, II, III, IV	A3	Distribution List
I, II, III, IV	A4 (DQO)	Project/Task Organization
I, II, III, IV	A5 (DQO)	Problem Definition/Background
I, II, III	A6 (DQO)	Project/Task Description
I, II, III	A7 (DQO)	Data Quality Objectives for Measurement Data
IV	A8	Project Narrative (ORD Only)
I	A9	Special Training Requirements/Certification
I, II, III	A10	Documentation and Records
Measurement/Data Acquisition		
I, II, III	B1 (DQO)	Sampling Process Design (Experimental Design)
I, II, III	B2	Sampling Methods Requirements
I, II, III	B3	Sample Handling and Custody Requirements
I, II, III	B4 (DQO)	Analytical Methods Requirements
I, II, III	B5	Quality Control Requirements
I, II	B6	Instrument/Equipment Testing, Inspection, and Maintenance Requirements
I, II, III	B7	Instrument Calibration and Frequency
I	B8	Inspection/Acceptance Requirements for Supplies and Consumables
I, II, III	B9	Data Acquisition Requirements (Non-direct Measurements)
I, II	B10	Data Management

TABLE 4-1 USE CATEGORY CHART (continued)

CATEGORY	ELEMENT	DESCRIPTION
Assessment/Oversight		
I, II, III	C1	Assessments and Response Actions
I, II, III	C2	Reports to Management
Data Validation And Usability		
I, II, III	D1	Data Review, Validation, and Verification Requirements
I, II	D2	Validation and Verification Methods
I, II, III	D3	Reconciliation with Data Quality Objectives

Group A, Project Management

A1 Title and Approval Sheet

Include:

- Title of the plan
- Name of the organization(s) implementing the project
- Names, titles, signatures of appropriate approving officials and approval dates for:

  Organization's Project Manager (Required)
  Organization's Quality Assurance Manager (Required)
  Project Subordinate Supervisors Concurrence (Optional)
  Region 6 EPA Project Manager *(Required)*
  Region 6 EPA Approving Official *(Required)*[4]
  Others, as needed (e.g., State, other Federal Agency)

- Title and Region 6 QTRAK number of the approved Quality

  Management Plan applicable to submitted QAPP

Submission of at least two original approval pages is recommended.

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[4] "EPA Approving Official" is the Region 6 Program Office Manager or staff person designated and authorized by Certification of the Region 6 QA Officer to approve QAPPs. If the EPA Project Manager/Officer is unable to determine the approving official, contact the Chief of Quality Assurance.

A2 Table of Contents

List the sections, figures, tables, references, and appendices. Document control format may be required at the option of the Project Manager and QA Manager, and is encouraged by EPA Region 6. When required, use document control format in the upper right-hand corner of each page following the Title and Approval Sheet. For example:

Section No. _____
Revision No. _____
Date _____
Page ___ of ___

A3 Distribution List

List the individuals and their organizations who will receive copies of the approved QAPP and any subsequent revisions. Include all managers who are responsible for implementing the plan, as well as the QA managers and representatives of all groups involved.

A4 Project/Task Organization (DQO)

Identify the individuals or organizations participating in the project and discuss their specific roles and responsibilities. Include the principal data users and the decision-makers. The project quality assurance manager **shall be** independent of the unit generating the data. This does not include senior officials, such as corporate managers or agency administrators, who are nominally but not functionally involved in data generation, data use, or decision-making. The QAPP should also identify the person(s) responsible for approving and accepting final products and deliverables.

Provide a concise **organization chart showing** the relationships and the lines of communication **among** all project participants. Include other data users who are outside of the organization generating the data, but for whom the data are nevertheless intended; e.g., modelers, risk assessors, design engineers, toxicologists, etc. Where direct contact between project managers and data users does not occur, such as, between a project consultant for a Potentially Responsible Party and EPA risk assessment staff, the organization chart should show the route by which information is exchanged. The organization chart should also identify any subcontractor relationships relevant to environmental data operations. This chart should be realistic and practical, and should reflect only actual lines of authority and communication for the project described. Names of current incumbent occupying a position is essential, as is the identification of vacant positions.

A5 Problem Definition/Background (DQO)

State the specific problem to be solved or decision to be made. Include sufficient background information to provide a historical perspective for this particular project. For example, this would include the regulatory or alleged toxic exposure situation that led to the need for this project. The discussion must include enough information about the problem, the past history, any previous work or data, and any regulatory or legal context to allow a technically trained reader to make sense of the project objectives and activities. This discussion also identifies the decision maker(s) and the principal customer(s) for the results. (When the Data Quality Objectives [DQO] process has been used, this information should be readily available.)

A6 Project/Task Description (DQO)

Provide a description of the work to be performed. This discussion may not need to be lengthy or overly detailed, but it should give a overall picture of how the project will resolve the problem or question described in A5. Describe in general terms the following, as needed:

- Measurements that are expected during the course of the project and the approach that will be used.
- Applicable technical, regulatory, or program-specific quality standards, criteria, or objectives.
- Any special personnel and equipment requirements that may indicate the complexity of the project.
- The assessment tools needed (i.e., program technical reviews, peer reviews surveillances, and technical audits as needed and/or specified by the QMP for the project.
- A schedule for the work to be performed.
- Project and quality records required, including the types of reports needed

A7 Quality Objectives and Criteria for Measurement Data (DQO)

Any QAPP must include a statement of the project quality objectives and measurement performance criteria. EPA recommends that a graded approach be used in planning, such as the Data Quality Objectives (DQO) Process. Even in those cases in which the formal DQO Process is not needed, a statement of the project quality objectives and measurement performance criteria is needed The DQO process provides quality objectives based on several factors chosen

by the user of the data. For details on the DQO Process and when it should be used, please see the EPA guidance document (QA/G-4)[5].

The project quality objectives should be stated in quantitative terms to the extent possible:

> Example: UV Treatment of Contaminated Groundwater. "The purpose of this project is to demonstrate whether or not the residual trichlorethene concentration in the treated water is less than 0.5 µg/L at a confidence level of 95 percent."

Without such quantitative goals, it is difficult to know whether the selected analytical method is sufficiently sensitive or precise, or whether a sufficient number of samples are being collected. Sometimes, of course, project objectives must be stated somewhat less quantitatively, particularly in those situations when the use of the formal DQO Process is not needed.

> Example: Oil Spill Remediation. "One objective of this project is to determine whether the populations of clams, mussels, and sand fleas recover more rapidly in the treated than the untreated area."

> Example: Epidemiology Study. "The purpose of this project is to determine whether the concentrations of indoor NO_2 and soot are greater in the residences of lung cancer patients than in the residences of healthy persons."

The section on project quality objectives and measurement performance criteria should address, as appropriate, the following:

- the **scope** of the project; that is, the domain (geographical locale and boundaries, environmental medium, time period, etc.) over which conclusions and decisions will apply;
- the time, resource, or other constraints on the measurement project;
- the intended uses of the data, in order of importance and the expected users of the data;
- the specific data needed: type, quantity, matrices involved;
- the action levels or standards upon which decisions will be made, including the detection limits and data reporting units, and the source(s) of this information;

5 EPA QA/G-4 is Guidance for Planning for Data Collection in Support of Environmental Decision Making Using the Data Quality Objectives Process.

- the population parameter(s) of interest; e.g., mean, maximum, or range, which specify the form the data will be in when compared against action levels or standards;

- the acceptable level of confidence in the data needed for the stated purposes or the acceptable amount of uncertainty;

- the quantitative **sensitivity**, **precision**, **bias**, and **completeness** criteria for each major measurement planned (including all pollutant and process measurements) for each sample matrix, based on the DQO statements;

- the units of expression of the precision and bias goals, which should correspond to the methods selected to assess data precision and bias; and

- the goals for achieving data **representativeness** and **comparability**, and the planning considerations for attaining these goals (unlike precision, bias, and completeness, these objectives are not usually expressed or assessed quantitatively);

Data quality or measurement performance criteria may be typically specified in terms of detection or quantitation limits, precision, bias, and comparability. However, simply listing requirements for precision, bias, and completeness without further discussion is not sufficient. Even statements such as "bias will be measured as percent recovery of a matrix spike sample" are of marginal help. In specifying data quality, it is thus essential to specify exactly how such quality will be measured and interpreted.

> Example: A possible statement of bias requirement. "Bias will be measured a minimum of five times throughout this project by the analysis of standard reference materials No. 956B. Recovery of TCE from this SRM should average 85 percent or greater, with a relative standard deviation of no more than 20 percent."

Data specifications should also be distinguished from the specific QC procedures that are routinely carried out as part of each measurement. QC procedures are used while carrying out specific procedures; data specifications are used for selecting the appropriate methods and QC criteria.

The QAPP may need to define different types of sensitivity (i.e., qualitative, quantitative, screening, etc.) that may be appropriate for different parts of the project.

The quantitative goals should reflect the *total measurement*, if possible, or address the field, laboratory, and data handling components separately. In the event there is no basis for defining data quality goals for the project, goals may be estimated based on prior knowledge of the measurement system, and on method validation studies (using replicates, spikes, standards, recovery, studies, etc.) Explain the circumstances under which these goals were established.

If defining quantitative goals is not relevant for certain measurements, indicate this and state the reason.

Data representativeness is the degree to which the environmental samples truly reflect the population or material in the real world. It can be affected by the time, place, and manner by which the samples are collected.

Data comparability is dependent upon consistency in sampling conditions, selection of sampling procedures, sample preservation methods, analytical methods, and data reporting units, throughout the project, and with previous projects with which these results will be compared.

The DQO Process for compliance and/or enforcement projects in the Regions may not be within the control of the EPA project manager and QA manager. The measurement performance criteria are specified in regulations, permits, or orders. Whether or not those criteria satisfy the requirements of this document, they are absolutely required. Often the results of the DQO Process are not expressible in the terms stated here, such as precision, bias, or comparability. The affected source is simply required to follow a specified method. In such cases, it is sufficient for the portion of the QAPP addressing the DQO Process to state that the testing will satisfy the regulatory requirements specified. This does not, however, relieve the project manager or QA manager from their responsibility to comply with all other applicable QAPP requirements in this document.

A8 Project Narrative

Discuss in a narrative form the following issues as they pertain to the project or task, as needed:

- work to be performed or hypothesis to be tested,
- anticipated use of the data,
- how (quantitatively or qualitatively) the success of the project or task will be determined (A7, D3),
- survey design requirements and description (B1),
- sample type and sampling location requirements (B2),
- sample handling and custody requirements (B3),
- selection of analytical methods (B4),
- calibration and performance evaluation samples for sampling and analytical methods used (B5),
- sampling or analytical instrumentation requirements (B6),
- plans for peer or readiness reviews prior to data collection (C1), and
- any on-going assessments during actual operation (oversight) (C1).

QAPP elements corresponding to the items to be addressed in the narrative are given in parentheses. The narrative should allow technical or QA readers to relate the project or task to the DQOs and to the Problem Definition stated earlier in the QAPP. (The use of the Project Narrative is consistent with the Use

Category scheme described in Appendix A. Since this element addresses in narrative form many other QAPP elements, it is not necessary to specifically include those elements in a Category IV QAPP. Moreover, because the elements listed above would be addressed in more detail in Category I, II, and III QAPPs, it is not necessary to include this element for those categories.)

A9 Special Training Requirements/Certification

Identify and describe any specialized training or certification requirements for personnel in order to successfully complete the project or task. Discuss how such training will be provided and how the necessary skills will be assured and documented.

A10 Documentation and Records

Itemize the information and records which must be included in a data report package for the project or task, and specify the reporting format, if desired. Documentation can include raw data, filed logs, instrument printouts, and results of calibration and QC checks. Specify the laboratory data reporting turnaround time. Specify whether a field sampling and/or laboratory analysis "case narrative"[6] is required to provide a complete description of any difficulties encountered during sampling or analysis.

Specify any requirements for the final disposition of records and documents from the project, including location and length of retention period.

Group B, Measurement/Data Acquisition

The following QAPP elements describe the requirements related to the actual methods to be used for the:

- collection, handling, and analysis of samples;
- direct measurement of parameters that do not require the actual collection of a sample; and
- the management (i.e., compiling, handling) of the data.

The methods described in these elements may have been cited earlier in element A6. however, the purpose here is to include sufficient detailed information to ensure that the methods are verified and documented. As long as the designated methods are well documented and are readily available to all project participants, specific citations are adequate. If these methods are not readily available, detailed copies of the methods and/or SOPs must accompany the QAPP as attachments.

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[6] "Case Narrative" refers to an annotated summary of the analytical work performed by a laboratory that describes in narrative form what activities were performed and identifies any problems encountered The case narrative provides additional information to user in interpreting the data received.

B1 Sampling Process Design (Experimental Design) (DQO)

Outline in general terms the experimental design of the project and the anticipated project activities, including the types of samples required, sampling network design, sampling frequencies, sample matrices, measurement parameters of interest, and the rationale for the design. If individual sampling plans will be developed for discrete project phases, include their preparation schedule.

Describe techniques or guidelines to be followed in selecting sampling points and frequencies, well installation design (when applicable), field decontamination procedures and materials needed, and sampling equipment. When field screening techniques will be used to identify samples for laboratory analysis, describe the criteria for sample selection. Similarly, when locational data are to be collected, stored, and transmitted, the method(s) used must be specified and described (or referenced). Key elements to be addressed include how locations and their bias are determined.

All measurements should be classified as critical (i.e., required to achieve project objectives) or non-critical (informational purposes only). Critical measurements will undergo closer scrutiny during the review and data gathering process, and will have first-claim on limited budget resources.

For non-standard methods or unusual sample matrices and situations, appropriate method validation study information is needed to confirm the performance of the method for the particular matrix. Such validation studies may included round-robin studies performed by other organizations. If previous validation studies are not available, they must be developed during the project and included as part of the project results. It is very important for this element to include complete documentation and validation of both the sampling and analytical methodologies. Identifying standard methods by number, date, and regulatory citation (as appropriate) is often sufficient. However, many published (and even regulatory) methods allow the user to select from various options. The method citations should state *exactly* which options are being selected.

Measurement of process conditions is often essential to a project (e.g., industrial plant or control equipment operation associated with a compliance test, meteorological parameters associated with impoundment volatization). In such cases, the experimental design must include the design and validation techniques as described above.

B2 Sampling Methods Requirements

Describe the procedures for collecting samples. Identify the required sampling methods (and/or equipment, if automated), including any implementation requirements, decontamination procedures and materials needed, and any specific performance requirements for the method. For each sampling method identify any support facilities needed. The discussion should also address what

to do if there is a failure in the sampling or measurement system and who is responsible for corrective action.

Describe the preparation and decontamination of sampling equipment, including disposal of decontamination by-products; the selection and preparation of sample containers, sample volumes, preservation methods, and maximum holding times to sample extraction and/or analysis. A tabular presentation format is strongly recommended, particularly when two or more sample matrices are involved.

B3 Sample Handling and Custody Requirements

Describe the provisions for sample handling and shipment, taking into account the nature of the samples and the maximum allowable sample holding times before extraction or analysis. Describes the following provisions for sample custody, in both the field and the laboratory:

- Forms, notebooks and procedures to record the exact location and ambient conditions associated with sample collection, possession and analysis. In the laboratory, a sample custody log should be maintained.
- Examples of sample documentation forms, such as sample labels, custody seals, and chain-of-custody forms.
- Labeling procedures and information entered on the forms, including sample preservation, if any, and dates and times of sample transfer and analysis.
- Procedures for transferring and maintaining custody of samples.

B4 Analytical Methods Requirements (DQO)

Identify the analytical methods and/or equipment required, including any extraction methods needed, laboratory decontamination procedures and materials needed (such as in the case of hazardous or radioactive samples), waste disposal requirements (if any), and any specific performance requirements for the method. The QAPP should also address what to do if there is a failure in the analytical system and who is responsible for corrective action

B5 Quality Control Requirements

Discuss QC procedures that should be associated with each sampling, analysis, or measurement technique. Such specific procedures are performed routinely during the measurement process, and the results are required to be evaluated immediately by the technician upon completion of the test. Results must fall within certain acceptance criteria, or specific corrective action is required. For projects at or beyond the "proof-of-concept" stage, or for projects employing well-characterized methods, this section should list each required QC procedure, along with the associated acceptance criteria and corrective

action. Because standard methods are often vague or incomplete in specifying QC requirements, simply relying on the cited method to provide this information is usually insufficient. In any case, QC procedures must frequently be modified on a project-specific basis in order to meet data specifications.

QC procedures must be compatible with the data specifications discussed above. This means, if a measurement must be precise within ±20 percent, the stability of calibration checks must be somewhat better than ±20 percent. For some research-oriented projects, the analytical technique may not be available until well into the project. In such instances, detailed QC requirements may not need to be specified in the initial QAPP. More appropriately, the initial document might specify general requirements for precision, bias, and detection limits, and the means of achieving these goals would be developed by the principal investigator during the course of the project.

List the required QC checks, such as matrix spikes, duplicates, blanks, laboratory control samples, surrogates, or second column confirmation. State the frequency of analysis for each type of QC check, and the spike compounds and levels. State or reference the required control limits for each QC check and corrective action required when control limits are exceeded.

Describe the procedures to be used to calculate each of the QC statistics, including the QC checks described in the preceding paragraph as well as precision and bias. Copies of the formulas are acceptable as long as the accompanying narrative or explanation specifies clearly how the calculations will address difficult situations such as missing data values and "less than" or "greater than" values.

B6 Instrument/Equipment Testing, Inspection, and Maintenance Requirements

Discuss how inspections and acceptance testing, including the use of QC standards and reference materials, of environmental sampling and measurement systems and their components must be performed and documented to assure their intended use as specified by the design. Identify and discuss how final acceptance shall be performed by independent personnel (e.g., personnel other than those performing the work). Discuss how deficiencies are to be resolved when acceptance criteria are not met, and how and when re-inspection will be performed as necessary.

Discuss how periodic preventive and corrective maintenance of measurement or test equipment shall be performed to ensure availability and satisfactory performance of the systems. Identify the equipment and/or systems requiring periodic maintenance. Discuss how the availability of critical spare parts, identified in the operating guidance and/or design specifications of the systems will be assured and maintained.

B7 Instrument Calibration and Frequency

Identify all tools, gauges, instruments, and other sampling, measuring, and test equipment used for data collection activities affecting quality that must be controlled and, at specified periods, calibrated to maintain bias within specified limits. Discuss how calibration shall be conducted using certified equipment and/or standards with known valid relationships to nationally recognized performance standards. If no such nationally recognized standards exist, document the basis for the calibration. Identify the certified equipment and/or standards used for calibration. Indicate how documentation of calibration shall be maintained and be traceable to the instrument.

B8 Inspection/Acceptance Requirements for Supplies and Consumables

Discuss how and by whom supplies and consumables shall be inspected and accepted for use in the project. Supplies and consumables are those items necessary to support the sampling and analytical operation. They include, but are not limited to: sample bottles, calibration gases, reagents, hoses, materials for decontamination of sampling equipment, deionized water, and potable water. Identify acceptance criteria for such supplies and consumables in order to satisfy the technical and quality objectives of the project or task.

B9 Data Acquisition Requirements (Non-direct Measurements)

Identify the type of data acquired from non-measurement sources such as computer data bases, spreadsheets, and programs, and literature files. Define acceptance criteria for the use of the data in this project. Discuss any limitations on the use of the data based on uncertainty in the quality of the data and discuss the nature of that uncertainty.

B10 Data Management

Outline the project data management scheme, tracing the path of the data, beginning from receipt from the field or laboratory, to the use or storage of the final reported form. Describe the standard recordkeeping procedures, document control system, and the approach used for data storage and retrieval on electronic media. Discuss the control mechanism for detecting and correcting paperwork errors and for preventing loss of data during data reduction (i.e., calculations), data reporting, and data entry to forms, reports, and databases. Provide examples of any forms or checklists to be used.

Identify and describe all data handling equipment and procedures that will be used to process, compile, and analyze the data. This includes procedures for addressing data generated as part of this project as well as data from other sources. The specifications should include any required computer hardware and software and should address any specific performance requirements for the hardware/software configuration used. Describe the procedures that will be

followed to demonstrate acceptability of the hardware/software configuration required.

Group C, Assessment/Oversight

C1 Assessments and Response Actions

Identify the number, frequency, and type of assessment activities needed for this project. Assessments include, but are not limited to, the following:

- surveillance,
- peer review,
- management systems review,
- readiness review,
- technical systems audit,
- performance evaluation,
- audit of data quality, and
- data quality assessment.

Discuss the information expected from the assessment and success criteria (i.e., goals, performance objectives, acceptance criteria specifications, etc.) for each assessment proposed. For each proposed assessment, list the approximate schedule of activities, and discuss the information expected from the assessment and the criteria for success. For any planned self-assessments (utilizing personnel from within the project groups), identify the participants and their exact relationship within the project organization. For independent assessments, identify the organization and person(s) that will perform the assessments. Discuss how and to whom the results of the assessments will be reported. Define the authorities of the assessors. For example, if the assessors should order a work suspension upon finding a significant condition, this section delineates clearly their authority to do so. Define explicitly the unsatisfactory conditions under which the assessors are authorized to act. Recognizing that assessments may be needed at any time during the project, provide a schedule for the assessments to be performed.

Discuss how response actions to non-conforming conditions will be addressed and by whom. Identify who is responsible for implementing the response action. Describe how response actions will be verified, validated, and documented.

C2 Reports to Management

Identify the frequency, content, and distribution of reports issued to inform management of the following:

- status of the project;
- results of performance evaluations and system audits;
- results of periodic data quality assessments; and
- significant quality assurance problems and recommended solutions.

Identify the responsible organization(s) that will prepare the reports, and the recipients of the reports. Identify any other status reports to management as well as their content and frequency.

Group D, Data Validation and Usability

D1 Data Review, Validation, and Verification Requirements

State the criteria used to review and validate that is, accept, reject, or qualify data, in an objective and consistent manner. Provide examples of any forms or checklists to be used.

Project-specific calculations or algorithms should be discussed. Some projects may require special calculation during or after data generation:

> Example: Indoor Air Pollution. Consider a project that is meant to estimate the number of residences within the greater Washington, D. C., area exhibiting NO_2 concentrations greater than 100 $\mu g/m^3$ at a frequency of 30 of more days per year. Once NO_2 measurements are available, one would attempt to extrapolate the limited information to the greater metropolitan area. The QAPP should explain the statistical techniques that will be employed, including how uncertainties will be assessed.
>
> For other projects, one may only need to calculate a mass balance of a destruction/removal efficiency. While these are much simpler requirements, the specific formulas and data inputs should be listed. This approach helps assure that at least the minimum necessary data are collected for the intended interpretation (even if additional interpretation schemes are eventually employed).

D2 Validation and Verification Methods

Describe the process to be used for validating and verifying data, including the chain of custody for data throughout the life cycle of the project or task. Discuss how issues shall be resolved and the authorities for resolving such issues. Describe how the results are conveyed to data users. The review of data can include checks of the following: transmittal errors, field and laboratory QC data. detection limits, instrument calibration, special sampling or analysis conditions. performance evaluations, technical systems audits, contract compliance issues (e.g., holding times), and statistical data treatments, such as tests for identification of potential outliers.

D3 Reconciliation with Data Quality Objectives

Describe how the results obtained from the project or task will be reconciled with the results of the DQO Process. Describe how issues will be resolved. Discuss how limitations on the use of the data will be reported to decision

makers. Identify the procedures used to assess precision, bias, and completeness for the project data.

A methodology has been developed to assist users in reconciling data results with the DQOs. The Data Quality Assessment (DQA) Process[7] is used to assess the scientific and statistical quality of data collected for a specific purpose. In the DQA Process, the data will be analyzed scientifically to inspect for technical anomalies and to judge that the context of the data is correct. At the same time, the data will be evaluated statistically to confirm that the statistical model was correct by selecting a statistical test and validating the test by verifying assumptions, such as for distribution and independence. The outcome of the DQA process will indicate whether a decision can be made using the existing data or additional data must be collected.

APPENDIX A

TERMS AND DEFINITIONS

Activity - an all-inclusive term describing a specific set of operations or related tasks to be performed, either serially or in parallel (e.g., research and development, field sampling, analytical operations, equipment fabrication), that in total result in a product or service.

Assessment - the evaluation process used to measure the performance or effectiveness of a system and its elements. In this Standard, assessment is an all-inclusive term used to denote any of the following: audit, performance evaluation, management systems review, peer review, inspection or surveillance.

Audit - a planned and documented investigative evaluation of an item or process to determine the adequacy and effectiveness as well as compliance with established procedures, instructions, drawings, QAPPs, and other applicable documents.

Characteristic - any property or attribute of a datum, item, process, or service that is distinct, describable, and measurable.

Computer Program - a sequence of instructions suitable for processing by a computer. Processing may include the use of an assembler, a compiler, an interpreter, or a translator to prepare the program for execution. A computer program may be stored on magnetic media, and be referred to as "software," or may be stored permanently on computer chips, and be referred to as "firmware." Computer programs covered by this Standard are those used for design analysis, data acquisition, data reduction, data storage (data bases), operation or control, and data base or document control registers when used as the controlled source of quality information.

Contractor - any organization or individual that contracts to furnish services or items or perform work.

Corrective Action - measures taken to rectify conditions adverse to quality and, where necessary, to preclude their recurrence.

Customer - any individual or organization for whom items or services are furnished or work performed in response to defined requirements and expectations.

Data Quality Assessment (DQA) - a process of statistical and scientific evaluation that is used to assess the validity and performance of the data collection design and statistical test, and to establish whether a data set is adequate for its intended use.

Data Quality Objectives (DQOs) - a statement of the precise data, the manner in which such data may be combined, and the acceptable uncertainty in those data in order to resolve an environmental problem or condition. This may also include the

criteria or specifications needed to design a study that resolves the question or decision addressed by the **DQO process**.

Data Quality Objectives Process - a Total Quality Management (TQM) tool, based on the Scientific Method and developed by the U.S. Environmental Protection Agency to facilitate the planning of environmental data collection activities. The DQO process enables planners to focus their planning efforts by specifying the use of the data (the decision), the decision criteria (action level), and the decision maker's acceptable decision error rates. The products of the DQO process are the DQOs (See also **Graded Approach**).

Data Usability - the process of ensuring or determining whether the quality of the data produced meets the intended use of the data.

Design Review - a documented evaluation by a team, including personnel other than the original designers, the responsible designers, the customer for the work or product being designed, and a QA representative to determine if a proposed design will meet the established design criteria and perform as expected when implemented.

Engineered Environmental Systems - an all-inclusive term used to describe pollution control devices and systems, waste treatment processes and storage facilities, and site remediation technologies and their components that may be utilized to remove pollutants or contaminants from the environment. Examples include wet scrubbers (air), soil washing (soil), granulated activated carbon unit (water), and filtration (air, water). Usually, this term will apply to hardware-based systems; however. it will also apply to methods or techniques used for pollutant reduction or containment of contamination to prevent further movement of the contaminants, such as capping, solidification or vitrification, and biological treatment.

Environmental Conditions - the description of a physical medium (e.g., air, water. soil, sediment) or biological system expressed in terms of its physical, chemical, radiological, or biological characteristics.

Environmental Data - any measurements or information that describe environmental processes or conditions, or the performance of engineered environmental systems.

Environmental Data Operations - work performed to obtain, use, or report information pertaining to environmental processes and conditions.

Environmental Monitoring - the process of measuring or collecting environmental data.

Environmental Processes - manufactured or natural processes that produce discharges to or impact the ambient environment.

Environmental Programs - an all-inclusive term pertaining to any work or activities involving the environment, including but not limited to: characterization of environmental processes and conditions; environmental monitoring; environmental

research and development; the design, construction, and operation of engineered environmental systems; and laboratory operations on environmental samples.

Environmentally Related Measurements - the data collection activity or investigation involving the assessment of chemical, physical or biological factors in the environment which affect human health or the quality of life.

Financial Assistance - the process by which funds are provided by one organization (usually government) to another organization for the purpose of performing work or furnishing services or items. Financial assistance mechanisms include grants, cooperative agreements, and government interagency agreements.

Graded Approach - the process of basing the level of application of managerial controls applied to an item or work according to the intended use of results and the degree of confidence needed in the quality of the results. (See **Data Quality Objectives Process**).

Hazardous Waste - any waste materials that satisfies the definition of "hazardous waste" as given in 40 CFR Part 261, "Identification and Listing of Hazardous Waste".

Independent Assessment - an assessment performed by a qualified individual, group, or organization that is not a part of the organization directly performing and accountable for the work being assessed.

Inspection - examination or measurement of an item or activity to verify conformance to specific requirements.

Item - an all-inclusive term used in place of the following: appurtenance, facility, sample assembly, component, equipment, material, module, part, product, structure, subassembly, subsystem, system, unit, documented concepts, or data.

Management - those individuals directly responsible and accountable for planning, implementing, and assessing work.

Management System - a structured non-technical system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for conducting work and producing items and services.

Management System Review (MSR) - the qualitative assessment of a data collection operation and/or organization(s) to establish whether the prevailing quality management structure, policies, practices, and procedures are adequate for ensuring that the type and quality of data needed are obtained.

May - denotes permission but not a requirement.

Method - a body of procedures and techniques for performing an activity (e.g., sampling, chemical analysis, quantification) systematically presented in the order in which they are to be executed.

Mixed Waste - hazardous waste material, as defined by 40 CFR part 261 (RCRA), mixed with radioactive constituents.

Must - denotes a requirement that has to be met.

Peer Review - a documented critical review of work generally beyond the state of the art or characterized by the existence of potential uncertainty. The peer review is conducted by qualified individuals (or organization) who are independent of those who performed the work, but are collectively equivalent in technical expertise (i.e., peers) to those who performed the original work. The peer review is conducted to ensure that activities are technically adequate, competently performed, properly documented, and satisfy established technical and quality requirements. The peer review is an in-depth assessment of the assumptions, calculations, extrapolations, alternate interpretations, methodology, acceptance criteria, and conclusions pertaining to specific work and of the documentation that supports them. Peer reviews provide an evaluation of a subject where quantitative methods of analysis or measures of success are unavailable or undefined, such as in research and development.

Performance Evaluation (PE) - a type of audit in which the quantitative data generated in a measurement system are obtained independently and compared with routinely obtained data to evaluate the proficiency of an analyst or laboratory.

Procedure - a documented set of steps or actions that systematically specifies or describes how an activity is to be performed.

Process - an orderly system of actions that are intended to achieve a desired end or result. Examples of processes include analysis, design, data collection, operation, fabrication, and calculation.

QTRAK - is a **Computer Program** that contains database information on Quality Management Plans and Quality Assurance Project Plans to the Program Managers, Project Officers, and the OQA for planning and assessment of the status of regional Quality Management Plans and the associated Project Plans.

Qualified Data - any data that have been modified or adjusted as part of statistical or mathematical evaluation, data validation, or data verification operations.

Quality - the sum of features and properties/characteristics of a process, item, or service that bears on its ability to meet the stated needs and expectations of the user

Quality Assurance (QA) - an integrated system of management activities involving planning, implementation, assessment, reporting, and quality improvement to ensure that a process, item, or service is of the type and quality needed and expected by the customer.

Quality Assurance Management Staff (QAMS) - the U.S. EPA's headquarters staff element that establishes and promulgates Quality Assurance Policy.

Quality Assurance Officer (QAO) - the designated Region 6 staff member that has the delegated authority for approval of all Quality Management Plans in Region 6, Chief of the Office of Quality Assurance.

Quality Assurance Program Description/Plan -see **Quality Management Plan.**

Quality Assurance Project Plan (QAPP) - a formal 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 criteria.

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.

Quality Improvement - a management program for improving the quality of operations. Such management programs generally entail a formal mechanism for encouraging worker recommendations with timely management evaluation and feedback or implementation.

Quality Indicators - measurable attributes of the attainment of the necessary quality for a particular environmental decision. Indicators of quality include precision, bias, completeness, representativeness, reproducibility, comparability, and statistical confidence.

Quality Management - that aspect of the overall management system of the organization that determines and implements the quality policy. Quality management includes strategic planning, allocation of resources, and other systematic activities (e.g., planning, implementation, and assessment) pertaining to the quality system.

Quality Management Plan (QMP) - a formal document that describes the quality system in terms of the organizational structure, functional responsibilities of management and staff, lines of authority, and required interfaces for those planning, implementing, and assessing all activities conducted.

Quality System - a structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities accountability. and implementation plan of an organization for ensuring quality in its work processes. products (items), and services. The quality system provides the framework for planning, implementing, and assessing work performed by the organization and for carrying out required QA and QC.

Radioactive Waste - waste material containing radionuclides, or contaminated by radionuclides.

Readiness Review - a systematic, documented review of the readiness for the startup or continued use of a facility, process, or activity. Readiness reviews are

typically conducted before proceeding beyond project milestones and prior to initiation of a major phase of work.

Remediation - the process of reducing the concentration of a contaminant (or contaminants) in air, water, or soil media to a level that poses an acceptable risk to human health.

Research (Applied) - a process, the objective of which is to gain knowledge or understanding necessary for determining the means by which a recognized and specific need may be met.

Research (Basic) - a process, the objective of which is to gain knowledge or understanding of the fundamental aspect of phenomena and of observable facts without specific applications toward processes or products in mind.

Research Development/Demonstration - Systematic use of the knowledge and understanding gained from research and directed toward the production of useful materials, devices, systems, or methods, including prototypes and processes.

Self-Assessment - Assessments of work conducting by individuals, groups, or organizations directly responsible for overseeing and/or performing the work.

Service - the category of economic activity that does not produce manufactured items. In environmental data operations or engineering projects, such activities include design, inspection, laboratory and/or field analysis, repair, and installation.

Shall - denotes a requirement that is mandatory and has to be met.

Should - denotes a guideline or recommendation.

Significant Condition - any state, status, incident, or situation of an environmental process or condition of an engineered environmental system in which the work being performed will be adversely affected in a manner sufficiently serious to require corrective action to satisfy quality objectives or specifications and safety requirements.

Software Life Cycle - the period of time that starts when a software product is conceived and ends when the software product is no longer available for routine use. The software life cycle typically includes a requirements phase, a design phase, an implementation phase, a test phase, an installation and check-out phase, an operation and maintenance phase, and sometimes a retirement phase.

Standard Operating Procedure (SOP) - a written document that details the method for an operation, analysis, or action with thoroughly prescribed techniques and steps, and that is
Officially approved as the method for performing certain routine or repetitive tasks.

Supplier - any individual or organization furnishing items or services or performing work according to a procurement document or financial assistance agreement. This is

an all-inclusive term used in place of any of the following: vendor, seller, contractor, subcontractor, fabricator, or consultant.

Surveillance - the act of monitoring or observing a process or activity to verify conformance to specified requirements.

Technical Review - a documented critical review of work that has been performed within the state of the art. The review is accomplished by one or more qualified reviewers who are independent of those who performed the work, but are collectively equivalent in technical expertise to those who performed the original work. The reviews are an in-depth analysis and evaluation of documents, activities, material, data, or items that require technical verification or validation for applicability, correctness, adequacy, completeness, and assurance that established requirements are satisfied.

Technical Systems Audit (TSA) - a thorough, systematic, on-site qualitative audit of facilities, equipment, personnel, training procedures, record keeping, data validation, data management, and reporting aspects of a system.

Total Quality Management (TQM) - the process of applying quality management to all activities of the organization, including technical and administrative operations. See Quality Management and Quality System.

Validation - an activity that demonstrates or confirms that a process, item, data set, or service satisfies the requirements defined by the user.

Verification - the act of authenticating or formally asserting the truth that a process, item, data set, or service is, in fact, that which is claimed.

Work - the process of performing a defined task or activity (e.g., research and development, field sampling, analytical operations, equipment fabrication).