Statewide Fish Tissue Monitoring Program
Tier 2 Fish Study

Contract Number 582-4-55861

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Quality Assurance Project Plan

Prepared by

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Prepared for

Texas Commission on Environmental Quality

Surface Water Quality Monitoring Program
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Field Supervisor & Data Manager: Michael Tennant — 10/25/04 Date
Michael Tennant
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Patrick Roques
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David W. Sullivan
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Pat Bohannon
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Compliance Support Division

Director: Jose A. Franco 11/2/04 Date

TCEQ Quality Assurance Manager: Stephen Stubbs 11/1/04 Date

QA Specialist: Sharon Coleman 11/1/2004 Date
Quality Assurance Program

U.S. Environmental Protection Agency
Region 6

Chief: for Approval Official 1-14-05 Date
Assistance Programs Branch

Project Officer: Sylvia Ritzky January 14, 2005 Date
Sylvia Ritzky
State and Tribal Programs Section

The DSHS Field Supervisor and Data Manager will secure written documentation from each sub-tier project participant stating the organization's awareness of and commitment to requirements contained in this Quality Assurance Project Plan (QAPP) and any amendments or revisions. The DSHS project team will maintain the documentation as part of the project's quality assurance records, and will ensure that the document is available for review.

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Attachments

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Appendix B	*Geochemical and Environmental Research Group (GERG)* *Texas A&M University* *Quality Assurance Management Plan*
Appendix C	*Geochemical and Environmental Research Group (GERG)* *Texas A&M University* *Quality Assurance Project Plan*
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A3 Distribution List

Texas Department of State Health Services (DSHS)
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Division for Regulatory Services

Kirk Wiles, Principal Investigator, Environmental and Consumer Safety Section

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Dr. Richard Beauchamp, Senior Medical Toxicologist, Epidemiology of Non-Infectious Disease Unit

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Monitoring Operation Division

Patrick Roques, Program Manager, Surface Water Quality Monitoring (SWQM) Program, MC-165

Pat Bohannon, Project Manager, SWQM Program, MC-165

Dr. David W. Sullivan, Section Manager, Monitoring Data Management and Analysis Section, MC-165

Brandon Harris, Program Manager, Monitoring Data Management & Analysis Section, MC-165

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Sub-tier Project Participants

Geochemcial & Environmental Research Group
Texas A&M University
833 Graham Road
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Dr. Terry L. Wade, GERG Environmental Sciences, Program Manager

Dr. Guy Denoux, GERG Environmental Sciences, Deputy Program Manager and Data Manager

I. Project Management

A4 Project/Task Organization

Roles and Responsibilities of Key Personnel

Texas Department of State Health Services

Kirk Wiles
Environmental and Consumer Safety Section, Principal Investigator
Kirk guides and oversees the work of the DSHS Project Manager and Field Supervisor and Data Manager. He reviews all reports prepared by the DSHS Field Supervisor / Data Manager and Project Manager.

Gary B. Heideman
Environmental and Consumer Safety Section, Project Manager and Co-Principal Investigator
Gary directs all aspects of the project except for the laboratory analyses conducted by the DSHS Bureau of Laboratories. His other responsibilities include serving as the SSD Quality Assurance (QA) Officer. This includes reviewing data quality to ensure that all data are collected in accordance with the specifications set forth in the QAPP. He is responsible for ensuring that tasks and other requirements in the contract are executed on time and with the quality assurance/quality control requirements in the system as defined by the contract and in the project QAPP; assessing the quality of subcontractor/participant work. He is responsible for verifying that the QAPP is distributed and followed by DSHS and that the project is producing data of known and acceptable quality. He is responsible for ensuring adequate training and supervision of all sampling activities and field data collection, including the facilitation of audits and the implementation, documentation, verification and reporting of corrective actions.

Michael Tennant
Environmental and Consumer Safety Section, Field Supervisor and Data Manager
Responsible for submitting accurate and timely deliverables to the TCEQ Project Manager.

<u>*Field Supervisor*</u> - Michael is responsible for supervising all aspects of the sample collection and measurement of other parameters in the field. He is also responsible for the acquisition of fish tissue samples and field data measurements in a timely manner that meet the quality objectives specified in Section A7 (Table A.2), as well as the requirements of Sections B1 through B8. His other responsibilities include field scheduling, staffing, and ensuring that staff is appropriately trained. If and when monitoring activities include TCEQ staff, the field supervisor will coordinate with the TCEQ Project Manager. The DSHS Field Supervisor and Data Manager reports project progress, status, and any problems to the TCEQ Project Manager.

<u>*Data Manager*</u> – Michael is responsible for the acquisition, verification, and transfer of data to TCEQ and oversees data management for the study. He performs data quality assurances prior to transfer of data to TCEQ and ensures that the data review checklist is completed and the data is submitted with the appropriate codes. He is also responsible for transferring data to the TCEQ

in an acceptable format and serves as the point of contact for the TCEQ Project Manager to resolve issues related to the data and assumes responsibility for the correction of any data errors. He assists in the development and review of the quantitative risk characterization.

Stephen Twidwell
Environmental and Consumer Safety Section, Environmental Specialist
He is responsible for assisting with all sample collection activities, measurement of field parameters, submitting tissue samples to the laboratory, data entry, and other assigned tasks.

Dr. Jerry Ward
Environmental and Consumer Safety Section, Toxicologist
She is responsible for developing the quantitative risk characterization based on the fish tissue data collected and analyzed for this project.

Dr. Richard Beauchamp
Epidemiology of Non-Infectious Disease Unit, Senior Medical Toxicologist
He is responsible for review of the quantitative risk characterization developed by the DSHS Toxicologist.

TCEQ Monitoring Operations Division
Laboratory & Mobile Monitoring Section

Patrick Roques
SWQM Program Manager
Patrick is responsible for oversight of the TCEQ SWQM Program. Reviews and approves all SWQM Projects, QA audits, corrective actions, reports, work plans, and contracts. He enforces corrective action, as required, where QA protocols are not met. He ensures that all TCEQ SWQM personnel are fully trained and SWQM projects are adequately staffed.

Pat Bohannon
Project Manager
Pat is responsible for ensuring that the project delivers data of known quality, quantity, and type on schedule to achieve project objectives. He provides the primary point of contact between the DSHS and the TCEQ. He tracks and reviews deliverables to ensure that tasks in the work plan are completed as specified in the contract. He reviews and approves QAPP and any amendments or revisions and ensures distribution of approved/revised QAPP's to TCEQ participants. He is responsible for verifying that the QAPP is followed by the DSHS. He notifies the TCEQ QAS of significant project nonconformances and corrective actions taken as documented in quarterly progress reports. He is responsible for receiving data (Event/Results Files) from the DSHS Field Supervisor and Data Manager, reviewing the data, and submitting the data to TCEQ Information Resources in compatible formats to be uploaded into TCEQ Regulatory Activities and Compliance System (TRACS).

Monitoring Data Management and Analysis Section

Brandon Harris
Data Manager
Brandon is responsible for overseeing the work of the Water Data Management and Analysis Team. This team reviews QAPP for valid surface water quality monitoring stations, checks validity of parameter, program and source codes, and ensures that data will be reported following the *Surface Water Quality Monitoring Data Management Reference Guide* September 2003 procedures or most current version. He surveys the TRACS database to monitor submittal of scheduled sampling data and provides data completeness reports to Project Managers as requested. He analyzes TRACS database to identify level 1 data validation inconsistencies and reports them to appropriate Project Managers. He serves as Monitoring Operations data management customer service representative for SWQM Project Manager. He provides training to the SWQM Project Manager to ensure proper data submittal.

TCEQ Compliance Support Division
Quality Assurance Program

Sharon Coleman
Quality Assurance Specialist
Sharon assists the TCEQ SWQM Project Manager on QA-related issues. She reviews and approves the QAPP and any amendments or revisions. She conveys QA problems to appropriate TCEQ management. She monitors implementation of corrective actions. She may coordinate or conduct audits.

U.S. EPA Region 6
State and Tribal Programs Section

Sylvia Ritzky
USEPA 106 Project Officer
Sylvia is responsible for managing the project for EPA. She reviews project progress.

Sub-tier Project Participants

Geochemical and Environmental Research Group (GERG) Texas A&M University

Terry L. Wade
GERG, Program Manager
Terry is responsible for overall GERG administration and execution of the project and is the designated study director. He establishes and documents the roles and responsibilities of GERG project personnel; coordinates auditing of GERG project activities; Establishes and conducts a self-assessment program; has final responsibility to insure all deliverables are provided on-time to DSHS; establishes and develops the implementing procedures; approves expenditures of funds for GERG; communicates with the DSHS Project Manager and DSHS Field Supervisor and Data Manager to coordinate sample submission and ensure fish or shellfish tissue sample chain of custody.

Guy Denoux
GERG, Deputy Program Manager and Data Manager
Guy reports to the GERG Program Manager and shares responsibility with the GERG Program Manager for the project in all financial, management, scientific, and quality assurance issues. He is the responsible party in the absence of the GERG Program Manager. He coordinates internal and external interfaces of GERG personnel involved with the project; oversees the activities of the GERG quality assurance unit for this project, designates GERG personnel to perform inspections, and maintains records related to these activities; ensures that the applicable quality control (QC) requirements are met; ensures that quality-related issues and problems are promptly identified and corrected; interfaces with the GERG QA Manager on program QA/QC considerations; implements cost effective quality improvements; supervises the progress of the analytical program and team; assists the GERG Organic Analytical Laboratories Manager in tracking corrective actions and analyzing data pertaining to quality; provides guidance to resolve quality problems and ensure that corrective action is taken and appropriately documented in response to occurrence reports, non-conformance reports, etc.; identifies areas where improvement could benefit the GERG program; communicates with the DSHS Project Manager and DSHS Field Supervisor and Data Manager to coordinate sample submission and ensure fish or shellfish tissue sample chain of custody.

Debz DeFreitas
GERG, Quality Assurance Manager
The Quality Assurance (QA) Manager is responsible for developing, enacting, and enforcing all QA/QC procedures and policies. The QA Manager ensures that all project activities are operated in a manner that provides confidence that project quality control (QC) objectives are met. The QA Manager is independent of project management, reports to the Senior Associate Director of GERG, and is responsible for ensuring all applicable QA/QC policies and directives are enforced, revised and improved to provide products of the highest quality to clients. She maintains and revises the GERG Quality Assurance Management Plan (QAMP) and the Generic Quality Assurance Manual (GQAM); advises the Program Manager, the Deputy Program Manager and the project team members on QA/QC matters; ensures that QA/QC requirements are effectively implemented for all project activities; ensures that the QAPP is

adequately developed to meet project needs and is effectively implemented; coordinating, preparing, approving and reviewing QA/QC documents including all quality requirements contained in standard operating procedures; identifies QA/QC requirements and assists in the development of procedures and other implementing instructions; assists in the identification of problems concerning, and taking actions to eliminate or minimize potential QA problems; evaluates quality performance including internal system audits, tracking of reports of QA/QC criteria, reviewing corrective actions, and overall project performance; provides QA/QC training to all project personnel when required; and has the authority to stop the work when severe conditions adverse to quality are detected and warrant immediate action.

Drs. Terry L. Wade, Jose Sericano, and Guy Denoux
Laboratory Managers
The Extraction Laboratory Manager and the Analytical Laboratory Managers are the technical supervisors responsible for the sample extract preparation and the instrumental analyses. The Laboratory Managers report to the Program Manager for this program and are responsible for supervision and coordination of all aspects of the laboratories and the analytical laboratories; coordination with the Program Manager and Deputy Program Manager to submit sample extracts to the laboratory to ensure technical quality and due dates are met on all projects; implementing the required standard operating procedures and the Quality Assurance Project Plan; ensuring the quality of assigned work by monitoring daily performance, calibration, and QC data; investigating quality problems, determining their root causes, proposing solutions, implementing corrective actions, and obtaining the concurrence of the Program Manager and the QA Manager on the appropriateness of the corrective action; implementing cost effective quality improvements; implementing training plans by assessing training needs, scheduling necessary training and ensuring that training is completed and documented; initiating corrective actions and stop-work actions when warranted by conditions adverse to analytical quality; approval of analytical data and submission of the final data to the Program Manager and Data Manager in a timely and professional manner.

Figure A1. Organization Chart

The State of Texas does not currently have a statewide monitoring program for contaminants in fish tissues to address potential concerns for human health and ecological risks. Various state and federal agencies coordinate their efforts to a limited degree through the interagency Toxic Substances Coordinating Committee, but no funds have been made available for a consistent, widespread program.

Three state agencies have significant interest in and responsibilities related to contaminants in fish tissues. The DSHS is responsible for determining if contaminants in fisheries resources pose a risk to consumers and issuing health advisories or closures when risks are found. The TCEQ is responsible for establishing state water quality standards, managing the quality of state waters, and addressing any pollution concerns in these waters. The Texas Parks and Wildlife Department (TPWD) is responsible for managing state fish and wildlife resources, addressing any pollution problems that may be adversely impacting these resources, and enforcing human health closures issued by DSHS.

The three agencies have entered into a cooperative effort to share resources and through funding from the U.S. Environmental Protection Agency (USEPA) implement a pilot statewide fish tissue monitoring program. This program will enable the assessment of contaminant levels in fisheries resources across the state for possible human health, water quality, and ecological risks for three years. Information gained in the pilot study could be used to seek additional funding to continue the statewide fish tissue monitoring program.

A6 Project/Task Description

The Statewide Fish Tissue Monitoring Project is designed as a cooperative effort, involving shared resources of the TCEQ, TPWD, and DSHS. The project is funded over state fiscal years 2004-07 through the TCEQ by the USEPA with most of the funding allocated to laboratory analysis of fish tissue.

The primary aim of the Tier 1 human health risk screening study is to identify frequently fished sites where commonly consumed fish may be chemically contaminated, posing a risk to human health. The TCEQ and DSHS will compare Tier 1 study laboratory results for project target analytes to DSHS-established human health screening values to identify samples with elevated concentrations and determine water bodies for Tier 2 study. TCEQ may include additional water bodies for Tier 2 analyses, based on previous data indicating fish tissue contamination. This QAPP addresses the DSHS portion of the project and will encompass the sampling and analytical procedures to meet the Tier 2 screening study. The Tier 1 study is addressed in a separate document.

Eight (8) of the screened water bodies are projected to require more in depth, Tier 2 human health risk studies by DSHS. Proposed fish tissue sample analyses budgets were developed based upon six (6) metals screening criteria exceedances and two (2) pesticides or polychlorinated biphenyls (PCBs) screening criteria exceedances. If analytical results from more than eight water bodies exceed DSHS-established screening values, TCEQ and DSHS will prioritize water bodies by angler use, fish consumption patterns, and extent of chemical contamination (e.g. highest priority will be assigned to water bodies where exposure of anglers

to chemical contaminants through consumption of fish is the greatest health risk). These studies will be conducted, beginning in FY05, on reservoir or river sites where elevated contaminant concentrations were revealed by the Tier 1 screening studies. The DSHS field personnel will collect thirty (30) fish tissue samples of individual established target species from each water body identified through Tier 1 screening and/or other water bodies designated by TCEQ. The Geochemical and Environmental Research Group (GERG) Laboratory Texas A&M University in College Station, Texas will conduct the fish tissue chemical contaminant analyses. The GERG Laboratory will complete the following analyses for each water body, as designated by DSHS: metals, pesticides, PCBs, semi-volatile organic compounds (SVOCs), and volatile organic compounds (VOCs). The individual chemical contaminants comprising the above mentioned chemical contaminant classification groups are described in the *DSHS Seafood Safety Division Survey Branch Standard Operating Procedures and Quality Control/Assurance Manual and Geochemical and Environmental Research Group Texas A&M University Quality Assurance Project Plan* (Appendix A; Appendix C). For each Tier 2 study water body, the DSHS will prepare a quantitative risk characterization to assess the theoretical human health risks associated with the consumption of chemically contaminated fish and issue consumption advisories or aquatic life orders (closures) where chemical contamination of fish poses a public health hazard.

Tier 2 monitoring will be conducted on five reservoirs in FY05, based on the results from the first year of the Tier 1 study and previous data indicating contaminants in fish tissue from Ellison Reservoir. The reservoirs to be sampled and the contaminants for which screening values were exceeded are listed in Table A.1.

Table A.1. Tier 2 reservoirs to be sampled in FY05.

Reservoir	Contaminant(s)	Exceedance(s) mg/Kg	Screening Value mg/Kg
Canyon Lake	Mercury	0.7	0.525
Lake Arrowhead	Arsenic	0.88	0.036
O. H. Ivie Reservoir	PCB congeners p,p DDE	0.03585 0.162	0.027 0.16
Lake Waco	PCB congeners	0.06976	0.027
Ellison Reservoir	Lead PCB congeners bis(2-ethylhexyl phthalate)	2.0 0.32 12.8	0.6 0.027 0.39

The following information will describe in detail the project objectives, tasks, and schedule of deliverables.

Program Element 1: Edible Tissue Monitoring

The edible tissue monitoring element is designed to ensure that concentrations of chemical contaminants in fish are adequately characterized. The DSHS will develop a QAPP, review Tier 1 study data, and collect fish tissue samples from designated water bodies. The GERG laboratory will analyze fish tissue samples collected for this study. The edible tissue monitoring element will increase fish tissue chemical contaminant data from Texas waters.

Objective: To ensure that concentrations of chemical contaminants in fish are adequately characterized in Texas water bodies.

Task 1.1 Develop a QAPP to ensure that appropriate data is utilized in all phases of the project following EPA requirements for Quality Assurance Plans for Environmental Data Operations, EPA QA/R-5 (March 2001) (DSHS SSD). The QAPP is reviewed by the TCEQ to help ensure that data generated for the purposes described are scientifically valid and legally defensible. This process will ensure that all data submitted to the SWQM portion of the TRACS database have been collected and analyzed in a way that guarantees its reliability and therefore, can be used in TMDL development, stream standards modifications, permit decisions, and water quality assessments.

Task 1.2 Coordinate monitoring sites in designated water bodies with the TCEQ Program (DSHS and TCEQ).

Task 1.3 Conduct intensive fish sampling utilizing information provided in the *EPA-Guidance for Assessing Chemical Contaminant Data for Use in Fish Advisories, Volume 1* and following all standard operating procedures described in the DSHS *Seafood Safety Division Survey Branch Standard Operating Procedures and Quality Control/Assurance Manual* (Appendix A). Utilize an intensive study approach in order to generate the maximum amount of high quality fish tissue chemical contaminant data (DSHS).

Task 1.4 Analyze fish tissue, as designated by DSHS, for metals, SVOCs, VOCs, PCBs, and pesticides (GERG Laboratory).

Measure of Success

1. Increase the availability of high quality chemical contaminant data in fish Texas water bodies.

Program Element 2: Risk Characterization

The risk characterization program element will utilize the fish tissue chemical contaminant data from Program Element 1. The risk characterization program element will utilize guidance from the *EPA-Guidance For Assessing Chemical Contaminant Data For Use In Fish Advisories, Volume 2* and other toxicological references to complete a quantitative risk characterization. The quantitative risk characterization will calculate and report the theoretical risks associated with consumption of fish from each water body identified through Tier 1 screening and other water bodies designated by TCEQ.

Objective: To utilize fish tissue chemical contaminant data to determine the public health risks associated with consumption of fish from designated Texas water bodies.

Task 2.1 Organize field and analytical data in an electronic format (Microsoft Excel) to facilitate review and transfer of the data and formats specified by TCEQ for efficient uploading of data to the TRACS database (DSHS).

Task 2.2 Use fish tissue chemical contaminant data developed under Program Element 1 to evaluate the theoretical health risks associated with consumption of fish from designated Texas water bodies (*EPA Guidance For Assessing Chemical Contaminant Data For Use in Fish Advisories, Volume 2* as well as other pertinent toxicological references) (DSHS).

Measure of Success

1. Develop a quantitative risk characterization that accurately reflects the theoretical health risks associated with consumption of fish from designated Texas water bodies.

Program Element 3: Risk Management

The Risk Management Program Element will utilize data from Program Element 2 to determine whether risk management actions are necessary. If an unacceptable level of risk to consumers is identified, appropriate actions to ensure public health protection will be determined. The DSHS acting under Chapter 436 of the Health and Safety Code could declare a public water body to be a prohibited fish, oyster, and/or crab harvesting area under the statute or advise the public of the potential health risks associated with consuming chemical contaminated fishes, oysters, or crabs.

Objective: Utilize Program Element 2 to make risk management decisions.

Task 3.1 Develop a risk management process to evaluate various options for reducing potential health risks associated with the human consumption of chemically contaminated fish (DSHS).

Task 3.2 Implement risk management decisions, if needed, to reduce unacceptable levels of risk to the fish consuming public (DSHS).

Measure of Success

Implement the appropriate risk management decisions to protect public health based upon data produced from Program Element 2.

A7 Quality Objectives and Criteria

The primary objective of the Tier 2 Statewide Fish Tissue Monitoring Program is to conduct more in depth human health risk assessment studies. The DSHS will conduct Tier 2 studies for water bodies identified by Tier screening as having potential human health risk concerns and/or water bodies designated by TCEQ. The Data Quality Objectives (DQO) were established by project professionals to address practical analytical capabilities, proper fish tissue collection, handling, storage, and chain-of –custody procedures,

The DQO for the project is to collect, prepare, and analyze fish tissue samples to provide data appropriate to determine the theoretical health risks associated with the consumption of fish from the study water bodies. Table A.2 lists the project parameters (analytes) and reporting limits to establish goals for the project. The project analytes and reporting limits are also listed in the *Geochemical and Environmental Research Group Texas A&M University Quality Assurance Project Plan* (Appendix C) and *DSHS Seafood Safety Division Survey Branch Standard Operating Procedures and Quality Control/Assurance Manual* (Appendix A). Methods will be implemented to meet these goals. This illustrates that the Measurement Quality Objectives (MQO) are the most appropriate mechanism to establish quality goals for the individual analyte measurements. The MQO are to provide data appropriate to meet the target concentrations presented in Table A.2 and are used as quality control criteria for the laboratory measurement processes to set the bounds of acceptable measurement error. Only data collected for this project, which have a valid TCEQ parameter code assigned in Table A.2 will be submitted to the SWQM portion of TRACS.

Critical Measurements

The DSHS field personnel will collect thirty (30) fish tissue samples of individual established target species from each water body identified through Tier 1 screening and other water bodies designated by TCEQ, as described in the *DSHS SSD Survey Branch Standard Operating Procedures and Quality Control/Assurance Manual* (Appendix A) as fish tissue sample specimens. Fish tissue sample data requirements and documentations instructions are also outlined in the *DSHS Seafood Safety Division Survey Branch Standard Operating Procedures and Quality Control/Assurance Manual* (Appendix A).

A Garmin GPSMAP 76S chart-plotting receiver will be used to locate sample sites. Locations will be identified using latitude and longitude, as well as physical descriptions.

The GERG Laboratory will analyze thirty (30) fish tissue samples for the following analytes from each water body, as designated by DSHS: metals, pesticides, PCBs, SVOCs, and VOCs. The GERG Laboratory has an accepted list of chemical contaminants for which analyses will be performed; the analyte list is included in Table 1, SSD *Standard Operating Procedures and Quality Control/Assurance Manual for Fish and Shellfish Tissue Collection* (Appendix A) and *Geochemical and Environmental Research Group Texas A&M University Quality Assurance Project Plan* (Appendix C). Reporting limits for chemical contaminants in fish have been reviewed by DSHS and are adequate to determine whether a human health concern is present. DSHS routinely conducts risk assessments of fish and shellfish tissue using this list of target analytes.

Non-critical Measurements

Air temperature, water temperature, specific conductance, salinity, and pH will be measured in the field using a Hydrolab Scout with a H20 sonde. Air and water temperature will be recorded to +/- 0.1 degrees Centigrade. Specific conductance will be measured to +/- 1 μS/cm. Salinity will be measured to +/- 0.1 parts per thousand. pH will be measured +/- 0.1 standard units.

The ancillary objective is to collect data that complies with TCEQ rules for the SWQM Program, which may be used to support decisions related to TMDL development, stream standard modifications, permit decisions, and water quality assessments. The measurement performance criteria to support the project objective are specified in Table A.2. Data collected that have a valid Parameter code assigned in Table A.2 may be stored in TRACS. DSHS will request Parameter codes for those parameters, which do not have valid codes. If Parameter codes for a particular parameter are not included in this QAPP or subsequent amendments submitted before data transmittal, data will not be loaded and stored in the TRACS database.

Table A.2 Data Quality Objectives for Measurement Data

PARAMETER	UNITS (all wet weight)	METHOD TYPE	METHOD	METHOD DESCRIPTION	Parameter	*Reporting Limits	PRECISION of laboratory duplicates (RPD)	ACCURACY of matrix spikes % Recovery	Laboratory Performing Analysis
Field Parameters (Accessory)									
PH	pH. units	NA	SSD SOP		00400	NA	NA	NA	NA
Specific conductance	µS/cm	NA	SSD SOP		00094	NA	NA	NA	NA
Temperature	B Celsius	NA	SSD SOP		00010	NA	NA	NA	NA
Metals in Fish Parameters *(*mg/kg tissue wet weight)									
Arsenic, Total	mg/kg	***	***	***	01004	0.10	***	***	GERG
Cadmium, Total	mg/kg	***	***	***	71940	0.10	***	***	GERG
Copper, Total	mg/kg	***	***	***	71937	0.40	***	***	GERG
Lead, Total	mg/kg	***	***	***	71936	0.40	***	***	GERG
Mercury, Total	mg/kg	***	***	***	71930	0.20	***	***	GERG
Selenium, Total	mg/kg	***	***	***	01149	0.10	***	***	GERG
Zinc, Total	mg/kg	***	***	***	71938	0.40	***	***	GERG
Pesticides in Fish Parameters *(*mg/kg tissue wet weight)									
Aldrin	mg/kg	***	***	***	34680	0.002	***	***	GERG
Alachlor	mg/kg	***	***	***	82571	0.008	***	***	GERG
BHC, alpha isomer	mg/kg	***	***	***	39074	0.002	***	***	GERG
BHC, beta isomer	mg/kg	***	***	***	34258	0.002	***	***	GERG

PARAMETER	UNITS (all wet weight)	METHOD TYPE	METHOD	METHOD DESCRIPTION	Parameter	*Reporting Limits	PRECISION of laboratory duplicates (RPD)	ACCURACY of matrix spikes % Recovery	Laboratory Performing Analysis
delta-BHC	mg/kg	***	***	***	34263	0.002	***	***	GERG
Chlordane (technical)	mg/kg	***	***	***	34682	0.010	***	***	GERG
chloropyrifos	mg/kg	***	***	***	81807	0.010	***	***	GERG
p,p'- DDD	mg/kg	***	***	***	39312	0.010	***	***	GERG
p,p'- DDE	mg/kg	***	***	***	39322	0.005	***	***	GERG
p,p'-DDT	mg/kg	***	***	***	39302	0.010	***	***	GERG
Dacthal	mg/kg	***	***	***	82004	0.003	***	***	GERG
Diazinon	mg/kg	***	***	***	81806	0.010	***	***	GERG
Dieldrin	mg/kg	***	***	***	39404	0.006	***	***	GERG
Endosulfan I (alpha)	mg/kg	***	***	***	34365	0.010	***	***	GERG
Endosulfan II (beta)	mg/kg	***	***	***	34360	0.010	***	***	GERG
Endosulfan sulfate	mg/kg	***	***	***	34355	0.010	***	***	GERG
Endrin	mg/kg	***	***	***	34685	0.006	***	***	GERG
Heptachlor	mg/kg	***	***	***	34687	0.002	***	***	GERG
Heptachlor Epoxide	mg/kg	***	***	***	34686	0.004	***	***	GERG
Hexachlorobenzene	mg/kg	***	***	***	34688	0.002	***	***	GERG
gamma-BHC (Lindane)	mg/kg	***	***	***	39075	0.002	***	***	GERG

PARAMETER	UNITS (all wet weight)	METHOD TYPE	METHOD	METHOD DESCRIPTION	Parameter	*Reporting Limits	PRECISION of laboratory duplicates (RPD)	ACCURACY of matrix spikes % Recovery	Laboratory Performing Analysis
Malathion	mg/kg	***	***	***	39534	0.020	***	***	GERG
Methoxychlor	mg/kg	***	***	***	81644	0.030	***	***	GERG
Mirex	mg/kg	***	***	***	81645	0.008	***	***	GERG
Ethyl parathion	mg/kg	***	***	***	20427	0.010	***	***	GERG
Methyl parathion	mg/kg	***	***	***	81809	0.010	***	***	GERG
Toxaphene	mg/kg	***	***	***	34691	0.100	***	***	GERG
Polychlorinated Biphenyls (PCBs) in Fish Tissue Parameters (mg/kg tissue wet weight)									
****Aroclor 1016	mg/kg	***	***	***	34674	0.040	***	***	GERG
Aroclor 1221	mg/kg	***	***	***	34664	0.040	***	***	GERG
Aroclor 1232	mg/kg	***	***	***	34667	0.040	***	***	GERG
Aroclor 1242	mg/kg	***	***	***	34689	0.040	***	***	GERG
Aroclor 1248	mg/kg	***	***	***	34669	0.040	***	***	GERG
Aroclor 1254	mg/kg	***	***	***	34690	0.040	***	***	GERG
Aroclor 1260	mg/kg	***	***	***	34670	0.040	***	***	GERG

*These are DSHS accepted reporting limits, and may differ from TCEQ AWRLs. The reporting limits listed in this table are the specifications at or above which data will be reported for this project. Ongoing ability to recover an analyte at the reporting limit is demonstrated through analysis of a calibration or check standard at the reporting limit. See *Geochemical and Environmental Research Group Texas A&M University Quality Assurance Project Plan* (Appendix C) for quality control details and acceptance criteria.
***See *Geochemical and Environmental Research Group Texas A&M University Quality Assurance Project Plan* (Appendix C)
****Aroclor is a registered trademark of the Monsanto Corporation
ND - Non Detected (detection limit not established)

Precision

The precision of laboratory data is a measure of the reproducibility of a result when an analysis is repeated. It is strictly defined as a measure of the closeness with which multiple analyses of a given sample agree with each other. Precision is assessed by replicate analyses, by repeated analyses of a stable standard. The *Geochemical and Environmental Research Group Texas A&M University Quality Assurance Project Plan* (Appendix C) specifies performance control limits for analytical measurement.

Accuracy

Accuracy is a statistical measurement of correctness and includes components of systemic error. A measurement is considered accurate when the value reported does not differ from the true value. Accuracy is verified through the analysis of laboratory matrix spikes, certified reference materials, and blank samples (Appendix C).

Representativeness

The concept of representativeness within the context of the Statewide Fish Tissue Monitoring Project refers to the ability of the project to accurately and precisely characterize contaminant concentrations in fishes from reservoirs and rivers across the state. The study design was established to provide comparable data for sample locations across the state. Sampling methods, target fish species to be sampled, sample preparation methods, and similar/consistent QA procedures have been developed to ensure the data quality attribute of representativeness applies not only to the overall sampling design, but also to individual measurements and samples obtained in the course of the monitoring program.

Comparability

Confidence in the comparability of data sets from this project to those for similar uses is based on the commitment of project staff to use only approved sampling and analysis methods and QA/QC protocols in accordance with quality system requirements and as described in this QAPP and project standard operating procedures (SOPs). Comparability is also guaranteed by reporting data in standard units, by using accepted rules for rounding figures, and by reporting data in a standard format as discussed in Section B10.

Completeness

The completeness of the data is basically a relationship of how much of the data is available for use compared to the total potential data. Ideally, 100% of the data should be available. However, the possibility of unavailable data due to accidents, insufficient sample volume, broken or lost samples, etc. is to be expected. Therefore, it will be a general goal of the project(s) that 95% data's completion is achieved.

A8 Special Training / Certification

The project requires staff with experience in fish collection, analytical chemical contaminant laboratory procedure, data and project management, statistical analysis, quantitative risk characterization development, and risk management. DSHS and GERG Laboratory project staff are experienced in all above mentioned project duties and are capable of completing all project requirements. Training and personnel requirements for the GERG Laboratory are covered in the *Geochemical and Environmental Research Group Texas A&M University Quality Assurance Management Plan* (Appendix B).

A9 Documents and Records

The DSHS field supervisor and data manager is responsible for archiving the QAPP and ensuring that the appropriate personnel have the most current, approved version of this QAPP. If any modifications of the QAPP are approved by the TCEQ, the DSHS Field Supervisor and Data Manager will distribute copies to the appropriate personnel.

Fish tissue sample and environmental data will be collected and recorded at the time of fish tissue collection on the *DSHS SSD Fish and Shellfish Tissue Data Form,* located in the *DSHS Seafood Safety Division Survey Branch Standard Operating Procedures and Quality Control/Assurance Manual* (Appendix A). Data collected in the field will include the water body name, site name, site code, sample date, sample collection time, TCEQ region, TCEQ station, TCEQ segment, TCEQ sequence collector identification, latitude and longitude, water temperature, salinity, pH, specific conductance, weather conditions, fish observations, hydrologic conditions, sample number, sample date collected, sample data processed, tissue analyses requested, gear type, EPA species code, species identification, species length, and species weight. Data form instructions and sample processing methodology is described in the *DSHS Seafood Safety Division Survey Branch Standard Operating Procedures and Quality Control/Assurance Manual* (Appendix A). Sample and species information will be verified and recorded on the *DSHS SSD Fish and Shellfish Tissue Data Form* prior to processing each sample. The individual weighing and measuring the samples will convey this information verbally to the recorder, who will then repeat the values for verification and record the information on the form. This information will also be recorded on the sample storage container by the recorder. A trip report documenting all tissue sample and environmental data, a description of the sampling effort, and maps of the sampling sites will be written for each sampling trip.

The *DSHS SSD Chain-of-Custody Record* (Appendix A) will serve as the shipment tracking record and chain of custody record for tissues samples sent to the GERG Laboratory. The GERG Laboratory will log in tissue samples following procedures outlined in the *Geochemical and Environmental Research Group Texas A&M University Quality Assurance Project Plan* (Appendix C).

Laboratory reports, as detailed in Section C2 of this QAPP, will be completed by the GERG Laboratory and delivered to the DSHS via U.S. mail transmitted electronically via email to the DSHS Field Supervisor and Data Manager. The GERG personnel will follow procedures

outlined in the *Geochemical and Environmental Research Group Texas A&M University Quality Assurance Project Plan* (Appendix C).

The DSHS will enter data from the laboratory reports and data recorded on the *DSHS SSD Fish and Shellfish Tissue Data Form* into Microsoft Excel data tables and convert to ASCII (DOS) pipe-delimited files for uploading to the TRACS database, as described in the TCEQ Data Management Guide (DMRG 2003) (http://www.tnrcc.state.tx.us/water/quality/data/wqm/wdma/dmrg/2003dmrg_ch7.pdf). Prior to submitting properly formatted datasets to the TCEQ Project Manager, the DSHS Data Manager will request unique TCEQ Tag numbers for association with the quantitative risk characterization data for each reservoir or river. The DSHS will submit the data tables electronically to the TCEQ.

The DSHS will develop a quantitative risk characterization that will include a background and statement of issues, methods, results, discussion, conclusions, recommendations, risk communication, and references sections. The DSHS will make the appropriate risk management decisions based on the recommendations of the quantitative risk characterization.

Record retention for written copies of the review forms, final report, trip reports, progress reports, *GERG Laboratory Report Forms*, Chain of custody records, *DSHS SSD Fish and Shellfish Tissue Data Forms* (Appendix A), and the final quantitative risk characterization will comply with both DSHS and TCEQ retention schedules. The DSHS will retain all written formats and electronic files at DSHS in Austin, Texas for a minimum of ten years after completion of the project. The TCEQ will retain electronic and written and electronic copies of status reports, quantitative risk characterizations, documentation for any fish consumption advisory or aquatic life order (closure) issued, and the fish tissue data tables for a minimum period of ten years.

Document Retention

The documents that describe, specify, report, or certify activities, requirements, procedures, or results for this project and the items and materials that furnish objective evidence of the quality of items or activities are listed in Table A.3.

Table A.3. Document and Record Retention

Document/Record	Location	Retention	Form
QAPP, amendments, and appendices	TPWD	4 years	Paper
QAPP distribution documentation	TPWD	4 years	Paper
Field SOPs	TPWD	4 years	Paper
Field corrective action documentation	TPWD	4 years	Paper
Field data sheets	TPWD Lab	4 yearsPaper	
Chain of custody records	TPWD Lab	4 yearsPaper	
Laboratory sample reception logs	TPWD Lab	4 years	Paper
Laboratory QA manuals	TPWD Lab	4 years	Paper
Laboratory SOPs	TPWD Lab	4 years	Paper
Laboratory internal/external standards	TPWD Lab	4 years	Paper
Laboratory instrument performance	TPWD Lab	4 years	Paper
Laboratory initial demonstration of capability	TPWD Lab	4 years	Paper
Laboratory procedures	TPWD Lab	4 years	Paper
Instrument raw data files	TPWD Lab	4 years	Paper/Electronic
Instrument readings/printouts	TPWD Lab	4 years	Paper
Laboratory data reports	TPWD Lab	4 years	Paper
Laboratory data verification for integrity, precision, accuracy and validation	TPWD Lab	4 years	Paper
Laboratory equipment maintenance logs	TPWD Lab	4 years	Paper
Laboratory calibration records	TPWD Lab	4 years	Paper/Electronic
Laboratory corrective action documentation	TPWD Lab	4 years	Paper
TPWD data verification/validation	TPWD Lab	4 years	Paper/Electronic*
TCEQ data files	TCEQ	4 years	Electronic*

*Electronic files should be ASCII (DOS) pipe delimited text files.

II. Data Generation and Acquisition

B1 Sampling Process Design

DSHS fish and shellfish tissue study design procedures (i.e. study objectives, site selection, target species and size class selection, sample type, target analyte selection, sampling times, and sample sizes) are described in detail in the *DSHS Seafood Safety Division Survey Branch Standard Operating Procedures and Quality Control/Assurance Manual* (Appendix A). For this project the DSHS field personnel will collect thirty (30) fish tissue samples of individual established target species from each water body identified through Tier 1 screening and/or other water bodies designated by TCEQ. The GERG Laboratory Texas A&M University in College Station, Texas will conduct the fish tissue chemical contaminant analyses. The GERG Laboratory will complete the following analyses, as designated by DSHS: metals, pesticides, PCBs, SVOCs, and VOCs.

B2 Sampling Methods

A Scientific Collection Permit is required from the TPWD to use electrofishing equipment, gill nets, and trap nets as collection devices. The DSHS SSD has been issued Scientific Permit Number SPR-0890-247.

The DSHS will measure air temperature, water temperature, specific conductance, salinity, and pH at each sample collection site using a Hydrolab Scout with a H20 sonde in °C, °C, µS/cm, ppt, and pH units (0.0-14), respectively.

The DSHS will collect fish tissue samples using electrofishing equipment, gill nets, trap nets, and if needed hook and line. DSHS sample collection methods are described in detail in the *DSHS Seafood Safety Division Survey Branch Standard Operating Procedures and Quality Control/Assurance Manual* (Appendix A).

The DSHS Field Supervisor and Data Manager is responsible for ensuring all field sampling activities comply with methods outlined in this QAPP and documenting any corrective actions that occurred and for determining and documenting that the corrective actions were effective.

B3 Sample Handling and Custody

The DSHS will process, handle, and store all fish tissue samples according to the procedures described in the *DSHS Seafood Safety Division Survey Branch Standard Operating Procedures and Quality Control/Assurance Manual* (Appendix A).

The DSHS will maintain fish tissue sample chain of custody and adhere to standard fish tissue sample shipping procedures described in the *DSHS Seafood Safety Division Survey Branch Standard Operating Procedures and Quality Control/Assurance Manual* (Appendix A).

B4 Analytical Methods

The GERG Laboratory analytical methods, techniques and detection limits for all contaminants are described in the *Geochemical and Environmental Research Group Texas A&M University Quality Assurance Project Plan* (Appendix C) *and DSHS Seafood Safety Division Survey Branch Standard Operating Procedures and Quality Control/Assurance Manual* (Appendix A). The GERG Laboratory Deputy Program Manager and QA Manager are responsible for documenting that corrective actions have occurred and that the actions were effective for their laboratory.

B5 Quality Control

Quality control procedures for DSHS fish tissue collection activities are outlined in *DSHS Seafood Safety Division Survey Branch Standard Operating Procedures and Quality Control/Assurance Manual* (Appendix A).

Quality control procedures for the GERG Laboratory fish tissue chemical contaminant analyses are outlined in the *Geochemical and Environmental Research Group Texas A&M University Quality Assurance Project Plan* (Appendix C)

B6 Instrument/Equipment Testing, Inspection, and Maintenance

Testing, inspection, and maintenance for DSHS instruments (i.e. Hydrolab Scout) and sampling equipment (i.e. boats, trailers, outboard motors, electofishing equipment, gill nets, trap nets) are inspected and tested prior to sample collection. Instrument and sampling equipment maintenance is documented in the *DSHS SSD Survey Branch Equipment Use and Maintenance Logbook.*

Testing, inspection, and maintenance for GERG Laboratory Equipment are outlined in *Geochemical and Environmental Research Group Texas A&M University Quality Assurance Project Plan* (Appendix C)

B7 Instrument/Equipment Calibration and Frequency

DSHS SSD field calibrations for the Hydrolab Scout are performed prior to and immediately following sampling and recorded on the *DSHS SSD Fish and Shellfish Tissue Collection Data Form* (Appendix A). These data are not critical to the success of this project and will not be loaded to TRACS. However, any deviations from the described procedures will be noted and required maintenance conducted.

GERG Laboratory instrument calibration and frequency for analytical analyses is outlined in the *Geochemical and Environmental Research Group Texas A&M University Quality Assurance Project Plan* (Appendix C).

B8 Inspection / Acceptance of Supplies and Consumables

The DSHS uses the following consumable supplies: heavy-duty aluminum foil, Ziploc® freezer bags, and de-ionized water. Only clean, unused aluminum foil and freezer bags will be used when preparing fish tissue samples. It is the responsibility of the DSHS staff to purchase, inspect, and properly store all consumable items in a clean environment and determine whether the item(s) are usable.

The GERG Laboratory procedures for the inspection and acceptance of supplies and consumables are described in the *Geochemical and Environmental Research Group Texas A&M University Quality Assurance Project Plan* (Appendix C).

B9 Non-direct Measurements

Only data collected or acquired under this QAPP will be submitted to the SWQM portion of the TRACS database. Any non-direct measurement data submitted to TRACS would be done so through a separate QAPP. Data will be validated using procedures listed in the SWQM DMRG (2003). There will be no sampling conducted by anyone other than DSHS.

All available data will be compiled in Microsoft Excel and data formats specified by the TCEQ for efficient uploading of data to the TRACS database. The DSHS Field Supervisor and Data Manager will determine and document that all non-measurement data collected, processed, analyzed, and qualified following procedures similar to DSHS procedures described by the *DSHS Seafood Safety Division Survey Branch Standard Operating Procedures and Quality Control/Assurance Manual* (Appendix A).

B10 Data Management

Field sample collection data requirements and documentation (section A9) and data management procedures are described in the *DSHS Seafood Safety Division Survey Branch Standard Operating Procedures and Quality Control/Assurance Manual* (Appendix A). All required fish tissue sample data observed and measured will be conveyed verbally to the data recorder, who then repeats the values for verification. DSHS staff will enter field collection data into a Microsoft Excel fish tissue table and convert to ASCII (DOS) pipe-delimited files for uploading of data to the TRACS database. The groomed data are then transmitted to the TCEQ Project Manager, per the requirements in the DMRG (2003). Field sample collection data entry quality control procedures are described in the *DSHS Seafood Safety Division Survey Branch Standard Operating Procedures and Quality Control/Assurance Manual* (Appendix A).

The DSHS will transfer tissue sample numbers and species to the *DSHS SSD Chain-of Custody Record.* The *DSHS SSD Chain-of Custody Record* and corresponding tissue samples will be shipped to the GERG Laboratory for specified chemical contaminant analyses. Tissue sample shipping instructions and chain of custody procedures are outlined in the *DSHS Seafood Safety Division Survey Branch Standard Operating Procedures and Quality Control/Assurance Manual* (Appendix A). The GERG Laboratory will log in and track all relinquished tissue samples. The

GERG Laboratory data reduction, review and validation, and reporting procedures are described in *Geochemical and Environmental Research Group Texas A&M University Quality Assurance Project Plan* (Appendix C)

The GERG Laboratory will produce laboratory analysis reports on paper containing specified chemical contaminant analyses results for each sample (Section A9). The GERG Laboratory will send these reports through U.S. mail and transmit reports electronically via email to the DSHS Field Supervisor and Data Manager.

The DSHS staff will enter chemical contaminant laboratory analysis data into a Microsoft Excel fish tissue table and convert to data formats specified by the TCEQ for efficient uploading of data to the TRACS database. Chemical contaminant laboratory analysis data entry quality control procedures are described in the *DSHS Seafood Safety Division Survey Branch Standard Operating Procedures and Quality Control/Assurance Manual* (Appendix A). The DSHS Field Supervisor and Data Manager will transfer the Microsoft Excel fish tissue table to the DSHS Toxicologist for quantitative risk characterization preparation.

The DSHS will transmit properly formatted data electronically via email to the TCEQ Project Manager as described in the TCEQ *Data Review Checklist* (Appendix D).

Summary of Data Flow

Field and laboratory data will be verified by the DSHS QA Manager prior to the DSHS Data Manager sending the properly formatted dataset, with Data Review Checklist (Appendix D), to the TCEQ Project Manager. The TCEQ Project Manager will review data and Checklist and send back to DSHS, if necessary, or forward to the TCEQ MDM&A Data Manager for uploading to TRACS.

III. Assessment and Oversight

C1 Assessments and Response Actions

The DSHS Field Supervisor and Data Manager will be responsible for assuring all DSHS SSD Survey Branch standard operating and quality control/assurance procedures (Appendix A) are followed and that all fish tissue samples collected meet the criteria outlined by these procedures. If the DSHS Field Supervisor and Data Manager determines that fish tissue samples do not meet criteria of the DSHS SSD Survey Branch standard operating and quality control/assurance procedures, DSHS will discard the tissue samples and collect additional tissue samples that meet criteria outlined by the DSHS SSD Survey Branch standard operating and quality control/assurance procedures (Appendix A). DSHS will not submit any fish tissue sample that does not meet target species criteria. The DSHS Field Supervisor and Data Manager is responsible for ensuring all field sampling activities comply with methods outlined in this QAPP and documenting any corrective actions that occurred and for determining and documenting that the corrective actions were effective.

The *Geochemical and Environmental Research Group Texas A&M University Quality Assurance Project Plan* (Appendix C) addresses the following laboratory assessments: QC parameters, analytical instrument performance checks, calibration verifications, and response actions. If a response action is necessary the GERG Deputy Program Manager and QA Manager, in consultation with the DSHS Project manager, will determine the corrective action. The GERG Deputy Program Manager and QA Manager will be responsible for implementing any necessary corrective actions. The GERG Deputy Program Manager and QA Manager will document that corrective actions have occurred and that the actions were effective.

C2 Reports to Management

Status Reports
The DSHS Field Supervisor and Data Manager will update DSHS and TCEQ project managers on the general status of the project activities on a regular basis and any time that significant problems arise. These updates will be informal and can be communicated by telephone and/or by email.

Trip Report(s)

Preparer: DSHS Environmental Specialist

Recipient: DSHS Field Supervisor / Data Manager, DSHS Project Manager and DSHS Principal Investigator

The DSHS Environmental Specialist will write a report for each sampling trip to document information detailed in A9 of this QAPP.

Laboratory Reports

Preparer: GERG Laboratory

Recipient: DSHS Field Supervisor / Data Manager

The GERG Program Manager or Deputy Program Manager will send via U.S. mail laboratory reports for each fish tissue sample to the DSHS Field Supervisor and Data Manager. Individual fish tissue sample laboratory reports will also be transmitted electronically via email to the DSHS Field Supervisor and Data Manager.

Quarterly Progress Reports

Preparer: DSHS Field Supervisor / Data Manager

Recipient: TCEQ Project Manager

The DSHS Field Supervisor / Data Manager will provide quarterly

reports, in electronic or written format, of sampling and laboratory progress.

Risk Assessment

Preparer: DSHS Toxicologist(s) & DSHS Field Supervisor / Data Manager

Recipient / Reviewer: DSHS Project Manager and Principal Investigator

The DSHS Toxicologist(s) develop a quantitative risk characterization that accurately reflects the theoretical health risks associated with consumption of fish from designated Texas water bodies. DSHS risk managers will use conclusions and recommendations of the quantitative risk characterization to implement the appropriate risk management decisions.

IV. Data Validation and Usability

D1 Data Review, Validation, and Verification

The DSHS data review, validation, and verification methods are outlined in the *DSHS Seafood Safety Division Survey Branch Standard Operating Procedures and Quality Control/Assurance Manual* (Appendix A).

The GERG Laboratory data review, validation, and verification methods are outlined in the *Geochemical and Environmental Research Group Texas A&M University Quality Assurance Project Plan* (Appendix C).

Only data reviewed, validated, and verified by the appropriate quality control that meet project data quality objectives will be acceptable (Table D1).

D2 Verification and Validation Methods

All data will be verified to ensure they are representative of the samples analyzed and locations where measurements were made, and that the data and associated quality control data conform to project specifications. The staff and management of the respective field, laboratory, and data management tasks are responsible for the integrity, validation and verification of the data each task generates or handles throughout each process. The field and laboratory tasks ensure the verification of raw data, electronically generated data, and data on chain-of-custody forms and hard copy output from instruments.

Verification, validation and integrity review of data will be performed using self-assessments and peer review, as appropriate to the project task, followed by technical review by the manager responsible for the task. The data to be verified are evaluated against project specifications (Section A7) and are checked for errors, especially errors in transcription, calculations, and data

input. Potential outliers are identified by examination for unreasonable data, or identified using computer-based statistical software. If a question arises or an error or potential outlier is identified, the manager responsible for the task generating the data is contacted to resolve the issue. Issues which can be corrected are corrected and documented electronically or by initialing and dating the associated paperwork. If an issue cannot be corrected, the task manager consults with higher level project management to establish the appropriate course of action, or the data associated with the issue are rejected. The performance of these tasks is documented by completion of the data review checklist by the DSHS Data Manager.

The DSHS Project Manager and QAO are each responsible for validating that the verified data are scientifically valid, defensible, of known precision, accuracy, integrity, meet the data quality objectives of the project, and are reportable to TCEQ. One element of the validation process involves evaluating the data again for anomalies. The DSHS QAO or Project Manager may designate other experienced fish tissue analysts familiar with the water bodies under investigation to perform this evaluation. Any suspected errors or anomalous data must be addressed by the manager of the task associated with the data, before data validation can be completed.

A second element of the validation process is consideration of any findings identified during the monitoring systems audit conducted by the TCEQ QAS assigned to the project. Any issues requiring corrective action must be addressed, and the potential impact of these issues on previously collected data will be assessed. Finally, the DSHS Project Manager, with the concurrence of the QAO validates that the data meet the data quality objectives of the project and are suitable for reporting to TCEQ.

The DSHS verification and validation methods are outlined in the *DSHS Seafood Safety Division Survey Branch Standard Operating Procedures and Quality Control/Assurance Manual* (Appendix A).

The GERG Laboratory verification and validation methods are outlined in the *Geochemical and Environmental Research Group Texas A&M University Quality Assurance Project Plan* (Appendix C).

D3 Reconciliation with User Requirements

Field Generated Data

The DSHS data quality control procedures are outlined in the *DSHS Seafood Safety Division Survey Branch Standard Operating Procedures and Quality Control/Assurance Manual* (Appendix A) and preceding sections of this QAPP. The DSHS QA Officer and Field Supervisor/Data Manager will review all field-generated data to ensure that all standard operating procedures are followed. If corrective action is warranted tissue sample(s) may be discarded and new samples collected.

Laboratory Generated Data

The GERG Laboratory follows standard operating and quality control procedures outlined in a quality assurance project plan and SOPs developed for their laboratory (Appendix C). The GERG Deputy Program Manager and QA Manager will review analytical data generated from

their laboratory to verify that analytical data meets all established laboratory quality objectives. Only data that meets the laboratory quality objectives will be utilized in the risk assessment.

Risk Assessment

The DSHS Toxicologist will prepare a quantitative risk characterization from data reconciled with the data quality objectives of this QAPP. Another DSHS toxicologist, DSHS SSD Principal Investigator, Project Manager and Field Supervisor/Data Manager will review the quantitative risk characterization to ensure its conclusions are acceptable. A draft quantitative risk characterization will be forwarded to TCEQ for review. Any comments from this review will be considered and a final quantitative risk characterization submitted to TCEQ.

Table D1. Data Verification Procedures

Data to be Verified	Field Task	Laboratory Task	Database (or DSHS Data Manager) Task
Sample documentation complete; samples labeled, sites identified	U	U	U
Field QC samples collected for all analytes as prescribed in the TCEQ SWQM Procedures Manual	U		U
Standards and reagents traceable	U	U	
Chain of custody complete/acceptable	U	U	
Sample preservation and handling acceptable	U	U	
Holding times not exceeded	U	U	
Collection, preparation and analysis techniques consistent with SOPs and QAPP	U	U	U
Field documentation (e.g. biological, stream habitat) complete	U		

Data to be Verified	Field Task	Laboratory Task	Database (or DSHS Data Manager) Task
Instrument calibration data complete	U	U	
QC samples analyzed at required frequencies	U	U	U
QC results meet performance and program specifications	U	U	U
Analytical sensitivity (AWRLs or RL) consistent with QAPP		U	U
Results, calculations, transcriptions checked	U	U	
Laboratory bench-level review performed		U	
All laboratory samples analyzed for all parameters		U	
Corollary data agree	U	U	U
Nonconforming activities documented	U	U	U
Outliers confirmed and documented; reasonableness check performed	U	U	U
Dates formatted correctly	U	U	U
Depth reported correctly	U		U
TAG IDs correct			U
TCEQ Station ID number assigned			U
Valid parameter codes			U
Source codes 1and 2 and program codes used correctly			U
Time based on 24-hour clock	U	U	U
Absence of transcription error confirmed	U	U	U
Absence of electronic submittal errors confirmed	U	U	U
Sampling and analytical data gaps checked (e.g., all sites for which data are reported are on the monitoring schedule)	U	U	U

Data to be Verified	Field Task	Laboratory Task	Database (or DSHS Data Manager) Task
Field QC results attached to data review checklist			U
Verified data log submitted			U
10% of the data have been manually reviewed			U

Appendix A

DSHS Seafood Safety Division Survey Branch Standard Operating Procedures and Quality Control/Assurance Manual

Appendix B

Geochemical and Environmental Research Group Texas A&M University Quality Assurance Management Plan (QAMP)

GERG Manual-9201

Quality Assurance Management Plan (QAMP)

for the

Geochemical and Environmental Research Group
Texas A&M University
833 Graham Road
College Station, TX 77845
(409) 862-2323

"A Plan for Excellence and Quality in Applied Geosciences"

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FOREWORD

The following document describes elements of the Quality Assurance (QA) and Quality Control (QC) system utilized by the Geochemical and Environmental Research Group (GERG) of the College of Geosciences at Texas A&M University to ensure that quality and performance standards are met. These standards ensure that the research, services, and data produced are of the appropriate type and quality for the intended programmatic use. These standards are the framework used to create detailed Quality Assurance Project Plans (QAPPs) or other planning documents. The QA objectives of each project are tailored to each client's needs while maintaining the flexibility needed to respond to diverse programs, and at the same time, allowing for innovation. While it is recognized that each individual program/project will have independent QA/QC requirements that are not always at the same level of detail, it is the intention of management that the spirit of this Quality Assurance Management Plan be implemented for all organizational activities.

Dr. Mahlon C. Kennicutt II, Director
Geochemical and Environmental Research Group

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Geochemical and Environmental Research Group
QUALITY ASSURANCE MANAGEMENT PLAN

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1.0 QUALITY ASSURANCE POLICY

1.1 Introduction

The commitment of the management of the Geochemical and Environmental Research Group (GERG) to excellence in the work place and to the highest quality for all organizational activities is reflected in the organizational mission statement.

Mission Statement

The Geochemical and Environmental Research Group serves the University and the State in matters pertaining to science and the environment. We support the mission of the College of Geosciences through an emphasis on applied geosciences research. Regionally, nationally, and globally we strive to serve by linking academic education and research in our College and in our University to the real-world needs of government and industry. As a team, we value initiative, innovation, and performance. We take pride in our flexible, state-of-the-art capabilities for research, analyses, and monitoring. We recognize that continued excellence in this area requires our personal commitment at every level of training and experience.

This Quality Assurance Management Plan (QAMP) has been developed in recognition of the need for highly reliable research and services. Application of the principles in the QAMP aid in ensuring that appropriate standards of quality and performance are achieved and maintained while complying with all contract requirements.

It is the policy of GERG to conduct and carryout activities in accordance with, or in the spirit of, this Quality Assurance Management Plan (QAMP). The QAMP serves as guidance for developing the Generic Quality Assurance Manual (GQAM) for Laboratory Staff and Operations, Quality Assurance Project Plans (QAPPs), implementation procedures, and other planning documents. These documents support GERG's management philosophy that emphasizes the importance of quality in carrying out all work-related activities in a consistent and professional manner.

Quality assurance (QA) involves all of the planned and systematic actions necessary to provide confidence that the work performed conforms to the applicable contract specifications, regulatory requirements, and state/national codes. Quality assurance encompasses quality control (QC) which involves the examination of work performed in the context of the standards agreed upon for those activities.

GERG management provides an environment that encourages and requires employees to adhere to QA/QC principles, and is responsible for ensuring that adequate resources are available

to implement the QA/QC system. The formal recognition of quality goals aids in ensuring that the requirements of our clients are met. Both the management and staff of GERG are committed to fostering the highest quality performance, continuous improvement, and excellence in the work place.

Each project is commonly conducted under a detailed written plan. This plan can take the form of a Quality Assurance Project Plan (QAPP) or other planning documents that include, but are not limited to, proposals, requests for proposals, contracts, and grants.

1.2 Statement of Authority

The QA Manager, in consultation with the Director, Senior Associate Director, and Program Managers, has the authority and responsibility for preparation and revision of this QAMP and the wherewithal to ensure organizational compliance. Within the management structure of GERG, the Quality Assurance (QA) Manager is responsible for all issues and matters related to quality assurance. The QA Manager monitors and directs the quality effort and is independent of Project Management.

The QA Manager shall identify quality problems and initiate, recommend, and provide solutions to remedy such problems. Any QA/QC disagreements are resolved by the Director or the Senior Associate Director of GERG in accordance with the policy set out in this QAMP and applicable contract and regulatory requirements. Projects/programs require a wide range of QA/QC activities and may not always require the level of documentation described in the QAMP, but the spirit of the QAMP is followed for all organizational activities.

Dr. Mahlon C. Kennicutt II	Grace E. Ekman
Director	QA Manager

1.3 Organization

The organizational structure of GERG is provided in Figure 1.0. The Director, Senior Associate Director, and Deputy Directors constitute the Senior Management Team (See Table 1.0). The immediate day-to-day supervision of operations is accomplished by Managers. All issues related to QA/QC are the responsibility of the QA Manager who reports to the Senior Associate Director.

Qualified staff are assigned to project management teams as needed. Project management teams are assembled to meet project requirements and their functions are detailed in individual Quality Assurance Project Plans or other planning documents. Job titles from the GERG organizational structure have some overlap with project specific responsibilities but should not be confused. GERG personnel fulfill different functions in different projects as needed. Typical functions of the senior management are provided in the following sections.

- **Director**

The Director of GERG reports to the Dean of the College of Geosciences at Texas A&M University and is responsible for:

- *establishing and documenting the roles and responsibilities of GERG personnel in consultation with the Senior Management Team and College Administration;*

- *facilitating internal and external personnel interactions;*

- *facilitating the implementation and spirit of the Quality Assurance Management Plan (QAMP) and approving such QA documents as required;*

- *facilitating auditing of organizational activities as needed;*

- *approving the funding for each project; and,*

- *facilitating self-assessment programs.*

- **Senior Associate Director**

The Financial Manager reports to the Director of GERG and is responsible for:

- *developing and supervising implementation of financial instruments, policies, and procedures required to support the Director in the sound management of financial, facilities, human resources, and computer systems at GERG;*

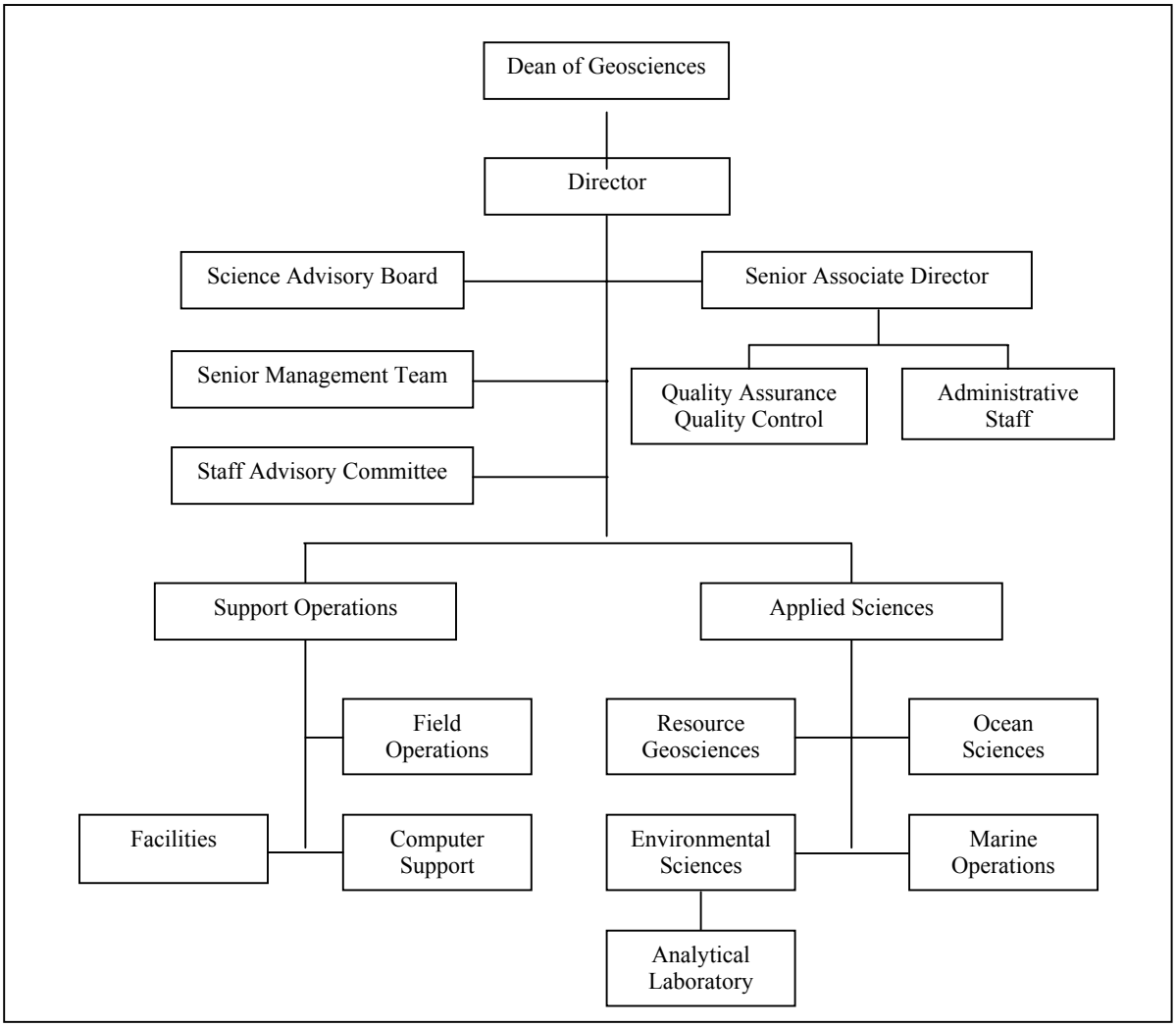

Figure 1.0. Geochemical and Environmental Research Group

Table 1.0. The Charge to the Senior Management Team.

To increase communication and provide an avenue for input to the Director regarding management decisions, a Senior Management Team has been formed. The Senior Management Team consists of the Director, the Senior Associate Director, and Deputy Directors. The Senior Management Team meets at least once a month and more frequently as warranted. The charge to the Team is to provide the Director advice on all areas of the operation and management of the organization. The role of the Senior Management Team is advisory. The members of the Team are tasked with providing an assessment of the opinions of all staff under their supervision regarding any issues under consideration.

The purposes of Senior Management Team meetings are: 1) to ensure that senior management is informed of all organizational activities, 2) provide a forum to coordinate cross-group resources and/or requirements, and 3) to advise the Director and to assist in the development of priorities for the organization. It is also a forum to resolve conflicts, discuss problems, air solutions, and to clarify policies and procedures as needed. The Team members are responsible for communicating the deliberations of the Team to the staff under their supervision.

- *advising the Director and Senior Management Team on program planning through analysis of financial performance and by the provision of strategic and tactical financial information, assessments, and projections;*

- *collection of all financial data and maintenance of records needed to monitor and maintain the fiscal stability of the organization, ensuring the use of a cost allocation system appropriate to project management and to the GERG organization as a whole;*

- *supervising the preparation of all financial budgets and reports both for use within GERG and for submission to the College on a monthly, annual, and as-needed basis;*

- *collaborating with Project Managers, overseeing the preparation of fully-costed program bids, and working closely with Project Managers to ensure sound financial performance of individual programs;*

- *overseeing contracting and purchasing; human resources and payroll; financial reporting and accounting; facilities management and maintenance; computer systems and operations;*

- *ensuring that the QA and safety requirements of this document are supported and reflected in all planning, investigative, analytical, and reporting activities; and,*

- *supporting the Director's accountability to the College and acting as liaison between GERG and Texas A&M Research Foundation, Texas A&M University, and Texas Engineering Experiment Station on all financial, administrative, and facilities matters.*

- **Deputy Directors**

Deputy Directors report to the Director of GERG and are responsible for:

- *ensuring that the QA requirements of this document are reflected in all planning, investigative, analytical, and reporting activities;*

- *assigning qualified team members to projects and providing an interface between the Director and the staff;*

- *submitting the appropriate documents to the QA Manager for comment, such as activity-specific Quality Assurance Project Plans, work plans, and investigative reports; and,*

- *implementing cost-effective quality improvements.*

- **QA Manager**

The QA Manager reports to the Senior Associate Director of GERG and is responsible for:

- *formulating and directing the QA/QC program, including its maintenance and continuous improvement;*

- *evaluating the effectiveness of the QA/QC program through audits and review;*

- *advising the Senior Management Team on QA/QC matters;*

- *coordinating, preparing, approving, and revising QA/QC and safety documents such as the QA Management Plan, the Generic Quality Assurance Manual (GQAM) and standard operating procedures (SOPs), GERG safety guidelines, implementation instructions, and appropriate standards in support of programs and projects;*

- *ensuring that QA/QC and safety training and awareness is established;*

- *ensuring that nonconformances are tracked, that a corrective action system is in place, and assisting in the resolution of quality problems; and,*

- *evaluating the QA/QC programs of subcontractors for conformances to GERG requirements*.

The QA Manager formulates and directs the QA program and has sufficient personnel, authority, access to work areas, and organizational freedom to:

- *verify implementation of the QA program;*

- *identify problems;*

- *identify, recommend, and provide solutions to problems;*

- *verify implementation of solutions;*

- *in cases where unsatisfactory conditions are discovered, ensure that further processing, delivery, installation, or use of the affected item or service is controlled until proper disposition can be made; and*

- *stop work when the severity of conditions adverse to quality are detected and warrant immediate action.*

- **Managers**

Managers report to the appropriate Deputy Director. The Managers are responsible for:

- *ensuring the QA/QC system is fully implemented;*

- *ensuring that applicable data quality objectives are met;*

- *ensuring that standard operating procedures (SOPs) and QAPPs are followed;*

- *ensuring that continuous quality is implemented, and that quality control issues and problems are promptly identified and corrected;*

- *interfacing with laboratory QC personnel and the QA Manager on all quality-related matters;*

- *implementing training plans by assessing training needs, scheduling necessary training, and ensuring that training is completed and documented; and,*

- *initiating stop-work actions when the severity of conditions adverse to quality warrants immediate action.*

2.0 QUALITY ASSURANCE/QUALITY CONTROL PROGRAM REQUIREMENTS, RESPONSIBILITIES, AND PROCEDURES

2.1 Purpose

This section of the Quality Assurance Management Plan (QAMP) provides guidance for developing controls and procedures that are used by GERG personnel to document and implement quality assurance and quality control policies and procedures. The Quality Assurance Management Plan is a blueprint to establish a quality assurance program that provides a planned and disciplined approach to achieving the highest quality research products, services, and data.

2.2 General Requirements

- The Quality Assurance Management Plan (QAMP) applies to all organizational activities.

- The QAMP is annually reviewed and revised as needed by the QA Manager and GERG's Senior Management Team.

- Where appropriate, all project activities performed by GERG personnel are described in written procedures that are used to conduct specific project activities.

- Project specific Quality Assurance Project Plans (QAPPs) and other planning documents are prepared prior to project initiation.

- Personnel are properly and adequately trained and this training is documented.

- Written policies have been developed for personnel training; production and storage of records related to personnel and projects; personnel qualifications; and methods used for periodic assessment of the quality assurance system.

2.3 Responsibility

Management is responsible for:

- Implementing and maintaining procedures that comply with applicable requirements of the Quality Assurance Management Program.

- Ensuring that tasks are performed in accordance with approved procedures and initiating improvements to such procedures when beneficial to data quality objectives or the organization as a whole.

- Ensuring that the necessary personnel orientation and training is provided to ensure compliance with existing, new, or revised procedures.

The Quality Assurance (QA) Manager is responsible for all issues and matters related to quality assurance. The QA Manager monitors and directs the quality effort. The QA Manager is specifically responsible for:

- Establishing, revising, approving and maintaining the GERG Quality Assurance Management Plan (QAMP) and the Generic Quality Assurance Manual (GQAM).

- Providing guidance for Quality Assurance Project Plans (QAPPs), as well as coordinating or initiating the preparation of Standard Operating Procedures (SOPs) and other QA/QC documents.

- Reviewing and approving quality related procedures or documents prepared by GERG personnel or received from other organizations to ensure that appropriate quality requirements are incorporated. This includes review and approval of external SOPs or QAPPs as required.

2.4 Procedure

- Activities are conducted in accordance with procedures that provide detailed information on the performance of the activity. The basis of these procedures are documents that describe each activity, i.e., standard operation procedures (SOPs).

- Training programs are integral to this process and include such subjects as the Generic Quality Assurance Manual (GQAM), Quality Assurance Project Plans, Standard Operating Procedures, Health and Safety Issues, and generally accepted good laboratory practices.

- The overall quality assurance program is reviewed at least once per year. The review is a management assessment of the effectiveness of the program and is accomplished by one or more of the following:

- An assessment by the QA Manager including such things as review of quality problems and their underlying causes, analysis of trends, review of other assessment actions such as audits, external calibrations, and corrective action status. This assessment is presented in a written report by the QA Manager to the Director and Senior Associate Director for review.

- Internal audits or management assessments may be directly ordered by the Director and Senior Associate Director to assess particular aspects of the program's effectiveness.

- External experts may be contracted to provide an assessment as necessary.

3.0 PERSONNEL QUALIFICATIONS AND DEMONSTRATION OF TRAINING

3.1 Purpose

This section describes training activities that are conducted to ensure that personnel are qualified to perform their assigned tasks. This training includes on the job training, internal classes/workshops, University classes, and external classes/workshops.

3.2 General Requirements

- All personnel must be proficient to perform the work required within the stated data quality objectives.

- Appropriate training is provided and documented to demonstrate proficiency in the assigned tasks.

- When job requirements change, the needs for re-training are evaluated.

3.3 Responsibility

Training is viewed as an important and integral responsibility of management:

- Management provides the resources for training and re-training.

- Employee training records are reviewed for adequacy before assignment to a project.

3.4 Procedure

- Managers undertake area specific training of new employees or assign qualified personnel to do so.

- General safety training is provided by the QA Manager, who also initiates quality related training and the training documentation needed for each employee.

- Employee performance is supervised and evaluated by a review of quality control activities or job specific requirements.

- An employee is deemed qualified by the immediate Manager by signing a descriptive statement of employee skills such as the Proficiency Orientation Checklist (POC) which is maintained in the employee's permanent training record.

4.0 PROCUREMENT OF ITEMS AND SERVICES

4.1 Purpose

The purpose of this section is to ensure procurement of items and services of adequate quality to implement the technical and quality objectives of each program.

4.2 General Requirements

- Procurement documents require suppliers to demonstrate a consistency with all appropriate standards.

- The procurement process is documented and controlled by the Purchasing Agent.

- Procured items and services conform to established specifications.

4.3 Responsibility

- Management is responsible for the quality of work performed or the items and services provided by its subcontractors and suppliers.

- Management is responsible for selection and specification of materials, instrumentation and equipment in keeping with the data quality objectives required for an activity.

- Quality issues concerning subcontractors should be reviewed by the QA Manager.

4.4 Procedure

- Management evaluates evidence of quality provided by suppliers.
- Reports of compliance with equivalency to QA standards are reviewed by the QA Manager.
- Deliverables are routinely inspected and documented as acceptable.

5.0 QUALITY DOCUMENTS AND RECORDS

5.1 Purpose

This section provides an overview of activities which affect quality and are detailed in written documents to ensure that the correct procedures are used for all tasks.

5.2 General Requirements

Documents or changes to documents which specify quality requirements or prescribe activities affecting quality are reviewed for adequacy, approved for release by the QA Manager and may be controlled to assure that the correct procedures are being used for each project.

5.3 Responsibility

- The management staff or the QA Manager designates the individuals responsible for preparing new or revised QAPPs or SOPs when required. After initial preparation and review, the designated individual provides such documents to the QA Manager in a timely fashion for review and final approval.
- The QA Manager may initiate revisions of existing manuals, quality-related documents, and new or revised SOPs. The QA manager is then responsible for coordinating the required reviews prior to providing final approval of such new or revised documents.
- The QA Manager is responsible for ensuring that quality related documents are consistent with QA and QC objectives for a specific activity. Control over the issuing, receipt, and storage of such documents including instructions, procedures, and illustrations is the responsibility of the QA Manager.

- Management personnel involved in document control are responsible for establishing and implementing procedures that describe the document control system in coordination with and with the approval of the QA Manager.

5.4 Procedure

- Standard operating procedures are provided that describe the review, approval, distribution, and revision of manuals, proposals, QAPPs and SOPs.

- Quality related documents are reviewed and approved by the QA Manager and by the Director, if required. The review of a given document may encompass comparison of the document to applicable contracts and applicable quality assurance guidelines.

- After review comments are resolved, document approvals are indicated in accordance with existing document control procedures. Document control procedures include a central document archive, a system of consecutive revision assignments, authorized signatures, and may include tracking the distribution of controlled items.

- Approved documents are issued to recipients designated by the QA Manager and/or a Program Manager.

6.0 USE OF COMPUTER SOFTWARE AND HARDWARE

6.1 Purpose

The purpose of this section is to ensure that the computer hardware and software utilized meet programmatic requirements. Changes in both hardware and software must be evaluated to assess the impact on system performance.

6.2 Requirements

- Analysts must only use software developed by approved methods.

- Employees must use only appropriately licensed software.

- Programs are independently validated, verified and documented according to the intended use of the software.

6.3 Responsibility

The Systems Manager is responsible for verifying the impact of changes in computer hardware and software.

6.4 Procedure

Computer software is maintained, developed and/or validated in accordance with the Texas A&M Computer Security Policy (Dec. 4, 1994).

7.0 QUALITY IMPLEMENTATION OF WORK PROCESSES

7.1 Purpose

This section provides the guidelines indicating how activities are to be performed in accordance with appropriate instructions, procedures, illustrations, and training requirements. Documents that incorporate controlled conditions for the process and the criteria that are used to judge the acceptability of the process are termed Standard Operating Procedures (SOPs).

7.2 General Requirements

- Written instructions, procedures, and illustrations are developed and approved for the performance of activities that establish or verify the quality of products or processes.

- Written instructions, procedures and illustrations provide directions for activities to be performed under controlled conditions and in proper sequence. They provide the basis for verification and for acceptability based on acceptance criteria that are incorporated into the document, i.e., standard operating procedures (SOPs).

7.3 Responsibility

- Deputy Directors and Managers are responsible for assuring that activities are prescribed and controlled by appropriate training instructions, procedures, and/or illustrations.

- The QA Manager will review applicable documents used to ensure that requirements and procedures are adhered to during all phases of an activity or project.

7.4 Procedure

Procedures are developed and maintained to provide direction on the preparation of instructions, procedures, illustrations, and required training used to control activities affecting quality.

- Management identifies those operations that need SOPs and prepares SOPs in accordance with established procedures.
- SOPs are prepared, reviewed, and verified by technically qualified personnel. All SOPs are coordinated through and approved by the QA Manager before use.
- When appropriate, external expert peer-review is procured.

8.0 QUALITY ASSESSMENT AND RESPONSE

8.1 Purpose

This section describes the system for assessment and documentation of the adequacy of the quality assurance and quality control programs. Assessment and response ensures effective implementation of the program while at the same time, satisfying the technical, administrative and quality objectives of each project.

8.2 General Requirements

- Management controls must be sufficient to ensure the achievement of programmatic quality objectives.
- Adequate resources and trained personnel are provided to assure quality goals are achieved in all activities.

8.3 Responsibility

- The QA Manager has overall responsibility to ensure an effective QA plan is established and implemented.
- Periodic assessment of quality related issues are conducted by the QA Manager.
- When appropriate, external independent experts will be utilized for institutional review.

8.4 Procedure

- Periodic assessment and QA/QC reviews are the responsibility of the QA Manager.
- Quality assurance issues are reported to the QA Manager and may be raised by any employee.

9.0 QUALITY IMPROVEMENT

9.1 Purpose

The purpose of this section is to provide guidelines to prevent and/or detect problems that adversely affect quality during planning, implementation, and assessment of technical and management activities. Management encourages a "no-fault" attitude among personnel and encourages the identification of problems.

9.2 General Requirements

- Continuous quality improvement in technical and management processes is encouraged.
- Measures of performance success and standards of excellence are established.

9.3 Responsibility

- All personnel.

9.4 Procedure

- The Director assures that the appropriate resources are allocated, difficult issues are resolved, and that the employee or client is informed of the resolution of any significant quality-related problems.
- Continuous quality improvement is encouraged by management and all personnel are encouraged to exceed client expectations whenever possible.
- Personnel are encouraged to actively participate in continuous quality improvement by regular meetings, discussions, and open lines of communication between management and personnel.

10.0 PROJECT PLANNING AND OBJECTIVES

10.1 Purpose

The purpose of this section is to establish guidelines to plan, implement, and document projects, thus providing the type and quality of data and services needed for the intended purpose. These guidelines establish the framework for the essential elements of a successful Quality Assurance Project Plan (QAPP) or other planning documents.

10.2 General Requirements

Before initiation, each project plan should include:

- Goals, ultimate information usage, implementation, and the scope of the program clearly defined in a project description.
- Identity of applicable technical, regulatory, or program-specific quality standards, criteria, or objectives.
- Designation of personnel, equipment, and other resources required to perform the program activities.
- Identification of controlled conditions required for collection and analysis of samples and data.
- Specific data to be collected and analyzed, including QA and QC considerations.
- Determination of assessment tools needed, and in particular, if a Quality Assurance Project Plan (QAPP) is appropriate.
- Identification of the standard operating procedures for field and analytical activities, including the mechanism for changing these documents and/or plans.
- Definition of the records and reports that are required.

10.3 Responsibility

- A Program Manager, in consultation with the QA Manager, plans and prepares the technical and quality related descriptions of the program/project.

11.0 DESIGN OF DATA COLLECTION OPERATIONS

11.1 Purpose

The purpose of this section is to establish written instructions or SOPs for the collection, handling, storage, shipping and preservation of materials and equipment that must meet quality control criteria to provide redundancy or to prevent damage, deterioration, contamination or loss. In addition, procedures to define analytical operations, data validation and verification methods, techniques for assessing limitations on data usage, and data reporting requirements are established. If a field activity is required, additional elements may need to be specified in the QAPP or other planning documents.

11.2 General Requirements

A description of the data collection operations should include:

- Designation of sample type and sampling locations.
- Handling, storage, shipping, cleanliness or preservation requirements defined in written instructions or SOPs.
- Inspection documents that specify appropriate inspection points to assure that collection, handling, storage, shipping and/or preservation requirements are met.
- A design process that ensures documentation of data that is traceable to the sampling and analytical procedures, performance standards, analysts, and measuring and test equipment.
- Definition of personnel requirements and qualifications, as appropriate, for surveys, sampling, and analytical activities.
- Designation of the survey, sampling, and analytical instrumentation or equipment required, and/or facility requirements.
- Selection of the appropriate data collection or analytical methods, including details of calibration and performance evaluation criteria for analytical methods (usually encompassed by the SOP).
- Specifications for data transfer, reduction, validation and verification.

- Designation of the required reports to management, including status reports, interim results, and project assessment summaries.

11.3 Responsibilities

- Written instruction or new or revised SOPs shall be prepared by the Program Manager, in consultation with the QA Manager.

- The Program Manager, in consultation with the QA Manager, is responsible for formulating Quality Assurance Project Plans or other planning documents.

- The QA Manager is responsible for ensuring that all quality assurance and quality control aspects of a project are documented and performed. The QA Manager is responsible for final approval of such documents.

11.4 Procedure

The design of the project is documented in written planning documents, including a Quality Assurance Project Plan (QAPP) when required. The project plan is reviewed by the QA Manager and appropriate Senior Management to assure accuracy and completeness. The QAPP includes sample and analysis plans, instruction guides, SOPs, and operating manuals when appropriate.

12.0 IMPLEMENTATION OF PLANNED OPERATIONS

12.1 Purpose

The purpose of this section is to ensure implementation of planning documents and the approved QAPPs, thus insuring that the type and quality of data obtained will meet program data quality objectives.

12.2 General Requirements

- Only qualified and accepted services or items are used as part of the project.

- All items must be traceable to original sources.

- Final acceptance of data is the responsibility of designated personnel. When acceptance criteria are not met, deficiencies are resolved and the data are re-inspected as necessary.

- Instruments must be calibrated on a routine basis and this calibration is fully documented and traceable to the instruments.

- Preventive and corrective maintenance is routinely performed and documented. A sufficient supply of replacement parts is maintained.

- Sample custody is tracked and documented according to the QAPP, SOPs, or other planning documents. All procedures used during a project must conform to the planning documents or the approved QAPP to prevent loss, damage, deterioration, and the introduction of artifacts or interferences.

- Data transmissions, storage, validation, assessment, and processing is performed in accordance with planning documents or the approved QAPP.

12.3 Responsibility

- The Program Manager is responsible for implementing the program. However, all personnel assigned to the project assist in ensuring that project goals are attained.

13.0 QUALITY ASSESSMENT AND RESPONSE

13.1 Purpose

The purpose of this section is to provide guidelines to identify conditions adverse to quality and to institute corrective actions as soon as practical.

13.2 General Requirements

- In the case of a condition adverse to quality, the cause of the condition shall be determined and corrective action taken to preclude recurrence.

- The identification, cause, and corrective action for significant conditions adverse to quality shall be documented and reported to appropriate levels of management.

- Follow-up action shall be taken to verify implementation of corrective action.

13.3 Responsibilities

- The QA Manager and Managers are responsible for reviewing the documentation, the record of evaluation, the specified corrective action, and performing verification of completion of corrective action for conditions adverse to quality.

- The Manager responsible for the activity in which the nonconforming condition occurred investigates the cause of the condition, determines corrective action, and documents the cause and the corrective action.

- The Manager responsible for implementing corrective action verifies the corrective work as acceptable in consultation with the appropriate QC personnel and/or the QA Manager to close out the corrective action request in writing.

13.4 Procedure

- GERG technical staff document any incidents of deficiencies or conditions adverse to quality, and provide such documentation to the Manager and the QA Manager.

- The responsible Manager or Supervisor identifies the cause and the corrective action to preclude recurrence and determines a schedule for implementation.

- The responsible Manager takes corrective action and ensures satisfactory completion of such actions.

- The Manager evaluates the results of the corrective action specified. The QA Manager is notified of the quality related problem, corrective action, and effect of its implementation.

- The Manager, in consultation with the QA Manager, verifies completion of the corrective action and maintains appropriate documentation.

14.0 ASSESSMENT OF DATA USABILITY

14.1 Purpose

The purpose of this section is to establish a records system for assessing and controlling all QA/QC records that represent objective evidence of quality. QA/QC records include, but are not necessarily limited to the following items as they specifically apply to a given project.

- Design - planning documents, calculations, applicable contractual requirements, drawings, and audits.

- Procurement - planning documents, purchase documents, material certifications, inspections, and audits.

- Inspection - intercalibrations, internal calibration data, audits and results.

- Personnel training and certification records.

14.2 General Requirements

- Records that furnish documentary evidence of collected project related information or data and its quality shall be specified, prepared and maintained.
- Quality records shall be legible, identifiable, and retrievable.
- Quality records shall be protected against damage, deterioration, or loss.
- Quality records shall be controlled by written instructions or procedures.

14.3 Responsibilities

- Managers are responsible for developing and maintaining instructions or procedure for identifying, assessing, and controlling QA/QC records within their department.
- The QA Manager is responsible for the review and approval of procedures dealing with quality assurance and quality control record maintenance.

14.4 Procedure

GERG shall maintain all QA/QC records for a minimum of three (3) years following completion of work unless otherwise specified by contract, codes, standards, or written authorization. Records will be transferred to the client at the end of the retention period if requested by the customer.

Appendix C

Geochemical and Environmental Research Group Texas A&M University Quality Assurance Project Plan (QAPP)

QUALITY ASSURANCE PROJECT PLAN (QAPP)

prepared by

Geochemical and Environmental Research Group
Texas A&M University
833 Graham Road
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May 10, 2004

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FOREWORD

The attached Quality Assurance Project Plan (QAPP) is based on the standards as defined in the Geochemical and Environmental Research Group (GERG) Quality Assurance Management Plan (QAMP). Each QAPP is specifically designed for an individual project and is intended to incorporate all principles enunciated in the GERG QAMP. The detailed QAPP provides the project design and QA objectives in sufficient detail to assure accomplishment of program goals in a timely, efficient, and cost effective manner. The implementation of this QAPP will insure environmental data of the appropriate type and quality as required for its intended use. The general format of the QAPP follows the guidance contained in the U.S. EPA's document QAMS-005/80.

QAPP Authorized by

Mahlon C. Kennicutt II, Ph.D.
Director, Geochemical and Environmental Research Group

5/10/04
Date

Terry L. Wade, Ph.D
Program Manager

5/11/04
Date

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1.0 PROJECT DESCRIPTION

1.1 General Overview

This quality assurance project plan (QAPP) is provided in support of studies conducted by the Texas Department of Health - Seafood Safety Division (TDH), for the analyses of trace amounts of organic and inorganic contaminants in the tissues of fish and shellfish. The Department of Health is the Texas's agency created to protect and promote the health and safety of the people of Texas. To this end, the Department administers a variety of programs designed to identify and reduce recognized health risks to the public. To implement programs to attain this goal the TDH continually collects, analyzes, and synthesizes information that will provide for sound and timely management decisions. One element of this decision making process requires determination of organic and inorganic contaminants found in organisms.

A wide spectrum of geographic areas and contaminant problems are studied including contamination from agriculture, energy development, and industrial activities. This project proposes for the Geochemical and Environmental Research Group (GERG), Texas A&M University (TAMU), to provide high quality environmental analyses of contaminant compounds in samples received from the TDH.

1.2 General Considerations

GERG will provide adequate personnel, equipment and resources to implement all trace analyses for the proposed project which are listed in Table 1.1. The analysis of all components as requested by TDH will be provided as described in this QAPP. The appropriate sample receipt, preparation equipment, and storage capacity are available at GERG. Gas chromatographs with appropriate detectors and other equipment and instruments required are available to analyze and report data from the samples generated by this project. In addition, a high resolution gas chromatography/high resolution mass spectrometer is available for dioxin/furan analyses. It is also clearly recognized that most samples submitted will arrive over a very short period of time, intermittently, each year. GERG is prepared to operate within the required time frames.

1.2.1 Sample Storage and Processing Requirements

The freezer capacity needed is available to store tissue samples received, all unanalyzed portions of a sample, and all extracts/digests for analysis will be stored for at least one year after the analytical report is accepted, until disposition or return is approved by the TDH COTR. Freezing is specified as -20°C ± 10°C.

Processing of samples received will be performed when requested. A sample batch is considered received (complete) when all samples have arrived at the laboratory intact and properly labeled, the sample identification number matches the delivery order received, and there is a match between the samples received with the work described in the delivery order.

All chemical contaminant concentrations will be reported on a wet weight basis. The laboratory methods and laboratory techniques listed are the current methods and techniques used by the GERG laboratory for metals, pesticides, polychlorinated biphenyls (PCBs), semi-volatile organic compounds (SVOCs), volatile organic compounds (VOCs), and dioxins/furans. For all samples, % moisture will be determined. For all organic analysis, % lipids will be determined.

Table 1.1. Target analytes and reporting limits to be determined for the TDH program.

Metals (mg/kg = parts per million) (Digestion Method: GERG 9408)

Analyte	*Reporting Limit	Technique
Arsenic	**0.10**	**GFAAS**
Cadmium	**0.10**	**ICP-MS**
Copper	**0.40**	**ICP-MS**
Lead	**0.40**	**ICP-MS**
Mercury	**0.20**	**CVAAS**
Selenium	**0.10**	**GFAAS**
Zinc	**0.40**	**ICP-MS**

Pesticides (μg/kg = parts per billion)

Analyte	*Reporting Limit	Analyte	*Reporting Limit
Aldrin	2.0	Endosulfan II	10
Alachlor	8.0	Endosulfan Sulfate	10
alpha BHC	2.0	Endrin	6.0
beta BHC	2.0	Heptachlor	2.0
delta BHC	2.0	Heptachlor epoxide	4.0
Chlordane[1]	10	Hexachlorobenzene	2.0
Chlorpyrifos	10	Lindane	2.0
p,p′DDE	5.0	Malathion	20
p,p′DDD	10	Methoxychlor	30
p,p′DDT	10	Mirex	8.0
Dacthal	3.0	Ethyl parathion	10
Diazinon	10	Methyl parathion	10
Dieldrin	6.0	Toxaphene	100
Endosulfan I	10		

Polychlorinated Biphenyls (analyzed at μg/kg = parts per billion)

Analyte	*Reporting Limit
Aroclor 1016**	40
Aroclor 1221**	40
Aroclor 1232**	40
Aroclor 1242**	40
Aroclor 1248**	40
Aroclor 1254**	40
Aroclor 1260**	40

** Aroclor is a registered trademark of the Monsanto Corporation

Table 1.1. (Cont.). Additional Required PCB Parameters[3]

Polychlorinated biphenyls to be individually identified and quantified.

PCB Congener Name	*IUPAC Number*	*CAS Reg Number*
2,4' dichlorobiphenyl	8	34883-43-7
2,2',5 trichlorobiphenyl	18	37680-65-2
2,4,4' trichlorobiphenyl	28	7012-37-5
3,4,4' trichlorobiphenyl	37	38444-90-5
2,2',3,5' tetrachlorobiphenyl	44	41464-39-5
2,2',4,5' tetrachlorobiphenyl	49	41464-40-8
2,2',5,5' tetrachlorobiphenyl	52	35693-99-3
2,3',4,4' tetrachlorobiphenyl	66	32698-10-1
2,3',4',5 tetrachlorobiphenyl	70	32598-11-1
2,4,4',5 tetrachlorobiphenyl	74	32690-93-0
3,3',4,4' tetrachlorobiphenyl	77	32598-13-3
3,4,4',5 tetrachlorobiphenyl	81	70362-50-4
2,2',3,4,5' pentachlorobiphenyl	87	38380-02-8
2,2',3,4',5 pentachlorobiphenyl	90	68194-07-0
2,2',4,5,5' pentachlorobiphenyl	101	37680-73-2
2,3,3',4,4' pentachlorobiphenyl	105	32598-14-4
2,3,4,4',5 pentachlorobiphenyl	114	74472-37-0
2,3',4,4',5 pentachlorobiphenyl	118	31508-00-6
2,3',4,4',6 pentachlorobiphenyl	119	56558-17-9
2',3,4,4',5 pentachlorobiphenyl	123	65510-44-3
3,3',4,4',5 pentachlorobiphenyl	126	57465-28-8
2,2',3,3',4,4' hexachlorobiphenyl	128	38380-07-3
2,2',3,4,4',5' hexachlorobiphenyl	138	35065-28-2
2,2',3,5,5',6 hexachlorobiphenyl	151	52663-63-5
2,2',4,4',5,5' hexachlorobiphenyl	153	35065-27-1
2,3,3',4,4',5 hexachlorobiphenyl	156	38380-08-4
2,3,3',4,4',5' hexachlorobiphenyl	157	69782-90-7
2,3,3',4,4',6 hexachlorobiphenyl	158	74472-42-7
2,3',4,4',5,5' hexachlorobiphenyl	167	52663-72-6
2,3',4,4',5',6 hexachlorobiphenyl	168	59291-65-5
3,3',4,4',5,5' hexachlorobiphenyl	169	32774-16-6
2,2',3,3',4,4',5 heptachlorobiphenyl	170	35065-30-6
2,2',3,4,4',5,5' heptachlorobiphenyl	180	35065-29-3
2,2',3,4,4',5,6 heptachlorobiphenyl	181	74472-47-2
2,2',3,4,4',6,6' heptachlorobiphenyl	184	74472-48-3
2,2',3,4,5,5',6 heptachlorobiphenyl	185	52712-05-7
2,3,3',4,4',5,6 heptachlorobiphenyl	190	41411-64-7
2,2',3,3',4,4',5,6 octachlorobiphenyl	195	52663-78-2
2,2',3,3',4,5,6,6' octachlorobiphenyl	200	52663-73-7
2,2',3,3',4,4',5,5',6 nonachlorobiphenyl	206	40186-72-9
2,2',3,3',4,4',5,5',6,6' decachlorobiphenyl	209	2051-24-3

Table 1.1. Volatile Organic Compounds (analyzed in μg/kg = parts per billion; Cont.).

Analyte	*Reporting Limit
1,1,1,2 - Tetrachloroethane	20
1,1,1-Trichloroethane	20
1,1,2,2-Tetrachloroethane	20
1,1,2-Trichloroethane	20
1,1-Dichloroethane	20
1,1-Dichloroethene	20
1,1-Dichloropropene	20
1,2,3-Trichlorobenzene	20
1,2,3-Trichloropropane	20
1,2,4-Trichlorobenzene	20
1,2,4-Trimethylbenzene	20
1,2-Dibromo-3-Chloropropane	20
1,2-Dibromoethane	20
1,2-Dichlorobenzene	20
1,2-Dichloroethane	20
1,2-Dichloropropane	20
1,3,5-Trimethylbenzene	20
1,3-Dichlorobenzene	20
1,3-Dichloropropane	20
1,4-Dichlorobenzene	20
2,2-Dichloropropane	20
2-Butanone (MEK)	100
2-Chlorotoluene	20
2-Hexanone	20
4-Chlorotoluene	20
4-Isopropyl toluene	20
4-Methyl-2-Pentanone	20
Acetone	200
Acrylonitrile	20
Benzene	20
Bromobenzene	20
Bromochloromethane	20
Bromodichloromethane	20
Bromoform	20
Bromomethane	50
Carbon Disulfide	50

Table 1.1. Volatile Organic Compounds (analyzed in μg/kg = parts per billion; Cont.).

Analyte	*Reporting Limit
Carbon Tetrachloride	20
Chlorobenzene	20
Chloroethane	50
Chloroform	20
Chloromethane	50
cis-1,2-Dichloroethene	20
cis-1,3-Dichloropropene	100
Dibromochloromethane	20
Dibromomethane	20
Dichlorodifluoromethane	50
Ethyl Methacrylate	20
Ethylbenzene	20
Hexachlorobutadiene	50
Iodomethane	50
Isopropylbenzene	20
m&p-Xylene	40
Methyl Methacrylate	20
Methyl-tert-butyl ether (MTBE)	20
Methylene chloride	50
n-Butylbenzene	20
n-Propylbenzene	20
Naphthalene	20
o-Xylene	20
sec-Butylbenzene	20
Styrene	20
tert-Butylbenzene	20
Tetrachloroethene	20
Tetrahydrofuran	50
Toluene	20
trans-1,2-Dichloroethene	20
trans-1,3-Dichloropropene	100
Trichloroethene	20
Trichlorofluoromethane	50
Vinyl Chloride	50

Table 1.1. Semi-Volatile Organic Compounds (analyzed in mg/kg = parts per million; Cont.)

Analyte	*Reporting Limit
Pyridine	1.0
N-Nitrosodimethylamine	1.0
N-Nitrosodiethylamine	1.0
Aniline	4.0
Phenol	1.0
bis(2-Chloroethyl)ether	2.0
2-Chlorophenol	1.0
1,3-Dichlorobenzene	1.0
1,4-Dichlorobenzene	1.0
Benzyl alcohol	1.0
1,2-Dichlorobenzene	1.0
2-Methylphenol	1.0
bis(2-Chloroisopropyl)ether	1.0
¾-Methylphenol (coelute)	1.0
N-Nitroso-di-n-propylamine	1.0
Hexachloroethane	1.0
Nitrobenzene	1.0
Isophorone	1.0
2-Nitrophenol	1.0
2,4-Dimethylphenol	1.0
bis(2-Chloroethoxy)methane	1.0
Benzoic Acid	1.0
2,4-Dichlorophenol	1.0
1,2,4-Trichlorobenzene	1.0
Naphthalene	0.4
4-Chloroaniline	4.0
Hexachlorobutadiene	1.0
N-Nitroso-di-n-butylamine	1.0
4-Chloro-3-methylphenol	1.0
2-Methylnaphthalene	1.0
1,2,4,5-Tetrachlorobenzene	1.0
Hexachlorocyclopentadiene	4.0
2,4,6-Trichlorophenol	1.0
2,4,5-Trichlorophenol	1.0
2-Chloronaphthalene	1.0
2-Nitroaniline	1.0
Dimethylphalate	1.0
Acenaphthylene	0.4

Table 1.1. Semi-Volatile Organic Compounds (analyzed in mg/kg = parts per million; Cont.)

Analyte	*Reporting Limit
2,6-Dinitrotoluene	1.0
3-Nitroaniline	2.0
Acenaphthene	0.4
2,4-Dinitrophenol	2.0
4-Nitrophenol	4.0
Dibenzofuran	1.0
2,4-Dinitrotoluene	1.0
Diethylphthalate	1.0
Fluorene	0.4
4-Chlorophenyl-phenylether	1.0
4-Nitroaniline	2.0
Diphenylhydrazine	1.0
4,6-Dinitro-2-methylphenol	2.0
N-Nitrosodiphenylamine	1.0
4-Bromophenyl-phenylether	1.0
Hexachlorobenzene	1.0
Pentachlorophenol	2.0
Alpha-BHC	1.0
Beta-BHC	1.0
Lindane	1.0
Delta-BHC	1.0
Phenanthrene	0.4
Anthracene	0.4
Di-n-butylphthalate	1.0
Heptachlor	1.0
Aldrin	2.0
Fluoranthene	0.4
Heptachlor epoxide	1.0
Pyrene	0.4
Alpha endosulfan	2.0
Benzidine	ND[2]
p,p´-DDE	1.0
Dieldrin	1.0
Butylbenzylphthalate	1.0
Endrin	1.0
Beta-Endosulfan	2.0
p,p´-DDD	1.0
Endrin aldehyde	ND2

Table 1.1. Semi-Volatile Organic Compounds (analyzed in mg/kg = parts per million; Cont.)

Analyte	*Reporting Limit
p,p´-DDT	1.0
bis(2-Ethylhexyl)adipate	1.0
Endosulfan sulfate	2.0
Benzo[a]anthracene	0.4
3,3-Dichlorobenzidine	4.0
Chrysene	0.4
Endrin ketone	1.0
Bis(2-Ethylhexyl)phthalate	1.0
di-n-Octylphthalate	1.0
Benzo[b]fluoranthene	0.4
Benzo[k]fluoranthene	0.4
Hexachlorophene	ND[2]
Benzo[a]pyrene	0.4
Indeno[1,2,3-cd]pyrene	0.4
Dibenz[a,h]anthracene	0.4
Benzo(g,h,i)perylene	0.4

Dioxins (analyzed in pg/g = parts per trillion)

Analyte	*Reporting Limit
2,3,7,8-Tetrachloro-dibenzo-p-dioxin	0.5
1,2,3,7,8-Pentachloro-dibenzo-p-dioxin	0.5
1,2,3,4,7,8-Hexachloro-dibenzo-p-dioxin	2.5
1,2,3,6,7,8-Hexachloro-dibenzo-p-dioxin	2.5
1,2,3,7,8,9-Hexachloro-dibenzo-p-dioxin	2.5
1,2,3,4,6,7,8-Heptachloro-dibenzo-p-dioxin	2.5
Octachloro-dibenzo-p-dioxin (Total)	5.0

Table 1.1. Furans (analyzed in pg/g = parts per trillion; Cont.).

Analyte	*Reporting Limit
2,3,7,8-Tetrachloro-dibenzo-p-furan	0.5
1,2,3,7,8-Pentachloro-dibenzo-p-furan	2.5
2,3,4,7,8-Pentachloro-dibenzo-p-furan	2.5
1,2,3,4,7,8-Hexachloro-dibenzo-p-furan	2.5
1,2,3,6,7,8-Hexachloro-dibenzo-p-furan	2.5
2,3,4,6,7,8-Hexachloro-dibenzo-p-furan	2.5
1,2,3,7,8,9-Hexachloro-dibenzo-p-furan	2.5
1,2,3,4,6,7,8-Heptachloro-dibenzo-p-furan	2.5
1,2,3,4,7,8,9-Heptachloro-dibenzo-p-furan	2.5
Octachloro-dibenzo-p-furan (Total)	5.0

[1] Chlordane value represents total chlordane, which is the sum of the primary constituents of technical –grade chlordane: alpha chlordane, gamma chlordane, cis-nonachlor, trans-nonachlor and oxychlordane, the major metabolite of chlordane.
[2] ND = Detection Limit not established.
[3] PCB congener information obtained from Toxicological Profile for Polychlorinated Biphenyls (Update) 1997. U.S. Department of Health and Human Services, Public Health Service, Agency for Toxic Substances and Disease Registry. pp 217-222 and Guidance for assessing chemical contaminant data for use in fish advisories. Vol. 1, Fish Sampling and Analysis, 3rd ed. Washington, D.C.: 2000. U.S. Environmental Protection Agency. p 4-53.
*Reporting Limit = The reporting limits (RLs) listed in these tables are the specifications at or above which chemical contaminant concentrations must be quantified. Ongoing ability to recover an analyte near the reporting limit is demonstrated through analysis of a calibration check standard at the reporting limit.

2.0 PROJECT ORGANIZATION AND RESPONSIBILITY

The project will be performed by personnel drawn from the Geochemical and Environmental Research Group (GERG) of the College of Geosciences at Texas A&M University. Dr. Mahlon C. Kennicutt, II is the Director of GERG which is located at 833 Graham Road in College Station, Texas, 77845. The telephone number is (979) 862-2323, and the FAX number is (979) 862-2361.

Dr. Terry L. Wade, Program Manager, will be responsible for the overall administration and execution of the project and Dr. Guy Denoux will function as the Deputy Program Manager and Data Manager. The management organization of the project is depicted in Figure 2.1.

2.1 Position Descriptions for Project Team

The responsibility of each project team member is summarized below and the project management organization is illustrated in Figure 2.1.

Program Manager

The Program Manager is responsible for overall administration and execution of the project and is the designated study director. Specific responsibilities include:

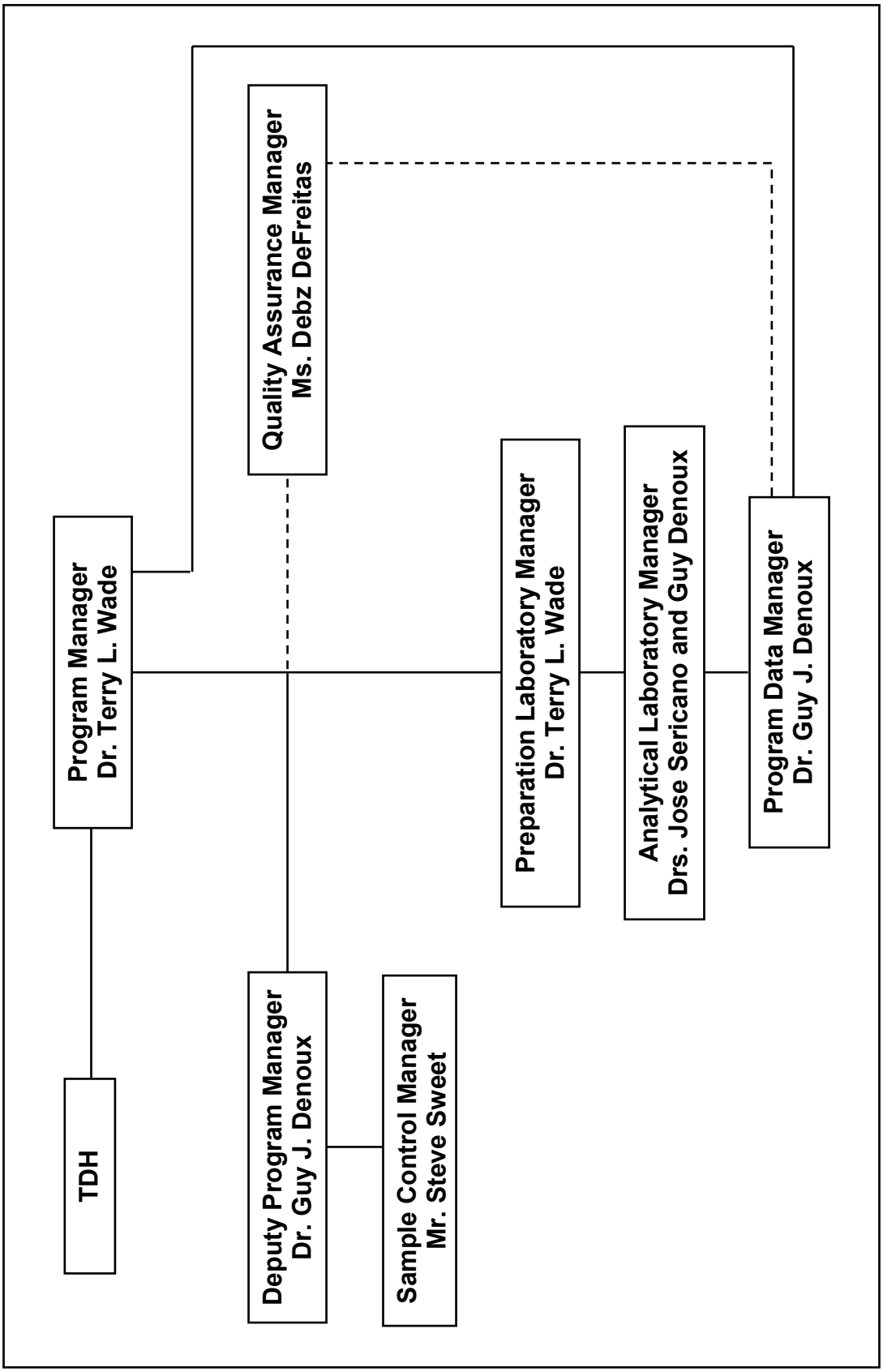

Figure 2.1. Project management structure.

- Establishes and documents the roles and responsibilities of project personnel.
- Coordinates auditing of project activities
- Establishes and conducts a self-assessment program.
- Has final responsibility to insure all deliverables are provided on-time to the client.
- Establishes and develops the implementing procedures
- Approves expenditures of funds for the project.

Deputy Program Manager

The Deputy Program Manager reports to the Program Manager and has responsibility with the Program Manager for the project in all financial, management, scientific, and quality assurance issues. The Deputy Program Manager is the responsible party in the absence of the Program Manager. The Deputy Program Manager:

- Coordinates internal and external interfaces of personnel involved with the project.
- Oversees the activities of the quality assurance unit for this project, designates personnel to perform inspections, and maintains records related to these activities.
- Ensures that the applicable QC requirements are met.
- Ensures that quality-related issues and problems are promptly identified and corrected.
- Interfaces with the QA Manager on program QA/QC considerations.
- Implements cost effective quality improvements.
- Supervises the progress of the analytical program and team.
- Assists the Organic Analytical Laboratories Manager in tracking corrective actions and analyzing data pertaining to quality.
- Provides guidance to resolve quality problems and ensure that corrective action is taken and appropriately documented in response to occurrence reports, non-conformance reports, etc.
- Identifies areas where improvement could benefit the program.

Quality Assurance Manager

The Quality Assurance (QA) Manager is responsible for developing, enacting, and enforcing all QA/QC procedures and policies. The QA Manager ensures that all project activities are operated in a manner that provides confidence that project quality control (QC) objectives are met. The QA Manager is independent of project management, reports to the Senior Associate Director of GERG, and is responsible for ensuring all applicable QA/QC policies and directives are enforced, revised and improved to provide products of the highest quality to clients. Specific responsibilities include:

- Maintains and revises the GERG Quality Assurance Management Plan (QAMP) and the Generic Quality Assurance Manual (GQAM).
- Advises the Program Manager, the Deputy Program Manager and the project team members on QA/QC matters.
- Ensures that QA/QC requirements are effectively implemented for all project activities.

- Ensures that the QAPP is adequately developed to meet project needs and is effectively implemented.
- Coordinating, preparing, approving and reviewing QA/QC documents including all quality requirements contained in standard operating procedures.
- Identifies QA/QC requirements and assists in the development of procedures and other implementing instructions.
- Assists in the identification of problems concerning, and taking actions to eliminate or minimize potential QA problems.
- Evaluates quality performance including internal system audits, tracking of reports of QA/QC criteria, reviewing corrective actions, and overall project performance.
- Provides QA/QC training to all project personnel when required.
- Has the authority to stop the work when severe conditions adverse to quality are detected and warrant immediate action.

Program Data Manager

The Program Data Manager reports to the Program Manager. The Program Data Manager is responsible for:

- Compiling, editing, and verifying all project data.
- Assuring data management, validation, and reporting conforms with the project requirements.
- Assuring that hard copy and electronic data formats are compatible with the intended users data requirements.
- Advising the Quality Assurance Manager on data management QA/QC issues.
- Assists in preparation of final project reports.

Laboratory Managers

The Extraction Laboratory Manager and the Analytical Laboratory Managers are the technical supervisors responsible for the sample extract preparation and the instrumental analyses. The Laboratory Managers report to the Program Manager for this program and are responsible for:

- Supervision and coordination of all aspects of the laboratories and the analytical laboratories.
- Coordination with the Program Manager and Deputy Program Manager to submit sample extracts to the laboratory to ensure technical quality and due dates are met on all projects.
- Implementing the required standard operating procedures and the Quality Assurance Project Plan.
- Ensuring the quality of assigned work by monitoring daily performance, calibration, and QC data.
- Investigating quality problems, determining their root causes, proposing solutions, implementing corrective actions, and obtaining the concurrence of the Program Manager and the QA Manager on the appropriateness of the corrective action.

- Implementing cost effective quality improvements.
- Implementing training plans by assessing training needs, scheduling necessary training and ensuring that training is completed and documented.
- Initiating corrective actions and stop-work actions when warranted by conditions adverse to analytical quality.
- Approval of analytical data and submission of the final data to the Program Manager and Data Manager in a timely and professional manner.

Laboratory Technician

The Laboratory Technician reports directly to his/her specific Laboratory Manager. The Laboratory Technician is responsible for:

- Being properly trained and fully knowledgeable about the SOPs required to complete the assigned work.
- Strictly adhering to SOPs.
- Identifying areas where improvement could benefit the program.
- Initiating corrective actions and stop-work actions when warranted by conditions adverse to analytical quality.
- Being familiar with the components of the project's Quality Assurance Project Plan.
- Reporting any conditions adverse to quality to the appropriate Laboratory Manager.
- Ensuring that internal chain of custody procedures are followed, and that all paperwork and forms are properly and completely maintained.
- Initiating stop-work actions when warranted by conditions adverse to analytical quality.

Sample Control Manager and Sample Custodians

The Sample Control Manager reports to the Program Manager and is responsible for overall activities associated with sample receipt, documentation, login, preparation, storage and disposal. The Sample Custodian reports directly to the Sample Control Manager. The Sample Custodian is responsible for:

- Ensuring the integrity of project samples through all stages of the project including final archiving or other disposition.
- Logging-in, verifying chain-of-custody paperwork, and inspecting all samples for proper storage, preservation and condition.
- Maintaining all records in compliance with the Quality Assurance Project Plan.
- Advising the Sample Control Manager and the Quality Assurance Manager on issues of quality control related to sample custody procedures.
- Notifying the client of any exceptions to chain-of-custody procedures, damage to samples, and inadequate practices that jeopardize sample integrity.

2.2 Personnel Training

Personnel training and continuing education are essential elements in providing high quality analytical data. GERG provides for the selection and training of personnel so that each employee is proficient and properly trained to perform their assigned activities. Personnel selection and training procedures are explicitly stated in GERG SOP-9702.

3.0 QUALITY ASSURANCE OBJECTIVES

Data quality assurance objectives specified for the TDH project are summarized in GERG standard operating procedures (SOPs) in most cases, meet or exceed these criteria. GERG procedures will be revised as necessary to meet all TDH criteria. A goal of 100% completeness is not always obtainable if, for example, no sample remains for reanalysis. Data is reported but qualified as out-of-control if no sample remains for reanalysis.

The implementation of the QA program is achieved through a team effort by the entire laboratory group. The general considerations and objectives of the overall QA/QC program are as follows:

- Sample integrity is preserved by following documented sample handling procedures relating to the preservation, custody, storage, labeling and record keeping associated with samples received by the laboratory.
- Properly approved standard analytical methods are followed. Routine analytical methods and procedures used for sample analyses are readily available and understood by all analysts using the procedures. Results generated from a method are evaluated to identify method weakness and detect needs for further analyst training.
- The analytical instrumentation is in proper working order. Instrument performance, calibration, and maintenance are documented.
- The accuracy and precision of analytical methods are recorded and maintained on a continuing basis. Accuracy and precision data are monitored using tabular formats to assess continuing performance and to detect trends. Control charts can be generated after the completion of analytical activities if required.
- Raw data is properly reduced and accurately transcribed into the proper reporting format. Various levels of data review from acquisition to the final report are incorporated to reduce the possibility of errors.

All of the above considerations are documented to validate the quality of the data.

3.1 Limits of Detection

The GERG SOPs proposed for this project have been shown in most cases to provide the required minimum limits of detection (Table 1.1). GERG procedures will be modified where necessary to add additional analytes and meet all required limits of detection. The method detection limits will be determined annually for each target compound using the EPA protocols detailed in 40 CFR Part 136, Appendix B. The method detection limit (MDL) is defined as the Student's t for 99% confidence interval times the standard deviation of at least seven replicate measurements of the same low level sample or spiked sample.

3.2 Precision and Accuracy Acceptance Criteria

The principal estimate of accuracy will be the recovery of spiked analytes. Program requirements for accuracy and precision criteria are summarized in Table 3.1. Some of the more volatile analytes may not meet these criteria's. Specific analytes exempted from these criteria are naphthalene, perylene, HCH's and HCB. In addition, PCB 170 is excepted due to frequent interference problems of the analyte with phthalates.

Relative percent difference (RPD) of duplicates is the principal measure of precision, as defined in QAPP Section 12.0. The required criteria for RPD are summarized in Table 3.1.

Table 3.1. QA objectives for precision and accuracy.

Data Quality Parameter	Method of Determination	Frequency	Required Objectives[a]
Accuracy			
• Matrix Spike	Pesticides	5% of samples[a,b]	40-120% Recovery
	PCB Congeners	5% of samples[a,b]	40-120% Recovery
	VOAs	5% of samples[a,b]	30-150% Recovery
	SVOAs	5% of samples[a,b]	30-150% Recovery
	Dioxin/Furans	5% of samples[a,b]	40-130% Recovery
	Trace Metals	5% of samples[a,b]	75-125% Recovery
Precision			
• Duplicates		5% of samples[b]	35% RPD[c]
• Matrix Spike Duplicates		5% of samples[b]	35% RPD[c]

a - at least one per analytical batch or run sequence
b - may be waived if insufficient sample
c - relative percent difference (see QAPP Section 12.0); if concentration is less than detection limit, use half the limit of detection for calculations.

4.0 SAMPLING PROCEDURES

GERG is not involved in sampling. TDH will provide all samples to the laboratory with appropriate chain-of-custody or other documentation.

5.0 SAMPLE CUSTODY PROCEDURES

The receiving, initial preparation, storage, tracking, archival or disposal of TDH samples are described in GERG SOP-9706 to 9712. The sample receipt date is the date that samples are received at the GERG laboratory. This date is established by the carrier or by certified mail. A diagram of the GERG sample log-in and record maintenance are shown in Figure 5.1.

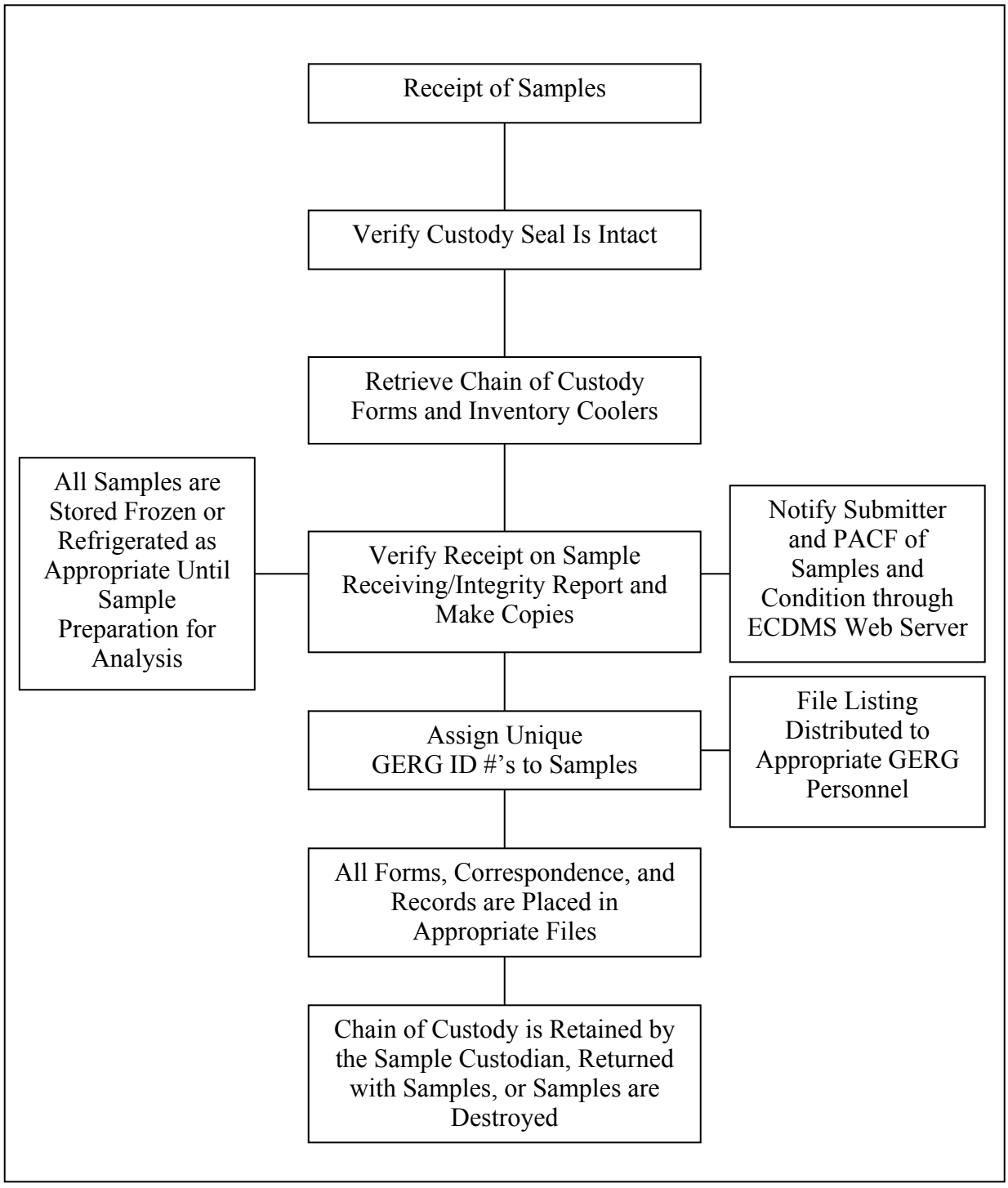

Figure 5.1. Sample log-in and record maintenance.

The Sample Custodian is responsible for all aspects of sample inventory and tracking for the samples in his/her custody. The Custodian is responsible for keeping a record of all samples under his/her jurisdiction, the names of all persons having access to the samples, the movement and analyses performed (including dates and names) on the samples and the location and custodianship of samples while they were away from the primary custodian's care. After aliquoting, any remaining sample and all sample tags or labels shall be returned to the Sample Custodian to be held until indicated otherwise. The Sample Custodian is also responsible for all archiving activities.

6.0 CALIBRATION FREQUENCY AND PROCEDURES

All standards will be "in date" as defined in the GERG SOPs. Standard curves are used for each analyte and consist of three or more calibration points in addition to zero. The calibration correlation evaluation for linearity must meet or exceed a regression coefficient of 0.995 to be accepted as in control. Calibration is checked, at a minimum, after each ten samples as well as at the beginning and end of each analysis batch or run sequence. All analyses employ surrogate and internal standards with specific compounds detailed in the SOPs. All analyses are conducted within the established calibration range of the instrument.

7.0 ANALYTICAL PROCEDURES

All methods are fully described in the GERG Standard Operating Procedures. All proposed methods have been extensively intercalibrated. GERG SOPs applicable to each analysis are listed in Table 7.1. Some analyses are based on published EPA methodology.

Table 7.1 Summary of GERG SOPs for the analytes of interest.

Item	Extraction/Purification	Instrumental Analysis
A. Pesticides	9807, 9720, 0009	9810
B. PCB Congener by HRGC/MS	9807, 9720, 0009	0205
C. Quantification of Individual Aroclors	9807, 9720, 0009	9810
D. Volatile Organic Analytes	NA	0301
E. Semivolatile Organic Analytes	9807, 0009	EPA 8270C
F. Dioxin and Furans	9719	9722
G. Tissue measurements		
1. % Lipids	9807	9727
2. % Moisture	NA	9415
H. Trace Metals		
1. Mercury	0006	0202
2. Cadmium, Copper, Lead, Zinc	9408	In Prep*
3. Arsenic, Selenium	9408	0201

*Based on EPA Method 6020

8.0 DATA REDUCTION, VALIDATION AND REPORTING

8.1 Data Reduction and Validation

All sample results entering the analysis data stream are subjected to continuous validation procedures as they progress from raw data through data reduction to the final data review. The generalized validation procedure is diagrammed in Figure 8.1. The analytical group's validation process is diagrammed in Figures 8.2 and 8.3. The first level of data review validation begins with the laboratory staff. The initial data validation review identifies questionable injections or results which are outside established analytical limits (e.g., instrument calibration range) and identifies a need for re-analysis if required. After successfully passing this first level of data validation and data reduction, each analytical group initiates the second level of data validation. The data is inspected for any failure of stated QC objectives (i.e., the concentration of target analytes in the blank). If problems are identified, corrective action is initiated per the SOP. After completion of peer review, validated data are compiled and sent to the Laboratory Manager where they undergo the final data review before being entered into the database by the Data Manager. The final data review is performed by Laboratory Managers, the Deputy Program Manager, and the QA Manager after the data are entered into the database. Any errors that might occur during this process (e.g., units, conversions, formatting) are identified, returned to the Project Data Manager, corrected, and re-entered into the database.

Approved data from the final review passes to the editorial staff for report preparation. The final report is reviewed by the Program Manager who routes any corrections required to the appropriate validation level. All data which appears in the final report will have undergone three levels of data validation and two levels of data review. These validation procedures assure the completeness and integrity of project data.

9.0 INTERNAL QUALITY CONTROL CHECKS

Quality control check samples and procedures include matrix spikes, laboratory spiked blanks, use of surrogate standards, procedural (method) blanks and other blanks (sampling, field, reagent and instrument), analysis of standard reference materials, use of independent standards, and calibration check standards, and detection limit determinations.

Matrix spikes (MS) are used to evaluate the effect of the sample matrix upon compounds being determined. Method blanks are used to evaluate the potential for sample contamination during preparation. Laboratory blank spikes may be used when sample availability, matrix concentration, or non-homogeneity are of concern in control monitoring.

Adequate statistical procedures are provided to monitor the precision and accuracy of the analytical data and to establish acceptable control limits. QC checks are numerous and methodology specific. The results of matrix spike sample analysis are used to demonstrate whether the laboratory method for sample preparation and analysis is working properly. The results of the MS (or MS/MSD pair) sample may be used to evaluate the accuracy (% recovery) of the analysis. The relative percent difference (RPD) determined using the concentration results of duplicate analyses (or the percent recovery for the MS/MSD pair) to evaluate precision limits

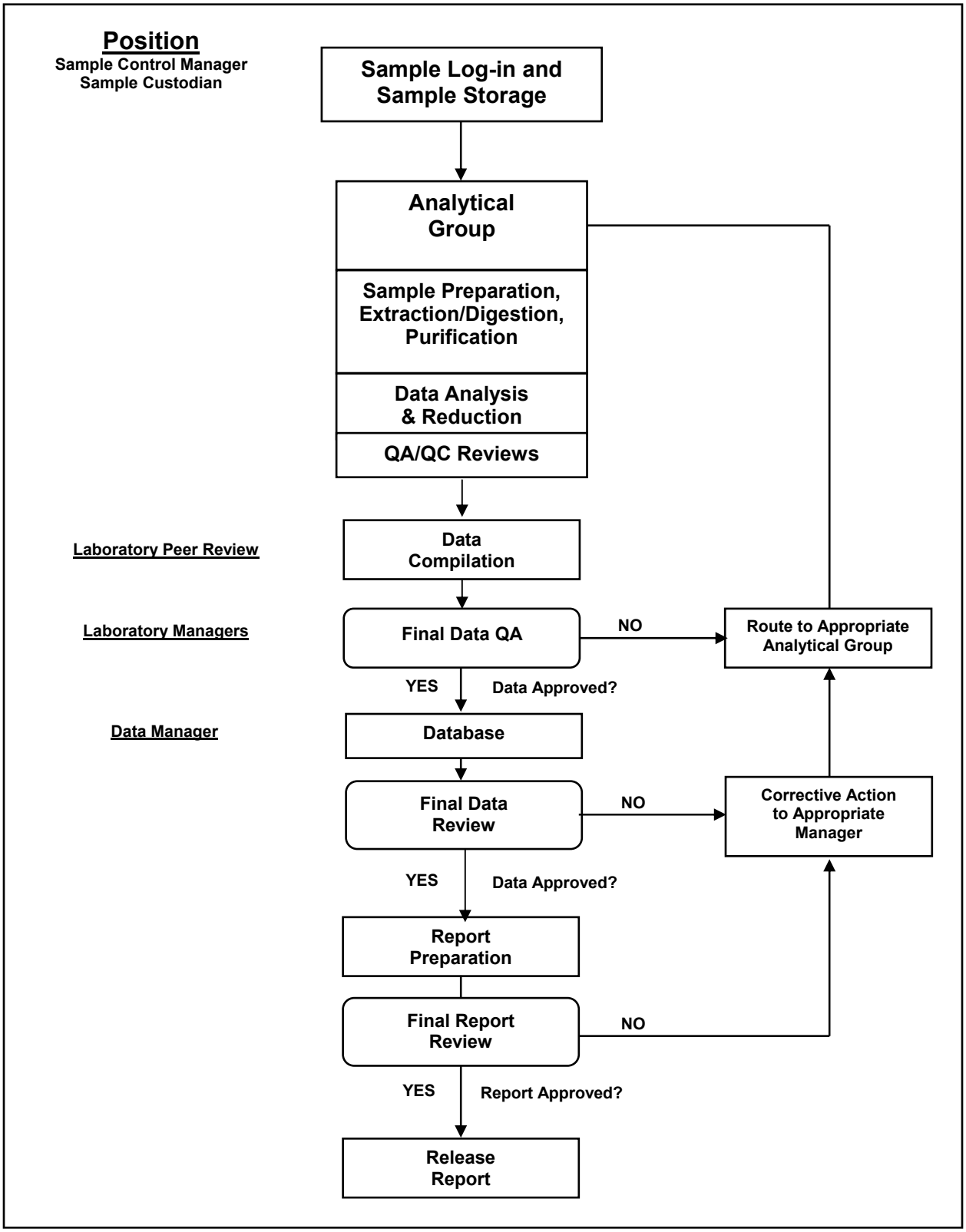

Figure 8.1. Generalized data reduction and validation process.

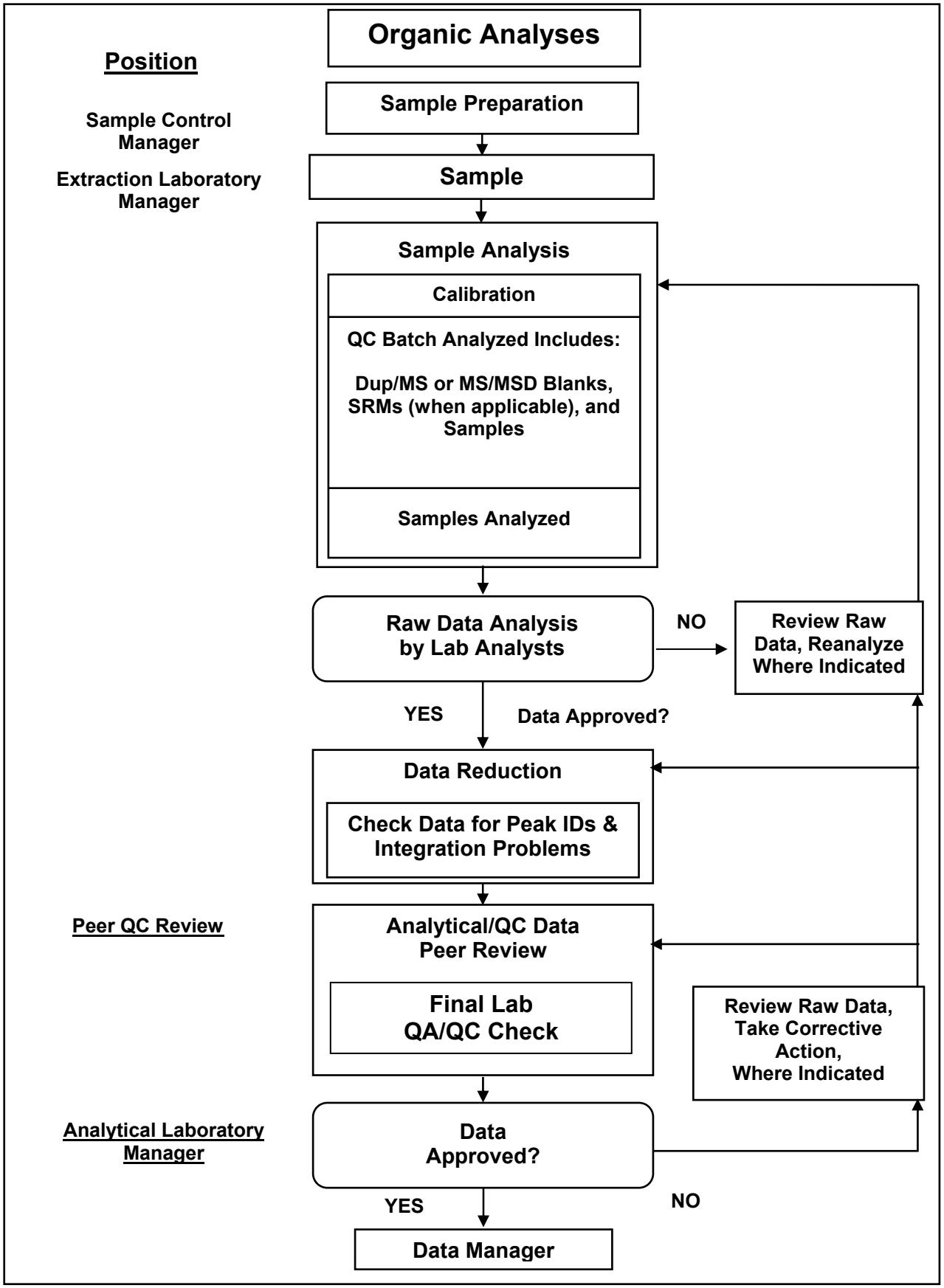

Figure 8.2 Data reduction and validation process for the Organic Analytical Group.

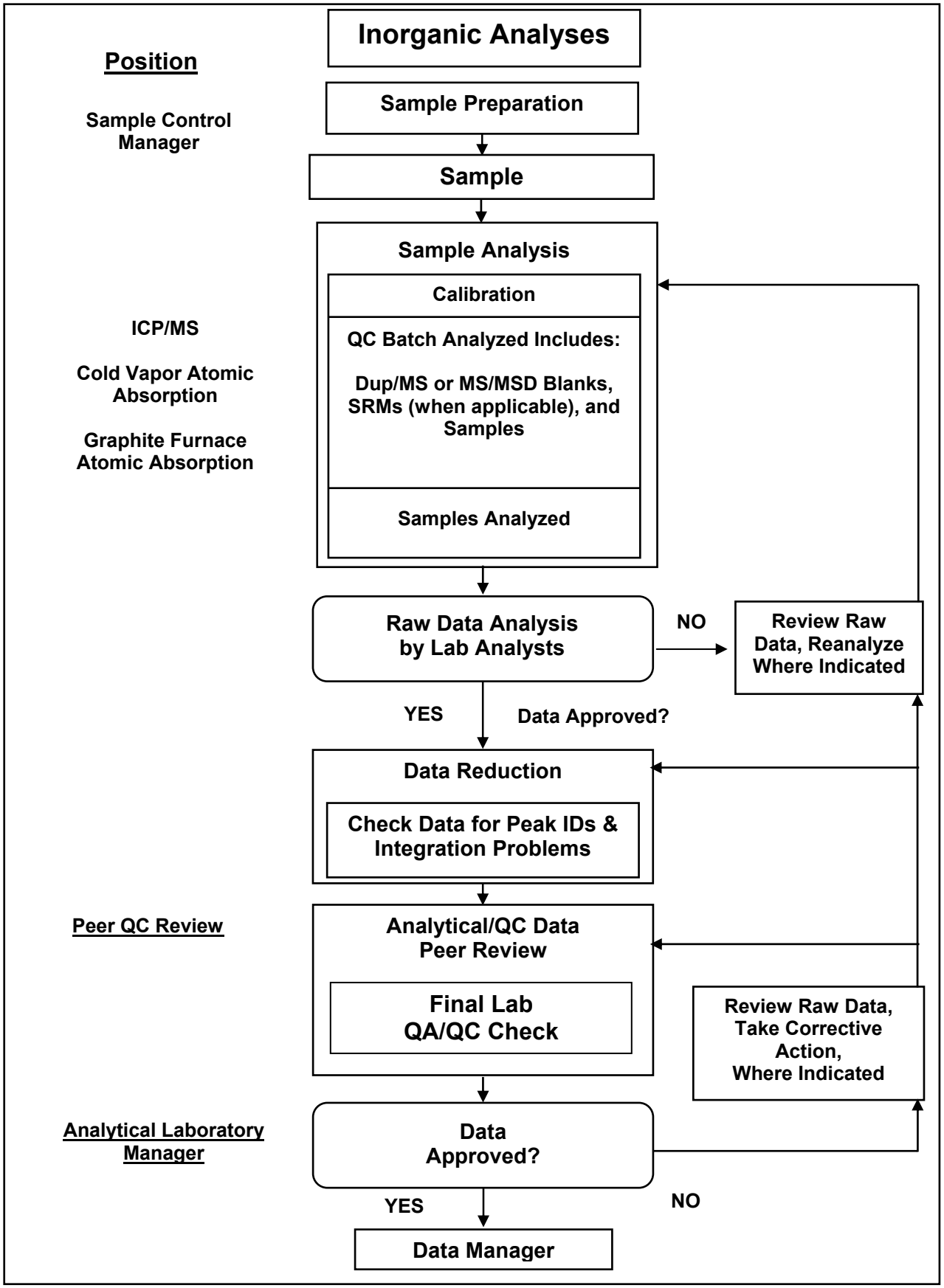

Figure 8.3 Data reduction and validation process for the Inorganic Analytical Group.

and is compared to requirements specified in this QAPP. Accuracy can also be evaluated based upon laboratory blank spike or SRM analyses, and these data can be compared to known concentrations.

9.1 Specific Requirements of this Program

GERG conforms with the following portions of 40 CFR, Part 160 that are specifically required for this program.

Subpart B Organization and Personnel

§160.29 Personnel

(a) Each individual engaged in the conduct of or responsible for the supervision of a study shall have education, training, and experience, or combination thereof, to enable that individual to perform the assigned functions.
(b) Each testing facility shall maintain a current summary of training and experience and job description for each individual engaged in or supervising the conduct of a study.
(d) Personnel shall take necessary personal sanitation and health precautions designed to avoid contamination of test, control, and reference substances and test systems.
(e) Personnel engaged in a study shall wear clothing appropriate for the duties they perform. Such clothing shall be changed as often as necessary to prevent microbiological, radiological, or chemical contamination of test systems and test, control, and reference substances.

§160.31 Testing Facility Management

For each study, testing facility management shall:

(a) Designate a study director as described in §160.33 before the study is initiated.
(b) Replace the study director promptly if it becomes necessary to do so during the conduct of a study.
(d) Assure that test, control, and reference substances or mixtures have been appropriately tested for identity, strength, purity, stability, and uniformity, as applicable.
(e) Assure that personnel, resources, facilities, equipment, materials, and methodologies are available as scheduled.
(f) Assure that personnel clearly understand the functions they are to perform.

§160.33 Study Director

For each study, a scientist or other professional of appropriate education, training, and experience, or combination thereof, shall be identified as the study director. The study director has overall responsibility for the technical conduct of the study, as well as for the interpretation, analysis, documentation, and reporting of results, and represents the single point of study control. The study director shall assure that:

(b) All experimental data, including observations of unanticipated responses of the test system are accurately recorded and verified.
(c) Unforeseen circumstances that may affect the quality and integrity of the study are noted when they occur, and corrective action is taken and documented.
(f) All raw data, documentation, protocols, specimens, and final reports are transferred to the archives during or at the close of the study.

§160.35 Quality Assurance Unit

(a) A testing facility shall have a quality assurance unit which shall be responsible for monitoring each study to assure management that the facilities, equipment, personnel, methods, practices, records, and controls are in conformance with the regulations in this part. For any given study, the quality assurance unit shall be entirely separate from and independent of the personnel engaged in the direction and conduct of that study. The quality assurance unit shall conduct inspections and maintain records appropriate to the study.
(b) The quality assurance unit shall:

(6) Review the final study report to assure that each report accurately describes the methods and standard operating procedures, and that the reported results accurately reflect the raw data of the study.

Subpart C - Facilities

§160.41 General

Each testing facility shall be of suitable size and construction to facilitate the proper conduct of studies. Testing facilities which are not located within an indoor controlled environment shall be of suitable location to facilitate the proper conduct of studies. Testing facilities shall be designed so that there is a degree of separation that will prevent any function or activity from having an adverse effect on the study.

§160.51 Specimen and Data Storage Facilities.

Space shall be provided for archives, limited to access by authorized personnel only, for the storage and retrieval of all raw data and specimens from completed studies.

Subpart D - Equipment

§160.61 Equipment Design

Equipment used in the generation, measurement, or assessment of data and equipment used for facility environmental control shall be of appropriate design and adequate capacity to function according to the protocol and shall be suitably located for operation, inspection, cleaning, and maintenance.

§160.63 Maintenance and Calibration of Equipment

(a) Equipment shall be adequately inspected, cleaned, and maintained. Equipment used for the generation, measurement, or assessment of data shall be adequately tested, calibrated, and/or standardized.
(b) The written standard operating procedures required under §160.81(b)(11) shall set forth in sufficient detail the methods, materials, and schedules to be used in the routine inspection, cleaning, maintenance, testing, calibration, and/or standardization of equipment, and shall specify, when appropriate, remedial action to be taken in the event of failure or malfunction of equipment. The written standard operating procedures shall designate the person responsible for the performance of each operation.
(c) Written records shall be maintained of all inspection, maintenance, testing, calibrating, and/or standardizing operations. These records, containing the dates of the operations, shall describe whether the maintenance operations were routine and followed the written standard operating procedures. Written records shall be kept of non-routine repairs performed on equipment as a result of failure and malfunction. Such records shall document the nature of the defect, how and when the defect was discovered, and any remedial action taken in response to the defect.

Subpart E - Testing Facilities Operation

§160.81 Standard Operating Procedures

(a) A testing facility shall have standard operating procedures in writing setting forth study methods that management is satisfied are adequate to insure the quality and integrity of the data generated in the course of a study. All deviations in a study from standard operating procedures shall be authorized by the study director and shall be documented in the raw data. Significant changes in established standard operating procedures shall be properly authorized in writing by management.
(b) Standard operating procedures shall be established for, but not limited to, the following:

(3) Receipt, identification, storage, handling, mixing, and method of sampling of the test, control, and reference substances.
(5) Laboratory or other tests.
(11) Maintenance and calibration of equipment.

(c) Each laboratory or other study area shall have immediately available manuals and standard operating procedures relative to the laboratory or field procedures being performed. Published literature may be used as a supplement to standard operating procedures.

§160.83 Reagents and Solutions

All reagents and solutions in the laboratory areas shall be labeled to indicate identity, titer or concentration, storage requirements, and expiration date. Deteriorated or outdated reagents and solutions shall not be used.

Subpart G - Protocol for and Conduct of a Study

§160.130 Conduct of a Study

(e) All data generated during the conduct of a study, except those that are generated by automated data collection systems, shall be recorded directly, promptly, and legibly in ink. All data entries shall be dated on the day of entry and signed or initialed by the person entering the data. Any change in entries shall be made so as not to obscure the original entry, shall indicate the reason for such change, and shall be dated and signed or identified at the time of the change. In automated data collection systems, the individual responsible for direct data input shall be identified at the time of data input. Any change in automated data entries shall be made so as not to obscure the original entry, shall indicate the reason for change, shall be dated, and the responsible individual shall be identified.

Subpart J - Records and Reports

§160.185 Reporting of Study Results

(a) A final report shall be prepared for each study and shall include, but not necessarily be limited to, the following:

(6) A description of the methods used.

9.2 Quality Control for Analytical Standards

All standards are certified and/or verified against NIST or other Standard Reference Materials when available.

9.3 Minimum Criteria for an Out-of-Control Condition

A laboratory process for a particular analyte is considered out of statistical control whenever, as a minimum, any one of the following conditions is demonstrated by a control chart monitoring that analyte.

(1) Any one point is outside of the control limits.
(2) Any three consecutive points are outside the ± two standard deviation warning limits.
(3) Any six consecutive points are such that each point is larger (smaller) than its immediate predecessor.
(4) Any obvious cyclic pattern is seen in the points.

9.4 Reactions to Out-of-Control Statistical Conditions on Control Samples

Out of control events are responded to in a number of ways as outlined in Section 13.0, Corrective Action.

9.5 Administration of the Control Charts

Control charts are used to monitor all analytical streams related to this project. Control samples are run with each batch of samples. The control charts are generated by designated laboratory staff, and distributed to the QA Manager, the Deputy Program Manager, and the Program Manager. Visual examination of QC sample data on a daily basis by the instrument operator and the Laboratory Manager highlights any immediate QC problems. QC limits can be updated periodically when sufficient additional data have been generated.

10.0 PERFORMANCE AND SYSTEM AUDITS

TDH may submit blank and/or control samples to provide an independent evaluation of GERG program. TDH staff may audit GERG operations at any time provided a fourteen calendar day notice is provided. GERG participates in intercomparison exercises organized by NIST and NRCC.

11.0 PREVENTIVE MAINTENANCE

Maintenance logs are kept for each instrument and include documentation of column changes, detector cleaning, and parts replacement. Past calibration reports are also maintained. Spare parts and necessary maintenance items are kept in stock at all times to minimize instrument down time. All instruments are calibrated prior to or during use and must meet SOP acceptance criteria or the instrument is cleaned and/or further remedial action is taken. Each Laboratory Manager is responsible for scheduling maintenance, assigning qualified personnel to maintenance tasks and recording all maintenance activities.

12.0 ROUTINE PROCEDURES TO ASSESS DATA QUALITY

Data quality is routinely assessed for precision, accuracy, and completeness. Method detection limits are also calculated annually to confirm compliance with method detection limit criteria.

12.1 Precision

Relative Percent Difference (RPD) is a measure of precision and can be calculated from the concentrations of field duplicates or laboratory duplicates, and from the percent recovery of matrix spike/matrix spike duplicates:

$$RPD = \frac{(C_1 - C_2) \times 100\%}{(C_1 + C_2)/2}$$

where: RPD = relative percent difference

C_1 = larger of the two observed values
C_2 = smaller of the two observed values.

When field or laboratory duplicates are used, concentrations less than detection limits are given the value of half the detection limit for this calculation.

12.2 Accuracy

Laboratory blank spikes and matrix spikes can be used to determine the accuracy of an analysis in the laboratory. For laboratory blank spikes or sample matrix spikes, the following formula is used to determine percent recovery, which is then compared to control limits based upon historical data:

$$\%R = 100\% \times \left(\frac{S - U}{C_{sa}} \right)$$

where: %R = percent recovery
S = measured concentration in spiked aliquot
U = measured concentration in unspiked aliquot
C_{sa} = actual concentration of spike added

Standard reference material (SRM) with certified analyte concentrations can also be used to determine the relative accuracy of the method. Laboratory blank spikes can also be used with the following equation to determine the accuracy of an analysis in the laboratory.

When a standard reference material (SRM) or a spiked method blank is used:

$$\%R = 100\% \times \left(\frac{C_m}{C_{srm}} \right)$$

where: %R = percent recovery
C_m = measured concentration of SRM
C_{srm} = median concentration of the SRM

These results are then compared to control limits specified in the appropriate SRM certificate or known concentrations for laboratory blank spikes.

12.3 Completeness

Completeness is defined as follows for all measurements:

$$\%C = 100\% \times \left(\frac{V}{n} \right)$$

where: %C = percent completeness
V = number of measurements judged valid
n = total number of measurements

12.4 Method Detection Limit (MDL)

MDL is defined as follows for all measurements:

$$MDL = t_{(n-1,\ 1-\alpha = 0.99)} \times s$$

where: MDL = method detection limit
s = standard deviation of the replicate analyses
$t_{(n-1,\ 1-\alpha = 0.99)}$ = students' t-value for a one-sided 99% confidence level and a standard deviation estimate with n-1 degrees of freedom.

13.0 CORRECTIVE ACTION

Whenever a quality control sample does not meet stated project goals the procedure is reviewed to ascertain the cause of the error. If errors are discovered the analysis is repeated from the point of the error. If no error can be pinpointed the analysis is repeated. When appropriate, corrective action is applied to all samples analyzed concurrently with the sample that initiated the action. It is not sufficient to simply flag quality control errors; corrective action must be taken and documented using a Sample Action Request Form. All QC data, including SRMs, calibration checks, duplicates, laboratory blank spikes, and MS/MSD results are inspected to determine if a system-wide change is present.

Corrective action constitutes a variety of responses to noncompliance with QC requirements. Responses include replacement of GC columns, cleaning of detectors, recalibration, re-extraction of samples, and repair or replacement of parts and/or instruments as necessary. If an unacceptable "method blank" is present, analyses for the related extraction batch cease until samples are reprocessed and an acceptable method blank is produced. If the response of the calibration check standard exceeds the QC criteria, a second calibration check is analyzed. If the results are still in non-compliance a recalibration is performed. These criteria are monitored daily by the Laboratory Manager. As defined in the SOPs, the retention times for each analyte in a sample must be within the stipulated time of that observed during the most recent acceptable calibration or remedial action is initiated including leak testing and column replacement, if necessary.

Non-compliance of calibration checks or spiked blanks causes immediate cessation of analysis. Whether instrument recalibration (calibration check) or reevaluation of all sample results is necessary will be decided by a conference of the Laboratory Manager and the Program Manager. In all cases, the stated criteria must be met. These criteria may also be independently monitored by the Quality Assurance Manager to insure that QC data are being properly acquired, tabulated, and compiled.

If no errors can be found and the quality control failure appears to indicate that the quality control failure impacted a small number of the analytes within the scan, the TDH Quality Assurance Officer will be contacted for a decision. Any corrective action must be applied to all samples analyzed concurrently with the sample that initiated the action.

14.0 QUALITY ASSURANCE REPORTS TO MANAGEMENT

The Quality Assurance Manager is the senior management person responsible for all QA policies at GERG. The QA Manager is not part of the analytical process and reports to the Director of GERG. The QA Manager prepares an annual report for the Director and the Senior Associate Director and also provides verbal and written reports on an as needed basis.

Changes in the SOPs must have final approval of the QA Manager. For the GERG Quality Assurance Management Plan (QAMP), the Generic Quality Assurance Manual for Laboratory Staff and Operations (GQAM), or for any QAPP, the signature of the Director of GERG is required as well.

Appendix D

TCEQ Data Review Checklist

Data Review Checklist

Title of associated QAPP: _____

U, Y, or N/A

Data Format and Structure

A. Are there any duplicate *Tag ID* numbers? _____
B. Are the *Tag prefixes* correct? _____
C. Are all *Tag ID* numbers 7 characters? _____
D. Are TCEQ station location (SLOC) numbers assigned? _____
E. Are sampling *Dates* in the correct format, MM/DD/YYYY? _____
F. Is the sampling *Time* based on the 24-hour clock (e.g. 13:04)? _____
G. Is the *Comment* field filled in where appropriate (e.g. unusual occurrence, sampling problems, unrepresentative of ambient water quality) and any punctuation deleted? _____
H. *Source Code 1, 2* and *Program Code* are valid and used correctly? _____
I. Is the sampling date in the *Results* file the same as the one in the *Events* file? _____
J. Values represented by a valid parameter (*STORET*) code with the correct units and leading zeros? _____
K. Are there any duplicate parameter codes for the same *Tag Id*? _____
L. Are there any invalid symbols in the Greater Than/Less Than (*GT/LT*) field? _____
M. Are there any tag numbers in the *Results* file that are not in the *Events* file? _____
N. Have confirmed outliers been identified? (with a "1" in the Verify_flg field) _____
O. Have grab data (bacteria, for example) taken during 24-hr events been reported separately as RT samples? _____
P. Is the file in the correct format (ASCII pipe-delimited text)? _____

Data Quality Review

A. Are all the values reported at or below the AWRL? _____
B. Have the outliers been verified? _____
C. Checks on correctness of analysis or data reasonableness performed? _____
   e.g.: Is ortho-phosphorus less than total phosphorus?
   Are dissolved metal concentrations less than or equal to total metals?
D. Have at least 10% of the data in the data set been reviewed against the field and laboratory data sheets? _____
E. Are all parameter codes in the data set listed in the QAPP? _____
F. Are all stations in the data set listed in the QAPP? _____

Documentation Review

A. Are blank results acceptable as specified in the QAPP? _____
B. Were control charts used to determine the acceptability of field duplicates? _____
C. Was documentation of any unusual occurrences that may affect water quality included in the Event file Comments field? _____
D. Were there any failures in sampling methods and/or deviations from sample design requirements that resulted in unreportable data? If yes, explain on next page. _____
E. Were there any failures in field and laboratory measurement systems that were not resolvable and resulted in unreportable data? If yes, explain on next page. _____

U = Yes **Y = No** **N/A** = Not applicable

Describe any data reporting inconsistencies with AWRL specifications. Explain failures in sampling methods and field and laboratory measurement systems that resulted in data that could not be reported to the TCEQ. (attach another page if necessary):

Date Submitted to TCEQ: _____
Tag ID Series: _____
Date Range: _____
Data Source: _____
Comments (attach README.TXT file if applicable): _____

Planning Agency's Data Manager Signature: _____

Date: _____