Enhanced Monitoring Program
Quality Assurance Program Plan

October 1997
(EPA-905-R-97-017)

QA Program Plan Identification And Approval

Title: ***Enhanced Monitoring Program Quality Assurance Program Plan***

As the Executive Steering Committee, the attached quality assurance program plan (QAPP) for the Enhanced Monitoring Program is hereby recommended for approval.

1) Signature _____ Date _____
Barry DeGraff, Acting Director, Water Division, U.S. EPA Region 5

2) Signature _____ Date _____
Lloyd Eagan, Air Division, Wisconsin Dept. of Natural Resources

3) Signature _____ Date _____
Christopher Grundler, Director, Great Lakes National Program Office, U.S. EPA

4) Signature _____ Date _____
Steve Hedtke, Director, Large Lakes Research Station, U.S. EPA

5) Signature _____ Date _____
Melissa McCullough, Office of Air Quality Planning & Standards, U.S. EPA

6) Signature _____ Date _____
Dale Pahl, Atmospheric Research & Exposure Assessment Laboratory, U.S. EPA

7) Signature _____ Date _____
Richard Powers, Director, Surface Water Quality, Michigan Dept of Natural Resources

QA Program Plan Cooperator Approval Form

Title: ***Enhanced Monitoring Program Quality Assurance Program Plan***

As a cooperating agency, the attached quality assurance program plan (QAPP) for the Enhanced Monitoring Program is hereby recommended for approval.

1) Signature _____ Date _____
Dan Bauer, Water Resources Division, U.S. Geological Survey, U.S. Dept. of Interior

2) Signature _____ Date _____
Brian Eadie, Sediment Co-chair, National Oceanic and Atmospheric Administration

3) Signature _____ Date _____
John Gannon, Biota Co-chair, National Biological Survey, U.S. Dept. of Interior

4) Signature _____ Date _____
Paul Horvatin, EMP TCC Co-Coordinator, Great Lakes National Program Office, U.S. EPA

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Acronyms and Abbreviations

CAAA	Clean Air Act Amendments
CWA	Clean Water Act
DQA	data quality audits
DQOs	data quality objectives
EDCA	environmental data collection activity
EMP	Enhanced Monitoring Program
EPA	Environmental Protection Agency
GALP	good automated laboratory practices
GLP	good laboratory practices
GLISP	Great Lakes International Surveillance Plan
GLNPO	Great Lakes National Program Office
IMC	information management chaiperson
IDL	instrument detection limit
IJC	International Joint Commission
IQAM	internal quality assurance manager
LaMP	lakewide management plans
LMMB	Lake Michigan Mass Budget/Mass Balance Program
MC	modeling chairperson
MDL	method detection limit
MQOs	measurement quality objectives
MSR	management system review
NOAA	National Oceanic and Atmospheric Administration
PC	personal computer
PE	performance evaluation
PI	principal investigator
PM	program manager
PO	project officer
QA	quality assurance
QAC	quality assurance coordinator
QAM	quality assurance manager
QAMS	Quality Assurance Management Staff
QAPjP	quality assurance project plan
QAPM	quality assurance program manager
QAPP	quality assurance program plan
QE/QC	quality evaluation/quality control
RLP	Relative Loadings Program
SDL	system detection limit
SOP	standard operating procedure
TCC	Technical Coordinating Committee
TSA	technical system audit

1.0 Introduction

This section serves to inform the reader on the rationale behind the Lake Michigan Enhanced Monitoring Program (EMP) and the scope and purpose of the QA Program Plan. Since the objective of the QA Program Plan is specifically the implementation of the QA Program, details of the overall. EMP are not required and are therefore brief

1.1 Program Background

Environmental policy makers and the general public have become increasingly concerned about the condition of ecological resources in the United States. Research has shown that ecosystem response to combinations of natural and anthropogenic disturbances are complex. The Great Lakes, representing about 21% of the worlds fresh water supply, is an ecosystem whose ecological integrity has long been of concern to the Canadian and American people.

Legislation protecting the Great Lakes ecosystem dates back to the Boundary Waters Treaty of 1909. This agreement established the International Joint Commission (IJC), with members from the U.S and Canada, to identify environmental problems. More recently, the U.S. and Canada have strengthened their positions on environmental integrity by signing the 1972 Great Lakes Water Quality Agreement, as amended in 1978, 1983, and 1987. Annex 2 of this agreement requires the two nations to identify and reduce loadings of critical pollutants. This Annex also identifies Remedial Action Plans and Lakewide Management Plans that will be developed to restore and protect the beneficial uses in Areas of Concern or in open lake waters. Annex 11 of this agreement specifies the use of surveillance and monitoring as one mechanism in support of Annex 2. In 1992, the Clean Air Act Amendments (CAAA), within Title III, section 112(m), require EPA and NOAA to conduct research and monitoring of hazardous air pollutants to determine relative contribution of air deposition to total loadings and to evaluate the adverse effects of this deposition. The Great Waters Program has been developed to meet the Clean Air Act legislation for the areas of the Great Lakes, Chesapeake Bay, Lake Champlain, and Coastal estuaries. The objectives of the Clean Air Act and the Great Lakes Water Quality Agreement have led to the creation of the Lake Michigan Enhanced Monitoring Program.

Monitoring is not a new occurrence in the Great Lakes. The Great Lakes International Surveillance Plan (GLISP) contained in the 1975 Great Lakes Water Quality Board (principle advisors to the IJC) report, and as revised, was declared as the model for the development of the binational monitoring and surveillance program. Since then, both air and water monitoring programs have been developed both nationally and binationally. Figure 1.1 attempts to demonstrate how various monitoring efforts in the Great Lakes Basin interrelate and support each other towards a common goal.

1.2 Program Scope and Purpose

In general, the primary goal of the EMP is to develop a sound, scientific base of information to guide future toxic load reduction efforts at the Federal, State and local levels. Functionally, the EMP has been divided into two programs: 1) a Relative Loadings Program (RLP), and 2) a Lake Michigan Mass Budget/Mass Balance Program (LMMB). More specifically, the RLP is intended:

> to identify relative loading rates of critical pollutants from major tributaries to the Lake Michigan basin in order to better target future load reduction efforts;
>
> to evaluate relative loading rates by media (tributaries, atmospheric deposition in order to better target future load reductions efforts and establish a baseline loading estimate to gauge future progress.

The LMMB is intended:

> to develop the predictive ability to determine the environmental benefits of specific load reduction scenarios for toxic substances and the time required to realize those benefits.

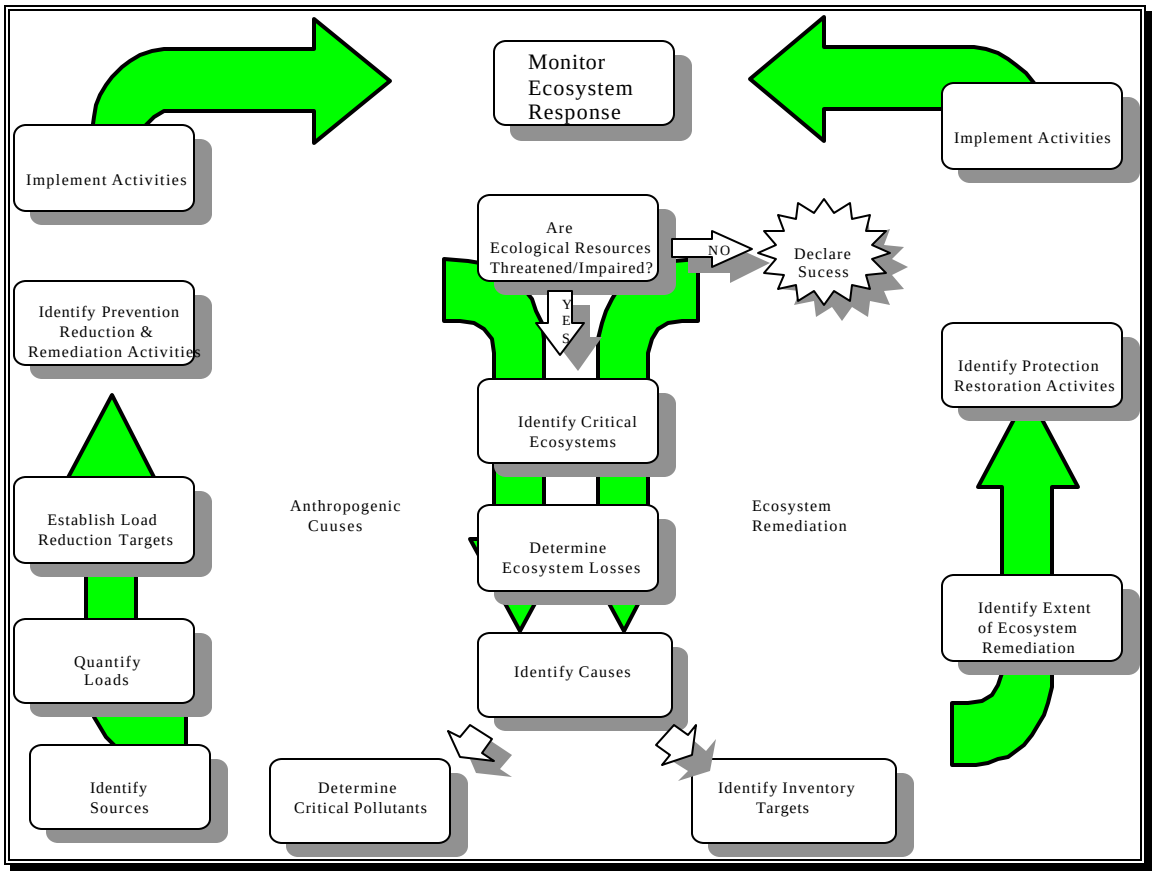


Figure 1.1 Great Lakes monitoring framework

This includes the evaluation of benefits of load reductions from existing environmental statutes and regulations required under Section 112(m) the CAAA, and section 303 of the Clean Water Act (CWA), and:

to improve our understanding of key environmental processes which govern the cycling and bioavailability of contaminants within relatively closed ecosystems.

Based upon the objectives mentioned above, the programs will parallel each other and be developed by

many of the same cooperators. The reason for the separation of the programs is due to their scope: the RLP being interested in air and tributary loadings of many types of pollutants, while the LMMB being interested in many more media pathways (sediments, biota, etc.) and fewer parameters. Details of LMMB can be found in the draft workplan developed in March 1995.

1.3 Measurement Parameters

The parameters selected for the RLP and the LMMB are listed in Table 1-1 and 1-2, respectively. A detailed parameter list within each media (air, tributaries, etc.) can be found in Appendix A. The critical pollutant list in the Great Lakes Water Quality Agreement and the critical pollutants for Lake Michigan were used to make the initial selection. The decision on which pollutants to measure were based upon the simple concept described in Figure 1.2. The present list contains parameters that: (1) can be sampled, analyzed and interpreted within a specific level of confidence, (2) can be sampled within the present budget, and (3) are known to be impacting the ecological health of Lake Michigan. There were some exceptions to these criteria when certain pollutants were included, because they are either causing ecological impairment, or assumed to have potential for impairment. As is illustrated in the tables, the two programs overlap on four major pollutants: PCB congeners, trans/cis nonachlor, atrazine, and total mercury.

The EMP will accomplish its objectives through balance models) activities. Models will be used as a tool to assess loadings data. Mass-balance models are a means with which to integrate the fate and distribution processes within the lakes such that a relationship between loadings and environmental integrity can be determined. In all cases, data will be used to make assessments. Managers and data users will use these data to make decisions on how pollutants

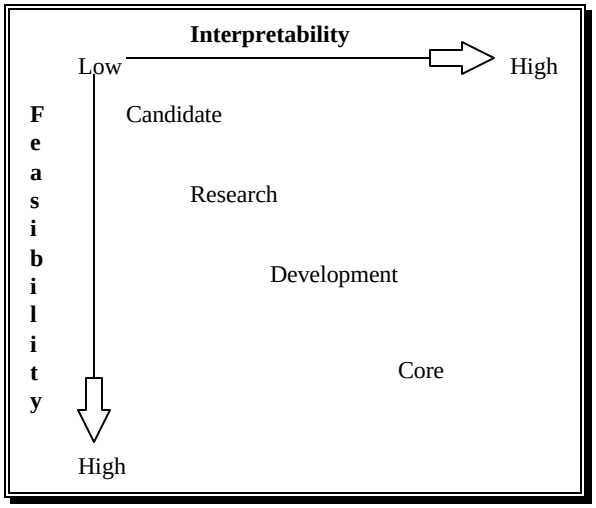


Figure 1.2 Process for continuous development of core measurements

loads are to be reduced. The choices they make will be based upon data derived from the EMP and similar programs. The decisions must be educated, because every decision has an associated risk. Managers look to minimize risks and maximize environmental successes.

In order to make educated decisions, appropriate data are required. This is data that, when evaluated, provide the manager with enough certainty that he/she is willing to risk making an inappropriate decision. inappropriate decision. This is the basis for quality assurance; assuring management that the risk is worth taking.

1.4 QA Program Plan Scope and Purpose

The QA program plan describes minimum requirements to which all organizations collecting data must adhere. These minimum requirements are developed in order to meet the EMP objectives - to provide data of sufficient quality for managers to make appropriate decisions. The goal of the program plan is to present the program, the consistent use of QA techniques among the various agencies collecting data for the EMP. In order for the program to successfully meet the EMP objectives, all cooperators must adhere to the guidance and policy set necessary to meet the objectives of the EMP. Major elements of the QAPP include:

- Quality Assurance Policy Statement
- Organizational Structure
- Data Quality Objectives
- QA Program Implementation
- Information Management

QA Reports

These elements will be described in the proceeding sections.

The QAPP will be developed by the Technical Coordinating Committee and Technical Workgroups, and approved by the Executive Steering Committee and various agency cooperators. The document is intended to be dynamic; changing as the objectives of the program change. Revisions will be made through the appropriate communication channels detailed in Section 3.0.

Table 1-1. Parameters and Measurements Proposed for the Relative Load Project of the EMP

Parameter	Specific	Media
PCB Congeners		A/P/T
Pesticides	Oxychlordane	T
	a-HCH	A/P/T
	g-HCH	A/P/T
	DDT	A/P/T
	DDD	A/P/T
	DDE	A/P/T
	HCB	A/P/T
	Dieldrin	A/P
	Trans-nonachlor	A/P/T
	Cis-nonachlor	T
	de-ethyl atrazine	A/P/T
	de-isopropyl atrazine	A/P/T
	Toxaphene	T
	a-Chlordane	A/P/T
	g-Chlordane	A/P/T
PAHs	acenaphthylene	A/P
	acenaphtene	A/P
	fluorene	A/P
	phenanthrene	A/P
	anthracene	A/P
	fluoranthene	A/P
	pyrene	A/P
	chrysene	A/P
	benzo(a)anthracene	A/P
	benzo(b)fluoranthene	A/P
	benzo(k)fluoranthene	A/P
	benzo(a)pyrene	A/P
	indeno(123cd)pyrene	A/P
	dibenzo(a,h)anthracene	A/P
	benzo(ghi)perylene	A/P
	retene	A/P
	coronene	A/P
	benzo(e)pyrene	A/P
Metals	Cd, Pb, Hg[a], Cr, Cu, Zn	A / P / T
	As	T
Major Ions	Ca, Mg, Na, K, Cl, SO_4	T
Conventional / Physical	Chloride	A / P / T
	Total Phosphorus	P / T
	Diss. Phosphorus	A / T
	Silica	A
	Diss Reactive Silica	T
	Nitrate	A / P / T
	Ammonia	T
	Ammonium	P
	Total Kjeldahl N	P / T /
	Total Organic Carbon	A
	Part. Organic Carbon	A / T
	Diss. Organic Carbon	T
	VOC	A
	Elemental Carbon	A
	Hardness	T
	Alkalinity	P / T
	Chlorophyll a	T
	SPM 0.7_m	A / T
	Temperature	A / T
	Dissolved Oxygen	T
	Conductivity	P / T
	pH	P / T
	Turbidity	T
	Wind Speed / Current	A / T
	Direction	A / T

	Volume	A / P / T
	Weight	A / T
	Location	A / P / T
	Relative Humidity	A
	Solar Radiation	A

A=Air, P= Precipitation, T= Tributaries
a= only collected at five sites for air

Table 1-2. Parameters and Measurements Proposed for the Mass Balance Project of the EMP

Parameter	Specific	Media
PCB Congeners		P/T/L/A/B/S
Pesticides	Trans-nonachlor	A/P/T/L/B/S
	cis-nonachlor	T/L/S
	de-ethyl atrazine	A/P/T/L/S
	de-isopropyl atrazine	A/P/T/L/S
Metals	Hg[a]	A / P / T / L / B
Conventional / Physical	Chloride	A / P / T / L / S
	Total Phosphorus	P / T / L / S
	Dissolved Phosphorus	A / T
	Silica	A / P / T / L
	Dissolved Reactive	T
	Silica	A / P / T / L
	Nitrate	T / L
	Ammonia	P
	Ammonium	P / T / L / S
	Total Kjeldahl N	A / S
	Total Organic Carbon	A / L / T
	Part. Organic Carbon	L / T
	Diss. Organic Carbon	A
	VOC	A
	Elemental Carbon	T
	Hardness	P / T / L
	Alkalinity	T / L
	Chlorophyll a	T
	Suspended Solids	A / T / L
	SPM 0.7_m	A / T / L
	Temperature	T / L
	Dissolved Oxygen	P / T / L
	Conductivity	P / T / L
	pH	L
	Water Clarity	T
	Turbidity	A / T
	Wind Speed / Current	A / T
	Direction	A / P / T / L
	Volume	A / T / L
	Weight	B
	Length	B
	Age	A / P / T / L / B
	Location	A
	Relative Humidity	A
	Solar Radiation	S
	% Water	S
	Porosity	S
	% Solids	S
	Redox Potential	S
	Particle size	

A=Air, P= Precipitation, T= Tributaries, L= Open Lake, B=Biota, S=Sediments
a= only collected at five sites for air

2.0 Quality Assurance Policy Statement

The Program Directors and Managers, as members of the Executive Steering Committee, are committed to fulfilling the objectives of the Lake Michigan Enhanced Monitoring Program (EMP). The Directors and Mangers will make decisions based upon the interpretive results of this program. These decisions usually depend on qualitative and quantitative measurements derived from various environmental data collection activities (EDCAs). These measurements are never true values and always contain some level of uncertainty. Decision makers must be able to use these measurements with some level of confidence in order to make informed decisions. The EMP is committed to a QA program whose goal is to assure that the quality of data derived from environmental data collection activities (EDCAs) is known (i.e., precision, accuracy, detectability, completeness, representativeness and comparability) and meets the needs for which the data were intended. Further, it is recognized that it is management's responsibility to create an environment in which all personnel may contribute to producing high quality products.

By way of signature approval, the Directors and Managers of the EMP have agreed to the policy and guidance developed in the QAPP. All organizations cooperating on the EMP will adhere to the guidance and policy within the QAPP. Any agency or group currently cooperating on the EMP, or considering cooperating, will receive a copy of the QAPP.

The QAPP is meant to be a dynamic document, changing as more information is acquired or as new agencies and regions enter into the program. The QAPP will be revised to reflect these changes and will update the approval page as major modifications occur and/or new agencies enter the program.

3.0 Organizational Structure

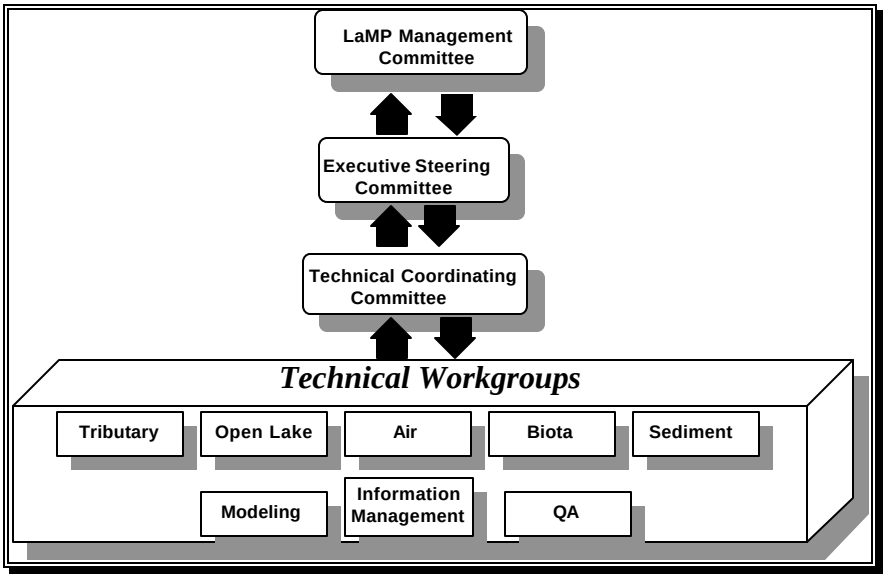


Figure 3.1 EMPorganizational structure

3.1 Lake Loading Organization

Figure 3.1 represents the organizational structure of the EMP. The following sections will detail the specific activities and responsibilities of each group.

3.1.1 Lake Michigan LAMP Management Committee

As stated in the draft Lake Michigan Lakewide Management Plan (LaMP) for Toxic Pollutants, the Lake Michigan LaMP Management Committee consists of numerous representatives from federal and state agencies. The Committee is responsible for:

- Providing overall policy recommendations for the Lake Michigan LaMP program, including recommendations on LaMP priorities;
- convening technical work groups composed of Federal, State, and other representatives as necessary;
- reviewing the Lake Michigan LaMP or specific elements of it, technical workgroup products/recommendations, and Lake Michigan Forum recommendations/comments; and
- working through participating agencies' and organizations' budget processes to secure resources necessary to develop and implement the Lake Michigan LaMP.

This committee as part of the defined responsibilities listed above will set the management objectives for the EMP and provide for the resources to implement the program.

3.1.2 Executive Steering Committee

The Executive Steering Committee members are the primary customers of the EMP data. This group will use EMP data in their decision-making processes in order to restore biological integrity, beneficial use, and other ecological objectives for the organization he/she represents. Table 3.1 identifies the Executive Steering Committee Members. The Executive Steering Committee has determined the need for EMP and have delegated the development of the program to the Technical Coordinating Committee. The Executive Steering Committee attempts to meet quarterly to receive updates and progress information on the EMP. The Executive Steering Committee will approve the QAPP.

Table 3-1 EMP Executive Steering Committee

Name	Affiliation
Barry DeGraff	U.S. EPA Region 5, Water Division
Lloyd Eagan	Wisconsin Dept. of Natural Resources
Chris Grundler	U.S. EPA, Great Lakes National Program Office
Steve Hedtke	U.S. EPA, Large Lakes Research Laboraory (ORD)
Melissa McCullough	U.S. EPA, Office of Air Quality Planning & Standards
Dale Pahl	U.S. EPA, Atmospheric Research & Exposure Assessment Lab.
Rich Powers	Michigan Dept. of Natural Resources, Surface Water Quality Div.

3.1.3 Technical Coordinating Committee

The Technical Coordinating Committee (TCC) is responsible for the development and the implementation of the EMP. The TCC includes two coordinators and the technical workgroup chairpersons. Each media technical workgroup has two co-chairs as indicated in Table 3-2. The membership reflects both State and Federal environmental concerns and allows for consensus development of EMP objectives. Responsibilities of the TCC include:

- Managing the program.
- Developing program objectives and data quality objectives (DQOs).
- Developing the EMP Monitoring Plan.
- Recommending the allocation and prioritization of resources and activities to the Executive Steering Committee.
- Reviewing and approving the QA Program Plan.
- Serving as the EMP communications center.
- Coordinating workgroup activities.
- Ensuring that workgroup responsibilities are met.

3.1.4 Technical Workgroups

The technical workgroups are composed of individuals responsible for implementing each program component and the experts necessary to plan and implement the activities for which the group is responsible. The responsibilities of the technical workgroups are explained in the following sections.

3.1.4.1 Media Workgroups --

Media Workgroups (air, tributaries, open lake, biota, sediments) are composed of principal investigators who are responsible for various data collection operations and other technical experts, such as statisticians, necessary to develop EDCAs that will meet the program objectives. Responsibilities of each workgroup include:

- Assisting in the development of the EMP Monitoring Plan
- Developing program objectives and (DQOs).
- Developing standard operating procedures.
- Developing QA Project Plans.
- Developing the media sampling design.
- Coordinating implementation activities.
- Reporting and interpreting data.

3.1.4.2 Modeling Workgroup

The Modeling Workgroup is composed of a chairperson, personnel familiar with developing and implementing the models needed for the study, and principal investigators that will be collecting the data as input to the model. Responsibilities include:

- Assisting in the development of the EMP Monitoring Plan
- Developing program objectives and DQOs.
- Reviewing data collection plan to determine compliance with modeling goals and objectives.
- Developing and implementing QA Project Plans for modeling activities.
- Defining the modeling requirements.
- Developing and implementing the model.

3.1.4.3 Information Management Workgroup

The Information Management Workgroup is composed of a chairperson, personnel familiar with developing, implementing, and maintaining information management systems, and personnel responsible within each coordinating agency for delivery of data to the "centralized" data repository. Responsibilities of this group include:

- Assisting in the development of the EMP Monitoring Plan
- Developing the information management system.
- Developing the data base structure.
- Developing field and laboratory data standards.
- Maintaining a current data base (editing etc.).
- Distributing data at regular intervals.
- Maintaining an archive of all EMP data.

· Developing a data base users guide.

Table 3-2 Technical Coordinating Committee Chairpersons

Workgroups	Name	Affiliation
TCC Coordinators	Paul Horvatin Glenn Warren	U.S. EPA, Great Lakes National Program Office U.S. EPA, Great Lakes National Program Office
Air	Angela Bandemehr Carrie Monosmith	U.S. EPA, Great Lakes National Program Office Michigan Dept. of Natural Resources
Biota	Paul Bertram John Gannon	U.S. EPA, Great Lakes National Program Office U.S. DOI, National Biological Survey
Open Lakes	Dave Anderson Phil Cook	U.S. EPA, Great Lakes National Program Office U.S. EPA, Office of Research & Development
Tributaries	Bob Day Gary Kohlhepp	Michigan Dept. of Natural Resources U.S. EPA, Region 5, Water Division
Sediments	Brian Eadie Rick Fox	National Oceanic and Atmospheric Administration U.S. EPA, Great Lakes National Program Office
Modeling	Bill Richardson	U.S. EPA, Office of Research & Development
Info. Management	Pranas Pranckevicius	U.S. EPA, Great Lakes National Program Office
QA	Louis Blume	U.S. EPA, Great Lakes National Program Office

3.1.4.4 QA Workgroup

The QA workgroup is composed of a chairperson, and project officers, who by EPA policy, are responsible for ensuring that QA is implemented for data collection activities. In most cases the project officers are also co-chairs for the various media workgroups, and are the first line of communication on any QA issues that might effect changes in sampling or analytical activities. QA workgroup responsibilities include:

- Assisting in the development of program objectives and DQOs.
- Assisting in the development of the EMP Monitoring Plan.
- Developing and implementing the EMP QA Program Plan.
- Providing guidance to principal investigators on the development of QA Project Plans.
- Reviewing and approving QA Project Plans.
- Tracking progress on QA Project Plan development.
- Coordinating and implementing assessments.
- Developing integrated data quality reports.
- Scheduling and facilitating technical systems audits.
- Developing data verification programs.

3.2 Responsibility of Individuals

The following individual titles are defined to help associate the responsibilities in following subsections with the titles used in this section.

3.2.1 Program Managers

Program Managers (PMs) are defined by their managerial role and are usually associated with agencies that provide funding and overall guidance to the program. Program managers are members of the Executive Steering. They include State, EPA representatives, and any other individuals responsible for directing the program. QA-related responsibilities of the PMs include:

- Establishing policies to ensure that QA requirements are incorporated in all data collection programs including the budget and planning processes.
- Assuring that the EMP develops and maintains a current and germane QA Program Plan and ensures adherence to the document by all agencies cooperating in the Program.
- Assuring that QA Project Plans are developed for all data collection activities and submitted to the QA Chairperson for review and approval prior to project initiation.
- Reviewing and evaluating QA implementation and progress.

· Maintaining an active line of communication with the QA Program Manager.

3.2.2 Project Officer

The EPA Project Officer (PO) is responsible for the performance and coordination of a specific project(s) and is EPA management's principal contact regarding the project(s). The Project Officer is responsible for all EPA-funded data collection activities and develops in cooperation with the principal investigator, the QA criteria based on the intended use of the data. QA criteria are communicated by the development of data quality objectives (DQOs) and QA project plans. POs must be participants on technical workgroup committees in order to understand the technical aspects of the program. QA-related responsibilities include:

· Developing data quality objectives (DQOs).
· Developing or ensuring the development of the QA Project Plan through negotiation with principal investigators, appropriate QA representatives and other technical personnel when needed, and having this plan submitted, reviewed and approved prior to project initiation.
· Ensuring the implementation of QA project plans.
· Ensuring that standard operating procedures (SOPs) for each data collection operation are reviewed and approved.
· Reviewing the QA project plan with project participants.
· Reviewing project QA/QC outputs.
· Participating in audits and assessments.
· Ensuring that required corrective actions are implemented.
· Reporting data quality problems to the QA Chairperson and QA Manager.
· Developing or ensuring the development of QA reports.

3.2.3 Principal Investigators

The principal investigator (PI) is responsible for carrying out a required task(s) and ensuring the data quality results of the task(s) by adhering to guidance and protocol specified in the EMP QA Program Plan and then specifically to the QA Project Plan of that data collection operation. Responsibilities include:

· Participating in the development of the QA project plan.
· Negotiating data quality requirements with the appropriate QA manager.
· Training staff in the requirements of the QA project plan and in the evaluation of QC measurements.
· Writing and modifying standard operating procedures (SOPs) and good laboratory practices (GLPs) and training data collection staff in these methods.
· Verifying that all required QA activities were performed and that measurement quality standards were met as required in the QA project plan.
· Following all manufacturer's specifications.
· Performing technical systems audits.
· Performing and documenting preventative maintenance.
· Documenting deviations from established procedures and methods.
· Reporting all problems and corrective actions to the PO, PMs, and QA Manager.
· Assessing and reporting data quality.
· Preparing and delivering reports to the PMs.
· Flagging suspect data.
· Preparing and delivering data to the EMP data base

3.2.4 Workgroup Chairpersons

Workgroup Chairpersons are responsible for coordinating the specific workgroup activities of the EMP and supporting the Program Management Committee. The main responsibilities of each chairperson are identified in the following sub-sections.

3.2.4.1 Media Workgroup Chairpersons

· Ensuring that data collection activities are developed within reasonable timeframes for review and approval.
· Ensuring that proper data collection training occurs.
· Coordinating the development of program objectives and data quality objectives (DQOs).
· Coordinating with other workgroups.
· Ensuring the development of standard operating procedures.
· Ensuring the development QA Project Plans.
· Ensuring the adherence to the EMP QA Program Plan
· Assisting in the development of the sampling design.
· Coordinating implementation activities.
· Ensuring the timely reporting and interpretation of data.

3.2.4.2 Modeling Chairperson

The Modeling Chairperson (MC) is responsible for coordinating the EMP modeling effort. Responsibilities include:

- Ensuring that data collection activities are developed within reasonable timeframes for review and approval.
- Coordinating the development of program objectives and data quality objectives (DQOs).
- Coordinating with other workgroups.
- Ensuring the development QA Project Plans for modeling activities.
- Ensuring the adherence to the EMP QA Program Plan.
- Ensuring the timely reporting and interpretation of data.

3.2.4.3 Information Management Chairperson

The Information Management Chairperson (IMC) is responsible for coordinating the information management activities of the EMP. The main responsibilities of the IMC is ensuring that data and information collected for the EMP are properly captured, stored, and transmitted for use by EMP participants. Responsibilities include:

- Ensuring that information management activities are developed within reasonable timeframes for review and approval.
- Coordinating the development of the information management system with data users.
- Coordinating with other workgroups.
- Ensuring the development of data standards for data structure, entry, transfer, and archive.
- Ensuring the adherence to the EMP QA Program Plan where applicable.
- Ensuring access to data for timely reporting and interpretation process.
- Ensuring the development of data base guides (data base structures, user guidance documents).

3.2.4.4 QA Chairperson

The QA Chairperson (QAC) is responsible for coordinating the QA activities of the EMP Program. The main responsibilities of the QAC is QA oversight, ensuring that all personnel understand the QA Program Plan and their QA/QC responsibilities. The QAC provides technical support and reviews and approves QA products. Responsibilities include:

- Interpreting Agency QA policy and developing the QA policy for the EMP Program in accordance with Agency QA policies and direction from PMs.
- Developing a QA Program Plan and revising it as necessary.
- Ensuring adherence to the QA Program Plan.
- Developing QA budgets.
- Assisting PMs, POs, and PIs in developing QA documentation and in providing answers to technical questions.
- Coordinating with other workgroups.
- Ensuring that all laboratory, field, or office personnel involved in environmental data collection have access to any training or QA information needed to be knowledgeable in QA requirements, protocols, and technology.
- Ensuring that all environmental data collection activities are covered by appropriate QA planning documentation (e.g., DQOs and QAPjP).
- Ensuring that routinely used sampling and analytical laboratory methods are covered by Standard Operating Procedures (SOPs).
- Ensuring that audits/reviews are accomplished to assure adherence to approved QA project plans and to identify deficiencies in QA/QC systems.
- Ensuring that adequate follow-through actions are implemented in response to audit/review findings.
- Tracking the QA/QC status of all programs.
- Assisting in solving QA-related problems at the lowest possible organizational level.
- Recommending required management-level corrective actions.

While PMs have primary responsibility for: developing QA policies, procedures, and criteria; delegating QA authority/responsibility; it is the QAC who actually prepares or assembles the finished QA Program Plan and shepherds it through the approval process.

QA Managers --

QA Managers (QAMs) include individuals responsible for the data quality of specific agencies providing EDCAs, as well as the individuals responsible for the review and approval of QA project plans. For EPA-funded activities, this would include QA officers. Responsibilities include:

- Assisting in the development of the QA Program Plan and QA Project Plans.
- Reviewing and approving of QA Project Plans under their jurisdiction.
- Scheduling and implementing audits and assessments.
- Ensuring adherence to the QA Program Plan and project plans.
- Ensuring that routinely used sampling and analytical laboratory methods are covered by Standard Operating Procedures (SOPs).

- Tracking the QA/QC status of programs under their jurisdiction.
- Assisting in solving QA-related problems at the lowest possible organizational level.

Internal QA Managers --

Each organization that is responsible for an EDCA must designate an internal QA Manager (IQAM). This person may be the PI or someone designated within the organization. Responsibilities include:

- Assisting in the development of QA Project Plans specific to their organization.
- Reviewing and approving of QA Project Plans under their jurisdiction.
- Scheduling and implementing internal audits and assessments.
- Ensuring adherence to the QA Program Plan and project plans.
- Ensuring that routinely used sampling and analytical laboratory methods are covered by Standard Operating Procedures (SOPs).
- Tracking the QA/QC status of programs under their jurisdiction.

Figure 3.2 serves to illustrate the association of the various QA personnel within the EMP. Whereas the EMP QA Program Plan will be developed and approved primarily at the QAC/QAM level; the quality assurance for individual projects will be developed and approved at the QAM/IQAM level. Figure 3.2 also illustrates that IQAMS may be responsible to more than one QAM. During QA workgroup discussions, the QAC, QAMs and IQAMS will be designated and there relationships documented. QAPjPs will also document this information.

provide to, the other workgroups. Workgroup chairpersons will be responsible for setting up the appropriate communication channels to keep the TCC updated on progress and problems occurring within the workgroup.

The TCC is the logical center for all EMP communication. The TCC will communicate with Program Directors to determine the goals and directions of the program. The TCC will then communicate this information to workgroup chairpersons and others as appropriate. Workgroup chairpersons will meet with the TCC to discuss progress and problems. The TCC will be responsible for evaluation and dissemination of information throughout the organizational structure.

For each specific EDCA, the QA project plan (QAPjP) will specify the line of communication which will be developed as part of the organizational structure for that EDCA. This is important so that issues identified in the field or laboratory get conveyed laterally (to other field/lab personnel) as well as vertically to the appropriate workgroups. All EDCAs must have communication lines to at least one workgroup.

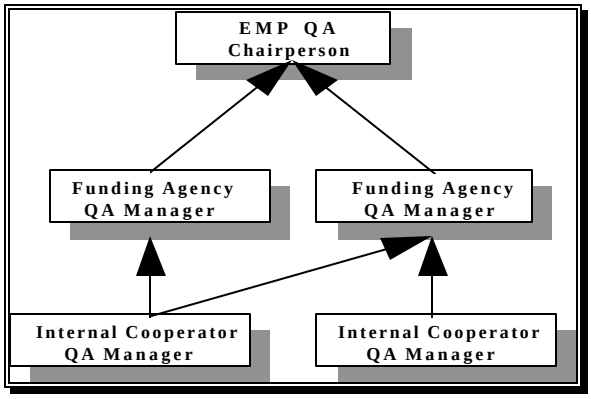


Figure 3.2 EMP QA Structure

3.3 Communication

In order to develop and implement the EMP, communication is essential. The organizational structure was developed for the efficient use of individuals and to develop an orderly communication network. Workgroups have been developed around specific tasks but are intrinsically linked to one
another. Workgroups must determine how best to accomplish their goals and what information they need from, and must

4.0 Data Quality Objectives

" Science is fact; just as houses are made of stone, so is science made of facts: but a pile of stones is not a house and a collection of facts is not necessarily science."

--Henri Poincare

4.1 Definition

In many instances, data are collected in order to make environmentally sound decisions. Data quality objectives (DQOs) are the full set of performance constraints needed to design a project, including a specification of the level of uncertainty that a decision maker (data user) is willing to accept in the answers to the questions of the study. These are data that, when evaluated, provide the decision maker with enough certainty that he/she is willing to risk making an inappropriate decision. Therefore, the data quality attributes that are associated with data are necessary for any educated ecological management decision.

Uncertainty can be illustrated as follows

$$S_o^2 = S_p^2 + S_m^2 \qquad \text{(equation 1)}$$

Where:

o= Overall Uncertainty
p= Total Population Uncertainty (spatial and temporal)
m= Measurement Uncertainty (data collection)

The estimate of the overall uncertainty is the DQO and must be defined by the data users. The term "uncertainty" is used as a generic term to describe the sum of all sources of error associated with a given portion of the measurement system. Confidence in estimates of population uncertainty can be controlled through the use of statistical sampling design techniques. *The goal of QA program is to control measurement uncertainty to an acceptable level through the use of various quality control and evaluation techniques*. The decision makers:

- Need to be actively involved in the specification of limits on uncertainty.
- Need to estimate the economic, health and ecological consequences of decision errors.
- Need to consider the political and social consequences when setting limits on uncertainty.
- Should work with a statistician during this step to ensure that the limits are reasonable and complete.

The DQO process is used to facilitate the planning of data collection activities. It asks the data user to focus their planning efforts by specifying the use of the data (the decision), the decision criteria, and the probability they can accept of making an incorrect decision based on the data. The DQO process:

- Establishes a common language to be shared by decision makers, technical personnel, and statisticians in their discussion of program objectives and data quality.
- Provides a mechanism to pare down a multitude of objectives into major critical questions.
- Facilitates the development of clear statements of program objectives and constraints which will optimize data collection plans.
- Provides a logical structure within which an iterative process of guidance, design, and feedback may be accomplished efficiently.

The DQO process contains the following steps:

- The problem to be resolved
- The decision
- The inputs to the decision
- The boundaries of the study
- The decision rule
- The limits on uncertainty
- Study design optimization

Appendix B contains detailed guidance for the development of DQOs.

4.2 Development of DQOs

The DQO process is an iterative planning tool. As one proceeds through the various stages of the process one must reassess decisions made at earlier stages. This helps to focus in on the priority objectives of the study and develop the

appropriate QA criteria and study design to meet those objectives.

4.2.1 The Relative Loads Program (RLP)

On December 8, 1992, various technical experts and managers participated in a DQO session for the RLP. Due to the limited time available, it was realized that the process could not be completed in one day but that the development of consensus objectives for the program would be the priority and that further program planning and staged implementation of the program would assist in acquiring the information necessary to complete the DQO process.

Section 1.2 details the RLP consensus objectives. Because a monitoring study of this magnitude using the parameters listed in Table 1-1 has not been implemented, many questions within the DQO process cannot be answered. Therefore, the RLP has developed a staged implementation approach. Through the use of pilot projects prior to full implementation, questions on sample design and uncertainty limits can be answered that will provide input into the DQO process. The parameter selection process, described in Section 1.3, follows a similar scenario - as more confidence is acquired in the procedures to collect and analyze various pollutants, the closer the parameters will be towards implementation in the program.

The RLP will measure two media; air (including precipitation), and tributary waters. Data from these two media will be used separately, as well as aggregated, for modeling efforts. This complicates the DQO process since a DQO for each media may be different than the DQO required for a model. Through the DQO process, one must determine what results are of the highest priority and establish the DQOs for their attainment.

As mentioned in the section above, the DQO is the overall uncertainty that the user is willing to accept in the result derived from the data while being able to make an informed decision. This means that both population and measurement uncertainties are understood or a process will be developed prior to full implementation to understand these uncertainties. The intent of the QAPP is to provide guidance on understanding, controlling, and assessing measurement uncertainties. ***The Air and Tributary Workgroups will be responsible for determining the overall uncertainties for all measurement parameters.*** This can be accomplished by developing a QA design (Section 4.4) and implementing a quality assurance program.

4.2.1.1 Tributary DQOs

The following DQO has been developed for the tributary estimates:

> ***"Estimate 90% of the tributary loads of PCBs to Lake Michigan at +/- 25% at the 95% confidence interval"***

Historical fish tissue and water concentration data were used to determine which tributaries were necessary to estimate 90% of loads for the priority pollutants and the sampling frequency for each tributary, based upon tributary flow/discharge characteristics. Tributary sampling site information can be found in the EMP Workplan.

The objective was developed from available data and estimates of some pollutants may not achieve the desired data quality. However, this objective allows PI's to develop the best sample and QA design with the data available. As data from pilot projects become available, the objectives will be reassessed.

The next step in this process is to determine the apportionment of uncertainty to population and measurement. This will allow for the development of measurement quality objectives (MQOs) to control measurement uncertainty within appropriate limits to meet the DQO.

4.2.1.2 Air DQOs

The following DQO has been developed for the air estimates:

> ***"Estimate atmospheric concentrations of identified parameters for Lake Michigan in a manner that will provide a annual atmospheric loading estimate within +/- 100% at the 95% confidence interval"***

Much less is known about the RLP critical pollutants in the air component. It has been suggested that the variability of air data may be considerably greater than the tributary data, using the proposed sampling design. This is to be expected since the boundary conditions of air and tributaries are quite different.

4.2.2 Lake Michigan Mass Budget/Mass Balance (LMMB) DQOs

The following is an excerpt from the Lake Michigan Mass Budget/Mass Balance Workplan:

> *"It is proposed that the model output should be within a factor of 2 of the observed concentrations in the water column and target fish species.... From the Green Bay Mass Balance Study, it is estimated that the required level of model accuracy can be achieved if loadings and contaminant mass in significant environmental compartments are determined to within +/- 20 to 30 percent of the actual value."*

Since the LMMB parameters for the tributary and air media are included in the RLP, the DQOs will be the same. For the remaining media, historical data will be used to provide the most realistic sampling design to meet this objective. It is realized that not all media and/or parameters may meet the criteria, but that the DQO is an objective with which to focus a design. As data become available from the initial sampling period it then can be used to assess uncertainties in estimates and possibly modify sample designs.

4.3 Uncertainty Estimates

Estimates of both the population and measurement uncertainties of the various measurement parameters will be needed in order to determine the confidence one has in the final estimates. The manner in which these estimates are derived must be statistically valid, and prior to full implementation, should be peer reviewed.

Equation 1 will be used in the evaluation of uncertainty. At present, it is not known what proportion of the uncertainty for the critical pollutants will be attributed to population or measurement. Taylor (1987) suggests that a measured value can be considered error-less for most uses if the uncertainty in that value is one-third or less the permissible tolerance for its use. Since variance is commonly used to express uncertainty, the equation becomes:

For: $S_o^2 = S_p^2 + S_m^2$ (equation 1)
(DQO) (MQO)

Taylor: $10 = 3^2 + 1^2$ (equation 2)

Or: $10 = 9 + 1$ (equation 3)

Therefore, measurement uncertainty can be assumed to be insignificant if its uncertainty estimate is 1/10 the overall uncertainty. In lieu of actual measurement data quality controls, the EMP can use this equation to determine whether measurement uncertainty needs to be controlled. This process is useful in determining where emphasis should be placed on reducing uncertainties. For example, if the overall uncertainty is inordinate and the measurement uncertainty is within 1/10 the overall, the data would suggest that management focus on reducing population uncertainty, since little benefit would be derived at reducing measurement uncertainty. The equation serves to identify where to focus QA resources. It should be noticed that the terms data quality objective (DQO) and measurement quality objective (MQO) have been added to equation 1. This serves to distinguish the fact that an MQO is not a DQO and that this QAPP serves to control the measurement uncertainty by establishing MQOs as defined in Section 4.5.

Measurement uncertainty can be further divided to the following components:

$S_m^2 = S_f^2 + S_{pp}^2 + S_l^2$ (equation 4)
(MQO) (MQO) (MQO) (MQO)

Where:

f = Field
pp= Preparation
l = Laboratory

Additionally, any one of these components also can be broken into subcomponents for which MQOs can also be developed. For example, laboratory uncertainty can be separated into within run, between run, and among laboratory uncertainties. The level that uncertainty estimates are separated is initially dependent on whether the overall measurement uncertainty is too great. If so, other estimates are needed to determine where the largest percentage of uncertainty is occurring and how best to reduce this uncertainty. PIs need to address this topic when developing QA project plans. An explanation will be required on how their data will assessed to determine both population and measurement uncertainties (Section 7). The methods used should be statistically validated.

4.4 QA Design

PIs, as part of QAPjP development, must develop a design to control and assess data uncertainty. The first two priorities in developing a QA design should be:

1) Development of real-time assessment and control.
2) Design for an estimate of overall measurement uncertainty.

In order to accomplish the first priority, data must be available for assessment in enough time to make corrections to the data collection system. Often, it is difficult to control field sampling errors in real-time, due to the time required to accumulate enough data to make statements of field sampling uncertainty. However, through the implementation of pilots and field auditing, information can be gathered prior to full scale implementation before errors seriously reduce the use of data. Another way of developing some real-time control is developing a QA design that verifies data quality in sets or batches that when aggregated will achieve the measurement quality objectives.

The second priority is important for the assessment of the significance of measurement uncertainty to overall uncertainty, as discussed in Section 4.3. A QA design must be developed that will allow for an assessment of overall measurement uncertainty. The QA design should not focus soley on estimates of overall uncertainty, but also on other data collection phases where the potential for errors are great. Figure 4.1 is an example of a QA design. It is presently being developed for verifying nutrient data from the Great Lakes National Program Office Water Quality Survey. The Water Quality Survey incorporates the concept of batch sample analysis, where samples collected in the field are combined into groups called batches. Within these batches, a series of different types of measurement quality samples are included which are used to evaluate and possibly control various types of measurement uncertainty. This design allows for the verification of the batch of data as well as creation of a data set that will allow assessment of the various components (field, preparation and laboratory), and attributes (system detection, precision, etc), as well as the achievement of program DQOs. Figure 4.1 segregates the measurement quality samples into either quality evaluation (QE) or quality control (QC) samples. QE samples are those samples which are known to the GLNPO technical staff but are either blind or double blind to the sampling crews, the preparation laboratory, or the analytical laboratory. A blind sample has a concentration range that is unknown to the analyst, whereas a double blind sample cannot be distinguished from a routine sample and has a concentration range that is unknown (Taylor, 1987). These samples provide an independent check on the QC process and can be used to evaluate whether the MQOs have been met for any given batch, or for all batches. In contrast, QC samples are known to the laboratory staff and can be used by the analysts to identify and control analytical measurement uncertainty. It is suggested that when possible, PIs attempt to develop sample analysis by batching.

4.5 Measurement Quality Objectives

Measurement quality objectives are designed to control various phases of the measurement process and to ensure that total measurement uncertainty is within ranges prescribed by the DQOs. MQOs will be defined in terms of precision, accuracy, completeness, detectability, representativeness, and comparability. The types of samples that can be used as measurement quality samples are defined in Appendix C. The codes identified in the list will be used when identifying these samples in the EMP data. These codes are used in Figure 4.1

Precision - A measure of mutual agreement among multiple measurements of the same property, usually under prescribed similar conditions.

Accuracy - The degree of agreement between a measurement (or an average of measurements of the same thing), and the amount actually present.

Completeness - For this QAPP completeness is the measure of the number of valid samples obtained compared to the amount that is needed to meet the DQOs. The EMP completeness goal is 90%.

Representativeness - Expresses the degree to which data accurately and precisely represent characteristics of a population, parameter variations at a sampling point, a process condition, or an environmental condition.

Detectability - The determination of the low-range critical value of a characteristic that a method-specific procedure can reliably discern. Three types of detection limits are important to address in the EMP; the system detection limit (SDL), the method detection limit (MDL), and the instrument detection limit (IDL). System detection limit is the concentration in routine samples that is detectable and distinguishable from the background "noise" or contamination of the complete

measurement system (sampling through analysis). This can be determined through the use of field blanks or low concentration reference material that enters the data collection system as early in the sampling phase as possible.

QA Design chart

Method detection limit is defined as the minimum concentration of a substance that can be measured and reported with 99% confidence that the analyte concentration is greater than zero. PIs will follow 40 CFR Pt. 136, APP.B when determining MDL. For MDLs all sample processing steps are included. IDLs differ in that they are usually utilized to determine the analytical instrument sensitivity and therefore may not proceed through sample processing.

Comparability - Express the confidence with which one data set can be compared to another. The comparability of one years data with another is maintained by adherence to standard operating procedures. When a procedure or an instrument is changed, a comparison is made to verify that the data are identical or more precise or accurate.

Comparability of data across media is important to the RLP and LMMB programsas well as to the future use of EMP data. Since each resource group will be measuring primarily the same parameters, it is important that detection limits, precision, and accuracy are comparable. There are two methods of controlling comparability; 1) requiring the use of specific methods, or 2) requiring consistent method performance criteria.

The media workgroups must review each parameterand decide on which method would best ensure comparability.

Once the various QE/QC samples have been identified, acceptance criteria for these samples must be developed. Meeting the acceptance criteria, in theory, ensures that the overall measurement quality objectives are met. Table 4-1 is an example of the measurement quality objective for total kjeldahl nitrogen for the Water Quality Survey nutrient sample QA design (Figure 4.1). Table 4.2 is another way of presenting MQOs which also affords comparison of media.

4.6 Summary

Section 4 describes the rationale for the DQO process and how a QA design can be developed to control and assess measurement uncertainty. When developing QA project plans for the EMP, PIs must address the following:

- DQOs of the project in quantifiable terms or how the data will be used to address the DQOs.
- A discussion of the both population and measurement uncertainities and how these will be controlled and evaluated.
- A QA design that at a minimum addresses overall measurement uncertainty in terms of precision, accuracy/bias, and detectability.
- MQOs for precision, accuracy, completeness, detectability, representativeness, and comparability.
- Procedures for ensuring data comparability across media

Table 4-1 Measurement Quality Objectives for Water Quality Survey Nutrient Category

Parameter	QC Type	Frequency	Acceptance Criteria
Total Kjeldahl N			
Precision	FD1	1/batch	Diff < 0.15 if mean < 0.37 or RPD < 40 if mean > 0.25
	FS1	1/batch	Diff < 0.10 if mean < 0.33 or RPD < 30 if mean > 0.25
	LS1	1/batch	Diff < 0.05 if mean < 0.25 or RPD < 20 if mean > 0.25
	LR1/2	1 pair/batch	Diff < 0.05 if mean < 0.25 or RPD < 20 if mean > 0.25
	LPC Pairs	2 pairs/batch	Diff < 0.05 if mean < 0.25 or RPD < 20 if mean > 0.25
Accuracy	LPC Pairs	2 pairs/batch	Mean within accuracy windows
	LR1/2	1 pair/batch	Mean within accuracy windows
	FR1	1/batch	Value within accuracy windows
Completeness	RFS	NA	95 %
Detectability	LRB	1/batch	> ___ AND < RMDL
	LCB	1/batch	> ___ AND < RMDL
	FRB	1/batch	> ___ AND < 2*RMDL

Table 4-2 Organic Contaminants Measurement Quality Objectives for the Air Media.

Comparison of QC Requirements for PCB Analysis			
Requirement	**QC Type**	**Air**	**Acceptance Criteria detail and Flag**
Holding Times (Days)	**NA**	Extract: 6 months of collection	
Reporting Units	NA	ng/L precipitation pg/m^3 particulate pg/m^3 vapor	
Clean XAD Frequency Criteria		1/lot < MDL	
Method Detection Limit Frequency Criteria	MDL	40 CFR APP B (part 136) 1/year ?	
System Detection Limit (LOD) Frequency Criteria	FRB	3 σ FRB 1/year 0.005 ng/L (precip) 0.003 ng/m^3 (vapor)	
Routine Sample Detectability Frequency Criteria	RFS	all RFS > MDL	If criteria not met flag **MDL**
Initial Calibration Levels Frequency Criteria	CLM	4 point 1/year $r^2 > 0.95$	Rerun until acceptable.
Continuing Calibration Frequency Criteria	LPC	1 point daily ± 10% T. PCBs & ± 25% per congener for 10 congener mix	Rerun until acceptable. Flag all congeners **FPC**
Blanks Field Blanks Frequency Criteria Lab Reagent Blank Frequency Criteria Lab Calibration Blank Frequency Criteria	 FRB LRB LDB 	 1/batch < 20% sample mass & < 5x MDL 1/batch < MDL 2/GC run <MDL	 Flag single congeners if > 5x MDL **FFR**. If > 50% of congeners > 5x MDL, flag all congeners **FFR**. Flag single congeners of the FRB if mass is > 20% of associated mass of the routine sample (RFS) **FFR**. If > 50% of congeners in FRB has a mass > 20% of associated routine sample (RFS), flag all congeners of FRB **FFR** Flag single congeners if > MDL **FBS**. If > 50% of congeners > MDL, flag all congeners **FBS** Rerun batch until acceptable. Flag **FDB**
Performance Standards Frequency % Recovery	LPC	Mullin (1985) 1/batch acceptance ranges	Acceptance criteria listed below. Rerun batch until acceptable. Flag all congeners **FPC**
Surrogate Standards Frequency % Recovery	LSS	3 (14, 65, 166) all samples 50-120% & RSD/sample set < 30%	If recovery not within acceptance criteria, flag congeners represented by the particular surrogate **FSS**. If RSD for all samples in a batch for a given surrogate is > 30, flag particular surrogate **FSS.** *(acceptance based upon the recovery of theoretical values listed below)*
Matrix Spike Standards Frequency ave % Recovery	LMS	610 mixture 1/batch 50-125%	Flag single congeners **FMS** if recovery not within acceptance criteria. If > 50% of congeners fail criteria flag all congeners for the sample **FMS** *(need the theoretical values of the spike)*
Internal Standards Frequency Criteria	LIS	Standards # 30 and #204 every sample Relative ratio RSD < 10% for sample set	Relative ratio = 30/204. If RSD for relative ratio for all samples in a batch is > 10, flag congeners 30 and 204 in batch **FIS**
Duplicates			

Field	FD1		No comparison made if both samples below MDL. If one sample is >5x MDL and one lower, use 100% criteria. Flag routine (RFS) and FD1 **FFD** if criteria not met.
Frequency		1/sample set	
Criteria		RPD; 100% <5x LOD < 50%	
Lab	LD1		No comparison made if both samples below MDL. If one sample is >5x MDL and one lower, use 50% criteria. Flag routine (RFS) and LD1 **FDL** if criteria not met.
Frequency		1/sample set	
Criteria		RPD; 50% <5x LOD < 25%	

5.0 Implementation of the QA Program

5.1 QA Project Plan Requirements

The EMP requires every EPA funded environmental data collection activity (EDCA) to have a written and approved quality assurance project plan (QAPjP) prior to the start of the EDCA. The purpose of the QAPjP is to specify the policies, organization, objectives, and the quality evaluation and quality control activities (QE/QC) needed to achieve the DQOs of the EMP. It is the responsibility of the Principal Investigator (PI) to adhere to this policy. The PI bears the responsibility of providing copies of the approved QAPjP to each individual who has a major responsibility in the EDCA and explaining the elements of the QAPjP to these individuals.

QAPjPs are prepared, reviewed and approved in accordance with QAMS-005/80, Interim Guidelines and Specifications for Preparing Quality Assurance Program Plans. QAMS-500/80 identifies and defines the 16 elements that must be addressed in all formal QAPjPs. The following subsection will present criteria for the development of EMP QAPjPs.

Original QAPjPs shall be filed with the EMP QAC. Tracking of QAPjPs will be accomplished by the QAC. If possible, a disk copy of QAPjPs should also be submitted.

5.1.1 Categories of QA Project Plans

The EMP will utilize a four-tiered project category approach to its QA Program in order to effectively focus QA. This approach was developed by the U.S. EPA, Risk Reduction Engineering Laboratory, Cincinnati, Ohio (EPA/600/9-89/087). Category I involves the most stringent QA approach, whereas Category IV is the least stringent. The following definition of the categories are quoted from the document listed above:

Category I Projects (EPA/600/8-91/003)

> Projects producing results that are autonomous. These projects are of sufficient scope and substance that their results could be used directly, without additional support, for compliance or other litigation. Such projects are of critical importance to Agency goals and must be able to withstand legal challenge. Accordingly, the quality assurance requirements will be the most rigorous and detailed to ensure that such goals are met.

Category II Projects (EPA/600/8-91/004)

> Projects producing results that compliment other inputs. These projects are of sufficient scope and substance that their results could be combined with the results of other projects of similar scope to produce narratives that would be used for rule making, regulation making, or policy making. In addition, projects that do not fit this pattern, but have high visibility, would also be included in this category.

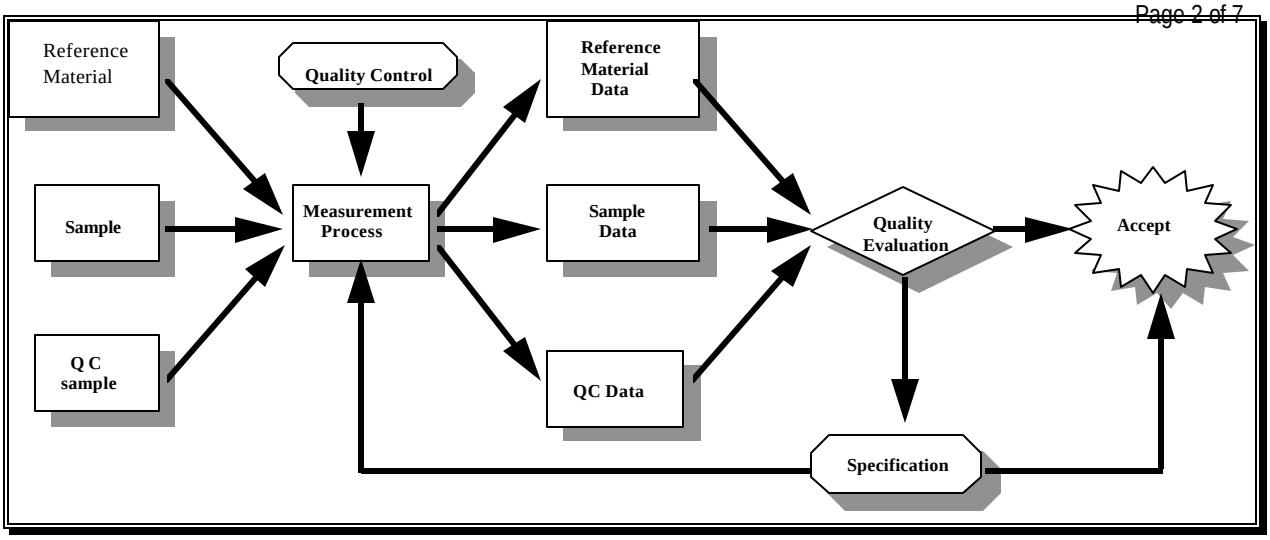
Category III Projects (EPA/600/8-91/005)

> Projects producing results for the purpose of evaluating and selecting basic options, or performing feasibility studies or preliminary assessments of unexplored areas which might lead to further work.

Category IV Projects (EPA/600/8-91/006)

> Projects producing results for the purpose of assessing suppositions.

The number of elements required for each category is reduced as one proceeds from category I to IV. Guidelines for each of these categories can be found in EPA document EPA/600/9-89/087. Each program cooperator will be provided a copy of these documents. A number of reference copies will also be available through the QAC. PIs, with consultation from the QAM, and the Project Officer will be required to designate the category of the QAPjP prior to developing this document. PIs should be aware that the QA workgroup, QAM and QAC are available to assist in the development of the QAPjP. PIs should seek assistance as early as possible. This early communication will help both the PI and QA staff come to a mutual understanding of each others expectations of the technical and QA aspects of the program/project.



5.1.2 Quality Evaluation, Quality Control

The major emphasis of the QAPjP is the definition of the projects objectives, the DQOs, and the development of a QA design (Figure 4.1) to meet the objectives. Quality evaluation and quality control (QE/QC) techniques must be used and included in the QAPjP to assure that the project objectives are met. Similar to the QE/QC samples mentioned in section 4.4, the QE techniques are an independent means of assessing measurement uncertainty, while the QC techniques are used for internal control of measurement uncertainty. Figure 5.1 lists various types of QE/QC techniques. PIs should discuss the use of the various techniques in the appropriate sections of the QAPjP.

5.1.3 QAPJP Review and Approval

At a minimum, QAPjP should be submitted 30 days prior to implementation of any EDCA. Data collection may not proceed without an **approved** QA project plan. Review of the QAPjP must include the PI, EPA Project Officer (if appropriate), the funding agencies QA manager (QAM) and the EPA QAM (if appropriate). It is recommended that the document is initially reviewed by the PI and Project Officer before submission to the QAM. It is also recommended that these plans be reviewed by a statistician. The QAM will review each QAPjP for the required elements and the soundness of the QE/QC. The QAPjP category guidance (I-IV) will be used in the review to determine adequacy of QAPjP material. The QAM will provide written comments within 15 working days from submission. All QA reviews are secured in a file in the QAMs office.

5.2 Standard Operating Procedures (SOPs)

Good laboratory practices (GLP) and good management of field sampling operations include the development and use of standard operating procedures (SOPs) for all routinely used sampling, preparation and analytical laboratory methods and the house keeping that supports them. SOPs are protocols for all routine activities involved in the EDCA which generally involve repetitious operations performed in a consistent manner. SOPs usually represent peer approval and provide a basis for comparability of data among users. SOPs will be reviewed as part of the QAPjP review/approval. SOPs should include the following:

- Scope and Application
- Method Summary
- Sample Handling and Preservation
- Interferences
- Safety
- Equipment/Materials/Reagents
- Calibration
- Procedure
- Calculations
- QA/QC
- References

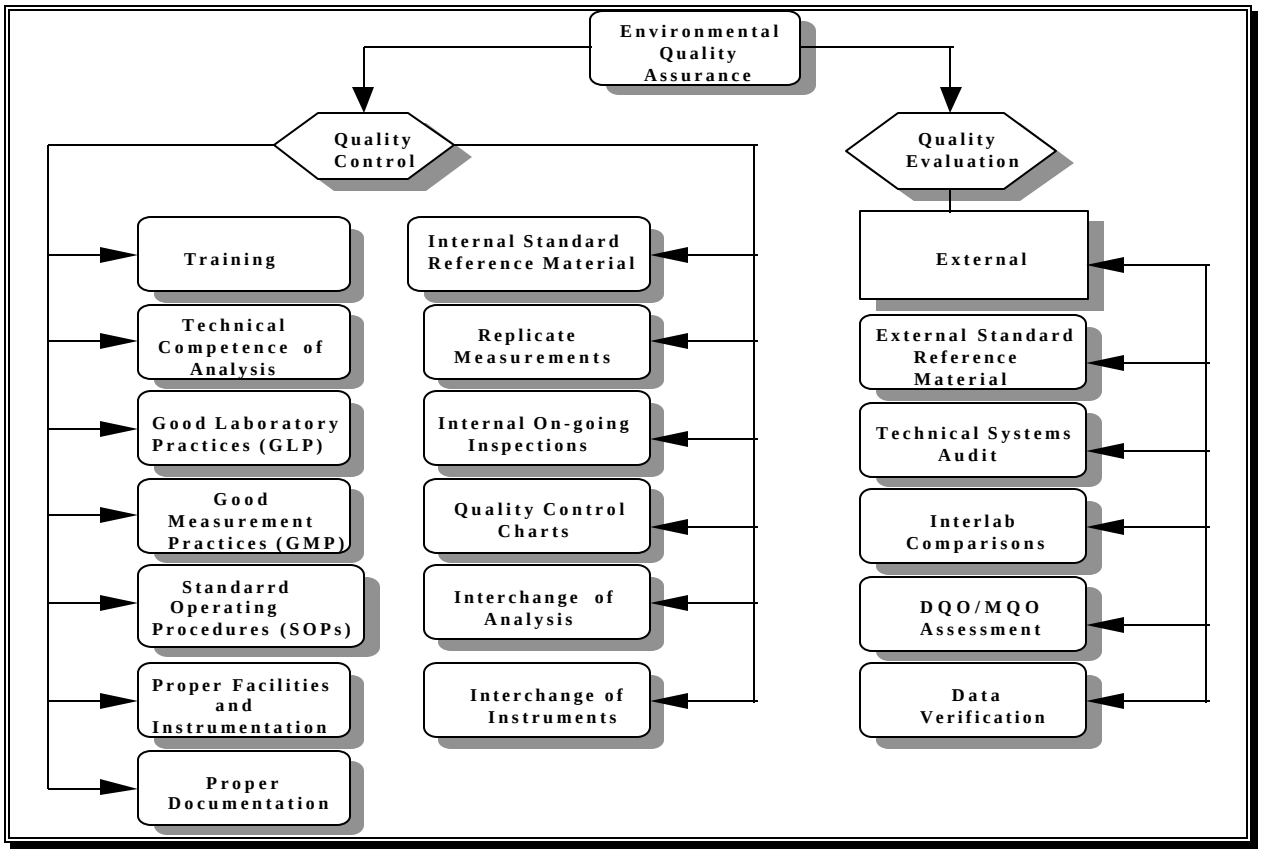


Figure 5.1 QE/ QC techniques

The elements listed above are recommended but will not be strictly enforced due to the fact that methods may be used that have been previously documented and considered acceptable. However, long-term programs should contain SOPs that include these elements, presented in a form that can be useful to anyone performing the method. SOPs can be placed either in the body of the QAPjP, included in an appendix, or referenced. Referenced methods must be available for access by the general public. If the referenced method is not followed precisely, addendums to this method must be included in a manner that is obvious to individuals using the method. If this modified method will be used for an extended periodof time, the method shall be revised to include the changes in the appropriate sections. A method cannot be revised during project implementation without the consent of the PI. If the modification is accepted, it must be documented

in a letter to the program management and the QAC and included in the next QA report. It is the responsibility of the PI to inform other project participants of the protocol change.

PIs must submit one copy of all SOPs for their project to the EMP QAC. The QAC will keep these on file for the duration of the project.

In addition, every laboratory shall have a good laboratory practices (GLPs) document that will be available for review during technical systems audits (TSAs). GLPs refer to the general practices that relate to the majority of measurements such as: facility and equipment maintenance, record keeping, chain-of custody, reagent control, glassware cleaning, and general safety.

5.3 Training Requirements

Training is essential to the success of data collection activities. Training enables personnel to complete each aspect of operations according to design and management objectives and in a standardized manner. Training will include practice in documented standard operating procedures (SOPs). Requirements for the development of SOPs are discussed in Section 5.2.

Prior to the start of any EDCA a training session shall be conducted. Training will include practice with each of

the SOPs. Training shall include some level of trainer review or certification by the trainer that individuals are performing the EDCA properly.

Any specialized training should be addressed, including safety training, training for leadership personnel, or instruction on instrument operation or maintenance. If outside organizations will be needed for any aspect of training (for example, the American Red Cross for First Aid/CPR instruction), discuss how their services are to be arranged.

5.4 Assessments

An audit or assessment is a formal evaluation of performance to pre-determined standards and the evaluation and documentation to effect change towards improved performance. Audits are the principal means to determine compliance and to control systems in a real-time manner to improve performance. Four types of audits are defined: 1) technical systems audits (TSAs), 2) data quality audits (DQAs), 3) management systems reviews (MSRs), and 4) performance evaluations (PEs). These audits will be utilized in the EMP.

5.4.1 Technical Systems Audits (TSAs)

Technical systems audits (TSAs) are qualitative on-site evaluations of a complete phase of an EDCA (i.e., sampling, preparation, analysis). This audit can be performed prior to the data collection activity, in order to verify the existence and evaluate the adequacy of equipment, facilities, supplies, personnel, and procedures that have been documented in the QAPjP. TSAs are also employed during the data collection activity in order to verify and evaluate the EDCA.

TSAs are performed by reviewing SOPs and other appropriate documentation of the EDCA and assessing whether protocol is: 1) adequate, 2) available to all appropriate participants, 3) is understood by participants, 4) is being followed as documented, and 5) will produce data of the quality required. Emphasis of the TSA must focus on improvement of the data collection system not in finding errors. In order to perform TSAs consistently, checksheets on the activities to be reviewed should be developed.

Two types of TSA's will occur, 1)internal, and 2) external. Internal audits will be conducted by IQAM on a quarterly basis. The PI and the IQAM will be responsible for planning and scheduling these audits. Reports (see 5.4.6) will be sent to the appropriate QAM and to the QAC. External audits will be planned and facilitated through the QAC and QAMs. External TSA's will occur for all major EDCA at a minimum of once during the EMP and will be scheduled in consultation with the PI.

5.4.2 Data Quality Audits (DQAs)

A data quality audit (DQA) focuses on collected data. It is used to determine if enough QA information exists with the data set to evaluate the quality of the data and whether this quality satisfies the stated DQOs of the EDCA. It is also used to assess the ability of the QAPjP to produce data of known and satisfactory quality.

DQAs are normally conducted on a second TSA, at the completion of an EDCA as part of the QA report, or at the request of a project officer, when concerns about data quality are identified.

Based on TSA reports, program management, or the QAM may suggest a DQA to the PI. The PI is responsible for determining the need for a DQA and will be responsible for conducting this audit and subsequent audit reports. The QAM can assist in facilitating the audit as necessary.

5.4.3 Management Systems Reviews (MSRs)

A management systems review (MSR) is an on-site evaluation by the organizations senior management to assess the organizations internal management structure and its documents to determine whether the organization is implementing a satisfactory QA program. It is used to determine the effectiveness of, and adherence to the QA program and the adequacy of resources and personnel provided to achieve and assure quality in all activities.

The MSR includes reviews of:

- Procedures for developing DQOs.
- Procedures for developing and approving QA Project Plans (QAPjPs).
- The quality of existing QAPjP guidance and QAPjPs.
- Procedures for developing and approving standard operating procedures (SOPs).
- Procedures and criteria for designing and conducting audits.

- Tracking systems for assuring that the QA program is operating, and that corrective actions disclosed by audits have been taken.
- The degree of management support.
- Responsibilities and authorities of the various line managers and the quality assurance program manager for carrying out the QA program.

An MSR of the QA program will be conducted by program management as frequently as appropriate. In order to achieve the MSRs objectives, the review should be conducted by an individual somewhat independent of the organization. The lead could then choose a review team from program management who would assist in the planning, scheduling, and implementing the review. The review team would determine the scope of the review which would include reviews of the bullets mentioned above.

The team will present their findings in a report directed to program management. Action items on any deficiencies will be developed and discussed in this report. Review of progress on actions items will be discussed at management meetings.

5.4.4 Performance Evaluations (PEs)

Performance evaluations (PEs) are a means of independently verifying and evaluating the quality of data from a measurement phase, or the overall measurement system. This is accomplished through the use of samples of known composition and concentration. These samples can be introduced into the measurement system as single blind (identity is known but concentration is not) or double blind (concentration and identity unknown). These samples can be used to control and evaluate accuracy and precision and to determine whether DQOs or MQOs have been satisfied. PEs can also be used to determine inter- and intra-laboratory variability and temporal variability over long projects, and to evaluate laboratories prior to contract awards.

PEs are required for projects whenever possible. At times, this is dependent on the availability of reference material from reliable sources. If time permits, reference samples can be developed from a bulk source. These samples can be preliminarily characterized and with the analysis of a statistically valid number, used as reference material. As part of the development of a QAPjP, PI's must consider the use of PEs and must document reasons for non-inclusion of PEs.

5.4.5 Audit Plan

Audit planning is a necessity in order to conduct efficient audits. An audit plan for all types of audits will include the following items:

Audit title.
Audit number - Year and number of audit can be combined; 94-1, 94-2
Audit date
Scope - Establishes the boundary of the audit and identifies the groups and activities to be evaluated. The scope can vary from general overview, total system, to part of system, which will effect the length of the audit.
Purpose - What the audit should achieve.
Standards **S**tandards are criteria against which performance is evaluated. These standards must be clear and concise and should be used consistently when auditing similar facilities or procedures. The use of audit checklists is suggested to assure that the full scope of an audit is covered.
Audit team -Team lead and members.
Auditees -People that should be available for the audit from the audited organization. This should include the Program Manager, Principal Investigator, organizations QA Representative, and other management, and technicians as necessary.
Documents -Documents that should be available in order for the audit to proceed efficiently. Too often documents are asked for during an audit, when auditors do not have the time to wait for these documents to be found. Documents could include QAPPs, QAPjPs, SOPs, GLPs, control charts, raw data, QE/QC data, previous audit reports etc.

Timeline -A timeline of when organizations (auditors/auditees) will be notified of the audit in order for efficient scheduling and full participation of all parties.

The audit plan document is not a major undertaking and in most cases will be a one page table or report. However, the document represents thoughtful and conscious planning for an efficient and successful audit. The audit plan should be made available to the organization audited, with adequate lead time to ensure that appropriate personnel and documents are available for the audit.

5.4.6 Audit Reporting

A debriefing will occur at the completion of the audit. Positive and negative aspects of the EDCA will be discussed between the audit team, management of the area audited, and, if necessary, technical personnel performing the measurement activity. Copies of the draft audit summary and findings should be provided to all those in attendance. Necessary action to improve the measurement system will be discussed with project participants.

In the case of TSA (internal), DQAs and PEs, the responsibility for reporting rests with the PI. Responsibility for reporting MSRs is the responsibility of the review team lead or an appointed designee.

The report will include:

- Audit title and number and any other identifying information.
- Audit team leaders, audit team participants and audited participants.
- Background information about the project, purpose of the audit, dates of the audit, particular measurement phase or parameters that were audited, and a brief description of the audit process.
- Summary and conclusions of the audit and corrective action requires.
- Attachments or appendices that include all audit evaluation forms and audit finding forms.

Appendix D presents examples of audit finding and response forms that can be presented in the audit report. For each audit finding form, an audit finding response form will be developed to track corrective actions. This information will be included in the audit file retained by the QAM. The report should be completed within five working days of completion of the audit. TSA, DQA, and PE reports will be reviewed, signed by the QAM and PI, and filed with the QAM. MSR reports will reviewed, signed by the audit lead and chairs of the TCC and filed by the QAC. It is the responsibility of the review team lead to forward audit reports to the appropriate project participants. The audit report has restricted distribution in order to foster constructive working relationships. When significant concerns are identified on audit finding forms, a meeting will be scheduled with the appropriate parties. The report will be discussed and action necessary to rectify and control the situation will be developed. Line management may be requested to assist in problem resolution as necessary.

5.5 Data Verification and Validation

Data verification is a process used to determine and control measurement uncertainty to produce accurate and reliable data. A method must be developed within the QAPjP that takes the various QE/QC information that has been included in the QA design and evaluates these data in a consistent manner. Data not meeting acceptance criteria are flagged. Depending on the types of flags associated with the routine samples, a sample or batch may be reanalyzed (if possible) or the data flagged in a manner that will inform the data user that it is not of sufficient quality to be used for the project. This process should not be considered as a means to eliminate subjective decisions made by the PI, but will allow for a consistent review using to measurement quality samples. In fact, if a verification system is properly developed, it should capture many of the thought processes used by the PI in his/her review of data. Table 5-2 represents a verification template developed for the verification of the measurement quality samples for the Water Quality Survey nutrient samples which where depicted in Figure 4.1 and Table 4-1. The verification of data takes place at the batch level. In theory, if the batch is verified as acceptable, it should meet the overall MQOs. For the Water Quality Survey, computer programs will be developed that 1) flag data out of compliance, and 2) evaluate the flags to determine if reanalysis is required.

Appendix C contains the flag codes that will be used for the project. This list contains mandated standard EPA codes. Some will obviously not be used for this program and there may be some codes that will need to be developed specifically for the EMP. As new codes are needed, they will be developed and distributed to all EMP cooperators. PIs developing QAPjPs must identify the codes they will use to flag data.

Data values ***must not be eliminated or censored***. All analyzed values must be archived. Flagged values will determine useful data.

Data validation is a process whereby either the PI or the technical workgroup review the project data and the associated flags in terms of the program requirements and determine what data will be placed into the central data base (see Section 6) to answer the program objectives. At present this procedure has not been developed. However, once it has, it must remain consistent throughout the programs duration. If not, all previous data must be processed through any modified procedure.

The EPA is anticipating the implementation of an automated data verification system called the Research Data Management and Quality Assurance System (RDMQ). This

system is being developed by Canada and modified for EPA use. It is anticipated that data would be recieved by the Information Management Staff and uploaded into this SAS based software package. Data could then be flagged by the criteria outlined in individual QAPjPs. Appendix E. provides a brief overview of the system

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responsibilities, mainly for PIs, for any environmental data collection activity. Key responsibilities. as detailed in the above sections include:

- PIs are responsible for the development of a QAPjP specific to there data collection activities. QAPjPs should be submitted at a minimum of 30 days prior to implementation. Special grant conditions overrule this criteria. QAPjPs must be approved by QAMs before EDCAs begin.

- PIs are responsible for the development and submittal for standard operating procedures . SOPs must be referenced or included in QAPjPs for all EDCAs. A copy of each SOP must be submitted to the QAC.
- PIs are responsible for training their staff in all appropriate protocols.
- PIs are responsible for the implementation of internal technical systems audits, data quality audits and performance evaluations and the reporting of results.
- As part of the QAPjP, PIs must develop data verification and validation requirements.

Table 5-2. Verification Template for the Water Quality Survey Nitrate/Nitrite Analysis

5.6 Summary

This section focused on various implementation

Measurement Quality Samples	**Major** Reanalysis if non-compliance in two or more categories	**Minor** Reanalysis if non-compliance in three more categories
LPC-1	If **one** relationship occurs: 1) Δ > 0.03 2) mean < 0.08 or > 0.12	If **one** relationship occurs: 1) Δ > 0.03 2) mean < 0.08 or > 0.12
LPC-2	If **one** relationship occurs: 1) RPD > 20 2) mean < 0.37 or > 0.43	If **one** relationship occurs: 1) RPD > 20 2) mean < 0.37 or > 0.43
FD1	None	Δ < 0.15 if mean < 0.37 or RPD < 40 if mean > 0.37
FS1	Δ > 0.10 if mean < 0.33 or RPD > 30 if mean > 0.33	Δ > 0.10 if mean < 0.33 or RPD > 30 if mean > 0.33
LS1	Δ > 0.03 if mean < 0.15 or RPD > 20 if mean > 0.15	Δ > 0.03 if mean < 0.15 or RPD > 20 if mean > 0.15
LR1	If **both** relationship occurs: 1) Mean within accuracy windows 2) Δ > 0.03 if mean < 0.15 or RPD > 20 if mean > 0.15	If **one** relationship occurs: 1) Mean within accuracy windows 2) Δ > 0.03 if mean < 0.15 or RPD > 20 if mean > 0.15
LRB	Value > RMDL	Value > RMDL
LCB	Value > RMDL	Value > RMDL
FRB	None	Value > 2* RMDL

6.0 Information Management

6.1 Introduction

Success of the EMP objectives rely on data and their interpretation. It is critical that data be available to a number of users and that these data are:

- Reliable
- Of known quality
- Easily accessible to a variety of users
- Aggregated in a manner consistent to the prime user

In order to accomplish this activity, information must be collected and managed in a manner that protects and ensures its integrity.

Virtually all of the data collected from the EMP will be collected through automated systems at various facilities. These systems must be effectively managed by using a set of guidelines and principles by which adherence will ensure data integrity. The EPA has a draft document entitled Good Automated Laboratory Practices (GALP). GALP defines six data management principles:

1. DATA: *The system must provide a method of assuring the integrity of all entered data.* Communication, transfer, manipulation, and the storage/recall process all offer potential for data corruption. The demonstration of control necessitates the collection of evidence to prove that the system provides reasonable protection against data corruption.

2. FORMULAE: *The formulas and decision algorithms employed by the system must be accurate and appropriate.* Users cannot assume that the test or decision criteria are correct; those formulas must be inspected and verified.

3. AUDIT: *An audit trail that tracks data entry and modification to the responsible individual is a critical element in the control process.* The trail generally utilizes a password system or equivalent to identify the person or persons entering a data point, and generates a protected file logging all unusual events.

4. CHANGE: *A consistent and appropriate change control procedure capable of tracking the system operation and application software is a critical element in the control process.* All software changes should follow carefully planned procedures, including a pre-install test protocol and appropriate documentation update.

5. STANDARD OPERATING PROCEDURES (SOPS): *Control of even the most carefully designed and implemented systems will be thwarted if appropriate procedures are not followed.* The principles implies the development of clear directions and Standard Operating Procedures (SOPs); the training of all users; and the availability of appropriate user support documentation.

6. DISASTER: *Consistent control of a system requires the development of alternative plans for system failure, disaster recovery, and unauthorized access.* The control principle must extend to planning for reasonable unusual events and system stresses.

The EMP will have two levels of information management; 1) local - systems used to enter field data or analytical data at the facility level (e.g., U. of Wisconsin Lab of Hygiene for tributary water organic data), and 2) a central repository where data are accessed by various users responsible for meeting the program objectives. The central repository does not have to be a physical entity but rather is identified as an information management system for the distribution, maintenance and archival of the EMP data. In this respect the central information management system may have qualities and attributes different than the local system even though the local system may actually be networked to the central system.3 discusses the objectives and responsibilities of the Information Management Workgroup. In general the groups goals are to develop and maintain a relevant information management system that can be used by all cooperating agencies. This demands close cooperation, and attention to detail. The following elements provide some guidance to the detail necessary to develop information management system for the EMP.

6.2 Elements

The principles listed above apply to both the local and central system. The detail in which the principels are addressed and enforced will vary. In order to address these principles the following elements will be discussed:

- Personnel
- Facilities
- Security
- Software
- Raw Data
- Records/Archive
- Quality Assurance
- Equipment
- Standard Operating Procedures
- Data Entry
- Data transfer
- Reporting

6.2.1 Personnel

When automated data collection systems are used, each party responsible for data on automated systems must identify a person within the organization responsible for this information management system. This person should have adequate education, training, and experience to enable him/her to perform the assigned system functions. This person will be identified in the organizational structure in the QAPjP and to the Information Management Technical Workgroup. To assist or assure user competence, users must be provided with clear standard operating procedures (SOPs) to enable them to perform the assigned functions and provided with sufficient training to clarify these SOPs.

Once a EMP information management system is in place, data must be made available to the system in a timely manner. Personnel responsible for local and central systems must be of sufficient number for the timely and proper conduct of the information management system. This assessment must be made by the Information Management Technical Workgroup.

6.2.2 Quality Assurance

As part of the quality assurance responsibility, a group/individual needs to be identified whose responsibilities would be primarily those of system and data inspection, audit and review. The objective of QA is to provide proof that the information management system operates in a correct manner consistent with its recommended functions. The Information Management Technical Workgroup will identify this individual/group that will also work closely with the QA Workgroup. This group/individual would be responsible for the development of an information management QA Plan. This plan would be developed within the Information Management Technical Workgroup.

6.2.3 Facilities

The facility used to house the information management system should have provisions to regulate the environmental conditions (temperature, humidity, electricity) adequately to protect the systems against data loss. The facility should also have adequate storage capability of the automated information management system or of the facility to provide for retention of raw data, including archives of computer resident data.

6.2.4 Equipment

Information management system equipment shall be of appropriate design and adequate capacity to function according to the specifications. The Information Management Technical Workgroup will develop guidelines for the minimum hardware specifications of the system. Hardware should be on a maintenance schedule.

Backup and recovery procedures should be accomplished on a routine basis and should be incorporated into SOPs.

6.2.5 Standard Operating Procedures

Standard operating procedures (SOPs) are protocols for routine activities involved in a data collection activity which generally involve repetitious operations performed in a consistent manner. SOPs usually represent peer approval and provide a basis for comparability of data among users. SOPs shall be established for:

- Maintaining system security.
- Defining raw data (distinction between raw and processed data).
- Entry of data.
- Verification of manually or electronically input data.
- Interpretation of error codes/flags and corrective action.
- Changing data.
- Data analysis, processing, transfer, storage, and retrieval.
- Backup and recovery.
- Electronic reporting (if applicable).

6.2.6 Software

Participants in the EMP shall consider software to be the operational instructions for the information management system and therefore, shall have SOPs setting forth methods that management is satisfied are adequate to ensure that the software is accurately performing its intended function. Tests of the software prior to implementation should occur and be documented. Algorithms should be checked

and source code reviewed as part of the process. Source code, including processing comments, must be archived and available. Procedures for reporting software problems and corrective action must be in place.

6.2.7 Data Entry/Formatting

Cooperators using information management systems must ensure that data input is traceable to the person who entered it. Also instruments transmitting data to the system must be identified. It must be possible to trace each record transmitted back to the source instrument, and date and time of generation.

Any change in data entry after initial entry must have an audit trail which indicates the new value, the old value, a reason for change, and person who entered the change. The Information Management Workgroup will decide a what data level this will be enforced.

As part of a cooperators QA project plan (data reduction), procedures must exist for validating the data entered manually or automatically.

Since many cooperators will be providing data to a central repository, any formatting accomplished at the local level that enhances the ease of transferring the data to the central data structure will be most advantageous. EPA now has data standard policies which must be followed. Some systems (CLP, RLIMS) have been recently developed that conform to these standards. The Information Management Technical workgroup will review these systems to determine the possibility of using the entry systems at local facilities. If this cannot be accomplished then data transfer standards (see 6.2.9) must be established.

6.2.8 Raw Data

Raw data are worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of that study.... "Raw data" may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, ... and recorded data from automated instruments" (40 CFR 792.3). Data entered into a system directly by keyboard or automatically by lab test devices are considered raw data. The Information Management Workgroup should define minimally what raw data are necessary. Cooperators will define raw data above this minimum and make provisions for their storage and retrieval.

6.2.9 Data Transfer

Data shall be provided in electronic format which conforms to the EPA Order 2180.2, Data Standards for Electronic Transmission of Laboratory Measurement Results, as modified in the exception for Superfund data, October 1991. This modification allows variable length records and fields which are comma delimited. Electronic transmission must be provided on standard electronic media and shall adhere to standard requirements for record identification, sequence, length, and content. Data provided in hardcopy and electronic format shall be identical. The data transnmission standard can be found in Appendix F and will be followed by all EMP partcipants.

6.2.10 Records and Archive

All raw data, documentation, and records shall be retained. Correspondence and other documentation relating to interpretation and evaluation of data collected, analyzed, processed, or maintained on the automated data collection system shall also be retained. The period of time for storage will be identified by the Information Management Workgroup. Other records to be maintained include but are not limited to:

- Software source code.
- Software and/or hardware acceptance test
- Records.
- Hardware maintenance records.
- Records of problems and corrective actions.
- Records of QA activities (inspections etc.).
- Records of backups and recoveries.

7.0 QA Reports

"Quality has to be defined as conformance to requirements, not as goodness."
--Philip B. Crosby

The QA report is a document that describes a project's quality assurance program, including the verification techniques and provides an assessment of the quality of the routine data, based upon the evaluation of measurement quality samples. The QA report is directed primarily towards the users of the data who will be analyzing the data and making various interpretive conclusions. Depending on the type of report (interim or final) the QA report will include the following:

Program Overview -The time sequence that the report covers, the activities that the report covers, a brief description of the program and reference to the appropriate QAPjP, and the structure of the report.

QA Summary -Summary of the QA program, its implementation, and accomplishments, and a summary of corrective actions taken.

Audits -Results of all audits during the appropriate time span. Actual audit reports should be included in an appendix.

Data Assessment -Assessment in terms of precision, accuracy, detectability, representativeness, completeness, and comparability in terms of the DQOs/MQOs. Uncertainty estimates for overall measurement uncertainty should be made. The statistical techniques used to make the assessments must be discussed. Include a discussion of whether the DQOs/MQOs were met, and the resulting impact on decision making. Discuss limitations on the use of the data. Identify what is considered invalid data (flagged data) for the program.

Conclusions -Assessment of the QA program both positive and negative. Include recommended changes for improvement of the program.

The QAPjP will identify the frequency of these reports and the specific content of progress and final reports. Final reports may be defined as a detailed QA report for data collected within a specific time period (e.g., annual report for a continuous monitoring activity) or a report which spans the entire length of a project (e.g., a 2-year project). At a minimum, the final report must cover the topics listed above. The QAPJP will specify who receives progress and final reports. At a minimum the reports should be distributed to the following individuals:

Progress Reports	Final Reports
EDCA Staff	EDCA Staff
Principal Investigators	PrincipalInvestigators
Project Officers	Project Officers
Workgroup Chairs	Workgroup Chairs
	QA Managers
	QA Coordinators
	Program Managers
	Data users

All QA reports will be archived by the EMP QAC. Further distribution of these documents will occur as data are distributed to users.

Appendix A
Media Parameters

The following tables represent the parameters to be measured by each media. Where appropriate, the relative load and mass balance project are separated.

Table A-1. Air Parameters and Measurements Proposed for Relative Loads Project of the EMP

Parameter	Specific	Precip	Part.	Vapor
PCB Congeners	103 congeners	x	x	x
Pesticides	a-HCH	x	x	x
	g-HCH	x	x	x
	DDT	x	x	x
	DDD	x	x	x
	DDE	x	x	x
	HCB	x	x	x
	Dieldrin	x	x	x
	Trans-nonachlor	x	x	x
	de-ethyl atrazine	x	x	x
	de-isopropyl atrazine	x	x	x
	a-Chlordane	x	x	x
	g-Chlordane	x	x	x
PAHs	acenaphthylene	x	x	x
	acenaphtene	x	x	x
	fluorene	x	x	x
	phenanthrene	x	x	x
	anthracene	x	x	x
	fluoranthene	x	x	x
	pyrene	x	x	x
	retene	x	x	x
	chrysene	x	x	x
	benzo(a)anthracene	x	x	x
	benzo(b)fluoranthene	x	x	x
	benzo(k)fluoranthene	x	x	x
	benzo(a)pyrene	x	x	x
	benzo(e)pyrene	x	x	x
	indeno(123cd)pyrene	x	x	x
	dibenzo(a,h)anthracene	x	x	x
	benzo(ghi)perylene	x	x	x
	coronene	x	x	x
Metals	Cd	x	x	
	Pb	x	x	
	Hg[a]	x	x	x
	Cr	x	x	
	Cu	x	x	
	Zn	x	x	
Conventional / Physical	Chloride	x	x	
	Total Phosphorus	x		
	Phosphorus		x	
	Silica		x	
	Nitrate	x		
	Ammonium	x		
	Total Kjeldahl N	x		
	Total Organic Carbon	x		
	Part. Organic Carbon		x	
	VOC			x
	Elemental Carbon		x	
	Alkalinity	x		
	TSP		x	
	Conductivity	x		
	pH	x		
	Volume	x		x
	Weight		x	
Site Measurements	Location			
	Air Temperature			
	Wind Speed			
	Wind Direction			
	Rainfall			
	Relative Humidity			
	Solar Radiation			

* Information obtained at the station
a = only collected at five sites for air

Table A-2.Air Parameters and Measurements Proposed for the Lake Michigan Mass Balance of the EMP

Parameter	Specific	Precip	Part.	Vapor
PCB Congeners		x	x	x
Pesticides	Trans-nonachlor	x	x	x
	de-ethyl atrazine	x	x	x
	de-isopropyl atrazine	x	x	x
Metals	Hg[a]	x	x	x
Conventional / Physical	Chloride	x	x	
	Total Phosphorus	x		
	Phosphorus		x	
	Silica		x	
	Nitrate	x		
	Ammonium	x		
	Total Kjeldahl N	x		
	Total Organic C	x		
	Part. Organic C		x	
	VOC			x
	Elemental Carbon		x	
	Alkalinity	x		
	TSP		x	
	Conductivity	x		
	pH	x		
	Volume	x		x
	Weight		x	
Site Measurements	Location			
	Air Temperature			
	Wind Speed			
	Wind Direction			
	Rainfall			
	Relative Humidity			
	Solar Radiation			

* Information obtained at the station
a= only collected at five sites for air

Table A-3. Tributary Parameters and Measurements Proposed for the Relative Loads Project of the EMP

Parameter	Specific	Diss.	Part.
PCB Congeners	Congener specific 65 peaks	x	x
Pesticides	Oxychlordane	x	x
	a-HCH	x	x
	g-HCH	x	x
	p,p' DDT	x	x
	p,p' DDD	x	x
	p,p' DDE	x	x
	HCB	x	x
	Dieldrin	x	x
	Trans/cis-nonachlor	x	x
	de-ethyl atrazine	x	x
	de-isopropyl atrazine	x	x
	Toxaphene	x	x
	a-Chlordane	x	x
	g-Chlordane	x	x
Major Ions	Ca, Mg, Na, K, Cl, SO_4	x	x
Metals	Cd, Pb, Hg, Cr, Cu, Zn	x	x
Conventional/Physical	Chloride	x	
	Total P	x	
	Dissolved P	x	
	Diss. Reactive Silica	x	
	Nitrate	x	
	Ammonia	x	
	Total Kjeldahl N	x	
	Total Organic Carbon	x	
	Part. Organic Carbon	**	**
	Diss. Organic C	x	
	SPM 0.7_m		x
	Temperature	*	
	Conductivity	*	
	pH	*	
	Speed	*	
	Direction	*	
	Volume	x	x
	Weight	x	x
	Location	*	
	Diss. Oxygen	x	
	Turbidity	x	
	Water Clarity	x	
	Chlorophyll a	x	

* Information obtained at the station
** Calculated
a = Lake superior only

Table A-4. Triburary Parameters and Measurements Proposed for the Mass Balance Project of the EMP

Parameter	Specific	Diss.	Part.
PCB Congeners		x	x
Pesticides	Trans/cis-nonachlor	x	x
	de-ethyl atrazine	x	x
	de-isopropyl atrazine	x	x
Metals	Hg	x	x
Conventional / Physical	Chloride	x	
	Total Phosphorus	x	
	Diss. Silica	x	
	Nitrate	x	
	Ammonia	x	
	Total Kjeldahl N	x	
	Part. Organic Carbon		x
	Diss. Organic C	x	
	Alkalinity	x	
	SPM 0.7_m		x
	Temperature	x	
	Conductivity	x	
	pH	x	
	Speed	*	*
	Direction	*	*
	Volume	x	x
	Weight	x	x
	Location	*	*
	Diss. Oxygen	x	
	Turbidity	x	
	Hardness	x	
	Chlorophyll a	x	

* Information obtained at the station

Table A-5.Sediment Parameters and Measurements Proposed for the Mass Balance Project of the EMP

Parameter	Specific
PCB Congeners	
Pesticides	Trans/cis-nonachlor de-ethyl atrazine de-isopropyl atrazine
Metals	Hg
Conventional / Physical	Chloride Total Phosphorus Nitrate Ammonia Total Kjeldahl N Volume Weight Location Particle size Porosity % Water % Solids Redox Potential Tot. Organic Carbon

* Information obtained at the station

Table A-6.Open Lake Parameters and Measurements Proposed for the Mass Balance Project of the EMP

Parameter	Specific	Diss.	Part.
PCB Congeners		x	x
Pesticides	Trans/cis-nonachlor	x	x
	de-ethyl atrazine	x	x
	de-isopropyl atrazine	x	x
Metals	Hg	x	x
Conventional / Physical	Chloride	x	
	Total Phosphorus	x	
	Diss. Silica	x	
	Nitrate	x	
	Ammonia	x	
	Total Kjeldahl N	x	
	Part. Organic Carbon		x
	Diss. Organic C	x	
	Alkalinity	x	
	SPM 0.7_m		x
	Temperature	x	
	Conductivity	x	
	pH	x	
	Wind Speed	*	*
	Direction	*	*
	Volume	x	x
	Weight	x	x
	Location	*	*
	Diss. Oxygen	x	
	Turbidity	x	
	Chlorophyll a	x	

* Information obtained at the station

Table A-7. Biota Parameters and Measurements Proposed for Mass Balance Project of the EMP

Parameter	Specific	Group				
		A	B	C	D	E
PCB Congeners	Whole fish w/o stomach	x	x			
	Whole fish w. stomach			x		
	Concentrations				x	x
Pesticides	**Trans/cis-nonachlor**					
	Whole fish w/o stomach	x	x			
	Whole fish w. stomach			x		
	Concentrations				x	x
	de-ethyl/de-isopropyl Atrazine	@	@			
	Whole fish w/o stomach			@		
	Whole fish w. stomach				@	@
	Concentrations					
Metals	**Hg**					
	Whole fish w/o stomach	x	x			
	Whole fish w. stomach			x		
	Concentrations				x	x
Conventional/Physical	% Lipid	x	x	x	x	x
	Sex	x	x	x		
	Age	x	x	x		
	Weight	x	x	x		
	Biomass				x	x
	% Moisture				x	x
	Gut contents	x	..x	x		
	Uptake/water	x	x	x	x	x
	Uptake/food	x	x	x	x	x
	Respiration rate	x	x	x	x	x
	Elimination Rate	x	x	x	x	x
	Cont. Exposure/food	x	x	x	x	x
	Cont. exposure/water	x	x	x	x	x
	Growth rate	x	x	x	x	x
	Cont. assimilation	x	x	x		
	Back excretion	x	x	x		
	Cont.uptake/gill	x	x	x		
	Cont. loss/gill	x	x	x		
	Conc.variability btwn. fish	x	x			
	Location	*	*	*	*	*

A= Lake Trout,coho salmon from lake Michigan;, Bloater chubs > 200mm.
B= Bloater chubs < 150 mm
C= Coho salmon from hatchery, alewife; smelt; sculpin
D= ***Mysis; Diporeia***
E= Zooplankton (Cladocera); phytoplankton
* Information obtained at the station
@ Presently unknown whether substance bioaccumulates

Appendix B

DQO Guidance

The following guidance is an interim draft developed by the EPA Quality Assurance Management Staff in Washington and represents the most current approach to the development of data quality objectives.

Appendix C

QA/QC Codes

The following codes are the EPA required standard codes for QA/QC samples.

Appendix D

Audit forms

The following forms will be used to document GLNPO audit activities. These forms are very similar to the finding forms published in:

Arter, D. 1989. Quality Audits for Improved Performance. ASQC Quality Press, Milwaukee, Wisconsin. 93 pp.

Audit Finding

Audit Title: _____ Audit #: _____ Finding #:_____

_____

Finding:

_____

Discussion:

Audit Finding
Response Form

Audit Title: _____ Audit #: _____ Finding #:_____

_____

Finding:

Cause of the problem:

Actions taken or planned for correction:

Responsibilities and timetable for the above actions:

Prepared by: _____ **Date:** _____

_____

Reviewed by: _____ **Date:** _____

Remarks:

Is this audit finding closed? _____ **When?** _____

Appendix E

Research Data Management and Quality Control System

The following is a brief description of the RDMQ system. The description is found in the User Manual that has been developed for this system.

Appendix F

Data Transmission Standard

The following standard will be used to transmit all EMP data to GLNPO for final storage of data.

Format for Reporting Analytical Data from the Lab or Field
(DRAFT: 27 October, 1994)

Accurate data in electronic format is necessary for the efficient handling and timely analysis of project results. As stated in the Quality Assurance Program Plan, all sampling and analytical information shall be reported electronically in the attached format. Requested modifications to this data reporting format must be approved by an EPA Data Management Officer prior to submission (call Marilyn Jupp 312/353-5882 or Phil Strobel 312/353-7996 with questions regarding this format).

GENERAL REQUIREMENTS

1. Data will be submitted to GLNPO in electronic media (i.e. diskette, magnetic tape, CD ROM, Internet transmission). All results submitted in electronic format will have been verified against laboratory records and will agree exactly with any hard copy submissions. Records of the verification should be made. Diskettes, tapes, or CDs shall bear one or more external labels, collectively supplying the following information: batch IDs, creation date, name and organization of submitter, brief description of contents and subdirectories.

2. Subdirectories must be used to segregate information. All sample results and batch data for a particular batch and analyte should be together in the same subdirectory (see the attached example of file structure).

3. All files shall be submitted in comma delimited ASCII format (or comma separated values .CSV). Field lengths should only be as long as necessary to contain the data; packing with blanks is not necessary. Missing or unknown values need not have anything entered (,,) but as this is an order format the place will need to be held.

4. All fields are alpha-numeric unless remarks state otherwise. Numeric fields may contain numeric digits, a decimal place and a leading minus (-) sign. A positive (+) sign is assumed and must not be entered into any numeric field. Results must be reported using the appropriate number of significant digits.

. Specific Format requirements:

? Report temperature values in degrees centigrade.
? Report dates numerically as YYMMDD.
? Report all analytes in the units specified in the QA Management Plan.

6. Sample results and detection limits will be reported in the same units. ????The result reported is the final value. Do not correct for blanks or surrogate recovery. Any correction factors applied are to be listed in Qualifying Value field and named in Qualifying Value Type field. If you have questions about value modifiers that may be applied, call your Project Officer or EPA Quality Assurance Manager.

7. Consistency in sample naming is crucial for GIS and modeling use of information. Please use the Field Sample ID reported to EPA from the samplers. *Exception: Internal laboratory sample ID's will be reported only for internal QC samples.* Sample IDs MUST be unique!

8. Lists of allowable values are attached for sample quality control identifiers and data qualifier remarks. You must use these lists.

9. All quality control data must be provided to EPA including, but not limited to: calibration samples, spikes, duplicates and performance material. See the attached table of allowable 3-character sample and results qualifier codes. Get approval from the EPA Quality Assurance Manager (Mike Papp 312/886-4063) prior to adding any new codes.

SPECIFIC INSTRUCTIONS

Delivery Header Record - A single Delivery Header Record shall be included on each diskette as a separate file in the root directory and appears once on each disk, tape or transmission from the same GLNPO program.

FORMAT for Delivery Header Record:

Record Position	Field Contents	Remarks or Explanation
1	**Project**	ex. LMMB, IADN, GLAD
2	**Date disk made**	Date format YYMMDD (ex: 940621)
3	**Laboratory**	Laboratory name {use attached list of allowable values}
4	**Contract or Grant #**	EPA grant or contract number
5	**Data contact name**	
6	**Data contact phone number**	

Sample and Batch Data - Create a subdirectory for each batch to contain two files, the Sample Batch File and the Sample Results File. For complex analyses such as PCBs, GC or GCMS, Batch Data files can be created and placed in one subdirectory. Any samples found to have any of these compounds are then reported in the same subdirectory. The analyte field in the Results records will prevent confusion both in single and multiple compound analyses.

FORMAT for **Sample Batch File**

Record Position	Field Contents	Remarks or Explanation
1	**Batch ID**	Unique identification of batch
2	**Parameter**	Major grouping in which an analyte is associated (ex: PCB) {use attached list of allowable values}
3	**Filter Fraction**	ex: Dissolved, particulate, total, filtered {use attached list of allowable values}
4	**Instr. Manufacturer**	Manufacturer of analytical instrument
5	**Instrument Model #**	Model number of analytical instrument
6	**Date of analysis**	YYMMDD date results generated
7	**Sample ID's**	Vertical list of sample ID's in this Batch
8	Submission #	Increments with resubmission of this batch data to EPA or reanalysis

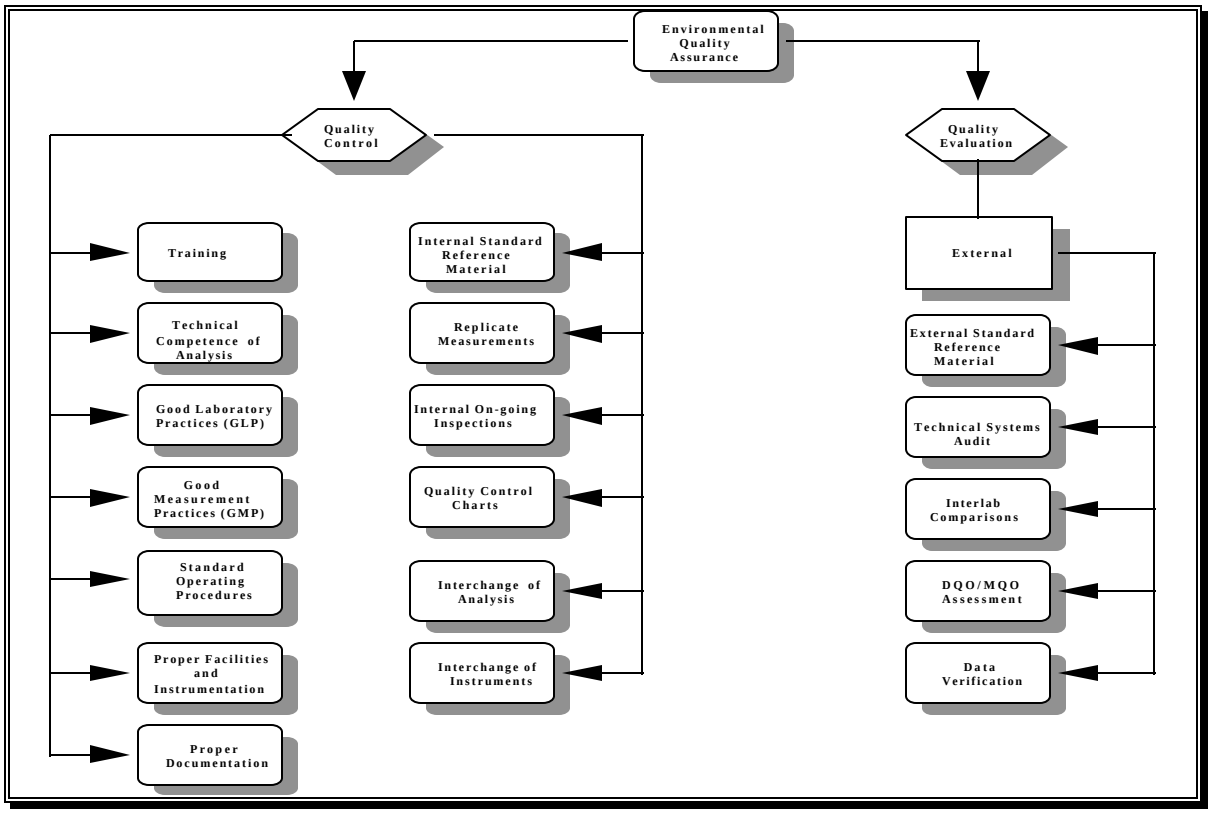
BOLD Fields must have a values for each record

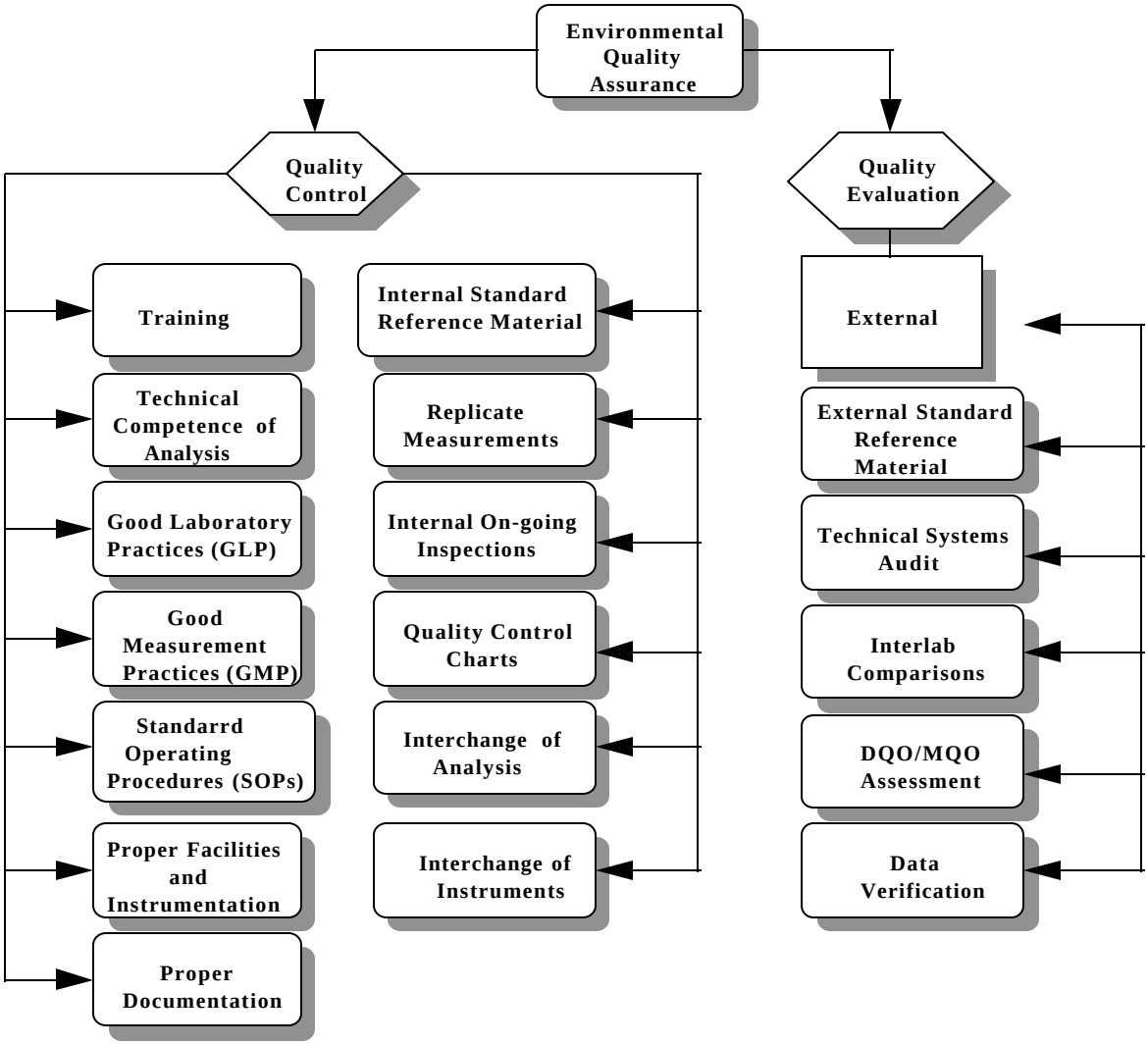
Sample Results - This should be a file of multiple lines of sample results. If a spreadsheet is used, the field contents listing would be the column headers and each sample would be one line.

FORMAT for Sample Results:

Record Field Position	Contents	Remarks or Explanation
1	**Field Sample ID**	Unique ID for a specific sample (use lab sample id for lab QC samples)
2	**QC Identifier**	Sample, Field Blank, etc.
3	**Analyte**	What the result reports (Hg)
4	**Result**	Numeric value
5	**Units (Abreviation)**	Metric measure units
6	Qualifying Value	Numeric
7	Qualifying Val. Type	Dilution factor, correction factor, % recovery
8	Lab Remark Code	3 character qualifier code (you may string as many codes as needed ex: RINLTLCON) {use attached list of allowable values}
9	Detection Limit	Numeric
10	Exception to Method	Text comment on any exceptions to the prescribed method (up to 254 characters)

BOLD Fields must have a values for each record


Environmental Quality Assurance
Quality Control
Quality Evaluation
Training
Technical Competence of Analysis
Good Laboratory Practices (GLP)
Good Measurement Practices (GMP)
Standard Operating Procedures
Proper Facilities and Instrumentation
Proper Documentation
Internal Standard Reference Material
Replicate Measurements
Internal On-going Inspections
Quality Control Charts
Interchange of Analysis
Interchange of Instruments
External
External Standard Reference Material
Technical Systems Audit
Interlab Comparisons
DQO/MQO Assessment
Data Verification


Environmental Quality Assurance
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Technical Competence of Analysis
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