ILLINOIS STATE WATER SURVEY

QUALITY MANAGEMENT PLAN

Version 2.2 April 21, 2014

Illinois State Water Survey
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Quality Management Plan Signature Page

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Document Change History

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2.0	updated to reflect transition to the University of Illinois discussion of QAPP and SOP templates added discussion of Archive Room added	11/24/2010
2.1	updated to reflect name change to Prairie Research Institute Figures 1 and 2 updated header and footer added	12/01/2013
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List of Figures

Abbreviations and Acronyms

ANSI	American National Standards Institute
ASTM	American Society for Testing and Materials
ASQC	American Society for Quality Control
CITES	Campus Information Technologies and Educational Services
DQO	Data Quality Objective
IEPA	Illinois Environmental Protection Agency
ISWS	Illinois State Water Survey
MSDS	Material Safety Data Sheets
NADP	National Atmospheric Deposition Program
PRI	Prairie Research Institute
QA	Quality Assurance
QAPP	Quality Assurance Project Plan
QC	Quality Control
QMP	Quality Management Plan
SOP	Standard Operating Procedure
UIUC	University of Illinois at Urbana-Champaign
US EPA	United States Environmental Protection Agency
USGS	United States Geological Survey
VCR	Vice Chancellor for Research
WARM	Water and Atmospheric Resources Monitoring Program

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1.0 Purpose of Plan

1.1 Background

The Illinois State Water Survey (ISWS) quality system consists of several components that together document the management practices used to ensure the quality and reliability of environmental data collected or developed at this scientific institution. The ISWS Quality Management Plan (QMP), the key component of the system, is the "umbrella" quality assurance document that describes the processes and procedures for staff and management to follow in the collection and reporting of environmental data. It is patterned after a national consensus standard, ANSI/ASQC E4-1994, and a United States Environmental Protection Agency (USEPA) guidance document developed to assist agency contractors in developing their own agency-specific QMPs. The USEPA requires all contractors producing environmental data for use by the Agency to develop QMPs that follow these guidelines. This QMP is intended to meet the requirements of the ISWS, USEPA, and other funding agencies that support environmental data collection and reporting activities at the ISWS.

1.2 Source Documents

ANSI/ASQ E4-2004, Quality Systems for Environmental Data Collection and Technology Programs: Requirements with Guidance for Use, American National Standards Institute, 2004. http://webstore.ansi.org/ (use document number for search)

US EPA QA/R-2, EPA Requirements for Quality Management Plans, US EPA Quality Assurance Division, March 2001 (Reissue Notice May 2006). EPA/240/B-01/002. http://www.epa.gov/quality/qa_docs.html

US EPA QA/R-5, EPA Requirements for Quality Assurance Project Plans, US EPA Office of Research and Development, March 2001 (Reissue Notice May 2006). EPA/240/B-01/003. http://www.epa.gov/quality/qa_docs.html

US EPA QA/G-4, Guidance on Systematic Planning using the Data Quality Objectives Process, US EPA Quality Assurance Division, February 2006. EPA/240/B-06/001. http://www.epa.gov/quality/qa_docs.html

US EPA QA/G-6, Guidance for Preparing Standard Operating Procedures, US EPA Quality Assurance Division, April 2007. EPA/600/B-07/001. http://www.epa.gov/quality/qa_docs.html

US EPA CIO 2105-P-01-0 (formerly 5360.1 A1), EPA Quality Manual for Environmental Programs, USEPA Quality Assurance Division, May 5, 2000. http://www.epa.gov/irmpoli8/ciopolicy/2105-P-01-0.pdf

1.3 Scope of Covered Activities

The quality system elements described in this QMP apply to all ISWS environmental programs. Externally funded projects, or ISWS activities conducted under an accreditation or certification program, may have quality management system requirements in addition to the requirements stated in this Plan.

1.4 Revisions to the Plan

This Plan will be reviewed annually and updated at least every three years, by the ISWS Quality Assurance/Quality Control (QA/QC) Committee. The review process is designed to maintain quality management practices that are consistent with current ISWS needs and regulatory requirements. Recommended changes will be reviewed and approved by the ISWS senior management team. If there are significant organizational or administrative changes within, or external to, the ISWS that make the QMP no longer applicable, a revised Plan should be prepared prior to the annual revision date.

2.0 Management and Organization

2.1 Mission Statement and Quality Policy

Mission Statement - The Illinois State Water Survey is the primary agency in Illinois for research and information on surface water, groundwater, and the atmosphere. Its mission is to characterize and evaluate the quality, quantity, and use of these resources. The mission is achieved through basic and applied research; by collecting, analyzing, archiving, and disseminating objective scientific and engineering data and information; and through service and extension programs. This information provides a sound technical basis for the citizens and policy makers of Illinois and the nation to make wise social, economic, and environmental decisions.

Quality Policy - The ISWS has implemented a quality system that utilizes a graded approach to quality assurance. The levels of managerial controls and resource allocation for quality assurance purposes are based on the intended use of the data that are collected and the degree of certainty needed in the data. The ISWS is committed to ensuring that quality management principles and practices are utilized for activities involving the production of environmental data and the appropriate use of historical data.

2.2 Administrative Structure and Senior Management Responsibilities

The ISWS is a Division of the Prairie Research Institute which is administered through the Office of the Vice Chancellor for Research (VCR) at the University of Illinois at Urbana-Champaign (UIUC). The ISWS, along with the other four Divisions, form the Institute which has as its advising body the Prairie Research Institute Advisory Board and is governed by the Board of Trustees of the University of Illinois. Funding from external grants and contracts to ISWS staff is administered through the University of Illinois. ISWS staff are subject to the policies and procedures of the University, and external funding agencies. The ISWS Director is responsible for the implementation of these policies and procedures with assistance from the

internal senior management team, which includes the Assistant Director for Administration, the Heads of each Section, and the Coordinator of the NADP. Section Heads and the Program Coordinator also have administrative and technical oversight responsibilities for the principal investigators within their group. This includes the preparation and implementation of appropriate quality assurance documentation. An organizational chart for the Institute is shown in Figure 1. A similar chart for ISWS is shown in Figure 2.

2.3 Quality Assurance Coordinator Responsibilities

The QA Coordinator is responsible for the development of the ISWS Quality Management Plan and for coordinating its review and revision, in conjunction with the ISWS QA/QC Committee. The Coordinator also provides resource materials and guidance to principal investigators who are developing activity-specific quality assurance project plans (QAPPs). At the discretion of the Director, the QA Coordinator may review internally-generated QAPPs for conformance with the Quality Management Plan and applicable requirements of external funding agencies. The QA Coordinator may also participate in project-specific internal reviews and systems audits at the request of the Director, senior management, or principal investigators.

2.4 Principal Investigator Responsibilities

Principal investigators and co-principal investigators (hereafter referred to as principal investigators) are defined as the individuals who are responsible for overseeing research and data collection activities funded from general revenue and external funding sources. Externally-funded projects often have contractually-defined responsibilities that have been agreed upon between the University of Illinois, the principal investigator(s), and the funding agency. Principal investigators have the primary responsibility for the development and implementation of appropriate project-specific quality assurance plans and for resolving disputes that may arise regarding questions of data quality. For externally-funded projects, quality assurance project plans must comply with the requirements of the funding agency, as well as the provisions of the ISWS Quality Management Plan. For environmental data collection and reporting activities that are supported by general revenue funds, quality assurance plans will be developed by individual principal investigators with guidance from the Quality Assurance Coordinator, the Director, and the appropriate Section Heads or Program Coordinator. The Director and the appropriate Heads or Program Coordinator will determine the need for quality assurance plans for general revenue-funded data collection activities. Multi-disciplinary projects that involve two or more Sections/Program may have shared quality assurance responsibilities among two or more co-principal investigators.

Principal investigators are responsible for implementing the provisions of the QAPP and providing each project team member (including graduate and undergraduate students) with a copy of the plan so that each member understands his/her responsibilities in carrying out the plan. Conducting periodic systems audits or reviews are also the responsibility of the principal investigator unless this function has been formally designated to another project team member with a specified quality assurance function. Principal investigators are also responsible for initiating and documenting corrective actions whenever deviations from the prescribed quality assurance plan occur.

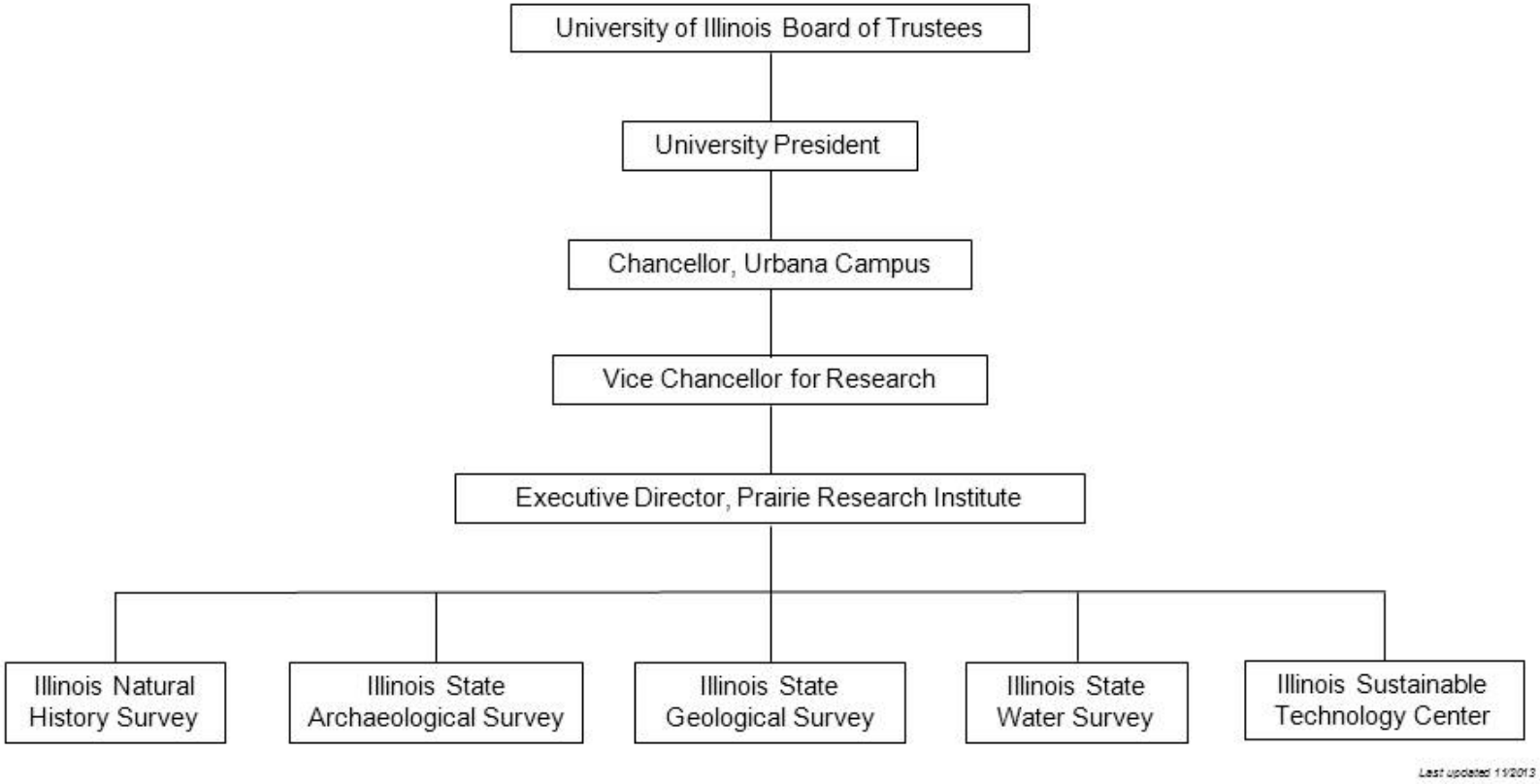

Figure 1. Prairie Research Institute (PRI) Organizational Chart.

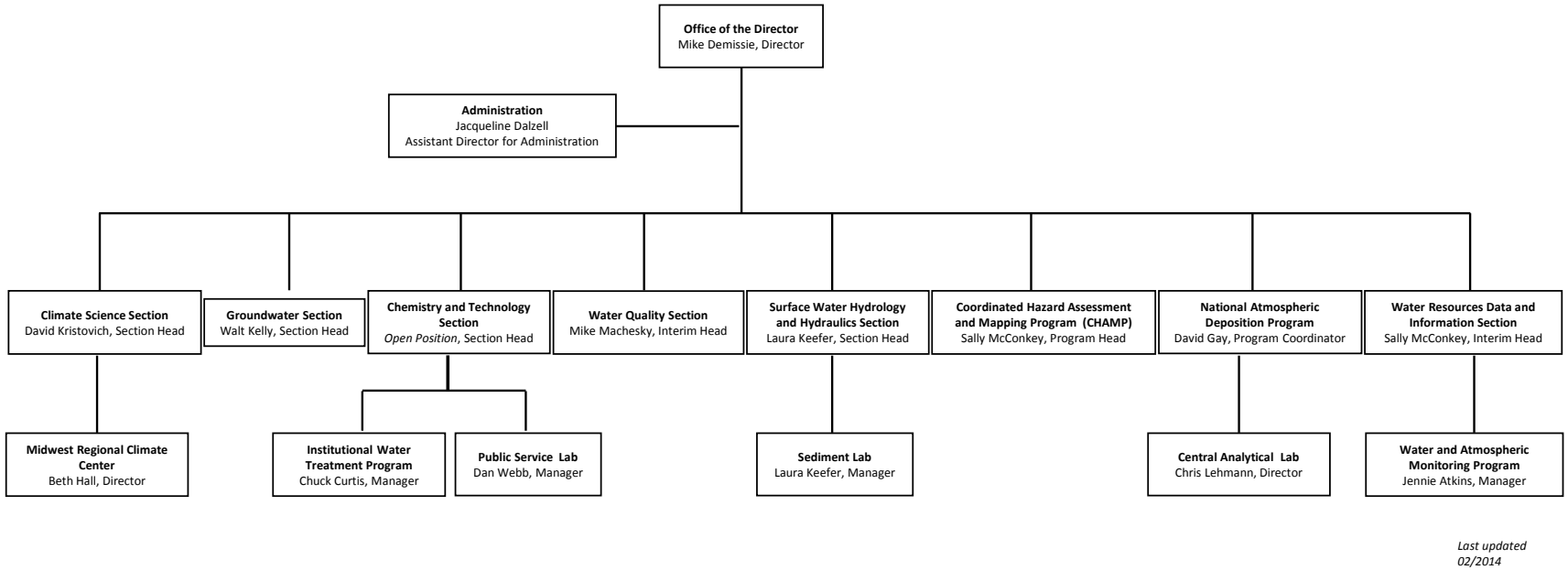

Figure 2. Illinois State Water Survey (ISWS) Organizational Chart.

2.5 Technical Staff Responsibilities

Technical staff are defined as all scientific project team members other than principal investigators. Technical staff are required to be familiar with the ISWS Quality Management Plan and all quality assurance practices contained in quality assurance project plans that pertain to their area of responsibility. Technical staff are responsible for compliance with all elements of the plan, including adherence to task-specific standard operating procedures (SOPs) that are integral to the plan or cited by reference in the plan. Technical staff are also responsible for reporting any deviations from the approved plan or SOPs to the principal investigator(s) and taking the necessary corrective action to bring the quality management system back into compliance.

2.6 Role of ISWS QA/QC Committee

The role of the ISWS QA/QC Committee is to promote the development and implementation of the ISWS Quality System for the data collection, research, and public service activities carried out by the staff of the ISWS. The Committee assists in the review and revision of the ISWS Quality Management Plan and provides guidance to staff in developing project-specific quality assurance plans and standard operating procedures. The Committee also serves as a resource for staff requesting information on approved quality assurance and quality control practices. Members of the Committee are appointed on an annual basis by the ISWS Director. The Quality Assurance and Site Safety Coordinator serves as the Chair of the Committee.

3.0 Elements of the ISWS Quality System

3.1 Quality Management Plan (QMP)

The ISWS Quality Management Plan is the "umbrella" document that describes the quality system and its various components. The Plan is intended to include ISWS environmental data collection and reporting programs that involve research and development, monitoring, laboratory operations on environmental samples, and modeling activities, regardless of the source of funding. The Director, Quality Assurance and Site Safety Coordinator, Section Heads, and the Program Coordinator have the responsibility for implementation of the Plan and its various elements.

The QMP is reviewed by the QA/QC Committee on an annual basis, incorporating revisions, edits and additions as necessary. The Committee will submit the QMP to the Senior Management Team for complete review and approval every three years or, more frequently, if major revisions are made.

3.2 Quality Assurance Project Plans (QAPPs)

Quality Assurance Project Plans are formal documents that describe in comprehensive detail the required quality control, quality assurance, and related technical activities that must be carried out for a specific project so that project deliverables are met and the data that result from the project are of sufficient quality to meet the project objectives. The USEPA provides guidelines

for the development of QAPPs on its web site (Section 1). These guidelines must be followed for USEPA and Illinois Environmental Protection Agency (IEPA) funded projects. Principal investigators for projects funded by other external sponsors will use QAPP guidelines approved by the sponsor and associated elements contained in the ISWS QMP. Principal investigators for internally funded programs will develop QAPPs following guidelines provided in the ISWS Quality Management Plan.

The QA Committee has developed a QAPP template which is available to staff who need to provide a QAP (or QAPP) for small, short-term, environmental data collection projects. This alternative documentation can be used in place of a full Quality Assurance Project Plan (QAPP) for grants that simply cannot support the production of elaborate quality system documents. Such grants may involve the collection of environmental data that are never going to be used to make an environmental decision, but rather are used as a means to raise public awareness of environmental issues or provide educational outreach.

The ISWS template provides a fill-in-the-field format for ease of use by staff. It also presents two examples, either a field project or a laboratory project, that are easily referenced as the user proceeds through the eight elements defined within the template. The template is based on the EPA's Elements of Systematic Planning (Chapter 3 of the EPA Quality Manual for Environmental Programs) and can be retrieved through the QA Committee's web page at:

http://www.isws.illinois.edu/staffonly/committees/qaqc/qaqc.asp.

3.3 Standard Operating Procedures (SOPs)

Standard Operating Procedures are written documents that describe the detailed procedures for a method of operation, activity, or analysis so that the procedure can be reproduced consistently. SOPs are generally developed for activities that are conducted on a repetitive basis, often by multiple staff members performing the same task. Areas appropriate for the development of SOPs include routine data collection activities, monitoring, and laboratory and field measurement activities. SOPs are included as a part of, or are referenced in, the QAPP. SOPs can be developed internally for specialized tasks or can be adopted from approved procedures developed by state and federal agencies or standards development organizations. The source for all SOPs must be clearly defined in the QAPP. Guidelines for the development of SOPs are available on the USEPA web site (Section 1).

An SOP template is provided on the QA Committee web page (url given in Section 3.2). It is designed as a step-by-step approach and is intended to be a starting point for SOP development. Users are allowed to change the format to fit their needs. This template may be adapted to fit many applications, including laboratory procedures, computing procedures, data or records review, equipment use, equipment maintenance, etc. Some examples are given in the template.

3.4 Management Assessments

Management assessments are routine and ongoing processes of review by ISWS senior management to monitor the effectiveness of the quality system. This process begins at the time of project inception for both externally and internally-funded projects. Senior managers and the

Director review all project proposals to determine if adequate protocols for quality assurance have been incorporated into the projects. They also have the responsibility for reviewing applicable sponsor guidelines for quality assurance for externally-funded work. Once projects are begun, senior managers are involved with the regular review of periodic progress reports, annual reports, and final reports to determine if data quality objectives have been met. At the discretion of the Director, external assessments may be requested in the form of outside review teams to assist in determining whether the projects are meeting their desired objectives.

3.5 Systematic Planning Processes

Project planning requires a systematic process that is coordinated by the principal investigator(s). Once the project objectives are identified, a scope of work (including project deliverables), budget, and time schedule are developed with proposed project team members who are involved in the planning process. Protocols covering quality assurance are also included in the project planning process and the financial and human resources necessary for implementation of the quality management program are included in the overall project budget. Project-specific data quality objectives (DQOs) also need to be identified during the planning process (Section 1). Data quality objectives can include the desired bias and precision (uncertainty), completeness, and representativeness characteristics that will be required to meet the project goals. The need for a separate QAPP will also be assessed during the planning process. If a stand-alone QAPP is not required, project proposals will, at a minimum, contain a section on the protocols of quality assurance that will be followed to meet the project objectives.

3.6 Technical Reviews

Periodic technical reviews, conducted during the course of a project, are documented assessments of project work to evaluate documents, activities, materials, data, or other work products that require technical verification for bias, precision, completeness, or representativeness. Technical reviews may be conducted by ISWS staff who are independent of the project team, but with equivalent experience and training in the project discipline. Reviews may also be conducted by external individuals. Technical reviews may be required by project sponsors for externally funded grants and contracts or may be requested by the Director and senior managers for internally funded projects. Technical reviews should result in a written record of the review findings with a documented response from the principal investigator that addresses the reviewers' findings. The principal investigator is responsible for retaining records that document the review findings and responses.

3.7 Data Quality Assessments

Data quality assessments are evaluations of results to determine their validity and appropriateness for their intended use. Routine data quality assessments need to be incorporated into the project design, with clear indication of the staff responsible for conducting the assessments. The assessments are to be conducted on a predetermined frequency and a written record maintained that documents the results of the data review. Any deviations from the data quality objectives that are discovered during the assessments will be reported to the principal

investigator for corrective action. For externally funded projects, sponsors may require that data quality assessments be conducted by the sponsoring agency or a qualified third party.

3.8 Modeling Guidelines

Modeling guidelines have been developed to provide investigators with criteria to determine both credibility of numerical values and release of models to outside individuals or organizations. A guideline establishing the credibility of a model was defined by addressing the issues of transparency, credibility and uncertainty. A second guideline on the release and review of models was created using six principles to define standards, review, timing, collaborative development and multi-institutional models. Both of these modeling guidelines are found on the web in the Staff Only section at:

http://www.isws.illinois.edu/staffonly/guidelines/modelguidelines.asp

4.0 Personnel Qualifications and Training

4.1 Guidelines for Staff and Management Training

ISWS staff are encouraged to attend applied training courses that are directly related to their job function. These may be offered at colleges and universities, by local, state, or federal agencies, through vendors of computer hardware and software, or by manufacturers of scientific instrumentation. Training in quality management practices is included in this category.

Participation in annual fire and severe weather drills is required of all staff. The University of Illinois Division of Research Safety provides a General Laboratory Safety course, required for all laboratory staff; Awareness Training for the Transport of Hazardous Material, required for staff shipping hazardous chemicals; and UIUC Chemical Waste Requirements Training, required of staff supervising disposal of chemicals. Additional training includes, but is not limited to, fire safety and extinguisher usage, laboratory safety, chemical hygiene, worker right-to-know laws, cardiopulmonary resuscitation (CPR), automated external defibrillator (AED) operation, and boating safety. Other links and references to safety manuals can be found on the staff-only web page of the Safety Committee at:

http://www.isws.illinois.edu/staffonly/committees/safcom/sc.asp

Minimum staff training requirements may need to be included in project QAPPs and/or SOPs depending on the level of expertise required for specific tasks.

4.2 Documentation of Staff Training and Education

Job opening announcements for new employees are based on the requirements of the position in terms of education and experience. All applicants must meet these minimum requirements to be hired. A permanent record of the successful applicant's resume, with education and work experience, is maintained in the Human Resources Office. New staff are required to provide written acknowledgments that appropriate policy and safety manuals have been provided and

that the employee understands the provisions contained in the documentation. Existing employees are to provide the same documented acknowledgments for new or revised guidelines. This documentation is maintained in the Human Resources Office. As a part of the annual staff evaluation process, all staff members provide updated resumes that include formal education and any other subsequent training, certifications, or licenses that have been received. These records are also maintained in the Human Resources Office.

5.0 Procurement of Items and Services

5.1 Procurement Source Evaluation and Selection

Principal investigators have the primary responsibility for determining that goods and services procured to meet project deliverables are of sufficient quality to provide reliable and consistent performance. Purchase requests for goods and services should include adequate detail to specify the quality and performance expectations of the acquired items. This is particularly important for goods and services that need to be bid. Bid evaluations need to take into account the quality aspects of the offered goods and services based on the performance specifications that were indicated on the request for bid forms.

University of Illinois purchasing agents are responsible for maintaining lists of approved vendors for a broad category of goods and services. They are also responsible for obtaining competitive pricing schedules for items sold to University staff. Any quality defects that affect the performance of goods and services obtained through the University or State should be reported through the ISWS procurement staff.

Contractors obtained to provide services must be pre-approved and have evidence of insurance, bonding, and/or appropriate documentation of licenses or certifications, depending on the vendor type. External providers of laboratory services must provide adequate documentation to show compliance with accreditation requirements, including the availability of QAPPs, QMPs, and SOPs, where applicable.

5.2 Evaluation of Quality of Vendor Supplied Commodities, Services, and Equipment

Project staff are responsible for providing specifications on the purchase request to determine that procured goods and services are of acceptable quality to meet the project objectives. Certifications of performance, quality, and warranty information that accompany goods and services must be maintained in a secure location under the control of the designated responsible staff member. This includes Material Safety Data Sheets that accompany chemical purchases. External providers of laboratory services must provide adequate quality control information to assess the bias and precision (uncertainty) of the reported results.

6.0 Documentation and Records

6.1 Records Requiring Document Control

Quality-related documents including Quality Management Plans, QAPPs, and SOPs will be prepared using a document control format to easily track revisions and to maintain a record of authorized approvals. Approvals will, at a minimum, include the principal investigator and the Section Heads or the Program Coordinator. For projects that have a designated quality assurance specialist, he/she will also review and approve all quality-related documents. Other approvals may be required at the discretion of the Director or an external funding agency. These documents need to contain: a title page with revision number and effective date, an approval page with authorized signatures, the text of the document, and a record of previous versions at the end of the document. Header information on each page of the text will include the title of the document, revision number, effective date, and page number.

Project principal investigators should designate a staff member to maintain the most recent document revisions and to assist in the secure archival of previous versions. Copies of previous versions of these documents are maintained in a secure location to provide a historical record of changes that have been made.

6.2 Document and Record Accessibility, Retention, and Protection

Principal investigators have the primary responsibility for controlling access to project data and for retaining appropriate records. The procedures for record control and retention are provided in the QAPP and must be consistent with all statutory, regulatory, and contractual requirements. Access to data from projects in progress should be controlled through the use of computer password protection and physical barriers such as locked doors and file cabinets. As a general guideline, provisional or raw data will not be available for public distribution. Final reports that are published as part of the ISWS publication series will be archived in the ISWS library as the permanent, long-term repository. The ISWS publications distribution coordinator is responsible for providing the archival copy of ISWS publications to the library, and disseminating reports to the public. Principal investigators are required to furnish a PDF file for any ISWS publication to the web administrator for web distribution; they are also required to provide copies of journal articles and published proceedings to the library.

Records containing water and atmospheric resources data important to the state are permanently archived and documented on appropriate media. Data archives will be accompanied by documentation (metadata) that describes the hardware and software used to read and write the archives, the variables stored in the archives, the format and units of the variables, the conditions under which they were collected, and any other information that may inform the user about the nature of the data, their quality, or their use. All data records will be archived in such a way that the quality of the records will not be compromised. Records will be stored in a secure location with controlled access and adequate temperature control to maintain their integrity.

6.3 Archive Record Room

The Archive Record Room provides long-term or permanent storage for research records or project data. All items being submitted for archiving shall be referred to as a "record series" and shall be defined as any group of documents which have been maintained together as a unit and which are all related to a particular project, subject, function or study resulting from the same activity or documenting a specific kind of transaction. All components of a record series shall have the same disposal authority and disposal date.

The QA Committee has devised a 3-step protocol for submitting any record series. The first step presents the Flowchart which defines the responsibilities for staff and indicates the procedures for submitting records. The Checklist in the second step uses a question-and-answer format to help staff purge files of unnecessary contents, correctly re-folder items, reorganize paper records, and label contents prior to submission. The third step requires completion of the Transmission Form which identifies the staff member submitting records, gives a title, description and justification for submitting records and also defines the retention period and substantiates disposal. These forms can be accessed from:

http://www.isws.illinois.edu/staffonly/archival/bldg11/

7.0 Computer Hardware and Software

7.1 Hardware Selection Procedures

Computer hardware selection should be based on the project requirements for data storage, retrieval, and processing. Hardware should be purchased from approved vendors with warranty periods that are consistent with industry norms. In selecting computers and peripherals, consideration should also be given to compatibility with existing hardware and software applications at the ISWS. The ISWS Information Management Committee and the Computer Applications Coordinator are available resources to consult when selecting computer hardware.

7.2 Software Procurement Procedures

Computer software should be purchased from an approved bidders list or a list of authorized vendors, whenever possible. Software should be selected to ensure compatibility with the host hardware. Upon receipt, the software version number should be documented with the effective date that it was placed into service. If the software is to be used to perform mathematical or computational functions, a description of the formulas and algorithms used should be documented, based on information available through the vendor. For certain types of software, a source code listing may be required to modify or customize the software for specific applications. Computer software covered under this section includes design, data handling, data analysis, modeling, data acquisition, geographic information system scripts, and database programs.

7.3 Documentation of Internally Developed Software

Internally-developed software, including mathematical models, should be designed with input from the users of the program(s). The software will contain adequate documentation to clearly state the purpose and limitations of the program and for what applications the software was developed. The author of the software will be identified and, whenever practicable, a complete program listing of the source code will be available to users. All mathematical algorithms used in the software are described in a narrative description that accompanies the source code. Prior to use, the newly-developed software should be rigorously tested using predetermined acceptance criteria. When feasible, manual calculations should be conducted on test data sets to confirm the reliability of the software prior to routine use. For mathematical models, comparison of newly-developed model results with other similar model outputs is recommended.

7.4 Assessment Procedures for Evaluating Computerized Data Products

Data integrity can be compromised during data entry, electronic capture from automated instruments, and transfers between different computers and databases. Written procedures for ensuring the accuracy and reliability of computerized data products are described in individual QAPPs and may be explained in detail in task-specific SOPs that are developed for data verification purposes. Data verification methods may include double entry of manually entered data, manual checking of a fixed percent of computer generated data, or manually reentering data that were entered electronically. Commercially available spreadsheet and database products do not commonly use the 'odd/even' rule when rounding values. For that reason, ISWS staff should indicate what rounding protocol is followed when reporting data.

7.5 Staff Computing Guidelines

Computing guidelines for ISWS staff have been developed by the Information Management Committee. The guidelines are available on the ISWS web site at: http://www.isws.illinois.edu/staffonly/guidelines/compproc.asp. These guidelines are to be followed in addition to those outlined by the University of Illinois Campus Information Technologies and Educational Services (CITES) guidelines which are referenced at the above site.

8.0 Planning Processes

8.1 Inclusion of Management, Sponsors, Project Personnel, Stakeholders, etc. in Planning Process for Environmental Programs

Principal investigators have the primary responsibility for implementing a project planning process that involves all relevant stakeholders, which may include project sponsors, the Director, appropriate Section Heads or Program Coordinator, co-investigators, external scientific experts, and project personnel. All of these participants need to be involved during the preliminary planning process in order to address all relevant scientific and administrative issues as early in the process as possible.

8.2 Written Descriptions of Project Goals, Objectives, and Issues to be Addressed

The planning process will include the development of written project proposals. It will include project goals, objectives, and the scientific questions that will be addressed in the project. The written project descriptions, which ultimately may be incorporated into the final QAPP, will be reviewed and approved by all project team principal investigators, key participants, the sponsor, appropriate ISWS senior managers, and the Director.

8.3 Identification of Project Timetable, Budget, Staff Resources, and Deliverables

The principal investigator has the responsibility for developing project timetables and budget requirements, including the proposed allocation of staff time necessary to meet the project goals. Project deliverables and deliverable dates are developed in conjunction with the project sponsor. A summary of the project deliverables should be clearly stated in a separate section of the written project proposal.

8.4 Identification of Data Collection Needs and How Data Will Be Used to Meet Project Goals

As part of the planning process, principal investigators and appropriate project team members must identify what data will need to be collected and what methods will be used for data collection. The data collection methods and types of data collected must be decided upon based on the stated objectives of the project. The methods for data collection and the types of data to be collected should be clearly stated in the written project proposal or the QAPP.

8.5 Identification of Required QA/QC Protocols to Meet Data Quality Objectives

The project proposal or QAPP describes in detail the protocols of quality assurance that will be used to meet the specified data quality objectives (DQOs). Written data quality objectives include bias and precision (uncertainty) characteristics for field and laboratory measurements, data completeness criteria, and a discussion of how data representativeness will be assessed. Specific quality control activities that will be used to meet the data quality objectives are also described. The parties that are responsible for implementing the quality assurance program must be identified, and a schedule for internal and external technical and systems audits should be addressed. See Section 1 for more detail on the development of data quality objectives.

8.6 Protocols for Development, Review, and Approval of a QAPP

The primary responsibility for the development of a QAPP resides with the principal investigator. Guidelines for the development of QAPPs are provided in Section 1. Depending on the nature and size of the project, however, this function may be delegated to a project team member with qualifications and experience in developing quality assurance documents. The ISWS Quality Assurance and Site Safety Coordinator, with the assistance of the ISWS QA/QC Committee, serves as a technical resource for developing and reviewing ISWS QAPPs. Once developed, QAPPs are reviewed by the principal investigator, project team personnel, ISWS Quality Assurance and Site Safety Coordinator, and project sponsors. QAPPs should be

reviewed, and revised if necessary, on an annual basis, or more frequently if changes in project scope, personnel responsibilities, or quality assurance goals occur. An inventory of previously prepared QAPPs is located on the ISWS QA/QC Committee web page.

9.0 Implementation of Work Processes

9.1 Responsibilities for Project Supervision

Principal investigators are responsible for overall project supervision to determine that work is performed according to approved project proposals, scopes of work, QAPPs, and contractual requirements. Intermediate supervisors may be identified, at the discretion of the principal investigator, depending on the size and complexity of the project.

9.2 Development of Standard Operating Procedures (SOPs) for Routine, Standardized, or Critical Operations

Project principal investigators, in conjunction with Section Heads or the Program Coordinator, will identify the need for the development of SOPs for critical and/or routine technical and administrative tasks that are important in satisfying the project objectives. The SOPs may be developed independently or may be adopted or modified from a previously approved SOP from an appropriate standards development organization such as the USEPA, the United States Geological Survey (USGS), or the American Society for Testing and Materials (ASTM). The use of SOPs is recommended to minimize the variability in tasks that are critical to meeting project data quality objectives. An inventory of ISWS SOPs is located on the ISWS QA/QC Committee web page. ISWS SOPs utilize a numbering scheme that begins with a prefix abbreviation of the originating Section or Program followed by an alpha-numeric designation consistent with previously developed SOPs (e.g. GW-GWL1.1 for a groundwater level measurement SOP from the Groundwater Section).

10.0 Assessment and Response

10.1 Procedures for Planning, Conducting, and Evaluating Environmental Program Assessments

The ISWS quality system will be evaluated at least once every three years to determine if the system is meeting the desired goals. The review process will include the ISWS Quality Assurance/Quality Control Committee, the Director, and Section Heads and the Program Coordinator. If changes to the quality management system are necessary, the ISWS Quality Management Plan will be revised accordingly. Individual project quality assurance assessments will be conducted by the principal investigator or his/her designee. The frequency of program assessments will be described in the QAPP or project proposal documentation.

10.2 Selection of Assessment Tools

The assessment tools to be used to determine if project data quality objectives are met are detailed in the QAPP. The principal investigator has the responsibility to select those tools that

best meet the data quality objectives of the project. These may include internal or external audits, data quality assessments, management systems reviews, peer reviews, and technical systems reviews. In selecting assessment tools, principal investigators must comply with all applicable statutory requirements (e.g. laboratory accreditation) and requirements imposed by external project sponsors.

10.3 Identification of Personnel Involved with Assessments

Each project proposal or QAPP must identify the individuals responsible for conducting quality assessments. Quality assessments should be conducted by individuals with knowledge, training, and experience in the technical area of the project, but they need not be project team members. Quality assessment participants must have free access to all data records, staff, and quality assurance information in order to conduct thorough reviews of the project.

10.4 Documentation of Assessment Findings

Quality assessment findings must be prepared in writing and transmitted to the principal investigator and the designated project quality assurance specialist, if such a person has been named. The principal investigator has the responsibility to review the assessment findings and take the necessary corrective action if any deficiencies in the quality management system are found. Written responses to the assessment findings should be prepared and the effective dates of all corrective actions noted. Follow-up reviews of all corrective actions should be conducted to confirm that the prescribed action was adequate to address any deficiencies noted in the quality assessment report.

11.0 Quality Improvement

The ISWS quality system is a dynamic set of guidelines and procedures that is intended to encourage ongoing quality improvement throughout the organization's activities. Staff involvement at all levels, however, is required to enhance the quality of ISWS data, reports, and publications. It is the responsibility of each employee to identify conditions that are adverse to quality and to suggest improvements to the quality management system. When shortcomings in the system are identified, swift corrective action, with thorough documentation, is required.

Appendix – Terms and Definitions

archive	the organized storage of documents and records in a secure location with adequate climate control to maintain their integrity. Electronic records shall be maintained on write-protected, secure electronic media following accepted data management practices in a format that is generally readable with current computer hardware technology.
assessment	the evaluation process used to measure the performance or effectiveness of a system and its elements. As used here, assessment is an all-inclusive term used to denote any of the following: audit, performance evaluation, management systems review, peer review, inspection, or surveillance.
audit (quality)	a systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.
bias	the systematic or persistent distortion of a measurement process that causes errors in one direction (i.e., the expected sample measurement is different from the sample's true value)
data quality assessment	a statistical and scientific evaluation of the data set to determine the validity and performance of the data collection design and statistical test, and to determine the adequacy of the data set for its intended use.
data quality objectives	the qualitative and quantitative measures of data quality that are desired from a specific activity or program. Data quality objectives may include characteristics of bias, precision, completeness, and representativeness
environmental data	any measurements or information that describe environmental processes, location, or conditions; ecological or health effects and consequences; or the performance of environmental technology. Environmental data include information collected directly from measurements, produced from models, and compiled from other sources such as data bases or the literature.
environmental programs	work or activities involving the environment, including but not limited to: characterization of environmental processes and conditions; environmental monitoring; environmental research and development; the design, construction, and operation of environmental technologies; and laboratory operations on environmental samples.
graded approach	the process of basing the level of application of managerial controls applied to an item or work according to the intended use of the results and the degree of confidence needed in the quality of the results.

independent assessment	an assessment performed by a qualified individual, group, or organization that is not a part of the organization directly performing and accountable for the work being assessed.
inspection	examination or measurement of an item or activity to verify conformance to specific requirements.
management	those individuals directly responsible and accountable for planning, implementing, and assessing work.
management system	a structured, non-technical system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for conducting work and producing items and services.
management systems review	the qualitative assessment of a data collection operation and/or organization(s) to establish whether the prevailing quality management structure, policies, practices, and procedures are adequate for ensuring that the type and quality of data needed are obtained.
material safety data sheet (MSDS)	a document that provides workers and emergency personnel the proper procedures for handling or working with a particular substance. MSDSs include information such as physical data (melting point, boiling point, flash point, etc.), toxicity, health effects, first aid, reactivity, storage, disposal, protective equipment, and spill/leak procedures.
metadata	information that describes the content, quality, condition, or other characteristics of data that aid the user in determining the applicability of a data set for a specific application.
peer review	a documented critical review of work by qualified individuals (or organizations) who are independent of those who performed the work, but are collectively equivalent in technical expertise. A peer review is conducted to ensure that activities are technically adequate, competently performed, properly documented, and satisfy established technical and quality requirements. The peer review is an in-depth assessment of the assumptions, calculations, extrapolations, alternate interpretations, methodology, acceptance criteria, and conclusions pertaining to specific work and of the documentation that supports them.
performance review	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.
precision	the degree of agreement of repeated measurements of a homogeneous sample by a specific procedure, expressed in terms of dispersion of the values obtained about the mean value. It is often reported as the sample standard deviation(s).

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quality assurance (QA)	an integrated system of management activities involving planning, implementation, documentation, assessment, reporting, and quality improvement to ensure that a process, item, or service is of the type and quality needed and expected by the client.
quality assurance project plan (QAPP)	a formal document describing in comprehensive detail the necessary QA, QC, and other technical activities that must be implemented to ensure that the results of the work performed will satisfy the stated performance criteria.
quality control (QC)	the overall system of technical activities that measures the attributes and performance of a process, item, or service against defined standards to verify that they meet the stated requirements established by the customer; operational techniques and activities that are used to fulfill requirements for quality.
quality improvement	a management program for improving the quality of operations. Such management programs generally entail a formal mechanism for encouraging worker recommendations with timely management evaluation and feedback or implementation.
quality management	that aspect of the overall management system of the organization that determines and implements the quality policy. Quality management includes strategic planning, allocation of resources, and other systematic activities (e.g., planning, implementation, documentation, and assessment) pertaining to the quality system.
quality management plan (QMP)	a document that describes the quality system in terms of the organizational structure, functional responsibilities of management and staff, lines of authority, and required interfaces for those planning, implementing, and assessing all activities conducted.
record	a completed document that provides objective evidence of an item or process. Records may include photographs, drawings, magnetic tape, and other data recording media.
senior managers	the ISWS administrative team that consists of the Director, the Assistant Director for Administration, the Heads of the Sections, the Coordinator of the National Atmospheric Deposition Program, and the Administrative Assistant for the Office of the Director.
specification	a document stating requirements and which refers to or includes drawings or other relevant documents. Specifications should indicate the means and the criteria for determining conformance.
standard operating procedure (SOP)	a written document that details the method for an operation, analysis, or action with thoroughly prescribed techniques and steps, and that is officially approved as the method for performing certain routine or repetitive tasks.

supplier	any individual or organization furnishing items or services or performing work according to a procurement document or financial assistance agreement. This is an all-inclusive term used in place of any of the following: vendor, seller, contractor, subcontractor, fabricator, or consultant.
technical review	a documented critical review of work that has been performed within the state of the art. The review is accomplished by one or more qualified reviewers who are independent of those who performed the work, but are collectively equivalent in technical expertise to those who performed the original work. The review is an in-depth analysis and evaluation of documents, activities, material, data, or items that require technical verification or validation for applicability, correctness, adequacy, completeness, and assurance that established requirements are satisfied.
technical systems audit	a thorough, systematic, on-site, qualitative audit of facilities, equipment, personnel, training, procedures, record keeping, data validation, data management, and reporting aspects of a system.
uncertainty	a numerical value assigned to a measurement to take into account two major components of error: 1) the systematic error, and 2) the random error attributed to the imprecision of the measurement process.