

Glen Canyon National Recreation Area Environmental Laboratories 2016 Quality Manual

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Glen Canyon National Recreation Area Aquatic Resources Management Branch

Glen Canyon Environmental Laboratories:
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Appendix: Colilert® Analytical Method

1.0 Recipients of the Quality Manual

Utah Department of Health:

Bureau of Laboratory Improvement

Utah Department of Environmental Quality:

Division of Water Quality

Arizona Department of Environmental Quality:

Division of Environmental Quality

Distribution within Glen Canyon National Recreation Area:

Superintendent (Billy Shott)

Chief, Resources Management (Ken Hyde)

Chief, Aquatic Resources Management (Mark Anderson)

Laboratory Director (Mark Anderson)

Quality Assurance Officer (Mark Anderson)

Wahweap Laboratory Supervisor (Julie Murchie)

Bullfrog Laboratory Supervisor (VACANT)

Public Health Beach Monitoring Technical Director (Mark Anderson)

Microscopy Technical Director (Julie Murchie)

Molecular Technical Director (VACANT)

Wahweap and Bullfrog Laboratory Staff

Safety Manager (VACANT)

Environmental Specialist (VACANT)

National Park Service Water Resources Division:

System Support Office

2.0 Scope

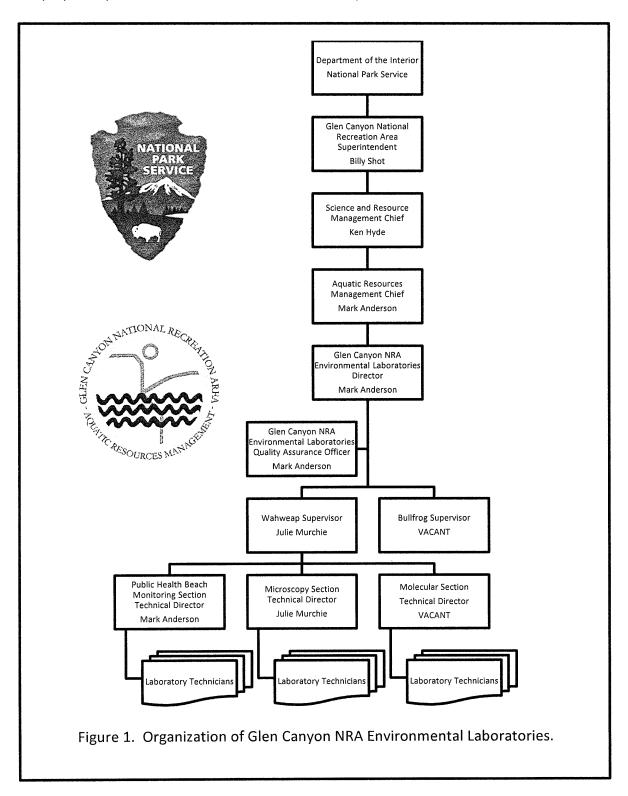
This Quality Manual serves to guide National Park Service (NPS) personnel working in the Glen Canyon National Recreation Area (NRA) Environmental Laboratories to the meet requirements for laboratory certification under Volume 1 of The NELAC (National Environmental Laboratory Accreditation Conference) Institute (TNI), inform interested parties of the Glen Canyon NRA Environmental Laboratories quality system, and produce high quality laboratory results.

3.0 Management Responsibilities

3.1 Organization

Glen Canyon NRA Environmental Laboratories are part of Glen Canyon National Recreation Area, a National Park Service unit in the Department of the Interior. Glen Canyon National Recreation Area was created in 1972 by Public Law 92-593. The Superintendent of Glen Canyon National Recreation Area is Billy Shott. Glen Canyon NRA Environmental Laboratories is part of the Aquatic Resources Management Branch in the Resource Management and Science Division (Figure 1). Laboratory personnel consist of a Laboratory Director, Quality Assurance Officer, Laboratory Supervisors, Laboratory Section Leads or Technical Directors, and Laboratory Technicians. Glen Canyon NRA Environmental Laboratories consist of two separate operating facilities, the Glen Canyon

— Wahweap and Glen Canyon — Bullfrog laboratories. Both laboratories are certified through the Utah Department of Health, Bureau of Laboratory Improvement as Environmental Testing Laboratories meeting TNI guidelines. Accreditation certificates are displayed in prominent locations in each laboratory.



3.2 Quality System

Glen Canyon NRA Environmental Laboratories maintain a quality system based on the required elements of The NELAC Institute (TNI). The laboratory documents its policies, systems, programs, procedures, and instructions to the extent necessary to assure high quality test results. Quality system documentation is available, understood, and implemented by all laboratory personnel.

Quality Policy Statement

The laboratory's management is committed to good professional practice and to the quality of its testing. The objective of the Quality Manual is to document the policies and procedures needed to maintain the highest possible standard of service. All personnel involved with Glen Canyon NRA Environmental Laboratories are required to adhere to the policies and procedures contained in the Quality Manual. Laboratory management is committed to complying with The NELAC Institute (TNI) Standards.

Data Quality Commitments

- To achieve the most accurate test results possible.
- To utilize consistency of technique.
- To maintain a thorough quality assurance and quality control program to provide confidence in test results.
- To maintain thorough documentation of all data associated with laboratory operations.

Data Quality Objectives

Through the Quality Assurance/Quality Control (QA/QC) program outlined in this Quality Manual and the Standard Operating Procedures, a high level of confidence is assured in the accuracy and precision of the data produced by Glen Canyon NRA Environmental Laboratories. The QA/QC methods used to ensure high data quality include: Proficiency Tests, Demonstrations of Capability Tests, Internal Audits for Precision, personnel requirements, regularly scheduled equipment maintenance, procedures for corrective and preventive actions, quality assurance audits of field and laboratory records, and maintaining high ethical standards.

3.3 Document Control

Glen Canyon NRA Environmental Laboratories maintain procedures to control all documents that form the quality system. All documents are approved by the Laboratory Director and Quality Assurance Officer prior to issue. Current editions of documents are distributed to all laboratory personnel and are available in the laboratories. Obsolete documents are removed from all points of use to assure against unintended use, and a copy is retained in a marked folder by either the Laboratory Director or Quality Assurance Officer. All documents are identified with a date of issue or revision identification, page numbering, and the total number of pages. Glen Canyon NRA Environmental Laboratories does not change documents after they have been issued, but will create a new issue if corrections are needed. Electronic copies of documents will be renamed by updating either the issue

number of the document or including the date as part of the document name. The Quality Manual and Standard Operating procedures are reviewed at least annually to ensure continuing suitability and compliance with applicable requirements.

Associated SOP's:

Public Health Beach Monitoring Section

SOP 5.09: Quality Assurance Audits, Managerial

Review, and the Quality Manual

SOP 5.10: SOP Creation and Revision

Microscopy Section

SOP 4.07: Quality Assurance Audits and Managerial

Review

SOP 4.09: SOP Creation and Revision

Molecular Section

SOP 7.03: Quality Assurance Audits and Managerial

Review

SOP 7.06: SOP Creation and Revision

3.4 Review of Requests, Tenders and Contracts (Reserved)

3.5 Subcontracting of Environmental Tests (Reserved)

3.6 Purchasing Services and Supplies

Glen Canyon NRA Environmental Laboratories control the purchase of materials, products, and services used for environmental testing. Supplies are only purchased from reputable vendors. If applicable to the supply, the vendor is required to provide a Certificate of Analysis, Quality Control Certificate, or Certificate of Performance. All laboratory supplies must be purchased with the Laboratory Director's knowledge.

Supplies are delivered to the Glen Canyon Wahweap Warehouse or the Glen Canyon Headquarters where they are received by a clerk. Laboratory personnel are notified as soon as possible to pick up supplies and take them to the laboratory. All supplies are inspected and, if acceptable, are marked as received, dated, and initialed by laboratory personnel before being entered into the supply log. All reagents must have an expiration date. If one is not provided by the manufacturer, then one must be assigned to the product. All chemicals must be inspected at least annually for deterioration.

Associated SOP's:

Public Health Beach Monitoring Section

SOP 5.03: Maintaining a Laboratory Supply Log and Chemical Inventory

Microscopy Section

SOP 4.04: Maintaining a Laboratory Supply Log and Chemical Inventory

Molecular Section

SOP 1.03: Maintaining a Laboratory Supply Log and Chemical Inventory

3.7 Service to the Client

The Laboratory Director is responsible for soliciting client feedback from the Aquatic Ecologist at least once annually. Record of soliciting client feedback and any response from the client are maintained for at least five years in the Complaint and Correspondence Log.

Associated SOP's:

Public Health Beach Monitoring Section

SOP 5.08: Complaint and Correspondence Policy

Microscopy Section

SOP 4.08: Complaint and Correspondence Policy

Molecular Section

SOP 7.05: Complaint and Correspondence Policy

3.8 Complaints

The Laboratory Director is responsible for documenting and addressing formal complaints against the Glen Canyon NRA Environmental Laboratories. Records of any complaints and the Laboratory Director's response are maintained for five years.

Associated SOP's:

Public Health Beach Monitoring Section

SOP 5.08: Complaint and Correspondence Policy

Microscopy Section

SOP 4.08: Complaint and Correspondence Policy

Molecular Section

SOP 7.05: Complaint and Correspondence Policy

3.9 Control of Nonconforming Environmental Testing Work

A Corrective Action Report must be immediately completed for all nonconforming work and the Laboratory Director and Quality Assurance Officer must be informed. An evaluation of the significance and acceptability of the nonconforming work will be made by the Laboratory Director and Quality Assurance Officer. All accepted nonconforming work is flagged in the data report as a mechanism to notify the client. Work that is not accepted is not included in the data report and the client is notified. In the event of an out-of-control situation where it is judged that the results possess no scientific value, work is stopped until the situation can be corrected. The Laboratory Director is responsible for authorizing work to resume. If previous reported data is or may be impacted, the client is immediately notified.

Associated SOP's:

Public Health Beach Monitoring Section

SOP 5.07: Corrective and Preventive Actions

Microscopy Section

SOP 4.05: Corrective and Preventive Actions

Molecular Section

SOP 7.04: Corrective and Preventive Actions

3.10 Corrective Actions

When nonconforming work, departures from the Quality Manual, and equipment malfunctions occur, a Corrective Action Report is immediately initiated and the Laboratory

Director and Quality Assurance Officer must be informed. Actions are appropriate to the magnitude and risk of the problem. Transcription errors may be corrected as described in SOP 5.01: Recording Data. All Corrective Actions must be addressed and resolved within one month of identification of the problem and creation of the associated Corrective Action Report.

Associated SOP's: Public Health Beach Monitoring Section

SOP 5.07: Corrective and Preventive Actions

Microscopy Section

SOP 4.05: Corrective and Preventive Actions

Molecular Section

SOP 7.04: Corrective and Preventive Actions

3.11 Preventive Actions

Preventive Action is a pro-active process to identify opportunities for improvement in laboratory operations and the quality system. It is primarily a mechanism to make corrections before problems have occurred.

Associated SOP's: Public Health Beach Monitoring Section

SOP 5.07: Corrective and Preventive Actions

Microscopy Section

SOP 4.05: Corrective and Preventive Actions

Molecular Section

SOP 7.04: Corrective and Preventive Actions

3.12 Control of Records

The Glen Canyon NRA Environmental Laboratories maintain unequivocal, accurate documentation of all laboratory activities. These records allow the historical reconstruction of laboratory activities. Records are maintained for all equipment, analytical methods, Quality Assurance/Quality Control Activities, and the identity of personnel involved in sampling, sample receipt, and testing and data reviews. When documents are updated, they are assigned a new issue number or the title is updated to reflect the date of the document. All computers that store data pertinent to the Glen Canyon NRA Environmental Laboratories are maintained to ensure proper functioning and provided with the environmental and operating conditions necessary to maintain the integrity of the data. Glen Canyon NRA Environmental Laboratories use Microsoft® Office software to store electronic documents. Electronic documents are stored in the Aquatics directory on the Glen Canyon NRA network. Only staff of Glen Canyon NRA Environmental Laboratories has access to this folder. Final test reports and other sensitive information, is stored on the private drive of the Laboratory Director. This drive is not accessible to any other individuals. All network drives are backed-up routinely by Glen Canyon NRA Information Technology staff. New software packages will be tested and documented to be adequate before a change is made. Records are stored as hard copies in secure locations for at least 5 years at the Glen Canyon NRA headquarters. Access to records is provided to any interested party with oversight by either the Laboratory Director or Quality Assurance Officer. Access to archived information is documented with an access log. Should the Glen Canyon NRA Environmental Laboratories ever fail to exist, the National Park Service Archive System shall maintain all records produced.

Associated SOP's: Public Health Beach Monitoring Section

SOP 5.01: Recording Data **SOP 5.04**: Data Entry

SOP 5.09: Recording Data Quality Assurance Audits,

Managerial Review, and the Quality Manual

SOP 5.10: SOP Creation and Revision

Microscopy Section

SOP 4.01: Recording Data

SOP 4.02: Data Entry in Microsoft Access

SOP 4.07: Quality Assurance Audits and Managerial

Review

SOP 4.09: SOP Creation and Revision

Molecular Section

SOP 1.04: Recording Molecular Laboratory Data

SOP 1.04: Molecular Laboratory Data Entry

SOP 7.03: Quality Assurance Audits and Managerial

Review

SOP 7.06: SOP Creation and Revision

3.13 Internal Audits

At least annually, the Quality Assurance Officer conducts an internal audit to verify that the laboratory's quality system meets Utah Department of Health certification and TNI requirements. If audit findings cast doubt on test results, corrective action is taken and the Laboratory Director is notified. The Laboratory Director is responsible for notifying the client of the events that cast doubt on the validity of the results in a timely manner. Audit findings and associated corrective actions are documented.

Associated SOP's:

Public Health Beach Monitoring Section

SOP 5.09: Quality Assurance Audits, Managerial

Review, and the Quality Manual

Microscopy Section

SOP 4.07: Quality Assurance Audits and Managerial

Review

Molecular Section

SOP 7.03: Quality Assurance Audits and Managerial

Review

3.14 Management Reviews

The annual Managerial Review evaluates the continuing suitability and effectiveness of the Glen Canyon NRA Environmental Laboratories along with any changes or improvements to the program. It also serves to inform top management of the status of laboratory operations. Associated SOP's:

Public Health Beach Monitoring Section

SOP 5.09: Quality Assurance Audits, Managerial

Review, and the Quality Manual

Microscopy Section

SOP 4.07: Quality Assurance Audits and Managerial

Review

Molecular Section

SOP 7.03: Quality Assurance Audits and Managerial

Review

4.0 Technical Requirements

4.1 General

4.2 Personnel

Glen Canyon NRA Environmental Laboratories use personnel who are employed by Glen Canyon NRA. With approval of laboratory management, and with proper training and supervision, volunteers may also assist Glen Canyon NRA Environmental Laboratories. Personnel consist of a Laboratory Director, Quality Assurance Officer, Glen Canyon -Bullfrog Laboratory Supervisor, Glen Canyon - Wahweap Laboratory Supervisor, Technical Directors/Section Leads, and Laboratory Technicians. All laboratory personnel are qualified, properly trained, adequately supervised, and equipped for the positions they hold. All personnel have the authority and resources needed to discharge their duties and to identify the occurrence of departures from the Quality Manual, and to initiate actions to prevent or minimize such departures. All laboratory personnel, after training, are familiar with field and laboratory methods and procedures, the objective of their actions, and the assessment of the results. All laboratory personnel must prove their competency with a Demonstration of Capability before independently performing any certified methods and annually thereafter. Internal audits for precision check the precision of personnel analyzing the samples. It is the responsibility of the Laboratory Director and Quality Assurance Officer to ensure compliance with TNI standards

Generating information for the management of natural resources and protecting public health is the primary focus of the Glen Canyon NRA Environmental Laboratories. No financial or commercial gains could reasonably be attained by falsifying data due to the fact the client is the Glen Canyon NRA Aquatic Ecologist. To ensure that undue pressure does not adversely affect the quality of the laboratory results, all staff must sign a statement of ethics and commitment to the highest quality of laboratory results possible. Unethical behavior may lead to termination. In addition, all federal employees must sign appointment affidavits when they enter into federal service.

Associated SOP's:

Public Health Beach Monitoring Section

SOP 5.05: Laboratory Technician Training

Microscopy Section

SOP 4.03: Laboratory Technician Training

Molecular Section

SOP 1.00: Molecular Laboratory Technician Training

Laboratory Director: The Laboratory Director oversees the Glen Canyon NRA Environmental Laboratories. The Laboratory Director is ultimately responsible for the administrative oversight and overall technical operation of the Glen Canyon – Wahweap and the Glen Canyon - Bullfrog laboratories. It is required that the Laboratory Director make a documented on-site visit at least every 15 calendar days to each of the laboratories during periods of operation. If the Laboratory Director is unable to meet this commitment, another full-time staff member meeting the qualifications of Laboratory Director must be designated to perform this function temporarily. Furthermore, to the extent possible, daily communication must occur between the Laboratory Director and the Laboratory Supervisors and laboratory staff. The Laboratory Director must verify that personnel with appropriate educational and/or technical background perform all tests for which the laboratory is accredited. The Laboratory Director supervises the Quality Assurance Officer, Laboratory Supervisors, Leads/Technical Directors, and Technicians. The Laboratory Director handles and documents all complaints. The Laboratory Director or delegate writes the annual Managerial Review, ensures the proper acceptance and analysis of samples, and the quality of all results reported. All new work must be approved by the Laboratory Director to ensure that the laboratory has the appropriate facilities and resources. Minimum requirements for the Laboratory Director include a Bachelor's Degree in microbiology, biology, chemistry, environmental science, physical science, or a related field with a minimum of 16 college semester credit hours in general microbiology and biology and at least two years of experience in a laboratory that maintains suitable accreditation. Alternative suitable qualifications are listed in TNI Volume 1, Module 2, 4.1.6 through 4.1.7.2.

The Laboratory Director also meets the personnel requirements and serves as the Quality Assurance Officer in his/her absence. The Chief of Aquatic Resources Management or the Quality Assurance Officer may also serve as the Laboratory Director in their absence. The accrediting body, Utah Department of Health, Bureau of Laboratory Improvement, must be informed within thirty calendar days of permanent changes in key personnel.

Quality Assurance Officer: The Quality Assurance (QA) Officer oversees all quality assurance and quality control for the Glen Canyon NRA Environmental Laboratories. The QA Officer does not regularly analyze samples nor input original data into the computer database. The QA Officer serves as the focal point for quality assurance, overseeing and reviewing quality assurance data, objectively evaluating data, and performing independent assessments without outside influence. All aspects of sample handling, testing, and report collation and distribution are objectively overseen by the QA Officer with the purpose of

producing high quality results. The QA Officer has direct access to the highest level of management at which decisions are taken on laboratory policy and resources. The QA Officer must notify laboratory management of deficiencies in the quality system and is responsible for initiating, implementing, and monitoring corrective and preventive actions. The QA Officer performs monthly reviews of all work performed in the laboratory and annually reviews the latest versions of TNI Standards, Utah's Environmental Laboratory Certification Program documentation, and Standard Methods for the Examination of Water and Wastewater, completes laboratory certification applications, and creates and submits necessary changes to the Quality Manual in order to stay current with all laboratory requirements. The QA Officer must document Proficiency Testing, Demonstration of Capability for each laboratory employee, and Internal Audits for Precision. The QA Officer maintains and distributes the Quality Manual. The QA Officer must have documented training or experience in quality assurance procedures and be knowledgeable in the quality system as defined under TNI Standards. The QA Officer must also have knowledge of the approved methods the certified laboratory uses in order to allow verification that the certified laboratory is following the approved methods.

Laboratory Supervisor: Both the Glen Canyon – Wahweap and Glen Canyon – Bullfrog laboratories have a Laboratory Supervisor who is responsible for the day-to-day operations. The Laboratory Supervisor oversees all Leads and Technicians working in the respective laboratory and is responsible for the production and quality of all data reported by the laboratory. The Laboratory Supervisor must meet or exceed the minimum requirements of Laboratory Technicians and must also perform Laboratory Technician responsibilities

Section Lead/Technical Director: Each technical discipline within the laboratory has a Section Lead or Technical Director who oversees the technical operations within that discipline. The Section Lead must meet or exceed the minimum requirements of Laboratory Technicians and must also perform Laboratory Technician responsibilities

Laboratory Technician: The Laboratory Technicians perform all aspects of sample collection and analysis, equipment maintenance, and other duties as assigned. Laboratory Technicians must possess a high school diploma and receive specific, detailed, and documented training before performing any task unsupervised in the laboratory. Technicians are responsible for initiating and carrying out corrective and preventive actions. Technicians are responsible for maintaining accurate and current training records and providing updates to the QA Officer and Laboratory Director.

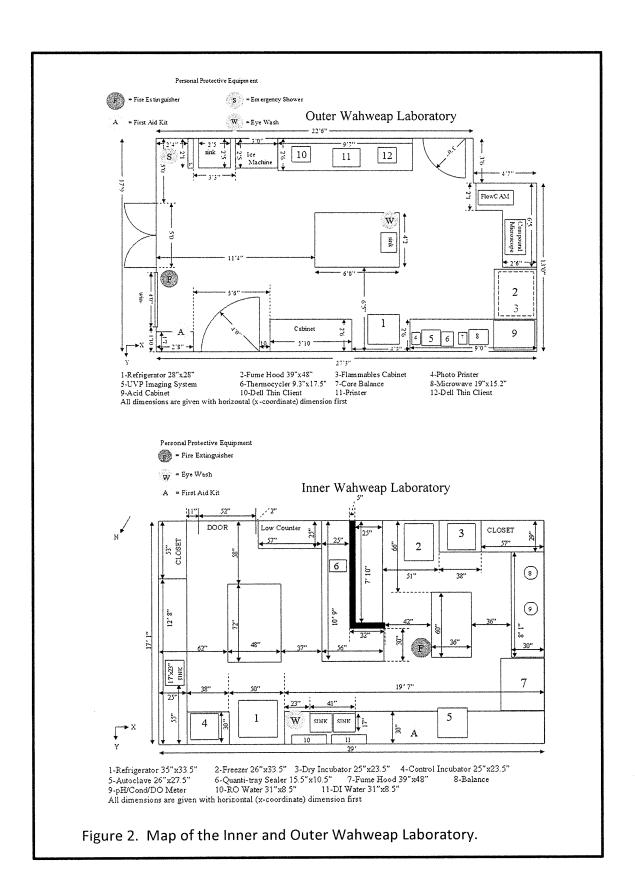
4.3 Accommodation and Environmental Conditions

The Glen Canyon – Wahweap laboratory is located in Wahweap, Arizona, in the National Park Service's Wahweap Maintenance Building next to the Boat and Vehicle Repair area. The laboratory has an area of approximately 530 square feet and has the capacity to accommodate several Technicians at one time. The Glen Canyon – Bullfrog laboratory is located in Bullfrog, Utah, in the National Park Service's maintenance area. The laboratory

has an area of approximately 150 square feet and has the capacity to accommodate two Technicians at one time.

The Glen Canyon NRA Environmental Laboratories meet the requirements incorporated by reference in Rule R444-14 authorized by Utah Code Section 26-1-30(2)(m) and TNI Volume 1, Module 2, 5.3 Technical Requirements – Accommodation and Environmental Conditions by:

- having suitable space, energy sources, lighting, heating and ventilation to allow for proper performance of the testing
- permitting the production of quality results by ensuring the unlikelihood of contamination and other variables that would adversely affect test results
- providing adequate work area for Technicians
- having controlled access (only laboratory staff have keys to the laboratories, and no additional personnel are allowed in the laboratories without approval from the Laboratory Director or QA Officer)
- separating incompatible tests, analyses, procedures, and materials
- maintaining separate areas for sample receipt, sample storage, chemical storage, waste storage, and data handling
- maintaining good housekeeping
- prohibiting plants, food, and drink in the laboratory work area



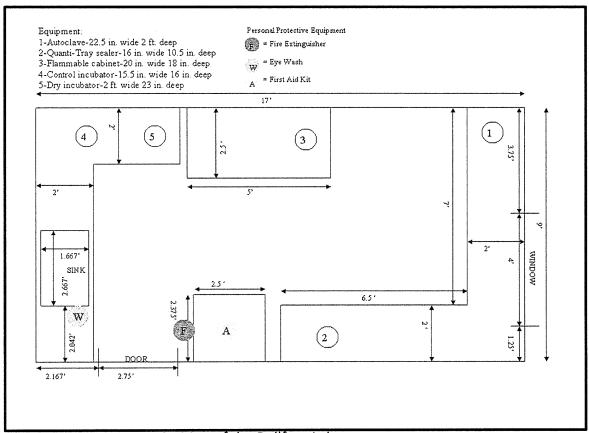


Figure 3. Map of the Bullfrog Laboratory.

4.4 Environmental Test Methods and Method Validation

Glen Canyon NRA Environmental Laboratories use appropriate methods and procedures for all tests and activities including sample collection, handling, transport, storage, preparation, and analysis.

4.4.1 Public Health Beach Monitoring Section Test Methods and Method Validation

Presently, Glen Canyon NRA Environmental Laboratories use the Colilert® Method, developed by IDEXX Laboratories, Inc., for *Escherichia coli* detection and enumeration. The Colilert® Method uses as a multi-well procedure to quantify *E. coli* concentrations as described in *Standard Methods for the Examination of Water and Wastewater*, 20th edition, Section 9223B2b (APHA 1998). The Colilert® Method has a minimum detection limit of 1 *E. coli* MPN (Most Probable Number)/100mL and a maximum detection limit of 2419.6 MPN/100mL. The Glen Canyon – Wahweap and the Glen Canyon – Bullfrog laboratories are certified by the Utah Department of Health (UDOH) - Bureau of Laboratory Improvement to use this method under the Clean Water Act, 9223B *E. coli – Chromogenic Technique*. Detailed sampling and laboratory procedures are described in the Glen Canyon NRA Environmental Laboratories Standard Operating Procedures (SOPs) and are summarized in the Colilert® Analytical Method, meeting TNI requirements.

Associated Documentation: Appendix – Colilert® Analytical Method

Proficiency Testing (PT): Glen Canyon NRA Environmental Laboratories conduct proficiency testing for certified methods at six month intervals. Environmental Resource Associates (1-800-372-0122) is the TNI approved Proficiency Test Provider. To the extent possible, the proficiency test is conducted by a Laboratory Technician who regularly processes laboratory samples in the same manner as real environmental samples. A Proficiency Test is a sample in which the MPN range is known to the Proficiency Test Provider, but is unknown to all laboratory personnel. The sample is analyzed by the laboratory and results of the test are submitted to the Proficiency Test Provider. The Proficiency Test Provider reports to both the laboratory and the accrediting authority whether test results were within an acceptable range.

Associated SOP's: Public Health Beach Monitoring Section SOP 4.10: Proficiency Testing.

Demonstration of Capability (DOC): Annually, laboratory personnel must demonstrate their ability to detect and enumerate *E. coli* by successfully performing a Demonstration of Capability before independently performing the Colilert® Method. A Demonstration of Capability must also be completed if there is a change in instrument type, or method. Analysts process, incubate, and analyze a sample with an established Most Probable Number range that is only known to the Quality Assurance Officer until the after test is completed by all personnel.

Associated SOP's: Public Health Beach Monitoring Section
SOP 4.12: Demonstration of Capability

Internal Audit for Precision: Monthly, analysis of the precision among all laboratory personnel is conducted by the Quality Assurance Officer. This is conducted by having all laboratory personnel independently determine MPN values from Quanti-Trays[®]. The audit passes if all of the Technicians' log transformed results are within ten percent of each other.

Associated SOP's: Public Health Beach Monitoring Section
SOP 4.11: Internal Audit for Precision.

Proactive Quality Assurance Program: The Glen Canyon NRA Environmental Laboratories proactive quality assurance program consists of the Quality Assurance Officer or Laboratory Director checking Technician work by recounting Quanti-Trays® at undisclosed times during the sampling season.

Associated SOP's: Public Health Beach Monitoring Section
SOP 4.13: Proactive Quality Assurance Program.

Control of Data: Procedures exist to ensure that all data are free from calculation and transcription errors, quality control measures are reviewed and evaluated before data are reported, and manual calculations are fully explained. Microsoft® Office software is used to store electronic copies of data and reports, in addition to hardcopies that are stored in the Laboratory Director's office. All computers and computer networks are

maintained in good working order by Glen Canyon NRA Information Technology staff. All data is stored in a secure directory assessable only to laboratory personnel.

Associated SOP's:

Public Health Beach Monitoring Section

SOP 5.04: Data Entry

SOP 5.09: Quality Assurance Audits, Managerial

Review, and the Quality Manual

4.4.2 Microscopy Section Test Methods and Method Validation

The Lake Powell Microscopy Laboratory uses appropriate methods and procedures for all tests and activities including sample collection, handling, transport, storage, preparation, and analysis. Presently, the Glen Canyon National Recreation Area Microscopy Laboratory uses a compound microscope and FlowCAM to visually analyze plankton samples for *dreissenid* veligers. These devices utilize cross-polarized light which illuminates birefringent *dreissenid* veligers and makes them clearly distinguishable from the rest of the plankton sample. Trained Laboratory Technicians should be able to identify the organism based on criteria such as size, shape, surface texture and appendages (Refer to Attachment D: Veliger, Ostracod, and Corbicula Comparison Chart). Detailed sampling and laboratory procedures are described in the Glen Canyon National Recreation Area Microscopy Laboratory's Standard Operating Procedures.

Demonstration of Capability (DOC): Annually, laboratory personnel must demonstrate their ability to detect the presence of dreissenid veligers in plankton samples by successfully performing a Demonstration of Capability before independently performing microscopy techniques. A Demonstration of Capability must also be completed if there is a change in instrument type or method. The QA Officer selects previously analyzed plankton samples and Technicians then use the compound microscope and FlowCAM to analyze the samples and quantify dreissenid veligers. The results are only known to the Quality Assurance Officer until the after test is completed by all personnel.

Associated SOP's:

Microscopy Section

SOP 3.02: Demonstration of Capability

Internal Audit for Precision: Analysis of precision among all laboratory personnel is conducted by the Quality Assurance Officer on a monthly basis. This is conducted by having all laboratory personnel independently determine the number of dreissenid veligers in a plankton sample. The audit passes if Technicians' results are similar.

Associated SOP's:

Microscopy Section

SOP 3.01: Internal Audit for Precision.

Control of Data: Procedures exist to ensure that all data are free from transcription errors. Quality control measures are reviewed and evaluated before data are reported. Microsoft° Office software is used to store electronic copies of data and forms, in addition to hardcopies that are stored in the Wahweap Water Laboratory. All computers and computer networks are maintained in good working order by Glen

Canyon NRA Information Technology staff. All data is stored in a secure directory accessible only to laboratory personnel.

Associated SOP's: Microscopy Section

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SOP 4.02: Data Entry

SOP 4.07: Quality Assurance Audits, Managerial

Review, and the Quality Manual

4.4.3 Molecular Section Test Methods and Method Validation

Glen Canyon NRA Molecular Laboratory uses appropriate methods and procedures for all tests and activities including sample collection, handling, transport, storage, preparation, and analysis. Detailed sampling and laboratory procedures are described in the Glen Canyon NRA Molecular Laboratory Standard Operating Procedures (SOPs).

Control of Data: Procedures exist to ensure that all data are free from calculation and transcription errors, quality control measures are reviewed and evaluated before data are reported, and manual calculations are fully explained. Microsoft Office software is used to store electronic copies of data and reports, in addition to hardcopies that are stored in the Laboratory Director's office. All computers and computer networks are maintained in good working order by Glen Canyon NRA Information Technology staff. All data is stored in a secure directory assessable only to laboratory personnel.

Associated SOP's:

Molecular Section

SOP 1.05: Molecular Laboratory Data Entry and

Storage

SOP 7.03: Molecular Laboratory Quality Assurance

Audits and Managerial Review

4.5 Equipment

The laboratory is furnished with all the items needed to achieve accurate test results and to perform quality control activities. All equipment is maintained in good working order on-site at the Glen Canyon NRA Environmental Laboratories. A Standard Operating Procedure exists for each piece of equipment detailing its use, operation, calibration, and Preventive maintenance requirements. Each piece of equipment also is properly documented and uniquely identified by a serial number and/or National Park Service property number. The documentation is kept in the equipment's respective laboratory in the Equipment Maintenance Log, or Autoclave Log. If a piece of equipment performs unsatisfactorily, the instrument is removed from service, tagged, and repaired with proper documentation, and all test results and quality controls are scrutinized. Equipment that has been repaired must be tested and/or calibrated prior to being returned to service. Through the use of a laboratory calendar, preventive maintenance is scheduled for each piece of equipment. Annually, all laboratory equipment is also inspected and calibrated, using NIST traceable references when applicable. Each piece of equipment is marked to indicate its calibration status. Equipment that is not within

acceptable calibration is either recalibrated or removed from service until it has been repaired or correction factors are established.

Associated SOP's: Molecular Section

SOP 7.01: Molecular Laboratory Demonstration of Capability and Internal Audit for Precision

Equipment Temperatures: The temperatures of the dry incubators, control incubators, refrigerators, and freezers must be within their respective proper ranges to insure quality data and suitable storage conditions. The temperature of any equipment which is in use (interacting with samples in terms of storage or incubation) must be monitored, even when personnel are not present. The temperature of all equipment is verified with a NIST traceable thermometer at least annually. Records of temperature verifications are maintained in the laboratory's Temperature Logbook.

Associated SOP's:

Public Health Beach Monitoring Section

SOP 3.12: Operation and Maintenance of Control

Culture Incubator

SOP 3.13: Dry Incubator Operation and

Maintenance

SOP 3.15a and 3.15b: Freezer Operation and

Maintenance

SOP 3.16a and 3.16b: Refrigerator Operation and

Maintenance

SOP 4.15: Thermometer Calibration

Molecular Section

SOP 6.18: Fisher Scientific Isotemp[®] Laboratory

Refrigerator

SOP 6.17: Fisher Scientific Isotemp[©] Laboratory

Freezer

SOP 6.20: Thermometer Calibration

4.6 Measurement Traceability

Whenever a piece of equipment goes outside the direct control of the laboratory, its performance, including any calibrations, must be checked and shown to be satisfactory before it is returned to service. All equipment is suitable to provide for the uncertainty of measurement needed. Where applicable, measurements are traceable to national standards. Procedures exist to document the suitability of all reference standards and materials, the transport and storage of reference standards and materials, and to purchase, receive and store consumable materials.

Associated SOP's: Public Health Beach Monitoring Section

SOP 5.03: Maintaining a Laboratory Supply Log and

Chemical Inventory

Microscopy Section

SOP 4.04: Maintaining a Laboratory Supply Log

and Chemical Inventory

Molecular Section

SOP 1.03: Maintaining a Molecular Laboratory

Chemical Supply Inventory

Thermometer Calibrations: The thermometers used in dry incubator, control culture incubator, and the refrigerator are calibrated on an annual basis. Calibration is checked against a standard traceable to the National Institute of Standards and Technology (NIST) within the range of use. If necessary, recorded temperatures are adjusted with a correction factor. Records of thermometer calibration are maintained in the Equipment Maintenance Logbook.

Associated SOP's: Public Health Beach Monitoring Section

SOP 5.06: Equipment Documentation **SOP 4.15**: Thermometer Calibration

Molecular Section

SOP 6.00: Molecular Laboratory Equipment

Documentation

SOP 6.20: Thermometer Calibration

Certificates of Quality: The vendor is required to provide a Certificate of Analysis, Quality Control Certificate, or Certificate of Performance for certain items. This minimizes the amount of in-house testing that must be conducted by Glen Canyon NRA Environmental Laboratories. Current test methods require a certificate of quality for Colilert® media, lauryl sulfate tryptose (LST) broth, sterile deionized water, IDEXX sterile vessels, Quanti-Tray®/2000, Colilert® Quanti-Tray®/2000 Comparator, and bacterial reference stocks. Certificates of Quality are stored in the Quality Control Logbook.

Media and Reagents: All media and reagents used in the Glen Canyon NRA Environmental Laboratories are of analytical reagent grade and are commercially purchased ready-to-use. Media and reagents are stored and used according to the manufactures instructions. All media must be accompanied with a Certificate of Quality documenting its acceptability. To be acceptable, all media must have documentation indicating the manufacturer, lot number, type and amount of media received, date of receipt, expiration date, and pH (for media).

Associated SOP's:

Public Health Beach Monitoring Section

SOP 5.03: Maintaining a Supply Log and Chemical

Inventory

Microscopy Section

SOP 4.04: Maintaining a Supply Log and Chemical

Inventory

Molecular Section

SOP 1.03: Maintaining a Molecular Laboratory

Chemical Supply Inventory

Bacterial Reference Stocks: New reference stocks are obtained at least annually from a traceable collection and are accompanied with suitable documentation. In order to maintain healthy stocks, new working stocks are made every three weeks during the sampling season and no more than five sequential working stocks may be made from a reference stock. Records of the stock preparations are recorded in the Quality Control Logbook of each laboratory.

Associated SOP's:

Public Health Beach Monitoring Section

SOP 4.02: Inoculation of Stock Cultures for Positive

Sterile Deionized Water: Sterile deionized (DI) water is purchased commercially or from another laboratory. A Certificate of Quality must document that the water is sterile and in accordance with Table 9020 II: Quality of Reagent Water Used in Microbiology Testing from *Standard Methods for the Examination of Water and Wastewater*, 20th edition. Certificates of Quality are stored in the Quality Control Logbook. An expiration date must be assigned to the sterile deionized water by Glen Canyon NRA Environmental Laboratories if one has not been provided by the manufacturer. If the expiration date is assigned by Glen Canyon NRA Environmental Laboratories, it will be 18 months from the date of receipt of the water.

Public Health Beach Monitoring Section Sample Vessels: All sample bottles are from IDEXX Laboratories Inc. and are provided with a certificate of performance that certifies the vessels meet requirements for sterility and full-line accuracy. IDEXX Laboratories uses a gravimetric method to determine full-line accuracy.

Labware: Glen Canyon NRA Environmental Laboratories only uses disposable labware to conduct the certified test method. All disposable labware must be discarded immediately following use.

Documentation and Labeling: The dates of receipt, opening, and expiration of consumable materials are recorded in the chemical inventory in the Supply Logbook and on the containers of consumable supplies. For appropriate supplies, certificates of analysis, or equivalent records, are maintained in the Quality Control Logbook. Procedures for documenting supplies were previously described in Section 3.6 Purchasing Services and Supplies of this Quality Manual. Records are maintained on all reagent,

standard, and reference material preparation. All prepared materials are uniquely identified and are traceable to purchased stocks. Prepared materials must contain the preparer's initials, date of preparation, and expiration date.

Associated SOP's: Public Health Beach Monitoring Section

SOP 5.03: Maintaining a Laboratory Supply Log and Chemical Inventory

Microscopy Section

SOP 4.04: Maintaining a Laboratory Supply Log and Chemical Inventory

Molecular Section

SOP 1.03: Maintaining a Molecular Laboratory Chemical Supply Inventory

4.7 Sampling

Detailed sampling procedures are contained in the Glen Canyon NRA Environmental Laboratories Standard Operating Procedures (SOPs). These SOPs must be followed exactly. If the client requires any deviation from these procedures, a reference to the technique followed must be made on all documentation associated with the sample and be approved by the Laboratory Director and Quality Assurance Officer. Records of all relevant information associated with all samples must be recorded on a Field Data Form.

Associated SOP's: Public Health Beach Monitoring Section

SOP 1.01: Site Selection Criteria and Routine Site List

SOP 1.02: Preparations for Field Sampling

SOP 1.03: Field Sampling Techniques

SOP 1.04: Sample Preservation, Custody, and

Holding Times

SOP 1.15: Sample Bottle Labeling

SOP 1.16: Random Site Selection

Microscopy Section

SOP 1.01: Site Selection

SOP 1.02: Preparations for Field Sampling

SOP 1.03: Field Sampling Techniques

SOP 1.04: Sample Bottle Labeling

SOP 1.05: Plankton Sample Preservation

SOP 2.03: Random Site Selection

Molecular Section

SOP 2.01: Plankton Sampling Site Selection

SOP 2.02: Plankton Field Sampling Techniques

SOP 2.03: Plankton Sample Bottle Labeling

SOP 2.04: Random Plankton Sampling Site selection

Using ArcMap

4.8 Handling of Samples

The laboratory has procedures for the transportation, receipt, handling, protection, storage, retention, and disposal of samples contained in the laboratory's SOPs.

When samples arrive in the laboratory, a Sample Tracking and Check-In Form must be completed. Samples are stored away from any potentially contaminating sources to prevent cross contamination.

For microscopy, samples collected in the field and preserved in 70% ethanol are immediately put into the flammables cabinet in the Wahweap Laboratory. They are to remain stored in the cabinet unless they are being processed. When the outer laboratory's flammables cabinet becomes full, the samples may be moved into the larger flammables cabinet in the inner laboratory. After analysis, processed samples may be condensed and put into smaller labeled glass vials for long term storage.

Associated SOP's:

Public Health Beach Monitoring Section

SOP 1.04: Sample Preservation, Custody, and

Holding Times

Microscopy Section

SOP 1.05: Plankton Sample Preservation

Molecular Section

SOP 2.02: Plankton Field Sampling Techniques **SOP 3.01a**: Plankton Sample Concentration –

Filtering

SOP 3.01b: Plankton Sample Concentration –

Centrifugation

SOP 3.02a: DNA Extractions – MoBio – Veligers **SOP 3.02b**: DNA Extractions – Qiagen – Adult Mussel

Tissue

SOP 4.00: Polymerase Chain Reaction Set-Up **SOP 5.01**: Sub-Cell GT Systems Agarose Gel Electrophoresis Operation and Maintenance

4.9 Assuring the Quality of Environmental Tests in Public Health Beach Monitoring

Every batch of samples processed for *Escherichia coli* enumeration must contain field blanks, positive controls, and negative controls. These controls ensure sterility of technique and that test conditions are conducive and selective for *E. coli* growth. Records of the test controls are maintained with the Water Quality Data Logbooks. Field blanks are samples of sterile deionized (DI) water processed to detect possible contamination during field sampling and handling. A field blank must be transferred before the first sample and after every tenth sample is collected in the field. Positive controls are produced in the laboratory from cultures of *E. coli*. Negative controls are produced from cultures of *Klebsiella pneumoniae* and *Pseudomonas aeruginosa*. Every batch of samples must contain positive and negative controls. New reference stocks of *E. coli*, *Klebsiella pneumoniae*, and *Pseudomonas aeruginosa* are obtained at least annually from a

recognized national collection, organization, or manufacturer recognized by the TNI Accrediting Body and stock certification is maintained. Working stocks are made from the reference stocks every three weeks during the sampling season and no more than five working stocks per laboratory may be made from a reference stock. Records of the culture inoculations are recorded in the Culture Log in the Quality Control Logbook of each laboratory.

Associated SOP's:

Public Health Beach Monitoring Section

SOP 1.03: Field Sampling Techniques

SOP 4.02: Inoculation of Stock Cultures for Positive

and Negative Controls

SOP 4.09: Colilert® Controls

SOP 5.03: Maintaining a Supply Log and Chemical

Inventory

4.10 Reporting the Results

Results are reported accurately, clearly, unambiguously, and objectively. Glen Canyon NRA Environmental Laboratories are in-house laboratories. The sole client of the laboratory is the Glen Canyon National Recreation Area. Final test reports are stored as electronic files on the Laboratory Director's P: drive and are provided to the Aquatic Ecologist. Additionally, hard copies of test reports are securely stored along with all field and laboratory records associated with the results in the Laboratory Director's office.

Associated SOP's:

Public Health Beach Monitoring Section

SOP 5.01: Recording Data

SOP 5.04: Data Entry

Microscopy Section

SOP 4.01: Recording Data

SOP 4.02: Data Entry in Microsoft Access

Molecular Section

SOP 1.04: Recording Molecular Laboratory Data

SOP 1.04: Molecular Laboratory Data Entry

5.0 References

- APHA. 1998. Standard Methods for the Examination of Water and Wastewater, 20th Edition. American Public Health Association, Washington D.C.
- Glen Canyon NRA. 2015. Superintendent's Compendium of Designations, Closures, Permit Requirements and Other Restrictions Imposed under Discretionary Authority. Glen Canyon National Recreation Area, Page, AZ.
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- USEPA. 1986. Ambient Water Quality Criteria for Bacteria 1986. EPA-440/5-84-002.

 U.S. Environmental Protection Agency, Office of Research and Development,

 Microbiology and Toxicology Division and Office of Water Regulations and

 Standards, Criteria and Standards Division, Washington, DC.
- USEPA. 2000. Draft *Implementation Guidance for Ambient Water Quality Criteria for Bacteria -- 198*6. January 2000. EPA-823/D-00-001. U.S. Environmental Protection Agency, Office of Water, Washington, DC.
- Utah Department of Health. July 1, 2005. Rule 444-14: Rules for the Certification of Environmental Laboratories. http://www.rules.utah.gov/publicat/code/r444/r444-014.htm, April 28, 2006.