EHD DIV-WIDE PLAN 001
Quality Assurance Manual—General

Environmental Health Division

Wisconsin State Laboratory of Hygiene
University of Wisconsin

This manual applies to accredited (1.1) methods within the following analytical sections:

Environmental Toxicology Section
Inorganic Chemistry Section
Trace Element Clean Lab
Metals Section
Organic Chemistry Section
Radiochemistry Section
Water Microbiology Section

This manual also includes the following support sections:

Glassware/Media, Horizon Data Management, Sample Receiving, & Customer Service

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Signature Page

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1. General Sections

1.1. Applicability

This Quality Assurance Manual—General, along with section supplements are designed to meet requirements of The NELAC Institute (TNI, also referred to as NELAP), Wisconsin Department of Natural Resources (NR 149), and the Environmental Protection Agency (EPA). Testing conducted under any of these accreditations, at any WSLH facility (see 1.17.7), must meet the requirements set forth in this manual. Testing conducted under other accreditations or non-accredited testing may use this manual as is to meet requirements. If other accrediting agencies have additional requirements not covered in this manual, those must be met in ancillary documents.

For current scopes of accreditation, see: http://www.slh.wisc.edu/about/compliance/

Note: TNI (The NELAC Institute) was formed in 2006 when NELAC (National Environmental Laboratory Accreditation Conference) combined with INELA (Institute for National Environmental Laboratory Accreditation). NELAP (National Environmental Laboratory Accreditation Program) is one program operated by TNI. For more information, see https://nelac-institute.org/content//programs.php

1.2. Manual Organization and Maintenance

1.2.1. Historical Perspective

The sections that are covered under this manual have, over the years, maintained various documents that have served as de facto Quality Assurance Manuals. In November of 1998 an attempt was made to construct a NELAP-compatible Quality Assurance Manual for the Inorganic and Organic Chemistry Departments (Revision 2.0). That manual was revised in May of 1999 (Revision 2.1).

Revision 3.0 was developed during the laboratory's NELAP application process. It was an attempt to cover all of the departments (now known as sections) in the laboratory that would be accredited under NELAP. Those sections are now Inorganic Chemistry, Trace Element Clean Lab, Metals, Organic Chemistry, and Radiochemistry. Annual reviews resulted in minor revisions (designated as 3.1, 3.2, etc.)

Within revision 4.0, it was necessary to update the NELAC concordance to comply with the new numbering scheme of the 2003 NELAC standards.

Revision 5.0 was completely reorganized so that each section had a separate chapter devoted to it.

Revisions 6.0, 7.0, and 8.0 were reviewed by each section and changes implemented as necessary.

Revision 9.0 was re-written and a new concordance compiled to comply with the new TNI (The NELAC Institute) Standard EL-V1-2009, which is consistent with ISO/IEC 17025:2005 requirements that are

relevant to the scope of environmental testing services.

Revisions 10.0 and 11 were reviewed by each section and changes implemented as necessary.

Revision 12 was completely reorganized by developing a template with required sections and content for each sectional chapter. The goal was to make the manual more concise, functional, and organized.

Revisions 13, 14, 15, 16, and 17 were reviewed by each section and changes implemented as necessary. Rev. 18 incorporated some updates and notes to correspond with 2016 TNI standards, and the concordance chart was updated for 2016 TNI. Revision 19 was reviewed by each section and changes implemented as necessary.

In Aug. 2022, the QA Manual was updated and then transitioned into the OnBase document management system as Version 1. The structure of the manual was changed as noted below. Subsequent versions of the sectional supplements are managed by each section. Subsequent versions of the General plan are managed by a divisional QA coordinator (see 1.2.3)

1.2.2. Structure

EHD DIV-WIDE PLAN 001, Quality Assurance Manual—General, contains general information that applies to all sections and testing covered by this manual. Each section then has a supplemental plan (e.g. EHD INORG PLAN 001) that contains information specific to that section.

SOP ID	Section	SOP Type	Title
EHD DIV-WIDE PLAN 001	DIV-WIDE	PLAN	Quality Assurance Manual--General
EHD INORG PLAN 001	INORG CHEM	PLAN	Quality Assurance Manual, Inorg/TECL/Metals*
EHD RAD PLAN 001	RAD CHEM	PLAN	Quality Assurance Manual, Radiochemistry*
EHD ENV TOX PLAN 001	ENV TOX	PLAN	Quality Assurance Manual, Environmental Toxicology*
EHD MICRO PLAN 001	WATER MICRO	PLAN	Quality Assurance Manual, Water Microbiology*
EHD ORG CHEM PLAN 001	ORG CHEM	PLAN	Quality Assurance Manual, Organic Chemistry*
EHD HDM PLAN 001	HDM	PLAN	Quality Assurance Manual, Horizon Data Management*
EHD MEDIA PLAN 001	MEDIA	PLAN	Quality Assurance Manual, Glassware/Media*

*Sub-title: (Supplement to EHD DIV-WIDE PLAN 001, QA Manual—General)

1.2.3. Maintenance

At least annually, Quality Assurance Coordinators will review and update EHD DIV-WIDE PLAN 001, QA Manual—General. In addition, each section of EHD will review and update their QA Manual supplement. Changes to the supplements may occur at any time as needed by the Sections. Changes to

the "General" plan will be facilitated by contacting the appropriate QA coordinator if outside of the annual renewal. The electronic version of the manual will reside and be managed in OnBase. Editing within OnBase is controlled through permissions to specific Active Directories. For details, refer to LABWIDE GENOP 700, OnBase User Guide.

1.3. Quality Policy Statement

This quality policy statement describes the overall objectives of the Environmental Health Division's quality system. The complete quality system is documented in the remainder of this Quality Assurance Manual—General, in the section supplements, and in policies and procedures that are referenced in this manual. This quality system is based on the required elements contained in the 2016 TNI (The NELAC Institute) Standard, Volume 1 "Management and Technical Requirements for Laboratories Performing Environmental Analysis." The management of the Environmental Health Division, under the authority of the division director, is committed to these quality objectives as a means of maintaining our status as a world class public and environmental health laboratory. Quality is everyone's responsibility.

Objectives of the Quality System:

High accuracy of work

The Environmental Health Division's quality system ensures that data is of excellent and documented quality. The management and laboratory professionals are committed to following good professional practices as defined by our quality system and to compliance with applicable standards.

Data Integrity

Management and laboratory staff are committed to ethical laboratory practices. All employees are responsible for following the data integrity, ethics, and data documentation policies, which in turn, assure high quality data.

Continuous quality improvement

Laboratory management is dedicated to continuous quality improvement by means such as corrective and preventive action, root cause analysis, internal audits, and management system reviews. All staff are encouraged to bring suggestions for quality improvement to supervisors.

Customer satisfaction

The laboratory's standard of service to our clients and the citizens of the State of Wisconsin includes meeting all quality system objectives, providing timely results, remaining fiscally responsible, and addressing customer questions, concerns and complaints. In addition, our customers often call on us to provide outreach services and outside training. Research and method development work are also requested, although this usually would fall outside of any accredited methods.

Compliance with applicable standards

The Environmental Health Division conducts testing that may be regulated under one or more of the following agencies: the United States Environmental Protection Agency (EPA), the Wisconsin Department of Natural Resources (DNR), The NELAC Institute (TNI), the Wisconsin Division of Health Services (DHS), Wisconsin Department of Agriculture, Trade and Consumer Protection (DATCP), and local public health agencies. The management and laboratory professionals are committed to upholding the requirements of these standards.

Staff training

Training includes initial and continuing instruction on the quality system documented in this manual and referenced policies and procedures as required for specific job duties. The training ensures that the quality system is communicated, understood, and implemented by the appropriate personnel.

1.4. Organization, Management Structure, and Responsibilities

Organizational charts can be found at O:\Organizational Charts\Current Org Charts.

The Wisconsin State Laboratory of Hygiene is a department of the University of Wisconsin—Madison within the School of Medicine and Public Health. The WSLH was created by state statute in 1903 and is overseen by the WSLH Board. The Board serves to set policy (1.26.3) and direction for the Laboratory, and its members are either designated by statute or appointed by the Governor. Operational management of the WSLH is the responsibility of the Laboratory Director.

University of Wisconsin-Madison Dept.	**WSLH Director**	**Assoc. Director of Non-Clinical Testing**
Wisconsin State Laboratory of Hygiene	Dr. James Schauer*	Steve Strebel (interim)

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1.4.1. Divisions

The Wisconsin State Laboratory of Hygiene (WSLH) is divided into several analytical divisions including the Environmental Health Division (EHD). The EHD is further divided into program areas that include Environmental Chemistry, Environmental Biology, Environmental Survey Programs, Forensic Toxicology, and Science & Research. This QA Manual is applicable to some sections within the Environmental Chemistry and Environmental Biology program areas. Lab Directors manage program areas.

Program Area Lab Directors report to the Associate Director of Non-Clinical Testing. In addition, Lab

Directors are ultimately responsible for data quality and compliance with applicable standards. They ensure the integrity of the management system when changes are planned and implemented. In the absence of the Lab Director, a temporary appointee will act in his/her place. Note: under TNI, WSLH has named certain staff as technical managers (see 2016 TNI V1M2, 5.2.6.1).

WSLH Division	**Applicable Program Area**	**Lab Director**
Environmental Health	Envir. Chemistry	Camille Danielson
Environmental Health	Envir. Biology	Jocelyn Hemming

1.4.2. Offices

The laboratory's analytical divisions are supported by the following: Office of Information Systems, Office of Finance (includes Purchasing, Accounts Receivable, & Accounting departments), Office of Human Resources, Office of the Director.

1.4.3. Sections

The Environmental Health Division and its Program Areas are divided into several sections (formerly known as departments): Shipping/Receiving, Horizon Data Management/Sample Receiving/Customer Service, Environmental Chemistry (including Organic Chemistry, Air Chemistry, Inorganic Chemistry, Metals, Trace Element Clean Lab, Radiochemistry, and Chemical Emergency Response), Environmental Microbiology (including Environmental Toxicology, Water Microbiology, Glassware/media, and Flow Cytometry), and Forensic Toxicology. Also within the EHD is the National Atmospheric Deposition Program, PFAS Research, and the Soil and Forage Lab.

All of the sections included in this QA Manual are part of the EHD. The Metals section does work for both EHD and Occupational Health and Safety Division.

Each section has a Supervisor who is responsible for day-to-day operation of the laboratory. Supervisors report to the Lab Directors, who report to the Associate Director of Non-Clinical Testing. As a group, these supervisors oversee technical operations, sample analysis, quality assurance activities, data entry, report generation, provision of resources, and all other related areas. In addition, they are responsible for employee management and review. Supervisors will appoint a person or persons to cover their duties during an absence. If substitution appointments have not been made in advance, the Lab Directors will make managerial decisions.

Sections covered by this QA Manual:

Program Area	Section	Supervisor
Environmental Chemistry	Inorganic Chemistry	Graham Anderson
	Metals	Graham Anderson
	Organic Chemistry	Erin Mani
	Trace Element Clean Lab	Christa Dahman Zaborske
	Radiochemistry	Jesse Wouters
	Horizon Data Management/ Customer Service	Kathleen Dax-Klister
Environmental Biology	Water Microbiology/ Glassware/Media	Martin Collins
	Environmental Toxicology	Dawn Perkins

1.4.4. QA Coordinators

The EHD QA Coordinators are responsible for implementing and maintaining quality assurance procedures throughout the laboratories, and ensuring compliance with applicable standards. They work with the supervisors, lab managers/directors, and division directors to ensure that QA procedures are followed by all staff. Responsibilities of the QA Coordinators include oversight of the procedures that generate quality control data. QA Coordinators are also responsible for conducting internal audits annually. The internal audit reports include a listing of deficiencies and a means of monitoring corrective action. The QA Coordinators oversee the laboratory's certification status and coordinate the various regulatory programs. They also maintain working relationships with regulatory agencies and closely monitor any program or statutory changes. Other duties of QA Coordinators include managing performance evaluation (proficiency testing) samples, coordinating the review and writing of SOPs (including the Quality Assurance Manual), and evaluating QC limits.

The QA Coordinators report to the Lab Director or Supervisor, and have access to higher levels of management through the Quality Assurance Committee. Their QA duties are independent of any laboratory work that they may perform, or oversight is such that objectivity is maintained.

All QA Coordinators have knowledge in the quality system as defined under TNI, DNR, & EPA and experience in the concomitant QA/QC procedures. Documentation of this knowledge and experience includes dated signatures (which may include electronic signatures or acknowledgement within the OnBase document management system) on the QA Manual, SOPs, DOC statements, and other documents that are part of the quality system. QA Coordinators also have general knowledge of the analytical test methods performed in their sections.

If a quality assurance question arises when the QA Coordinator for a particular section is absent, the question may be directed to the section director, supervisor, or a QA Coordinator from another section.

1.4.5. Laboratory Staff

It is the primary responsibility of the frontline laboratory staff (bench analysts and support/administrative staff) to produce quality data within the structure of each individual method and within the parameters of the laboratory's quality control guidelines. It is also the responsibility of the staff to identify existing problems or inefficiencies, and to improve the processes of the laboratory whenever possible. Management should be informed of any staff needs or concerns.

1.4.6. Position Descriptions

Specific position descriptions for all personnel are located in the main WSLH Human Resources Office (465 Henry Mall). In addition, each section supervisor has copies of the position descriptions for their staff. Organizational charts for WSLH and all divisions are located at O:\Organizational Charts\Current Org Charts.

1.4.7. Education and Experience—Division-wide Employees

Name	**Title**	**Degree**
Steve Strebel	Assoc. Director (interim) of Non-Clinical Testing	BS Chemistry
Camille Danielson	Lab Director (Envir. Chemistry)	BA Biology/Chemistry Minor, MS Aquatic Toxicology
Jocelyn Hemming	Lab Director (Envir. Biology)	BA Biology, PhD Environmental Toxicology
Susan Hill	QA Coordinator	BS Chemistry, MS Water Chemistry

1.5. Security and Access

Access to the Wisconsin State Laboratory of Hygiene (WSLH) Agriculture Drive site is restricted to authorized individuals to insure the safety of all staff members and to maintain the integrity of all samples. The exterior doors of the main entrance and the loading dock areas are open to our customers from 7:45 a.m. to 4:30 p.m., Monday through Friday. Saturday hours are 6:30 a.m. – 12:30 p.m. Both of these areas will be secured from the rest of the laboratory by electronic locks. Only staff members, custodial staff, and authorized visitors will have access beyond these two secured areas. LABWIDE GENOP 1101, "Visitor Access to WSLH Facilities and LABWIDE GENOP 1004, "Building Access "Authorization" detail the specifics of security and access.

1.6. Service to the Customer & Complaint Resolution

The WSLH will maintain communication with customers to ensure testing is completed as requested by the customer or according to agreement between the customer and the lab (also see section 1.15, Review of Requests, Tenders, and Contracts). Any questions, problems, or major delays with a sample will be

communicated to the customer as appropriate. Documentation of customer communications will be maintained. When samples and test request/chain of custody forms have already been received at the lab, these communications are documented either on the paperwork (which will then be scanned and saved in Horizon) or in Horizon (go to Clients/Phone Log). E-mail communications with clients will be saved according to the applicable RDA (1.12). Sampling kits or other supplies needed by customers will be sent out in a timely manner according to procedures. Questions will usually be answered by Customer Service representatives. Technical questions regarding specific tests can be passed on to sectional representatives.

Although the Laboratory strives to provide services in a timely and high quality fashion, it is expected that we will occasionally make mistakes or fail to please a customer. When complaints occur, it is expected that the laboratory staff will handle them in a consistent, courteous, and prompt manner. EHD DIV-WIDE GENOP 017 "Managing Customer Feedback" details how complaints and other feedback should be handled and documented.

The Environmental Health Division seeks feedback from clients in regular meetings with the Department of Natural Resources and the Department of Health Services. The division has also sent surveys to targeted customer groups.

1.7. Confidentiality Policy

We will handle oral or written requests for sample results according to the following policy:

We will release sample results to the person(s) or entity that submitted the sample and/or is paying for the testing. We will also release sample results to the person(s) or agency that was identified as the receiver of the report.

Note: Under Wis. Stat. 280.13(1)(d) and Admin. Rule NR 812 private drinking water test results are released electronically to the WDNR.

If information is requested under the Freedom of Information Act, the request is forwarded to the WSLH Director's Office.

Most test results within the EHD are not considered protected health information under the Health Insurance Portability and Accountability Act (HIPAA).

Laboratory records that support accreditations will be made available to the applicable accreditation bodies. These include, but are not limited to quality records, technical records, information necessary for the historical reconstruction of data, administrative records, purchasing records, and personnel records.

Personal information about all staff of WSLH is considered confidential. Conversations regarding staffs' personal and professional information must be conducted in a site where confidentiality can be maintained.

1.8. Hiring Process

The Wisconsin State Laboratory of Hygiene (WSLH) is part of the University of Wisconsin and conforms to the University of Wisconsin's policies for hiring staff. We are committed to hiring the right talent to ensure that our university continues to be a world-class institution of higher education. Our goal is to provide opportunities for talented people from all backgrounds to help us maintain a highly productive, welcoming, empowering, and inclusive community. The WSLH Human Resources and UW Madison Office of Human Resources (OHR) are responsible for developing and maintaining policies, procedures, and documentation related to hiring personnel at the WSLH. Records associated with hiring staff for the WSLH will be retained by WSLH-HR. HR will be responsible for the maintenance and final disposal of these records. For details on the hiring process, please see HR Website http://slhicmsprod/administrative-services/human-resources/

1.9. Safety

The "Chemical Hygiene Plan and General Laboratory Safety Plan" (LABWIDE SAFETY 102), contains comprehensive information on general laboratory safety procedures and operations for the WSLH's Agriculture Drive facility. Information includes chemical storage, waste disposal, safety showers, fume hoods, controlling exposure, employee safety training, housekeeping, emergency procedures, personal protective equipment, and more.

For details related to waste management, see EHD DIV-WIDE GENOP 038. This division-level SOP includes a strategy for managing waste streams and promoting techniques such as waste reduction, re-use, recycling, and recovery to protect human health and the environment. It also includes instructions for managing, storing, and disposing of biohazardous, radioactive, and chemical wastes.

At the University level, see UW-Madison policy UW-6066, Chemical Hygiene Plan and Policy: https://policy.wisc.edu/library/UW-6066. Incorporated into this Chemical Hygiene Plan is the "Chemical Safety Guide," https://ehs.wisc.edu/labs-research/chemical-safety/chemical-safety-guide/, which is a collection of chemical safety information that can be used to improve laboratory operations, develop standard operating procedures, and inform staff of the latest safety and regulatory requirements. A Previous guide can be used during the UW's transition to a new website organization: https://ehs.wiscweb.wisc.edu/wp-content/uploads/sites/25/2017/01/LabSafetyGuide_Full.pdf

The WSLH has a Safety committee that meets regularly and conducts safety inspections. Minutes of this committee are available at O:\Teams\Safety\Minutes and Attendance. Membership of this committee

consists of a cross section of laboratory personnel.

1.9.1. Note regarding Safety Data Sheets

A Safety Data Sheet (SDS) is a document containing chemical hazard and safe handling information. There are 16 sections including: Section 2: Hazard identification, Section 4: First aid measures, Section 7: Handling and storage. For more information about Safety Data Sheets, see the Chemical Hygiene Plan and the Chemical Safety Guide noted above.

1.10. Training

1.10.1. Initial Training of New Employees

Training of employees takes place in a logical progression that meets applicable requirements. The Office of Human Resources has an employee onboarding checklist (http://slhicmsprod/administrative-services/human-resources/) that includes some lab-wide training items (click on the New Employee tab)

WSLH has an Employee Handbook available through the intranet home page: http://slhicmsprod/ (click on button near center of the home page).

To ensure the safety and well-being of all Wisconsin State Laboratory of Hygiene personnel, new employees must become familiar with basic safety precautions before working in the laboratory. A key tool in safety training is the Agriculture Drive Employee Safety Checklist (LABWIDE SAFETY 100), which comprehensively lists safety issues such as the location of safety showers and fire extinguishers, evacuation procedures, policies on eating and drinking in the lab, use of potentially dangerous instruments and chemicals, safety apparel use, fume hood use, and much more. The AD Employee Safety Checklist in OnBase also lists external references that contain more information on laboratory safety. Other safety training tools that new employees are required to review are the AG Drive Chemical Hygiene Plan (LABWIDE SAFETY 102) and the Emergency Response Plan for Agriculture Drive (LABWIDE SAFETY 101). All employees are required to take fire extinguisher training offered by the university. Depending on their position, some employees may require more specialized instruction such as a review of the Blood borne Pathogens Reference and Training Manual, or participation in the Radiation Safety Training offered by the University. In addition, members of the Shipping and Receiving area receive training in the "Handling and Shipping of Hazardous Materials," also offered by the University.

New employee training continues with:

- Data Integrity training (EHD DIV-WIDE GENOP 029) and the WSLH Statement of Ethical Expectations (WSLH-WIDE POLICY 001, which is available through employees' My UW accounts in the Canvas app).

- A review of the EHD Quality Assurance Manual (General and applicable section supplement(s).
- Occurrence management training (also see section 1.21.5). The occurrence management training is available in OnBase as SOPs: LABWIDE GENOP 707 Occurrence Management System Policy and LABWIDE GENOP 706 Occurrence Reporting Procedure. The attestation form is on the intranet (on the home page, hover over the Regulatory & Compliance drop-down list, choose the Quality Management button, then click on the Quality Tools tab (http://slhicmsprod/regulatory-compliance/quality-management/).
- HIPAA—Varying levels of HIPAA Privacy Rule training are required depending on an employee's position. For HIPAA training information, consult HR and see the University of Wisconsin—Madison, Office of Compliance, HIPAA training website: https://compliance.wisc.edu/hipaa/training/.
- Review of the *QA & You Brown Bag* video. Submit an attestation statement to Human Resources. The video and attestation statement are located on our intranet: http://slhicmsprod/regulatory-compliance/quality-management/.
  Once there, select the *Quality Tools* tab (began 8/2020).
- OnBase document management platform training is available through employees' My UW accounts.
  - Access enrollment via: https://canvas.wisc.edu/enroll/68JDHH.
  - Enroll in the Introduction to OnBase module in the Canvas app.
  - Complete the training and quiz as instructed.
  - Staff that will be involved with editing or approving SOPs will also need to take the more advanced OnBase Workflow training provided within the same Canvas course.
  - For further information go to the WSLH TeamDynamix Service Desk Knowledge Base (access via intranet).

Each section has a new employee training form or checklist (see section supplements), which ensures that a new employee receives information important to working in that section. Usually an experienced employee guides the new employee through the checklist.

These items complete the initial training of new employees. Next, they will move on to analytical method training if required for their position. Other non-testing training materials may be required by the sections.

1.10.2. Analytical Method Training

Analytical method training is for new employees who have completed the initial training and for any employee who is learning a new procedure. Sections may have method training forms (see section supplements), which help guide a person through the process of learning a new method. Generally, the trainee will review the section's SOP and/or the regulatory method as well as the instrument manual.

He/she will observe an experienced analyst prepare samples and operate the instrument. He/she will next work under the direct supervision of the experienced analyst until becoming familiar with the analytical procedures. Training includes sample handling and preparation, safety specific to the method, documentation procedures, calibration procedures, QC requirements, data management, data reporting, and troubleshooting.

If applicable, the trainee will perform an initial Demonstration of Capability (DOC) and document the results on a DOC Certification Statement (EHD DIV-WIDE QA 115, "Initial and Ongoing DOC Procedures"). In addition, the trainee must sign a Certification Statement for Current Technical Methods (Figure 1) or an attestation statement at the end of an SOP, which states that he/she has read, understood, and agreed to perform the most recent version of the test method. When initial DOC criteria have been satisfied and the experienced analyst and supervisor are confident that the employee is thoroughly familiar with the test, that employee is allowed to work on his/her own with only routine supervision.

1.10.3. Continuing Training

All employees receive continuing training and must demonstrate continued proficiency. Whenever there is a change in instrument type, personnel, or test method a new DOC must be performed. Annually, each analyst must demonstrate continued proficiency on technical methods for which they are responsible (see section supplements for procedures). When a new revision of an SOP is written, analysts who are responsible for that method must sign a new Certification Statement for Current Technical Methods.

All employees must annually review the following documents:

a. Quality Assurance Manual
b. Chemical Hygiene Plan
c. Data Integrity, Ethics, and Data Documentation Procedure
d. Emergency Response Plan

1.10.4. Additional Education/Training

- Occasionally, the university and the WSLH offer or require training (e.g. sexual harassment awareness and prevention, HIPAA, Performance Management & Development Program, disability accommodation, Cybersecurity Awareness, and others). E-mails will detail requirements.
- The laboratory supports continuing education that may include seminars, training offered by vendors, or formal higher education. All employees are encouraged to keep up with changes or advances in analytical methods and instrumentation.

1.10.5. Training Documentation

All training forms, checklists, sign-off sheets, certification statements, and DOC forms related to the above requirements will be signed and dated by the employee and given to the QA coordinator responsible for

that section or documented according to University requirements (e.g. documented within the Canvas learning management system). Electronic forms and signatures may be used see 1.11.3 for signature policy. The QA coordinator will ensure that the documentation is complete and filed appropriately for training within the section. Most training documentation will be filed in the personnel training files in each section or into electronic folders.

1.10.6. Data Integrity Procedures

All employees have access (via OnBase) to the Data Integrity, Ethics, Data Documentation Procedure for the WSLH, Environmental Health Division (EHD DIV-WIDE GENOP 029). The procedure includes our organizational mission relating to data integrity, our steps for data integrity training and training documentation, our methods for monitoring data integrity, and steps for the reporting of data integrity concerns. In addition, it documents our Ethics Policy and our Data Documentation procedure.

1.10.7. Quality Assurance Training

All employees must watch the *QA & You Brown Bag* video once and submit an attestation statement to their supervisor, who in turn will send it to Human Resources. HR will file the statements in employees' P-files. The video and attestation statement are located on our intranet:
http://slhicmsprod/regulatory-compliance/quality-management/.
Once there, select the *Quality Tools* tab.

1.10.8. Employee Training Summary Tables:

Initial Training of New Employees

Training Document	**Link or Reference to Document**	**Documentation of Training**
Lab-wide new employee checklist	http://slhicmsprod/administrative-services/human-resources/	Sign checklist & complete referenced documentation
Dept. new employee checklist	See section supplements	Sign checklist
EHD Employee Safety Checklist (LABWIDE SAFETY 100)	Access in OnBase	Sign checklist
Chemical Hygiene Plan for Ag Dr (LABWIDE SAFETY 102)	Access in OnBase	Through My UW account, Canvas app
Emergency Response Plan for Ag Dr (LABWIDE SAFETY 101)	Access in OnBase	Through My UW account, Canvas app
EHD Data Integrity Procedure (EHD DIV-WIDE GENOP 029)	Access in OnBase	Through My UW account, Canvas app
Statement of Ethical Expectations (WSLH-WIDE POLICY 001)	Access in OnBase	Through My UW account, Canvas app
QA Manual	Access in OnBase	Through My UW account, Canvas app
Occurrence Management (LABWIDE GENOPs 706, 707)	Access in OnBase	Training form/attestation statement
HIPAA	https://compliance.wisc.edu/hipaa/training/	Through UW website
QA & You video	http://slhicmsprod/regulatory-compliance/quality-management/	Attestation statement
OnBase Document Management	https://canvas.wisc.edu/enroll/68JDHH	Through My UW account, Canvas app

*may be electronic

Analytical Method Training

	Link or Reference to Document	**Documentation of Training**
Method Training form	See section supplements	Sign form
DOC Certification Statement	EHD DIV-WIDE QA 115	Sign DOC statement
Cert. Statement for Current Technical Methods (METHOD SOPs)	QAM-General Figure 1 (Note: other forms such as SOP Attest Statement are also acceptable)	Sign Certification statement (may be electronic)

Continuing Training

Training Document	Link or Reference to Document	Documentation of Training
DOC or Annual Continued Proficiency documentation (annually or when there is a change)	EHD DIV-WIDE QA 115 (OnBase)	Sign DOC statement or other doc.
Cert. Statement for Current Technical Methods (when new SOP revision is written)	QAM-General Figure 1 (Note: other forms are also acceptable)	Sign Certification statement*
QA Manual (annually)	OnBase	Through My UW account, Canvas app
EHD Chemical Hygiene Plan (annually)	LABWIDE SAFETY 102 (OnBase)	Through My UW account, Canvas app
EHD Data Integrity Procedure (annually)	EHD DIV-WIDE GENOP 029 (OnBase)	Through My UW account, Canvas app
EHD Emergency Response Plan (annually)	LABWIDE SAFETY 101 (OnBase)	Through My UW account, Canvas app

***may be electronic**

Additional Education & Training

Training Document	Link or Reference to Document	Documentation of Training
Course or class work		Certificate or note about title and content of course
HIPAA	https://compliance.wisc.edu/hipaa/training/	Through UW website
QA & You video	http://slhicmsprod/regulatory-compliance/quality-management/	Attestation statement
Sexual Harassment Awareness & Prevention	https://compliance.wisc.edu/titleix/employee-training/	Through UW website
Cybersecurity Awareness	https://it.wisc.edu/services/cybersecurity-awareness-training/	Completion of two badges on training site
Disability Accommodation Training	Reading materials provided by HR via e-mail	Quiz provided by HR

Figure 1: Example of a Certification Statement for Current Technical Methods

Analyst Certification Statement
For Current Technical Methods

Analyst Name: _____

SOP Number: _____

SOP Title: _____

SOP Revision Number: _____

SOP Effective Dates: _____

I, the undersigned, CERTIFY that I have read, understood, and agreed to perform the most recent version of the above test method.

_____ _____
Analyst Signature Date

1.11. Document Control System

1.11.1. Control & Maintenance of Standard Operating Procedures (SOPs)

SOPs that may apply to operations covered by this QA Manual exist at three different levels: Lab-wide, EHD Division-wide, and section-level.

SOPs will be stored, maintained, and accessed through OnBase, an electronic document management platform. OnBase has search and retrieval functions as well as customized workflow for editing and version tracking. Within OnBase, documents are organized by category, or groups of document types that have similar characteristics, purpose, or management requirements. Search and retrieval functions are available.

There are two ways of accessing OnBase: Web Client and Unity Client. Web Client is available via the intranet home page for general access to locate and view approved SOPs (all SOPs are accessible to all staff unless specially restricted). Unity Client must be used for operational, permission-based functions within workflow such as editing or approving documents. Unity Client must be installed on individual workstations, if needed. The history of any particular document within OnBase workflow, including version numbers, effective dates, and who approved each version, is saved within the system.

Within OnBase, approved SOP versions are found under POLICIES-PLANS-PROCEDURES (PPP), SOP-Approved document type.

- Lab-wide: Division=LABWIDE
- EHD Division-wide: Division=EHD, Section=DIVISION-WIDE
- Section-level: search by appropriate division and section

Within OnBase Workflow, various lifecycles (permission-based) exist for updating SOPs:

- SOP Review/Approval_LABWIDE
- SOP Review/Approval_EHD_DIVISION-WIDE
- Each section has a separate lifecycle

For more information regarding the use of OnBase, see LABWIDE GENOP 700, OnBase User Guide. Training is available (see section 1.10 of this document).

Analytical method SOPs will contain all accreditation-required sections and information as applicable.

All SOPs associated with drinking water testing (including administrative as well as technical) must be reviewed for content annually and updated if necessary.

This QA Manual is reviewed at least annually, and it is updated when necessary. OnBase includes a Timers and Notifications module, which tracks review periods, due dates, and automatically sends notifications to assigned people.

1.11.2. Components of Document Control

All internally-generated documents (SOPs, policy statements, spreadsheets, forms, bench record cover sheets, certification statements, sign-off sheets, instruction sheets, etc.) must be listed in a table of contents (or equivalent list generated in OnBase) and have document control [TNI V1M2 4.3.2.3; WI NR 149.39(1)] including:

a. Issuing authority (e.g. WSLH, division, section)
b. Unique ID (number or title)
c. Effective date and/or revision number
d. Page x of y

1.11.3. Electronic Signature Policy

Electronic signatures through cloud-based services such as DocuSign are acceptable in place of handwritten signatures on hard copy documents. The electronic signatures are unique, traceable, and secure. Within the quality system, staff and supervisor signatures are most often needed on DOCs and other training documents. Documents with electronic signatures must be saved to shared drives (or OnBase) where they are backed up and retained according to the applicable RDA. It is not acceptable to save the electronically signed documents only within the cloud-based signatory service.

1.12. Records Retention, Control, & Storage

1.12.1. Records Disposition Authorization (RDA)

RDAs are also called records schedules. They are key documents for establishing a records management program for organizations within Wisconsin State government. In essence, records schedules describe the organization's information resources, how long they are going to be retained, and what their ultimate disposition will be. They are the policy statements that govern the ultimate disposition of records.

Some EHD records fall under General Records Retention Schedules (GRS), which are approved for UW-Madison campus-wide use. General records schedules codify retention policies for record types that are common to all offices across the UW system. WSLH also has some UDDS/Department-specific RDAs. Refer to https://www.library.wisc.edu/archives/records-management/retention-disposition/

If an RDA needs to be amended or resubmitted upon 10-year sunset, contact:

University Records Officer, University of Wisconsin-Madison
432 Steenbock Library
550 Babcock Drive
Madison, WI 53706-1201
Phone: 608-262-3284

recmgmt@library.wisc.edu

1.12.2. Laboratory Notebook/Logbook

A laboratory notebook or logbook is any physical book in which testing data is recorded; this includes experimental data, standards logs, instrument logs, etc.

All laboratory notebooks are assigned a unique number by QA staff. This number is then used for tracking notebooks in the laboratory. Each notebook will be labeled with the following information: organization name, unique laboratory notebook number, analyst or instrument assigned to, section, notebook's contents, start date and end date.

All notebook information on the label is entered into a database, which also includes information on archival date, storage location, archival box number and disposal date. The database is on drive: R:/EHD/QC/Archived Records.mdb

For more information about the identification labels, see EHD DIV-WIDE GENOP 104, How to Print Laboratory Logbook Labels.

Notebooks will be retained according to the applicable RDA.

1.12.3. Storage of Records in Basement room 14

Refer to LABWIDE GENOP 1002, "Records Storage and Disposal," section 4.0 for the procedure for storing documents in record storage boxes. Boxes may be immediately sent to the State Records Center or may be placed in an approved storage area at the WSLH. Approved storage areas are organized with specific locations where new inventory may be added. The approved storage area for Agriculture Drive is room 14 in the basement. Complete records of items placed in storage must be maintained by the divisional or sectional records coordinator. The records coordinator has the responsibility for knowing what is in each box, where each box is located, and the destruction date of each box.

If it is necessary to temporarily remove records (under NELAC-accreditation) from boxes stored in room 14, information including date removed and returned will be recorded in the Archived File Checkout logbook (ESS801) that is hung near the entrance of room 14 nearest the stairwell. Logbook pages can be printed from the file located at: M:\EHD\Forms\Drafts\Archived File Checkout Log for AD basement EHD rev. 2.doc

1.12.4. Sending Records to the State Records Center

LABWIDE GENOP 1002, contains information regarding how to use the State Records Center Versatile Enterprise Web Module, which is an on-line, web-based process that allows users to submit new inventory (e.g. record storage boxes) to the SRC and to search for and request return of boxes stored there.

1.12.5. Other Records Information

LABWIDE GENOP 1002 also details the procedure for immediate destruction of records and the procedure for electronic records.

1.13. Traceability of Measurements

All analytical results and measurements are fully traceable to standards, reagents, reference materials, and instrumentation used in deriving the results. Stock and working standards are given codes that are documented in the analytical runs in which they are used. Reagents (including pH paper and other chemical test strips) are also given traceability codes. Standards along with effective and expiration dates are retained in the LIMS and linked to the batches and samples associated with them. Analytical instrumentation and equipment (including filters, pipets, and thermometers) are assigned identification numbers, which are also tracked at the batch level in analytical runs.

Date and time of analysis and analyst initials are documented at the batch and/or sample level with all functions in the Horizon LIMS being marked with date/time/users initials. Test results are entered into LIMS either automatically from the instrument or through manual entry by the analyst. All results are directly linked to each sample.

Individual sections may have more detailed information on how they achieve traceability.

1.14. Policy for Estimating Uncertainty of Measurement

Each section must write a policy or procedure for estimating uncertainty of measurement. The policies will cover all analytical tests performed by the section. The uncertainty needs to be reported only if required by the regulating agency, but it must be available upon request. The policies must attempt to identify all the components of uncertainty, make a reasonable estimation, and ensure that the form of reporting of the result does not give a wrong impression of the uncertainty. Reasonable estimation will be based on knowledge of the performance of the method, on the measurement scope, and will make use of previous experience and validation data.

If the section analyzes samples following a well-recognized test method, which specifies limits to the values of the major sources of uncertainty and also specifies how calculated results will be reported, then the section meets the uncertainty requirements for that method.

1.15. Procedures for Accepting New Work/Review of Requests, Tenders, & Contracts

1.15.1. Requests for service

General water test information for the public can be found on the extranet:
http://www.slh.wisc.edu/environmental/water/

To offer a new test to the public on a fee for service basis, consult with Office of the Director. Contracts and requests for service are reviewed before approval, and if a major change in the scope of a contract is requested a new contract will be required. The applicable WSLH unit will review the new contract to ensure they have the capability to provide the services. Copies of WSLH executed contracts are maintained and available by contacting the Contract and Grant Administrator Specialist in the WSLH Office of Finance.

WSLH also offers fee for service tests to public water suppliers. Tests requests are made on test request forms that are sent with samples.

1.15.2. Requests for non-standard analysis:

- Use the template found in the following folder: O:\Quotes\EHD\COC Template
- Update the form for the specific client.
- Update the room number and contact information on the address under the Wisconsin emblem.
- Update the sample description and analysis fields to meet the needs of the client.
- If samples will be logged into Horizon, include the acode number in the analysis field and identify the Horizon account in the section for notes.
- Delete unnecessary rows for small submissions to limit the number of pages to be printed.
- Save a copy of the form in the file directory of your choice. You may use the subfolder “Edited for Clients”; a naming convention similar to the quotes is advised (Organization_Contact_Date).

1.15.3. Review of laboratory capability

If new work is to be accepted, a review of laboratory capability and the scope of work is conducted. The following items may be considered:

- Availability of desired analytical methods and accreditations
- Adequate capacity for facilities, supplies, and instrumentation
- Adequate staffing, training, and experience (both analytical and support staff)
- Capability to meet desired LODs and LOQs
- QA/QC that meets data quality objectives
- Desired turn-around-time

- Desired reporting capabilities and information technology resources
- Appropriate funding to complete the project
- Desired records retention period

1.15.4. Approved Signatory

Contact the Office of Finance for any agreements or purchase orders from an outside entity that require a signature from WSLH. The Wisconsin State Laboratory of Hygiene Director is authorized by the University of Wisconsin-Madison to sign contracts that create a binding legal or financial obligation upon the university. For information that is more detailed please refer to the Signature Authority Memo linked at https://legal.wisc.edu/contract-approval/. Contracts with various entities follow UW policies and procedures.

1.15.5. Review of requests for service

Routinely, the lab receives samples or requests from the public and WDNR staff who are not sure what they want the samples to be tested for. In other cases, the client has asked for tests that may not be ideal for their samples. In these cases, WSLH staff work with the client to determine the best tests that will meet their objectives. When samples and test request/chain of custody forms have already been received at the lab, these communications are documented either on the paperwork (which will then be scanned and saved in Horizon) or in Horizon. E-mail communications with clients may also be attached to the sample in Horizon. Each contract (written or oral agreement to provide a customer with testing services) will be acceptable both to the lab and the customer; any differences will be resolved prior to work commencing on the samples.

Records will be maintained of reviews of requests, tenders, and pertinent discussions with a customer relating to the customer's requirements, the results of work, any deviation from the accepted contract, and any significant changes to the work being done. If a contract needs to be amended after work begins, the review process noted above will be repeated and all changes communicated to affected personnel. Contract modifications may result in a new contract. These records may be in the form of comments appended to test results in Horizon, e-mails, notes from conversations, or written correspondence.

This process also applies to sample testing that may need to be sub-contracted (see section 1.23). The complete history of client and staff agreement regarding sample testing will be traceable through Horizon and associated documentation. See also section 1.6, Service to the Customer and Complaint Resolution.

Additional details regarding accepting new work may be found in the section supplements of the Quality Assurance Manual.

1.16. Sample Handling and Submission Procedures

1.16.1. Sample Acceptance Policy

Samples arrive at the laboratory in several ways: they may be mailed, shipped by a commercial carrier, brought to the laboratory by client field representatives, or brought to the front desk of the laboratory by the general public. Environmental Toxicology samples may be collected and brought to the lab by WSLH personnel. Each sample received is accompanied by a test request form (TRF). The TRFs, chain of custody forms, and any other documentation received with the sample are retained according to section 1.12. Please see EHD DIV-WIDE GENOP 033, "Sample Acceptance Policy," which describes the policy used by the Environmental Health Division Receiving Section for accepting samples, into the lab for environmental testing. This SOP also includes links to sectional SOPs that describe specific acceptance and rejection policies for each section.

1.16.2. Horizon LIMS

Samples logged into the LIMS receive a unique sample number as described below. Other attributes of the sample documented in the LIMS at the time of sample log-in are preservatives, container type, client/project name, date/time of receipt at the lab, field ID, collection date/time, tests requested, and sample condition at receipt. Durable labels, with unique workorder/letter identifiers and barcodes, are printed for each sample container and test request form. Two labels are generated for each sample container—one is placed on the body of the container, and another one is placed on the lid of the container (if desired for convenience).

Samples are received and noted in the LIMS as being located in the sample receiving section. As samples move through the lab, the location of the sample is changed in the LIMS. Disposal of samples is noted in the LIMS.

1.16.3. Sample ID Generation in Horizon LIMS

Summary

The workorder ID is generated from a database sequencer and is always unique and chronological.
The sample ID is derived from the workorder ID if the sample is part of a workorder, or it is generated from a database sequencer if the sample is an internal QC sample. In both situations the sample ID is unique. The container ID is derived from the sample ID with a letter suffix for each container in the sample, -A, -B, -C, etc. and is always unique. Sub-sample (extracts, aliquots, etc.) IDs are derived from the container ID followed by a number, -1, -2, -3, etc.

Workorder ID Generation

A workorder is a collection of samples that all share various things in common, like customer, due date,

collection time, etc. Each workorder is assigned a unique number in the database field PROJECT_SEQ. The system installation setting PSEQASSIGN controls how the PROJECT_SEQ is assigned to the workorder. The laboratory uses the NEXTVAL setting, which assigns each workorder a unique number generated by an Oracle database sequencer and is always unique. Each workorder also has a laboratory identifier in the database field LAB_WO_ID. This ID can be the same as the PROJECT_SEQ or formatted differently, and is controlled by the system installation setting named WO_ASSIGN. The laboratory uses the SYSTEM setting, which sets the LAB_WO_ID equal to the PROJECT_SEQ.

Sample ID Generation

Each sample is assigned a unique number in the database field HSN. The system installation setting HSN_ASSIGN controls how the HSN is assigned to a sample. The laboratory uses the NEXTVAL setting, which assigns each sample a unique number generated by an Oracle database sequencer and is always unique. If a sample is part of a workorder (i.e. not an internal QC sample) the HSN number is derived from the PROJECT_SEQ, using three digits to indicate the number of samples within the workorder (i.e. 001, 002, 003, etc.). This creates a unique number for each sample in a workorder. Each sample also has a laboratory identifier in the database field LAB_SAMPLE_ID. This ID can be the same as the PROJECT_SEQ or formatted differently, and is controlled by the system installation setting named LAB_ASSIGN. The laboratory uses the SYSTEM setting, which sets the LAB_SAMPLE_ID equal to the HSN.

Container ID Generation

Each container in the LIMS is assigned a unique number in the database field CONTAINER_SEQ. This number is assigned using an Oracle database sequencer, and is always unique. Each container also has a container ID in the database field CONTAINER_ID. The container ID is derived from the LAB_SAMPLE_ID, and is controlled using the system installation setting CONTNAME. The laboratory uses the setting ALPHABETIC, which results in a –A, -B, -C, etc. suffix to the LAB_SAMPLE_ID.

Documentation access

Requisition forms that are submitted with samples are scanned into Horizon, associated with the samples via the workorder and are available for viewing. Instrument data that is transferred into the LIMS via Horizon Data Exchange (the results upload feature) is captured, associated with each sample in the run and available for viewing.

1.16.4. Labeling of sub-samples

After initial sample log-in, all sample aliquots or sub-samples must be labeled or otherwise identified to ensure that there can be no confusion regarding the identity of such samples at any time.

All digestion or other intermediate processing step tubes, containers, or vessels must have an ID number and associated documentation that will give a one-to-one correspondence between this ID number and the unique sample ID number generated by Horizon. Examples include etching an ID number onto a digestion tube, creating a Horizon aliquot label to place on a container, and using a permanent marker to label a drying pan. There would then be a bench sheet, run log, logbook, or work-list that documents the aliquot ID number and the corresponding Horizon number.

All autosampler vessels will be labeled as above or alternately, the autosampler tray will have ID numbers at each position. These ID numbers will be recorded, and a one-to-one correspondence will be established between this number and the unique sample ID number generated by Horizon.

1.17. Instrumentation, Equipment, & Facilities

1.17.1. General

The Environmental Health Division relies heavily on instrumentation. It is imperative that all equipment and instruments are calibrated, verified, operated, and maintained in a proper manner in order to obtain reliable data.

The section supplements of the QA Manual contain lists or references to information about support equipment and analytical instruments used in that section. These lists or references include type of instrument, make and model, type of analysis conducted, where the instrument/equipment is located, and assigned instrument numbers or serial numbers. Calibration, maintenance, and verification procedures are found in the appropriate instrument operation manual, instrument operating procedure (IOP), or standard operating procedure (SOP).

If an instrument fails to operate within defined limits or specifications, the problem is identified, corrective action performed, and samples re-run or qualified as required by the method. It is the responsibility of the analyst to notify the section supervisor if non-routine maintenance is required. Instrument vendor technical staff may be contacted if trouble-shooting is unsuccessful.

Preventive maintenance (general maintenance) should be performed at the frequency recommended by the manufacturer to avoid instrument failure. Most instruments and equipment are on some form of preventive maintenance schedule. Some instruments are covered by maintenance contracts directly with the instrument manufacturer. Preventive maintenance is always recorded in the instrument log (physical logbook or electronic).

If equipment is sent out of the lab, its calibration and function will be verified when it is returned to the lab before the equipment is returned to service. The exception to this is when equipment (e.g. motorized

pipets) is sent out for calibration. If the equipment is returned to the lab with a certificate of calibration, this certificate will be reviewed, and if acceptable, the instrument will not need independent verification in the lab.

Maintenance and repair (routine or non-routine) performed by other than SLH staff needs to be summarized in a document provided to SLH. This document must detail the work performed, which should include as found and as left information. If software updates are required, OIS should be notified to determine if a copy of the computer should be taken prior to the new software being installed.

1.17.2. Laboratory Reagent Grade Water

Reverse Osmosis (RO) Water

RO water is plumbed to all the laboratories and is maintained by a service contract with a water treatment vendor. The RO system consists of a pre-filter of graded density non-woven polypropylene for the carbon bed, a filter cartridge of non-woven polypropylene for the 3 - RO/DI 5µm resin traps (replaced every 6 months), a UV Sterilizer in which the Aqua Fine replacement lamp and the Aqua Fine Quartz Sleeve will be replaced annually, a submicron Absolute Rated 0.2 µm bacteria eliminating filter (replaced every 6 months), a recirculating tank vent filter (replaced annually), and cation, anion and mixed bed tanks that will be replaced as needed. The water is ASTM Type II and is used for the glass washing activities, filling water baths, and as a precursor for other "polished" water throughout the building.

ASTM Type I Polisher

These polishers are located throughout the laboratory and provide ASTM Type I water used in the preparation of media, reagents, standards and QC samples (i.e. method blanks) as applicable. There is a service contract with a water treatment vendor to maintain the polishers. On a six-month schedule, the vendor will exchange the carbon filter, the mixed bed cartridges and the organic scavenging Type II ultra-pure anion resin. The UV lamp will be changed based on hours of use. Please see EHD DIV-WIDE GENOP 032 "Monitoring and Maintaining Water Purification Systems", for specific water purification system monitoring and maintenance procedures.

1.17.3. Ovens, Incubators, Cold Rooms, Refrigerators, Freezers, and Muffle Furnaces

Please see EHD DIV-WIDE GENOP 013 "Responding to Freezer/Refrigerator/Incubator Failures," which describes the procedures that shall be used at the Agriculture Drive facility when constant-temperature storage equipment (e.g. freezers, refrigerators, incubators) fails. The procedure describes the processes that shall be followed to keep samples within the required temperature range after a failure and the steps necessary to obtain service for the repair of constant-temperature storage equipment.

Each Section maintains a logbook for its temperature sensitive equipment. The temperatures of the walk-

in refrigerators/incubators are monitored continuously, and an alarm will be activated if limits are exceeded. Each section has procedures for monitoring and documenting temperatures according to requirements.

1.17.4. Computers

The WSLH Office of Information Systems (OIS) maintains a number of quality objectives to insure the integrity, security and reliability of our systems.

The OIS quality objectives include:

- A state-of-the-art data center with exceptional security, redundant connectivity and a climate controlled environment that meets the following certifications:
    - HIPAA/HITECH
    - PCI DSS v3.2.1
    - ISO/IEC 27001:2013
    - EU-U.S. EU Privacy Shield Framework
- Whenever possible, independent test systems are created alongside production to allow a safe environment for training as well as a place where changes can be tested prior to being put into production.
- The use of ITILv4 (Information Technology Infrastructure Library) and risk management frameworks to provide continual process improvement and apply best practices such as Change Management.
- Utilizing a risk-based approach to backup and recovery planning, taking advantage of multiple recovery options when it makes sense to do so (e.g. point-in-time recovery for databases; shadow copies at set intervals during the day) to improve backup and disaster recovery efforts. Backups to tape media utilize a grandfather-father-son rotation scheme and are kept for a corresponding timeframe of weeks, months, or years. These tapes are stored in “media proof safes” that are UL-125 rated (will not exceed 125 degrees Fahrenheit).
- Multiple, redundant network paths for our servers and workstations employing a secure IPSEC tunnel over a fiber-optic ring owned by the “Metropolitan Unified Fiber Network (MUFN) Consortium” <https://mufn.org/> (of which we are a voting member) back to the UW-Madison campus and protected behind firewalls. The UW-Madison is our Internet service provider. Secured VPN service with Remote Desktop Connections (RDC) is used for remote access to enterprise resources.
- Policies, standards, and procedures governing user account creation, system access, personal information protection, and the appropriate use of information systems and resources including the use of HIPAA’s “minimum necessary standard” whereby users are only granted the minimum access necessary to do their jobs.

- Inventory and asset management including anti-malware/antivirus, vulnerability scans, and routine patching for operating system and 3rd party patches (e.g. all servers are patched within 30 days of critical/security operating system patch releases).
- When computers, drives, and media are no longer useful or usable they are sanitized and/or disposed of in a manner consistent with UW-Madison HIPAA policy.
- See the OIS GENOP 50, "WSLH IT Security Plan" for details and additional items.

Special protections for our Instrument Workstations:

- Instrument workstations typically cannot run the latest operating system patches for fear of breaking the acquisition/analysis software. These are protected by 2 different, segregated VLAN's (virtual networks) with firewall rules:
    - **Instrument VLAN** - contains instrument workstations capable of running antivirus/anti-malware software. These PCs are allowed open access to internal servers but Internet traffic is restricted to only a small number of whitelisted sites (e.g. www.PerkinElmer.com).
    - **Protected VLAN** – contains instrument workstations that cannot run antivirus/anti-malware software or those that meet other high risk criteria. These PCs have very limited access to internal resources and no Internet access.
- When possible, instrument interfaces are established to directly pull data into our LIMS systems (e.g. Epic, WindoPath, Horizon) to improve data integrity and increase laboratory productivity.
- Instrument data is stored locally and then backed-up to shared drives on the network using a centralized job scheduler (i.e. the instrument workstation is configured to store its data on the local C:\ drive and then at scheduled times is picked up and copied by one of our servers to a shared drive location). OIS staff work with laboratory staff to ensure the correct data is being backed-up. The shared drive location is then backed-up to tape using our routine processes. It is the laboratory's responsibility to ensure any new data storage locations on the local machine are being backed up to our servers and to work with OIS to ensure ongoing backups work as expected.
- We also maintain "bare metal" backups of our instrument workstations using disk imaging software on an annual basis or whenever laboratory staff notify us of a change to the workstation. It is preferred to take a backup image prior to any vendor changes in case these changes need to be rolled-back. When the work is complete and verified, another backup image should be taken to allow future disaster recovery. It is the responsibility of laboratory staff to notify OIS in advance of these changes so the work can be scheduled. These backups are maintained to allow recovery of the PC configuration in case of a catastrophic loss of hardware at the PC level.
- All vendor technicians are required to have their removable media scanned before it can be inserted into the instrument PC to prevent the spread of viruses and malware.

1.17.5. Bulk Argon

The Agriculture Drive facility has a bulk liquid argon tank near the loading dock that supplies argon gas throughout the building for instruments that require it. Our supplier of the bulk argon (purity = 99.999%) is Airgas Merchant Gases, Madison, WI.

1.17.6. Thermometers (& other temperature measuring devices)

Thermometers used for NELAC, WDNR, or EPA testing must be calibrated or verified annually. The calibration or verification must be traceable to NIST. If the thermometer is used over a range of ≤ 10 °C, a single point verification within that range can be used. If the thermometer is used over a range of > 10 °C, the verification must bracket the range of use. The calibration may be done in-house, by a third-party calibration company, or by the device manufacturer or vendor.

If thermometers are calibrated in-house, the thermometer will be labeled with the date calibrated and the expiration date (same month of next year-e.g. calibrated 01/12/2017, exp. 01/2018). If sections calibrate thermometers in-house, they must have a procedure for doing so. The procedure must include how to do the calibration, how to use correction factors if there is a bias, evaluation criteria, and what to do with thermometers that fail the evaluation criteria.

If thermometers are purchased new annually with a certificate of calibration (NIST-traceable), the thermometer will be labeled with the date it was received and the expiration date (same month of next year-e.g. rec'd 05/10/2017, exp. 05/2018). The person who receives the thermometers must review the calibration certificates to ensure the thermometers have been calibrated within the range of use, and that the expiration date on the certificate extends to cover the section's planned last date of use.

1.17.7. Facilities

The Wisconsin State Laboratory of Hygiene (WSLH) is currently housed in four separate facilities: 465 Henry Mall on the UW Madison Campus, 2810 Walton Commons, 2601 Agriculture Drive on the southeast side of the city of Madison, and 4626 University Ave (Soils and Forage Lab). The Agriculture Drive facility includes the original building built in 1999 and a newer co-located building completed in 2013. The analytical sections covered in this manual are located in the Agriculture Drive facility.

The WSLH is a part of the University of Wisconsin System under the School of Medicine and Public Health. As part of the University, the WSLH benefits from services and expertise offered by the University such as the Biological and Chemical Safety Department, Radiation Safety Department, collaborations with faculty, and access to the library system. Although the Environmental Health Division laboratory is not physically located on the University of Wisconsin campus, the staff are University employees and must follow university policies, procedures, and rules.

The activities of the various sections are supported by a fully automated glassware washing room, a media preparation room, shipping & receiving section, and the offices mentioned in section 1.4. Some of these support sections/offices are located at the main Henry Mall facility or at Walton Commons.

The Agriculture Drive facility is equipped with an air handling system that is maintained by the Department of Administration. The system consists of three intake fans and three exhaust fans. The air handling system ensures that there is always negative pressure in all fume hoods and snorkels. Except for the trace metal clean lab (rm. 256), there is a 100% exchange of air, (i.e., what comes in, goes out; there is no recirculation) and the volume of air in the building is changed approximately once per minute. In addition, the building is designed so that the laboratories will generally be under a negative pressure. The air will flow from the office/cubicle space, into the lab, and then be exhausted.
Section supplements describe facilities that are used within each section.

1.18. Purchasing

1.18.1. Supplies and Services

WSLH Purchasing purchases goods and services necessary for operations performed by the WSLH except as noted below. Procedures for purchasing services are the same as for purchasing supplies with the addition of a certificate of insurance, provided by the vendor, prior to coming on-site. Some items are ordered through Acumatica, which is accessed through the WSLH Intranet Home Page. For instructions on submitting purchase requests, see "Purchase Requests" Business Process Procedure in OnBase. Purchasing operates under authority of the UW Madison Purchasing Department and must adhere to University and State of Wisconsin Policies.

In addition to submitting a purchase request through Acumatica, sections have designated staff who are responsible for ordering supplies for their sections from specified vendors. These orders are placed through the University of Wisconsin's procurement tool called ShopUW+ on the Procure-to-Pay (P2P) automated, cloud-based system, https://shopuwplus.wisc.edu/.

A third purchasing option is the use of a Procurement Card (ProCard), which is a State of Wisconsin VISA credit card. A limited number of employees are authorized, following strict guidelines, to make purchases using a ProCard. Please see the WSLH internal website under Administrative Services, Purchasing Department for policies and procedures.

1.18.2. Capital Equipment

Capital equipment purchases (i.e., > $5000, with a useful life of more than one year) are generally sent out for bid. Laboratory staff works closely with Purchasing to assure that all necessary specifications are included in the bid. All items are purchased through Purchasing.

1.18.3. Receipt of Supplies

When standards, reagents, reference materials, and media are received, assign them unique traceability codes (see section 1.13), document their receipt in the appropriate logbook, and file the certificates of analysis in the appropriate sectional file (either paper or electronic). Certificates of analyses must be maintained at the lab if the manufacturer has them available (in either hard copy or electronic format). It is the responsibility of the person receiving the supplies to seek out the certificates of analysis if they do not arrive with the items. The certificates must be labeled with the unique traceability code. For original containers of standards, reagents, reference materials, chemicals, media, etc., if an expiration date is provided by the manufacturer or vendor it must be recorded on the container.

1.18.4. Verification and Evaluation of Supplies

It is the responsibility of the individual user of supplies, reagents, and consumable materials to verify that the supplies comply with requirements specified in METHOD SOPs. An example would be checking blanks on autosampler tubes that come from a vendor. The records of these verification checks would be maintained along with the normal data output from the instrument that is used. Individual METHOD SOPs also state specific grades of reagents, standards, or chemicals required for the procedure and the reception and storage requirements for reagents, standards, and chemicals.

If goods or supplies are received that do not meet requirements, are damaged, or orders are incomplete, Purchasing must be notified promptly so that they can follow up with the vendor.

1.18.5. Approved Vendor Criteria

The criteria for approval of vendors may include:

- Acceptable historical performance as determined by the verification and evaluation procedure noted above or in specific METHOD SOPs.
- Acceptable reliability and robustness as required by the application are met by instrumentation and equipment.
- Specific applications may require the vendor to hold certification by third parties.
- Acceptable use by other labs with applications similar to ours.
- Acceptability by UW Purchasing and WSLH Purchasing
- All details of vendor acceptability beyond what is noted here will be in section supplements of this QA Manual or in SOPs.

1.18.6. Approved Vendor List

The approved vendor list (O:/ drive) contains vendors commonly used by the sections covered in this QA Manual. Other vendors are used occasionally, and information about them can be found either in the section supplements or in individual SOPs. The approved vendor list is reviewed annually by analytical

sections and WSLH Purchasing.

1.19. Management Review of the Quality System

The WSLH Associate Director of Non-Clinical Testing will review the quality system spelled out in this manual annually, and a report will be written. The report will include: suitability of our policies and procedures, reports from supervisors, a review of important findings from internal audits, major corrective actions that took place in the past year, a review of any external audit reports, any problems with PT samples that need to be addressed, changes in the volume or type of work performed by the sections, a review of client feedback and complaints, and other relevant factors. For details, please see EHD DIV-WIDE GENOP 023 "Procedure for the Management Review of the Quality System." A schedule for the Management Reviews can be found at O:\Teams\EHD QC Team\Schedules

1.20. Internal Audits & Data Review

1.20.1. Internal Audits:

Internal audits address all elements of the quality system along with environmental testing activities as related to each specific section. Internal audit findings are summarized in the annual management review document.

Internal audits are conducted annually according to EHD DIV-WIDE QA 120, "Internal Audit Procedures." The purpose of internal audits is to help meet quality goals such as:

- Ensure that procedures specified in SOPs and regulatory methods are being followed.
- Promote consistent practices across all areas of the section.
- Ensure that the section is meeting requirements of regulating agencies (e.g. TNI, USEPA, and Wis. DNR).

Internal Audits will be conducted by the Quality Assurance (QA) Coordinators or designees. They will be done annually or when corrective or preventative actions reveal a need for one. Internal audits consist of two parts: a system internal audit and a group/series of method internal audits. All accredited methods will be audited. Non-accredited methods may also be audited.

- System internal audits are a general review of each section's quality system.
- Method internal audits look at one method or a group of methods in greater detail.

Internal audit reports, including findings/deficiencies, will be generated. There are templates for the audits in O:\SOP\EHD\Division Wide\Final. Corrective actions in response to the internal audit report will be coordinated by the supervisor and reported back to the QA Coordinator. In some cases an

occurrence management report will be filed. If any of the findings of the internal audit casts doubt on the validity of client results, the client will be notified, in writing, within one month of the findings.

A schedule for internal audits can be found at O:\Teams\EHD QC Team\Schedules

1.20.2. Data Review:

Some data calculations are housed within the LIMS and are performed when results are entered. All data is reviewed by a second person before it is released. Review of data is documented in the LIMS with date/time and reviewer's initials. Note that for results calculated by spreadsheets or other software, the software calculations must be verified as giving accurate results before initial use of the software. This verification must be documented and kept on file. Once verified, the calculations must be secured to prevent unauthorized amendment (see EHD DIV-WIDE GENOP 040, "Protecting Excel and Access Data.") If a calculation cannot be secured (for example, by locking a cell), then some other means of preventing unauthorized amendment must be documented. Software used to record data must have some means of maintaining data integrity and preventing unauthorized amendment of those records. This could include printing out spreadsheets or using a track changes feature to document that data was not changed at a later date. Details on review of data for specific analytical tests can be found at the sectional level.
Quality control samples that are analyzed and entered in the LIMS are given a unique sample number. Those QC samples are related to all samples in the batch in LIMS. The LIMS does an evaluation of the QC sample results based on limits entered into the LIMS and displays pass or fail and the samples related to those QC samples.

1.21. Corrective and Preventive Action

1.21.1. Corrective Action for Non-Conforming Work

Generally, when any aspect of sample testing does not conform to our standard operating procedures (nonconforming work), including quality control procedures, corrective action will be promptly performed, starting with a correction of the issue, followed by root cause analysis, and documentation of the occurrence. Section-specific details of corrective action documentation within analytical runs can be found in the chapter of this manual dedicated to that section and in individual METHOD SOPs. Corrective actions will be performed by the analyst in consultation with the peer review auditor and their supervisor. Responsibility for the management and evaluation of non-conforming work rests with the supervisor. The supervisor is responsible for halting work or withholding test reports if deemed necessary and will authorize resumption of work. The supervisor may consult with the client (data user) to determine the usefulness of any qualified data and to determine a subsequent course of action. In some cases, more samples may need to be collected. If a data report has already been released when an error is discovered,

the client will be notified as soon as possible and an amended report will be released once the issue has been resolved. All communications with clients will be documented and archived using e-mail, telephone logbooks, written records, or Occurrence Management Reports (through Footprints software). If the non-conformance of work casts doubt on the laboratory's compliance with its own policies and procedures or compliance with TNI standards, an internal audit will be performed.

1.21.2. Corrective action for departures from policies, procedures & quality control

Generally, when departures from documented policies, procedures and quality assurance occur corrective action will be promptly performed and documented. Section-specific details of corrective action documentation can be found in the supplemental plan of this manual dedicated to that section and in individual METHOD SOPs. Section-specific corrective action procedures identify the person responsible for assessing each QC data type and initiating and recommending corrective action. The treatment of a data set, the reportability of test sample results, and the use of appropriate laboratory-defined data qualifiers is outlined in section-specific methods. Departures from policies and procedures and out-of-control situations and their subsequent corrective actions are documented through the use of occurrence management reports (through Footprints software). If the departures from documented policies, procedures and quality control cast doubt on the laboratory's compliance with its own policies and procedures or compliance with NELAC standards, an internal audit will be performed.

1.21.3. Permitting Departures from Documented Policies and Procedures

Invariably there will be exceptions to the policies and procedures documented and referenced in this QA Manual where corrective action as noted above does not resolve the problem. If an analyst is unsure about how to proceed, they should ask their supervisor or quality assurance coordinator. Any decision to proceed with work that does not conform to standard procedures must be approved by a supervisor or quality assurance coordinator. The supervisor may consult with the client (data user) or scientific experts to determine the usefulness of any qualified data and to determine a subsequent course of action. Decisions must be documented.

1.21.4. Preventive Action

Preventive action is essential in providing accurate, reproducible, reliable data. Preventive action is necessary to ensure that equipment and all quality systems are functioning properly and to prevent potential occurrences. If needed improvements or nonconformities arise, actions are taken to ensure that future occurrences are prevented. Use of the Occurrence Management reports will allow for the identification and implementation of further preventive actions. Preventative action is routinely implemented by the laboratory staff. Preventative action includes (but is not limited to):

- Reviewing operational procedures
- Reviewing occurrence management reports
- Reviewing QC data for trends
- Conducting periodic instrument maintenance
- Reviewing instrument logs for problems
- Reviewing customer (internal & external) comments and complaints
- Reviewing PT results
- Reviewing staffing and training needs
- Performing DOCs

1.21.5. Occurrence Management (OM) Reports

The Wisconsin State Laboratory of Hygiene utilizes Footprints software for tracking Occurrence Management Reports. Guidelines for use of Occurrence Management Reports for documentation of corrective action include when there is a non-routine QC failure that cannot be resolved within the analytical batch or a systemic problem that needs to be tracked over time. Examples of occurrences entered are PT failures, customer complaints, reporting errors, HIPAA violations, etc. Our internal web site includes a link to the Footprints software for Occurrence Management Reports.

There are two lab-wide SOPs that document the use of Occurrence Management forms:
LABWIDE GENOP 706, Occurrence Reporting Procedure
LABWIDE GENOP 707, Occurrence Management System Policy

The procedure for review, monitoring, and close-out of Occurrence Management forms is detailed in LABWIDE GENOP 707. For testing under the quality system as documented in this QA Manual (1.1), open Occurrence Management Reports are discussed at section staff meetings or at the EHD QA team meeting. This allows dissemination of information and encourages progression of corrective actions and follow-up activities.

For occurrences associated with TNI-accredited testing, a root cause analysis must be conducted and documented in the root cause tab on the OM form. Where applicable, follow-up monitoring must be conducted and documented in the OM form. Whenever possible, link all supporting documentation to the OM form in the attachments tab.

Documentation of occurrences must be made by the person discovering the problem, their supervisor, or their QA representative. The documentation must be made as soon as possible after discovery, and at most within a week. Follow-up action taken, monitoring results, and root cause determinations must be documented within the OM form. Documentation of these processes must also be completed in a timely

manner, and at most within a week of the action taken.

OM training: Training consists of reading LABWIDE GENOPs 706 and 707. All employees of EHD must document this training by filling out and signing the WSLH Occurrence Management System Awareness Attestation form (available on the Intranet—hover over the Regulatory & Compliance drop-down list, choose the Quality Management button, then click on the Quality Tools tab). The completed attestation statement must be given to the supervisor, who will make a copy for the employee's personnel training file, and send the original to HR. Also see section 1.10 of this QA Manual.

Any questions regarding the use of the Occurrence Management Reports in Footprints can be directed to any quality assurance coordinator.

1.21.6. Opportunities to Improve Processes

The WSLH offers a Quality and Safety Award to recognize and celebrate staff efforts to find improvements to the work environment, processes, or experience for staff, or the delivery of services to our customers. Staff can nominate co-workers at any time through the internal website. Awards are presented twice per year.

1.22. Reporting Analytical Results

Analytical documentation

Reporting of data from the LIMS can be accomplished through either electronic transfer, printed, faxed or emailed version of the result report.

WSLH Laboratory Reports generated by Horizon LIMS for the Environmental Health Division contain:

- Address and contact information for the Agriculture Drive laboratory site and the responsible managers
- A title, unique report ID, and pagination
- Customer name and address
- Sample identification and information related to sampling if applicable
- Analytical method used and date of analysis
- Test results along with appropriate units, LODs, LOQs, comments, qualifiers, test conditions, and additional information as necessary
- Statements indicating compliance with applicable standards, applicability of test results, and instructions for reproducibility of reports.
- Pending tests, if results are reported prior to the completion of all requested analysis

1.22.1. Amendments to Test Reports

- If a report is amended after issue, the amended report will meet all of the requirements listed above.

- The amended report will refer to the original report ID.
- The amended report will include a note stating why it was amended.

Drinking Water Requirement for Chemical Testing

If an MCL (Maximum Contaminant Level) for an analyte regulated under ch. NR 809 has been exceeded for a PWS (Public Water Supply) sample, the water supply facility must be notified within 48 hours of completing the analyses [Wis. Admin. Code (06/29/2021) NR 149.47(1)(f)]. The analysis is considered complete when a batch is finalized in Horizon after the peer review audit. Applicable MCLs will be listed in SOPs. Horizon LIMS automatically flags results above the applicable MCL.

1.23. Subcontracting of Environmental Tests

If there is an emergency such as an instrument break-down where accredited work would need to be subcontracted, there are several considerations and requirements:

- DNR work certified under NR 149 must only be subcontracted to another lab certified under the same code for the specific field of certification.
- Drinking water compliance samples must only be analyzed by laboratories certified by the EPA or via reciprocity by an authorized state.
- TNI-accredited work must only be subcontracted to another lab that complies with TNI standards for the specific field of accreditation.
- The WSLH must advise the data users of the subcontract arrangement. This must be documented.
- The WSLH must request proof from the subcontractor of compliance with applicable standards (e.g. a certificate and scope of accreditation). These documents must be kept on file.
- The final WSLH report must include the name of the sub-contracted laboratory (and Wisconsin Facility Identification Number—FID, if applicable) performing any subcontracted work. The subcontractor's full report must be made available to the data user if requested.

1.23.1. Subcontract Lab Contingency Lists for Emergencies

- Labs certified under Wisconsin Administrative Code NR 149 (lists include scopes of accreditation): https://dnr.wisconsin.gov/topic/labCert/certified-lab-lists
- Labs accredited under TNI (searchable by location and scope): https://lams.nelac-institute.org/Search
- Labs certified by EPA for drinking water: https://www.epa.gov/dwlabcert/contact-information-certification-programs-and-certified-laboratories-drinking-water

1.24. Proficiency Testing Sample Procedures

All proficiency testing samples are analyzed in the same manner as used for routine environmental samples, including:

- same staff
- Same methods (ensure method codes match NELAP scope of accreditation, where applicable)
- Same procedures
- Same equipment and facilities

The lab independently analyzes proficiency testing samples and reports the results according to the following rules:

- Does not sub-contract the analysis nor analyze another lab's PT sample
- Does not communicate with another lab about a PT sample prior to the close of the study
- Does not attempt to obtain the PT results from the proficiency testing provider prior to close of the study

Each section is responsible for ordering, analyzing, and reporting PT samples and results that they need to maintain accreditation. See section supplements and associated SOPs for details.

Each section is responsible for performing appropriate corrective action for PT failures and documenting the corrective action in Occurrence Management reports.

Each section must notify the non-clinical QA coordinator of any PT failures.

Each section is responsible for organizing and maintaining PT records including bench sheets, instrument printouts, data calculations, data summary reports, and PT study report forms according to the applicable RDA.

1.25. Method References

1.25.1. Policy

Approved editions of reference methods will be used when required by State of Wisconsin administrative codes or federal rules.

1.26. General References

1.26.1. WSLH Lab-wide Procedures and Policies

Lab-wide policies and references to University of Wisconsin and State of Wisconsin policies and procedures that apply to the WSLH are found in the WSLH Employee Handbook (see intranet home page). In addition, lab-wide approved SOPs are stored in the OnBase (Web-client) document management platform (see 1.11.1).

1.26.2. EHD Division-wide Procedures and Policies

Division-wide approved SOPs are stored at in the OnBase (Web-client) document management platform.

1.26.3. WSLH Board Policies and Procedures

Policies and Procedures of the WSLH Board are stored on the extranet at:

http://www.slh.wisc.edu/about/board/

1.27. Major Changes

1.27.1. Ver.2 (OnBase)

Section	Change
	Began version tracking table
	Updated header, footer
	Updated signature page
1.2.1	Added info re. updates of subsequent versions of the QA Plans after 08/2022
1.3	Added "Quality is everyone's responsibility" as per APHL
1.4	Updated the organization of EHD and staff names
1.4	Deleted specific info re. TNI technical managers (left reference)
1.6	Added cross-ref. to RDA (section 1.12), deleted outdated references
1.10.1, 1.10.8	Added WSLH Statement of Ethical Expectations (WSLH-WIDE POLICY 001)
1.10.5	Updated documentation of training to Canvas app
1.11	Updated for OnBase Timers & Notifications module
1.12	Updated RDA info and hyperlink
1.12.3	Deleted, "…for up to three years."—No longer policy
1.15.1	Added Copies of WSLH executed contracts are maintained and available by contacting the Contract and Grant Administrator Specialist in the WSLH Office of Finance (deleted the previous link to a shared drive).
1.15.3	Added item to be considered for new work: desired records retention period
1.15.4	Changed link to access the actual memo rather than the webpage (suggestion by Kevin Karbowski)
1.17.4	Updates to Computers section as directed by Allen Benson
1.18	Updated Purchasing section on the advice of Mark Conklin and Tina Mathew, WSLH Purchasing
1.19	Updated position name
1.20	Added link for internal audit templates
1.21.6	Added new section for opportunities to improve processes (verbal suggestion by TNI auditor Bill Hall, May, 2023).