

**Quality Management Plan
for the
Integrated Petroleum Environmental Consortium**

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Signature Approval Sheet

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Acronyms used in this document

IPEC	Integrated Petroleum Environmental Consortium
IPEC QAO	IPEC Quality Assurance Officer
IPEC EC	IPEC Executive Committee
IPEC ED	IPEC Executive Director
PI	Principal Investigator
QA	Quality Assurance
QC	Quality Control
QAPP	Quality Assurance Project Plan
QAN	Quality Assurance Narrative
PQO	Project Quality Objective
MQO	Model Quality Objective
TSA	Technical Systems Audit
DQA	Data Quality Audit
QAD	Quality Assurance Division

The IPEC mission and quality policy

The mission of the Integrated Petroleum Environmental Consortium is to increase the competitiveness of the domestic petroleum industry through a reduction in the costs of compliance with U.S. environmental regulations.

The success of environmental technology in more effectively assessing and managing risk, or in remediating waste sites, depends largely on the design of the technology, its proper fabrication and construction, and its proper operation. Consequently, quality assurance (QA) and quality control (QC) practices are needed to ensure that environmental technology successfully performs its intended role.

The quality management philosophy of IPEC is as follows:

- ◆ In all technical work, each investigator will ensure that all measures are taken to ensure the quality of collected data, mathematical models, technical analyses, etc. and to predetermine whether these research activities will meet the client's objectives for data and product quality. To this end our project documentation will reflect these measures.
- ◆ We will seek review and feedback by peers, management and stake holders, where appropriate, at all stages of our technical work – before initiation, while in progress, and after the work is completed. From the comments and constructive advice that we receive, we will take actions to continually improve the quality of our research.

Assuring the quality of environmentally related measurements is a critical factor in assessing the quality of environmental research. It is through appropriate QA and QC practices that confidence in the validity of data generated from these measurements is achieved. Each principal investigator for an IPEC funded project will address the particular needs for QA/QC in a project specific QA project plan (QAPP). Intrinsic in the IPEC vision is a dedication and a commitment to quality and continuous improvement. As an aid to interpreting the QMP a glossary of QA terms is provided in Appendix 5.

The purpose of the QMP is to (1) develop QA systems and techniques to maintain and continually improve the quality of environmental data obtained for research, development, and related purposes. (2) Foster the concept of continuous improvement and provide the tools whereby such improvement can be demonstrated, and (3) Integrate the essential elements of quality and quality assessment into the planning, implementation, and review of each project.

Roles and Responsibilities of with Respect to QA/QC Activities

IPEC Structure and Organization

The Integrated Petroleum Environmental Consortium (IPEC) is a consortium of four universities in Oklahoma and Arkansas: The University of Tulsa (TU), The University of Oklahoma (OU), Oklahoma State University (OSU), and The University of Arkansas (UA) at Fayetteville. The fiscal center of IPEC is The University of Tulsa. The mission of IPEC is to increase the competitiveness of the domestic petroleum industry through a reduction in the costs of compliance with U.S. environmental regulations through more effective risk assessment and risk management. Specifically IPEC will:

- ◆ provide the infrastructure to achieve and maintain an outstanding R&D program to address risk assessment and risk management in the domestic petroleum industry,
- ◆ focus R&D expenditures on solving environmental problems in the domestic petroleum industry which pose the greatest risk to human health and the environment,
- ◆ work with the EPA to maintain a close working relationship with the domestic petroleum industry,
- ◆ support the development of outstanding environmental scientists and engineering, and
- ◆ provide technology transfer to the domestic petroleum industry.

The operational activities of IPEC are directed by an IPEC Executive Committee composed of representatives from the four IPEC institutions. The core leadership of this committee is the consortium Director and three Associate Directors. The IPEC Executive Committee and IPEC Directors will be advised by two bodies, an Industrial Advisory Board (IAB) and a Scientific Advisory Committee (SAC). Each element of the IPEC administrative structure is detailed below.

IPEC Executive Committee: The IPEC Executive Committee is composed of three representatives from each IPEC institution, one administrator and two faculty researchers. This committee controls all funding within IPEC subject only to EPA oversight, IAB and SAC input, and restrictions imposed by assurances and testimony to Congress. The current chair of the IPEC Executive Committee is Dr. Joe Suflita (OU).

Director: The Director of IPEC will be a member, but not necessarily chair, of the IPEC Executive Committee and will be responsible for promoting the consortium to industry, the EPA, other government agencies and Congress. The Director will also interface with the other consortia to develop joint research opportunities and other projects of mutual interest. The Director of IPEC is Dr. Kerry Sublette (TU).

Associate Directors: Each IPEC institution not represented by the Director will name an Associate Director from their two faculty representatives to the Executive Committee. The Associate Directors will work with the Director in promoting the consortium. The Associate Directors of IPEC are Dr. Robert Babcock (UA), Dr. Joseph Suflita (OU), and Dr. Khaled Gasem (OSU).

Consortium Staff Assistance: The Consortium Staff Assistance consists of 1.3 FTE staff positions with responsibility of assisting the Director and the IPEC Executive Committee in all matters related to the functioning of the consortium. One full-time staff position resides at the IPEC institution where the Director is employed.

Quality Assurance Officer: The responsibilities of the IPEC QAO include:

- ◆ establish and maintain an IPEC quality management program;
- ◆ develop, prepare, issue and periodically revise, as the need arises, the IPEC QMP
- ◆ prepare documents to be used as guidelines by the researchers to insure successful adherence to EPA's QA/QC requirements;
- ◆ ensure that all affected personnel have a good understanding of the IPEC QMP, of their individual QA responsibilities, and appreciation of the importance of their roles to the overall success of IPEC;
- ◆ consult with IPEC principal investigators on analytical problems, review the QA/QC project plans and their implementation, and make necessary recommendations for revision/implementation;
- ◆ give final approval for all QAPPs prior to release of funds or commencement of work on the project
- ◆ audit periodically the activities of the principal investigators for compliance with approved QA/QC protocol, and issue stop-work directives if serious QA violations are found;
- ◆ transmit QA and other appropriate technical information received from EPA's Office of Research and Development to IPEC researchers; and
- ◆ maintain contact with EPA's Quality Assurance Division (QAD), through subscription to the QAD email listserver, in order to keep-up-to-date regarding QA requirements, documents, etc.

Dr. Greg Thoma currently holds the position of IPEC QAO. IPEC provides one month of salary support QA management activities. Funds for travel related to QA management and training are also provided. The cost of audits is borne by IPEC for Dr. Thoma's role and by the PI for his role (primarily QAPP and QC report preparation). The QAO is on the research faculty at the University of Arkansas, and as such participates as an active IPEC researcher. Conflict of interest concerns regarding the QAO's participation in IPEC research are addressed by the explicit requirement that all projects for which the QAO is a principal or co-principal investigator will have an external QA review and

QA Implementation

Assuring the quality of environmentally related measurements is a critical factor in assessing the quality of the results of environmental research. It is through appropriate QA/QC practices that confidence in the validity of data generated from these measurements is achieved. Each principal investigator for an IPEC funded project will address the particular needs for QA/QC in a project specific QA/QC plan. The project QA/QC plan will describe the parameters to be studied, experimental design features, sampling protocol, QA objectives, analytical procedures, data reduction, validation and reporting, internal QC checks, and a plan for corrective action when necessary. Such a project plan must be submitted and approved by the IPEC Quality Officer before funds are released and experimental begins. In the sections that follow, the general characteristics and requirements of such a plan are described. In addition, a working template is available electronically, and is reproduced in Appendix 5. An overview of the planning process is given below.

Table 1. IPEC Project Level QA Planning Process

STEP	Responsible Individual
1 Set Objectives	PI develops
a) Project Quality Objectives (PQOs)	
b) Modeling Quality Objectives (MQOs)	
2 Develop Quality Assurance Project Plan (QAPP)	PI develops
a) IPEC Standard Template	QAO provides
b) Modeling QAPP	
3 Submit for Review & Revision	PI & QAO
4 QAPP acceptance notification	QAO
5 Start Project	PI

The IPEC QAO and ED have the responsibility to notify PIs with SAC-approved proposals of the requirements of the IPEC QMP. This is accomplished through the notification of award letter from the ED and follow-up communication and assistance in preparation of the QAPP by the QAO.

Systematic Project Planning

Project Quality Objectives (PQOs)

Most IPEC research projects are classified as applied or basic research and will generally not require formal Data Quality Objectives (DQOs) as defined by EPA QAG-4, "Guidance for the Data Quality Objectives Process" (August, 2000). Rather, project quality objectives (PQOs) will be developed using the same basic elements as the DQO process, but will be generally less elaborate and time consuming. PQOs will normally be incorporated in project specific QAPPs. The following elements should be addressed:

- ◆ The principal investigator should specifically define the hypothesis, question, or objective to be addressed, in writing, typically in a work plan or QAPP.
- ◆ Identification of a project schedule.
- ◆ The type and quantity of data needed to answer the hypothesis, question, or objective should be defined.
- ◆ Performance criteria for measuring the quality of the collected data should be specified. These specifications may range from purely qualitative statements to quantitative, statistically defined statements.
- ◆ Specification of QA/QC activities required to meet the quality performance specified (e.g., duplicates, spikes, assessments, etc.)
- ◆ A description of how the collected data will be evaluated and assessed against the quality performance criteria and its intended use.

Model Quality Objectives (MQOs)

IPEC projects that involve the development of mathematical and empirical models require a model quality objective (MQO). The following guidelines are suggested:

- ◆ The MQO shall identify the model client.
- ◆ The intended use of the model should be described.
- ◆ The specifications for the model should be defined.
- ◆ The planned approach to evaluating model uncertainty should be described.
- ◆ The relationship of the model to other models both within and outside EPA should be described.

The modeling QAPP must address the following areas.

- ◆ PQOs are stated.
- ◆ Descriptions or references are provided for techniques, analytical methodologies, and basic theory that will be used to meet research objectives.
- ◆ An experimental design is provided that incorporates statistical considerations.
- ◆ Quality control considerations are addressed.

- ◆ A schedule for audits and/or peer review is presented.

An active EPA modeling group within the National Health and Environmental Effects Laboratory located in Duluth, Minnesota has developed QA planning guidelines customized for modeling projects. These are described in a document titled "Quality Assurance Guidelines for Modeling Development and Application Projects", which can be found in Appendix 3.

These guidelines are adopted as guidance for use on modeling projects. In the future, revisions that reflect the concerns of IPEC modelers will be drafted.

QAPP Elements

Data Quality Assessment

The quality of all measurement data generated and processed will be assessed for precision, accuracy, representativeness, comparability, and completeness. Whenever possible, EPA-recommended procedures will be followed. When deviations from such procedures become necessary, a detailed justification for the changes will be provided.

Precision: Interpretation of precision data must always be based on a clear knowledge of how the data were created. For example, the precision of data derived from a total sampling and analysis effort can only be established through analysis of multiple samples taken (not split) in the field. Precision data generated from multiple measurements of standards only describe the stability of the measurement device or instrument and only represent the ultimate precision which could be achieved for a field sample if the sampling activity, subsequent sample preparation steps, and the sample matrix had no impact on final results. It must be kept in mind that specific sampling and analysis situations may require additional precision information. If this is the case, a clear indication of "what will be done and why" will be provided by the principal investigator in the QA/QC project plan.

Accuracy: EPA-approved methodologies contain a mechanism for demonstrating the relationship of reported data compared to the "true" values (quality control/performance evaluation samples) and/or estimated "true" values (spiked samples). As is the case with precision, the point in the sampling and analysis scheme at which spiking takes place will affect the interpretation of recovery results. Standard EPA-approved methodologies regarding use of analytical standards and spiked samples will be followed or any changes will be clearly indicated and justified by the principal investigator in the QA/QC project plan.

Representativeness: Each QA/QC project plan will contain procedures to ensure and document that each sample collected represents the medium sampled insofar as it possible. Conceptually, this will involve detailed consideration of the total matrix of the

system being sampled and its manipulation in relation to the validity of raw data finally recorded.

Comparability: Elements to be addressed will include: consistency of reporting units (generally weight/weight, weight/volume, or volume/volume); reporting data to the appropriate number of significant figures; traceability of standard reference materials; use of Federal Reference, equivalent, or alternate test procedures; and standardization of data format. QA/QC project plans developed by the principal investigators will reference standard sampling techniques, when applicable.

Completeness: When relevant, the QA project plan will measure the amount of valid data obtained from a measurement system compared to the amount that was expected to be obtained in order to achieve a particular statistical level of confidence in the data resulting from that measurement process.

Data sources outside EPA: The use of data not obtained from projects with EPA-approved QAPPs is acceptable provided that the data are evaluated and qualified for the specific use intended. A common use of data of this type would be literature data used for verification of mathematical models. In general, the use of data from non-peer reviewed sources should be avoided unless documentation of data quality is available to the data user (the PI in this case).

Sample Accession and Handling

The success of any data collection program depends ultimately on its ability to produce valid data and to demonstrate this validity. In addition to proper sample collection, preservation, storage, and handling, appropriate sample identification and chain-of-custody procedures are necessary to help ensure data validity.

Sample Collection: It is recognized that sampling is one of the most critical steps in chemical measurement. The aim of sampling is to provide a reproduction of a portion of the environment on a scale that enables the samples to be handled in the laboratory. The sampling sites, techniques, frequency of sampling, and the size and number of samples must allow the analytical results to be statistically evaluated and replicated at a later time for confirmation. If storage of samples prior to analysis is necessary, it must be proven that no alteration in the nature of the residue has occurred.

EPA- approved collection methodologies will be followed by the principal investigators whenever feasible. This includes care and use of sampling equipment and sample containers, as well as sample preservation and storage.

Sample Integrity and Chain-of-Custody: A sample is physical evidence collected from a facility or from the environment. An essential part of the investigation effort is that the evidence gathered be controlled. In order to accomplish this, each sample collected (either in the field or in the laboratory) will be properly labeled with sample number, description, and time of collection. This information, along with preservatives added

and any information regarding the samples and method of shipment, will be recorded on a preprinted sample logging form.

Samples will be stored in coolers for transportation to the appropriate laboratories, whereupon a designated sample custodian (generally the principal investigator or a designee) will verify that each item listed on the log sheet is present and correctly identified. The appropriate information will then be entered into the laboratory's sample logbook and the samples will be stored according to EPA-approved protocols. A sample data log will be maintained as a means of tracking the status of the sample analyses.

Sample Storage: It is essential that each laboratory have an adequate storage facility for samples. This area, separate from the area where chemical standards are stored, should minimize the possibility of sample contamination, deterioration, or damage. It is advisable that those samples suspected of having large quantities of organics be segregated either by storing in a separate refrigerator or by employing some other means of preventing cross contamination such as placing in a capped, charcoal- filled container.

Calibration Procedures and Frequency

A calibration plan will be developed and implemented for all measuring and test equipment and calibration standards. Implicit in such a plan is the incorporation of frequent calibration checks. Method blanks, duplicate samples, and calibration samples containing internal standards, surrogate standards, and target compounds will be run on a daily basis. A multilevel calibration will be used to establish response factors and to correct for non-linearities in recovery or response, and a 3 point curve will be run daily to verify that significant deviations in response factors have not occurred.

Analytical Procedures

EPA- approved methodologies will be used whenever feasible. In those cases in which EPA methods are not available, the analytical method followed will be described in detail as an appendix to the QAPP. Non-standard methods must be validated to ensure that the results obtained are meaningful. Normally standard operating procedures (SOPs) are prepared and maintained near the instrument used in the SOP. The PI is responsible for updating SOPs in work areas and destroying obsolete versions.

Data Reduction, Validation, and Reporting

The procedures, which describe how data is to be reviewed and validated, will be specified in each QA/QC project plan. These shall include procedures for computing and interpreting the results from QC samples and independent procedures to verify that the analytical results are reported correctly. In addition, routine procedures used to monitor precision and bias, including evaluations of reagent, equipment rinsate, and trip blanks, calibration standards, control samples, duplicate and matrix spike samples, and surrogate recovery, will be detailed in the procedures.

All data taken in the field and in the laboratory will be entered into laboratory notebooks, and reduced data will be stored in an appropriate medium. Laboratory operations records may include laboratory notebooks, instrument performance logs and maintenance logs, control charts, reference material certification, laboratory procedures, and corrective action reports. Project specific records may include sample log records, calibration data records, raw and finished analytical and QC data, data reports, and procedures used.

Data Quality Audits

Once data quality goals are defined, it is essential to monitor progress toward the goals to ensure that they are being met. Audits of data quality measure the effectiveness of an environmental data operation in achieving data quality goals. This measure of effectiveness allows the data user to determine if the quality of the data is adequate for the intended use of the data. Such audits also identify those areas needing corrective action.

Audits are of two types, system and performance audits. The systems audit consists of an evaluation of all components of the measurement system to determine proper selection and use of personnel and equipment, including an evaluation of both field and laboratory QC procedures. The IPEC QAO will conduct the initial systems audit during the first quarter of active measurements. Such audits will then be performed periodically during the lifetime of the project, with a minimum frequency of one audit per project year. After measurement systems are operational, annual performance audits will be conducted to determine the efficacy of the total measurement system. More details regarding the audit process are given in Appendix 4 and the QA Assessment section below.

Preventive Maintenance

To ensure consistently high data quality, a plan for routine inspection and preventive maintenance will be developed and followed by each principal investigator for all facilities and equipment used in a project. Establishment of a particular preventive maintenance schedule is based upon the identification of critical components that are most likely to fail without the program, and the overall effect of facility or equipment failures on data quality.

An accurate log of all maintenance -- scheduled or not -- is essential to monitoring and documenting data quality. Permanent records of the maintenance histories of all equipment, including description of all parts replaced, will be kept in individual bound notebooks and dated and signed by the principal investigator or his/her designee.

Corrective Action

The procedures describing how to identify and correct deficiencies in the analytical process shall be specified. These will include the specific steps to be taken in

correcting the deficiencies, including preparation of new standards and reagents, recalibration and restandardization of equipment, reanalysis of samples, and additional training of laboratory personnel in methods and procedures. The project principal investigator(s) and IPEC QAO will be responsible for determining the cause(s) and initiating corrective action.

Training / Certification

The PI for each project has the responsibility to assure that the personnel are properly trained or certified to perform the work. This assessment may be made with the assistance of the IPEC QAO. If training or certification is required for a specific project, the PI has the responsibility for insuring that personnel receive the training or certification and documenting it. This would include familiarization of students and technicians with the contents and requirements of the QAPP. A corollary responsibility of each PI is the determination of which procedures or operations require development of SOPs and the dissemination of the procedures to the appropriate technical personnel. When changes in the QAPP have been implemented and approved by the IPEC QAO, the PI bears responsibility for assuring that the changes are implemented in the program. Implementation of any changes in quality procedures will be verified through documented self-assessment and performance audits by the IPEC QAO.

Implementation of Work Processes

The implementation of the IPEC QMP is the responsibility of the IPEC QAO. The most significant aspects of this QMP are the generation, review, approval, and implementation of QAPPs and the documentation, through assessment reports, that the procedures of each QAPP are followed. Each PI bears the responsibility to assure that the QAPP is suited to the specific project and that it is implemented accurately. Typically the QAPP review process requires two or three iterations before approval. Procedures in effect at IPEC assure that each project will have a QAPP; specifically, funds are not released from the fiscal center until the QAO has approved the QAPP. Assessment actions described below indicate the mechanisms IPEC uses to document quality data collection.

Quality Assurance Reports to Management

The results of QA tests will be reported to the IPEC QAO by the principal investigator(s) or other project personnel. The project annual report will include a section on QA that summarizes the appropriate QA/QC information. The IPEC QAO in the QA Annual Report and Work Plan will summarize these annual reports. The QAARWP will be reviewed by the IPEC EC and submitted to the EPA Project Officer

Records Management

At the Consortium level several quality documents will be maintained. These include the QMP (this document), QAPPs from individual research projects, the QA Annual Report and Work Plan (QAARWP), and documentation of project audits. The following table outlines the preparation, review, approval, and distribution of these documents. These records will be stored with those identified in the distribution column of Table 2. Obsolete records will be moved to archival storage, and destroyed after a 5 year holding time. Records over one year old that are not obsolete will also be moved to archival storage and kept at least 5 years past the date of final activity associated with the record.

Table 2 Preparation and disposition of quality records.

Document type	Preparation	Review	Approval	Distribution
QMP	IPEC QAO	EPA, IPEC EC	USEPA	USEPA, IPEC EC, IPEC QAO
QAPP	PI	IPEC QAO	IPEC QAO	PI, IPEC ED, IPEC QAO
QAARWP	IPEC QAO	IPEC ED	NA	USEPA, IPEC EC, IPEC ED, IPEC QAO
Audit Reports	IPEC QAO	PI	NA	IPEC QAO, IPEC ED, PI

Conflict Resolution

When constraints of time, cost or other problems significantly affect the PIs capability to satisfy the IPEC QMP or the project QAPP, the IPEC QAO will negotiate with the PI by the following procedure to establish acceptable measures for the project data quality.

- ◆ If problems occur, the PI notifies the IPEC QAO and ED.
- ◆ The IPEC QAO negotiates and documents an acceptable agreement with the PI.
- ◆ If agreement can not be reached, the EPA QAD will be asked to resolve the dispute.

General Safety Considerations

The analyst should exercise good laboratory techniques at all times when handling toxic chemicals, including utilization of protective gloves, safety glasses, and fume hoods. OSHA, state, and university regulations will be observed for handling, storage, and disposal of reagents and waste. Each campus has an office responsible for institutional compliance (e.g. biosafety or toxic substances protocols). All projects will be required to satisfy the health and safety requirements of their respective campus.

QA Assessment

Audits and assessments are management tools and will be components of the IPEC QA program. They allow the manager to evaluate performance against predetermined specifications. Broadly, a manager is a person responsible for ensuring customer (client) satisfaction. In IPEC, a manager may be the laboratory director, a principal investigator, or a technician. Each must determine their client's quality expectations and specifications. Each must plan to conduct periodic audits to evaluate how well they are meeting those expectations and specifications and to determine where they might improve their performance. A properly designed and conducted audit should yield specific information that can be used to improve the performance of people, systems, and processes. Therefore, an audit followed by timely corrective action is a key to quality (i.e., improved performance). IPEC will use two types of audits. These are Technical Systems Audits (TSA), and Data Quality Audits (DQA). Laboratories at each consortium member institution will be visited, on an annual basis, for a technical systems audit. The IPEC QAO will perform DQA for selected projects annually. Each investigator, at their discretion, will schedule self-audits.

Personnel qualifications, responsibility, and authority

Authority to lead audits is delegated to the IPEC QAO or PI (for self-audits). When available, the IPEC QAO will attend training QA training offered by the EPA. Auditors have the responsibility and authority to

- ◆ Identify, document, and disseminate (where applicable) practices that demonstrate high quality data collection.
- ◆ Identify and document problems affecting the quality of the project's data.
- ◆ Suggest procedures for resolving data quality problems.
- ◆ Require suspension of data collection for any project for which serious deficiencies are found. In the event that problems warranting suspension of work are identified, the work suspension will continue until corrective action is taken and risk to the project is removed. See the discussion on page 17 regarding conflict resolutions. Responsibility for taking corrective action in such cases is principally that of the principal investigator involved.
- ◆ Confirm implementation and effectiveness of any corrective action taken.

Technical Systems Audit

The TSA is a qualitative on-site evaluation of a measurement system. The objective of the TSA is to assess and document all facilities, equipment, systems, record keeping, laboratory procedures, data validation, operations, maintenance, calibration procedures,

reporting requirements, and QC procedures. Also examined are essential elements contained in QAPP. Although the TSA evaluates the technical aspects of a measurement system, it does not provide any quantitative information. However, the information collected during the audit helps the auditor to determine quickly whether data quality is likely to be adequate for its intended use or whether problems observed during the audit may lead to erroneous or unsubstantiated results. A TSA checklist is provided in Appendix 4. The evaluator should assess the applicability of this checklist to the project being evaluated and tailor the checklist accordingly.

Audit of Data Quality (ADQ)

An ADQ involves assessing the methods used to collect (i.e., system/performance audit), interpret, and report the information required to characterize data quality for assessing data integrity. Assessing a data set or a database requires a detailed review of (1) the electronic or manual -recording and transfer of raw data; (2) data calculations; (3) documenting procedures; (4) the selection and discussion of appropriate data-quality indicators (i.e., precision, accuracy, completeness, comparability, and representativeness) (5) security procedures and (6) back-ups.

The Audit Process

The process steps listed below are presented as guidance and will be followed for conducting audits, as appropriate. The steps involving documentation are particularly important to maintaining a credible system of corrective action and quality improvement.

- 1) The Pre-Audit Phase
 - a) Determine the type of project being audited
 - b) Select the appropriate type of audit process
 - c) Notify the auditee of the planned date, intent, scope, and purpose of the preliminary review or audit
 - d) Provide the auditee with self-assessment material
 - e) Review of self-assessment results may be appropriate
- 2) The Audit Planning Phase
 - a) Assign the auditing responsibility
 - b) Conduct the preliminary review of data collection activities
 - c) Summarize the preliminary review
 - d) Select the data collection projects for detailed review
 - e) Prepare the audit checklist and agenda
- 3) The Audit Phase
 - a) Notify the auditee of the scope and purpose of the audit
 - b) Conduct interviews and review the QA documents, data, information, and reports
 - c) Develop audit team consensus on significant positives and negatives and discuss the root cause of negatives

- d) Prepare the debriefing report on findings (positive and otherwise)
 - e) Conduct exit interviews and report preliminary audit findings with the auditee.
- 4) Report Preparation Phase
- a) Prepare the draft audit report
 - b) Review the draft audit report
 - c) Prepare the final audit report
 - d) Distribute the audit report (normally restricted)
 - e) Review and file the auditee's response to the audit report
- 5) Follow-up Audit Phase
- a) Request detailed information on corrective actions
 - b) Evaluate corrective actions
 - c) Prepare follow-up audit agenda (within 45 days, if necessary)
 - d) Conduct formal follow-up audit session
 - e) Prepare the follow-up audit report
 - i) Document areas of agreement
 - ii) Document areas of disagreement
- 6) Audit Closure Phase
- a) Prepare closeout memorandum (notice of no further follow-up)
 - b) Forward closeout memorandum to the appropriate manager

Quality Improvement

After submission and review of the IPEC QAAWRP, the IPEC QAO and EPA QAD personnel will recommend improvements to the plan. The negotiations for these improvements may take place at an annual meeting or through a video conference.

Detecting and correcting quality problems

IPEC PIs and the IPEC QAO report quality problems to the IPEC Executive Committee. Areas that will be monitored include:

- ◆ adequacy of the quality system
- ◆ consistency of the quality system
- ◆ implementation of the quality system
- ◆ completeness of documentation
- ◆ quality of data
- ◆ implementation of the work process

The IPEC QAO will work to correct problems identified as quickly as practical. The IPEC Directors and EC will each receive copies of this QMP and will have the responsibility of insuring that PIs on their respective campuses are aware of the quality requirements of IPEC. The IPEC QAO will contact PIs of funded projects to provide guidance on the preparation of quality documents.

Appendix 1

Glossary of QA Terms

Glossary of Terms

- ◆ **Absolute method** - a body of procedures and techniques for which measurement is based entirely on physically defined, fundamental quantities.
- ◆ **Acceptable quality level** - a limit above which quality is considered satisfactory and below which it is not. In sampling inspection, the maximum percentage of defects or failures that can be considered satisfactory as an average.
- ◆ **Acceptable quality range** - the interval, between specified upper and lower limits of a sequence of values within which the values are considered to be satisfactory.
- ◆ **Acceptable value** - an observed or corrected value that falls within the acceptable range. See Corrected value and Observed value.
- ◆ **Acceptance sampling** - the procedure of drawing samples from a lot or population to determine whether to accept or reject a sampled lot or population.
- ◆ **Accepted reference value** - a numerical quantity that serves as an agreed-upon basis for comparison, and which is derived as; 1) a theoretical or established quantity based on scientific principles, 2) an assigned value, based on experimental work of some recognized organization, or 3) a consensus quantity based on collaborative experimental work under the auspices of a scientific or engineering group.
- ◆ **Accreditation criterion** - a requirement that a laboratory must meet to receive authorization and approval to perform a specified task.
- ◆ **Accreditation** - a formal recognition that an organization (e.g., laboratory) is competent to carry out specified tasks or specific types of tests. See also Certification
- ◆ **Accredited laboratory** - a laboratory which has been evaluated and given approval to perform a specified measurement or task, usually for a specific property or analyte and for a specified period of time.
- ◆ **Accuracy** - the degree of agreement between an observed value and an accepted reference value. Accuracy includes a combination of random error (precision) and systematic error (bias) components, which are due to sampling and analytical operations; a data quality indicator. EPA recommends that this term not be used and that precision and bias be used to convey the information usually associated with accuracy. See Precision and Bias.
- ◆ **Action limit** - see Control limit.
- ◆ **Adjusted value** - the observed value after adjustment for values of a blank or bias of the measurement system.
- ◆ **Aliquant** - a subsample derived by a divisor that divides a sample into a number of equal parts but leaves a remainder; a subsample resulting from such a divisor. See Subsample.

- ◆ **Aliquot** - a subsample derived by a divisor that divides a sample into a number of equal parts and leaves no remainder; a subsample resulting from such a division. In analytical chemistry the term aliquot is generally used to define any representative portion of the sample.
- ◆ **Alpha error** - see Type 1 Error.
- ◆ **Alternate method** - any body of procedures and techniques of sample collection and/or analysis for a characteristic of interest which is not a reference or approved equivalent method but which has been demonstrated in specific cases to produce results comparable to those obtained from a reference method.
- ◆ **Analysis (chemical)** - the determination of the qualitative and/or quantitative composition of a substance.
- ◆ **Analyte** - the substance, a property of which is to be measured by chemical analysis.
- ◆ **Analytical batch** - a group of samples, including quality control samples, which are processed together using the same method, the same lots of reagents, and at the same time or in continuous, sequential time periods. Samples in each batch should be of similar composition and share common internal quality control standards.
- ◆ **Analytical blank** - see Reagent blank.
- ◆ **Analytical limit of discrimination** - see Method detection limit
- ◆ **Analytical reagent (AR)** - the American Chemical Society's designation for the highest purity of certain chemical reagents and solvents. See Reagent grade.
- ◆ **Arithmetic mean** - the sum of all the values of a set of measurements divided by the number of values in the set. usually denoted by \bar{X} ; a measure of central tendency. See Measure of central tendency.
- ◆ **Assignable cause** - a factor or an experimental variable shown to significantly change the quality of an effect or a result
- ◆ **Audit** - a systematic evaluation to determine the conformance of some operational function or activity to quantitative specifications. See Audit of data quality, Performance evaluation audit, and Technical systems audit, and also Review and Management systems review.
- ◆ **Audit of data quality (ADO)** - a qualitative and quantitative evaluation of the documentation and procedures associated with environmental measurements to verify that the resulting data are of acceptable quality.
- ◆ **Audit sample** - See Performance evaluation sample.
- ◆ **Average** - see Arithmetic mean.

- ◆ **Background level (environmental)** - the concentration of substance in a defined control area during a fixed period of time before, during or after a data gathering operation.
- ◆ **Batch** - a quantity of material produced or processed in one operation, considered to be a uniform discrete unit.
- ◆ **Batch-lot** - the samples collected under sufficiently uniform conditions to be processed as a group. See Batch, Batch size.
- ◆ **Batch-sample** - one of the samples drawn from a batch.
- ◆ **Batch-size** - the number of samples in a batch-lot
- ◆ **Beta error** - see Type II Error.
- ◆ **Bias** - the systematic or persistent distortion of a measurement process which deprives the result of representativeness (i.e., the expected sample measurement is different than the sample's true value.) A data quality indicator.
- ◆ **Blank sample** - a clean sample or a sample of matrix processed so as to measure artifacts in the measurement (sampling and analysis) process.
- ◆ **Blind sample** - a subsample submitted for analysis with a composition and identity known to the submitter but unknown to the analyst and used to test the analyst's or laboratory's proficiency in the execution of the measurement process. See Double-blind sample.
- ◆ **Bulk sample** - a sample taken from a larger quantity (lot) for analysis or recording purposes.
- ◆ **Calibrant** - see Calibration standard.
- ◆ **Calibrate** - to determine, by measurement or comparison with a standard, the correct value of each scale reading on a meter or other device, or the correct value for each setting of a control knob. The levels of the calibration standards should bracket the range of planned measurements. See Calibration curve.
- ◆ **Calibration curve** - the graphical relationship between the known values for a series of calibration standards and instrument responses.
- ◆ **Calibration drift** - the difference between the instrument response and a reference value after a period of operation without recalibration.
- ◆ **Calibration standard** - a substance or reference material used to calibrate an instrument
- ◆ **Calibrant** - see Calibration standard
- ◆ **Calibration-check** - see Calibrate.
- ◆ **Calibration-check standard** - see Calibration standard.

- ◆ **Candidate method** - a body of procedures and techniques of sample collection and/or analysis that is submitted for approval as a reference method, an equivalent method. or an alternative method.
- ◆ **Certified Reference Material (CRM)** - a reference material that has one or more of its property values established by a technically valid procedure and is accompanied by or traceable to a certificate or other documentation issued by a certifying body. See Certification and Reference material.
- ◆ **Carrying-agent** - any diluent or matrix used to entrain, dilute or to act as a vehicle for compound of interest.
- ◆ **CAS#** - Chemical Abstracts Service registry number of elements, chemical compounds, and certain mixtures.
- ◆ **Cause**-effect diagram - a graphical representation of an effect and possible causes. A popular one is the Ishikawa fish bone diagram.
- ◆ **Central line** - the line on a control chart that represents the expected value of the control chart statistics; often the mean. See Control chart
- ◆ **Certification** - the process of testing and evaluation against specifications designed to document, verify, and recognize the competence of a person, organization, or other entity to perform a function or service usually for a specified time. See also Accreditation.
- ◆ **Certification of Data Quality** - the real-time attestation that the activities of an environmental data collection operation's individual elements (e.g., sampling design, sampling, sample handling, chemical analysis, data reduction, etc..) have been carried out in accordance with the operation's requirements and that the results most the defined quality criteria.
- ◆ **Certified value** - the reported numerical quantity that appears on a certificate for a property of a reference material.
- ◆ **Chain**-of-custody - an unbroken trail of accountability that insures the physical security of samples, data and records.
- ◆ **Chance cause** - an unpredictable, random determinant of variation of a response in a sampling or measurement operation.
- ◆ **Characteristic** - see Property.
- ◆ **Check sample** - an uncontaminated sample matrix spiked with known amounts of analytes usually from the same source as the calibration standards. It is generally used to establish the stability of the analytical system but may also be used to assess the performance of all or a portion of the measurement system. See also Quality control sample.
- ◆ **Check standard** - a substance or reference material obtained from a source independent from the source of the calibration standard; used to prepare check samples.

- ◆ **Chi-square test** - a statistical test of the agreement between the observed frequency of events and the frequency expected according to some hypothesis.
- ◆ **Clean sample** - a sample of a natural or synthetic matrix containing no detectable amount of the analyte of interest and no interfering material.
- ◆ **Coefficient of variation (CV)** - a measure of relative dispersion (precision.) It is equal to the ratio of the standard deviation divided by the arithmetic mean. See also Relative standard deviation.
- ◆ **Collaborative testing** - the evaluation of an analytical method by typical or representative laboratories using subsamples prepared from a homogeneous standard sample.
- ◆ **Collocated sample** - one of two or more independent samples collected so that each is equally representative for a given variable at a common space and time.
- ◆ **Collocated samplers** - two or more identical sample collection devices, located together in space and operated simultaneously, to supply a series of duplicate or replicate samples for estimating precision of the total measurement system/process.
- ◆ **Comparability** - the degree to which different methods, data sets and/or decisions agree or can be represented as similar; a data quality indicator.
- ◆ **Completeness** - the amount of valid data obtained compared to the planned amount, and usually expressed as a percentage; a data quality indicator.
- ◆ **Component of variance** - a part of the total variance associated with a specified source of variation.
- ◆ **Composite sample** - a sample prepared by physically combining two or more samples having some specific relationship and processed to ensure homogeneity. See Flow-portioned sample and Time-proportioned sample.
- ◆ **Confidence coefficient** - the probability statement that accompanies a confidence interval and is equal to unity minus the associated type I error rate (false positive rate). A confidence coefficient of 0.90 implies that 90% of the intervals resulting from repeated sampling of a population will include the unknown (true) population parameter. See Confidence Interval.
- ◆ **Confidence Interval** - the numerical interval constructed around a point estimate of a population parameter, combined with a probability statement (the confidence coefficient) linking it to the population's true parameter value. .If the same confidence interval construction technique and assumptions are used to calculate future intervals, they will include the unknown population parameter with the same specified probability. See Confidence coefficient
- ◆ **Control sample** - see Quality control sample and Check sample.

- ◆ **Control chart** - a graph of some measurement plotted over time or sequence of sampling, together with control limit(s) and, usually, a central line and warning limit(s). See central line, Control limit and Warning limit.
- ◆ **Control limit** - a specified boundary on a control chart that, if exceeded, indicates a process is out of statistical control, and the process must be stopped, and corrective action taken before proceeding (e.g., for a Shewhart x chart the control limits are the mean plus and minus three standard deviations, i.e., the 99.72% confidence level on either side of the central line.)
- ◆ **Control standard** - see Check standard.
- ◆ **Controlled variable** - a variable that is set at a pre-selected level when a controlled experiment is conducted.
- ◆ **Correlation** - a measure of association between two variables. See Correlation coefficient.
- ◆ **Correlation coefficient** - a number between -1 and 1 that indicates the degree of linearity between two variables or sets of numbers. The closer to -1 or +1, the stronger the linear relationship between the two (i.e., the better the correlation.) Values close to zero suggest no correlation between the two variables. The most common correlation coefficient is the product moment, a measure of the degree of linear relationship between two variables.
- ◆ **Critical-toxicity range** - the interval between the highest concentration at which all test organisms survive and the lowest concentration at which all test organisms die within the test period.
- ◆ **Daity standard** - synonym for Calibration standard.
- ◆ **Data** - facts or figures from which conclusions can be inferred.
- ◆ **Data Quality Objective (DQO)** - qualitative and quantitative statements of the overall level of uncertainty that a decision-maker is willing to accept in results or decisions derived from environmental data. DQO provide the statistical framework for planning and managing environmental data operations consistent with the data user's needs
- ◆ **Data quality** - the totality of features and characteristics of data that bears on their ability to satisfy a given purpose; the sum of the degrees of excellence, for factors related to data.
- ◆ **Data quality indicators** - quantitative statistics and qualitative descriptors that are used to interpret the degree of acceptability or utility of data to the user. The principal data quality indicators are bias, precision, accuracy, comparability, completeness, and representativeness.
- ◆ **Data reduction** - the process of transforming raw data by arithmetic or statistical calculations, standard curves, concentration factors, etc., and collation into a more useful form

- ◆ **Data set** - all the observed values for the samples in a test or study; a group of data collected under similar conditions and which, therefore, can be analyzed as a whole.
- ◆ **Datum** - the singular of data. See Data and Value.
- ◆ **Defensible** - the ability to withstand any reasonable challenge related to the veracity or integrity of laboratory documents and derived data.
- ◆ **Degrees of freedom** - the total number of items in a sample minus the number of independent relationships existing among them; the divisor used to calculate a variance term; in the simplest cases, it is one less than the number of observations.
- ◆ **Dependent variable** - see Response variable.
- ◆ **Detection limit (DL)** - the lowest concentration or amount of the target analyte that can be determined to be different from zero by a single measurement at a stated level of probability. See Method detection limit
- ◆ **Determination** - the application of the complete analytical process of measuring the property of interest in a sample from selecting or measuring a test portion to the reporting of results. See Test determination
- ◆ **Diluent** - a substance added to another to reduce the concentration and resulting in a homogenous end product without chemically altering the compound of interest.
- ◆ **Dilution factor** - the numerical value obtained from dividing the new volume of a diluted substance by its original volume.
- ◆ **Document control** - a systematic procedure for indexing documents by number, date and revision number for archiving, storage, and retrieval.
- ◆ **Double-blind sample** - a sample submitted to evaluate performance with concentration and identity unknown to the analyst. See Blind sample.
- ◆ **Duplicate** - an adjective describing the taking of a second sample or performance of a second measurement or determination. Often incorrectly used as a noun and substituted for a duplicate sample. Replicate is to be used if there are more than two items. See Replicate.
- ◆ **Duplicate analyses or measurements** the analyses or measurements of the variable of interest performed identically on two subsamples of the same sample. The results from duplicate analyses are used to evaluate analytical or measurement precision but not the precision or sampling, preservation or storage internal to the laboratory.
- ◆ **Duplicate samples** - two samples taken from and representative of the same population and carried through all steps of the sampling and analytical procedures in an identical manner. Duplicate samples are used to assess variance of the total method including sampling and analysis.

- ◆ **Dynamic blank** - a sample-collection material or device (e.g., filter or reagent solution) that is not exposed to the material to be selectively captured but is transported and processed in the same manner as the sample. See Field blank, Instrumental blank and Sampling equipment blank.
- ◆ **Dynamic calibration** - standardization of both the measurement and collection systems using a reference material similar to the unknown. For example, a series of air-mixture standards containing sulfur dioxide of known concentrations could be used to calibrate a sulfur dioxide bubbler system.
- ◆ **Environmental sample** - a sample of any material that is collected from an environmental source.
- ◆ **Environmentally related measurement** - any assessment of environmental concern generated through or for field, laboratory, or modeling processes; the value obtained from such an assessment.
- ◆ **Equivalent method** - any method of sampling and/or analysis demonstrated to result in data having a consistent and quantitatively known relationship to the results obtained with a reference method under specified conditions, and formally recognized by the EPA.
- ◆ **Error (measurement)** - the difference between an observed or corrected value of a variable and a specified, theoretically correct or true value.
- ◆ **Error function** - the mathematical relationship of the results obtained from the measurement of one or more properties and the error of the applied measurement process. See Normal distribution.
- ◆ **Experimental variable** - See Independent variable.
- ◆ **External quality control** - the activities which are routinely initiated and performed by persons outside of normal operations to assess the capability and performance of a measurement process.
- ◆ **False negative decision** - see Type 11 Error.
- ◆ **False negative result** - estimating (incorrectly) that an analyte is not present when it actually is present.
- ◆ **False positive decision** - see Type I Error.
- ◆ **False positive result** - estimating (incorrectly) that an analyte is present when it is actually not present.
- ◆ **Field blank** - a clean sample (e.g., distilled water), carried to the sampling site. Exposed to sampling conditions (e.g., bottle caps removed, preservatives added) and returned to the laboratory and treated as an environmental sample. Field blanks are used to check for, analytical artifacts and/or background introduced by sampling and analytical procedures. See Dynamic blank and Sampling equipment blank.

- ◆ **Field duplicates** - see Duplicate sample.
- ◆ **Field reagent blank** - see Field blank.
- ◆ **Field sample** - see Sample.
- ◆ **Flow rate** - the quantity-per-unit time of a substance passing a point, plane, or space; for example the volume or mass of gas or liquid emerging from an orifice, pump, or turbine or moving through a point in a conduit or channel.
- ◆ **Flow**-proportioned sample - a sample or subsample collected from a fluid system at a rate that produces a constant ratio of sample accumulation to matrix flow rate.
- ◆ **Fortify** - synonym for Spike
- ◆ **Full-scale response** - the maximum output of a measurement Instrument In a given range as displayed on a meter or scale.
- ◆ **Functional analysis** - a mathematical evaluation of each component of the measurement system (sampling and analysis) in order to quantitate them for each component. A functional analysis Is usually performed prior to a ruggedness test in order to determine those variables which should be studied experimentally.
- ◆ **Geometric mean** - the antilogarithm of the mean of the logarithms of all the values in a set
- ◆ **Good laboratory practices (GLP)** - either general guidelines or formal regulations for performing basic laboratory operations or activities that are known or believed to influence the quality and integrity of the results.
- ◆ **Goodness-of-fit** - the measure of agreement between the data in a data set and the expected or hypothesized values.
- ◆ **Grab sample** - a single sample that is collected at one point In time and place.
- ◆ **Homogeneity** - the degree of uniformity of structure or composition.
- ◆ **In-control** - a condition Indicating that performance of the quality control system is within the specified control limits, i.e., that a stable system of chance is operating and resulting in statistical control. See Control chart.
- ◆ **Independent variable** - see Controlled variable.
- ◆ **Inspection criterion** - the specification(s) and rationale for rejecting and accepting samples in a particular sampling plan.
- ◆ **Instrument blank** - a clean sample processed through the Instrumental steps of the measurement process; used to determine Instrument contamination. See Dynamic blank.
- ◆ **Internal quality control** - see Intra-laboratory quality control.
- ◆ **Interference** - a positive or negative effect on a measurement caused by a variable other than the one being investigated.

- ◆ **Interference equivalent** - the mass or concentration of a foreign substance which gives the same measurement response as one unit of mass or concentration of the substance being measured.
- ◆ **Interlaboratory calibration** - the process, procedures, and activities for standardizing a given measurement system to ensure that laboratories participating in the same program can produce comparable data.
- ◆ **Interlaboratory method validation study (IMVS)** - the formal study of a sampling and/or analytical method, conducted with replicate, representative matrix samples, following a specific study protocol and utilizing a specific written method, by a minimum of seven laboratories, for the purpose of estimating inter-laboratory precision, bias and analytical interference.
- ◆ **Interlaboratory precision** - a measure of the variation, usually given as the standard deviation, among the test results from independent laboratories participating in the same test.
- ◆ **Intelaboratory test** - a test performed by two or more laboratories on the same material for the purpose of assessing the capabilities of an analytical method or for comparing different methods.
- ◆ **Internal quality control** - see Intra-laboratory quality control.
- ◆ **Internal standard** - a standard added to a test portion of a sample in a known amount and carried through the entire demonstration procedure as a reference for calibration and controlling the precision and bias of the applied analytical method.
- ◆ **Intra-laboratory precision** - a measure of the method/sample specific analytical variation within a laboratory; usually given as the standard deviation estimated from the results of duplicate/replicate analyses. See also Standard deviation and Variance.
- ◆ **Intra-laboratory quality control** - the routine activities and checks, such as periodic calibrations, duplicate analyses and spiked samples, that are included in normal internal procedures to control the accuracy and precision of measurements.
- ◆ **Laboratory control sample** - see Quality control sample
- ◆ **Laboratory accreditation** - see Accredited laboratory and Accreditation.
- ◆ **Laboratory blank** - see Reagent blank.
- ◆ **Laboratory duplicates** - synonym for Duplicate analyses
- ◆ **Laboratory performance check solution** - a solution of method and surrogate analytes and internal standards; used to evaluate the performance of the instrument system against defined performance criteria.
- ◆ **Laboratory replicates** - see Replicate analysis or measurement

- ◆ **Laboratory sample** - a subsample of a field, bulk or batch sample selected for laboratory analysis.
- ◆ **Laboratory spiked blank** - see Spiked laboratory blank.
- ◆ **Laboratory spiked sample** - see Spiked sample.
- ◆ **Laboratory sample** - subsample of a field, bulk or batch sample selected for laboratory analysis.
- ◆ **Least squares method** - a technique for estimating model coefficients which minimizes the sum of the squares of the differences between each observed value and its corresponding predicted value derived from the assumed model.
- ◆ **Limit of detection (LOD)** - see Method detection limit.
- ◆ **Limit of quantification (LOQ)** - the concentration of analyte in a specific matrix for which the probability of producing analytical values above the method detection limit is 99 percent.
- ◆ **Linearity** - the degree of agreement between the calibration curve of a method and a straight-line assumption.
- ◆ **Lot** - a number of units of an article or a parcel of articles offered as one item; commonly, one of the units, such as a sample of a substance under study. See Batch.
- ◆ **Lot size** - the number of units in a particular lot. See Batch lot and Batch size
- ◆ **Lower control limit** - see Control limit.
- ◆ **Lower warning limit** - see Warning limit.
- ◆ **Management systems review (MSR)** - the qualitative assessment of a data collection operation and/or organization(s) to establish whether the prevailing quality management structure, practices, and procedures are adequate for ensuring that the type and quality of data needed and expected are obtained. See Review and Audit
- ◆ **Matrix** - a specific type of medium (e.g., surface water, drinking water) in which the analyte of interest may be contained. See Medium.
- ◆ **Matrix spike** - see Spiked sample.
- ◆ **Matrix spike duplicate sample analysis** - see Matrix, Duplicate analysis and Spiked sample.
- ◆ **Maximum contaminant level** - the highest permissible concentration of a pollutant that may be delivered to any receptor.
- ◆ **Maximum holding time** - the length of time a sample can be kept under specified conditions without undergoing significant degradation of the analyte(s) or property of interest.
- ◆ **Mean** - see Arithmetic mean.

- ◆ **Measure of central tendency** - a statistic that describes the grouping of values In a data set around some common value (e.g., the median, arithmetic mean, or geometric mean.)
- ◆ **Measure of dispersion** - a statistic that describes the variation of values In a data set around some common value. See Coefficient of variation, Range, Variance and Standard deviation.
- ◆ **Measurement range** - the range over which the precision and/or recovery of a measurement method are regarded as acceptable. See acceptable quality range.
- ◆ **Measurement standard** - a standard added to the prepared test portion of a sample (e.g. to the concentrated extract or the digestate) as a reference for calibrating and controlling measurement or instrumental precision and bias.
- ◆ **Median** - the middle value for an ordered set of n values; represented by the central value when n is odd or by the mean of the two most central values when n is even.
- ◆ **Medium** - a substance (e.g., air. water. soil) which serves as a carrier of the analytes of interest See Matrix.
- ◆ **Medium blank** - see Field blank and/or Laboratory blank.
- ◆ **Method** - a body of procedures and techniques for performing a task (e.g., sampling,. characterization. quantification) systematically presented In the order In which they are to be executed.
- ◆ **Method blank** - a clean sample processed simultaneously with and under the same conditions as samples containing an analyte of Interest through all steps of the analytical procedure.
- ◆ **Method check sample** - see Spiked laboratory blank.
- ◆ **Method detection limit (MDL)** - the minimum concentration of an analyte that In a given matrix and with a specific method, has a 99% probability of being Identified, qualitatively or quantitatively measured, and reported to be greater than zero. See Detection limit
- ◆ **Method of least squares** - see Least squares method.
- ◆ **Method performance study** - see Inter-laboratory method validation study.
- ◆ **Method quantification limit (MOL)** - see Limit of quantification and also Method detection limit.
- ◆ **Minimum detectable level** - see Method detection limit.
- ◆ **Mode** - the most frequent value or values in a data set.
- ◆ **Multipoint calibration** - the determination of correct scale values by measuring or comparing Instrument responses at a series of standardized analyte concentrations; used to define the range for generating quantitative data of acceptable quality.

- ◆ **Noise** - the sum of random errors in the response of a measuring instrument.
- ◆ **Normal distribution** - an idealized probability density function that approximates the distribution of many random variables associated with measurements of natural phenomena and takes the form of a symmetric A bell-shaped curve.
- ◆ **Observation** - a fact or occurrence that is recognized and recorded.
- ◆ **Observed value** - the magnitude of a specific measurement; a variable; a unit of space, time or quantity; a datum. The observed value is that reported before correction for a blank value. See Corrected value.
- ◆ **Outlier** - an observed value that appears to be discordant from the other observations in a sample. One of a set of observations that appears to be discordant from the others. The declaration of an outlier is dependent on the significance level of the applied Identification test. See also Significance level.
- ◆ **Parameter** - any quantity such as a mean or a standard deviation characterizing a population. Commonly misused for “variable”, “characteristic” or “property”.
- ◆ **Percentage standard deviation** - synonym for Relative standard deviation.
- ◆ **Performance evaluation audit** - 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.
- ◆ **Performance evaluation sample (PE sample)** - a sample, the composition of which Is unknown to the analyst and Is provided to test whether the analyst/laboratory can produce analytical results within specified performance limits. See Blind sample and Performance evaluation audit.
- ◆ **Population** - all possible items or units which possess a variable of Interest and from which samples may be drawn.
- ◆ **Precision** - the degree to which a. set of observations or measurements of the same property usually obtained under similar conditions, conform to themselves; a data quality Indicator. Precision Is usually expressed as standard deviation, variance or range, in either absolute or relative terms. See also Standard deviation and Variance.
- ◆ **Preventative maintenance** - an orderly program of activities designed to ensure against equipment failure.
- ◆ **Primary reference standard** - see Primary standard.
- ◆ **Primary standard** - a substance or device, with a property or value that is unquestionably accepted (within specified limits) in establishing the value of the same or related property of another substance or device.
- ◆ **Probability** - a number between zero and one Inclusive, reflecting the limiting proportion of the occurrence, of an event in an increasingly large number of

Identical trials, each of which results in either the occurrence or nonoccurrence of the event.

- ◆ **Probability sampling** - sampling in which: (a) every member of the population has a known probability of being included in the sample; (b) the sample is drawn by some method of random selection consistent with these probabilities; and (c) the known probabilities of inclusion are used in forming estimates from the sample. The probability of selection need not be equal for members of the population.
- ◆ **Procedure** - a set of systematic instructions for performing an operation.
- ◆ **Proficiency testing** - a systematic program in which one or more standardized samples is analyzed by one or more laboratories to determine the capability of each participant.
- ◆ **Property** - a quality or trait belonging and peculiar to a thing; a response variable is a measure of a property. Synonym for Characteristic.
- ◆ **Protocol** - a detailed written procedure for a field and/or laboratory operation (e.g., sampling, analysis) which must be strictly adhered to.
- ◆ **Quality** - the sum of features and properties/characteristics of a product or service that bear on its ability to satisfy stated needs.
- ◆ **Quality assessment** - the evaluation of environmental data to determine if they meet the quality criteria required for a specific application.
- ◆ **Quality assurance (QA)** - an integrated system of activities involving planning, quality control, quality assessment, reporting and quality improvement to ensure that a product or service meets defined standards of quality with a stated level of confidence.
- ◆ **Quality Assurance Narrative Statement** - a description of the quality assurance and quality control activities to be followed for a research project.
- ◆ **Quality Assurance Objectives** - the limits on bias, precision, comparability, completeness and representativeness defining the minimal acceptable levels of performance as determined by the data user's acceptable error bounds.
- ◆ **Quality Assurance Program Plan (QAPP)** - a formal document describing the management policies, objectives, principles, and organizational authority, responsibilities, accountability, and implementation plan of an agency, organization or laboratory for ensuring quality in its products and utility to its users.
- ◆ **Quality Assurance Project Plan (QAPIP)** - a formal document describing the detailed quality control procedures by which the quality requirements defined for the data and decisions pertaining to a specific project are to be achieved.
- ◆ **Quality Circle** - a small group of individuals from an organization or unit who have related interests and meet regularly to consider problems or other matters related to the quality of the product or process.

- ◆ **Quality control (QC)** - the overall system of technical activities whose purpose is to measure and control the quality of a product or service so that it meets the needs of users. The aim is to provide quality that is satisfactory, adequate, dependable, and economical.
- ◆ **Quality control chart** - see Control chart.
- ◆ **Quality control check sample** - see Calibration standard.
- ◆ **Quality control sample** - an uncontaminated sample matrix spiked with known amounts of analytes from a source independent from the calibration standards. It is generally used to establish intra-laboratory or analyst specific precision and bias or to assess the performance of all or a portion of the measurement system. See also Check sample.
- ◆ **Quantitation limits** - the maximum or minimum levels or quantities of a target variable that can be quantified with the certainty required by the data user.
- ◆ **Random** - lacking a definite plan, purpose or pattern; due to chance.
- ◆ **Random error** - the deviation of an observed value from a true value, which behaves like a variable in that any particular value occurs as though chosen at random from a probability distribution of such errors. The distribution of random error is generally assumed to be normal.
- ◆ **Random sample or subsample** - a subset of a population or a subset of a sample, selected according to the laws of chance with a randomization procedure.
- ◆ **Random variable** - a quantity which may take any of the values of a specified set with a specified relative frequency or probability. It is defined by a set of possible values, and by an associated probability function giving the relative frequency of occurrence of each possible value.
- ◆ **Randomization** - the arrangement of a set of objects in a random order; a set of treatments applied to a set of experimental units is said to be randomized when the treatment applied to any given unit is chosen at random from those available and not already allocated.
- ◆ **Randomness** - a basic statistical concept and property implying an absence of a plan, purpose or pattern, or of any tendency to favor one outcome rather than the another.
- ◆ **Range** - the difference between the minimum and the maximum of a set of values.
- ◆ **Raw data** - any original factual information from a measurement activity or study recorded in laboratory worksheets, records, memoranda, notes, or exact copies thereof and that are necessary for the reconstruction and evaluation of the report of the activity or study. Raw data may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments. If exact copies of raw data have been

prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted.

- ◆ **Reagent blank** - a sample consisting of reagent(s), without the target analyte or sample matrix, introduced into the analytical procedure at the appropriate point and carried through all subsequent steps to determine the contribution of the reagents and of the involved analytical steps to error in the observed value.
- ◆ **Reagent grade** - the second highest purity designation for reagents that conform to the current specifications of the American Chemical Society Committee on Analytical Reagents.
- ◆ **Records system (or plan)** - a written documented group of procedures describing required records, steps for producing them, storage conditions, retention period and circumstances for their destruction or other disposition.
- ◆ **Recovery efficiency** - in an analytical method, the fraction or percentage of a target analyte extracted from a sample containing a known amount of the analyte.
- ◆ **Reference material** - a material or substance, one or more properties, of which are sufficiently well established to be used for the calibration of an apparatus, the assessment of a measurement method, or assigning values to materials.
- ◆ **Reference method** - a sampling and/or measurement method which has been officially specified by an organization as meeting its data quality requirement
- ◆ **Reference standard** - see Calibration standard.
- ◆ **Relative standard deviation** - the standard deviation expressed as a percentage of the mean recovery, i.e., the coefficient of variation multiplied by 100.
- ◆ **Reliability** - the likelihood that an instrument or device will function under defined conditions for a specified period of time.
- ◆ **Repeatability** - the degree of agreement between mutually independent test results produced by the same analyst using the same test method and equipment on random aliquots of the same sample within a short period of time.
- ◆ **Replicability** - see Repeatability.
- ◆ **Replicate** - an adjective or verb referring to the taking of more than one sample or to the performance of more than one analysis. Incorrectly used as a noun in place of replicate analysis. Replicate is to be used when referring to more than two items. See Duplicate.
- ◆ **Replicate analyses or measurements** - the analyses or measurements of the variable of interest performed identically on two or more subsamples of the same sample within a short time interval. See Duplicate analyses or measurements.
- ◆ **Replicate samples** - two or more samples representing the same population characteristic, time, and place, which are independently carried through all steps of the sampling and measurement process in an identical manner. Replicate

samples are used to assess total (sampling and analysis) method variance. Often incorrectly used in place of the term “replicate analysis”. See Duplicate samples and Replicate analysis.

- ◆ **Representativeness** - the degree to which data accurately and precisely represent the frequency distribution of a specific variable in the population; a data quality Indicator.
- ◆ **Representative sample** - a sample taken so as to reflect the variable(s) of interest in the population as accurately and precisely as specified. To ensure representativeness, the sample may be either completely random or stratified depending upon the conceptualized population and the sampling objective (i.e., upon the decision to be made.)
- ◆ **Reproducibility** - the extent to which a method, test or experiment yields the same or similar results when performed on subsamples of the same sample by different analysts or laboratories.
- ◆ **Response variable** - a variable that is measured when a controlled experiment is conducted.
- ◆ **Result** - the product of a calculation, test method, test or experiment. The result may be a value, data set, statistic, tested hypothesis or an estimated effect
- ◆ **Review** - the assessment of management/operational functions or activities to establish their conformance to qualitative specifications or requirements. See Management systems review and also, Audit
- ◆ **Risk** - the probability or likelihood of an adverse effect.
- ◆ **Risk (statistical)** - the expected loss due to the use of a given decision procedure.
- ◆ **Robustness** - (in)sensitivity of a statistical test method to departures from underlying assumptions. See Ruggedness
- ◆ **Rounded number** - a number, reduced to a specified number of significant digits or decimal places using defined criteria
- ◆ **Routine method** - a defined plan of procedures and techniques used regularly to perform a specific task.
- ◆ **Ruggedness** - the (in)sensitivity of an analytical test method to departures from specified analytical or environmental conditions. See Robustness.
- ◆ **Ruggedness testing** - the carefully ordered testing of an analytical method while making slight variations in test conditions (as might be expected in routine use) to determine how such variations affect test results. If a variation affects the results significantly, the method restrictions are tightened to minimize this variable.
- ◆ **Sample** - a part of a larger whole or a single item of a group; a finite part or subset of a statistical population. A sample serves to provide data or information concerning the properties of the whole group or population.

- ◆ **Sample data custody** - see Chain-of-custody.
- ◆ **Sample variance (statistical)** - a measure of the dispersion of a set of values. The sum of the squares of the difference between the individual values of a set and the arithmetic mean of the set, divided by one less than the number of values in the set. (The square of the sample standard deviation.) See also Measure of dispersion.
- ◆ **Sampling** - the process of obtaining a representative portion of the material of concern.
- ◆ **Sampling equipment blank** - a clean sample that is collected in a sample container with the sample-collection device and returned to the laboratory as a sample. Sampling equipment blanks are used to check the cleanliness of sampling devices. See Dynamic blank.
- ◆ **Sampling error** - the difference between an estimate of a population value and its true value. Sampling error is due to observing only a limited number of the total possible values and is distinguished from errors due to imperfect selection, bias in response, errors of observations, measurement or recording, etc. See also Probability sampling.
- ◆ **Scheduled maintenance** - see Preventative maintenance
- ◆ **Screening test** - quick test for coarsely assessing a variable of interest.
- ◆ **Secondary standard** - a standard whose value is based upon comparison with a primary standard.
- ◆ **Selectivity (analytical chemistry)** - the capability of a method or instrument to respond to a target substance or constituent in the presence of nontarget substances.
- ◆ **Sensitivity** - capability of method or instrument to discriminate between measurement responses representing different levels of a variable of interest.
- ◆ **Significance level** - the magnitude of the acceptable probability of rejecting a true null hypothesis or of accepting a false null hypothesis; the difference between the hypothetical value and the sample results.
- ◆ **Significant digit** - any of the digits 0 through 9, excepting leading zeros and some trailing zeros, which is used with its place value to denote a numerical quantity to a desired rounded number. See Rounded number.
- ◆ **Significant figure** - see Significant digit.
- ◆ **Single operator precision** - the degree of variation among the individual measurements a series of determinations by the same analyst or operator, all other conditions being equal.
- ◆ **Site** - the area within boundaries established for a defined activity.

- ◆ **Span-drift** - the change in the output of a continuous monitoring instrument over a stated time period during which the instrument is not recalibrated.
- ◆ **Span-gas** - a gas of known concentration which is used routinely to calibrate the output level of an analyzer. See Calibration check standard.
- ◆ **Specimen** - see Sample.
- ◆ **Spike** - a known mass of target analyte added to a blank sample of subsample; used to determine recovery efficiency or for other quality control purposes.
- ◆ **Spiked laboratory blank** - see Spiked reagent blank.
- ◆ **Spiked reagent blank** - a specified amount of reagent blank fortified with a known mass of the target analyte; usually used to determine the recovery efficiency of the method.
- ◆ **Spiked sample** - a sample prepared by adding a known mass of target analyte to a specified amount of matrix sample for which an independent estimate of target analyte concentration is available. Spiked samples are used, for example, to determine the effect of the matrix on a method's recovery efficiency.
- ◆ **Spiked sample duplicate analysis** - see Duplicate analysis and Spiked sample.
- ◆ **Split samples** - two or more representative portions taken from a sample or subsample and analyzed by different analysts or laboratories. Split samples are used to replicate the measurement of the variable(s) of interest.
- ◆ **Standard (measurement)** - a substance or material with a property quantified with sufficient accuracy to permit its use to evaluate the same property in a similar substance of material. Standards are generally prepared by packing a reference material in a matrix. See Reference material.
- ◆ **Standard addition** - the procedure of adding known increments of the analyte of interest to a sample to cause increases in detection response. The level of the analyte of interest present in the original sample is subsequently established by extrapolation of the plotted responses.
- ◆ **Standard curve** - see Calibration curve.
- ◆ **Standard deviation** - the most common measure of the dispersion or imprecision of observed values expressed as the positive square root of the variance. See Variance.
- ◆ **Standard material** - see Standard (measurement), Reference material.
- ◆ **Standard method** - an assemblage of techniques and procedures based on consensus or other criteria, often evaluated for its reliability by collaborative testing and receiving organizational approval.
- ◆ **Standard operating procedure (SOP)** - a written document which details the method of an operation, analysis or action whose techniques and procedures are

thoroughly prescribed and which is accepted as the method for performing certain routine or repetitive tasks.

- ◆ **Standard reference material (SRM)** - a certified reference material produced by the U.S. National Institute of Standards and Technology and characterized for absolute content independent of analytical method.
- ◆ **Standard reference sample** - see Secondary standard
- ◆ **Standard solution** - a solution containing a known concentration of analytes, prepared and verified by a prescribed method or procedure and used routinely in an analytical method.
- ◆ **Standardization** - the process of establishing the quantitative relationship between a known mass of target material (e.g., concentration) and the response variable (e.g., the measurement system or instrument response) See Calibration, Calibration curve and Multipoint calibration.
- ◆ **Statistic** - an estimate of a population characteristic calculated from a data set (observed or corrected values), e.g., the mean or standard deviation.
- ◆ **Stratification** - the division of a target population into subsets or strata which are internally more homogeneous with respect to the characteristic to be studied than the population as a whole.
- ◆ **Stratified sampling** - the sampling of a population that has been stratified, part of the sample coming from each stratum. See Stratification.
- ◆ **Stock solution** - a concentrated solution of analyte(s) or reagent(s) prepared and verified by prescribed procedure(s), and used for preparing working standards or standard solutions.
- ◆ **Subsample** - a representative portion of a sample. A subsample may be taken from any laboratory or a field sample. See Aliquant, Aliquot, Split sample and Test portion.
- ◆ **Surrogate analyte** - a pure substance with properties that mimic the analyte of interest. It is unlikely to be found in environmental samples and is added to them for quality control purposes.
- ◆ **Surveillance** - the act of maintaining supervision of or vigilance over a well-specified portion of the environment so that detailed information is provided concerning the state of that portion.
- ◆ **Synthetic sample** - a manufactured sample. See Quality control sample.
- ◆ **Systematic error** - a consistent deviation in the results of sampling and/or analytical processes from the expected or known value. Such error is caused by human and methodological bias.
- ◆ **Systems audit** - see Technical systems audit.
- ◆ **Systems error** - see Total systems error.

- ◆ **Target** - the chosen object of investigation, for which qualitative and/or quantitative data or information is desired, e.g., the analyte of interest.
- ◆ **Technical systems audit** - a thorough systematic on-site, qualitative review of facilities, equipment, personnel, training, procedures, record keeping, data validation, data management, and reporting aspects of a total measurement system.
- ◆ **Technique** - a principle and/or the procedure of its application for performing an operation.
- ◆ **Test** - a procedure used to identify or characterize a substance or constituent. See Method.
- ◆ **Test determination** - see Determination.
- ◆ **Test method** - see Method.
- ◆ **Test portion** - a subsample of the proper amount for analysis and measurement of the property of interest. A test portion may be taken from the bulk sample directly, but often preliminary operations, such as mixing or further reduction in particle size, are necessary. See Subsample.
- ◆ **Test result** - a product obtained from performing a test determination- See Determination.
- ◆ **Test sample** - see Test portion.
- ◆ **Test specimen** - see Test portion.
- ◆ **Test unit** - see Test portion.
- ◆ **Time-proportioned sample** - a composite sample produced by combining samples of a specific size, collected at preselected, uniform time intervals.
- ◆ **Total measurement error** - the sum of all the errors that occur from the taking of the sample through the reporting of results; the difference between the reported result and the true value of the population that was to have been sampled.
- ◆ **Total Quality Management (TQM)** - the process whereby an entire organization, led by senior management, commits, to focusing on quality as a first priority in every activity. TQM implementation creates a culture in which everyone in the organization shares the responsibility for continuously improving the quality of products and services, (i.e., for "doing ft right thing, the right way, the first time, on time in order to satisfy the customer.
- ◆ **Traceability** - an unbroken trail of accountability for verifying or validating the chain-of-custody of samples, data, the documentation of a procedure, or the values of a standard.
- ◆ **Treatment (experimental)** - an experimental procedure whose effect is to be measured and compared with the effect of other treatments.

- ◆ **Trip blank** - a clean sample of matrix that is carried to the sampling site and transported to the laboratory for analysis without having been exposed to sampling procedures.
- ◆ **Tuning** - the process of adjusting a measurement device or instrument, prior to its use, to ensure that it works properly and meets established performance criteria.
- ◆ **Type I error, (alpha error)** - an (incorrect) decision resulting from the rejection of a true hypothesis. (A false positive decision.)
- ◆ **Type II error, (beta error)** - an (incorrect) decision resulting from acceptance of a false hypothesis. (A false negative decision.)
- ◆ **Uncertainty** - a measure of the total variability associated with sampling and measuring that includes the two major error components: systematic error (bias) and random error.
- ◆ **Upper control limit**- see Control limit.
- ◆ **Upper warning limit** - see Warning limit.
- ◆ **User check** - an evaluation of a written procedure (e.g., chemical analysis method) for clarity and accuracy in which an independent laboratory analyzes a small number of spiked samples, following the procedure exactly.
- ◆ **Valid study** - a study conducted in accordance with accepted scientific methodology, the results of which satisfy predefined criteria.
- ◆ **Validated method** - a method that has been determined to meet certain performance criteria for sampling and/or measurement operations.
- ◆ **Validation** - the process of substantiating specified performance criteria.
- ◆ **Value** - the magnitude of a quality. A single piece of factual information obtained by observation or measurement and used as a basis of calculation.
- ◆ **Variable** - an entity subject to variation or change.
- ◆ **Variance** - see Sample variance.
- ◆ **Verifiable** - the ability to be proven or substantiated.
- ◆ **Warning limit** - a specified boundary on a control chart that indicates a process may be going out of statistical control and that certain precautions are required. For example; for a Shewhart x chart the warning limits are placed at plus and minus two standard deviations of the mean (i.e., at the 95% confidence interval.)
- ◆ **Working standard** - see Secondary standard.
- ◆ **Zero drift** - the change in instrument output over a stated period of non-recalibrated, continuous operation, when the initial input concentration is zero; usually expressed as a percentage of the full scale response.

Appendix 2

Scientific Notebook

Scientific Record Keeping

Users of scientific information have a vested self-interest in developing systems of record keeping that are capable of preserving and retrieving original experimental data. A strategy for achieving some consistency in scientific record keeping among scientists of different disciplines, backgrounds, and education is to develop a written policy stating minimum requirements for maintaining a laboratory notebook. While the laboratory notebook has a long and proven tradition in science, there is no doubt that the wide spread use of computers for recording information about all phases of experimental work (hypotheses, results, conclusions etc.) will require that the specifics of notebook record keeping be continually realigned with way electronic media are used.

Statement of Policy

Maintaining a notebook as a complete and easily available record of scientific work shall be the responsibility of each individual IPEC scientist.

Implementation Guidelines

The following points outline the basic features of the notebook record keeping system. For reference, an example notebook page is provided below.

- A. The PI should issue all notebooks and maintain a tracking system to cross-references notebook numbers to individual post-docs, graduate students, and technicians. When completed, notebooks should be archived safely.
- B. The notebook will be used to record or reference research goals, hypotheses, assumptions, experimental data, interim summaries and conclusions. Experimental procedures, apparatus, data and readings, (including units of measure) must be recorded with sufficient detail that another individual trained in an appropriate discipline could reconstruct the experiment. Published papers and reports that summarize research results will be referenced.
- C. Used properly, the notebook will serve as the central source of information from which access can be gained to all of a researcher's original data. For example, data recorded on forms or in computer files needs to be cross-referenced in the notebook and stored an orderly and retrievable manner. Experimental apparatus, procedures, etc previously described in a numbered notebook can be referenced by notebook and page number.
- D. Each major data collection effort should have its own dedicated notebook(s). Individuals who work on many short-term projects may wish to record several projects in one notebook, listing each in the table of contents. The notebook may

also be dedicated a single use, such as for use as a standards log, maintenance log, reagent log, injection log, etc.

- E. A descriptive title will be provided at the top of the notebook page for each new experiment. The title and associated page numbers should be recorded in the notebook table of contents. To clarity, not every page will need a descriptive title or have separate entry in the table of contents. (A common approach is to simply label multiple pages for the same experiment as continuations (i.e., cont).
- F. The notebook record must establish clear identification of all original samples, reagent and supplies. It is important to identify each item by an ordered and documented numbering system. One approach is of the form: NB-P-LN, where
- NB Notebook Number
 - Page Page Number
 - LN Line Number
- G. For example, ID Number 10-2-5 would be identified In notebook number 10, page 2, line 5 accompanied by a detailed description of the item to which the ID number applies.
- H. Entries in the notebook should be made in ink if the data are being collected in a controlled environmental setting (such as inside a building) and pencil if they are being made under field conditions.
- I. Incorrect entries should be corrected by:
- placing one line through the incorrect entry,
 - initialing and dating the correction,
 - providing a short explanation of why the correction was made, especially for anything other than obvious transcription type errors.
 - White-out, erasing, and blocking out the entry so as to make it illegible are not acceptable methods for correcting entries.
- J. Each day's entries should be signed and dated by the notebook user in order to indicate the responsible party. The signature box labeled "recorded by" is available for this purpose.
- K. Entries into notebooks must be entered sequentially or clearly indicate that an insert, has been made at a later date (i.e. the insertion is clearly identified, dated, and signed. Any areas of a page left intentionally blank should be crossed out.
- L. A line should be drawn across a comer of the pasted materials and onto the notebook page. The line should be initialed and dated. Then, if the materials fall out, the notations will indicate that original materials are missing.

- M. Do not record data on loose sheets of paper and do not store loose sheets of paper the notebook; neither should any pages be removed from the notebook.
- N. Modifications and/or expansion of these basic record-keeping procedures can be described in a QAPP.

Appendix 3

QA Guidelines for Modeling Projects

Quality assurance guidelines for model development

The principal idea behind QA guidelines is to insure that minimum standards of quality are achieved during the modeling process. The main mechanism for implementation is to maintain accountability of all activities and results. QA guidelines for modeling are crucial to both model development and model application; they should be an integral part of project planning and should be applied to all phases of the modeling process. A classification of mathematical models is provided below.

QA procedures can provide safeguards against faulty models, improper modeling or inappropriate application. However, regulators and decision makers should understand that there is no way to guarantee that modeling based advice is entirely correct or that the model can ever be proven, verified, or validated in the strictest sense of these terms. Rather, a model can only be invalidated by disagreement of its predictions with independently derived observations regarding real systems.

A major role of the QA process in modeling is to provide documentation of procedures so that the modelers, peers, and decision-makers are aware of the accuracy, uncertainty, and reliability of the model. QA procedures should never become so cumbersome that modelers are reluctant to explore new avenues or that an inappropriately large part of the project budget is consumed by procedural requirements. Furthermore, the risk that QA procedures may deteriorate to become only a checklist for installing false confidence in modeling results should also be avoided.

Definitions

- A. Quality assurance (QA) is the procedural and operational framework put in place by the organization managing the modeling study to assure technically and scientifically adequate execution of all project tasks included in the study and to assure that all modeling-based analysis is verifiable and defensible.
- B. Quality control (QC) refers to the procedures that ensure the quality of the final product. These procedures include the use of appropriate methodology, adequate validation, and proper use of the selected methods and models.

The following definitions, for modeling specific QC are provided as an extension of the Glossary of Terms presented on page 23.

- (a) calibration - the ability of the code predictions to fit field data
- (b) comparability - the applicability of the data base(s) for answering scientific questions, e.g.. do differences in objectives, designs, methods, or analyses among the data base(s) limit their usefulness collectively
- (c) completeness - the limitations of the data base(s) due to missing data, e.g., were measurements for a crucial time period or whole treatment missing

- (d) prediction - the ability of the model to fit experimental data using modeling-independent estimates of the parameters (typically unavailable)
 - (e) validation - comparison of model results with numerical data independently derived from experiments or observations
 - (f) verification - confirmation that original intent of the user requirements is represented
- C. Quality assessment is applied to monitor the quality control procedures and to evaluate the quality of the modeling study through auditing and technical review. Audits determine the degree of compliance with CIA requirements while technical reviews evaluate the technical and scientific basis of the project.

Quality Assurance Plan Guidelines

A QA Plan should be submitted as part of the work plan at the beginning of a model development or application project. The QA plan should contain a complete set of QA procedures. These procedures should list the degree of quality and the measures required for achieving prescribed quality objectives. QA/QC data may be requested periodically and must be accessible to the QA staff during project reviews.

A recommended format for the QA plan is provided below.

Example Quality Assurance Plan Outline

1. Project Description
 - 1.1. Scope, purpose, objectives
 - 1.2. Products, completion timetable
 - 1.3. Project personnel
 - 1.4. Key support facilities and services
2. Model Description
 - 2.1. Model parameters
 - 2.2. Computer aspects
 - 2.3. Data source/quality/input-output
3. Model Development
 - 3.1. Code selection, development and maintenance
 - 3.2. Model documentation
 - 3.3. Code verification
 - 3.4. Code documentation
4. Model Validation
5. Model Application

- 5.1. Outline restrictions
- 5.2. Assess validity

The following Sections provide detailed guidance for the recommended sections of a QA Plan.

Project description (Responsibility of the Project Manager)

The project description should include the following:

- ◆ a brief statement of the scope, purpose, and objectives of the project;
- ◆ the product(s) and a timetable for completion;
- ◆ a diagram showing the project personnel, their titles and duties/responsibilities, and the lines of authority and information flow among them;
- ◆ a short narrative about individual responsibilities when they cannot be clearly delineated in a diagram;
- ◆ a brief discussion about the key support facilities and services used (including computer facilities);

Model description (Responsibility of the model developer)

The model description should include:

Model parameters

- ◆ model origin and its original purpose
- ◆ parameters and variables
- ◆ spatial extent (individual, group. population)
- ◆ spatial resolution (location independent/dependent, dimensionality)
- ◆ temporal extent (length of modeling period)
- ◆ temporal resolution (time step)
- ◆ model structure (e.g., theoretical vs. data driven, stochastic vs. deterministic. structural framework)

Computer aspects

- ◆ programming language (FORTRAN, BASIC, etc.) and ANSI standard
- ◆ model portability
- ◆ memory requirements
- ◆ required hardware/software for application (monitor, line printer, graphics)
- ◆ approximate execution time for a typical run

Data quality

The purpose of assessing data quality is to evaluate, to the extent possible, the reliability of the existing data base(s). Procedures for determining precision, accuracy, representativeness, completeness, and comparability of existing data should be summarized. Specific parameters to be discussed include:

- ◆ source of original data and criteria for acceptance or rejection
- ◆ any modifications from original data
- ◆ sampling protocol
- ◆ data format, maintenance, and archiving

Model development

Code development and maintenance

QA for code development and maintenance should include complete record keeping of the model development, of modifications made in the code, and of the code validation process. The media trail for QA in model development consists of reports and computer files on the development of the model. The reports should include a description of assumptions parameter values and sources changes and verification of changes made in code actual input used output of model runs and interpretation validation (or at least calibration) of model.

In addition, the following files may be retained (in hard-copy and, at higher levels, in digital form):

- ◆ version of source code used
- ◆ verification input and output
- ◆ validation input and output
- ◆ application input and output

If any modifications are made to the model coding for a specific problem, the code should be tested again; all QA procedures for model development should again be applied, including accurate record keeping and reporting. All new input and output files should be saved for inspection and possible reuse.

Model documentation

Computer model documentation is defined as the information recorded during the design, development, and maintenance of computer applications, in order to explain pertinent aspects of a data processing system, including purposes, methods, logic, relationships, capabilities, and limitations. It is the principal instrument of communication used by the model author, the model user, and the system operator.

Good documentation includes a complete description of:

- ◆ the equations on which the model is based
- ◆ the underlying assumptions
- ◆ the boundary conditions that can be incorporated in the model the method used to solve the equations
- ◆ limiting conditions

The documentation must also include:

- ◆ user's instructions for operating the code
- ◆ instructions for preparing data files
- ◆ example problems complete with input and output
- ◆ programmer's instructions
- ◆ computer operator's instructions
- ◆ a report of the initial code verification.

Code verification

The objective of the code verification process is to check the correctness and accuracy of the computational algorithms used to solve the governing equations and to assure that the computer code is fully operational. It should be noted that most models are verified only with respect to segments of their coding or for only a part of the tasks for which they were designed.

Code documentation

The inspection of the computer code is part of the model review process. In this inspection, attention is given to the manner in which modern programming principles have been applied with respect to code structure, compliance with programming standards, efficient use of programming languages, and internal documentation. This step may reveal programming or logic errors that are difficult or impossible to detect in verification runs.

The code documentation should include:

- ◆ model specifications
- ◆ model description
- ◆ flow charts
- ◆ description of routines
- ◆ data base description
- ◆ source listing
- ◆ error messages.

Model Validation (Responsibility of model developer)

Model validation is defined as the comparison of model results with numerical data independently derived from laboratory experiments or observations of the environment. For many types of models, a complete set of test problems and adequate data sets for the described testing procedure is not yet available. Development of such data sets is critical in establishing the validity of models.

Model development is an evolutionary process responding to new research results, developments in technology and changes in user requirements. Model validation needs to follow this dynamic process and should be applied each time the model is modified.

Model application (Responsibility of the Project Manager)

Model application QA procedures should provide a clear formulation of the project objectives and the modeling approach used to meet these objectives. The specific rules for proper application of the model should be documented and available to users. The suitability, reliability, and efficiency of the model should be addressed.

Restrictions of model application should be outlined. Additionally, those that are accounted for by the code and those that are the responsibility of the user should be identified. Categories of restrictions include:

- ◆ assumptions
- ◆ parameter values and sources
- ◆ boundary and initial conditions
- ◆ validation/calibration of the model
- ◆ output and interpretation of model runs.

Whether a model is valid for a particular application should be assessed by using performance criteria. Using these criteria, three levels of validity for single variable models can be distinguished as outlined below:

Statistical Validity: Using statistical measures to check agreement between two different distributions, the calculated one and the measured one; validity is established by using an appropriate performance or validity criterion.

Deviate Validity: If not enough data are available for statistical validation, a deviation coefficient D can be established. The deviation coefficient might be expressed as a summation of relative deviations.

Qualitative Validity: Using a qualitative scale for validity levels representing subjective judgement e.g., excellent, good, fair, poor or unacceptable. Qualitative validity is often established through visual inspection of graphic representations of calculated and measured data.

The aforementioned tests apply to single variables and determine local or single variable validity; if more than one variable is present in the model, the model should also be checked for global validity and for validity consistency.

There are analogous tests for multivariate systems:

Qualitative validity: Can be determined one variable at a time using a series of graphic representations.

Deviative validity: Can be measured using a vector or state space, approach, where the deviation coefficient is the distance between two vectors in a multidimensional space.

Statistical validity: Can be measured using a state space approach and an appropriate multivariate statistical measure such as multivariate analysis of variance.

Classification of Mathematical Models

Static models, invariant in space and/or time;

Dynamic models, as those varying in space and/or time;

Deterministic models, as those with elements that are sufficiently specified, so that the model behavior, performance, or operation is exactly determined:

Stochastic models, as those that use uncertainties or ... (random) ... data, for which model behavior, performance, or operation is only probabilistically determined:

Feedback models, as those in which the input depends on the output: such as in systems under control (either automatic or due to human intervention);

Feedforward models, as those in which the output depends on the input, only, and no feedback exists

Analytical models, as those that describe the output via specific mathematical equations;

Numeric models, as those through which the output is expressed, approximately, by numerical equivalents (used when one cannot feasibly solve the analytical expressions for the output);

Mechanistic models, as those in which the model is based on any applications of physical or mechanistic theories governing the system; and

Empirical -models, as those used when the system's mechanisms are unknown, and the model is determined by statistically fitting equations to the data.

Appendix 4

QA Audit Checklists

Technical Systems Audit Checklist

QA Management Systems

- ◆ Is the staff familiar with the IPEC Quality Management Plan?
- ◆ Are QA planning documents available for in-house research projects?
- ◆ Have the QA planning documents been approved?
- ◆ Have Standard Operating Procedures (SOPs) been written where appropriate
- ◆ Have the requirements given in QA planning documents been met?
- ◆ Have the IPEC QA program been clearly communicated?

Project Management Systems

- ◆ Are project objectives clearly stated and understood?
- ◆ Are schedules reasonable and achievable?
- ◆ Are deliverables on time?
- ◆ Is sufficient coordination occurring with the industrial partner?
- ◆ Are supplies obtainable in a timely manner?
- ◆ Are notebooks being kept in accordance with laboratory policy?
- ◆ Are project files available?
- ◆ Is sufficient information available in hard copy format to understand basic aspects of the research project?
- ◆ Are software packages adequately described in project files?
- ◆ Have program review comments been addressed?
- ◆ Have document review procedures been followed?

Laboratory Management Systems

Personnel

- ◆ Do personnel have appropriate academic training?
- ◆ Have personnel received sufficient on the job training?

Facilities

- ◆ Has sufficient laboratory space been allocated?
- ◆ Are laboratory areas maintained in a clean and organized manner?
- ◆ Is sufficient lighting provided?
- ◆ Is a safety plan available?
- ◆ Are facilities properly sanitized?

- ◆ If needed, are specialized laboratories available for working microbial, chemical, and/or radiological hazards.

Equipment and Supplies

- ◆ Are QC procedures adequate for the pH/conductivity meter?
- ◆ Are QC procedures for the autoclave adequate?
- ◆ Are QC procedures for the refrigerators/freezers adequate?
- ◆ Are QC procedures for the microscopes adequate?
- ◆ Are sample containers available?
- ◆ Are reagent grade or higher purity chemicals used to prepare standards?
- ◆ Is the following information documented for all reagents/standards used?
 - ◆ Manufacturer
 - ◆ Date of receipt
 - ◆ Date opened
 - ◆ Purity
 - ◆ Lot number
- ◆ Does documentation exist for standards preparation that uniquely identifies the reagents /solvents used and the method of preparation?
- ◆ Does documentation exist for identification of standard preparer and date of standard preparation?
- ◆ Are calibration standards validated prior to use?
- ◆ Are standards being replaced at the proper intervals?
- ◆ Are manufacturer's maintenance manuals available?
- ◆ Are maintenance logs kept for lab equipment/instrumentation?
- ◆ Is service on equipment/instrumentation readily available?
- ◆ Are replacement parts for equipment/ instrumentation available?
- ◆ Is the analytical balance located in an area free from drafts and rapid temperature changes?
- ◆ Do balances have calibration stickers showing date of last certified calibration and date of next scheduled calibration?
- ◆ Are records available for in-house calibration of balances?
- ◆ Do micropipettors have logs indicating calibration checks performed in-house?
- ◆ Do records exist for monitoring of laboratory water systems?
- ◆ Are glassware cleaning procedures adequate?
- ◆ Are temperature logs available for ovens and incubators?
- ◆ Are sterilization procedures documented and sufficient?

- ◆ Are media preparation procedures adequate?

Analytical Methods

- ◆ Are appropriate controls being used?
- ◆ Are verification tests being conducted?

Sample Collection/Handling

- ◆ Are SOPs available for describing correct collection of samples?

Data Management System

- ◆ Are entries to logbooks signed, dated, and legible?
- ◆ Are changes to logbooks dated and initialed by person who made them?
- ◆ Can data be tracked from the project files?
- ◆ Do the project files identify the specific pieces of instrumentation that were used?
- ◆ Have lab data management systems been validated prior to use?
- ◆ Are data manipulation procedures adequately described?
- ◆ Are data (electronic and hard copy) archived in a retrievable fashion?

Problem Resolution

- ◆ Has a person been designated to follow-up on previously identified problems?
- ◆ Has a timeframe been stipulated for resolving problems?
- ◆ Does documentation of the resolution of problems exist?

Appendix 5

QAPP Template

Project Management

Instructions (italics) which appear in this guidance document are a hidden font and will not print. To print these instructions, from the “Tools” menu, choose “Options” and toggle the hidden text option on the “Print” tab. If you do not wish to view the hidden text during editing, toggle the hidden text option on the “View” tab of the “Options” dialog box. Information within curly braces is used for identifying table of contents entries, and square brackets around some items are bookmarks used to create the running header – these are easily deleted by accident, and to see them (e.g., around the words “Project Title” below, check the bookmark box in the “View” tab of the “Options” dialog box. Bookmarks are easily deleted by accident, it is best to highlight them by double clicking, then typing over the highlighted text.

Each heading requires an entry. If a particular heading does not apply, state this rather than delete the heading.

Quality Assurance Project Plan

for the IPEC project

Title

Award #:

Revision No: 1

Revision Date: 6/15/20002

to be performed by:

PI: _____ (Institution)
Co-Pi: _____ (Institution)
Co-Pi: _____ (Institution)

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Signature Approval Sheet

Double click "Name" and type the person's name. A chain of responsible persons should be established where signatures are required for each independent PI or manager. Subordinates do not need to sign the approval page.

Signature indicates that this QAPP is approved and will be implemented in conducting the research of this project.

Name	_____	
Principal Investigator	Signature	Date
Name	_____	
Co-Principal Investigator	Signature	Date
Name	_____	
Co-Principal Investigator	Signature	Date
Name	_____	
Subcontract manager	Signature	Date
Greg Thoma	_____	
IPEC QQA Officer	Signature	Date
Name	_____	
Others, as needed	Signature	Date

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Distribution List

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

Table 3 QAPP Distribution List

Bala Krishnan	EPA Project Officer
Greg Thoma	IPEC Quality Assurance Officer
	Principal Investigator, Institution
	Co- Principal Investigator, Institution
	Post doctoral RAs; Analyst(s)
	Graduate Students
	Field Personnel
	Subcontractors

Project/Task Organization

Place the cursor on the blank line above, and in a brief narrative, identify the individuals or organizations participating in the project and discuss their specific roles and responsibilities. Include the principal data users, the decision-makers, the project QA manager, and all persons responsible for implementation. Subcontractors should be included in the description. A flow chart may be a useful way of presenting the lines of responsibility

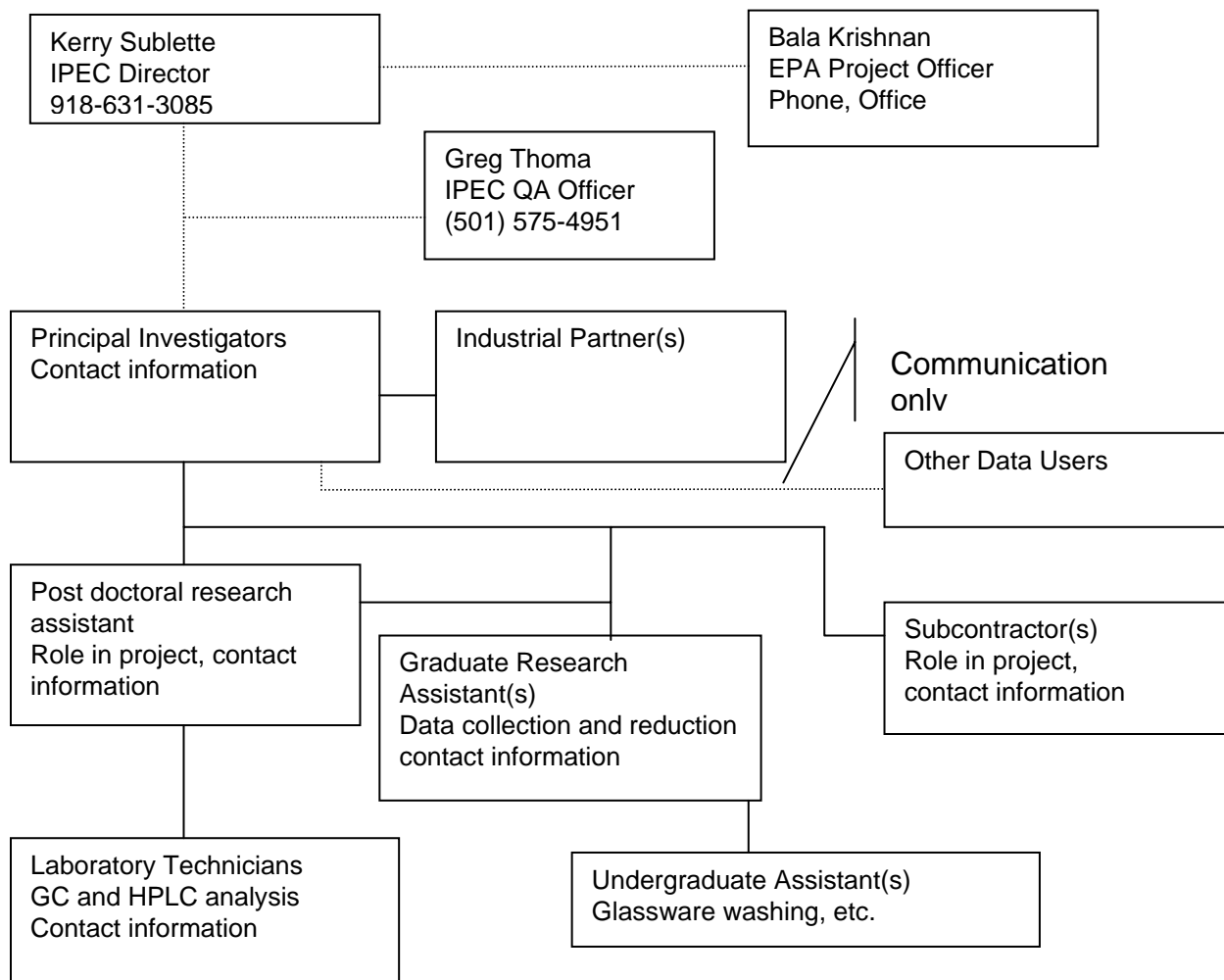


Figure 2 Project Organizational Chart

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Problem Definition/Background

Place the cursor on the blank line above, and present a brief introduction describing the need for the research, how this work relates to previous work and the context of the project in relation to accepted knowledge and practice (literature review). An extensive introduction presumably already exists in the proposal that was intended to convince the reader of the need and worthiness of this project. Please don't copy that introduction, but rather make this brief, but sufficient for the reader to understand why the work is important.

Project/Task Description and Schedule

This section should provide a description of the work to be performed and the schedule for implementation. A bulleted list of project goals, which address the manner in which the work performed will provide answer(s) to the problem(s), raised in the previous section or a Gantt chart would be appropriate. This discussion need not be lengthy or overly detailed, but it should give an overall picture of how the project will resolve the problem or question described above. Describe in general terms the following, as needed:

Measurements that will be made during the course of the project.

- ◆ *Applicable technical, regulatory, or program-specific quality standards, criteria, or objectives.*
- ◆ *Any special personnel and equipment requirements.*
- ◆ *The assessment tools needed (i.e., program technical reviews, peer reviews, surveillance, and technical audits) for the project.*
- ◆ *A schedule for the work to be performed.*

Quality Objectives

The QAPP must include a statement of the project quality objectives and measurement performance criteria. EPA supports the use of a graded approach to QA and recommends that planning be accomplished using the DQO Process. DQOs establish the data user's requirements for precision, accuracy, completeness, representativeness, and comparability. For details on the DQO Process and guidance on how and when it may be used, see the EPA guidance document (EPA QA/G-4). This guidance document is written with larger projects or clusters of projects in mind, and much of the information presented goes beyond what would normally be needed in a research project. EPA is currently preparing a guidance document on the DQO process for researchers.

Even in those cases in which the formal DQO Process is not used, a statement of the project quality objectives and measurement performance criteria is needed.

With a list of specific goals the research scientist first decides what information is needed to answer the questions posed. This discussion should include aspects of data quality and can usefully be captured as a statement of data quality objectives. Some of this information lends itself to presentation in a table format, but representativeness and comparability are the products of an appropriate experimental design and are understood better in that discussion.

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One method to determine the required data quality objectives (DQOs) is to make a list of all measurements needed to answer the questions posed in the research. Determine the level of precision, accuracy, and completeness needed to accomplish your goals. This can often be presented in a table format (example). It is important to remember that the values presented as your data quality objectives will be the standards for evaluating the data collected. Make sure that the DQOs reflect the needs of the project and are not too restrictive nor too lax. Remember that the DQOs may be changed if in the course of the project you have been too optimistic regarding your measurement ability or that your analysis requires greater precision, accuracy or completeness.

Table 4 Example of QA Objectives

Critical measurement	Method	Reference ⁵	Precision ¹	Accuracy ²	Complete-ness	MDL ³
HCB (in soil)	GC/MS	EPA 8270	25	D-152	95%	1.9mg/g
HCB (in water)	GC/MS	EPA 625	25	D-152	95%	1.9mg/L
TCA (in soil)	GC/MS	EPA 8240	5	52-150	95%	5.0mg/L
TCA (in water)	GC/MS	EPA 624	5	52-150	95%	5.0mg/L
Anionic surfactant	MeBI assay	Std. Mtd. 512B	15	90-110	90%	10mg/L

1. As relative percent of lab duplicates.
2. As percent recovery of lab matrix samples.
3. MDL(method detection limit) as reported in the reference.
4. D = detected, must be greater than zero.
5. References: 40 CFR Part 136, Appendix A, Federal Register, Washington, D.C. (1991); Standard Methods for the Examination of Water and Wastewater, 16 th edition, APHA/AWWA/WPCF, Washington, D.C. (1985); Test Methods for Evaluating Solid Wastes, SW-846, U. S. EPA, Washington, D.C. (1982).

Modeling/database projects

DQOs are typically not applicable to modeling activities. A simple statement indicating that condition should be included under the DQO heading in the QAPP.

Where existing data are used (ie, in modeling, GIS exercises and in reviews) the quality of data to be used should be specified in the DQO in the same manner as if measurements were part of the research plan. Data quality will, obviously, dictate the research design and should be addressed in that discussion. If no QA indices exist, a plan to acknowledge that condition and to appropriately alert the reader of the output should be included.

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Special Training Requirements/Certification

Place cursor above, and identify and describe any specialized training or certification requirements needed by personnel in order to successfully complete the project or task. For field work at hazardous sites it may be necessary to include the HAZWOPR 40 hour course – this can be determined with the campus safety officer. Discuss how such training will be provided and how the necessary skills will be assured and documented.

Documentation and Records

Place cursor above, and itemize the information and records that must be collected and maintained to assure clear and concise documentation of the project activities impacting data quality. Documents that should be considered include field logs, laboratory notebooks, instrument and calibration logs, chain of custody forms, sample handling logs, corrective action reports, etc. The discussion should detail the recording medium for the project, guidelines for hand-recorded data (e.g., using indelible ink), procedures for correcting data (e.g., single line drawn through errors and initialed by the responsible person), and documentation control. Specification of the proper reporting format, compatible with data validation (section D of the QAPP), will facilitate clear, direct communication of the investigation. The guidance document, EPA/QA 5-G, provides some examples of the types of records that should be considered for inclusion in this element. Appendix C of that document provides some useful checklists for preparation of this QAPP and items for consideration in the various data logs that may be necessary. Appendix 2 of this document is excerpted from the EPA guidance document.

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Measurement/Data Acquisition

This group of QAPP elements covers all aspects of measurement systems design and implementation, ensuring that appropriate methods for sampling, analysis, data handling, and QC are employed and are properly documented.

Experimental Design

Describe the experimental design or data collection design for the project, including as appropriate:

- *Hypothesis(es) to be tested*
- *the types and numbers of samples required,*
- *the design of the sampling network,*
- *the sampling locations and frequencies,*
- *sample matrices,*
- *measurement parameters of interest, and*
- *the rationale for the design (The choice between a probability-based (statistical) data collection design or a nonrandom (judgmental) data collection methodology depends on the ultimate use of the data being collected. This information is specified in Steps 5 and 6 of the DQO Process..*

All measurements should be classified as critical (i.e., required to achieve project objectives) or non-critical (informational purposes only). This information could be presented as table:

Appendix 3 presents a sample narrative (delete prior to printing this document).

Sampling Methods Requirements

Describe the procedures for collecting samples and identify the sampling methods and equipment, including any implementation requirements, sample preservation requirements, decontamination procedures, and materials needed. Identifying sampling methods by number, date, and regulatory citation (as appropriate) is often sufficient (include a citation in the References section). Non standard procedures must be fully described (or attached as an appendix) to the QAPP. EPA's guidance document provides a bibliography of sources for sampling methods.

Describe specific performance requirements for the method. Address what to do when a failure in the sampling occurs, who is responsible for corrective action, and how the effectiveness of the corrective action shall be determined and documented.

Sample Handling and Custody Requirements

Describe the requirements and provisions for sample handling and custody in the field, laboratory, and transport, taking into account the nature of the samples, the maximum allowable

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sample holding times before extraction or analysis, and available shipping options and schedules. Sample handling includes preservation, packaging, shipment from the site, and storage at the laboratory. For most IPEC projects, the main purpose of these forms is sample tracking, and the rigor needed in support of litigation is not needed.

Examples of sample labels, custody forms, and sample custody logs should be included (a checklist of items that should be considered for inclusion on these is available in the EPA guidance document appendix, QA G-5. Examples of these forms are also in the guidance document on pp 25-27. I am currently preparing templates (i.e. not PDF format), but may not have them ready for this round of QAPP).

Table 5 Examples of sample collection, handling and preservation activities

Sample Type	Parameter Measured	Sample Container	Minimum Sample Size	Preservation Method/ Storage
filtered sea water	pesticide dissolved fraction	glasss, muffled, solvent rinsed	100 ml	store in freezer at -20°C
sediment	grain size	beaker	9-16g	store in freezer at -20°C
filtered sea water	ammonium, phosphate, nitrate	polyethylene bottles	125 ml	store in freezer at -80°C, max of 1 week
liver tissue	metals	glass, muffled, acid rinsed	15g wet	store in freezer at -20°C

Analytical Methods Requirements

Identify the analytical methods and equipment required, including sub-sampling or extraction methods, laboratory decontamination procedures and materials (such as in the case of hazardous or radioactive samples), waste disposal requirements (if any), and any specific performance requirements for the method. Address what to do when a failure in the analytical system occurs and who is responsible for corrective action and how the effectiveness of the corrective action shall be determined and documented. Identifying analytical methods by number, date, and regulatory citation (as appropriate) is often sufficient.

For non-standard methods, such as unusual sample matrices and situations, appropriate method performance study information is needed to confirm the performance of the method for the particular matrix. If previous performance studies are not available, they must be developed during the project and included as part of the project results. For non-standard methods, including modified standard methods, details of the procedures used must be included here or as an appendix.

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Quality Control Requirements

Table AE.2 in the guidance document, EPA QA G-5, lists QC requirements for a series of programs, and will provide information on minimum levels of QC activity. Table AE.3 in the guidance document, EPA QA G-5, lists the QC requirements of various EPA measurement methods and presents the required frequencies for different kinds of QC operations. The table is divided into four sections, one for each general type of QC problem:

- *Contamination: This occurs when the analyte of interest or an interferant is introduced through any of a number of sources, including contaminated sample equipment, containers, and reagents. The contaminant can be the analyte of interest or another chemical that interferes with the measurement of the analyte or causes loss or generation of the analyte.*
- *Calibration Drift: This is a nonrandom change in the measurement system over time, such as a (systematic) change in instrument response over time. It is often detectable by periodic remeasurement of a standard.*
- *Bias: This can be regarded as a systematic error caused by contamination and calibration drift and also by numerous other causes, such as extraction efficiency by the solvent, matrix effect, and losses during shipping and handling.*
- *Imprecision: This is a random error, observed as different results from repeated measurements of the same or identical samples. For internal consistency, the names of QC operations used in Table AE.3 are those given in the specific reference methods.*

In this element, identify required measurement QC checks for both the field and the laboratory; for example, blanks, duplicates, matrix spikes, laboratory control samples, surrogates, or second column confirmation. State the frequency of analysis for each type of QC check, and the spike compounds sources and levels. State or reference the required control limits for each QC check and corrective action required when control limits are exceeded and how the effectiveness of the corrective action will be determined and documented.

Table 6 Common QC checks

replace table with types and frequency of QC checks needed for this project.

QC Check	Information Provided
Blanks field blank reagent blank rinsate blank method blank	transport and field handling bias contaminated reagent contaminated equipment response of entire laboratory analytical system
Spikes matrix spike matrix spike replicate analysis matrix spike surrogate spike	analytical (preparation + analysis) bias analytical bias and precision instrumental bias analytical bias
Calibration Check Samples zero check	calibration drift and memory effects

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span check	calibration drift and memory effects
mid-range check	calibration drift and memory effects
Replicates, splits, etc.	
collocated samples	sampling + measurement precision
field replicates	precision of all steps after acquisition
field splits	shipping + interlaboratory precision
laboratory splits	interlaboratory precision
laboratory replicates	analytical precision
analysis replicates	instrument precision

QC check data is often used to compute data quality indicators (DQI) such as precision (e.g., relative percent error) and accuracy (as percent spike recovery). The formulas used for computation of these DQI should be included in this section. An example discussion of the calculation of the accuracy DQI for an existing project is presented in Appendix 4

Instrument/Equipment Testing, Inspection, and Maintenance Requirements

Describe how inspections and acceptance testing of environmental sampling and measurement systems and their components will be performed and documented to assure their intended use as specified by the design. Identify and discuss the procedure by which final acceptance will be performed by independent personnel (e.g., personnel other than those performing the work) and/or by the EPA Project Officer. Describe how deficiencies are to be resolved and when re-inspection will be performed.

Instrument Calibration and Frequency

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

Table 7 Example of calibration procedures

Instrument	Calibration Procedure	Frequency
Sartorius PT1200 Balance	Calibrated by service technician during annual maintenance	yearly
Gas Chromatograph	Calibrated by injecting series of standards over expected range of quantitation	every session
pH meter	Calibrated using standard buffers	every session
Dissolved Oxygen meter	Calibrated using air-saturated water procedure	every session

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ICP Emission Spectrometer	Calibrated introducing a series of standards over expected range of quantitation	every session
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Table 8 Example quality control checks for instruments

Instruments	QC Check	Frequency	Data Summary	Acceptance Criteria	Action if values are unacceptable
Gas (GC) Chromatograph	Concentration standards covering expected range injected	before each session	Plot linear regression	linear response, $r^2 > 0.95$	repeat calibration or perform maintenance
Pipetman or Eppendorf pipettes	determine mass of dispensed volume	before each session	Single measurement	Within +/- 1% of expected volume	Clean, adjust, replace pipette. Return defective pipettes to vendor for service
Sartorius PT1200 Balance	Record readings for NIST traceable std weights	before and after each session	Calculate accuracy	greater than stated MQO	reweigh samples on another balance. Arrange to have balance serviced

Inspection/Acceptance Requirements for Supplies and Consumables

Describe how and by whom supplies and consumables shall be inspected and accepted for use in the project. State acceptance criteria for such supplies and consumables.

Data Acquisition Requirements (Non-direct Measurements)

Identify any types of data needed for project implementation or decision making that are obtained from non-measurement sources such as computer data bases, programs, literature files, and historical data bases. Define the acceptance criteria for the use of such data in the project and discuss any limitations on the use of the data resulting from uncertainty in its quality. Document the rationale for the original collection of data and indicate its relevance to this project.

Data Management

Trace data from collection to the final report. This may include various steps such as: entry into field notebook, transcription into computer spread sheet or database, verification, proof reading, outlier identification, editing, analysis, report writing. Include identification of units, when they change and how such changes are accomplished, (i.e., original data may be captured as peak

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height from some detector, changed to quantity based on a standard, changed to concentration by dividing by amount injected into detector, changed into concentration of tissue by dividing by mass of tissue in the sample, changed to concentration on area basis by a regression of mass to area, and finally reported on the basis of amount per hectare by another regression). The issue for QA is to specifically identify each data transformation and justify the use of auxiliary information when it is used to alter the values or the form of presentation. Some modifications introduce additional error, such as the error in measuring a second variable like area or mass. It is important to propagate all errors associated with any data generated in the laboratory or obtained from the literature.

Provide information on your computer system, method and frequency of file back-up. Discuss how long sample data should be stored, by whom and where.

Assessment/Oversight

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

Assessments and Response Actions

Identify the number, frequency, and type of assessment activities needed for this project. Assessments include, but are not limited to surveillance, management systems review, readiness review, technical systems audit, performance evaluation, audit of data quality, and data quality assessment. 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.

Reports to Management

Identify the frequency and distribution of reports issued to inform management of the status of the project. Identify the preparer and the recipients of the reports, and the specific action management is expected to take as a result of the reports.

The QA portion of the progress reports should address:

- *A summary of precision, accuracy and completeness for all samples analyzed.*
- *Any problems that could affect the quality of the data collected, the project schedule or the completion of the project.*
- *A summary of any corrective actions implemented and the result.*
- *Changes in the project's experimental design, objectives, or staffing.*
- *Identify any problems with equipment.*
- *A summary of data quality evaluation (especially for modeling or data review projects).*

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Data Validation and Usability

This group of QAPP elements covers the QA activities that occur after the data collection phase of the project is completed. Implementation of these elements ensures that the data conform to the specified criteria, thus achieving the project objectives.

Data Review, Validation, and Verification Requirements

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

Validation and Verification Methods

Describe the process to be used for validating and verifying data, including the chain of custody for data throughout the life cycle of the project or task. Discuss how issues shall be resolved and the authorities for resolving such issues. Describe how the results are conveyed to data users. Precisely define and interpret how validation issues differ from verification issues for this project

Reconciliation with User Requirements

Describe how the results obtained from the project or task will be reconciled with the requirements defined by the data user or decision-maker. Outline the proposed methods to analyze the data and determine possible anomalies or departures from assumptions established in the planning phase of data collection. Describe how issues will be resolved and discuss how limitations on the use of the data will be reported to decision-makers.

References

Please site by author and year in the text of this document. Any standard format for the reference list will be acceptable.

Appendices

Appendix 1 Standard operating procedures for analytical instrumentation

To include other appendices in the table of contents, simply copy the following 2 lines, and edit.

Appendix 2 Information Included in the Reporting Packages

The following is excerpted from the document EPA QA G-5.

Field Operation Records

The information contained in these records documents overall field operations and generally consists of the following:

- ◆ Sample collection records. These records show that the proper sampling protocol was performed in the field. At a minimum, this documentation should include the names of the persons conducting the activity, sample number, sample collection points, maps and diagrams, equipment/method used, climatic conditions, and unusual observations.
- ◆ Chain-of-custody records. Chain-of-custody records document the progression of samples as they travel from the original sampling location to the laboratory and finally to their disposal area.
- ◆ QC sample records. These records document the generation of QC samples, such as field, trip, and equipment rinse blanks and duplicate samples.
- ◆ General field procedures. General field procedures record the procedures used in the field to collect data and outline potential areas of difficulty in gathering specimens.
- ◆ Corrective action reports. Corrective action reports show what methods were used in cases where general field practices or other standard procedures were violated and include the methods used to resolve noncompliance. If applicable, to show regulatory compliance in disposing of waste generated during the data operation, procedures manifest and testing contracts should be included in the field procedures section.

Laboratory Records

The following list describes some of the laboratory-specific records that should be compiled if available and appropriate:

- ◆ Sample Data. These records contain the times that samples were analyzed to verify that they met the holding times prescribed in the analytical methods. Included should be the overall number of samples, sample location information, any deviations from the SOPs, time of day, and date. Corrective action procedures to replace samples violating the protocol also should be noted.

- ◆ Sample Management Records. Sample management records document sample receipt, handling and storage, and scheduling of analyses.
- ◆ Test Methods. Unless analyses are performed exactly as prescribed by SOPs, this documentation will describe how the analyses were carried out in the laboratory.
- ◆ QA/QC Reports. These reports will include the general QC records, such as initial demonstration of capability, instrument calibration, routine monitoring of analytical performance, calibration verification, etc. Project-specific information from the QA/QC checks such as blanks (field, reagent, rinsate, and method), spikes (matrix, matrix spike replicate, analysis matrix spike, and surrogate spike), calibration check samples (zero check, span check, and mid-range check), replicates, splits, and so on should be included in these reports to facilitate data quality analysis.
- ◆ Data Handling Records These records document protocols used in data reduction, verification, and validation. Data reduction addresses data transformation operations such as converting raw data into reportable quantities and units, use of significant figures, recording of extreme values, blank corrections, etc. Data verification ensures the accuracy of data transcription and calculations, if necessary, by checking a set of computer calculations manually. Data validation ensures that QC criteria have been met.

Appendix 3 Example narrative: Experimental design section

(This narrative is for a project investigating capping of contaminated sediments as a means of isolating the contaminants from the aquatic ecosystem)

Increasing the cap depth should increase the chemical containment effectiveness of the cap and increase the breakthrough time but not affect the ultimate pseudo-steady state flux. This hypothesis has not yet been experimentally tested. A 2³ factorial series (Table 2.1) of experiments will be performed to test this hypothesis. Two sets of five duplicates will be run (i.e. 10 Capping Simulator Cells (CSCs) will be used for each experimental run). The first set will include treatments A,C,F,H; the second will include the B,D,E,G. Both will include duplicate no-cap control CSCs. These experiments should also verify earlier results that the steady state flux of tracer through a cap layer is not a function of the sorptive capacity of the cap, and that the breakthrough time is dependent on the tracer's partition coefficient to the cap material (2).

Information regarding the applicability of the model will be obtained from both the measured release rate of the analytes into the overlying water, and the concentration profile of the analytes in the sediment bed following the experiment. Post mortem coring/sectioning of the sediment/cap beds followed by thin sectioning (2mm) and analysis of sediment analyte load will be used to determine the in bed concentration profile. The pore-water volume will be insufficient for direct analysis; it will be estimated based on the partition coefficient and the measured sediment load for the analyte.

Table 9 Capping Factorial Design

Treatment	Cap Depth	Cap K _d	Initial C ₀
A	H	H	H
B	H	H	L
C	H	L	H
D	H	L	L
E	L	L	L
F	L	L	H
G	L	H	L
H	L	H	H

H represents the high level for the parameter

L represents the low level for the parameter

Cap thicknesses of 3 and 7mm (for high organic carbon caps) and 7 and 12mm (for low organic carbon caps) will be used in order to have breakthrough times which are of reasonable length (on the order of 3 to 30 days). Although the flowrate through the cell could be varied to assess the effect of water side

resistance to mass transfer, this effect is not expected to be significant in the field under most situations and will not be experimentally investigated in this study.

(Subsequent discussion focuses on the apparatus used to make the measurements, and the way in which the samples are collected and handled.)

Appendix 4 Example narrative: Computation of accuracy as a data quality indicator

Aqueous samples The accuracy of aqueous sample concentration measurements will be verified by sample matrix spikes for experimental runs using inoculated sediment. The spike will be added after subsampling since the experimental setup precludes collection of duplicate samples from the same CSC (i.e. only one sample collected per channel and replicate treatments (channels) serve to check the within treatment precision). If the spike were added directly to the collection bottle, there would be no sample for a background concentration estimate.

Laboratory matrix spike samples will be performed for 10% of the samples. Since we anticipate 10 experimental samples per day, this means that one spiked sample will be prepared and analyzed each day that samples are taken. The samples will be spiked by adding a concentrated solution of the analytes (dibenzofuran, phenanthrene, and pyrene) in acetonitrile. The mass of analyte spiked will be adjusted to fall within the range of 50-150% of the expected mass of analyte in the sample. This will be estimated from the previous sample for the particular channel to be spiked. Analysis of the spiked samples will follow the same procedure described above. Spike recovery will be calculated as follows

$$\%R = \frac{100(M_s - M_0)}{M_a} 1$$
 where M_s is the analyte mass recovered from the spiked

sample, M_0 is the analyte mass recovered from the background sample, and M_a is the actual mass of analyte added to the spiked sample. The QA acceptance criteria for spike recovery will be generated from statistical control charts prepared and updated, for each analyte, as the experiment progresses. Previous results in our lab suggest that the expected 3σ spike recovery range will be approximately 50-125%. This range will be used until sufficient data have been collected to construct control charts for each analyte. Corrective action will be taken if two successive spikes fall out of this range

Appendix 5 Example narrative: Calibration procedures and frequency

Stock solutions will be prepared gravimetrically. 99% pure pyrene, 98% pure phenanthrene, 98% pure anthracene, and 99+% pure dibenzofuran (Aldrich) will be weighed on a microbalance (Mettler AE 50) and dissolved in HPLC grade acetonitrile. Anthracene or fluoranthene (98%) from Chemical Service, Inc. will be used as the surrogate for solid extraction monitoring. At this time the compounds mentioned above are planned as the working tracers for experiments involving inoculated sediments. However, other compounds with similar chemical properties to polyaromatic hydrocarbons may also be used. In the event that additional compounds are used, the same methodology will apply as described here. Standards will be prepared by serial dilution from individually prepared stock solutions.

We have found that the efficiency of the chromatographic separation (on our system) is enhanced with approximately 10% hexane added to the standard. This also is the matrix of our samples after solvent exchange to acetonitrile following the liquid-liquid extraction with hexane. Therefore, during the serial dilution to prepare the standards, 10% hexane will be added at the final step. A 5 point external calibration (approximately 50, 150, 500, 1000, and 2000 µg/L in each analyte) will be used to establish response factors and to correct for non-linearities, and a 3 point curve (i.e. 3 concentration levels) will be run with each sample set analyzed to verify that significant (i.e. greater than ± 15%) deviations in response factors have not occurred.

All concentration measurements from our HPLC analysis will be reported in either µg/L (parts per billion) or mg/L (parts per million). An example calculation for calibration and calculation of the concentration in an unknown sample is as follows.

- (1) Calculate the response factor (RF) for each calibration standard, according to the following equation:

$$RF_i = \frac{A_i}{C_i}$$

where A_i = response for a specific volume of the i th calibration standard (peak area) and C_i = concentration of the i th standard (mg/L).

- (2) Calculate the average Response Factor, \overline{RF} , and the relative standard deviation (RSD), from the following equations:

$$\overline{RF} = \frac{1}{n} \sum_{i=1}^n RF_i$$
$$RSD = \frac{100 \sqrt{\frac{1}{(n-1)} \sum_{i=1}^n (RF_i - \overline{RF})^2}}{\overline{RF}}$$

Note that $\overline{RF} 3$ is in fact the slope of a plot of A_i versus C_i , if the intercept is forced through zero. This is applicable only if the calibration curve is linear in the range of interest.

(3) The acceptance criterion for initial calibration for RF is that RSD must be less than or equal to 20%. The acceptance criterion for continuing calibration check will be that the percent difference between the calibration check RF and initial calibration $\overline{RF} 4$ must be less than or equal to 20% for all analysis. For percent difference greater than 20%, a new initial calibration must be run.

(4) Calculate the analyte concentration in the sample as follows:

$$C_{extract} = \frac{A}{\overline{RF}}$$
$$C_{effluent} = (C_{extract})(Extraction\ ratio)$$

where $C_{extract}$ = concentration of the analyte in the extract.

A = Peak area for the analyte.

$\overline{RF} 5$ = Average response factor for the analyte.

The extraction ratio will be 2.5/47.5 or 4/96

The following calibration plan will be implemented:

- (a) Duplicate check standards: A new 5 point calibration curve and the instrument stability checked by obtaining the response factor with a minimum frequency of every 6 weeks and after any substantive changes to the system (i.e. installation of a new column or after extensive column flushing). A standards log book will be maintained to document the preparation of all standards used in the project.
- (b) Laboratory method blanks: To assess that the measurement system is in control, a laboratory pure water blank will be analyzed for every 10 experimental samples.
- (c) Reagent blanks: All reagents used in these experiments will be of HPLC grade. These will be stored in the laboratory under custody of the analyst, and each new lot will be tested by injection in the HPLC system for possible interference.