# Quality Management Plan

Lake Superior Research Institute  
University of Wisconsin-Superior

## DOCUMENT REVIEW AND APPROVAL:

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<th>Role</th>
<th>Printed Name</th>
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<tr>
<td>Director of LSRI</td>
<td>Mary Balcer</td>
<td></td>
<td>23 April 2014</td>
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<td>LSRI Quality Assurance Manager</td>
<td>Kelsey R. Prihoda</td>
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## REVISION HISTORY

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ORGANIZATION, RESPONSIBILITY, AND AUTHORITY

LSRI Quality Policy

The Lake Superior Research Institute (LSRI) is committed to a comprehensive quality assurance (QA) and quality control (QC) program in its environmental data operations. Environmental data is defined by the United States Environmental Protection Agency (US EPA) as “any data or information pertaining to the environment that describe measured outputs from processes; environmental conditions in a specific location; ecological effects and consequences; health effects and consequences; biological, chemical, and radiological conditions; or the performance of environmental technology” (US EPA 2012). The LSRI Quality Management System (QMS) is based on US EPA requirements as outlined in the Quality Standard for Environmental Data Collection, Production, and Use by Non-EPA (External) Organizations, CIO Standard 2106-S-02 (US EPA 2012).

All LSRI staff and students involved in environmental data operations are accountable for the quality of the data they generate. The QA requirements of each project are met by the cooperative effort between project management and the LSRI Quality Assurance Manager (QAM). Copies of the LSRI Quality Management Plan (QMP) are distributed to all staff and students associated with projects requiring QA. The Director of LSRI assumes the ultimate responsibility for adherence to the practices described in this document.

The objectives of LSRI’s QMS are to:

1. Provide assurance to LSRI senior staff and management that the facilities, equipment, personnel, methods, practices, records, and controls for each project requiring QA oversight conform to US EPA CIO Standard 2106-S-02 (2012).
2. Maintain independence from personnel engaged in project direction/conduct while providing satisfactory QA/QC for each project.
3. Provide assurance to funding agencies and to the public that data generated under the LSRI QMS have scientific integrity and transparency. Furthermore, that any decisions based on the data are based on sound science, are reliable and defensible.
4. Provide a method for continual improvement of LSRI’s environmental data operations.

The purpose of this QMP is to ensure the generation of scientific information having the accuracy, completeness, and documentation necessary to fulfill the requirements of each project conducted at LSRI. The QMP is designed to aid project personnel in accomplishing the project goals and providing confidence in the results of each scientific investigation.

This QMP is applicable to all research projects conducted by LSRI requiring QA oversight (i.e., those projects collecting environmental data). Each individual project has additional QA/QC components, which augment this QMP and generally consist of written standard operating procedures (SOPs), either provided by the funding agency or prepared by LSRI staff in conjunction with the funding agency. Projects may also require a specific Quality Assurance Project Plan (QAPP) detailing the data quality objectives (DQOs) and measurement quality objectives (MQOs) inherent to the particular project.
Organization

The Lake Superior Research Institute, formerly the Center for Lake Superior Environmental Studies, was created in 1967 and formally recognized by the University Of Wisconsin Board Of Regents in 1969. LSRI’s mission includes environmental research, environmental education, and public information for the Great Lakes Region. Since LSRI’s inception, numerous faculty, staff, and students have conducted studies in areas such as water quality; regional flora and fauna; mineral resources; Lake Superior and inland fisheries resources; red clay erosion; harbor sediment quality; air quality; bioaccumulation, biodegradation, and toxicity of chemicals; chemical contamination of fish and other environmental samples; structure-activity relationships; and effects of pesticides and contaminants on ecosystems. Faculty and academic staff associated with LSRI possess expertise in chemistry, biology, toxicology, microbiology, geology, statistics, database management, data processing, computer programming, and geographic information systems.

LSRI established an independent QMS in 1991. LSRI’s QMS conforms to US EPA CIO Standard 2106-S-02, Quality Standard for Environmental Data Collection, Production, and Use by Non-EPA (External) Organizations (2012). LSRI uses the graded approach to address QA and QC needs on a project-specific basis. Projects requiring planning documentation follow the basic format of the US EPA Handbook on Quality Assurance Project Plans (2012a). LSRI has conducted high-quality, applied environmental research for the past 45 years and has published more than 100 peer-reviewed journal articles. The adherence to a scientific ethical code of conduct is reflected in the QMS training requirements for LSRI staff and students. Since its creation, LSRI has been funded through extramural sources. The funding for the QMS has been project dependent and is not a permanent state-funded entity.

LSRI is divided into several functional divisions providing technical expertise and support to current and ongoing projects. Divisions include: Biological Research, Analytical Chemistry, and Public Education and Outreach. The Biological Research and Analytical Chemistry Divisions are supported by a QAM. The Director of LSRI reports to the Vice Chancellor for Academic Affairs and Dean of the Faculty at the University of Wisconsin-Superior (UWS). Approximately 15-20 academic staff members have appointments with LSRI at any given time. These staff members are primarily toxicologists, biologists, and chemists who are involved in conducting extramurally funded environmental research and education programs. Faculty from the UWS Department of Natural Sciences and university students also participate in research in cooperation with LSRI staff. More information about LSRI can be found at the LSRI website (www.uwsuper.edu/lsri/index.cfm). Figure 1 shows LSRI’s current organizational chart. Historic and current copies of LSRI organizational charts are kept on file at LSRI.

Current projects in each division include:

- **Biological Research**
  - Lake Superior Basin Floristic Quality Assessment (2011 – Present): Funded by the Wisconsin Department of Natural Resources (WDNR) through the US EPA Region 5 Watersheds and Wetlands Branch, this project is the first phase of a multiphase project designed to carry out botanical field surveys to establish a baseline biological condition gradient using Floristic Quality Assessment parameters.
  - Wisconsin Lake Superior Coastal Monitoring Project (2010 – Present): Funded by the US EPA Great Lakes Restoration Initiative (GLRI) through the Great Lakes National Program Office (GLNPO), this project establishes 71 permanent monitoring stations in coastal wetlands, small craft harbors, nearshore areas, and tributaries identified as priority resources by the WDNR.
Ballast Water Treatment Technology Testing (2005 – Present): Funded by the Northeast-Midwest Institute through US EPA GLRI, US Maritime Administration, and many other sources, this project examines the ability of various ballast treatment technologies to minimize the potential introduction of exotic species such as zebra mussels, ruffe, and goby by commercial ships.


Aquatic and Terrestrial Toxicology Testing (1990s – Present): Sediment toxicity testing, culturing of aquatic macroinvertebrates, and water-only acute and chronic toxicity testing.

Effects of Pollutants on Aquatic Macroinvertebrates (1990s – Present): Contaminants studied have included pesticides, leachate from landfills, deicing compounds, pollutants within US EPA Superfund Sites, and industrial pollutants.

Field Surveys of Aquatic Macroinvertebrates (1990s – Present): Surveys of rare and endangered aquatic macroinvertebrates on state-owned land in Wisconsin, and surveys for water quality monitoring.

**Analytical Chemistry**

Analysis of Metals in Fish Tissue, Wild Rice, Mussels, and Other Biological Samples (1990s – Present): Funded by a variety of agencies including the Great Lakes Indian Fish and Wildlife Commission, this project determines heavy metal concentrations in fish, wild rice, and mussel tissues from the Upper Midwest and helps establish safe consumption levels for humans.

**Public Education and Outreach**

Environmental Education and Stewardship (1990s – Present): Encompassed in this division are the Watershed Stewardship and the Northern Wisconsin Watershed Education Resource Center projects. Local students sample and identify aquatic insects, learn about aquatic plants, and measure water chemistry parameters. LSRI also houses the Douglas County Aquatic Invasive Species Coordinator for Douglas County, WI.
Figure 1. LSRI Organizational Chart (Current as of December 2013).
Roles and Responsibilities

- **Director of LSRI**
  - Ensure all LSRI research activities comply with the LSRI QMP
  - Ensure all elements of the QMS are understood and implemented in applicable research projects
  - Assure there is QA and adequate technical and QMS training programs available for personnel to perform assigned functions
  - Approve SOPs and assure SOPs are adequate to ensure the quality and integrity of study data
  - Designate project management
  - Designate QAM

- **Quality Assurance Manager**
  - Review and approve the LSRI QMP
  - Review and approve individual QAPPs and other quality documents
  - Order audits and specify the audit scope
  - Conduct internal system and performance audits
  - Prepare QA samples for use in performance audits
  - Report results of audits to project managers
  - Technically evaluate project methodology, protocols, and SOPs
  - Review final reports
  - Report results of QA activities to the LSRI Director
  - Make QA recommendations to project management and the LSRI Director
  - Ensure QAM maintains independence and separation from project personnel involved in directing and conducting study
  - Train staff and students in LSRI’s QMS
  - SOP training and compliance

- **Project Management**
  - Design proposals for conducting scientific investigation
  - Work with other staff in developing project methods
  - Supervise staff and students
  - Monitor and stimulate project progress
  - Manage budgets/finances
  - Coordinate the preparation of the deliverables needed for project completion

- **Technical Staff**
  - Perform technical duties such as sampling, analysis, data treatment, and method development

Dispute Resolution

Quality-related disputes, such as a disagreement between a project manager and the LSRI QAM regarding corrective actions that are necessary to resolve an audit finding of non-conformance, must be addressed immediately and resolved in the most efficient way possible to ensure that a project’s schedule and performance are not impeded.
All quality-related disputes must be fully documented in writing by the concerned parties, and should only be brought to the attention of the LSRI Director if a resolution cannot be made between the staff members involved. The ultimate resolution must also be documented in writing.

QUALITY MANAGEMENT SYSTEM DESCRIPTION

The LSRI QMS is managed and organized by utilizing several components, including: quality system documentation, routine procedures documentation, training, project-specific quality documentation, and project and data assessments. The following are tools used to implement the main components of the LSRI QMS:

- Quality Management Plans (quality system documentation)
- Quality assurance reports (quality system documentation)
- Laboratory and study notebooks (quality system documentation)
- Standard operating procedures (routine procedures documentation)
- Quality system training and other relevant training (training)
- Quality Assurance Project Plans (project-specific quality documentation)
- Data verification, validation, and quality assessments (project and data assessments)

Quality System Documents

QUALITY MANAGEMENT PLAN

The LSRI QMP details the structure of the QMS at LSRI, and describes quality policies, procedures, application, roles, responsibilities, and authorities. The QMP also describes LSRI’s policies and procedures for implementing and assessing the effectiveness of the quality system. The QMP is prepared by the QAM and reviewed by LSRI senior staff members, including the Director. The Director of LSRI must give final approval of the QMP. The QMP is valid for five years unless significant changes have been made to the LSRI QMS that would require a revised QMP be written. These changes include, but are not limited to (US EPA 2012a):

- Change in the QAM reporting relationship
- A corrective action that prompts the need to revise the existing QMS
- Expansion of a division within LSRI to include new categories of methods and analytes
- Significant decreases in resources to the QMS

The QMP is intended to be used by all LSRI staff and students involved in the research division of LSRI. An electronic copy of the QMP is available to all LSRI students and staff, and hard copies are maintained with the QAM and LSRI Director. Hard copies of the QMP are also available in three-ring binders containing the LSRI SOPs, which are located in laboratory work station areas.

PROJECT AND DATA ASSESSMENTS

Each project is audited by the LSRI QAM at intervals adequate to ensure the integrity of the project, but must be audited at least once during a critical phase of the project. The audit serves to assess the training/competency of project staff, determine if the SOPs are being followed, determine if SOP
deviations have occurred, and review raw data to date. Each audit is followed by a written QA report for the project that is submitted to LSRI Director and the project manager.

Following project-specific final report preparation and review by the project manager, final reports are be reviewed by the QAM. The purpose of this review is to promote clarity, completeness, and accuracy in the scientific information contained in the report. Final report review assures that the study was conducted according to the project planning documentation, circumstances affecting data quality are reported, and tables/figures/text accurately reflect the raw data.

**QUALITY ASSURANCE REPORTS**

Each project requiring QA oversight is audited at intervals adequate to ensure the integrity of the project data. Quality assurance reports are submitted to the project manager and other project staff (where applicable) that detail audit findings, suggestions/recommendations, and any corrective action(s) taken. LSRI uses the ISO 9001 model of reporting audit findings (ISO 2008).

**LABORATORY AND STUDY NOTEBOOKS**

All laboratory notebooks used to record primary data should be bound with consecutively numbered pages, and should be assigned a unique identification code by the QAM. Three-ring binders used to store datasheets should also be assigned a unique identification code by the QAM. If multiple projects or studies are contained in one notebook, the study/project number or descriptor should be recorded on each page. A notebook that is dedicated to a single project or study has the study/project number and a description on the front cover of the notebook. All manually recorded data must be recorded directly, promptly, and legibly in ink. All data entries must be dated on the day of entry and signed or initialed by the person entering the data. Any change in entries must be done so as to not obscure the original entry (i.e., single line through original entry), and must be initialed, dated, and accompanied by a reason for the change (Table 1). Laboratory notebooks and datasheets must be scanned and saved as .pdf files on the LSRI Local Area Network. Electronic data must be saved (raw data) and hard copies must be included with project data. Hard copies of electronic data must indicate the date that the data was collected and the scientist(s) collecting the data. The entries should be detailed enough to allow unambiguous interpretation upon review by another scientist.

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<th>Examples of Error Codes that may be Used:</th>
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<tr>
<td>RE: Recording Error</td>
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<td>CE: Calculation Error</td>
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<td>WD: Wrong Date</td>
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<tr>
<td>FN: See Footnote</td>
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<td>LE: Late Entry</td>
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<td>NU: Data not Used</td>
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ROUTINE PROCEDURES DOCUMENTS

All standard procedural methods must be in written form and be immediately available to personnel who have occasion to use them. Routine, working methods are documented in the form of SOPs. The QAM, or designee, authorizes the use of the procedural method as the SOP to be used. The SOP is the document outlining the methods used to perform a procedure. Currently, there are approximately 120 SOPs in active use at LSRI. The SOPs are categorized accordingly: personnel (PER), recordkeeping (REC), quality assurance (QA), animal care/test systems (AC), aquatic toxicology (AT), field studies (FS), general lab maintenance (GLM), test substances (TS), and sample analysis (SA). There are approximately 100 SOPs that are archived in an inactive file and related to previous projects.

PERSONNEL TRAINING

All LSRI staff and students must be familiarized with the QA practices associated with their work. At a minimum, staff and student personnel must attend the training session “LSRI Quality System Orientation” and the QAM maintains copies of the training records.

Inexperienced personnel work with experienced professionals in gaining proficiency with the methodology. Specific SOP training is conducted by the immediate supervisor, project manager, or QAM, depending on the nature of the procedure. Competency testing is required for certain SOPs following hands-on training, and is the preferred method for documenting staff and student proficiency. Project managers are encouraged to develop competency tests for project SOPs, where applicable. The QAM maintains copies of the training records on file.

PROJECT-SPECIFIC PLANNING DOCUMENTATION

Certain projects may require a QAPP or other planning documentation be written. The QAPP is prepared by the QAM and the project manager, and is reviewed by all key study personnel. The QAPP must detail the DQO specific to the project, and encompasses all of the quality system details specified by the LSRI QMP.

PERSONNEL COMPETENCE

All LSRI employees must have an initial employee orientation with the QAM, which details employee responsibilities in maintaining QA, personnel records needed on file, SOP assignments, and training needed. All LSRI students and staff have a personnel file maintained by the QAM that includes their resume (current and historic copies), current job description, LSRI and project SOP training documentation, and verification of additional training received. It is the responsibility of LSRI staff and students to inform the QAM of significant resume changes and to provide documentation of extramural training attendance. An LSRI student’s resume should contain: name/address/phone number; current position; education; major/minor; pertinent courses; awards/honors; employment history; and volunteer activities. The LSRI staff member resume should contain: name; current position; education/training; employment history; selected publications; scientific and professional involvement; and academic honors/awards. Resumes for LSRI staff members are reviewed annually and updated as needed. Historic copies are maintained in staff personnel files. The QAM maintains job descriptions for staff members.
It is the responsibility of the supervisors, QAM, and project managers to adequately train their staff for job performance competency, and to verify the competency of each individual and ensure that appropriate training is provided. All staff and students are required to attend a training/orientation session on the LSRI QMS. Staff being trained in any procedure must be supervised by a person qualified in that procedure. Upon successful completion of the training, a Certificate of Completion (Appendix 1) and a separate Certificate of Compliance/Training Competency (Appendix 2) form are completed by the trainer. These forms must be signed and dated by the trainer and/or supervisor and the employee. All signed Certificate of Completion/Compliance forms must be sent to the QAM and are kept in a personnel file for that individual. Additional training opportunities for LSRI staff that should be included with the previously listed training records are: on-the-job training; in-service training; out-service courses; seminars and conferences attended by the individual. The records should note the subject matter of the training, source of training, the names of the facilitators, and whenever possible should provide verification (e.g., certificate of completion, personalized itinerary, etc.).

EXTERNAL AGREEMENTS

LSRI must ensure that sub-contractors associated with environmental data operations follow the LSRI QMS by conducting audits or inspections of sub-contractor laboratories (e.g., field sampling services, laboratory testing, or information technology support), and/or by validating data supplied by contract laboratories.

DOCUMENTS AND RECORDS MANAGEMENT

Required documents and records are those that specify project plans, policies, procedures, assessments, and guidelines. Documents and records required by the LSRI QMP include, but are not limited to: QMP, QAPPs, and SOPs.

Preparation and Responsibilities

All documents and records must be prepared using a consistent format that allows for easy tracking of revisions. The documents should indicate the issue/effective date and provide a record of previous versions or amendments to the original document. The QAM is responsible for preparation of the QMP along with the LSRI Director. The QAPP is prepared by the QAM and the project manager. SOPs are prepared by LSRI staff having technical expertise in the subject matter covered by the SOP.

Review and Approval

The QAM is responsible for implementing the review of the QMP. The QMP should be reviewed by the LSRI QAM, LSRI senior scientists, LSRI Director, and any other applicable staff. Reviewers should be given at least 14 days to review the QMP. The LSRI Director is responsible for final approval of the QMP, which should be signed off by the Director and LSRI QAM.

The QAPP should be reviewed by the LSRI QAM, project managers and/or principal investigators, and other key technical personnel. Reviewers should be given at least 14 days to review the QAPP. The QAPP should be approved by the QAM and project manager.
SOPs should be reviewed by the LSRI QAM, project managers, and other applicable staff involved with the procedure. If necessary, the SOP review process should include a trial use of the SOP with a less-experienced staff member to determine the adequacy of the SOP as a guide and training document. Reviewers should be given at least 14 days to review SOPs. The SOPs require approval by the author of the SOP, a member of the quality staff, and LSRI senior staff.

**Implementation and Distribution**

Following the review and approval process, all documents and records are given an issue/effective date, after which LSRI staff and students must comply with the documents. The QMP is distributed electronically to all LSRI students and staff, however, only those students and staff that are involved in research projects at LSRI requiring QA oversight are responsible for complying with the QMP. QAPPs are distributed electronically to all staff and students responsible for the direction and conduct of the project/study. SOPs are distributed electronically via “SOP Change Notices” sent via e-mail by the QAM. The title page of each SOP has a “Distribution List” describing the LSRI staff and students that are responsible for reading/complying with the SOP. Staff and students who receive the “SOP Change Notice” are required to reply to the QAM via e-mail and indicate that they have read the revised SOP and understand the revisions that were made. A response must be received within 14 days from the original “SOP Change” notification. Hard copies of all required documents and records are maintained and provided by the QAM.

**Revision, Retention, and Archival Procedures**

The QMP is valid for five years after the issue date, however, it should be systematically reviewed annually to determine if any significant changes have been made that would warrant revision of the QMP. Conditions requiring the revision of an approved QMP include: expiration of the five-year life span, major changes in mission and responsibilities, reorganization of existing functions that affect programs covered by the QMP, and assessment of findings requiring corrective actions and response. Previous versions of the QMP are be retained permanently by the QAM.

For projects lasting one year or less, the QAPP should be revised whenever changes affect the scope, implementation, or assessment of the outcome to keep project information current. For multi-year projects, the QAPP is systematically reviewed annually by the project manager to determine if revision is needed. QAPP retention and archival is project-specific and is determined by the Project/Study director and written in the QAPP.

SOPs are systematically reviewed every two years to determine if revision is needed. SOPs are revised whenever significant changes are made to the procedure. Current and inactive SOPs are retained permanently by the QAM; read-only electronic copies of current versions are also available to all LSRI staff and students and are located on the LSRI local area network (e.g., LSRI Temp Drive) and on the LSRI web page (http://www.uwsuper.edu/lsri/sops/sops2.cfm).

Each quality document contains a record of amendments that describes all document revisions and the date of revision. Each time a document is amended/revised a new version number is assigned. The QAM is responsible for updating the record of amendments for all quality documents and maintaining document version control. To ensure proper version control, the QAM is also responsible for editing all quality documents per LSRI staff recommendations.
All other documents and records, including project-related data are retained for a period of at least five years unless specified in the QMP or QAPP.

**USE OF INFORMATION TECHNOLOGY METHODS AND SOURCES**

**Developing, Installing, Testing, Using, Maintaining, Controlling, and Documenting Computer Hardware and Software**

Development, use, maintenance, and control of LSRI computer hardware and software are driven by a combination of LSRI project requirements and the need to maintain compliance and compatibility with current UWS campus software and networking. Particular projects or campus compatibility issues may require hardware purchases and configurations, software development, software revisions, or a combination of these. LSRI staff, the UWS Computer and Networking staff, or a combination of these two groups are responsible for hardware and software development, installation, testing, use, maintenance, control, and documentation. Roles and responsibilities are dependent on the nature and requirements of the specific task and are detailed below.

All LSRI computer hardware is purchased through the UWS Help Desk and billed to appropriate LSRI accounts, allowing UWS Computer and Networking staff to maintain the campus inventory and hardware registering system. Vendor-packaged software purchases and inventory are the sole responsibility of LSRI, with the exception of networking-related software and campus-wide installed software purchased through the UWS Help Desk.

Hardware and software installation is performed by LSRI staff, UWS Computer and Networking staff, or by an outside contractor, depending on where the hardware or software was purchased, complexity of the installation, and the familiarity of LSRI staff with the hardware or software. Initial testing is normally done by a combination of these parties, and testing continues by qualified LSRI staff until it is determined that the hardware or software may be used by others. Additional future maintenance and control is usually the responsibility of LSRI.

LSRI designs a large volume of in-house written customized software. This is often necessary to meet the specific requirements of projects for which there are no vendor software packages available. Also, in many cases it is much more cost effective and time efficient to design project related software in-house and software designed in-house provides LSRI with complete control over the software. Paper source documentation for vendor-provided hardware and software is stored generally in Old Main 324. In most cases, there are also electronic versions of the documentation as part of the installation.

Documentation for software designed in-house is usually written after the software design has been completed and tested. In most cases there is paper source documentation available for the software in the same previously mentioned locations and available in appropriate computer network locations. There are also help screens and electronic documentation designed into this in-house software that is available to the user as the software is used.

**Evaluating Purchased Hardware and Software**
Hardware evaluation is typically conducted as soon as possible after purchase. Vendor purchased software may be evaluated following purchase and installation, depending on whether there are vendor specific configurations that need to be tested or if there are time-sensitive license issues.

**Evaluating In-House Designed Customized Software**

Evaluation of software designed in-house can be a more time-consuming process than vendor-purchased software, since vendor-purchased software should be pre-evaluated by the vendor before installation. In-house designed software is evaluated after each software design phase, usually on a per module basis as the software is being designed. After design is complete, the entire software package is evaluated. In-house software is typically evaluated on a continuous basis while the software is being utilized for a project. This is because there are usually revisions, or sometimes even minor errors that need attention for some time after the initial design and installation are completed.

**Roles, Responsibilities, and Authorities in Description of Above Processes**

The primary responsibility and authority for LSRI computer hardware and software lies with the LSRI Database Administrator (see Figure 1 for the LSRI organizational chart), who provides most of the networking, software design, web site, PC, and GIS support for LSRI. However, for cases where additional support is needed, other LSRI staff, UWS Computer and Networking staff, or an outside contractor may provide assistance.

**Electronic Data Security**

LSRI data security is achieved using three security tiers, which include the UWS domain, LSRI server, and additional security for databases and website data. UWS domain security is achieved through the use of Windows Network login accounts, and represents the first security tier. No access to any files or electronic data is allowed without this login account. The second security tier is through the configuration of the LSRI server. All shared LSRI data resides on the LSRI Server, which is located in Swenson Hall on the UWS campus. This is obtained through the configuration of shared folders and devices. Appropriate read/write access is granted to specific login accounts within the specific folders and devices. This allows for additional customization per account in the security scope. The third security tier is in place for LSRI data that resides in several relational databases and website links. All of the databases require a separate database login to gain access. In a similar manner, the website data requires a separate website login that uses web authentication technology.

**Electronic Data Backup**

A complete backup of all files on the LSRI server is automatically performed every 24 hours. The LSRI server backup is maintained by the UWS Computer and Networking Services. The backups are stored on a separate server on the UWS campus. It is an overwrite backup, rather than a sequential backup, meaning that each server backup is valid for only the previous day. The purpose of this backup is mainly to protect from catastrophe (e.g., fire or flood, server damage, etc.). However, it may be used for file retrieval within a 24-hour time frame. The LSRI server contains all of the most vital shared and project related data.

The LSRI server has an additional form of backup using RAID software. The server contains two 300GB hard drives. This server software creates a ghost mirror of each transaction from the primary hard drive...
to the secondary hard drive. In this way, there is always a second hard drive available that is an exact copy to use, preventing loss of data if something happens to the primary drive (e.g., hard drive crash).

Due to the highly varied nature of personal data and projects that reside on the individual PCs within LSRI, and for storage purpose concerns, it is up to each individual to backup files they deem necessary in whatever manner they choose for data that resides only on their personal PC. If they wish to have some of their personal data automatically backed up by copying it to the server, they should contact the LSRI Database Administrator or a member of the UWS Computer and Networking Services staff. Most LSRI historical and legacy data (e.g., sampling image files) has been archived to two 640GB external drives.

**PLANNING**

Systematic planning is essential to ensuring the data/information collected for each project conducted at LSRI is of the needed and expected quality to fulfill the project goals and objectives. The US EPA recommends using the DQO Process as an effective approach to systematic project planning (US EPA 2012). Prior to implementation of a project at LSRI, performance/acceptance criteria and an appropriate data collection plan must be systematically developed by a planning team that consists of key project personnel (i.e., LSRI Director, project manager, QAM, technical staff, etc.). The LSRI Director begins the planning process by appointing a project manager, as well as, identifying the funding organization (when applicable), project personnel, stakeholders (when applicable), and any scientific experts that may facilitate planning and implementation of the project. The LSRI Director works with the project manager and the funding agency (when applicable) to determine the goals/objectives of the project and study questions/issues to be answered. The planning team develops a data collection plan by utilizing the following elements as guidelines (planning elements are project-specific and may vary):

- **Organization:** Identification and involvement of the project manager, sponsoring organization, project personnel, and quality manager. All relevant customers, stakeholders, and interested parties are identified, as well as, their needs and expectations for the results of the work to be performed.
- **Schedule:** A preliminary project schedule is developed, which includes project milestones to be reached. Project resources, including budget, are identified. Applicable project SOPs are also identified.
- **Project Goal:** Description of the project goals, objectives, study questions, etc.
- **Quality Assurance:** Needed QA and QC activities to determine the quality performance criteria are specified.
- **Data Needs:** The type of data needed and how to use the data to support project goals/objectives are identified.
- **Criteria:** The quantity of data needed (i.e., number of samples, number of replicates, etc.) and the performance criteria for measuring data quality are specified.
- **Data Collection:** How and where the data are obtained (includes existing literature search) is described and any constraints on data collection are identified.
- **Analysis:** Data analysis, evaluation, and performance criteria assessment are described.

This systematic planning process leads to the development of the QAPP or other project planning documentation, which is written by members of the planning team (most likely the project manager and
the QAM). The QAPP is reviewed by key project personnel, collaborators, funding agency, and any project stakeholders. It is approved by the funding agency (when applicable), LSRI Director, QAM, and the project manager and is revised whenever significant changes to the original data collection plan or study personnel occur.

IMPLEMENTATION OF WORK

General Considerations

The details of each project’s implementation are detailed in the QAPP. In general, the LSRI QAM and project manager work together to ensure all work involving environmental data collection, production, or use is performed according to approved planning and technical documents. It is the responsibility of the LSRI QAM to ensure that each project’s QAPP is approved prior to data collection. In addition, it is the responsibility of the project manager to ensure that project-specific SOPs are drafted and have undergone internal review prior to the routine data collection activities that they detail.

Documentation of Implementation Procedures

QMP DEVELOPMENT AND IMPLEMENTATION

The LSRI QMP is reviewed annually by the QAM to determine if revision is needed. A thorough review of the QMP is conducted by the QAM and LSRI Director every five years or when significant changes to the organization have occurred. All LSRI staff and students are notified each time the QMP is revised. Hard copies of the QMP are available from the LSRI QAM. Electronic copies are sent out via e-mail and can be accessed from the LSRI Temp Drive.

QAPP DEVELOPMENT AND IMPLEMENTATION

Each QAPP is revised by the QAM and project manager whenever significant changes to the original data collection plan or study personnel occur. All project personnel are notified each time the QAPP is revised. Hard copies of the QAPP are available from the LSRI QAM and the project manager. Electronic copies are sent out via e-mail and can be accessed from the LSRI Temp Drive (\lsri-data-5898).

SOP DEVELOPMENT AND IMPLEMENTATION

New SOPs are created for routine and repetitive procedures according to LSRI SOP REC/1, Preparation and Revision of Standard Operating Procedures. The SOPs are used as training tools for students and new staff members and serve as technical guidelines for the QAM during audits. SOPs are reviewed every two years by a subject matter expert to determine if revision is needed. A record of revisions is kept up-to-date on the cover page of each SOP. If no revision is needed, the SOP is marked “reviewed with no revisions needed” and the date of review is indicated. If revision is needed, the SOP is reviewed by appropriate staff and approved by the QAM, LSRI Director, and the author of the SOP. SOPs may be retired or inactivated if the procedure is no longer conducted and the SOP is not needed.

An SOP Change Notice is sent out by the QAM to all LSRI staff and students if an SOP is created, revised, or retired. The cover page of each SOP has a distribution list of applicable staff and students who must comply with the new or revised SOP. Hard copies of each SOP are available in the LSRI QAM office, and
Sample and Data Integrity

The project manager and LSRI QAM determine whether a chain of custody must be maintained for the project. If a chain of custody is not used for a project, the QAPP must describe how sample and data integrity is maintained. The project manager is responsible for training the technical staff and students on the proper sample collection and handling procedures. Training documentation must be provided to the LSRI QAM and maintained on file.

Performance Monitoring

Whenever possible, the implementation of work processes is monitored by an independent staff member, such as the LSRI QAM, who is not directly involved with data collection activities. The independence needed from personnel performing QA/QC activities is project specific, and is outlined in the QAPP. If complete independence cannot be achieved, it may be possible to have an independent individual oversee just the portion of the project that the LSRI QAM, or designee, is involved with and the LSRI QAM may be able to independently evaluate the remainder of the project.

Deviations from Approved Processes

A deviation is defined as an unplanned change from an original SOP or QAPP that is not permanent and is the result of unforeseen circumstances. Deviations may include oversights, weather, and failure to record observations. Project personnel are responsible for communicating any known LSRI SOP, project SOP/method, and QAPP deviation to their immediate supervisor as soon as possible after the deviation has occurred (i.e., less than 24 hours). The project staff member reporting the deviation documents the details of the deviation, along with their immediate supervisor and the project manager, by completing an LSRI Deviation Form (Appendix 4). The project manager informs the LSRI QAM of the deviation as soon as possible, and together they determine the effect of the deviation on data quality and on the project timeline and include this information on the LSRI Deviation Form. In addition, the LSRI QAM documents any deviations that are discovered during technical systems audits, procedural audits, or during data verification on the LSRI Deviation Form. The LSRI QAM is responsible for informing the project manager of any deviations discovered during assessments and data verification as soon as possible.

ASSESSMENT, OVERSIGHT, AND RESPONSE

Types of Assessments

US EPA (2012a) defines an assessment as “…an evaluation process used to measure the performance or effectiveness of a system and its elements”. The types of assessments used by US EPA include the following:

- **Data Quality Audit (DQA)**: A scientific and statistical evaluation of validated data to determine if the data are of the right type, quality, and quantity to support their intended use.
• **Performance Evaluation (PE):** A type of audit in which the quantitative data generated in a measurement system are obtained independently and compared with routinely obtained data to evaluate the proficiency of an analyst or laboratory.

• **Quality System Audit (QSA):** A documented activity performed to verify, by examination and evaluation of objective evidence, that applicable elements of the QMS are suitable and have been developed, documented, and effectively implemented in accordance with specified requirements.

• **Readiness Review:** A systematic, documented review of the readiness of the start-up or continued use of a facility, process, or activity. Readiness reviews are typically conducted before proceeding beyond project milestones and prior to initiation of a major phase of work.

• **Surveillance:** Continual or frequency monitoring and verification of the status of an entity and the analysis of records to ensure that specified requirements are being fulfilled.

• **Technical Systems Audit (TSA):** A thorough, systematic, on-site, qualitative audit of a project or operation that may include facilities, equipment, personnel, training, procedures, recordkeeping, data validation, data management, and reporting aspects of a technical system.

At LSRI, the most commonly utilized assessments are readiness reviews, surveillance, and TSAs.

**Assessment Planning**

Fulfilling QA goals for each project is the joint responsibility of all project personnel together with the QAM and LSRI Director. After implementation of a QAPP and work has commenced, the project manager must assess the appropriateness of the QA practices in meeting project objectives. The project manager is assisted by the QAM. The project manager should contact the QAM for consultation and discussion regarding any problems that may arise.

The QAM periodically designs and implements a QA audit of the project. An assessment plan is developed by the QAM to provide documentation of the type of assessment to be used, the scope of the assessment, the information needed and expected from the assessment, and any limits or constraints encountered (e.g., seasonal considerations when collecting water or sediment samples). The QAM provides the assessment plan to the project manager for review prior to conducting the assessment.

**Assessment Conduct and Follow-Up**

The QAM, or designee, performs internal QA audits of projects. The audit may include observation of staff performance and their compliance with written procedures, inspection of staff reagent preparation and instrument maintenance/calibration notebooks, verification of calculations, inspection of forms reporting experimental results or other records documenting the project program. The audit results are submitted to the project manager. Quality assurance activities including noncompliance instances are reported to the Director of LSRI.

The responsibility for maintenance of quality for a project lies with every member of the project. All project personnel aid in identifying perceived problems that may affect quality and report such problems to the supervisor and to the QAM. Upon consultation with the QAM, the supervisor should take corrective action.

The need for corrective action may also be identified by the results of audits or the failure to achieve the
quality of information as designed in the QAPP or SOP. Upon detection of QA deficiencies, the project manager must take immediate steps to determine and implement corrective actions.

QUALITY IMPROVEMENT

LSRI is dedicated to continuous QMS improvement. QMS improvement is the responsibility of all LSRI staff and students. It is the responsibility of the QAM to encourage an open dialogue with LSRI staff and students that promote regular discussion of how the LSRI QMS can be improved to help staff and students better perform their job functions. LSRI staff members are encouraged to meet with the QAM as necessary to identify quality assurance issues of concern.

Quality documents are reviewed regularly to ensure that these documents are still adequate for their function(s). The QMP is reviewed annually by the QAM and LSRI staff and it is modified if needed to reflect changing needs and/or additional guidance. LSRI SOPs are reviewed every two years from their date of issue or last revision and revised as needed (i.e., whenever significant changes in procedure or equipment changes occur).

Regular meetings, conference calls, and data quality assessments should occur during the course of projects conducted at LSRI to identify any needed improvements in data quality. Project SOPs should be revised during the course of a project to reflect any changes and improvements in procedures that develop as the project progresses.

DATA REVIEW, VALIDATION, VERIFICATION, AND DATA USABILITY REPORTING

Planning for Data Review

US EPA CIO Standard 2106-S-02 requires that “results obtained from products or services involving environmental data shall be reviewed, verified, validated, and qualified according to their intended use”. During project planning, the LSRI QAM works with the project manager to determine the appropriate frequency of project data review. The agreed-upon frequency and associated roles and responsibilities are detailed in the QAPP. The LSRI QAM, or designee, is responsible for conducting an independent review of the project data. At a minimum, each project involving environmental data is reviewed by the LSRI QAM after data collection for that project is completed. Project data review consists of:

- Reviewing the raw data to determine whether LSRI’s Good Documentation Practices (Appendix 3) were followed and that adequate documentation exists to allow for the intended use
- Ensuring the completeness of the raw data
- Where applicable, double-checking calculations and data entry
- Ensuring the DQO outlined in the QAPP were met

In addition, US EPA CIO Standard 2106-S-02 requires that “any project reports that contain data, or report the results of environmental data operations (e.g., data summaries), shall be reviewed independently (i.e., by others than those who produced the data or the reports) to confirm that the data or results are presented correctly”. The LSRI QAM, or designee, is responsible for conducting project
report review. Final reports must also be reviewed by the project manager and any other applicable technical staff prior to submission to EPA or any external review to confirm the report’s conclusions and ensure that the DQOs were met. Project reports have a separate QA/QC section that describes the project QA/QC, including data review, and discuss the usability of the data in terms of the DQOs.

**Special Considerations for Data Review**

Whenever possible, the project manager and LSRI QAM review and evaluate environmental data collected from sources that do not have a QMS in place or whose quality is unknown or undocumented. The project manager and LSRI QAM must agree on the suitability of these data for use in the project. Examples of secondary sources that may require data evaluation include (US EPA 2012a):

- Academic research and journal articles
- Reports from volunteer groups
- Previous studies conducted at a particular location of interest

In these cases, the data are reviewed and evaluated according to this QMP. Any deviations from the routine processes described in this QMP must be documented.

**Related Types of Reviews**

Peer review can be a useful tool and should begin as early in the project planning process as possible. According to the US EPA (2012), “peer review is a documented critical review of a specific scientific or technical work product”. Project planning documents, such as QAPPs, may be subject to peer review if the project manager and LSRI QAM deem it necessary. In addition, project reports may be subject to peer review. At LSRI, peer review is an internal process and involves non-project staff and may also involve the LSRI Director.
REFERENCES


# APPENDIX 1. LAKE SUPERIOR RESEARCH INSTITUTE SOP COMPLIANCE FORM

## SOP COMPLIANCE FORM

LAKE SUPERIOR RESEARCH INSTITUTE

CERTIFICATE OF COMPLIANCE FOR STANDARD OPERATING PROCEDURES

I, ____________________, have read and understand the following Standard Operating Procedure(s) (SOP(s)):

<table>
<thead>
<tr>
<th>SOP No.</th>
<th>SOP Title</th>
<th>Version No./Date Read</th>
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</table>

By signing this document I agree to execute the requirements of the above SOP(s) and all subsequent revisions to the above SOP(s).

**Employee’s Signature**

**Date**

By signing this document I acknowledge that this employee has read and understands the above SOP(s). I agree to properly train and supervise this employee in the execution of the above SOP(s). I also agree that this employee will not conduct the procedures in the above SOP(s) until competency has been demonstrated.

**Supervisor’s Signature**

**Date**

*Please forward to QA Manager upon completion.*
APPENDIX 2. LAKE SUPERIOR RESEARCH INSTITUTE
EMPLOYEE TRAINING/COMPETENCY FORM

EMPLOYEE TRAINING/COMPETENCY TESTING FORM

LAKE SUPERIOR RESEARCH INSTITUTE

CERTIFICATE OF TRAINING COMPLETION/COMPETENCY TESTING FOR
STANDARD OPERATING PROCEDURES

Trainee’s Name (print)

Has successfully completed the required hands-on training for the following procedure(s), and
has demonstrated competency through the following proficiency tests:

<table>
<thead>
<tr>
<th>SOP No.</th>
<th>SOP Title</th>
<th>Date(s) Training Completed</th>
<th>Description of Proficiency Testing</th>
<th>Competency Demonstrated? (YES or NO)</th>
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Comments:

By signing this document the trainer and trainee acknowledge that the trainee has received the proper training on
the above SOP(s), and has demonstrated competency to carry out the above procedure(s) safely and exactly as
outlined. The employee is able to carry out the above procedure(s) independently.

Trainer/Supervisor’s Signature:

Title:

Trainee/Employee’s Signature:

Date:

Please forward to the QA Manager upon completion.

Lake Superior Research Institute, University of Wisconsin-Superior
APPENDIX 3. LAKE SUPERIOR RESEARCH INSTITUTE GOOD DOCUMENTATION PRACTICES

Good Documentation Practices

Lake Superior Research Institute

WHAT ARE LSRI’S QUALITY DOCUMENTATION STANDARDS?

1. **Truthful** – what has been documented is actually what occurred.
2. **Accurate** – to the best of your knowledge the documentation is correct.
3. **Legible** – can be easily read by others.
4. **Permanent** – documented in indelible ink (never use pencil).
5. **Clear** – can be understood by everyone who reads it.
6. **Complete** – all information required for reconstruction has been documented.
   a. Document the SOPs (when applicable) or record all the methods used during the study.
   b. When applicable, identify the equipment used in obtaining study data.
   c. Identify all units of measurement (i.e., mg/L, cm, g, etc.).
   d. Write down all calculations.
7. **Attributable** – complete with dated signature or initials.
8. **Consistent** – documented the same way every time (i.e., following LSRI SOP REC/9 – Preparing Laboratory Notebooks).
9. **Prompt** – documented at the time the observation is made or the activity is completed.
10. **Direct** – documented in the proper place on the form or in the laboratory notebook and not transcribed.
11. **Organized** – readily available and easy to locate.
12. **Secure** – safely stored during the study and archived at the end of the study.

WHAT IS NEEDED FOR MY DOCUMENTATION TO BE COMPLETE?

1. **Date**: The current date (do not pre-date or post-date data).
2. **Initials**: Everyone who is directly responsible for the data (i.e., recorders, observers, etc.). **Remember to use three initials (XXX)!**
3. **Data**: Including procedures, observations, and any information needed for reconstruction. Information needed for reconstruction includes the SOPs or methods used during the study, the equipment used, observations, units of measurement, and calculations.
WHAT DOES MY SIGNATURE (AND/OR INITIALS) MEAN TO LSRI?

1. Identity: Remember to write your initials (use three initials) and full name on the front cover of every laboratory notebook you write in, or on the signature page of a three-ring binder!
2. Responsibility: You are accountable for your data.
3. Agreement: You agree with what you have recorded, and to the best of your ability the data is truthful and accurate.

I MADE A MISTAKE – HOW DO I CORRECT MY ERRORS?

1. Write a SINGLE LINE through the original entry so it can still be read.
2. INITIAL the correction.
3. DATE the correction.
4. Write the CORRECT ENTRY.
5. Record the specific REASON for the correction (use error codes or a superscript if a longer explanation is needed):

<table>
<thead>
<tr>
<th>Examples of Error Codes that may be Used:</th>
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<tbody>
<tr>
<td>RE: Recording Error</td>
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<td>CE: Calculation Error</td>
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<td>WD: Wrong Date</td>
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<td>FN: See Footnote</td>
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<tr>
<td>LE: Late Entry</td>
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<tr>
<td>NU: Data not Used</td>
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*From LSRI SOP RES/9 – Preparing Laboratory Notebooks*
# APPENDIX 4. LAKE SUPERIOR RESEARCH INSTITUTE EXAMPLE DEVIATION FORM

## LAKE SUPERIOR RESEARCH INSTITUTE DEVIATION FORM

<table>
<thead>
<tr>
<th>DEVIAITION FROM:</th>
<th>□ LSRI SOP</th>
<th>□ PROJECT SOP</th>
<th>□ QAPP</th>
<th>□ TEST PLAN</th>
<th>□ OTHER: ______________________________</th>
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<td>DATE/TIME:</td>
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<td>LSRI STAFF MEMBER NAME/TITLE:</td>
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<tr>
<th>LSRI SOP or Project Code (If Applicable)</th>
<th>Description of Deviation</th>
<th>Detailed Description of Impact on Study (If Any)</th>
<th>Description of Corrective Actions Taken (If Needed)</th>
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**LSRI Staff Member Comments (Continue comments on a second page, if needed):**

*LSRI staff member responsible for communicating deviation, please add comments here regarding when and how the project manager was notified of the deviation.*

Signature: ____________________________  Date: ____________________

**LSRI Project Manager Comments (Continue comments on a second page, if needed):**

*LSRI project manager, please add comments regarding when and how the funding agency was notified of the deviation, when and how the LSRI QAM was notified of the deviation, the potential impact on the project, and any corrective actions taken.*

Signature: ____________________________  Date: ____________________

**LSRI Quality Assurance Manager Comments (Continue comments on a second page, if needed):**

*LSRI QAM, please add comments regarding the potential impact on the project, any corrective actions taken, and any opportunities presented for continual improvement of LSRI’s quality system.*

Signature: ____________________________  Date: ____________________