Quality Management System, U.S. Geological Survey National Water Quality Laboratory

By Douglas L. Stevenson, Editor

Unpublished Report (2012)

U.S. Department of the Interior
U.S. Geological Survey

Suggested citation:
Stevenson, D.L.., ed., 2012, Quality management system, U.S. Geological Survey National Water Quality Laboratory: unpublished U.S. Geological Survey Report, version 2.0, 3 January 2012, chapters variously paged.

Mailing address:
U.S. Geological Survey
National Water Quality Laboratory
P.O. Box 25585
Denver, Colorado 80225-0585

Any use of trade, product, or firm names is for descriptive purposes only and does not imply endorsement by the U.S. Government.

National Water Quality Laboratory
Quality Management System

NELAP Certification Statement

We, the undersigned, understand and acknowledge that the U.S. Geological Survey National Water Quality Laboratory is required to be continually in compliance with The NELAC Institute standards and shall be subject to the penalty provisions provided therein for deviations.

Approved by: SIGNED

John S. Zogorski — 1-10-12 Date
Laboratory Chief
(303) 236-3500

Concurred with: SIGNED

David W. Reppert — 1/10/12 Date
Assistant Laboratory Chief
(303) 236-3548

Patricia E. Johnson — 1/9/2012 Date
Administrative Officer
(303) 236-3570

Douglas L. Stevenson — 4 JAN 2012 Date
Chief, Quality Assurance
(303) 236-3762

Thomas J. Bushly — 1/9/2012 Date
Chief, Information Technology
(303) 236-3722

Jeff W. McCoy — 1/9/2012 Date
Chief, Methods Research
and Development
(303) 236-3940

Carlos E. Arozarena — 1/9/2012 Date
Safety Officer, Safety, Health,
and Environmental Compliance
(303) 236-3302

Duane S. Wydoski — 1/9/2012 Date
Chief, Analytical Services
(303) 236-3240

Milton E. Marshall — 1/9/2012 Date
Acting Chief, Support Services
(303) 236-3710

Date of Issue: 3 January 2012
Issue Number: 2.0

This page is intentionally blank.

CONTENTS

1 Introduction 1
1.1 Scope of Testing 1
1.2 Management of the QMS 1
2 Organization 3
2.1 USGS, NWQL 3
2.2 Conflict of Interest and Undue Pressure 5
3 Laboratory Infrastructure and Environment 6
3.1 Work Areas 6
3.2 Air and Surface Monitoring 8
3.3 Fume Hood Testing 9
3.4 Maintenance, Repair, and Replacement: Responsible Parties 9
3.5 USGS Equipment Maintenance Responsibilities 9
3.6 NWQL Housekeeping Procedures 10
3.7 Building 95 Floor Plan 11
3.8 Building Security 11
Management Requirements
4 Management 12
4.1 Management Requirements 12
4.2 Management Roles and Responsibilities 13
4.2.1 Office of the Chief, NWQL 13
4.2.2 Chief, QAS 14
4.2.3 Chief, Administrative Services Section 15
4.2.4 Safety Officer (Chief), Safety, Health, and Environmental Compliance Section 15
4.2.5 Chief, Analytical Services Section 16
4.2.6 Chief, Information Technology Section 16
4.2.7 Chief, Methods Research and Development Program 16
4.2.8 Chief, Support Services Section 17
4.2.9 Key Laboratory Staff Deputies 17
4.3 Quality Policy 18
4.4 Ethics and Data Integrity 18
4.5 Documentation of the QMS 18
4.5.1 Standard Operating Procedures (SOPs) 18
4.5.2 Order of Precedence 20
5 Staff..... 21
5.1 Position Descriptions 21
5.2 Training 21
6 Review of Requests, Tenders, and Contracts 22
7 Analytical Contracts 23
7.1 Contract Laboratories 23
7.2 Subcontract Laboratories 23
8 Purchasing Services and Supplies 25
8.1 Procedure 25
8.2 Acquisition Payment Documentation 26
8.3 Approval of Suppliers 26

9 Customer Service 27
9.1 Customer Confidentiality 27
9.2 Customer Support 27
9.3 Customer Feedback 27
10 Complaints 28
11 Improvement 29
12 Control of Nonconforming Work 30
12.1 Requesting a Departure from Documented Policies and Procedures 30
12.2 Nonconforming Work 30
12.3 Stop Work Procedures 31
13 Document Control 32
13.1 Controlled Documents 32
13.2 Obsolete Documents 35
14 Records Management 36
14.1 Records Maintained 36
14.2 Records Management and Storage 39
14.3 Legal Chain-of-Custody Records 40
15 Audits 41
15.1 Internal Audits 41
15.2 External Audits 42
15.3 Performance Audits 42
15.4 System Audits 42
15.5 Handling Audit Findings 43
16 Preventive Action 44
17 Corrective Action 45
17.1 General Procedure 45
17.1.1 Cause Analysis 46
17.1.2 Selection and Implementation of Corrective Actions 46
17.1.3 Monitoring a Corrective Action 46
17.2 Additional Audits 47
17.3 Technical Corrective Action 47
18 Data Integrity 49
18.1 Elements of the NWQL Ethics and Data Integrity Program 49
18.2 Ethics and Data Integrity Procedures 50
18.3 Training 51
18.4 Confidential Reporting 51
19 Management Review 52

Technical Requirements

20 Field Supplies, Sample Collection, Preservation Requirements, and Holding Time 53
20.1 Field Supplies 53
20.2 Sample Collection 53
20.3 Preservation Requirements 54
20.4 Holding Time 54
21 Sample Receipt and Handling 56

22 Equipment 57
22.1 General 57
22.2 Records Maintained for Laboratory Equipment 57
22.3 Support Equipment 58
23 Methods and Method Validation 59
23.1 Test Methods Used at the NWQL 59
23.2 NWQL-Developed Methods 60
23.3 Computer and Electronic Data Requirements 61
23.4. Data Reduction, Review, and Reporting 62
24 QA for Environmental Testing 63
25 Calibration 64
26 Measurement Traceability 65
27 Reporting Results 66

Other

28 Literature Cited 67
29 Glossary 69

FIGURES

1 Organization of the National Water Quality Laboratory 4

ABBREVIATIONS

C&A	certification and accreditation
DOC	demonstration of capability
DOI	U.S. Department of the Interior
GSA	General Services Administration
IDMS	integrated document management system
ISO/IEC	International Organization for Standardization/International Electrochemical Commission
LIMS	laboratory information management system
NELAC	National Environmental Laboratory Accreditation Conference
NELAP	National Environmental Laboratory Accreditation Program
NWIS	National Water Information System
NWQL	National Water Quality Laboratory
OWQ	Office of Water Quality
PM	policy memorandum
QA	quality assurance
QA/QC	quality assurance/quality control
QAS	Quality Assurance Section
QC	quality control
QMS	quality management system
RN	Rapi-Note
SOP	standard operating procedure
TM	technical memorandum
URL	uniform resource locator
USGS	U.S. Geological Survey
WWW	web page; World Wide Web
WRD	Water Resources Discipline

1 INTRODUCTION

The purpose of the *Quality management system, U.S. Geological Survey National Water Quality Laboratory* (QMS) is to outline the management system for the United States Geological Survey (USGS) National Water Quality Laboratory (NWQL). The QMS defines the policies, procedures, and documentation that assure analytical services continually meet a defined standard of quality that is designed to provide customers with data of known and documented quality and, where applicable, demonstrate regulatory compliance.

The QMS sets the standard under which all laboratory operations are performed, including the laboratory's organization, objectives, and operating philosophy. The QMS has been prepared to assure compliance with the *Environmental laboratory sector standard – Volume 1 – Management and technical requirements for laboratories performing environmental analysis*, Module 2 – *Quality systems general requirements* (The NELAC Institute, 2009). This standard is consistent with the International Organization for Standardization/International Electrochemical Commission (ISO/IEC) 17025:2005 requirements that are relevant to the scope of environmental testing services and thus, the laboratory operates a quality system in conformance with ISO/IEC 17025:2005(E). In addition, the policies and procedures outlined are compliant with the various accreditation and certification programs in which the NWQL participates.

The sections, appendixes, and other information in this document are generally arranged to facilitate the audit process. Management and technical requirements are presented in the text. The requirements are further supported by information contained in the NWQL manual *Laboratory quality assurance and quality control, U.S. Geological Survey National Water Quality Laboratory* (Stevenson and Barnard, 2012) and also on the NWQL intranet, including, but not limited to, information for analytes for which the NWQL is accredited by the National Environmental Laboratory Accreditation Program (NELAP), holding time, additional quality control (QC) and quality assurance (QA) requirements, and information contained in the appendixes.

1.1 Scope of Testing

The laboratory’s scope of analytical testing services includes those listed on its web site at NWQL USGS-visible intranet > Quality > Laboratory Accreditation, Accredited Test Methods and presented in the NWQL services catalog accessible at USGS-visible intranet > LIMS Catalog.

1.2 Management of the QMS

The Chief, Quality Assurance Section (QAS), is responsible for maintaining the QMS, which is reviewed annually and updated as required to ensure it reflects current practices and meets the requirements of any applicable regulations or customer specifications. Sections of the manual requiring revision are updated and the revision number is adjusted. A new signature page is prepared and signed by all members of the NWQL Management Team. If necessary, the Contents page is revised.

Confidentiality is maintained on all data produced by the NWQL. Once data are received by the laboratory, laboratory sample identifications are used rather than project designations. Data are only

released to the submitter, based upon the associated laboratory information management system (LIMS) and National Water Information System (NWIS) user identification. Access to data associated with a specific project or proposal is limited to personnel working on the projects.

Reference: TNI V1:M2 – Sections 1, 2, and 3

2 ORGANIZATION

The laboratory is a legally identifiable organization. The laboratory is responsible for carrying out testing activities that meet the requirements of The National Environmental Laboratory Accreditation Conference (NELAC) Institute (TNI) Standard (The NELAC Institute, 2009), the ISO/IEC 17025 Standard, and that meet the needs of the customer. Through application of the policies and procedures outlined in this Section and throughout the QMS:

The laboratory assures that it is impartial and that personnel are free from undue commercial, financial, or other undue pressures that might influence their technical judgment.

Management and technical personnel have the authority and resources to carry out their duties and have procedures to identify and correct departures from the laboratory's management system.

Personnel understand the relevance and importance of their duties as related to the maintenance of the laboratory's management system.

Ethics and data integrity procedures (see Section 18, *Data integrity*) ensure personnel do not engage in activities that diminish confidence in the laboratory's capabilities.

2.1 USGS, NWQL

The USGS NWQL, also known as the Branch of Analytical Services, reports directly to the Chief, Office of Water Quality (OWQ), who in turn reports to the Associate Director for Water, the head of the Water Mission in Reston, Va. The USGS is a bureau within the U.S. Department of the Interior (DOI).

The NWQL's management structure provides clear lines of authority and responsibility to help ensure timely, informed decision-making. The laboratory is comprised of sections, each with its own manager and subordinate supervisors as required (fig. 1). All Section Chiefs report directly to the Laboratory Chief or Assistant Laboratory Chief. The NWQL Management Team includes the Laboratory Chief, Assistant Laboratory Chief, and all Section Chiefs. The NWQL Management Group includes the Management Team plus all subordinate supervisors.

The laboratory is operated primarily with Federal employees. However, non-Federal (including contract) staff is used to provide additional support and capabilities for various laboratory operations. Federal employees are prohibited from supervising contract personnel. Contract employees are administered by a government contracting officer, who is assisted by an appointed contracting officer's representative in the laboratory. The contractor is responsible for all task recruitment and task assignments for its employees.

Throughout the QMS, the terms "staff" and "personnel" refer collectively to all persons, Federal or non-Federal (including contract) employees, responsible for adhering to the requirements set forth by the QMS. These terms should not be confused with the actual employer of a particular individual.

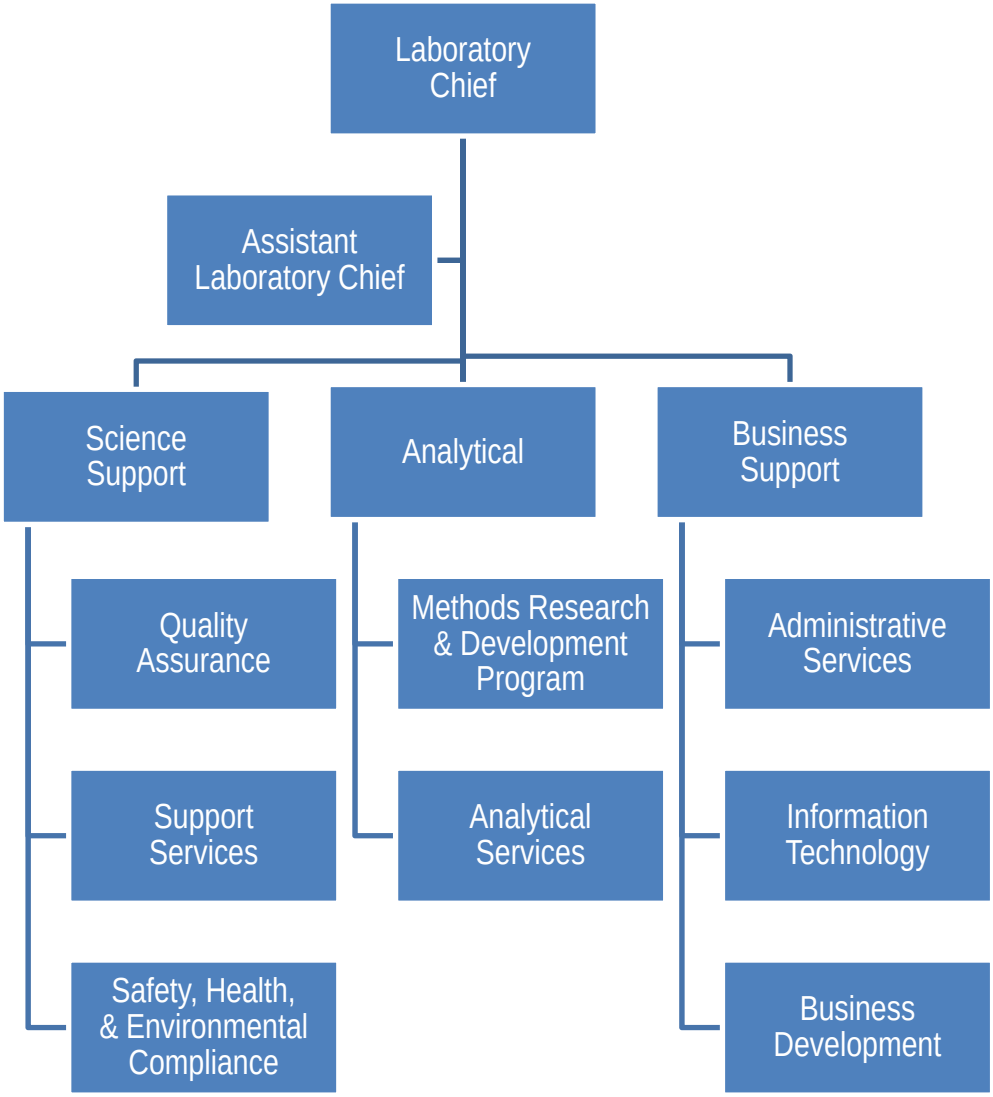

Figure 1. Organization of the National Water Quality Laboratory.

Additional information regarding responsibilities, authority, and relationships of personnel who manage, perform or verify testing is included in Sections 4, *Management*, and 5, *Staff*. These sections also include information on supervision, training, technical management, job descriptions, quality personnel, and appointment of deputies for key managerial staff.

The laboratory has the resources and authority to operate a management system capable of identifying departures from that system and from procedures during testing, and initiates actions to minimize or prevent departures.

2.2 Conflict of Interest and Undue Pressure

The organizational structure indicated above minimizes the potential for conflicting interests that might influence the technical judgment of analytical personnel. In addition, procedures are in place to prevent outside pressures or involvement in activities that may affect competence, impartiality, judgment, operational integrity, or the quality of the work performed at the laboratory.

Arrangements, such as policies and procedures to prevent commercial, financial or other influences that may negatively affect the quality of the work or negatively reflect on the competence, impartiality, judgment or operational integrity are described in the

- USGS ethics policy
  <http://www.doi.gov/ethics>
  <http://internal.usgs.gov/ops/hro/ethics/index.html >

- DOI Scientific Integrity Policy
  <http://elips.doi.gov/elips/release/3889.htm>
  and the document on scholarly integrity at
  <http://www.whitehouse.gov/sites/default/files/microsites/ostp/a_thornhill_presentation.pdf >),

- DOI Conflicts of Interest policy
  <http://elips.doi.gov/elips/release/3889.htm>

Reference: TNI V1:M2 – Section 4.1

3 LABORATORY INFRASTRUCTURE AND ENVIRONMENT

The NWQL is the primary laboratory used by the USGS for the determination of organic and inorganic constituents in samples of groundwater, surface water, river and lake sediments; aquatic plant and animal tissues; identification and enumeration of benthic invertebrate populations; and atmospheric precipitation collected in the United States and its protectorates. The NWQL shares Building 95 at the Federal Center in Denver, Colo., with the National Research Program, the Branch of Quality Systems, the USGS OWQ, and Central Region Drilling Unit. The building has 10,876 square meters of laboratory and office space, and occupies an 8.3-hectare plot.

The laboratory facility is designed and organized to facilitate testing of environmental samples. The facility represents the efforts of the architects and staff to ensure that safety, health, and environmental concerns were incorporated, incompatible laboratory processes were not located near one another, and that design features, such as the layout of shelves and cabinets, special air and power requirements, the need for walls between laboratories and workstations, location and types of fume hoods, and any other special needs, were addressed satisfactorily. Environmental conditions are monitored to ensure that conditions do not invalidate results or adversely affect the required quality of any measurement. Environmental tests are stopped when the environmental conditions possibly jeopardize the safety of employees or results.

The NWQL, in compliance with the Alternative Work Schedule Handbook, defined hours of operation and operational management controls in NWQL policy memorandum 2010.02, *NWQL hours of operation*. This document is available at NWQL USGS-visible intranet > Technical > Policy Memoranda > NWQL Hours of Operation.

3.1 Work Areas

Work areas may include access and entryways to the laboratory, sample receipt area, sample storage area, sample process area, instrumental analysis area, chemical and waste storage area and data handling and storage area. Access to, and use of, areas affecting the quality of the environmental tests is controlled by restriction to laboratory areas by authorized personnel only.

The laboratories are adequate for their use and appropriately clean to support environmental testing and ensure an unencumbered work area.

Important safety and design features of the NWQL facility include the following:

1. The two wings each passes about 2,000 cubic meters per minute (m^3/min) [70,000 cubic feet per minute, (ft^3/min)] of air through high efficiency particulate air filters to provide the building with clean, conditioned air. It is exhausted after one pass in laboratory areas. During the exhaust process, the air is passed through a heat exchanger to improve efficiency, but the air is not reused. Clean air moves from office spaces through laboratory areas, up and out. This minimizes exposure to exhaust air.

2. The preparation area for organic samples has full-length hoods to enclose the liquid-liquid extraction process completely.

3. Individual or manifold snorkel ventilation is provided for many instruments to ensure that all exhaust is vented to the work areas.

4. Authorized entry to the area reserved for chain of custody is controlled by key card as described in NWQL standard operating procedure (SOP) QUAX0030.x, *Chain of custody*. Access to the computer server room is controlled by cipher locks. Access to entry may be tracked for safety and security purposes.

5. The sample/waste disposal area is near the loading docks for easy access. This area has individual alcoves for different types of waste. Each alcove has a dam at the bottom of the alcove door to ensure that spills can be contained. Each alcove has features for the chemicals contained within; explosion-proof lights and/or special air handling when needed.

6. The floor in the waste disposal area has been sealed to prevent spills from contaminating the floor or the ground under the floor.

7. Automatic doors from the loading dock allow personnel to move incoming samples and packages easily and safely to the areas where they are unpacked. Automatic doors also are placed in the major corridors to allow personnel to easily and safely move chemicals, samples, and equipment.

8. Closed laboratories have glass in the doors and often have extra windows for workers' safety and allow visitors to tour the laboratory without having to enter work areas.

9. The deionized water system continually circulates water through the building. This prevents any portion of water from becoming "stale" or developing biological activity to degrade its quality. Return water is treated again before being placed in the storage tank. (See NWQL SOP SSSX0039.x, *Management of the deionized water system*.)

10. The central corridor was designed to move samples and chemicals into and from laboratory areas.

11. The central corridor in each laboratory wing has room for support equipment, such as chillers and refrigerators to reduce noise and clutter within the analytical laboratories.

12. The central corridor has safety showers and spill response kits.

13. Each wing has several small conference rooms to allow work units to meet close to where they work. This allows analysts to check instruments during meetings and minimize lost instrument time.

14. Servers are in a room with special power and temperature requirements, and an uninterrupted power supply to keep information technology equipment operational.

15. The building has controlled access.

16. A special floor sink was installed in the sample login area so the login staff could easily dispose of the plastic and ice from the unpacked coolers. The ice can melt overnight and the plastic bags can be disposed of in the morning.

17. A computer controls air flow in the fume hoods. As more fume hoods are used, variable speed motors increase air flow to ensure laboratory safety.

18. An emergency generator for critical systems is installed in the event of a power loss.

19. Automated external defibrillators (specialized devices designed to recognize and treat certain lethal heart rhythms during cardiac arrest) are in place, with a number of trained staff members available throughout the laboratory. A list of trained personnel is maintained by the Safety, Health, and Environmental (SHE) Compliance Section.

Isolating incompatible areas. The laboratory in which volatile organic compounds are determined is isolated from the preparation area and laboratories for organic analyses. Laboratory design and other considerations included the following:

1. The laboratory determining volatile organic compounds has a separate heating, ventilation, and air conditioning (HVAC) system and is in a separate laboratory wing (the south wing) from where organic samples are routinely processed (the north wing) to minimize contamination.

2. Each wing has a separate air-handling system.

3. Because the prevailing wind is from the west, the air for both wings has intake vents on the west side of the building and outlets on the east side to minimize potential contamination from laboratory exhaust.

4. The North wing is set slightly east of the South wing, in part, to reduce the chances of north-wing exhaust from entering the south-wing intake.

5. Entry/exit alcoves prevent volatile compounds from entering while doors are open for access to the laboratory.

6. The temperature in the laboratory in which volatile organic compounds are determined is kept lower than other laboratory areas.

3.2 Air and Surface Monitoring

The NWQL contracts with the U.S. Public Health Service to provide industrial hygiene services. Air monitoring and quantitative exposure evaluations are performed to assess levels of airborne contaminants in accordance with Occupational Safety and Health Administration Permissible Exposure Limits, National Institute of Occupational Safety and Health Recommended Exposure Limits, or American Conference of Governmental Industrial Hygienists' recommendations.

Monitoring is performed at various times and locations for airborne contamination of lead, mercury, formaldehyde, methylene chloride, chloroform, ethyl acetate, and more. Laboratory fume hoods and work benches are tested for contaminants to protect the employee and prevent sample contamination. Surveys are performed for noise hazard levels and exposure.

3.3 Fume Hood Testing

Engineering controls are used to the greatest extent possible to either eliminate or reduce respiratory hazards to acceptable levels. To ensure that fume hoods are in proper working order, mean face velocities of all fume hoods are determined at least annually. This measurement is documented on labels attached to the fume hood. Hoods found to be not working properly are removed from service until adjustment or repairs can be made. An added benefit of a properly working fume hood is the reduced likelihood of contamination of samples from airborne particles.

3.4 Maintenance, Repair, and Replacement: Responsible Parties

The USGS is responsible for maintenance, repair, and replacement of USGS-owned and/or programmatic equipment, fume hoods, and corresponding equipment. Cleaning of fume hoods, exhaust fans, and exhaust ductwork is the responsibility of the USGS.

The General Services Administration (GSA) is responsible for operation and maintenance of the building operating equipment, as well as daily operation and maintenance of the building. The GSA performs normal maintenance of the blower motors in the penthouse supporting the fume hoods. Any other work assumed by USGS personnel should be described in writing and agreed to by the GSA community Business Center Manager.

3.5 USGS Equipment Maintenance Responsibilities

The NWQL is responsible for maintenance of the

1. deionized water system;
2. acid-neutralization system and acid waste lines;
3. agency-operated and -owned equipment (including fume hoods);
4. USGS-installed fire extinguishers;
5. perchloric and radioisotope systems;
6. Kjeldahl system;
7. house nitrogen, argon gas, and compressed air systems (does not include the air compressors);
8. specialized filters within laboratories (carbon and high efficiency particulate air filters);
9. plumbing within laboratories; and
10. walk-in cooler.

For maintenance or building concerns during a regular work week between the hours of 6:30 a.m. to 3:00 p.m., call Building 95 Facility personnel in the Support Services Section on cell/office phone; a list of those phone numbers is attached to every phone throughout Building 95. Between 3 p.m. and 5:30 p.m. a member of the Safety, Health, and Environmental Compliance Section is available on cell and office telephones.

Cell phone numbers are more appropriate for calls after work hours and on weekends. All work requests require a Facility work order form with proper signatures and priorities. The form is available in room 1135 or at NWQL intranet > Admin > Forms (Support Services Forms) > Facility Work Request. Any operation or maintenance not covered on the above list must be requested through GSA Building Service and the Mega Center. Any GSA Service requests outside regular working hours, holidays, and weekends must go to the Mega Center. For general services after hours, call the GSA Mega Center at 303-236-6709. If it is an emergency after hours, contact the Federal Protective Services Mega Center at 303-236-2911.

3.6 NWQL Housekeeping Procedures

The Safety, Health, and Environmental Compliance Section conducts combined orientations on safety and good housekeeping procedures for new arrivals of housekeeping and maintenance personnel to the NWQL. Safety and the minimal use of contaminating cleaners, polishers, deodorizers, solvents, and paints in the building are emphasized. How to handle spills of any kind, the disposal of used containers, liquid disposal, and the disposal locations are described.

Janitorial service for offices and common areas is provided by contractor through GSA. Requests for custodial service in the laboratories are handled by special request submitted by supervisors. Requests are submitted using form NWQL SSS.01, which is available for downloading from the NWQL intranet > Admin > Forms (Support Services Forms) > Custodial Services Request.

Because not all housekeepers speak English, a translator describes the procedures and regulations. Communication with GSA enables the NWQL to receive prior notification when spraying of pesticides, herbicides, snowmelt chemicals or any product that could be harmful to laboratory operations is planned. The GSA notifies the NWQL 24 hours prior to performing any work in the facility.

Housekeeping and maintenance personnel are required to maintain copies of material safety data sheets of all cleaners and polishers used in the building, and in their work area. A copy of each material safety data sheet used in the building is provided to the Safety, Health, and Environmental Compliance Section. Any cleaners used by the janitorial staff or solutions used by maintenance personnel must be approved by the NWQL before use.

3.7 Building 95 Floor Plan

A complete floor plan of the NWQL—Building 95—is located outside the main conference room, immediately north (to the left) of the visitor's desk upon entering the building. Plans of the relevant wing are mounted on the wall opposite each elevator in the central service corridor in the north and south wings on the first and second floors.

3.8 Building Security

The NWQL is located on the Denver Federal Center, designated a Federal Emergency Management Area hardened security center. Access to the site is controlled through inspection gates with guards or key card access. Building 95 has controlled access at all times.

The laboratory has a fire and security system that is wired to a response panel at Federal Protective Services (onsite police force).

Limited or restricted access. The NWQL has controlled access at all times. There are areas within the building that have limited or restricted access, such as the chain-of-custody area, the hazardous waste processing areas, the Information Technology Section's server rooms, and the entire third floor that contains air handling and other critical building equipment.

Visitors. All Federal and non-Federal (including contract) employees are issued magnetic key cards to access the building through controlled access doors. During normal business hours, all visitors and service professionals sign in and out of the building at the main entrance, where they are provided with "visitor" identification badges and safety glasses. The NWQL SOP ADMX0485.x, *Visitors to Building 95, Denver Federal Center*, provides additional information. Delivery personnel are allowed to sign in at the warehouse entry, and their access is limited to that area of the building only. A visitor's log book is maintained since every visitor must sign in and out. A visitor must be accompanied at all times by a Federal employee. Minors must have an adult escort at all times.

Mail. The NWQL is responsible for picking up and sending out all official mail for building personnel. Mail duties are performed by staff in the Administrative and Support Services Sections. The NWQL SOP ADMX0484.x, *Mail handling*, describes the procedures and personnel who oversee the collection, delivery, and distribution of local campus (internal), U.S. Postal Service mail and packages, and outside contractor mail source.

Reference: TNI V1:M2 – Section 5.3

4 MANAGEMENT

4.1 Management Requirements

The NWQL's Management Team includes the Laboratory Chief, Assistant Laboratory Chief, and other Section Chiefs and supervisors as shown in the organization chart in fig. 1. This includes supervisors and Section Chiefs of other key laboratory activities, including Analytical Services; Administrative Services; Methods Research and Development Program; Safety, Health and Environmental Compliance; Information Technology; Support Services; and the QA Sections.

Management's commitment to good professional practice and to the quality of its products is defined in the NWQL quality policy statement (see §4.3).

Management has overall responsibility for technical operations and the authority needed to generate the required quality of laboratory operations. Management ensures communication within the organization to maintain an effective management system and communicate the importance of meeting customer, statutory, and regulatory requirements. Management assures that the system documentation is known and available so that appropriate personnel can implement their part. When changes to the management system occur or are planned, managers ensure that the integrity of the system is maintained.

Management is responsible for carrying out testing activities that meet the requirements of the TNI standard, the ISO/IEC 17025 standard, and the needs of the customer.

Managers implement, maintain, and improve the management system, and identify noncompliance with the management system of procedures. Managers initiate actions to prevent or minimize noncompliance.

Management ensures technical competence of personnel operating equipment, performing tests, evaluating results, or signing reports, and limits authority to perform laboratory functions to those appropriately trained and/or supervised.

Management is responsible for defining the minimal level of education, qualifications, experience, and skills necessary for all positions in the laboratory and assuring that technical staff have demonstrated capabilities in their tasks.

Training is kept up to date as described in Section 5, *Staff*, by periodic review of training records and through employee performance review.

Management bears specific responsibility for maintenance of the management system. This includes defining roles and responsibilities to personnel, approving documents, providing required training, providing a procedure for confidential reporting of data integrity issues, and periodically reviewing data, procedures, and documentation. The assignment of responsibilities, authorities, and interrelationships of the personnel who manage, perform, or verify work affecting the quality of environmental tests is documented in §4.2.

Management ensures that audit findings and corrective actions are completed within required time frames as described in NWQL SOP QUAX0084.x, *Assessment program*.

Designated deputies are appointed by management during the absence of the Laboratory Chief (Laboratory Manager), the Assistant Laboratory Chief (Technical Manager), or the Chief, QAS (Quality Manager), and always if the absence is more than 15 days. The administrative assistant to the Laboratory Chief sends an email message to all staff informing them of the delegation of authority and its duration.

4.2 Management Roles and Responsibilities

4.2.1 Office of the Chief, NWQL

The Office of the Chief includes the Laboratory and Assistant Laboratory Chiefs. The Assistant Laboratory Chief is delegated the full authority of the Chief in his or her absence. The Assistant Laboratory Chief serves as the Laboratory Technical Manager and designates a Deputy Laboratory Technical Director to serve in his or her absence.

In addition to setting priorities, budgets and capital expenditures are developed within the NWQL to optimize human and material resources for routine and nonroutine support requirements. The Office of the Chief is ultimately responsible for maintaining a safe working environment for all personnel and ensuring the quality of all products and services.

Laboratory Chief (Laboratory Manager). The Laboratory Chief is responsible for the overall operation and management of all aspects of the laboratory, ensuring the NWQL provides mission critical analytical support services to the Water Mission and other USGS components. The Laboratory Chief provides the resources necessary to implement and maintain an effective quality and data integrity program, and also has overall responsibility for ensuring that:

1. personnel are free from any on site commercial, financial and other undue pressures that might adversely affect the quality of their work;

2. all analysts and supervisors have the appropriate education and training to carry out the duties assigned to them properly and seeing that this training has been documented;

3. all NWQL policies are reviewed and approved prior to their implementation, ensuring that policies are provided to laboratory personnel and compliance is achieved; and

4. appropriate corrective actions are taken to address analyses identified as requiring such actions by internal and external performance or procedural audits. Procedures that do not meet the standards set forth in the QMS, laboratory SOP, or laboratory policies may be temporarily suspended by the Laboratory Chief.

Assistant Laboratory Chief (Technical Manager). The Assistant Laboratory Chief is a full-time laboratory staff member who supervises laboratory operations and data reporting. The Assistant Laboratory Chief's proof of experience in the fields of accreditation is documented in QAS files. The Assistant Laboratory Chief has duties that include monitoring standards of performance in QA/QC, the performance data, and the validity of the analyses for the laboratory.

4.2.2 Chief, QAS

The Chief, QAS (Quality Manager), is responsible for the oversight and review of QC data, but is independent from analytical laboratory operations. His or her training and proof of experience in QA/QC procedures, knowledge of analytical methods, and the laboratory's management system are available in the QAS files. The Chief, QAS, is responsible for:

1. serving as a focal point for QA/QC,
2. overseeing the annual internal audits and surveillances,
3. notifying management of deficiencies and monitoring corrective actions,
4. overseeing and reviewing QA and QC data,
5. administering performance evaluation studies,
6. monitoring corrective actions,
7. ensuring that the management system related to quality is implemented and followed at all times,
8. monitoring and maintaining laboratory certifications,
9. implementing the ethics and data integrity plan,
10. overseeing the QA studies of National Field Supply Services' supplies, and
11. maintaining the QMS.

Customer support activities are also under the supervision of the Chief, QAS. These responsibilities include:

1. serving as the primary laboratory contact for customers;
2. managing all primary customer communications, including online publications and database;
3. focusing on customer needs and satisfaction with services offered by the NWQL;
4. developing effective communication pathways and techniques to improve focus and consistency;
5. assisting customers with concerns and data tracking;
6. providing analytical expertise to customers requesting assistance in developing project plans; and
7. developing enhancements for the NWQL communication tools, including the web sites and newsletter.

4.2.3 Chief, Administrative Services Section

The Chief, Administrative Services, provides administrative direction, management, and coordination to management, and Federal and non-Federal (including contract) employees. The responsibilities of the position include:

1. financial and accounting management;

2. commitments, obligations, and expenditures that include processing requisitions, bankcard purchases, and convenience checks; preparing travel authorizations and vouchers, purchase orders and contracts; initiating and authorizing vendor payments; and reconciling monthly and annual financial reports;

3. budget management;

4. provides centralized budget and expenditure controls based on fiscal-year budget estimates; initiates program funding levels from allocated and Working Capital Fund customer income; initiates internal vouchers that convert customer income into cost-center cash flow; reconciles financial records throughout the fiscal year for both current and active prior fiscal years;

5. personnel management; and

6. processing personnel actions; providing guidance on position descriptions, employee relations, awards, training, and performance plans; provide assistance and guidance to the supervisor; and process time and attendance records for Federal employees.

4.2.4 Safety Officer (Chief), Safety, Health, and Environmental Compliance Section

The Safety Officer or Chief, Safety, Health, and Environmental Compliance Section, manages and directs processes, policies, and procedures to ensure a safe and healthy work environment for Federal and non-Federal employees, and provides proper disposal of all laboratory hazardous waste. The Safety Officer ensures that the NWQL procedures, techniques, hazardous materials, and waste streams are in compliance with all pertinent rules and regulations and is responsible for:

1. the safety and occupational health of Federal and non-Federal (including contract) employees, the safe operation of the NWQL, and all environmental compliance requirements associated with laboratory operations and hazardous waste storage and disposal;

2. all operational responsibilities, including hazardous waste management, sewer monitoring and compliance, required regulatory activities, accident and incident coordination, fire safety, and security; and

3. overseeing emergency response coordination, managing health and safety, environmental compliance, and employee training and certification and observing the mandatory Federal regulations (U.S. Geological Survey, 2002a) and NWQL guidelines.

4.2.5 Chief, Analytical Services Section

The Chief, Analytical Services Section, oversees production of analytical chemical and biological data of known and documented quality that meet customers' requirements. The duties and responsibilities include:

1. offering a range of analytical services to support an integrated approach to water-quality monitoring by NWQL customers;

2. providing organic and inorganic analytical services, in-house and contract radiochemical analytical services, biological taxonomic services and population estimates;

3. assisting in development of custom services proposals; and

4. providing customer data services and consultation.

4.2.6 Chief, Information Technology Section

The Chief, Information Technology Section, provides computer infrastructure and software support, assure data integrity and security, and provide continuous quality improvement through state-of-the-art technology and practices.

1. Plan, coordinate, install, and maintain the Information Technology infrastructure at the NWQL, which includes the LIMS, analytical databases, and NWIS interface.

2. Research advanced software and hardware technology.

3. Make recommendations concerning information technology innovations and data security, and their possible effect on the laboratory environment.

4. Serve and advise the NWQL on compatible software and hardware and develop and deploy corporate and custom software required to support the laboratory and its staff.

4.2.7 Chief, Methods Research and Development Program

The Chief, Methods Research and Development Program, oversees the development, testing, evaluation, and implementation of new methods and improves existing methods required for the chemical analysis of surface water, groundwater, and sediments for the USGS. The duties and responsibilities include:

1. applying newly developed methods in national and regional water-quality studies in collaboration with other scientists;

2. providing consultation on the design of experimental programs, including sampling protocols, and the QA/QC of data produced by analytical methods;

3. providing new method development and implementation, method improvement, and specialized support for NWQL Analytical Services and to meet the mission requirements of other customers, such as national programs;

4. managing method development expenditures, supporting QA/QC functions, consulting on the selection and acquisition of scientific instrumentation, and providing USGS-wide technical training; and

5. interacting with the scientific community through attendance and presentations at scientific and other technical meetings, publishing and reviewing journal articles, and committee participation.

4.2.8 Chief, Support Services Section

The Support Services Section provides logistical, sample processing, warehousing, supplies, and facilities support to NWQL analytical functions, and sample collection supplies to the Water Mission's field operations. The Chief, Support Services Section, provides:

1. logistical and facilities support to all NWQL functions,
2. critical sample receipt and login functions for the NWQL,
3. supply support to Water Mission's field activities,
4. ongoing communication with customers, as well as
5. determining existing support requirements,
6. specifying facility needs, and
6. defining future logistical and facility needs.

4.2.9 Key Laboratory Staff Deputies

Whenever critical members of the Management Team are unable to perform their duties or are absent from the laboratory, designated staff assume their responsibilities, as follows:

Laboratory Chief → Assistant Laboratory Chief

Assistant Laboratory Chief → Chief, Analytical Services

Chief, QAS → Senior QAS/Business Development personnel (as available)

Chief, Analytical Services → Senior Analytical Services unit supervisor (as available)

4.3 Quality Policy

Management's commitment to quality and to the management system is stated in the quality policy below, which is upheld through the application of related policies and procedures described in this document, laboratory SOPs, and USGS OWQ and NWQL policy memoranda.

NWQL quality policy statement. The objectives of the NWQL QMS and the commitment of management are to provide customers with data of known and documented quality that meet their requirements. The NWQL seeks to provide the most consistent, cost-effective data of known quality that a laboratory can produce, providing scientists, planners, policy-makers, and decision-makers with sound, impartial data.

4.4 Ethics and Data Integrity

All laboratory science and business practices are performed to ethical standards. The NWQL staff understands the consequences of unethical behavior and actions. Using training and observation, the NWQL Management Team actively promotes the prevention of unethical, fraudulent, or questionable practices throughout the laboratory's technical, financial, and personnel operations.

The NWQL endorses and follows the set of fundamental principles and policies issued in 2006 that underlie USGS science practices. The fundamental science practices focus on how science is carried out and how the products are produced and disseminated (U.S. Geological Survey, 2007; Fundamental Science Practice Advisory Committee, 2011).

The NWQL ethics and data integrity program, annual refresher training, and investigations are discussed in Section 18, *Data integrity*.

4.5 Documentation of the QMS

The quality management system is defined through the policies and procedures provided in this document, the NWQL manual *Laboratory quality assurance and quality control, U.S. Geological Survey National Water Quality Laboratory* (Stevenson and Barnard, 2012), laboratory SOPs, and USGS OWQ and NWQL technical and policy memoranda.

4.5.1 SOPs

All NWQL SOPs represent all phases of current laboratory operations and are available to all staff. They contain sufficient detail such that someone with comparable knowledge, experience, and qualifications could perform the procedures. Two types of SOPs are used in the laboratory: (1) laboratory or analytical SOPs with specific requirements outlined below and (2) general use SOPs that document general or nonanalytical procedures. The NWQL SOP QUAX0001.x, *Preparing, maintaining, and approving standard operating procedures (SOPs)*, identifies specific requirements for writing, reviewing, amending, approving, and training to SOPs.

All NWQL analytical SOPS include or reference the following topics, where applicable:

1. identification of the method;
2. applicable matrix or matrices;
3. limits of detection and quantitation;
4. scope and application, including parameters to be analyzed;
5. summary of the method;
6. definitions;
7. interferences;
8. safety;
9. equipment and supplies;
10. reagents and standards;
11. sample preservation and storage;
12. QC;
13. calibration and standardization;
14. procedure;
15. data analysis and calculations;
16. method performance;
17. pollution prevention and hazardous waste disposal and management procedures;
18. data assessment and acceptance criteria for QC measures;
19. corrective actions for out-of-control data;
20. contingencies for handling out-of-control or unacceptable data;
21. waste management;
22. references; and
23. applicable tables, diagrams, and flowcharts.

Validation data to support a method are contained in the method history file, which is maintained by the appropriate analytical section.

4.5.2 Order of Precedence

In the event of a conflict or discrepancy among policies unless otherwise noted, the order of precedence is as follows:

1. USGS technical memoranda;
2. USGS OWQ technical memoranda;
3. this document (*Quality management system, U.S. Geological Survey National Water Quality Laboratory,* version 2.0);
4. *Laboratory quality assurance and quality control, U.S. Geological Survey National Water Quality Laboratory* (Stevenson and Barnard, 2012);
5. NWQL technical memoranda;
6. NWQL general and analytical procedural SOPs; and
7. other (for example, work instructions, memos, flow charts).

Reference: TNI V1:M2 – Section 4.2

5 STAFF

Staff members are qualified to perform the tasks to which they are assigned, based upon education, training, experience, and demonstrated skill as required. Those who analyze samples, evaluate results, or sign data packets, must demonstrate competence through the demonstration of capability procedure for the test methods for which they are responsible. Appropriate supervision is required for any staff member in training and the trainer is accountable for the quality of a trainee's work.

The NWQL provides objectives with respect to education, training and skills of its staff. These objectives are identified annually and appear in each employee's annual performance plan. Training needs are identified at the time of employment and reviewed annually or when an employee is moved to a new position or new responsibilities are added to his or her position. Ongoing training is provided as needed to maintain competency of staff in their current jobs. The effectiveness of the training must be evaluated before the training is considered complete.

All non-Federal (including contract) employees, when used, must achieve the same competency standards and follow the same policies and procedures as Federal employees.

5.1 Position Descriptions

A position description includes the specific tasks, minimum education and qualifications, skills, and experience required for each position. Position descriptions are available for all positions in the NWQL and are maintained in the Administrative Services Section. Managerial requirements, roles, and responsibilities are discussed in Section 4, *Management*.

5.2 Training

Training of new employees, ongoing training, and technical training (for example, quality policies and practices; SOPs; demonstrations of capability; ethics and data integrity; course, workshops, seminars, and conferences; health and safety; and waste management) are described in Chapter 9, *Training*, of the NWQL manual *Laboratory quality assurance and quality control, U.S. Geological Survey National Water Quality Laboratory* (Stevenson and Barnard, 2012).

Employees' training files. Maintenance of employees' training documents and training database is the responsibility of QAS. An employee's training history file contains the forms confirming the documents read, such as general and analytical procedural SOPs, demonstrations of capability, the QMS, Stevenson and Barnard (2012), and technical and policy memoranda, as well as attendance records documenting participation in labwide staff ethics and data integrity refreshers and hazardous waste and materials training. The Administrative Services Section ensures that employees participate as required for mandatory Department of Interior courses through the DOI Learn program. These courses cover topics of broader scope, such as records management and computer security issues.

6 REVIEW OF REQUESTS, TENDERS, AND CONTRACTS

The review of all new work assures that oversight is provided, requirements are clearly defined, the laboratory has adequate resources and capability, and the test method is applicable to the customer's needs. This process assures that all work will be given adequate attention without shortcuts that may compromise data quality.

Requests for new work may be received via a number of sources, such as interagency agreements, QA project plans, signed documents, and verbal and electronic communications. The customer's requirements, including the methods to be used, must be clearly defined, documented and understood. Requirements might include target analyte lists, project specific reporting limits (if any), project specific QC requirements (if any), turnaround time, and requirements for data deliverables. The review must also cover any work that will be subcontracted by the laboratory.

Requests for work received at the NWQL are usually based on ongoing projects at USGS coordinated sites. A proposal must be written and approved whenever part of a project requires a NWQL employee to perform nonstandard work. This includes copying run reports; running samples in a specific sequence; using custom methods; designing custom methods; or modifying run parameters; and other cases listed previously. The QAS staff works with the appropriate staff from Analytical Services or Methods Research and Development Program to evaluate the need for a proposal and is responsible for its being written, implemented, and tracked.

The customer is informed of any deviation from the proposal including the test method or sample handling processes. All differences between the request and the final contract are resolved and recorded before any work begins. It is necessary that the contract be acceptable to both the laboratory and the customer. Business Development Team personnel track proposal through the review and approval process in accordance with the requirements identified in BDTX0075.x, *Proposal process*.

The review process is repeated annually and when there are amendments to the original proposal requested by the customer. Amendments are available to the participating personnel. The proposal, amendments, and updates are maintained on the server (currently, "Archie"), which is backed up daily during the week.

Reference: TNI V1:M2 – Section 4.4

7 ANALYTICAL CONTRACTS

A contract laboratory is defined as a laboratory external to the NWQL or a USGS laboratory at a different location that performs analyses for the NWQL. These laboratories generally perform work of a limited scope that the NWQL does not have sufficient manpower or equipment to handle on a routine basis.

Where applicable, USGS and NWQL policies require that all contracted laboratories be accredited by The NELAC Institute or meet other applicable statutory and regulatory requirements for performing the tests. This requirement is included in all statements of work that form the solicitation and request for proposals. The following procedure is required for contracting analytical services:

1. The need is determined and the requirements are developed by the technical expert.

2. The acquisition package, which contains a requisition (DI-1 form), statement of work, period of performance, and estimate of cost is submitted to the contracting office.

3. The Contracting Office issues a Solicitation Offer and Award, General Services Administration Standard Form 33 (SF-33) request in accordance with Federal Acquisition Regulations and DOI Acquisition Regulations policies.

4. The Technical Evaluation Committee, usually chaired by the technical expert, rates and ranks all proposals from applicants. Although cost is a consideration, the rankings are based on technical merit.

5. The process concludes with the final award of the contract.

7.1 Contract Laboratories

The Administrative Services Section maintains a list of NWQL contractors, including laboratories that are under contract to the NWQL. The Contracting Officer's Technical Representative at NWQL maintains the contract laboratories accreditation certificates, where applicable, reviews all data, and verifies that the data meet the QA/QC criteria required by contracts. Results from all contract laboratories are entered into LIMS or provided to the requestor in a specified format. When requested, copies of the analytical data package from the contractor laboratory are made available.

7.2 Subcontract Laboratories

Occasionally, a specific laboratory is required to perform work in support of a contract laboratory, requiring a subcontract agreement to be put in place. These laboratories generally perform work of a limited scope that the contracted laboratory does not have sufficient expertise, manpower or equipment to handle on a routine basis. A copy of the subcontracted laboratory's accreditation certificate and analyte list are reviewed by the Department of Defense Earth Science Program project manager at the NWQL to ensure the subcontracted laboratory has the appropriate accreditation and expertise to perform the work

required. He or she, or Business Development Team personnel, notifies the customer in writing of the intent to subcontract the work. When possible, the NWQL gains the approval of the customer to subcontract their work prior to implementation, preferably in writing.

The NWQL assumes the responsibility to the customer for a subcontractor's work, except in the case where a customer or a regulating authority has specified the subcontractor to be used. The laboratory performing the work is identified in the final report.

Reference: TNI V1:M2 – Section 4.

8 PURCHASING SERVICES AND SUPPLIES

The NWQL ensures procured goods and/or services that have an effect on the quality of environmental tests, are of the highest quality per specified requirements. This is accomplished by utilizing marketing research of approved suppliers and products. Procedures are set in place for procurement, receiving and the storage of supplies that affect the quality of environmental tests.

8.1 Procedure

The Section supervisor reviews and approves the supplier of services and supplies and approves technical content of purchasing documents prior to submitting the documents to the Administrative Services Section for ordering. The internal web site providing guidance on processing acquisition requirements can be found at URL <http://internal.usgs.gov/ops/acquisition/acqguide.html>. The technical expert is responsible for observing all NWQL policies and procedures when performing a review that can lead to an acquisition. This ensures the following:

1. The requirements are adequately defined, documented, and understood. The requirements include chemical and laboratory supplies, service and maintenance of laboratory equipment, and equipment acquisition.

2. Depending upon the acquisition requirement and dollar amount, an acquisition may require a statement of work prepared by the technical expert in accordance with established acquisition requirements.

3. For acquisitions in contracts, the NWQL meets requirements through established acquisition procedures. Bureau procurement offices assign a contracting officer for the contract process and the laboratory assigns a contracting officer's (technical) representative as the chair of the Technical Evaluation Committee and technical representative of the contract once awarded. The contracting officer’s representative is responsible for accepting the service and authorizing vendor payment.

4. A contract or purchase order is a written agreement that outlines the laboratory requirements.

5. The technical expert is responsible for submitting the appropriate acquisition documents to the Administrative Services Section.

6. Submission of an acquisition request to the Administrative Services Section determines the appropriate acquisition method, which is based upon dollar amount and acquisition requirements.

7. Acquisition methods include bankcard, convenience check, purchase order and/or contract, depending upon the requirement and dollar amount.

8. The guidelines for procurement include the following:

   - Federal acquisition regulation;

- DOI acquisition regulations; and
- established Bureau policies in conjunction with the method of procurement, dollar limitations, and procurement authority.

9. Acquisition documentation depends upon acquisition method (requisition, statement of work, sole-source justification, or vendor quote).

8.2 Acquisition Payment Documentation

The packing slip and the receiving approval signature for acceptance of item(s) are required for the payment to the vendor that is processed through the Financial Business Management System. The requisitioner of goods and/or services completes the acquisition package by filling out a goods receipt or a service entry sheet in the management system and completes a work flow task. This signals the contracting officer that the order for supplies or goods has been completed and is now ready for payment. These actions are also in accordance with the Prompt Pay Act and Bureau-established guidelines. Documents received with supplies and services, such as certificates of analyses, warranties, maintenance records, and calibration records, are kept by the group receiving the supplies.

Suppliers are evaluated by ensuring that the supplier ships the product or material ordered and the material is of the appropriate quality by signing packing slips or other supply receipt documents. The purchasing documents contain the data that adequately describe the services and supplies ordered. The description may include type, class, grade, identification, specifications or other technical information.

The supplies received are inspected for breakage, leaks or any other damage. Supplies and chemicals are checked for conditions and quality, such as expiration date, concentration, grade, storage conditions (where applicable) to verify that the product matches what was ordered. The supplies received are stored according to manufacturer's recommendations, laboratory SOPs, or test method specifications. Purchased supplies and reagents that affect the quality of the tests, however, are not used until they are inspected or otherwise verified as complying with requirements defined in the test method.

8.3 Approval of Suppliers

Evaluation and selection of suppliers and vendors is performed, in part, on the basis of the quality of their products, their ability to meet the demand for their products, the overall quality of their services, their past history and competitive pricing. This is achieved through evaluation of objective evidence of quality furnished by the supplier, which can include certificates of analysis, recommendations, and proof of historical compliance with similar programs for other customers.

Reference: TNI V1:M2 – Section 4.6

9 CUSTOMER SERVICE

The NWQL works with its customers and/or their representatives directly and through its LabHelp@usgs.gov mailbox and 1-866-ASK-NWQL (1-866-275-6975) telephone to clarify requests and to monitor laboratory performance related to the work. Each request is reviewed to determine the nature of the request and the laboratory's ability to comply within the confines of prevailing statutes and/or regulations without risk to the confidentiality of other customers.

9.1 Customer Confidentiality

The NWQL confidentiality policy is to not divulge or release any information to a third party without proper authorization. Third party requests for data and information are referred to the customer. Data and records identified as proprietary, privileged, or confidential are exempt from disclosure. All electronic data (storage or transmissions) are kept confidential, based upon technology and laboratory limitations, as required by customer or regulation.

Confidentiality is maintained on all data produced by the NWQL. Once samples are received by the NWQL, laboratory sample identification numbers are used rather than project designations. Data are only released to the submitter, based upon the associated LIMS and NWIS user identifications. Access to data associated with a specific project or proposal is limited to personnel working on the projects.

9.2 Customer Support

Communication provides proper instruction and modification for testing. Staff is available to discuss any technical questions or concerns a customer may have and reasonable access to laboratory areas to witness testing. The NWQL provides customers with all requested information pertaining to the analysis of their samples. However, an additional charge may apply for additional data or information that were not requested prior to the time of sample analysis or previously agreed upon.

Delays or major deviations to the testing are communicated to the customer(s) immediately by direct electronic mail from LabHelp or using the NWQL Rapi-Note distribution to a wider audience.

9.3 Customer Feedback

The laboratory seeks both negative and positive feedback following the completion of projects and periodically for ongoing projects. Feedback provides acknowledgement, corrective actions where necessary, and opportunities for continuous improvement.

Negative customer feedback is documented as a customer complaint (see Section 10, *Complaints*).

Reference: TNI V1:M2 – Section 4.7

10 COMPLAINTS

The NWQL customer service staff uses the labhelp@usgs.gov electronic mailbox to track and respond customers' questions, requests, and complaints. This includes requests to verify results or analytical data. Complaints provide the laboratory an opportunity to improve laboratory operation and customer satisfaction. The mailbox also receives a copy of correspondence from NWQL laboratory scientists that was not originally sent to customer service for resolution. This enables tracking of the resolutions of all requests and complaints. Requests and complaints are assigned to general categories for tracking upon receipt. The categories and types of requests and complaints are reviewed for timeliness of response. This information is forwarded to the Management Team, and included as part of the annual quality system review.

Complaints by customers or other parties are reviewed by management and an appropriate action is determined. All customer complaints are documented by the person receiving the complaint and addressed to the responsible manager.

If it is determined that the complaint has merit, the procedures outlined in Chapter 17, *Corrective action*, are utilized. If it is determined that a complaint is without merit, it is documented, and the customer is contacted by a customer service staff member.

A complaint, such as a concern that data are repeatedly late, should be reviewed for preventive action (see Chapter 16, *Preventive action*) to reduce the likelihood of a recurrence.

Reference: TNI V1:M2 – Section 4.8

11 IMPROVEMENT

Improvement is possible when an integrated approach is implemented that incorporates a number of actions and activities to ensure that the data produced by the NWQL meet the defined standards of quality with the stated level of confidence. The QMS describes the most critical of these:

1. quality policy and objectives (Section 4, *Management*),
2. internal auditing practices (Section 15, *Audits*),
3. preventive action process (Section 16, *Preventive action*),
4. corrective action (Section 17, *Corrective action*),
5. annual quality system review presented by QAS (Section 19, *Management review*), and
6. review and analysis of data (Section 24, *QA for environmental testing*).

The annual quality system review is the single integrating activity for improvement. The Chief, QAS, notifies management and supervisory personnel before a review. During the review the information is discussed and critical issues are given priority. The outcome of the review is a list of critical issues for management to resolve during the next year. Prior to the next annual review, the Chief, QAS, summarizes the status of the issues identified in the previous review, the actions taken, any problems encountered, and the outcome.

Reference: TNI V1:M2 – Section 4.10

12 CONTROL OF NONCONFORMING WORK

Nonconforming work occurs whenever the results or any other aspect of a test do not conform to procedures established for that work, requirements established with the customer, or work that does not meet laboratory acceptance criteria or requirements. Nonconformances can include departures from SOPs or test methods, or unacceptable QC results (see Section 24, *QA for environmental testing*). Identification of nonconforming work can come through customer complaints, QC, instrument calibration, evaluating consumable materials, staff observation, final report review, management reviews, and internal and external audits.

12.1 Requesting a Departure from Documented Policies and Procedures

Occasionally, it is necessary to allow an exception to or departure from established procedure. This is permissible with approval of the unit supervisor and documentation of the sample(s) affected by the departure in the LIMS. Requests for departures from laboratory procedures are documented in an email to the customer and/or the Chief, QAS. Planned departures from procedures or policies do not require audits or investigations.

12.2 Nonconforming Work

The NWQL policy for control of nonconforming work is to identify the nonconformance, determine if it will be permitted, and take appropriate action. All employees have the authority to stop work on samples when any aspect of the process does not conform to laboratory requirements.

The responsibilities and authorities for the management of nonconforming work are described in detail in Chapter 5, *Nonconformance* (Stevenson and Barnard, 2012). The procedure for investigating and taking appropriate corrective actions of nonconforming work is also documented in this volume in Section 17, *Corrective action*. Paragraph 17.3 describes the procedures for technical corrective actions. Formal corrective action procedures must be followed for nonconforming work that could recur (beyond expected random QC failures) or where there is doubt about the laboratory's compliance to its own policies and procedures. When an evaluation of a nonconformance indicates the possibility of a recurrence, the Chief, QAS, is notified and the corrective actions are documented.

The investigation and associated corrective actions of nonconforming work involving alleged violations of the USGS and NWQL ethics and data integrity policies must follow the procedures outlined in Section 18, *Data integrity*, of this volume.

The NWQL evaluates the significance of the nonconforming work and takes corrective immediate action. The customer is notified if the data have been affected. Nonconforming data are released only on a case-by-case basis with the approval of the Chief, Analytical Services. Nonconforming data are clearly identified in a final report (see Section 27, *Reporting results*).

The discovery of a nonconformance for results that have already been reported to the customer must be immediately evaluated for significance of the nonconformance, its acceptability to the customer, and determination of the appropriate corrective action.

12.3 Stop Work Procedures

An analyst, supervisor, or representative of QAS may stop work at any time until the nonconformance is resolved. NWQL personnel are responsible for documenting a nonconformance. A nonconformance is reported to the supervisor in charge of the work, who reviews it and documents the corrective action to be taken. The evaluation and corrective action consider the immediacy of the actions to be taken and the acceptability of the nonconforming work.

When an evaluation of a nonconformance indicates the possibility of a recurrence, the Chief, QAS, is notified and the corrective actions are documented.

Resumption of work after work has been stopped is authorized by the Chief, Analytical Services.

Reference: TNI V1:M2 – Section 4.9

13 DOCUMENT CONTROL

Procedures for document management include controlling, distributing, reviewing, and incorporating modifications. Effective document management precludes the use of invalid and/or obsolete documents. Although virtually any document on any medium may be managed, the NWQL has been selective in its choices of those tracked in its automated document management system.

The NWQL manages three types of documents: controlled, approved, and obsolete. A *controlled* document is one that is uniquely identified, issued, tracked, and kept current as part of the management system. Controlled documents may be internal or external documents. An *approved* document has been reviewed and either signed and dated or acknowledged in writing or by secure electronic means by the issuing authority(ies). An *obsolete* document has been superseded by more recent versions or is no longer needed. Superseded or earlier versions of SOPs are referred to as "historical" on the NWQL intranet and "inactive" in the NWQL integrated document management system. A user's guide is accessible for downloading from the NWQL intranet at Information Technology Section > Web Applications.

13.1 Controlled Documents

A comprehensive list of controlled internal documents is maintained in the document management system that includes basic information about them. These documents are available for viewing and downloading in virtually all instances (exception: training forms and demonstrations of capability) on the NWQL intranet (internal access only) and USGS-visible intranet web sites. Controlled external documents consist of citations of publications that include NWQL authors and are listed, with links in many instances to the document, on the USGS-visible intranet site > Publications. The content of the IDMS is maintained by the QAS, which is notified directly about virtually all such documents, with technical assistance from Information Technology. The NWQL includes the following documents in its IDMS:

Document type	Abbreviation	Approved by	Distribution
certification and accreditation	C&A	designated QAS staff	USGS-visible intranet
demonstration of capability	DOC	unit supervisor, Analytical Services	internal, analyst's training file
no document category	none	various	various
policy memorandum	PM	Chief, NWQL (final authority) or designated Management Team member(s)	distribution depends upon content (internal or Water Mission)
Rapi-Note	RN	Chief, NWQL	WRD
standard operating procedure	SOP	Section Chief, unit supervisor (Analytical Services only)	NWQL Federal and non-Federal (contract) employees
technical memorandum	TM	subject-matter expert(s) and Chief, NWQL (final authority)	distribution depends upon content (internal or WRD)
web page	WWW	content: Section Chiefs, Management Team standards and templates: Information Technology	(1) NWQL intranet (lab only) (2) USGS-visible intranet (3) public (worldwide)

SOPs. New laboratory SOPs or changes to an existing SOP that represent a change to the method, equipment, reagents, or data quality are reviewed by the Management Team, revised as necessary, and initially approved for use by the QAS auditor assigned to the Section or unit, and the initiating Section Chief and unit supervisor (if the SOP is within Analytical Services) prior to issue. The effective date is the date the document approval transmittal form is signed by the Section Chief claiming ownership. The preparation, maintenance, and approval of SOPs are described in NWQL SOP QUAX0001.x.

The SOPs for most NWQL procedures are reviewed at 3-year intervals to ensure the contents comply with current management systems or accreditation requirements and accurately describe current operations. The NWQL has identified low-demand SOPs for procedures that are not used on a recurring basis. These documents, maintained on a separate intranet site, are subject to a 5- rather than 3-year review cycle and, consequently, may require revision, updating and/or reapproval prior to use.

Distribution. The initial distributions of these documents varies by document, but all except DOCs and training forms are posted to either the NWQL intranet (SOPs) or the USGS-visible intranet site (certificates and accreditation documents, policy memoranda, Rapi-Notes, and technical memoranda) upon release. All NWQL Federal and non-Federal (including contract) employees are notified by electronic mail when a new SOP is available or an existing SOP has been amended, revised, or classified as low-demand. This notification enables the affected staff to replace the now obsolete controlled version with a current one. The footer of every SOP states that the paper copy of an SOP is only valid if its revision number matches the controlled copy posted on the intranet. It is the user's responsibility to verify that the revision numbers match. Rapi-Notes are distributed to all employees within the USGS Water Mission, but the distribution of policy and technical memoranda depends upon content, either internal (NWQL only) or within the Water Mission.

Approved copies of these NWQL documents (except DOCs) may be downloaded by any staff member from any laboratory computer work station.

Attributes of controlled documents. Controlled internal documents are identified with many to most of the following attributes: a unique name or number identification, an issue or effective date, revision number where utilized, page number(s), the total number of pages (for example, 1 of x pages) (or a mark to indicate the end of the document), and the signature(s) of the issuing authority (for example, management).

Attributes	Document							
	C&A	DOC	None	PM	RN	SOP	TM	WWW*
unique name or identification number	yes	no	varies	yes	yes	yes	yes	yes
issue or effective date(s)	yes; valid for 1 yr	yes	varies	yes	yes	yes; expires in 3 yr	yes	varies
revision number	no	no	varies	varies	no	yes	varies	no
page number(s)	yes	no	varies	yes	no	yes	no	no
total number of pages	varies	no	varies	no	no	yes	no	no
signature(s) of issuing authority (management)	varies by agency	yes	varies	varies	no	yes	no	no
approved by Chief, NWQL	no	no	varies	yes	yes	no	no	varies
approved by other	yes	yes	varies	varies	no	yes	no	yes

*Individual web pages are reviewed internally by authors at intervals determined by content. The USGS has established strict guidelines, with standards available at <http://internal.usgs.gov/gio/eweb/requirements.html> and templates at <http://internal.usgs.gov/visual/specs/web/index.html>.

Approval procedures for controlled documents. Approval procedures for various documents tracked by the IDMS vary. The current certificates and accreditations issued to the NWQL are provided already approved by the issuing agency or organization. Laboratory certifications are accessible on the NWQL USGS-visible intranet at Quality > Accreditation Certificates. The "no document category" includes documents, such as this one (*Quality management system, U.S. Geological Survey National Water Quality Laboratory*) and the NWQL manual *Laboratory quality assurance and quality control, U.S. Geological Survey National Water Quality Laboratory* (Stevenson and Barnard, 2012). Both these documents contain an approval sheet signed by the members of NWQL Management Team.

The demonstration of capability certification statement completed annually by an NWQL analyst for each method she or he performs is reviewed and approved by the Analytical Services Section/unit supervisor.

Final approval authority for technical and policy memoranda resides with the Chief, NWQL, as described in NWQL SOP BDTX0285.x, *Issuing technical and policy memoranda*.

Rapi-Notes are prepared by subject-matter experts within the NWQL and issued under the final approval authority of the Chief, NWQL.

Unit supervisors may also approve the final version of an SOP, but final approval for laboratory SOPs resides with the Section Chief of the author(s). Approval is documented on the SOP approval transmittal form. See NWQL SOP QUAX0001.x, *Preparing, maintaining, and approving standard operating procedures (SOPs)*.

Individual web pages are prepared by subject-matter experts within the NWQL, with content approved by an author's Section Chief and unit supervisor, where applicable. The Information Technology Section has procedures in place to handle the registration, approval, and maintenance of web servers and the display of their associated pages. The publication of web pages must conform to NWQL, USGS, and DOI directives. These systems are audited regularly to ensure that procedures are followed. In addition, the systems are a part of a Certification and Accreditation Enclave and must be reviewed and tested yearly. The procedures are described in NWQL SOP ITCX0419.x, *Information technology web services*.

Changes to controlled documents.

- *Paper documents.* The NWQL does not allow handwritten modifications to controlled documents. Minor changes or corrections to SOPs are handled as amendments, described in NWQL SOP QUAX0001.x.

- *Electronic documents.* Documents, such as policy and technical memoranda, are typically superseded by a replacement. The Rapi-Note is an informal NWQL notification system, not requiring a formal procedure other than sending out a new message. Laboratory SOPs are the principal documents managed electronically that are on an established review/revision schedule. The procedure for performing changes to SOPs and summarizing any changes for the convenience of users and auditors is described in NWQL SOP QUAX0001.x.

13.2 Obsolete Documents

Obsolete documents, such as historical/inactive SOPs and superseded policy or technical memoranda, are removed from general distribution or otherwise prevented from unintended use. Electronic versions are kept in perpetuity in the IDMS.

Laboratory SOPs are transferred electronically from the active to the historical SOP web pages and labeled within the IDMS as inactive; analysts and other users in the laboratory destroy obsolete controlled versions and replace them with current ones, following NWQL SOP QUAX0001.x.

Outdated or superseded web pages are not archived. Once any modifications have been made, the old page is expunged. Backup media are available and searchable, but not indexed. These media are only available by special request.

Reference: TNI V1:M2 – Section 4.3

14 RECORDS MANAGEMENT

As a Federal analytical laboratory, the NWQL manages its records using a mission-specific disposition schedule prepared by the USGS Water Mission. The schedule was approved by the National Archives and Records Administration, the legal authority for disposition of USGS records. In 2008, the agency also approved the NWIS and NWQL LIMS legacy databases as permanent and the additions were posted to Schedule 1400, the Water Mission's disposition schedule. As the schedules are created or revised, they are included as part of USGS policy in the Survey Manual (U.S. Geological Survey, 2009).

A records disposition schedule provides mandatory instructions on what to do with records (and non-record materials) no longer required for current business and the authority to dispose of recurring or non-recurring records. Records disposition schedules ensure that records with permanent value are preserved, destroy records of temporary value when they have served the purpose for which they were created, and remove noncurrent records from local storage areas (for example, offices and laboratory filing cabinets) to long-term storage facilities (U.S. Geological Survey, 1990)

Data (hardcopy and electronic records) and other records are filed and maintained with the assistance and oversight of the NWQL records management technician as described in NWQL SOP ADMX0431.x, *Records management maintenance and disposition procedures*.

NWQL information systems. The NWQL must adhere to policies and procedures defined by the DOI and the USGS regarding data security, software development processes, and quality of information. These procedures and policies are located on the USGS Information Technology Security web page (accessible at URL http://internal.usgs.gov/gio/security/index.html) and the System Development Life Cycle web page (accessible at URL http://internal.usgs.gov/gio/irm/sdlc.html).

All USGS information systems are certified and accredited for operation in accordance with DOI and National Institute of Standards and Technology requirements. The NWQL complies with these requirements by conducting certification and accreditation of its systems (see NWQL intranet > Information Technology > Systems and Support > Information Technology Security > Certification and Accreditation). An annual audit of management, technical, and operational controls is required. The internal control review document is prepared by the Information Technology Section Chief and reviewed by the Management Team.

The Information Technology Section has designated space available on a network appliance to store LIMS unprocessed data, which are backed up nightly to a remote site as well as to magnetic media. These are stored in safes according to procedures both on site and off site. These procedures are an integral part of the continuity of operations plan, which is accessible on the NWQL intranet web site at Safety > Safety Links > Plans and Documents > Continuity of Operations Plan (2007).

14.1 Records Maintained

The NWQL maintains records that support its management and technical policies, confirm that procedures have been followed, and provide support for the technical interpretations, judgments, and discussions concerning laboratory results. These records, particularly those that are anticipated to be used

as evidentiary data, provide the historical evidence needed for later reviews and analyses. SOPs identify the records necessary to meet this commitment.

Records of all procedures to which a sample is subjected while in the possession of the NWQL are maintained. The NWQL retains all original observations, calculations and derived data (with sufficient information to produce an audit trail), calibration records, personnel records, and a copy of the data packet from generation of the last entry in the records following the Schedule 1400 disposition schedule. These and other documents, such as log books kept for instruments and standards, reagents, and solutions, are described in the laboratory QA/QC manual (Stevenson and Barnard, 2012). At a minimum, the following records are maintained by the NWQL to provide the information needed for historical reconstruction:

SOPs. Any revisions to laboratory procedures are written, dated, and initialed by the supervisor and Chief, QAS, and distributed to all affected individuals to ensure implementation of changes.

Laboratory notebooks. A record of the method and other information pertinent to the conduct of analytical tests, such as prepared and procured reagent solvents, standards, and spiking solutions, must be kept. Reference to the specific notebook must be included in the associated SOP. References to notebooks or log books in this document are interchangeable.

Calibration records. the date of analysis, initials or signature, frequency, conditions, standards, and reference materials.

Sample management. A record of procedures to which a sample is subjected while in the possession of the NWQL is maintained. These include records pertaining to the following:

- sample preservation, including appropriateness of sample container and compliance with holding-time requirement;
- sample identification, receipt, acceptance, or rejection and login;
- sample storage and tracking for shipping receipts, transmittal forms, and internal routing and assignment records, where possible;
- sample preparation and analysis documents; and
- disposal of hazardous samples, including the date of sample or subsample disposal and name of the responsible person.

Data packets. A data packet is a compilation of analytical data needed to reconstruct an analysis. The description of the contents of the data packet produced for each analytical run is part of the discussion of records management incorporated into each NWQL analytical procedure SOP. Data packet contents for a specific method may include calibration information, analytical sequence/sample pour-up protocol, instrumental method, QC summaries, unprocessed (area counts and signal readings) and processed data for reagent spikes, reagent blanks, continuing calibration verification standards, standard reference materials, and certified reference materials.

Unprocessed (raw) data. The unprocessed data and calculated results for samples are maintained in laboratory notebooks, logs, bench sheets, electronic files, or other sample-tracking or data-entry forms as appropriate for the method. Instrumental data information is stored in a computer file or a paper report.

Many of the laboratory's analytical instruments now include data processing systems and proprietary software. The software that controls laboratory equipment must be installed according to the manufacturer's instructions and verified to be operating correctly.

These records may include the following:

- laboratory sample identification code;
- date of analysis;
- instrument identification and instrument operating conditions/characteristics;
- analytical method used and sample preparation information, including sample aliquots processed, cleanup, and separation protocols;
- manual, automated, or statistical calculations;
- confirmatory analytical data, when required to be performed;
- the analyst's or operator's initials or signature;
- unprocessed data and calculated results for all QC samples; and
- source and lot numbers of standards and reagents for traceability.

Correspondence. Correspondence (paper and electronic) for QA Project Plans and NWQL proposals pertinent to a project, usually a written agreement between USGS Water Science Center and NWQL personnel, and communications regarding the progress of the project, are kept in accordance with U.S. Geological Survey (2003) general records disposition schedule 432-1-S1, chap. 100, 102–02, Project Case Files.

Deviations. Deviations from established methods are documented in appropriate SOPs or individual data packets.

QA records from activities performed by QAS. These records may include the following:

- QA program summaries,
- in-house audit findings,
- data and certificates of analysis for QA studies of National Field Supply Service field supplies,
- QMS,
- radiochemistry and stable isotope contracts,
- files of all changes to each method that could affect data quality,
- analysts' training records,
- demonstration of capability for each analyst, and
- log of names, initials, and signatures for all individuals who are employed at the NWQL.

Administrative records. These records include personnel qualifications, experience, and training records.

Electronic data. Electronic data are stored on secure servers or password-protected personal computers and backed up on a regular schedule. Data are stored so that they are protected from damage and destruction.

14.2 Records Management and Storage

The storage and retention of records is in compliance with Federal record retention requirements found in USGS General Records Disposition Schedule 432-1-S1 and the WRD Schedule 1400 series (U.S. Geological Survey, 2003). Records to be maintained are sufficient to reconstruct laboratory activities that produce analytical data. Records include, but are not limited to, documentation of facilities, equipment, analytical methods, all aspects of sample handling and data verification.

Records are legible, recorded in indelible ink, identifiable, and retrievable, and protected against damage, deterioration, or loss.

Records maintained on site. Records that are stored or produced by computers or personal computers have paper copies or electronic backup copies. These laboratory records usually are maintained near the analytical laboratory or the analysts' workstation until final analysis and data submission. These records may be stored locally for several months or up to 2 years with space available. The records are archived following the process described in NWQL SOP ADMX0431.x, *Records management maintenance and disposition procedures*.

Storage and disposition standards for all laboratory records are identified in the General Records Schedule developed in accordance with 44 U.S.C. Chapter 33, *Basic laws and authorities of the National Archives and Records Administration* (U.S. Code of Federal Regulations, 2005). Usually, administrative files have short retention periods, less than 3 years. Program subject files may be needed by the agency for 30 years or more, and may have archival value as well. Administrative records are maintained separately from program records, such as laboratory analytical data. The USGS protocols have established that laboratory data should be kept for 30 years.

It is the responsibility of supervisors in each laboratory unit to use the correct disposition schedule to ensure that all records are stored in a secure manner and are readily retrieved. Records disposition schedules are identified in the USGS general records disposition schedule 432-1-S1 (U.S. Geological Survey, 2003) and 432-1-S2, the WRD scientific records disposition schedule containing its mission-specific series 1400 (U.S. Geological Survey, 2006).

Paper copies of administrative and analytical records are kept in the unit or section for about 2 years. The records are then boxed and moved to the NWQL records staging area on the first floor of Building 95, for a period of 1 additional year. Records that need to be retained for a longer period are then transferred to the Federal Records Center. All records are disposed of after a period of 30 years unless otherwise specified by legal or other written agreements.

Electronic records disposition criteria are being developed at the agency and National Archives, but have not been completed. At the present time, paper files are considered as the official record. Electronic files of analytical results are available on individual analytical instruments and in the folders used by LIMS for data processing and on designated NWQL backup media. Raw values and final concentrations

for analytes are stored in the LIMS. The current LIMS includes results since 1992. Migration of data to new systems is a fundamental consideration that is addressed when operating systems are upgraded.

As a Federal laboratory, all analytical data produced at the NWQL may be accessible by the public through the Freedom of Information Act. Requests by a third party for access to any records must be accompanied by a request. The Chief, QAS, is the control point for all requests for information from the NWQL.

14.3 Legal Chain-of-Custody Records

Evidentiary sample data are used as legal evidence. Procedures for evidentiary samples are described in NWQL SOP QUAX0030.x, *Chain of custody*.

Reference: TNI V1:M2 – Section 4.13

15 AUDITS

Audits measure laboratory performance and verify compliance with accreditation/certification and project requirements. Audits specifically provide management with an on-going assessment of the management system. They are also instrumental in identifying areas where improvement in the management/quality system will increase the reliability of data. Audits are of four main types: internal, external, performance, and system. Resolving audit findings is discussed in §15.5.

15.1 Internal Audits

Health, and Environmental Compliance; Support Services; QA, Information Technology; and to a certain extent, Administrative Services Sections. Each year internal audits cover all technical aspects of laboratory activities, with an audit of each operation, including analytical methods, login and other support services, QA functions, and information technology processes. Audits are performed throughout the year by members of the QAS audit team. This process allows for scheduling, researching and preparation, interviewing staff, and preparing the audit report.

Internal audits are conducted under the guidance and direction of the Chief, QAS. Trained and qualified personnel who are independent of the audited activity implement these audits. The audit team interviews laboratory personnel, observes procedures, and examines records and documentation.

Audits verify that current laboratory activities follow published methods, approved SOPs, and the QMS. An important function of these audits is to ensure that policies and objectives of the QMS are documented in unit SOPs, have been communicated to and are understood by unit personnel, and have been fully integrated into the unit workflow.

Nonconformances to documented procedures are identified in the audit reports as deficiencies requiring corrective actions.

Audit reports are provided to the Chief, QAS, the Laboratory Chief, the Section Chief, the unit supervisor, unit personnel, and the audit team. Unit supervisors respond in writing to audit reports and identify corrective actions to be addressed. Audit report responses are documented and tracked by the lead auditor. The internal audit process, including timelines for responding to the audit findings and resolution

X0084.x, *Assessment program*

Annually, the QAS auditors prepare a schedule of internal audits to be performed during the year. These audits verify compliance with the requirements of the quality management system, including analytical methods, SOPs, the NWQL manual *Laboratory quality assurance and quality control, U.S. Geological Survey National Water Quality Laboratory* (Stevenson and Barnard, 2012), ethics policies, data integrity, other laboratory policies, and The NELAC Institute's standard.

It is the responsibility of the Chief, QAS, to plan and organize audits as required by the schedule and requested by management.

In addition to the scheduled internal audits, it may sometimes be necessary to conduct special audits as a follow-up to corrective actions, proficiency test results, complaints, regulatory audits or alleged data integrity issues. These audits address specific issues.

The area audited, the audit findings, and corrective actions are recorded and maintained in a database. Audits are reviewed after completion to assure that corrective actions were implemented and effective.

15.2 External Audits

It is the laboratory's policy to cooperate and assist with all external audits, whether performed by customers or an accrediting body. Management ensures that all areas of the laboratory are accessible to auditors as applicable and that appropriate personnel are available to assist in conducting the audit.

Confidential business information considerations. During onsite audits, auditors may obtain information claimed as business confidential. A business confidentiality claim is defined as "a claim or allegation that business information is entitled to confidential treatment for reasons of business confidentiality or a request for a determination that such information is entitled to such treatment."

When information is claimed as business confidential, the laboratory must place on (or attach to) the information at the time it is submitted to the auditor, a cover sheet, stamped or typed legend or other suitable form of notice, employing language such as "trade secret," "proprietary," or "company confidential." Confidential portions of documents otherwise nonconfidential must be clearly identified. Confidential business information may be purged of references to a customer's identity by the responsible laboratory official at the time of removal from the laboratory. However, sample identifiers may not be obscured from the information.

15.3 Performance Audits

Performance audits may be proficiency test samples, internal single-blind samples, double-blind samples through a provider or customer, or anything that tests the performance of the analyst and method. Proficiency test samples are discussed further in Section 24, *QA for environmental testing*.

15.4 System Audits

The NWQL management system is audited though annual management reviews. Refer to Section 19, *Management review*, for further discussion of the quality system reviews.

15.5 Handling Audit Findings

Reponses to internal audit findings must be reviewed and submitted within the time frame described in NWQL SOP QUAX0084.x, *Assessment program*. The SOP contains a table that provides all audit timelines to supplement the requirements described in the text. Timelines for submitting responses to external audit findings are determined by the organization performing the audit.

The person responsible for developing and implementing corrective actions to internal audit findings is the Section Chief or unit supervisor responsible for the audit finding. He or she must review and investigate each finding to provide and schedule appropriate corrective action (to prevent recurrence). A corrective action response will include the results of such review and investigation as appropriate and indicate the date by which corrective action will be completed. Corrective actions are documented through the corrective action process described in Section 17, *Corrective action*, and in greater detail in Chapter 6, *Corrective action*, in Stevenson and Barnard (2012).

Audit findings that result from external audits, such as the biennial audits performed to maintain TNI/NELAC accreditation, are reviewed by the Management Team. The NWQL has 30 days to prepare its formal response, identifying the corrective actions and any changes required to ensure compliance. The auditors either accept the proposed corrective actions or decline, prompting further discussion with NWQL staff. The response to the external auditor is coordinated by the Chief, QAS.

Audit findings that cast doubt on the effectiveness of the laboratory operation to produce data of known and documented quality or that question the correctness or validity of sample results must be investigated. Corrective action procedures described in Stevenson and Barnard (2012) must be followed.

A customer must be notified in writing if the investigation reveals that the laboratory results have been negatively affected and the customer's requirements have not been met. The customer will be initially notified within 2 weeks after the laboratory discovers the issue. Two weeks is sufficient to allow discussion of the problem at the Management Team meetings and allow time to review all correspondence with the customer. A more formal notification will occur once the problem has been investigated.

All investigations that result in findings of inappropriate activity are documented and include any disciplinary actions involved, corrective actions taken, and all appropriate notifications of customers. See Section 18, *Data integrity*, for additional procedures for resolving situations of inappropriate activity.

Reference: TNI V1:M2 – Section 4.14

16 PREVENTIVE ACTION

Preventive action is a proactive process to identify opportunities for improvement rather than a reaction to the identification of problems or complaints.

Preventive action includes, but is not limited to a review of QC data to identify quality trends, regularly scheduled staff quality meetings to ensure staff is knowledgeable in quality procedures, review of customer feedback to look for improvement opportunities, review of proficiency testing data to look for analytes that were nearly missed, annual quality system reviews, and scheduled instrument maintenance.

When improvement opportunities are identified or if preventive action is required, action plans are developed, implemented and monitored to reduce the likelihood of the occurrence of nonconformities.

Procedures for preventive actions include the initiation of such actions and subsequent monitoring to ensure that they are effective.

All personnel have the authority to offer suggestions for improvements and to recommend preventive actions. However, management is responsible for implementing preventive action.

Reference: TNI V1:M2 – Section 4.12

17 CORRECTIVE ACTION

Corrective action is the action taken to eliminate the causes of an existing nonconformity, defect, or other undesirable situation in order to prevent recurrence.

Deficiencies cited in external assessments, internal quality audits, data reviews, customer feedback/complaints, control of nonconforming work or managerial reviews are documented and may require corrective action. Corrective actions taken are appropriate for the magnitude of the problem and the degree of risk.

17.1 General Procedure

The NWQL uses an assessment and corrective action tracking database to document and track corrective actions, as described in the NWQL SOP QUAX0084.x, *Assessment program*.

The supervisor of the responsible unit must initiate the corrective action on routine data reviews where a nonconformance is found that could recur (beyond expected random QC failures). The Chief, QAS, is responsible for investigating where there is doubt about the compliance of the laboratory to its own policies and procedures. The QAS audit team that performs assessments is responsible for monitoring and documenting corrective actions.

All deficiencies are investigated and a corrective action plan is developed and implemented if determined necessary. The implementation is monitored for effectiveness. Corrective action is required when a nonconformance or other departure from NWQL policies or procedures is identified. QC samples are used for ongoing corrective action of analytical processes. Conditions adverse to quality are identified by a number of other processes, including the following:

1. results of performance evaluation studies,
2. internal audits,
3. internal and external QA programs,
4. customer complaints, and
5. the annual quality system review.

The objective of corrective action is not only to eliminate such events, but also to reduce repetition of the causes. The identification and resolution of any nonconformance or departure from NWQL policies and procedures include the following:

1. analysts and supervisors using the available features in LIMS or analytical software to review and chart QC data to monitor process performance;
2. realizing that QC data outside the acceptance limits or exhibiting a trend are evidence of unacceptable error in the analytical process;

3. initiating prompt corrective action to determine and eliminate the source(s) of error; and

4. maintaining records of all out-of-specification events, the causes determined, and the corrective action(s) taken.

If a condition adverse to quality is identified, a proposed corrective action is prepared and submitted for approval by the Chief, QAS. The proposed corrective action requires an evaluation of the need for action(s) to prevent any recurrence of the problem. The corrective action is based upon a determination of the root cause, assigns responsibility for the action, and includes completion dates.

Verification of the completion of corrective actions from audits or surveillances is the responsibility of the QAS audit team members. Corrective actions are tracked to determine their effectiveness. Subsequent audit(s) may be performed to confirm that the corrective actions have been implemented and are effective.

17.1.1 Cause Analysis

When failures due to systematic errors have been identified, typically during a surveillance or audit, the first step of the corrective action process starts with the initial investigation and determination of root cause(s) of the problem. Records of nonconformances requiring corrective action are maintained as part of the surveillance and audit files to show that the root cause(s) was investigated and includes the results of the investigation.

Where there may be nonsystematic errors and, as such, the initial cause is readily identifiable or expected random failures (for example, failed QC), a formal root cause analysis is not performed and the process begins with selection and implementation of corrective action (also see §17.3, *Technical corrective actions*).

17.1.2 Selection and Implementation of Corrective Actions

Where uncertainty arises regarding the best approach for analysis of the cause of exceedances that require corrective action, QAS audit team members and Section/unit supervisors will recommend corrective actions that are appropriate to the magnitude and risk of the problem and that will most likely eliminate or mitigate the problem and prevent recurrence.

The unit supervisor ensures that corrective actions are discharged within the agreed upon time frame.

17.1.3 Monitoring a Corrective Action

The QAS audit staff monitors implementation and documentation of the corrective action to assure that the corrective actions were effective.

17.2 Additional Audits

Where the identification of nonconformances or departures from normal laboratory procedures cast doubt upon the laboratory's compliance with its own policies and procedures, or its compliance with the TNI Standard, the QAS lead auditor ensures that the affected area(s) is audited in accordance with Section 15, *Audits*, as soon as possible.

In many cases the additional audits or spot surveillances conducted as follow-ups after the corrective action has been implemented to ensure its effectiveness. These are performed when a serious issue or risk to the laboratory has been identified.

17.3 Technical Corrective Action

Sample data associated with failed QC are evaluated for the need to be reanalyzed or qualified. Unacceptable QC results are documented and if the evaluation requires cause analysis, the cause and solution are recorded (also see Section 12, *Control of nonconforming work,* in this document). Analysts routinely implement corrective actions for data with unacceptable QC. First-level correction may include repeating the analysis without further assessment. If the test method SOP addresses the specific actions to take, they are followed. Otherwise, corrective actions start with assessment of the cause of the problem.

Corrective actions for nonsystematic errors or expected random failures are documented in the assessment and corrective action tracking database. Corrective actions for nonconformances that may reoccur (beyond expected random QC failures) or where there is concern that the laboratory is not in compliance with its own policies and procedures require that a surveillance, that includes a finding and corrective action report, be completed.

The Chief, QAS, other Management Team members, supervisors, audit team members, and auditees have the opportunity to review audit reports, which include corrective actions, and may suggest improvements, alternative approaches, and procedures as needed. If the data reported are affected adversely by the nonconformance, they must be clearly identified in the report, and the customer is notified.

Corrective action begins with the analyst, who is responsible for knowing when the analytical process is meeting acceptable performance requirements. The analyst initiates corrective actions when a QC check exceeds the acceptance limits or exhibits trending. If the problem is not corrected by the actions, the analyst should report the out-of-specification event to the supervisor. Such events include the following:

1. QC outliers,
2. holding-time failures,
3. loss of sample,
4. equipment malfunctions, and
5. evidence of sample contamination.

In addition, assessments of method performance from various internally and externally administered QA programs are used to evaluate technical performance. When unsatisfactory performance is evident from these evaluations, corrective actions are required. Internal QA functions include automated QC trending and third-party checks traceable to the National Institute of Standards and Technology.

The USGS Branch of Quality Systems administers four external QA functions —the Inorganic Blind Sample Project, the Organic Blind Sample Project, the Blind Blank Project, and the long-term method detection level. Control charts and detailed summary-statistic information are routinely prepared. Concerns arising from these QA programs are discussed at meetings coordinated by the Branch of Quality Systems project chiefs. Analytical Services Section, QAS, and Method Research and Development Program staff participate in these meetings to resolve technical issues.

The Quality Systems staff prepares QA summary reports that describe analytical methods that have indicated a bias or higher than expected variability. These reports list comments from the NWQL that may include corrective actions to be addressed. The QA summary reports are available at NWQL USGS-visible intranet > Technical > Inorganic Blind Sample Project > IBSP qadata summaries.

Reference: TNI V1:M2 – Section 4.11

18 DATA INTEGRITY

The NWQL, through its management, Federal and non-Federal (including contract) employees, is committed to maintaining a sound and active ethics and data integrity program. The NWQL Management Team recognizes its technical and fiduciary responsibilities and the role model it must establish that allows all staff to express concerns openly and freely. The Management Team further commits itself to provide adequate resources for promoting and maintaining ethical behavior by all Federal and non-Federal (including contract) employees.

This program, established by management, was developed to ensure that the commitment to ethics and data integrity is functional and accountable. The primary component of the program is the *U.S. Geological Survey National Water Quality Laboratory ethics and data integrity plan* (July, 2007), available at NWQL USGS-visible intranet > Quality > NWQL Ethics and Data Integrity Plan. It is supported by the NWQL employee code of ethics, available at NWQL intranet > Quality > NWQL Employee Code of Ethics.

USGS policy for scientific integrity and the fundamental science practices. The NWQL uses the USGS manual chapter 500.25 — *Scientific integrity* (U.S. Geological Survey, 2007) as the basis for its ethics and data integrity plan. As described, its purpose is to establish USGS policy to ensure "scientific integrity in the conduct of scientific activities and procedures for reporting, investigating, and adjudicating allegations of scientific misconduct by USGS employees and volunteers. Volunteers include all scientists working under Scientist Emeritus agreements."

The NWQL also endorses and follows the set of fundamental principles and policies that underlie USGS science practices. The fundamental science practices (Fundamental Sciences Practices Advisory Committee, 2011) focus on how science is carried out and how the products are produced and disseminated. The USGS fundamental science practices are overseen by the Office of Science Quality and Integrity. In particular, this office is involved with taking corrective actions that deal with implementing policies and maintaining the policy documents and procedures related to the fundamental science practices.

18.1 Elements of the NWQL Ethics and Data Integrity Program

Critical elements of the NWQL ethics and data integrity program include:

1. the NWQL ethics and data integrity plan, signed and dated by the members of the NWQL Management Team, July, 2007;

2. the *Ethics guide for DOI employees, January 2009* (<http://www.usbr.gov lc/region/g5000/eod/EthicsGuide.pdf>) and the NWQL employee code of ethics;

3. an ethics and data integrity policy statement signed by all managers and staff (new staff within 30 days of their work start date), entitled *Ethics and data integrity agreement for Federal personnel at the National Water Quality Laboratory* (attachment 1 of the NWQL ethics and data integrity plan);

4. the USGS code of scientific conduct, included in the USGS manual chapter 500.25 — *Scientific integrity*;

5. the NWQL signature log book;

6. annual data integrity refresher training for all Federal and non-Federal (including contract) employees (see §18.3, *Training*);

7. procedures for confidential reporting of alleged data integrity issues, described in annual refresher training and included in a handout with contact information for USGS ethics staff and their specialties, and the *Ethics guide for DOI employees* (January, 2010) (additional information in §17.4, *Confidential reporting of ethics and data integrity issues*);

8. the investigation of scientific misconduct and the corrective action procedure to be followed are described in attachment 3 of the NWQL ethics and data integrity plan and described and illustrated (fig. 25-1) in USGS manual chapter 500.25 — *Scientific integrity* (U.S. Geological Survey, 2007);

9. laboratory audit and surveillance programs managed by the Chief, QAS, monitor data integrity (Section 15, *Audits*) and are documented in NWQL SOP QUAX0084.x, *Assessment program*; and

10. NWQL Rapi-Notes, used to notify customers of issues involving or affecting data and its quality, are archived at NWQL USGS-visible intranet > Technical > Rapi-Notes.

18.2 Ethics and Data Integrity Procedures

Written procedures considered part of the ethics and data integrity program include:

1. USGS manual chapter 500.25 — *Scientific integrity* (U.S. Geological Survey, 2007);

2. attachment 3, “Scientific misconduct investigation and corrective action procedure,” in the NWQL ethics and data integrity plan;

3. Chapter 6, *Corrective action*, in the NWQL manual *Laboratory quality assurance and quality control, U.S. Geological Survey National Water Quality Laboratory* (Stevenson and Barnard, 2012);

4. NWQL SOP ANLX0414.x, *Manual integration policies and guidelines*;

5. NWQL SOP ANLX0364.x, *Secondary data review*;

6. NWQL SOP ANLX0478.x, *Documentation, verification, and labeling of standard solutions/materials, reference materials, and reagents for analyses*; and

7. Rapi-Notes. These short messages are sent to customers to apprise them of items of importance, such as data reloads and other data-related issues.

18.3 Training

Ethics and data integrity training requirements are summarized in the NWQL ethics and data integrity plan. Ethics and data integrity training is provided as a formal part of new employee orientation and participation at an annual refresher is required for all Federal and non-Federal (including contract) employees. Employees must understand that any infractions of the laboratory data integrity procedures shall result in a detailed investigation that could lead to serious consequences including immediate termination, disbarment, or civil/criminal prosecution. This is included in the ethics and data integrity policy statement that every employee is required to sign and is maintained in the employee's document training file. Participation at all required NWQL training is monitored through a signature attendance sheet and compliance is documented in the employee's training database record.

At the refresher training, each trainee is provided with a handout that includes all the presentation slides in the training class so he or she is able to follow along and has a record of the material discussed. In addition, the handouts are available at NWQL intranet > Quality > NWQL <year> Presentation on Ethics and Data Integrity.

18.4 Confidential Reporting

he DOI, the parent agency of the USGS NWQL, provides a frequently updated *Ethics guide for DOI employees* (January, 2010) (download from http://www.doi.gov/ethics/ docs/eth-don.html) and subscribes to the *Standards of ethical conduct for employees of the Executive Branch* (U.S. Office of Government Ethics, 2002). If an employee has an ethics question, he or she is advised to contact an ethics counselor before taking action, provide him or her with all the relevant facts, and receive advice on the course of action to take. USGS employees contact:

USGS Ethics Office
12201 Sunrise Valley Drive, Mail Stop 603
Reston, Virginia 20192
FAX: (703) 648-4132
Email: EthicsOffice@usgs.gov

Nancy Baumgartner
Deputy Ethics Counselor
Voice: (703) 648-7474
Email: nbaumbartner@usgs.gov

Ken Belongia
Assistant Ethics Counselor
Voice: (703) 648-7422
Email: kbelongia@usgs.gov

Sharon Bonney
Ethics Program Specialist
Voice: (703) 648-7439
Email: sbonney@usgs.gov

Reference: TNI V1:M2 – Section 4.16

19 MANAGEMENT REVIEW

The quality system is reviewed annually by the Management Team and supervisory personnel and led by the Chief, QAS. The objective of the review is to determine the adequacy and effectiveness of each aspect of the quality system and establish priorities for implementation of necessary improvements. The review is a documented examination using specified criteria to provide objective feedback about the laboratory's quality system and considers, but is not limited to, the following actions:

1. suitability of policies and procedures;
2. suggestions and reports from managers and supervisors;
3. outcomes of recent internal audits;
4. corrective and preventive actions;
5. assessments by external bodies;
6. results of interlaboratory comparisons or proficiency tests;
7. changes in the volume and types of work;
8. customer feedback;
9. complaints;
10. recommendations for improvement;
11. previous management reviews; and
12. other relevant factors, such as quality-control activities, resources, and staff training.

Procedure. The annual quality system review is scheduled during the last quarter of the calendar year, typically in December. At least 1 month prior to the review, the Chief, QAS, gathers information about performance indicators used to assess the quality system, such as in-house audit reports, corrective action reports, proficiency testing sample results, customer feedback and complaints, results of the equipment monitoring system, and results of reviews by external bodies. Also, the suitability of policies and procedures and the changes in the volume and types of work received may be examined.

Managers and supervisory personnel are required to attend the review. During the review the information is discussed and critical issues are prioritized. The outcome of the review is a list of critical issues for management to resolve during the next year. The presentation of the status for the issues identified in the previous review is an agenda item at the following quality system review and includes the actions taken, any problems encountered, and the outcome.

Reference: TNI V1:M2 – Section 4.15

20 Field Supplies, Sample Collection, Preservation Requirements, and Holding Time

The laboratory's responsibility in the sample collection process lies in supplying customers with sample containers, certain preservatives, custody seals, forms for chain of custody, and other necessary quality-assured field supplies, and providing online instructions for packing and shipping to ensure that samples arrive undamaged and in accordance with all applicable U.S. Department of Transportation requirements.

20.1 Field Supplies

The procedures identified in the *U.S. Geological Survey National Water Quality Laboratory Quality assurance surveillance plan for the National Field Supply Service* (January, 2010) ensure that purchased supplies that could affect the quality of environmental tests are not used until they are inspected, tested, and considered suitable for use. The document is available at NWQL USGS-visible intranet > Quality > National Field Supply Service Quality Assurance Surveillance Plan.

The National Field Supply Service is managed by the NWQL Support Services Section, which oversees the procurement, sale, and distribution of supplies used by USGS Water Science Center staff for sample collection. The procedures used by the staff are described in NWQL SOP SSSX0453.x, *National Water Quality Laboratory (NWQL) National field supply service (NFSS) management.*

Under this surveillance plan, the NWQL tests specific field supplies, such as some bottle types, filters, preservatives, purified water, and extraction cartridges, to ensure the quality for use prior to sale. The QAS prepared the plan to establish QA protocols and acceptance criteria for the specified field supplies, collection of statistically representative numbers of supplies for testing, preparation of the QA test solutions for the supplies, submission of the test solutions for analyses, compilation and analysis of results, approval or rejection of supplies, and preparing and posting QA certificates to the NWQL USGS-visible intranet. (See NWQL USGS-visible intranet > Quality > Accreditation Certificates.)

Additional information on the QA of field supplies is available in two additional documents, posted at NWQL USGS-visible intranet site > Quality > NFSS-QASP, Procedures by NFSS Stock Number, and NWQL USGS-visible intranet site > Quality > NFSS-QASP, NWIS Lot Numbers and Certificates of Analysis.

More detailed information is available in Chapter 3, *Procurement of Items and Services*, in the NWQL QA/QC manual (Stevenson and Barnard, 2012). Discussion of controlling the quality of purchased items, corrective action for failure to meet required specifications, and documentation of quality of procured items and services is included.

20.2 Sample Collection

Samples are collected by customers following the protocols published in the *National Field Manual* (U.S. Geological Survey, variously dated). The *National Field Manual* provides guidelines for the collec-

tion of water-quality data that establish and communicate defensible methods and procedures; promote consistent use of field methods to produce nationally comparable data; provide methods that minimize data bias, and, when properly applied, result in data that are reproducible within acceptable limits of variability; and provide citable documentation for USGS water-quality data-collection protocols. Courses offered through the USGS National Training Center in Denver provide training and field apprenticeship so that the sampling protocols and guidelines are implemented correctly.

Typical instruction includes (1) the 2-week course "Field Water-Quality Methods for Ground-Water and Surface-Water" (QW1028), designed to introduce all Federal and non-Federal (including contract) employees involved in collecting and processing samples to USGS methodologies for water-quality analyses; and (2) the 5-day course "Quality-control sample design and interpretation" (QW2034), which introduces techniques for using quality-control samples in water-quality projects.

The latter course is designed for hydrologists responsible for implementing water-quality data-collection programs and projects and interpreting water-quality data. Courses are offered in Denver, as well as in selected USGS Water Science Centers throughout the United States. Refer to the national and regional courses available through the USGS Office of Employee Development.

Requirements for shipping samples to the laboratory are documented in NWQL technical memorandum 11.01, *Requirements for the proper shipping of samples to the National Water Quality Laboratory*. This document is available at NWQL USGS-visible intranet > Technical > Technical Memoranda > Requirements for the Proper Shipping of Samples to the National Water Quality Laboratory.

20.3 Preservation Requirements

The NWQL sample acceptance policy is described in NWQL SOP SSSX0076.x, *Login unit*, and includes a discussion of the procedure used for sample preservation verification. All procedures established to receive, verify, process, distribute, and store environmental samples arriving at the laboratory for analysis are based upon laboratory requirements. Any sample preservation requirements are included in the NWQL services catalog associated with a laboratory code or schedule as well as the method holding time table (location provided in §20.4, *Holding time*). The catalog is accessible at USGS-visible intranet > LIMS catalog. Sample preservation is also discussed in §15.2, *Sample preservation* (Stevenson and Barnard, 2012).

If preservation requirements are not met based upon the check performed at sample login or within an Analytical Services Section show that samples were not preserved in accordance with requirements, the procedures described in Section 12, *Control of nonconforming work*, are used.

20.4 Holding Time

A table summarizing current information for all holding times used at the NWQL and associated matrix, parameter, laboratory code or schedule, parameter–method code pair, description, container type or label, preservation requirements, and reference information is posted for customers' viewing at NWQL USGS-visible intranet > Quality > NWQL Quality Management System > 25 May 2010, Method Holding Times. See also Section 15.3, *Holding time*, in Stevenson and Barnard (2012).

If holding time requirements are not met, data are automatically flagged by the LIMS, In addition, the procedures outlined in Section 12, *Control of nonconforming work*, are followed. Additional discussion is available in Chapters 5, *Nonconformance*, and 6, *Corrective action*, in Stevenson and Barnard (2012).

References: TNI V1:M2 – Section 5.7

21 SAMPLE RECEIPT AND HANDLING

NWQL SOP SSSX0076.x, *Login unit*, includes a discussion of all procedures established to receive, verify, process, distribute, and store environmental samples arriving at the laboratory for analysis are based upon laboratory requirements. Sample receipt and handling are also discussed in Chapter 15, *Sample receipt and handling*, of the NWQL manual entitled *Laboratory quality assurance and quality control, U.S. Geological Survey National Water Quality Laboratory* (Stevenson and Barnard, 2012). Topics covered include agreement to perform analysis, sample preservation, sample holding times, chain of custody, sample receipt, storage of samples, subsampling strategies, and sample disposal, including laboratory sample waste byproducts and sample waste.

Other relevant NWQL SOPs include:

Topic(s)	QCM, Section or description	Relevant NWQL SOP	
		Number	Title
chain of custody	15.4, Chain of custody	QUAX0030.x	*Chain of custody*
receipt of samples available to analysts	15.5, Sample receipt 15.2, Sample preservation (verification) 15.6, Storage of samples	SSSX0076.x	*Login unit*
designate samples "rush" using custom proposal		QUAX0429.x	*Procedures for handling designated rush-status custom samples*
waste disposal		MULX0430.x	*Handling of potential biohazardous samples*
sample disposal	15.8, Sample disposal	SHEX0355.x	*Waste disposal*
disposal of soils	See NWQL intranet > Safety > USGS Soil Permit Compliance Agreement	—	—
waste disposal	15.8.1, Laboratory sample waste byproducts 15.8.2, Laboratory sample waste	SHEX0479.x	*Ion exchange treatment of industrial wastewater*

References: TNI V1:M2 – Section 5.8
TNI V1:M3–7– Section 1.7

22 Equipment

22.1 General

The general discussions in §3.4, *Maintenance, repair, and replacement: Responsible parties*, and §3.5, *USGS equipment maintenance responsibilities*, of this volume describe maintenance, repair, and replacement responsibilities of the NWQL for the USGS-owned and/or programmatic equipment, fume hoods, and corresponding equipment. Cleaning of fume hoods, exhaust fans, and exhaust ductwork is the responsibility of the USGS. The GSA is responsible for operation and maintenance of the building operating equipment, as well as daily operation and maintenance of the building.

General maintenance of laboratory equipment used to prepare, analyze, and store environmental samples is described in NWQL SOP ANLX0360.x, *Maintenance of equipment*. Examples of applicable equipment include refrigerators, steam baths, liquid chromatographs, gas chromatographs, Alpkem and Kone analyzers, inductively coupled argon plasma emission spectrometers, and analytical balances.

Routine maintenance and verification of proper operation of specific support equipment, such as balances and fume hoods, is conducted at least annually. Maintenance on other support equipment, such as ovens, refrigerators, and freezers that are routinely monitored for proper operation, is performed on an as-needed basis.

22.2 Records Maintained for Laboratory Equipment

As a USGS laboratory, the NWQL must adhere to the defined responsibilities for the management of Federal property. The Support Services Section oversees compliance with the Supply Management Unit, Federal Property Management Regulation, and the Property Management Handbook 408-2-H, prepared by the Administrative Division Branch of Property Management (December, 1991) (U.S. Geological Survey, 1991).

This document provides information regarding the receiving, transferring, inventorying and disposing of excess government property to maintain accurate property records of system controlled and Bureau-managed property using the web-based property management interface system and the NWQL internal fixed asset tracking system. The activities performed by the Support Services Section in overseeing and managing the laboratory's equipment and other property are described in NWQL SOPs SSSX0041.x, *Property management*, and SSSX0450.x, *Fixed asset tracking system*.

Equipment and other property are managed by Support Services Section personnel under the Federal property management system, with some property under local control. Local control is based upon current property management definitions. Laptop and computer workstations (except monitors) are managed locally under the computer management information system, a subset of the Federal property management system.

Records of maintenance to support equipment are documented in instrument maintenance log books. Each piece of support equipment does not necessarily have its *own* log book, but all records must be documented. Maintenance log books may be shared with equipment housed in the same laboratory area.

22.3 Support Equipment

Support equipment used at the NWQL includes items such as balances, thermometers, refrigerators and freezers, incubators, ovens and autoclaves, glassware, pipettes, and fume hoods. When quantitative results are dependent on their accuracy, as in standard preparation and dispensing or dilution into a specified volume, then the equipment must be uniquely identified, calibrated, and maintained according to established schedules. The NWQL uses physical standard reference materials, such as certified weights and National Institute of Standards and Technology (NIST) thermometers, to calibrate equipment. Analysts document maintenance to support equipment in instrument maintenance logs. These items are described in detail in (Stevenson and Barnard, 2012) in the sections identified in the following table.

Support equipment	QCM, Section or description	Supporting NWQL SOP	
		Number	Title
analytical balances	13.2.1, Balances	QUAX0029.x,	*Calibrating, operating, and maintaining balances*
thermometers		ANLX0376.x	*Calibrating, maintaining, and adjusting thermometers*
refrigerators and freezers (NWQL intranet > Information Technology > NWQL Temperature Monitors > Temperature Monitor Data Viewer)	13.2.2, Refrigerators and freezers	ANLX0375.x	*Calibrating, recording, and maintaining the temperature monitoring program*
		ANLX0376.x	*Calibrating, maintaining, and adjusting thermometers*
volumetric dispensing devices	13.2.5, Pipettes and volume dispensing devices	QUAX0356.x	*Calibration and maintenance of mechanical volumetric dispensing devices*
deionized water system (reagent water supply system)	13.2.4, Reagent water supply system	SSSX0039.x,	*Management of the deionized water system*
ovens	13.2.3, Ovens	ANLX0375.x,	*Calibrating, recording, and maintaining the temperature monitoring program*
		ANLX0376.x	*Calibrating, maintaining, and adjusting thermometers*
glassware (Class A volumetric glassware)	any cleaning and storage procedures not specified by a method are documented in laboratory records and SOPs; Class A glassware verified before use	SSSX0369.x	*Cleaning and sterilizing glassware*

References: TNI V1:M2 – Section 5.5 and
TNI V1:M3–7– Section 1.

23 METHODS AND METHOD VALIDATION

Methods and/or procedures are available for all activities associated with the analysis of the sample, including preparation and testing. For purposes of this chapter, "method" may refer to both the sample preparation and analytical methods. Additional discussion of analytical methods, including method selection, method SOPs, determining method capability, and demonstration of capability, is available in Chapter 10, *Analytical methods*, in the NWQL QA/QC manual (Stevenson and Barnard, 2012).

The USGS OWQ technical memorandum 04.01, *Revised policy for the approval of U.S. Geological Survey (USGS) water-quality analytical methods* (U.S. Geological Survey, 2004), requires that all water-quality analytical data collected by the Water Mission for release to the public in data reports, Water Science Center annual data reports, and in databases that are directly accessible by the public, must be produced using Water Mission-approved methods. This policy was established to ensure that USGS data are of *known and documented* quality and that the analytical methods used to produce the data are thoroughly tested, documented, peer-reviewed, and available to the public.

Sources of automatically approved methods include those already accepted and published by the following sources: U.S. Environmental Protection Agency, American Society for Testing and Materials, and the American Public Health Association in *Standard methods*. Procedures to be used if water-quality data are produced using unapproved methods are discussed in USGS OWQ technical memorandum 04.01 (U.S. Geological Survey, 2004).). Unapproved data, including data from custom methods in project proposals, are qualified with a data quality indicator code of "U" for unapproved data.

23.1 Test Methods Used at the NWQL

The NWQL maintains a comprehensive services catalog on its USGS-visible intranet site for its internal customers. Users are able to search for information by laboratory schedule (suites of organic analytes), laboratory code, parameter code, CAS Registry Number®, analyte, analyte identification number, and container. Destination pages for inorganic analytes or laboratory schedules include:

1. description (for example, parameter or description, matrix, field preparation, method),
2. specific information on the parameter or analytes included,
3. laboratory code(s),
4. NWIS parameter code(s),
5. NWIS method code,
6. data quality indicator code,
7. CAS (Chemical Abstracts Service) Registry Number®,
8. report level, reporting unit(s), and reporting level type,

9. whether the analyte is a NELAP certified analyte, and

10. type and description of the sample container.

Bottle and general field treatments for parameters are included as reference information for field personnel. Links to applicable method references and historical reporting levels are provided.

Links to other NWQL web sites [sample status, electronic analytical services request, long-term method detection level, price list for all procedures and schedules (restricted access)], USGS sites (National Field Manual, Water Mission, One-Stop Shopping, Branch of Quality Systems, Reston stable isotope laboratory, Menlo Park), and useful external sites (for example, National Environmental Methods Index, U.S. Environmental Protection Agency) are provided on the NWQL USGS-visible intranet site > Related Sites.

External access to information on NWQL test methods. In addition, a portion of the catalog has been made available to the public on compact disk, which contains information such as the laboratory's reporting levels and the analyte's CAS Registry Number®. This abridged catalog includes the most commonly requested tests such as anions, cations, volatile organic compounds, nutrients, and pesticides. In addition, information is included for tests of increasing public interest, including hormones, waste water indicators, pharmaceuticals, and other compounds of concern to the environment.

23.2 NWQL-Developed Methods

The Methods Research and Development Program at the NWQL is the primary developer of water-quality methods for chemical analysis within the USGS. Analytical Services Section chemists also may develop methods with the research chemists' consultation and/or participation. Methods developed by all NWQL chemists must meet the criteria described in USGS OWQ technical memorandum 04.01, *Revised policy for the approval of U.S. Geological Survey (USGS) water-quality analytical methods* (U.S. Geological Survey, 2004), including review and approval, before they can be implemented. See NWQL SOP MRDX0015.x, *Guidelines for method validation and publication at the National Water Quality Laboratory*, for a complete description of the procedure and requirements.

Approval of USGS water-quality analytical methods. The USGS OWQ technical memorandum 04.01 includes a description of the process and requirements to obtain Water Mission's approval of a new analytical method or modification to an approved method, the process for releasing data to the public prior to method approval, and procedures for handling these data in publicly accessible databases. Submission of a final draft of the method report and the SOP is required.

To be approved as an official USGS method of analysis by the USGS OWQ, data for the following characteristics must be evaluated and reported: bias and variability (the preferred terms used by the NWQL and the USGS Branch of Quality Systems), method detection limit, comparability to superseded methods, interferences, sample preservation requirements, stability of reagents and standards, instrument performance, holding time, and safety information. (See SOP MRDX0015.x for details.)

Approval of other water-quality analytical methods. A laboratory providing data to the USGS may request approval of a new water-quality analytical method from the USGS OWQ by providing documentation, including a final draft of the water-resources report and an SOP from the originating

laboratory. The originating laboratory must also be approved by the Water Mission (U.S. Geological Survey, 1998).

23.3 Computer and Electronic Data Requirements

The NWQL is certified and accredited by the Federal Information Security Management Act. This uses the National Institute of Standards and Technology process, which is for unclassified information, referred to as sensitive but unclassified. The security act consolidates security requirements and guidance into a framework to manage information security and requires all Federal agencies, as part of the E-Government Act of 2002, to submit annual reports on information technology security to the Office of Management of the Budget.

The NWQL must adhere to policies and procedures defined by the DOI and the USGS regarding data security, software development processes, and quality of information. These procedures and policies are located on the USGS Information Technology Security web page (accessible at URL http://internal.usgs.gov/gio/security/index.html) and the System Development Life Cycle web page (accessible at URL http://internal.usgs.gov/gio/irm/sdlc.html).

In addition, the Information Technology Section assures that computers, user-developed computer software, automated equipment, or microprocessors used for the acquisition, processing, recording, reporting, storage, or retrieval of environmental test data are:

1. documented in sufficient detail and validated as being adequate for use;

2. protected for integrity and confidentiality of data entry or collection, data storage, data transmission, and data processing;

3. maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain the integrity of environmental test data; and

4. held secure including the prevention of unauthorized access to, and the unauthorized amendment of, computer records. Data archive security is addressed in Section 14, *Records management*, and building security is described in Section 3, *Laboratory infrastructure and environment*. The NWQL SOP ITCX0409.x, *Information Technology systems security*, provides further details.

Continuity of operations. In addition to the database, the Information Technology Section has designated space available on a network appliance to store processed and unprocessed data files, which is backed up nightly to a remote site as well as to magnetic media, which are stored in safes according to procedures both on site and off site. These procedures are an integral part of the Comprehensive Continuity of Operations Plan Fall 2007 (accessible at NWQL intranet > Safety > Continuity of Operations Plan (2007)).

23.4 Data Reduction, Review, and Reporting

Sample analytical data are interpreted following the protocols described in method SOPs. Available information used in the calculations (for example, unprocessed data, calibration files, tuning records, results of standard additions, sample response, and blank or background-correction protocols) is recorded to reconstruct the final result, if necessary.

All QC sample analyses are reviewed and evaluated before data are reported (NWQL SOP ANLX0364.x, *Secondary data review*). The manual integration procedures that must be followed to integrate peaks during data reduction are described in NWQL documents: NWQL SOP ANLX0414.x, *Manual integration policies and guidelines,* and Chapter 16, *Data reduction, review, and reporting*, in Stevenson and Barnard (2012).

The USGS OWQ technical memorandum 02.11, *Policy for storing and reporting significant figures for chemical data* (U.S. Geological Survey, 2002b), establishes the policy for storing and reporting the appropriate number of significant figures for chemical data in the USGS NWIS.

References: TNI V1:M2 – Section 5.4 and
TNI V1:M3–7– Sections1.4–1.6

24 QA FOR ENVIRONMENTAL TESTING

Quality assurance information in the technical portion of this document is discussed in more general terms, with guidelines and specific requirements being contained or discussed in greater detail in a separate quality manual entitled *Laboratory quality assurance and quality control, U.S. Geological Survey National Water Quality Laboratory* (Stevenson and Barnard, 2012). Additional implementation procedures are contained in individual analytical SOPs.

The NWQL prepared the quality manual as a companion volume to the QMS to allow expanded discussions of topics and their maintenance. The items covered in the manual include both management and technical requirements.

Topics of management interest include discussion of technical and quality-related documents and records requiring control and records management, procurement of items and services, customer service, nonconformances, corrective action, the NWQL audit process, and performance and trend analysis. Technical issues covered include training; analytical methods; detection and reporting limits; internal and external QC samples; calibration; measurement traceability; sample receipt and handling; and data reduction, review, and reporting.

References: TNI V1:M2 – Section 5.9 and
TNI V1:M3–7– Section 1.7

25 Calibration

Initial instrument calibration and continuing instrument calibration verification are an important part of ensuring data of known and documented quality. If more stringent calibration requirements are part of a mandated method or by regulation, those calibration requirements override any requirements outlined here or in laboratory SOPs. Generally, procedures and criteria regarding instrument calibrations are provided in analytical SOPs.

Information related to instrument calibration, including selection of calibration models, initial calibration, initial calibration verification, continuing calibration verification, and calibration documentation, may be found in the NWQL quality manual entitled *Laboratory quality assurance and quality control, U.S. Geological Survey National Water Quality Laboratory* (Stevenson and Barnard, 2012)

References: TNI V1:M2 – Section 5.5 and
TNI V1:M3–7– Section 1.7

26 MEASUREMENT TRACEABILITY

The NWQL SOP ANLX0478.x, *Documentation, verification, and labeling of standard solutions/ materials, reference materials, and reagents for analyses,* describes procedures used to document, label, and verify standard solutions, reagent materials, and reference materials. In addition, this document describes the preparation of standard solutions. The solutions of concern include calibration standards, continuing calibration verification standards, surrogates, reagent spikes, internal standards, third party checks, reagent materials, solvents, reference materials, vendor supplied materials and any similar materials used in the technical operations at the NWQL.

Records are maintained for solvents, reagents, and the preparation of standards. These records indicate the source of standard materials (National Institute of Standards and Technology-traceable standards are preferred, if available), with reference to the method of preparation, date of preparation, expiration date, and preparer's initials. The NWQL SOP SHEX0480.x, *Chemical inventory system (CIS)*, documents the procedure used to track and manage all chemicals from receipt to disposal within the NWQL.

All containers holding materials from vendors (working standards and their precursors tracing back to the vendor-purchased containers, and working reagents and their precursors tracing back to vendor-purchased containers) are marked with the contents and concentrations, date prepared, initials of the preparer, and expiration date.

All of this information is recorded and maintained in a log book. These prepared reagents, standards, and other solutions bear an identifier and are linked to the documentation requirements presented in Chapter 14, *Measurement traceability*, in the NWQL quality manual entitled *Laboratory quality assurance and quality control, U.S. Geological Survey National Water Quality Laboratory* (Stevenson and Barnard, 2012). Additional information related to measurement traceability, including traceability of standard reference materials, reagents, acids, and solvents, verification, and documentation and labeling, is included.

References: TNI V1:M2 – Section 5.6

27 REPORTING RESULTS

Data are reported following procedures that require a strict format that allows transmission and storage in the USGS NWIS, a long-term database and information delivery system. Additional paper or database-derived reports are not standard and must be requested with specific report format, protocols, or QC samples on a custom basis, as described in NWQL SOP BDTX0075.x, *Proposal process*. Reporting follows NWQL guidelines, primarily as stated in the relevant published analytical method or approved SOP. Less-certain results than specified in these policy statements are qualified appropriately or deleted according to method-specific acceptance criteria outlined in the appropriate SOP.

If there is doubt concerning the validity of results provided in any test report or amendment to a report, customers are notified in writing. Notification may be by individual electronic mail, USGS OWQ technical memorandum, or Rapi-Note.

A comprehensive discussion of data reduction, review, and reporting appears in the NWQL manual entitled *Laboratory quality assurance and quality control, U.S. Geological Survey National Water Quality Laboratory* (Stevenson and Barnard, 2012). Discussions of data reduction, including calculations and data (value) qualifiers; data review, with discussions of the analyst's, second-level (peer), and QA reviews and codes for data quality indictors; and data reporting, including information about data deliverable reports, electronic data deliverables, and amendment to reports is contained in Chapter 16, *Data reduction, review, and reporting*.

References: TNI V1:M2 – Section 5.10

28 Literature Cited

American Public Health Association, 1998, Standard methods for the examination of water and wastewater (20th ed.): Washington, D.C., American Public Health Association.

American Society for Testing and Materials, 2000, ASTM dictionary of engineering science & technology (9th ed.): West Conshohocken, Penn., p. 489.

Childress, C.J.O., Foreman, W.T., Connor, B.F., and Maloney, T.J., 1999, New reporting procedures based on long-term method detection levels and some considerations for interpretations of water-quality data provided by the U.S. Geological Survey National Water Quality Laboratory: U.S. Geological Survey Open-File Report 99-193, 19 p, accessed September 18, 2002, at URL http://water. usgs.gov/owq/OFR_99-193/index.html

Colorado Department of Public Health and Environment, 1995, Colorado hazardous waste regulations: 6 CCR 1007-3, November 1995, variable pagination with updated pages.

Forman, R.L., and Vitale, R.J., 1999, Lessons learned from performance-evaluation studies, *in* Proceedings from the 15th Annual Waste Testing & Quality Assurance Symposium: Arlington, Virginia, July 18-22, 1999, p. 36 and 38, accessed September 14, 2005, at URL http://www.epa.gov/epaoswer/hazwaste/test/pdfs/final99.pdf

Fundamental Science Practices Advisory Committee, 2011, U.S. Geological Survey Fundamental Science Practices: U.S. Geological Survey Circular 1367, 8 p.

International Organization for Standardization, 2005, General requirements for the competence of testing and calibration laboratories, Reference number ISO/IEC 17025:2005(E), 2nd ed., 2005-05-15: Geneva, Switzerland, no pagination.

Maloney, T.J., ed., 2005, Quality management system, U.S. Geological Survey National Water Quality Laboratory: U.S. Geological Survey Open-File Report 2005-1263, version 1.3, 9 November 2005, accessed July 23, 2011, at URL http://nwql.usgs.gov

National Environmental Laboratory Accreditation Conference, 2003, Appendix A—Glossary, chap. 1, p. 1A-1–1A-14, *in* NELAC standard, 2003, EPA/600/R-04/003, accessed July 23, 20011, at http://nelac-institute.org/docs/2003nelacstandard.pdf

Stevenson, D.L., and Barnard, A.R., eds., 2012, U.S. Geological Survey National Water Quality Laboratory, laboratory quality assurance and quality control: unpublished U.S. Geological Survey Report, version 1.0, January 2012, chapters and appendixes variously paged.

Taylor, J.K., 1987, Quality assurance of chemical measurements: Chelsea, Mich., Lewis Publishers, 328 p.

Taylor, J.K., 1990, Statistical techniques for data analysis: Boca Raton, Fla., CRC Press, 200 p.

The NELAC Institute, 2009, Quality system general requirements, module 2, p. 19–46, *in* TNI standard, Environmental laboratory sector, vol. 1, Management and technical requirements for laboratories performing environmental analysis, accessed May 26, 2011, at URL http://www.nelac-institute.org/docs/standards/2009/EL_Volume1_2011.pdf

U.S. Code of Federal Regulations, 2005, Disposal of records, chap. 33: Title 44—Public printing and documents (Basic laws and authorities of the National Archives and Records Administration), accessed October 31, 2005, at URL http://www.archives.gov/about/laws/disposal-of-records.html

U.S. Department of Energy, 2003, Procedure—Document control: Office of Civilian Radioactive Waste Management, AP-6.1Q, rev. 7/ICN 0, January 18, 2003, p. 5–7.

U.S. Environmental Protection Agency, 2005, Guidelines establishing test procedures for the analysis of pollutants: U.S. Code of Federal Regulations, title 40, pt. 136, §136.3 and Appendixes B and C, accessed May 26, 2005, at http://ecfr.gpoaccess.gov

U.S. Geological Survey, variously dated, National field manual for the collection of water-quality data: U.S. Geological Survey Techniques of Water-Resources Investigations, book 9, chaps. A1–A9, available online at http://pubs.water.usgs.gov/twri9A

U.S. Geological Survey, 1990, U.S. Geological Survey Manual, Handbook for managing USGS records, 432-1-H, accessed March 15, 2011, at URL http://www.usgs.gov/usgs-manual/handbook/hb/432-1-h.html

U.S. Geological Survey, 1991, U.S. Geological Survey Manual, Property management handbook, SM 408-2-H, December 1991, accessed May 2, 2011, at URL http://www.usgs.gov/usgs-manual/handbook/hb/408-2-h.html

U.S. Geological Survey, 1994, Description and use by districts of laboratory QC sample information in organic determinations: National Water Quality Laboratory Technical Memorandum 1994.07, accessed July 19,

2003, at URL http://nwql.usgs.gov/Public/tech_memos/nwql.94-07.html

U.S. Geological Survey, 1998, Policy for the evaluation and approval of production analytical laboratories: Office of Water Quality Technical Memorandum 98.03 (revised), accessed September 19, 2003, at URL http://water.usgs.gov/admin/memo/QW/qw98.03.html

U.S. Geological Survey, 2002a, Occupational safety and health program requirements handbook: SM 445-2-H, September 2002, variable pagination.

U.S. Geological Survey, 2002b, Policy for storing and reporting significant figures for chemical data: Office of Water Quality Technical Memorandum 2002.11, accessed April 26, 2011, at URL http://water.usgs.gov/admin/memo/QW/qw02.11.html

U.S. Geological Survey, 2003, U.S. Geological Survey general records disposition schedule 432-1-S1: Water Resources Discipline Mission-Specific Records Disposition Schedule, 1400 series, October 1990.

U.S. Geological Survey, 2004, Revised policy for the approval of U.S. Geological Survey (USGS) water-quality analytical methods: Office of Water Quality Technical Memorandum 04.01, accessed April 27, 2011, at URL http://water.usgs.gov/admin/memo/QW/qw04.01.html

U.S. Geological Survey, 2006, U.S. Geological Survey Water Resources Discipline scientific records disposition schedule 432-1-S2, accessed July 11, 2006, at URL http://www.usgs.gov/usgs-manual/schedule/432-1-s2/index.html

U.S. Geological Survey, 2007, U.S. Geological Survey manual, chap. 500.25 —Scientific integrity, accessed July 30, 2007, at URL http://www.usgs.gov/usgs-manual/500/500-25.html

U.S. Geological Survey, 2009, U.S. Geological Survey manual, U.S. Geological Survey Records Disposition Schedules, accessed March 14, 2011, at URL http://www.usgs.gov/usgs-manual/schedule/index.html

U.S. Office of Government Ethics, 2002, Standards of ethical conduct for employees of the Executive Branch, Final regulation issued by the U.S. Office of Government Ethics, codified in 5 C.F.R. Part 2635 (1/1/02 Edition), as amended at 67 FR 61761–61762 (Oct. 2, 2002), unnumbered front matter + 78 pp.

29 Glossary

acceptance criteria — specified limits placed on characteristics of an item, process, or service defined in requirement documents (National Environmental Laboratory Accreditation Conference, 2003)

accreditation — the process by which an agency or organization evaluates and recognizes a program of study or an institution as meeting certain predetermined qualifications or standards, thereby accrediting the laboratory. In the context of the National Environmental Laboratory Accreditation Program (NELAP), this process is a voluntary one (National Environmental Laboratory Accreditation Conference, 2003).

analyte — a substance determined in an analysis

analytical services request (ASR) — an order form for analytical services that allows customers and the U.S. Geological Survey National Water Quality Laboratory to identify samples and processing, and keep a record of analytical requests and any comments from the customer. An electronic version (E-ASR) also is available.

attachment — a secondary document that is attached to and supports the procedures presented in the standard operating procedure (SOP). An attachment provides supplementary information that is not included within the body of the SOP but is necessary to correctly perform the procedure or clarify statements made within the SOP. Attachments must be referenced within the text of the SOP. Attachments go through the same review procedures as the rest of the SOP and are part of the SOP.

Examples of attachments are manifold diagrams, computer instructions, acceptance ranges for specific quality-control samples, forms required to complete a procedure, and formatting instructions. Attachments must be posted on the NWQL intranet web site with the corresponding SOP.

audit — a systematic assessment to determine the conformance to quantitative specifications of some operational function or activity (National Environmental Laboratory Accreditation Conference, 2003)

bias — systematic error inherent in a method or measurement system. The error can be positive (for example, contamination or spectral interference) or negative (for example, analyte loss or signal suppression) (Taylor, 1987). It differs from random error, which shows no such consistent or systematic deviation.

Bias is the preferred term used by the NWQL and USGS Branch of Quality Systems.

blank — a sample that has not been exposed to the analyzed sample stream to monitor contamination during sampling, transport, storage or analysis. The blank is subjected to the usual analytical and measurement process to establish a zero baseline or background value and is sometimes used to adjust or correct routine analytical results (National Environmental Laboratory Accreditation Conference, 2003).

blind sample — a subsample for analysis with a composition known to the submitter. The analyst/ laboratory may know the identity of the sample but not its composition. It is used to test the analyst's or laboratory's proficiency in the execution of the measurement process (National Environmental Laboratory Accreditation Conference, 2003).

calibration — the set of operations that establishes, under specified conditions, the relation between values or quantities indicated by a measuring instrument or system, or values represented by a material measure or a reference material, and the corresponding values realized by standards. In calibration of support equipment, the values realized by standards are established through the use of reference standards traceable to the International System of Units.

In calibration according to test methods, values realized by standards are typically established using reference materials that are either purchased by the laboratory with a certificate of analysis or purity, or prepared by the laboratory using equipment calibrated or verified to meet specifications (National Environmental Laboratory Accreditation Conference, 2003).

certified reference material (CRM) — a reference material one or more of whose property values are certified by a technically valid procedure, accompanied by or traceable to a certificate or other documentation that is issued by a certifying body (National Environmental Laboratory Accreditation Conference, 2003)

chain of custody (COC) (legal chain of custody) — an unbroken trail of accountability that ensures the physical security of samples, data, and records. A chain-of-custody form is a record that documents the possession of the samples from the time of collection to receipt in the laboratory and generally includes the number and types of containers, the mode of collection, collector, time of collection, preservation, and requested analyses (National Environmental Laboratory Accreditation Conference, 2003).

continuing calibration verification standard (CCV) — a standard solution used in instrumental analysis to check instrument stability in relation to the calibration curve. It is prepared from the same materials in the same manner as the calibration standards. Concentration of the CCV should be chosen to allow easy review by the analyst and is typically in the midrange of the calibration curve.

controlled document — a document that is maintained and updated. Controlled documents are formally approved and their distribution is traceable to enable changes to be made. A controlled document meets one or more of the following criteria (U.S. Department of Energy, 2003):

- is prepared, reviewed, modified, and approved using established implementing documents, and is subject to controlled distribution and a defined process for change;
- users require a copy of the current version of a controlled document at the site where the work is to be performed and must perform the work in accordance with the controlled document;
- could adversely affect project or program activities if used in its noncurrent version;
- specifies technical or quality requirements or prescribes activities affecting quality (that is, implementing documents); or
- a supervisor or chief has requested it to be controlled.

corrective action — action taken to eliminate the cause(s) of an existing nonconformity, defect, or other undesirable situation to prevent recurrence (National Environmental Laboratory Accreditation Conference, 2003)

data — a carrier of information and knowledge, having no real meaning, and lacking any relational connection or interpretation. It can exist in any form, and need not be usable.

data integrity — the ability to maintain and/or preserve a piece of data or information, and to recreate a piece of data or information if accidental loss occurs

data packet — a compilation of analytical data needed to reconstruct an analysis. Contents of the data packet are based upon the standard operating procedure for the specific method and may include calibration information, analytical sequence/sample pour-up protocol, instrumental method, quality-control summaries, unprocessed (area counts and signal readings) and processed data for reagent spikes, reagent blanks, continuing calibration verification standards, standard reference materials, and certified reference materials.

data reduction — the process of transforming unprocessed data by arithmetic or statistical calculations, concentration factors, standard curves, and collation into a more usable form (National Environmental Laboratory Accreditation Conference, 2003)

data review — the process of validating and/or approving data after analysis or processing. Once approved, the data are flagged as ready to be released to the customer.

demonstration of capability — a procedure to establish an analyst's ability to perform a test with acceptable accuracy (National Environmental Laboratory Accreditation Conference, 2003)

detection limit — see “method detection limit”

document control — act of ensuring that documents (and revisions thereto) are proposed, reviewed for accuracy, approved for release by authorized personnel, distributed properly, and controlled to ensure use of the correct version at the location where the prescribed activity is performed (National Environmental Laboratory Accreditation Conference, 2003)

double-blind sample — a sample submitted to evaluate performance with concentration and identity unknown to the analyst

field blank — a blank prepared on-site by filling a clean container with deionized water and appropriate preservative, if any, for the specific sampling activity being undertaken (National Environmental Laboratory Accreditation Conference, 2003)

hazardous samples — samples considered to contain high concentrations of contaminants and may have deleterious effects on human health or the environment

hazardous waste — a solid, liquid, or contained gaseous material that is no longer used or that no longer serves the purpose for which it was produced and could pose dangers to human health and the environment after it is discarded (Colorado Department of Public Health and Environment, 1995)

holding time (maximum allowable holding time; sample or method holding time) — the maximum time(s) that a sample may be held prior to analysis and its analytical results still be considered valid (U.S. Environmental Protection Agency, 2005)

internal standard — a known amount of standard added to a test portion of a sample and carried through the entire measurement process as a reference for evaluating and controlling the bias and variability of the applied analytical test method (in part from National Environmental Laboratory Accreditation Conference, 2003)

International Organization for Standardization (ISO) — a non-governmental federation of the national standards bodies of 157 countries, including developed, developing, and transitional economies; a global network that identifies what international standards are required by business, government, and society, develops them in partnership with the sectors that will put them to use, adopts them by transparent procedures based on national input, and delivers them to be implemented worldwide. ISO standards distill an international consensus from the broadest possible base of stakeholder groups (ISO, 2005).

laboratory — a body or organization that calibrates and/or tests (National Environmental Laboratory Accreditation Conference, 2003)

laboratory code (LC) — a 1- to 4-digit code in the NWQL services catalog, always preceded by the letters “LC,” that uniquely represents a variable determined by a particular method of chemical analysis. For example, iron by atomic absorption and iron by inductively coupled plasma have different LCs. The NWQL services catalog is available on

the USGS-visible intranet web site at URL http://wwwnwql.cr.usgs.gov/USGS/catalog/index.cfm

laboratory information management system (LIMS) — a centralized data management and storage system that maintains data security, and data and information integrity. The system gathers or receives data from other analytical systems, and enforces quality-control measures, operating procedures, and business rules to process information and ensure data of known quality.

laboratory manager — the title used by The NELAC Institute for the laboratory chief (The NELAC Institute, 2009)

long-term method detection level (LT–MDL) — a detection level derived by determining the standard deviation (or F-pseudosigma) of a minimum of 24 method detection limit (MDL) spike-sample measurements over an extended period. LT–MDL data are collected continually to assess year-to-year variations in the LT–MDL. The LT–MDL controls false positive error. The chance of falsely reporting a concentration at or greater than the LT–MDL for a sample that did not contain the analyte is predicted to be less than or equal to 1 percent (Childress and others, 1999).

marginal exceedance (ME) — laboratory control sample (LCS) data that are beyond the LCS control limit of three standard deviations around the mean, but within the ME limits of three and four standard deviations around the mean. If a large number of analytes is in the LCS, it is statistically likely that a few will be outside control limits. This may not indicate that the system is out of control and corrective action may not be necessary. Upper and lower ME limits can be established to determine when corrective action is necessary (National Environmental Laboratory Accreditation Conference, 2003).

matrix — the component or substrate that contains the analyte of interest; the substrate of a test sample. For purposes of batch and QC requirements determination, the following matrix distinctions shall be used: aqueous—any aqueous sample excluded from the definition of drinking water (National Environmental Laboratory Accreditation Conference, 2003).

method — a way to perform an analysis that has been peer-reviewed, approved, and published or standardized that may produce data for one to many analytes; see “test method”

NWQL — National Water Quality Laboratory

performance audit — the routine comparison of independently obtained quantitative measurement system data with routinely obtained data to evaluate the proficiency of an analyst or laboratory (National Environmental Laboratory Accreditation Conference, 2003)

proficiency testing (PT) — performance or proficiency testing by evaluating a laboratory's performance under controlled conditions relative to a given set of criteria through analysis of unknown samples provided by an external source (National Environmental Laboratory Accreditation Conference, 2003) and determining a laboratory's calibration or testing performance by means of interlaboratory comparisons. The results of PT samples show whether or not a laboratory has an analytical bias, if the bias is continuing, and/or if the bias is increasing. If results are not within the control limits, a sample is analyzed again.

Test samples are prepared by spiking known concentrations of select analytes into a well-characterized matrix. Typically, PT samples are made in a single matrix such as an aqueous, solid, or oil matrix. PT samples can be distributed as single- or double-blind samples. PT samples are used to determine a laboratory's accuracy as it relates to the execution of a particular analytical method (Forman and Vitale, 1999).

A PT program provides controlled and standardized environmental samples to participating laboratories for analysis, reporting of results, statistical evaluation of the results in comparison to peer laboratories, and the collective demographics and results summary of all participating laboratories (National Environmental Laboratory Accreditation Conference, 2003).

preservation — refrigeration and/or reagents added at the time of sample collection or later to maintain the chemical and/or biological integrity of the sample National Environmental Laboratory Accreditation Conference, 2003)

procedure — a process, method, or instrument used and documented by an approved standard operating procedure (SOP); a specified way to carry out an activity or process (National Environmental Laboratory Accreditation Conference, 2003)

protocol — a detailed written procedure for field and/or laboratory operation (for example, sampling, analysis) that must be strictly followed (National Environmental Laboratory Accreditation Conference, 2003)

QAS — Quality Assurance Section

Quality Assurance (Project) Plan (QAPP) — a formal document describing the detailed quality-control procedures by which the quality requirements defined for the data and decisions pertaining to a specific project are to be achieved (National Environmental Laboratory Accreditation Conference, 2003)

quality assurance (QA) — a set of operating principles that, if strictly followed during sample collection and analysis, will produce data of known and defensible quality. That is, the accuracy of the analytical result can be stated with a high level of confidence. It is a definitive program for laboratory operation that specifies the requirements that will produce data of known bias and

variability. Included in QA are quality control and quality assessment (American Public Health Association, 1998).

In a more general context, QA is an integrated system of activities involving planning, quality control, quality assessment, reporting, and quality improvement to ensure that a product or service meets the defined standards of quality with a stated level of confidence (National Environmental Laboratory Accreditation Conference, 2003).

quality control (QC) — a set of measures within a sample analysis methodology to assure that the process is in control (American Public Health Association, 1998); the overall system of technical activities whose purpose is to measure and control the quality of a product or service so that it meets the needs of users (National Environmental Laboratory Accreditation Conference, 2003)

quality management system (QMS) — a comprehensive document describing the policies, processes, and procedures necessary to plan and perform the core business of an organization; it state the quality policy, quality system, and quality practices of an organization. This also may be called a quality assurance plan or a quality plan.

Note: The document may include by reference other documentation relating to the laboratory's quality arrangements (National Environmental Laboratory Accreditation Conference, 2003).

quality system — a structured, documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring quality in its work processes, products (items), and services. The quality system is the framework for planning, implementing, and assessing work performed by the organization and for carrying out required quality assurance and quality control (National Environmental Laboratory Accreditation Conference, 2003).

reagent blank (method reagent blank) — a sample consisting of reagent(s), without the specified analyte or sample matrix, introduced into the analytical procedure at the appropriate point and carried through all subsequent steps to determine the contribution of the reagents and of the involved analytical steps (National Environmental Laboratory Accreditation Conference, 2003)

reagent spike — a synthetic matrix fortified with known concentrations of all, or a representative selection of, the method analytes. The synthetic matrix usually is the same as the method blank, for example, organic-free water or sodium sulfate. For the purpose of interpreting the corrective action guidelines described in this document, a reagent spike failure is defined as an out-of-control recovery for any relevant spiked analyte (U.S. Geological Survey National Water Quality Laboratory Technical Memorandum 94-07, 1994).

records management technician — the individual responsible for the life cycle of data management, including accessioning, disposition, reference, retrieval, arrangement, description, records appraisal, and records preservation

reference material — a material or substance, one or more properties of which are sufficiently well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials (National Environmental Laboratory Accreditation Conference, 2003)

requirement — denotes a mandatory specification; often designated by the term "shall" (National Environmental Laboratory Accreditation Conference, 2003)

sample — one or more portions of a liquid, gas, or solid material (including biological tissues) taken in an unbiased manner from a batch, lot, process stream, or on-site from the environment and considered to be representative of the whole for subsequent testing to determine the chemical, physical, mechanical, or other quality characteristics of the material, or combination thereof (modified from American Society for Testing and Materials, 2000)

sample preparation — any predefined test or process performed on a sample before analysis. This may be done by personnel at a U.S. Geological Survey Water Science Center at the time of sample collection or employees at the USGS National Water Quality Laboratory after login of samples, or both.

schedule — a collection of tests, analytes, variables, or any combination that is defined by the U.S. Geological Survey National Water Quality Laboratory as a routine (a test or suite of tests that can be obtained directly from an analytical services request form) or a customer-defined request; see "method"

spike — a known mass of specified analyte added to a blank sample or subsample; used to determine recovery efficiency or for other quality-control purposes (National Environmental Laboratory Accreditation Conference, 2003)

standard operating procedure (SOP) — a document that describes the analytical methods to be used in the laboratory in sufficient detail that a competent analyst unfamiliar with the method can conduct a reliable review and/or obtain acceptable results.

Where applicable, an SOP may include title of referenced, consensus test method; sample matrix or matrixes; method detection level (MDL); scope and application; summary of SOP; definitions; interferences; safety considerations; waste management; apparatus, equipment, and supplies; reagents and standards; sample collection, preservation, shipment, and storage requirements; specific quality control practices, frequency, acceptance criteria, and required corrective action if acceptance criteria are not met; calibration and standardization; details on the actual test procedure, including sample preparation; calculations; qualifications and performance requirements for analysts

(including number and type of analyses); data assessment/ data management; references; and any tables, flowcharts, and validation or method performance data.

At a minimum, validate a new SOP before use by first determining the MDL and performing an initial demonstration of capability using relevant regulatory guidelines (American Public Health Association, 1998).

standard reference material (SRM) — certified reference material produced by the U.S. National Institute of Standards and Technology or other equivalent organization, and characterized for absolute content, independent of analytical test method (National Environmental Laboratory Accreditation Conference, 2003)

supervisor — individual designated as being responsible for a particular area, unit, or category of scientific analysis. This responsibility includes direct day-to-day supervision of technical employees; supply and instrument adequacy and upkeep; quality assurance/quality control duties; and ascertaining that technical employees have the required balance of education, training, and experience to perform the required analyses (National Environmental Laboratory Accreditation Conference, 2003).

supervisory review — a review of a standard operating procedure (SOP) by a unit Supervisor, who evaluates the SOP for technical accuracy, use of the appropriate document format, and completeness. The supervisor reviews the SOP twice, once after it has gone through peer review but before it is passed to the Section Chief, and again, after the SOP is revised following the inter-Section reviews prior to final Section approval.

surrogate — a substance with properties that mimic the analyte(s) of interest. It is unlikely to be found in environmental samples and is added to them for quality-control purposes (National Environmental Laboratory Accreditation Conference, 2003).

technical manager — the title used by The NELAC Institute for the assistant laboratory chief (The NELAC Institute, 2009)

test — a technical operation that consists of the determination of one or more characteristics or performance of a given product, material, equipment, organism, physical phenomenon, process, or service according to a specified procedure. The result of a test is normally recorded in a document sometimes called a test report or a test certificate (National Environmental Laboratory Accreditation Conference, 2003).

test method — a defined technical procedure to perform a test. It also may be the adaptation of a scientific technique for a specific measurement problem, as documented in a laboratory SOP or as published by a recognized authority (National Environmental Laboratory Accreditation Conference, 2003).

The NELAC Institute (TNI) — an organization that promotes the production of environmental data known and documented quality and overseeing a national laboratory accreditation program

TNI (The NELAC Institute) standard — the protocol and/or requirements established by the National Environmental Laboratory Accreditation Conference (NELAC). The plan of procedures for consistently evaluating and documenting the ability of laboratories performing environmental measurements to meet nationally defined standards (National Environmental Laboratory Accreditation Conference, 2003).

traceability — the property of a result of a measurement whereby it can be related to appropriate standards, generally international or national standards, through an unbroken chain of comparisons (National Environmental Laboratory Accreditation Conference, 2003)

turnaround — the maximum time between login of a sample at the U.S. Geological Survey National Water Quality Laboratory and the availability of data on the World Wide Web. Turnaround is a variable-specific time that is defined by the laboratory to be shorter than the holding time to allow re-analysis if needed.

uncontrolled document — a working copy of a document that has been verified by the user as current or a field-controlled copy that contains identification of outstanding changes to the controlled document and can be used on site (U.S. Department of Energy, 2003). If a document is uncontrolled, there is no assurance that it is the most recent or current version available. Uncontrolled copies can be copied and modified by users and are not considered to be official copies.

U.S. Environmental Protection Agency (USEPA) — the agency of the Federal government with the responsibility of protecting public health and safeguarding and improving the natural environment (that is, the air, water, and land) upon which human life depends (National Environmental Laboratory Accreditation Conference, 2003)

unprocessed data — any original factual information from a measurement activity or study recorded in a laboratory notebook, worksheets, records, memoranda, notes, or exact copies thereof that is necessary to reconstruct and evaluate a report of the activity or study. Unprocessed data may include photography, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments. If exact copies have been prepared (for example, tapes that have been transcribed verbatim and data verified accurate by signature), the exact copy or exact transcript may be submitted (National Environmental Laboratory Accreditation Conference, 2003).

update — a minor reworking of an SOP. The changes will not affect data quality. Examples of an update would be a

chemical disposal change, minor data-entry changes, or change in vendor that require minor modification of procedure without affecting data quality. Updates go through a limited review process prior to approval.

validation — the process of substantiating specified performance criteria; confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use are fulfilled (National Environmental Laboratory Accreditation Conference, 2003)

variability — random error in independent measurements as the result of repeated application of the process under specific conditions. Variability can be statistically described by the standard deviation (standard error) (Taylor, 1990). All data contain some experimental error and individual measurements change or fluctuate within limits. Precision is a measure of variability in experimental data. Variability is the preferred term used by the NWQL and USGS Branch of Quality Systems.

verification — confirmation by examination and provision of evidence that specified requirements have been met

Note: In connection with the management of measuring equipment, verification provides a means for checking that the deviations between values indicated by a measuring instrument and corresponding known values of a measured quantity are consistently smaller than the maximum allowable error defined in a standard, regulation, or specification peculiar to the management of the measuring equipment.

The result of verification leads to a decision either to restore in service, to perform adjustments, to repair, to downgrade, or to declare obsolete. In all cases it is required that a written trace of the verification performed shall be kept on the measuring instrument's individual record (National Environmental Laboratory Accreditation Conference, 2003).

volatile organic compound(s) (VOC) — a compound having high-vapor pressure and low-water solubility. VOCs are typically industrial solvents, constituents in petroleum-fuel products, or by-products produced by chlorination in water treatment.

waste — a solid, liquid, or contained gaseous material no longer used or no longer serves the purpose for which it was produced