Integrating Quality Assurance into Project Development

Presented at:

Managing Environmental Quality Systems
Summer Training Conference - 2000

August 9-10, 2000
EPA Region 5, Metcalfe Federal Building
Chicago, IL

CHECKLIST FOR REVIEWING EPA QUALITY MANAGEMENT PLANS

Instructions: For each item below, note on an answer sheet (included) the page number(s) in the QMP where the item is located and any comments, including positive remarks.

General Information

- An approval page for the signatures (dated) of the senior accountable manager, senior line management[1] (as appropriate), and the QA manager of the organization. This approval page may be part of a title page or a separate sheet following the title page. It should contain a line for EPA QA authority approval.

(1) Management and Organization

1. A discussion of the general organizational structure.

2. A description of the organization's mission.

3. A statement of the organization's policy on quality assurance, including the general objectives/goals of the quality system.

4. A statement of the policy for resource allocation for the quality system, including personnel, extramural funding, and travel funding. Note: Although this is described generally in the QMP, but the actual resource levels should be reported in the QA Annual Report and Work Plan (QAARWP).

5. A current organization chart that identifies all of the components of the organization and, in particular, the organizational position and lines of reporting of the QA Manager that confirms and documents that the QA Manager is independent of groups generating, compiling, and evaluating environmental data.

6. A discussion of the responsibilities and authorities of the QA Manager and any other QA staff members.

7. A brief discussion of the technical activities or programs that are supported by the quality system and to which it applies; that is, **all** of the specific programs that require quality management controls; where oversight of delegated, contracted, or

[1]Senior line management may include Division Directors, Branch Chiefs, and other supervisory personnel as defined for a particular organization.

other extramural programs is needed to assure data quality; and where internal coordination of QA and QC among the group's organizational units needs to occur.

8. A discussion of the QA/QC roles and responsibilities of line management, technical staff, and any other staff, and how these roles and responsibilities are incorporated into performance standards.

9. A discussion of the organization's process for resolving disputes regarding quality system requirements, QA/QC procedures, assessments, or corrective actions.

10. A discussion of how management assures that applicable elements of the quality system are understood and implemented in all environmental programs.

(2) Quality System and Description

11. A discussion of the principal components (or "tools") comprising the quality system and how they are used to implement the quality system. These components include, but are not limited to QMPs, management assessments (self and independent), systematic planning processes, QA Project Plans, Standard Operating Procedures, technical assessments (self and independent), and Data Quality Assessments. Include a policy statement regarding how and when the components of the quality system are to be applied to individual projects and tasks.

(3) Personnel Qualifications and Training

12. A statement of the organization's policy regarding training in QA policy and procedures.

13. A description of the processes and the management and/or staff responsible for:

    A. identifying statutory, regulatory, or professional certifications that may be required to perform certain operations; and
    B. identifying, designing, performing, and documenting technical, quality, and project management training.

14. A description of how staff proficiency in critical technical disciplines is maintained and documented (and with what frequency).

(4) Extramural Agreements and Procurement of Items and Services

15. A description of the organization's process for ensuring that all appropriate extramural agreements, including grants, cooperative agreements, and contracted and subcontracted activities, involving or affecting environmental programs:

    A. contain appropriate QA/QC requirements in all applicable documents;
    B. receive the same review and approval for changes as for the original documents;
    C. address satisfactorily all QA/QC requirements in applicable responses to solicitations and include QA as an integral criterion in the evaluation criteria;
    D. provide objective evidence of quality (documentation) furnished by suppliers and subcontractors for applicable items and services, including source selection, source inspections, supplier audits, and examination of deliverables; and
    E. provide evidence of the suppliers capability to satisfy EPA QA/QC requirements as defined in the extramural agreement or applicable regulation (e.g., 40 CFR 30, 40 CFR 31,10 CFR 46, *Federal Acquisition Regulations [FAR]*).

16. A description of how procurement documents or financial assistance agreements require suppliers (i.e., contractors, subcontractors, or financial assistance recipients) to have a quality system consistent with EPA requirements. This requirement applies only to those suppliers who provide services or items that directly affect the quality of results or products from environmental programs.

    The description should include responsible person and process for assessing need for, preparing, reviewing and approving appropriate QA/QC requirements in all applicable procurement documents or final agreements and changes, including:

    Regional QMPs, which must also include a discussion of how QA/QC requirements are to be satisfied in State-EPA Agreements or Performance Partnership Agreements, when this happens (in relation to award of funds, beginning of work, etc.).

(5) Documents and Records

17. Description of the process, including the roles and responsibilities of management and staff members for:

    A. identifying quality-related documents and records requiring control;
    B. handling documents and records to assure their accessibility, protection

from damage and deterioration, and means of retention, including discussion of the roles and responsibilities for management and staff;

C. developing technical guidance documents which are prepared, reviewed, approved, issued, used, and revised;

D. filing all planning documents (e.g., QA Project Plans, Sampling and Analysis Plans) are prepared, reviewed, approved, issued, used, and revised; and

E. ensuring compliance with all statutory, contractual, and assistance agreement requirements for records from environmental programs and that provides adequate preservation of key records necessary to support the mission of the organization.

Documents and records, including revisions, must be reviewed for conformance with the quality system requirements and approved by authorized personnel before general use.

18. Description of or reference to the management process that ensures that records accurately reflect completed work and/or fulfill statutory and contractual requirements, including any specific record keeping requirements defined in EPA Order 2160 and EPA Directive 2100, Chapter 10. The maintenance of records includes defining requirements and responsibilities for record transmittal, distribution, retention, protection, preservation, traceability, disposition, and retrievability.

19. Description of how the disposition of records is accomplished, in accordance with regulatory requirements, schedules, or directives from senior management.

(6) Computer Hardware and Software

20. Description of the roles and responsibilities for:

A. addressing how applicable EPA requirements for information resources management are addressed (EPA Directive 2100), for example, Year 2000 compliance, security, and privacy requirements (Chapters 5, 8, and 11 of EPA Directive 2100, respectively);

B. ensuring the process for ensuring that computer hardware used in environmental programs meets technical requirements and quality expectations (i.e., configuration testing);

C. controlling changes to hardware to assess the impact of the change on performance;

D. developing computer software, for validating, verifying, and documenting

the software for its use, and for assuring that the software meets the requirements of the user (EPA Directive 2182);

E. evaluating how purchased software is evaluated to meet user requirements and to comply with applicable contractual requirements and standards; and

F. ensuring that data and information produced from or collected by computers meet applicable EPA information resources management requirements and standards (EPA Directive 2100).

The QMP must cover all computer hardware and software operations that directly impact the quality of the results of environmental programs. Computer programs include, but are not limited to, design, design analysis, data handling, data analysis, modeling of environmental processes and conditions, operations or process control, and data bases.

(7) Planning

21. A description of the review and approval process for QMPs submitted by external organizations as part of extramural agreements.

22. A description of the preparation, review, and internal approval process for the QAARWP.

23. Description of the process for the systematic, scientific method-based planning of environmental programs, including how general project planning is documented and who is involved with the following elements:

    A. identification and involvement of the project manager, sponsoring organization and responsible official, project personnel, stakeholders, scientific experts, etc. (e.g., all customers and suppliers);

    B. description of the project goal, objectives, and questions and issues to be addressed;

    C. identification of project schedule, resources (including budget), milestones, and any applicable requirements (e.g., regulatory requirements, contractual requirements);

    D. identification of the type of data needed and how the data will be used to support the project's objectives;

    E. determination of the quantity of data needed and specification of performance criteria for measuring quality;

    F. description of how, when, and where the data will be obtained (including existing data) and identification of any constraints on data collection;

    G. specification of needed QA/QC activities to assess the quality performance

criteria (e.g., QC samples for both the field and laboratory, audits, technical assessments, performance evaluations, etc.);

H. description of how the acquired data will be analyzed (either in the field or the laboratory), evaluated (i.e., QA review, validation, verification), and assessed against its intended use and the quality performance criteria.

24. Description of how the results of planning for environmental data operations are documented in a Quality Assurance Project Plan (QAPP) and approved by authorized personnel for implementation, including the process for developing, reviewing, approving, implementing, and revising a QAPP and identify the staff members who are authorized to approve QAPPs.

25. Description of how data obtained from sources outside EPA that did not use an EPA-approved QAPP (or equivalent planning document) for data collection are evaluated and qualified for use.

26. Description of the process for qualifying outside EPA source data, including the application of any statistical methods used.

(8) Implementation of Work Processes

27. Description of the process of how and by whom work is implemented within the organization for:

A. ensuring that work is performed as planned;

B. development and implementation of procedures for appropriate routine, standardized, special, or critical operations, including those that address, but are not limited to:
   - identification of operations needing procedures;
   - preparation of procedures, including form, content, and applicability; and
   - review and approval of procedures.

C. use of QA/QC "tools" such as standard operating procedures (SOPs).

28. Description of how appropriate measures for controlling the release, change, and use of planned procedures are implemented, including the necessary approvals, specific times and points for implementing changes, removal of obsolete documentation from work areas, and verification that the changes are made as prescribed.

(9) Assessment and Response

29. Description of how and by whom assessments of environmental programs are planned, conducted, and evaluated, and which tools are chosen, and the expected frequency of their application to environmental programs. Available assessment tools include audits, data quality assessments, management systems reviews, peer reviews and technical reviews, performance evaluations, readiness reviews, technical systems audits, and surveillance. Senior management shall assess (at least annually) the adequacy of the quality system.

30. Description of the following items pertaining to management and technical assessments:

    A. how the process for the planning, scheduling, and implementation of assessments works, as well as how the organization shall respond to needed changes;
    B. responsibilities, levels of participation, and authorities for all management and staff participating in the assessment process; and
    C. how, when, and by whom actions shall be taken in response to the findings of the assessment, and how the effectiveness of the response shall be determined.

31. Description of how the level of competence, experience, and training necessary to ensure the capability of personnel conducting assessments are determined. Management is responsible for choosing the assessors, defining acceptance criteria, approving audit procedures and check lists, and identifying goals prior to initiation of an assessment. Assessors shall be technically knowledgeable and they must have no direct involvement or responsibility for the work being assessed, except for self-assessments.

32. Description of how personnel conducting assessments have sufficient authority, access to programs and managers, access to documents and records, and organizational freedom to:

    A. identify quality problems;
    B. identify and cite noteworthy practices that may be shared with others to improve the quality of their operations and products;
    C. propose recommendations for resolving quality problems; and
    D. independently confirm implementation and effectiveness of solutions.

33. Description of conditions under which a "stop work" order may be needed and when and how authority for such decisions is made.

34. Description of how assessment results are documented, reported to, and reviewed by management, and how management responds to the results (or findings) and recommendations from assessments in a timely manner, indicating how follow-up action shall be taken and documented to confirm the implementation and effectiveness of the response action. Include a description of how disputes, if encountered, as a result of assessments are addressed and by whom.

(10) Quality Improvement

35. Description of how the organization shall detect, correct, and prevent quality problems, including a process for ensuring continual quality improvement, including the management process for determining, planning, implementing, and evaluating the effectiveness of quality improvement activities; who (organizationally) is responsible for quality improvement; and the corrective action program to ensure that conditions adverse to quality are identified promptly and corrected as soon as practical.

36. Description of how staff at all levels are encouraged to identify and establish communications among customers and suppliers, identify process improvement opportunities, identify problems, and offer solutions to those problems.

(11) Other Review Criteria

37. Check for accuracy of regulatory or other citations (both correctness and most recent version).

38. Check for inconsistencies in the text.

39. Check for clarity of writing to ensure users will understand the QMP.

40. Check for mistakes like misidentification of organizational units (especially given the recent reorganizations) and inconsistency with Agency QA policy.

41. Check the QAD file for resolution of past MSR findings, QAARWPs for activities indicating support for policy, and any changes submitted with QAARWPs and past QMPs to highlight potential areas of difficulty with implementing the quality system.

42. Check other EPA QMPs, (or with QA managers) for verification that the responsibility for tasks proposed for other organizations not covered solely by this

QMP are documented elsewhere.

HANDOUT #7

Answer Form

Checklist Number	QMP Page	Comments, both positive and negative
(1) 1.		
(1) 2.		
(1) 3.		
(1) 4.		
(1) 5.		
(1) 6.		
(1) 7.		
(1) 8.		
(1) 9.		
(1) 10.		
(2) 11.		
(3) 12.		
(3) 13. A.		
(3) 13. B.		
(3) 14.		
(4) 15. A.		
(4) 15. B.		
(4) 15. C.		
(4) 15. D.		
(4) 15. E.		
(4) 16.		
(5) 17. A.		
(5) 17. B.		

(5) 17. C.		
(5) 17. D.		
(5) 17. E.		
(5) 18.		
(5) 19.		
(6) 20. A.		
(6) 20. B.		
(6) 20. C.		
(6) 20. D.		
(6) 20. E.		
(6) 20. F.		
(7) 21.		
(7) 22.		
(7) 23. A.		
(7) 23. B.		
(7) 23. C.		
(7) 23. D.		
(7) 23. E.		
(7) 23. F.		
(7) 23. G.		
(7) 23. H.		
(7) 24.		
(7) 25.		
(7) 26.		
(8) 27. A.		

(8) 27. B.		
(8) 27. C.		
(8) 28.		
(9) 29.		
(9) 30. A.		
(9) 30. B.		
(9) 30. C.		
(9) 31.		
(9) 32. A.		
(9) 32. B.		
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(9) 32. D.		
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(11) 43.		

"Independence"

INTRODUCTION TO QUALITY MANAGEMENT PLANS

Reuse w/ Ref. to
- D. Stds
- OTOP (for hardware "stds")
-

AUGUST 7, 2000
CHICAGO, IL
INSTRUCTORS: Diann Sims
Patricia Lafornara
Quality Staff
Washington, D.C.

Q.S. response to an IG Audit was to develop a "check list"

QUALITY MANAGEMENT PLAN OVERVIEW

Course Goals

At the conclusion of this training, you will be able to:

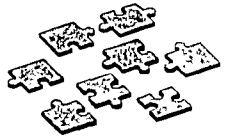
- Explain the basic considerations for Quality System design
- Explain what a Quality Management Plan (QMP) is and why it is required
- List the requirements for a QMP and what must be included in each

Why Are You Here?

- Any organization conducting environmental programs by or on behalf of EPA must have a documented quality system
- The QMP documents that quality system

➡ You help develop a QMP.

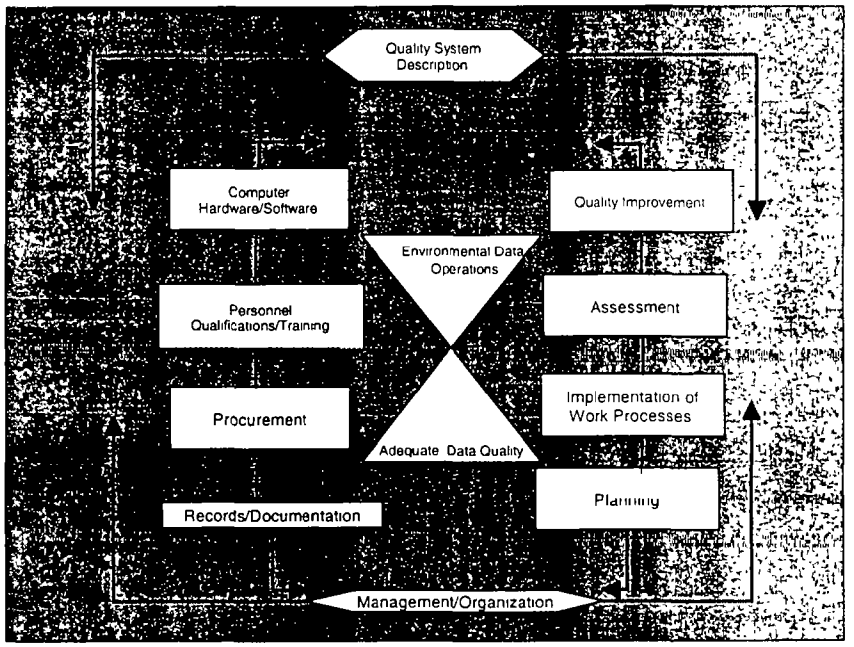
How is an organization vulnerable if inadequate data are collected?



What Is A Quality System?

A framework of management and technical practices that assure that environmental data used to support decisions are:

- Of adequate quality and usability for their intended purpose
- Defensible



Common Steps in Quality System Design

- Prepare an overview of the current organization and its environmental data operations
- Identify existing Quality System components or tools
- Document existing procedures as appropriate
- Develop procedures where necessary
- Document the Quality System design

System Overview

Org	Data Use	Technical Activities	Responsibility	Quality System Tools Used	Notes

Questions to Ask

- How does your organization use data (data generator, decision maker, regulatory)?
- What is the scope of technical activities within your organization (monitoring, regulatory actions, inspections, characterizations, program oversight)?
- Who is responsible for planning, implementing, and assessing these technical activities?
- What tools are already in use or are mandated (QAPPs, SOPs, TSAs)? Tech. Sys. Audit/Assess. on implementation

Graded Approach

QA and QC requirements commensurate with:

- Importance of work
- Available resources
- Unique needs of organization
- Consequences of potential decision errors

Tips for Design and Implementation

- Don't delegate responsibility for success of the Quality System too low in organization
- In larger organizations, avoid communicating QMP requirements to everyone all at once
- Use value added assessments rather than rigid audits
- Build success measures into the system so that you will know when it is working well

QMP Requirements Overview

QMP Requirement

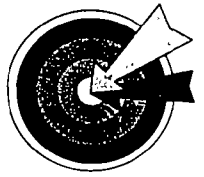
All work performed by EPA organizations and by external organizations funded by EPA that involves acquisition of environmental data generated from direct measurement activities, collected from other sources, or compiled from computerized data bases and information systems shall be covered by an Agency-approved QMP.

Internal and External Requirements

- Internal: EPA Order 5360.~~1 CHG 1~~ 2A (July 1998) (FMFIA can be a hammer to create QMP)
- External: States / Locals / grants
  - 48 CFR Part 46 (contracts)
  - 40 CFR Part 30, 31, and 35 (assistance agreements)
  - Other (e.g., consent agreements in enforcement actions)

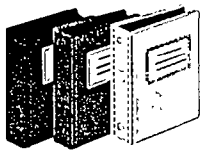
QMP Purpose

- The QMP documents what you are going to do, how you are going to do it, and how you know you did it.



Important Terms

- Quality Management
- Quality Assurance
- Quality Control



Scope of QMP

- Must reflect or emphasize actual practices, not planned practices
- Should use the graded approach
- Should be constructed and written so its effectiveness can be assessed

Revision

- QMP must be kept accurate and up-to-date in accordance with changes in QA policy and procedures
- Notify all appropriate personnel about changes to quality system and QMP

Revision (Cont'd)

- Internal: Submit revisions made during year to the Quality Staff with QA Annual Report and Work Plan.
- External: Submit revisions to the designated EPA official as a report when they occur. If changes are significant, submit entire QMP.

General Requirements

10 QMP Requirements

1. Management and Organization
2. Quality System Components
3. Personnel Qualifications and Training
4. Procurement of Items and Services
5. Documents and Records

10 QMP Requirements (Cont'd)

6. **Computer Hardware and Software**
7. **Planning**
8. **Implementation of Work Processes**
9. **Assessment and Response**
10. **Quality Improvement**

Approval Page

- Approval page signatures
  - Management
  - QA Manager of organization
  - Quality Staff Director (internal)
  - Senior EPA Official for Quality (internal)
  - Responsible EPA official (external)
- May be either part of title page or separate sheet following title page

If Not Applicable

If element is not applicable to an organization's quality system, a statement about why it is not must be included in QMP

Management and Organization

Overview: Management and Organization

A description of:

- QA Policy
- Organizational structure
- Staff roles, responsibilities, and authorities
- Technical activities
- Dispute resolution
- Quality System implementation

QA Policy

A statement of the organization's policy on quality assurance, including:

- Importance of QA and QC to organization and why
- General objectives/goals of Quality System
- Policy for resource allocation for the Quality System

Organization Chart

- An organization chart must:
  - Identify all components of the organization
  - Identify the position and lines of reporting for QA Manager and any QA staff
  - Show independence of the QA Manager from groups generating, compiling, and evaluating environmental data

Already req EPA Order 5360.1A

Responsibilities and Authorities

Discuss the responsibilities and authorities of:

- QA Manager
- Any other QA staff

Technical Activities

- Discuss the technical activities or programs supported by the quality system
  - Specific programs that require quality management controls
  - Where oversight of extramural programs is needed to assure data quality
  - Where internal coordination of QA and QC activities needs to occur

Process for Resolving Disputes - Internal Only

Discuss the organization's process for resolving disputes regarding:

- Quality system requirements applicability
- QA and QC procedures application
- Assessments
- Corrective actions

Quality System Implementation

Discuss how management will ensure that applicable elements of the Quality System are understood and implemented in all environmental programs

Quality System Components

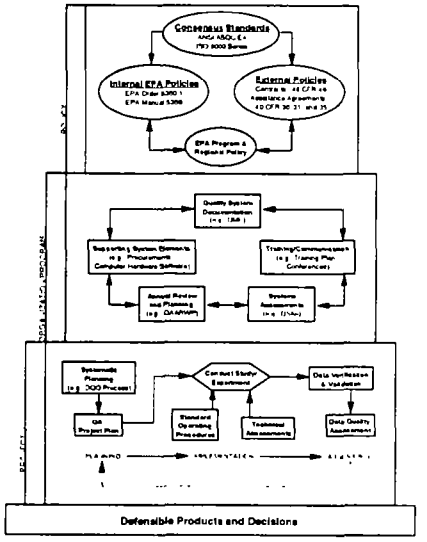
Overview: Quality System Components

1. Discuss principal components of Quality System and tools used to manage the system
   - What components comprise Quality System
   - What tools are used to manage Quality System
   - Who uses them and how

Quality System Components (Cont'd)

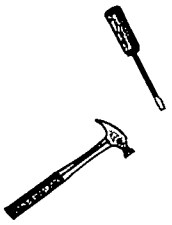
2. List parts of the organization that are required to prepare QMPs

3. Discuss the review and approval process for QMPs from external organizations



Quality System "Tools"

- QMPs
- Management Assessments - Self and Independent
- Technical Assessments
- Systematic Planning
- Standard Operating Procedures (SOPs)
- Quality Assurance Project Plans (QAPPs)
- Data Quality Assessments



Personnel Qualifications and Training

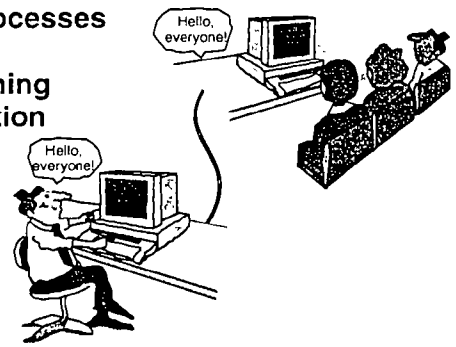
Overview: Personnel Qualification and Training

Describe organization's process for:

- Establishing training requirements
- Identifying training needs
- Assigning training priorities
- Meeting training needs

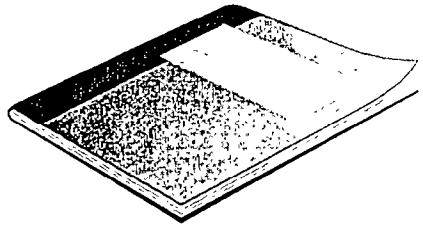
Three Areas to Cover

1. Training policy
2. Training processes
3. Critical training documentation



Policy

State the policy regarding training for management and staff

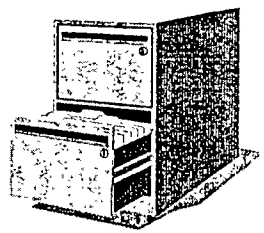


Processes

- Describe processes and management/staff responsible for:
  - Identifying statutory, regulatory, or professional certifications required
  - Identifying, designing, performing, and documenting training
    - Technical
    - Quality
    - Project management

Documenting Training

Describe how staff proficiency in critical technical disciplines is maintained and documented



Procurement of Items and Services

Overview: Procurement of Items and Services

- Describe organization's process for ensuring that suppliers provide items and services that:
  - Are of known and documented quality
  - Meet the technical requirements

Four Areas to Cover

1. Review and approval of procurement documents
2. Review and approval of QA responses to solicitations
3. Objective evidence of adequate quality from suppliers
4. QA document review and approval

Review and Approval of Procurement Documents

- Describe process and responsibilities for ensuring that documentation clearly states:
  - Item or service required
  - Technical and quality requirements
  - Quality System elements that the supplier is responsible for
  - How supplier's conformance to requirements will be verified

Review and Approval of QA Responses to Solicitations

- Describe roles, responsibilities, and process for review and approval of responses to solicitations to ensure:
  - That all technical and quality requirements are satisfied
  - That there is adequate evidence of supplier's capability to satisfy EPA Quality System requirements

Quality From Suppliers

- Describe process for determining adequate quality from suppliers, including:
  - How procurement sources are evaluated and selected
  - How and when source inspections are used
  - How deliverables are examined for conformance to specifications

QA Document Review and Approval

- Describe roles, responsibilities, processes and policies for:
  - Review and approval of mandatory quality related documentation
  - Delegation of review and approval of mandatory quality-related documentation
  - Ensuring that EPA quality-related contracting policies are satisfied

Documents and Records

Overview: Documents and Records

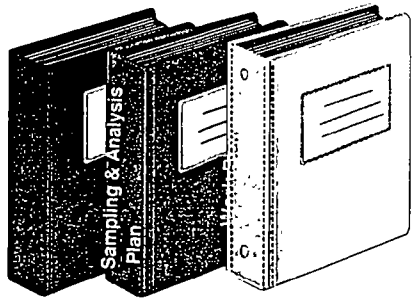
Discuss procedures for documents and records:

- Timely preparation
- Review
- Approval
- Issuance
- Use
- Control
- Revision
- Maintenance

Document

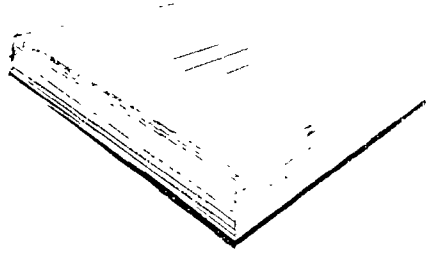
Any compilation of information that:

- Describes
- Defines
- Specifies
- Reports
- Certifies



Record

A completed document that provides objective evidence of an item or process



Identify Documents and Records

Describe or reference process for identifying quality-related documents and records requiring version and release control

QA-Related Documents and Records

Describe or reference process by which all QA-related documents and records are:

- Accessible
- Protected from damage and deterioration
- Subject to retention requirements
- Prepared, reviewed, and approved
- Issued and revised

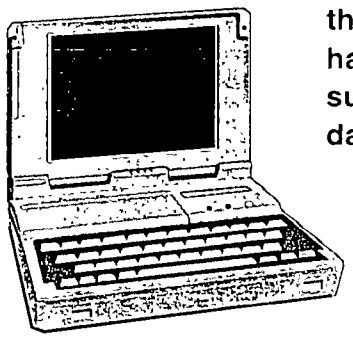
Compliance

Describe or reference process for ensuring compliance with all statutory, contractual, and assistance agreement requirements for records from environmental programs

EPA Directive 2100 chap 10] a Requirement for Record Retention

Computer Hardware and Software

Overview: Computer Hardware and Software



The QMP must describe QA and QC processes for the use of computer hardware and software to support environmental data operations

General Requirements

- Computer hardware must be appropriate for its intended application
- Computer programs must be developed using an approved software development methodology

Examples of Hardware Covered

- Data acquisition/logging systems
- Computers used with analytical instruments
- Automated sampling systems in which system failure would adversely affect quality and potential usability of collected data for decisions

Examples of Software Covered

- Programs
- Models
- Data bases
- Data analysis systems

Hardware QA and QC Processes

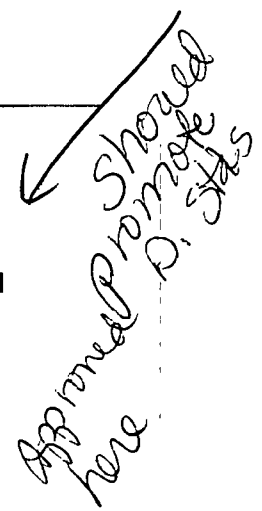
- Describe or reference process for ensuring that computer hardware used in environmental programs meets technical requirements and quality expectations
- Describe or reference how changes to hardware will be controlled to assess impact of change on performance

Software Development QA and QC Processes

- Describe or reference process for:
  - Developing computer software
  - Validating, verifying, and documenting software for its use
  - Assuring that software meets requirements of user

IRM Policies

- Describe or reference process for ensuring:
  1. That data and information produced and collected by computers meet applicable information resource management requirements and standards



IRM Policies (Cont'd)

2. That applicable EPA requirements for information resources management are addressed, including:
   - Year 2000 compliance (Chapter 5)
   - Security (Chapter 8)
   - Privacy requirements (Chapter 11)

Planning

Overview: Planning

- Description of process for planning environmental programs
- Discussion of QAPP process
- Discussion of organization's secondary data policy

Systematic Planning

- Use systematic planning process based on scientific method
- Apply the principle of graded approach and common sense

Systematic Planning Requirements

- Describe process used for general project planning, including:
  - How it is accomplished
  - How planning will be documented
  - Who uses planning "tools"
  - Roles and responsibilities of management and staff

Quality Assurance Project Plans (QAPPs)

Describe process for:

- Developing
- Reviewing
- Approving
- Implementing
- Revising

the QAPP

Secondary Data

- Discuss process for evaluating and qualifying secondary data
- Describe application of any statistical methods used

Implementation of Work Processes

Overview: Implementation of Work Processes

- Describe process for implementing work within organization
  - Procedures for ensuring work is performed according to plan
  - Procedures for routine, standardized, special, or critical operations
  - Procedures for controlling and documenting the release, change, and use of planned procedures

Developing and Implementing Procedures

- Describe process for:
  - Ensuring that work is performed according to plan
  - Developing and implementing procedures for appropriate routine, standardized or special operations, including:
    - Identifying operations needing procedures
    - Preparation of procedures
  - Reviewing and approving procedures

Planned Procedures

- Describe measures for controlling planned work processes or procedures:
  - Their release
  - Their change
  - Their use

Controlling Measures

- Measures should provide for:
  - Necessary approvals
  - Specific times and points for implementing changes
  - Removal of obsolete documentation from work area
  - Verification that changes are made as prescribed

Assessment and Response

Overview: Assessment and Response

- Describe:
  - How and by whom assessments of environmental programs are planned, conducted, and evaluated
  - Process by which management determines:
    - Assessment activities and tools appropriate for a particular project
    - Expected frequency of use

SIC/NAICS

Examples of Assessment Tools

- Management systems reviews
- Surveillance
- Technical systems audits
- Performance evaluations
- Audits of data quality
- Peer reviews and technical reviews
- Readiness reviews
- Data quality assessments

Two General Types of Assessment

1. **Management**
2. **Technical**

Assessment Activities

- Describe process:
  - For planning, conducting, and evaluating assessments
  - By which management chooses the appropriate assessment for a particular project

Assessment Activities (Cont'd)

- Describe:
  - How frequency of assessments is determined
  - Process for reporting and responding to results
  - Responsibilities, levels of participation, and authorities for all management and staff participating in assessment process

Assessor Qualifications

- Assessor qualifications
  - Technically knowledgeable
  - No real or perceived conflict of interest

Assessor Authority

- Describe how personnel conducting assessments will have:
  - Sufficient authority
  - Access to programs and managers
  - Access to documents and records
  - Organizational freedom

Assessment Results

- Describe process for review of assessment results
- Include:
  - Documentation of results
  - Reports to management
  - Management review procedures

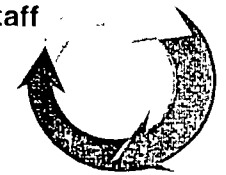
Response Actions

- Describe process for responding to findings:
  - How corrective actions will be taken
  - When they will be taken
  - By whom they will be taken
- Describe how effectiveness of response will be determined and documented

Quality Improvement

Overview: Quality Improvement

- Describe:
  - How organization will detect and prevent quality problems and ensure continual quality improvement
  - Communication of expectations about quality improvement to staff



Quality Problems

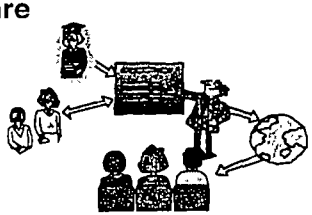
- Often inherent in existing management and technical systems
- Workers by themselves have little control over eliminating these problems or improving performance
- Action is required from management to commit to quality improvement

Quality Improvement Activities

- Describe management process and responsibilities for:
  - Identifying, planning, implementing, and evaluating quality improvement activities
  - Ensuring that conditions adverse to quality are identified promptly and corrected

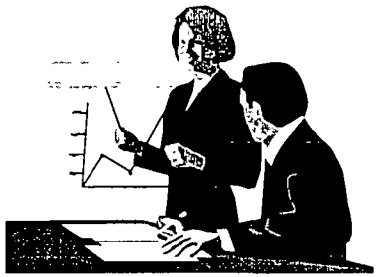
Communicating Quality Improvement

- Describe how expectations for quality improvement are communicated



Implementing Quality Improvement

- Identify process improvement opportunities
- Identify problems
- Offer solutions to problems



Now You Can ...

- ✓ Explain what a Quality Management Plan (QMP) is and why it is required
- ✓ State the benefit of the QMP
- ✓ Describe the process and responsibilities for developing QMP within your program

Now You Can Also ...

- ✓ List 10 requirements for the QMP
- ✓ Describe what must be included in each requirement

Remember

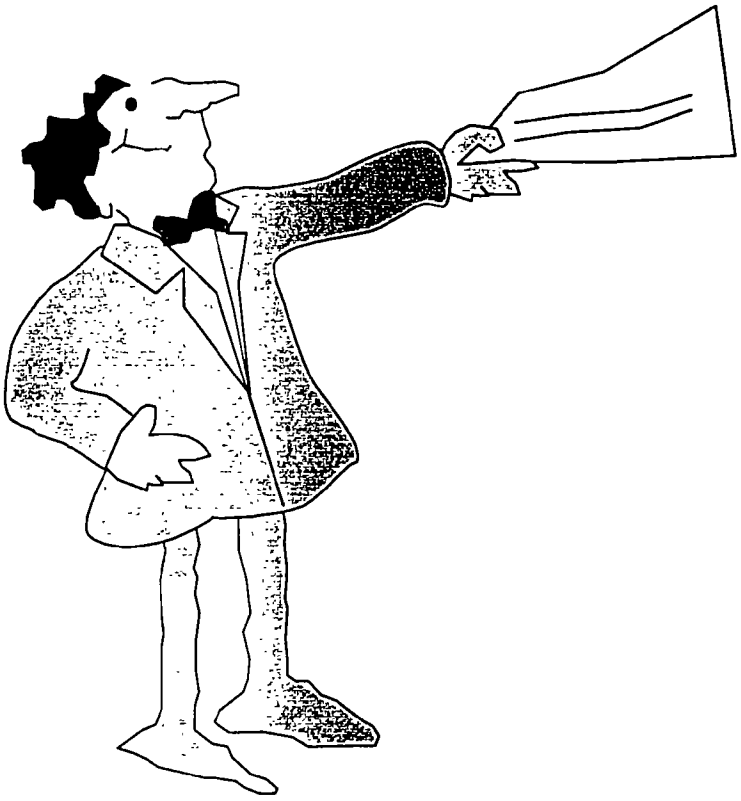
Use

the

graded

approach!

HANDOUTS



.earning is not compulsory but neither is survival.

W. Edwards Deming ~

HANDOUT #1 - DEFINITIONS

1. **Assessment** - The evaluation process used to measure the performance or effectiveness of a system and its elements. As used here, assessment is an all-inclusive term used to denote any of the following: audit, performance evaluation, management review, peer review, inspection, or surveillance.

2. **Environmental data** - Any measurements or information that describe environmental processes, location, or conditions; ecological or health effects and consequences; or the performance of environmental technology. For EPA, environmental data include information collected directly from measurements, produced from models, and compiled from other sources such as data bases or the literature.

3. **Environmental data operations** - Work performed to obtain, use, or report information pertaining to environmental processes and conditions.

4. **Environmental programs** - 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 environmental technologies; and laboratory operations on environmental samples.

5. **Environmental technology** - 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 or prevent them from entering the environment. Examples include wet scrubbers (air), soil washing (soil), granulated activated carbon unit (water), and filtration (air, water). Usually, this term applies to hardware-based systems; however, it also applies to methods or techniques used for pollution prevention, pollutant reduction, or containment of contamination to prevent further movement of the contaminants, such as capping, solidification or vitrification, and biological treatment.

6. **Extramural agreement** - A legal agreement between EPA and an organization outside EPA for items or services to be provided. Such agreements include contracts, work assignments, delivery orders, task orders, cooperative agreements, research grants, state and local grants, and EPA-funded interagency agreements.

7. **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.

8. **Management systems review (MSR)** - The qualitative assessment of a data collection operation and/or organization 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.

HANDOUT #2

SAMPLE QUALITY POLICY STATEMENTS

Spectra-Physics Scanning Systems

We the employees of Spectra-Physics Scanning Systems make the personal commitment to, first, understand our customers' expectations, then, to meet or exceed our commitment to those expectations by performing the correct tasks defect free, on time, every time.

Richardson Electronics Ltd.

It is the policy of Richardson Electronics Ltd. (REL) to:

1. Provide products and services of the highest possible standards to satisfy our customer needs, expectations of quality, safety, reliability and service.
2. Accomplish quality objectives by establishing, implementing, and maintaining a documented effective Quality Assurance System which complies with the requirements of ISO 9002.

Lancaster Laboratory

We strive to provide the highest quality data achievable by:

- Describing clearly and accurately all activities performed; documenting "real time" as the task is carried out; understanding that it is never acceptable to "back date" data entries and should additional information be required at a later date, the actual date and by whom the notation is made must be documented.

- Providing accountability and traceability for each sample analyzed through proper sample handling, labeling, preparation, instrument calibration/qualification, analysis, and reporting; establishing an audit trail that identifies date, time, analyst, instrument used, instrument conditions, quality control samples (where appropriate and/or required by the method), and associated standard material.

- Emphasizing a total quality management process which provides accuracy, and strict compliance with agency regulations and client requirements, giving the highest degree of confidence; understanding that meeting the requirements of the next employee in the work flow process is just as important as meeting the needs of external clients.

HANDOUT #3 - DISPUTE RESOLUTION

Oversight responsibilities for QA/QC may sometimes result in disagreements between the oversight group and the program reviewed regarding the results of the activity. Such disputes may occur in situations involving technical issues (e.g., audits, surveillance, data quality assessments) and management issues (e.g., QMP reviews, management systems reviews). This section discusses the process for resolving such disputes.

Technical Disputes

For those situations in which technical issues regarding QA/QC are in dispute, resolution should be sought at the lowest management level practicable. All parties should make every effort to resolve disputes through discussion and negotiation. If unsuccessful, final resolution should be made by the senior manager for the organization.

It is recommended that an organization's QMP include a process for dispute resolution within that organization. While the process described below may be used for technical disputes, an organization may develop a process that meets its particular needs.

Management Systems Disputes

Implementation of the Agency-wide Quality System may create disagreements arising from the results of the review and approval of Quality Management Plans (QMPs) and from the performance of management assessments using Management Systems Reviews (MSRs). The dispute resolution process should only be used when parties cannot achieve mutual resolution of their disagreement at the lowest possible administrative level. The dispute resolution process is terminated at any point where resolution is achieved and the issue resolved.

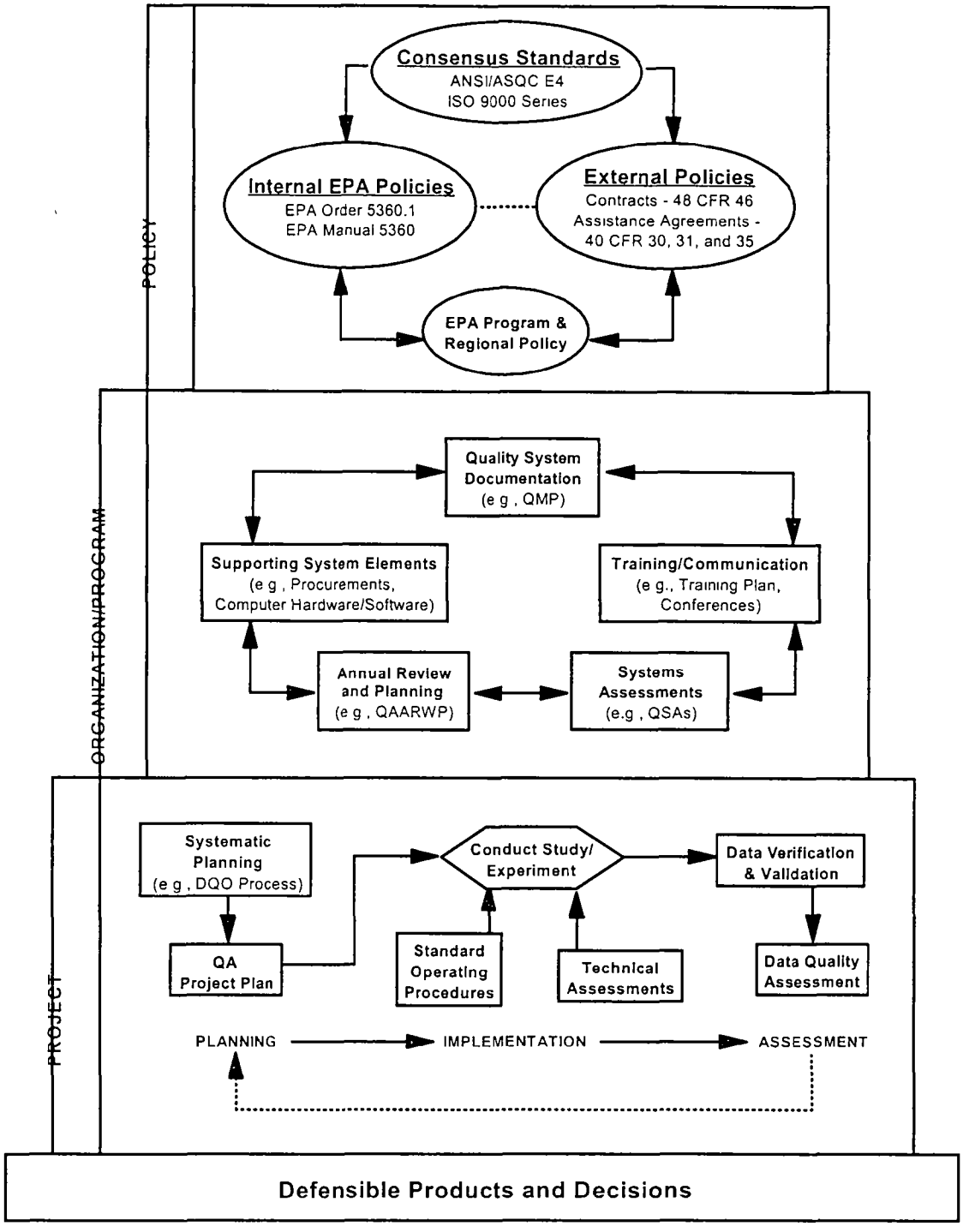
Disagreements should be resolved at the lowest administrative level possible. The dispute resolution process has the following steps:

1. The process begins when either disagreeing party declares an issue to be unresolvable and sends a memorandum to the other party invoking this dispute resolution process, defining the disputed issue, and presenting supporting arguments for the first party's position on the issue.

2. Within 30 days, the second party must send a draft dispute resolution package to the first party. As soon as possible after this, the two parties, working together, must submit a dispute resolution package to the dispute resolution official. This package would contain both parties' arguments, both parties' rebuttals, and any supporting materials.

3. The dispute resolution official shall schedule a meeting for resolving the dispute within 30 to 60 days from receipt of the dispute resolution package and for notifying both parties of this date. Both parties are invited to attend the resolution meeting to present arguments and answer questions. The dispute resolution official may get advice from third parties. The decision of the dispute resolution official shall be binding on both parties.

HANDOUT #4 - EPA QUALITY SYSTEM



HANDOUT #5 - REFERENCES

Requirements and Guidance Documents

1. Chapter 3, EPA Order 5360, EPA Quality Manual for Environment Programs, 1998 (Internal)

2. EPA QA/R-2, EPA Guidance for Quality Management Plans for Environmental Data Operations (External)

3. EPA QA/G-2, EPA Guidance for Quality Management Plans

Web Page Information Resources

1. QAD: http://es.epa.gov/ncerqa/qa/

2. IRM Policy Manual: http://www.epa.gov/irmpoli8/polman

HANDOUT #6

ELEMENTS OF SYSTEMATIC PLANNING

- Identification and involvement of the project manager, sponsoring organization and responsible official, project personnel, stakeholders, scientific experts, etc. (e.g., all customers and suppliers);
- Description of the project goal, objectives, and questions and issues to be addressed;
- Identification of project schedule, resources (including budget), milestones, and any applicable requirements (e.g., regulatory requirements, contractual requirements);
- Identification of the type of data needed and how the data will be used to support the project's objectives;
- Determination of the quantity of data needed and specification of performance criteria for measuring quality;
- Description of how, when, and where the data will be obtained (including existing data) and identification of any constraints on data collection;
- Specification of needed QA/QC activities to assess the quality performance criteria (e.g., QC samples for both the field and laboratory, audits, technical assessments, performance evaluations, etc.);
- Description of how the acquired data will be analyzed (either in the field or the laboratory), evaluated (i.e., QA review, validation, verification), and assessed against its intended use and the quality performance criteria.

Overview of EPA Quality System Requirements

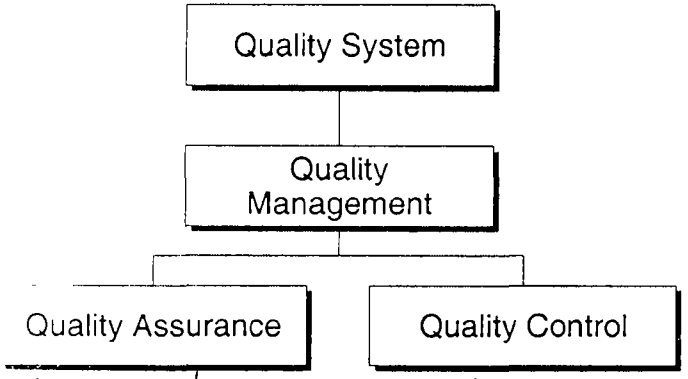
Course Goals

At the completion of this course, you will:

- Understand EPA's quality system requirements
- Understand the roles and responsibilities in implementing a quality system that meets EPA requirements
- Be familiar with the basic tools of the EPA Quality System

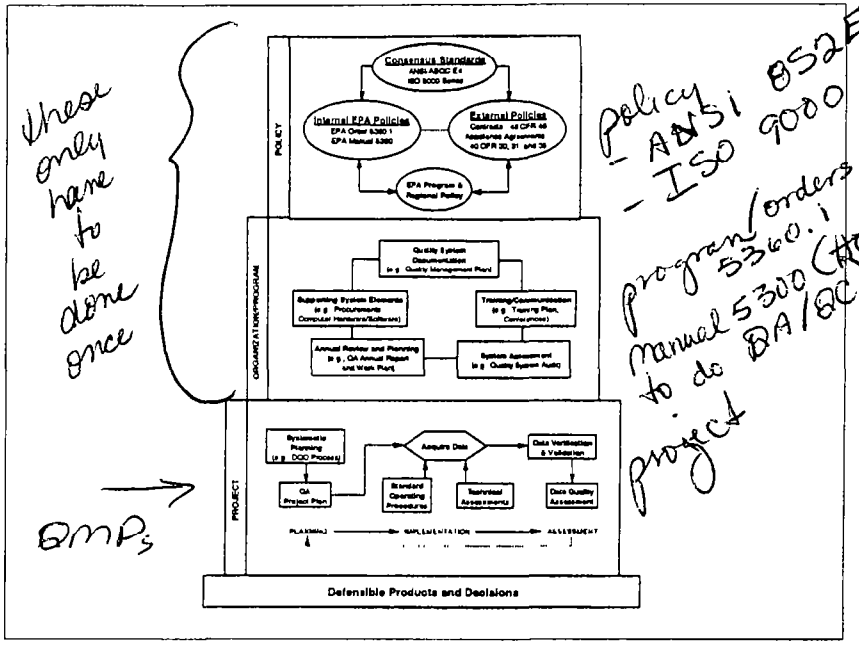
What is a Quality System?

a management sys. for Q.



management + oversight

hands-on methodology control the science



policy
- ANSI E4
- ISO 9000

program/orders
5360.1
Manual 5300 (How to do QA/QC)
project

Goal - to get data needed for making correct decisions

the general 'good data' is a myth.

QA is an insurance policy

EPA Quality System Requirements

EPA and non-EPA Organizations
- American National Standard, ANSI/ASQC E4

EPA Organizations
- EPA Order 5360.1 A2
- EPA Order 5360 A1 (Quality Manual)
- Contracts Management Manual (EPA Order 1900)

Non-EPA Organizations
- Federal Acquisition Regulations (for non-EPA Organizations

Just updated 2000 for also Just update

American National Consensus Standard

ANSI/ASQC E4, *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs*

- American National Consensus Standard provides the basis for planning, implementing, documenting, and assessing a quality system
- Includes non-mandatory guidelines for going beyond minimum requirements

Goals of the EPA Quality System

- Protect human health and the environment
- Make correct decisions
- Conserve/optimize resource use
- Ensure that environmental programs and decisions are supported by data of the type and quality needed for their intended use

Graded Approach

QA and QC requirements commensurate with:

- Importance of work
- Available resources
- Unique needs of organization
- Consequences of potential decision errors

EPA Order 5360.1 A2

- EPA Order 5360.1 A2, *Policy and Program Requirements for the Mandatory Agency-wide Quality System*, 2000
- Defines Quality System requirements for EPA organizations
- Requires participation by every EPA organization collecting and using environmental data for decision making
- Requires that the EPA Quality System comply with ANSI/ASQC E4-1994

EPA Order 5360 A1

- EPA Order 5360 A1, *EPA Quality Manual* (for 2000)
- Defines procedures for satisfying the internal EPA Quality System Requirements

also defines the "inherently gov. functions"

Internal EPA Quality System Requirements

EPA Organizations must:

- Assign a Quality Assurance Manager (QAM) independent of the data generation line of management
- Document the organization's quality system in a Quality Management Plan (QMP)
- Provide sufficient resources to implement the quality system
- Submit a QA Annual Report and Work Plan annually
- Assess its quality system annually

who does what (responsibility)

(who did what how many)

Beam counting not perf. measurement

Internal EPA Quality System Requirements - Continued

EPA Organizations must:

- Use of a systematic planning approach for work
- Approve QA Project Plans prior to start of work
- Ensure corrective actions from assessments are implemented
- Implement Quality System requirements in all EPA funded extramural agreements
- Assess "secondary data"
- Provide appropriate training for all management and staff

Quality System Requirements for Extramural Agreements

- EPA requirements for extramural agreements include:
  - Conformance to ANSI/ASQC E4-1994
  - Documentation of the organization's quality system (usually called a Quality Management Plan) which should be approved prior to initiating environmental work, and/or
  - Documentation of the application of quality assurance and quality control activities to activity-specific efforts (usually called a Quality Assurance Project Plan) which should be approved prior initiating environmental data collection.

EPA Acquisitions 48 CFR Part 46

- Proposal from offeror must include:
  - Quality Management Plan and/or
  - QA Project Plan and/or
  - Combination Quality Management Plan/QA Project Plan
- QA Project Plan is required for individual projects after award

Extramural Agreements

- Extramural Agreements include:
  - Acquisitions including: contracts, work assignments, task orders, technical directives
  - Financial assistance including:
    - Cooperative agreements
    - Grants to state and local governments
    - Research grants
    - Grants to non-profit organizations
  - Interagency agreements

Authorizing Regulations for Quality Requirements

- 48 CFR Part 46, "Federal Acquisition Regulations"
- 40 CFR Part 30, "Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations"
- 40 CFR Part 31, "Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments"
- 40 CFR Part 35, "State and Local Assistance"
- EPA ICR #0866, OMB #2080-033, "QA Specifications and Requirements

EPA Contracts Management Manual

- Requires QA Review Form for contracts, work assignments, delivery orders, and task orders.
- QA Review Form signed by EPA QA Manager or authorized representative.

Financial Assistance- Non-Profit Group 40 CFR Part 30

- Applications must include:
  - Quality Management Plan or
  - Combination Quality Management Plan and QA Project Plan
- QA Project Plan is required for individual projects after award

use graded approach / flexibility is up to the org. depends on size of proj. & its importance (Reg-related or not, etc.)

Financial Assistance- State and Local Governments 40 CFR Parts 31 and 35

- Pre-Award/Application
  - Quality Management Plan required
    - ✓ Must demonstrate suitability and effectiveness of Quality System to Award Official
    - ✓ Must demonstrate conformance to ANSI/ASQC E4
- Post-Award
  - QA Project Plans required for individual projects

Financial Assistance- Research Grants 40 CFR Part 30

- Applications must include:
  - Quality Management Plan or
  - Combination Quality Management Plan and QA Project Plan
- QA Project Plan is required for individual projects after award

Interagency Agreements

- EPA Quality System requirements cannot be unilaterally imposed (Office of General Counsel opinion)
- When EPA provides funding:
  - Add a special condition to invoke conformance with ANSI/ASQC E4
- When another Agency provides funding to EPA:
  - EPA Quality System requirements are applicable

But E4 is invoked by most other fed. Ag. we work with
- Interior
- DOD

Aids for Implementing the Quality System-Documentation

- For EPA, requirements are given in *EPA Quality Manual for Environmental Programs (EPA Order 5360 A1)*
- For holders of extramural agreements, requirements are given in *EPA Requirements Documents (QA/R-Series)* produced by the Quality Staff
- For everyone, non-mandatory guidelines are given in *EPA Guidance Documents (QA/G-Series)* produced by the Quality Staff
- Documents, regulations, and QA contacts are available at www.epa.gov/quality

Regional
Rep. — there's a lot of inconsistency btwn Plans from States
R2 = QMPs
R5 = QA proj plans (chap 5 of Q. manual)

(Region 6 — exercises absolute control — 'no qmp — no $')

G-Series = EPA guidance docs (recommendations)

Quality Management Tools

Quality Management Plans

Planning:	QA Project Plans Data Quality Objectives Process
Implementation:	QA Project Plans Standard Operating Procedures QA Annual Report and Work Plans
Assessment:	Management Assessments Technical Assessments Data Quality Assessment Data Validation and Verification

Quality Management Plans

Purpose:	To document how an organization will plan, implement, and assess its Quality System
Responsibility:	Senior Management
Documentation:	EPA Users: *Chapter 3, EPA Quality Manual for Environmental Programs* (EPA Order 5360 A1, May 2000) Extramural Users: *EPA Requirements for Quality Management Plans (QA/R-2)*

Good for 5 years, according to R2 unless major changes take place

Quality Management Plan General Requirements

The Quality Management Plan must discuss:

- Mission and quality policy of the organization
- Specific roles and responsibilities with respect to QA and QC activities
- Means and structure to assure effective communication
- Processes used to plan, implement and assess work and effectiveness for QA and QC activities
- Process for continual improvement of the Quality System

QMPs cover all routine requirements so these don't have to be addressed in QAPPs

QA Project Plans (QAPPs)

Purpose:	To document type and quality of data for environmental decisions; a blueprint for collecting and assessing data
Responsibility:	Organization performing activity
Documentation:	EPA Users: Chapter 5, EPA Quality Manual for Environmental Programs (EPA Order 5360 A1, May 2000) R5 Extramural Users: *EPA Requirements for Quality Assurance Project Plans (QA/R-5)* Everyone: *Guidance for Quality Assurance Project Plans (QA/G-5)*, February 1998

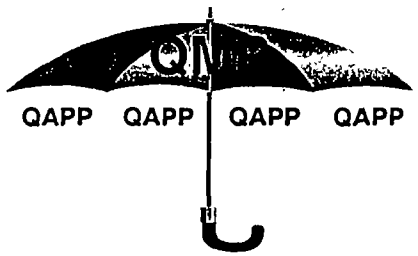
QA Project Plans (QAPPs)

- Required planning documents that explain how environmental data collection activities are planned, implemented, documented, and assessed during the life cycle of a specific program, project, or task
- QA Project Plans are required when environmental data operations occur for:
  - Contracts, work assignments, delivery orders
  - Grants, cooperative agreements
  - Interagency agreements (when negotiated)
  - State-EPA agreements
  - Responses to statutory or regulatory requirements and to consent agreements

Can be many single prog. smaller projects or add addendum to existing plan.

QMPs vs. QAPPs

- Quality Management Plans reflect activities and policies common to all projects.
- Quality Assurance Project Plans reflect specific projects.



Systematic Planning

- Planning is the key to successful programs
- EPA policy requires that all work be planned using a *Systematic Planning Process*
- Quality requirements should be based on a *Graded Approach*
- Effective planning must include all stakeholders (data users, data producers, decision makers) to ensure needs are defined at the outset
- Planning must be documented

Data Quality Objectives (DQO) Process

Purpose:	To define type and quality of data that a decision maker needs before carrying out data collection - Saves time and money - Doing it right the first time - Obtaining data sufficient for analysis
Responsibility:	Developed by project team of data users and data generators
Guidance:	Guidance for the DQO Process (QA/G-4), September 1994
Software:	DEFT Software for the DQO Process (QA/G-4D) September 1994

Common Elements in All Systematic Planning Approaches

- Questions to be answered:
  - Who is making the decision?
  - Why are data being collected?
  - What data are needed to make the decision?
  - Why does the decision maker need that type and quality of data?
  - How does the decision maker plan to use the data to make a defensible decision?
  - What are the "measures of success" for the project?
- Get only the type, quantity, and quality of data necessary

Ask - Who, what, when, where, why, + How?

Standard Operating Procedures (SOPs)

Purpose:	To document routine technical and administrative activities to ensure consistency in the quality of the product
Responsibility:	Appropriate technical personnel working with QA Manager
Documentation:	*Guidance for the Preparation of Standard Operating Procedures (QA/G-6)*, November 1995

Cook Bk -

Standard Operating Procedures (SOPs)

- Written documents that give precise descriptions of routine procedures
- Detail stepwise process for sample collection operations, laboratory analyses, or equipment use
- Ensure consistency and conformance with organizational practices
- Serve as training aids on methods and instrument use
- Provide ready reference and documentation of proper procedures

Quality Assurance Annual Report and Work Plans (QAARWPs)

Purpose:	To summarize the results of the implementation of an EPA organization's quality system in the previous fiscal year and to describe QA activities planned for the upcoming year
Responsibility:	Senior Management
Documentation:	EPA *Quality Manual for Environmental Programs* (EPA Order 5360 A1)

SOPs - so work can be duplicated later, or continued if someone else steps in

(Gary) QMP - QS looks for National/trends/issues

Biggest Issue: (abuse does occur)

Trend - Misplacement of QA mang. - mostly they report to RS+T manager but the "order" req. that these report to the Senior manager - to avoid conflict

Independence mandated by Order 5360 A1

(2) another Issue - Training Needs - QS resources are thin

(3) Inconsistency * QS is trying to address through Audits. One idea - pull procurement auth for grants - if QA not implemented acc. to docs.

(4) unbalance of Resources toward Superfund & not other programs

Quality Assurance Annual Report and Work Plans (QAARWPs)

QAARWPs are:

- Management tools for documenting the past fiscal year's activity and for estimating the workload for the current year
- Required by EPA Order 5360.1 A2
- Submitted annually (usually in November) to the Quality Staff, Office of Environmental Information

Quality System Assessment

- Management
- Technical
- Data Quality

Management Assessments

Purpose:	To determine conformance with an approved QMP and to assess the suitability and effectiveness of its implementation
Responsibility:	EPA Managers of individual organizations
Documentation:	*Guidance for the Management Systems Review (MSR) Process (QA/G-3MSR)*

How many per year?

Management Assessment Tools

- Quality System Audits — conformance audit (to docs) — QMP etc.
- Management Systems Reviews — Qualitative assess. of QA/QC practices
- Process Quality Audits
- Product/Service Quality Audits

IG + OS perform similar functions to some degree (audits)

OS. Audits typically involve - tracking the paper trail to see if all plans & protocols were followed.

* Criminal enforcement Div. is just now starting to do QMPs - Their criminal enforce. data seldom have QA procedures to back them.

ISO 9000 being revised + will be issued in the Fall

ISO 19011 — State of Art criteria for auditing Quality Manag. Sys.

ISO 17025 — Lab evaluation std.

Quality System Audit

- A documented activity performed to verify, by examination and evaluation of objective evidence, that applicable elements of the quality system are appropriate and have been developed, documented, and effectively implemented in accordance and in conjunction with specified requirements.
- Such requirements may be defined by:
  - EPA Orders
  - Extramural Agreement Regulations
  - Approved Quality Management Plans

one "conforms" to stds
" "complies" w/ guidance

Quality System Audit

- QSA uses quantitative approach to documented quality systems.
- Findings are based on objective evidence.
- QSA is a conformance/compliance audit:
  - Does the quality system conform to specifications?
  - Does the quality system comply with regulations?
  - Does the quality systems satisfy the QMP?
- QSA does not judge quality of individual data sets.

These do not look a "performance" - only proj. perform. audits do - these are resource - intensive

Management Systems Review

- The qualitative assessment of QA and QC practices to establish if they conform to policies and requirements and are adequately implemented to satisfy needs and expectations.

- Such policies and requirements may be given by:
  - EPA Orders
  - Extramural Agreement Regulations
  - Approved Quality Management Plans

Management Systems Review

- Similar, but less quantitative than QSA.
- Applies best to situations where the quality system is not well-documented.
- Investigative in nature - - seeks to determine what is actually happening.
- Interview is primary data collection method.
- MSR does not judge the quality of individual data sets.

Process Quality Audits

- A verification by evaluation of an operation or method against documented instructions and standards to measure conformance to these standards and the effectiveness of the instructions.
- PQA examines a PART of the quality system.
- Process is largely the same as the QSA.

Process Quality Audits

- PQA is typically shorter and less complex than a QSA.
- PQA is less labor intensive.
- Reporting of results may be less formal and quicker.

Product/Service Quality Audit

- An in-depth examination of a particular product, result, or service to evaluate whether it conforms to the documented specifications, performance standards, and customer/user requirements.
- PSQA determines the value-added of the quaity system to the results achieved.
- The quality of individual data sets and other results are integral to the PSQA with:
  - conformance to Agency policy
  - compliance with regulations

Product/Service Quality Audit

- PSQA is labor intensive and typically time consuming.
- PSQA requires extensive planning to determine:
  - scope of the audit
  - issues to be addressed
  - potential impacts or vulnerabilties of non-compliances
  - limits of time and resources
- PSQA uses interviews, detailed file and case study reviews, and analyses of data to determine value of results.

Product/Service Quality Audit

- PSQA requires detailed reporting to link the results to the audit criteria.
- PSQA provides high potential for:
  - Comprehensiveness
  - Value to management
  - Contentiousness

Technical Assessments

Purpose:	To evaluate the implementation of a project or activity against its defined technical or quality procedures or criteria
Responsibility:	Project Managers with the assistance of the appropriate technical personnel, their EPA Manager, and QA Manager
Documentation:	*Guidance on Technical Assessments for Environmental Data Operations (QA/G-7)*, January 2000

Data Quality Assessment (DQA)

- Determine if environmental data are of the type, quantity, and quality needed
- Scientific and statistical evaluation of data
- The DQA Process may be performed:
  - During a project to check the process of data collection
  - At the end of a project to check if objectives were met
- The DQA Process provides a tool for confirming that the systematic planning criteria were met

SUMMARY

Authorities
- Internal EPA Policies
  - ➤ *EPA Order 5360.1 A2*
  - ➤ *EPA Manual 5360 A1*
- External Policies
  - ➤ *48 CFR 46*
  - ➤ *40 CFR 30, 31, 36*

Quality System Tools
- Quality Management Plans
- QA Project Plans
- Standard Operating Procedures
- Systematic Planning and the Data Quality Objectives Process
- Assessments
- Quality Assurance Annual Report and Work Plan

Technical Assessments (Audits)

- Technical Assessments are self or independent evaluation processes used to measure the conformance, performance, or effectiveness of systems

- Technical Assessments include:
  - Technical Systems Audits
  - Readiness Reviews
  - Surveillances
  - Performance Evaluations
  - Audits of Data Quality — quantitative
  - Peer Reviews

Data Quality Assessment (DQA)

Purpose:	To assess type, quantity, and quality of data - Verifies DQOs - Develops DQOs objectives if not fully developed - Verifies QAPP components - Verifies sample collection procedures
Responsibility:	Appropriate technical personnel
Documentation:	*Guidance for DQA: Practical Methods for Data Analysis (QA/G-9)*, July 1996 *Data Quality Evaluation Statistical Toolbox (DataQUEST) (QA/G-9D)*, December 1997

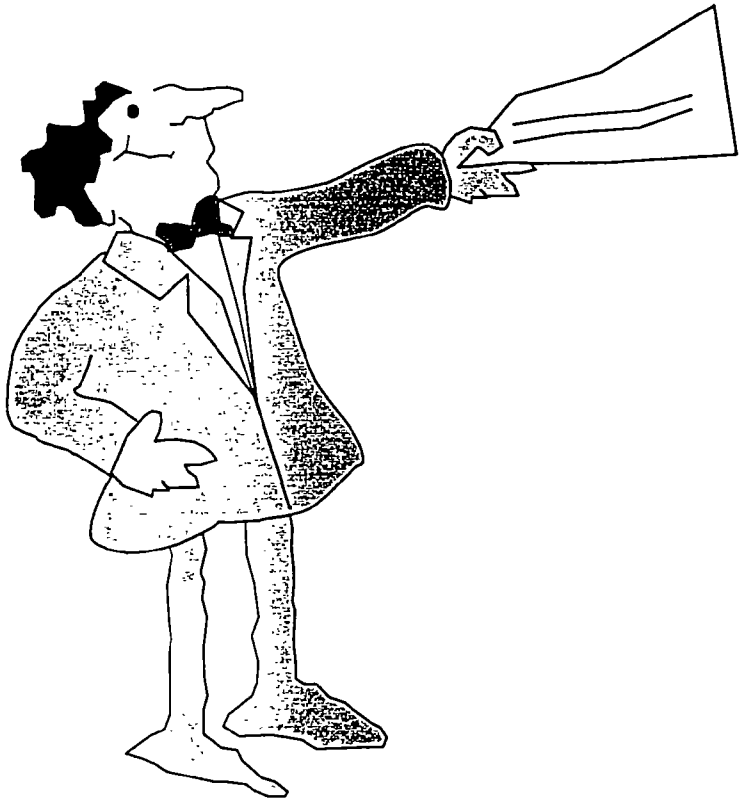
SUMMARY (continued)

- EPA Quality System Documents
  - EPA Requirements for Quality Management Plans (QA/R-2)
  - EPA Requirements for Quality Assurance Project Plans (QA/R-5)
  - Guidance for Quality Assurance Project Plans (QA/G-5)
  - Guidance for the Data Quality Objectives Process (QA/G-4)
  - Guidance for the Preparation of Standard Operation Procedures for Quality-Related Documents (QA/G-6)

Gary Johnson Margo Hunt (Both on G.S.)
Close to half attendants from States

HANDOUTS

sits on Interint Boards (I-50 etc.)



Learning is not compulsory but neither is survival.

~ W. Edwards Deming ~

Kevin Bolger R5 QA manager
(Opened workshop)

HANDOUT #1

OVERVIEW OF QUALITY SYSTEM REQUIREMENTS

Pre-Course Self Assessment

	Yes	No
1. I know what a Quality System is.		
2. I can describe my organization's Quality System.		
3. I know who my Quality Assurance Manager is.		
4. I know EPA's Quality System requirements.		
5. I understand the purpose and applicability of: - Quality Management Plans		
- Quality Assurance Project Plans		
- Systematic Planning		
- Assessments		
- Standard Operating Procedures		

HANDOUT #2

Quality-Related Definitions

(From EPA Manual 5360, July 1998)

assessment - the evaluation process used to measure the performance or effectiveness of a system and its elements. As used here, 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 (quality) - a systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.

bias - the systematic or persistent distortion of a measurement process which causes errors in one direction (i.e., the expected sample measurement is different from the sample's true value).

calibration - comparison of a measurement standard, instrument, or item with a standard or instrument of higher accuracy to detect and quantify inaccuracies and to report or eliminate those inaccuracies by adjustments.

data quality assessment (DQA) - a statistical and scientific evaluation of the data set to determine the validity and performance of the data collection design and statistical test, and to determine the adequacy of the data set for its intended use.

data quality objectives (DQOs) - qualitative and quantitative statements derived from the DQO Process that clarify study objectives, define the appropriate type of data, and specify tolerable levels of potential decision errors that will be used as the basis for establishing the quality and quantity of data needed to support decisions.

data quality objectives process - a systematic planning tool to facilitate the planning of environmental data collection activities. Data quality objectives are the qualitative and quantitative outputs from the DQO Process.

design - specifications, drawings, design criteria, and performance requirements. Also the result of deliberate planning, analysis, mathematical manipulations, and design processes.

document - any compilation of information which describes, defines, specifies, reports, certifies, requires, or provides data or results pertaining to environmental programs.

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,

location, or conditions; ecological or health effects and consequences; or the performance of environmental technology. For EPA, environmental data include information collected directly from measurements, produced from models, and compiled from other sources such as data bases or the literature.

environmental data operations - work performed to obtain, use, or report information pertaining to environmental processes and conditions.

environmental processes - manufactured or natural processes that produce discharges to, or that impact, the ambient environment.

environmental programs - work or activities involving the environment, including but not limited to: characterization of environmental processes and conditions; environmental monitoring; environmental research and development; and the design, construction, and operation of environmental technologies; and laboratory operations on environmental samples

environmental technology - 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 or prevent them from entering the environment. Examples include wet scrubbers (air), soil washing (soil), granulated activated carbon unit (water), and filtration (air, water). Usually, this term applies to hardware-based systems; however, it also applies to methods or techniques used for pollution prevention, pollutant reduction, or containment of contamination to prevent further movement of the contaminants, such as capping, solidification or vitrification, and biological treatment.

extramural agreement - a legal agreement between EPA and an organization outside EPA for items or services to be provided. Such agreements include contracts, work assignments, delivery orders, task orders, cooperative agreements, research grants, state and local grants, and EPA-funded interagency agreements.

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 the results and the degree of confidence needed in the quality of the results.

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.

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

management assessment - the qualitative assessment of a particular program 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 results needed are obtained. A management assessment may either be performed by those immediately responsible for overseeing and/or performing the work (i.e., a management self-assessment) or by someone other that the group performing the work (i.e., a management independent assessment).

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 systems 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.

measurement and testing equipment - tools, gauges, instruments, sampling devices or systems used to calibrate, measure, test, or inspect in order to control or acquire data to verify conformance to specified requirements.

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.

observation - an assessment conclusion that identifies a condition (either positive or negative) which does not represent a significant impact on an item or activity. An observation may identify a condition which does not yet cause a degradation of quality.

organization - a company, corporation, firm, enterprise, or institution, or part thereof, whether incorporated or not, public or private, that has its own functions and administration. In the context of this Manual, an EPA organization is an office, region, national center or laboratory.

peer review - a documented critical review of work by qualified individuals (or organizations) who are independent of those who performed the work, but are collectively equivalent in technical expertise. A 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.

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.

precision - a measure of mutual agreement among individual measurements of the same property, usually under prescribed similar conditions, expressed generally in terms of the standard deviation.

process - a set of interrelated resources and activities which transforms inputs into outputs. Examples of processes include analysis, design, data collection, operation, fabrication, and calculation.

quality - the totality of features and characteristics of a product or service that bear on its ability to meet the stated or implied needs and expectations of the user.

quality assurance (QA) - an integrated system of management activities involving planning, implementation, documentation, 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 manager (QAM) - the individual designated as the principal manager within the organization having management oversight and responsibilities for planning, documenting, coordinating, and assessing the effectiveness of the quality system for the organization.

quality assurance project plan (QAPP) - a document describing in comprehensive detail the necessary QA, QC, and other technical activities that must be implemented to ensure that the results of the work performed will satisfy the stated performance 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; operational techniques and activities that are used to fulfill requirements for quality.

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 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, documentation, and assessment) pertaining to the quality system.

quality management plan (QMP) - a document that describes a quality system in terms of the organizational structure, policy and procedures, functional responsibilities of management and staff, lines of authority, and required interfaces for those planning, implementing, documenting, 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, documenting, and assessing work performed by the organization and for carrying out required QA and QC.

readiness review - a systematic, documented review of the readiness for the start-up 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.

record - a completed document that provides objective evidence of an item or process. Records may include photographs, drawings, magnetic tape, and other data recording media.

scientific method - the principles and processes regarded as necessary for scientific investigation, including rules for concept or hypothesis formulation, conduct of experiments, and validation of hypotheses by analysis of observations.

self-assessment - assessments of work conducted by individuals, groups, or organizations directly responsible for overseeing and/or performing the work.

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 (quality) - continual or frequent monitoring and verification of the status of an entity and the analysis of records to ensure that specified requirements are being fulfilled.

technical assessment - the evaluation process used to measure the performance or effectiveness of a technical system and its elements with respect to documented specifications and objectives. Such assessments may include qualitative and quantitative evaluations. A technical assessment may either be performed by those immediately responsible for overseeing and/or performing the work (i.e., a technical self-assessment) or by someone other that the group performing the work (i.e., a technical independent assessment).

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 review is 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.

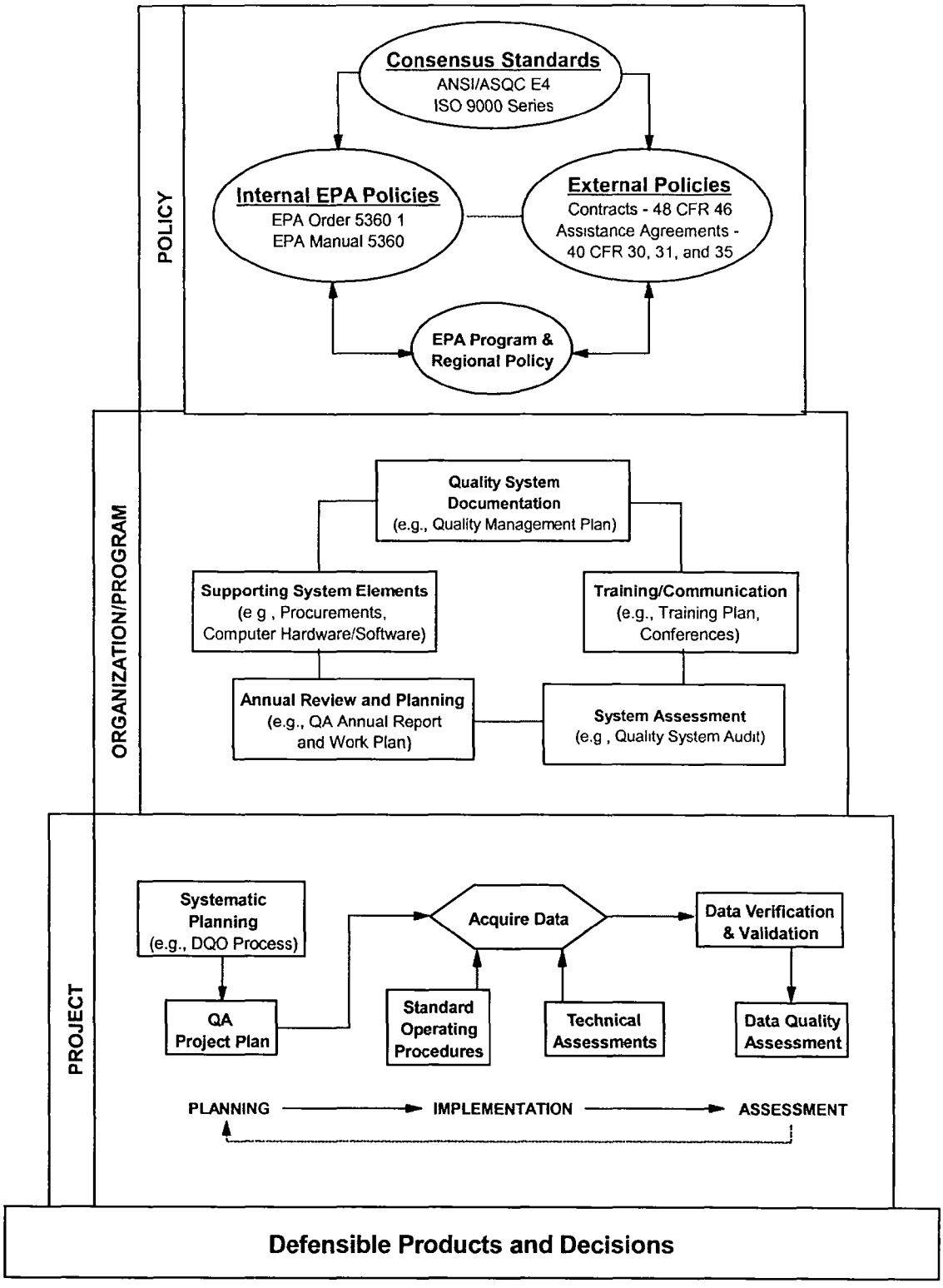
technical systems audit (TSA) - a thorough, systematic, on-site, qualitative audit of facilities, equipment, personnel, training, procedures, record keeping, data validation, data management, and reporting aspects of a system.

user - an organization, group, or individual that utilizes the results or products from environmental programs or a customer for whom the results or products were collected or created.

validation - confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use are fulfilled. In design and development, validation concerns the process of examining a product or result to determine conformance to user needs.

verification - confirmation by examination and provision of objective evidence that specified requirements have been fulfilled. In design and development, verification concerns the process of examining a result of a given activity to determine conformance to the stated requirements for that activity.

HANDOUT #3


POLICY
Consensus Standards
ANSI/ASQC E4
ISO 9000 Series
Internal EPA Policies
EPA Order 5360 1
EPA Manual 5360
External Policies
Contracts - 48 CFR 46
Assistance Agreements -
40 CFR 30, 31, and 35
EPA Program &
Regional Policy
ORGANIZATION/PROGRAM
Quality System
Documentation
(e.g., Quality Management Plan)
Supporting System Elements
(e g , Procurements,
Computer Hardware/Software)
Training/Communication
(e.g., Training Plan,
Conferences)
Annual Review and Planning
(e.g., QA Annual Report
and Work Plan)
System Assessment
(e.g , Quality System Audit)
PROJECT
Systematic
Planning
(e.g., DQO Process)
Acquire Data
Data Verification
& Validation
QA
Project Plan
Standard
Operating
Procedures
Technical
Assessments
Data Quality
Assessment
PLANNING
IMPLEMENTATION
ASSESSMENT
Defensible Products and Decisions

HANDOUT #4

E4 Structure

ANSI/ASQC E4-1994, *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs*

EPA has adopted the American National Standard ANSI/ASQC E4-1994, *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs*, as the basis for its quality system. E4 is a national consensus standard authorized by the American National Standards Institute (ANSI) and developed by the American Society for Quality (ASQ).

The standard is modular in design and is organized into three parts. Part A describes the quality management elements that are common to environmental programs regardless of their technical scope. The other parts of the standard contain the quality system elements applicable to technical areas. The specific applicability of the standard (or parts thereof) to individual environmental programs is left to the user of the standard to determine.

Part A describes the quality management elements needed for managing environmental programs effectively. These include:

- management and organization,
- quality system and description,
- personnel qualification and training
- procurement of items and services,
- documentation and records,
- computer hardware and software,
- planning,
- implementation of work processes,
- assessment and response, and
- quality improvement.

Part A defines the framework containing the common quality management practices that enable project-specific operations to be planned, implemented, and assessed. These elements are used in conjunction with the other parts of the standard to formulate a complete quality system.

Part B contains the additional quality system elements needed to plan, implement, and assess environmentally-related data operations, including the collection, handling, analysis, and evaluation of environmentally-related data. The Part B elements must be used in conjunction with Part A in order to provide an adequate quality system for collecting and evaluating environmental data. Such data include chemical, biological, toxicological, ecological, radiological, and physical data. These data may be obtained directly from the environment or from systems representing environmental conditions, such as laboratories or test chambers. The activities described in Part B have traditionally been associated with environmental monitoring.

Part B elements also apply to the collection of environmental data that are used directly to design, construct, or operate environmental technology. The program elements contained in Part B are:

- planning and scoping,
- design of data collection operations,
- implementation of planned operations,
- quality assessment and response, and
- assessment and verification of data usability.

Environmental data also include data derived from samples collected from the environment, the results of other analytical testing (e.g., geophysical, hydrogeological) of environmental conditions, and process or physical parameters from the operation of environmental technologies.

Part C provides the additional quality system elements pertaining to environmental technology (and their system components) that remediate environmental contamination, prevent or remove pollutants from process discharges, or dispose of or store hazardous, radioactive, and/or mixed wastes. The Part C elements must be used in conjunction with Part A to provide an adequate quality system for the design, construction, and operation of environmental technology. The program elements contained in Part C are:

- planning,
- design of systems,
- construction/fabrication of systems and components,
- operation of systems,
- quality assessment and response, and
- verification and acceptance of systems

The Part C elements describe the project-specific activities needed to plan, implement, and assess the design, construction, and operation of such technologies, and to ensure that the technologies will perform as intended. Environmental process or condition characterization activities that produce data used in support of the design, construction, and operation of environmental technology must be conducted according to the specifications of Part B.

Copies of the ANSI/ASQC E4 may be purchased from:

ASQC Quality Press
P.O. Box 3005
Milwaukee, WI 53201-3005
Phone: (800) 248-1946
www.asq.org

$25.00

ANSI stds must be reviewed every 5 years — E4 is being reauthorized this year

HANDOUT #5

Determining the Quality Requirements for Financial Agreements with EPA

	Contract	Cooperative Agreement	Grant*	Inter-Agency Agreement	Unfunded Mandate
Contractor	48 CFR 1546 48 CFR 46	N/A	N/A	N/A	N/A
Federal Agency	N/A	N/A	N/A	Negotiated into each agreement	Contained in specific Federal Regulation that requires data collection
Hospital	48 CFR 1546 48 CFR 46	40 CFR 30	40 CFR 30	N/A	Contained in specific Federal Regulation that requires data collection
Institute of Higher Education	48 CFR 1546 48 CFR 46	40 CFR 30	40 CFR 30	N/A	Contained in specific Federal Regulation that requires data collection
Local Government	48 CFR 1546 48 CFR 46	40 CFR 31 40 CFR 35	40 CFR 31 40 CFR 35	N/A	Contained in specific Federal Regulation that requires data collection
Non-profit Organization	48 CFR 1546 48 CFR 46	40 CFR 30	40 CFR 30	N/A	Contained in specific Federal Regulation that requires data collection
Regulated Entity	N/A	N/A	N/A	N/A	Contained in specific Federal Regulation that requires data collection
State Government	48 CFR 1546 48 CFR 46	40 CFR 31 40 CFR 35	40 CFR 31 40 CFR 35	N/A	Contained in specific Federal Regulation that requires data collection
Tribal Government	48 CFR 1546 48 CFR 46	40 CFR 31 40 CFR 35	40 CFR 31 40 CFR 35	N/A	Contained in specific Federal Regulation that requires data collection

*Grants include Performance Partnership Grants and Performance Partnership Agreements.

Federal Regulations

48 CFR 1546: Requires the development of a Quality Management Plan and/or a Quality Assurance Project Plan. This regulation will be removed pending notice in the Federal Register.

48 CFR 46: Allows Federal Agencies to select a national consensus standard as a basis for their quality requirements. EPA intends to select ANSI/ASQC E4 as the basis for its quality requirements and require that applicants/contractors, through revised clauses, submit a Quality Management Plan (or equivalent) and/or a Quality Assurance Project Plan (or equivalent) to demonstrate conformance to the standard. The selection of E4, the revised contracting clauses, and the removal of 48 CFR 1546 will be effective pending notice in the Federal Register.

40 CFR 30: Grantee must comply with the American National Standard, ANSI/ASQC E4. EPA requires that grantees submit a Quality Management Plan and/or a Quality Assurance Project Plan to demonstrate conformance.

40 CFR 31: Requires grantee to develop and implement quality assurance practices to produce data of adequate quality to meet project objectives. To clarify this requirement, EPA has issued clarifying language, posted at www.epa.gov/ogd/qa.htm, which is consistent with 40 CFR Part 30. In essence, the clarifying language states that a grantee must have a quality system that conforms to the American National Standard, ANSI/ASQC E4-1994 and is required to submit a Quality Management Plan and/or a Quality Assurance Project Plan.

40 CFR 35: Requires grantee to comply with 40 CFR 31. For the full text of 40 CFR 35, see qa_cfrs.html#40PART35.

QUALITY MANAGEMENT PLAN

FOR

THE OFFICE FOR A CLEAN ENVIRONMENT
(Document Control No. OA-OCE-01)

Office for a Clean Environment

Office of the Assistant Administrator
for Ensuring a Clean Environment

U. S. Environmental Protection Agency

October 1, 1994

QUALITY MANAGEMENT PLAN (QMP) EXAMPLE

INSTRUCTIONS:

You have just been appointed Director of the Office for a Clean Environment (OCE). Among the items waiting on your desk for approval is your new office's Quality Management Plan submission. You study this document carefully in order to learn how a key component of your organization is structured.

Since you understand the importance of Quality Management Plans (QMPs) and know what belongs in them, it's easy for you to determine that the document you are reviewing is a dreadful mess. There are at least ten fundamental flaws in this plan. Your new office clearly needs help!

In order to focus on the necessary revision process, you should now do the following:

1. On a piece of paper, list the major deficiencies in this QMP.

2. Briefly describe how to correct each deficiency. After you have listed the plan's deficiencies and described how to correct them, be prepared, as part of the ensuing class discussion, to discuss them.

3. Discuss some consequences to your organization's quality assurance effort if the deficiencies are left uncorrected.

QUALITY MANAGEMENT PLAN IDENTIFICATION AND APPROVAL FORM

Document Title:	Quality Management Plan
Document Control No.:	QA-OCE-01
Organization Title:	Office for a Clean Environment
Address:	P. O. Box 12345 Washington, DC 20460
Responsible Official:	Your name Phone No. 555-1212
QA Manager:	James MacArthur Phone No. 555-1414
Date:	October 1, 1994
Concurrence:	_____ Your name
Title:	Director, Office for a Clean Environment
Date:	October 3, 1994
Approval for the Agency:	_____ Robert J. Huggett, Ph.D.
Title:	Assistant Administrator for Research and Development
Date:	_____

TABLE OF CONTENTS

1. MANAGEMENT AND ORGANIZATION

1.1 ENVIRONMENTAL DATA COLLECTION ACTIVITIES (EDCAs)

OCE is responsible for ensuring that all aspects of the environment we live in are clean and healthy. To carry out its mission, OCE is organized into five divisions: 1) the Division of Clean Air; 2) the Division of Clean Water; 3) the Division of Clean Land; 4) the Division of Research and Development; and 5) the Division of Administration and Support. Each division is headed by a Division Director who reports directly to the Director, OCE. The Director, OCE, determines which aspects of the environment are not clean and healthy and reports these findings to the Assistant Administrator, EPA. OCE's Quality Assurance Officer reports directly to the Director of the Division of Administration and Support.

Data collection activities are carried out under the direction of the responsible Division Director, who communicates the results of these activities to the Director, OCE.

1.1.1 In-House Projects

Intramural projects involving environmentally-related measurements are conducted by the Divisions of Clean Air, Clean Water, and Clean Land. The Division Director determines which projects require QA Project Plans.

1.1.2 Extramural Projects

Extramural projects involving environmentally-related measurements are also conducted by independent contractors. The Division Director designates a staff person to oversee the implementation of these projects. The designated individual determines the need to develop QA Project Plans.

1.2 DATA GENERATION DELEGATED TO REGIONAL OFFICES

OCE periodically meets with Regional personnel on QA issues to assure that the Regional Offices give appropriate priority to QA.

1.3 QA RESPONSIBILITIES

1.3.1 Organization, Delegations, and Responsibilities

The Director, OCE, is responsible for ensuring that QA is an integral part of OCE operations. Division Directors are responsible for overseeing the collection of data derived from environmentally-related measurements whose quality is known. Management of in-house and extramural projects is delegated to a responsible staff person.

1.3.2 Responsibilities/Authorities of the QAO

The Quality Assurance Officer (QAO) is an important link in the management and implementation of OCE's QA program. The QAO reports directly to the Chief, Administration Section in the Division of Administration and Support. The QAO is responsible for ensuring that OCE has an approved Quality Management Plan.

2.0 QUALITY SYSTEM AND DESCRIPTION

2.1 QA POLICY STATEMENT

It is the policy of the Office for a Clean Environment (OCE) to ensure the generation of data derived from the environmentally-related measurements whose quality (i.e., precision, bias, completeness, representativeness, and comparability) is known. The Office's quality assurance effort is accomplished through the development and implementation of a Quality Management Plan.

This document sets forth the QA policies, procedures, and management systems needed by OCE to implement its QA program.

2.2 QA PROGRAM TOOLS

The OCE uses the latest QA tools available to obtain good data. These tools include QA Project Plans (QAPPs), audits, and Standard Operating Procedures (SOPs). The OCE always uses the latest guidance from headquarters on these QA tools and adds changes to the guidance for application to specific projects as determined by the project officer.

3. PERSONNEL QUALIFICATIONS AND TRAINING

OCE has a trained and competent staff capable of ensuring that the Office's QA effort is carried out efficiently and in a timely manner. Consequently, there is no need for a formal QA training program.

4. PROCUREMENT OF ITEMS AND SERVICES

The OCE follows the procurement regulations to the letter in acquiring any necessary items or services. The project officer determines if QA is required on any procurement and tells the procurement office what should be included in the procurement.

5. DOCUMENTS AND RECORDS

5.1 DOCUMENTS

The OCE keeps its documents in a library where all staff can have access to them, including documents prepared by contractors and others.

5.2 RECORDS

The official records for a contract are kept by the Contracts Officer. Other records may be kept by the Project Officer until a project is finished. The Project Officer determines how long to retain the records and how to dispose of them.

6. COMPUTER HARDWARE AND SOFTWARE

The OCE uses the latest in personal computers to perform project work. Project officers use PCS to evaluate data collected and to track projects with spreadsheets. When too many data are received, the data are loaded into the EPA mainframe computer so that models can be used on that data.

The OCE has a cooperative agreement with Whatsamatta U. that provides a Ph.D. statistician and two part-time statistics students to perform analyses of data collected and audit results.

7. PLANNING

7.1 PLANNING FOR DATA GENERATION

7.1.1 Data Quality Objectives

Data Quality Objectives (DQOs) are established for many projects conducted by the Divisions of Clean Air, Clean Land, and Clean Water. The decision to develop DQOs for a specific project rests with the Division Directors. When the decision is made to develop DQOs for a particular project, they are developed by the Project Officer with lead responsibility for the activity. (DQOs are based primarily on the capabilities and limitations of the applicable equipment and measurement methods.)

7.2 ANNUAL PLANNING

The Director, Division of Administration and Support, meets annually with the QAO to plan OCE quality assurance efforts for the year. Although QA activities are not a line item in the OCE budget, the QAO tries to ensure that adequate resources are provided for OCE's quality assurance program.

8. IMPLEMENTATION OF WORK PROCESSES

The Project Officer is responsible for implementing the projects of the OCE through contracts, work assignments, cooperative agreements, and grants.

9. ASSESSMENT AND RESPONSE

9.1 THE AUDIT/REVIEW PROGRAM

OCE periodically conducts audits of its QA program and data collection activities. The Division of Administration and Support schedules and conducts the following audits on an "as needed" basis:

- Data quality audits;
- Performance evaluations;
- Technical systems audits.

Follow-up of audit results is left up to the appropriate Project Officer.

10. QUALITY IMPROVEMENT

The Director, OCE, reviews the performance of Project Officers in the Office to determine where improvements can be made. Division Directors determine when corrective actions are needed to improve work.

Alison Boshes Malcolm Bertoni, RTP Institute Nancy Hassig

EBJD ARCHIVE EPA 905 K- 00- 004

INTEGRATING QUALITY ASSURANCE INTO PROJECT DEVELOPMENT

AGENDA

* see G-9 on data Q. Assessment

August 9, 2000

G5-S- Draft avail. end August on statistical methods

8:30 Introductions and Welcome
Implementing the Quality System
BREAK
QAPP Part A: Project Management and Sampling Design
Developing DQOs: Steps 1-5
Boundaries Setting Activity

12:00 LUNCH

1:00 DQO Process Step 6: Setting Limits on Decision Errors
DQO Step 7/Sampling Design Process
BREAK
Sampling Design (DEFT) Exercise
5:00 Dismiss

August 10, 2000

8:30 Reconvene, Overview of Day 2
Relating DQIs to Sampling Design
Design Comparison I
BREAK
QAPP Part B: Measurement/Data Acquisition
QAPP Part B Activity
QAPP Part C: Assessment/Oversight and Data Validation and Usability

12:00 LUNCH

1:00 QAPP Part C Journal Activity
The Data Quality Assessment Process
DQA Exercise
BREAK
Design Comparison II
Application Planning
5:00 Wrap-up and Dismiss

Integrating Quality Assurance into Project Development

Trainers

Malcolm Bertoni
Alison Boshes
Research Triangle Institute
202/728-2067

Nancy Hassig
Battelle Pacific Northwest Division
650/969-3969

Overview

This course is advanced and requires prerequisite training and/or experience.

Day One

- **How do you plan to collect the right data?**
- **How are your project and data quality objectives translated into a sampling design?**

Day Two

- **How do you document your planning and implementation activities in the project's QAPP?**
- **How do you verify that the data you collected met the assumptions you made during planning?**
- **What do your data tell you?**

Learning Objectives

1. **Participants will be able to explain the value of systematic processes in developing QAPPs.**

2. **Participants will be able to describe the links between DQOs, DQIs, DQA, and the QAPP.**

3. **Participants will be aware of and be able to use QAD resources and tools, including: G-4, G-4D (DEFT), G-5, G-9, and G-9D (DataQUEST).**

4. **Participants will be able to explain how the outputs of DQO Process Steps 6 and 7, precision and bias assumptions, and distributional assumptions are used to develop a sample collection design.**

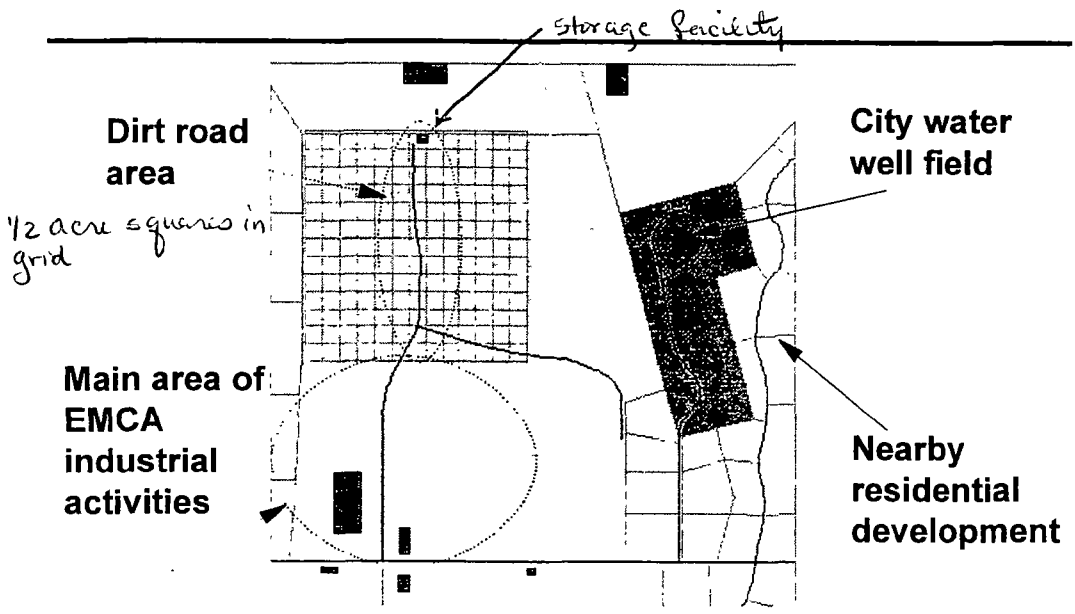
Approach

- This training workshop is interactive. It will consist of small and large group discussions, group and individual exercises, lecture, and demonstrations.
- You will work in teams. Your team is comprised of the people sitting around your table. Together, you will complete part of the DQO Process, develop a sampling design, prepare sections of a QAPP, and analyze data.
- The site you will be working with during the training exercises is a simulated hazardous waste site. It is called the Electronic Manufacturing Corporation of America (EMCA) site, also known as SimSITE and is based on an actual Superfund site.

Day 1

8:30	Introductions and welcome
	Implementing the Quality System
	Quality System exercise
	BREAK
	QAPP: project management & sampling design
	DQO Process Steps 1-5
	Boundaries setting activity
12:00	LUNCH
1:00	DQO Process Step 6
	DQO Process Step 7
	BREAK
	Sampling design exercise
5:00	Summarize and dismiss

Map of EMCA site



The Conceptual Site Model

- Source: waste oil contaminated with PCBs (>50 ppm) sprayed over dirt road to control dust
  - PCBs are carcinogens and cause harmful liver, skin, reproductive, and developmental effects
- Contaminated media: surface soil
- Primary pathways: direct ingestion of soil, inhalation of dust
- Receptors: adults, children

Regulatory Context

- Superfund site (CERCLA/SARA)
  - Site is on National Priorities List
- Currently in early Remedial Investigation stage
  - Preliminary Assessment / Site Inspection determined the types of contamination
- Candidate for the streamlined approach advocated by the EPA Region
- Focus will be on one operable unit of site (the grid)

Sociopolitical Context

- Nearby residential development has a homeowners association; some members are active in environmental advocacy
- Mayor and majority of City Council interested in redevelopment of site (economic interest)
- Residential developer and Fortune 500 manufacturer both interested in property (Re-development)
- EPA Regional Administrator is interested in promoting Superfund streamlining process

Project Resources and Constraints

- Site manager has access to EPA scientists, contractors, and consultants with expertise in a variety of scientific and engineering disciplines
- Project funded by Superfund; preliminary field investigation budget of $200K for PCB area
- Schedule calls for draft report on field investigation results in 6 months

Writing Activity

- Turn to the back of your notebook and locate the participant's journal.
- Answer the following questions in the space provided on page J-1.

What are the one or two most pressing or important QA issues that you have to deal with in your work?

Considering the objectives, agenda, and your personal experience, list some expectations you have of this course.

Warm-up Activity

- At your tables, please introduce yourself to your teammates by giving the following information:
  - Name,
  - Affiliation, and
  - A brief summary of your technical background.

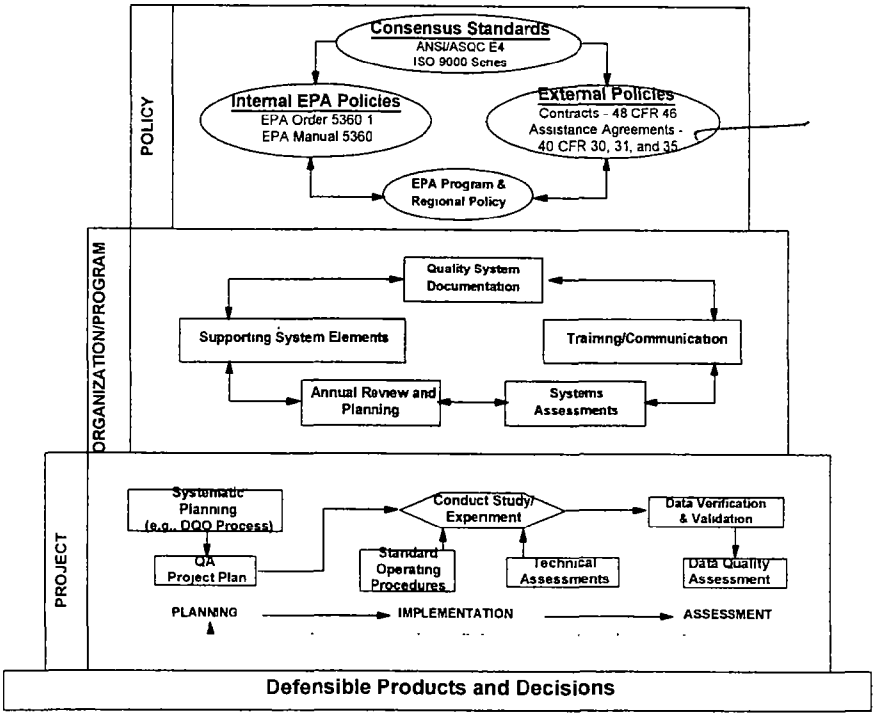
  (please be brief)

Implementing the Quality System

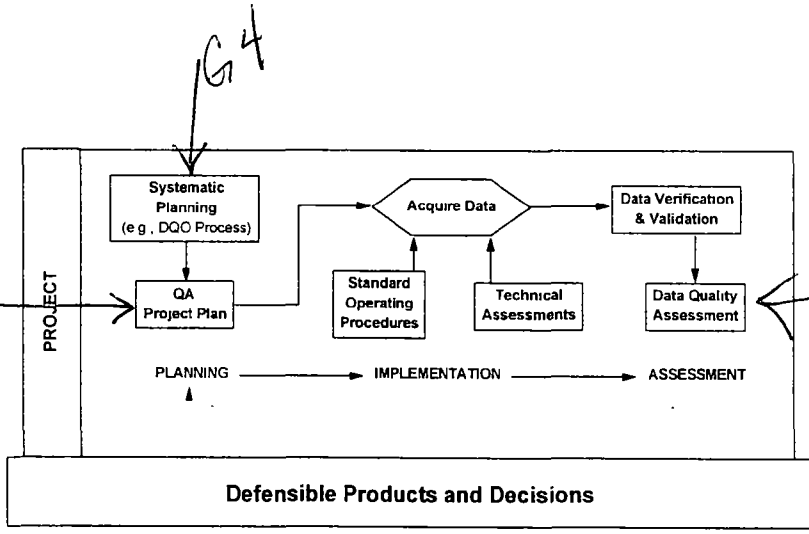
What is a Quality System?

- A structured and documented management system.
- Describes the policies, objectives, principles, organizational authority, responsibility, accountability, and implementation plan of an organization for ensuring quality in its work processes, products (items), and services.
- Provides the framework for planning, implementing, and assessing work performed by the organization and for carrying out required QA and QC activities.

EPA Quality System Model



EPA Quality System - Project Level



Graded Approach to QA

Common Sense

The *Graded Approach* defines quality requirements according to:

- The type of work being done; and
- The risk of making a wrong decision from the data collected

what's at stake if you get it wrong

Examples of *Varying Quality Requirements*:

- Bench-level research investigation
- Superfund remedial investigation
- Enforcement/compliance determination

QA in a Project's Lifecycle

There are three key phases to a project:

- Planning (Data Quality Objectives)
- Implementation (QA Project Plans)
- Assessment (Data Quality Assessment)

QAPPs are Required

- QAPPs are required for all environmental data collection operations involving direct measurements performed by or for EPA.

  (EPA Order 5360.~~1 CHG 1~~ A2 (July 1998) "Policy and Program Requirements to Implement the Mandatory Quality Assurance Program")

QAPPs must demonstrate...

- The project's technical and quality objectives are identified and agreed upon by management
- Intended measurements and acquisition methods are consistent with project objectives
- Assessment procedures are sufficient for determining if data are of type and quality needed for decision-making
- Limitations on the use of data are identified

Data Quality Objectives Process

The DQO Process is the Agency's recommended planning process for decision making that provides for:

- Early involvement of the decision maker
- A graded approach to data quality requirements
- More effective sampling and analysis programs
- A basis for judging the usability of the collected data

Data Quality Objectives (DQOs)

The full set of planning information needed to design a project, including:

- What decision will be made?
- What data will be gathered?
- Where and when?
- How will data be used?
- What quality must the data be?
- How much time and money is available and needed?
- What are tolerable levels of uncertainty?

This information can be used to produce an optimal study design meeting the decision maker's needs in a resource-effective manner

Seven Steps of the DQO Process

1. State the Problem
2. Identify the Decision
3. Identify Inputs to the Decision
4. Define the Boundaries
5. Develop a Decision Rule
6. Specify Limits on Decision Errors
7. Optimize the Design

QA Project Plans (QAPPs)

QAPPs must be approved by EPA prior to the start of the data collection

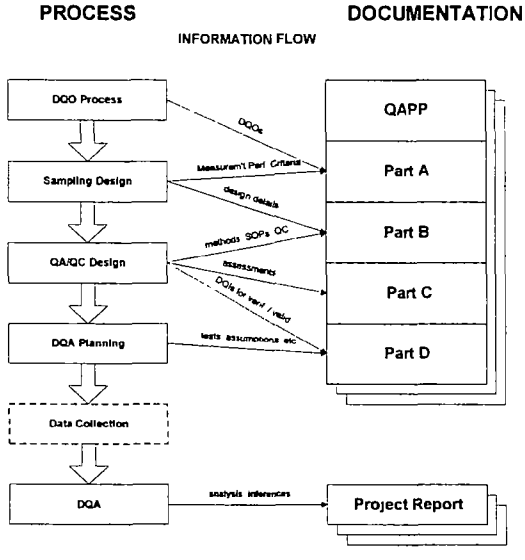
QAPPs are mandatory when environmental data operations occur for:

- Contracts, work assignments, and delivery orders
- Assistance agreements
- Interagency agreements (when negotiated)

QAPP Structure

- QAPP is composed of 24 elements
- Elements are grouped into 4 classes:
  - Part A: Project Management
  - Part B: Measurement/Data Acquisition
  - Part C: Assessment/Oversight
  - Part D: Data Validation and Usability
- Not all projects require 24 elements
- Other projects may require additional information not in 24 elements

Integrating QA Processes with Documentation Requirements



DQA Process - Retrospective

- Were the data quality objectives achieved?
- Where the data quality objectives meaningful?
- Where the assumptions viable?
- Were the statistical tests powerful enough?

DQA Process - Prospective

- What supplemental information is needed?
- Are further data really necessary?
- Should parts of the DQOs be changed?
- Where can the DQO process be improved?

Steps of the DQA Process

1. Review the DQOs and Sampling Design
2. Conduct Preliminary Data Review
3. Select a Statistical Test
4. Verify Assumptions Underlying Test
5. Draw Conclusions from the Data

EPA Guidance

- Planning: EPA QA/G-4, *Guidance for the Data Quality Objectives Process*
- Implementation: EPA QA/G-5, *EPA Guidance for Quality Assurance Project Plans*
- Assessment: EPA QA/G-9, *Guidance for Data Quality Assessment*

Exercise

Turn to page J-2 of your participant handbook.

1. Circle the component(s) of the Quality System with which you have the most experience or for which you have the most responsibility.

2. Think about your answer to question 1 on page J-1 and draw a box around the components involved in addressing the issues you identified as especially pressing or important.

Discuss your answers at your tables.

Day One-- Planning

- QAPP Part A
- DQO Process
- Sampling design

Day Two-- Implementation and Assessment

- Data Quality Indicators
- QAPP Part B
- QAPP Parts C and D
- Data Quality Assessment
- Application Planning

Summary

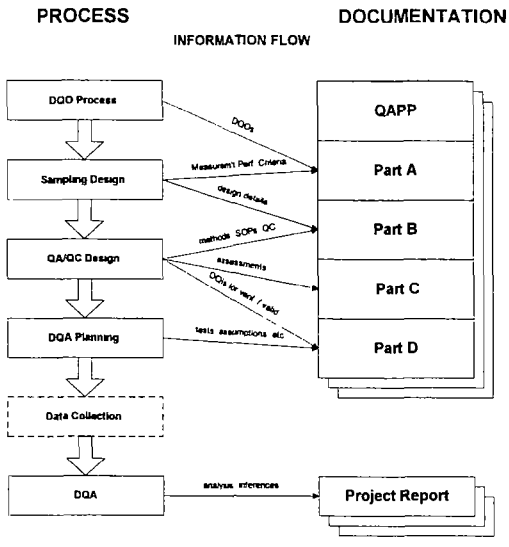
The EPA Quality System captures the data life cycle (planning, implementation, assessment, and documentation) at three levels:

- policy
- organization
- project

This course focuses on the elements of the quality system at the project level.

Quality Assurance Project Plan: Project Management and Sampling Design

Integrating QA Processes with Documentation Requirements



QAPP Documents

Requirement document:

- EPA QA/R-5 *EPA Requirements for Quality Assurance Project Plans for Environmental Data Operations*

Guidance documents:

- EPA QA/G-5 *EPA Guidance for Quality Assurance Project Plans*
- EPA QA/G-5S *Guidance on Sampling Design to Support Quality Assurance Project Plans* (Draft)
  EPA QA/G-5i *Data Quality Indicators* (Draft)

QAPP Structure

- QAPP is composed of 24 elements
- Elements are grouped into 4 classes:
  - Part A: Project Management
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  - Part C: Assessment/Oversight
  - Part D: Data Validation and Usability
- Not all projects require 24 elements
- Other projects may require additional information not in 24 elements

QAPP Structure
A. Project Management

Project history and objectives, roles and responsibilities of participants

A1 - Title and Approval Sheet
A2 - Table of Contents and Document Control Format
A3 - Distribution List
A4 - Project/Task Organization
A5 - Problem Definition/Background
A6 - Project/Task Description and Schedule
A7 - Quality Objectives and Criteria for Measurement Data
A8 - Special Training Requirements/Certification
A9 - Documentation and Records

Seven Steps of the DQO Process

1. **State the Problem**
2. **Identify the Decision**
3. **Identify Inputs to the Decision**
4. **Define the Boundaries**
5. **Develop a Decision Rule**
6. **Specify Limits on Decision Errors**
7. **Optimize the Design**

DQO and QAPP Linkage

QAPP Element
Project Management

	DQO Step 1	2	3	4	5	6	7
A1							
A2							
A3							
A4	★						
A5	★	★					
A6			★	★	★	★	
A7					★	★	★
A8				★			
A9							

Source EPA QA/G-5, A4

A4: Project/Task Organization

- **Identifies key individuals, with their responsibilities (data users, decision-makers, project QA manager, subcontractors, etc.)**
  DQO Step 1, State the Problem

- **Organization chart showing lines of authority and reporting responsibilities**

A5: Problem Definition/Background

- Clearly states the problem or decision to be resolved
  DQO Step 2, Identify the Decision

- Provides historical and background information
  DQO Step 1, State the Problem

A6: Project/Task Description and Schedule

- Lists measurements to be made
  DQO Step 3, Identify Inputs to the Decision;
  DQO Step 5, Develop a Decision Rule

- Cites applicable technical, regulatory, or program-specific quality standards, criteria, or objectives
  DQO Step 3, Identify Inputs to the Decision;
  DQO Step 6, Specify Tolerable Limits on Decision Errors

- Specifies special personnel or equipment requirements
  DQO Step 4, Define Boundaries

- Provides work schedule

- Specifies required project and QA records/reports

A7: Quality Objectives and Criteria for Measurement Data

- States project objectives and limits, both qualitatively and quantitatively
  DQO Step 5, Develop a Decision Rule;
  DQO Step 6, Specify Tolerable Limits on Decision Errors;
  DQO Step 7, Optimize the Design

- States and characterizes measurement quality objectives for the applicable action levels or criteria
  DQO Step 6, Specify Tolerable Limits on Decision Errors;
  DQO Step 7, Optimize the Design

QAPP Structure
B. Measurement/Data Acquisition

B1 - Sampling Process Design
B2 - Sampling Methods Requirements
B3 - Sampling Handling and Custody Requirements
B4 - Analytical Methods Requirements
B5 - Quality Control Requirements
B6 - Instrument/Equipment Testing, Inspection, and Maintenance Requirements
B7 - Instrument Calibration and Frequency
B8 - Inspection/Acceptance Requirements for Supplies and Consumables
B9 - Data Acquisition Requirements (Non-direct Measurements)
B10- Data Management

DQO and QAPP Linkage

QAPP Element Measurement/ Data Acquisition

DQO Steps

	1	2	3	4	5	6	7
B1				★	★	★	★
B2			★				★
B3			★				
B4			★				★
B5			★				
B6			★				
B7			★				
B8			★				
B9	★						★
B10		★					

Source EPA QA/G-5

B1: Sampling Process Design (Experimental Design)

- Type and number of samples required
  DQO Step 7, Optimize the Design
  DQI: Precision, Completeness, Representativeness

- Sampling design and rationale
  DQO Step 5, Develop a Decision Rule;
  DQO Step 6, Specify Tolerable Limits on Decision Errors;
  DQO Step 7, Optimize the Design

- Sampling location and frequency
  DQO Step 7, Optimize the Design;
  DQO Step 4, Define the Boundaries

- Schedules for collection and laboratory analysis

- Document key assumptions underlying design

QAPP Structure
C. Assessment/Oversight

Assessing the effectiveness of the implementation of the project and associated QA/QC

C1 - Assessments and Response Actions
C2 - Reports to Management

QAPP Structure
D. Data Validation and Usability

Determining whether or not the data conform to the specified criteria

D1 - Data Review, Validation, and Verification Requirements
D2 - Validation and Verification Methods
D3 - Reconciliation with Data Quality Objectives

DQOs and QAPP: Planning Phase

- Outputs of DQO Process and resulting sampling design are documented in the QAPP
- QAPP includes additional information: management authorities, personnel, schedule, policies, and procedures for data collection (including SOPs)
- Analytical lab methods (i.e., SW846 methods, specify equipment needs) selection part of DQO Process
- DQO Process identifies
  - Type
  - Quantity
  - Quality of data required for decision making

DQOs and QAPP: Implementation Phase

- Data collected according to methods and procedures documented in QAPP
- During data collection, technical assessments (TAs) conducted to evaluate compliance with QAPP (and hence DQOs)
- TAs generate QA/QC data (which was justified and prescribed in sampling design - DQO Step 7)
- Any change to the following elements may require another iteration of DQO Process
  - conceptual model
  - boundaries
  - decisions to be made
  - feasibility of sampling design
  - decision error limits

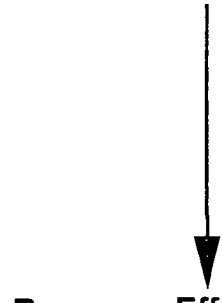
DQOs and QAPP: Assessment Phase

- Data Quality Assessment (DQA) Process assesses whether data meets:
  - Stakeholder's performance criteria (DQO Step 6)
  - Assumptions of conceptual model (DQO Steps 2 and 3), and
  - Choice of statistical test for decision rule (DQA Step 3, DQO Step 7)
- If DQOs/DQIs cannot be met with data being collected, "may" require a second iteration of DQO Process
  - Collect more data
  - Relax decision performance criteria
  - Select a more appropriate (or more powerful) statistical test
  - Change the decision rule

Developing DQOs
Steps 1 - 5

The DQO Process

Problem
(Investigation or Study)



Resource Effective Data Collection Design

- **State the Problem**
- **Identify the Decision**
- **Identify Inputs to the Decision**
- **Define Boundaries of the Study**
- **Develop a Decision Rule**
- *Specify Limits on Decision Errors*
- *Optimize the Design*

Overview

Goal: Develop Data Quality Objectives for EMCA Site

- Gain experience with DQO Process
- Use results later to develop sampling designs and a quality assurance project plan (QAPP)

Approach: Work through the first 5 steps of the DQO process

- Discuss background information and DQO Process as a group
- Use worksheets to document DQO outputs

What is the DQO Process?

The DQO Process is a systematic planning process for generating environmental data that will be sufficient for their intended use.

The DQO Process

Designed to answer:

- What do you need to know?
- Why do you need environmental data?
- How will you use the data?
- How good does the answer need to be?

What are DQOs?

DQOs are quantitative and qualitative criteria that:

- Clarify study objectives
- Define appropriate types of data to collect
- Specify the tolerable probabilities of potential decision errors
- Identify the effects of these decision errors

DQO Process: Underlying Principles

1. All collected data have error
2. Absolute certainty comes with a high price
3. DQO Process defines tolerable error rates
4. Without DQOs, the quality of decisions are unknown
5. DQO Process is based on the scientific method

from hypothesis - to prove/disprove

Getting Ready

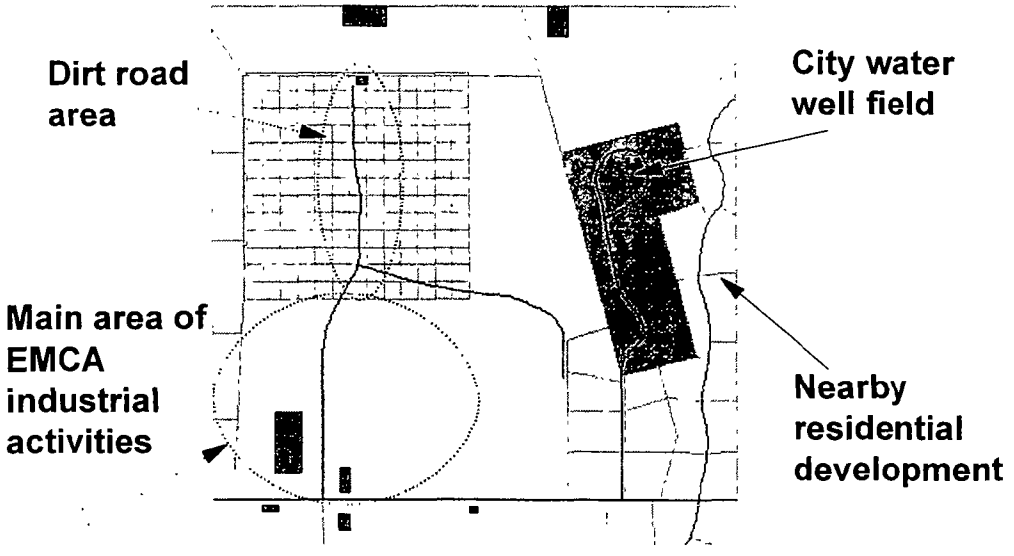
- Get the right people involved in the right way
  - Stakeholders > anyone who can ask us to collect more data
  - Decision maker
  - Technical experts
  - Environmental scientist with statistical training
- Prepare for developing DQOs
  - Gather existing site knowledge
  - Consider overall project objectives
  - Be realistic about resource and sociopolitical constraints

work w/ smaller core grp to narrow the problem - then pull in others

Step 1: State the Problem

- Activities
  - Identify planning team members
  - Develop conceptual site model
  - Develop list of anticipated contaminants and define exposure scenarios
  - Consider resource and logistical constraints
  - Summarize knowledge of site
- Outputs
  - List of known and expected contaminants
  - Conceptual site model, exposure scenarios
  - Summary of previous response actions, data collection activities

Map of EMCA Site



Elements of Conceptual Site Model

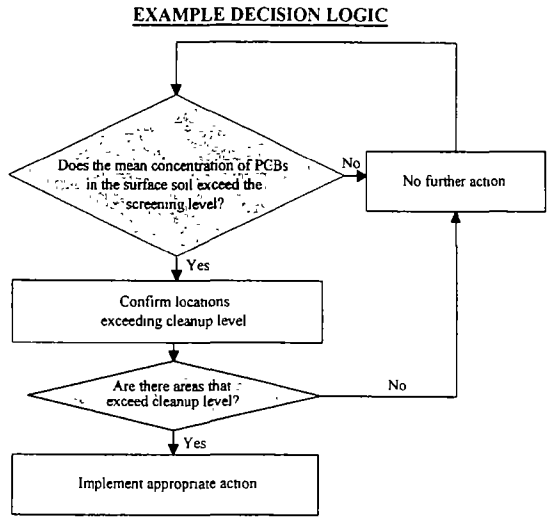
- Source: waste oil contaminated with PCBs (>50 ppm) sprayed over dirt road to control dust
  - PCBs are carcinogens and cause harmful liver, skin, reproductive, and developmental effects
- Contaminated media: surface soil
- Primary pathways: direct ingestion of soil, inhalation of dust
- Receptors: adults, children

Step 2: Identify the Decision

- Principal study questions:
  - Does PCB contamination pose an unacceptable risk at the EMCA/ECC site?
  - If so, what is the extent of unacceptable contamination?
- Alternative actions:
  - Site evaluation accomplished; no further action
  - Design and implement remedial action

Identify the Decision

- What actions will resolve the problem?
- State each decision in terms of whether to take action.
- Identify <u>each</u> data-driven decision and develop DQOs for <u>each</u>.



Identify each data-driven decision and develop DQOs for each

Step 3: Identify Inputs to the Decision

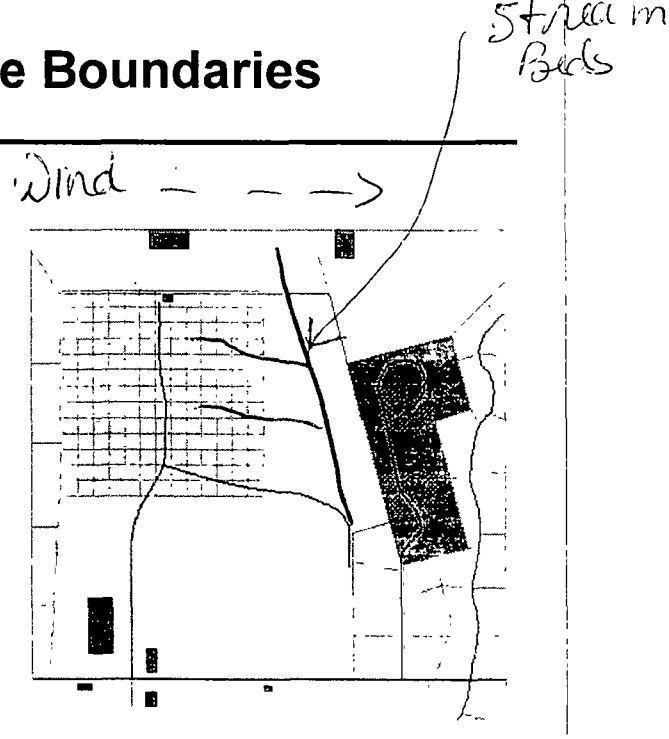
- Identify the information needed to resolve the decision statement and to establish the action level (e.g., applicable technical, regulatory, program-specific quality standards, criteria, or objectives)
- Determine sources for the needed information
- Confirm that appropriate measurement methods exist to provide the data

Inputs and Sources of Information

- PCB action level = 1 ppm
  - Policy, soil screening guidance
- Future land use = industrial
  - Community groups, regulators
- PCB toxicity = carcinogenic; chronic, long-term exposure
  - Toxicologist
- Remediation options = removal, washing
  - Vendors, stakeholders

Step 4: Define Boundaries

- Spatial and temporal boundaries
  - Definition of target population
  - Specification of subpopulations (i.e., areas/time periods within which target population is heterogeneous)
- Scale of decision making
- Practical constraints



Boundaries for EMCA Site

- Spatial boundaries
  - Surface soil ≤ top two inches of soil
  - Subpopulations -- left for exercise
- Temporal boundaries
  - Data used for estimating long-term exposures
  - Low volatility & stability of PCBs in soil, moderate climate => temporal flexibility in sampling
- Scale of decision making
  - Residential scenario => 1/2 acre
  - Industrial scenario => larger areas

Setting the Scale of Decision Making

What is the basis for the action level:

- if risk based, what is appropriate scale(s) for data aggregation, given expected future land use?
- if remediation based, what is smallest practical volume/area that can be remediated using the most likely remedial alternatives (e.g., removal, in situ treatment)?
- if regulatory based, what time/space requirements are specified by regulations?

1ppm = Action Level

Tips for Setting Boundaries

- Ensure that each subpopulation for which a separate decision is desired is well-defined and appropriate
  - Each additional subpopulation will increase data requirements
- Utilize site maps to depict subpopulation of interest and corresponding sampling design
- Make sure the design team has an adequate understanding to select appropriate sampling methods (e.g., depth of surface soil)

Step 5: Develop a Decision Rule

- Combine the decision rule elements into an "If... then..." statement that provides the logical basis for choosing among alternative actions
  - Parameter of interest = mean
  - Action level = PCB Soil Screening Level is 1 ppm
  - Alternative actions = design remedial action, no action
  - Scale of decision making = sampling zone
  - Surface soil definition = top 2 inches
- After Step 7, ask "Will collected data be sufficient to resolve this decision?"

Decision Rule Example

If the *mean* concentration of PCBs within a *decision unit* *(size, depth, location)* is greater than 1 ppm, then take remedial action. Otherwise, no further action is required.

Data Quality Objectives: Outputs from Each Step of the Process

DQOs

Problem: _____

Decision: _____

Inputs: _____

Boundaries: _____

Decision Rule: _____

Limits on Decision Errors: _____

Get consensus from all stakeholders

Next Steps

- Documenting DQO Outputs in the QAPP
- Step 6: Specify Limits on Decision Errors
  - How to determine decision error rates based on potential consequences of an error
- Step 7: Optimizing the Data Collection Design
  - How the DQO outputs from Steps 1 to 6 are used in sampling design
  - Different types of designs

Boundaries Setting Activity

1. **Open the "Boundaries Setting Activity" envelope that contains instructions, one 11 x 17 OU2 site map, and several 8.5 x 11 copies of that map.**

2. **Turn to pages J-5 through J-7 in your journal to view other site maps and a conceptual site model. Given this information, discuss a rationale for multiple decision units (DUs).**

3. **In your group, reach consensus on DU boundaries.**

4. **Using the ruler and colored pencils at your table, document your group's boundaries on the 11 x 17 OU2 map.**

DQO Process Step 6: Specifying Limits on Decision Errors

Step 6 Overview

- Describe decision errors
- Determine potential consequences
- Define the baseline condition
- Specify quantitative limits on decision errors

What are Decision Errors?

Decision errors occur when data mislead a decision maker to draw a conclusion that is inconsistent with the true state of nature

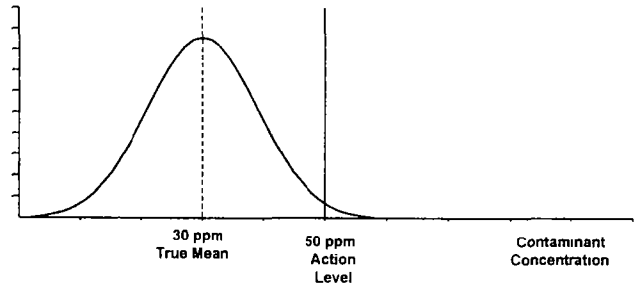
- We're doing our best by basing our decision on scientific observations (good decision)
- However, by chance (or undetected problems) our observations unwittingly lead us to an erroneous conclusion (bad outcome)

Good News / Bad News

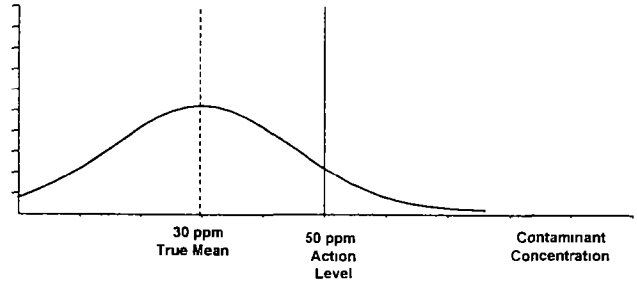
- Usually the data will be "close enough" to the truth and we will make the right decision
- The consequences of being wrong might be severe enough to impact negatively on human health
  - If so, we need to reduce the chance of making a decision error to tolerably low levels

Probability of Making Decision Errors Depends on Variance

- Variability in observations is due to variation in the population and random errors from sampling and measurement

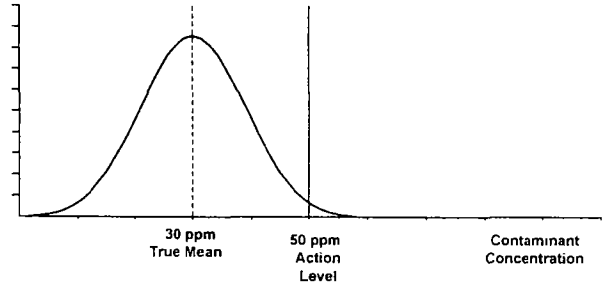


- The greater the variation, the greater the chance of observing values that are far away from the true mean

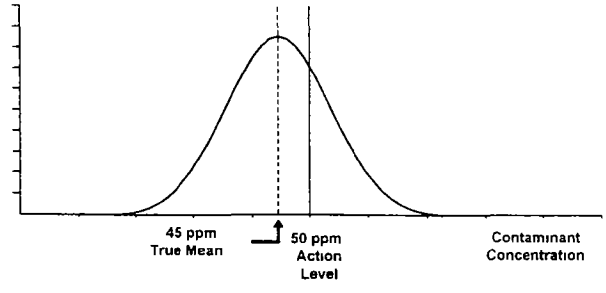


Probability of Making Decision Errors Also Depends on Context

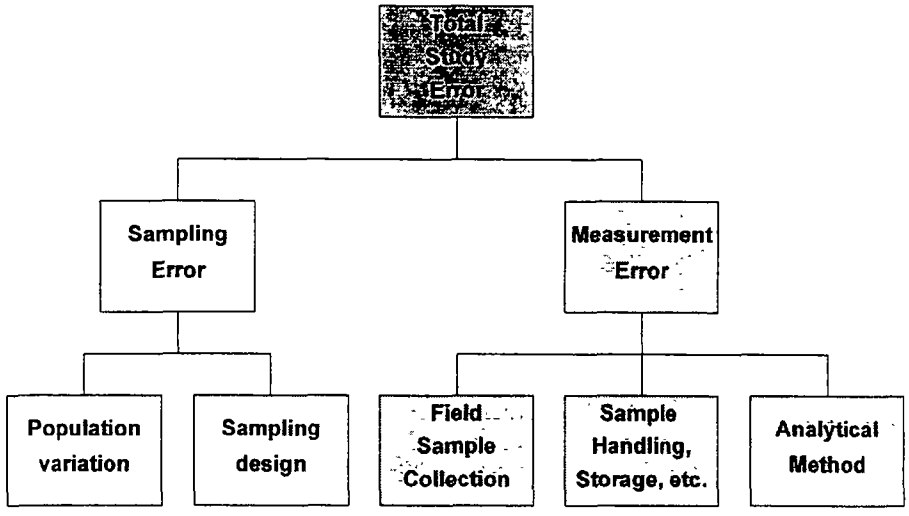
- If the true mean is much less than the action level, high values are less likely to be observed, which reduces the chance of reaching a wrong conclusion



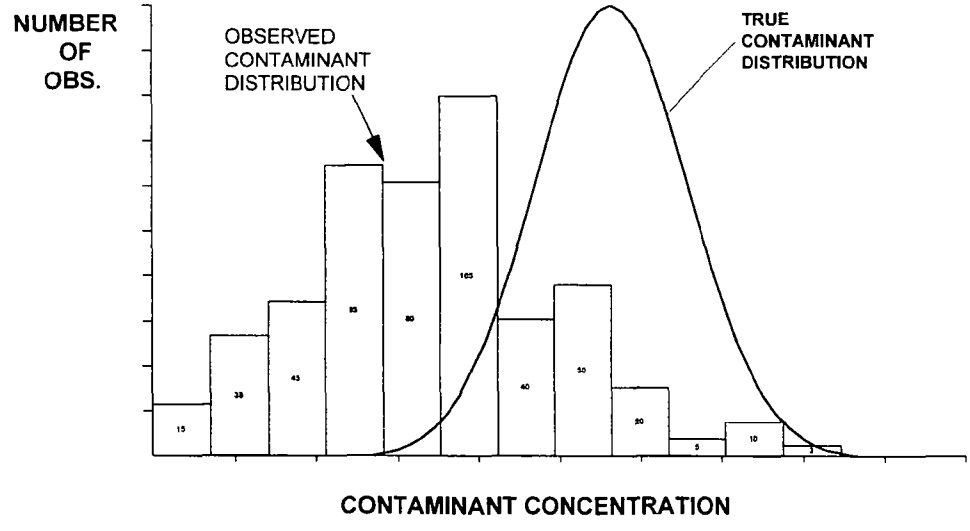
- If the true mean is close to the action level, higher values are more likely to be observed, which increases the chance of drawing an erroneous conclusion



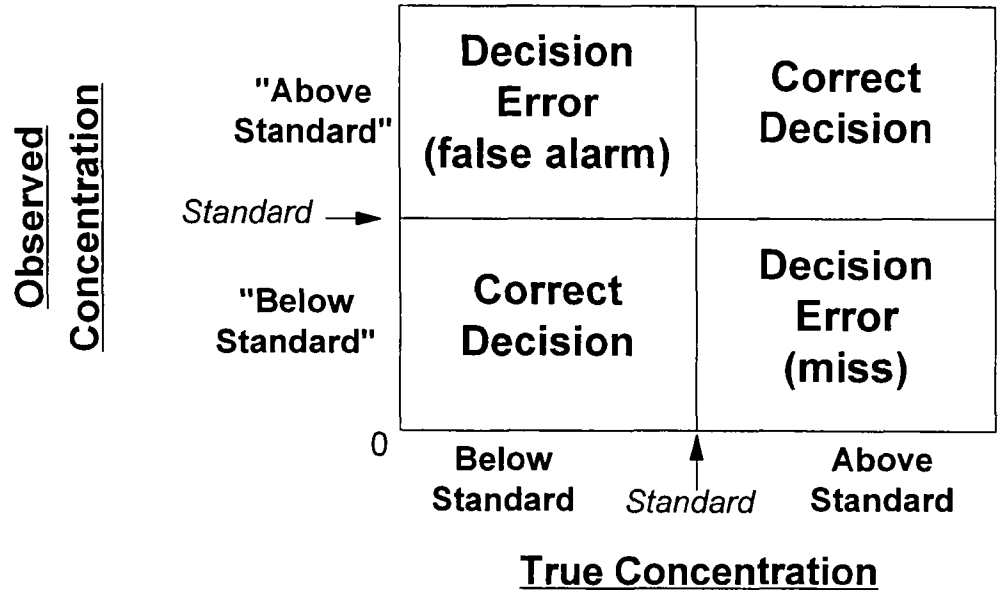
Decision Errors Derive from Total Study Error



Data values may not agree with the true population distribution



Another View: Truth Table



EMCA Decision Errors

The two decision errors for the EMCA Site:

- Decide to proceed with remedial design when the true mean PCB concentration is less than 1 ppm
- Decide to take no further action when the true mean PCB concentration is greater than 1 ppm

Determine Potential Consequences of Decision Errors

- Anticipate what might happen if you commit a decision error
- Consequences may include:
  - Human health risks
  - Ecological risks
  - Political risks
  - Social risks
  - Economic risks
  - Schedule risks

Worksheet: Consequences of Decision Errors

Proceed with remedial design when true PCB mean < 1	Take no further action when true PCB mean >1
• no serious risks	• sensitive pop. at risk esp.
• "	• damaged eco sys.
• if later discovered could be pol. fallout	• "
• spend $s needed elsewhere	• could cost more later to remediate
• none	•

Define the Baseline Condition

- Establishes where the "burden of proof" lies
- Can be based on any of several considerations:
- Regulatory requirements
  - Severity of decision error consequence
  - Preponderance of prior evidence
  - Technical issues
- Under Soil Screening framework (Superfund and Agency guidance), presume that the site is contaminated

Site Condition

Baseline: Site is unacceptably contaminated (i.e., true mean PCB concentration is greater than 1)

- *Scientists and statisticians call this the Null Hypothesis*

Alternative: Site is considered clean (i.e., true mean PCB concentration is less than 1)

- Scientists and statisticians call this the *Alternative Hypothesis*

Decision Errors

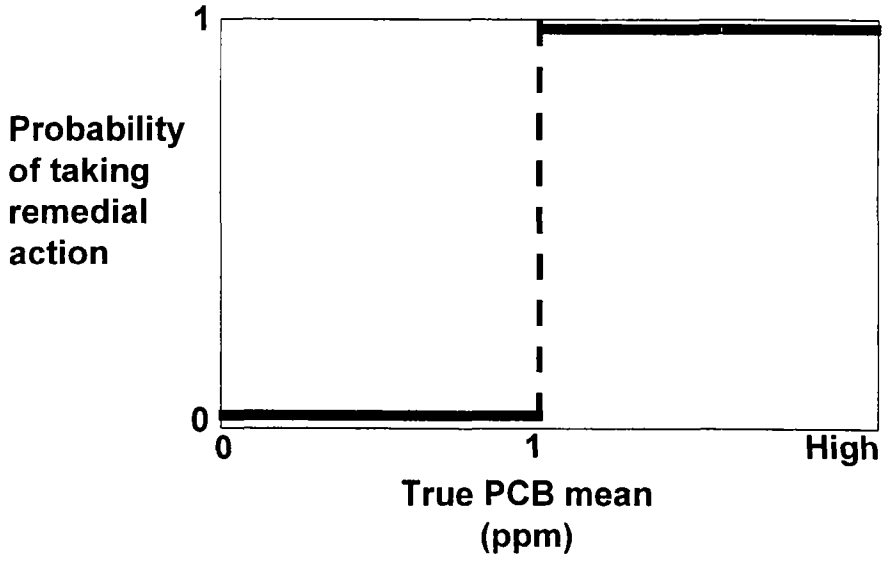
Baseline Condition: true PCB mean > 1

- Type I Error (false positive or false rejection): Data indicate the site is clean when, in fact, the site is unacceptably contaminated
- Type II Error (false negative or false acceptance): Data indicate the site is unacceptably contaminated when, in fact, the site is clean

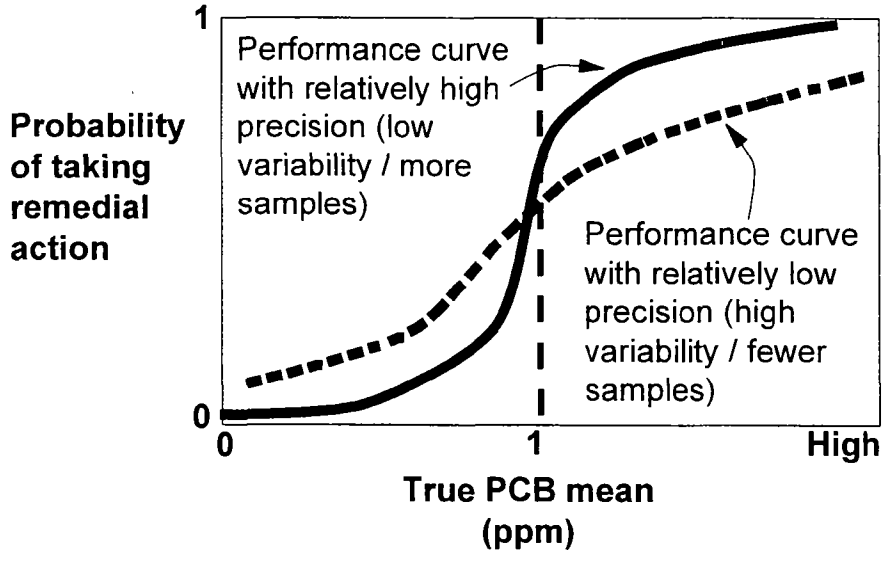
Setting Quantitative Limits

- What range of mean PCB contamination is possible at the site?
- What is the range of the true PCB mean concentrations where the consequences of your decision are relatively minor?
- What are your tolerable probability limits for making an incorrect decision?

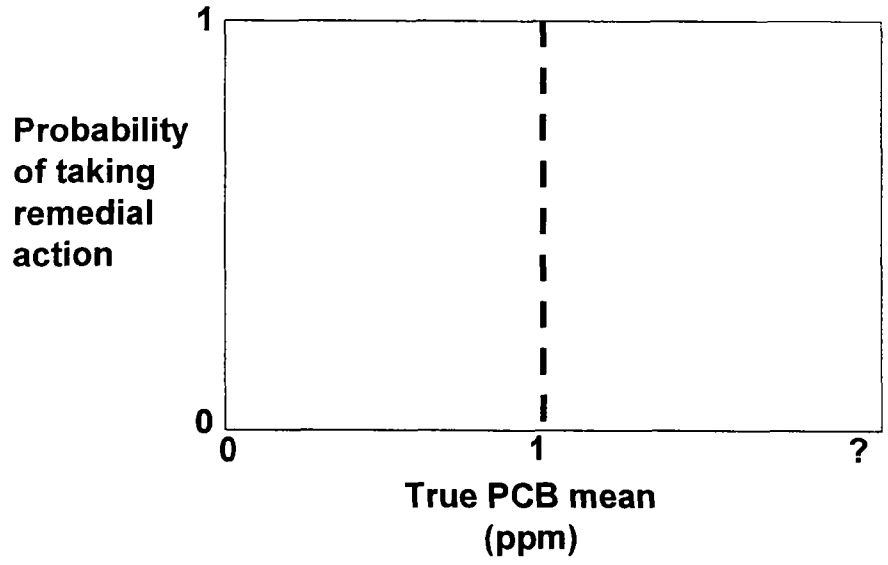
An Ideal Sampling and Measurement System



Real-World Sampling and Measurement Systems



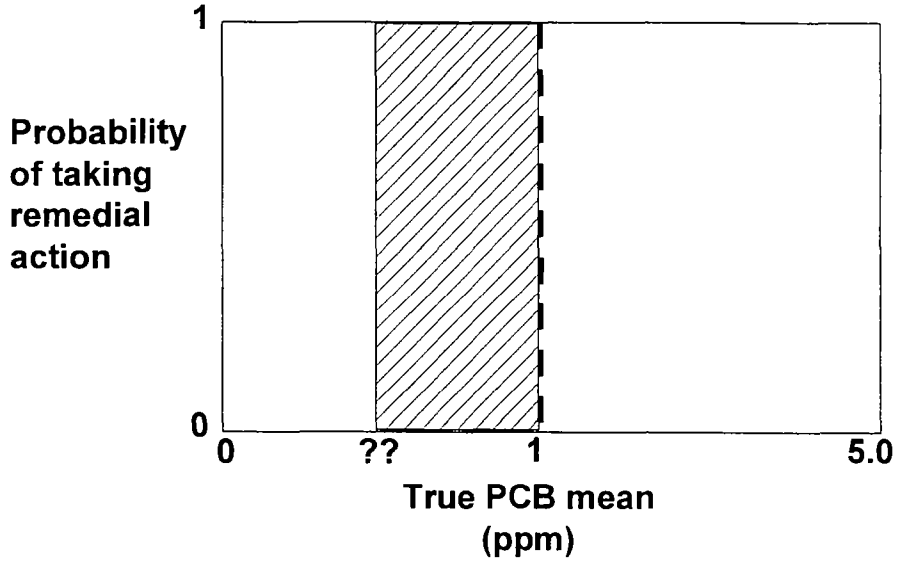
Decision Performance Goal Diagram: Parameter Range of Concern



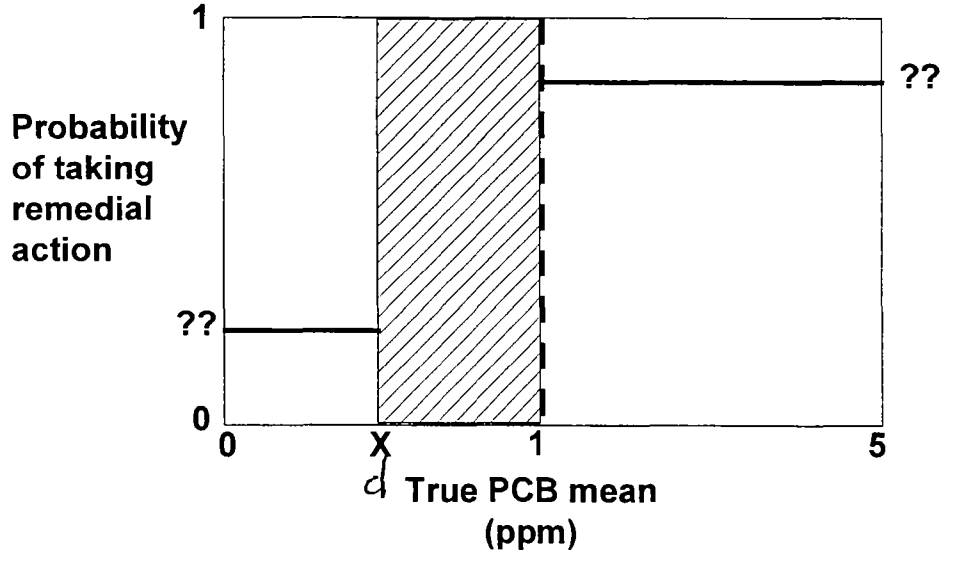
Gray Region

- Gray region - the range of possible mean PCB concentration values where the consequences of decision errors are relatively minor (too close to call)
- Bounded on one side by the action level (1 ppm)
- Bounded on the other side by the mean PCB concentration where consequences of making a decision error begins to be significant

Quantitative Limits: Example of Gray Region



Assigning Probability Limits



Setting Decision Error Limits: Some Existing Starting Values

Organization	Media	Baseline condition	Gray Region	Type I error rate (alpha)	Type II error rate (beta)
Superfund Soil Screening Guidance	soil	Contaminated	1/2 SSL to 2xSSL	05	.2
Superfund DQO Guidance	soil, groundwater, air	Contaminated	none specified	01	01
Superfund Data Usability for Risk Assessment	all media	(Not contami-nated)	(no specific recom-mendation)	20	.10
Washington State	soil, groundwater			.05 for comparing data with background or standard	
RCRA ASTM	groundwater			.05 for detection monitoring .01 for single comparison	

Construct a "What If" Table for the EMCA Site

Measured Conc. (ppm)	Decision	True Conc. (ppm)	Error Type	Tolerable Decision Error Rate
>1	Cleanup	0-d	II	
>1	Cleanup	d-1	I	Gray Region
<1	Leave	1-5	I	

d = the lower bound of the gray region

Next Steps

- Complete your DQOs (exercise)
  - Specify your team's limits on decision errors
- DQO Step 7: Optimizing the Data Collection Design
  - Sampling design process
  - DEFT software

Step 7: Optimizing the Design for the EMCA Site

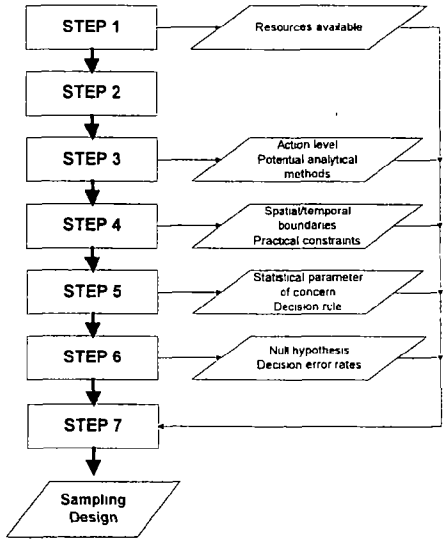
What is Needed to Complete Step 7?

- The Decision
  - parameter of interest (mean, boundary, maximum)
  - decision unit
- The Decision Error Limits
  - consequences of inappropriate actions
  - how decision errors could be made based on sampling data
- Conceptual Site Model
  - where do we expect to find contamination?
  - how do we expect it is distributed?
- Cost information

"Optimize" the Sampling Design

- "Optimal" measured in terms of decision error
- Provides suitable data to make decisions about the site
- Risk versus cost tradeoffs are required
  - EPA QA/G-4 is silent on how to make the tradeoffs
  - Methods are available: cost/benefit, decision analysis, value of information
  - Must be acceptable to all stakeholders
- Step 7 outputs
  - Number of samples required (in DQI & DQA lectures)
  - Quality of samples required (in DQI lecture)
  - Type of samples required (Step 4, DQO Process)
  - Location (spatial) and timing (temporal) of samples required (focus of this lecture)

What do DQOs tell us for developing the design?



Types of Sampling Design Approaches

- Haphazard
- Judgmental
- Search <-- begin in likely areas - where find contamination, move out from there
- Probability Based
  - Simple random
  - Stratified
  - Multistage
  - Cluster
  - Systematic
  - Composite
  - Double

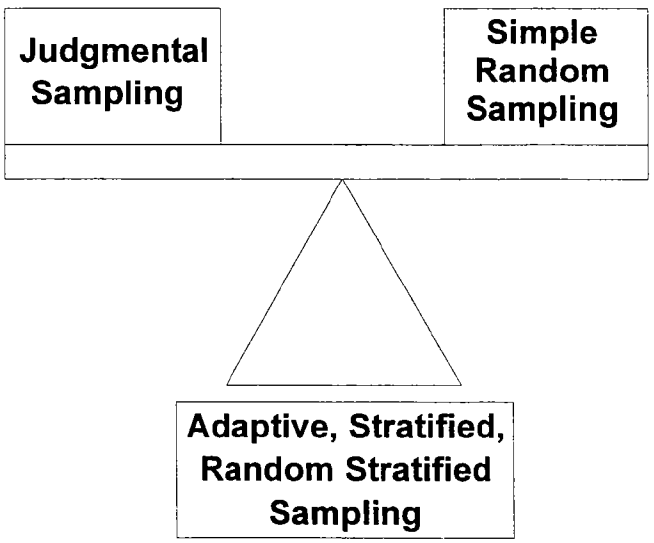
Non-Probability Based Designs

- Benefits
  - Useful in exploratory and feasibility studies
  - Analysis of historical data
- Drawbacks
  - Judgment samples are non-probability-based, and inference to the general population is problematic
  - Utility of a judgment sample is only as good as the conceptual model used to define the target population and the expert's knowledge
  - Cannot determine decision error or data variability

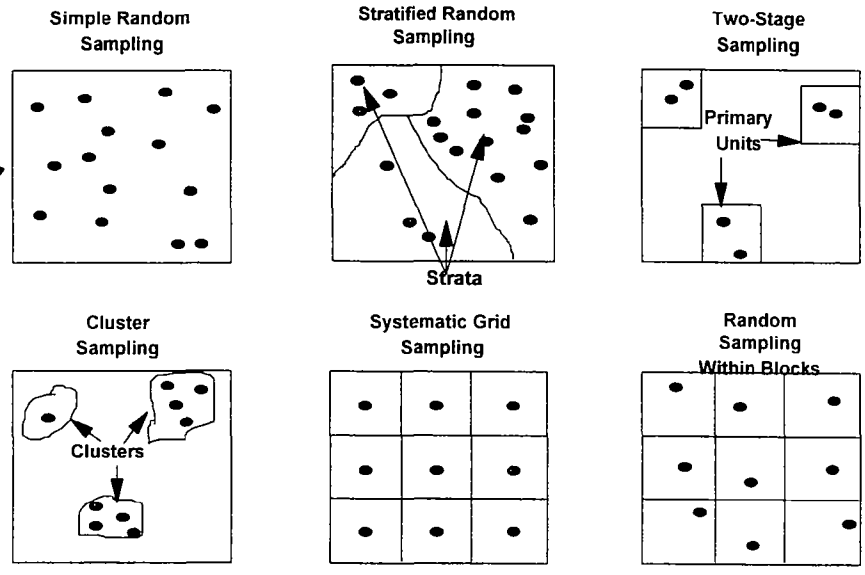
Probability Based Designs

- Benefits
  - Provides ability to estimate uncertainty
  - Reproducible results within decision error limits
  - Provides ability to make statistical inferences
  - Ability to handle multiple objectives and decision error criteria
- Drawbacks
  - Can be more expensive than judgmental sampling
  - Optimal design depends on a good conceptual model

Type of Sample: Hybrid



Probability Based Sampling



If have no assumpt. or info, yet Reg. more samples

Which designs may work best?

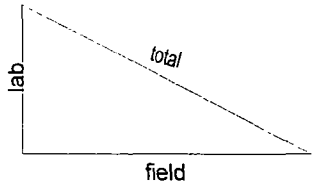
- Simple random sampling -- hard to do in the field; not feasible given project constraints.
- Systematic grid sampling -- inconsistent with DQOs (not searching for hot spots).
- Composite sampling -- potentially feasible; will investigate.
- Stratified random sampling -- potentially feasible will investigate later if necessary.
- Other designs -- may be possible if initial designs are infeasible; will investigate later if necessary.

Evaluating design alternatives

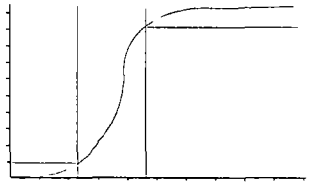
- Professional judgment may be necessary to reduce the number of potential designs to a more manageable number.
- Each design must be associated with a statistical test that can be applied to the data, consistent with DQOs.
- Statistical aspects of sampling design -- design will control decision error by controlling major sources of data variability (e.g., spatial, support, lab)
- Resources: *Guidance on Sampling Design to Support Quality Assurance Project Plans* (EPA QA/G-5S); *Guidance for Data Quality Assessment* (EPA QA/G-9).

How should we evaluate the performance and cost of each design?

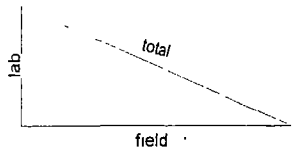
1. Model variability (sources are additive)



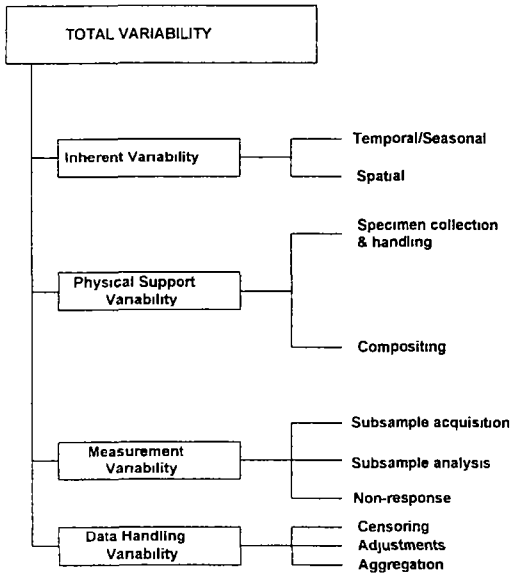
2. Model performance (design statistical test)



3. Model cost



Modeling Variability



- **Develop a model for the sampling variability of the parameter of interest.**
- **To estimate variability, examine data from a pilot study, studies of a similar population, or expert opinion.**
- **Variability is measured by variance or standard deviation**

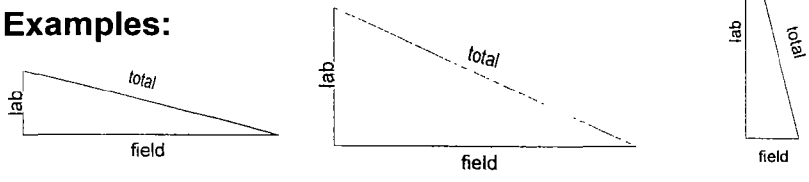
variance = Std. Dev.^{2}

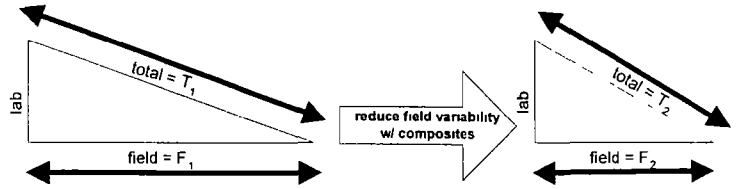
Modeling Variance (or Standard Deviation)

Generally speaking:

Total variability = laboratory variability + field variability

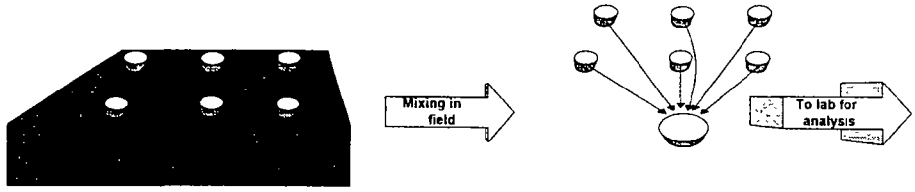
Examples:





longest leg gives biggest bang for buck in reducing variability

Compositing



- Compositing is a "physical averaging" that reduces the variability of data
- Usually applied when estimating a mean
- Very useful when cost of analysis is high compared to cost of sample collection in the field
- Very useful when relatively large field variability obscures interpretation of data

The Effect of Compositing

- The effectiveness of compositing depends on the ratio of laboratory variability to total variability

  Define $r = \frac{\text{standard deviation (lab)}}{\text{standard deviation (total)}}$

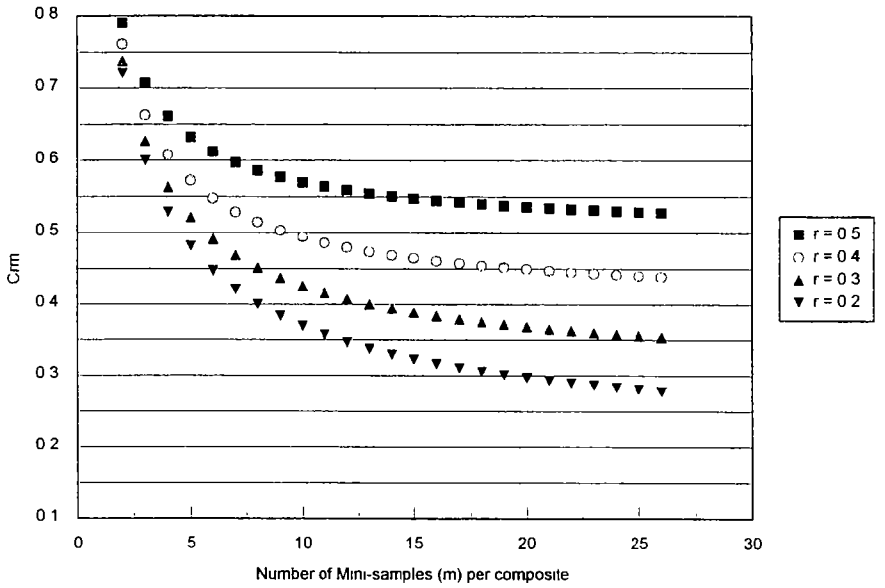
- Then form "n" composite samples having "m" mini-samples, and the composite standard deviation is:

  Standard Dev(composite) = C_{rm} * standard dev (total)

  Where: C_{rm} is a constant depending on "r" and the number of mini-samples

To reduce the size of Std. Deviation

Increasing Compositing Is Not Always Cost-effective



Improving/Reducing the Estimate of Variance

- Improve the estimate of variability using past records, preliminary results, expert opinion, or a pilot study
- Reduce variance using design features
  - Divide the problem into homogenous areas
  - Further reduce variability by compositing within decision units
- Investigate the use of more sophisticated schemes
  - Double sampling screening
  - Sequential systematic compositing
  - Adaptive cluster sampling

EMCA/ECC Site

- Decision made to use composite sampling
- Team must:
  - Review budget constraints specified earlier in the DQO Process
  - Develop a cost model based upon estimates of field and lab costs and calculate the cost of collecting and analyzing n samples with m increments per sample.

Tradeoffs Will Be Necessary

- The exact combination of:
  - samples (n), mini-samples (m);
  - quality versus quantity of data;
  - risk versus cost-benefit

  will be subject to negotiation.
- Each team will probably take a slightly different approach in evaluating these tradeoffs
- A more complex task may need simulation studies and computer-intensive methods

Selecting the Design...

- Team must document the design, overall rationale for selecting that design, and implementation procedures (QAPP element B1).
- This includes types of samples required, the sample size, decision units, temporal frequency, matrices, parameter(s) of interest, and rationale for the design.
- Documenting key assumptions of the design will be a starting point for Data Quality Assessment.

Selecting the Design...

- If none of the acceptable designs are affordable, revisit the DQOs and revise the budget constraints, alter the method(s) used to collect and/or analyze the data, or revise the performance criteria.
- If the least-cost design that satisfies the DQOs is too inexpensive, tighten the performance criteria or use a better (and presumably more expensive) method to achieve even higher power.
- If one of the designs achieves the DQOs and is cost-feasible, select this design.

The EMCA Site - Preliminaries

- Contract laboratory indicates $SD^{LABORATORY}$ to be about 0.3 (SD^{TOTAL} = 1.2) making the r-ratio about 0.25
- Project manager wants to use compositing to reduce variability by about two-thirds

The EMCA Site - Composite Mini-Samples

- Reducing total variability by roughly 66% (i.e., C_m=.33) with an r-ratio of 0.25 implies roughly 16 mini-samples needed per composite
- Field crew experienced in obtaining composites of 16
- Cost of collecting mini-samples relatively low

Sampling Design Exercise

Overview

- Exercise is divided into three parts:
  - Review/confirm decision unit (DU) boundaries and estimate total variability
  - Establish sample size(s) subject to a budget constraint
  - Document your design
- You have a $200,000 budget to establish a sampling design by working through these three tasks with your team.

Getting started...

1. Review DU boundaries.

2. Inventory exercise packet:
   - Instructions
   - 1 Sampling Design Calculations worksheet
   - 1 OU2 Sampling Plan (11" X 17")
   - 3 pilot study envelopes (DO NOT OPEN!)
   - 1 diskette

3. Decide whether you will purchase pilot study package(s) to improve your estimate of variability.

4. Revise boundaries of DUs, if necessary.

5. Use available information to generate estimates of total variability for each DU (record on worksheet).

6. Using SimCost.xls, calculate "r" for each DU.

Developing Your Design...

1. Use DEFT to generate sample size (n) and number of increments per sample (m) for each DU.
   - Laboratory costs per sample = $300
   - Field costs per sample = $15

2. Use SimCost.xls to calculate the cost of the design you established using DEFT. Are you within budget? If not, iterate back to Step 1.

3. Record final design on worksheet and save SimCost file as your team name on disk.

Documenting Your Design...

1. **Draw your decision units on your Sampling Plan (11" x 17"). Number the DUs and write m and n for each DU on the map.**

2. **Document costs on Sampling Design Calculations (SDC) worksheet.**

3. **Turn in completed: 1) Sampling Plan, 2) SDC worksheet, 3) diskette, 4) pilot packages**

4. **Make sure to write your team name on EVERYTHING!**

Integrating Quality Assurance into Project Development
Day 2

Overview

Day One

- How do you plan to collect the right data?
- How are your project and data quality objectives translated into a sampling design?

Day Two

- How do you document your planning and implementation activities in the project's QAPP?
- How do you verify that the data you collected met the assumptions you made during planning?
- What do your data tell you?

Learning Objectives

1. **Participants will be able to explain the value of systematic processes in developing QAPPs.**
2. **Participants will be able to describe the links between DQOs, DQIs, DQA, and the QAPP.**
3. **Participants will be aware of and be able to use QAD resources and tools, including: G-4, G-4D (DEFT), G-5, G-9, and G-9D (DataQUEST).**
4. **Participants will be able to explain how the outputs of DQO Process Steps 6 and 7, precision and bias assumptions, and distributional assumptions are used to develop a design.**

Day 2

8:30	Reconvene, overview of Day 2
	Relating DQIs to Sampling Design
	Design Comparison I
	BREAK
	QAPP Part B
	QAPP Part B exercise
	QAPP Parts C and D
12:00	LUNCH
1:00	QAPP C exercise
	Data Quality Assessment
	DQA exercise
	BREAK
	Design comparison II
	Application planning
5:00	Wrap up and dismiss

What's in store for today...

- QAPP Parts B, C, and D; DQIs; DQA.
- We used SimSITE to generate data for each table's design. You will assess your data.
- Combination of lecture, exercises, discussion, and hands-on practice will be similar to yesterday.

Nancy Hassig

Relating DQIs to Sampling Design

A Review: What Was Done in DQO Step 7

- Select an "Optimal" Sampling Design
  - Number of Samples
  - Type of Samples
  - Location of Samples
  - *Quality of Samples (e.g., field screening vs. CLP) must match with* $\hat{\sigma}^2_{total}$ *in sample size calculation*
- Cost of Desired Samples. If not within budget, need to make tradeoffs (revisit Step 6, possibly Steps 1-6, relax decision error rates, accept lower data quality)

DQO and DQIs

DQOs

How good does this decision have to be?

DQIs

How good do the data have to be?

DQOs are Driver for DQIs

DQIs = used in interpreting the degree of acceptability or utility of data.

What are the Primary and Secondary DQIs?

Primary DQIs: The **PARCCS** Parameters

- **Precision**
- **Accuracy (or Bias)**
- **Representativeness**
- **Comparability**
- **Completeness**
- **Sensitivity**

Secondary DQIs

- Recovery
- Memory Effects
- Selectivity
- Limit of Quantitation
- Repeatability
- Reproducibility

PARCCS Parameters

- **Precision, Accuracy, and Sensitivity**
  - Quantitative measures
- **Representativeness, Comparability and Completeness**
  - Qualitative measures
- **Accuracy (or Bias), Precision, Completeness and Comparability should be addressed in QAPP Section A7.3, *Specifying Measured Performance Criteria.* Representativeness should be discussed in QAPP Section B4.2, *Subsampling*, and B1, *Sampling Design.***
- **Sensitivity should be discussed in Section B4, *Analytical Methods.***

Precision

Definition: measure of agreement among replicates of the same property, under prescribed similar conditions

Options for Measure Reported:

Range	(x_{MIN}, x_{MAX})
Relative Range	$\left(\frac{x_{MIN}}{\bar{x}}, \frac{x_{MAX}}{\bar{x}}\right)$
Standard Deviation	$s = \sqrt{\frac{\sum_{i=1}^{n} (x_i - \bar{x})^2}{n-1}}$
Relative Standard Deviation	$\left(\frac{s}{\bar{x}}\right)$

Precision (cont.)

- **Components of precision:**
  - Sampling error
  - Field instrument measurement variation
  - Laboratory measurement variation
  - Temporal/spatial variation
  - Seasonality
  - Data preparation variation
- **Key driver for number of samples required, type of methods used to select and analyze samples**
- **Relative importance of components of precision should be considered (see Guidance QA/G-5I, *Data Quality Indicators***

Accuracy (Bias)

Accuracy comprised of both precision and bias and use of this term is archaic.

Definition: systematic or persistent distortion of a measurement process that causes errors in one direction.

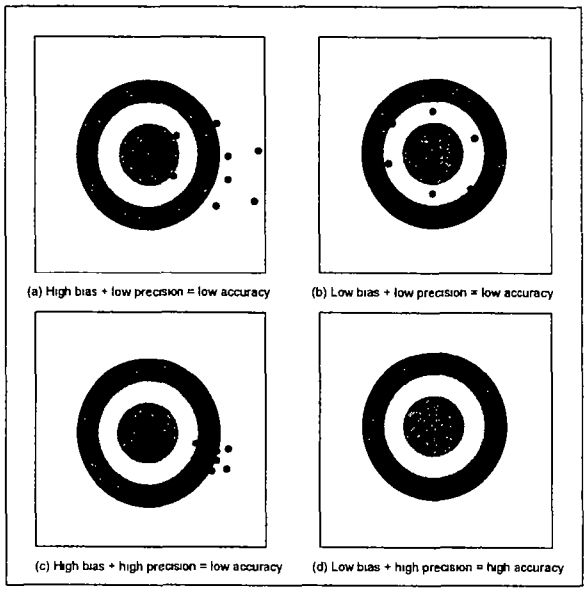
Options for Measure Reported:

Bias $(\bar{X} - T)$, where $\bar{X}$ is average value of a set of measurements of a standard and **T** is the reference value of the standard.

Percent Bias $\left(\frac{\bar{X} - T}{T}\right) \times 100$

Accuracy (cont.)

Shooting at a Target



* Representativeness

one of biggest sources of decision error

Definition: measure of the degree to which data represents a characteristic of:

- A population,
- A process condition, or
- An environmental condition.

Measure Reported: a qualitative statement of degree of representativeness and difficult to define precisely.

Statement may include justification of sample collection and handling techniques, description of sampling population vs. target population, and justification of sampling design used.

Only PARCC parameter that is defined outside of laboratory management process.

Representativeness (cont.)

- **Sources of Error**
  - Sample not representative of population
    - unknown or unequal sample selection probabilities
    - small sample volumes cannot capture full diversity of populations units
  - Sample selection method does not accurately capture material from natural setting
- **If data are not representative in some way, little significance can be assigned to other PARCC parameters.**
- **Lack of agreement during planning (in DQO Process) on the decision to be made may result in unrepresentative data.**

Comparability

Definition: measure of the degree to which two data sets can contribute to a common analysis and interpretation, and are equivalent with respect to measurement of a specific variable or group of variables.

Measure Reported: a qualitative statement of degree of comparability needing expert opinion.

Description of similarity/dissimilarity of variable(s) measured units, QA/QC methods used, time frame, sampling methods, analysis methods, and sampling designs.

Completeness

Definition: a measure of the amount of valid data obtained from a measurement system. Data may be lost, found invalid, or sampling design may be infeasible to implement.

The basis for determining the invalid data can have a large impact on bias.

Measure Reported:

- $\frac{\text{number of valid samples}}{\text{number of samples planned to be collected}}$
- Where the invalid data are located with respect to the valid data

Sensitivity

Definition: The capability of a method or instrument to discriminate between measurement responses representing different levels of a variable of interest.

Measure reported: The standard deviation of values at different concentration levels accompanied, when possible, by a probabilistic statement on the differentiation between adjacent values in the range of concentration of concern.

Where do targets for DQIs come from?

- **Regulations, Statement of Work, Record of Decision (Superfund)**
- **Laboratory or contractual requirements**

Answer: From risk versus cost tradeoffs established in the DQO Process

- Agreement established through Performance Based Measurement Systems

Quality Level Tradeoffs

Tradeoffs	Considerations
• **Large number of lower quality samples vs. small number of high quality samples.**	• **If both options meet decision performance criteria, select one with minimum cost.**
• **Spend more resources on better (more precise) methods**	• **If can't meet decision performance criteria must modify criteria sampling design.**
• **Increase duplicates, replicates, split samples, etc. to reduce component variabilities**	• **Budget constraints, sample collection method**

Components of Total Variability

$$\sigma^2_{TOTAL} = \sigma^2_{FIELD} + \sigma^2_{PHYSICAL\ SUPPORT} + \sigma^2_{LAB} + \sigma^2_{INSTRUMENT\ REPEATABILITY}$$

Sometimes can't decrease, only estimate more accurately

- Can spend resources to decrease
- Can select among options

Two Principal Sources of Variability

LABORATORY

- **Term to describe: precision**
- **Source: random errors in collection and measurement equipment**
- **Issue: since multiple measurements show range of values, what value to report?**

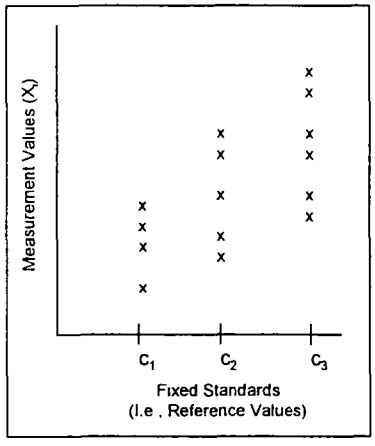
FIELD

- **Term to describe: variability**
- **Source: natural variability (spatial, temporal in population). Value varies from sample to sample. Major component of variability**
- **Issue: since multiple measurements show a "different view" of population, what decision to make regarding parameter of population?**

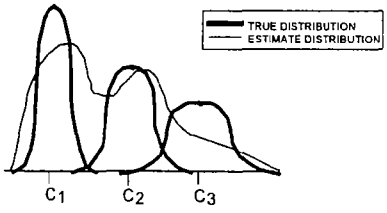
Reporting for Two Sources of Variability

(Also Called Random Errors, Precision, Uncertainty)

What Labs Mean by Uncertainty



What Statisticians Mean by Uncertainty



SAMPLE 1	SAMPLE 2
C_1	C_1
C_1	C_1
C_2	C_1
C_2	C_1
C_3	C_2
OVERESTIMATE TRUE CONCENTRATION	UNDERESTIMATE TRUE CONCENTRATION

Step 7: Optimize the Design

Sample Size Formula

$$n = \frac{(z_{1-\alpha} + z_{1-\beta})^2 \hat{\sigma}_T^2}{\Delta^2} + \frac{(z_{1-\alpha})^2}{2}$$

assuming Normality

Use Sample Size Formula to Help Make Tradeoffs

Type I ε Type II ε

$$n = \frac{(z_{1-\alpha} + z_{1-\beta})^2 (\hat{\sigma}^2_{POP} + \hat{\sigma}^2_{SAMPLE} + \hat{\sigma}^2_{LAB})}{\Delta^2} + \frac{(z_{1-\alpha})^2}{2}$$

grey area

- n is set by tradeoffs made in Step 7
- Prior estimates of the variance components are needed ($\hat{\sigma}$)

- the larger the grey area And/or
- the larger the α or β — the → larger N must be

Equipment/Method Selection Using Iterative Method with Sample Size Formula

Step 1: Calculate sample size formula using best quality estimate for $\sigma^2_T = \sigma^2_{POP} + \sigma^2_{SAMPLE} + \sigma^2_{LAB}$. Call this n_1.

Step 2: Compare cost for n_1 to sampling budget. If cost < budget, stop. If not, go to Step 3.

Step 3: Put negotiated n_2 into sample size formula and solve for σ^2_{LAB}. If equipment is available and within budget, stop. If not, iterate.

Guidance Document QA/G-5I: *Data Quality Indicators*, addresses this problem

Conclusions

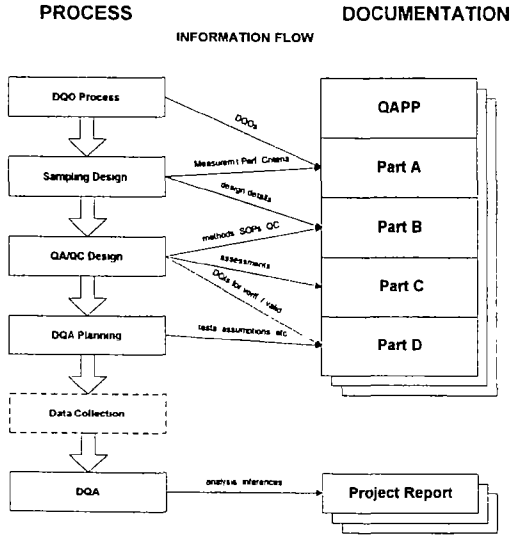
- DQOs are source for DQIs targets.
- Precision and bias have different interpretations depending on field vs. lab setting.
- Can't forget population variability and representativeness when considering overall effect of DQIs on decision making.
- No simple answers for DQIs. Sequential search techniques, tradeoffs, and performance evaluations are useful tools.

Team Exercise

- Identify significant sources of variability.
- Order them by relative magnitude.
- Identify ways to reduce the magnitude of variability.

Quality Assurance Project Plan: Measurement/Data Acquisition

Integrating QA Processes with Documentation Requirements



QAPP Structure
B. Measurement/Data Acquisition

- B1 - Sampling Process Design
- B2 - Sampling Methods Requirements
- B3 - Sampling Handling and Custody Requirements
- B4 - Analytical Methods Requirements
- B5 - Quality Control Requirements
- B6 - Instrument/Equipment Testing, Inspection, and Maintenance Requirements
- B7 - Instrument Calibration and Frequency
- B8 - Inspection/Acceptance Requirements for Supplies and Consumables
- B9 - Data Acquisition Requirements (Non-direct Measurements)
- B10- Data Management

DQO and QAPP Linkage

DQO Steps

QAPP Element Measurement/ Data Acquisition	1	2	3	4	5	6	7
B1				★	★	★	★
B2			★				★
B3			★				
B4			★				★
B5			★				
B6			★				
B7			★				
B8			★				
B9	★						★
B10		★					

Source EPA QA/G-5

B1: Sampling Process Design (Experimental Design)

- Type and number of samples required
  DQO Step 7, Optimize the Design
  DQI: Precision, Completeness, Representativeness

- Sampling design and rationale
  DQO Step 5, Develop a Decision Rule;
  DQO Step 6, Specify Tolerable Limits on Decision Errors;
  DQO Step 7, Optimize the Design

- Sampling location and frequency
  DQO Step 7, Optimize the Design;
  DQO Step 4, Define the Boundaries

- Schedules for collection and laboratory analysis

- Document key assumptions underlying design

B2: Sampling Methods Requirements

- Describe/reference the methods by which samples will be collected.
  DQO Step 3, Identify Inputs into the Decision;
  DQO Step 7, Optimize the Design

- Describe physical sample, including sample mass, sample volume, and/or sample matrix
  DQO Step 7, Optimize the Design

- What area or volume the sample will represent
  DQO Step 3, Identify inputs to the Decision;
  DQO Step 7, Optimize the Design
  DQI: Representativeness

B2: Sampling Methods Requirements (continued)

- Corrective actions for failure/inability to obtain samples
  DQO Step 7, Optimize the Design
- Procedures to prevent contamination / deterioration of the sample after collection

B3: Sample Handling and Custody Requirements

- Provisions for ensuring samples are handled by authorized personnel
- Provisions for ensuring sample integrity is maintained
- Procedures for maintaining written records of all phases of sample analysis
- Procedures for maintenance of chain-of-custody
  DQO Step 3, Identify Inputs to the Decision

B4. Analytical Methods Requirements

- Identify the analytical methods to be used (for PBMS, the performance characteristics)
- Procedures for sub-sampling necessary for the proposed analytical method(s)
- Procedures for sample preparation
- Sensitivity requirements/standards
- Identify all needed Standard Operating Procedures
  DQO Step 3, Identify Inputs to the Decision

B5. Quality Control Requirements

- Specify the technical activities necessary to produce data of the quality established by DQOs
- Other QAPP elements where QC data is specified (to be cross-referenced in this element):
  - B1, Sampling Process Design
  - B2, Sampling Methods Requirements
  - B3, Sample Handling and Custody
  - B4, Analytical Methods Requirements
  - B5, Instrument Calibration
- Include information on blanks, spikes, replicates used to control variability
  DQO Step 3, Identify Inputs to the Decision
  DQI: Precision, Bias

B6. Instrument/Equipment Testing, Inspection, and Maintenance Requirements

- Identify the method(s) and procedures for inspection and testing
- Specify the schedule and procedures for maintenance of QC performance measures
- Identify personnel responsible for maintenance and testing

DQO Step 3, Identify Inputs to the Decision

B7. Instrument Calibration and Frequency

- Identify procedures for and frequency of calibration
- Identify the documentation required for:
  - Calibration apparatus
  - Calibration standards
  - Calibration frequency

DQO Step 3, Identify Inputs to the Decision

B8. Inspection/Acceptance Requirements for Supplies and Consumables

- Identify items/supplies requiring inspection
- Document acceptance criteria
- Identify tracking procedures and frequency of inspection of supplies and consumables
  DQO Step 3, Identify Inputs to the Decision

B9. Data Acquisition Requirements (Non-direct Measurements)

- Identify types of data needed for project that are obtained from non-measurement sources
- Document rationale and relevance to project objectives
- Define acceptance criteria for and limitations on the use of data resulting from uncertainty in their quality
  DQO Step 1, State the Problem;
  DQO Step 3, Identify Inputs to the Decision

B10. Data Management

- Describe project data management scheme, including:
  - Data entry checks
  - Data transmittal procedures
  - Data tracking
  - Data storage and retrieval

DQO Step 2, Identify the Decision

QAPP Part B Activity

1. **As a team, consider elements B2 through B10 of the sample QAPP.**
2. **Assign each team member to review at least one of these elements in the sample QAPP.**
3. **Review your assigned element(s) and document your comments/findings on your QAPP review form.**
4. **In your group, discuss the questions listed on the exercise instruction sheet.**

Quality Assurance Project Plan: Assessment/Oversight Data Validation and Usability

C. Assessment/Oversight
D. Data Validation and Usability

- Assessing the effectiveness of the implementation of the project and associated QA/QC
  - C1 - Assessments and Response Actions
  - C2 - Reports to Management
- Determining whether or not the data conform to the specified criteria
  - D1 - Data Review, Validation, and Verification
  - D2 - Validation and Verification Methods
  - D3 - Reconciliation with User Requirements

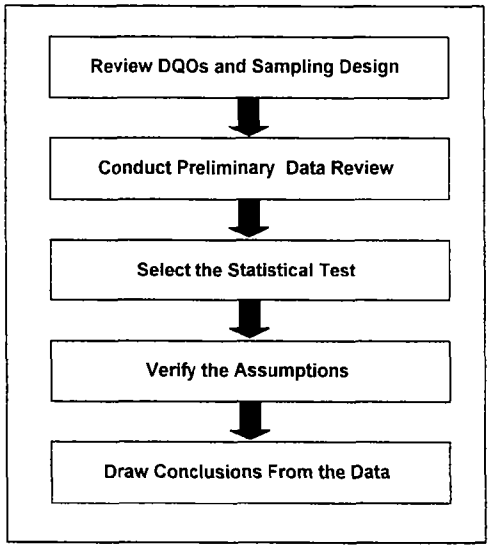
C1: Assessment and Response Actions

- Surveillance
  The observation of project implementation activities
- Technical Systems Audit (TSA)
  Formal audit of facilities, personnel, equipment, and record-keeping
- Performance Evaluation (PE)
  Independent evaluation for proficiency in analytical work
- Audit of Data Quality (ADQ)
  How the data were handled; were uncorrected mistakes present?
- Peer Review
  Refer to the Agency's peer review policy and guidance
- Data Quality Assessment (DQA)
  Application of statistics to the data

DQA Process

- Were the DQOs achieved?
- Should parts of the DQOs be changed?
- Where the assumptions made during planning viable?
- Were the statistical tests powerful enough?
- What supplemental information is needed?

Steps of the DQA Process



But is it really necessary to address DQA in a QAPP?

NO!

- How can you include statistical analyses if the data has yet to be collected? A QAPP must be approved before data collection.

YES!

- How else can you know if the data appear likely to meet the project objectives (DQOs)?

Resolution

- C1 should contain an outline of the proposed methods of DQA that will be used during the implementation phase to check:
  - key data assumptions
  - whether the DQOs are likely to be met

- C1 should also include a cross-reference to D3, which specifies the assessment-phase DQA procedures and where the complete DQA report/documentation may be obtained.

C2. Reports to Management

- Project status
- Results of Performance Evaluations and Technical Systems Audits
- Results of Data Quality Assessment
- Significance of QA problems and recommended solutions

D1. Data Review, Validation, and Verification Requirements

- Purpose of this element:

  To synthesize previously conducted activities and describe how deviations from the requirements specified in the QAPP will be addressed.

D2. Validation and Verification Methods

- Define verification and validation, e.g.,

  Verification: ***Have the procedures outlined in the QAPP been carried out properly?***

  Validation: ***Were the procedures used to generate the data consistent with the intended use of the data?***

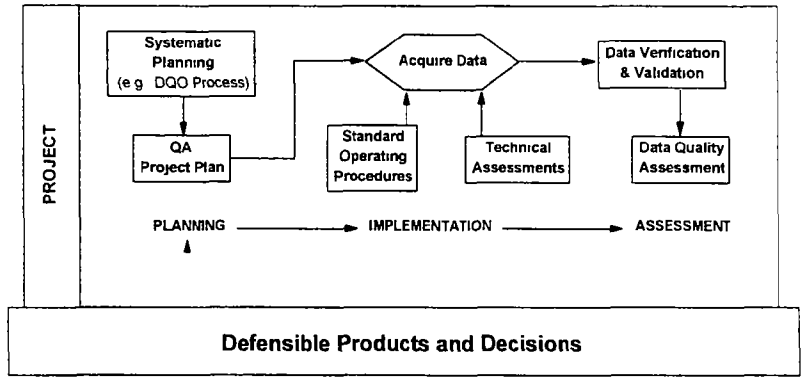
- Discuss the process for validation and verification of the data

- Describe how data verification and validation issues will be resolved and conveyed

D3. Reconciliation with DQOs

- Describe how the results will be reconciled with the DQOs established by the data user(s)
  - What types of calculations will be needed to check the DQO assumptions and draw conclusions?
- Define how the DQA results will be documented
- Discuss how limitations of the data will be reported to decision-makers

EPA Quality System - Project Level



QAPP Part C Journal Activity

1. **Turn to page J-8 in your journal and review the activity instructions.**
2. **Read an excerpt from EPA QA/G-5 about element C1 and an overview of technical assessments.**
3. **Write your responses to the questions listed on J-8.**
4. **In your group, discuss your individual responses.**

The Data Quality Assessment Process

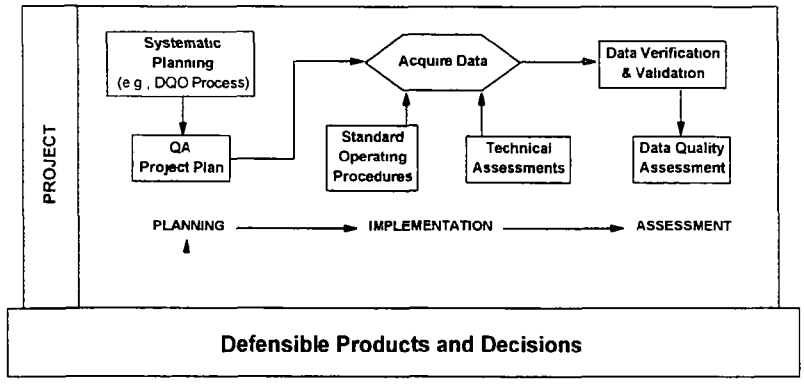
Objectives

- Participants will understand how DQOs are essential to DQA
- Participants will understand the meaning and value of verifying assumptions made when selecting the statistical test
- Participants will be able to produce various displays of data and understand the impact the visual display has on interpreting the results
- Participants will learn how to use and will be given the opportunity to conduct DQA on their own data sets.

What is the Data Quality Assessment Process?

- The statistical analysis of environmental data to determine whether the quality of data is sufficient to support the decision.
- Decisions (based on sample data collected) are made during the DQA Process.
- Does data provide "sufficient evidence" to draw conclusions about the site?

EPA Quality System- Project Level



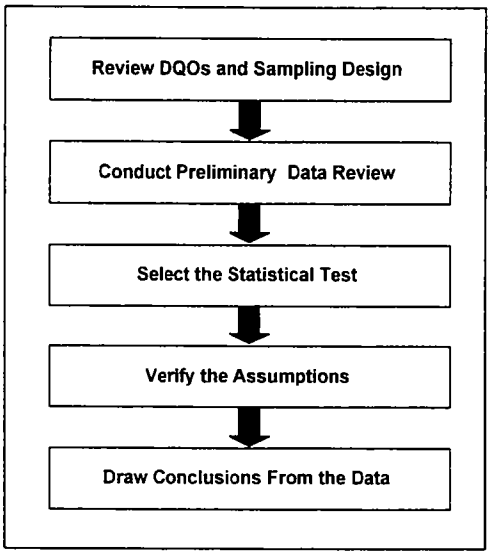
DQA Process: Answers it can provide

- Do the data violate the conceptual site model or test assumptions?
- Did I collect enough data?
  - Were the data quantity and quality consistent with the DQO assumptions and limits on decision errors?
- What do I conclude about the state of contamination at the site?

DQA Process: Answers it cannot provide

- Did I make a decision error?
  (good decision -- bad outcome)
- What are the "true" site conditions?
- Do I need different types of data?
  (may require another iteration through the DQO Process)

The Data Quality Assessment Process



The Data Quality Assessment Process

Guidance for the Data Quality Assessment Process (G-9)

- Written for non-statisticians
- Supplements Agency guidance
- Does not replace statistical texts
- Regular supplements
  - Current examples
  - Updated techniques
  - Shared information

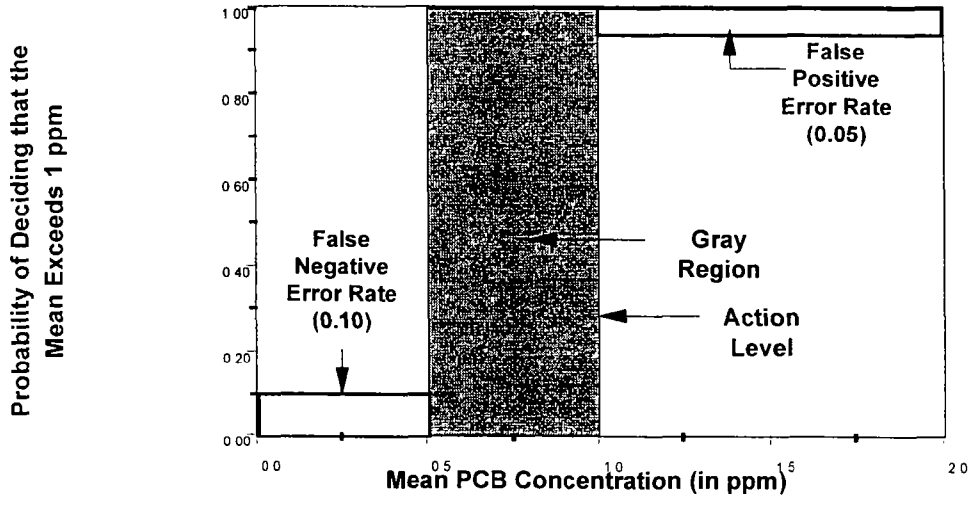
Data Quality Evaluation Statistical Toolbox (G-9D)

- Runs on most IBM-compatible personal computers
- Interactive and easy to use
- Implements tools from G-9

DQA Step 1:
Review DQOs and Sampling Design

- If DQO were previously developed, verify hypotheses, limits on decision errors
- If DQOs were not previously developed, consult the data user(s) to develop a hypothesis and limits on decision errors retrospectively.
- Review sampling design
  - Small deviations vs. major deviations
  - Was the design correctly implemented?

Tolerable Limits on Decision Errors



Investigation of Assumptions

- Conceptual model
- Sampling design
  - Independence of data
  - Variability estimates
  - Equal probabilities for sampling units
- Statistical test
  - Standard (parametric) versus non-parametric
  - Most powerful for data
- Performance Goal Diagram
  - Range of values for true parameter
  - Severity of consequences

Primary Statistical Hypotheses

If the mean concentration of total PCBs in surface soil (top 1 inch) over the Northeast quadrant (96,000 sq. ft.) decision unit exceeds 1 ppm, then investigate the area further; otherwise, take no further action. Baseline condition or assumption is that the true mean level of contamination is at least 1 ppm.

Baseline Condition (Null Hypothesis): Mean $\geq$ 1 ppm

vs.

Alternative Condition (Alternative Hypothesis): Mean < 1 ppm

Discussion Question

Given that we hold onto the baseline condition unless we have clear and convincing evidence otherwise, what would be clear and convincing numerical evidence?

Where Did the Samples Come From?

- The sampling area in the Northeast quadrant has been divided into 10 ft x 10 ft sampling units.
- The entire Northeast quadrant is 40 sampling units across by 24 sampling units down, creating a total of 960 sampling units.
- 60 sampling units will be selected on a rectangular grid with a random start.
- Each selected sampling unit will be further subdivided into a 3x3 grid (with a random start location). Nine minisamples will be collected and composited to form a single sample for analysis.

Sample Size Formula*

Assuming approximate normality,

$$n = \frac{(z_{1-\alpha} + z_{1-\beta})^2 \hat{\sigma}_T^2}{\Delta^2} + \frac{(z_{1-\alpha})^2}{2}$$

$$= \frac{(1.64 + 1.28)^2 (1.3)^2}{(.5)} + \frac{(1.64)^2}{2}$$

$$= 60$$

***Note:** α **= .05,** β **= .10**

DQA Step 2: Conduct Preliminary Data Review

- **Review quality assurance reports for anomalies**
- **Calculate standard statistical quantities**
- **Display the data using graphical representations**

Data (N=60)

PCB concentration levels were measured (in ppm) from 60 surface soil samples (top one inch of soil) from the area of concern. Each soil sample consists of 9 minisamples composited together.

2.9714918	0.3944508	0.0636396	0.0135851	0.2141057	0.8270809
0.4256530	0.3517509	7.4508734	0.0100000	0.2305239	0 0100000
0.1370552	0.3279608	2.0771547	0.0823492	0.5161426	2.4257983
0.4162389	0.4958090	0.2064603	2.0352892	0.2907452	0.0116283
0.3611203	0.0111995	0.1429569	0.5941579	0.4145329	0.0294908
0 1116369	0.5943270	0.5467844	0.0586851	0.0929529	0 4828711
0.1715708	0.0901670	0.0345738	0.0921064	0.2474780	0.1591530
0.0428163	0.0521538	3.1877187	0.0424898	0.0939190	4.9384590
0.3583117	0.0472357	0.1374893	0.0196463	2.2771285	0.2121811
0.0526599	0.1130365	0 4680810	2.2941993	0.1808077	0 0240088

Summary Statistics

Number of Observations: 60

Minimum:	**0.010**	**Maximum:**	**7.451**
Mean:	**0.670**	**Median:**	**0.209**
Variance:	**1.680**	**Standard Deviation:**	**1.296**
Range:	**7.441**	**Interquartile Range:**	**0.428**

Coefficient of Variation: 1.935
Coefficient of Skewness: 3.357
Coefficient of Kurtosis: 12.542

Percentiles:

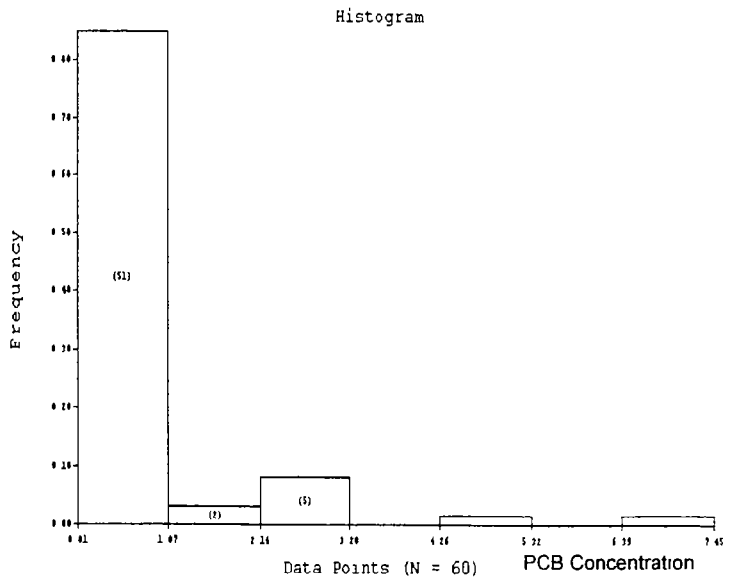
1st:	**0.010**	**75th:**	**0.489**
5th:	**0.011**	**90th:**	**2.286**
10th:	**0.022**	**95th:**	**3.080**
25th:	**0.061**	**99th:**	**7.451**

Cleaning-up the Data

Data rounded to the closest hundredth:

2.97	0.39	0.06	0.01	0.21	0.83
0.43	0.35	7.45	0.01	0.23	0.01
0.14	0.33	2.08	0.08	0.52	2.43
0.42	0.50	0.21	2.04	0.29	0.01
0.36	0.01	0.14	0.59	0.41	0.03
0.11	0.59	0.55	0.06	0.09	0.48
0.17	0.09	0.03	0.09	0.25	0.16
0.04	0.05	3.19	0.04	0.09	4 94
0.36	0.05	0.14	0.02	2.28	0.21
0.05	0.11	0.47	2.29	0.18	0 02

Viewing the Data (Frequency Histogram)

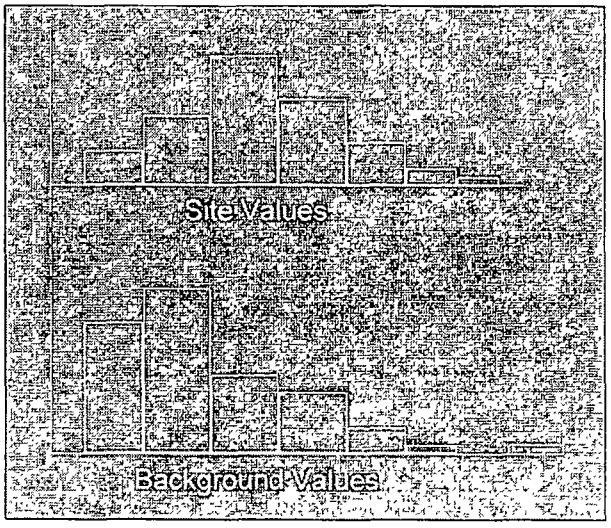


Care should be taken to ensure that the box sizes have contextual meaning.

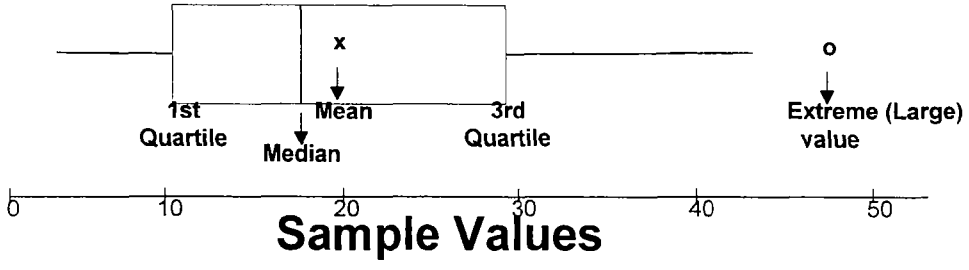
G-9, Section 2.3 1, G-9D - Graphs,1

Graphical Displays

- **Multiple histograms can be similarly useful:**

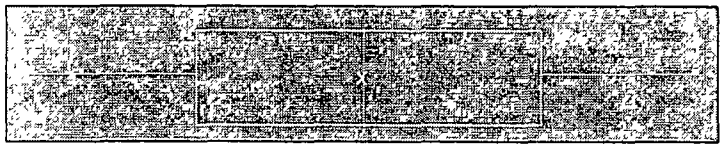


Boxplot (Box and Whiskers)

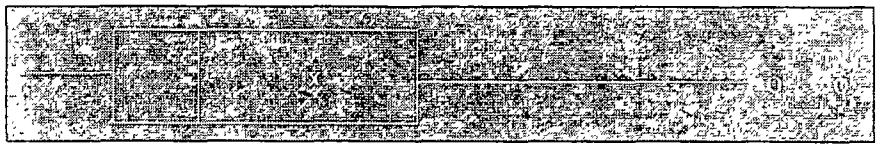


Boxplot Examples

- Boxplot for normal data:

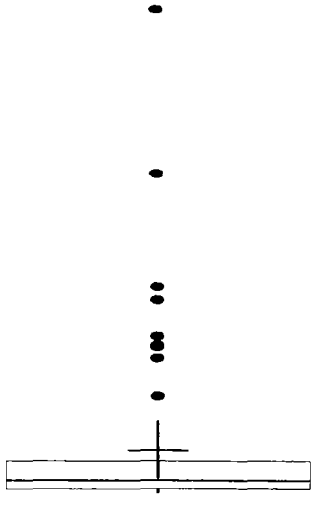


- Boxplot for lognormal data:



  - Data transformation may be useful

Graphical Representations
Boxplot for EMCA data



G-9, Section 2 3 3, G-9D - Graphs,3

DQA Step 3: Select the Statistical Test

- Select the statistical test based on the data user's objectives and the preliminary data review
- Identify assumptions underlying the statistical test:
  - Distributional form
  - Independence
  - Dispersion characteristics
  - Homogeneity
  - Basis for randomization

Statistical Tests

- One sample tests
  - Standard (parametric) vs. non parametric
  - one sample t-test, Wilcoxon signed rank test, sign test, one sample proportion test
- Two sample tests
  - Student's two sample t-test (equal variances)
  - Satherwaite's two sample t-test (unequal variances)
  - Wilcoxon rank sum test, slippage test, quantile test, two sample proportion test

Select Test and Identify Assumptions

e.g., ONE SAMPLE t-TEST

- No outliers (sample mean and standard deviation are very sensitive to outliers)
- Sample mean is approximately normally distributed
- Random sample (independence of the data values)
- Has difficulty in dealing with less-than values, e.g., values below the detection limit

G-9, Section 3.2 1.1

DQA Step 4: Verify the Assumptions of the Statistical Test

- Determine approach for verifying assumptions
- Perform tests of assumptions
- If necessary, determine any corrective actions

Identifying Outliers

- Is the extreme value of 7.45 a statistical outlier?
- Extreme Value Test will be used
- Test assumes data without outlier are normally distributed

Discordance Test for Outliers

Null Hypothesis: The value 7.45 belongs to the rest of the data.
Alternative: The value 7.45 is an outlier.

Value Tested: 7.451
Sample Value: 5.231
Tabled Value: 2.956

For this test, reject the Null if sample value exceeds tabled value.

Conclude 7.451 is an outlier at a 1% significance level.

G-9, Section 4 4 4; G-9D - Tools, 3, 2

Testing Data for Normality

Filliben Test

Null Hypothesis: Data are normally distributed.
Alternative: Data are not normally distributed.

Sample Value: 0.736
Tabled Value: 0.970

For this test, reject the Null if the sample value is less than tabled value.

Conclude that non-normality has been detected at a 1% significance level.

G-9, Section 4.2.2; G-9D - Tools, 1, 1, 1

Not Normally Distributed - What Should We Do?

- **Data appear to be skewed in the histogram, which may indicate a lognormal distribution.**
- **So, apply Filliben Test to natural logarithms of the data to test for lognormality. If logged data are normally distributed, then untransformed data are lognormally distributed.**
- **Original data value 0.011 becomes -1.951, 7.451 becomes 0.872, etc.**

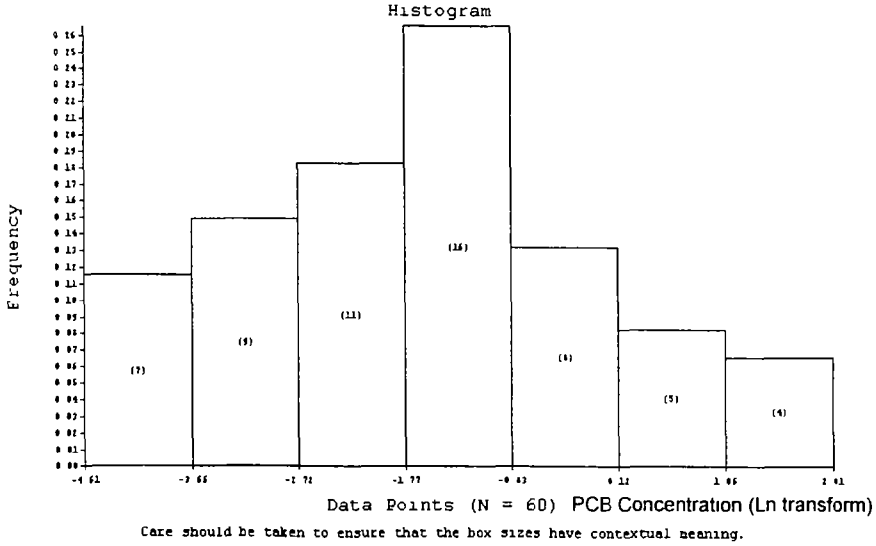
Summary Statistics: Transformed Data

Number of Observations:	60		
Minimum:	-4.605	Maximum:	2.008
Mean:	-1.620	Median:	-1.564
Variance:	2.607	Standard Deviation:	1.615
Range:	6.614	Interquartile Range:	2.080
Coefficient of Variation:	-0.997		
Coefficient of Skewness:	0.107		
Coefficient of Kurtosis:	-0.451		

Percentiles:

1st:	-4.605	75th:	-0.715
5th:	-4.473	90th:	0.827
10th:	-3.830	95th:	1.124
25th:	-2.795	99th:	2.008

Viewing the Transformed Data

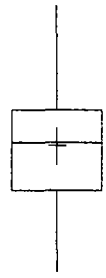


Care should be taken to ensure that the box sizes have contextual meaning.

G-9, Section 2 3 1, G-9D - Graphs,1

Box and Whiskers Plot

- Natural log transformed data



Testing Data for Lognormality

Filliben Test

Null Hypothesis: Data are normally distributed.
Alternative: Data are not normally distributed.

Sample Value:	**0.978**
Tabled Value:	**0.970**

For this test, reject the Null if the sample value is <u>less</u> than tabled value.

There is not enough evidence to reject the assumption of lognormality with a 1% significance level.

G-9, Section 4 2.3, G-9D - Tools, 1, 1, 1

Testing Data for Lognormality

- Cannot reject the assumption that the data are lognormally distributed and that the logs of the data are normally distributed.
- Apply test for outliers on the logged data.
- Extreme value of 7.451 becomes 2.008.

G-9, Section 4 6, G-9D - Tools, 5

Discordance Test for Outliers: Transformed data

Discordance Test for Outliers

Null Hypothesis: The value 2.008 belongs to the set of data.

Value Tested: 2.008
Sample Value: 2.247
Tabled Value: 2.956

For this test, reject the Null if sample value exceeds tabled value.

There is not enough evidence to conclude that 2.008 is an outlier at a 1% significance level.

G-9, Section 4 4 4; G-9D - Tools, 3, 2

Are Assumptions Satisfied?

- ✓ Outliers? None; high values can be expected with lognormally distributed data.
- ✓ Sample mean approximately normally distributed? Invoke Central Limit Theorem (or perform tests on natural logs of data).
- ✓ Random sample? Rectangular grid with a random start location and composite samples.
- ✓ Data below the detection limit? Only 2 non-detects in this example. Detection limit is much smaller than action level, so impact is minimal.

DQA Step 5: Draw Conclusions from the Data

- Perform the calculations for the statistical hypothesis test
- Evaluate the statistical test results and draw conclusions
- Evaluate the performance of the sampling design if the design is to be used again

Perform Calculations -- Natural Log Scale

Student's t-Test for a One-Sample Mean

In natural log scale, action level is 0 (i.e., ln(1)=0)

Null Hypothesis Ho: mean $\geq$ 0.0
Alternative: mean < 0.0

Sample Value (t) = -7.770
Tabled Value = -1.671

For this test, reject the Null if the sample value is <u>less</u> than the tabled value.

Reject null hypothesis at a 5% significance level.

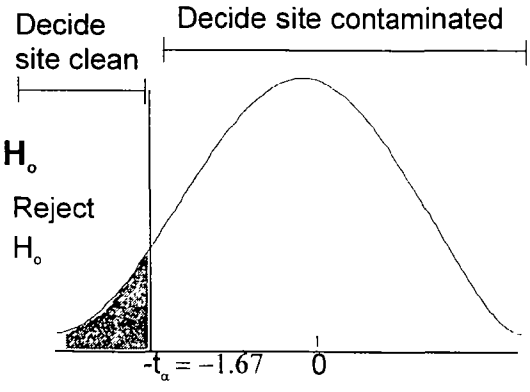
G-9, Section 3 2 1 1, G-9D - Hypothesis, 1

Perform Statistical Test

- **Calculate *t* test statistic for transformed data**

$$t = \frac{\bar{x} - \mu}{s/\sqrt{n}} = \frac{-1.62 - 0}{1.615/\sqrt{60}} = -7.77$$

- **For H_o: μ_T >0 ppm**
  Reject H_o if $t \leq -t_\alpha$
  Since -7.77 $\leq$ -1.67, reject H_o



Interpreting Statistical Results

"Significant at 5%"

- If the Null Hypothesis is true yet the statistical test rejects the null hypothesis at a 5% significance level, such chance sampling results will occur with a chance of less than one-in-twenty.
- Even though the sample mean fell in the "gray region," the test provided sufficient evidence to conclude that the true mean was below the action level.

Conclusions

- First 2 steps of DQA involve "getting to know" your data
  - how they were generated and why
  - how they look from a variety of perspectives
- Next 2 steps of DQA involve exploring appropriate methods and assumptions
  - Some tests of assumptions require their own verification of assumptions
  - Logic and context can be employed to support verification of assumptions
- You <u>will</u> make some decision based on data. You can know what the data are "doing to you," or be blind to it. DQA puts you in control.

DQA Exercise

1. **Open exercise packet, read instructions, and confirm other contents of packet as directed.**
2. **Confirm data files for each DU is on your diskette. Start DataQUEST and specify a file name for the DU your team will analyze.**
3. **Review and record summary statistics.**
4. **View graphical representation of data.**
5. **Test assumption for the one-sample t-test.**
6. **Conduct hypothesis test.**
7. **Record results on DQA worksheet.**
8. **Open next file and repeat steps 3-8 until data from all DUs have been analyzed.**

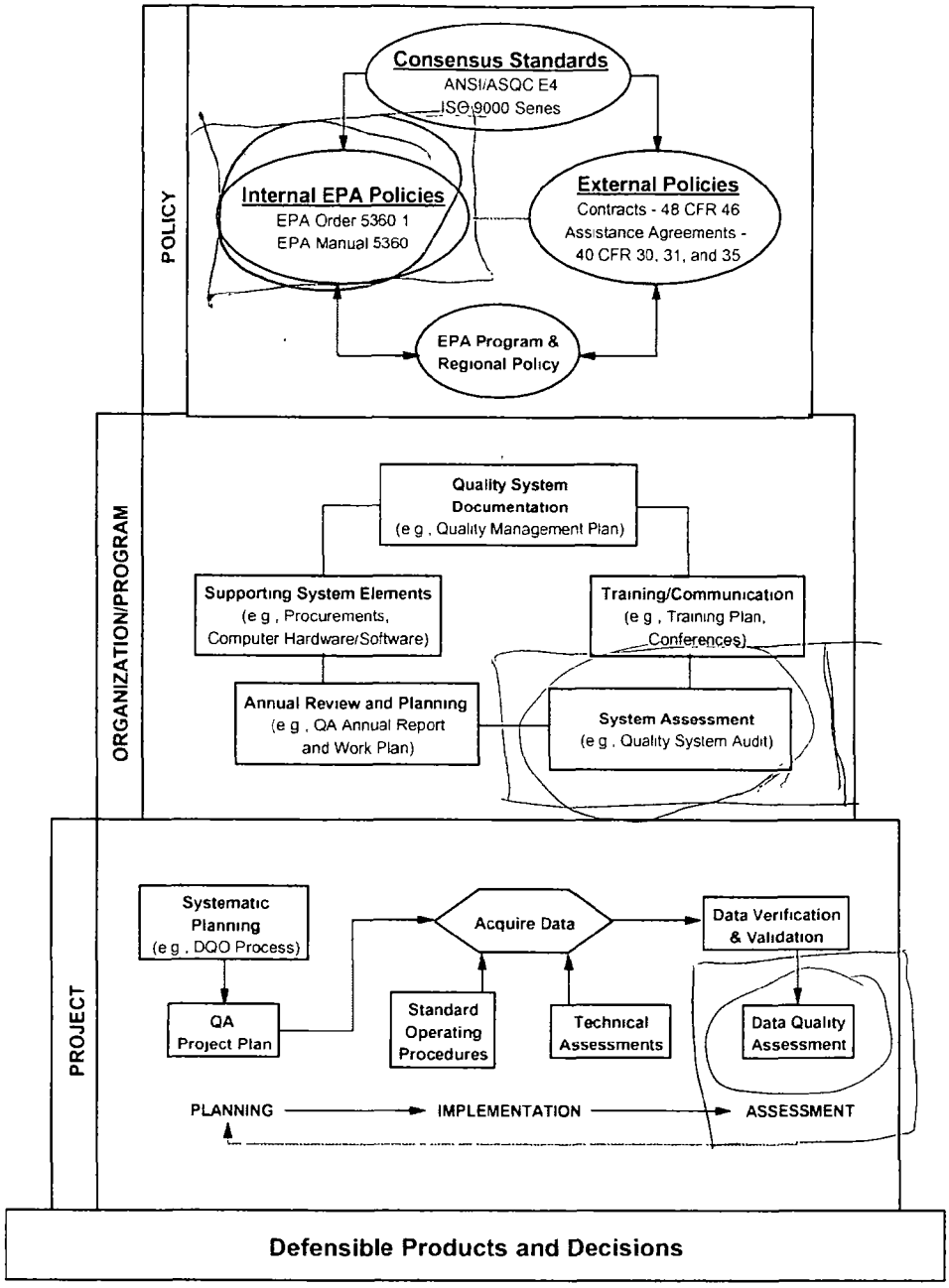
Think about the following questions and write your answer in the space below.

1. What are the one or two most pressing or important QA issues that you have to deal with in your work?

- understanding if the QA procedures used by others in developing + managing their databases ~~wese~~ are adequate
- making assumptions about data when the QA procedures followed (or not) are not clear

2. Considering the objectives, agenda, and your personal experience, list some expectations you have of this course.

- I want the course to help me better assess the work of others in following appropriate QA + QA procedures for their project (data system management)



1. Circle the component(s) of the Quality System with which you have the most experience or for which you have the most responsibility.

2. Think about your answer to question 1 on page J-1 and draw a box around the components of the Quality System that are involved in addressing the issue(s) you identified.

Consequences of Decision Errors

Proceed with remedial design when the true mean [PCB] < 1	**Take no further action when the true mean [PCB] > 1**
Health Risks	Health Risks
Ecological Risks	Ecological Risks
Political Risks	Political Risks
Social Risks	Social Risks
Resource Risks	Resource Risks

Exercise: Setting Quantitative Limits on Decision Errors

With your team, work through the following 5 steps in order to complete a decision performance goal diagram for the Artificial Site scenario. Document your results on the flip chart at your table in the same form as the decision performance goal diagram shown below. All questions marks should be replaced when you are finished.

1. Confirm the action level and the baseline (i.e., null hypothesis).

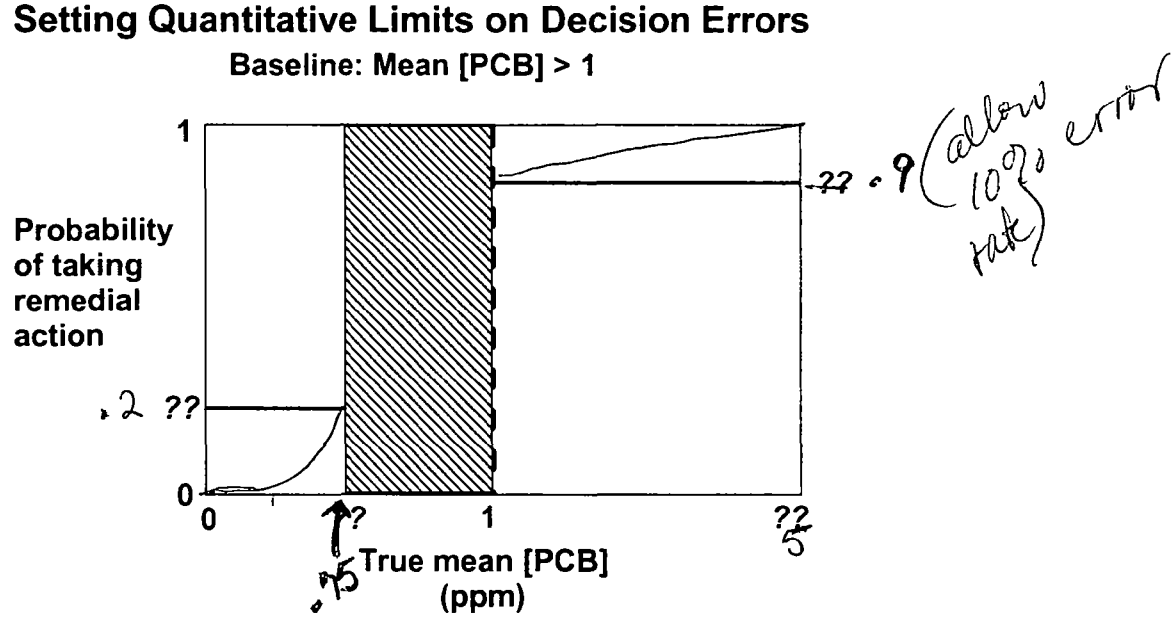
2. Set the parameter range of concern (i.e., the range of mean PCB contamination that is possible at the site).

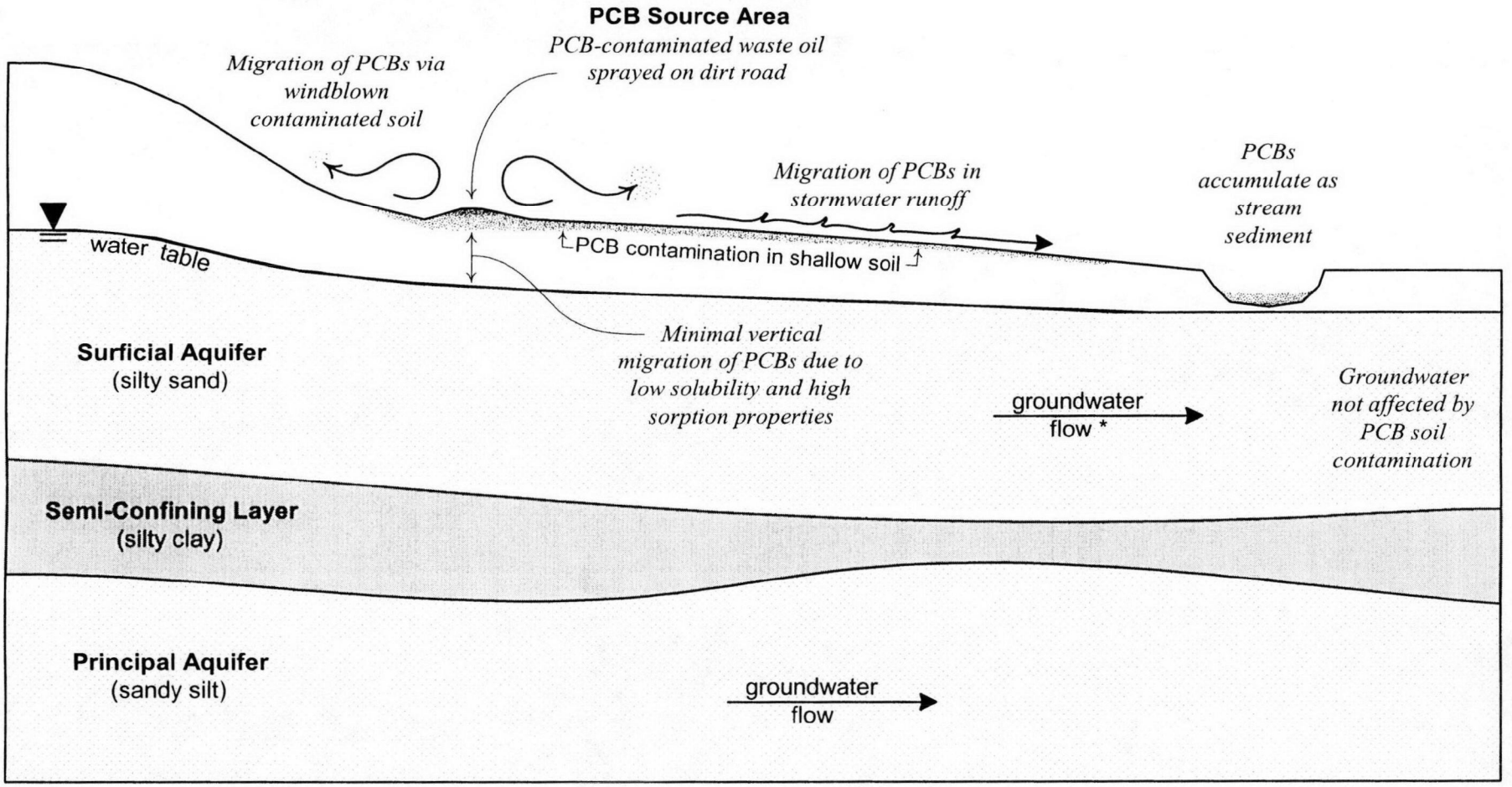
3. Establish the gray region (i.e., the range of mean PCB concentrations where the consequences of a decision error are relatively minor).

4. Specify your team's tolerable probability limits for making a type I error (i.e., reject the null hypothesis when it is true).

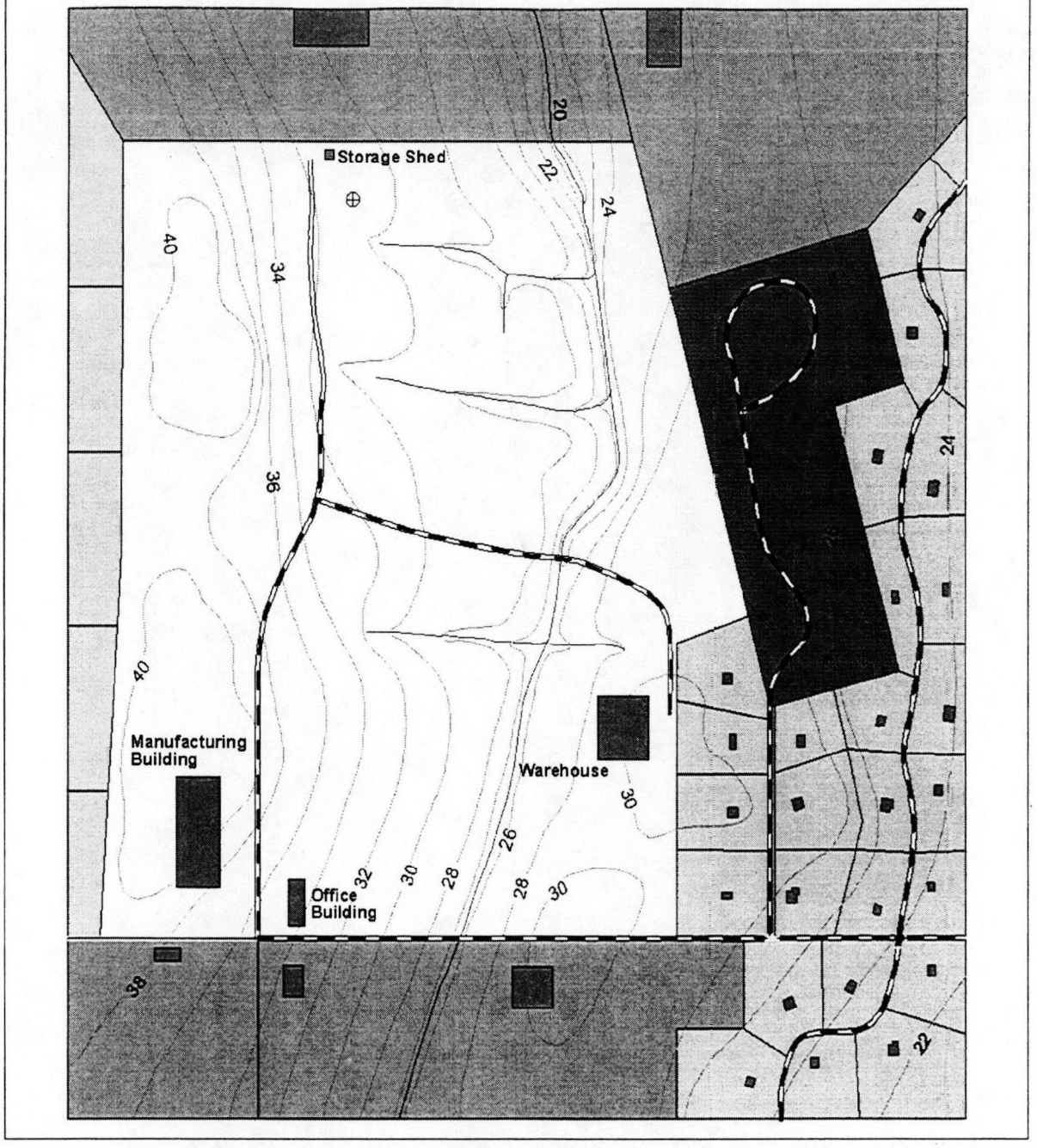
5. Specify your team's tolerable probability limits for making a type II error (i.e., do not reject the null hypothesis when it is false).

Your team will use these quantitative outputs later in this training course, but you will have the opportunity to make revisions. Remember to consider the consequences of your choices.





Conceptual Site Model of OU2 PCB Contamination at the EMCA/ECC Superfund Site



Site Legend

Unimproved Roads
Paved Roads
Streams
Topographic Contours (ft. above MSL)
Buildings

Landuse

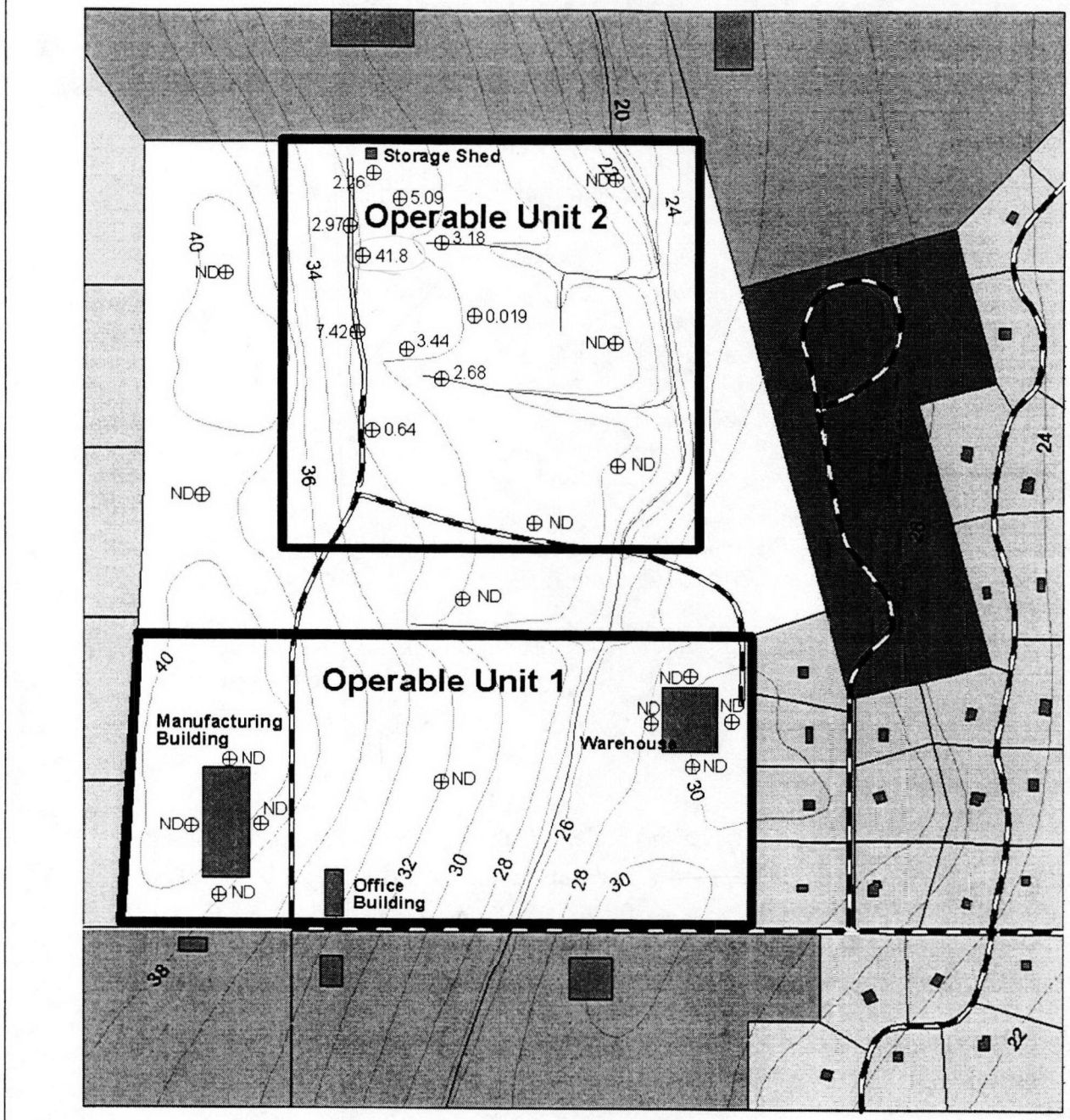
Industrial
Residential
Site Property
Wellfield

Scale
One Inch = 700 Feet
0 Feet 700

North

Figure 2. Site Map

EMCA/ECC Superfund Site



Site Legend

- Unimproved Roads
- Paved Roads
- Streams
- Topographic Contours (ft. above MSL)
- Buildings
- 7.42 ⊕ Soil Sampling Location with Total PCB Concentration (mg/Kg)
- ND ⊕ PCBs Not Detected above the Reporting Limit (0.01 mg/Kg)

Landuse

- Industrial
- Residential
- Site Property
- Wellfield

Scale
One Inch = 700 Feet
0 Feet 700

North

Figure 4. Total PCB Concentrations Reported for Preliminary Soil Samples
EMCA/ECC Superfund Site

QAPP Part C Activity

This exercise involves individual reading and reflection, followed by discussion at your table.

1. Turn to the next page in this journal for reading assignments A and B:

   Reading Assignment A: Section C1, Assessments and Response Actions (an excerpt from EPA QA/G-5, *EPA Guidance for Quality Assurance Project Plans*, Final - EPA/600/R-98/018, February 1998), which identifies the requirements for documenting assessments and response actions in a QAPP.

   Reading Assignment B: Overview of Technical Assessments, which addresses readiness reviews, technical systems audits, surveillance, performance evaluations, and audits of data quality.

2. For each of these five types of assessments, think about the following questions and write down some brief notes to capture your thoughts:

   a. What kind of information does this type of assessment generate?
   QA information to verify that the QAPP is being followed closely

   b. What kinds of issues or problems is the assessment designed to detect?
   - ~~failures in the~~ weaknesses/omissions in the QAPP
   - where stated procedures are not being followed

   c. What kinds of response actions could result from this assessment?
   - adjustments in a procedure
   - catch + refine an SOP before it causes a problem

   d. How would you document the assessment procedures in the QAPP to ensure that the assessment detects problems and triggers response actions in a timely manner?
   - w/ Chuck lists and/or If, then scenarios to alert the team to potentional problems

3. Discuss your answers to these questions at your table.

QAPP Part C Activity

Reading Assignment A: Section C1, Assessments and Response Actions (from EPA QA/G-5, *EPA Guidance for Quality Assurance Project Plans*, Final 2/98)

C ASSESSMENT/OVERSIGHT

C1 ASSESSMENTS AND RESPONSE ACTIONS

Identify the number, frequency, and type of assessment activities needed for this project.

List and describe the assessments to be used in the project. Discuss the information expected and the success criteria for each assessment proposed. List the approximate schedule of activities, identify potential organizations and participants. Describe how and to whom the results of the assessments shall be reported.

Define the scope of authority of the assessors, including stop work orders. Define explicitly the unsatisfactory conditions under which the assessors are authorized to act and provide an approximate schedule for the assessments to be performed.

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

Decision units should be
- homogeneous within
- heterogeneous between them

* find out what the decision makers need/want to make their decision and be sure and collect data w/those characteristics

QAPP Part C Activity

Reading Assignment B: Overview of Technical Assessments

Readiness Review

A readiness review is performed prior to the initiation of data collection to verify that the project personnel have brought the facility to a state of readiness. Readiness means achieving a configuration in which the right people are in the right places at the right times working with the right hardware, software, and materials according to the right procedures and management controls.

Technical Systems Audits (TSA)

A TSA is a qualitative on-site evaluation of all components of the measurement system, including technical and QA management personnel. Assessors travel to the site, gather evidence in person, and produce a report. The main function of a TSA is to determine that project personnel and equipment are physically in place and functioning as stated in the QAPP. It includes an evaluation of both field and laboratory staff, equipment and procedures. The optimal time for performance of a TSA is during the first few days of the project, after all measurement systems are operational, but before significant amounts of data have been collected. TSAs should be performed on a regular schedule throughout the project. Checklists are the basis of a TSA and are prepared based on the QAPP.

Surveillance

Surveillance is the real-time observation of a specific activity of an ongoing project. It may be done on multiple occasions during a project. Its objective is to provide confidence that the activity is being performed in accordance with approved methods and procedures. It allows for immediate identification of any problems and initiation of corrective action. Surveillance offers the opportunity for the assessor to develop a close working relationship with the project team and to encourage the work to be performed correctly, rather than just pointing out errors or deficiencies after they occur.

Performance Evaluation (PE)

A PE is a quantitative assessment in which analytical results are generated by a measurement system for a sample that originates outside of the project. A PE sample mimics actual samples in all possible aspects, except that its composition is unknown to the analyst and is known to the assessor. In the context of the Quality System, a PE is used to determine if measurement system's results are within data quality goals specified in the QAPP. PE results are often used to estimate the degree of bias in the measurement system.

Audit of Data Quality (ADQ)

An ADQ is an examination of data after they have been collected. It is done to determine how well the measurement system performed with respect to the data quality goals specified in the QAPP. ADQs entail tracing data though processing steps and duplicating intermediate calculations. The focus is on identifying a clear, logical connection between the steps. The product is a report which details custody tracing, data transfers, recalculations, incidents which resulted in lost data, and a review of QA data and summary statistics.

Application Planning

Think about the following questions and write your answers and ideas in the space provided.

1) **Turn back to question 1 on page J-1 in this journal and review the QA issues you identified yesterday morning as the most pressing to you. What concepts, skills, or tools have you learned over the past two days that will help you begin to address these issues?**

2) **What are some specific actions you could take in the upcoming days or weeks to begin to apply the concepts, skills, or tools you've learned that will help you address the important QA issues and problems that you face?**

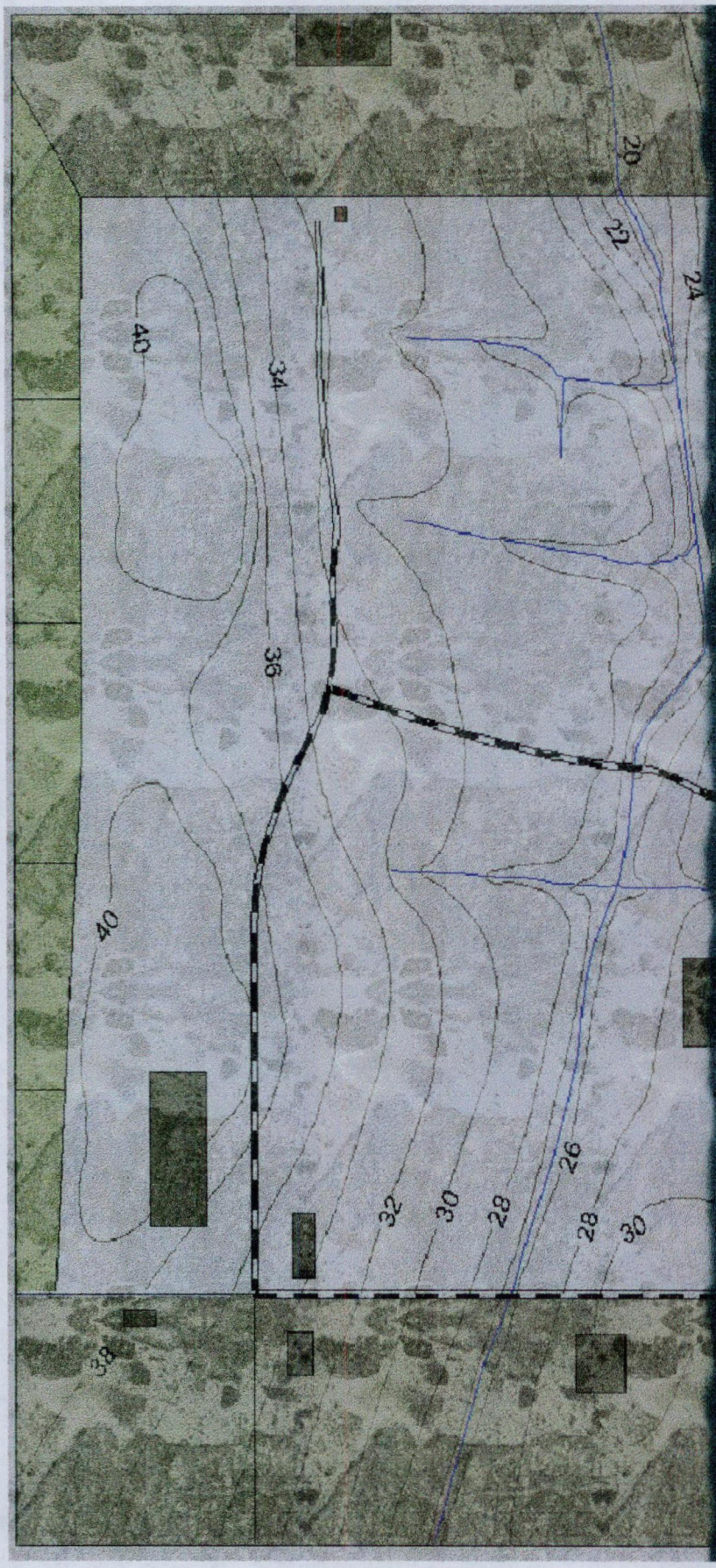
3) **Identify a current or upcoming project where you might be able to apply the tools, skills, and information you learned in this workshop.**

Project: _____

Write down some specific actions you would like to take in the upcoming days or weeks to apply what you've learned here, and identify the kind of support or resources you need to accomplish these tasks.

Action	Support/Resources

4) **Are there any topics in project QA that came up during this workshop that you think you want to learn more about? If so, how could you access appropriate training or other learning opportunities?**



Revision 1

QUALITY ASSURANCE PROJECT PLAN

For a Preliminary Remedial Investigation of Operable Unit 2 PCB Contamination at the EMCA/ECC Superfund Site

March 31, 1998

Prepared by:
Sandra Lowem & Associates
Environmental Consultants, Inc.

Prepared for:
U. S. Environmental Protection Agency
Region IV Superfund Section

This is an example Quality Assurance Project Plan. The referenced Superfund site and contractors are fictitious.

QUALITY ASSURANCE PROJECT PLAN

FOR A PRELIMINARY REMEDIAL INVESTIGATION OF OPERABLE UNIT 2 PCB CONTAMINATION AT THE EMCA/ECC SUPERFUND SITE

REVISION 1

March 31, 1998

Prepared by:
Sandra Lowem & Associates Environmental Consultants, Inc.

Prepared for:
U.S. Environmental Protection Agency, Region 4 Superfund Section

Document Approval Signatures:

Andrew Miller, EPA Remedial Project Manager	Date
Joseph Braswell, EPA Remedial Site Manager	Date
Elizabeth Wall, EPA Quality Assurance Officer	Date
James Boyd, Sandy Lowem & Associates Project Manager	Date
Susan Davis, Sandy Lowem & Associates QA Manager	Date
Mark Roberts, Bunse & Burner Laboratory Project Manager	Date
Richard Allison, Bunse & Burner Laboratory QA Officer	Date

QUALITY ASSURANCE PROJECT PLAN FOR A PRELIMINARY REMEDIAL INVESTIGATION OF OPERABLE UNIT 2 PCB CONTAMINATION AT THE EMCA/ECC SUPERFUND SITE

A1 - A3 DOCUMENT INTRODUCTION

A1 EXECUTIVE SUMMARY

The U.S. Environmental Protection Agency (EPA) is conducting a remedial investigation (RI)/feasibility study (FS) under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or Superfund) program at the Electronic Manufacturing Corporation of America (EMCA)/Energy Components Company, Inc. (ECC), Superfund site. EPA is conducting this work in a phased approach. The RI activities described in this Quality Assurance Project Plan (QAPP) are designed to assess only polychlorinated biphenyl (PCB) contamination in shallow soil within operable unit 2 (OU2). OU2 has been defined as approximately 70 acres of land that includes roughly 1,200 feet of dirt road on which PCB-contaminated waste oil was sprayed as a dust suppressant by EMCA from the 1970s through 1985.

The sampling program involves collection of composite surface soil samples using handheld tools within 54 delineated decision areas (DAs). Each decision area is either: (1) a linear segment of the dirt road; (2) a plot of land 0.5 to 4.5 acres in size that may have received PCB contamination from overspray, air-blown particles, or stormwater runoff; or (3) a reach of ephemeral stream that may contain deposits of PCB-contaminated soil. The samples will be submitted to Bunse & Burner Laboratory for analysis of individual PCBs (congeners) by SW-846 Method 8082. Total PCB concentrations will be calculated by summing the congener concentrations. The laboratory analytical reports will contain most of the elements required for an EPA Contract Laboratory Program data package. After the data are validated, data of acceptable quality will be statistically evaluated using a robust generalized version of the Student's t-test called the Chen test. A soil screening level of 1.0 ppm total PCBs will apply. The results of these analyses will indicate which DAs will: (1) be characterized as not posing an unacceptable risk to human health or the environment and dismissed from further RI/FS activities, (2) be included in the FS to evaluate remedial alternatives for surface soil PCB contamination cleanup and targeted for characterization of subsurface soil contamination in a subsequent RI phase, or (3) require additional surface soil

PCB data before a determination can be made within the established decision error limits as to which of the first two categories applies.

This QAPP presents the Data Quality Objectives (DQOs) established for the project; the prescribed data collection methods and procedures; project management structure and protocol; quality assurance and quality control procedures to be implemented during the project, including use of a data management system; and the prescribed data assessment methodology. This QAPP contains each of the elements presented in *EPA Requirements for Quality Assurance Project Plans for Environmental Data Operations,* EPA QA/R-5 (EPA, 1994b) and described in *EPA Guidance for Quality Assurance Project Plans,* EPA QA/G-5 (EPA, 1997). The DQOs presented in Section A3 have been established in accordance with *Guidance for the Data Quality Objectives Process,* EPA QA/G-4 (EPA, 1994c) and *Data Quality Objectives Process for Superfund,* EPA 540-R-93-071 (EPA, 1993). Following the requirements of EPA QA/R-5 and the guidance of EPA QA/G-5, this QAPP contains the essential elements of a CERCLA RI sampling and analysis plan; field sampling methods and procedures are presented in Section B in sufficient detail that a companion field sampling plan would be redundant.

A2 TABLE OF CONTENTS

LIST OF FIGURES

LIST OF TABLES

LIST OF ACRONYMS/ABBREVIATIONS

bgs	Below Ground Surface
CAS	Chemical Abstract Service
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act (Superfund)
CERCLIS	CERCLA Information System
CFR	Code of Federal Regulations
CLP	Contract Laboratory Program
COC	Chain of Custody
CV	Coefficient of Variation
DA	Decision Area
DQA	Data Quality Assessment
DQO	Data Quality Objective
ECC	Energy Components Company, Inc.
ECD	Electron Capture Detector
EDD	Electronic Data Deliverable
EMCA	Electronic Manufacturing Corporation of America
EPA	U. S. Environmental Protection Agency
FS	Feasibility Study
GALP	Good Automated Laboratory Practices
GC	Gas Chromatograph
GPS	Global Positioning System
H&SP	Health and Safety Plan
HRS	Hazard Ranking System
IDW	Investigation-Derived Waste
IUPAC	International Union of Pure and Applied Chemistry
LIMS	Laboratory Information Management System
LOQ	Limit of Quantitation
MDL	Method Detection Limit
MS	Matrix Spike
MSD	Matrix Spike Duplicate
msl	Mean Sea Level
NIST	National Institute of Standards and Technology
NPL	National Priorities List
OSHA	Occupational Safety and Health Administration
OU1	Operable Unit 1
OU2	Operable Unit 2
PA	Preliminary Assessment
PCB	Polychlorinated Biphenyl
PE	Performance Evaluation

%R	Percent Recovery
PM	Project Manager
ppm	Parts Per Million
QA	Quality Assurance
QAM	Quality Assurance Manager
QAPP	Quality Assurance Project Plan
QC	Quality Control
RI	Remedial Investigation
RPD	Relative Percent Difference
RPM	Remedial Project Manager
RSM	Remedial Site Manager
SI	Site Inspection
SOP	Standard Operating Procedure
SSL	Soil Screening Level
TSA	Technical Systems Audit
TSCA	Toxic Substances Control Act
USGS	U.S. Geological Survey
VOC	Volatile Organic Compound

A3. DISTRIBUTION LIST

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QUALITY ASSURANCE PROJECT PLAN FOR A PRELIMINARY REMEDIAL INVESTIGATION OF OPERABLE UNIT 2 PCB CONTAMINATION AT THE EMCA/ECC SUPERFUND SITE

A4 - A9 PROJECT INTRODUCTION AND MANAGEMENT

A4 PROJECT/TASK ORGANIZATION

The U.S. Environmental Protection Agency (EPA) Region 4 Superfund Section has overall responsibility for the remedial investigation (RI) of polychlorinated biphenyl (PCB) contamination at the Electronic Manufacturing Corporation of America (EMCA)/Energy Components Company, Inc. (ECC) site. EPA's contractor, Sandra Lowem & Associates Environmental Consultants, Inc. (Sandy Lowem & Associates), will perform the field investigation, evaluate the data, and prepare project deliverables, including the RI report. The various quality assurance (QA) and management responsibilities are divided between EPA and Sandy Lowem & Associates key project personnel as defined below. The lines of authority between key personnel for this project are shown on the project organization chart, Figure 1.

A4.1 Management Responsibilities

Project management responsibilities are divided among the EPA Region 4 Superfund Section personnel and Sandy Lowem & Associates personnel described below.

A4.1.1 EPA Region 4 Remedial Project Manager

The EPA Region 4 Remedial Project Manager (RPM), Andrew Miller, has overall responsibility for the investigation. He is responsible for granting final approval of project plans and reports and seeing that plans are implemented according to schedule, and he has the authority to commit the resources necessary to meet project objectives and requirements.

A4.1.2 EPA Region 4 Remedial Site Manager

The EPA Region 4 Remedial Site Manager (RSM), Joseph Braswell, has the responsibility to ensure that technical, financial, and scheduling objectives are achieved successfully. The RSM reports directly to the RPM and is the major point of contact and control for matters concerning the project. The RSM performs the following tasks:

- Define project objectives and develop a detailed work plan schedule
- Establish project policy and procedures to address the specific needs of the project as a whole and the needs of each task
- Evaluate project and/or task staffing requirements and acquire EPA or contractor resources as needed to ensure performance within budget and schedule constraints
- Orient contractor personnel concerning the project's special considerations
- Review work progress for each task to ensure that budgets and schedules are met
- Review and analyze overall task performance with respect to task goals and objectives
- Approve all plans and reports before their submission to the RPM for final approval
- Represent the project team at meetings and public hearings

A4.1.3 Sandy Lowem & Associates Project Manager

The Sandy Lowem & Associates Project Manager (PM), James Boyd, is responsible for task implementation and technical quality control (QC). As requested, the PM will assist the RSM in carrying out appropriate RSM responsibilities listed above. In addition, the PM is responsible for monitoring and directing the field teams and the Field Team Leader, preparing monthly progress reports, updating and distributing revisions of this Quality Assurance Project Plan (QAPP) as necessary, and performing or overseeing data evaluation activities and RI report preparation.

A4.2 Quality Assurance Responsibilities

QA responsibilities are divided among the EPA Region 4 Superfund Section personnel and Sandy Lowem & Associates personnel described below.

A4.2.1 EPA Quality Assurance Officer

The EPA QA Officer, Elizabeth Wall, will remain independent of direct job involvement and day-to-day operations and will be available to resolve any QA issues that may arise. Specific functions and duties of the EPA QA Officer include approving the contents of this QAPP and subsequent revisions; reviewing QA reports prepared by Sandy Lowem & Associates, including QA evaluations and discussions presented in the final RI report; and providing QA technical assistance to the RPM and RSM.

A4.2.2 Sandy Lowem & Associates Quality Assurance Manager

The Sandy Lowem & Associates QA Manager (QAM), Susan Davis, reports directly to the PM and will be responsible for ensuring that the QA/QC procedures described in this QAPP are followed. In addition, the Sandy Lowem & Associates QAM will:

- Maintain regular communication with the EPA QA Officer regarding QA issues
- Report on the adequacy, status, and effectiveness of the QA program on a regular basis to the PM (see Section C2.4)
- Conduct two audits of field activities and two audits of laboratory activities (see Section C1.1) and preparing audit reports
- Validate each laboratory data report (see Section D2) and prepare data validation reports
- Ensure that corrective action, if necessary, is properly implemented and documented (see Section C1.4).

A4.3 Field Responsibilities

The responsibilities of the Sandy Lowem & Associates field technical staff and Field Team Leader are described below.

A4.3.1 Field Team Leader

The PM will be supported by the Field Team Leader, Scott Michael, who is responsible for leading and coordinating day-to-day field activities. The Field Team Leader also will:

- Coordinate and oversee the efforts of the subcontracted land surveyor (see Section B2.3)
- Ensure that the each field team is properly equipped to execute the field sampling methods and procedures described in Section B2 and the sample handling and custody procedures described in Section B3
- Prepare the tables and figures described in Section B2.4 for selecting and surveying soil specimen sampling locations
- Package coolers for shipment to the analytical laboratory as described in Section B3
- Identify problems at the field team level, resolve difficulties in consultation with the PM and QAM, implement and document corrective action procedures, and provide communication between the field teams and upper management
- Prepare sections of the final RI report that document field activities.

A4.3.2 Sandy Lowem & Associates Field Technical Staff

The field technical staff for this project will be drawn from Sandy Lowem & Associates' pool of corporate resources. All of the designated technical team members are experienced professionals who possess the degree of specialization and technical competence required to perform the

required work effectively and efficiently and to meet the training requirements described in Section A8.

A4.4 Laboratory Responsibilities

For this project, Sandy Lowem & Associates has subcontracted Bunse & Burner Laboratory. The responsibilities of Bunse & Burner Laboratory personnel are described below.

A4.4.1 Laboratory Project Manager

The Bunse & Burner Laboratory Project Manager, Mark Roberts, will:

- Ensure resources of the laboratory are available on an as-needed basis
- Carry out liaison activities and scheduling with the Sandy Lowem & Associates PM
- Review and approve final analytical reports prior to submission to Sandy Lowem & Associates.

A4.4.2 Laboratory Operations Manager

The Bunse & Burner Laboratory Operations Manager, Bob O'Neill, will report to the Laboratory Project Manager and will:

- Coordinate laboratory analyses
- Supervise in-house chain-of-custody
- Schedule sample analyses
- Oversee data review
- Oversee preparation of analytical reports.

A4.4.3 Laboratory Quality Assurance Officer

The Bunse & Burner Laboratory QA Officer, Richard Allison, has the overall responsibility for data quality. The Laboratory QA Officer will:

- Oversee laboratory quality assurance activities
- Prepare laboratory standard operating procedures (SOPs) and see that they are implemented
- Conduct detailed review of analytical data and QA/QC documentation
- Identify when laboratory corrective action is warranted and oversee its implementation and documentation
- Review analytical reports prior to submission to the Bunse & Burner Laboratory Project Manager.

A4.4.4 Laboratory Sample Custodian

The Bunse & Burner Laboratory Sample Custodian, Peter Rogers, will report to the Laboratory Operations Manager. The Laboratory Sample Custodian will:

- Receive and inspect the incoming coolers, sample containers, and custody seals
- Record the condition of the incoming coolers, sample containers, and custody seals
- Sign the chain-of-custody (COC) form and other appropriate documents
- Verify chain-of-custody and its correctness
- Notify Laboratory Project Manager and Operations Manager of sample receipt and inspection results

- Assign a unique identification number and customer number to each sample and enter each into the sample receiving log

- With the help of the Laboratory Operations Manager, transfer samples to appropriate laboratory sections

- Control and monitor access/storage of samples and extracts.

A4.4.5 Laboratory Technical Staff

The Bunse & Burner Laboratory technical staff will be responsible for analyzing samples and notifying the Laboratory QA Officer when the need for corrective actions is identified. The laboratory technical staff will report directly to the Laboratory Operations Manager.

A5 HISTORICAL AND BACKGROUND INFORMATION

The subject property is a 275-acre site located in the southeastern United States. The property was occupied from 1965 until 1985 by EMCA for production of electronic parts and manufacturing equipment. During these 20 years of operation, EMCA used large quantities of chlorinated solvents in the manufacturing process and in cleaning the products. Additionally, EMCA began recycling substation transformers in the 1970s to recover copper. The transformers each contained approximately 200 to 300 gallons of contaminated waste oil, which was composed of a mixture of mineral oil and PCBs. To dispose of this waste oil, EMCA used it as a dust suppressant and sprayed it over approximately 1,200 feet of a north-south oriented dirt road in the northwest portion of the site. In 1985, EMCA relocated its operation to the Midwest and sold the subject property to ECC. ECC operated a battery recycling/lead recovery business on the property for 5 years before declaring bankruptcy in 1990. EMCA also went out of business in 1990. In 1991, the city detected volatile organic compounds (VOCs) in water supply wells to the east of the site that primarily provide water to nearby light industry, and the city contacted EPA with this finding.

After reviewing the site history and in response to the city's detection of VOC groundwater contamination, EPA added the site to the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or Superfund) Information System (CERCLIS). EPA then performed a Preliminary Assessment (PA) followed by a Site Inspection (SI) that included limited soil sampling and analysis. Using the results of these activities, EPA evaluated the site using the Hazard Ranking System (HRS), and the site was added to the National Priorities List (NPL) as a Superfund site.

Prior to EPA's adding the site to the Superfund NPL, the local media widely publicized the probable connection between EMCA's prior use of chlorinated solvents at the subject property and the VOC groundwater contamination detected in the city's water supply wells. In addition, a land developer had expressed interest in the subject property for residential development, and the city encouraged this redevelopment effort as part of their brownfields initiative. Subsequently, several newspaper articles focused on the potential exposure of future residents to PCB and VOC contamination in surface soil and to VOC vapors. In response to the media attention and the shutdown of several of the city's water supply wells, community interest and concern remain elevated.

A5.1 Site Description

Figure 2 is a map of the EMCA/ECC Superfund site and surrounding area. The EMCA/ECC site occupies approximately 275 acres in the center of a light industrial corridor. Active industrial areas are located just south and north of the site, and the industrial well field that is owned and operated by the city borders the EMCA/ECC site to the east. The remaining property east and west of the EMCA/ECC site includes residential subdivisions with private lots that typically occupy several acres. The EMCA/ECC property had been logged several times before EMCA occupied the site, and the property currently is covered by a canopy of young pine trees with little undergrowth.

A5.2 Site Topography and Drainage

Topographic contours and streams also are shown on Figure 2. There is approximately 20 feet of relief in the study area with the ground surface generally sloping toward the east. Ground elevations range from a high of just over 40 feet above mean sea level (msl) in the western portion of the study to below 20 feet msl in the northeast corner of the site. An unnamed stream flows across the eastern portion of the study area from the south to the north. Three small tributaries to this stream extend to the west into the central portion of the EMCA/ECC site. These tributaries typically are dry and flow only during storm events and seasonal periods (typically spring) of high water table. Other than the stream incisions, the northeastern third of the EMCA/ECC site is relatively flat with elevations typically between 22 and 32 feet msl.

A5.3 Site Geology and Hydrogeology

Figure 3 is a conceptual site model of the EMCA/ECC site presenting the site geology and hydrogeology on a schematic cross section. The unconsolidated sediments underlying the subject property consist of silty sand deposits. These sediments typically are loose and have a relatively low organic component. Underlying these sediments at a depth of approximately 10 to 30 feet below ground surface (bgs) is a silty clay deposit that ranges in thickness from 0 to 15 feet. The sediment beneath the clay consists of a sandy silt that is at least 80 feet thick.

Where the clay exists, it serves as a semiconfining layer that separates a surficial water table aquifer and a semiconfined principal aquifer. The water table in the surficial aquifer exists within the unconsolidated sandy sediments described above. The water table is situated at a depth of about 10 feet bgs at the western part of the EMCA/ECC site. Surficial-aquifer groundwater flows due east and, during periods of high water table, discharges to the streams described in Section A5.2. Groundwater in the principal aquifer flows to the east-northeast.

A5.4 Past Data Collection Activities

A county groundwater appraisal report prepared by the U.S. Geological Survey (USGS) in 1954 provides the basic hydrogeologic framework of the study area. Several observation wells were installed in the study area by the city in the early 1960s to evaluate water supply capacity of the

principal aquifer for the planned industrial corridor. In addition, several foundation geotechnical investigations were performed in 1964 and 1965 for the EMCA manufacturing building and the former EMCA/ECC administrative building. The information from these older geotechnical soil test borings, plus those from the surrounding industrial sites, was used by the EPA contractor, Sandy Lowem & Associates, to help define the basic stratigraphy and hydrogeologic characteristics of the site described in Section A5.3.

Limited soil contamination information was developed by EPA in performing the SI. The findings suggest that VOC soil contamination is limited to an area surrounding the manufacturing building located in the southern part of the property. This southern area of VOC contamination has been defined by EPA as operable unit 1 (OU1) for the Superfund RI/feasibility study (FS). The SI analytical results also confirmed elevated levels of PCB contamination in surface soil along the dirt road located in the north portion of the site. Additionally, PCBs were detected east (downhill) from the dirt road in surface soil and in stream sediment. This northern area of PCB soil contamination has been defined by EPA as operable unit 2 (OU2) for the CERCLA RI/FS. The total PCB concentrations reported for the SI soil samples are shown in Figure 4.

A5.5 Applicable PCB Standards and Criteria

PCBs in surface soil present a potential risk to the site biota and to humans who may be exposed to the contamination. Known and suspected risks of PCB exposure are summarized in Table 1.

Given the potential future residential use of the EMCA/ECC site, EPA's soil screening methodology is applicable as documented in *Soil Screening Guidance: Technical Background Document* (EPA, 1996a) and *Soil Screening Guidance: User's Guide* (EPA, 1996b). The soil screening level (SSL) for total PCBs presented in the *Technical Background Document* is 1.0 ppm. Therefore, 1.0 ppm has been selected as an appropriate SSL for data assessment.

The disposal of PCBs is governed by the Toxic Substances Control Act (TSCA). Title 40, Part 761, Subpart G of the *Code of Federal Regulations* (CFR) contains EPA's PCB Spill Cleanup Policy of 1987. However, the 1987 TSCA Spill Cleanup Policy does not apply to the EMCA/ECC site PCB contamination because the policy applies only to releases of PCBs occurring after May 4, 1987. Nevertheless, since 1990, the Superfund program has adopted an

approach to cleanup of PCBs that relies heavily on the TSCA policy. The TSCA PCB Spill Policy at Section 761.120 recommends PCB spills be cleaned up to 1 ppm total PCBs on the surface to a depth of 10 inches in the case of remediation for residential land use. Therefore, use of EPA's Soil Screening Guidance and selection of 1.0 ppm as the SSL for data assessment are consistent with the 1987 TSCA Spill Cleanup Policy.

A6 PROJECT DESCRIPTION

This section briefly describes the project tasks and the work schedule.

A6.1 Project Tasks

The following RI tasks have been established to address the Data Quality Objectives (DQOs) presented in Section A7:

Task 1. **Project planning and QAPP preparation.** This QAPP represents the results of initial project planning as summarized by the DQOs (Section A7). However, the project planning/DQO process is iterative, and the DQOs and this QAPP will be revised if warranted by information developed through execution of this project.

Task 2. **Health & Safety Plan and Community Relations Plan preparation.** A written Health & Safety Plan (H&SP) is required for hazardous site investigations according to the Occupational Safety and Health Administration (OSHA), CFR 1910.120(b). A project-specific H&SP currently is being prepared. Section B2.11 discusses the minimum requirements of an H&SP. A Community Relations Plan also is being prepared for this project. The requirements of the Community Relations Plan will include the public meetings listed below as Task 10.1.

Task 3. **Survey Decision Areas.** Before soil sampling begins, the boundaries of each of the 54 decision areas (DAs) will be surveyed and marked as described in Section B2.3. The DAs to be surveyed are described in Section A7.4.2.

Task 4. **Collect soil samples.** As described in Section A7.7, six composite soil samples will be collected from each DA, and each composite sample will be formulated from five soil specimens. Detailed soil sampling procedures are presented in Section B2.7.

Task 5. **Laboratory analysis of soil samples.** The composite soil samples will be submitted to Bunse & Burner Laboratory for analysis of individual PCBs (congeners) by SW-846 Method 8082. The laboratory method and laboratory requirements are described in Sections B4 though B6.

Task 6. **Data validation.** The laboratory analytical results will be subject to validation to assess for bias and to review for completeness, representativeness, and acceptable levels of precision and accuracy. The acceptance criteria for measurement data are described in Section B5.2. Data validation procedures are presented in Section D.

Task 7. **Data quality assessment.** The validated analytical results will be assessed using the Chen test to evaluate whether decision error limits have been met (Section A7.6) or whether additional valid sample results are required from certain DAs in order to meet the decision error limits. Use of the Chen test for data quality assessment (DQA) is further described in Section B5.2.5.2. If necessary to meet decision error limits, a second round of sample collection, analysis, and validation may be implemented.

Task 8. **Data analysis and RI report preparation.** After the DQA process has verified that enough valid data have been generated to meet the decision error limits, maps and tables will be prepared to illustrate those DAs that are to be included in a subsequent RI phase to characterize subsurface soil contamination and included in the FS to evaluate remedial alternatives for surface soil PCB contamination cleanup. These tables and maps will be included in an RI report that also documents field activities and the results of laboratory analyses, data validation, and DQA.

Task 9. **Auditing.** Field and laboratory activities will be audited twice throughout the project. These technical systems audits (TSAs) are further described in Section C1.1.

Task 10. Project support

Task 10.1 Public meetings. As discussed in Section A7.1.3, public participation is an important aspect of this project, and several public meetings are planned throughout the project. The projected timing of public meetings is presented in Section A6.2.

Task 10.2 Data management. Data management is a critical activity that begins upon conception of the DQOs and continues through and after the duration of the project. Data management procedures are discussed in detail in Section B10.

Task 10.3 Progress reports. Monthly progress reports will be prepared throughout the duration of the project as discussed in Section A9.3.1.

A6.2 Work Schedule

As discussed in Sections A7.1.3 and A7.4.3, EPA has made a commitment to the city to report the results of this phase of the RI within 6 months of the issuance of Revision 1 of this QAPP. The tasks described in Section A6.1 are shown in the project schedule, Figure 5, along with the duration of each task. Because the laboratory turnaround time is 3 weeks and there is the potential for a second round of surface soil sampling, there is little flexibility in the project schedule if the 6-month deadline is to be met. Figure 5 also presents the anticipated timing of TSAs and public meetings.

A7 DATA QUALITY OBJECTIVES

DQOs are qualitative and quantitative statements derived from the output of the first six steps of the DQO process shown in Figure 6. The DQO process is an iterative, strategic planning approach designed to ensure that the type, quality, and quantity of environmental data used in decision making are appropriate for the intended application. Once established, the DQOs are used to develop a scientific and resource-effective data collection design.

A7.1 DQO Step 1: Statement of the Problem

This section presents historical and background information about the project, describes the conceptual site model, and lists the involved parties, project resources, and deadlines.

A7.1.1 Historical and Background Information

Historical and background information relevant to the problem addressed by this QAPP is presented in Section A5. In summary:

- Waste oil contaminated with PCBs was sprayed for dust suppression along a dirt road in the northern part of the property (OU2).
- Preliminary sampling performed by EPA confirmed PCB contamination in soil along the road, in soil downhill from the road, and in onsite stream sediment.
- Preliminary sampling also suggests that most of the property may be free of PCB contamination.
- The site is under consideration for redevelopment as a residential neighborhood.
- Community interest and concern are high.

A7.1.2 Conceptual Site Model

Figure 3 is a schematic cross section through the EMCA/ECC Superfund site showing the conceptual model of OU2 PCB contamination. This figure displays the following concepts and assumptions:

- The highest concentrations of PCBs in soil (i.e., PCB source area) are along the dirt road where PCB-contaminated waste oil was sprayed.
- PCB-contaminated soil has migrated from the source to adjacent areas via stormwater runoff and as windblown dust.
- Adjacent areas contaminated with PCBs are predominantly downhill of the dirt road.
- PCB-contaminated soil has accumulated as sediment in streams.
- Due to their low solubility and high sorption properties, PCBs have not migrated into subsurface soil.
- Groundwater flowing to the east in the surficial aquifer and, seasonally, discharging to surface streams has not been affected by PCB soil contamination.
- Groundwater flowing to the east in the principal aquifer has not been affected by PCB soil contamination.

A7.1.3 Involved Parties, Resources, and Deadlines

The principal organizations involved in performing this PCB investigation include EPA; EPA's contractor, Sandy Lowem & Associates; and Sandy Lowem & Associates' subcontracted analytical laboratory, Bunse & Burner Laboratory. Specific roles and responsibilities of each team member are described in Section A4. In addition to these organizations, this QAPP reflects comments received from the city's environmental department and from representatives of the concerned citizens coalition. Furthermore, several public meetings have been scheduled to be held before, during, and after the activities described in this QAPP are executed. A project-specific Community Relations Plan is currently in preparation.

A Superfund budget has been authorized for this phase of the RI that will support the scope of services described in this QAPP plus a 20 percent contingency. EPA has made a commitment to the city and to the concerned citizens coalition to report the results of this investigation within 6 months of the date of issuance of Revision 1 of this QAPP. The project schedule is discussed further in Section A6.2.

A7.2 DQO Step 2: Decision Statement

The decision to be made from this investigation is to:

- Determine whether PCB contamination in surface soils exceeds an acceptable risk-based soil concentration.

EPA plans to perform a focused followup phase of the RI to characterize subsurface soil PCB contamination and to evaluate whether groundwater quality is impacted or threatened by subsurface soil PCB contamination. As part of the followup subsurface investigation, EPA will confirm that areas screened out by the above decision statement do not contain PCBs in subsurface soils. A separate QAPP and set of DQOs will be generated to address the subsurface soil investigation.

A7.3 DQO Step 3: Inputs into the Decision

The following informational inputs are required to resolve the decision statement presented in Section A7.2:

- **PCB concentrations in surface soil.** This information will be gathered through the sampling and analysis activities described in this QAPP.

- **Future land use scenario.** As described in Section A5, a land developer has expressed interest in the subject property for residential development.

- **Soil screening level.** As discussed in Section A5.5, EPA's soil screening guidance (EPA, 1996a and 1996b) presents a soil screening level of 1.0 ppm for total PCBs. This soil screening level has been adopted because the residential exposure scenario described in the soil screening guidance potentially applies to this site.

Additional information will be required for the followup phase of the RI, which will be designed to characterize subsurface soil PCB contamination. For example, soil characteristics such as soil

texture, dry bulk density, soil organic carbon, and pH will be assessed to evaluate whether groundwater quality is threatened by subsurface soil PCB contamination.

A7.4 DQO Step 4: Study Boundaries

This section describes the planned soil sampling depths, the derivation and configuration of 54 DAs, and the temporal study boundaries of the project.

A7.4.1 Sampling Depth

As included in the conceptual site model (Section A7.1.2), PCBs are not expected to have migrated into subsurface soil due to their low solubility and high sorption properties. EPA's soil screening guidance (EPA, 1996a and 1996b) considers surface soil as the top 2 centimeters. Considering the relatively loose, sandy soils at the EMCA/ECC Superfund site, however, it is reasonable to assume that PCBs may be present somewhat deeper. Therefore, the sampling depth selected for this investigation is 2 inches. As included in the DQO decision statement (Section A7.2), subsurface soil (deeper than 2 inches) PCB contamination will be characterized in a followup phase of the RI.

A7.4.2 Decision Areas

Figure 7 shows OU2 subdivided into 54 DAs. The DAs have been established based on the likelihood of contamination as inferred from the conceptual site model (Figure 3) and from previous analytical results (Figure 4). DAs are defined as one of the following:

- A linear segment of the dirt road approximately 200 feet long
- A plot of land 0.5 to 4.5 acres in size that may have received PCB contamination from overspray, air-blown particles, and/or stormwater runoff
- A reach of ephemeral stream approximately 300 to 400 feet long that may contain deposits of PCB-contaminated soil.

Several DAs are larger than 0.5 acres, which is the suggested maximum size of "exposure areas" presented in EPA's soil screening guidance (EPA, 1996a and 1996b). This size of DAs was selected due to the funding and time constraints imposed on the project (Section A7.1.3). However, the sizes of these DAs are considered appropriate because, as suggested by the conceptual site model, the variability of PCB concentrations within each area is expected to be low. If the variability within a DA is found to be greater than the acceptance criteria (see Section A7.6, Limits on the Decision Error), then additional samples will be collected from the area or from subdivisions of the area. Furthermore, if PCB contamination is found within any DA at the perimeter of OU2, then the boundary of OU2 will be expanded by creating additional DAs for subsequent sampling and analysis (see Section A6.2, Work Schedule).

A7.4.3 Temporal Study Boundaries

The latest date that PCBs are known to have been disposed of at the site is 1985. The low volatility and solubility in soil of PCBs and the fact that this contamination has been present for at least 13 years provide temporal flexibility for executing this investigation, subsequent RI/FS activities, and remediation. Nevertheless, EPA has made a commitment to the city to report the results of this phase of the RI within 6 months of the date of issuance of Revision 1 of this QAPP. Because the laboratory turnaround time is 3 weeks and there is the potential for a second round of surface soil sampling (see Section A6.2 and Figure 5, Project Schedule), there is little flexibility in the project schedule if the 6-month deadline is to be met.

An additional time constraint concerning collection of sediment samples from the ephemeral streams is that the sampling must take place when the streams are not flowing. Other than during large storm events, the streams flow during seasonal periods of high water table, which is typically February through April. Therefore, sampling within the ephemeral stream DAs may have to be conducted toward the end of field activities since field activities are scheduled to commence in April.

A7.5 DQO Step 5: The Decision Rule

The following statements describe the decision rule to apply to this investigation:

- If the mean concentration of total PCBs in surface soil (top 2 inches) averaged over each DA exceeds the action level, then the area will be targeted for characterization of subsurface soil contamination in a subsequent RI phase and included in the FS to evaluate remedial alternatives for surface soil PCB contamination cleanup.

- Otherwise, the area will be characterized as not posing an unacceptable risk to human health or the environment and will be dismissed from further RI/FS activities.

The action level to be used in implementing this decision rule differs from the screening level value of 1.0 ppm because of the way the limits on decision errors have been specified in the EPA soil screening guidance (EPA, 1996a and 1996b) and adopted for this project. This is explained in the next section.

A7.6 DQO Step 6: Limits on Decision Error

The default decision errors presented in EPA's soil screening guidance (EPA, 1996a and 1996b) have been selected for this investigation. Before describing the probability limits on decision errors, the issue of the how the action level described in the decision rule for this project differs from the soil screening level must be addressed. EPA's soil screening guidance (EPA, 1996a and 1996b) identifies a default decision-making gray region of one-half to two times the SSL. Within this gray region, relatively large decision error rates are considered tolerable with minor consequences. Considering that the SSL identified for this project is 1.0 ppm, the lower bound (one-half the SSL) of the gray region is 0.5 ppm, and the upper bound (two times the SSL) of the gray region is 2.0 ppm. The upper bound of the gray region is where EPA specifies a tolerable limit on the probability of making a decision error that would result in mischaracterizing a DA that truly poses an unacceptable risk to human health and the environment. EPA believes that setting

the upper bound of the gray region at two times the SSL is appropriate because the SSLs are sufficiently conservative.

The baseline condition (null hypothesis) adopted for this site is that the true mean contaminant concentration for each DA is less than or equal to one-half the SSL (lower bound of the gray region). The conceptual site model and existing soil analytical results suggest that this condition should be valid for most of OU2. Moreover, this will allow the use of a robust statistical procedure called the Chen test, which is described in the soil screening guidance. From a statistical perspective, the "action level" therefore is 0.5 ppm, or one-half the SSL. That is, if the data demonstrate convincingly that the true mean is significantly greater than 0.5 ppm, then the baseline condition (null hypothesis) will be rejected and the DA will be subject to further investigation and remediation. There is a chance that this will be an erroneous decision (a "false positive" or Type I error), but the consequences are merely further investigation of a DA that in truth does not pose an unacceptable risk.

From a site management perspective, EPA wants to ensure that whenever the results show that the baseline condition **cannot** be rejected (i.e., the data do **not** provide conclusive evidence that the mean is significantly above 0.5 ppm), the data provide sufficient evidence to allow EPA to characterize that DA as not posing an unacceptable risk to human health or the environment. Most of the time this will be clear (such as when most or all of the data values are "non-detects"). However, sometimes the baseline condition cannot be rejected because the data are inconclusive--for example, the average of the data values is greater than 0.5 ppm, but not "significantly" greater. Under these conditions, EPA wants to ensure that sufficient data have been collected so that there is only a small chance of mischaracterizing a DA that could, in truth, pose an unacceptable risk. Therefore, from a site management perspective, it may be useful to think of the upper bound of the gray region as a "threshold" for controlling the chance of misclassifying DAs that truly pose an unacceptable risk. By specifying a maximum tolerable probability of making a "false negative" (Type II) error at 2 times the SSL and by ensuring that a proper DQA is performed whenever the baseline condition is not rejected, EPA's concern for mischaracterizing DAs is addressed. The soil screening guidance provides direction on how to perform calculations to ensure that the chance of mischaracterizing a DA is sufficiently small, which avoids mistakes due to inconclusive data.

These two decision errors and the probability goals limits adopted for each can be summarized as follows:

1. The Type I decision error occurs when the null hypothesis is incorrectly rejected (false positive). With respect to the Chen test, the Type I error occurs when a DA is incorrectly included in followup phases of the RI and evaluated in the FS for remedial alternatives when, in actuality, the PCB concentrations do not pose an unacceptable risk to human health or the environment. The limit set on the probability that the Type I decision error will occur is 0.2 (20 percent) at 0.5 ppm, the lower end of the gray region. Following the Chen test procedures ensures that the Type I decision error limit is met.

2. The Type II decision error occurs when the null hypothesis is incorrectly accepted (false negative). With respect to the Chen test, the Type II error occurs when a DA is incorrectly dismissed from further RI/FS activities when, in actuality, the PCB concentrations warrant further study and remediation. The limit set on the probability that the Type II decision error will occur is 0.05 (5 percent) at 2.0 ppm, the upper end of the gray region. As opposed to the Type I decision error, hypothesis test procedures do not ensure that the Type II decision error limit is met. The DQA statistical protocol must be used for each DA for which the baseline condition was **not** rejected (see DQA activities under Section B5.2.5.2) to demonstrate whether enough valid data have been generated to meet the Type II decision error limit.

A7.7 DQO Step 7: Design Optimization

This section presents design-optimization details including the rationale for collecting composite soil samples and the rationale for the sampling pattern and the number of samples. In general, the soil screening guidance was used to guide professional judgments about the type of designs that would be appropriate. Time constraints and design cost considerations precluded a more exhaustive search for optimal designs.

A7.7.1 Composite Sampling

Because the objective of surface soil sampling is to estimate the mean contaminant concentration for each DA, the physical "averaging" that occurs during compositing is consistent with the intended use of the data. The PCB concentration in each composite sample should represent an estimate of the mean PCB concentration for the DA because individual soil specimens that make up a composite sample are collected from across the DA.

A7.7.2 Sampling Pattern

Each composite sample will be comprised of five soil specimens. Within each DA, soil specimen locations will be selected using a stratified random sampling procedure, and each composite sample will be formulated using a random compositing scheme. Specific protocols for identifying soil specimen locations and creating composite samples are presented in Section B2.4.

A7.7.3 Numbers of Samples

Six composite samples will be collected from each of the 54 DAs. This number of samples was developed by assuming a conservatively high coefficient of variation (CV) of 2.5 for the soil sample analytical results to be generated for each DA. This CV is thought to be conservative because each of the composite samples should represent an estimate of the mean PCB concentration for the DA, and each DA was constructed to avoid straddling areas that the conceptual site model suggests would have different degrees of contamination. Specifying five soil specimens per composite sample and using the Chen test with a CV of 2.5, Table 26 in EPA's Soil Screening Guidance Technical Background Document (EPA, 1996a) indicates that six samples per DA is the minimum sample size needed to achieve the decision errors prescribed in Section A7.6.

A8 SPECIAL PERSONNEL TRAINING REQUIREMENTS

In addition to studying the methods and procedures described in Section B of this QAPP, each field team member must be experienced or have received proper training on this project's requirements for soil sampling, sample handling and custody, and field documentation. Each field team member will have received the OSHA-required 40-hour hazardous waste site worker training and will be current on the required 8-hour refresher training, medical monitoring, and first-aid/CPR training. The Field Team Leader is required to have attended the OSHA 8-hour hazardous waste site worker Supervisor Training Course. At least one field team member must have received the training mandated by the U.S. Department of Transportation in association with the International Air Transportation Association for shipping hazardous materials. Sandy Lowem & Associates has a rigorous training program and, as of the date of this QAPP, each of these requirements has been satisfied.

The method chosen for analysis of PCBs in the laboratory (SW-846 Method 8082) is restricted to use by, or under the supervision of, analysts experienced in the use of a gas chromatograph (GC) and skilled in the interpretation of gas chromatograms. Each analyst must demonstrate his or her ability to generate acceptable results with the method.

Bunse & Burner Laboratory has been subcontracted by Sandy Lowem & Associates to conduct the analyses. This laboratory has performed Method 8082 or its predecessor method for over 10 years, has a comprehensive laboratory QA plan, and possesses the required sample preparation and analytical equipment. Furthermore, Bunse & Burner Laboratory has experienced staff members who have demonstrated continuous proficiency in analysis of PCBs in water and soil matrices. Each analyst is required to satisfactorily analyze a PCB standard reference material in the appropriate matrix before beginning a project. Bunse & Burner Laboratory has participated in EPA-sponsored performance evaluation studies for 5 years and has consistently achieved high ratings with respect to PCB identification and quantification.

A9 DOCUMENTATION, RECORDS, AND REPORTS

This section identifies the documents and reports to be generated throughout the investigation and the information to be included in these documents and reports. A description of the data management system established for this project, including a description of the types of data that will be collected in this effort and their relationship to the final report, is presented in Section B10.

A9.1 Field Documentation

Field documentation requirements are fully described in Section B2.8. Examples of selected forms are included in Appendix A. In summary, the field team will be responsible for maintaining the following field documents:

- Soil sampling data sheet
- Sample container labels
- COC forms
- Health and safety documentation
- Photograph log
- Daily diary of activities in a bound field notebook.

Section B2.4 describes the methods to be followed by the field team to determine soil sampling locations. As shown in Appendix A on the example soil sampling data sheet, the location where each soil specimen is collected will be recorded as feet north and feet east of the southwest corner of each DA. As backup documentation to these measurements, the field team will operate a Global Positioning System (GPS) at each soil-specimen sampling location. At each location, the field team will enter the soil specimen identification number into the GPS data logger, thereby associating a sampling time and location with the specific soil specimen.

A9.2 Laboratory Documentation

The laboratory data reports will be consistent with current EPA Contract Laboratory Program (CLP) documentation requirements (CLP forms not required). Each laboratory data report will include a case narrative, an analytical results package, a copy of the completed COC form, and an Electronic Data Deliverable (EDD). Section B4.7 provides a full description of the required components of each of these four elements of the laboratory data reports.

A9.3 Management and QA Reports

Management and QA reports include monthly progress reports, audit reports, data validation reports, and the final RI report.

A9.3.1 Monthly Progress Reports

Sandy Lowem & Associates will prepare a monthly progress report and submit it to EPA no later than the 15th of the month following the period being reported. This report will state technical and financial progress for the duration of the reporting period (1 month) and cumulatively for the entire project. Narrative descriptions of work accomplished, problems encountered, and projected work in the next reporting period will be included for each task in progress. The monthly progress report also will contain a QA summary. The QA summary provides an overview of the QA observations and findings presented in the QA reports and forms described in the next two subsections. The QA summary also will indicate the status of corrective action documentation and implementation (see Section C2.1), if any.

A9.3.2 Audit Reports

As described in Section C1, two TSAs will be conducted of field activities and two will be conducted of laboratory activities. The auditor will prepare an audit report summarizing the observations and findings of each of these audits. As needed, the audit reports will be supplemented by a Corrective Action Request and Tracking Form(s) to correct each observation and finding. These forms are further discussed in Section C2.1, and audit reports are further discussed in Section C2.2.

A9.3.3 Data Validation Reports

A data validation report will be prepared for each laboratory data report generated. The data validation report will identify biases inherent in the data including assessment of laboratory performance and overall precision, accuracy, representativeness, and completeness. Data validation flags will be applied to those sample results that fall outside of specified tolerance limits and, therefore, do not meet the program's QA objectives. The data validation report will address whether the quality of the flagged data affects the ability to use the data as intended. As needed, data validation reports will be supplemented by a Corrective Action Request and Tracking Form(s). These forms are further discussed in Section C2.1, and data validation reports are further discussed in Section C2.3.

A9.4 Final Report

Following data validation and DQA activities, a final report on OU2 PCB contamination will be prepared for this phase of the EMCA/ECC site RI. The final report will document field activities and summarize the results of QA and DQA activities. The final RI report will specifically indicate which DAs: (1) are characterized as not posing an unacceptable risk to human health or the environment and dismissed from further RI/FS activities, and (2) are to be targeted for characterization of subsurface soil contamination in a subsequent RI phase and included in the FS to evaluate remedial alternatives for surface soil PCB contamination cleanup. The final report will include maps and tables that illustrate those DAs that fall into each of these two categories. Appendixes to the final report will include the laboratory analytical reports, data validation reports, audit reports, and corrective action documentation.

The final RI report also will describe whether a second round of field activities was conducted. The results of the DQA process may indicate that some DAs require additional surface soil PCB data in order for decision error limits to be met. As discussed in Section A7.4.2, a second round of field activities also would be warranted if PCB contamination is found within any DA at the perimeter of OU2. In that situation, the boundary of OU2 would be expanded by creating additional DAs for subsequent sampling and analysis.

B DATA ACQUISITION

B1 EXPERIMENTAL DESIGN

The experimental design and rationale were established through the DQO process as documented in Section A7. The following sections present implementation details regarding that design.

B1.1 Sample Matrix and Target Analytes

Composite soil samples will be analyzed for concentrations of PCBs by SW-846 Method 8082. The laboratory will report analytical results for at least 22 individual PCBs (congeners) as further discussed in Section B4.1. Five soil specimens will make up each composite sample. Each soil specimen will be collected at a unique location from the ground surface to 2 inches bgs. The site soils typically are relatively loose silty sand.

B1.2 Types, Numbers, and Locations of Samples

Six composite soil samples will be collected from each of the 54 DAs shown in Figure 7. Several categories of DAs have been established as follows:

- Seven DAs are linear segments of dirt road.
- Nine DAs are reaches of ephemeral stream.
- Nine DAs are 0.5-acre plots that have the dirt road running through them.
- Thirteen DAs are 1.0-acre plots that are adjacent to 0.5-acre plots.
- Eight DAs are 2.0-acre plots that are adjacent to 1.0-acre plots.
- Eight DAs are 4.5-acre plots that cumulatively make up the eastern half of OU2.

Within each DA, a random compositing scheme will be implemented to create six composite samples, each made up of five soil specimens. The procedures for identifying soil specimen sampling locations are detailed in Section B2.4.

B1.3 Criticality of Measurements

Three types of measurements or observations will be made in the field and laboratory activities described in this QAPP: (1) laboratory measurements of PCB concentrations in soil, (2) field observations of soil appearance, and (3) field sampling locations measured using a GPS. Of these three types of information, only the first, soil PCB concentrations, is considered critical to achieve project objectives and limits on decision errors. Field observations of soil appearance are to be recorded for information purposes only. Measurement of field sampling locations using a GPS is to be performed essentially to validate that, within each DA, the field team successfully occupied the general vicinity of each randomly selected soil specimen sampling location.

B2 FIELD SAMPLING METHODS AND PROCEDURES

This section describes the field procedures for collecting composite soil samples.

B2.1 Preparation for Field Work

Before field work begins, Sandy Lowem & Associates will establish field headquarters in the onsite office building (see Figure 2). The headquarters will serve as the central point of communication for project personnel as well as the temporary storage area for field equipment, completed field documentation, soil samples not yet delivered to Bunse & Burner Laboratory, and investigation-derived waste (IDW).

One room in the office building will be designated for clean field supplies to include an ample stock of the following consumable equipment:

- Laboratory-supplied, wide-mouth, 4-ounce glass sample jars with labels
- Heavy-duty plastic spoons (large serving spoons)
- Paper buckets
- Personal protective equipment as required by the project H&SP
- Custody seals and blank forms described in Section B2.8.2
- Paper towels
- Zip-sealing plastic bags, several sizes

- Plastic garbage bags
- Bubble wrap packing material
- Clear packing tape and duct tape.

A separate room will contain a locking temperature-monitored refrigerator/freezer and reusable equipment that may come in contact with site soils. As samples are collected and until they are shipped to Bunse & Burner Laboratory, they will be stored in the refrigerator according to the custody procedures described in Section B3. Reusable equipment includes the following:

- Portable ice chests (coolers)
- Cold packs (blue ice) and bags of water ice (regular ice)
- Wooden forms (see Section B2.7)
- Yard sticks or other flat rigid object longer than the wooden form.

An additional area within the office building will be used to calibrate, maintain, and store field instruments required by the project H&SP (e.g., photoionization detector and calibration gas) and the GPS instrumentation.

A staging area will be established outside the office building for storage of IDW. The staging area will be set off with caution tape and will consist of covered 55-gallon drums that are labeled and stored on plastic sheeting. The IDW will remain at this staging area until implementation of soil remediation activities.

B2.2 Support Organizations

In addition to the organizations discussed in Section A4, other organizations that will provide support on this project include:

- Sample courier: Frederick's Express Service (Fred Ex)
- Performance evaluation (PE) sample vendor: Amount Known, Inc.
- Land Surveyor: Shootit Wright Surveyors.

B2.3 Presampling Survey of Decision Areas

The four corners of each DA will be identified and marked by a licensed land surveyor. The surveyor will drive a labeled wooden stake into the ground that indicates the direction of each adjacent DA. For example, one stake in the northwest portion of OU2 will read "SE of DA1; NE of DA5; SW of DA8; NW of DA9." In addition, the surveyor will record the locations of these stakes using GPS equipment and will present the survey data both in digital format and on survey drawings. The staked corners of the DAs will be surveyed again using GPS equipment by the field sampling team as each DA is occupied for sampling. The two sets of GPS measurements will be compared so that the GPS measurements of soil sampling locations measured by the field team can be calibrated to the land surveyor's records.

B2.4 Selection and Surveying of Sampling Locations

Before sampling begins in a DA, the Field Team Leader will prepare a schematic map and a table of 30 pairs of sampling coordinates (six composite samples, five soil specimens per sample) for the DA. A pin flag then will be set at each soil sampling location. Appendix B presents an example worksheet for establishing soil specimen sampling locations. The procedures to be followed for each DA are as follows:

1. Using a random-number-generating computer program or preprinted table of random numbers, obtain 60 random numbers ranging from 0 to 99. For 0.5- to 4.5-acre DAs that have a segment of dirt road or stream segment within, obtain an additional 10 contingency random numbers.

2. On a piece of graph paper, draw a schematic of the DA and divide the DA along its long dimension into five sectors of equal length and width. Label the sectors 1 through 5 beginning with the south sector for DAs elongated north-south or the west sector for DAs elongated east-west.

3. Convert the first 30 random numbers into sampling coordinates along the long axis of the DA. For DAs elongated north-south, these coordinates will be expressed as feet north of the southwest corner of the DA. For DAs elongated east-west, these

coordinates will be expressed as feet east of the southwest corner of the DA. Six random numbers will be converted into coordinates for each of the five DA sectors using the following equation:

$$X = [(R/100)*(D/5)]+[(D/5)*(N-1)]$$

where

X = long-axis coordinate (feet from southwest corner of DA)
R = random number
D = long dimension of DA (feet)
N = sector number (1 through 5).

4. Following the format shown in Appendix B, create a table that assigns each of the long-axis coordinates to a composite sample.

5. Convert the second 30 random numbers into sampling coordinates along the short axis of the DA. For DAs elongated north-south, these coordinates will be expressed as feet east of the southwest corner of the DA. For DAs elongated east-west, these coordinates will be expressed as feet north of the southwest corner of the DA. Six random numbers will be converted into coordinates for each of the five DA sectors using the following equation:

$$Y = (R/100)*d$$

where

Y = short-axis coordinate (feet from southwest corner of DA)
R = random number
d = short dimension of DA (feet).

6. Assign each of the short-axis coordinates to a composite sample by filling in the table created in Step 4 (see example, Appendix B).

7. Plot each of the soil-specimen sampling locations on the schematic figure of the DA and label the locations within each sector 1 through 6 corresponding to the assigned composite sample as listed on the generated coordinate table.

8. For those 0.5- to 4.5-acre DAs that have a segment of dirt road or stream segment within, soil specimens are not to be collected from the dirt road or stream segment (these features are identified as separate DAs). Coordinates that fall on these features are to be discarded and replaced with a set of coordinates generated from the contingency random numbers mentioned in Step 1.

9. Starting at the wooden stake identifying the southwest corner of the DA, place a tape measure on the ground along the long axis of the DA. At each long-axis coordinate generated in Step 3, identify each soil specimen sampling location using the short-axis coordinates generated in Step 5 and a second tape measure placed perpendicular to the first tape measure. Set a pin flag in the ground at each location and, using an indelible marker, label the pin flag with the assigned composite sample number identified in Step 6.

10. Record each of the 30 pin flag locations using a GPS instrument. The GPS instrument will be operated according to the standard operating procedures established by the manufacturer.

B2.5 Sample Containers, Preservation, and Maximum Holding Times

Table 2 summarizes the sampling plan, showing the types and numbers of samples to be collected. This table also shows required sample containers, preservation, and maximum holding times.

Each composite soil sample collected for laboratory analysis will be submitted in two 4-ounce glass jars. The field sampling protocol requires that the soil be homogenized before the jars are filled so that the contents of each of the two jars equally represents the composite soil sample. Although only 2 to 30 grams of soil are required for a single PCB analysis by SW-846 Method 8082, two soil-filled jars are required for this project to: (1) protect against complete loss of a sample in the event that one jar breaks during shipment, and (2) to enable the laboratory to have ample soil for samples selected for matrix spike (MS) and MS duplicate (MSD) analyses in case the sample also has to be re-extracted.

As shown in Table 2, the maximum holding time for soil samples to be analyzed for PCBs is 14 days from the time the sample is collected to the time that it is extracted, and 40 additional days from the time it is extracted to the time the extract is analyzed. Within the initial 14-day holding period, the soil samples will not be affected by being stored in glass; plastic containers are not appropriate for storage of the samples because long-term contact could result in container-induced phthalate ester contamination of the soil, and the presence of phthalate ester compounds could interfere with the PCB analysis.

The only requirement for preserving soil samples to be analyzed for PCBs is to maintain the samples in a chilled state. As further described in Section B3, collected soil samples will be placed in clean coolers that contain sufficient coolant to chill the samples to 4 ± 2 °C. Once transferred to the onsite refrigerator and while stored at the analytical laboratory, the samples will be stored and maintained at 4 ± 2 °C.

B2.6 Field Quality Control Samples

The following field QC samples will be collected to assess laboratory and field precision and laboratory accuracy.

B2.6.1 Field Duplicate Samples

Field duplicate samples will be collected and analyzed to evaluate sampling and analytical precision. Field duplicates will be prepared by filling two sets of sample bottles with the homogenized soil. One of the bottle sets will be labeled as the primary sample and one will be submitted to the laboratory blind with a fictitious sample identification number. The blind field duplicate will be analyzed in the same manner as the primary samples. One field duplicate will be collected for every 12 primary samples; that is, half of the DAs will have a blind field duplicate included with its set of six primary soil samples.

B2.6.2 Performance Evaluation Samples

A total of four double-blind solid-matrix PE samples will be submitted to the analytical laboratory to evaluate analytical accuracy. The first PE sample will be submitted along with the first sample

shipment, and the remaining PE samples will be interspersed throughout the project at regular intervals; i.e., the second, third, and fourth PE samples will be submitted after 18, 36, and 54 DAs have been sampled, respectively. Double-blind PE samples will be prepared using National Institute of Standards and Technology (NIST) traceable standards. The PE samples will contain known concentrations of PCBs. Blind laboratory results will be evaluated against the Certificates of Analyses by the Sandy Lowem & Associates QAM to ensure that the laboratory maintains good performance. Double-blind PE samples will be obtained from a commercial vendor, Amount Known, Inc. The PE samples will be shipped from the field to the analytical laboratory in 4-ounce glass jars identical to those used for the field samples. Although the amount of PE sample provided by the vendor (50 grams) will not fill two glass jars, the PE sample will be split into two jars. The resultant headspace will not affect the integrity of the sample. The PE samples will be kept chilled and under custody until they are submitted to the analytical laboratory for analysis of PCBs by EPA Method 8082. In addition to making an entry on the COC form under a fictitious name, an entry will be made on the soil sampling data sheet described in Section B2.8.2 for each PE sample.

B2.7 Soil Sampling Procedures

Procedures for collection of six composite soil samples within each DA are as follows:

1. Begin the sampling procedure at each DA as follows:

   1.1 Label six paper buckets (disposable paint buckets) with the identification names to be applied to each of the six composite soil samples (see Section B2.8.1). Place each bucket in a separate clean plastic bag (wastepaper basket liner) and fold the bag over the bucket to protect the bucket from cross-contamination. Place the six protected buckets into coolers equipped with blue ice so that the buckets will not tip over. Onto the lid of each cooler, tape a sketch that indicates the position of each bucket in the cooler (bucket identification synonymous with soil sample identification).

   1.2 Place a mark on the handle of an unused, rigid, large, plastic spoon (that is dedicated to the composite sample) at a measured distance from its end

equal to 2 inches plus the thickness of the wooden form described in Step 2.1.

2. Conduct the following procedures at each of the six soil specimen sampling locations within the first DA sector (one soil specimen is collected from each of the five sectors for each composite soil sample):

2.1 Put on a clean pair of latex gloves (and/or other personal protective equipment prescribed by the H&SP). Clear any pine needles or other loose nonsoil material from the sampling location and place an untreated wooden form on the cleared area. The form is to have an opening approximately 12 inches by 12 inches.

2.2 Using the plastic spoon that is dedicated to the composite sample (see Step 1.2), scrape soil from an approximately 6-inch diameter area in the center of the form and place the soil into a clean quart-size zip-sealing plastic bag.

2.3 Continue scraping soil from the area and placing the soil into the quart-size bag until a concave excavation has been created with a maximum depth of 2 inches. Measure the depth of the excavation by placing a yard stick (or other flat rigid object longer than the wooden form) across the top of the wooden form. Then place the handle of the plastic spoon into the deepest point of the excavation and slide the yard stick against the handle. The excavation is 2 inches deep when the mark placed on the spoon handle in Step 1.2 is level with the bottom of the yard stick. To avoid cross-contamination, do not measure the depth of the excavation with any object other than the spoon that is dedicated to the corresponding composite soil sample.

2.4 Using an indelible pen, mark the soil-filled level on the outside of the quart-size bag.

2.5 Empty the contents of the quart-size bag into the paper bucket dedicated to the composite sample. As much as possible, break apart any soil clods with the plastic spoon.

2.6 Place the spoon into the bucket and place the bucket back into the larger storage bag. Place the quart-size bag next to the bucket in the larger storage bag, fold the storage bag over its contents, and return the bag to its previous position in the chilled cooler.

2.7 Remove the pin flag from the ground.

3. Conduct the following procedures at each of the remaining 24 soil specimen sampling locations within the DA:

3.1 At each soil specimen sampling location, follow procedures 2.1 through 2.3 being careful to use the correct set of disposable, dedicated equipment for each of the six composite samples. As closely as possible, achieve the 2-inch excavation depth just as the quart-size bag is filled to the mark placed on the bag while sampling in the first sector.

3.2 Add the contents of the quart-size bag to the soil already in the paper bucket. As much as possible, break apart any soil clods with the plastic spoon and thoroughly homogenize the soil with the spoon.

3.3 Repeat Steps 2.6 and 2.7.

4. Conduct the following procedures for each of the six composite samples after a soil specimen has been collected from each of the five sectors:

   4.1 Fill two (four if a duplicate sample is being collected) unused laboratory-provided 4-ounce glass jars with the homogenized soil using the plastic spoon dedicated to that sample. Fill no more than one-quarter of each jar at a time, alternating between the jars.

   4.2 Once the jars are filled, follow the sample labeling and handling procedures described in Section B3 and the waste handling procedures described in Section B2.9.

B2.8 Field Documentation

Field documents will be kept by each field sampling team. Entries will be made in blue or black indelible ink. Multiple-page documents will be consecutively numbered. Corrections will consist of a single line-out deletion that is initialed and dated. If only part of a page or form is used, the remainder of the page or form will have an "X" drawn across it and it will be initialed and dated.

B2.8.1 Sample Numbering System

Sample identification numbers will be assigned to each soil specimen and composite sample collected. Each identification number will be unique and will consist of an alphanumeric string as follows:

[ZZAA]-[BB]-[C]

where

ZZ = one- or two-character abbreviation that identifies the type of DA, as follows:

DA = 0.5- to 4.5 acre DA
R = dirt road segment DA
ST = stream segment DA

AA = two-character decision-area number as shown in Figure 7

BB = two-character sequential number differentiating the composite samples collected from the same DA

C = one-character sequential number differentiating the soil specimens that make up each composite sample.

For example, identification number ST09-04-5 represents the fifth soil specimen of the fourth composite soil sample collected from stream segment decision area 09. The composite soil sample associated with this soil specimen would have the identification number ST09-04.

As discussed in Section B2.6.1, field duplicate samples will be submitted to the laboratory as blind QC samples. Therefore, fictitious sample identification numbers will be recorded on the sample label and COC form (COC forms discussed in Sections B2.8.2 and B3). These fictitious numbers will follow the same general format described above, but will include a sequential DA number that is not presented in Figure 7. As discussed in Section B2.8.2, the actual depth and sequential sampling location number associated with the field duplicate will be recorded on the soil sampling data sheet, which will not be submitted to the analytical laboratory.

B2.8.2 Field Forms

Each field sampling team will be responsible for maintaining the following field forms:

- An entry will be made on a soil sampling data sheet for each sample collected. The intent of the soil sampling data sheet is to document the time that each soil specimen is collected, any known deviation from the planned sampling location,

and other pertinent field observations associated with the soil specimen. For samples submitted to the laboratory as blind QC samples with fictitious identification numbers, the sampling data sheet provides documentation of the primary sample associated with the blind QC sample. Appendix A of this QAPP includes an example soil sampling data sheet.

- Sample container labels, custody seals, and COC forms will be maintained as described in Section B3. Appendix A of this QAPP includes an example container label, custody seal, and COC form.

- Health and safety documentation will be submitted as required by the project-specific H&SP.

- A photograph log will be kept that describes each subject image and the time and date that the photograph was taken.

- A field notebook will serve as a diary of field activities and record of pertinent data not included on the other forms described above. Recorded information will include general site conditions, daily weather, equipment used onsite, equipment problems, description of field QC samples, handling and disposal of IDW, and other relevant information.

B2.9 Handling Investigation-Derived Waste

Two types of IDW will be generated during this investigation: (1) excess soil remaining in paper buckets after the sample jars are filled, and (2) disposable materials that have come in contact with site soils. The latter category includes the dedicated sampling equipment described in Section B2.7 as well as disposable personal protective equipment. These two categories of IDW will be kept separated and stored in the 55-gallon drums described in Section B2.1. The IDW will be treated and/or disposed of as a site remediation activity. Because all sampling equipment is disposable, decontamination is not prescribed in this QAPP. If decontamination is required by the H&SP, then the decontamination fluids will be contained in separate 55-gallon drums and also treated and/or disposed of as a site remediation activity.

B2.10 Field Corrective Action

Corrective actions will be initiated if the field team is not adhering to the prescribed sampling or documentation procedures or if laboratory analyses are experiencing interference or systemic contamination due to field sampling procedures or sample handling protocol. Field corrective action responsibilities and documentation requirements are discussed in further detail in Sections C1.4.1 and C2.1.

B2.11 Health and Safety

Health and safety training requirements are discussed in Section A8. A written H&SP is required for hazardous site investigations according to OSHA, CFR 1910.120(b). A project-specific H&SP is being prepared and will be completed before field activities begin. The H&SP will include the following elements:

- Overview of the site history, project objectives and scope of work, and health and safety responsibilities
- Hazard assessment
- Safety procedures
- Field decontamination
- Emergency response plan
- Maps showing the work areas and route to hospital
- Tables summarizing potential chemical hazards, action levels, and emergency telephone numbers.

B3 SAMPLE HANDLING AND CUSTODY

Immediately after each sample jar is filled, the threads and the outside of the jar will be wiped clean with a paper towel, the lid will be tightly screwed onto the jar, and the jar will be labeled. The label to be affixed to each sample jar will indicate the sample identification number, the sampling date and time, the sampler's initials, and the requested analysis. Additionally, a set of three bar-code stickers will be applied to each sample: one bar-code sticker will be applied to each of the two sample bottles and one will be applied to the COC form next to the entry for the

sample. A custody seal will be placed on each sample jar extending from the lid onto the glass (not covering the label or bar-code sticker). Custody seals provide assurance that the samples are not tampered with until opened at the laboratory.

The glass jars will be securely packed in plastic bubble wrap and then sealed in zip-sealing plastic bags. The samples then will be placed in a clean cooler and kept chilled until they are transferred to the onsite refrigerator or packed for shipment to the laboratory. The coolers will contain sufficient coolant to chill the samples to 4 ± 2 °C. Once transferred to the onsite refrigerator and while stored at the analytical laboratory, the samples will be stored and maintained at 4 ± 2 °C. The onsite refrigerator will be equipped with a high-low alarm system and temperature-recording device.

For each sample to be submitted to the laboratory for analysis, an entry will be made on a COC form. Information to be recorded includes sampling date and time, sample identification number, requested analytes and methods, and sampler's name. The COC also will contain a bar-code sticker for each sample that matches the bar-code stickers applied to the sample jars. Appendix A includes a sample COC form.

Sampling team members will maintain custody of the samples until they are transferred to the onsite refrigerator or the sample courier service. The COC form will accompany the samples from the time of collection until they are received by the laboratory. Each party in possession of the samples (except the professional courier service) will sign the COC form signifying receipt. A copy of the original completed form will be provided by the laboratory along with the report of results. The onsite refrigerator will be kept locked at all times when samples are in storage. The COC form will indicate the dates and times that the samples were placed into the refrigerator and retrieved from the refrigerator. If the refrigerator is opened when samples are in storage, the responsible individual will sign a refrigerator custody log, enter onto the log the date and time the refrigerator was unlocked and relocked, and list the group of samples that were stored when the refrigerator was opened.

Samples will be shipped via overnight delivery service to Bunse & Burner Laboratory approximately every other day. It is important that coolers are packed properly to prevent

breakage of sample containers and to maintain proper sample temperature. Standardized procedures for packing sample coolers for shipment are as follows:

1. Place blue ice in the bottom of the sample cooler. Place layers of bubble wrap over the blue ice. Line the cooler with an open plastic garbage bag, place the samples upright inside the garbage bag and seal the bag.

2. Double-bag and seal loose ice in sealing plastic bags. Place the sealed bags of ice outside the garbage bags containing the samples.

3. Pack any extra space in the cooler with packing material so that contents cannot shift during handling, even after the ice used in the cooler loses its shape after melting.

4. Enclose COC forms in a zip-sealing plastic bag and tape the bag to the inside of the cooler lid. If more than one cooler is being shipped, note on the COC form whether the contained information applies only to the samples within the individual cooler or to those shipped in several coolers.

5. Seal the cooler with signed and dated custody seals so that the cooler cannot be opened without breaking the custody seal. Place clear packing tape over the custody seal to prevent incidental damage to the seal.

6. Tape the cooler shut with packing tape. Place duct tape over the cooler drain plug, if there is one.

7. To ensure that the cooler does not run out of coolant while in the custody of the overnight delivery service, the samples must be shipped for delivery on the next calendar day. If a weekend or holiday will prevent delivery of the samples on the next calendar day, retain custody of the samples in the onsite refrigerator until after the weekend or holiday.

Upon receipt of the samples, the laboratory shall immediately notify the Sandy Lowem & Associates PM if conditions or problems are identified that require immediate resolution. Such conditions include container breakage, missing or improper COC forms, holding time exceedances, custody seals that indicate potential tampering, or missing or improper sample labeling.

B4 ANALYTICAL METHOD REQUIREMENTS

The analytical methods selected for this investigation are described in the December 1996 Update III of *Test Methods for Evaluating Solid Waste; Physical/Chemical Methods, SW-846* (EPA, 1996c). SW-846 Method 8082, "Polychlorinated Biphenyls by Gas Chromatography," will be used to identify and quantify individual PCB congeners in the soil samples. The internal standard calibration method will be used. A dual-column GC configuration will be used to allow confirmation of target analyte identifications. Method 8082 will be used in conjunction with Method 3541, "Automated Soxhlet Extraction," and Method 8000B, "Determinative Chromatographic Separations." Method 8000B gives procedures for multiconcentration calibrations, evaluating linearity of the calibration, establishing retention time windows, and various QC aspects of analysis. Cleanup Methods 3660B and 3665A will be used as needed to remove interfering elemental sulfur and phthalate ester contaminants, respectively, should they be present.

B4.1 List of Target Analytes

Oil/PCB mixtures were sprayed on the soil at the EMCA/ECC site beginning about 25 years ago and continuing until 13 years ago. Because the PCB compounds have weathered over time, the relative distributions of individual PCB congeners initially present in the Aroclor(s) (recognizable groupings of congeners) has changed. Thus, identification and quantification schemes based on recognition of Aroclor patterns will not be reliable and cannot be used. Method 8082 highly recommends that individual congeners be identified instead. Their concentrations will be summed to give a "total PCB" value in terms of ppm by weight.

Table 3 lists the PCB congeners present in the seven Aroclors that make up the Method 8082 Aroclor target analyte list. All but three of these congeners (IUPAC Numbers 12, 28, and 118)

are listed in SW-846 as having been tested by Method 8082, but SW-846 further states that Method 8082 may be appropriate for additional congeners. Therefore, Bunse & Burner Laboratory has performed method validation studies for these three congeners. Bunse & Burner Laboratory will begin the project by providing analytical results for the three recently validated congeners plus the 19 congeners found on the Method 8082 target analyte list. This project-specific list of 22 target congeners is presented in Table 4. To improve the robustness of the "total PCB" estimate, Bunse & Burner Laboratory will carefully review chromatograms for unidentified PCB congeners and attempt to identify and quantify peaks with heights greater than 10 percent of the nearest internal standard peak height. As necessary, Bunse & Burner Laboratory will perform additional method validation studies for congeners not listed in Table 4 that are manually identified in several samples, and these congeners will then be added to the project-specific target analyte list.

B4.2 Method Sensitivity Requirements

Method 8082 is very sensitive and is appropriate for meeting the project DQOs. As described in Section A7.5, the intent of the current project is to identify DAs for remediation by comparing concentrations of "total PCBs" in surface soil to a soil screening level of 1 ppm and an associated statistical gray region of 0.5 to 2.0 ppm. Soils with total PCB concentrations above the "action level" of 0.5 ppm (see Section A7.6) would require remediation if the land were to be used for residences.

The limit of quantitation (LOQ) is the lowest concentration that can be reliably determined within specified limits of precision and accuracy. Analytical laboratories identify the LOQ for each analyte using the method detection limit (MDL) and the procedures given in Section 5.0 of Chapter 1, Quality Control, of SW-846. The Bunse & Burner Laboratory Method 8082 MDLs and LOQs vary by congener and are shown in Table 4.

B4.3 Required Equipment and Reagents

The following equipment and reagents will be required to conduct soil sample preparation and analyses for PCB congeners:

- Gas chromatograph. A dedicated analytical system complete with a GC suitable for on-column and split-splitless injection and all required accessories including syringes, autoinjectors, analytical columns, gases, electron capture detectors (ECDs), and recorder/integrator or data system.

- Narrow-bore GC columns for dual-column analysis. Columns are specified in SW-846 Method 8082, Section 4.2.1.

- Automated Soxhlet extraction system. This system is described in SW-846 Method 3541.

- Analytical balance, readable to the nearest 0.1 mg.

- Explosion-proof refrigerator to store extracts of soil samples awaiting analysis.

- Reagent-grade solvents (hexane and acetone) for extraction.

- Commercial calibration standards for each PCB congener that has been well-characterized by Method 8082. Standards for other PCB congeners as necessary, based on the findings of the initial analyses.

- Internal and surrogate standards (decachlorobiphenyl and tetrachloro-meta-xylene, respectively).

- Miscellaneous laboratory glassware and supplies.

B4.4 Corrective Action Process for Analytical System Failure

Analytical system upsets caused by sample contaminants will be handled by the analyst in consultation with the Bunse & Burner Laboratory Operations Manager and QA Officer. For failures of the GC's mechanical, electronic, or thermal subsystems, Bunse & Burner Laboratory technical staff will inform the Operations Manager who will in turn call on the manufacturer's service representative for assistance in repairing and/or replacing failed components. Laboratory corrective action responsibilities and documentation requirements are discussed in further detail in Sections C1.4.2 and C2.1.

B4.5 Laboratory Turnaround Time Requirements

Although the maximum recommended holding time for soil samples to be extracted is 14 days (see Table 2), Bunse & Burner Laboratory will strive to extract each sample within 2 days of receipt. Similarly, the sample extracts may be refrigerated and stored out of light for up to 40 days before analysis (Method 8082, Section 6.2), but Bunse & Burner Laboratory is contractually required to issue a final laboratory data report containing the components described in Section B4.7 within 3 weeks of sample receipt.

B4.6 Safety and Hazardous Material Disposal Requirements

All employees of Bunse & Burner Laboratory will follow the safety and industrial hygiene rules specified in the company's safety manual and standard operating procedures. Additionally, Bunse & Burner Laboratory has strict protocol for handling and disposal of potentially contaminated samples and has contracts with permitted waste transportation and waste disposal facilities. These protocols are documented in Bunse & Burner Laboratory SOPs and are in conformance with all federal, state, and local requirements. The company's safety manual and written SOPs are available for review at the laboratory facility.

B4.7 Laboratory Data Report

The laboratory data reports will be consistent with current EPA CLP documentation requirements (CLP forms not required). Portions of these reports are produced under software control thus enabling reproducibility of outputs. Full traceability is provided through sample codes whereby specific raw data are fully traceable to sample identity and location through instrument-identification and time stamps. The laboratory data reports will include the following four elements:

1. **Case Narrative.** It is the policy of Bunse & Burner Laboratory to fully document any difficulties encountered during sample preparation and analysis. Case narratives will be prepared from the laboratory notebook entries and from information entered into the laboratory information management system (LIMS). Case narratives will include the following information plus a complete description of any difficulties encountered during sample handling and analysis:
    - Date the laboratory data report is issued
    - Laboratory analyses performed
    - Deviations from intended analytical strategy
    - Laboratory batch number
    - Numbers of samples and respective matrices
    - QC procedures used and references to the acceptance criteria
    - Laboratory report contents
    - Project name and number
    - Condition of samples "as received"
    - Discussion of whether or not sample holding times were met
    - Discussion of technical problems or other observations that may have created analytical difficulties
    - Discussion of laboratory QC checks that failed to meet project criteria, corrections made, and effectiveness of corrective actions
    - Signature of the Bunse & Burner Laboratory QA Officer.

2. **Analytical Results Package**. The analytical results package will include the following data and summary forms:
   - Summary page indicating dates of analyses for samples and laboratory QC checks
   - Cross-reference of laboratory sample to project sample identification numbers
   - Description of data qualifiers
   - Sample preparation and analysis methods
   - Sample results
   - Raw data for sample results and laboratory QC samples
   - Results of (dated) initial and continuing calibration checks and GC tuning results
   - Results of laboratory QC analyses listed in Table 5
   - Labeled (and dated) chromatograms/spectra of sample results and laboratory QC checks.

3. **Completed Chain-of-Custody Form.**

4. **Electronic Data Deliverable.** The EDD will be formatted according to the requirements of the data management system described in Section B10.

B5 LABORATORY QUALITY CONTROL ELEMENTS

B5.1 Quality Control Checks and Procedures

A number of QC checks will be required to ensure the quality of data generated by SW-846 Method 8082. In all cases, a second-column technique will be used to confirm the identities and concentrations of PCB congeners in the soil samples. In the dual-column analysis technique, a single injection of sample extract is split between two columns that are mounted in the same GC. The chromatograph is dedicated to the project. Once the operating conditions are established for the two columns, the same conditions will be used for analysis of samples and standards. Agreement of retention-time-based identification of any PCB congener by both columns will be required in order to report a value.

The laboratory also will evaluate blanks, calibration check standards, QC reference standards, internal standards, surrogate standards, laboratory control standards, MSs, and MSDs. These QC samples will be analyzed at various points in the analytical process, often as part of a sample analysis batch of 20 samples or less. Table 5 describes each of these QC samples and lists their frequency of use, control limits, and required corrective actions if control limits are exceeded. Section B5.2 further discusses QC acceptance limits. Refer to Section B4.4 and to the methods themselves for additional detail on laboratory corrective action.

B5.2 Quality Control Acceptance Criteria for Measurement Data

The QC limits set as project acceptance limits for measurement data are presented in the following sections and listed in Table 5. These criteria will be used in data validation to assess whether the program's QA objectives have been met and whether the quality of the flagged data affects the ability to use the data as intended. Data validation procedures are presented in Section D2.

B5.2.1 Precision

Precision measures the reproducibility of repetitive measurements. It is strictly defined as the degree of mutual agreement among independent measurements as the result of repeated application of the sample process under similar conditions. Precision acceptance limits for the QC analyses discussed below are shown in Table 5.

Analytical precision is a measure of the variability associated with duplicate or replicate analyses of the same sample in the laboratory and is evaluated by analysis of laboratory QC samples, such as duplicate control samples, MSDs, and sample duplicates. If the recoveries of analytes in the specified control samples are comparable within established control limits, then precision is within limits.

Total precision is a measure of the variability associated with the entire sampling and analytical process. It is evaluated by analysis of duplicate or replicate field samples and measures variability introduced by both the laboratory and field operations. Field duplicate samples are analyzed to assess field and analytical precision. One field duplicate will be collected for every 12 primary

samples; that is, half of the DAs will have a blind field duplicate included with its set of six primary soil samples.

Duplicate results will be assessed using the relative percent difference (RPD) between duplicate measurements. RPD limits for laboratory MSD analyses will be 30 percent. If the RPD for laboratory QC samples exceeds the established limit, data will be qualified as described in the applicable validation procedure. If the RPD between primary and duplicate field samples exceeds 50 percent, data will be qualified as described in the applicable validation procedure (see Section D2). The RPD will be calculated as follows:

$$RPD = (200)\ (X_1 - X_2)\ /\ (X_1 + X_2)$$

where X_1 is the larger of the two observed values, and X_2 is the smaller of the two observed values.

B5.2.2 Accuracy

Accuracy is a statistical measure of correctness and includes components of random error (variability due to imprecision) and systematic error. It reflects the total error associated with a measurement. A measurement is accurate when the value reported does not differ from the true value or known concentration of the spike or standard. Accuracy acceptance limits for the QC analyses discussed below are given in Table 5.

Accuracy of laboratory analyses will be assessed by initial and continuing calibrations of instruments and analysis of blanks, laboratory control samples, surrogate and internal standards, MSs, and blind PE samples. Laboratory accuracy is expressed as the percent recovery (%R). If the percent recovery is calculated to be outside of acceptance criteria, data will be qualified as described in the applicable validation procedure (see Section D2). Percent recovery will be calculated as follows:

$$\%R = (100)\ (X_s - X)\ /\ T$$

where X_s is the measured value of the spiked sample, X is the measured value of the unspiked sample, and T is the true value of the spike solution added.

Field accuracy often is assessed through the analysis of trip blanks, field blanks, and field equipment blanks. Analysis of blanks monitors errors associated with the sampling process when volatile compounds are under investigation or when sampling equipment is decontaminated between samples and reused. Field accuracy will not be evaluated for this project because PCBs are not volatile and, as described in Section B2, sampling tools will be previously unused and will be disposed of after each use.

B5.2.3 Representativeness

Representativeness is the degree to which data accurately and precisely represent a characteristic of a population, parameter variations at a sampling point, a process condition, or an environmental condition.

Representativeness of data collection will be addressed by careful preparation of sampling and analysis programs. This QAPP addresses representativeness by specifying sufficient and proper numbers and locations of samples and incorporating appropriate sampling methodologies; the sampling network has been designed to provide data representative of site conditions by considering past waste disposal practices, existing analytical data, and physical setting and processes. This QAPP further addresses representativeness by specifying appropriate laboratory methods for the preparation and analysis of samples and establishing and following proper QA/QC procedures.

B5.2.4 Comparability

Comparability is an expression of the confidence with which one data set can be compared to another. The objective of comparability is to ensure that soil PCB data developed during the investigation may be readily compared to other soil PCB data collected at this or other sites and to applicable criteria or standards. This QAPP addresses comparability by specifying appropriate field and laboratory methods that are consistent with the current standards of practice as approved by EPA.

B5.2.5 Completeness

Completeness is the amount of valid data obtained compared to the amount that was planned. The number of valid results divided by the number of planned results, expressed as a percentage, determines the completeness of the data set. Completeness is calculated as follows:

$$\%completeness = (100)\ (number\ of\ valid\ results\ /\ number\ of\ planned\ results).$$

B5.2.5.1 Completeness of Field and Laboratory Activities

The completeness acceptance criteria for collection of field samples is 100 percent; there are no foreseeable obstacles in collecting six composite soil samples from each DA with each composite sample comprising five soil specimens. The percent completeness of laboratory performance will be calculated upon completion of data validation and compared to a contractual acceptance criteria of 95 percent or greater.

B5.2.5.2 Data Quality Assessment Using the Chen Test

The analytical results that are found to be of acceptable quality through data validation will be used in the DQA process using the Chen test. The Chen test directions to be followed for the valid data generated for each DA are presented in Appendix C. DQA using the Chen test is considered an evaluation of whether the completeness acceptance criteria have been met in that the Chen test identifies for a given data set whether or not the minimum sample size has been obtained to achieve the decision error limits established in Section A7.6.

B6 INSTRUMENT EQUIPMENT TESTING, INSPECTION, AND MAINTENANCE REQUIREMENTS

The Bunse & Burner Laboratory technical staff analyst will be responsible for maintaining the GC and related extraction equipment. Routine maintenance items may involve capillary GC column rinsing, cleaning the metal GC injector body, and servicing the splitter connections. Other maintenance will be performed as needed. Major maintenance will be conducted by the manufacturer's service representative through the laboratory's maintenance and servicing contract.

B7 INSTRUMENT CALIBRATION AND FREQUENCY

The GC system will be initially calibrated using calibration standards for individual PCB congeners. A minimum of five different concentrations covering the expected working range will be employed. Their concentrations will be related to the internal standard as described in SW-846 Methods 8000B and 8082. Each sample analysis session will be bracketed by an acceptable initial calibration, calibration check standard(s) (each 12-hour shift), or calibration check standards interspersed within the samples. Sample injection may continue for as long as the calibration verification standards and standards interspersed with the samples meet QC requirements. Standards will be analyzed after no more than 20 samples have been analyzed. The sequence will end when the set of samples has been injected or when qualitative or quantitative QC criteria are exceeded, at which time corrective action must be taken.

B8 INSPECTION/ACCEPTANCE REQUIREMENTS FOR SUPPLIES AND CONSUMABLES

The Bunse & Burner Laboratory technical staff analyst will be responsible for inspecting incoming equipment and supplies before placing them in service. The manufacturer's specifications for product performance and purity will be used as criteria for acceptance or rejection of supplies and consumables.

B9 DATA ACQUISITION REQUIREMENTS FOR NON-DIRECT MEASUREMENTS

No types of data are needed for project implementation or decision making that would be obtained from non-measurement sources such as computer databases, programs, literature files, or historical databases.

B10 DATA MANAGEMENT

This section identifies the activities and processes planned for documenting the traceability of the conclusions and information in the final report and data package to the data collected in this project. This process is shown schematically in Figure 8.

B10.1 Data Recording

Data for this project will be collected by computer and by handwritten entries. Field observations and records such as sample collection information and shipping data will be primarily recorded manually using the forms described in Section B2.8.2 and shown in Appendix A. Additional field-generated data include the locations of soil specimen sampling locations and the locations of the corners of DAs. These locations will be recorded by the GPS data logger. After they are recorded by hand or by the GPS data logger, the field observations and records will be entered into the Sandy Lowem & Associates computer data management system for subsequent integration with other project data. This computer data management system was certified in 1995 by Snoopit Consulting, Inc., to satisfy EPA's Good Automated Laboratory Practices (GALP) guidelines and has undergone no major revision since then.

Computer-generated data are primarily associated with laboratory activities and will be managed under the control of the automated LIMS used by Bunse & Burner Laboratory. This data management system is maintained to the manufacturer's current revision under contract to the manufacturer and is certified to be compliant with EPA's GALP guidelines. This data system is used to produce a majority of the components of the laboratory data reports described in Section B4.7.

The data generated by the licensed land surveyor, Shootit Wright Surveyors, will be recorded both manually (traditional survey records) and by the GPS data logger. Of these records, the only pieces of information to be entered into the Sandy Lowem & Associates data management system are the manually calculated coordinates and the GPS-measured coordinates (state plane coordinate system) of the corners of each DA.

Integration of manually recorded and computer-recorded data will be done by the Sandy Lowem & Associates data management system to produce data summary output for evaluation and for the final RI report.

B10.2 Data Quality Assurance Checks

QA checks of data as early as possible in a project are essential to provide early warning of potential problems. Several levels of QA checks are routinely performed by Sandy Lowem & Associates staff, according to the type of data collected.

First, range checks are specified where appropriate for computerized data operations; this permits a level of "real-time" QA checking. Range checks are automated at Bunse & Burner Laboratory in that the LIMS immediately notifies the technical staff analyst of out-of-range data for each monitored variable. Range checks also are programmed into the GPS equipment to be used on this project. Manual field observations to be made during this project do not have value-range limitations and, therefore, the project-specific field forms do not specify acceptable variable ranges.

After the range checks, appropriate relational checks by the LIMS are performed (e.g., comparing sampling records and analysis data against the required sample turn-around-time), and the operator is warned so that appropriate corrective action can be taken as soon as possible.

Additional QA assessment activities and data validation procedures established for this project are discussed in detail in Sections C and D.

B10.3 Data Transformations

Conversions, also termed transformations, established in the data management system are all reversible. Manually recorded observations and data are entered into the Sandy Lowem & Associates data system as recorded; data entry screens match the respective field form. For this project, transformations of manually recorded field records performed under control of the data system will be restricted to reformatting and tabulation routines that do not involve mathematical transformation calculations.

For the computerized data acquisition performed by the LIMS, sensor voltages are transformed to chemical concentrations using a series of relationships. The relationships are not subject to change: applicable parameters depend on specific experimental conditions. These parameters are specified by the operator or are established on the basis of routine calibration and then are combined to produce the reported PCB concentrations. The relationships and parameter values will be delivered as part of the final data package.

The GPS equipment uses transformations to convert satellite-based measurements to state plane coordinates. These transformation routines are validated procedures built into the GPS data loggers and associated software by the manufacturers.

B10.4 Data Transmittal

Observations and data manually recorded on the field forms described in Section B2.8.2 will be faxed daily to Sandy Lowem & Associates' office by the Field Team Leader, and the originals will be stored temporarily in a locked file cabinet in the field office. Data will be entered into the Sandy Lowem & Associates data system daily for ongoing management.

The manually calculated coordinates and the GPS-measured coordinates of the corners of each DA will be transmitted from Shootit Wright Surveyors to Sandy Lowem & Associates in the surveyor's final report. This transmission will take place within 1 week of completion of field survey activities, at which time the data will be entered into the Sandy Lowem & Associates data management system.

Data entered into Bunse & Burner Laboratory's system are managed by the LIMS, beginning with sample check-in on the sample-receiving data terminal. Certain data in the LIMS, such as sample tracking information and final QA-checked analytical results in the proper EDD format, are transmitted nightly to the Sandy Lowem & Associates data system. This transmission not only ensures that project records are maintained current but also provides for a *de facto* data backup capability. Checksums used in the commercially procured telecommunications software verify the correctness of each packet of a transmission. The full laboratory data reports described in Section B4.7 will be delivered to Sandy Lowem & Associates within 3 weeks of the laboratory's receipt of the associated samples.

B10.5 Data Analysis

Data analysis in this project will be performed by Sandy Lowem & Associates project staff using add-on routines to the production version of the data management system. These add-on routines follow the Chen test data analysis procedures discussed in Section D3. Additionally, the data management system produces data summary tables showing user-selected parameters that can be formatted according to numerous data comparison and sorting procedures. Data analysis results such as mean PCB concentrations for each DA will be superimposed on the site map to assist with interpretation of project data.

B10.6 Data Tracking

The Sandy Lowem & Associates data management system will include the milestones of planned project activity and the numbers of samples to be collected. Routines in the data system will use this information to assist the PM and the field teams by monitoring the progress of sample collection and processing to ensure that samples are indeed collected as planned. This monitoring will continue throughout laboratory sample analysis by tracking the specified turn-around times for each sample.

B10.7 Data Storage and Retrieval

Once delivered to the Sandy Lowem & Associates office, the hard-copy originals of field forms containing manually recorded information will be bound. The completed forms and notebooks will be stored in the custody of the PM for the duration of the project, and the full laboratory data reports submitted to Sandy Lowem & Associates will be stored in the custody of the Sandy Lowem & Associates QAM. Bunse & Burner Laboratory will maintain possession of original laboratory hard-copy documents and magnetic tape backups of GC data.

The project records entered into the Sandy Lowem & Associates data management system will be downloaded weekly to a CD-ROM disk. This disk is stored in a locked fireproof cabinet under custody of the Sandy Lowem & Associates PM.

Following the management policy of Sandy Lowem & Associates, project files will be archived offsite at a secure facility for a minimum of 10 years following delivery of the final report. The records will not be destroyed without written approval from EPA.

C ASSESSMENT/OVERSIGHT

C1 ASSESSMENT ACTIVITIES

EPA has conducted a thorough management systems review of Sandy Lowem & Associates as part of the contractor selection process. Similarly, Sandy Lowem & Associates implements an ongoing management evaluation program of each regularly used subcontractor, including Bunse & Burner Laboratory. These evaluations have established that the QA management structure, policies, practices, and procedures of these organizations are adequate for ensuring that the type and quality of data needed for this investigation can be obtained.

In addition to the management system reviews, the QA assessment activities presented below are planned for this project. Table 6 lists these assessment activities and, for each activity, indicates the frequency, number of assessments, timing, and responsible personnel.

C1.1 Technical Systems Audits

Two TSAs will be conducted of field activities and two will be conducted of laboratory operations. The audits will be conducted by the Sandy Lowem & Associates QAM. The first laboratory and field TSAs will be conducted within the first week of activity. The second audit will be conducted approximately halfway through the program. Additional TSAs will be scheduled if warranted by audit observations and findings.

A TSA is a thorough, systematic, onsite, qualitative audit of project systems. For both the field TSA and the laboratory TSA, the QAM will develop a checklist to guide the audit that is based on the requirements included in this QAPP. Field TSAs focus on the appropriateness of personnel assignments and expertise; availability and proper use of field equipment; adherence to project-controlling documents for sample collection, identification, handling, and transport; proper collection and handling of QC samples; and adherence to established COC, equipment decontamination, and documentation procedures. Laboratory TSAs include reviews of sample handling procedures, internal sample tracking, SOPs, analytical data documentation, QA/QC protocols, and data reporting.

C1.2 Data Validation

The laboratory analytical results will be subject to validation to assess for bias and to review for completeness, representativeness, and acceptable levels of precision and accuracy. The acceptance criteria for measurement data are described in Section B5.2. Data validation procedures are presented in Section D2. The validation of data quality is, in part, based on the analytical results of field duplicate soil samples submitted to the laboratory blind (laboratory is unaware that the sample is a QC duplicate) and the analytical results of PE soil samples submitted to the laboratory as double-blind samples (laboratory is unaware that the sample is a QC sample and also does not know the spiked concentration in the sample). In addition to the blind field QC samples, the validation of data quality is based on the results of laboratory QC procedures discussed in Section B5 and shown in Table 5.

C1.3 Data Quality Assessment

As discussed in Section B5.2.5.2, the analytical results that are found to be of acceptable quality through data validation will be used in the DQA process using the Chen test. The Chen test is a statistical tool that evaluates whether the minimum sample size has been obtained to achieve the decision error limits established in Section A7.6. The Chen test directions to be followed to assess the valid data generated for each DA are further discussed in Section D3. The results of the DQA process will be presented in the final RI report and, therefore, cannot warrant mid-project corrective action or QA documentation as described in the next two sections.

C1.4 Corrective Action Process and Responsibility

The first level of responsibility for identifying the need for corrective action lies with the field and laboratory technical staff during routine sampling and analysis activities. The second level of responsibility lies with any person observing deviations during field audits, while reviewing field documentation, or while reviewing laboratory results (e.g., field observations made by the Field Team Leader, deficiencies identified by the Bunse & Burner Laboratory QA Officer during preparation and review of laboratory data reports, or observations and findings made by the Sandy Lowem & Associates QAM during TSAs or data validation).

Each time the need for corrective action is identified, the problem will be documented on the Corrective Action Request and Tracking Form as described in Section C2.1. The form indicates the person(s) responsible for identifying, implementing, and assessing the effectiveness of the corrective action. It is the responsibility of the Sandy Lowem & Associates QAM to track the progress of the corrective action and update management on the progress (see Section C2.4).

C1.4.1 Field Corrective Action

Corrective actions will be initiated if the field team is not adhering to the prescribed sampling or documentation procedures or if laboratory analyses are experiencing interference or systemic contamination due to field sampling procedures or sample handling protocol. Corrective actions begin with identifying the source of the problem. Corrective action responses may include more intensive staff training, modification of field procedures, or removal of the source of systemic contamination. Once resolved, the corrective action procedure will be fully documented as described in Section C2.1. In an extreme situation, a revision of this QAPP will be prepared and distributed for implementation.

C1.4.2 Laboratory Corrective Action

Analytical system upsets caused by sample contaminants will be handled by the analyst in consultation with the Bunse & Burner Laboratory Operations Manager and QA Officer. Sections 3.0 and 7.11 of SW-846 Method 8000B discuss methods to reduce interferences, improve performance, and maintain the GC system. Potential problems include carryover contamination due to samples with unexpectedly high concentrations, elevated baseline problems, contamination with high-boiling materials, and carrier gas contaminants. Additional cleanup of the sample extract may be required. Changeout of columns and detectors may be required. All corrective actions will be recorded in the laboratory notebook and reviewed periodically by the Bunse & Burner Laboratory Project Manager and QA Officer. Once resolved, the corrective action procedure will be fully documented as described in Section C2.1. In an extreme situation, this QAPP will be revised and distributed for implementation.

For failures of the GC's mechanical, electronic, or thermal subsystems, Bunse & Burner Laboratory technical staff will inform the Laboratory Operations Manager who will, in turn, call on the manufacturer's service representative for assistance in repairing and/or replacing failed components. This procedure also applies to failures (crashes) of the computerized data acquisition system. Bunse & Burner Laboratory has multiple analytical systems available as backup. Repair and replacement activities will be documented in the instrument logbook maintained with each analytical or data acquisition system.

C2 ASSESSMENT DOCUMENTATION AND REPORTS

This section describes documentation and reporting requirements for the assessment activities described in Section C1.

C2.1 Corrective Action Request and Tracking Form

Any one who identifies the need for corrective action will document the nature of the problem on a Corrective Action Request and Tracking Form. An example form is included in Appendix A. The initiator will submit the form to the Sandy Lowem & Associates QAM. The QAM will identify appropriate parties responsible for recommending, implementing, and evaluating a corrective action strategy. Each of these corrective action steps will be documented on the form. It is the overall responsibility of the Sandy Lowem & Associates QAM to track the progress of the corrective action and update management on the progress (see Section C2.4). Once the corrective action is deemed successful, the issue is closed out as indicated by the signatures of the RSM, EPA QA Officer, Sandy Lowem & Associates PM, and Sandy Lowem & Associates QAM.

C2.2 Audit Reports

The Sandy Lowem & Associates QAM will prepare an audit report summarizing the observations and findings, if any, of each of the TSAs. The audited group will be allowed to comment on the audit reports before they are finalized. Each audit report will present recommendations of observations or findings that warrant commencement of a Corrective Action Request and Tracking Form (see Section C2.1). The distribution list for audit reports will be the same as the

distribution list for this QAPP, except that Bunse & Burner Laboratory personnel will not receive reports of field TSAs. Audit reports will be included as appendixes to the final RI report.

C2.3 Data Validation Reports

A data validation report will be prepared for each laboratory data report generated. Data validation procedures are discussed in Section D2. The data validation report will address whether the quality of the data is appropriate for the intended use of the data.

Each data validation report will include a tabulation of QA/QC issues, findings, and deficiencies. The Sandy Lowem & Associates QAM will issue a draft report to the Bunse & Burner Project Manager and QA Officer. These individuals will address QA/QC issues, findings, and deficiencies that are found to be correctable (e.g., omitted information). After these corrections are made, the final data validation report will be prepared. The final report will present recommendations of QA/QC issues, findings, and deficiencies that warrant commencement of a Corrective Action Request and Tracking Form (see Section C2.1). The distribution list for data validation reports will be the same as the distribution list for this QAPP. Data validation reports will be included as appendixes to the final RI report.

C2.4 Monthly QA Summaries

As described in Section A9.3.1, Sandy Lowem & Associates will prepare a monthly progress report and submit it to EPA no later than the 15th of the month following the period being reported. The monthly progress report will contain a QA summary prepared by the Sandy Lowem & Associates QAM. The QA summary also will indicate the status of each deficiency that is being tracked on a Corrective Action Request and Tracking, if any. The QA summary also will provide an overview of other QA/QC observations and findings identified within the reporting period that have not warranted corrective action.

D DATA VALIDATION AND USABILITY

D1 DATA REVIEW, VALIDATION, AND VERIFICATION

The purpose of this section is to describe the process for documenting the degree to which the collected data meet the project objectives, individually and collectively, and to estimate the effect of any deviations on the ability to use the data for addressing the decision rule described in Section A7.5.

D1.1 Sampling Design

For this project, the critical sampling design variable is that each composite sample is representative of the intended DA; that is, that the state plane coordinates reported for each soil specimen fall within the intended DA sector (see Section B2.4). Considering that the intent of the sampling plan is to collect each soil specimen from a randomly selected location within a DA sector, specimen sampling location errors are acceptable as long as the location still falls within the sector boundaries and the errors are random.

As described in Section B2.3, the GPS data collected by the field sampling teams at each soil specimen sampling location will be calibrated to the boundaries of each DA reported by the licensed land surveyor. After this calibration is performed, a routine built into the Sandy Lowem & Associates data management system will check whether the location of each specimen sampling location falls within the intended DA sector. The Sandy Lowem & Associates PM will review this documentation, evaluate the suitability of each sample for use in the project, and accept or reject each sample. The rationale of the PM's decision will be noted in the data management system for any sample that contained at least one soil specimen falling outside the intended DA sector.

D1.2 Sample Collection Procedures

Deviations from the prescribed sampling procedures are noted on the sample collection forms and/or in TSA reports. Such deviations may include inappropriate soil specimen sampling depths or inconsistent soil specimen volumes that are homogenized to form a composite (see Section B2.7). The documented deviations will be included in the computerized data management system. The PM will review the rationale for the deviations, evaluate the suitability of each sample for use in the project, and accept or reject each sample. The rationale of the PM's decision will be noted in the data management system for any sample with noted deviations.

D1.3 Sample Handling

Deviations from the planned sample handling procedures (e.g., preservation, custody, and transport as described in Section B3) will be noted on the COC forms and in the field notebooks. These sample handling deviations will be included in the computerized data management system. The PM will review the deviations, evaluate the suitability of each sample for use in the project, and accept or reject each sample. The rationale of the PM's decision will be noted in the data management system for any sample with noted deviations.

Sample handling information relevant to laboratory issues will also be supplied to the Sandy Lowem & Associates data management system from Bunse & Burner Laboratory's LIMS. Deviations noted by Bunse & Burner Laboratory are to be noted in the LIMS and in the laboratory data report case narrative. Once integrated into the master data management system, sample handling information is compared against specified variables (e.g., turnaround time) by the data system software. Deviations are reviewed by the Sandy Lowem & Associates QAM as part of the data validation process described in Section D2.

D1.4 Analytical Procedures

Deviations from SW-846 Method 8082 will be noted in the LIMS by the Bunse & Burner Laboratory technical staff analyst or QA Officer and will be discussed in the laboratory data report case narrative. Such deviations will include any change of conditions from the published method (e.g., change in temperature of the capillary column). The LIMS entry and case narrative

will also contain the Bunse & Burner Laboratory QA Officer's recommended use of the associated data. This information will be transferred into the Sandy Lowem & Associates data management system and will be reviewed by the QAM as part of the data validation process described in Section D2.

D1.5 Quality Control

Laboratory QC analyses are monitored by the LIMS; the specified QC samples must be analyzed in response to the directives of the LIMS (work cannot continue until the specified QC sample is analyzed). Since all samples and standards are uniquely identified by bar-code labels, the LIMS is able to track each. In addition, the sample sequence in the autosampler is verified by the system before the system "accepts" a batch of samples for processing.

Field QC samples submitted to the laboratory blind will be identified by the field teams on soil sampling data sheets and in field notebooks. The true identity of these samples will be entered into the Sandy Lowem & Associates data management system. Once the finalized analytical results of primary soil samples, blind QC samples, and laboratory QC samples are transmitted from the LIMS to the master data management system, the software will calculate applicable parameters such as RPD and %R and compare the calculations to the QC acceptance limits discussed in Section B5.2 and shown in Table 5. These data and QC calculations will be reviewed by the Sandy Lowem & Associates QAM as part of the data validation process described in Section D2.

D1.6 Calibration

Field GPS instruments have been calibrated using validated procedures built into the GPS data loggers and associated software by the manufacturers.

Laboratory calibration will be monitored by the LIMS, which has a record of the sample analysis plan including the number, sequence, and acceptable concentration(s) of calibration samples. The LIMS will monitor the sample loading of the autosampler for conformance to the planned sequence and will "accept" only batches of samples that conform to the plan. The results of initial and continuing calibrations will be transmitted from the LIMS to the master data management

system and will be included in the laboratory data report. The calibration data will be reviewed by the Sandy Lowem & Associates QAM as part of the data validation process described in Section D2.

D2 VALIDATION AND VERIFICATION METHODS

This section describes the process for verifying (i.e., determining that project data were collected in a way that meets at least the specified QC acceptance criteria) and validating (i.e., determining that project results are suitable for use in making the specified decision) project data.

Data validation will be performed largely under the Sandy Lowem & Associates data management system and will be reviewed and interpreted by the Sandy Lowem & Associates QAM. The validation results will be presented in reports as described in Section C2.3. Data will be verified by the PM through review of the validated data reports.

Each analytical laboratory report will be reviewed for compliance with the applicable method and for the quality of the data reported. The *EPA Contract Laboratory Program National Functional Guidelines for Organic Data Review* (EPA, 1994a) provides general data validation guidelines that will be applied to the generated data. The data validation procedures described in the *Functional Guidelines* are designed to review each data set and identify biases inherent in the data including assessment of laboratory performance, overall precision and accuracy, representativeness, and completeness. Data validation flags presented in these guidelines will be applied to those sample results that fall outside of the QC acceptance criteria presented in Section B5.2 and in Table 5. An explanation of the data flags is provided in Table 7. The following areas of data validation will be applied to every laboratory data report using the automated routines in the Sandy Lowem & Associates data management system:

- Data completeness
- Holding times
- Blanks
- Initial and continuing calibrations
- QC reference and internal standards
- Laboratory control samples

- MS/MSDs
- Surrogates
- Field and laboratory duplicates
- PE samples.

In addition to the above validation areas, a manual comparison of the EDD to the laboratory hardcopy report will be performed, and the raw data for 25 percent of the laboratory analytical results packages will be scrutinized according to the procedures in the *Functional Guidelines* to verify compound identification and quantification.

D3 RECONCILIATION WITH DATA QUALITY OBJECTIVES

After the data are validated, data of acceptable quality will be statistically evaluated using the Chen test (see Section A7.6). The Chen test directions to be followed for the valid data that were generated for each DA are presented in Appendix C. This data analysis procedure provides an overall reconciliation with the project DQOs because: (1) the only data used in the Chen test analysis are those that, through extensive QC procedures and the data validation process, have been demonstrated to meet project QA/QC acceptance criteria, and (2) it ensures that the limits on the decision error established in DQO Step 6 (Section A7.6) have been met. The limit set on the probability that the Type I decision error will occur is 0.2 (20 percent) at 0.5 ppm, the lower end of the gray region. Following the Chen test procedures ensures that the Type I decision error limit is met. The limit set on the probability that the Type II decision error will occur is 0.05 (5 percent) at 2.0 ppm, the upper end of the gray region. As opposed to the Type I decision error, hypothesis test procedures do not ensure that the Type II decision error limit is met. The Chen test statistical protocol must be used for each DA for which the baseline condition was **not** rejected to demonstrate whether enough valid data have been generated to meet the Type II decision error limit.

The results of the Chen test analyses will indicate which DAs will be: (1) characterized as not posing an unacceptable risk to human health or the environment and dismissed from further RI/FS activities, (2) targeted for characterization of subsurface soil contamination in a subsequent RI phase and included in the FS to evaluate remedial alternatives for surface soil PCB contamination cleanup, or (3) characterized as requiring additional surface soil PCB data before a determination can be made within the established decision error limits as to which of the first two categories applies. For the DAs falling into the third category, additional composite soil samples will be collected until the total set of valid data indicate that the decision error limits are met. If necessary, the DA will be subdivided into smaller DAs for separate evaluation in order to meet the decision error limits.

E REFERENCES

U.S. EPA, 1993. Data Quality Objectives Process for Superfund, Interim Final Guidance. Office of Emergency and Remedial Response. Washington, DC. EPA 540-R-93-071.

_____, 1994a. Contract Laboratory Program National Functional Guidelines for Organic Data Review. Office of Emergency and Remedial Response. Washington, DC. EPA-540/R-94-012.

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_____, 1994c. Guidance for the Data Quality Objectives Process, EPA QA/G-4. Office of Research and Development. Washington, DC. EPA/600/R-96/055.

_____, 1996a. Soil Screening Guidance: Technical Background Document. Office of Solid Waste and Emergency Response. Washington, DC. EPA/540/R95/128.

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_____, 1996c. Test Methods for Evaluating Solid Waste, Physical/Chemical Methods, SW-846, Third Edition, Office of Solid Waste and Emergency Response, Washington, DC.

_____, 1997. EPA Guidance for Quality Assurance Project Plans, EPA QA/G-5. Office of Research and Development. Washington, DC. EPA/600/R-96/055.

U.S. Geological Survey, 1954. Ground Water Resources of Whoostano County. U.S. Government Printing Office. Alexandria, VA.

Figures

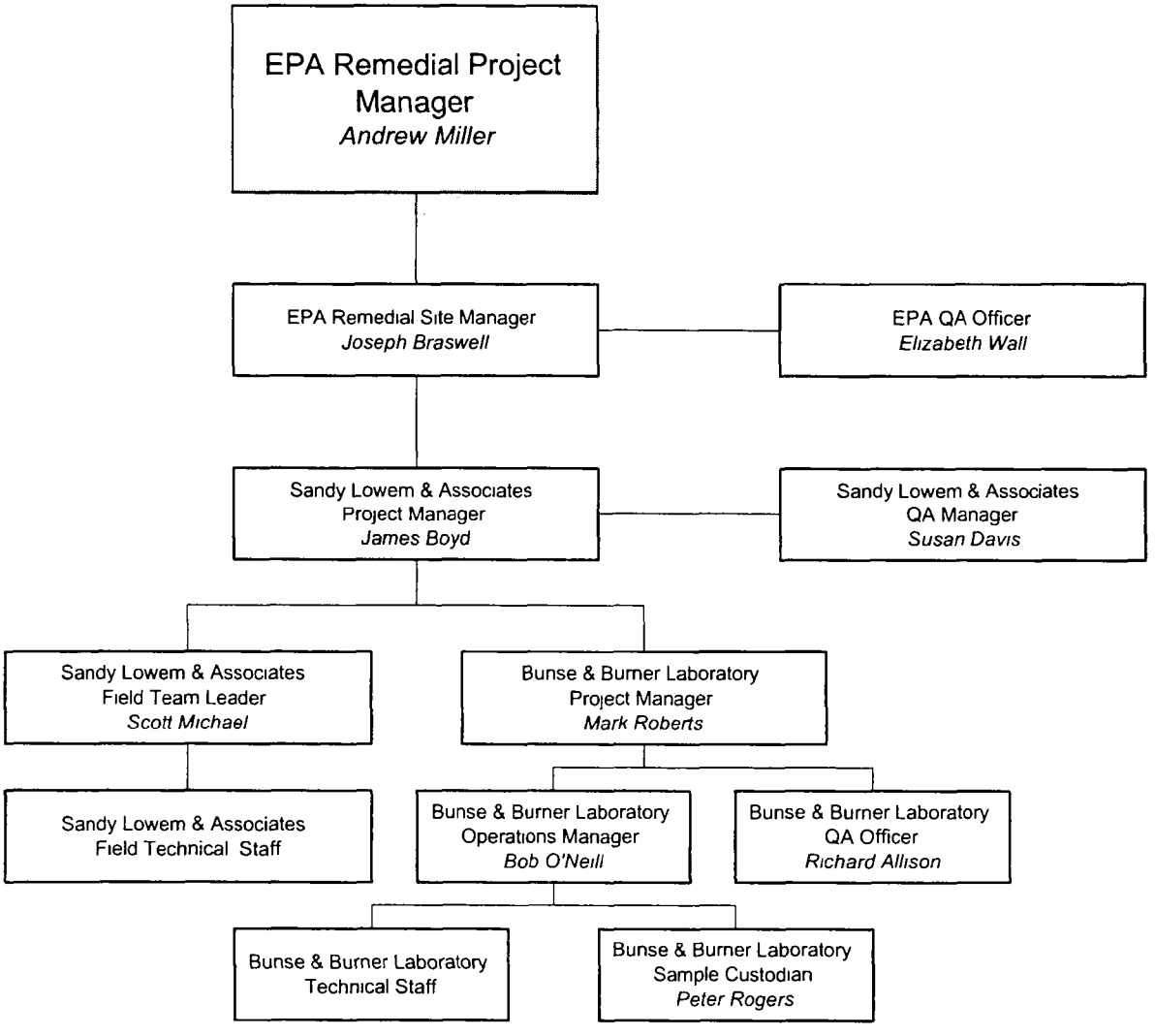


Figure 1. Project Organization Chart

OU2 PCB Contamination RI, EMCA/ECC Superfund Site

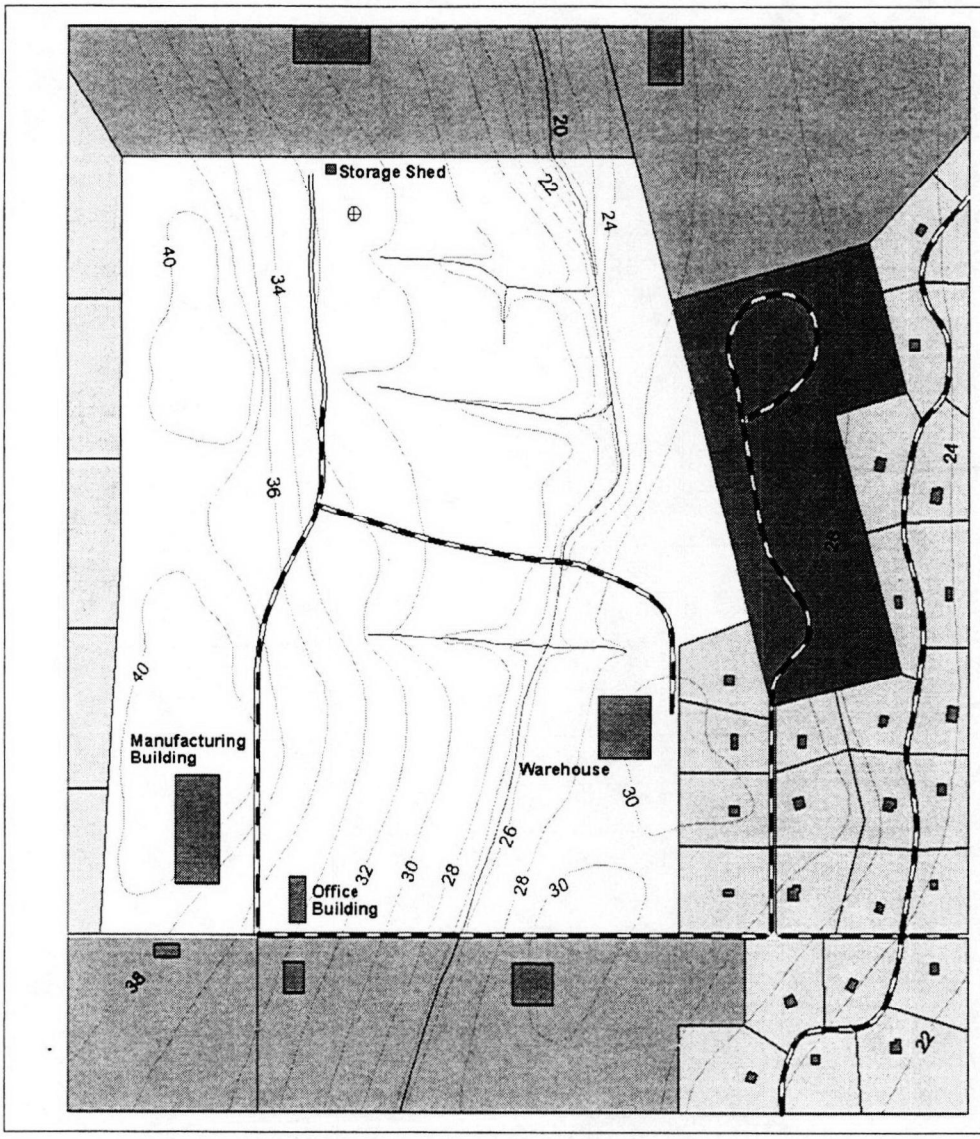


Figure 2. Site Map

EMCA/ECC Superfund Site

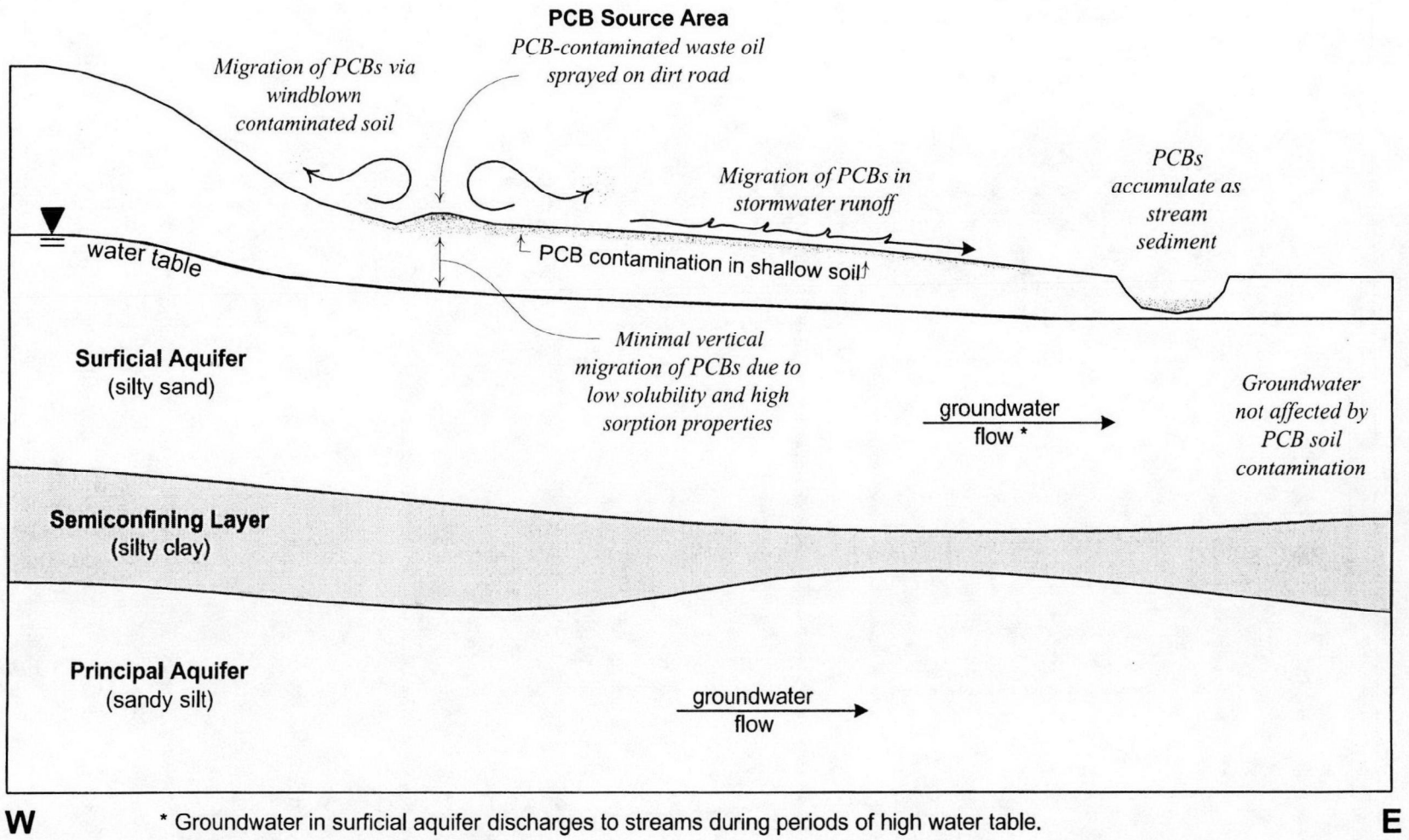
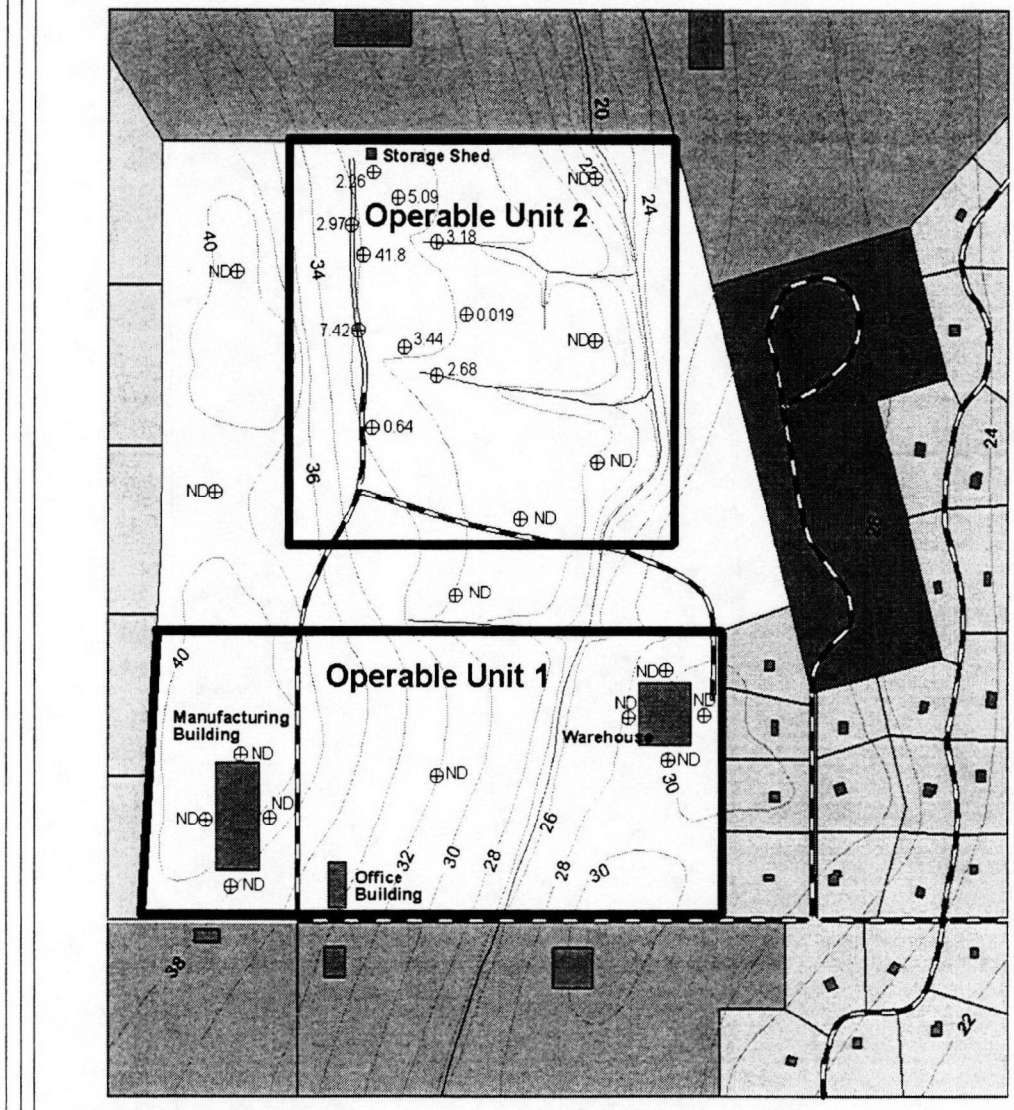


Figure 3. Conceptual Site Model of OU2 PCB Contamination at the EMCA/ECC Superfund Site



Site Legend

Unimproved Roads
Paved Roads
Streams
Topographic Contours (ft. above MSL)
Buildings

Landuse

Industrial
Residential
Site Property
Wellfield

Scale
One Inch = 700 Feet
0 Feet 700

North

7.42 ⊕ Soil Sampling Location with Total PCB Concentration (mg/Kg)

ND ⊕ PCBs Not Detected above the Reporting Limit (0.01 mg/Kg)

Figure 4. Total PCB Concentrations Reported for Preliminary Soil Samples

EMCA/ECC Superfund Site

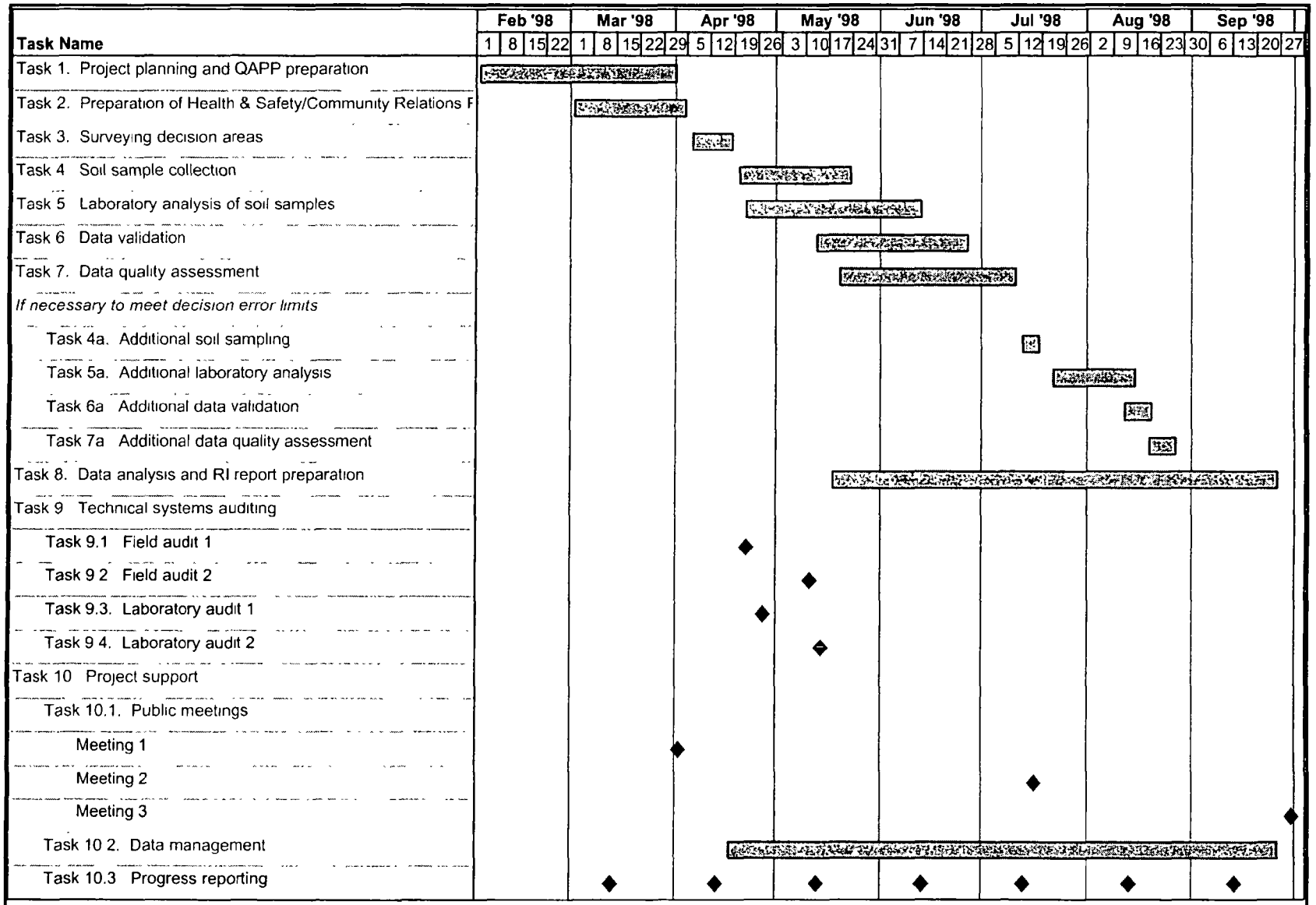


Figure 5. Project Schedule - OU2 PCB Contamination RI, EMCA/ECC Superfund Site

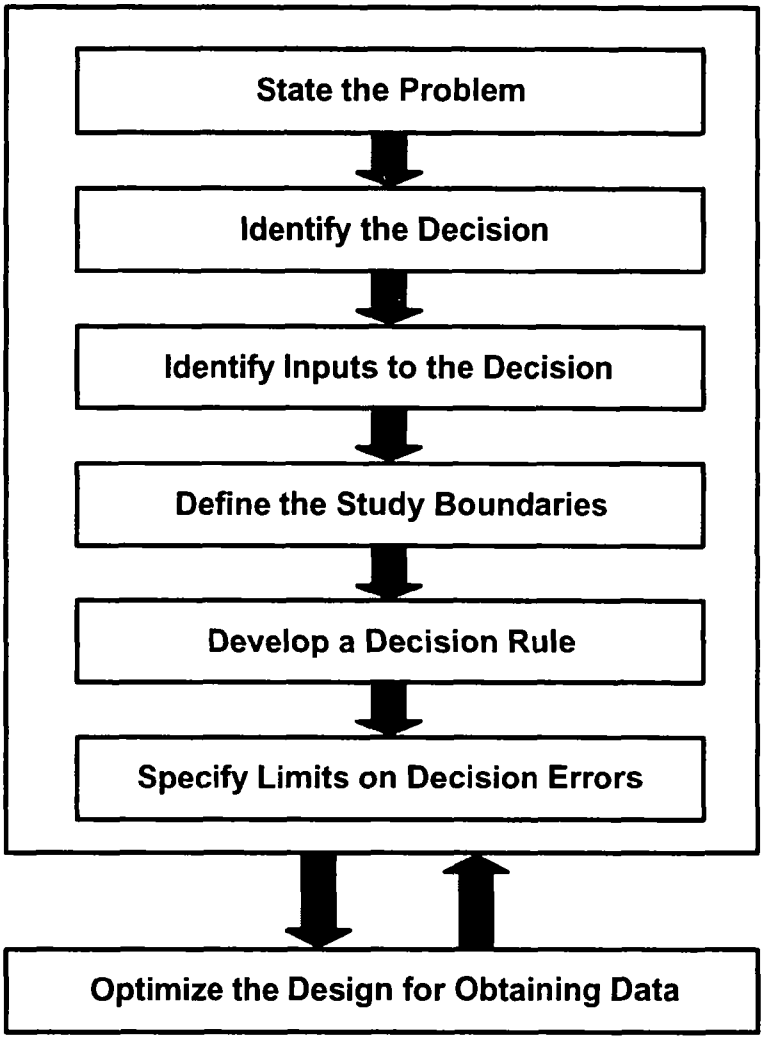
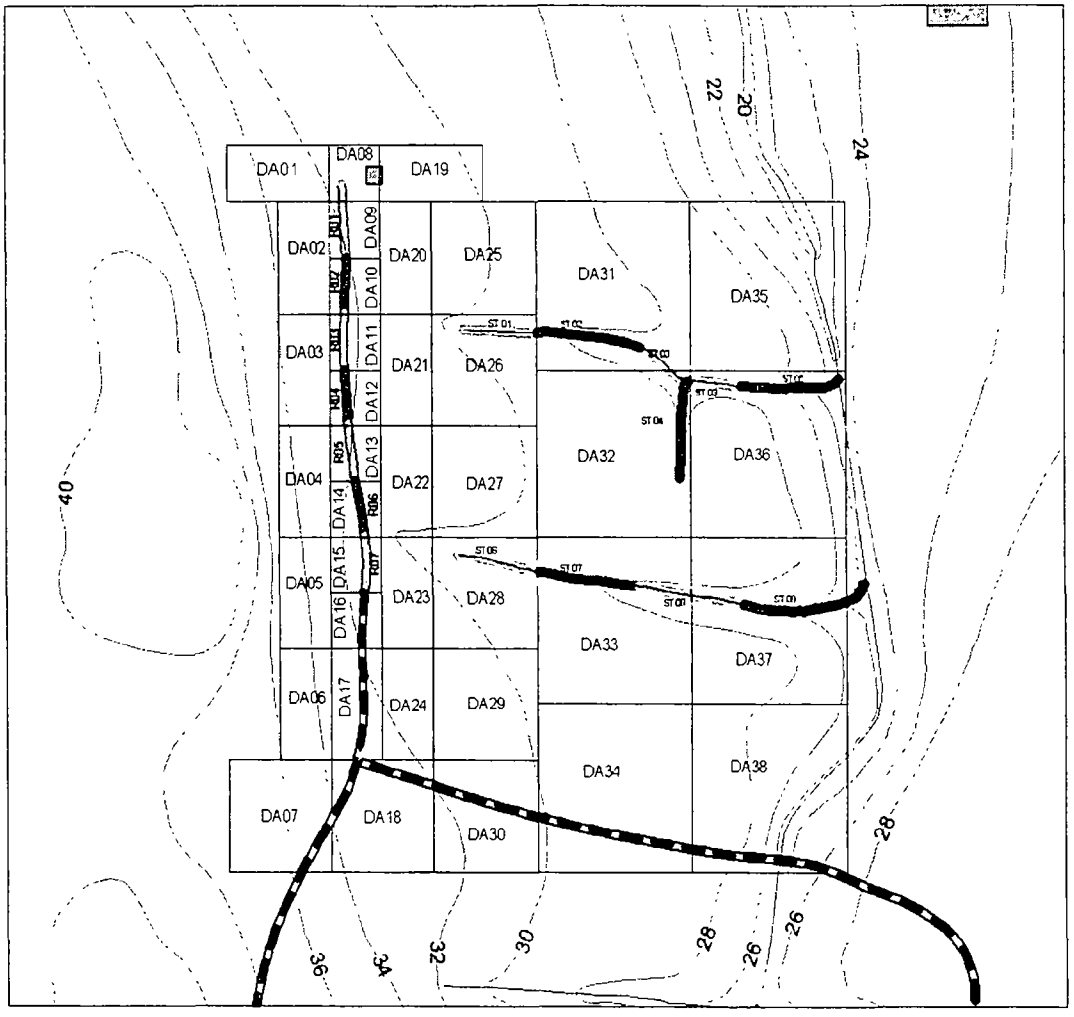


Figure 6. Data Quality Objective Process



Site Legend

- Unimproved Roads
- Paved Roads
- Streams
- Topographic Contours (ft. above MSL)
- Buildings
- DA07 — 0.5 acre to 4.5 acre Decision Area
- RD4 — Dirt Road Segment Decision Area
- ST 04 — Stream Segment Decision Area

Scale
One Inch = 400 Feet
0 Feet 400

North

Figure 7. Operable Unit 2 Decision Areas

OU2 PCB Contamination RI, EMCA/ECC Superfund Site

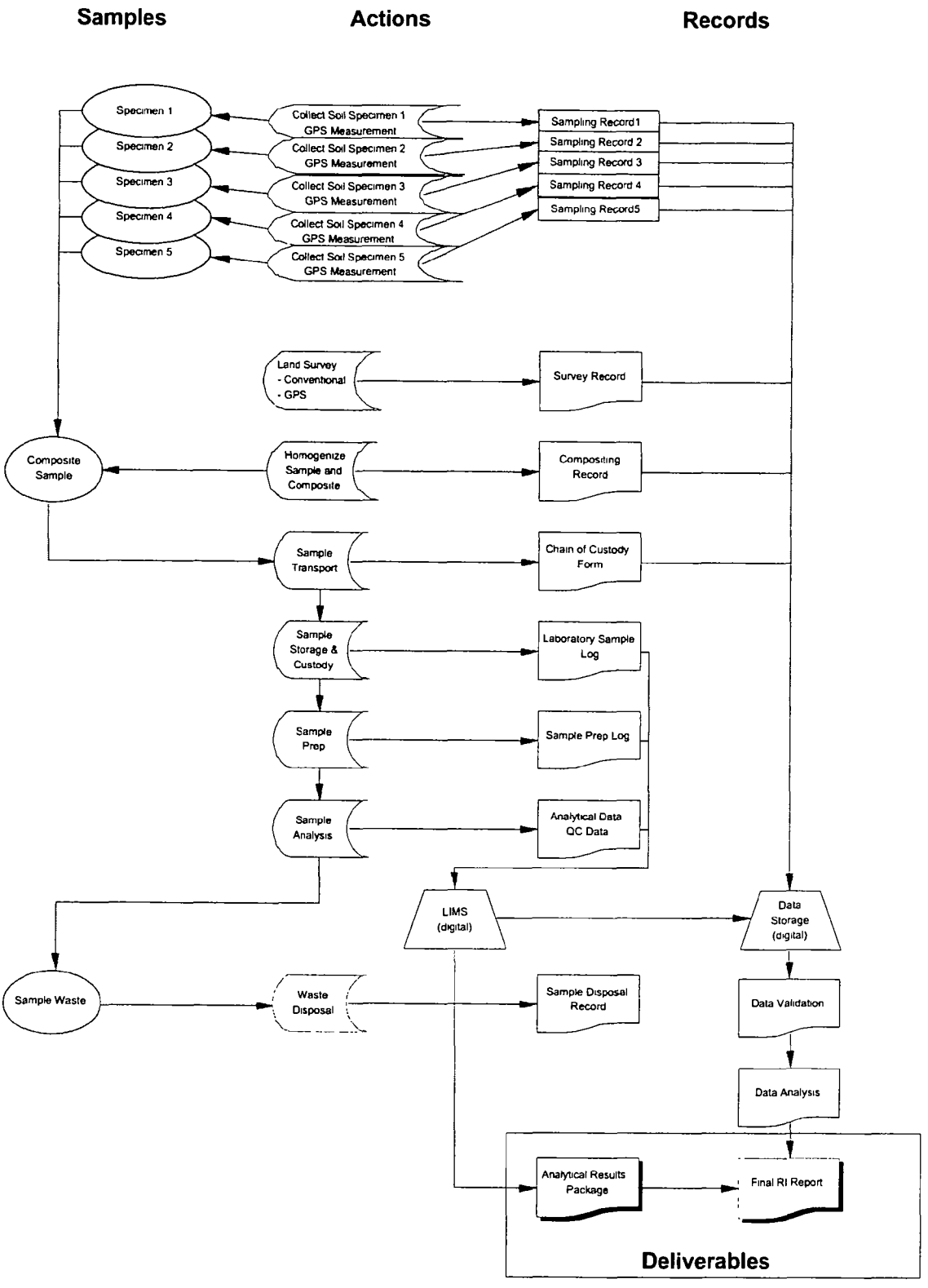


Figure 8. Data Management Process

Tables

Table 1. Health and Environmental Risks from PCBs

Human Health

- Some evidence (limited human data) for increased breast cancer rates
- Accumulation in adipose; especially in fatty deposits of liver
- Known carcinogen in rats and mice (liver); nonmutagenic
- Group 2A classification: limited human data and sufficient animal data to classify as a carcinogen
- Human evidence that it is a female teratogen
- Diffusion of PCB-containing compounds through skin can cause irritation and sensitization through biotransformation (acute topical exposures)
- Hepatic microsomal enzyme disrupters— not directly linked to hepatic carcinoma but directly associated with promotion of thyroidal carcinoma
- Immunosuppressive effect (especially on HIV, HBV, and other CMI-related infections)

Environmental

- Bioaccumulation in terrestrial vertebrates, especially second-order avian populations (documented teratogenic effects)

Table 2. Sampling Plan Summary

Sample Type	Frequency of Collection	Number of Samples	Parameters/ Analytical Methods	Sample Container	Preservation*	Maximum Holding Time
Primary composite soil sample consisting of five homogenized soil specimens	6 from each of the 54 decision areas	324	22 project-specific PCB congeners by SW-846 Method 8082	(2) 4-ounce glass jars	4 ± 2 °C	14 days from sample collection to extraction, 40 days from extraction to analysis
Blind duplicate composite soil sample	1 per 12 primary samples (1 for every other decision area)	27	22 project-specific PCB congeners by SW-846 Method 8082	(2) 4-ounce glass jars	4 ± 2 °C	14 days from sample collection to extraction, 40 days from extraction to analysis
Double blind performance evaluation soil sample	1 upon project startup, and 1 at approximate 25%, 50%, and 75% completion points	4	22 project-specific PCB congeners by SW-846 Method 8082	(2) 4-ounce glass jars	4 ± 2 °C	14 days from receipt by laboratory to extraction, 40 days from extraction to analysis

* Upon sample collection, samples will be maintained in a cooler with sufficient coolant to chill the samples to 4 ± 2 °C until placed in the onsite refrigerator or delivered to the analytical laboratory. While in the onsite refrigerator and in the laboratory, samples will be stored and maintained at 4 ± 2 °C.

Table 3. Specific PCB Congeners in Aroclors

Congener	IUPAC No.	Aroclor						
		1016	1221	1232	1242	1248	1254	1260
Biphenyl	-		X					
2-CB	1	X	X	X	X			
23-DCB	5	X	X	X	X	X		
34-DCB	12	X		X	X	X		
244'-TCB	28	X		X	X	X	X	
22'35'-TCB	44			X	X	X	X	X
23'44'-TCB	66					X	X	X
233'4'6-PCB	110						X	
23'44'5-PCB	118						X	X
22'44'55'-HCB	153							X
22'344'5'-HCB	138							X
22'344'55'-HpCB	180							X
22'33'44'5-HpCB	170							X

IUPAC = International Union of Pure and Applied Chemistry

Table 4. Project-Specific List of Target Analytes and Reporting Limits

Congener	CAS Registry No.	IUPAC Number	Laboratory LOQ (ppb)	Laboratory MDL (ppb)
2-Chlorobiphenyl	2051-60-7	1	3	1.7
2,3-Dichlorobiphenyl	16605-91-7	5	2	0.8
3,4-Dichlorobiphenyl	2974-92-7	12	0.7	0.3
2,2',5-Trichlorobiphenyl	37680-65-2	18	0.7	0.3
2,4,4'-Trichlorobiphenyl	7012-37-5	28	0.3	0.2
2,4',5-Trichlorobiphenyl	16606-02-3	31	0.3	0.2
2,2'3,5'-Tetrachlorobiphenyl	41464-39-5	44	0.3	0.2
2,2',5,5'-Tetrachlorobiphenyl	35693-99-3	52	0.3	0.2
2,3',4,4'-Tetrachlorobiphenyl	32598-10-0	66	2	0.8
2,2',3,4,5'-Pentachlorobiphenyl	38380-02-8	87	0.3	0.2
2,2',4,5,5'-Pentachlorobiphenyl	37680-73-2	101	0.3	0.2
2,3,3',4',6-Pentachlorobiphenyl	38380-03-9	110	0.3	0.2
2,3',4,4',5-Pentachlorobiphenyl	31508-00-6	118	0.3	0.2
2,2',3,4,4',5'-Hexachlorobiphenyl	35065-28-2	138	0.3	0.2
2,2',3,4,5,5'-Hexachlorobiphenyl	52712-04-06	141	0.3	0.2
2,2',3,5,5',6-Hexachlorobiphenyl	52663-63-5	151	2	0.8
2,2',4,4',5,5'-Hexachlorobiphenyl	35065-27-1	153	0.3	0.2
2,2',3,3',4,4',5-Heptachlorobiphenyl	35065-30-6	170	0.3	0.2
2,2',3,4,4',5,5'-Heptachlorobiphenyl	35065-29-3	180	0.7	0 3
2,2',3,4,4',5',6-Heptachlorobiphenyl	52663-69-1	183	0.3	0.2
2,2',3,4',5,5',6-Heptachlorobiphenyl	52663-69-1	187	0.3	0.2
2,2',3,3',4,4',5,5',6-Nonachlorobiphenyl	41086-72-9	206	0.3	0.2

CAS = Chemical Abstract Service
IUPAC = International Union of Pure and Applied Chemistry
LOQ = Limit of quantitation
MDL = Method detection limit

Table 5. Quality Control Sample Analyses and Acceptance Criteria

Description and Use	Frequency of Application	Acceptance Criteria	Laboratory Corrective Action
Method blank. PCB-free soil extracted and cleaned up with regular samples. Checks for contaminants in total analytical system.	At least once per batch of 20 samples.	Each target analyte not detected above the limit of quantitation.	Reanalyze method blank once, reprepare and reanalyze samples that showed similar detections.
Solvent blank. Pure solvent or solvent mixture. Checks for column carryover of analytes.	Once per batch of 20 samples, immediately following the calibration standard.	Each target analyte not detected above the limit of quantitation.	Clean system and reanalyze affected samples.
Calibration check standard. Solution of one or more target congeners at midpoint of calibration range. Also contains the internal standard compound.	After each batch of 20 samples.	Response factor within 15% of initial calibration.	Stop analysis, make corrections, recalibrate, and reanalyze associated samples.
Quality control reference sample. Independently prepared mixture of congeners, including the internal standard. Checks accuracy of calibration standards responses.	Minimum of 1 per 20 samples or 1 per batch if batch is less than 20 samples.	Compound recovery between 80% and 120%.	Evaluate system and prepare/ analyze a new set of calibration standards.
Check of internal standard response. An evaluation of the response of the internal standard (decachloro-biphenyl).	Each sample.	Area of internal standard peak within 50% of average calculated during calibration.	Reanalyze all samples outside this limit on a different instrument to verify matrix effects.
Surrogate standard. Tetrachloro-meta-xylene added to each soil sample prior to extraction. Allows continual evaluation of congener recoveries.	Each sample.	Bunse & Burner Laboratory acceptance range is 60% to 130%.	Reanalyze all samples outside this limit.

Table 5 (continued)

Description and Use	Frequency of Application	Acceptance Criteria	Laboratory Corrective Action
Laboratory control standard (LCS). A clean matrix similar to the sample matrix and of same weight and volume. Spiked identically to matrix spike.	Once per batch of 20 samples.	Bunse & Burner Laboratory acceptance range is 80% to 120%.	Reanlyze the LCS, evaluate extraction/ cleanup procedure, reextract and reanalyze associated samples.
Matrix spike. A project soil sample spiked with one or more congeners to evaluate effect of soil matrix on recovery.	Once per batch of 20 samples.	Bunse & Burner Laboratory acceptance range is 75% to 125%.	Evaluate extraction/ cleanup to improve.
Matrix spike duplicate. Duplicate of matrix spike process using the same project soil sample.	Once per batch of 20 samples.	Compare to matrix spike results, relative percent difference less than 30%.	Evaluate extraction/ cleanup to improve.
Performance evaluation samples (blind from field). Evaluates analytical accuracy.	Four for entire project.	Limits provided by vendor, typically 75% to 125%.	Evaluated during data validation. No immediate corrective action possible.
Field duplicate samples (blind from field). Evaluates overall precision.	One per 12 primary samples (one for every other decision area).	Relative percent difference less than 50%.	Evaluated during data validation. No immediate corrective action possible.

Table 6. Internal Quality Assurance Assessment Activities

Type of assessment	Frequency of assessment	Number of assessments	Approximate date	Responsible Personnel
Management Systems Review, EPA Contractor	None specific to this project	Review of Sandy Lowem & Associates performed as part of contractor selection	March 1997	Various EPA personnel
Management Systems Review, Analytical Laboratory	None specific to this project	Review of Bunse & Burner Laboratory performed routinely by Sandy Lowem & Associates	January 1998	Various Sandy Lowem & Associates personnel
Technical Systems Audits	Upon project startup and approximately at project midpoint	Two of field activities and two of laboratory activities	April and May 1998*	Sandy Lowem & Associates QA Manager
Laboratory Analysis of QC Samples	See Table 5	See Table 5	April through June 1998*	Internal review by Bunse & Burner Laboratory QA Officer
Data Validation	Once per laboratory data report	10	May through June 1998*	Sandy Lowem & Associates QA Manager
Data Quality Assessment Chen Test Analyses	Once per decision area	54	May through July 1998*	Sandy Lowem & Associates PM

* If necessary to meet decision error limits, additional activities may be scheduled for July through August 1998.

Table 7. Explanation of Data Validation Qualifiers

Data Flag	Data Qualifier Explanation
U	The analyte was analyzed for, but was not detected above the reported sample quantitation limit.
J	The analyte was positively identified; the associated numerical value is the approximate concentration of the analyte in the sample.
N	The analysis indicates the presence of an analyte for which there is presumptive evidence to make a "tentative identification."
NJ	The analysis indicates the presence of an analyte that has been "tentatively identified," and the associated numerical value represents its approximate concentration.
UJ	The analyte was not detected above the reported sample quantitation limit. However, the reported quantitation limit is approximate and may or may not represent the actual limit of quantitation necessary to accurately and precisely measure the analyte in the sample.
R	The sample results are rejected due to serious deficiencies in the ability to analyze the sample and meet quality control criteria. The presence or absence of the analyte cannot be verified.

Appendix A

APPENDIX A

Example Project Documentation Forms

- Chain of Custody Form
- Sample Jar Label and Custody Seal
- Soil Sampling Data Sheet
- Corrective Action Request and Tracking Form

Chain of Custody

DATE _____ PAGE ___ OF ___

PROJECT MANAGER

COMPANY: _____

ADDRESS: _____

BILL TO: _____

COMPANY: _____

ADDRESS: _____

_____ ( ) .

SAMPLERS (Signature) PHONE NUMBER

ANALYSIS REQUEST

SAMPLE ID	DATE	TIME	MATRIX	LAB ID

Petroleum Hydrocarbons (418.1)	(MOD 8015) Gas/Diesel	Diesel/Gasoline/BTXE (MOD 8015/8020)	BTXE (8020)	Chlorinated Hydrocarbons (601/8010)	Aromatic Hydrocarbons (602/8020)	MTBE	Pesticides/PCB (608/8080)	Herbicides (615/8150)	Base/Neutral/Acid Compounds GC/MS (625/8270)	Volatile Organics GC/MS (624/8240)	SDWA Primary Standards	SDWA Secondary Standards	SDWA Volatiles (502.1/503.1)	The 13 Priority Pollutant Metals	The 6 EP Tox Metals by EP Tox Prep. (1310)	The 6 EP Tox Metals by Total Digestion	The 6 EP Tox Metals by TCLP	NUMBER OF CONTAINERS

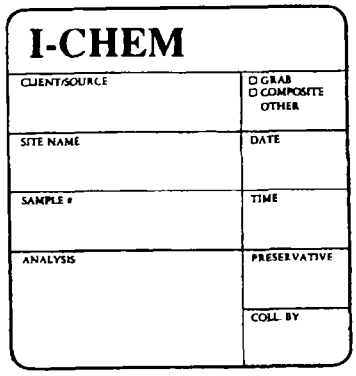
PROJECT INFORMATION	SAMPLE RECEIPT
PROJECT NO:	TOTAL NO. OF CONTAINERS
PROJECT NAME:	CHAIN OF CUSTODY SEALS
P O NO:	INTACT?
VIA:	RECEIVED GOOD COND./COLD
TAT ☐ 24HR ☐ 48 HRS ☐ 1 WK ☐ 2 WKS	LAB NUMBER

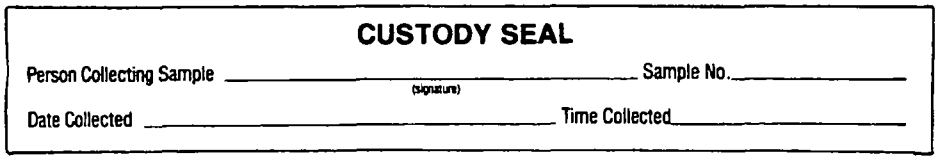
SAMPLE DISPOSAL INSTRUCTIONS

☐ Disposal @ $5 00 each ☐ Return ☐ Pickup (will call)

Comments.

RELINQUISHED BY: 1.	RELINQUISHED BY: 2.	RELINQUISHED BY: 3.
Signature Time.	Signature Time	Signature Time:
Printed Name Date	Printed Name: Date	Printed Name: Date
Company.	Company	Company:
RECEIVED BY: 1.	**RECEIVED BY: 2.**	**RECEIVED BY: (LAB) 3.**
Signature: Time	Signature: Time:	Signature: Time
Printed Name: Date:	Printed Name: Date	Printed Name: Date:
Company	Company	





Sample Jar Label and Custody Seal

Sampling Team Members:________________________________
Page_____ of _____

Soil Sampling Data Sheet
EMCA/ECC Superfund Site
OU2 PCB Contamination RI

Soil Specimen										Composite Sample	
Identification Number				Coordinates, ft. from SW corner of Decision Area		Sampling		Noted Deviations from Planned Sampling Location	Soil Appearance and Other Observations	COC ID for Primary Sample	COC ID for Blind Duplicate Sample
Decision Area		Composite Sample No.	Soil Specimen No.	North	East	Date	Time				
Type*	No.										
	-	-								_______	_______
	-	-									
	-	-									
	-	-									
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* DA = 0.5-, 1 0-, 2 0, or 4.5-acre decision area
ST = stream segment decision area
R = dirt road segment decision area

COC ID for Blind PE Sample: __________________

Corrective Action Request and Tracking Form

EMCA/ECC Superfund Site, OU2 PCB Contamination RI

Problem		
Date(s) Problem Identified:		
Nature of Problem:		
Originator		
Name (print or type)	Signature	Date
Recommendation		
Recommended Action and Timing:		
Recommending Party		
Name (print or type)	Signature	Date
Implementation		
Date Corrective Action Began:		
Implementing Party's Observations/Comments:		
Implementing Party		
Name (print or type)	Signature	Date
Evaluation		
Evaluation of Corrective Action Effectiveness/Implementability:		
Evaluator		
Name (print or type)	Signature	Date
Approval		
Sandy Lowem & Associates Project Manager		
Name (print or type)	Signature	Date
Sandy Lowem & Associates QA Manager		
Name (print or type)	Signature	Date
EPA Remedial Site Manager		
Name (print or type)	Signature	Date
EPA QA Officer		
Name (print or type)	Signature	Date

Corrective action tracking number: _____

Appendix B

APPENDIX B

Example Worksheet for Establishing Soil Specimen Sampling Locations

Decision Area: DA17
Long Dimension Orientation: North-South
Long Dimension Length in feet (D): 418
Short Dimension Orientation: East-West
Short Dimension Length in feet (d): 209

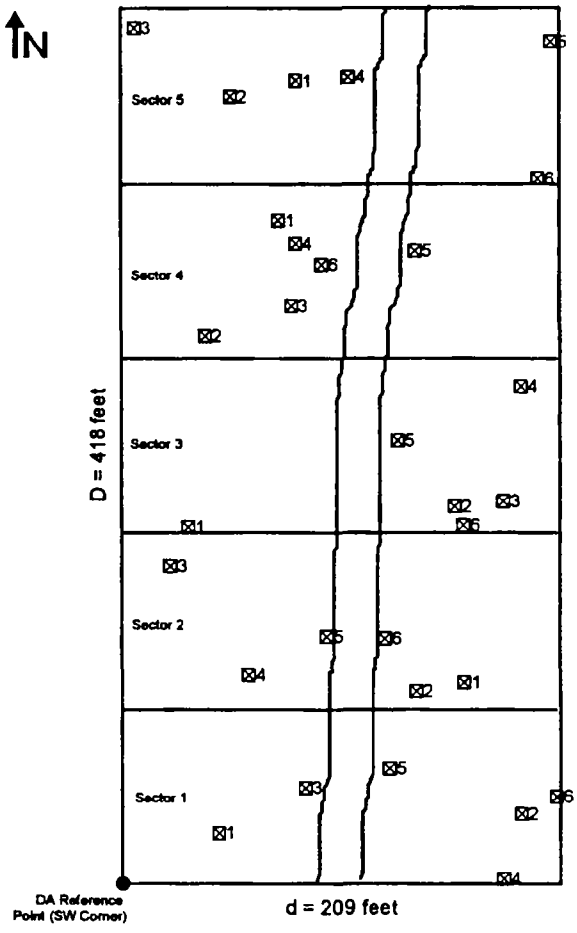
$X = [(R/100)*(D/5)]+[(D/5)*(N-1)]$
$Y = (R/100)*d$

Random Numbers (R):					
29	41	30	22	47	39
40	40	66	91	60	40
55	3	62	42	15	67
3	15	54	87	76	46
66	18	59	61	87	40
50	84	50	99	91	25
15	52	89	78	63	3
10	4	61	67	78	52
81	79	81	11	36	98
19	13	3	29	19	95

Contingency Random Numbers for DAs with Intervening Road or Stream
80
94
87
31
39
53
58
79
54
25

DA Sector (N)	Composite Sample	R	X	R	Y
1	1	29	24.2	22	46.0
	2	40	33.4	91	190.2
	3	55	46.0	42	87.8
	4	3	2.5	87	181.8
	5	66	55.2	61	127.5
	6	50	41.8	99	206.9
2	1	15	96.1	78	163.0
	2	10	92.0	67	140.0
	3	81	151.3	11	23.0
	4	19	99.5	29	60.6
	5	41	117.9	47	98.2
	6	40	117.0	60	125.4
3	1	3	169.7	15	31.4
	2	15	179.7	76	158.8
	3	18	182.2	87	181.8
	4	84	237.4	91	190.2
	5	52	210.7	63	131.7
	6	4	170.5	78	163.0
4	1	79	316.8	36	75.2
	2	13	261.7	19	39.7
	3	30	275.9	39	81.5
	4	66	306.0	40	83.6
	5	62	302.6	67	140.0
	6	54	295.9	46	96.1
5	1	59	383.7	40	83.6
	2	50	376.2	25	52.3
	3	89	408.8	3	6.3
	4	61	385.4	52	108.7
	5	81	402.1	98	204.8
	6	3	336.9	95	198.6

Decision Area DA17



Appendix C

APPENDIX C

Chen Test Procedures for Data Quality Assessment

Directions for the Chen Test

from: U S EPA, 1996 Soil Screening Guidance Technical Background Document
Office of Solid Waste and Emergency Response Washington, D C. EPA/540/R95/128

Let $x_1, x_2, \ldots, x_N$, represent concentration measurements for N random sampling points or N pseudo-random sampling points (i e., from a design that can be analyzed as if it were a simple random sample) The following describes the steps for a one-sample test for H_o: $\mu \le 0.5$ SSL at the 100α% significance level that is designed to achieve a 100β% chance of incorrectly accepting H_o when $\mu = 2$ SSL.

STEP 1: Calculate the sample mean $\bar{x} = \left[\sum_{i=1}^{N} x_i\right] \frac{1}{N}$

STEP 2: Calculate the sample standard deviation

$$s = \sqrt{\frac{1}{N-1}\sum_{i=1}^{N}\left(x_i - \bar{x}\right)^2}$$

STEP 3. Calculate the sample skewness

$$b = N\,\frac{\sum_{i=1}^{N}\left(x_i - \bar{x}\right)^3}{(N-1)\,(N-2)\,s^3}$$

STEP 4: Calculate the Chen test statistic, t_2, as follows:

$$a = \frac{b}{6\sqrt{N}}$$

$$t = \frac{\bar{x} - 0.5\ \mathrm{SSL}}{s / \sqrt{N}}$$

$$t_2 = t + a\left(1 + 2t^2\right) + 4a^2\left(t + 2t^3\right)$$

STEP 5 Compare t_2 to z_α, the 100(1 - α) percentile of the standard normal probability distribution.

If $t_2 > z_\alpha$, the null hypothesis is rejected, and the EA needs further investigation

If $t_2 \le z_\alpha$, there is insufficient evidence to reject the null hypothesis Proceed to Step 6 to determine if the sample size is sufficient to achieve a 100β% or less chance of incorrectly accepting the H_o when $\mu = 2$ SSL.

STEP 6 Let C represent the number of specimens composited to form each of the N samples, where each of $x_1, x_2, \ldots, x_N$ is a composite sample consisting of C specimens selected so that each composite is representative of the EA as a whole (If each of $x_1, x_2, \ldots x_N$ is an individual random or pseudo-random sampling point, then C = 1.)

If Max $(x_1, x_2, \ldots, x_N) < \frac{\mathrm{SSL}}{\sqrt{C}}$, then no further data quality assessment is needed and the EA needs no further investigation.

Otherwise proceed to Step 7.

STEP 7 Calculate the sample estimate of the coefficient of variation, CV, for individual concentration measurements from across the EA.

$$CV = \frac{\sqrt{C}\ s}{\bar{x}}$$

NOTE: This calculation ignores measurement error, which results in conservatively large sample size requirements.

STEP 8. Use the value of the sample CV calculated in Step 7 as the true CV of concentrations in Tables 25 through 30 to determine the minimum sample size, N*, necessary to achieve a 100β% or less chance of incorrectly accepting H_o when $\mu = 2$ SSL.

If $N \ge N^*$, the EA needs no further investigation.

If $N < N^*$, further investigation of the EA is necessary The further investigation may consist of selecting a supplemental sample and repeating this hypothesis testing procedure with the larger, combined sample

Table 25. Minimum Sample Size for Chen Test at 10 Percent Level of Significance to Achieve a 5 Percent Chance of "Walking Away" When EA Mean is 2.0 SSL, Given Expected CV for Concentrations Across the EA

Number of specimens per composite[b]	Coefficient of variation (CV)[a]				
	1.0	1.5	2.0	2.5	3.0
2	7	9	>9	>9	>9
3	5	7	9	>9	>9
4	4	6	8	>9	>9
5	4	5	6	8	>9
6	4	4	5	7	9

[a]The CV is the coefficient of variation for individual, uncomposited measurements across the entire EA and includes measurement error.
[b]Each composite consists of points from a stratified random or systematic grid sample across the entire EA.
NOTE: Sample sizes are based on 1,000 simulations that assume that each composite is representative of the entire EA, that half the EA has concentrations below the limit of detection, and that half the EA has concentrations following a gamma distribution (a conservative distributional assumption).

Table 26. Minimum Sample Size for Chen Test at 20 Percent Level of Significance to Achieve a 5 Percent Chance of "Walking Away" When EA Mean is 2.0 SSL, Given Expected CV for Concentrations Across the EA

Number of specimens per composite[b]	Coefficient of variation (CV)[a]					
	1.0	1.5	2.0	2.5	3.0	3.5
1	9	>9	>9	>9	>9	>9
2	5	7	>9	>9	>9	>9
3	4	5	7	9	>9	>9
4	4	4	6	7	>9	>9
5	4	4	4	6	8	>9
6	4	4	4	5	8	9

[a]The CV is the coefficient of variation for individual, uncomposited measurements across the entire EA and includes measurement error.
[b]Each composite consists of points from a stratified random or systematic grid sample across the entire EA.
NOTE: Sample sizes are based on 1,000 simulations that assume that each composite is representative of the entire EA, that half the EA has concentrations below the limit of detection, and that half the EA has concentrations following a gamma distribution (a conservative distributional assumption).

Table 27. Minimum Sample Size for Chen Test at 40 Percent Level of Significance to Achieve a 5 Percent Chance of "Walking Away" When EA Mean is 2.0 SSL, Given Expected CV for Concentrations Across the EA

Number of specimens per composite[b]	Coefficient of variation (CV)[a]						
	1.0	1.5	2.0	2.5	3.0	3.5	4.0
1	5	9	>9	>9	>9	>9	>9
2	4	4	8	9	>9	>9	>9
3	4	4	5	7	>9	>9	>9
4	4	4	4	5	8	>9	>9
5	4	4	4	5	6	9	>9
6	4	4	4	4	5	8	9

[a]The CV is the coefficient of variation for individual, uncomposited measurements across the entire EA and includes measurement error.
[b]Each composite consists of points from a stratified random or systematic grid sample across the entire EA.
NOTE: Sample sizes are based on 1,000 simulations that assume that each composite is representative of the entire EA, that half the EA has concentrations below the limit of detection, and that half the EA has concentrations following a gamma distribution (a conservative distributional assumption).

Table 28. Minimum Sample Size for Chen Test at 10 Percent Level of Significance to Achieve a 10 Percent Chance of "Walking Away" When EA Mean is 2.0 SSL, Given the Expected CV for Concentrations Across the EA

Number of specimens per composite[b]	Coefficient of variation (CV)[a]					
	1.0	1.5	2.0	2.5	3.0	3.5
2	6	7	>9	>9	>9	>9
3	4	5	7	>9	>9	>9
4	4	4	6	7	>9	>9
5	4	4	5	6	8	>9
6	4	4	4	5	7	9

[a]The CV is the coefficient of variation for individual, uncomposited measurements across the entire EA and includes measurement error.
[b]Each composite consists of points from a stratified random or systematic grid sample across the entire EA.
NOTE: Sample sizes are based on 1,000 simulations that assume that each composite is representative of the entire EA, that half the EA has concentrations below the limit of detection, and that half the EA has concentrations following a gamma distribution (a conservative distributional assumption).

Table 29. Minimum Sample Size for Chen Test at 20 Percent Level of Significance to Achieve a 10 Percent Chance of "Walking Away" When EA Mean is 2.0 SSL, Given Expected CV for Concentrations Across the EA

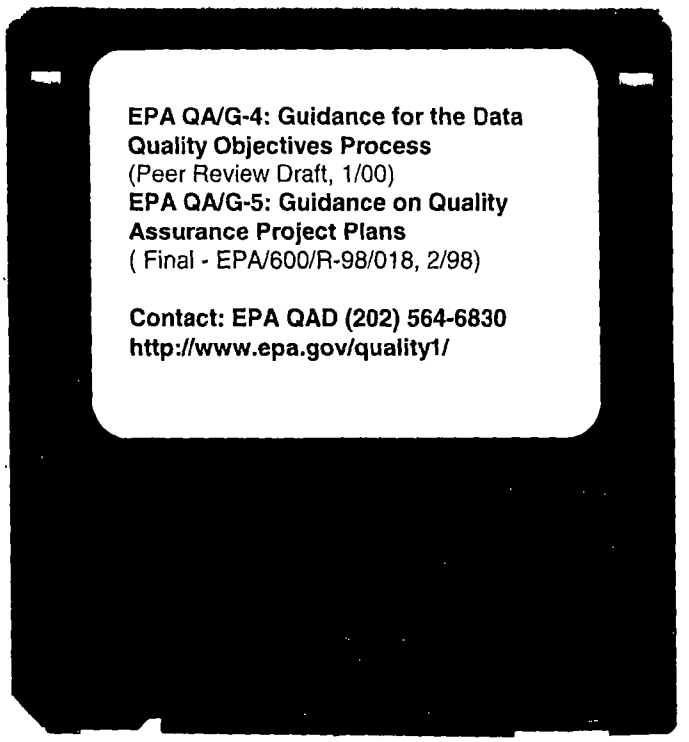
Number of specimens per composite[b]	Coefficient of variation (CV)[a]						
	1.0	1.5	2.0	2.5	3.0	3.5	4.0
1	7	9	>9	>9	>9	>9	>9
2	4	5	8	>9	>9	>9	>9
3	4	4	5	8	>9	>9	>9
4	4	4	4	5	8	>9	>9
5	4	4	4	5	6	8	>9
6	4	4	4	4	5	7	9

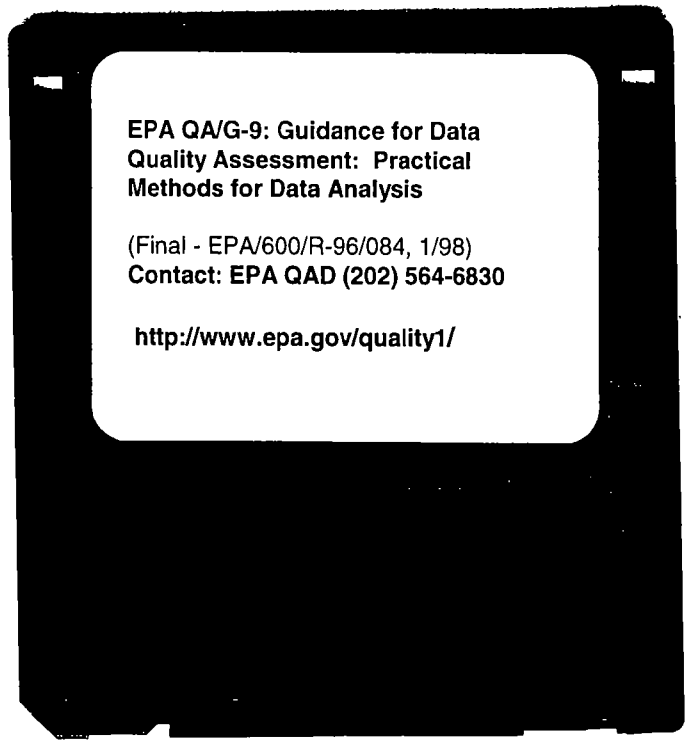
[a]The CV is the coefficient of variation for individual, uncomposited measurements across the entire EA and includes measurement error.
[b]Each composite consists of points from a stratified random or systematic grid sample across the entire EA.
NOTE: Sample sizes are based on 1,000 simulations that assume that each composite is representative of the entire EA, that half the EA has concentrations below the limit of detection, and that half the EA has concentrations following a gamma distribution (a conservative distributional assumption).

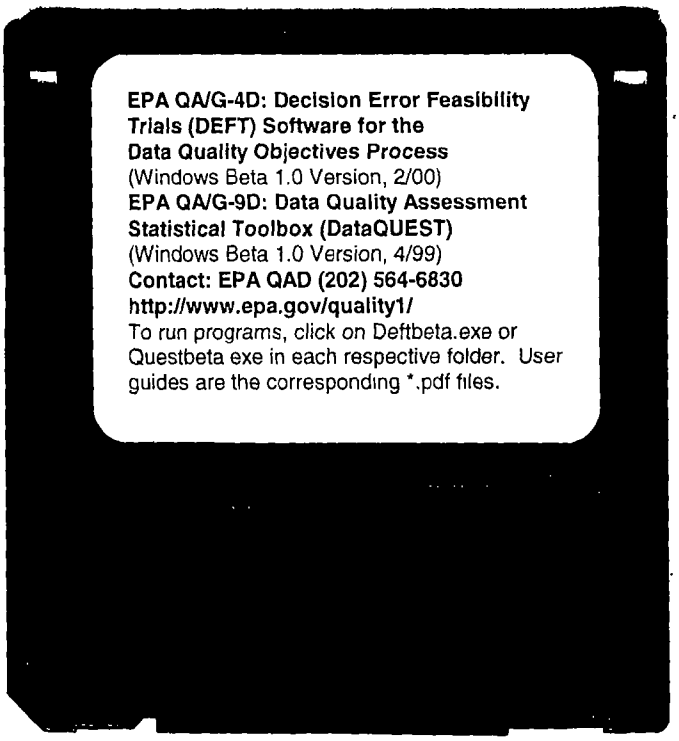
Table 30. Minimum Sample Size for Chen Test at 40 Percent Level of Significance to Achieve a 10 Percent Chance of "Walking Away" When EA Mean is 2.0 SSL, Given Expected CV for Concentrations Across the EA

Number of specimens per composite[b]	Coefficient of variation (CV)[a]						
	1.0	1.5	2.0	2.5	3.0	3.5	4.0
1	4	7	9	>9	>9	>9	>9
2	4	4	5	8	9	>9	>9
3	4	4	4	5	7	9	>9
4	4	4	4	4	5	7	>9
5	4	4	4	4	5	6	8
6	4	4	4	4	4	5	6

[a]The CV is the coefficient of variation for individual, uncomposited measurements across the entire EA and includes measurement error.
[b]Each composite consists of points from a stratified random or systematic grid sample across the entire EA.
NOTE: Sample sizes are based on 1,000 simulations that assume that each composite is representative of the entire EA, that half the EA has concentrations below the limit of detection, and that half the EA has concentrations following a gamma distribution (a conservative distributional assumption).


EPA QA/G-4: Guidance for the Data Quality Objectives Process
(Peer Review Draft, 1/00)
EPA QA/G-5: Guidance on Quality Assurance Project Plans
(Final - EPA/600/R-98/018, 2/98)
Contact: EPA QAD (202) 564-6830
http://www.epa.gov/quality1/


EPA QA/G-9: Guidance for Data
Quality Assessment: Practical
Methods for Data Analysis
(Final - EPA/600/R-96/084, 1/98)
Contact: EPA QAD (202) 564-6830
http://www.epa.gov/quality1/


EPA QA/G-4D: Decision Error Feasibility
Trials (DEFT) Software for the
Data Quality Objectives Process
(Windows Beta 1.0 Version, 2/00)
EPA QA/G-9D: Data Quality Assessment
Statistical Toolbox (DataQUEST)
(Windows Beta 1.0 Version, 4/99)
Contact: EPA QAD (202) 564-6830
http://www.epa.gov/quality1/
To run programs, click on Deftbeta.exe or
Questbeta exe in each respective folder. User
guides are the corresponding *.pdf files.