Quality Management Plan
for
Technical Support for AWBERC and ESF Aquatic Research Facilities, Field Activities and Identification of Laboratory and Field Collections of Bacteria, Plants and Animals

Molecular Indicator Research Branch
Ecological Exposure Research Division
U.S. EPA National Exposure Research Laboratory

Contract Number EP-D-11-073
Work Assignment 4-04

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1.0 Management and Organization

1.1 Distribution List

James Lazorchak, U.S. EPA Work Assignment Contracting Officer's Representative
Ruth Corn, U.S. EPA Contracting Officer's Representative
Margie Vazquez, U.S. EPA NERL/EERD QA Manager
Dennis McMullen, CSS-Dynamac, Program Manager/Work Assignment Leader
Katherine Gilson, CSS-Dynamac, Program QA Officer

1.2 Project/Task Organization

The effective implementation of the quality assurance/quality control (QA/QC) requirements of this Work Assignment (WA)-specific Quality Management Plan (QMP), coupled with CSS-Dynamac's Program Quality Management Plan (PQMP) submitted previously to the Environmental Protection Agency (EPA) ensures the quality of all CSS-Dynamac/TMG environmental programs. Managers and staff at all levels have the authority and responsibility to stop work under their direction when personnel safety is compromised or when continued work will produce unacceptable results.

The project organization for WA 4-04 is shown in **Figure 1**, in which solid lines represent direct reporting relationships and dashed lines represent lines of communication. All personnel are employed by CSS-Dynamac/TMG, unless otherwise indicated. The responsibilities of each QA/QC function represented in the chart are detailed in the PQMP and are summarized below.

CSS-Dynamac's President, Doug Britt, and Helene McConnell (The McConnell Group Program Manager and Chief Operating Officer) provide CSS-Dynamac/TMG, with overall direction, guidance and management support for the PQMP. Both individuals have ultimate responsibility for the success of the QA Program.

The CSS-Dynamac Corporate QA Manager (CQAM)/Senior Vice President of Emergency Response & Disaster Recovery, Georgeann Morekas, reports to CSS-Dynamac's President, and maintains communication with the subcontractor on WAs in which subcontractors are employed. CSS-Dynamac's Program Manager (PM) for this contract, Dennis McMullen, reports to Ms. Morekas.

The CSS-Dynamac PM has overall responsibility for technical quality, cost control, laboratory personnel management, and adherence to project schedules. The PM is also responsible for directing and approving all technical work performed in a manner that meets the QMP specifications.

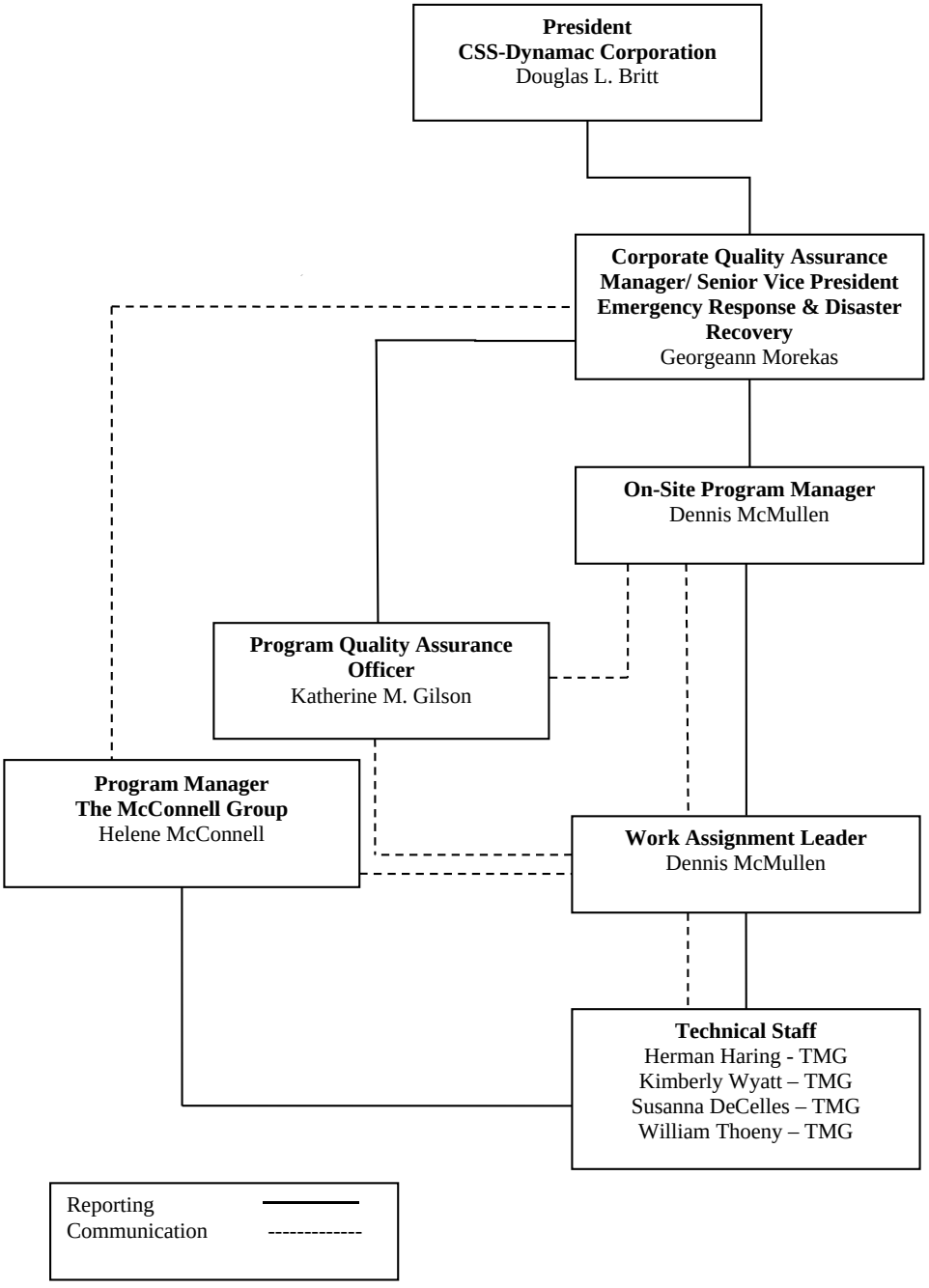
The CSS-Dynamac CQAM oversees QA/QC in all program areas. The CQAM develops QA/QC policy and reports directly to the Corporate President in all areas related to QA. The CQAM maintains communication with the Program Quality Assurance Officer (PQAO), Katherine Gilson, and the PM. The CQAM, located off-site, is independent of related technical activities, and has the authority to approve QMPs, conduct QA management assessments, and implement corrective actions. The CQAM notifies the CSS-Dynamac PM if significant deficiencies are found. The PM then notifies the EPA Contracting Officer's Representative (COR) and Work Assignment Contracting Officer's Representative (WA-COR) of the deficiencies. The CQAM may stop work on a project until corrective action is in place. This process ensures consistent quality management in all products and services.

The PQAO, with expertise in QA/QC as well as the technical objectives of the project, is responsible for maintaining, monitoring, auditing and enforcing the QA program. The PQAO is responsible for the quality of all work performed. The PQAO is accountable to the CQAM to ensure that appropriate quality standards are maintained and conflict of interest is avoided. The PQAO reports to and derives authority to enforce corrective actions from the CQAM.

The WAL for this WA, Dennis McMullen, is also the CSS-Dynamac PM. The WAL and project staff have responsibilities for fulfilling day-to-day QC requirements. These include taking corrective actions and responding to QC review requests from the PQAO. The WAL/PM reports directly to the CSS-Dynamac Corporate QA Manager (CQAM)/ Senior Vice President of Emergency Response & Disaster Recovery, and maintains communication with the PQAO and The McConnell Group Program Manager. The WAL is responsible for the technical quality of work within the respective laboratory or section, including adherence to prescribed procedures for calibration, preventive maintenance, data validation, training and corrective actions. The WAL is also responsible for the correct implementation of the Standard Operating Procedures (SOPs), for meeting project commitment dates (including preparation and analysis of samples within holding times), and for reporting data and QA information as required by the WA-COR. The WAL reports any problems to the PM and WA-COR when they are detected, and summarizes the status of the project in written reports on at least a monthly basis.

Project Staff have routine responsibility for implementing and documenting this QMP in daily activities. Full-time staff members for Contract No. EP-D-11-073, WA 4-04 are employed by The McConnell Group, a subcontractor to CSS-Dynamac. WA staff members report to the WA 4-04 WAL for technical direction.

Figure 1. CSS-Dynamac/The McConnell Group WA 4-04 Organizational Chart



1.3 Problem Definition/Background

The research mission of the US EPA's National Exposure Research Laboratory (NERL) is to develop, apply, and integrate exposure methods, measurements, databases, models, and assessments to reduce uncertainty for risk assessment and risk management. CSS-Dynamac/TMG provides technical support to the NERL Molecular Indicator Research Branch (MIRB) laboratory, Ecological Exposure Research Division (EERD), in Cincinnati, Ohio, (NERL-CI) through maintenance of aquatic cultures, biological support, toxicity assessments, laboratory and field work to support exposure studies, data collection, and statistical support. Other programs supported include Principal Investigators in Regional and Program Office Collaborators and partners as it pertains to water quality, ecosystem services related to contaminated sediments, Great Lakes Legacy and Restoration Areas of Concern (AOCs), pesticides, endocrine disrupting compounds (EDCs), pharmaceuticals, nanomaterials and other emerging contaminants, EPA's Experimental Streams Facility (ESF) studies, eco-restoration, real-time and near real-time biomonitoring research, Regional Methods Initiatives (RMI), Regional Assisted Research Efforts (RARE), and other ORD initiatives. Contractor support includes conducting laboratory and field exposure assessments and collections, toxicity testing of water and sediment, identification of field organism collections, and providing reports on results, as requested, during the contract period from July 1, 2015 - June 30, 2016.

Technical support work provided by CSS-Dynamac/TMG consists of the following tasks, which are discussed in detail in this Quality Management Plan (QMP). The objective of this QMP is to ensure, assess, and document that all data collected, stored, reported, or used by CSS-Dynamac/TMG for the MIRB (as well as other EPA entities supported by the WA - NRMRL and OSWER Superfund) are scientifically valid, defensible, and of the precision and accuracy required to meet measurement objectives.

CSS-Dynamac/TMG provides technical support through WA 4-04 in the following areas:

- Culture Maintenance

- Indicator Development and Technical Support for Bioassessment and Biomarker Activities
    - aquatic and/or terrestrial toxicity tests
    - develop new methods for these exposures
    - field collection studies
    - taxonomic identification and enumeration of aquatic invertebrate samples and algae samples

- Superfund/Contaminated Waste Treatment Projects
    - aquatic toxicity tests
    - sediment toxicity tests

2.0 Quality System Description

2.1 Project Task Development

Development of new testing methods follows established guidelines, with proper development and validation of the new methods. For example, prior to beginning the development of a new method, a Work Plan is developed that addresses the issues related to determining the success of the effort. The Work Plan includes the number of successful pure chemical tests required to provide an estimate of the precision, accuracy and reproducibility of the new method, and the number of side-by-side tests required with the new method and the established method it might replace. This method development is performed in a manner such that sufficient data is generated for an adequate comparison of the two methods. Other issues that might need to be addressed during method development include the number of tests required with a single natural sample, so that sufficient data is generated to provide an estimate of reproducibility, as well as the number of different natural samples needed for testing, either individually or as part of a comparison between the new method and any applicable existing method(s). As stated, these are just some of the possible questions to be addressed.

Products generated by this WA may include:

- Draft sections for peer-reviewed journal articles or complete article drafts;
- Standard Operating Procedures (SOPs) for use by other groups performing similar types of studies; and
- Summary reports for work performed, including the analysis and summary of the data, along with recommendations as to how to interpret the results and a synopsis of the meaning of the results.

Due to the scope of this work, exact schedules are difficult to develop. The culture work takes place on a daily basis, including weekends and holidays. The other projects are scheduled to fit the time available and to fulfill the basic requirements of the contract. A detailed description of all WA 4-04 tasks is provided in the WA 4-04 Work Plan.

2.2 Quality Objectives and Criteria for Measurement Data

All projects assigned to CSS-Dynamac/TMG by the MIRB include specific SOPs (or guidelines to develop SOPs) and QA techniques for proper performance of the projects. The Data Quality Objectives (DQOs) supplied by the EPA include items such as minimum acceptable survival and/or growth of the test animals in the control samples, specific culture performance criteria such as survival, reproduction or growth and specific water quality parameters that must be met for test and culture water to be acceptable.

Standard procedures for assessing the precision and completeness of data derived from laboratory-analyzed samples are employed for all activities. Procedures may include splitting of samples for QA of laboratory analysis and/or other techniques as determined in the Work Plan for each activity. QA/QC of the samples analyzed include side-by-side testing of the samples with known reference toxicant materials, in order to provide a measure of the response of the test animals used in a specific study to a known toxicant. Analysis of the known toxicant data from a test is used to judge the acceptability and usefulness of the test data. If the known toxicant tests fail to meet specific requirements, the test data generated are considered suspect. All efforts are made to repeat the test of these samples with animals that provide acceptable results. For the cultures, specific culture criteria include the minimum average number of young (or eggs) produced each day by the invertebrate and fish cultures. If these minimum requirements are not met, the WA-COR is notified, and efforts are made to resolve the problem. Each SOP contains a listing of the performance criteria that must be attained before a particular animal or plant culture, toxicity test, or water quality parameter is considered acceptable.

2.3 Quality Assurance Reviews

Contract personnel participate, as requested, in external EPA audits. The PQAO also performs internal on-site technical system audits at least annually to monitor the implementation of the QMP. The audit includes a complete review of all analytical, instrumental, and data systems described in the SOPs. A written report describing deficiencies is submitted to the CQAM, the WAL, the EPA WA-COR, the PM, the McConnell Group Senior Program Manager, the EPA EERD QA Manager, and the EPA COR. Corrective actions are implemented and documented for each deficiency, as appropriate. CSS-Dynamac/TMG maintains hard copies of the audit reports for the duration of the contract.

At the completion of each study, all data sets are reviewed completely by senior WA personnel from raw data, instrumental print-outs, bench sheets, and lab notebooks. These materials are used to prepare the final study reports that are submitted to the EPA and must be accurate and complete. Problems found in the data are addressed, corrected if possible, and recorded. If it is not possible to take a corrective action to retrieve the lost or unrecorded data, the reason is also recorded. If necessary, a QA review form is completed and submitted to the WAL for corrective action. Corrective actions are submitted in writing to the PQAO who verifies them for effectiveness. Copies of the completed QA review forms are filed with associated data sets.

2.4 Sampling Methods

Samples of fish, algae and aquatic invertebrates are field collected and returned to AWBERC for analysis. When these samples are returned to AWBERC, they are logged into the appropriate log book based on established SOPs. **Appendix A** contains a list of all WA SOPs. These are located on the server at L:\Priv\Cin\NERL\Dynamac\QA\SOPs\Current SOPs\Aquatic Toxicology.

2.5 Sample Handling and Custody

Several sample handling and custody procedures are followed:

- Handling of samples is in strict accordance with procedures outlined in CSS-Dynamac/TMG SOP #T-01-008, Sample Handling and Safety Procedures. This SOP lists procedures for tracking samples as well as the proper storage location for all samples.
    - The WAL is the designated sample custodian and has overall responsibility for maintaining records for all samples received and the use and disposition of these samples. These samples are discarded according to instructions received from the WA-COR.
    - All water and sediment samples received have a defined holding period, in which tests must be completed. This makes sample tracking even more important, as it is possible to lose the ability to analyze a sample if it is not tested in time.
    - Sample information is maintained in spreadsheets located at:
        - L:\Priv\Cin\NERL\Dynamac\TMG \Chem Logs and at L:\Priv\Cin\NERL\Dynamac\TMG WA 06\TMG\EMAP-GRE Sed Tox.

      These spreadsheets contain information on the sample date, the sample received date, the test date, and the location of the samples. The records for these samples are maintained on the Chain of Custody (COC) forms or sample tracking sheets used for each project. These forms or sheets contain information on the Site ID, date the sample was collected, sample type, and number of containers for the sample. If sites are being sampled more than once in a study, the form also records the visit number for that sample.
    - The tracking records for the other projects are maintained as hard copies in project specific binders. These copies list information on the dates tests are run and the specimens used.

- All samples received are logged into a project binder maintained by the WA staff. This includes a listing of all samples, the date sampled, the date the sample was received, the initials of the person logging the samples, the type of sample (i.e. water or sediment) and the routine chemical analysis performed on water samples, upon arrival. These analyses

include pH, dissolved oxygen, conductivity, temperature, alkalinity and hardness.

- Superfund samples received are tracked using standard COC procedures. Depending on the source of the samples, some non-Superfund samples also follow Superfund procedures. These samples are identified by the WA-COR.
- Other samples are tracked by internal (CSS-Dynamac/TMG/EPA) custody procedures if the agency or group collecting the samples does not require COC for the samples. These procedures include maintaining hard copy records in project-specific binders. These records list information on the dates the tests are run and specimens used.
- Some of the sample freezers are monitored as part of METASYS. The single door sample refrigerator, the walk-in refrigerator and the double door freezer are not on METASYS. A logbook is maintained to track the temperatures for these units. The temperatures of non-METASYS units in other rooms are monitored by the primary user of the room.
- Excess fish, as determined by CSS-Dynamac/TMG SOP #T-03-101, Procedures for Euthanasia and Disposal of Excess Fish, from the FHM Culture Unit are sacrificed and discarded following the procedures outlined in CSS-Dynamac/TMG SOP #T-03-101, and in accordance with good laboratory practices. This SOP is based on approved animal care and handling protocols.

2.6 Quality Control

QC samples are used and equipment calibrations are performed at a frequency adequate to satisfy the specific QC parameters. For example:

- The reproduction of certain cultures is monitored daily.
- The growth of other cultures is monitored for quality each month.
- QA/QC parameters related to the different test or sample analysis methods are monitored as part of the ongoing analysis of samples.
- Related SOPs provide the calculations related to the culture or testing QA/QC parameters.

2.7 Instrument/Equipment Inspection, and Maintenance

Prior to the daily use of an instrument or piece of equipment for culture or testing procedures, the instrument is tested, inspected, and maintained. All meters and instruments are calibrated daily before use. All probes are inspected prior to and after use, to ensure proper working order. All equipment are tested, inspected, and maintained according to the manufacturer's specifications. If needed, in-house SOPs are developed for calibration and use of a specific instrument. Spare parts, such as calibration standards, replacement membranes and replacement probes are kept on hand. Once replacement/spare parts are used, replacements are re-ordered, to avoid equipment downtime due to a lack of replacement parts.

In the event of equipment failure, the WAL immediately informs the EPA WA-COR and tags the equipment as unusable. The WA-COR then directly contacts, or requests the WAL to contact, the equipment vendor or a suitable repair specialist to arrange for equipment repair at the earliest possible date. The WAL records the equipment failure and subsequent actions to bring the equipment back into operational order in the logbook for that piece of equipment.

2.8 Instrument/Equipment Calibration and Frequency

Each piece of equipment has a specific logbook in which all calibration records and maintenance are recorded. This logbook is labeled with the equipment manufacturer, type of equipment, model number and serial number, so that the logbook can be traced to the specific instrument.

All of the analytical scales, pH meters, dissolved oxygen meters and conductivity meters, are calibrated each day prior to use.

Standard equipment including pipettes, metering pumps, etc. are calibrated and maintained according to manufacturer recommendations.

Pipettes are calibrated by an outside vendor, annually. Calibration checks are performed on pipettes used for algal sample processing. These calibration checks are performed weekly or before each use. Pipette calibration checks are recorded in the pipette log book in the Algae Laboratory.

Centrifuges are calibrated by an outside vendor, annually.

Balances are calibrated by an outside vendor, annually. The accuracy of each balance is checked using NBS certified analytical balance weights appropriate to the weighing range, daily or before use. The balance calibration checks are recorded in the balance log book located with the balance.

Bench top chemical measurements are taken three times weekly (M-W-F) on the Labline water system to monitor water quality parameters. This includes temperature, pH, conductivity, dissolved oxygen, hardness, alkalinity, total chlorine and free chlorine. (SOP# T 02-008, Standard Operating Procedure for Routine Chemical measurements). Hardness is the only Labline parameter actively manipulated via a $CaCl_2$ pump to supplement dechlorinated tap water. New water quality parameters will be instituted at year's end after sufficient chemistry data have been gathered over multiple seasons with the new Labline system. A series of four activated carbon filters in Room 742 are changed out every 3-4 months by Dayton Water. A new filter has been installed in Room 740 to gather fine particulate breakthrough from Room742 activated carbon filters and is changed every two months. Filters at terminal Labline delivery pipes at sinks in labs are changed on an as needed basis.

Currently, all Labline water parameters are also monitored 24/7 by a series of meters recently installed in Room 742 as part of the Infrastructure Improvement Project (IRP). Water level, temperature, and chlorine have alarms monitored by the AWBERC Facilities contractor. However, some of these meters have failed since they were installed, and discrepancies exist between values measured by these meters and the bench top chemical measurements, so their value to the Work Assignment has yet to be proven. The discrepancies are noted under "Difficulties Encountered and Remedial Actions" section of the monthly reports.

3.0 Personnel Qualifications and Training

3.1 Training

All personnel who maintain aquatic or terrestrial cultures or perform toxicity testing exposures must receive proper training that is overseen and certified by qualified personnel (usually the first-line supervising scientist). Terrestrial field sampling crews are trained by the Terrestrial Specialist in collection of non-target invertebrates. Primary aquatic field staff members train other staff in aquatic field sampling.

Training includes:

- Reading the SOPs developed by CSS-Dynamac/TMG for use in maintaining cultures or conducting toxicity tests.
- A briefing from qualified personnel on the basics of culture maintenance and toxicity testing, including proper animal handling, methods for preparing samples for toxicity testing and calibration methods for all instrumentation used during toxicity testing.
- Direction from the supervising scientist on proper record keeping, including maintenance of laboratory data sheets, notebooks and equipment logbooks.
- Successful performance of a reference toxicity test under the direction of the trainer (i.e., supervising scientist). This includes isolating the animals to be used in the test, preparation of the test solutions, monitoring of the routine test chemical parameters, handling of all test animals and performance of statistical analysis of the test data. Related reagent preparation or other tasks associated with preparing for the conduct of the experiment must be performed by the trainee.
- Personnel involved in the necropsy of adult fish are trained by experienced staff. Personnel are instructed in the proper techniques to sedate an animal, the types of instrumentation used for the procedure and the location of all organs of concern to be collected. Instruction includes the procedures for labeling the collection vials and cleaning the instruments between usages on all fish.
- Certification of successful completion of training by the supervising scientist, including observation of successful performance of tasks.

- Field crews are instructed in the proper methods for field collection, using SOPs and demonstrations. The WAL evaluates crew performance and will institute retraining should results from field form and sample reviews indicate tasks are being performed incorrectly.

    - Field crews also complete eight hours of Field Safety training put on by Safety Health and Environmental Management (SHEM).

Original records associated with training are maintained in the trainee's lab notebook or project files. The trainer must maintain a record of the trainee's successful completion of the training program in their notebook or files.

4.0 Documents and Records

Proper record keeping, data collection, and documentation are essential for maintaining the history of the culture animals or for processing and analysis for each sample.

4.1 Record Handling and Storage

Appendix A provides a list of all SOPs used by WA 4-04. All SOPs can be accessed from the LAN share drive at L:\Priv\Cin\NERL\Dynamac\QA\SOPs\Current SOPs\Aquatic Toxicology. The WAL is responsible for oversight of the preparation and revision of CSS-Dynamac-generated SOPs. Guidance and assistance for SOP preparation is provided by the PQAO. When a draft is prepared, it is reviewed and approved by the PQAO and the On-Site PM. The PQAO assigns SOP numbers and revision numbers to approved SOPs.

All work completed by contract personnel is recorded on the related test datasheets or in their respective laboratory notebooks. All datasheets for a specific study are maintained in a study specific binder. In addition, all studies are summarized in an electronic report format. These summaries include a description of the study, a summary of the test methods used to analyze the samples, a summary of the test data generated (including routine chemical parameters) and a summary analysis of the results from the test. The electronic version of the text report is prepared in WORD. Applicable spreadsheets are maintained in Excel. A hard copy of the electronic report is maintained in the study binder. This data is in a format commensurate with requirements of the EPA for archival in the EPA relational databases, and is maintained electronically in a location specified by EPA for as long as requested by the EPA. All bench sheets, data analysis printouts, and report hard copies for a study are maintained in properly labeled binders. Electronic copies of reports and data are maintained on the Local Area Network (LAN) (either WAL directory or share drive), CD-Rom or on labeled diskettes in the WAL's office. Records are maintained until submitted to the WA-COR for storage under EPA requirements.

Calibration logbooks are kept with the instrument until full. Once full, the old logbook is submitted to the WA-COR, and a new calibration logbook is put into service. Each of the SOPs for a specific culture organism contains a detailed listing of all basic culture records to be maintained for that culture.

Preparation details of any chemicals used in sample analysis and/or toxicity testing are recorded on the applicable sample analysis and/or toxicity testing log sheet. These notes detail the material prepared, the formula of the reagent used in preparation, the amount of reagent used, the vehicle into which the reagent was dissolved and the amount of vehicle used.

Copies of audit reports, corrective action forms, and QA data review forms are maintained by the WAL and the PQAO. Where appropriate, the forms are filed with associated data sets. These forms are made available, upon request, to the EPA. These records are retained by CSS-Dynamac/TMG for the duration of the contract. All electronic communications between the WAL and WA-COR are maintained by the WAL.

A Labline water quality parameter log book is maintained and updated three times per week, when chemical measurements are taken, to assure water quality indices are within desired target range. An electronic spreadsheet (L:\Priv\Cin\NERL\Dynamac\TMG WA 06\Monthly Report\LLCHEM\LLDATA) is updated on a monthly basis for inclusion into a monthly report, which is then submitted to the principal investigator.

4.2 Toxicity Test Records

Proper record keeping, data collection, and documentation are essential for maintaining the history of each toxicity test. Data are recorded on a real-time basis to prevent loss of information or introduction of errors. All data are maintained as a hard copy for an indefinite period. Errors are corrected by drawing one line through the incorrect entry, writing EE beside it, initialing and dating the error, and writing the correct entry. All data sheets are completed in ink, initialed or signed, and dated. All data pertaining to a test are maintained together in the appropriate notebook and reviewed by the laboratory supervisor upon completion of the test. A complete file is maintained for each toxicity test. This test file includes:

- A copy of the chain-of-custody record, when applicable.
- A Test Data Log Sheet.
- Original laboratory bench sheets for all procedures performed in the test.
- Copy of the final report.

All final reports include a project summary, the type(s) of tests or analysis used, a summary of the test data, a summary of the water chemistry parameters and a summary of the test results, including a discussion interpreting the results. The discussion section includes variations from standard testing methods, and discussion of problems encountered and remedial actions taken.

5.0 Assessment and Response

5.1 Assessments and Response Actions

The WAL and WA staff monitor the quality of data produced during this WA on a daily basis. If data are detected that do not meet the MIRB (or NRMRL/Superfund) QA standards, the EPA WA-COR is notified immediately, and corrective action is taken to improve the quality of the data. This may include changes to culture procedures to increase productivity or conducting tests a second time (if applicable) to obtain quality data. If these actions fail to produce data of acceptable quality, the EPA WA-COR is notified. WA personnel then suggest resolutions to the problem.

5.2 Reports to Management

Contract personnel provide a monthly technical report to the PM. The PM furnishes one copy of the written detailed WA status report to the EPA WA-COR by the 15th of the month. This report includes all task numbers, and whether each is completed or work-in-progress. This report also includes: a description of work performed for each task within the past reporting period; a description of work performed within each broad task; and addresses problems encountered and /or solutions, work planned for the next report period, staffing, budget and changes in technical direction. The reports are prepared by the WAL, with input from staff, for delivery to the PM. Once approved by the PM, the monthly status report is submitted to the EPA WA-COR. The WA-COR may either acknowledge receipt of the report, or provide feedback.

QA/QC audits performed annually are reported to the EPA, as part of the regular WA monthly report, and in a separate QA/QC Audit report. This report includes all WA areas checked for QA/QC conformance, any areas that were not in conformance and all steps taken to address and resolve the non-conformance issues.

WA 4-04 personnel also attend meetings with the EPA WA-COR, as required, to discuss progress and results.

6.0 Quality Management

The WAL and senior WA staff review data from all culture or toxicity testing procedures. Throughout the recording, manipulation, entry, analysis and summation of the data, numerous checks are used to ensure the data entered and all data manipulations are correct.

- WAL and staff review bench sheets daily throughout the study, to ensure all data are recorded promptly and correctly.

- Once data are entered into an analysis package, spreadsheet, or word processing program, other staff members review the data against the bench sheets, to ensure the data entered are correct.
- The use of data analysis packages or spreadsheets is reviewed by performing basic computations with a calculator, to verify the accuracy of the mathematical manipulations.
- Data sheets are signed when reviewed, or a notation is made on the log sheets when data are reviewed.
- Computation reviews are recorded on hard copy and entered into the study logbook.

6.1 Verification and Validation Methods

Verification and validation is carried out by MIRB staff upon data review and acceptance by the WAL. The EPA WA-COR is responsible for verifying the methods to be used by the WA, with input from the WAL and the staff. Verification may include multiple tests with reference toxicant materials, to establish a data set to measure the reproducibility of the data generated by the method. It may also involve side-by-side testing of different methods, to determine which method produces the most consistent data. Culture methods may also be verified using these same types of tools.

6.2 Reconciliation with User Requirements

Before submission to the EPA, contractor personnel review and verify the data generated by WA 4-04 according to the criteria described in section 6.3. Once the WA-COR has reviewed the data, requests may be made to re-examine, re-format or re-analyze the data. These operations may include but are not limited to; conversion of data formatting, modification of approaches to data analysis, and reanalysis of previously analyzed data. WA staff makes every effort to provide the data to the WA-COR and other Principal Investigators in a format that meets the requirements established by the SOW and WA Work Plan. Requirements to reconcile data with user needs are documented in the resubmitted data as well as in the next monthly report. The reports on reconciliation include the problems encountered by the EPA with the data and the steps taken by the WA to reconcile the existing dataset with the specific data requirement. If the data are such that limitations on the use are required, these limitations are explained in detail in all reports concerning the data in question, and in all appropriate WA monthly reports.

6.3 Data Management and Analysis

Unless instructed to implement other procedures by the MIRB WA-COR, data obtained through aquatic or terrestrial culture and toxicity testing analysis are managed in strict accordance with procedures outlined in the SOP specific to each test or culture procedure **(Appendix A)**, or in the applicable USEPA testing methods manuals. Both an electronic copy and hard copy of all data generated are maintained by the WAL. The electronic copies are maintained on the M-drive,

with copies also maintained on the share drive where they can be accessed by the WA-COR or any interested principal investigator. The individual files are named using a combination of the study name and date. All laboratory derived data are recorded on appropriate data logsheets or into laboratory notebooks. These logsheets and notebooks are maintained in the laboratory as long as the study remains in progress. Once the study is completed, the binders are moved to one of the office locations for data entry and report preparation. Once a study is completed, the data are entered into one of the data analysis programs or into Excel spreadsheets for further manipulations prior to analysis. When data analysis programs are used that are not designed for the storage of data electronically, only hard copies of these analysis results are available. These hardcopies are maintained in the study binders. For those analysis programs that do allow for electronic data storage, the data for each study are stored on the LAN share-drive under an electronic folder specific to that study, or on CD-Rom for long term storage of data that is no longer active. At the completion of the data analysis, all raw summary data for a study, as well as the reduced data, statistical analysis results and all related chemical data are entered into a summary report that is used to transfer the data and all data interpretation to the WA-COR for use by him or other Principal Investigators. Once the datasheets are no longer required for the task, the study notebooks are maintained in one of the office locations.

Data are analyzed using approved methods for analyzing aquatic toxicity testing data. These include, but are not limited to, Probit V1.5, Trimmed Spearman-Karber V1.0, Linear Interpolation V1.5 and Dunnett's V1.7. These programs are available from the USEPA Website and have been downloaded for use onto the various computers assigned to the staff of this WA. More involved data analysis is conducted using Systat Version 11.

Some data require more specialized analysis. When more specific analysis is required, programs such as Systat and Excel are used. These analyses may include t-tests, analysis of variance for large datasets, or other analysis not included in the EPA-specific statistical analysis programs.

The guidelines described above were developed with input from the USEPA WA-COR, and conform to the system required to manage, analyze and report all data.

7.0 Procurement of Items and Services

7.1 Inspection and Acceptance of Supplies and Consumables

Only materials that have been approved by the EPA WA-COR are used in the course of this WA. Only brands of reagents and / or equipment that are specified in the SOPs for culture, toxicity testing, and field collection are ordered and used by contract personnel unless otherwise directed by the EPA WA-COR. The WAL inspects all shipments on arrival to determine the suitability, for use by the WA staff, of the items. The items are acceptable as long as an item meets analytical grade requirements, or FDA requirements for plastic items. Items not found to be

acceptable are returned to the supplier for replacement. Reagent lot numbers are recorded so that they can be tracked should any problems occur.

8.0 Computer Hardware and Software

8.1 Computer Hardware

Computer hardware used for the WA is that assigned by the EPA to contract staff. The systems available are suitable for the data entry and analysis and report preparation required.

8.2 Computer Software

Computer software used for the WA is that provided by EPA. This includes word processing, spreadsheet and data analysis software.

9.0 Planning

Schedule of Work.
Planning for work to be conducted is discussed in the WA 4-04 Work Plan. Generally, the WA-COR provides notice for an activity not specified in the Statement of Work in a timeframe that is task/project dependent. The WAL then prepares a schedule of work for the requested task/project.

10.0 Implementation of Work Processes

Responsibilities. The WA 4-04 Work Plan discusses the lines of responsibility for the work and the associated quality of data. All staff members are responsible for various activities, but the WAL is ultimately responsible for the implementation of the Work Plan, QMP and necessary QAPPs.

Appendix A. List of WA 4-04 SOPs

SOP	Group	SOP Title
T-01-001	General	Chain of Custody Record
T-01-003	General	Randomization and Color Chart
T-01-004	General	Range Finding Tests
T-01-005	General	Record Keeping
T-01-007	General	Sample Dilution Series Determination, for use with Unknown Water Column Samples
T-01-008	General	Sample Handling and Safety Procedures
T-01-009	General	Shipment of Animals to Outside Users
T-01-010	General	Statistical Analysis Procedures
T-01-011	General	Calibration and use of Orion Model 920 Meter and Model 905-12 Ammonia Electrode
T-01-013	General	Glassware Cleaning Procedure
T-02-001	Water	Super Q Water System
T-02-002	Water	Labline Water Supply
T-02-004	Water	Moderately Hard Reconstituted Water
T-02-006	Water	Reformulated Moderately Hard Reconstituted Water
T-02-007	Water	Labline - Super-Q Water Prep
T-02-008	Water	Routine Chemical Measurements
T-03-001	Culture-food	Algal Culture (*Selenastrum capricornutum*)
T-03-002	Culture-food	Brine Shrimp Culture (*Artemia salina*)
T-03-003	Culture-food	CGFF (*Hyalella azteca*) Food Prep
T-03-004	Culture-food	Digested Flake Food Alfalfa Yeast (FFAY)
T-03-005	Culture-food	*Chironomus tentans* Food Preparation
T-03-006	Culture-food	Supplemental Alfalfa Food Preparation
T-03-007	Culture-food	Rotifer Multiculture for Zebrafish Fry
T-03-100	Culture	Fathead Minnow Culture Method (*Pimephales promelas*)
T-03-101	Culture	Procedures for Euthanasia and Disposal of Excess Fish
T-03-102	Culture	FHM Processing for Identification
T-03-200	Culture	Zebrafish Culture Method - Danio rerio
T-03-300	Culture	Mass Culture (*Daphnia magna*)
T-03-302	Culture	Mass Culture Methods (*Ceriodaphnia dubia*)
T-03-304	Culture	Culture Method (*Hyalella azteca*) note: still in review
T-03-306	Culture	*Chironomus tentans* Culture Method

T-03-307	Culture	Individual Tracking Culture (*Ceriodaphnia dubia*)
T-03-309	Culture	*D magna* tracking culture
T-03-502	Culture	Neocloeon Culture
T-04-001	Ref Tox	Current Monthly Std Ref Toxicity Tests Concentration Guidance
T-04-002	Ref Tox	Standard Reference Toxicity Test Method for Acute Toxicity: (*Pimephales promelas*)
T-04-003	Ref Tox	Standard Reference Toxicity Test Method for Acute Toxicity: (*Ceriodaphnia dubia*)
T-04-005	Ref Tox	Standard Reference Toxicity Test Method for Chronic Toxicity: (*Daphnia magna*)
T-04-009	Ref Tox	Fathead Minnow Embryo-Larval Reference Toxicity Test
T-04-011	Ref Tox	Standard Reference Toxicity Method for Acute Toxicity: (*Daphnia magna*)
T-04-012	Ref Tox	*C triangulifer* Acute Ref Tox
T-04-013	Ref Tox	*C triangulifer* Chronic Ref Tox
T-04-014	Ref Tox	*H azteca* Acute Ref Tox
T-04-016	Ref Tox	*C tentans* Chronic Ref Tox
T-05-001	Gene Exp	FHM Adult Gene Expression Test Procedure
T-05-002	Gene Exp	FHM Fry Gene Expression Test Procedure
T-05-003	Gene Exp	Necropsy Procedures for Adult *Pimephales promelas*
T-05-004	Gene Exp	Procedures for conducting Aquatic Gene Expression Toxicity Testing using *Chironomus tentans*
T-05-005	Gene Exp	Conducting FHM Adult Gene Exp Toxicity Tests with a Flow-thru Diluter System
T-05-006	Gene Exp	Flow-through Diluter System KCL Dilution Testing
T-05-007	Gene Exp	Larval FHM WET EDC Tests
T-05-008	Gene Exp	Pesticide Phase I Diluter Exposure
T-05-009	Gene Exp	Whole Effluent Thyroid Disruption FHM Larvae
T-06-001	Sed Tox	Artificial Sediment Prep (Sand Control)
T-06-002	Sed Tox	EMAP Sediment Toxicity Testing for Modified Zumwalt Renewal System
T-06-005	Sed Tox	*Lemna minor* 4-day Sediment Toxicity Test
T-06-006	Sed Tox	*P. promelas* Embryo-Larval Sediment Toxicity Test
T-06-007	Sed Tox	Sediment Reference Toxicity Testing Reduced Volume Testing with *Hyalella azteca*
T-06-008	Sed Tox	Sediment Test Food Preparation (*Chironomus tentans*)
T-06-010	Sed Tox	Sediment Toxicity Test Method, 10-Day, *C. tentans*

T-06-011	Sed Tox	Sediment Toxicity Test Method, 10-Day, *H. azteca*
T-06-012	Sed Tox	Sediment Toxicity Testing, Reduced Volume, *C. tentans*
T-06-013	Sed Tox	Sediment Toxicity Testing, Reduced Volume, *H. azteca*
T-06-015	Sed Tox	*H azteca* Automated Sed Tox
T-07-001	Aqua Tox Acute	Acute Toxicity Test Methods (*Ceriodaphnia dubia*) Superfund
T-07-002	Aqua Tox Acute	Acute Toxicity Test Methods (*Pimephales promelas*) Superfund
T-07-003	Aqua Tox Acute	Acute Toxicity Testing, *D. magna*, NPDES
T-07-004	Aqua Tox Acute	Acute Toxicity Tests (*Ceriodaphnia dubia*) NPDES
T-07-005	Aqua Tox Acute	Acute Toxicity Tests (*Chironomus tentans*) NPDES
T-07-006	Aqua Tox Acute	Acute Toxicity Tests (*Hyalella azteca*) NPDE
T-07-007	Aqua Tox Acute	Acute Toxicity Tests (*Pimephales promelas*) NPDES
T-08-001	Aqua Tox Chronic	Chronic Toxicity Test Method, *Daphnia magna*
T-08-003	Aqua Tox Chronic	Chronic Toxicity Tests (*Ceriodaphnia dubia*) NPDES
T-08-004	Aqua Tox Chronic	Chronic Toxicity Tests (*Pimephales promelas*) NPDES
T-08-005	Aqua Tox chronic	Fathead Minnow Embryo-Larval Test (*Pimephales promelas*)
T-08-006	Aqua Tox Chronic	*Lemna minor* 4-day Water Column Toxicity Test
T-10-001	Chlor-a	Chlorophyll-a Extraction, and Analysis
T-11-001	Field	Boat Electrofishing
T-11-002	Field	Backpack Electrofishing
B-03-001	Algae	Periphyton Identification and Enumeration Login and Sample Splitting
B-03-002	Algae	Identification And Enumeration Of The Total Algal Community Using A Palmer Cell
B-03-003	Algae	Diatom Identification and Enumeration; Acid Digestion of Diatom Samples
B-03-005	Algae	Taxonomic References for Algal Identification
B-03-013	Algae	Diatom Slide Preparation
B-03-014	Algae	Diatom Identification and Enumeration
ESF SOP 023	Macroinvertebrates	Sorting, Enumeration, Taxonomic Identification, and Measurement of Invertebrate Samples
B-01-004	Macroinvertebrates	Macroinvertebrate Sample Processing for ID and DNA Barcoding
B-02-003	Macroinvertebrates	Annotated List of Taxonomic References Used for Identification of Aquatic Macroinvertebrates: Note: in review
B-02-010	Macroinvertebrates	Identification and Enumeration of Macroinvertebrate Samples for I D and DNA Barcoding