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Washington, DC 20374-5065

NFESC

Special Report

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NAVY INSTALLATION RESTORATION CHEMICAL DATA QUALITY MANUAL (IR CDQM)

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NAVY INSTALLATION RESTORATION CHEMICAL DATA QUALITY MANUAL (IR CDQM)

This manual replaces previous guidance issued as “Navy Installation Restoration Laboratory Quality Assurance Guide”, NFESC Interim Guidance Document, dated February 1996.

Original edition September 1985
Revised June 1986
Revised June 1988
Revised February 1996
Revised September 1999

Executive Summary

Background

Restoration testing is conducted pursuant to requirements in the following laws; Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA); Superfund Amendments and Reauthorization Act of 1986 (SARA); Resource Conservation and Recovery Act (RCRA). Navy's compliance with the procedural and substantive requirements of CERCLA and SARA, as well as regulations issued under these acts or by state law, are defined in the Navy/Marine Corps Installation Restoration Manual.

The goal of the Navy Installation Restoration (IR) Program is to reduce, in a cost-effective manner, the risk to human health and the environment from hazardous substance contamination resulting from past Department of Defense (DOD) activities in the U.S. and its territories. The IR Program may include the following phases: preliminary assessment/site inspection (PA/SI), remedial investigation/feasibility study (RI/FS), remedial design/remedial action (RD/RA) and long-term monitoring. During any of these phases, collection and analysis of environmental or waste samples may be required to support project decisions or satisfy regulatory requirements.

Due to the direct impact of data quality on important remediation project decisions, the Naval Facilities Engineering Command (NAVFACENGCOM) authorized the development and implementation of an analytical quality assurance/quality control (QA/QC) program in September 1984. NAVFACENGCOM tasked the Naval Energy and Environmental Support Activity (NEESA), now the Naval Facilities Engineering Services Center (NFESC), with implementing the program. This and other programs that support environmental clean-up are funded by the Environmental Restoration, Navy (ER, N) and Base Realignment and Closure (BRAC) through NAVFACENGCOM's Engineering Field Divisions/Engineering Field Activities (EFDs/EFAs).

Purpose

The purpose of the IR QA/QC program is to promote consistent and dependable high quality data.

The purpose of this manual is to define the Navy's elements of chemical data quality management and to provide Navy IR Program participants and contributors with a clear definition of program requirements and guidance.

Scope

This manual contains requirements and guidance[1] designed to ensure that Navy sample collection and laboratory analysis activities generate data that meet project requirements, and are technically defensible and legally admissible. This manual implements NAVFACENGCOM policy and serves as the NFESC QA Program Plan. This manual is a revision of and replacement for the Navy Installation Restoration Laboratory Quality Assurance Guide, Interim Guidance Document, dated February 1996.

Nothing in this manual relieves any program participant from the responsibility of complying with contract requirements or with applicable federal, state or local regulations. NFESC should be notified of substantive technical conflicts between this manual and other applicable requirements.

Program participants with questions regarding the information provided in this manual are encouraged to contact the NFESC QA/QC representative, Ms. Patricia Moreno at DSN 551-1659 or commercial (805) 982-1659.

[1] Clarification of *mandatory* (requirements) and *optional* (guidance) program elements are provided on page iv.

Program Introduction

Navy IR projects funded by ER, N and BRAC (excluding compliance) are subject to the requirements outlined in this manual. Throughout this document, "IR projects" will be used to describe both the ER, N and BRAC (excluding compliance) projects. Navy EFDs/EFAs manage IR projects with a wide range of scope and objectives. The Navy IR QA/QC program is designed to accommodate project-specific quality requirements, and to ensure that all sampling and analysis activities are conducted under consistent and reasonable protocols. The design of the program is responsive to the diversity of remediation projects and characterization needs.

Definitions

Relevant definitions for terms used in this manual are provided in the Glossary. Requirements that are mandatory for program participants are specified throughout this manual by the use of the terms "shall" or "must," and required elements are identified below as a "mandatory program element." Information provided as guidance is specified by the terms "should" or "may," and elements implemented at the direction of the EFD/EFA are identified "project specified program element." All program elements are implemented at the direction of the EFDs/EFAs.

Program Overview

All Navy IR projects require a comprehensive and multifaceted approach to QA/QC in order to achieve and document attainment of appropriate quality for the intended data usage. Elements, which shall be applied to assist in generating data of known quality are described in more detail in Section 2.0, and include:

Data quality objectives (DQO) - (mandatory program element)

Laboratory assessment - (mandatory program element)

- Ongoing proficiency testing program - (mandatory program element)

Project assessment - (project specified program element)

- Project document assessments - (project specified program element)
- Field assessment - (project specified program element)

Data quality assessment (DQA) - (project specified program element)

Data validation - (project specified program element)

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Acronyms

ASQ	American Society for Quality
BRAC	Base Realignment and Closure
CBI	Confidential Business Information
CCV	Continuing Calibration Verification
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
CFR	Code of Federal Regulations
CLEAN	Comprehensive Long-Term Environmental Action Navy
CLP	Contract Laboratory Program
CNO	Chief of Naval Operations
CoC	Chain of Custody
CRDL	Contract Required Detection Limit
CRQL	Contract Required Quantitation Limit
CRM	Certified Reference Material
CV	Coefficient of Variation
DQA	Data Quality Assessment
DQO	Data Quality Objective
EDL	Environmental Detection Limit
EFA CHES	EFA Chesapeake
EFA MW	EFA Midwest
EFA NW	EFA Northwest
EFD/EFA	Engineering Field Division/Engineering Field Activity
EPA	Environmental Protection Agency
ER, N	Environmental Restoration, Navy
FOIA	Freedom of Information Act
FS	Feasibility Study
GC	Gas Chromatograph
GC-MS	Gas Chromatography - Mass Spectrometer (interfaced together)
GPC	Gel Permeation Chromatography
GFAA	Graphite Furnace Atomic Absorption (Spectroscopy)
HPLC	High Performance Liquid Chromatography
ICB	Initial Calibration Blank
ICP	Inductively Coupled Plasma (Atomic Emission Spectroscopy)
ICP/MS	Inductively Coupled Plasma/Mass Spectrometry
ICV	Initial Calibration Verification
IR	Installation Restoration
ISO	International Organization for Standardization
LANTDIV	EFD Atlantic Division
LC	Liquid Chromatograph
LCS	Laboratory Control Sample
LCSD	Laboratory Control Sample Duplicate
LD	Analytical Detection Limit
LIMS	Laboratory Information Management System
MB	Method Blank
MDL	Method Detection Limit
MQL	Method Quantitation Limit

MRL	Method Reporting Limit
MS	Matrix Spike
MSD	Matrix Spike Duplicate
NAVFACENGCOM	Naval Facilities Engineering Command
NFESC	Naval Facilities Engineering Service Center
NIST	National Institute of Standards and Technology
NORTHDIV	EFD Northern Division
OSHA	Occupational Safety and Health Administration
PA	Preliminary Assessment
PACDIV	EFD Pacific Division
PDS	Post Digestion Spike
PT	Proficiency Testing
PBMS	Performance Based Measurement System
QA	Quality Assurance
QMS	Quality Management System
QC	Quality Control
R	Average Recovery
RA	Remedial Action
RAC	Remedial Action Contract
RD	Remedial Design
RCRA	Resource Conservation and Recovery Act
RI	Remedial Investigation
RL	Reporting Limit
RPM	Remedial Project Manager
RSD	Relative Standard Deviation
S	Standard Deviation
SAP	Sampling and Analysis Plan
SARA	Superfund Amendments and Reauthorization Act
SI	Site Inspection
SOP	Standard Operating Procedure
SOUTHDIV	EFD Southern Division
SOUTHWESTDIV	EFD Southwest Division
SOW	Statement of Work
TCLP	Toxicity Characteristic Leaching Procedure
TIC	Tentatively Identified Compounds
USACE	United States Army Corps of Engineers
USACE HTRW-CX	U.S. Army Corps of Engineers Hazardous, Toxic & Radioactive Waste, Center of Expertise
WP	Water Pollution
WS	Water Supply

1.0 General Information

1.1 Roles and Responsibilities

1.1.1 Navy

The Navy has oversight responsibility for contractors that provide services to installation restoration (IR) projects.

1.1.1.1 Naval Facilities Engineering Command (NAVFACENGCOM)

The Naval Facilities Engineering Command (NAVFACENGCOM) is responsible for providing direction, policy guidance, and funding for QA/QC issues. NAVFACENGCOM reviews appeal claims submitted by a laboratory concerning both the Naval Facilities Engineering Service Center's (NFESC) decision to deny, suspend, or revoke a laboratory's acceptance, and, NFESC's decision to declassify confidential business information (CBI).

1.1.1.2 Engineering Field Divisions/Engineering Field Activities (EFD/EFA)

The EFDs/EFAs have oversight responsibility for their contractors' performance, and compliance with the Navy's IR quality assurance/quality control (QA/QC) program. The EFDs/EFAs also:

- Determine whether the contractor or NFESC will be tasked with executing laboratory assessments.
- Provide funds to agencies for laboratory and project assessments.
- Designate an individual to address environmental QA/QC issues and coordinate QA/QC efforts with NFESC to maximize resources and minimize duplication.
- Collaborate with NFESC on the acceptance of laboratories for use in support of IR projects.
- Serve as the IR project manager.
- Determine the extent to which non-mandatory project assessments should be performed.
- Review laboratory assessor qualifications and pre-approve them with the concurrence of NFESC.
- Review project assessor, data quality assessor, and data validator qualifications and approve them.

1.1.1.3 Naval Facilities Engineering Service Center (NFESC)

The NFESC is the IR QA/QC program manager and will serve as a central agency for QA/QC program administration. NFESC shall:

- Be the central repository for information pertaining to laboratory assessments.
- Manage the proficiency testing (PT) program for all laboratories assessed in support of the Navy IR QA/QC program.
- Review laboratory assessment documentation for conformance with Navy standards contained in this manual.
- Perform an annual review of EFDs/EFAs' QA/QC systems as outlined in the Navy's internal protocol document (to be developed).
- Develop and update QA/QC documents as needed.
- Ensure assessor qualifications and performance meets the requirements of the IR Program.
- Execute laboratory assessments as requested by the EFDs/EFAs.
- Collaborate with EFDs/EFAs on the status of laboratories, including decisions to accept, deny, suspend, or revoke a laboratory's status in support of IR projects, and issue appropriate letters.
- Track the status of laboratories in the program and distribute monthly status reports to the EFDs/EFAs.
- Collaborate with the EFDs/EFAs to determine the validity of a CBI claim, in accordance with federal and state law.

1.1.2 Contractors

Contractors who provide environmental services for Navy IR projects are responsible for ensuring that their data collection and reporting activities and the associated activities of their subcontractor(s), comply with Navy's QA requirements as defined in this manual. Contractors shall:

- Ensure that laboratories they nominate and sponsor are fully aware of the responsibilities and requirements under this program.
- Ensure that assessments are performed independently and are free from conflict of interest.
- Execute laboratory assessments at the direction of the EFD/EFA.
- Provide an assessment documentation and a letter of recommendation to the EFD/EFA when proposing a laboratory.
- Provide documented evidence of successful corrective action for deficiencies that may be identified by Navy's verification assessment.
- Seek input from parties (i.e., laboratories and other subcontractors) involved in sampling and analysis planning and execution, to ensure that appropriate methods are selected.

1.1.3 Assessment Organizations

Organizations performing evaluations in accordance with this manual (i.e., laboratory assessment organizations, project document assessors, field assessors, data validators, data quality assessors) shall ensure that each assessor or validator:

- Is familiar with standards of ethical conduct as detailed in Appendix A.
- Signs a statement certifying that there is no conflict of interest as detailed in Appendix A.
- Complies with all applicable requirements of this manual.

Specific information on assessor qualifications can be found in the appropriate appendix (e.g., Appendix B for laboratory assessors).

1.1.4 Laboratories

Laboratories providing analytical data for IR projects are responsible for ensuring that their data collection and reporting activities and the associated activities of their subcontractors comply with Navy's IR QA/QC requirements as defined in this manual.

To be accepted for use in the Navy's IR Program, all laboratories must:

- Successfully complete a laboratory assessment in accordance with Appendix B[2.]
- Meet the laboratory requirements as detailed in Appendix C.
- Meet all specified deadlines; nonconformance may result in termination of reviews under the IR Program at the discretion of the EFD/EFA.
- Allow the Navy to perform follow-up assessments on an announced or unannounced basis.
- Comply with the PT program as detailed in Appendix D.
- Designate staff member(s) as the responsible party of record (e.g., laboratory director, technical director, laboratory supervisor, or laboratory manager).
- Provide NFESC and the EFD/EFA with written notification of significant changes to the laboratory. Notification must be made within 30 calendar days unless specified below. Failure to notify the Navy of significant changes may be cause for dismissal from the program, at the discretion of the EFD/EFA. Significant changes are those circumstances or conditions which may be reasonably expected to impact the capacity or capability of the laboratory, or which may impact the policy or implementation of the laboratory's QA/QC program. Examples of conditions which require notification include, but are not limited to:

[2] To the extent practical, results from other DOD assessment programs (i.e., Air Force and USACE), and NELAP may be used as outlined in Section 2.2 of Appendix B.

- Addition or removal of major analytical instrumentation.
- Addition or cancellation of multiple shift operations.
- Addition of new methods after successfully demonstrating method performance.
- Discontinuing use of specific methods.
- Receipt or loss of certifications from state agencies.
- Expansion, closure, or relocation of a laboratory facility (notification must be made to all appropriate parties at least 30 days prior to action).
- Change in majority ownership.
- Significant change in number of laboratory personnel (25 percent or more).
- Change in senior technical management or senior QA/QC staff.
- Major change in scope or approach of the QA/QC program.
- Debarment or suspension from federal contracting.
- Contract termination resulting from deficient performance.
- Cooperate with the requests and needs of the assessment team. As requested by the assessment team, laboratory management must:
- Provide the Navy or its representatives with access to documentation, materials, and records relevant to assessments.
- Allow the assessment team to observe operations and interview personnel.
- Appoint a staff member(s) to serve as an on-site escort for the assessment team.
- Comply with reasonable and valid requests from authorized data validators. As appropriate to the scope of the project under review, this may require the laboratory to provide copies of data or supporting documentation (e.g., superseded standard operating procedures (SOPs), standards records, training records, calibration files, etc.).

1.1.5 Other Agencies

In addition to the Navy and its representatives, government agencies with relevant interests in a given site or project may request to participate in the assessment. Participation will be permitted at the EFDs/EFAs' discretion to an extent commensurate with the agency's regulatory or programmatic interests.

1.2 Mobile Laboratories

The processes described in this manual are generally directed toward fixed laboratories. However, assessments can be performed through careful planning between the EFD/EFA and NFESC.

The following strategies concerning the use of mobile laboratories are recommended:

- Split or duplicate samples should be sent to a fixed/evaluated laboratory so the results from the mobile laboratory can be compared to those from the fixed laboratory. The number of samples to send will typically be about ten percent of the total number of samples taken.
- When field analytical methods are used to determine vertical and horizontal extent of contamination, a confirmation of the boundaries using fixed laboratories is recommended. A 20 percent confirmation is usually sufficient.

Unless specified in project planning documents, the contractor should determine the appropriate percentage of each type of sample required, and obtain concurrence from the Navy Remedial Project Manager (RPM).

The contract for the mobile laboratory should specify the analytical requirements, including Navy IR QA/QC requirements and reference the EPA's Good Laboratory Practices, and Good Automated Laboratory Practices.

1.3 Reciprocity

The Navy (NFESC and the EFDs/EFAs) will review assessments conducted by other Department of Defense (DOD) agencies (i.e., the Air Force Center for Environmental Excellence (AFCEE) or the United States Army Corps of Engineers (USACE), or under the National Environmental Laboratory Accreditation Program (NELAP). If these assessments meet Navy IR Program and project requirements, the assessment may be used as a basis for Navy acceptance and use. If requirements are not met, an assessment may be required. NFESC and the EFD/EFA shall collaborate to determine if an assessment is warranted. The information maintained by NFESC and EFDs/EFAs may be shared with other DOD agencies. The information shared may include assessment documentation and PT information.

1.4 Records Retention

Contributors to site records (i.e., contractors or subcontractors, laboratories, etc.) shall maintain, forward, or dispose of records as specified by the EFD/EFA. Site records are defined as "information collected during the IR response," and include electronic files. If a retention period is not specified, then the records shall be kept for a minimum of five years. At the end of the retention period, the Navy shall be afforded the opportunity to take possession of the records. Organizations that cease operations shall inform the

cognizant EFD/EFA at least 30 days prior to closure, and shall provide them the opportunity to receive any or all records related to Navy samples.

The Navy requirements for records retention are specified in Section 5.17 of the Navy/Marine Corps Installation Restoration Manual, dated February 1997. This section states that "Site records must be maintained for a period of 50 years following the discovery (by either the installation or the EFD/EFA)."

2.0 Elements of Chemical Data Quality Management

2.1 Data Quality Objectives (DQOs)

Data Quality Objectives (DQO) provide the objective basis for quantitative definition of project requirements. DQOs shall be developed and used to ensure that the amount, type, and quality of data obtained during a field sampling project are adequate to support project decisions with a known level of confidence. The EFD/EFA, as the project manager, shall decide who will be tasked to develop the DQOs and to what extent the DQOs shall be developed.

Detailed guidance on DQOs can be found in the most recent version of the EPA's Guidance for the Data Quality Objectives Process EPA QA/G-4. DQOs must be defined in project planning documents and must be approved by the responsible EFD/EFA prior to field sampling initiation.

2.2 Laboratory Assessment

Laboratory assessments may be executed by the contractor or NFESC and are performed at the direction of the EFD/EFA. When assessments are executed by NFESC, personnel other than those that conducted the assessment shall conduct oversight reviews (i.e., peer review). When laboratory assessments are warranted (see Appendix B Section 2.2 and 2.3) the protocols described in Sections 2.2.1 through 2.2.8 would be taken.

2.2.1 Nomination

Contractors who plan on using a laboratory for Navy IR projects must nominate the laboratory for assessment as outlined in Appendix B.

NFESC and the EFD/EFA will determine the scope of the assessment and the EFD/EFA will determine whether NFESC or the contractor will conduct the assessment.

If the Navy has already accepted a laboratory, and it is nominated for use of a method/matrix for which it has not been assessed, another full assessment may not be required. Instead, a more limited project assessment may be performed to evaluate the laboratory for project specific methods and matrices.

2.2.2 Assessment

The contractor or NFESC will perform a laboratory assessment in accordance with Appendix B. Requirements for laboratories performing analysis for IR projects can be found in Appendix C.

2.2.3 Proposal

A laboratory may be proposed for Navy use upon successfully completing an assessment conducted in accordance with Appendix B. To propose a laboratory for Navy use, the contractor or NFESC will submit the required documentation associated with the assessment to the appropriate EFD/EFA. The EFD/EFA will then review it and forward it to NFESC.

2.2.4 Acceptance

Assessment documentation will be reviewed by the EFD/EFA and NFESC to determine if the stated requirements have been met. A brief on-site verification assessment may be conducted to verify the information provided in the assessment report. If the requirements have been met, NFESC will issue a letter of acceptance and the laboratory will be accepted to perform analysis (on a method/matrix specific basis) under the IR QA/QC program Navywide for 24 months from the time the letter is issued. This acceptance does not override the need for state or other certifications that may be required, nor does it relieve any program participant from the responsibility of complying with contract requirements or with applicable federal, state, or local regulations.

2.2.4.1 Suspension

The Navy may suspend a laboratory's acceptance for up to six months to allow time to correct deficiencies or areas of noncompliance. If the laboratory is unable to correct the reason for the suspension, the laboratory’s acceptance status shall be revoked in part or in full.

2.2.4.2 Revocation

The Navy may revoke a laboratory’s acceptance status if the laboratory is unable to conform to the requirements presented in this manual.

2.2.5 Denial

If the requirements have not been met, the EFD/EFA and NFESC will identify the issues that are deficient and forward this information to the contractor or NFESC. It is the responsibility of the agency executing the assessment (Contractor or NFESC) to coordinate resolution of the issues identified, if the use of the laboratory is pursued.

2.2.6 Follow-up Assessments

Follow-up assessments may be conducted anytime during the 24-month acceptance period with the written concurrence of the EFD/EFA on an announced or unannounced basis and will be conducted to satisfy a limited set of objectives. The objective of a follow-up assessment is to verify that laboratory protocols continue to be implemented that effectively address findings presented in the

original assessment. The laboratory may be required to analyze PT samples as part of a follow-up assessment.

2.2.7 PT Program

Once accepted for use, a laboratory shall participate in the Navy's ongoing PT program.

Every six months the laboratory shall demonstrate method performance through the submittal of copies of PT results (including corrective actions as appropriate) from nationally recognized PT programs it participates in, including as applicable: EPA Contract Laboratory Program (CLP) Quarterly Blinds; EPA EMSL-LV Radiochemistry Intercomparison Program; and AFCEE PT samples. Navy will review the results and determine if PT samples are needed to demonstrate acceptable performance. The parameters subject to review are limited to those for which the laboratory has been accepted.

Samples for the ongoing PT program will usually be generated and scored by the U.S. Army Corps of Engineers Hazardous, Toxic & Radioactive Waste, Center of Expertise (USACE HTRW-CX). Specific information pertaining to the analysis, reporting and scoring of PT samples can be found in the USACE manual Validation of Analytical Chemistry Laboratories (EM 200-1-1, dated 1 July 1994 or the latest version).

More detailed information on proficiency testing can be found in Appendix D.

2.2.8 Reassessment

Six months prior to the end of the laboratory's acceptance period, NFESC with input from the EFDs/EFAs, will determine the appropriate course of action to take concerning reassessment of the laboratory. NFESC will notify the laboratory in writing of the Navy's decision. The Navy may elect to:

- Let the laboratory's acceptance status lapse if there are no IR projects that require the laboratory's services.
- Perform a complete reassessment.
- Perform an abbreviated review (e.g., paper review, brief Navy on-site, PT, etc.).
- Details of the reassessment process can be found in Appendix B.

2.3 Project Assessment

The EFD/EFA will determine if a project assessment should be conducted. For projects involving either high risk or low tolerance for risk, project assessments should be performed. Project assessments may be performed at various stages of a project in an effort to promote data quality. There are two types of project assessments described in

this manual:

- Project document(s) assessment
- Field assessment

Navy policy on field sampling must be considered when assessing project planning documents, proposed field operation documents and performing field assessments. Navy policy on field sampling is specified in the latest version of OPNAVINST 5090.1B, CH-1, Chapter 25 and is detailed in Appendix E.

2.3.1 Project Document Assessment

As the project manager, the EFD/EFA shall review project documents. Third party reviews of draft project documents minimize deficiencies that may adversely impact data quality, or hinder effective decision making. Project documents are reviewed to determine if:

- The basis for all planned sampling and analysis activities are technically and statistically valid
- The documents are technically defensible and Compliant with applicable quality standards and regulations
- The proposed sampling design will satisfy the project DQOs.

Project documents include:

- Planning documents
- Field operations documents
- Analytical plans

Appendix F provides more detail on conducting project document assessments.

2.3.2 Field Assessment

Field assessments are performed to provide objective evidence of field operations effectiveness and the representativeness of samples. Field assessments are detailed in Appendix G, with checklists for various field sampling activities provided as attachments.

The frequency and duration of oversight visits should be determined by the project technical team to ensure quality work and attainment of DQOs. Factors that may influence the decision to conduct a field assessment include:

- Magnitude of the sampling effort
- Severity or sensitivity of the environmental problem
- Concern about the field operations team

Any corrective action resulting from a field assessment will be executed at the discretion of the EFD/EFA.

2.4 Data Validation

Data validation is the systematic process for reviewing a body of data against a pre-established set of acceptance criteria defined in a project document (i.e., QA Project Plan). Data validation is performed to determine how well the project data meet the project acceptance criteria. The EFD/EFA, as the project manager, shall establish the required frequency and level of effort for data validation in project planning documents and should define the process through which the specific data intended for validation will be selected. The overall scope of a project's data validation effort may be relatively large for data critical to making decisions on projects with either high risk or low tolerance for risk. Conversely, limited, summary level, or no validation may be warranted for routine project data that will be used to support noncritical or low-risk decisions.

Data validation is conducted to ensure that:

- QC data provided in the laboratory deliverables are scientifically sound, appropriate to the method, and completely documented.
- QC samples are within established guidelines.
- The laboratory appropriately flags data.
- Anomalies in sample preparation and analysis are completely and accurately documented.
- Corrective action forms, if required, are complete.
- Holding times and preservations were documented.
- Data are ready for incorporation into the final report.
- The data package is complete and ready for data archive.

The EFD/EFA will decide who will execute the data validation. Appendix H provides detailed information on data validation.

2.5 Data Quality Assessment (DQA)

A Data Quality Assessment (DQA) is a process to determine whether the type, quantity, and quality of data needed to support remediation decisions has been achieved. The EFD/EFA, as project manager, is responsible for making the decision to use the DQA process. There are five steps in the DQA process:

- Review the DQOs and sampling design
- Conduct a preliminary data review.
- Select the statistical test.
- Verify the assumptions of the statistical test.
- Draw conclusions from the data.

Detailed guidance on DQA is outlined in the Guidance for Data Quality Assessment EPA G-9, dated February 1996 (or latest version).

2.5.1 Electronic Data Assessment

Electronic data assessment is designed to independently verify the data generated by an individual laboratory. This type of assessment is typically performed when there are concerns regarding the integrity of the data.

All of the raw data from a given batch is recalculated by the assessor and is compared to the results reported by the laboratory. The data quality is measured by laboratory compliance with the required methods and accepted laboratory practices for analysis and for data reduction.

Electronic data assessments can be performed only when a specific analytical instrumental raw data output has been stored electronically. In addition, a means to read the data must be made available. If an electronic data assessment is required, the laboratory will be required to provide copies of the relevant electronically stored files as well as references to the appropriate versions of the software used to generate the subject data packages.

Appendix A
Standards of Ethical Conduct

Standards of Ethical Conduct

Personnel who perform assessments must be free from conflict of interest that could affect the performance of an assessment. Prior to performing an assessment, each assessor must sign the Conflict of Interest Statement, provided as Attachment 1, certifying that no conflict of interest exists. This statement must be submitted to the appropriate EFD/EFA prior to beginning the assessment. The assessor must submit any supporting information as required by the EFD/EFA. Failure to provide this information could, at the discretion of the EFD/EFA, make the proposed assessor ineligible to perform the assessment.

Assessors must adhere to the following general standards for ethical conduct. Assessors shall:

1. Put forth honest effort in performance of their duties.

2. Act impartially and not give preferential treatment to any organization or individual.

3. Provide equal treatment to all persons and organizations regardless of race, color, religion, sex, national origin, age, or handicap.

4. Not use their position for private gain.

5. Not solicit or accept any gift or other item of monetary value from any laboratory, laboratory representative or other affected individual or organization doing business with or affected by the actions of the assessor's employer or the Navy.

6. Not hold financial interests that conflict with the conscientious performance of their duties[1].

7. Not engage in financial transactions using information gained through their positions to further any private interest.

8. Not engage in employment or activities, including seeking or negotiating for employment, that conflict with their duties and responsibilities as assessors[1].

9. Not knowingly make unauthorized commitments or promises of any kind purporting to bind their organizations or the Navy.

10. Avoid any actions creating the appearance that they are violating any of the standards for ethical conduct.

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[1] For purposes of interpreting standards #6 and #8, a conflict of interest is defined as a relationship with an entity that may impair the objectivity of the assessor in performing his or her responsibilities.

Appendix A
Attachment 1
Conflict of Interest Statement

Conflict of Interest Statement

As an assessor conducting assessments for the Navy Installation Restoration Program, I shall:

1. Put forth honest effort in performance of my duties.

2. Act impartially and not give preferential treatment to any organization or individual.

3. Provide equal treatment to all persons and organizations regardless of race, color, religion, sex, national origin, age, or handicap.

4. Not use my position for private gain.

5. Not solicit or accept any gift or other item of monetary value from any laboratory, laboratory representative or other affected individual or organization doing business with or affected by the actions of the assessor's employer or the Navy.

6. Not hold financial interests that conflict with the conscientious performance of my duties[1].

7. Not engage in financial transactions using information gained through their positions to further any private interest.

8. Not engage in employment or activities, including seeking or negotiating for employment, that conflict with my duties and responsibilities as assessors[1].

9. Not knowingly make unauthorized commitments or promises of any kind purporting to bind my organizations or the Navy.

10. Avoid any actions creating the appearance that I may be violating any of the standards for ethical conduct.

I certify that I have read and understand the Conflict of Interest Statement:

Signature	Date
Printed Name	Company

[1] For purposes of interpreting standards #6 and #8, a conflict of interest is defined as a relationship with an entity that may impair the objectivity of the assessor in performing his or her responsibilities.

Appendix B
Laboratory Assessment

Appendix B, Laboratory Assessment

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1.0 Laboratory Assessment General Information

Clear, forthright, and effective communication between the assessment team and the laboratory is the foundation for a successful assessment. All participants shall strive to ensure that nothing hampers direct, timely communication between the laboratory and the assessment team.

The laboratory, Contractor or Navy may terminate the laboratory assessment if there is sufficient reason. Sufficient reason to terminate the process may include, but is not limited to, a change in project requirements, or a failure of the laboratory to meet the protocol requirements (i.e., time requirements, access requirements) of the Installation Restoration (IR) Quality Assurance (QA) Program as detailed in the Navy Installation Restoration Chemical Data Quality Manual (Navy IR CDQM).

From the time the assessment is announced through the completion of the assessment process, the lead assessor is the designated contact for the assessment team. At the direction or designation of the lead assessor, another member of the assessment team may serve as a secondary contact for the assessment team. At the initiation of the assessment process, the laboratory shall also designate primary and secondary contacts. Typically, the laboratory's primary contact is a representative from the QA staff, or a member of management.

When assessments are executed by the Naval Facilities Engineering Service Center (NFESC), oversight reviews shall be conducted by personnel other than those who conducted the review (i.e., peer review).

1.1 Objectives

Assessments serve as an independent and systematic investigation. In general terms, the objectives of these investigations are to determine if program participants are complying with applicable requirements (detailed in Appendix C), are technically capable of acceptably performing the specified types of analytical testing, and to determine if the laboratory's QA Program and systems are being effectively implemented and have systematic controls and procedures necessary to ensure continued acceptable performance.

1.2 Scope

This appendix describes the process and approach for laboratory assessments conducted in accordance with the Navy IR CDQM.

1.3 Roles and Responsibilities

Information on the roles and responsibilities of laboratories, the Navy, and Contractors can be found in the Navy IR CDQM.

1.3.1 Lead Assessors

The lead assessor is ultimately responsible for all phases of the assessment and has designated authority to make decisions regarding conduct of the assessment, assignment of team members, and activities involving members of the team.

The lead assessor:

- Represents the assessment team in discussions and communication with laboratory management
- Directs the preparation of the assessment report
- Authorizes the assessment report and follow-on corrective action correspondence by signature
- Facilitates daily briefs and the exit brief

1.3.2 Assessment Team Members

Assessment team members shall:

- Comply with the requirements of this manual
- Plan and carry out their assessment assignments in an effective manner
- Document all assessment activities in an appropriate manner
- Safeguard information in the assessment program files
- Verify the effectiveness of corrective actions taken in response to the assessment

1.3.3 Standards of Ethical Conduct

Each assessor must be familiar with standards of ethical conduct and submit a signed statement declaring freedom from conflict of interest as detailed in Appendix A.

1.4 Assessor Qualifications

Assessor qualifications must be submitted to the Engineering Field Division/Enginering Field Activity (EFD/EFA) for review and approval prior to conducting assessments. The assessors must be familiar with confidential business information (CBI) considerations as detailed in Attachment 1.

1.4.1 Education

Assessors shall possess a bachelor's degree in a scientific discipline, or have equivalent education and experience in laboratory assessment or related fields.

1.4.2 Training

Assessors shall have training in QA program assessment skills and techniques. Competence may be developed through orientation, training programs (e.g., those training programs offered by RAB, A2LA, ASQ, etc.), and on-the-job training. All new assessors shall undergo a training period in which they work side-by-side with an experienced assessor for a minimum of four assessments or until the new candidate is judged proficient by NFESC and the EFD/EFA.

1.4.3 Knowledge

The assessor shall have detailed knowledge and understanding of the subject matter area(s) in which they conduct assessments of Navy IR QA requirements and the theory and application of current and technical issues, including the following:

- Federal and state regulations
- Techniques and procedures for assessing laboratory performance in accordance with ISO Guide 25, the on-site assessment checklists, and other applicable technical documents (e.g., ISO Guide 58)
- Laboratory record-keeping practices
- Laboratory data collection, reduction, analysis, and reporting techniques and requirements
- Analytical methods applicable to the fields of testing for which the laboratory is being assessed

1.4.4 Experience

Assessors shall be experienced professionals having relevant experience in an environmental laboratory in the areas they are reviewing.

1.4.5 Personal Attributes

Assessors should possess personal and professional attributes and characteristics that enable them to effectively and professionally perform their assessor duties. Assessors should:

- Be fair, adaptable to different personality styles, logical, firm and decisive
- Have good judgment and listening skills
- Demonstrate leadership, planning ability, and an ability to use investigative techniques
- Be detail oriented, have tenacity, and stay focused on scientific reason
- Clearly and effectively communicate in direct personal conversations with individuals that range from entry level technicians to senior members of management
- Discuss and present technical issues at a level commensurate with the disciplinary expertise of the individuals being interviewed
- Prepare written documents that describe and document assessment results and activities in a clear and impartial manner
- Have proven technical presentation skills that demonstrate the ability to successfully present, support, and defend a technical position

1.5 Lead Assessor

The lead assessor shall meet the assessor requirements identified above and, in addition, shall meet the requirements defined in the subsequent paragraphs.

1.5.1 Experience

Lead assessors shall have at least five years of relevant environmental laboratory experience.

1.5.2 Training

Lead assessors shall have relevant training in management skills.

2.0 Conducting Laboratory Assessments

This section presents the various protocols associated with a laboratory assessment. Flowcharts associated with these processes are provided at the end of this section.

2.1 Nomination

Contractors who plan to use a laboratory for Navy IR projects shall nominate the laboratory for assessment by forwarding a completed nomination form (Attachment 2) to the appropriate EFD/EFA.

The Contractor shall only nominate a laboratory for methods which the laboratory has satisfactorily demonstrated method performance in accordance with relevant Environmental Protection Agency (EPA) guidelines (40 CFR, Part 136, Appendix A). The Contractor shall request and review the information in the initial laboratory assessment package (Attachment 3) to substantiate the nomination. A copy of the documentation submitted by the laboratory shall accompany the nomination form submitted to the EFD/EFA.

2.2 Nomination Review

The EFD/EFA and NFESC will review the nomination, and determine the following:

- Whether or not an assessment of the laboratory is needed. Recent assessments conducted by other Department of Defense (DOD) agencies may be used as the basis for Navy acceptance and will be used if the scope of the assessments meet Navy IR Program and project requirements.
- Scope of services subject to review. The scope will establish whether the laboratory is being assessed for their capability to perform Contract Laboratory Program (CLP) methods, non-CLP methods, or a combination of methods. (A limited scope project assessment may be performed if the Navy currently accepts the laboratory for other methods.)
- Which agency will execute the assessment (i.e., the Contractor or NFESC).

2.3 Nomination Review Action

Within 14 calendar days of receiving the nomination form, the EFD/EFA will inform the Contractor and NFESC of the determinations made regarding the items presented in the bullets above.

2.3.1 Acceptance of Other DOD Agency Assessment Documentation

As previously stated, recent assessments conducted by other DOD agencies may be used as the basis for Navy acceptance and will be used if the scope of the assessments meet Navy IR Program and project requirements. In these instances,

the laboratory will be accepted for the period specified by the other agency. Upon acceptance, the laboratory shall participate in the on-going Proficiency Testing (PT) Program as described in Appendix D

2.3.2 Nomination Rejection

A laboratory nomination may be rejected if the information is incomplete or does not meet the requirements specified in this section or Appendix C. Rejected nomination packages will be returned to the Contractor without action. A letter issued by NFESC that summarizes the basis of the rejection will accompany the returned package.

2.3.3 Nomination Acceptance

If a laboratory nomination is accepted, an assessment in accordance with this manual shall be performed. The EFD/EFA will specify the agency that will be tasked with executing the assessment. The NFESC or Contractor chosen must then retain the services of assessors that meet the requirements of this manual. Assessor qualifications must be submitted to the EFD/EFA and NFESC for review and approval prior to conducting assessments. NFESC shall issue a letter advising the assessor of the approval, and maintain a central roster of approved assessors.

The following sections represent the protocol for conducting an assessment.

2.4 Initial Laboratory Assessment Package

The EFD/EFA authorizing the assessment shall forward a copy of the initial laboratory assessment package reviewed as part of the nomination process (Sections 2.1 and 2.2) to the NFESC or Contractor. This package will provide basic information needed by the assessors to initiate the assessment. The lead assessor (or the designated lead assessor) shall request any additional supporting information as required.

2.5 Areas of Review

The lead assessor shall assign areas of review to individual assessors. The reviews are performed to assess the laboratory's compliance with the requirements presented in Appendix C. Non-conformances identified as a result of the reviews will be documented in the laboratory assessment report as deficiencies (see Section 2.11 of this appendix). The assessors shall attempt to understand the nature of observed deficiencies (e.g., are they indicative of isolated individual problems, a lack of control systems, or a failure to effectively comply with existing systems). This effort is necessary so that the assessor can be in a position to evaluate the effectiveness of the laboratory's corrective action.

The scope of the assessment may influence whether certain elements are emphasized. However, the following sections present the various elements subject to review.

2.5.1 QA Program and Support Operations

The assessor responsible for review of support areas and the QA program shall at a minimum review the following general areas:

- Sample receiving, management, and custody control
- Data management (generation, reduction, reporting, review, and archival)
- Personnel training and qualification
- Method performance and validation
- QA Quality control (QC) program
- Document and record control
- Internal and external audits and proficiency assessments;
- Corrective action program
- Statistical QC
- Project management
- Laboratory equipment operation and maintenance
- Software QA: The scope of the software QA review element shall be tailored to reflect the scope of the laboratory's electronic data processing. As appropriate to the laboratory's capabilities, the review may address:
- Validation and continuing verification of software and data reporting spreadsheets
- Configuration control system for software versions and spreadsheets
- Documentation of data record changes

2.5.2 Methods

The assessment shall include the following as applicable to the method:

- Review of reference method SOPs
- Laboratory operations SOPs
- Record management system
- Procurement of items and services
- Initial demonstration and continuing demonstration of method performance certificates and supporting data
- Method performance data (method detection limits (MDLs), laboratory control samples (LCS), MS/MSD, and any other accuracy or precision data.)
- Proficiency testing results (if available)
- Data deliverable
- Interviews with analysts

The actual number and type of procedures subject to review will be commensurate with the services the laboratory provides or will provide to Navy. Additional methods and operations shall be reviewed as necessary to meet the scope of the evaluation as specified by the EFD/EFA authorizing the review.

2.5.2.1 CLP Methods

The primary objective of a CLP assessment is to determine if a laboratory has systems and practices in place to perform the documented version(s) of the statement of work (SOW) without deviation.

The assessors shall evaluate the laboratory's written instructional procedures (standard operating procedures (SOP)) to determine if execution of the procedures as written will comply with the SOW. The assessors shall also review bench-level practices and data records to determine which version(s) of the SOW is being used and documented by the laboratory. Inconsistencies between the SOW and the laboratory's procedures or practices shall be identified.

The majority of IR projects use SW-846 methods, CLP methods should only be reviewed if the project requires them.

2.5.2.2 Non-CLP Methods

Assessment of a laboratory's capability to acceptably perform non-CLP methods (e.g., SW-846 methods, Clean Water Act methods, Performance Based Measurement System (PBMS), or "specialty" methods and procedures[1]) requires a two step process:

- Review of the laboratory's SOPs (for technical adequacy)
- Determination of whether or not the laboratory's performance complies with the written policies and procedures, as evidenced by staff interviews and laboratory practices and records

PBMS[2] is a new proposal by the EPA to allow for more flexibility and technology innovation.

2.5.2.3 Organic

For organic methods and operations, the following, at a minimum, shall be reviewed:

- Gas Chromatograph (GC) volatile method(s)

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[1] Specialty methods are methods or procedures not considered routine in the environmental testing industry.

[2] PBMS is a set of processes wherein the data quality needs, mandates, or limitations of a program or project are specified, and serve as criteria for selecting appropriate methods to meet those needs in a cost-effective manner.

- Gas Chromatography–Mass Spectrometer (GC-MS) volatile method(s)
- Organic sample preparation and clean-up method(s)
- GC semivolatile method(s)
- GC-MS semivolatile method(s)
- GC fuel hydrocarbon method(s) and
- High Performance Liquid Chromatography (HPLC) polynuclear aromatic hydrocarbon (PAH) method
- HPLC explosive method

2.5.2.4 Inorganic

For inorganic methods and operations, the following at a minimum shall be reviewed:

- Acid digestion of waters and soils
- Inductively Coupled Plasma (ICP) analysis of digestates
- Graphite Furnace Atomic Absorption (GFAA) analysis of digestates
- Inductively Coupled Plasma/Mass Spectrometry (ICP/MS) analysis of digestates (if performed)
- Preparation and analysis for determination of mercury
- Trace ICP
- High salinity sample handling

2.5.2.5 General Chemistry

For general chemistry methods and operations, the following at a minimum shall be reviewed:

- Distillation and analysis methods for determination of cyanide
- Preparation and analysis methods for determination of hexavalent chromium (if performed)
- Method(s) for determination of percent moisture or percent solids
- Method(s) for determination of oil and grease, or total recoverable hydrocarbons
- Leachate/Extraction methods (i.e., Toxicity Characteristics Leaching Procedure (TCLP))
- Method(s) for determination of water quality anions (Cl^-, NO_3^-)
- Method for determination of total organic carbon and total organic halides

2.5.2.6 Specialty

For “specialty” methods, the assessor shall review the procedures performed by analysts, and determine if the practices are compliant with laboratory SOPs, technically valid, appropriately documented, and are

performed under the necessary systems and controls for the method. Examples of these types of "specialty" methods include:

- Radiochemistry
- National Oceanographic and Atmospheric Administration (NOAA) Status & Trends
- GC-MS low and high-resolution dioxin method(s) (if performed)
- Determination of alkyltins
- Analysis of biota
- Determination of contaminants at ultra-low trace levels
- Determination of high explosives

2.5.3 Project Documentation

In some circumstances a specific project may be associated with the laboratory assessment. Prior to initiation of on-site activities, the assessment team shall review a copy of the project documents (e.g., sampling and analysis plan, QA project plan) in order to assess the laboratory's capabilities to support the project. These documents shall also be reviewed to determine if actual laboratory practices and procedures conform to the project documents.

2.6 Pre-On-Site Review

The assessment team will identify significant deficiencies to the laboratory, and to the Contractor or NFESC in the form of an initial assessment recommendation letter, submitted within 14 calendar days of receiving the Initial Laboratory Assessment Package.

The letter shall also include a recommended course of action of either continuing or terminating the assessment process. The Contractor or NFESC shall forward a copy of the initial assessment recommendation letter to the EFD/EFA.

2.6.1 Continuation

If there are no significant deficiencies, the assessment will continue. Any deficiencies identified will be incorporated into the assessment report (Section 2.11). The laboratory shall address the deficiencies as a part of the corrective action phase (Section 2.13).

2.6.2 Termination

If the pre-on-site assessment indicates that the laboratory will not be able to meet Navy requirements, a summary of the issues shall be provided to the Contractor or NFESC. The summary shall be forwarded to the EFD/EFA, which will determine the appropriate course of action and notify the laboratory (via letter

generated by NFESC). It is the responsibility of the Contractor to reinitiate the process if use of the laboratory is pursued.

2.7 Proficiency Testing (PT)

2.7.1 Historical PT

A review shall be conducted of the PT results from the past two years. Appendix D provides more information regarding this review.

2.7.2 Current PT

As part of the assessment process, a laboratory shall successfully analyze PT samples, which test proficiency, and are reflective of the methods the laboratory will use on Navy samples. The assessing organization is responsible for providing the laboratory with PT samples obtained from a PT provider that is compliant with the provisions of Appendix D.

2.8 On-Site Assessment Schedule

Unless an assessment is intended as an unannounced on-site assessment, the lead assessor shall provide the laboratory with an advance copy of the proposed schedule and agenda for the on-site assessment. The laboratory shall be afforded the opportunity to comment on the proposed agenda, to identify any likely conflicts, and to propose a revision that better accommodates site-specific operations. Unless a laboratory's proposed agenda changes will impede the assessment team's ability to successfully complete the assessment in a timely manner, every effort shall be made to accommodate the laboratory's suggested revisions.

2.9 On-Site Assessment

A checklist[3] is to be used as a tool for conducting laboratory on-site assessments. Assessors must exercise professional judgment to determine if additional information (not covered by the checklist) is required to provide a complete assessment of a laboratory.

Deficiencies identified during the on-site assessment shall be discussed with staff members at the time the deficiencies are identified. If the responsible personnel have questions regarding the basis for a deficiency, the assessor shall be prepared to explain the applicable requirement and the evidence that indicates that the requirement is not met. If laboratory personnel believe that a deficiency is not valid and they can provide supporting evidence for their position, such evidence shall be presented to the assessor for consideration. The evidence shall be presented when the deficiency is identified. The assessor shall take the evidence into consideration prior to noting the deficiency.

[3] Navy will develop a checklist upon finalization of Enclosure (1) to Appendix C.

2.9.1 Safety Concerns

Assessors are required to comply with all applicable site-specific safety requirements, as defined by site management.

Laboratory practices that present safety concerns shall be presented to laboratory personnel at the time of observation and documented in the observation section of the assessment report.

2.9.2 Opening Meeting

The opening meeting serves as the initiation of on-site assessment activities. The laboratory's management is invited to participate to whatever extent they determine to be appropriate, but at a minimum, the laboratory's QA representative shall be present. The lead assessor conducts the opening meeting, and a list of attendees shall be generated for the assessment file. The objectives of the opening meeting are to:

- Introduce the assessment team members (and invited observers, as appropriate).
- Describe the scope, objectives, and approach for the assessment.
- Address the procedures related to confidential business information (CBI).
- Discuss any special safety procedures that the laboratory may think necessary for the protection of the assessment team. Under no circumstance is an assessment team required or allowed to sign any waiver of responsibility on the part of the laboratory for injuries incurred by a team member during an inspection to gain access to the facility.
- Confirm that the proposed agenda is acceptable, or negotiate revisions as necessary to accommodate critical site operations.
- Provide direct clarification to address the laboratory's concerns or questions.

2.9.3 Laboratory Walk-Through

A brief tour of the laboratory will be conducted to provide the assessment team with a general orientation of areas subject to review, and to introduce the assessors to the operational staff.

2.9.4 Assessment

The assessment team will review and assess the laboratory's procedures (e.g., SOPs), systems, practices, and records related to the performance of environmental testing, and will observe and interview laboratory personnel regarding their practices. This systems approach requires that the assessors be thoroughly familiar with the Navy's QA requirements, and with the requirements of the methods, since all the relevant technical criteria and requirements are not reiterated in questionnaire format.

The team should determine the laboratory's past, present, and future capabilities to perform testing of acceptable, known, and documented quality. The assessors

shall examine or collect objective evidence as the basis for making determinations of compliance.

2.9.4.1 Staff Interviews

Detailed interviews with staff members who perform the procedures will enable the assessors to understand and assess activities not necessarily reflected in documents, and should occupy a majority of the assessment team's on-site time. Supervisory personnel are welcome to attend staff interviews but the assessors shall ensure that questions are directed to, and answered by, the operational level staff, without interruption by their supervisor.

During interviews, the assessors shall ask individual staff members to provide a detailed, step-by-step description of their duties in the area under review. The assessor shall ask the staff member to provide details, documentary evidence, or demonstrations for each step in the process. For example, if a staff member states that a parameter is checked on a routine basis, the assessor should ask to see documentary evidence of the practice. As appropriate to the subject area, the interviews shall address the use of the equipment and supplies, calculations performed, data and records generated, and the identification and resolution of problems. Deficiencies identified during the interview process shall be discussed with the individual at a level commensurate with their responsibilities.

The interview process can be perceived as unpleasant or threatening. To mitigate this situation, the assessors shall adapt their interview style to the individual, without sacrificing the importance of the interview process.

2.9.4.2 Methods Review

A review of a laboratory's capability to perform a method shall be conducted in accordance with Section 2.5.2.

2.9.4.3 Records Review

The assessment team will review and assess laboratory records to determine if these materials are accurate, complete, internally consistent, and compliant with Navy requirements. The assessment team will also assess the laboratory's systems and procedures to ensure that after-the-fact reconstruction of the entire analytical process is possible.

Records subject to on-site review and assessment include, but are not limited to:

- Instrument run logs
- Instrument maintenance logs
- Standard material preparation and use records
- Reagent preparation records

- SOPs
- Procedures for the make-up and calibration of stock solutions and standard reagents
- Origins, purities, assays and expiration dates of primary standards, analytical reagents, and standard reference materials
- Method validation data
- Initial and continuing demonstration of method performance data
- Method detection limit and instrument detection limit data
- Records associated with the methods used to estimate precision and accuracy in general, and for specific analysis
- Analyst training and qualification records
- Proficiency test results
- Assessment reports and corrective action documentation for:
    - Previous assessments
    - Internal assessments and management reviews
- Deficiency tracking records
- Corrective action reports
- Statistical control data
- Precision and accuracy data
- Sample receipt and handling records
- Sample custody records
- QA reports
- Calibration records for instruments, methods, and equipment

2.9.4.4 Data Package Review

The assessment team selects and conducts a brief review of at least one fully validatable data package from each analytical functional area. The data packages shall have been produced within the previous year, using the laboratory's current data reduction and reporting systems. The purpose of this review is to determine if the laboratory's data reporting systems are complete and effectively implemented, and are capable of producing a data package that allows after-the-fact reconstruction of the entire analytical process.

Whenever possible, the data deliverables reviewed during the assessment shall be selected from recent Navy sample data or other DOD clients. If recent DOD data deliverables are not available, the assessment team, in consultation with the laboratory QA officer, may select a fully validatable data deliverable from another source.

2.9.4.5 Quality Assurance Program and Operations

The assessment team reviews and assesses the content and implementation of selected non-analytical procedures. The purpose of this assessment is to determine whether the laboratory's procedures:

- Provide for complete, accurate, and acceptable implementation of the laboratory's QA program
- Comply with Navy's QA requirements
- Are effectively and accurately implemented by the laboratory staff

Examples of procedures that are routinely subject to review include the laboratory's procedures for document control, statistical control, determination and use of method detection limits, internal assessments, and personnel qualification.

2.9.4.6 Laboratory Information Management System (LIMS)

The assessment team shall review the content and implementation of the laboratory's software QA plan. The purpose of the review is analogous to the information provided in Section 2.9.4.5.

2.9.4.7 Daily Debrief

At the conclusion of each day of an on-site assessment, the lead assessor will conduct a debrief meeting for the assessment team and the laboratory. Debriefs are open to all laboratory representatives, at management's discretion. The purpose of the daily debrief is to provide an informal presentation of assessment findings and give the laboratory an opportunity to request or provide additional information.

2.9.5 Documentation of Assessment Activities

The correspondence, records, documents, copies, and all supporting information that is generated, obtained, compiled, or reviewed during the assessment process shall be managed and maintained in the assessment files. The records must allow after-the-fact reconstruction of the overall assessment process from planning the assessment scope through final resolution of deficiencies based on corrective action documentation.

These files shall be forwarded by the assessment organization to the Contractor or NFESC when an assessment recommendation is made. The Contractor or NFESC shall maintain the files as specified by the EFD/EFA, and make them available to the EFD/EFA upon request.

Members of the assessment team are responsible for keeping complete and accurate records of all assessment activities. Each assessing organization shall issue their assessors a controlled notebook for the purpose of recording observations and notes. The assessment notebooks shall be used to record all

relevant information and observations during an on-site assessment. Unused spaces shall be lined out, as practical. The assessment notebooks shall be completed as official records and written legibly in ink.

Assessors that conduct interviews shall document the following:

- Participant(s)
- Subject(s) discussed
- Area(s) reviewed
- Method(s) reviewed
- Results, conclusions, or observations noted during the interview

Assessors that review laboratory methods, data, documents, or records shall document:

- Type of records reviewed
- Deficiencies, including the specific record(s) that were the basis for the deficiency. As appropriate to the nature of the deficiency, the assessor shall request or make a copy of the relevant material.

Assessors' observations of laboratory operations, practices, or conditions that may be identified as deficiencies shall be documented in the assessment notebook. The notebook shall also be used to document observations that may merit the attention of organization or project management.

2.9.6 Exit Brief

Upon conclusion of the on-site assessment, the lead assessor will conduct an exit brief to provide the laboratory with informal information regarding the assessment. The assessors shall inform the laboratory of all categories of on-site assessment deficiencies and observations and provide the laboratory with a written list of these findings. This list shall be used as the basis for the on-site assessment section of the assessment report, new categories of on-site deficiencies may only be added with the consent of the EFD/EFA, and discussion with the laboratory. However, deficiencies resulting from other phases of the assessment (i.e., PT and pre-on-site assessment phases) may be added to the final assessment report.

In addition, the lead assessor will provide a description of the schedule and objectives of the final assessment report, corrective action phase, and final assessment status.

The lead assessor will also provide the laboratory with a questionnaire (Attachment 4) that solicits feedback regarding assessor performance. The questionnaire should be forwarded to NFESC in the stamped, addressed envelope provided with the questionnaire. NFESC will forward a copy of the completed

questionnaire to the Contractor upon closure of the assessment. The Contractor will provide the feedback to the assessing organization as a resource for evaluating and improving assessor performance.

2.10 Team Self-Assessment

At the conclusion of each laboratory assessment, the lead assessor will hold an informal "lessons learned" meeting with assessment team members. A Navy representative may elect to participate. The assessment team will review the overall assessment, and attempt to identify and define any problems or issues that relate to the assessment process or the assessors' performance. During this continuous quality improvement process, the emphasis will be on determining whether assessment team corrective actions are warranted. The level of effort required for this self-assessment is at the discretion of the organization, or as directed by the Contractor or NFESC.

If the assessment team included a new assessor fulfilling training requirements, the senior assessors on the team shall submit an evaluation of his or her performance to the EFD/EFA and NFESC, which will be used to determine proficiency.

2.11 Assessment Report

An assessment report shall be generated by the assessors upon completion of the on-site assessment. The final assessment report shall be issued to the laboratory within 14 calendar days of completion of the on-site assessment.

2.11.1 Objectives

The primary objective of the assessment report is to document the results of the assessment, and provide the laboratory with the information necessary to address and resolve all deficiencies.

2.11.2 Format

Attachment 5 contains an example assessment report. The report represents an acceptable format that should be used as a template to provide a consistent means of documenting assessment results and conclusions.

2.11.3 Content

2.11.3.1 General Information

The assessment report is signed and distributed by the lead assessor and shall include the following information as appropriate to the individual assessment:

- Date(s) and location(s) of the assessment.
- Identification of assessment team members and observers.
- Identification of opening and exit brief meeting participants.

- Identification of persons contacted during assessment (by name or title).
- Description of each deficiency.
- Due date(s) and required response(s) from the laboratory.

2.11.3.2 Deficiencies

Deficiencies identify those activities, practices, or procedures that represent a departure from Navy requirements or that threaten the quality, technical defensibility, or project acceptance of Navy data.

A description of each deficiency shall be provided in sufficient detail so that it is clearly understood by the laboratory. In addition, the basis for each deficiency (e.g., reference method section, CFR citation, or Navy IR CDQM) shall be stated or referenced.

Some deficiencies may be identified although the laboratory has an appropriate and acceptable policy and procedure that addresses the issue. In this case, the laboratory's system is acceptable, but the implementation of the system is not. The assessment report shall identify implementation deficiencies that are identified despite an acceptable quality system.

The assessment report shall identify systematic deficiencies, which are a result of incomplete or ineffective quality systems, and those that are a result of the laboratory's failure to comply with technical requirements.

2.11.3.3 Observations

The assessors shall note observations that reflect on the capabilities and capacity of the laboratory, but do not constitute deficiencies. Response from the laboratory is not required. As stated in Section 2.9.1, observations that present safety concerns shall be presented in this section.

2.11.4 Review and Approval

The lead assessor shall review and approve the final version of the assessment report to ensure that the report is complete, accurate, and conforms to the requirements of this manual.

2.11.5 Distribution

The assessment report is transmitted to the designated point of contact at the laboratory's organization, with a copy provided to the Contractor or NFESC. A laboratory that takes exception to one or more deficiencies may make an appeal as detailed in Section 2.20.

2.12 Voluntary Withdraw

A laboratory may choose to voluntarily withdraw from the evaluation process without prejudice. Upon receipt of written notice of withdrawal from the laboratory, the assessor

will terminate the evaluation process and provide the Contractor or NFESC with notification that the evaluation process has been terminated.

2.13 Corrective Action Phase

Immediately upon receipt of the assessment report, the laboratory enters the corrective action phase of the assessment process, in which the laboratory implements corrective actions, and the assessment team assesses whether the laboratory has successfully closed the deficiencies.

2.13.1 Corrective Action Plan

Within 21 calendar days of receipt of the assessment report, the laboratory shall provide a written corrective action plan. The corrective action plan shall:

- Describe the planned corrective actions for resolution of deficiencies. The plan must provide sufficient detail to allow the assessment team to determine if the planned actions will successfully resolve the root cause of the deficiencies.
- Provide a proposed schedule for development and implementation of corrective actions (the completion schedule shall call for all of the corrective actions to be implemented within 60 calendar days from the date of receipt of the assessment report).

2.13.2 Assessment of Corrective Action Plan

The assessor shall supply a written assessment of the laboratory's corrective action plan within 14 calendar days of receipt of the plan. The written assessment shall notify the laboratory if any of the planned corrective actions are determined to be nonresponsive or would not successfully resolve the deficiency. The written assessment shall provide sufficient detail to ensure that the laboratory understands the deficiency, and why the corrective action was determined to be deficient. Corrective actions must be resolved within 60 calendar days from the date of receipt of the assessment report.

A laboratory that takes exception to the decision(s) made during the corrective action phase may submit an appeal as detailed in Section 2.20.

2.13.3 Request for Extension of Corrective Action Phase

A written request for an extension to the corrective action phase of up to 21 calendar days may be submitted (to the lead assessor) by a laboratory as soon as the need is identified, but no later than 21 calendar days prior to the end of the corrective action phase. The lead assessor shall forward the request to the Contractor or NFESC who will determine if an extension will be granted (based on input from the EFD/EFA) and inform the lead assessor of the decision. The lead assessor shall then provide written notification to the laboratory.

2.13.4 Implementation and Documentation of Corrective Actions

During the corrective action phase, the laboratory shall implement corrective actions to resolve each of the deficiencies identified in the assessment report.

For example: If the corrective action required to resolve a deficiency was to revise an operating procedure, the laboratory shall complete the revision, issue controlled copies of the new procedure, train responsible personnel in the new provisions, and adopt use of the new version.

Within 60 calendar days from the date of first receipt of the assessment report, the laboratory shall supply documentation (to the assessment team), which provides demonstrable evidence that new policies, systems, controls, procedures, or practices have been implemented, and are now part of the laboratory's routine operation. Documentation that indicates that a new practice is proposed or planned, will not support closure of the associated deficiency.

2.13.5 Evaluation of Corrective Action Documentation

Upon receipt of the laboratory's documentation of corrective actions, the assessment team will review the documentation, and determine if it demonstrates that the deficiencies have been successfully resolved. A deficiency will be considered resolved if the root cause of the deficiency has been addressed, and documentation indicates that the laboratory has developed and implemented internally consistent policies, procedures, and practices that comply with Navy requirements. In some instances the first submittal by the laboratory may not satisfy these criterion. If this is the case, the lead assessor shall inform the laboratory (in writing within ten days of receipt of the documentation). If the laboratory is unable to provide sufficient documentation in their second submittal, the assessor will notify the Contractor or NFESC, who in turn will advise the assessor if the assessment should be continued.

A laboratory that takes exception to the decision(s) made during the evaluation of corrective action phase may submit an appeal as detailed in Section 2.20.

2.14 Follow-Up Assessment

At the conclusion of the corrective action period, the assessment team may conduct a laboratory follow-up assessment. The follow-up assessment may be conducted on an announced or unannounced basis to satisfy a limited set of objectives in accordance with the provisions of this manual. Follow-up assessments shall be conducted with the concurrence of the EFD/EFA. If the follow-up assessment indicates that the laboratory has successfully implemented all required corrective actions, the assessment can be successfully closed. If the follow-up assessment indicates that deficiencies are still unresolved, they shall be resolved in order for the laboratory to successfully complete the assessment.

2.15 Assessment Recommendation

The assessment team shall determine the recommended assessment status of the laboratory within ten calendar days of the conclusion of the corrective action period, following review of the corrective action documentation submitted by the laboratory. The lead assessor shall prepare a letter that describes the recommended assessment status of the laboratory, to include the method(s) and matrix(ces) for which the laboratory is deemed acceptable to perform analyses, and the conclusions of the assessment team regarding the laboratory's ability to comply with all applicable requirements. This letter shall be distributed under the signature of the lead assessor to the laboratory and the Contractor or NFESC. The lead assessor shall also forward the original assessment files (i.e., correspondence, records, documents, copies, and supporting information that is generated, compiled, or reviewed during the assessment process) to the Contractor or NFESC as detailed in Section 2.9.5.

If a small percentage of deficiencies remain unresolved, the assessment team may determine that it is appropriate to document those cases where resolution is not demonstrated and distribute the assessment recommendation letter. This may only be done if the deficiencies will not impact Navy projects, and the corrective action response provides demonstrable evidence that the laboratory requires additional time in order to successfully close the deficiency.

If the final assessment status is determined to be unsuccessful, the report shall include a description of the unresolved deficiencies. It is the responsibility of the Contractor or NFESC to resolve the deficiencies before a laboratory may be proposed.

2.16 Laboratory Proposal

A laboratory may be proposed for Navy use upon successful completion of an assessment conducted in accordance with this manual. To propose a laboratory for Navy use, the Contractor or NFESC will submit the originals or certified copies of all documentation specified in Attachment 6 (Laboratory Proposal Package Checklist) to the appropriate EFD/EFA. Certified copies are those that have been verified by the sender as true copies of the original. Certification may be communicated via a memo that accompanies the documents sent. The EFD/EFA will review the package and forward the package to NFESC within ten calendar days with a letter of transmittal summarizing their evaluation of the package. NFESC will review the package to determine if the stated requirements have been met and collaborate with the EFD/EFA on the appropriate course of action. Within ten calendar days from receipt of the package from the EFD/EFA, NFESC will inform the laboratory of their decision. If the Navy determines that the requirements were not met, acceptance will be denied.

If the Navy determines that the requirements were met, a verification assessment may be conducted to confirm the results of the assessment. If the verification assessment confirms that the requirements are met, the laboratory is accepted. If the verification assessment demonstrates that requirements have not been met, the laboratory is denied acceptance.

NFESC shall maintain the files as specified by the EFD/EFA.

2.16.1 Acceptance

Once the EFD/EFA and NFESC determine that a laboratory has met the requirements of this appendix, the laboratory is accepted to perform analyses (on a method/matrix specific basis) under the IR Program Navywide for 24 months from the time the letter was issued. A letter of acceptance detailing which methods the laboratory is approved for shall be generated by NFESC and sent to the laboratory with a copy to the EFD/EFA and the Contractor.

2.16.1.1 Suspension

The Navy may suspend a laboratory's acceptance in total or in part for up to six months to allow time for the correction of deficiencies or areas of noncompliance. Reasons for suspension include, but are not limited to:

- Failure to successfully analyze and report PT samples pursuant to Navy requirements.
- Failure to submit an acceptable corrective action report, in response to a deficiency report and failure to implement corrective action(s) related to any deficiencies found during laboratory assessments within the required time period as required by Navy requirements.

- Failure to notify the Navy of any significant changes in the laboratory, as set forth in the Navy IR CDQM Section 1.1.4.

EFD/EFA shall determine whether to continue to use the laboratory on a case-by-case basis in consultation with NFESC. If the laboratory is unable to correct the deficiency within the time allotted, the laboratory's acceptance status shall be revoked in total or in part. A laboratory may appeal this decision as detailed in Section 2.20.

2.16.1.2 Revocation

The Navy may revoke a laboratory's acceptance status if the laboratory is not able to comply with this manual. Reasons for revocation of acceptance include, but are not limited to:

- Submittal of proficiency test sample results generated by another laboratory as its own.
- Misrepresentation of any material fact pertinent to receiving or maintaining acceptance.
- Denial of entry during normal business hours for an on-site assessment.
- Conviction of charges for the falsification of any report of or relating to a laboratory analysis.

After correcting the reason/cause for revocation, the laboratory may be reassessed. A laboratory may appeal this decision as detailed in Section 2.20.

2.17 Denial

If requirements have not been met the laboratory will not be accepted for use. NFESC will identify the issues that are deficient and forward this information to the Contractor or the laboratory (if NFESC is executing the assessment). It is the responsibility of the Contractor or NFESC to coordinate resolution of the issues identified, if the use of the laboratory is pursued. A laboratory may appeal this decision as detailed in the appeals Section 2.20.

2.18 Once Accepted

Once a laboratory is accepted for Navy use, the laboratory may perform analysis under the IR Program Navywide for 24 months from the time the letter was issued. Announced and unannounced assessments may be conducted with the written concurrence of the appropriate EFD/EFA.

2.19 Reassessment

NFESC will keep track of which EFDs/EFAs are using the laboratory. Six months prior to the end of the laboratory's acceptance period, NFESC (with input from the EFDs/EFAs) will determine the appropriate course of action to take concerning reassessment of the laboratory. NFESC will notify the laboratory in writing of the Navy's decision. The Navy may elect to let the laboratory's acceptance status lapse if there are no projects that require the laboratory's services.

2.19.1 Complete Reassessment

The Navy may require the laboratory to be reassessed in accordance with this appendix. The EFD/EFA, in collaboration with NFESC, will determine if a Contractor will be tasked with executing the assessment, or if NFESC will perform the assessment. The process will begin without the laboratory being nominated.

2.19.2 Document Review

The Navy may elect to perform a document review of the laboratory. NFESC will request and review specific documents from the laboratory such as:

- SOPs
- PT results
- Control charts
- Initial and continuing demonstration of method performance capability certificates
- Reports from internal and management reviews with the corresponding corrective action documentation
- MDLs for applicable methods
- Quality manual

Based on this review, and the laboratory’s recent performance, the Navy will determine if an on-site assessment is warranted or if the laboratory should be accepted for another 24 months. As part of the document review, NFESC may send the laboratory PT samples as part of the ongoing PT program, detailed in Appendix D.

2.19.3 On-Site Assessment

As part of the reassessment process, the Navy may elect to perform an on-site assessment to verify the information submitted as part of the document review, to assess areas of concern, or to verify that laboratory protocols continue to be implemented that effectively address findings presented in the original assessment.

2.20 Appeal of Decisions

A laboratory may appeal decisions made during the evaluation process. Sections 2.20.1 and 2.20.2 outline the procedures to appeal decisions made by assessors or the Navy. A laboratory must make an appeal in writing, within 14 days of receiving written notification of the decision. The laboratory's response shall identify the decision being appealed and the basis for taking exception to the decision. Unsupported conclusions and claims that are unsubstantiated by corroborating documentation will not provide sufficient evidence to support a successful appeal claim.

When an appeal claim is determined to be valid, the exception is immediately corrected by issuing a revised assessment report, evaluation, or letter. Unsubstantiated appeal claims will remain unchanged.

2.20.1 Assessor

Laboratories that take exception to decisions made by assessors (e.g., deficiencies in the assessment report, evaluation of the corrective action plan, or notification that a deficiency has not been successfully resolved) shall notify the lead assessor in writing.

Immediately upon receipt of an appeal claim, the lead assessor will notify and provide a copy of the appeal to the Contractor or NFESC. The Contractor or NFESC shall then notify the EFD/EFA. The lead assessor will review the laboratory's exception documentation and provide the Contractor or NFESC with a written assessment of the validity of the laboratory's claim within seven calendar days of receipt of the claim. The Contractor or NFESC shall forward a copy of appeal claim and supporting documentation to the EFD/EFA. As requested by the Contractor or NFESC, the laboratory and the assessment team members may provide additional information or participate in follow-on discussions.

The Contractor or NFESC shall collaborate with the EFD/EFA to determine the disposition of appeal claims. The final decision regarding disposition of appeal claims rests with the EFD/EFA. The Contractor or NFESC will inform the lead assessor of the outcome of the evaluation. The lead assessor will then notify the laboratory in writing and issue any required revisions with a copy to NFESC or the Contractor. A copy of all correspondence and communication logs regarding exception appeals will be maintained in the corresponding assessment file.

2.20.2 Navy

Laboratories that take exception to decisions made by NFESC and the EFD/EFA (e.g., decisions to suspend, revoke, or deny acceptance) may make an appeal to the Naval Facilities Engineering Command (NAVFACENGCOM).

NAVFACENGCOM will review the laboratory's appeal claim and assess whether it is valid and substantiated, within 30 calendar days of receipt of the appeal. As requested by NAVFACENGCOM, the laboratory, Navy, Contractor, and assessment team members shall provide additional information or participate in

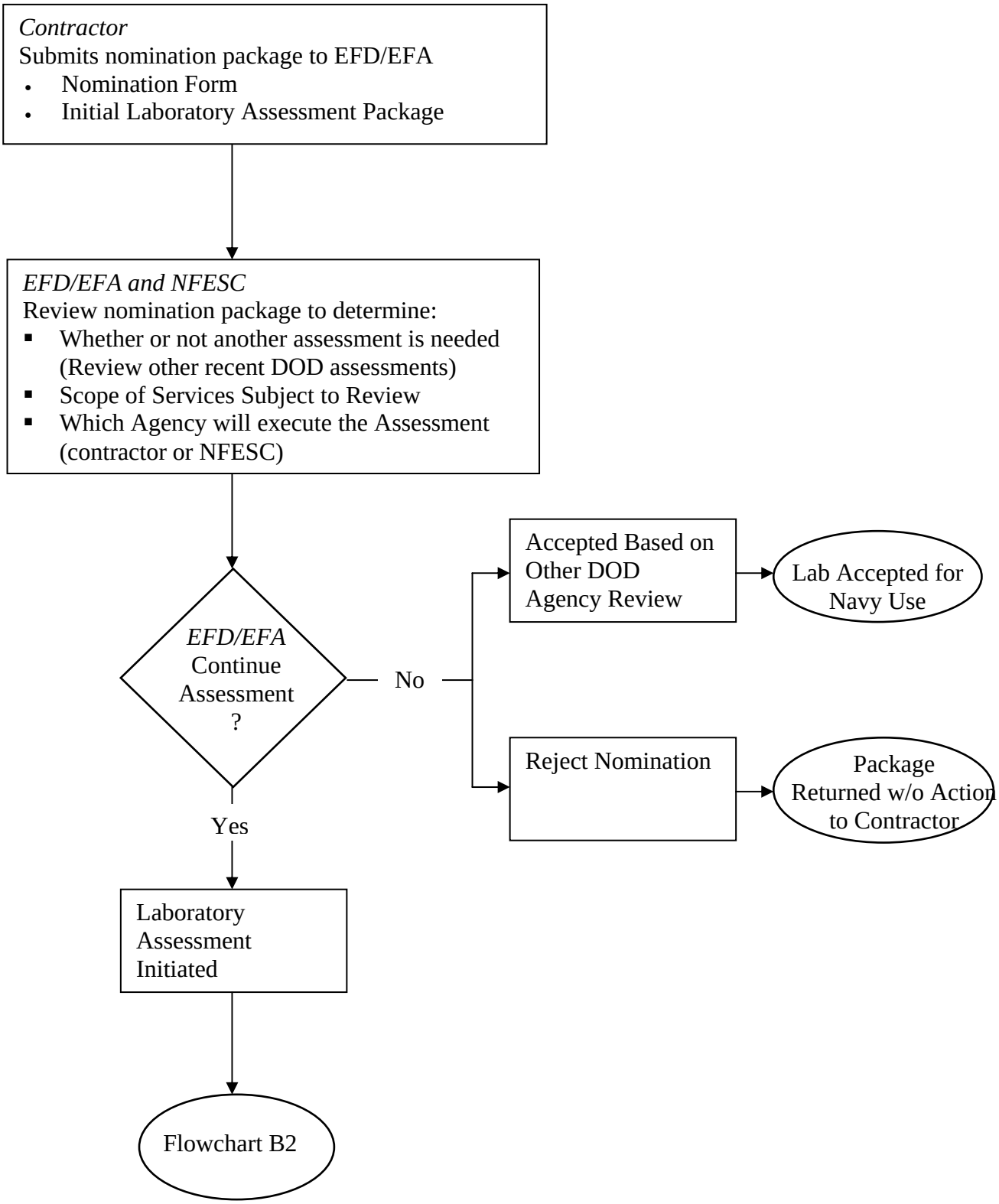
discussions. The final decision regarding the disposition of appeal claims rests with NAVFACENGCOM.

When the appeal claim has been evaluated, NAVFACENGCOM will inform the laboratory, NFESC, and other interested parties of the decision via a letter. A copy of all correspondence regarding the appeal will be forwarded by NAVFACENGCOM to NFESC. NFESC will maintain this information in the corresponding laboratory file.

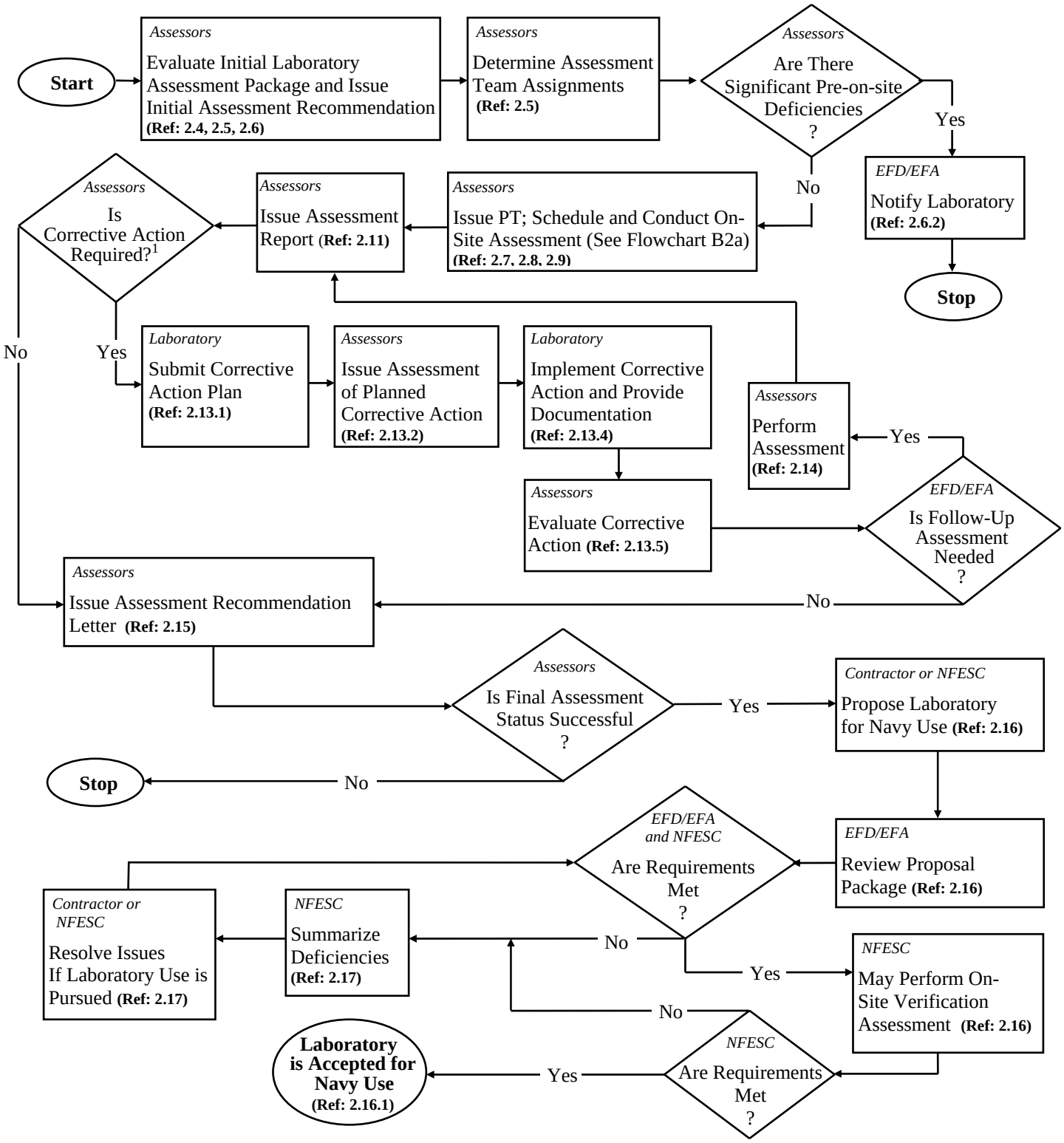
Appeals should be sent to:

Commander
NAVFACENGCOM
Washington Navy Yard
1322 Patterson Ave SE STE 1000
Washington, DC 20374-5065

Flowchart B1:
Laboratory Assessment General Overview



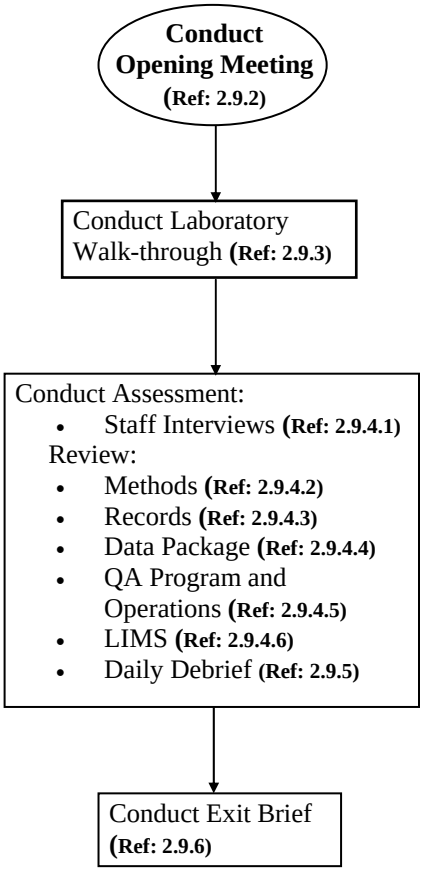
Flowchart B-2:
Laboratory Assessment Procedure Flowchart



Note: The process may be terminated at anytime by the contractor, Navy, or the laboratory. (Ref 1.0)

[1] If the laboratory decides to appeal any deficiencies noted in the assessment report, they must do so within 14 calendar days. (Ref: 2.20)

Flowchart B2a:
Laboratory On-Site Assessment Procedure



Note 1: A daily debrief will be conducted at the conclusion of each day during the on-site assessment (Ref: 2.9.4.7).

Note 2: Each member of the assessment is responsible for keeping complete and accurate records of all assessment activities (Ref: 2.9.5).

Appendix B
Attachment 1
Confidential Business Information

1.0 Purpose

This attachment details confidential business information (CBI) considerations of the Navy Installation Restoration (IR) Program.

During the assessment process, assessors may come into possession of information claimed as business confidential by the laboratory. The laboratory may protect this information from public disclosure under the Freedom of Information Act (FOIA) by declaring the information business confidential.

2.0 Protocol

During the opening meeting, the lead assessor shall provide Enclosure (1) to the appropriate laboratory management and answer any questions the laboratory management may have concerning CBI.

2.1 Making a CBI Claim

Information may be claimed as business confidential during the on-site assessment by the responsible laboratory official in one of two ways:

- Marking each item (e.g., each page, file, or sample) that is claimed as business confidential as “confidential business information,” “trade secret,” “proprietary,” or some other suitable phrase prior to the close of the on-site assessment.
- Submittal of the "Assessment Confidentiality Notice" form provided as Enclosure (2).

CBI may be purged of references to client identity by the responsible laboratory official prior to the conclusion of the on-site assessment. However, sample identifiers may not be obscured from the information.

After the on-site assessment, CBI claims may only be made by submitting the “Assessment Confidentiality Notice” to the appropriate agency as detailed below:

- If the laboratory has not completed the assessment process the claim shall be submitted to the Contractor or NFESC as appropriate.
- If the laboratory has been proposed to the Navy, the claim shall be submitted to NFESC.

The Navy is not responsible for disclosures made prior to receiving the claim.

2.2 Receiving a CBI Claim

Immediately upon receipt of the CBI claim, the receiving organization will:

- Take custody of the claimed items by listing them on a chain of custody sheet.

- Maintain controlled custody of the claimed information in all subsequent transfers of the information.
- Ensure that either each page is marked as “business confidential” by the laboratory or that a copy of the Assessment Confidentiality Notice is used as a cover sheet on claimed items.

Information claimed as CBI shall be held in a secure manner throughout the holding period of the assessment records and may not be reproduced or distributed inconsistently with 40 CFR Part 2.

If a CBI claim is received after the on-site assessment, the appropriate organization (i.e., assessment organization, Contractor, EFD/EFA, or NFESC) shall expedite the claim as soon as it is received, but the organization is not responsible for previous disclosures. The organization shall make efforts to associate the late claim with copies of the previously submitted information in its files.

3.0 Determining the Validity of a CBI Claim

NFESC (with input from the EFD/EFA) shall determine the validity of the CBI claim, in accordance with federal and state law. The following criteria will be used to judge the validity of the laboratory's claim:

- Measures taken by the laboratory to protect the confidentiality of the information, and the intent to continue such measures.
- Access to the information is not, and has not been, reasonably obtainable without the laboratory’s consent by other persons (other than governmental bodies) by use of legitimate means (other than discovery based on showing of special need in a judicial or quasi-judicial proceeding).
- Availability of the information from public sources.
- Disclosure of the information would cause substantial harm to the laboratory’s competitive position.

If the Navy questions the claim that certain information is CBI, the laboratory will be contacted in writing and given 21 calendar days to exercise one (or more) of the following options:

- Provide justification of their claim to CBI
- Remove the claim of CBI
- Resolve the issue in a manner agreeable to both the laboratory and the Navy
- Engage legal assistance
- Appeal the action to NAVFACENGCOM
- Withdraw without prejudice from the evaluation process

Appendix B
Attachment 1
Enclosure 1
Navy Installation Restoration Program Assessment Confidentiality Notice- To Assert a Confidentiality Business Information Claim

NAVY INSTALLATION RESTORATION PROGRAM

ASSESSMENT CONFIDENTIALITY NOTICE

LABORATORY NAME	ASSESSOR NAME
LABORATORY ADDRESS	ASSESSOR ADDRESS
CHIEF EXECUTIVE OFFICER NAME	TITLE

TO ASSERT A CONFIDENTIALITY BUSINESS INFORMATION CLAIM

It is possible that the Navy will receive public requests for release of the information obtained during assessment of the facility above. Such requests will be handled by the Navy in accordance with provisions of the Freedom of Information Act (FOIA), 5 USC 552 and as defined in the Navy IR CDQM, Attachment 1 of Appendix B. The Navy is required to make assessment data available in response to FOIA requests unless the Navy determines that the data contain information entitled to confidential treatment or may be withheld from release under other exceptions to FOIA.

Any or all information collected during the assessment may be claimed confidential if it relates to trade secrets or commercial or financial matters that you consider to be confidential business information. If you assert a CBI claim, the Navy will disclose the information only to the extent, and by means of the procedures set forth in the regulations and guidelines (cited above) governing the Navy's treatment of confidential business information. The regulations require that the Navy notify you in advance of publicly disclosing any information you have claimed as confidential business information.

A confidential business information (CBI) claim may be asserted at any time. You may assert a CBI claim prior to, during, or after the information is collected. The declaration form was developed to assist you in asserting a CBI claim. It is not necessary for you to use this form. If it is more convenient, you may assert a CBI claim by marking the individual documents or samples “confidential business information.” The assessor will be glad to answer any questions you may have regarding the Navy's CBI procedures.

While you may claim any collected information or sample as confidential business information, such claims are unlikely to be upheld if they are challenged unless the information meets the following criteria:

1. Your company has taken measures to protect the confidentiality of the information, and it intends to continue to take such measures.
2. The information is not, and has not been, reasonably obtainable without your company’s consent by other persons (other than governmental bodies) by use of legitimate means (other than discovery based on showing of special need in a judicial or quasi-judicial proceeding).
3. The information is not publicly available elsewhere.
4. Disclosure of the information would cause substantial harm to you company’s competitive position.

At the completion of the assessment, you will be given a receipt for all documents, samples, and other materials collected. At that time, you may make claims that some or all of the information is confidential business information.

If your are not authorized by your company to assert a CBI claim, this notice will be sent by certified mail, along with the receipt for documents, samples, and other materials to the Chief Executive Officer of your firm within 2 days of this date. The Chief Executive Officer must return a statement specifying any information that should receive confidential treatment.

The statement from the Chief Executive Officer should be addressed to (assessor, enter assessment organization address here):

Send registered mail, return-receipt requested within 7 calendar days of receipt of this notice. Claims may be made any time after the assessment but assessment data will not be entered into the special security system for confidential business information until an official confidentiality claim is made. The data will be handled under the agency’s routine security system unless and until a claim is made.

TO BE COMPLETED BY FACILITY OFFICIAL RECEIVING THIS NOTICE: I have received and read this notice.	If there is no one on the premises of the facility who is authorized to make business confidentiality claims for the firm, a copy of this Notice and other assessment materials will be sent to the company’s chief executive officer. If there is another company official who should also receive this information, please designate below.
SIGNATURE	NAME
NAME	TITLE
TITLE DATE SIGNED	ADDRESS

Appendix B
Attachment 1
Enclosure 2
Navy Installation Restoration Program Assessment Confidentiality Notice-Information Designated as Confidential

NAVY INSTALLATION RESTORATION PROGRAM

ASSESSMENT CONFIDENTIALITY NOTICE

LABORATORY NAME	Date
LABORATORY ADDRESS	
ASSESSOR NAME	CHIEF EXECUTIVE OFFICER NAME
ASSESSOR ADDRESS	TITLE

INFORMATION DESIGNATED AS CONFIDENTIAL

No.	DESCRIPTION

ACKNOWLEDGMENT BY CLAIMANT

The undersigned acknowledges that the information described above is designated as Confidential Business Information as defined in the Navy IR CDQM, Attachment 1 of Appendix B. The undersigned further acknowledges that he/she is authorized to make such claims for his/her firm.

The undersigned understands that challenges to confidentiality claims may be made, and that claims are not likely to be upheld unless the information meets the following guidelines: (1) The company has taken measures to protect the confidentiality of the information and it intends to continue to take such measures; (2) The information is not, and has not been reasonably attainable without the company's consent by other persons (other than governmental bodies) by use of legitimate means (other than discovery based on a showing of special need in a judicial or quasi-judicial proceeding); (3) The information is not publicly available elsewhere; and (4) Disclosure of the information would cause substantial harm to the company's competitive position.

TO BE COMPLETED BY FACILITY OFFICIAL RECEIVING THIS NOTICE I have received and read this notice (signature):	If there is no one on the premises of the facility who is authorized to make business confidentiality claims for the firm, a copy of this Notice and other assessment materials will be sent to the company's chief executive officer. If there is another company official who should also receive this information, please designate below.
ASSESSOR'S SIGNATURE	NAME
NAME	TITLE
TITLE DATE	ADDRESS

Appendix B

Attachment 2
Laboratory Nomination Form

Navy Installation Restoration Laboratory Nomination Form

Nominating Contractor Information:

Name: _____

Street Address: _____

_____

_____

Name of Contact: _____

Position and Title: _____

Phone Number: _____ Fax Number: _____

Type of Contract: ☐ RAC ☐ CLEAN ☐ Other: _____

EFD/EFA Associated With Contract:
☐ NORTHDIV ☐ EFA NORTHWEST ☐ PACDIV
☐ SOUTHDIV ☐ SOUTHWESTDIV ☐ EFA WEST
☐ EFA CHESAPEAKE ☐ LANTDIV

Laboratory Information:

Full Legal Name: _____

Street Address: _____

_____

_____

Name of Contact: _____

Position and Title: _____

Phone Number: _____ Fax Number: _____

Methods that the Contractor is nominating the laboratory to perform[1]:

☐ SW846 ☐ CLP ☐ Other: _____

Below are types common to Navy:

Type	Matrix		Method (Latest Version of):
	Soil/ Sediment	Water	
VOC (8260)			8260
VOC (8021)			8021
BNA			8270
PCB			8082
Metals(23 metals)			6010/7000
Pest			8081
TPH*			8015

* SOP and lab practices will be reviewed during assessment. because a PT from USACE is not available. The lab shall have State certification or shall have successfully analyzed a private PT provider PT sample in the last six months.

Provide additional types below:

Type	Matrix		Method (Latest Version of):
	Soil/ Sediment	Water	

[1] The laboratory shall be nominated for methods for which the Contractor has confidence in the laboratory's ability to demonstrate satisfactory method performance in accordance with relevant EPA guidance.

Appendix B
Attachment 3
Initial Laboratory Assessment Package Requirements

Initial Laboratory Assessment Package Requirements

Laboratories that have been nominated to provide analytical support for Navy Installation Restoration (IR) or Base Realignment and Closure (BRAC) environmental programs shall supply the items listed below to the assessment organization. The assessors will use the information provided to make an initial assessment of the laboratory's capabilities to support IR and BRAC environmental projects.

Initial laboratory assessment package items shall be compiled/submitted in the following order:

1. *Navy Installation Restoration Laboratory Information Sheet*: Enclosure (1)
2. *Organization Chart*: An organization chart depicting the lines of authority for laboratory positions, with identification of individuals for key positions including:
   - Lab Director
   - Quality Manager
   - Quality Assurance (QA) Officer
   - Operations Manager
   - Inorganic Section Supervisor
   - Organic Section Supervisor
   - Classical Section Supervisor
   - LIMS Systems Manager
   - Data Reporting Section Supervisor
   - Sample Management Supervisor
3. *Resumes*: Resumes for the individuals in key positions, including those identified in number 2 above.
4. *Laboratory Facility(ies) Floor Plan*: A floor plan of the laboratory facility(ies) with general production areas identified including:
   - Organic and inorganic sample preparation laboratories
   - Inorganic instrument laboratories
   - Volatile organic instrument laboratories
   - Semi volatile organic instrument laboratories
5. *List of Major Analytical Instrumentation*: A list of major analytical instrumentation (limited to those instruments that are routinely applied to production analyses).
6. *Completed Laboratory Compliance Checklist*: The laboratory shall complete this checklist, Enclosure (2), to demonstrate its compliance with Navy requirements (detailed in IR CDQM Appendix C[1]). More information may be provided on additional sheets of paper as needed. The checklist is available electronically from the Navy QA contact. This checklist is based on the DOD QS document.
7. *Quality Manual:* The laboratory's current document(s) that describe the laboratory's QA program, typically called the QA manual, QA program plan, or QA plan.
8. *Methods Information*: A list of methods (by EPA or other method reference as appropriate) routinely performed by the laboratory, with the applicable matrices specified. The laboratory

[1] This checklist will be generated upon finalization of Appendix C.

must include initial demonstration of method performance certificates as detailed in Appendix C (Laboratory Requirements Appendix) and MDLs for applicable methods. Supporting data and documentation does not need to be included.

9. *SOPs*: A list of titles of the laboratory's currently approved standard operating procedures (SOPs), with SOP number, revision number, and date of approval. As applicable to the assessment, the laboratory shall submit at least one SOP associated with each of the following categories:

   - Organics
   - Inorganics
   - General Chemistry
   - Radiochemistry
   - QA Program and Operations

   Note: The laboratory shall compile a complete set of all applicable SOPs for assessor review. The assessors may also request additional specific SOPs.

10. *Proficiency Testing*: Copies of the results (including corrective actions as appropriate) from nationally recognized PT programs completed during the last two years, including as appropriate: EPA CLP Quarterly Blinds; EPA EMSL-LV Radiochemistry Intercomparison Program; and United States Army Corps of Engineers (USACE) PT Program; Air Force Center for Environmental Excellence (AFCEE) PT Program.

Navy Installation Restoration Laboratory Information Sheet

Legal Name of Laboratory: _____

Street Address: _____
_____
_____

Mailing Address: _____
(if different)
_____
_____

Fax Number: _____ Hours of Operation: _____

Name of Owner: _____

Owner Address: _____
(If different from above) _____
_____

	Name	Phone Number
Laboratory Director:		
Laboratory Quality Manager:		
Quality Assurance Officer:		

The undersigned persons understand and acknowledge that the laboratory will be assessed in accordance with the *Navy Installation Restoration Chemical Data Quality Manual*. The laboratory has received and reviewed this manual and is prepared to proceed.

The under-signed persons understand and acknowledge that the Navy or its Contractor will conduct an on-site assessment and may perform unannounced follow-up assessments.

I hereby certify that I am authorized to sign this form on behalf of the owner and that there are no misrepresentations in the information provided in the initial laboratory assessment package.

_____ _____
Signature of Quality Manager Date

_____ _____
Signature of Laboratory Director Date

Appendix B
Attachment 3
Enclosure 2
Laboratory Compliance Checklist

This checklist will be generated upon finalization of the Department of Defense Quality Systems Manual for Environmental Laboratories (Enclosure 1 to Appendix C)

Appendix B
Attachment 4
Assessor Evaluation Questionnaire

Please complete and return this form in the envelope provided. The feedback you provide will be used to evaluate and improve assessor performance. It will not affect the current assessment. Information provided on this questionnaire will not be communicated to the assessors until the laboratory completes the assessment process.

Assessor Name: _____
Laboratory Name: _____
Date of On-Site Assessment: _____
EFD/EFA Lab Will be Proposed to: _____

Please rank the assessor from 1 (low) to 5 (highest)

1. Ability to communicate orally	1	2	3	4	5
2. Ability to communicate in writing	1	2	3	4	5
3. Ability to act objectively and fairly	1	2	3	4	5
4. Ability to describe assessment results in a clear and impartial manner	1	2	3	4	5
5. Ability to adapt to different personalities during interviews	1	2	3	4	5
6. Professional characteristics	1	2	3	4	5
7. Knowledge of :					
a. Environmental laboratory methods	1	2	3	4	5
b. Quality assurance issues	1	2	3	4	5

Overall Rank: 1 2 3 4 5

Please provide comments: _____

If there is no self addressed envelope provided, please return this form to NFESC:

Commanding Officer
Naval Facilities Engineering Service Center, Code 413/ Pati Moreno
1100 23rd Avenue
Port Hueneme, CA 93043-4370

Appendix B
Attachment 5
Example Assessment Report

ABC Auditors, Inc.
123 Central Ave.
New York, NY 99999
8 April 1998

Geo Labs
888 Pollo del Mar
Los Angeles, CA 99999

Subject: On-Site Assessment Report of Geo Labs, Los Angeles, CA

Dear Mr. Bond:
The attached report provides the results of the assessment of Geo Labs in Los Angeles, CA, preformed by ABC Auditors Inc., including information pertaining to the review of; laboratory preliminary documentation; Performance Testing (PT) information; and the on-site assessment.

As outlined in Appendix B of the *Navy Installation Restoration Chemical Data Quality Manual (IR CDQM)*, Geo Labs has 14 calendar days to submit a corrective action plan addressing the deficiencies identified in this report. For each finding, your response should include a discussion of the scope and approach for planned corrective actions, as well as a schedule for their implementation. The plan of action must provide sufficient detail to determine if the approach is technically reasonable. The completion schedule should call for all corrective actions to be completed within 60 calendar days of receipt of this report. Additional information pertaining to the procedures for responding to the enclosed assessment report can be found in IR CDQM, Appendix B, Section X.XX.

Your corrective action plan should be directed to my attention at the following address:

ABC Auditor, Inc.
123 Central Ave.
New York, NY 99999

I would like to express my appreciation to the members of the Geo Labs staff who were helpful and candid during our visit. Should you have any questions, or wish to discuss assessment deficiencies or proposed corrective actions, please contact me at (888) 888-8888, or call Ms. Elaine Eus at (888) 888-8888. Thank you for your attention.

Respectfully,

Gene Eric
ABC Auditor, Inc.

Attachment: Assessment Report

cc: G. Brooks/Acme Contracting

Assessment Report
of

Geo Labs
Los Angeles, CA

Requested by:
Acme Contracting

Prepared by:

ABC Auditor, Inc.
123 Central Ave.
New York, NY 99999

17 April 1998

1.0 Introduction

As requested by Acme Contracting, ABC Auditors, Inc. conducted an assessment of Geo Labs, Los Angeles, California. This audit process includes three primary phases: 1) Review of laboratory preliminary documentation; 2) Performance Testing (PT) review; 3) On-site assessment.

2.0 General Information

The laboratory assessment was initiated by the Commander, Midwest Division, Naval Facilities Engineering Command (COMMIDWESTDIV), and executed by ACME Contracting. ACME contracted with ABC Auditors, Inc., to conduct the assessment. Gene Eric and Elaine Eus were the assigned assessors, Gene Eric served as lead assessor. The assessment was structured as a general assessment to support Navy Installation Restoration (IR) projects.

Geo Labs has been providing commercial and government clients with routine environmental analysis services since 1982. Geo Labs has current work for Acme Contracting and XYZ Engineers. Geo Labs occupies three closely situated buildings, totaling 17,000 square feet. Copies of floor plans supplied by the laboratory are provided as Appendix A. At present, the laboratory has the ability to operate with multiple shifts during the week, and day shifts on the weekend.

3.0 Laboratory Preliminary Documentation Review

A review of laboratory supplied documentation was conducted. Documentation included the laboratory's quality assurance (QA) manual, selected standard operating procedures (SOPs) and SOP master list (Appendix B), list of major analytical instrumentation (Appendix C), and historical PT information.

The documentation was reflective of a laboratory that was prepared for the Navy's evaluation, as documented in ABC Auditor, Inc. initial assessment letter dated 16 Mar 98. Deficiencies associated with this documentation are found in Section 6.0 of this report.

PT Review

Geo Labs participates in a number of external certification and PT programs, including the US Army Corps of Engineers (USACE) laboratory evaluation program, and Environmental Protection Agency (EPA) WP/WS proficiency sample program. The laboratory also participates in the EPA Contract Laboratory Program (CLP) for Inorganics. A list of the external evaluations in which the laboratory participates in, is provided in Appendix D. The laboratory has successfully analyzed all PT samples processed within the past two years.

PT samples reflective of the Navy standard suite (i.e., VOC/8260/water, BNA/8270/water & soil, Pest/8081/water, PCBs/8082/water & soil, Metals (23 Metals)/6010/7000 series/water & soil) were ordered by ABC Auditor, Inc., and generated and scored by TestCo. The PT samples were received by the laboratory on 02 Feb 98, and the results were due on or before 3 Mar 98. Geo Labs processed the sample and submitted the results to TestCo on 25 Feb 98, copies of all sample summary data sheets are provided as Appendix E. Geo Labs also generated a data package for the PT sample. The data package was received by the assessors on 10 Mar 98. Deficiencies associated with the data package are provided in Section 6.8. The results of PT analysis were received from TestCo on 12 Mar 98, a copy is provided as Appendix F. The laboratory passed all PT samples.

5.0 On-Site Assessment

The following information is presented in association with the on-site assessment performed by ABC Auditors Inc., of Geo Labs – Los Angeles, California, from 01 through 03 Apr 98.

5.1 Scope and Objective

The scope of the assessment included an assessment of the laboratory's capability to perform CLP and SW-846 methods. The objective of the on-site assessment of the Geo Labs laboratory was to determine whether the laboratory's quality assurance (QA) program and QC practices meet the requirements of the Navy's IR QA Program and are consistent with good laboratory practices.

5.2 Evaluation Criteria

The on-site assessment of the laboratory was based on the Navy's IR QA program requirements as defined in the *Navy Installation Restoration Chemical Data Quality Manual,* dated Jun 98.

EPA's Test Methods for Evaluating Solid Waste SW-846, EPA Contract Laboratory Program Statement of Work, Exhibit F for evidentiary requirements and the Geo Labs Quality Assurance Plan dated 7 Jun 93(for internal requirements), and SOPs were also used as performance standards.

5.3 Description

Upon arrival at the laboratory, the assessors held an orientation meeting with management, QA, and technical personnel, during which the elements of the Navy's IR laboratory assessment program were described. A summary of items discussed is presented as Appendix G, Opening Meeting Checklist.

Following a description of the scope and schedule for the assessment, the assessors adjourned the opening meeting, and initiated their review of laboratory operations. The assessment of Geo Labs addressed all aspects of routine laboratory operations, including:

- sample management
- data handling
- quality control (QC) practices
- record-keeping
- training
- sample preparation
- organic, inorganic, and classical analysis sections

The adequacy of the laboratory's QA program was assessed. The facility, instrumentation, documentation, and support practices were reviewed. Spot checks were performed on standard operating procedures (SOPs). The assessors interviewed the QA manager, information systems manager, section managers, analysts, technicians, and support personnel. A list of areas reviewed is provided as Appendix H. At the conclusion of each day, the assessors met with the QA manager, laboratory manager, company vice-presidents, and section managers to provide a summary debrief of the day's deficiencies and observations.

At the conclusion of the assessment, the assessors conducted an exit brief with laboratory management, the QA manager, and technical personnel. During the brief the assessors presented verbal review of deficiencies and observations identified during the course of the on-site assessment, and the laboratory was supplied with a written summary deficiencies and observations. This summary is the basis of deficiencies and observations presented in Section 6.0. The lead assessor verbally presented the actions that would be taken upon conclusion of the on-site assessment. Laboratory personnel asked questions as needed throughout the exit brief. A summary of items discussed is presented in Appendix G, Exit Brief Checklist.

Attendee lists for meetings held are provided in Appendix I.

6.0 Deficiencies

During the course of the assessment, assessors noted policies, practices, documents, or records that did not comply with evaluation criteria identified in Section 5.2. Deficiencies must be resolved in order to comply with Navy IR QA Program requirements. Detailed information regarding the corrective action process is identified in the Navy IR CDQM, Appendix B, Section X.XX. Checklists that document deficiencies and observations are provided in Appendix G, Laboratory Operations Checklist, and Method Review Checklist.

6.1 Geo Labs' QA manager also has project management responsibilities. This practice is not compliant with Navy policy.
(Requirement reference: Navy IR CDQM, Appendix C, Enclosure 1, Section X.XX)

6.2 The QA manager spends approximately 10 hours per week on QA activities. This amount of time is insufficient for a laboratory of Geo Labs' size, as reflected by the deficiencies associated with the laboratory's QA program (see Section 6.3 of this report).
(Requirement reference: Navy IR CDQM, Appendix C, Enclosure 1 Section X.X).

6.3 Laboratory QA program deficiencies were identified in the following areas:

- Corrective Action System: Procedures for the corrective action to be taken
when testing discrepancies are detected, are not documented, or implemented.
Examples include:
  - For cyanide determination, two sequential out-of-control situations were recorded on the control chart. There was no documentation available to indicate if and what corrective actions were implemented.
  - Corrective action related to transcription errors that resulted in order of magnitude errors on WP samples were not documented.

  (Requirement reference: Navy IR CDQM, Appendix C, Enclosure 1, Section X.XX , Item S).

- Internal Assessments: An internal assessment of the QA system has not been performed within the past 12 months.
(Requirement reference: Navy IR CDQM, Appendix C, Enclosure 1, Section X.X)

- Documentation:
  - QA Manual: Although the QA manual is well written, it has not been updated since 1993, and is not reflective of current practices. Specific QA manual deficiencies include:
    - Job descriptions of key staff are not included
    - Corrective action policies and procedures are not clearly defined
    - Procedures for dealing with complaints is absent
    - QC checks seem to be biased toward the requirements of organic analyses, and contain very vague descriptions of metals and inorganic analyses.

    (Requirement reference: Navy IR CDQM, Appendix C, Enclosure 1, Section X.X and X.XX)
  - SOPs are not controlled documents.

(Requirement reference: Navy IR CDQM, Appendix C, Enclosure 1, Section X.XX)

- Test Conditions: There are no measures in place to assure constant and consistent test conditions (e.g., temperature, humidity, light, or specific instrument conditions).
  (Requirement reference: Navy IR CDQM, Appendix C, Enclosure 1, Section X.XX, Item H)

6.4 Method Deviations:

6.4.1 Method 9010: Cyanide calibration is performed with five calibration levels and a blank. The method requires six levels and a blank.
(Requirement Reference Method 9010, Section X.X)

6.4.2 Method detection limit (MDL) studies were not performed for solids for organic methods.
(Requirement reference: Navy IR CDQM, Appendix C, Enclosure 1, Section X.XX)

6.4.3 Method 6010: The continuing claibration verification (CCV) standard is not being run every ten samples.
(Requirement reference: Method 6010, Section X.X.X).

6.5 Equipment:

6.5.1 The thermometer used to determine temperature during TCLP extraction is not certified or monitored.
(Requirement reference: Navy IR CDQM, Appendix C, Enclosure 1, Section X.XX).

6.5.2 The laboratory does not have the equipment required to run volatile solid samples. The laboratory is currently running volatile solid samples, however, they do not have heated purge capability.
(Requirement reference: Method 5030A Section X.X.X and X.X.X.X)

6.6 Record Keeping: Corrections in log books and on bench sheets are not always initialed and dated and unused lines are not always "Z'd" through.
(Requirement reference: Navy IR CDQM, Appendix C, Enclosure 1, Section X.X.XX)

6.7 Personnel:

6.7.1 Continuing demonstration of method performance (i.e., successful completion of a PT sample within the past 12 months) has not been initiated for the following analysts/analysis:

- Joe Smith/Mercury
- Amy Martinez/Cyanide

(Requirement reference: Navy IR CDQM, Appendix C, Enclosure 1, Section X.X.XX).

6.7.2 There is no SOP that defines Geo Labs' training and qualification requirements. (Requirement reference: Navy IR CDQM, Appendix C, Enclosure 1, Section X.X.XX)

6.8 Data Package: The data package received (by ABC Auditors Inc., on 10 Mar 98) was reviewed for conformance with Navy requirements. The data package, identified as Geo Labs job number 1055, was a compilation of results generated from the PT sample ordered by ABC Auditors Inc. The data package did not include sufficient information for accurate interpretation. Including:

- Discussion of all re-analyses and dilutions References to methods and revisions was not provided
- A statement of estimated uncertainty was not included
- TIC data was not reported
- Second column analytes were not reported
- Method 8260:
  - Run log was not provided
  - Tune data was not summarized
- Method 8021
  - LCS outliers were not addressed
  - An ending calibration was not performed
  - Spiking levels were not documented for LCS or surrogates

(Requirement reference: Navy IR CDQM, Appendix C, Enclosure 1, Section X.X.XX).

7.0 Observations

This section presents general observations which reflect on the capabilities and capacity of the laboratory. Response from the laboratory is not required.

7.1 The laboratory's facility provides ample space for production analytical work and support activities, with appropriate segregation of functional areas.

7.2 The laboratory does not routinely perform volatile low-level soil analysis.

8.0 Conclusions

Geo Labs has the staff, facilities, equipment, and infrastructure necessary to provide Navy IR projects with environmental analytical services. However, the laboratory QA program is

inadequate to support the size and complexity of the laboratory and is the cause of many failures to meet Navy IR QA requirements. The staff members are generally qualified for their positions and have relatively long associations with the laboratory.

Geo Labs has been advised to respond in writing to the assessment deficiencies in this report within 14 calendar days of receipt of this report. For each deficiency (and each individual "bullet"), the response must address the laboratory's plan of action and completion schedule for implementation of corrective actions. All corrective actions must be completed, with supporting documentation received by ABC Auditors Inc., within 60 calendar days of receipt of this report. Laboratory management may request an extension of up to 21 calendar days by providing rationale for why an extension is needed. In addition, if the laboratory takes exception to any of the deficiencies in this report, the laboratory's response must identify and provide an explanation for the exception(s). Detailed information regarding extensions is found in Navy IR CDQM, Appendix B, Section X.X.XX, and information regarding exceptions is found in Section X.XX.

APPENDICES:

Appendix A: Floor Plan of the Laboratory
Appendix B: List of Current SOPs
Appendix C: List of Instrumentation
Appendix D: List of Current Status for External Evaluations
Appendix E: Sample Summary Data Sheets
Appendix F: PT Sample Results
Appendix G: Assessment Checklists

- Opening Meeting
- Laboratory Operations
- Method Reviews
- Exit Brief

Appendix H List of Areas Reviewed
Appendix I Attendees Lists

- Opening Meeting
- Exit Brief

Appendix B
Attachment 6
Laboratory Proposal Package
Checklist

Laboratory Proposal Package Checklist

The following is a checklist of the documents (original documents or certified copies) that must be included in the proposal package forwarded by the Contractor (or NFESC) to the EFD/EFA when the laboratory is proposed for use.

Q Initial Laboratory Assessment Package

Q Initial Assessment Recommendation Letter

Q Current Proficiency Testing Documents

Q On-site Assessment Report

Q Laboratory Corrective Action Plan

Q Assessment of Planned Corrective Actions

Q Documentation of Corrective Actions Implementation

Q Request for Extension of Corrective Action Documentation (if applicable)

Q Follow-Up Assessment Documentation (if applicable)

Q Assessment Recommendation Letter

Appendix C
Laboratory Requirements

Appendix C, Laboratory Requirements
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General Information **1**

Enclosure

Department of Defense Quality Systems Manual for Environmental Laboratories Enclosure 1

General Information

Enclosure (1) is the Department of Defense (DOD) Quality Systems Manual for Environmental Laboratories. This document provides implementation guidance on the establishment and management of quality systems for environmental testing laboratories that perform work for DOD.

Enclosure (1) is provided to supply interested parties with insight to the direction of upcoming laboratory requirements. Questions or comments concerning the draft should be directed to the contact specified on the manual. NFESC is not generating the document, and is not the agency designated to receive comments.

The Navy Installation Restoration Quality Assurance Program will adopt the DOD document when it has been finalized. In the interim, Section 3 of the Navy Installation Restoration Laboratory Quality Assurance Guide, dated February 1996 will be used.

Enclosure 1

Department of Defense
Quality Systems Manual for Environmental Laboratories

Department of Defense
Environmental Data Quality Workgroup
Quality Systems Manual

The Department of Defense (DoD) is seeking comment on a draft "Quality Systems Manual" for environmental laboratories performing work for DoD. All comments should be submitted to the address listed below by 15 November 1999.

HIGHLIGHTS

- Based upon National Environmental Laboratory Accreditation Conference (NELAC) Quality System standards (Chapter 5) and ISO/IEC Guide 25.
- Provides a standard for quality system implementation for all laboratory testing performed for DoD.
- Will serve as a standard reference for DoD Components who design, implement, and oversee contracts with environmental testing laboratories.

A UNIFIED APPROACH TO QUALITY

The draft "DoD Quality Systems Manual" is designed to unify common elements of the following DoD Component documents:

- United States Navy - *Installation Restoration Laboratory Quality Assurance Guide. Interim Document*. February 1996.
- Air Force Center for Environmental Excellence - *Quality Assurance Project Plan, Version 3*. March 1998.
- Army Corps of Engineers (USACE – HTRW) – *Interim Chemical Data Quality Management (CDQM) Policy for USACE HTRW Projects*. 8 December 1998.

AN APPROACH THAT BENEFITS ALL

Standardization of Processes. The draft Quality Systems Manual is a consensus agreement by the DoD Environmental Data Quality Workgroup (EDQW) Component representatives (Army, Air Force and Navy) on essential elements of a laboratory quality system. DoD expects that contract laboratories will be able to create standardized Quality Systems that meet the requirements of multiple DoD Components. It is planned that quality systems audits by one Component will be acceptable to all Components. The result will be saved resources for both the government and the private sector.

A MANUAL THAT ALL CAN USE

This Manual is designed to meet the needs of many audiences, including:

- Public and private laboratories;
- DoD implementing agency representatives, including contracting agents; and
- DoD oversight personnel and assessors.

COMMENTS SOUGHT:

The language of the base document comes directly from the NELAC Quality Systems standards. The DoD draft language is presented in text boxes as "clarifications" throughout the document. Comments are sought **on the DoD clarifications only**, as the remainder of the document is an official standard of the NELAC.

Comments are sought from the Stakeholder community, including: DoD Components; public or private laboratories; Environmental Protection Agency; State regulatory agencies; and any other parties with an interest in the quality of analytical data. In addition to any technical comments on the document, areas of particular interest include potential impacts:

- On the cost and quality of laboratory data
- On innovation in analytical approaches as the community moves toward Performance Based Measurement Systems in the laboratory.

SUBMIT COMMENTS VIA EMAIL TO:

Ms. Nicole Weymouth
Versar, Inc.
E-mail: weymonic@versar.com

SUBMIT COMMENTS VIA TRADITIONAL MAIL TO:

Versar Inc
Attn Nicole Weymouth
6850 Versar Center
Springfield, VA 22151

Department of Defense

Quality Systems Manual for Environmental Laboratories

DRAFT FOR REVIEW

Based Upon

National Environmental Laboratory Accreditation Program (NELAP)
Chapter 5 (Quality Systems)
NELAP Voted Version 12 – 1 July 1999

DRAFT

Authors

DoD Quality Assurance Authors - Technical Task Action Team
Quality Assurance Subgroup – Environmental Data Quality Workgroup

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PREFACE TO THE DoD QUALITY SYSTEMS MANUAL

Purpose

The purpose of this document is to provide implementation guidance on the establishment and management of quality systems for environmental testing laboratories that intend to perform work for DoD. This guidance is based upon National Environmental Laboratory Accreditation Conference's (NELAC) Quality System requirements, and provides implementation clarification and expectations for DoD environmental programs. It is designed to serve as a standard reference for DoD representatives from all components who design, implement, and oversee contracts with environmental testing laboratories.

Background

To be accredited under the National Environmental Laboratory Accreditation Program (NELAP), laboratories shall have a comprehensive Quality System in place, the requirements for which are outlined in NELAP Chapter 5 (Quality Systems). Using NELAP Chapter 5 as its textual base, the "DoD Quality Systems Manual" is designed to replace common components of the following documents, previously issued by individual components of DoD:

- United States Navy - *Installation Restoration Laboratory Quality Assurance Guide*, Interim Document, February 1996.
- Air Force Center for Environmental Excellence - *Quality Assurance Project Plan, Version 3.* March 1998.
- Army Corps of Engineers (USACE – HTRW) – *Interim Chemical Data Quality Management (CDQM) Policy for USACE HTRW Projects.* 8 December 1998.

In combining the common components of these three documents, this Manual allows laboratories to design Quality Systems to meet basic requirements for laboratory accreditation under NELAP, as well as the implementation needs of all DoD components. The document achieves this by clarifying and elaborating upon DoD's expectations of the laboratory, with respect to the implementation of specific components of the NELAC Quality System.

Full implementation of this Manual's requirements is expected within two years following release. This standardized document is only one of several efforts planned for implementation by DoD. As such, until such time as further standardization by DoD occurs, this document may be supplemented by component-specific requirements. In addition, specific requirements outlined in project-specific QAPP's will also provide additional guidance that shall be followed. Requirements contained in this Manual are superceded by more stringent or more specific project-specific requirements or regulations. The laboratory bears the responsibility for meeting all State requirements. Nothing in this document relieves any laboratory from complying with contract requirements or with Federal, State, and/or local regulations.

Results and Benefits

The side-by-side integration of NELAP requirements with DoD implementation clarifications creates several benefits for the laboratory, DoD, and the regulatory communities.

- **Standardization of Processes** – Because this Manual provides laboratories with a comprehensive set of requirements that meet the needs of all DoD clients, as well as NELAP, the laboratory may use it to create a standardized Quality System. Ultimately, this standardization will save laboratory resources, by establishing one set of consistent requirements for all DoD environmental work. The standardized guidance will also serve to "level the playing field" for laboratories competing for DoD contracts, because the expectations will be identical across all DoD components.

- **Uniformity of Expectations, Conservation of Resources** – Because this Manual has been accepted by all DoD components, an audit that satisfies the needs of one component will satisfy comparable needs of the other components as well. As such, this standardized Manual will result in standardized audits, which are consistent and transferable between components. The result will be saved resources for both the government and private sector.

- **Deterrence of Fraud** – Fraudulent activities by only a few laboratories have implications throughout the industry, with negative impacts upon all laboratories. This Manual addresses this issue, establishing a minimum threshold program for all laboratories to use to deter and detect fraud.

- **Compliance Requirement Specification** – Because this Manual applies to all laboratories performing environmental work for DoD, it represents the first policy guidance for laboratories involved in compliance testing.

- **Foundations for the Future** – A standardized approach to Quality Systems, shared by laboratories, NELAP, and DoD paves the way for the standardization of other processes in the future. For example, this Manual might serve as a platform for a standardized strategy for Performance Based Measurement System (PBMS) implementation. In addition, as noted above, DoD plans to supplement this document with other standardized tools, including standard report formats..

Audience

This Manual is designed to meet the needs of the following audiences:

- Public (i.e., government) and private laboratories, contracted with DoD either directly, or through a prime contractor or subcontractor;
- DoD Implementing Agency representatives, who will use this document to ensure consistency with NELAP when drafting contracts; and
- DoD Oversight Personnel and Assessors, who will use this document to uniformly and consistently evaluate the laboratory's implementation of NELAP and DoD program requirements.

Document Format

Because the DoD Quality Systems Manual is designed to complement and implement NELAP Chapter 5 (Quality Systems), that document serves as the primary text for this Implementation Manual. As such, DoD clarifications that elaborate upon specific NELAP requirements are presented in gray text boxes, placed at the applicable section of the document. This allows laboratories preparing for NELAP accreditation to implement their Quality Systems in a way that fulfills the needs of DoD, as well as NELAP. For ease of reference, each gray box in the draft document is numbered.

5.0 QUALITY SYSTEMS

Quality Systems include all quality assurance (QA) policies and quality control (QC) procedures, which shall be delineated in a Quality Manual and followed to ensure and document the quality of the analytical data. Laboratories seeking accreditation under the National Environmental Accreditation Program (NELAP) must assure implementation of all QA policies and the essential applicable QC procedures specified in this chapter. The QA policies, which establish essential QC procedures, are applicable to environmental laboratories regardless of size and complexity.

The intent of this Chapter is to provide sufficient detail concerning quality management requirements so that all accrediting authorities evaluate laboratories consistently and uniformly.

NELAC is committed to the use of Performance Based Measurement Systems (PBMS) in environmental testing and provides the foundation for PBMS implementation in these standards. While this standard may not currently satisfy all the anticipated needs of PBMS, NELAC will address future needs within the context of State statutory and regulatory requirements and the finalized EPA implementation plans for PBMS.

Chapter 5 is organized according to the structure of ISO/IEC Guide 25, 1990. Where deemed necessary, specific areas within this Chapter may contain more information than specified by ISO/IEC Guide 25.

All items identified in this chapter shall be available for on-site inspection or data audit.

5.1 SCOPE

a) This Standard sets out the general requirements in accordance with which a laboratory has to demonstrate that it operates, if it is to be recognized as competent to carry out specific environmental tests.

b) This Standard includes additional requirements and information for assessing competence or for determining compliance by the organization or accrediting authority granting the recognition (or approval).

   If more stringent standards or requirements are included in a mandated test method or by regulation, the laboratory shall demonstrate that such requirements are met. If it is not clear which requirements are more stringent, the standard from the method or regulation is to be followed.

c) This Standard is for use by environmental testing laboratories in the development and implementation of their quality systems. It shall be used by accreditation authorities, in assessing the competence of environmental laboratories.

DoD Implementation Clarification:

- These standards are applicable to any laboratory providing sample analysis to support environmental programs for DoD installations and facilities within the United States and its possessions.
- These standards are intended to apply to laboratories that produce definitive data (i.e., technically defensible and legally admissible data).
- These standards may be supplemented by project-specific requirements, as agreed upon by the agency, regulators, laboratories, and other involved parties.
- The laboratory bears the responsibility for meeting all State requirements. Nothing in this document relieves any laboratory from complying with contract requirements or with Federal, State, and/or local regulations.

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5.2 REFERENCES

See Appendix A.

5.3 DEFINITIONS

The relevant definitions from ISO/IEC Guide 2, ISO 8402, ANSI/ASQC E-4, 1994, the EPA "Glossary of Quality Assurance Terms and Acronyms," and the *International vocabulary of basic and general terms in metrology (VIM*) are applicable, the most relevant being quoted in NELAP Chapter 1 Appendix A Glossary together with further definitions applicable for the purposes of this Standard.

DoD Implementation Clarification: For reference purposes, applicable terms from the NELAC Glossary are included as Appendix B in this DoD Manual. Furthermore, additional terms not currently included in the NELAP Glossary are defined by DoD to aid the laboratory in implementing this standard appropriately. These terms are also in Appendix B.

2

5.4 ORGANIZATION AND MANAGEMENT

5.4.1 Legal Definition of Laboratory

The laboratory shall be legally identifiable. It shall be organized and shall operate in such a way that its permanent, temporary, and mobile facilities meet the requirements of this Standard**.**

5.4.2 Organization

The laboratory shall:

a) Have managerial staff with the authority and resources needed to discharge their duties;

b) Have processes to ensure that its personnel are free from any commercial, financial, and other undue pressures, which might adversely affect the quality of their work;

c) Be organized in such a way that confidence in its independence of judgment and integrity is maintained at all times;

d) Specify and document the responsibility, authority, and interrelationship of all personnel who manage, perform, or verify work affecting the quality of calibrations and tests;

   Such documentation shall include:

   1) A clear description of the lines of responsibility in the laboratory and shall be proportioned such that adequate supervision is ensured and

   2) Job descriptions for all positions.

e) Provide supervision by persons familiar with the calibration or test methods and procedures, the objective of the calibration or test, and the assessment of the results. The ratio of supervisory to nonsupervisory personnel shall be such as to ensure adequate supervision, to ensure adherence to laboratory procedures and accepted techniques.

f) Have a technical director(s) (however named) who has overall responsibility for the technical operation of the environmental testing laboratory;

The technical director(s) shall certify that personnel with appropriate educational and/or technical background perform all tests for which the laboratory is accredited. Such certification shall be documented.

The technical director(s) shall meet the requirements specified in the Accreditation Process. (See NELAC Section 4.1.1.1.)

g) Have a quality assurance officer (however named) who has responsibility for the quality system and its implementation. The quality assurance officer shall have direct access to the highest level of management at which decisions are taken on laboratory policy or resources, and to the technical director. Where staffing is limited, the quality assurance officer may also be the technical director or deputy technical director;

The quality assurance officer (and/or his/her designees) shall:

1) Serve as the focal point for QA/QC and be responsible for the oversight and/or review of quality control data;

2) Have functions independent from laboratory operations for which they have QA oversight;

3) Be able to evaluate data objectively and perform assessments without outside (e.g., managerial) influence;

4) Have documented training and/or experience in QA/QC procedures and be knowledgeable in the Quality System, as defined under NELAC;

5) Have a general knowledge of the analytical test methods for which data review is performed;

6) Arrange for or conduct internal audits on the entire technical operation annually; and

7) Notify laboratory management of deficiencies in the quality system and monitor corrective action.

DoD Implementation Clarification: The Quality Assurance Officer shall also be responsible for ensuring continuous improvement at the laboratory through the use of control charts and other method performance indicators.

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h) Nominate deputies in case of absence of the technical director(s) and/or quality assurance officer;

i) Have documented policy and procedures to ensure the protection of clients' confidential information and proprietary rights (this may not apply to in-house laboratories);

j) When available, participate in inter-laboratory comparisons and proficiency testing programs. For purposes of qualifying for and maintaining accreditation, each laboratory shall participate in a proficiency test program as outlined in NELAP Chapter 2.0.

DoD Implementation Clarification: Technical directors are responsible for following through with proficiency testing programs and for ensuring that corrective actions are implemented after testing.

4

5.5 QUALITY SYSTEM - ESTABLISHMENT, AUDITS, ESSENTIAL QUALITY CONTROLS, AND DATA VERIFICATION

5.5.1 Establishment

The laboratory shall establish and maintain a quality system based on the required elements contained in this Chapter and appropriate to the type, range, and volume of environmental testing activities it undertakes.

a) The elements of this Quality System shall be documented in the organization's quality manual.

b) The quality documentation shall be available for use by the laboratory personnel.

DoD Implementation Clarification: This documentation includes the Quality Manual, Standard Operation Procedure (SOP) documents, and other appropriate reference documents and texts.
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c) The laboratory shall define and document its policies and objectives for, and its commitment to accepted laboratory practices and quality of testing services.

d) The laboratory management shall ensure that these policies and objectives are documented in a Quality Manual and communicated to, understood, and implemented by all laboratory personnel concerned.

e) The Quality Manual shall be maintained current under the responsibility of the quality assurance officer.

5.5.2 Quality Manual

The Quality Manual and related quality documentation shall state the laboratory's policies and operational procedures established in order to meet the requirements of this Standard.

The Quality Manual shall list on the title page: a document title; the laboratory's full name and address; the name, address (if different from above), and telephone number of individual(s) responsible for the laboratory; the name of the quality assurance officer (however named); the identification of all major organizational units, which are to be covered by this quality manual; and the effective date of the version.

DoD Implementation Clarification: The following list reflects topic areas that shall be included in the Quality Manual. Additional details about each topic area are provided in the sections that follow. The Manual shall be reviewed at least annually for accuracy and adequacy, and updated as appropriate. All such reviews shall be documented and available for inspection.
6

The Quality Manual and related quality documentation shall also contain:

a) A quality policy statement, including objectives and commitments, by top management;

b) The organization and management structure of the laboratory, its place in any parent organization, and relevant organizational charts;

DoD Implementation Clarification: This includes the laboratory's relationship(s) to corporate affiliations and networks.
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c) The relationship between management, technical operations, support services, and the quality system;

d) Procedures to ensure that all records required under this Chapter are retained, as well as procedures for control and maintenance of documentation through a document control system that ensures that all standard operating procedures, manuals, or documents clearly indicate the time period during which the procedure or document was in force;

DoD Implementation Clarification: Consistent with the definition of "Document Control" provided in NELAP Appendix B, this control system shall ensure that each updated SOP is distributed to all analysts implementing the task(s) or procedure(s) described in that SOP.

8

e) Job descriptions of key staff and reference to the job descriptions of other staff;

DoD Implementation Clarification: At a minimum, the following managerial and supervisory staff (however named), shall be considered key, and their job descriptions included in the Quality Manual and other related documents: Executive Staff (e.g., Chief Executive Officer, Chief Operating Officer, Laboratory Director, Technical Director); Technical Directors/Supervisors (e.g., Section Supervisors for Organics and Inorganics); Quality Assurance Systems Directors/Supervisors (e.g., QA Officer, Quality Auditors); and Support Systems Directors/Supervisors (e.g., Information Systems Supervisor, Purchasing Director, Project Managers). In addition, the Quality Manual shall include job descriptions for key staff in each of these four areas, as appropriate to the laboratory.

Technical staff are those individuals who conduct the work of the laboratory (e.g., sample receipt and documentation staff, the chemists who run the analytical equipment). Support staff administer the business practices of the laboratory, as well as information management and contractual systems. Quality Assurance staff oversee the implementation of the quality system, and report to the Quality Assurance Officer or his/her designee.

If the size and organization of the laboratory precludes separate managers and/or supervisors in each of these key areas, the functions covered in the four areas shall be addressed in the job descriptions provided for the key staff.

Finally, the Quality Manual shall describe the relationship of key staff to other technical and support staff.

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f) Identification of the laboratory's approved signatories; at a minimum, the title page of the Quality Manual must have the signed and dated concurrence, (with appropriate titles) of all responsible parties including the QA officer(s), technical director(s), and the agent who is in charge of all laboratory activities, such as the laboratory director or laboratory manager;

g) The laboratory's procedures for achieving traceability of measurements;

DoD Implementation Clarification: Standards addressing this issue are included in Section 5.9 (Measurement Traceability and Calibration), Section 5.10.5 (Documentation and Labeling of Standards and Reagents), and Section 5.12 (Records).

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h) A list of all test methods under which the laboratory performs its accredited testing;

i) Mechanisms for ensuring that the laboratory reviews all new work to ensure that it has the appropriate facilities and resources before commencing such work;

j) Reference to the calibration and/or verification test procedures used;

k) Procedures for handling submitted samples;

l) Reference to the major equipment and reference measurement standards used, as well as the facilities and services used by the laboratory in conducting tests;

m) Reference to procedures for calibration, verification, and maintenance of equipment;

n) Reference to verification practices including interlaboratory comparisons, proficiency testing programs, use of reference materials, and internal quality control schemes;

o) Procedures to be followed for feedback and corrective action whenever testing discrepancies are detected or departures from documented policies and procedures occur;

p) The laboratory management arrangements for exceptionally permitting departures from documented policies and procedures or from standard specifications;

q) Procedures for dealing with complaints;

r) Procedures for protecting confidentiality (including national security concerns) and proprietary rights;

s) Procedures for audits and data review;

DoD Implementation Clarification: The Quality Manual shall also specify which records are considered necessary to conduct an adequate review.

11

t) Processes/procedures for establishing that personnel are adequately experienced in the duties they are expected to carry out and are receiving any needed training;

u) Processes/procedures for educating and training personnel in their ethical and legal responsibilities, including the potential punishments and penalties for improper, unethical, or illegal actions;

DoD Implementation Clarification: Additional descriptions related to this requirement are included in Section 5.6.2.

12

v) Reference to procedures for reporting analytical results; and

w) A Table of Contents and applicable lists of references, glossaries, and appendices.

5.5.3 Audits

DoD Implementation Clarification: The following subsections of 5.5.3 refer to Internal Assessment Tools to be used by the laboratory. Section 5.5.3.1 discusses Systems and Technical Audits, both of which shall be conducted annually to evaluate whether the quality system is being implemented at the operational level of the laboratory. Section 5.5.3.2 addresses higher-level managerial reviews, designed to evaluate whether the quality system itself is effective. This section also addresses requirements for a Fraud Prevention program. Section 5.5.3.3 addresses the review of all auditing activities. Section 5.5.3.4 addresses continuous quality control practices, that shall be conducted by the laboratory on an ongoing basis.

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5.5.3.1 Internal Audits

The laboratory shall arrange for annual internal audits to verify that its operations continue to comply with the requirements of the laboratory's quality system. It is the responsibility of the quality assurance officer to plan and organize audits as required by a predetermined schedule and requested by management. Such audits shall be carried out by trained and qualified personnel who are, whenever resources permit, independent of the activity to be audited. Personnel shall not audit their own activities except when it can be demonstrated that an effective audit will be carried out. Where the audit findings cast doubt on the correctness or validity of the laboratory's calibrations or test results, the laboratory shall take immediate corrective action and shall immediately notify, in writing, any client whose work may have been affected.

DoD Implementation Clarification: These Internal Audits shall include both Technical and Systems Audits. Technical Audits verify compliance with method-specific requirements, as well as operations related to the test method (e.g., sample preparation). (These operations include all actions related to data generation and the assurance of its quality.) Systems Audits verify compliance with the laboratory's quality system, based upon the NELAP Quality System, and documented in the laboratory's Quality Manual. Response to complaints, sample acceptance policies, and sample tracking methodologies are examples of procedures that would be reviewed as part of a Systems Audit.

An audit schedule shall be established such that all elements/areas of the laboratory are reviewed over the course of one year.

Personnel performing an internal audit shall complete the audit under the direction of the Quality Assurance Officer, however named. To be considered "trained and qualified," the Internal Auditor shall be trained and qualified in conducting the type of audit under review.

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5.5.3.2 Managerial Review

The laboratory management shall conduct a review, at least annually, of its quality system and its testing and calibration activities to ensure its continuing suitability and effectiveness and to introduce any necessary changes or improvements in the quality system and laboratory operations. The review shall take account of reports from managerial and supervisory personnel, the outcome of recent internal audits, assessments by external bodies, the results of inter-laboratory comparisons or proficiency tests, any changes in the volume and type of work undertaken, feedback from clients, corrective actions, and other relevant factors. The laboratory shall have a procedure for review by management and maintain records of review findings and actions.

DoD Implementation Clarification: This is a separate review from the Internal Audit discussed in Section 5.5.3.1, and shall be completed by laboratory managerial personnel.

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5.5.3.3 Audit Review

All audit and review findings and any corrective actions that arise from them shall be documented. The laboratory management shall ensure that these actions are discharged within the agreed timeframe.

DoD Implementation Clarification: The timeframe for these actions shall be based upon the magnitude of the problem and its impact upon the defensibility and use of data.

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5.5.3.4 Performance Audits

In addition to periodic audits, the laboratory shall ensure the quality of results provided to clients by implementing checks to monitor the quality of the laboratory's analytical activities. Examples of such checks are:

a) Internal quality control procedures using, whenever possible, statistical techniques (See Section 5.5.4 below);

b) Participation in proficiency testing or other interlaboratory comparisons (See NELAC Chapter 2.0);

c) Use of certified reference materials and/or in-house quality control using secondary reference materials, as specified in Section 5.5.4;

d) Replicate testings using the same or different test methods;

e) Re-testing of retained samples; and

f) Correlation of results for different parameters of a sample (e.g., total phosphorus should be greater than or equal to orthophosphate).

DoD Implementation Clarification: This section requires the laboratory to continuously evaluate the quality of generated data, by systematically and routinely implementing control checks that go beyond those required by the test methods. The results of these checks (examples of which are listed above) shall be routinely reviewed after they are performed to monitor and evaluate the quality and usability of data generated by the laboratory. Although a supplemental review of these checks shall be included as part of the annual internal audits, the laboratory shall also ensure that the results of these checks are reviewed (and corrective action taken) on a regular and timely basis following the actual completion of the check to remedy the problem, avoid its reoccurrence, and improve the Quality System overall.

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5.5.3.5 Corrective Actions

a) In addition to providing acceptance criteria and specific protocols for corrective actions in the Method Standard Operating Procedures (Section 5.10.1.1), the laboratory shall implement general procedures to be followed to determine when departures from documented policies, procedures, and quality control have occurred. These procedures shall include, but are not limited to, the following:

   1) Identify the individual(s) responsible for assessing each QC data type;

   2) Identify the individual(s) responsible for initiating and/or recommending corrective actions;

   3) Define how the analyst should treat a data set if the associated QC measurements are unacceptable;

   4) Specify how out-of-control situations and subsequent corrective actions are to be documented; and

   5) Specify procedures for management (including the QA officer) to review corrective action reports.

DoD Implementation Clarification: Management, including the QA Officer, is also responsible for acting upon these reviews, ensuring that corrective actions are taken, and checking the adequacy of those corrective actions. Furthermore, management is ultimately accountable for the follow-through and verification of these corrective actions. Further explanatory clarifications of DoD expectations are provided as follows:

Nonconformance. The laboratory shall have an established, documented policy and procedures to identify and control work and test results that do not or may not meet expected or specified requirements, or are nonconforming or suspected to be nonconforming. Policy and procedures shall ensure that:

- Responsibilities and authorities for management of nonconforming work/results are designated.
- Actions to be taken upon identification of a nonconformance are defined and implemented, and include, but are not limited to: evaluating the significance of a nonconformance; halting work and investigating the contributors to the nonconformance (e.g., equipment, personnel, methods); withholding of reports and certificates, as necessary; informing clients of nonconformance resulting from their samples and the need to recall results of nonconforming work already released to them; and implementing corrective action as needed. (See corrective action requirements below.)

Corrective Action. The laboratory shall have an established, documented policy, and procedures for actions to be taken to eliminate the causes of a nonconformance and to prevent recurrence. The corrective action process shall identify and implement corrective actions likely to eliminate the root cause of nonconformance(s). Laboratory policies and procedures shall ensure that:

- Responsibilities and authorities for instituting corrective action are designated.
- Possible causes of the nonconformance(s) are investigated.
- Root cause analysis is performed.
- Changes resulting from corrective action are recorded.
- Corrective action(s) are monitored.
- Preventative action is taken to prevent recurrence.

Monitoring of Corrective Actions. After implementation of corrective action(s), the laboratory shall monitor their effect to determine if action(s) taken are effective in overcoming the nonconformance identified (i.e., the root cause has been eliminated and its reoccurrence prevented). Historical corrective action reports should be periodically reviewed to identify long-term trends or recurring problems.

Preventive Action. All operations shall be systematically and thoroughly reviewed at regular intervals to:

- Obtain input on the laboratory's operations;
- Determine what considerations need to be given to input (from reviews); and
- Determine how corrective action(s), if necessary, shall be carried out.

Reference: American Society for Quality Control. 1991. *Q2 – Quality Management and Quality System Elements for Laboratories – Guidelines.*

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b) To the extent possible, samples shall be reported only if all quality control measures are acceptable. If a quality control measure is found to be out of control, and the data are to be reported, all samples associated with the failed quality control measure shall be reported with the appropriate data qualifier(s).

DoD Implementation Clarification: These standard data qualifiers include the following:

U – Undetected; The associated number is the method reporting limit, adjusted by any dilution factor used in the analysis.
J – Estimated; The analyte was positively identified; the quantitation is an estimation.
B – Blank contamination; Analyte detected above the method reporting limit in an associated blank.
R – Rejected; Data are unusable for their intended project use.
N – Nontarget analyte; Tentatively identified compound (using mass spectroscopy).

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5.5.4 Essential Quality Control Procedures

These general quality control principles shall apply, where applicable, to all testing laboratories. The manner in which they are implemented is dependent on the types of tests performed by the laboratory (i.e., chemical, whole effluent toxicity, microbiological, radiological, air) and are further described in Appendix D. The standards for any given test type shall ensure that the applicable principles are addressed:

a) All laboratories shall have protocols in place to monitor the following quality controls:

DoD Implementation Clarification: Quality control actions should be both batch-specific and time-based (i.e., those required to be conducted at specific time periods, such as for tunes and method detection limits [MDLs]).

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1) Adequate positive and negative controls to monitor tests, such as blanks, spikes, reference toxicants;

2) Adequate tests to define the variability and/or repeatability of the laboratory results, such as replicates;

3) Measures to assure the accuracy of the test method, including sufficient calibration and/or continuing calibrations, use of certified reference materials, proficiency test samples, or other measures;

4) Measures to evaluate test method capability, such as detection limits and quantitation limits or range of applicability, such as linearity;

5) Selection of appropriate formulae to reduce raw data to final results, such as regression analysis, comparison to internal/external standard calculations, and statistical analyses;

6) Selection and use of reagents and standards of appropriate quality;

6) Measures to ensure the selectivity of the test for its intended purpose; and

7) Measures to ensure constant and consistent test conditions (both instrumental and environmental) where required by the test method such as temperature, humidity, light, or specific instrument conditions.

b) All quality control measures shall be assessed and evaluated on an ongoing basis, and quality control acceptance criteria shall be used to determine the usability of the data. (See Appendix D.)

c) The laboratory shall have procedures for the development of acceptance/rejection criteria where no method or regulatory criteria exist. (See Section 5.11.2, Sample Acceptance Policy.)

d) The quality control protocols specified by the laboratory's method manual (Section 5.10.1.2) shall be followed. The laboratory shall ensure that the essential standards outlined in Appendix D are incorporated into its method manuals.

The essential quality control measures for testing are found in Appendix D of this chapter.

5.6 PERSONNEL

5.6.1 General Requirements for Laboratory Staff

The laboratory shall have sufficient personnel, having the necessary education, training, technical knowledge, and experience for their assigned functions.

All personnel shall be responsible for complying with all quality assurance/quality control requirements that pertain to their organizational/technical function. Each technical staff member must have a combination of experience and education to adequately demonstrate a specific knowledge of his/her particular function and a general knowledge of laboratory operations, test methods, quality assurance/quality control procedures, and records management.

DoD Implementation Clarification: Required qualifications for the Technical Director(s) are addressed further below. DoD stresses that a director or designee meeting the qualifications below shall be present in each area of analytical service. Laboratory management, as addressed in Section 5.6.2, is defined as designees (e.g., Laboratory Manager, Technical Director, Supervisors, and Quality Assurance Officers, however named) having oversight authority and responsibility for laboratory output.

The following requirements are direct excerpts from NELAP Chapter 4 (Accreditation Process), Revision 12 – July 1, 1999.

4.1.1 Personnel Qualifications

Persons who do not meet the education credential requirements of Section 4.1.1.1 of the NELAC standards and are the technical director(s) on the date that the laboratory becomes subject to these NELAC Standards, and obtains accreditation, shall qualify as technical director(s) for the field of testing of that laboratory or any other NELAC-accredited laboratory.

4.1.1.1. Definition, Technical Director(s)

The technical director(s) means a full-time member of the staff of an environmental laboratory who exercises actual day-to-day supervision of laboratory procedures and reporting of results. The title of such person may include, but is not limited to, laboratory director, technical director, laboratory supervisor, or laboratory manager. A laboratory may appoint one or more technical directors for the appropriate fields of testing for which they are seeking accreditation. His/her name shall appear in the national database. This person's duties shall include, but not be limited to, monitoring standards of performance in quality control and quality assurance; monitoring the validity of the analyses performed and data generated in the laboratory to assure reliable data; ensuring that sufficient numbers of qualified personnel are employed to supervise and perform the work of the laboratory; and providing educational direction to laboratory staff. An individual shall not be the technical director(s) of more than one accredited environmental laboratory without authorization from the primary Accrediting Authority. Circumstances to be considered in the decision to grant such authorization shall include, but not be limited to, the extent to which operating hours of the laboratories to be directed overlap, adequacy of supervision in each laboratory, and the availability of environmental laboratory services in the area served. The technical director(s) who is absent for a period of time exceeding 15 consecutive calendar days shall designate another full-time staff member meeting the qualifications of the technical director(s) to temporarily perform this function. If this absence exceeds 65 consecutive calendar days, the primary

accrediting authority shall be notified in writing.

Qualification of the Technical Director(s):

a) Any technical director of an accredited environmental laboratory engaged in chemical analysis shall be a person with a bachelors degree in the chemical, environmental, biological sciences, physical sciences, or engineering, with at least 24 college semester credit hours in chemistry and at least two years of experience in the environmental analysis of representative inorganic and organic analytes for which the laboratory seeks or maintains accreditation. A masters or doctoral degree in one of the above disciplines may be substituted for one year of experience.

b) Any technical director of an accredited environmental laboratory limited to inorganic chemical analysis, other than metals analysis, shall be a person with at least an earned associate's degree in the chemical, physical, or environmental sciences, or two years of equivalent and successful college education, with a minimum of 16 college semester credit hours in chemistry. In addition, such a person shall have at least two years of experience performing such analysis.

c) The technical director(s) of an accredited environmental laboratory engaged in microbiological or biological analysis shall be a person with a bachelors degree in microbiology, biology, chemistry, environmental sciences, physical sciences, or engineering with a minimum of 16 college semester credit hours in general microbiology and biology and at least two years of experience in the environmental analysis of representative analytes for which the laboratory seeks or maintains accreditation. A masters or doctoral degree in one of the above disciplines may be substituted for one year of experience.

   A person with an associate's degree in an appropriate field of the sciences or applied sciences, with a minimum of four college semester credit hours in general microbiology may be the technical director(s) of a laboratory engaged in microbiological analysis limited to fecal coliform, total coliform, and standard plate count. Two years of equivalent and successful college education, including the microbiology requirement, may be substituted for the associate's degree. In addition, each person shall have one year of experience in environmental analysis.

d) Any technical director of an accredited environmental laboratory engaged in radiological analysis shall be a person with a bachelor's degree in chemistry, physics, or engineering with 24 college semester credit hours of chemistry with two or more years of experience in the radiological analysis of environmental samples. A masters or doctoral degree in one of the above disciplines may be substituted for one year experience.

e) Any technical director of an accredited environmental laboratory engaged in microscopic examination of asbestos and/or airborne fibers shall meet the following requirements:

   i) For procedures requiring the use of a transmission electron microscope, a bachelors degree, successful completion of courses in the use of the instrument, and one year of experience, under supervision, in the use of the instrument. Such experience shall include the identification of minerals.

   ii) For procedures requiring the use of a polarized light microscope, an associate's degree or two years of college study, successful completion of formal coursework in polarized light microscopy, and one year of experience, under supervision, in the use of the instrument. Such experience shall include the identification of minerals.

   iii) For procedures requiring the use of a phase contrast microscope, as in the determination of airborne fibers, an associate's degree or two years of college study, documentation of successful completion of formal coursework in phase contrast microscopy, and one year of experience, under supervision, in the use of the instrument.

f) Any technical director of an accredited environmental laboratory engaged in the examination of radon in air shall have at least an associate's degree or two years of college and one year of experience in radiation measurements, including at least one year of experience in the measurement of radon and/or radon progeny.

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5.6.2 Laboratory Management Responsibilities

In addition to Section 5.4.2.d., the laboratory management shall be responsible for:

a) Defining the minimal level of qualification, experience, and skills necessary for all positions in the laboratory. In addition to education and/or experience, basic laboratory skills, such as using a balance, colony counting, aseptic, or quantitative techniques, shall be considered.

b) Ensuring that all technical laboratory staff have demonstrated capability in the activities for which they are responsible. Such demonstration shall be documented (See Appendix C).

Note: In laboratories with specialized “work cells” (a well-defined group of analysts that together perform the method analysis), the group as a unit must meet the above criteria and this demonstration must be fully documented).

DoD Implementation Clarification: Additional guidance on this issue is provided in Section 5.10.2.1.f and g. A “work cell” is considered to be all those individuals who see a sample through the complete process of preparation/extraction and analysis. To ensure that the entire preparation-extraction-analysis process is completed by a collection of capable individuals, the laboratory shall ensure that **each member** of the work cell demonstrates capability in his/her area of responsibility in the sequence. Even though the work cell operates as a “team,” the Demonstration of Capability at each individual step in the sequence as performed by each individual analyst/team member, remains of utmost importance. A work cell may NOT be defined as a group of analysts that performs the same step in the same process (e.g., extractions for Method 8270), represented by one analyst who has demonstrated capability for that step.

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c) Ensuring that the training of each member of its technical staff is kept up-to-date (on-going) by the following:

1) Evidence must be on file that demonstrates that each employee has read, understood, and is using the latest version of the laboratory's in-house quality documentation, which relates to his/her job responsibilities.

2) Training courses or workshops on specific equipment, analytical techniques, or laboratory procedures shall all be documented.

3) Training courses in legal and ethical responsibilities include the potential punishments and penalties for improper, unethical, or illegal actions. Evidence must also be on file that demonstrates that each employee has read, acknowledged, and understood their personal ethical and legal responsibilities, including the potential punishments and penalties for improper, unethical or illegal actions.

DoD Implementation Clarification: Additional descriptions related to this requirement are included in Section 5.6.2.

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4) Analyst training shall be considered up to date if an employee training file contains a certification that technical personnel have read, understood, and agreed to perform the most recent version of

the test method (the approved method or standard operating procedure) and documentation of continued proficiency by at least one of the following once per year:

i. Acceptable performance of a blind sample (single blind to the analyst);

ii. Another demonstration of capability;

iii. Successful analysis of a blind performance sample on a similar test method using the same technology (e.g., gas chromatography/mass spectrometry [GC/MS] volatiles by purge and trap for 524.2, 624, or 5035/8260 would only require documentation for one of the test methods);

iv. At least four consecutive laboratory control samples with acceptable levels of precision and accuracy;

v. If i-iv cannot be performed, analysis of authentic samples that have been analyzed by another trained analyst with statistically indistinguishable results.

d) Documenting all analytical and operational activities of the laboratory;

e) Supervising all personnel employed by the laboratory;

f) Ensuring that all sample acceptance criteria (Section 5.11) are verified and that samples are logged into the sample tracking system and properly labeled and stored; and

g) Documenting the quality of all data reported by the laboratory.

h) Developing a proactive program for the prevention and detection of improper, unethical, or illegal actions. The components of this program could include: internal Proficiency testing (single and double blind); post-analysis electronic and magnetic tape audits; effective reward program to improve employee vigilance and co-monitoring; and separate SOPs identifying appropriate and inappropriate laboratory and instrument manipulation practices.

DoD Implementation Clarification: In order to perform work for DoD under this Manual, the laboratory shall have a documented Fraud Prevention Program. To facilitate the implementation of this required program, DoD has compiled the following text to (1) clearly define the term fraud, (2) outline fraud prevention and detection program elements, and (3) identify examples of inappropriate (i.e., potentially fraudulent) laboratory practices. Data shall be produced according to the project-specific requirements as specified in the final approved project documents. The laboratory shall be aware of these requirements and be able to show that these requirements were followed.

Definition. Laboratory fraud is defined as the deliberate falsification of analytical or quality assurance results, where failed method or contractual requirements are made to appear acceptable. It is also defined as an intentional gross deviation from contract-specified or method-specified analytical practices, combined with the intent to conceal the deviation. Prevention of laboratory fraud begins with a zero tolerance philosophy established by management. Fraud is detected through the implementation of oversight protocols.

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Fraud Detection & Prevention Program. Laboratory management shall implement a variety of proactive measures to promote prevention and detection of fraudulent activities. The following components constitute the baseline and minimum requirements for a fraud prevention program and shall be included as part of the laboratory's comprehensive quality program.

- An ethics policy that is read and signed by all personnel;
- Annual ethics training;
- Internal audits, as described elsewhere in Section 5.5.3;
- Inclusion of anti-fraud language in subcontracts;
- Analyst notation and sign-off on manual integration changes to data (See also Section 5.8.a); and
- Active use of electronic audit functions are mandatory, when they are available in the instrument software.

A proactive, "beyond the basics" approach to fraud prevention is a necessary part of laboratory management. As such, in addition to the mandatory requirements above, the laboratory shall institute other fraud deterrence and detection programs, as required by NELAC.

Examples of Data Fraud/Inappropriate Practices. Documentation that clearly shows how all analytical values were obtained shall be maintained by the laboratory, and supplied to the data user when necessary. To avoid miscommunication, a laboratory shall clearly document all errors, mistakes, and basis for manual integrations within the case narrative. Notification should also be made to the appropriate people such that appropriate corrective actions can be initiated. Gross deviations from specified procedures should be investigated for potential fraud, and findings of fraud prosecuted to the fullest extent of the law. Examples of fraudulent practices are identified below:

- Inappropriate use of manual integrations to meet calibration or method QC criteria would be considered fraud (e.g., peak shaving or peak enhancement are considered fraudulent activities if performed solely to meet QC requirements);
- Manipulation of time travel of analyses to meet method 12-hour clock requirements;
- Falsification of results to meet method requirements;
- Reporting of results without analyses to support (e.g., dry-labbing);
- Selective exclusion of data to meet QC criteria (i.e., initial calibration points dropped without technical or statistical justification).
- Misrepresentation of laboratory performance by presenting calibration data or QC limits within data reports that are not linked to the data set reported, or QC control limits presented within LQMP that are not indicative of historical laboratory performance or used for batch control; and
- Notation of matrix inference as basis for exceeding acceptance limits (typically without implementing corrective actions) in interference-free matrices (e.g., method blanks or laboratory control samples).

References:
California Military Environmental Coordination Committee (EPA, CAL EPA, and DoD). March 1997. "Best Practices for the Detection and Deterrence of Laboratory Fraud."
Army Corps of Engineers (USACE – HTRW) – *Interim Chemical Data Quality Management (CDQM) Policy for USACE HTRW Projects.* 8 December 1998.

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5.6.3 Records

Records on the relevant qualifications, training, skills and experience of the technical personnel shall be maintained by the laboratory, including records on demonstrated proficiency for each laboratory test method, such as the criteria outlined in Section 5.10.2.1 for chemical testing. (See Section 5.6.2.c.)

5.7 PHYSICAL FACILITIES - ACCOMMODATION AND ENVIRONMENT

5.7.1 Environment

a) Laboratory accommodation, test areas, energy sources, lighting, heating, and ventilation shall be such as to facilitate proper performance of tests.

b) The environment in which these activities are undertaken shall not invalidate the results or adversely affect the required accuracy of measurement. Particular care shall be taken when such activities are undertaken at sites other than the permanent laboratory premises.

c) The laboratory shall provide for the effective monitoring, control, and recording of environmental conditions, as appropriate. Such environmental conditions may include biological sterility, dust, electromagnetic interference, humidity, mains voltage, temperature, and sound and vibration levels.

d) In instances where monitoring or control of any of the above mentioned items are specified in a test method or by regulation, the laboratory shall meet and document adherence to the laboratory facility requirements.

NOTE: It is the laboratory's responsibility to comply with the relevant health and safety requirements. This aspect, however, is outside the scope of this Standard.

5.7.2 Work Areas

a) There shall be effective separation between neighboring areas when the activities therein are incompatible, including culture handling or incubation areas and volatile organic chemicals handling areas.

b) Access to and use of all areas affecting the quality of these activities shall be defined and controlled.

c) Adequate measures shall be taken to ensure good housekeeping in the laboratory and to ensure that any contamination does not adversely affect data quality.

e) Work spaces must be available to ensure an unencumbered work area. Work areas include:

   1) Access and entryways to the laboratory;

   2) Sample receipt area(s);

   3) Sample storage area(s);

   4) Chemical and waste storage area(s); and

   5) Data handling and storage area(s).

5.8 EQUIPMENT AND REFERENCE MATERIALS

DoD Implementation Clarification: Equipment shall be capable of achieving the accuracy and precision required for the intended use of the generated data. The laboratory shall implement documented procedures to ensure that set-up, maintenance, and adjustments to instrument operating parameters are documented, and that adjustments to instruments do not exceed the limits specified in the approved SOPs.

The use of Outside Support Services and Supplies is further addressed in Section 5.15.

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a) The laboratory shall be furnished with all items of equipment (including reference materials) required for the correct performance of tests for which accreditation is sought. In those cases where the laboratory needs to use equipment outside its permanent control, it shall ensure that the relevant requirements of this Standard are met.

b) All equipment shall be properly maintained, inspected, and cleaned. Maintenance procedures shall be documented.

c) Any item of the equipment that has been subjected to overloading or mishandling, gives suspect results, or has been shown by verification or otherwise to be defective, shall be taken out of service, clearly identified, and, wherever possible, stored at a specified place until it has been repaired and shown by calibration, verification, or test to perform satisfactorily. The laboratory shall examine the effect of this defect on previous calibrations or tests.

d) Each item of equipment, including reference materials, shall, when appropriate, be labeled, marked, or otherwise identified to indicate its calibration status.

e) Records shall be maintained of each major item of equipment and all reference materials significant to the tests performed. These records shall include documentation on all routine and nonroutine maintenance activities and reference material verifications.

   The records shall include:

   1) The name of the item of equipment;

   2) The manufacturer's name, type identification, and serial number or other unique identification;

   3) Date received and date placed in service (if available);

   4) Current location, where appropriate;

   5) If available, condition when received (e.g., new, used, reconditioned);

   6) Copy of the manufacturer's instructions, where available;

   7) Dates and results of calibrations and/or verifications and date of the next calibration and/or verification;

   8) Details of maintenance carried out to date and planned for the future; and

   9) Histories of any damage, malfunction, modification, or repair.

5.9 MEASUREMENT TRACEABILITY AND CALIBRATION

5.9.1 General Requirements

All measuring operations and testing equipment having an effect on the accuracy or validity of tests shall be calibrated and/or verified before being put into service and on a continuing basis. The laboratory shall have an established program for the calibration and verification of its measuring and test equipment. This includes balances, thermometers, and control standards.

5.9.2 Traceability of Calibration

a) The overall program of calibration and/or verification and validation of equipment shall be designed and operated so as to ensure that, wherever applicable, measurements made by the laboratory are traceable to national standards of measurement, where available.

b) Calibration certificates, when available, shall indicate the traceability to national standards of measurement and shall provide the measurement results and associated uncertainty of measurement and/or a statement of compliance with an identified metrological specification. The laboratory shall maintain records of all such certifications.

c) Where traceability to national standards of measurement is not applicable, the laboratory shall provide satisfactory evidence of correlation of results (e.g., by participation in a suitable program of interlaboratory comparisons, proficiency testing, or independent analysis).

5.9.3 Reference Standards

a) Reference standards of measurement held by the laboratory (such as Class S or equivalent weights or traceable thermometers) shall be used for calibration only and for no other purpose, unless it can be demonstrated that their performance as reference standards have not been invalidated. Reference standards of measurement shall be calibrated by a body that can provide, where possible, traceability to a national standard of measurement.

b) There shall be a program of calibration and verification for reference standards.

c) Where relevant, reference standards and measuring and testing equipment shall be subjected to in-service checks between calibrations and verifications. Reference materials shall, where possible, be traceable to national or international standards of measurement, or to national or international standard reference materials.

5.9.4 Calibration

Calibration requirements are divided into two parts: (1) requirements for analytical support equipment, and (2) requirements for instrument calibration. In addition, the requirements for instrument calibration are divided into initial instrument calibration and continuing instrument calibration verification.

5.9.4.1 <u>Support Equipment</u>

These standards apply to all devices that may not be the actual test instrument, but are necessary to support laboratory operations. These include but are not limited to: balances, ovens, refrigerators, freezers, incubators, water baths, temperature measuring devices (including thermometers and thermistors), thermal/pressure sample preparation devices and volumetric dispensing devices (such as Eppendorf®, or automatic dilutor/dispensing devices) if quantitative results are dependent on their accuracy, as in standard preparation and dispensing or dilution into a specified volume. All support equipment shall be:

a) Maintained in proper working order. The records of all repair and maintenance activities, including service calls, shall be kept.

b) Calibrated or verified at least annually, using NIST traceable references when available, over the entire range of use. The results of such calibration shall be within the specifications required of the application for which this equipment is used or:

   1) The equipment shall be removed from service until repaired; or

   2) The laboratory shall maintain records of established correction factors to correct all measurements.

c) Raw data records shall be retained to document equipment performance.

d) Prior to use on each working day, balances, ovens, refrigerators, freezers, incubators, and water baths shall be checked with NIST traceable references (where possible) in the expected use range. Additional monitoring as prescribed by the test method shall be performed for any device that is used in a critical test (such as incubators or water baths). The acceptability for use or continued use shall be according to the needs of the analysis or application for which the equipment is being used.

e) Mechanical volumetric dispensing devices (except Class A glassware) shall be checked for accuracy on a monthly use basis. Glass microliter syringes are to be considered in the same manner as Class A glassware, but must come with a certificate attesting to established accuracy or the accuracy must be initially demonstrated and documented by the laboratory.

f) For chemical tests, the temperature, cycle time and pressure of each run of autoclaves must be documented by the use of appropriate chemical indicators or temperature recorders and pressure gauges.

g) For biological tests, the sterilization temperature, cycle time, sterilization time, and pressure of each run of autoclaves must be documented by the use of appropriate chemical or biological sterilization indicators. Autoclave tape may be used to indicate by color change that a load has been processed, but not to demonstrate completion of an acceptable sterilization cycle. Demonstration of sterilization shall be provided by a continuous temperature recording or with the frequent use of spore strips.

DoD Implementation Clarification: The following table provides specific guidance with respect to the calibration and performance measurements associated with specific types of analytical support equipment. The criteria presented that go beyond those established by the American Society for Testing and Methods (ASTM) Standards are currently in use by DoD Components. They are presented here in consolidated form, and will be formally adopted across DoD as a standardized requirement. ASTM Standards presented here are based upon the latest edition available at this Manual's publication date. As new editions are released, the latest revision of each ASTM Standard reference shall be followed, unless State or project requirements differ.

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Analytical Support Equipment Assessment	Frequency of Check	Acceptance Criteria	Calibration Check Procedures and Performance Criteria References (latest edition)
Balance calibration check	Daily or before use with two weights that bracket target weight(s) AND Annual calibration by certified technician	1% performance criterion to top-loading balances, and 0.1% to analytical balances. (Expanded criteria from 0.1 to 1% for top-loaders, for no standard existed for this balance type.)	ASTM E 898, Standard Practice for the Evaluation of Single-Pan Mechanical Balances, E 319, Standard Practice for the Evaluation of Single-Pan Mechanical Balances, and D 5522, Standard Specification for Minimum Requirements for Laboratories Engaged in Chemical

Analytical Support Equipment Assessment	Frequency of Check	Acceptance Criteria	Calibration Check Procedures and Performance Criteria References (latest edition)
			Analysis of Soil, Rock, and Contained Fluid
Refrigerator/Freezer temperature Monitoring	Daily	Refrigerators: 4 ± 2 °C, Freezers: -10 to -20° C (This ASTM standard does not address freezers, but SW-846 has noted this freezer range in some methods)	ASTM D 5522, Standard Specification for Minimum Requirements for Laboratories Engaged in Chemical Analysis of Soil, Rock, and Contained Fluid
Thermometer calibration check	Mercury - annually Electronic - quarterly at two temperatures that bracket target temperature(s) against an NIST traceable thermometer	Appropriate correction factors applied	ASTM Methods E 77, Standard Test Method for Inspection and Verification of Thermometers, and D 5522, Standard Specification for Minimum Requirements for Laboratories Engaged in Chemical Analysis of Soil, Rock, and Contained Fluid
Variable volume pipettes (i.e., Eppendorf)	Monthly	3% of known or true value. (Standard criteria for Class B transfer pipettes were used – tolerance varied depending on volume delivered, with widest % associated with smaller volume pipettes - 2.4% tolerance applied to 0.5 milliliter pipette – so expanded to 3% for consistency)	ASTM E 542, Standard Practice for Calibration of Volumetric Apparatus, and E 969, Standard Specification for Volumetric (Transfer) Pipettes
Nonvolumetric glassware/labware verification (Requirement applicable only when used for measuring initial sample and final extract/digestate volumes)	By lot at the time of purchase	3% of known or true value. (Standard tolerance does not exist – Class B volumetric flasks criteria vary between 0.8 to 0.05% for 5 mL to 2,000 mL, respectively – set at 3% to maintain consistency with pipette tolerance designation)	ASTM E 542, Standard Practice for Calibration of Volumetric Ware
Drying ovens	Before and after use	Compliance with method-specific requirements	ASTM D 5522, Standard Specification for Minimum Requirements for Laboratories Engaged in Chemical Analysis of Soil, Rock, and Contained Fluid

5.9.4.2 Instrument Calibration

This standard specifies the essential elements that will define the procedures and documentation for initial instrument calibration and continuing instrument calibration verification to ensure that the data will be of known quality and be appropriate for a given regulation or decision. This standard does not specify detailed procedural steps ("how to") for calibration, but establishes the essential elements for selection of the appropriate technique(s). This approach allows flexibility and permits the employment of a wide variety of analytical procedures and statistical approaches currently applicable for calibration. If more stringent standards or requirements are included in a mandated test method or by regulation, the

laboratory shall demonstrate that such requirements are met. If it is not apparent which standard is more stringent, then the requirements of the regulation or mandated test method are to be followed.

Note: In the following sections, initial instrument calibration is directly used for quantitation and continuing instrument calibration verification is used to confirm the continued validity of the initial calibration.

DoD Implementation Clarification: The DoD Implementation Clarifications included in Section 5.9.4.2 are only applicable when method-specific guidance does not exist.

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5.9.4.2.1 ***Initial Instrument Calibrations:***

The following items are essential elements of initial instrument calibration:

a) The details of the initial instrument calibration procedures, including calculations, integrations, and associated statistics must be included or referenced in the test method SOP.

b) Sufficient raw data records must be retained to permit reconstruction of the initial instrument calibration, e.g., calibration date, test method, instrument, analysis date, each analyte name, concentration and response, calibration curve or response factor.

DoD Implementation Clarification: Raw records shall also include the analyst's name.

When manual integrations are performed, raw data records shall include a complete audit trail for those manipulations, raw data output showing the results of the manual integration (i.e., chromatograms of manually integrated peaks), and notation of rationale, data, and signature/initials of person performing manual operation.

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c) Sample results must be quantitated from the initial instrument calibration and may not be quantitated from any continuing instrument calibration verification.

d) All initial instrument calibrations must be verified with a standard obtained from a second source and traceable to a national standard, when available.

DoD Implementation Clarification: Second source standards shall be obtained from a different manufacturer than the original standard, unless one is not available. Deviations from this requirement require project-specific approval from appropriate DoD personnel (e.g., Project Manager, Quality Assurance Officer).

The freshness of each standard shall be considered when evaluating its suitability for use – this consideration shall include an assessment of the stability of the standard solution, as well as its degradation rate.

The concentration of the second source standard shall be at or near the middle of the calibration range. Criteria for the acceptance of second source verification standard results shall be established. Values chosen should be at least as stringent as those established for the continuing instrument calibration verification. The initial calibration verification shall be successfully completed prior to running any samples.

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e) Criteria for the acceptance of an initial instrument calibration must be established, e.g., correlation coefficient or relative percent difference.

DoD Implementation Clarification: Exclusion of initial calibration points without technical justification is not allowed.

For example, in establishing an initial calibration curve, the calibration points used shall be a contiguous subset of the original set. In addition, the minimum linearity of the curve shall either be determined by a linear regression correlation coefficient greater than or equal to 0.995 or a maximum mean percent Relative Standard Deviation (%RSD) of 20% (with no individual analyte greater than 30%).

Deviations from the above are permitted with the approval of DoD personnel (e.g., Project Manager, Quality Assurance Officer). See DoD Clarification Box #33 for guidance on the number of points required for a calibration curve.

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f) Results of samples not bracketed by initial calibration standards (within calibration range) must be reported as having less certainty, e.g., defined qualifiers or flags or explained in the case narrative. The lowest calibration standard must be above the detection limit.

DoD Implementation Clarification.

The range of the accepted initial calibration curve reflects the quantitation range of the samples (i.e., only those sample results with concentrations contained within the range of the calibration curve are considered to be quantitative). Any data reported outside the calibration range shall be qualified as an estimated value (i.e., by a data qualifier "flag") and explained in the case narrative.

When sample concentrations **exceed** the upper limit of the calibration curve (i.e., upper quantitation limit), samples shall be diluted and reanalyzed (if possible) to bring them within the calibration curve. When sample concentrations **fall below** the lower limit of the calibration curve (i.e., below the lower quantitation limit), then either the method shall be modified (e.g., initial calibration re-run, thereby re-establishing the potential range of quantitative values), or the resulting data shall be qualified as having estimated values.

The laboratory's **reporting limit** shall lie within the calibration range, at or above the lower quantitation limit. If the client **requires** a reporting limit that lies **below** the lower limit of the calibration curve (i.e., below the quantitation limit), then method modification is required. For methods that require only one standard (i.e., lower limit of curve is the origin), the reporting limit shall be no lower than a low level check standard, designed to verify the integrity of the curve at the lower limits.

See also DoD Clarification Box D-10 addressing Detection Limits, as well as Definitions for Quantitation Limit and Reporting Limit

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g) If the initial instrument calibration results are outside established acceptance criteria, corrective actions must be performed. Data associated with an unacceptable initial instrument calibration shall not be reported.

h) Calibration standards must include concentrations at or below the regulatory limit/decision level, if these limits/levels are known by the laboratory, unless these concentrations are below the laboratory's demonstrated detection limits (See D.1.4 Detection Limits).

DoD Implementation Clarification: DoD recognizes that achievability of these limits/levels by the required method is a key variable. To avoid conflicts related to this issue, DoD expects laboratory involvement (government or private) during the planning phase of the project (QAPP preparation) to ensure proper selection of methods and instrumentation. If the proposed laboratory for the project work is unavailable for this consultation (e.g., not yet selected), a government laboratory may be consulted to establish these parameters. This early involvement of a laboratory is integral in ensuring efficient planning and implementation of the project.

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i) If a reference or mandated method does not specify the number of calibration standards, the minimum number is two, not including blanks or a zero standard. The laboratory must have a standard operating procedure for determining the number of points for establishing the initial instrument calibration.

DoD Implementation Clarification: In completing work for DoD, when the number of calibration points is not specified by the method, the initial calibration range shall consist of a minimum of 5 contiguous calibration points for organics and a minimum of 3 contiguous calibration points for inorganics. All reported target analytes and surrogates shall be included in the initial calibration. See DoD Clarification Box #30 in Section 5.9.4.2.1.e for additional implementation requirements pertaining to this subject.

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5.9.4.2.2 *Continuing Instrument Calibration Verification*

When an initial instrument calibration is not performed on the day of analysis, the validity of the initial calibration shall be verified prior to sample analyses by a continuing instrument calibration verification with each analytical batch. The following items are essential elements of continuing instrument calibration verification:

DoD Implementation Clarification: The DoD Implementation Clarifications included in Section 5.9.4.2 are only applicable when method-specific guidance does not exist.

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a) The details of the continuing instrument calibration procedure, calculations and associated statistics must be included or referenced in the test method SOP.

b) A continuing instrument calibration verification must be repeated at the beginning and end of each analytical batch. The concentrations of the calibration verification shall be varied within the established calibration range. If an internal standard is used, only one continuing instrument calibration verification must be analyzed per analytical batch.

DoD Implementation Clarification: At least one of the continuing calibration verification (CCV) standards shall fall below the middle of the calibration range. At a minimum, additional periodic CCVs shall be run whenever required by the applicable method. When the methods specify that CCVs shall be run at specific sample intervals (e.g., every 10 samples), the count of these samples shall include all QC samples (i.e., each injection is considered to be a sample). If the method does not specify an interval at which periodic CCVs shall be completed, they shall, at a minimum, bracket every preparatory batch (i.e., at least every 20 samples). More frequent CCVs are recommended for more difficult matrices.

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c) Sufficient raw data records must be retained to permit reconstruction of the continuing instrument calibration verification, e.g., test method, instrument, analysis date, each analyte name, concentration and response, calibration curve or response factor.

DoD Implementation Clarification: Raw records shall also include the analyst's name.

When manual integrations are performed, raw data records shall include a complete audit trail for those manipulations, raw data output showing the results of the manual integration (i.e., chromatograms of manually integrated peaks), and notation of rationale, data, and signature/initials of person performing manual operation.

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d) Criteria for the acceptance of a continuing instrument calibration verification must be established, e.g., relative percent difference.

DoD Implementation Clarification:

- The source of the standard(s) for analysis shall be the standard(s) used for the initial calibration or standard(s) from another source.
- All reported target analytes applicable to the method shall be included in the CCV.
- The baseline for comparison for the CCV is the initial calibration (and the original standards). Specific criteria for evaluation of success or failure of the CCV include: percent difference/drift from the RSD established for the initial calibration, minimum response factor checks, and confirmation that the retention time is within an acceptable window. For DoD, the %RSD of the CCV standard shall be less than 15% of the initial calibration.

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e) If the continuing instrument calibration verification results obtained are outside established acceptance criteria, corrective actions must be performed. If routine corrective action procedures fail to produce a second consecutive (immediate) calibration verification within acceptance criteria, then either the laboratory shall demonstrate performance after corrective action with two consecutive successful calibration verifications, or a new instrument calibration must be performed. If the laboratory has not demonstrated successful performance, additional sample analyses shall not occur until a new initial calibration curve is established and verified.

DoD Implementation Clarification: If the CCV results are outside established acceptance criteria, and the laboratory chooses to demonstrate the success of routine corrective action through the use of two consecutive CCVs, then the concentrations of the two CCVs must be at two different levels within the original calibration curve.

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However, sample data associated with an unacceptable calibration verification check may be reported as qualified data under the following special conditions:

i. When the acceptance criteria for the continuing calibration verification are exceeded high, i.e., high bias and there are associated samples that are non-detects, then those non-detects may be reported. Otherwise the samples affected by the unacceptable shall be reanalyzed after a new calibration curve has been established, evaluated and accepted.

ii. When the acceptance criteria for the continuing calibration verification are exceeded low, i.e., low bias, these sample results may be reported if they exceed a maximum regulatory limit/decision level. Otherwise the samples affected by the unacceptable verification shall be reanalyzed after a new calibration curve has been established, evaluated and accepted.

DoD Implementation Clarification: Project-specific permission from appropriate DoD personnel is required to report data generated from the initial run with the non-compliant CCV. If this permission is granted, and these data are reported, they shall be qualified through the use of a "J" flag, and explained in the case narrative.

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5.10 TEST METHODS AND STANDARD OPERATING PROCEDURES

5.10.1 Methods Documentation

a) The laboratory shall have documented instructions on the use and operation of all relevant equipment, on the handling and preparation of samples, and for calibration and/or testing, where the absence of such instructions could jeopardize the calibrations or tests.

b) All instructions, standards, manuals, and reference data relevant to the work of the laboratory shall be maintained up-to-date and be readily available to the staff.

5.10.1.1 Standard Operating Procedures (SOPs)

Laboratories shall maintain standard operating procedures (SOPs) that accurately reflect all phases of current laboratory activities such as assessing data integrity, corrective actions, handling customer complaints, and all test methods.

a) These documents, for example, may be equipment manuals provided by the manufacturer or internally written documents.

b) The test methods may be copies of published methods as long as any changes in the methods are documented and included in the methods manual. (See Section 5.10.1.2.)

DoD Implementation Clarification: Where existing methods are specified as required for a project, requirements contained within that method shall be followed. Any modifications to existing method requirements require project-specific approval by DoD personnel.

Each SOP shall provide sufficient detail such that a technically qualified analyst can perform the analysis without reference to other documents. While published test methods may be included as part of an SOP, to fulfill the complete requirements of the SOP as listed in Section 5.10.1.2.b) Items 1-23, it is anticipated that additional information beyond the published test method documentation shall be required.

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c) Copies of all SOPs shall be accessible to all personnel.

d) The SOPs shall be organized.

e) Each SOP shall clearly indicate the effective date of the document, the revision number, and the signature(s) of the approving authority.

DoD Implementation Clarification: All SOPs shall be archived for historical reference in accordance with Section 5.12.1 (Record Keeping Systems).

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5.10.1.2 Laboratory Method Manual(s)

a) The laboratory shall have and maintain an in-house methods manual(s) for each accredited analyte or test method.

DoD Implementation Clarification: Where existing methods are specified as required for a project, requirements contained within that method shall be followed. Any modifications to existing method requirements require project-specific approval by DoD personnel.

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b) This manual may consist of copies of published or referenced test methods or standard operating procedures that have been written by the laboratory. In cases where modifications to the published method have been made by the laboratory or where the referenced test method is ambiguous or provides insufficient detail, these changes or clarifications shall be clearly described. Each test method shall include or reference where applicable:

DoD Implementation Clarification: These requirements apply to all Analytical Method SOPs. While published test methods may be included as part of an SOP, to fulfill the complete requirements of the SOP, as listed immediately below, it is anticipated that additional information beyond the published test method documentation will be required.

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1) Identification of the test method;
2) Applicable matrix or matrices;
3) Method detection limit;
4) Scope and application, including components to be analyzed;
5) Summary of the test method;
6) Definitions;
7) Interferences;
8) Safety;
9) Equipment and supplies;
10) Reagents and standards;
11) Sample collection, preservation, shipment, and storage;
12) Quality control;
13) Calibration and standardization;
14) Procedure;
15) Calculations;
16) Method performance;
17) Pollution prevention;
18) Data assessment and acceptance criteria for quality control measures;
19) Corrective actions for out-of-control data;
20) Contingencies for handling out-of-control or unacceptable data;
21) Waste management;
22) References; and
23) Any tables, diagrams, flowcharts, and validation data.

5.10.2 Test Methods

a) The laboratory shall use appropriate test methods and procedures for all tests and related activities within its responsibility (including sample collection, sample handling, transport and storage, sample preparation, and sample analysis). The method and procedures shall be consistent with the accuracy required, and with any standard specifications relevant to the calibrations or tests concerned.

1) When the use of specific test methods for a sample analysis is mandated or requested, only those methods shall be used.

2) Where test methods are employed that are not required, as in the Performance-Based Measurement System (PBMS) approach, the methods shall be fully documented and validated, and be available to the client and other recipients of the relevant reports. (See Section 5.10.2.1 and Appendix C).

5.10.2.1 Demonstration of Capability

a) Prior to acceptance and institution of any test method, satisfactory demonstration of method capability is required (See Appendix C and Section 5.6.2). In general, this demonstration does not test the performance of the method in real world samples, but in the applicable and available clean matrix (a sample of a matrix in which no target analytes or interferences are present at concentrations that would impact the results of a specific test method), e.g., water, solids, biological tissue, and air. In addition, for analytes which do not lend themselves to spiking, the demonstration of capability may be performed using quality control samples.

DoD Implementation Clarification: In the case where the laboratory is introducing a new method, demonstration of performance shall be determined using an external source of information (e.g., the published method, Standards, or certified reference materials). The laboratory shall not "benchmark against itself" by using internal comparisons to initial runs to demonstrate capability.

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b) Thereafter, continuing demonstration of method performance, as per the quality control requirements in Appendix D, (such as laboratory control samples) is required.

DoD Implementation Clarification: The initial and continuing demonstration of capability shall include verification of method sensitivity checks (e.g., through the use of quarterly method detection verification) and demonstrated measurements of accuracy and precision (e.g., such as the production and review of quality control charts). These requirements apply to each matrix of concern.

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c) In all cases, the appropriate forms, such as the Certification Statement (See Appendix C), must be completed and retained by the laboratory to be made available upon request. All associated supporting data necessary to reproduce the analytical results summarized in the Certification Statement must be retained by the laboratory.

d) A demonstration of capability must be completed each time there is a significant change in instrument type, personnel, or test method.

DoD Implementation Clarification: "Significant change" always refers to a change in personnel. In addition, it includes any change in instrumentation or in test methods that potentially impacts the precision and accuracy of the output (e.g., a change in the detector, column, matrix, or a method revision). Requirements for meeting a "Demonstration of Capability" are further addressed in Appendix C.

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e) In laboratories with a specialized work cell(s)" (a group consisting of analysts with specifically defined tasks that together perform the test method), the group as a unit must meet the above criteria and this demonstration of capability must be fully documented.

f) When a work cell(s) is employed, and the members of the cell change, the new employee(s) must work with experienced analysts in the specialty area and this new work cell must demonstrate

acceptable performance through acceptable continuing performance checks (appropriate sections of Appendix D, such as laboratory control samples). Such performance must be documented and the 4 preparation batches following the change in personnel must not result in the failure of any batch acceptance, e.g., method blank and laboratory control sample, or the demonstration of capability must be repeated. In addition, if the entire work cell is changed/replaced, the work cell must repeat the demonstration of capability (Appendix C).

g) When a work cell(s) is employed, the performance of the group must be linked to the training record of the individual members of the work cell (See Section 5.6.2).

DoD Implementation Clarification: A "work cell" is considered to be all those individuals who see a sample through the complete process of preparation/extraction and analysis. To ensure that the entire preparation-extraction-analysis process is completed by a collection of capable individuals, the laboratory shall ensure that **each member** of the work cell demonstrates capability in his/her area of responsibility in the sequence. Even though the work cell operates as a "team," the Demonstration of Capability at each individual step in the sequence as performed by each individual analyst/team member, remains of utmost importance.

A work cell may NOT be defined as a group of analysts that performs the same step in the same process (e.g., extractions for Method 8270), represented by one analyst who has demonstrated capability for that step.

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5.10.3 Sample Aliquots

Where sampling (as in obtaining sample aliquots from a submitted sample) is carried out as part of the test method, the laboratory shall use documented procedures and appropriate techniques to obtain representative sub-samples.

DoD Implementation Clarification: Sampling procedures shall also address laboratory practices for the handling and documenting of extraneous materials (e.g., rocks, twigs, vegetation) present in samples. When a client requires deviations from the laboratory's documented sampling procedure, all deviations shall be recorded in detail in laboratory records and in all test reports. Additionally, the laboratory shall use recognized consensus standards (e.g., ASTM standards) where available for these procedures.

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5.10.4 Data Verification

Calculations and data transfers shall be subject to appropriate checks.

a) The laboratory shall establish SOPs to ensure that the reported data are free from transcription and calculation errors.

b) The laboratory shall establish SOPs to ensure that all quality control measures are reviewed and evaluated before data are reported.

DoD Implementation Clarification: Data verification (review) shall consist of at least the following procedures:

1. Determinations of whether the results of testing, examining, or analyzing the sample meet the laboratory's requirements for interpretation, precision and accuracy.
2. Checks to determine accuracy of calculations, conversions, and data transfers.
3. Checks for transcription errors, omissions, and mistakes.
4. Checks to determine consistency with project-specific data quality objectives (DQOs).
5. Checks to ensure that the appropriate preparatory and analytical SOPs and standardized methods were followed, and that Chain-of-Custody (COC) and holding time requirements were met.
6. Checks to ensure that calibrartion and calibration verification standards were met, and that QC samples (e.g., method blanks, LCSs) met criteria for precision, accuracy, and sensitivity.
7. Procedures for verifying the reliability of the test or analytical results shall be explained to include descriptions of programmed self-protection, self-correction, or warning measures, if the laboratory uses an electronic data processor.
8. The case narrative shall accurately explain any anomalous results and any corrective actions taken, and all data flags shall be checked to ensure appropriate and accurate use.
9. A tiered or sequential system of verification, consisting of at least three levels with each successive check performed by a different person. This three-tier approach should include (at a minimum): 100% review by the analyst, 100% verification review by a supervisor, and a final administrative review.

Additionally, as part of its internal quality assurance program, the Quality Assurance Officer shall review at a minimum, 10% of all data packages for technical completeness and accuracy. This review is part of the oversight program and does not have to be completed in "real time."

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5.10.5 Documentation and Labeling of Standards and Reagents

Documented procedures shall exist for the purchase, reception, and storage of consumable materials used for the technical operations of the laboratory.

a) The laboratory shall retain records for all standards including the manufacturer/vendor, the manufacturer's Certificate of Analysis or purity (if supplied), the date of receipt, recommended storage conditions, and an expiration date after which the material shall not be used, unless it is verified by the laboratory.

b) Original containers (such as provided by the manufacturer or vendor) shall be labeled with an expiration date.

c) Records shall be maintained on reagent and standard preparation. These records shall indicate traceability to purchased stocks or neat compounds, reference to the method of preparation, date of preparation, expiration date, and preparer's initials.

d) All containers of prepared reagents and standards must bear a unique identifier and expiration date and be linked to the documentation requirements in Section 5.10.5.c) above.

5.10.6 Computers and Electronic Data Related Requirements

Where computers or automated equipment are used for the capture, processing, manipulation, recording, reporting, storage, or retrieval of test data, the laboratory shall ensure that:

a) All requirements of this Standard (i.e., NELAP Chapter 5) are complied with. Sections 8.1 through 8.11 of the EPA Document "2185 - Good Automated Laboratory Practices" (1995), shall be adopted

as the standard for all laboratories employing microprocessors, computers, as well as, laboratories employing Laboratory Information Management Systems.

b) Computer software is documented and adequate for use.

c) Procedures are established and implemented for protecting the integrity of data; such procedures shall include, but not be limited to, integrity of data entry or capture, data storage, data transmission, and data processing.

DoD Implementation Clarification: At a minimum, for those processes that are automated, a sample data test set shall be used to test and verify the correct operation of these data reduction procedures (including data capture, manipulation, transfer, and reporting). This shall be done anytime the programming code is modified or otherwise manipulated, and applies even in cases where commercial software is used as part of the process.

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d) Computer and automated equipment are maintained to ensure proper functioning and provided with the environmental and operating conditions necessary to maintain the integrity of calibration and test data.

e) It establishes and implements appropriate procedures for the maintenance of security of data including the prevention of unauthorized access to, and the unauthorized amendment of, computer records.

5.11 SAMPLE HANDLING, SAMPLE ACCEPTANCE POLICY, AND SAMPLE RECEIPT

While the laboratory may not have control of field sampling activities, the following are essential to ensure the validity of the laboratory's data.

5.11.1 Sample Tracking

a) The laboratory shall have a documented system for uniquely identifying the items to be tested to ensure that there can be no confusion regarding the identity of such items at any time. This system shall include identification for all samples, subsamples and subsequent extracts and/or digestates. The laboratory shall assign a unique identification (ID) code to each sample container received in the laboratory. The use of container shape, size, or other physical characteristic, such as amber glass or purple top, is not an acceptable means of identifying the sample.

b) This laboratory code shall maintain an unequivocal link with the unique field ID code assigned each container.

c) The laboratory ID code shall be placed on the sample container as a durable label.

d) The laboratory ID code shall be entered into the laboratory records and shall be the link that associates the sample with related laboratory activities such as sample preparation or calibration. (See Section 5.11.3.d.)

e) In cases where the sample collector and analyst are the same individual or the laboratory preassigns numbers to sample containers, the laboratory ID code may be the same as the field ID code.

5.11.2 Sample Acceptance Policy

The laboratory shall have a written sample acceptance policy that clearly outlines the circumstances under which samples will be accepted. Data from any samples that do not meet the following criteria must be flagged in an unambiguous manner, clearly defining the nature and substance of the variation. This sample acceptance policy shall be made available to sample collection personnel and shall include, but is not limited to, the following areas of concern:

DoD Implementation Clarification: The laboratory shall have procedures documented in the Quality Manual or related documentation (as discussed in Sections 5.5.2.i. and 5.5.2.k.) which address methods by which the laboratory confirms that it has the capability and capacity to accept new samples before such acceptance occurs. The laboratory shall also follow any additional method specific requirements concerning sample acceptance.

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a) Proper, full, and complete documentation, which shall include sample identification, the location, date and time of collection, collector's name, preservation type, sample type, and any special remarks concerning the sample;

b) Proper sample labeling to include unique identification and a labeling system for the samples with requirements concerning the durability of the labels (water resistant) and the use of indelible ink;

c) Use of appropriate sample containers;

d) Adherence to specified holding times;

e) Adequate sample volume. Sufficient sample volume must be available to perform the necessary tests; and

f) Procedures to be used when samples show signs of damage or contamination.

5.11.3 Sample Receipt Protocols

a) Upon receipt, the condition of the sample, including any abnormalities or departures from standard condition as prescribed in the relevant test method, shall be recorded. All items specified in Section 5.11.2 above shall be checked.

   1) All samples that require thermal preservation shall be considered acceptable if the arrival temperature is either within +/-2° C of the required temperature or the method specified range. For samples with a specified temperature of 4° C, samples with a temperature ranging from just above the freezing temperature of water to 6° C shall be acceptable. Samples that are hand delivered to the laboratory immediately after collection may not meet this criterion. In these cases, the samples shall be considered acceptable, if there is evidence that the chilling process has begun, such as arrival on ice.

DoD Implementation Clarification: The temperature measurement shall be verified through the use of a temperature blank (for each cooler) when applicable.

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   2) The laboratory shall implement procedures for checking chemical preservation using readily available techniques, such as pH or free chlorine, prior to or during sample preparation or analysis.

DoD Implementation Clarification: This shall also be performed when the continued preservation of the sample is in question (due to sample interaction with the preservative); as applicable to samples that cannot be checked upon receipt; and/or for samples whose preservative may have deteriorated for any other reason.

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b) The results of all checks shall be recorded.

c) Where there is any doubt as to the item's suitability for testing, where the sample does not conform to the description provided, or where the test required is not fully specified, the laboratory should consult the client for further instruction before proceeding. The laboratory shall establish whether the sample has received all necessary preparation, or whether the client requires preparation to be undertaken or arranged by the laboratory. If the sample does not meet the sample receipt acceptance criteria listed in Sections 5.11.3.a), 5.11.3.b), or 5.11.3.c), the laboratory shall either:

DoD Implementation Clarification: This consultation shall be immediate and timely (i.e., by the next business day).

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1) Retain correspondence and/or records of conversations concerning the final disposition of rejected samples; or

2) Fully document any decision to proceed with the analysis of samples not meeting acceptance criteria.

   i. The condition of these samples shall, at a minimum, be noted on the chain of custody or transmittal form and laboratory receipt documents.

   ii. The analysis data shall be appropriately "qualified" on the final report.

DoD Implementation Clarification: Additional guidance on this issue is provided in Section 5.13.a) (Laboratory Report Format and Contents).

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d) The laboratory shall utilize a permanent chronological record, such as a log book or electronic database, to document receipt of all sample containers.

DoD Implementation Clarification: Use of electronic database systems shall meet the requirements specified in Section 5.10.6. (Computer and Electronic Data Related Requirements).

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1) This sample receipt log shall record the following:

   i. Client/Project Name;

   ii. Date and time of laboratory receipt;

   iii. Unique laboratory ID code (See 5.11.1); and

   iv. Signature or initials of the person making the entries.

2) During the log in process, the following information must be unequivocally linked to the log record or included as a part of the log. If such information is recorded/documented elsewhere, the

records shall be part of the laboratory's permanent records, easily retrievable upon request, and readily available to individuals who will process the sample. Note: the placement of the laboratory ID number on the sample container is not considered a permanent record.

i. The field ID code that identifies each container must be linked to the laboratory ID code in the sample receipt log.

ii. The date and time of sample collection must be linked to the sample container and to the date and time of receipt in the laboratory.

iii. The requested analyses (including applicable approved test method numbers) must be linked to the laboratory ID code.

iv. Any comments resulting from inspection for sample rejection shall be linked to the laboratory ID code.

e) All documentation, such as memos or transmittal forms, that is transmitted to the laboratory by the sample transmitter shall be retained.

f) A complete chain-of-custody (COC) record (Section 5.12.4), if utilized, shall be maintained.

DoD Implementation Clarification: Legal COC procedures, as addressed in Section 5.12.4, shall be required only as specified by DoD Project or Contract personnel. Standard requirements for sample custody are outlined in Sections 5.12.1, 5.12.2, and 5.12.3 and shall be followed as the default requirement.

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5.11.4 Storage Conditions

The laboratory shall have documented procedures and appropriate facilities to avoid deterioration, contamination, or damage to the sample during storage, handling, preparation, and testing; any relevant instructions provided with the item shall be followed. Where items have to be stored or conditioned under specific environmental conditions, these conditions shall be maintained, monitored, and recorded where necessary.

a) Samples shall be stored according to the conditions specified by preservation protocols:

1) Samples that require thermal preservation shall be stored under refrigeration which is +/-2° C of the specified preservation temperature unless method specific criteria exist. For samples with a specified storage temperature of 4° C, storage at a temperature above the freezing point of water to 6° C shall be acceptable.

DoD Implementation Clarification: When refrigeration is required, the laboratory shall ensure that monitoring is performed 7 days per week to assure that the samples remain within an acceptable range. A variety of techniques can be used to ensure that the proper temperature is continuously maintained.

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2) Samples shall be stored away from all standards, reagents, food, and other potentially contaminating sources. Samples shall be stored in such a manner to prevent cross contamination.

DoD Implementation Clarification: The laboratory shall have procedures in place to ensure that cross-contamination does not occur. For example, samples designated for volatile organics testing shall be segregated from other samples, while samples suspected to contain high levels of volatile organics should be further isolated from other volatile organics samples. Storage blanks may be used to verify that no cross-contamination has occurred.

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b) Sample fractions, extracts, leachates, and other sample preparation products shall be stored according to Section 5.11.4.a) above or according to specifications in the test method.

c) Where a sample or portion of the sample is to be held secure (e.g., for reasons of record, safety or value, or to enable check calibrations or tests to be performed later), the laboratory shall have storage and security arrangements that protect the condition and integrity of the secured items or portions concerned.

5.11.5 Sample Disposal

The laboratory shall have SOPs for the disposal of samples, digestates, leachates, and extracts or other sample preparation products.

DoD Implementation Clarification: The laboratory shall maintain appropriate documentation and records demonstrating that samples have been properly disposed, in accordance with Federal, State, and local regulations.

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5.12 RECORDS

The laboratory shall maintain a record system to suit its particular circumstances and comply with any applicable regulations. The system shall produce unequivocal, accurate records that document all laboratory activities. The laboratory shall retain on record all original observations, calculations and derived data, calibration records, and a copy of the test report for a minimum of 5 years.

There are two levels of record keeping: (1) sample custody or tracking and (2) legal or evidentiary chain-of-custody. All essential requirements for sample custody are outlined in Sections 5.12.1, 5.12.2, and 5.12.3. The basic requirements for legal chain-of-custody (if required or implemented) are specified in Section 5.12.4.

DoD Implementation Clarification: Legal COC procedures, as addressed in Section 5.12.4, shall be required only as specified by DoD Project or Contract personnel. Standard requirements for sample custody are outlined in Sections 5.12.1, 5.12.2, and 5.12.3 and shall be followed as the default requirement.

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5.12.1 Record Keeping System and Design

The record keeping system must allow historical reconstruction of all laboratory activities that produced the resultant sample analytical data. The history of the sample must be readily understood through the documentation. This shall include interlaboratory transfers of samples and/or extracts.

a) The records shall include the identity of personnel involved in sampling, preparation, calibration, or testing.

b) All information relating to the laboratory facilities equipment, analytical test methods, and related laboratory activities, such as sample receipt, sample preparation, or data verification, shall be documented.

c) The record keeping system shall facilitate the retrieval of all working files and archived records for inspection and verification purposes.

d) All documentation entries shall be signed or initialed by responsible staff. The reason for the signature or initials shall be clearly indicated in the records such as “sampled by,” “prepared by,” or “reviewed by.”

e) All generated data, except those that are generated by automated data collection systems, shall be recorded directly, promptly, and legibly in permanent ink.

f) Entries in records shall not be obliterated by methods such as erasures, overwritten files, or markings. All corrections to record keeping errors shall be made by one line marked through the error. The individual making the correction shall sign (or initial) and date the correction. These criteria also shall apply to electronically maintained records.

g) Refer to Section 5.10.6 for Computer and Electronic Data.

5.12.2 Records Management and Storage

a) All records (including those pertaining to calibration and test equipment), certificates, and reports shall be safely stored, and held secure and in confidence to the client. NELAP-related records shall be available to the accrediting authority.

b) All records, including those specified in Sections 5.12.3 and 5.12.4, shall be retained for a minimum of five years from last use. All information necessary for the historical reconstruction of data must be maintained by the laboratory. Records stored only on electronic media must be supported by the hardware and software necessary for their retrieval.

c) Records stored or generated by computers or personal computers (PCS) shall have hard copy or write-protected backup copies.

d) The laboratory shall establish a record management system for control of laboratory notebooks, instrument logbooks, standards logbooks, and records for data reduction, validation storage, and reporting.

e) Access to archived information shall be documented with an access log. These records shall be protected against fire, theft, loss, environmental deterioration, vermin, and in the case of electronic records, electronic or magnetic sources.

f) The laboratory shall have a plan to ensure that the records are maintained or transferred according to the clients’ instructions in the event that a laboratory transfers ownership or goes out of business. (See NELAP Section 4.1.8.e.)

5.12.3 Laboratory Sample Tracking

5.12.3.1 <u>Sample Handling</u>

A record of all procedures to which a sample is subjected while in the possession of the laboratory shall be maintained. These shall include but are not limited to all records pertaining to:

a) Sample preservation, including appropriateness of sample container and compliance with holding time requirement;

b) Sample identification, receipt, acceptance or rejection, and log-in;

c) Sample storage and tracking, including shipping receipts, transmittal forms, and internal routing and assignment records;

d) Sample preparation, including cleanup and separation protocols, ID codes, volumes, weights, instrument printouts, meter readings, calculations, and reagents;

e) Sample analysis;

f) Standard and reagent origin, receipt, preparation, and use;

g) Equipment receipt, use, specification, operating conditions, and preventative maintenance;

h) Calibration criteria and frequency and acceptance criteria;

i) Data and statistical calculations, review, confirmation, interpretation, assessment, and reporting conventions;

j) Method performance criteria, including expected quality control requirements;

k) Quality control protocols and assessment;

l) Electronic data security, software documentation and verification, software and hardware audits, backups, and records of any changes to automated data entries;

m) All automated sample handling systems; and

n) The laboratory shall have documented procedures for the receipt, retention or safe disposal of calibration or test items, including all provisions necessary to protect the integrity of the laboratory.

5.12.3.2 Laboratory Support Activities

In addition to documenting all the above-mentioned activities, the following shall be retained:

a) All original raw data, whether hard copy or electronic, for calibrations, samples, and quality control measures, including analysts work sheets and data output records (chromatograms, strip charts, and other instrument response readout records);

b) A written description or reference to the specific test method used, which includes a description of the specific computational steps used to translate parametric observations into a reportable analytical value;

c) Copies of final reports;

d) Archived standard operating procedures;

e) Correspondence relating to laboratory activities for a specific project;

f) All corrective action reports, audits, and audit responses;

g) Proficiency test results and raw data; and

h) Data review and cross checking.

5.12.3.3 Analytical Records

The essential information to be associated with analysis, such as strip charts, tabular printouts, computer data files, analytical notebooks, and run logs, shall include:

a) Laboratory sample ID code;

b) Date and time of analysis;

c) Instrumentation identification and instrument operating conditions/parameters (or reference to such data);

d) Analysis type;

e) All manual calculations; and

f) Analyst's or operator's initials/signature.

5.12.3.4 Administrative Records

The following shall be maintained:

a) Personnel qualifications, experience, and training records;

b) Records of demonstration of capability for each analyst; and

c) A log of names, initials, and signatures for all individuals who are responsible for signing or initialing any laboratory record.

5.12.4 Legal/Evidentiary Custody

The use of legal COC protocols may be required by some State or Federal programs. In addition to the records listed in Section 5.12.3 and the performance standards outlined in Sections 5.12.1 and 5.12.2, the following protocols shall be incorporated if legal COC is implemented by the organization.

DoD Implementation Clarification: The requirements for legal COC, as specified in Section 5.12.4, shall be required only when specified by DoD Project or Contract personnel. In all other cases, the standard requirements for sample custody, as outlined in Sections 5.12.1, 5.12.2, and 5.12.3, shall be followed and documented.

Legal COC begins at sample collection, unless otherwise specified by the applicable regulatory program. Legal COC ends after laboratory analysis of the sample is completed, at the point when the sample, sample aliquot, and sample extracts/digestates are disposed of. In all cases, laboratory disposal procedures shall be in accordance with Section 5.11.5 (Sample Disposal).

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5.12.4.1 Basic Requirements

The legal COC records shall establish an intact, continuous record of the physical possession, storage, and disposal of sample containers, collected samples, sample aliquots, and sample extracts or digestates. For ease of discussion, the above-mentioned items shall be referred to as samples:

a) A sample is in someone's custody if:

   1) It is in one's actual physical possession.

   2) It is in one's view, after being in one's physical possession.

   3) It is in one's physical possession and then locked up so that no one can tamper with it.

   4) It is kept in a secured area, restricted to authorized personnel only.

b) The COC records shall account for all time periods associated with the samples.

c) The COC records shall identify individuals who physically handled individual samples.

h) In order to simplify record keeping, the number of people who physically handle the sample should be minimized. A designated sample custodian, who is responsible for receiving, storing, and distributing samples, is recommended.

e) The COC records are not limited to a single form or document. However, organizations should attempt to limit the number of documents that would be required to establish COC.

f) Legal COC shall begin at the point established by the Federal or State oversight program. This may begin at the point that cleaned sample containers are provided by the laboratory or the time sample collection occurs.

g) The COC forms shall remain with the samples during transport or shipment.

h) If shipping containers and/or individual sample containers are submitted with sample custody seals and any seals are not intact, the lab shall note this on the COC.

i) Mailed packages should be registered with return receipt requested. If packages are sent by common carrier, receipts should be retained as part of the permanent COC documentation.

j) Once received by the laboratory, laboratory personnel are responsible for the care and custody of the sample and must be prepared to testify that the sample was in their possession and view or secured in the laboratory at all times from the moment it was received from the custodian until the time that the analyses are completed or the sample is disposed.

5.12.4.2 Required Information in Custody Records

In addition to the information specified in Sections 5.11.1.a) and 5.11.1.b), tracking records shall include, by direct entry or linkage to other records:

a) Time of day and calendar date of each transfer or handling procedure;

b) Signatures of all personnel who physically handle the sample(s);

c) All information necessary to produce unequivocal, accurate records that document the laboratory activities associated with sample receipt, preparation, analysis, and reporting; and

d) Common carrier documents.

5.12.4.3 Controlled Access to Samples

Access to all legal samples and subsamples shall be controlled and documented.

a) A clean, dry, isolated room, building, and/or refrigerated space that can be securely locked from the outside must be designated as a custody room.

b) Where possible, distribution of samples to the analyst performing the analysis must be made by the custodian(s).

c) The laboratory area must be maintained as a secured area, restricted to authorized personnel only.

d) Once the sample analyses are completed, the unused portion of the sample, together with all identifying labels, must be returned to the custodian. The returned tagged sample must be retained in the custody room until permission to destroy the sample is received by the custodian or other authority.

5.12.4.4 Transfer of Samples to Another Party

Transfer of samples, subsamples, digestates, or extracts to another party are subject to all of the requirements for legal COC.

5.12.4.5 Sample Disposal

a) If the sample is part of litigation, disposal of the physical sample shall occur only with the concurrence of the affected legal authority, sample data user, and/or submitter of the sample.

b) All conditions of disposal and all correspondence between all parties concerning the final disposition of the physical sample shall be recorded and retained.

c) Records shall indicate the date of disposal, the nature of disposal (such as sample depleted, sample disposed in hazardous waste facility, or sample returned to client), and the name of the individual who performed the task.

5.13 LABORATORY REPORT FORMAT AND CONTENTS

The results of each test, or series of tests carried out by the laboratory shall be reported accurately, clearly, unambiguously, and objectively. The results shall normally be reported in a test report and shall include all the information necessary for the interpretation of the test results and all information required by the method used. Some regulatory reporting requirements or formats, such as monthly operating reports, may not require all items listed below; however, the laboratory shall provide all the required information to its client for use in preparing such regulatory reports.

a) Except as discussed in Section 5.13.b), each report to an outside client shall include at least the following information (those prefaced with “where relevant” are not mandatory):

   1) A title (e.g., "Test Report," or "Test Certificate," "Certificate of Results," or "Laboratory Results”);

   2) Name and address of laboratory, and location where the test was carried out if different from the address of the laboratory, and phone number with name of contact person for questions;

   3) Unique identification of the certificate or report (such as serial number) and of each page, and the total number of pages;

      This requirement may be presented in several ways:

i. The total number of pages may be listed on the first page of the report as long as the subsequent pages are identified by the unique report identification and consecutive numbers, or

ii. Each page is identified with the unique report identification, the pages are identified as a number of the total report pages (e.g., 3 of 10, or 1 of 20).

Other methods of identifying the pages in the report may be acceptable as long as it is clear to the reader that discrete pages are associated with a specific report and that the report contains a specified number of pages.

4) Name and address of client, where appropriate, and project name, if applicable;

5) Description and unambiguous identification of the tested sample, including the client identification code;

6) Identification of test results derived from any sample that did not meet NELAC sample acceptance requirements, such as improper container, holding time, or temperature;

7) Date of receipt of sample, date and time of sample collection, date(s) of performance test, and time of sample preparation and/or analysis, if the required holding time for either activity is less than or equal to 48 hours;

8) Identification of the test method used or unambiguous description of any nonstandard method used;

9) If the laboratory collected the sample, reference to sampling procedure;

10) Any deviations from (such as failed quality control), additions to, or exclusions from the test method (such as environmental conditions), and any nonstandard conditions that may have affected the quality of results, and including the use and definitions of data qualifiers.

11) Measurements, examinations, and derived results supported by tables, graphs, sketches, and photographs, as appropriate, and any failures identified; identify whether data are calculated on a dry weight or wet weight basis; identify the reporting units such as grams per liter (g/L) or milligrams per kilogram (mg/kg); and for Whole Effluent Toxicity, identify the statistical package used to provide data;

12) When required, a statement of the estimated uncertainty of the test result;

13) A signature and title, or an equivalent electronic identification of the person(s) accepting responsibility for the content of the certificate or report (however produced), and date of issue;

14) At the laboratory's discretion, a statement to the effect that the results relate only to the items tested or to the sample as received by the laboratory;

15) At the laboratory's discretion, a statement that the certificate or report shall not be reproduced except in full, without the written approval of the laboratory;

16) Clear identification of all test data provided by outside sources, such as subcontracted laboratories, clients, etc.; and

17) Clear identification of numerical results with values outside of quantitation levels.

b) Laboratories that are operated by a facility and whose sole function is to provide data to the facility management for compliance purposes (in-house or captive laboratories) shall have all applicable information specified in 1 through 17 above readily available for review by the accrediting authority. However, formal reports detailing the information are not required if:

   1) The in-house laboratory is itself responsible for preparing the regulatory reports; or

   2) The laboratory provides information to another individual within the organization for preparation of regulatory reports. The facility management must ensure that the appropriate report items are in the report to the regulatory authority if such information is required.

c) Where the certificate or report contains results of tests performed by subcontractors, these results shall be clearly identified by subcontractor name or applicable accreditation number.

d) After issuance of the report, the laboratory report shall remain unchanged. Material amendments to a calibration certificate, test report, or test certificate after issue shall be made only in the form of a further document or data transfer, including the statement "Supplement to Test Report or Test Certificate, serial number . . . [or as otherwise identified]", or equivalent form of wording. Such amendments shall meet all the relevant requirements of this Standard.

e) The laboratory shall notify clients promptly, in writing, of any event, such as the identification of defective measuring or test equipment that casts doubt on the validity of results given in any calibration certificate, test report or test certificate, or amendment to a report or certificate.

f) The laboratory shall ensure that, where clients require transmission of test results by telephone, telex, facsimile, or other electronic or electromagnetic means, staff will follow documented procedures that ensure that the requirements of this Standard are met and that confidentiality is preserved.

g) Laboratories accredited to be in compliance with these standards shall certify that the test results meet all requirements of NELAC or provide reasons and/or justification if they do not.

DoD Implementation Clarification: As noted in the DoD Introduction to this document, DoD plans to supplement this Manual with other standardized documents and formats to support and unify the laboratory analysis and reporting process. It is anticipated that a standardized Laboratory Report format will be issued as part of this continuing effort. In the meantime, there may be additional component-specific or project-specific requirements that supplement those listed above.

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5.14 SUBCONTRACTING ANALYTICAL SAMPLES

a) The laboratory shall advise the client in writing of its intention to subcontract any portion of the testing to another party.

b) Where a laboratory subcontracts any part of the testing covered under NELAP, this work shall be placed with a laboratory accredited under NELAP for the tests to be performed.

c) The laboratory shall retain records demonstrating that the above requirements have been met.

5.15 OUTSIDE SUPPORT SERVICES AND SUPPLIES

a) Where the laboratory procures outside services and supplies other than those referred to in this Standard in support of tests, the laboratory shall use only those outside support services and supplies that are of adequate quality to sustain confidence in the laboratory's tests.

b) Where no independent assurance of the quality of outside support services or supplies is available, the laboratory shall have procedures to ensure that purchased equipment, materials, and services comply with specified requirements. The laboratory should, wherever possible, ensure that purchased equipment and consumable materials are not used until they have been inspected, calibrated, or otherwise verified as complying with any standard specifications relevant to the calibrations or tests concerned.

DoD Implementation Clarification: The laboratory **shall** ensure that materials are inspected, calibrated, or otherwise verified as complying with any standard specifications relevant to the calibrations or tests concerned.

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c) The laboratory shall maintain records of all suppliers from whom it obtains support services or supplies required for tests.

DoD Implementation Clarification: These records shall include date of receipt, expiration date (where applicable), source (i.e., provider or supplier), lot number, and calibration and verification records and certifications for whatever supplies and services may impact the usability of associated test results. Examples of these materials that may have an impact on the quality of data include: solvents, standards, and Class A glassware. Furthermore, all of these supplies shall be maintained according to the applicable requirements specified in Sections 5.9.3 and 5.10.5.

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5.16 COMPLAINTS

The laboratory shall have documented policy and procedures for the resolution of complaints received from clients or other parties about the laboratory's activities. Where a complaint, or any other circumstance, raises doubt concerning the laboratory's compliance with the laboratory's policies or procedures, or with the requirements of this Standard or otherwise concerning the quality of the laboratory's calibrations or tests, the laboratory shall ensure that those areas of activity and responsibility involved are promptly audited in accordance with Section 5.5.3.1. Records of the complaint and subsequent actions shall be maintained.

DoD Implementation Clarification: The laboratory’s Quality System shall contain a process for responding to complaints and/or problems. Documentation of this response and resolution of the problem, as applicable to DoD, shall be maintained. In addition, the laboratory is expected to use this information as part of its Quality System to identify patterns of problems and to correct them. These logs shall be available for DoD review, to help DoD assess the effectiveness of the laboratory’s corrective action process. This information will be considered to be confidential, but will, nonetheless, be used by DoD to assess the effectiveness of the laboratory’s quality system.

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Appendix A - REFERENCES

40 CFR Part 136, Appendix A, paragraphs 8.1.1 and 8.2

American Association for Laboratory Accreditation April 1996. General Requirements for Accreditation

"American National Standards Specification and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs (ANSI/ASQC E-4)", 1994

Catalog of Bacteria, American Type Culture Collection, Rockville, MD

EPA 2185 - Good Automated Laboratory Practices, 1995 available at www.epa.gov/docs/etsdwe1/irm_galp/

"Glossary of Quality Assurance Terms and Acronyms", Quality Assurance Division, Office of Research and Development, USEPA

"Guidance on the Evaluation of Safe Drinking Water Act Compliance Monitoring Results from Performance Based Methods", September 30, 1994, Second draft.

International vocabulary of basic and general terms in metrology (VIM): 1984. Issued by BIPM. IEC. ISO. and OIML

ISO Guide 3534-1: "Statistics, vocabulary and symbols - Part 1: Probability and general statistical terms"

ISO Guide 7218: Microbiology - General Guidance for Microbiological Examinations

ISO Guide 8402: 1986. Quality - Vocabulary

ISO Guide 9000: 1994 Quality management and quality assurance standards - Guidelines for selection and use

ISO Guide 9001: 1994 Quality Systems - Model for quality assurance in design/development, production, installation and servicing

ISO Guide 9002: 1994 Quality systems - Model for quality assurance in production and installation

ISO/IEC Guide 2: 1986. General terms and their definitions concerning standardization and related activities

ISO/IEC Guide 25: 1990. General requirements for the competence of calibration and testing laboratories

"Laboratory Biosafety Manual", World Health Organization, Geneva, 1983

Manual for the Certification of Laboratories Analyzing Drinking Water Revision 4, EPA 815-B-97-001

Manual of Method for General Bacteriology, Philipp Gerhard et al., American Society for Microbiology, Washington, 1981

Performance Based Measurement System, EPA EMMC Method Panel, PBMS Workgroup, 1996

Appendix B - DEFINITIONS FOR QUALITY SYSTEMS

The following definitions are used in the text of Quality Systems. In writing this document, the following hierarchy of definition references were used: ISO 8402, ANSI/ASQC E-4, EPA's Quality Assurance Division Glossary of Terms, and finally definitions developed by NELAC. The source of each definition, unless otherwise identified, is the Quality Systems Committee.

DoD Implementation Clarification: Terms not included in the NELAC Glossary, but defined by DoD, are included in gray text boxes throughout this Appendix.

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Acceptance Criteria: Specified limits placed on characteristics of an item, process, or service defined in requirement documents. (ASQC)

Accreditation: The process by which an agency or organization evaluates and recognizes a laboratory as meeting certain predetermined qualifications or standards, thereby accrediting the laboratory. In the context of the National Environmental Laboratory Accreditation Program (NELAP), this process is a voluntary one. (NELAC)

Accrediting Authority: The Territorial, State, or Federal agency having responsibility and accountability for environmental laboratory accreditation and which grants accreditation NELAC) [NELAC Section 1.5.2.3]

Accuracy: The degree of agreement between an observed value and an accepted reference value. Accuracy includes a combination of random error (precision) and systematic error (bias) components which are due to sampling and analytical operations; a data quality indicator. (QAMS)

Aliquot – A discrete, measured, representative portion of sample taken for analysis. (Source: TEAM, EPA QAD Glossary)

Analysis Duplicate: The second measurement of the target analyte(s) performed on a single sample or sample preparation.

Analyst: The designated individual who performs the "hands-on" analytical methods and associated techniques and who is the one responsible for applying required laboratory practices and other pertinent quality controls to meet the required level of quality. (NELAC)

Analyte – The specific chemicals or components for which a sample is analyzed; may be a group of chemicals that belong to the same chemical family, and which are analyzed together. (Source: EPA Risk Assessment Guide for Superfund; OSHA Glossary)

Analytical Detection Limit: The smallest amount of an analyte that can be distinguished in a sample by a given measurement procedure throughout a given (e.g., 0.95) confidence interval. (Applicable only to radiochemistry)

Analytical Reagent (AR) Grade: Designation for the high purity of certain chemical reagents and solvents given the American Chemical Society. (Quality Systems)

Assessment: The evaluation process used to measure or establish the performance, effectiveness, and conformance of an organization and/or its systems to defined criteria.

Audit: A systematic evaluation to determine the conformance to quantitative and qualitative

specifications of some operational function or activity. (EPA-QAD)

Batch: Environmental samples which are prepared and/or analyzed together with the same process and personnel, using the same lot(s) of reagents. A **preparation batch** is composed of one to 20 environmental samples of the same matrix, meeting the above mentioned criteria and with a maximum time between the start of processing of the first and last sample in the batch to be 24 hours. An **analytical batch** is composed of prepared environmental samples (extracts, digestates or concentrates) and/or those samples not requiring preparation, which are analyzed together as a group using the same calibration curve or factor. An analytical batch can include samples originating from various environmental matrices and can exceed 20 samples.

Blank: A sample that has not been exposed to the analyzed sample stream in order to monitor contamination during sampling, transport, storage or analysis. The blank is subjected to the usual analytical and measurement process to establish a zero baseline or background value and is sometimes used to adjust or correct routine analytical results. (ASQC)

Blind Sample: A subsample for analysis with a composition known to the submitter. The analyst/ laboratory may know the identity of the sample but not its composition. It is used to test the analyst's or laboratory's proficiency in the execution of the measurement process. (NELAC)

Calibrate: To determine, by measurement or comparison with a standard, the correct value of each scale reading on a meter or other device, or the correct value for each setting of a control knob. The levels of the applied calibration standard should bracket the range of planned or expected sample measurements. (NELAC)

Calibration: The set of operations which establish, under specified conditions, the relationship between values indicated by a measuring device, or the correct value of each setting of a control knob. The levels of the applied calibration standard should bracket the range of planned or expected sample measurements. (NELAC)

Calibration Curve: The graphical relationship between the known values, such as concentrations, of a series of calibration standards and their analytical response. (NELAC)

Calibration Method: A defined technical procedure for performing a calibration. (NELAC)

Calibration Standard: A substance or reference material used to calibrate an instrument. (QAMS)

Certified Reference Material (CRM): A reference material one or more of whose property values are certified by a technically valid procedure, accompanied by or traceable to a certificate or other documentation which is issued by a certifying body. (ISO Guide 30 - 2.2)

Chain of Custody: An unbroken trail of accountability that ensures the physical security of samples, and includes the signatures of all who handled the samples.

Chemical -- Any element, compound or mixture of elements and/or compounds. A substance that is classified by the CAS rules of nomenclature for the purposes of identification for a hazard evaluation. (Source: OSHA Glossary)

Client -- The party that has agreed to pay the bill for services rendered by the laboratory, and with whom the laboratory has a contractual relationship for that project. For a laboratory, this is typically the prime contractor who originally hires the laboratory for the project, and who signs the contract as the receiver of services and resulting data. In cases where the laboratory has a direct contractual relationship with DoD, the client shall be the government's authorized technical representative. It is understood that typically other "clients" are present at other levels of the project, but they may be removed from the day-to-day

decisionmaking (e.g., installation representatives, service center representatives, various other government officials). Specific circumstances may require the direct notification of these other clients, in addition to the prime contractor or DoD representative; these circumstances shall be included as part of specific project requirements. (Source Team)

Compound -- A unique combination of chemical elements, existing in combination to form a single chemical entity. (Source: Team)

Component – A single chemical entity, such as an element or compound. Multiple components may comprise one analyte. (Source: OSHA Glossary, Team)

Compromised Samples: Those samples which are improperly sampled, insufficiently documented (chain of custody and other sample records and/or labels), improperly preserved, collected in improper containers, or exceeding holding times when delivered to a laboratory. Under normal conditions compromised samples are not analyzed. If emergency situations require analysis, the results must be appropriately qualified. (NELAC)

Confirmation: Verification of the presence/identity of a component that may include (NELAC):

- Second column confirmation;
- Alternate wavelength;
- Derivatization;
- Mass spectral interpretation;
- Alternative detectors;
- Additional cleanup procedures, or;
- Alternative technique or conditions.

Conformance: An affirmative indication or judgement that a product or service has met the requirements of the relevant specifications, contract, or regulation; also the state of meeting the requirements. (ANSI/ ASQC E4-1994)

Consensus Standards – A protocol established by a recognized authority (e.g., American Society for Testing and Materials [ASTM], American National Standards Institute [ANSI], or the Institute for Electrical and Electronic Engineers [IEEE]).

Corrective Action: action taken to eliminate the causes of an existing nonconformity, defect or other undesirable situation in order to prevent recurrence. (ISO 8402)

Data Audit: A qualitative and quantitative evaluation of the documentation and procedures associated with environmental measurements to verify that the resulting data are of acceptable quality (i.e., that they meet specified acceptance criteria.) (NELAC)

Data Reduction: The process of transforming raw data by arithmetic or statistical calculations, standard curves, concentration factors, etc., and collation into a more useful form. (EPA-QAD)

Deficiency: An unauthorized deviation from acceptable procedures or practices, or a defect in an item. (ASQC)

Definitive Data – Data that are generated using rigorous analytical methods, such as approved EPA reference methods. Data are analyte-specific, with confirmation of analyte identity and concentration. Methods produce tangible raw data in the form of paper print-outs or electronic files. Data shall satisfy QA/QC requirements. For data to be definitive, either analytical or total measurement error shall be determined. (Source: Data Quality Objectives Process for Superfund)

Demonstration of Capability: a procedure to establish the ability of the analyst to generate acceptable accuracy. (NELAC)

Desorption Efficiency: The mass of target analyte recovered from sampling media, usually a sorbent tube, divided by the mass of target analyte spiked on to the sampling media expressed as a percentage. Sample target analyte masses are usually adjusted for the desorption efficiency. (NELAC)

Detection Limit: The lowest concentration or amount of the target analyte that can be determined to be different from zero by a single measurement at a stated degree of confidence. See Method Detection Limit, Quantitation Limit, and Limit of Detection. (NELAC)

Document Control: The act of ensuring that documents (and revisions thereto) are proposed, reviewed for accuracy, approved for release by authorized personnel, distributed properly and controlled to ensure use of the correct version at the location where the prescribed activity is performed. (ASQC)

Duplicate Analyses: The analyses or measurements of the variable of interest performed identically on two subsamples of the same sample. The results from duplicate analyses are used to evaluate analytical or measurement precision but not the precision of sampling, preservation or storage internal to the laboratory. (EPA- QAD)

Environmental program – An organized effort that assesses environmental concerns and leads to the collection of data, either in the field or though laboratory analysis. (Source: Variation on EPA QAD Glossary for Terms: Environmentally related measurement, environmental sample)

Holding Times (Maximum Allowable Holding Times): The maximum times that samples may be held prior to analysis and still be considered valid. (40 CFR Part 136).

Inspection: an activity such as measuring, examining, testing, or gauging one or more characteristics of an entity and comparing the results with specified requirements in order to establish whether conformance is achieved for each characteristic. (ANSI/ ASQC E4-1994)

Internal Standard: a known amount of standard added to a test portion of a sample as a reference for evaluating and controlling the precision and bias of the applied analytical method. (NELAC)

Instrument Blank: A clean sample (e. g., distilled water) processed through the instrumental steps of the measurement process; used to determine instrument contamination. (EPA-QAD)

Laboratory: A body that calibrates and/or tests.

NOTES:

1. In cases where a laboratory forms part of an organization that carries out other activities besides calibration and testing, the term "laboratory" refers only to those parts of that organization that are involved in the calibration and testing process.

2. As used herein, the term "laboratory" refers to a body that carries out calibration or testing at or from a permanent location, from a temporary facility, or a mobile facility. (ISO 25)

Laboratory Control Sample (however named, such as laboratory fortified blank or spiked blank): A sample matrix, free from the analytes of interest, spiked with verified known amounts of analytes from a source independent of the calibration standards or a material containing known and verified amounts of analytes. It is generally used to establish intra-laboratory or analyst specific precision and bias or to assess the performance of all or a portion of the measurement system. (NELAC).

Laboratory Duplicate: Aliquots of a sample taken from the same container under laboratory conditions and processed and analyzed independently.

Limit of Detection (LOD): The lowest concentration level that can be determined by a single analysis and with a defined level of confidence to be statistically different from a blank. See also Method Detection Limit, Detection Limit, and Quantitation Limit (Analytical Chemistry, 55, p. 2217, December 1983, modified)

Manager (however named): The individual designated as being responsible for the overall operation, all personnel, and the physical plant of the environmental laboratory. A supervisor may report to the manager. In some cases, the supervisor and the manager may be the same individual. (NELAC)

Matrix: The component or substrate that may contains the analyte of interest. For purposes of batch determination, the following matrix types shall be used:

- Aqueous: Any aqueous sample excluded from the definition of a drinking water matrix or
- Saline/Estuarine source. Includes surface water, groundwater and effluents.
- Drinking water: Any aqueous sample that has been designated a potable or potential potable water source.
- Saline/ Estuarine: Any aqueous sample from an ocean or estuary, or other salt water source such as the Great Salt Lake.
- Non- aqueous liquid: Any organic liquid with <15% settleable solids.
- Biological Tissue: Any sample of a biological origin such as fish tissue, shellfish, or plant material. Such samples shall be grouped according to origin.
- Solids: Includes soils, sediments, sludges and other matrices with >15% settleable solids.
- Chemical Waste: A product or by-product of an industrial process that results in a matrix not previously defined.
- Air: Whole gas or vapor samples including those contained in flexible or rigid wall containers and the extracted concentrated analytes of interest from a gas or vapor that are collected with a sorbent tube, impinger solution, filter or other device.

Matrix Spike (spiked sample, fortified sample): Prepared by adding a known mass of target analyte to a specified amount of matrix sample for which an independent estimate of target analyte concentration is available. Matrix spikes are used, for example, to determine the effect of the matrix on a method's recovery efficiency. (QAMS).

Matrix Spike Duplicate (spiked sample/ fortified sample duplicate): A second replicate matrix spike is prepared in the laboratory and analyzed to obtain a measure of the precision of the recovery for each analyte. (QAMS).

May: Denotes permitted action, but not required action. (NELAC)

Media: Material that supports the growth of a microbiological culture.

Method Blank: A sample of a matrix similar to the batch of associated samples (when available) in which no target analytes or interferences are present at concentrations that impact the analytical results. It is processed simultaneously with samples of similar matrix and under the same conditions as the samples. (NELAC).

Method Detection Limit: The minimum concentration of a substance (an analyte) that can be measured and reported with 99% confidence that the analyte concentration is greater than zero and is determined from analysis of a sample in a given matrix containing the analyte. (40 CFR Part 136 Appendix B).

Must: Denotes a requirement (mandatory). (Random House College Dictionary)

National Laboratory Accreditation Conference (NELAC): A voluntary organization of State and Federal environmental officials and interest groups purposed primarily to establish mutually acceptable standards for accrediting environmental laboratories. A subset of NELAP. (NELAC)

National Environmental Laboratory Accreditation Program (NELAP): The overall National Environmental Laboratory Accreditation Program of which NELAC is a part. (NELAC)

Negative Control: Measures taken to ensure that a test, its components, or the environment do not cause undesired effects, or produce incorrect test results. (NELAC)

Objective Evidence: Any documented statement of fact, other information, or record, either quantitative or qualitative, pertaining to the quality of an item or activity, based on observations, measures, or tests that can be verified. (ASQC)

Performance Audit: The routine comparison of independently obtained qualitative and quantitative measurement system data with routinely obtained data in order to evaluate the proficiency of an analyst or laboratory. (NELAC)

Performance Based Measurement System (PBMS): a set of processes wherein the data quality needs, mandates or limitations of a program or project are specified and serve as criteria for selecting appropriate test methods to meet those needs in a cost-effective manner. (NELAC)

Positive Control: Measures taken to ensure that a test and/or its components are working properly and producing correct or expected results from positive test subjects. (NELAC)

Precision: The degree to which a set of observations or measurements of the same property, obtained under similar conditions, conform to themselves; a data quality indicator. Precision is usually expressed as standard deviation, variance or range, in either absolute or relative terms. (NELAC)

Preservation: Refrigeration and or reagents added at the time of sample collection (or later) to maintain the chemical and or biological integrity of the sample. (NELAC)

Proficiency Test Sample (PT): A sample, the composition of which is unknown to the analyst and is provided to test whether the analyst/laboratory can produce analytical results within specified acceptance criteria. (QAMS)

Proficiency Testing: A means of evaluating a laboratory's performance under controlled conditions relative to a given set of criteria through analysis of unknown samples provided by an external source. (NELAC Section 2.1]

Proficiency Testing Program: The aggregate of providing rigorously controlled and standardized environmental samples to a laboratory for analysis, reporting of results, statistical evaluation of the results and the collective demographics and results summary of all participating laboratories. (NELAC)

Protocol: A detailed written procedure for field and/ or laboratory operation (e. g., sampling, analysis) which must be strictly followed. (EPA- QAD)

Pure Reagent Water: Shall be water (defined by national or international standard) in which no target analytes or interferences are detected as required by the analytical method. (NELAC)

Quality Assurance: An integrated system of activities involving planning, quality control, quality assessment, reporting and quality improvement to ensure that a product or service meets defined standards of quality with a stated level of confidence. (QAMS)

Quality Assurance (Project) Plan (QAPP): a formal document describing the detailed quality control procedures by which the quality requirements defined for the data and decisions pertaining to a specific project are to be achieved. (EPA- QAD)

Quality Control: The overall system of technical activities whose purpose is to measure and control the quality of a product or service so that it meets the needs of users. (QAMS)

Quality Control Sample: An uncontaminated sample matrix with known amounts of analytes from a source independent from the calibration standards. It is generally used to establish intra- laboratory or analyst specific precision and bias or to assess the performance of all or a portion of the measurement system. (EPA- QAD)

Quality Manual: A document stating the quality policy, quality system and quality practices of an organization. This may also be called a Quality Assurance Plan or Quality Plan.

NOTE – The quality manual may call up other documentation relating to the laboratory's quality arrangements.

Quality System: A structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring quality in its work processes, products (items), and services. The quality system provides the framework for planning, implementing, and assessing work performed by the organization and for carrying out required QA and QC. (ANSI/ ASQC E- 41994)

Quantitation Limits: The maximum or minimum levels, concentrations, or quantities of a target that can be quantified with the accuracy required by the intended use of the data user. (NELAC)

Quantitation Limits (DoD Clarification) – The value at which an instrument can accurately measure an analyte at a specific concentration (i.e., a specific numeric concentration can be quantified). These points establish the upper and lower limits of the calibration range.

Range: Tthe difference between the minimum and the maximum of a set of values. (EPA- QAD)

Raw Data: Any original factual information from a measurement activity or study recorded in a laboratory notebook, worksheets, records, memoranda, notes, or exact copies thereof that are necessary for the reconstruction and evaluation of the report of the activity or study. Raw data may include photography, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments. If exact copies of raw data have been prepared (e. g., tapes which have been transcribed verbatim, data and verified accurate by signature), the exact copy or exact transcript may be submitted. (EPA- QAD)

Reagent Blank (method reagent blank): A sample consisting of reagent(s), without the target analyte or sample matrix, introduced into the analytical procedure at the appropriate point and carried through all subsequent steps to determine the contribution of the reagents and of the involved analytical steps. (QAMS)

Record Retention: The systematic collection, indexing and storing of documented information under secure conditions. (EPA-QAD)

Reference Material: A material or substance one or more properties of which are sufficiently well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials. (ISO Guide 30- 2.1)

Reference Method: A method of known and documented accuracy and precision issued by an organization recognized as competent to do so. (NELAC *)*

Reference Standard: A standard, generally of the highest metrological quality available at a given location, from which measurements made at that location are derived. (VIM- 6.08)

Reference Toxicant: The toxicant used in performing toxicity tests to indicate the sensitivity of a test organism and to demonstrate the laboratory's ability to perform the test correctly and obtain consistent results (see Chapter 5, Appendix D, Section 2.1). (NELAC)

Replicate Analyses: The measurements of the variable of interest performed identically on two or more sub-samples of the same sample within a short time interval. (NELAC)

Reporting Limit – A specific concentration at or above the lower quantitation limit that is reported to the client with confidence. It is often defined on a project-specific basis. If set by the client below the lower quantitation limit, method modification is required. For methods that only require one standard (e.g., lower limit of calibration curve is the origin), the reporting limit shall be no lower than the low level check standard.

Requirement: Denotes a mandatory specification; often designated by the term "shall". (NELAC)

Sample – Portion of material collected for chemical analysis, identified by a single, unique term. A sample may consist of portions in multiple containers, if a single sample is submitted for multiple or repetitive analysis.

Sampling Media: Material used to collect and concentrate the target analytes(s) during air sampling such as solid sorbents, filters, or impinger solutions.

Selectivity: (Analytical chemistry) The capability of a test method or instrument to respond to a target substance or constituent in the presence of nontarget substances.

Sensitivity: The capability of a test method or instrument to discriminate between measurement responses representing different levels (e. g., concentrations) of a variable of interest.

Shall: Denotes a requirement that is mandatory whenever the criterion for conformance with the specification requires that there be no deviation. This does not prohibit the use of alternative approaches or methods for implementing the specification so long as the requirement is fulfilled. (ANSI).

Should: Denotes a guideline or recommendation whenever noncompliance with the specification is permissible. (ANSI).

Species – A chemical entity that exists in a specific form (e.g., ions, molecules, solid phase compounds). (Source: Combination of multiple sources)

Spike: A known mass of target analyte added to a blank, sample or subsample; used to determine recovery efficiency or for other quality control purposes.

Standard: The document describing the elements of laboratory accreditation that has been developed and established within the consensus principles of NELAC and meets the approval requirements of NELAC procedures and policies. (ASQC)

Standard Operating Procedure (SOP): A written document which details the method of an operation, analysis or action whose techniques and procedures are thoroughly prescribed and which is accepted as

the method for performing certain routine or repetitive tasks. (QAMS).

Standard Reference Material (SRM): A certified reference material produced by the U. S. National Institute of Standards and Technology and characterized for absolute content, independent of analytical test method.

Supervisor (however named): The individual(s) designated as being responsible for a particular area or category of scientific analysis. This responsibility includes direct day- to- day supervision of technical employees, supply and instrument adequacy and upkeep, quality assurance/ quality control duties and ascertaining that technical employees have the required balance of education, training and experience to perform the required analyses.

Surrogate: A substance with properties that mimic the analyte of interest. It is unlikely to be found in environment samples and is added to them for quality control purposes. (Glossary of Quality Assurance Terms, QAMS, 8/ 31/ 92).

Systems Audit (also Technical Systems Audit): a thorough, systematic, qualitative on-site assessment of the facilities, equipment, personnel, training, procedures, record keeping, data validation, data management, and reporting aspects of a total measurement system. (EPA- QAD)

Technical Director: (however named) has overall responsibility for the technical operation of the environmental testing laboratory. (NELAC Section 4.1.1.1).

Test: a technical operation that consists of the determination of one or more characteristics or performance of a given product, material, equipment, organism, physical phenomenon, process or service according to a specified procedure. The result of a test is normally recorded in a document sometimes called a test report or a test certificate. (ISO/IEC Guide 2-12.1, amended)

Test Method: an adoption of a scientific technique for a specific measurement problem, as documented in a laboratory SOP. (NELAC)

Testing Laboratory: Laboratory that performs tests. (ISO/ IEC Guide 2 - 12.4)

Test Sensitivity/Power: the minimum significant difference (MSD) between the control and test concentration that is statistically significant. It is dependent on the number of replicates per concentration, the selected significance level, and the type of statistical analysis (see Chapter 5, Appendix D.2.4.). (NELAC)

Tolerance Chart: A chart in which the plotted quality control data is assessed via a tolerance level (e. g. +/- 10% of a mean) based on the precision level judged acceptable to meet overall quality/ data use requirements instead of a statistical acceptance criteria (e. g. +/- 3 sigma). (ANSI N42.23- 1995, Measurement and Associated Instrument Quality Assurance for Radioassay Laboratories)

Traceability: the property of a result of a measurement whereby it can be related to appropriate standards, generally international or national standards, through an unbroken chain of comparisons. (VIM - 6.12)

Validation: the process of substantiating specified performance criteria. (EPA- QAD)

Verification: confirmation by examination and provision of evidence that specified requirements have been met. (NELAC)

NOTE -Verification provides a means for checking that the deviations between values indicated by a measuring instrument and corresponding known values of a measured quantity are consistently smaller than the maximum allowable error defined in a standard, regulation or specification peculiar to the

management of the measuring equipment.

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

Work Cell: a well defined group of analysts that together perform the method analysis. The members of the group and their specific function/s within the work cell must be fully documented. (NELAC)

Sources:

American Society for Quality Control (ASQC), Definitions of Environmental Quality Assurance Terms, 1996

American National Standards Institute (ANSI), Style Manual for Preparation of Proposed American National Standards, Eighth Edition, March 1991

ANSI/ ASQC E4, 1994

ANSI N42.23- 1995, Measurement and Associated Instrument Quality Assurance for Radiobioassay Laboratories

International Standards Organization (ISO) Guides 2, 30, 8402

National Institute of Standards and Technology (NIST)

National Environmental Laboratory Accreditation Conference (NELAC), July 1998 Standards

Random House College Dictionary

US EPA Quality Assurance Management Section (QAMS), Glossary of Terms of Quality Assurance Terms, 8/31/92 and 12/6/95

US EPA Quality Assurance Division (QAD)

40CFR Part 136

Webster's New World Dictionary of the American Language

Appendix C - DEMONSTRATION OF CAPABILITY

C.1 PROCEDURE FOR DEMONSTRATION OF CAPABILITY

A demonstration of capability (DOC) must be made prior to using any test method, and at any time there is a significant change in instrument type, personnel, or test method. (See Section 5.10.2.1.)

DoD Implementation Clarification: "Significant change" always refers to a change in personnel. In addition, it includes any change in matrix, instrumentation, or in test methods that potentially impacts the precision and accuracy of the output (e.g., a change in the detector, column, or a method revision). All new analysts, regardless of experience on that instrument in another laboratory, shall complete a Demonstration of Capability.

C-1

Note: In laboratories with specialized "work cells" (a well-defined group of analysts that together perform the method analysis), the group as a unit must meet the above criteria and this demonstration must be fully documented.

DoD Implementation Clarification: Additional guidance on this issue is provided in Section 5.10.2.1.f. A "work cell" is considered to be all those individuals who see a sample through the complete process of preparation/extraction and analysis. To ensure that the entire preparation-extraction-analysis process is completed by a collection of capable individuals, the laboratory shall ensure that **each member** of the work cell demonstrates capability in his/her area of responsibility in the sequence. Even though the work cell operates as a "team," the Demonstration of Capability at each individual step in the sequence as performed by each individual analyst/team member, remains of utmost importance.

A work cell may NOT be defined as a group of analysts that performs the same step in the same process (e.g., extractions for Method 8270), represented by one analyst who has demonstrated capability for that step.

C-2

In general, this demonstration does not test the performance of the method in real world samples, but in the applicable and available clean matrix (a sample of a matrix in which no target analytes or interferences are present at concentrations that would impact the results of a specific test method), e.g., water, solids, biological tissue, and air. However, before any results are reported using this method, actual sample spike results may be used to meet this standard, i.e., at least four consecutive matrix spikes within the past 12 months. In addition, for analytes which do not lend themselves to spiking, e.g., TSS, the demonstration of capability may be performed using quality control samples.

All demonstrations shall be documented through the use of the form in this appendix.

The following steps, which are adapted from the EPA test methods published in 40 CFR Part 136, Appendix A, shall be performed if required by the mandatory test method or regulation. (Note: for analytes for which spiking is not an option and for which quality control samples are not readily available, the 40 CFR approach is one way to perform this demonstration. It is the responsibility of the laboratory to document that other approaches to DOC are adequate, and this shall be documented in the laboratory's Quality Manual.)

a) A quality control (QC) sample shall be obtained from an outside source. If not available, the QC sample may be prepared by the laboratory using stock standards that are prepared independently from those used in instrument calibration.

b) The analyte(s) shall be diluted in a volume of clean matrix sufficient to prepare four aliquots at the concentration specified, or, if unspecified, to a concentration approximately 10 times the method-stated or laboratory-calculated method detection limit.

c) At least four aliquots shall be prepared and analyzed according to the test method either concurrently or over a period of days.

d) Using all of the results, calculate the mean recovery in the appropriate reporting units (such as micrograms per liter) and the standard deviations of the population sample (n-1) (in the same units) for each parameter of interest. When it is not possible to determine mean and standard deviations, such as for presence/absence and logarithmic values, the laboratory will assess performance against established and documented criteria.

DoD Implementation Clarification: In the case where the laboratory is introducing a new method, these criteria shall be determined using an external source of information (e.g., the published method, Standard, or certified reference material). The laboratory shall not "benchmark against itself" by using internal comparisons to initial runs to establish these criteria.

C-3

e) Compare the information from (d) above to the corresponding acceptance criteria for precision and accuracy in the test method (if applicable) or in laboratory-generated acceptance criteria (if there are no established mandatory criteria). If all parameters meet the acceptance criteria, the analysis of actual samples may begin. If any one of the parameters do not meet the acceptance criteria, the performance is unacceptable for that parameter.

f) When one or more of the tested parameters fail at least one of the acceptance criteria, the analyst must proceed according to 1) or 2) below.

   1) Locate and correct the source of the problem and repeat the test for all parameters of interest beginning with c) above.

   2) Beginning with c) above, repeat the test for all parameters that failed to meet criteria. Repeated failure, however, will confirm a general problem with the measurement system. If this occurs, locate and correct the source of the problem and repeat the test for all compounds of interest beginning with c).

C.2 CERTIFICATION STATEMENT

The following certification statement shall be used to document the completion of each demonstration of capability. A copy of the certification statement shall be retained in the personnel records of each affected employee. (See Sections 5.6.3 and 5.12.3.4.b.)

DoD Implementation Clarification: All repeated incidences of testing to meet a Demonstration of Capability shall be documented and packaged with the final Certification Statement.

C-4

Demonstration of Capability
Certification Statement

Date: Page __of __
Laboratory Name:
Laboratory Address:
Analyst(s) Name(s):

Matrix: _____ (Examples: laboratory pure water, soil, air, solid, biological tissue)

Method number, SOP#, Rev #, and Analyte, or Class of Analytes or Measured Parameters:
_____ (Examples: barium by 200.7, trace metals by 6010, benzene by 8021, etc.)

We, the undersigned, CERTIFY that:

1. The analysts identified above, using the cited test method/s, which is in use at this facility for the analyses of samples under the National Environmental Laboratory Accreditation Program, have met the Demonstration of Capability.

2. The test method was performed by the analyst(s) identified on this certification.

3. A copy of the test method(s) and the laboratory-specific SOPs are available for all personnel on-site.

4. The data associated with the demonstration capability are true, accurate, complete and self-explanatory (1).

5. All raw data (including a copy of this certification form) necessary to support these analyses have been retained at the facility, and that the associated information is well organized and available for review by authorized inspectors.

_____	_____	_____
Technical Director's Name and Title	Signature	Date
_____	_____	_____
Quality Assurance Officer's Name	Signature	Date

This certification form must be completed each time a demonstration of capability study is completed.

(1) True: Consistent with supporting data.
Accurate: Based on good laboratory practices consistent with sound scientific principles/practices.
Complete: Includes the results of all supporting performance testing.
Self-explanatory: Data properly labeled and stored so that the results are clear and require no additional explanation.

Appendix D - ESSENTIAL QUALITY CONTROL REQUIREMENTS

The quality control (QC) protocols specified by the laboratory's method manual (Section 5.10.1.2) shall be followed. The laboratory shall ensure that the essential standards outlined in Appendix D are incorporated into its method manuals.

All QC measures shall be assessed and evaluated on an ongoing basis and quality control acceptance criteria shall be used to determine the validity of the data. The laboratory shall have procedures for the development of acceptance/rejection criteria where no method or regulatory criteria exists.

The requirements from the body of Chapter 5, e.g., Section 5.5.4, apply to all types of testing. The specific manner in which they are implemented is detailed in each of the sections of this Appendix, i.e., chemical testing, W.E.T. testing, microbiology testing, radiochemical testing and air testing.

DoD Implementation Clarification: When quality control measures fail the acceptance criteria specified in these requirements, corrective action shall be taken. Different corrective responses may be appropriate in different situations, based upon project-specific requirements and the magnitude of the problem. Examples of corrective actions that may be required include:

- Notifying the client,
- Reprocessing samples,
- Using data qualifiers to "flag" data, and
- Adding commentary in laboratory reports.

D-1

D.1 CHEMICAL TESTING

D.1.1 Positive and Negative Controls

a) Negative Controls

1) Method Blanks - Shall be performed at a frequency of one per batch of samples per matrix type per sample extraction or preparation method. The results of this analysis shall be one of the QC measures to be used to assess batch acceptance. The source of contamination must be investigated, and measures taken to correct, minimize, or eliminate the problem, if:

   i) the blank contamination exceeds a concentration greater than 1/10 of the measured concentration of any sample in the associated sample batch, or

   ii) the blank contamination exceeds the concentration present in the samples and is greater than 1/10 of the specified regulatory limit.

   Any sample associated with the contaminated blank shall be reprocessed for analysis or the results reported with appropriate data qualifying codes.

DoD Implementation Clarification: The following paragraphs restate the requirements of Section D.1.1.a)1 above, with DoD expectations with respect to the requirement highlighted in bold.

Method Blanks - Shall be performed at a frequency of one per **preparatory** batch of samples per matrix type per sample extraction or preparation method. The results of this analysis shall be one of the QC measures to be used to assess batch acceptance. The source of **method blank** contamination shall be investigated, and measures taken to correct, minimize, or eliminate the problem, if **the concentration exceeds the method reporting limit. If the method reporting limit [MRL] is exceeded, the laboratory shall evaluate whether reprocessing of the samples is necessary, based upon the following criteria:**

i) The blank contamination exceeds a concentration greater than 1/10 of the measured concentration of any sample in the associated **preparatory** batch, or
ii) The blank contamination exceeds the concentration present in the samples and is greater than 1/10 of the specified regulatory limit.

Any samples associated with a blank that fail these criteria checks shall be reprocessed, except when the sample analysis resulted in a nondetect. If no sample volume remains for reprocessing, the results **shall be** reported with appropriate data qualifying codes.

D-2

b) Positive Controls

1) Laboratory Control Sample (LCS) - (QC Check Samples) Shall be analyzed at a minimum of 1 per batch of 20 or less samples per matrix type per sample extraction or preparation method except for analytes for which spiking solutions are not available, such as total suspended solids, total dissolved solids, total volatile solids, total solids, pH, color, odor, temperature, dissolved oxygen, or turbidity. The results of these samples shall be used to determine batch acceptance. NOTE: the Matrix spike may be used in place of this control as long as the acceptance criteria are as stringent as for the LCS. (See 2 below.)

DoD Implementation Clarification: The LCS shall, as a minimum, meet limits specified in the method. In addition, the laboratory shall establish its own limits, based upon in-house statistical analysis of historical LCS limits. The acceptability of LCS results within any preparatory batch shall be based upon these in-house limits, unless the method-specified limits are more stringent, or the client has specified limits based upon the intended use of the data.

D-3

2) Matrix Spikes (MS) - Shall be performed at a frequency of 1 in 20 samples per matrix type per sample extraction or preparation method except for analytes for which spiking solutions are not available, such as total suspended solids, total dissolved solids, total volatile solids, total solids, pH, color, odor, temperature, dissolved oxygen, or turbidity. The selected sample(s) shall be rotated among client samples so that various matrix problems may be noted and/or addressed. Poor performance in a matrix spike may indicate a problem with the sample composition and shall be reported to the client whose sample was used for the spike.

DoD Implementation Clarification: Matrix spikes shall be performed at a frequency of 1/20 samples per matrix type. Additional matrix spikes may be required by project specific needs for field quality control. The selection of these samples is particularly critical when additional sample volumes are necessary to complete the analyses.

D-4

3) Surrogates - Surrogate compounds must be added to all samples, standards, and blanks for all organic chromatography methods except when the matrix precludes its use or when a surrogate is not available. Poor surrogate recovery may indicate a problem with the sample composition and shall be reported to the client whose sample produced the poor recovery.

4) If the mandated or requested test method does not specify the spiking components, the laboratory shall spike all reportable components to be reported in the Laboratory Control Sample and Matrix Spike. However, in cases where the components interfere with accurate assessment (such as simultaneously spiking chlordane, toxaphene, and polychlorinated biphenyls [PCBs] in Method 608), the test method has an extremely long list of components or components are incompatible, a representative number (at a minimum 10%) of the listed components may be used to control the test method. The selected components of each spiking mix shall represent all chemistries, elution patterns and masses, permit specified analytes, and other client requested components. However, the laboratory shall ensure, that all reported components are used in the spike mixture within a two-year time period.

DoD Implementation Clarification:

- The protocols above shall only be required if the test method **or project-specific requirements** do not specify the spiking compounds.
- The list of "reportable components" is specified by the project.
- For DoD, "an extremely long list of components" means "greater than 50 components."

D-5

D.1.2 Analytical Variability/Reproducibility

Matrix Spike Duplicates (MSDs) or Laboratory Duplicates - Shall be analyzed at a minimum of 1 in 20 samples per matrix type per sample extraction or preparation method. The laboratory shall document its procedure to select the use of appropriate type of duplicate. The selected sample(s) shall be rotated among client samples so that various matrix problems may be noted and/or addressed. Poor performance in the duplicates may indicate a problem with the sample composition and shall be reported to the client whose sample was used for the duplicate.

DoD Implementation Clarification: Each duplicate named above shall be analyzed by the same specifications as its respective matrix spike. For example, matrix spike duplicates shall be performed at a frequency of 1/20 samples per matrix type. Additional matrix spikes duplicates may be required by project specific needs. The selection of these samples is particularly critical when additional sample volumes are necessary to complete the analyses.

D-6

D.1.3 Method Evaluation

In order to ensure the accuracy of the reported result, the following procedures shall be in place:

a) Demonstration of Analytical Capability - (Section 5.10.2.1) shall be performed initially (prior to the analysis of any samples) and with a significant change in instrument type, personnel, matrix or test method.

DoD Implementation Clarification: "Significant change" refers to any change in personnel. In addition, it includes any change in instrumentation or in test methods that potentially impacts the precision and accuracy of the output (e.g., a change in the detector, column, or a method revision). Requirements for meeting an "Demonstration of Capability" are further addressed in Appendix C.

D-7

b) Calibration - Calibration protocols specified in Section 5.9.4 shall be followed.

DoD Implementation Clarification: Protocols in Section 5.9.4 shall be followed, unless method specific criteria are available.

D-8

c) Proficiency Test Samples - The results of such analyses (Section 5.4.2.j or 5.5.3.4) shall be used by the laboratory to evaluate the ability of the laboratory to produce accurate data.

DoD Implementation Clarification: Proficiency Testing is discussed further in NELAP Chapter 2. If such testing reveals inaccuracies in data generation, corrective action shall be taken in accordance with the laboratory's documented procedures. DoD shall submit its own proficiency testing samples, as it deems necessary.

D-9

D.1.4 Detection Limits

The laboratory shall utilize a test method that provides a detection limit that is appropriate or relevant for the intended use of the data. Detection limits shall be determined by the protocol in the mandated test method or applicable regulation, e.g., MDL. If the protocol for determining detection limits is not specified, the selection of the procedure must reflect instrument limitations and the intended application of the test method.

DoD Implementation Clarification: A Method Detection Limit (MDL) is defined as the minimum concentration of a substance that can be measured and reported with 99% confidence that the analyte concentration is greater than zero, and is determined from analysis of a sample in a given matrix containing the analyte.

Requirements established in 40 CFR 136B are the baseline source of information for determining MDLs. Other published statistical methods may be appropriate as supplemental resources in determining MDLs (e.g., Hubaux and Vos studies may be appropriate for methods that do not require prep, such as GC/MS volatiles in water). The following list provides clarification and expansions upon the fundamental requirements and principles outlined in 40 CFR 136 B, and shall be followed when performing work for DoD:

- As stated in 40 CFR 136 B, MDLs shall be determined using a minimum of 7 replicates. If more than 7 replicates are processed, data cannot be excluded, unless exclusion is supported with sound, documented, technically-based justification.
- MDLs are to be calculated for each analyte, matrix, and instrument. If multiple instruments with identical configurations are used in the laboratory, then the laboratory may conduct an MDL study on one of the instruments, and confirm the attainability of that MDL on all instruments using an MDL check sample.
- If multiple MDL results are generated from multiple instruments with identical configurations, then the highest MDL among those may be used in reporting data from all of those instruments. If a lower MDL is reported for specific samples, then the samples must have been run on that specific instrument on which the lower MDL was generated.
- MDLs shall be generated for all applicable matrices, using, at a minimum, a purified matrix free of the analytes of interest (e.g., Ottawa sand, reagent grade water).
- MDLs shall be generated for all prep and cleanup methods routinely used on samples.
- An MDL check shall always be performed immediately following an MDL study. DoD requires that the MDL check sample be spiked at **approximately two times** the current reported MDL.
- MDL verification checks shall be performed **quarterly**, if an annual MDL study is not performed. If the quarterly MDL verification fails, then the MDL study shall be re-conducted.
- For DoD, the MDL check sample shall always produce a response that lies at least three times above the instrument's noise level.

D-10

a) A detection limit study is not required for any component for which spiking solutions or quality control samples are not available, such as odor and temperature.

b) The detection limit shall be initially determined for the compounds of interest in each test method in a matrix in which there are not target analytes nor interferences at a concentration that would impact the results, or the detection limit must be determined in the matrix of interest (see definition of matrix).

c) Detection limits must be determined each time there is a significant change in the test method or instrument type.

d) It is essential that all processing steps of the analytical method be included in the determination of the detection limit.

e) All procedures used must be documented. Documentation must include the matrix type. All supporting data must be retained.

f) The laboratory must have established procedures to tie detection limits with quantitation limits.

D.1.5 Data Reduction

The procedures for data reduction, such as use of linear regression, shall be documented.

DoD Implementation Clarification: At a minimum, for those processes that are automated, a sample data test set shall be used to test and verify the correct operation of these data reduction procedures (including data capture, manipulation, transfer, and reporting). This shall be done anytime the programming code is modified or otherwise manipulated, and applies even in cases where commercial software is used as part of the process.

D-11

D.1.6 Quality of Standards and Reagents

a) The source of standards shall comply with Section 5.9.2.

b) Reagent Quality, Water Quality and Checks:

1) Reagents - In methods where the purity of reagents is not specified, analytical reagent grade shall be used. Reagents of lesser purity than those specified by the test method shall not be used. The labels on the container should be checked to verify that the purity of the reagents meets the requirements of the particular test method. Such information shall be documented.

2) Water - The quality of water sources shall be monitored and documented and shall meet method specified requirements.

DoD Implementation Clarification: When water quality is not specified in the method, the default water quality shall be specified in the method-specific Standard Operating Procedures (SOPs) (for example, American Society for Testing and Materials [ASTM] Type I or II).

D-12

D.1.7 Selectivity

a) Absolute retention time and relative retention time aid in the identification of components in chromatographic analyses and to evaluate the effectiveness of a column to separate constituents. The laboratory shall develop and document acceptance criteria for retention time windows.

DoD Implementation Clarification: The laboratory shall follow method-specific requirements for frequency of retention time verification and criteria for acceptance.

D-13

b) A confirmation shall be performed to verify the compound identification when positive results are detected on a sample from a location that has not been previously tested by the laboratory. Such confirmations shall be performed on organic tests such as pesticides, herbicides, or acid extractable or when recommended by the analytical test method except when the analysis involves the use of a mass spectrometer. Confirmation is required unless stipulated in writing by the client. All confirmation shall be documented.

DoD Implementation Clarification: This requirement may be waived by the client in the case of periodic monitoring of well-characterized media, which are tested by the same laboratory. For data that are required to be confirmed, all results shall be reported as confirmed or unconfirmed. If unconfirmed data are reported, they shall be identified separately in the report, with a narrative explaining why the data were not confirmed. Evaluation criteria for the confirmation of results shall be as specified by the method (e.g., SW846-8000B requires a relative percent difference [RPD] of less than 40% in order for the data to be considered "confirmed".)

D-14

c) The laboratory shall document acceptance criteria for mass spectral tuning.

DoD Implementation Clarification: These acceptance criteria are specified by the method.

D-15

D.1.8 Constant and Consistent Test Conditions

a) The laboratory shall assure that the test instruments consistently operate within the specifications required of the application for which the equipment is used.

b) Glassware Cleaning - Glassware shall be cleaned to meet the sensitivity of the test method.

Any cleaning and storage procedures that are not specified by the test method shall be documented in laboratory records and SOPs.

D.2 WHOLE EFFLUENT TOXICITY TESTING

D.2.1 Positive and Negative Controls

a) Positive Control - Reference Toxicants - Reference toxicant tests indicate the sensitivity of the test organisms being used and demonstrate a laboratory's ability to obtain consistent results with the test method.

1) The laboratory must demonstrate its ability to obtain consistent results with reference toxicants before it performs toxicity tests with effluents for permit compliance purposes.

   i. An intra-laboratory coefficient of variation (%CV) is not established for each test method. However, a testing laboratory shall maintain control charts for the control performance and reference toxicant statistical endpoint (such as NOEC or ECp) and shall evaluate the intralaboratory variability with a specific reference toxicant for each test method. In addition, a laboratory must produce test results that meet test acceptability criteria (such as greater than 80% survival in the control), as specified in the specific test method.

   ii. Intra-laboratory precision on an ongoing basis must be determined through the use of reference toxicant tests and plotted in quality control charts. As specified in the test methods, the control charts shall be plotted as point estimate values, such as EC25 for chronic tests and LC 50 for acute tests, over time within a laboratory.

2) The frequency of reference toxicant testing shall comply with the EPA or State permitting authority requirements.

3) The EPA test methods for EPA/600/4-91-002, EPA/600/4-91-003, and EPA/600/4-90-027F do not currently specify a particular reference toxicant and dilution series; however, if the State or permitting

authority identifies a reference toxicant or dilution series for a particular test, the laboratory shall follow the specified requirements.

4) Test Acceptability Criteria (TAC) - The test acceptability criteria (e.g., the chronic *Ceriodaphnia* test, requires 80% or greater survival and an average 15 young per female in the controls), as specified in the test method, must be achieved for both the reference toxicant and effluent test. The criteria shall be calculated and shall meet the method specified requirements for performing toxicity:

   i. The control population of *Ceriodaphnia* shall contain no more than 20% males.

   ii. An individual test may be conditionally acceptable if temperature, dissolved oxygen, pH and other specified conditions fall outside specifications, depending on the degree of the departure and the objectives of the tests. (See test conditions and test acceptability criteria specified for each test method.) The acceptability of the test shall depend on the experience and professional judgment of the technical employee and the permitting authority.

b) Negative Control - Control, Brine Control, or Dilution Water - The standards for the use, type, and frequency of testing are specified by the test methods and by permit and shall be followed.

D.2.2 Variability and/or Reproducibility

Intra-laboratory precision shall be determined on an ongoing basis through the use of further reference toxicant tests and related control charts as described in item D.2.1.a) above.

D.2.3 Accuracy

This principle is not applicable to Whole Effluent Toxicity.

D.2.4 Test Sensitivity

a) Test sensitivity (or test power) of the tests will depend in part on the number of replicates per concentration, the significance level selected (0.05), and the type of statistical analysis. If the variability remains constant, the sensitivity of the test will increase as the number of replicates is increased. Test sensitivity is the minimum significant difference (MSD) between the control and test concentration that is statistically significant. If the Dunnett's procedure is used, the MSD shall be calculated according to the formula specified by the EPA test method and reported with the test results.

b) Estimate the MSD for non-normal distribution and or heterogenous variances.

c) Point estimates: (LCp, ICp, or ECp) - Confidence intervals shall be reported as a measure of the precision around the point estimate value.

d) The MSD shall be calculated and reported for only chronic endpoints. In addition, the calculated endpoint is typically a lethal concentration of 50% (LC 50); therefore, confidence intervals shall be reported as a measure of the precision around the point estimate value. In order to have sufficient replicates to perform a reliable MSD, such tests shall have a minimum of four replicates per treatment so that either parametric or non parametric tests can be conducted.

D.2.5 Selection of Appropriate Statistical Analysis Methods

a) The methods of data analysis and endpoints will be specified by language in the permit or, if not present in the permit, by the EPA methods manuals for Whole Effluent Toxicity.

b) Dose Response Curves - When required, the data shall be plotted in the form of a curve relating the dose of the chemical to cumulative percentage of test organisms demonstrating a response such as death.

D.2.6 Selection and Use of Reagents and Standards

a) The grade of all reagents used in Whole Effluent Toxicity tests is specified in the test method except the reference standard. All reference standards shall be prepared from chemicals, which are analytical reagent grade or better. The preparation of all standards and reference toxicants shall be documented.

b) All standards and reagents associated with chemical measurements, such as dissolved oxygen, pH, or specific conductance, shall comply with the standards outlined in Appendix D.1 above.

DoD Clarification: The above reference should read Appendix D.1.6, instead of D.1.

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D.2.7 Selectivity

This principle is not applicable. The selectivity of the test is specified by permit.

D.2.8 Constant and Consistent Test Conditions

a) If closed refrigerator-sized incubators are used, culturing and testing of organisms shall be separated to avoid loss of cultures due to cross-contamination.

b) The laboratory or a contracted outside expert shall positively identify test organisms to species on an annual basis. The taxonomic reference (citation and page(s) and the names(s) of the taxonomic expert(s) must be kept on file at the laboratory.

c) Instruments used for routine measurements of chemical and physical parameters such as pH, dissolved oxygen (DO), conductivity, salinity, alkalinity, hardness, chlorine, and weight shall be calibrated and/or standardized per manufacturer's instructions and Section D.1. Temperature shall be calibrated per Section 5.9.4.2.1. All measurements and calibrations shall be documented.

DoD Implementation Clarification: Instruments used for routine measurements of chemical and physical parameters, such as pH, DO, conductivity, salinity, alkalinity, hardness, chlorine, weight, and temperature shall be calibrated and/or standardized per manufacturer's instructions and Section 5.9.4.2.1 All measurements and calibrations shall be documented.

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d) Test temperature shall be maintained, as specified in the methods manuals. The average daily temperature of the test solutions must be maintained within 1° C of the selected test temperature, for the duration of the test. The minimum frequency of measurement shall be once per 24-hour period. The test temperature for continuous flow toxicity tests shall be recorded and monitored continuously.

e) Water used for culturing and testing shall be analyzed for toxic metals and organics annually or whenever the minimum acceptability criteria for control survival, growth, or reproduction are not met and no other cause, such as contaminated glassware or poor stock, can be identified. The method specified analytes and concentration levels shall be followed.

f) New batches of food used for culturing and testing shall be analyzed for toxic organics and metals. If food combinations or recipes are used, analyses shall be performed on the final product upon the use of new lot of any ingredient. If the concentration of total organic chlorine exceeds 0.15 microgram per gram wet weight, or the total concentration of organochlorine pesticides plus PCBs exceeds 0.30 microgram per gram wet weight, or toxic metals exceeds 20 microgram per gram wet weight, the food must not be used.

g) Test chamber size and test solution volume shall be as specified in the methods manuals.

h) Test organisms shall be fed the quantity and type food specified in the methods manuals. They shall also be fed at the intervals specified in the test methods.

i) Light intensity shall be maintained, as specified in the methods manuals. Measurements shall be made and recorded on a yearly basis. Photoperiod shall be maintained as specified in the test methods and shall be documented at least quarterly. For algal tests, the light intensity shall be measured and recorded at the start of each test.

j) At a minimum, during chronic testing, DO and pH shall be measured daily in at least one replicate of each concentration. DO may be measured in new solutions prior to organism transfer, in old solutions after organisms transfer, or both.

k) All cultures used for testing shall be maintained, as specified in the methods manuals.

l) Age and the age range of the test organisms must be as specified in the manuals.

m) The maximum holding time (lapsed time from sample collection to first use in a test) shall not exceed 36 hours without the permission of the permitting authority.

n) All samples shall be chilled to 4° C during or immediately after collection. They shall be maintained at a temperature range from just above the freezing temperature of water to 6° C and the arrival temperature shall be no greater than 6° C. Samples that are hand delivered to the laboratory immediately after collection (i.e., within 1 hour) may not meet the laboratory temperature acceptance criteria. In these cases, the laboratory may accept the samples if there is evidence (such as arrival on ice) that the chilling process has begun.

o) Organisms obtained from an outside source must be from the same batch.

D.3 MICROBIOLOGY

These standards apply to laboratories undertaking the examination of materials, products, and substances involving microbiological analysis, recovery, or testing. The procedures involve the culture media, the test sample, and the microbial species being isolated, tested, or enumerated.

a) Microbiological testing refers to and includes the detection, isolation, enumeration, and identification of microorganisms and their metabolites, as well as sterility testing. It includes assays using microorganisms, as part of a detection system and their use for ecological testing.

b) These standards are concerned with the quality of test results and not specifically with health and safety measures. In the performance of microbiological testing, laboratories must be aware of and have SOPs that conform with local, State, and national regulatory policies for the safety and health of personnel.

D.3.1 Positive and Negative Controls

a) Negative Controls:

The laboratory shall demonstrate that the cultured samples have not been contaminated through sample handling/preparation or environmental exposure. These controls shall include sterility checks of media, blanks such as filtration blanks, bottle, and buffer blanks.

1) All blanks and uninoculated controls, specified by the test method, shall be prepared and analyzed at the frequency stated in the method.

2) A minimum of one uninoculated control shall be prepared and analyzed, unless the same equipment set is used to prepare multiple samples. In such cases, the laboratory shall prepare a series of blanks using the equipment. At least one beginning and ending control shall be prepared, with additional controls inserted after every 10 samples.

3) Analyze a known negative culture.

b) Positive Controls:

Positive controls demonstrate that the medium can support the growth of the test organism and that the medium produces the specified or expected reaction to the test organism.

1) On a monthly basis, each lot of media shall be tested with at least one pure culture of a known positive reaction and shall be included with the sample test batch.

2) If routine culturing is not part of the laboratory's testing and pre-prepared media are routinely used, strict control of the storage conditions and expiration date of media shall be maintained. A positive growth control from a known positive sample shall be run with each lot to ensure that the media support growth.

3) If the laboratory has at least one known positive result of the appropriate organism during the month, a separate positive control is not required.

D.3.2 Test Variability/Reproducibility

a) Duplicates - At least 5% of the suspected positive samples shall be duplicated. In laboratories with more than one analyst, each shall make parallel analyses on at least one positive sample per month.

DoD Implementation Clarification: If a sample tests positive, repeated sampling may be required to fulfill duplication requirements.

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b) Where possible, participation in, or organization of collaborative trails, proficiency testing, or interlaboratory comparisons, either formal or informal, must be done.

D.3.3 Method Evaluation

a) In order to demonstrate the suitability of a test method for its intended purpose, the laboratory shall demonstrate and document its ability to meet acceptance criteria either specified by the method or by the EPA or State program requirements. Acceptance criteria must meet or exceed these requirements and must demonstrate that the test method provides correct/expected results with respect to specified detection capabilities, selectivity, and reproducibility.

1) Accepted (official) test methods or commercialized test kits for official test methods, or test methods from recognized national or international standard organizations, may not require a specific validation. Laboratories are required, however, to demonstrate proficiency with the test method prior to first use. This can be achieved by simultaneous, side-by-side analysis by several analysts.

2) Qualitative microbiological test methods in which the response is expressed in terms of presence/absence, shall be validated by estimating, if possible, the specificity and reproducibility. The differences due to the matrices must be taken into account when testing different sample types.

3) The validation of microbiological test methods shall be performed under the same conditions as those for routine sample analysis. This can be achieved by using a combination of naturally contaminated products and spiked products with results that can be statistically analyzed to demonstrate that the test meets its intended purpose.

4) All validation data shall be recorded and stored at least as long as the test method is in force, or if withdrawn from active use, for at least 5 years past the date of last use.

b) Laboratories shall participate in the Proficiency Test programs (interlaboratory) identified by NELAP (See Section 5.4.2.j or 5.5.3.4.)

D.3.4 Test Performance

All growth and recovery media must be checked to assure that the target organisms respond in an acceptable and predictable manner. (See Section D.3.1.b.)

D.3.5 Data Reduction

a) The calculations, data reduction, and statistical interpretations specified by each test method shall be followed.

b) If the test method specifies colony counts, such as membrane filter or colony counting, then the ability of individual analysts to count colonies shall be verified at least once per month, by having two or more analysts count colonies from the same plate.

D.3.6 Quality of Standards, Reagents and Media

The laboratory shall ensure that the quality of the reagents and media used is appropriate for the test concerned.

a) Culture media may be prepared in the laboratory from the different chemical ingredients, from commercial dehydrated powders, or may be purchased ready to use.

b) Reagents, commercial dehydrated powders, and media shall be used within the shelf-life of the product and shall be documented according to 5.10.5. The laboratory shall retain all manufacturer supplied “quality specification statements,” which may contain such information as shelf life of the product, storage conditions, sampling regimen/rate, sterility check including acceptability criteria, performance checks including the organism used, their culture collection reference and acceptability criteria, date of issue of specification, or statements assuring that the relevant product batch meets the product specifications.

c) Distilled water, deionized water or reverse osmosis produced water free from bactericidal and inhibitory substances shall be used in the preparation of media solutions and buffers. The quality of the water shall be monitored for attributes such as pH, chlorine residual, specific conductance, or metals at the specified frequency and evaluated according to the stated standards. Records shall be maintained on all activities.

d) Media, solutions, and reagents shall be prepared, used, and stored according to a documented procedure following the manufacturer's instructions or the test method.

e) All laboratory media shall be checked to ensure they support the growth of specific microbial cultures. In addition, selective media shall be checked to ensure they suppress the growth of nontarget organisms. Media purchased pre-prepared from the manufacturer shall be checked monthly except when the use and maintenance of pure cultures is not part of laboratory procedures. In preference to using the commonly used streak method, it is better to use a quantitative procedure, where a known (often low) number of relevant organisms are inoculated into the medium under test and the recovery evaluated.

f) Each lot of laboratory detergent shall be checked to ensure that residues from the detergent do not inhibit or promote growth of microorganisms, for example, with an inhibitory residue test.

D.3.7 Selectivity

a) All confirmation/verification tests specified by the test method shall be performed according to method protocols.

b) In order to demonstrate traceability and selectivity, laboratories shall use reference cultures of microorganisms obtained from a recognized national collection or an organization recognized by the assessor body.

1) Reference cultures may be subcultured once to provide reference stocks. Appropriate purity and biochemical checks shall be made and documented. The reference stocks shall be preserved by a technique that maintains the desired characteristics of the strains. Examples of such methods are freeze-drying, liquid nitrogen storage, and deep-freezing methods. Reference stocks shall be used to prepare working stocks for routine work. If reference stocks have been thawed, they must not be refrozen and reused.

2) Working stocks shall not be sequentially cultured more than five times except when:

i. It is required by standard test methods, or

ii. Laboratories can provide documentary evidence demonstrating that there has been no loss of viability, no changes in biochemical activity, and/or no change in morphology.

3) Working stocks shall not be subcultured to replace reference stocks.

4) A scheme for handling reference cultures is included in Figure D.1.

Figure D-1. USE OF REFERENCE CULTURES (BACTERIA)

Flow Chart

Reference culture from source recognized by NELAC (usually American Type Culture Collection)

Culture once
Appropriate Purity Checks and Biochemical Tests

Reference Stocks
Retained under specific Conditions:
Freeze dried, liquid nitrogen, or deep frozen storage

Thaw/Reconstitute
Purity Checks and Biochemical Tests as Appropriate

Working Stocks
Maintained under specific conditions and storage times

Regular/Daily Quality Controls

D.3.8 Constant and Consistent Test Conditions

a) The laboratory shall devise an appropriate environmental monitoring program to indicate trends in levels of contamination appropriate to the type of testing being carried out. Acceptable background counts shall be determined, and there shall be documented procedures to deal with situations in which these limits are exceeded.

b) Walls, floors, ceilings, and work surfaces shall be nonabsorbent and easy to clean and disinfect. Wooden surfaces of fixtures and fitting shall be adequately sealed. Measures shall be taken to avoid accumulation of dust by the provision of sufficient storage space by having minimal paperwork in the laboratory and by prohibiting plants and personal possessions from the laboratory work area.

c) Temperature measurement devices;

1) Where the accuracy of temperature measurement has a direct effect on the result of the analysis, temperature measuring devices, such as liquid-in-glass thermometers, thermocouple, platinum resistance thermometers used in incubators, autoclaves, and other equipment, shall be the appropriate quality to achieve the specification in the test method. The graduation of the temperature measuring devices must be appropriate for the required accuracy of measurement, and they shall be calibrated to national or international standards for temperature. (See Section 5.9.2.1.) Calibration shall be done at least annually.

DoD Implementation Clarification: The reference at the end of this paragraph should read Section 5.9.2 instead of Section 5.9.2.1.

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2) The stability of temperature, uniformity of temperature distribution, and time required to achieve equilibrium conditions in incubators, waterbaths, ovens, and temperature controlled rooms shall be established (e.g., position, space between and height of stacks of Petri dishes).

d) Autoclaves:

1) The performance of each autoclave shall be initially evaluated by establishing its functional properties (e.g., heat distribution characteristics with respect to typical uses). Autoclaves shall be capable of meeting specified temperature tolerances. Pressure cookers fitted only with a pressure gauge are not recommended for sterilization of media or decontamination of wastes.

2) Records of autoclave operations, including temperature and time, shall be maintained. This shall be done for every cycle. Acceptance/rejection criteria shall be established and used to evaluate the autoclave efficiency and effectiveness.

e) Volumetric equipment such as automatic dispensers, dispenser/diluters, mechanical hand pipettes, and disposal pipettes, may all be used in the microbiology laboratory. Regular checks, as outlined in Section 5.9.4.2.1, shall be performed and documented.

f) UV Sterilizers

1) Are to be tested quarterly for effectiveness with positives (either reference cultures or positive monitoring samples) and this is to include testing of the power output of the UV bulb.

g) Conductivity meters, oxygen meters, pH meters, hygrometers, and other similar measurement instruments shall be calibrated according to the method specified requirements. Mechanical timers shall be checked regularly against electronic timing devices to ensure accuracy.

D.4 RADIOCHEMICAL ANALYSIS

These standards apply to laboratories undertaking the examination of environmental samples by radiochemical analysis. These procedures for radiochemical analysis may involve some form of chemical separation, followed by detection of the radioactive decay of analyte (or indicative daughters) and tracer isotopes where used. For the purpose of these standards procedures for the determination of radioactive isotopes by mass spectrometry (e.g., ICP-MS or TIMS) or optical (e.g., KPA) techniques are not addressed herein.

D.4.1 Negative Controls

a) Method Blank - Shall be performed at a frequency of one per preparation batch. The results of this analysis shall be one of the QC measures used to assess batch acceptance. The method blank result shall be assessed against the specific acceptance criteria [Section 5.10.1.2] specified in the laboratory method manual [Section 5.10.1.2]. When the specified method blank acceptance criteria is not met, the specified corrective action and contingencies [Sections 5.10.1.2] will be followed. The occurrence of a failed method blank acceptance criteria and the actions taken shall be noted in the laboratory report [Section 5.13.a)11].

b) In the case of gamma spectrometry where the sample matrix is simply aliquoted into a calibrated counting geometry, the method blank shall be of similar counting geometry that is empty or filled to similar volume with ASTM Type II water to partially simulate gamma attenuation due to a sample matrix.

c) There shall be no subtraction of the required method blank [Section D.4.1.a)] result from the sample results in the associated preparation or analytical batch. This does not preclude the application of any correction factor (e.g., instrument background, analyte presence in tracer, reagent impurities, peak overlap, calibration blank, etc.) to all analyzed samples, both program/project submitted and internal quality control samples. However, these correction factors shall not depend on the required method blank result in the associated analytical batch.

d) The method blank acceptance criteria [Section 5.10.1.2.b)18] shall address the presumed aliquot size on which the method blank result is calculated and the manner in which the method blank result is compared to sample results of differing aliquot size.

D.4.2 Positive Controls

a) Laboratory Control Samples - Shall be performed at a frequency of one per preparation batch. The results of this analysis shall be one of the QC measures to be used to assess batch acceptance. The laboratory control sample result shall be assessed against the specific acceptance criteria [Section 5.10.1.2.b)18] specified in the laboratory method manual [Section 5.10.1.2]. When the specified laboratory control sample acceptance criteria are not met, the specified corrective action and contingencies [Section 5.10.1.2.a)19 and 20] will be followed. The occurrence of a failed laboratory control sample acceptance criteria and the actions taken shall be noted in the laboratory report [Section 5.13.a)11.]

b) Matrix Spike - Shall be performed at a frequency of one per preparation batch for those methods that do not utilize an internal standard or carrier and for which there is a physical or chemical separation process and where there is sufficient sample to do so. The results of this analysis shall be one of the QC measures to be used to assess batch acceptance. The matrix spike result shall be assessed against the specific acceptance criteria [Section 5.10.1.2.b)18] specified in the laboratory method manual [Section 5.10.1.2]. When the specified matrix spike acceptance criteria are not met, the specified corrective action and contingencies [Section 5.10.1.2.a)19 and 20] will be followed. The occurrence of a failed matrix spike acceptance criteria and the actions taken shall be noted in the laboratory report [Section 5.13.a)11]. The lack of sufficient sample aliquot size to perform a replicate analysis should be noted in the laboratory report.

c) The activity of the laboratory control sample and matrix spike analyte(s) shall be greater than ten times and less than 100 times the a priori detection limit.

d) The laboratory standards used to prepare the laboratory control sample and matrix spike shall be from a source independent of the laboratory standards used for instrument calibration.

e) Where a radiochemical method, other than gamma spectroscopy, has more than one reportable analyte isotope (e.g. isotopic uranium: U-234, -235, and -238) only one of the analyte isotopes need be included in the laboratory control or matrix spike sample at the indicated activity level. However, where more than one analyte isotope is present above the specified activity level, each shall be assessed against the specified acceptance criteria.

f) Where gamma spectrometry is used to identify and quantitate more than one analyte isotope, the laboratory control sample and matrix spike shall contain isotopes that represent the low (e.g., americium-241), medium (e.g., cesium-137) and high (e.g., cobalt-60) energy range of the analyzed gamma spectra. As indicated by these examples, the isotopes need not exactly bracket the calibrated energy range or the range over which isotopes are identified and quantitated.

D.4.3 Test Variability/Reproducibility

a) Replicate - Shall be performed at a frequency of one per preparation batch where there is sufficient sample to do so. The results of this analysis shall be one of the QC measures to be used to assess batch acceptance. The replicate result shall be assessed against the specific acceptance criteria [Section 5.10.1.2.b)18] specified in the laboratory method manual [Section 5.10.1.2]. When the specified replicate acceptance criteria are not met, the specified corrective action and contingencies [Section 5.10.1.2.a)19 and 20] will be followed. The occurrence of a failed replicate acceptance criteria and the actions taken shall be noted in the laboratory report [Section 5.13.a)11].

D.4.4 Other Quality Control Measures

a) Tracer - For those methods that utilize a tracer (i.e. internal standard), each sample result will have an associated tracer recovery calculated and reported. The tracer recovery for each sample results shall be one of the QC measures to be used to assess the associated sample result acceptance. The tracer recovery shall be assessed against the specific acceptance criteria [Section 5.10.1.2.b)18] specified in the laboratory method manual [Section 5.10.1.2]. When the specified tracer recovery acceptance criteria are not met, the specified corrective action and contingencies [Section 5.10.1.2.a)19 and 20] will be followed. The occurrence of a failed tracer recovery acceptance criteria and the actions taken shall be noted in the laboratory report [Section 5.13.a)11].

b) Carrier - For those methods that utilize a carrier (i.e. internal standard) each sample will have an associated carrier recovery calculated and reported. The carrier recovery for each sample shall be one of the QC measures to be used to assess the associated sample result acceptance. The carrier recovery shall be assessed against the specific acceptance criteria [Section 5.10.1.2.b)18] specified in the laboratory method manual [Section 5.10.1.2]. When the specified carrier recovery acceptance criteria is not met the specified corrective action and contingencies [Section 5.10.1.2.a)19 and 20] will be followed. The occurrence of a failed carrier recovery acceptance criteria and the actions taken shall be noted in the laboratory report [Section 5.13.a)11].

D.4.5 Method Evaluation

In order to ensure the accuracy of the reported result, the following procedures shall be in place:

a) Demonstration of Capability - (Section 5.10.2.1) shall be performed initially (prior to the analysis of any samples) and with a significant change in instrument type, personnel, or method.

b) Proficiency Test Samples - The results of such analysis (Section 5.4.2.j or 5.5.3.4) shall be used by the laboratory to evaluate the ability of the laboratory to produce accurate data. The providers of such proficiency test samples should conform to the requirements of ANSI N42.22.

D.4.6 Radiation Measurement System Calibration

Due to the stability and response nature of modern radiation measurement instrumentation, it is not typically necessary to calibrate these systems in the day of use manner done so for some types of chemical measurement instrumentation. As well, due to the nature of some radiation measurement instrumentation calibrations, it may not be practical to calibrate in a day of use manner. In addition, the calibration of modern radiation measurement instrumentation has significant differences from chemical measurement instrumentation. This section will address those practices that are necessary for proper calibration and those requirements of Section 5.9.4.3 (Instrument Calibrations) that are not applicable to some types of radiation measurement instrumentation.

a) Calibration Curves - The requirements of Sections 5.9.4.3.b)1 through 5.9.4.3.b)4 for the determination of the appropriate number of standards for initial calibration are not applicable to the performance of radiochemical methods. For those radiochemical methods that may require multiple standards for initial calibration (e.g., gas-proportional counting and liquid scintillation counting) the required number shall be addressed in the laboratory method manual [Section 5.10.1.2.], if not addressed in the method.

b) Calibration Curve Regression - The requirements of Section 5.9.4.3.c) are not necessarily applicable for all radiochemical methods. Instead, where linear regression is used to fit standard response or calibration standard results to a calibration curve, the correlation coefficient shall be determined. Where nonlinear regression is used to fit standard response or calibration standard results to a calibration curve, the correlation coefficient should be determined.

c) Calibration Range - The requirements of Section 5.9.4.3.d) are not applicable to the performance of radiochemical methods given the noncorrelated event nature of decay counting instrumentation.

d) Calibration Verification - The LCS may fill the requirements for the performance of an initial calibration and continuing calibration verification standard as specified in Sections 5.9.4.4.1 and 5.9.4.4.2. The calibration verification acceptance criteria shall be the same as specified for the LCS.

e) Background Calibration - Background calibration measurements shall be made on a regular basis and monitored using control charts or tolerance charts to ensure that a laboratory maintains its capability to meet required data quality objectives. These values are subtracted from the total measured activity in the determination of the sample activity

1) For gamma spectroscopy systems, background calibration measurements shall be performed on at least a monthly basis.

2) For alpha spectroscopy systems, background calibration measurements shall be performed on at least a monthly basis.

3) For gas-proportional and scintillation counters, background calibration measurements shall be performed on a day of use basis.

f) Calibration - Instrument calibration shall be performed with reference standards as defined in Section D.4.9.a). The standards shall have the same general characteristics (i.e., geometry, homogeneity, density, etc.) as the associated samples.

g) The frequency of calibration shall be addressed in the laboratory method manual [Section 5.10.1.2.13] if not addressed in the method. A specific frequency (e.g., monthly) or observations from the associated control or tolerance chart, as the basis for calibration shall be specified.

D.4.7 Method Detection Limits

Note: To be addressed in the next Chapter 5 revision.

D.4.8 Data Reduction

a) Refer to Section 5.10.6, ”Computers and Electronic Data Related Requirements,” of this document.

b) Method Uncertainties - The laboratory shall have the ability to trace all sources of method uncertainties and their propagation to reported results. The ISO "Guide to the Expression of Uncertainty in Measurement" and/or the NIST Technical Note 1297 on "Guidelines for Evaluating and Expressing the Uncertainty of NIST Measurement Results" should be used in this regard.

D.4.9 Quality of Standards and Reagents

a) The QC program shall establish and maintain provisions for radionuclide standards.

1) Reference standards that are used in a radiochemical laboratory shall be obtained from the NIST, EPA, or suppliers who participate in supplying NIST standards or NIST traceable radionuclides. Any reference standards purchased outside the United States shall be traceable back to each country's national standards laboratory. Commercial suppliers of reference standards should conform to ANSI N42.22 to assure the quality of their products.

2) Reference standards shall be accompanied with a certificate of calibration whose content is as described in ANSI N42.22 - 1995, Section 8, Certificates.

3) Laboratories should consult with the supplier if the lab's verification of the activity of the reference traceable standard indicates a noticeable deviation from the certified value. The laboratory shall not use a value other than the decay corrected certified value.

b) All reagents used shall be analytical reagent grade or better.

D.4.10 Constant and Consistent Test Conditions

a) To prevent incorrect analysis results caused by the spread of contamination among samples, the laboratory shall establish and adhere to written procedures to minimize the possibility of cross-contamination between samples.

b) Instrument performance checks - Instrument performance checks using appropriate check sources shall be performed on a regular basis and monitored with control charts or tolerance charts to ensure that the instrument is operating properly and that the calibration has not changed. The same check source used in the preparation of the tolerance chart or control chart at the time of calibration shall be used in the performance checks of the instrument. The check sources must provide adequate counting statistics for a relatively short count time and the source should be sealed or encapsulated to prevent loss of activity and contamination of the instrument and laboratory personnel. For alpha and gamma spectroscopy systems, the instrument performance checks shall include checks on the counting efficiency and the relationship between channel number and alpha or gamma ray energy.

1) For gamma spectroscopy systems, the performance checks for efficiency and energy calibration shall be performed on a day of use basis along with performance checks on peak resolution.

2) For alpha spectroscopy systems, the performance check for energy calibration shall be performed on a day of use basis and the performance check for counting efficiency shall be performed on at least a monthly basis.

3) For gas-proportional and scintillation counters, the performance checks for counting efficiency shall be performed on a day of use basis.

D.5 AIR TESTING

Analysis for Air Toxics shall follow the essential quality controls for chemistry outlined in Appendix D.1. For air testing, the blank, laboratory control sample, and a desorption efficiency (such as charcoal tubes) shall be used. Matrix spikes and duplicate samples shall be used when feasible.

Appendix D
Proficiency Testing

Appendix D, Proficiency Testing

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Tables

Table 1 Navy IR Standard PT Suite 3

1.0 Objectives

Laboratories participating in the Installation Restoration (IR) Program must successfully analyze proficiency test (PT) samples as part of the laboratory assessment process and on an ongoing basis once the Navy accepts them for use.

Proficiency testing is used to evaluate the performance of a laboratory and the quality of the data produced on a parameter, matrix, and method specific basis. PT sample results are used as a tool to evaluate the entire laboratory analysis process. This includes sample tracking, preparation, analysis, method selection (i.e., selection of particular options within specified standard operating procedures (SOPs)), record keeping, and data reduction and reporting.

2.0 Roles and Responsibilities

2.1 Assessment Organizations

The assessment organization is responsible for administering the PT sample phase of the laboratory assessment. In this capacity they are responsible for:

- PT design.
- Selecting and using a PT provider that meets the requirements described in Section 2.2.
- Assessing the PT information generated by the laboratory, and scored by the PT provider.

2.2 PT Sample Providers

PT sample providers are responsible for generating and scoring PT samples in accordance with the requirements specified in this appendix, and must:

- Use a manufacturing quality system that meets the requirements of both:
    - ISO 9001 for the design, production, testing, and distribution of performance evaluation samples
    - ISO Guide 34 Quality System Guidelines for the Production of Reference Materials
- Meet the requirements of ISO Guide 43, Proficiency Testing by Interlaboratory Comparisons regarding the design and operation of the PT provider's proficiency testing program.
- Limit disclosure of laboratory specific results or evaluations to the Navy, the specific laboratory, and the assessing organization.

2.2.1 Conflict of Interest

PT providers must be free of any organizational conflict of interest. A PT sample provider shall never split a sample lot and offer these samples for sale as known-value check samples before the unknown samples are used in a PT study. In addition, each provider shall demonstrate that its security procedures are adequate to maintain confidentiality and security of all target values through the closing date of each study.

2.3 Laboratories

Laboratories shall analyze PT samples and report the results in accordance with the requirements specified in this appendix, and the directions specified by the PT supplier. Laboratories shall:

- Ensure that management and all analysts handle (i.e., manage, analyze, and report) all PT samples in the same manner as real environmental samples to the extent possible.
- Use the same staff, procedures, equipment, facilities, and frequency of analysis for PT samples as for real environmental samples.

2.3.1 Restrictions

Laboratories must comply with the following restrictions on the transfer of PT samples and communication of PT sample results prior to the time the results of the study are released, regardless of what PT provider instructions imply:

- A laboratory shall not send any PT sample or a portion of a PT sample to another laboratory for any analysis for which it seeks acceptance.
- A laboratory shall not knowingly receive any PT sample or portion of a PT sample from another laboratory for any analysis for which the sending laboratory seeks acceptance.
- A laboratory shall not allow management or staff to communicate with any individual at another laboratory (including intracompany communication) concerning the PT sample.
- Laboratory management and staff shall not attempt to obtain the target value of any PT sample from the provider.

3.0 PT Design

The lead assessor is responsible for coordinating the PT phase of a laboratory assessment at the direction of the Contractor or the Naval Facilities Engineering Service Center (NFESC). The lead assessor shall collaborate with the Contractor or NFESC to determine which types of PT samples should be sent to the laboratory.

The assessing organization must design the PT sample such that the types of PT samples sent to the laboratory are commensurate with the fields of testing to be provided to Navy IR projects (i.e., to the extent possible, resemble the methods and matrices of the analysis to be provided).

PT samples for the laboratory assessment are single blind. The sample is known by the analyst to be a PT sample, but the composition is unknown.

If the scope of services to be provided by the laboratory is unknown, the representative samples listed in Table D-1 shall be sent to the laboratory for analysis:

Table D-1. Navy IR Standard PT Suite

Abbrev	Matrix	Parameter	Method (latest version)	Instrument
VOCs	water	Volatile Organic Compounds	EPA 8260	GC/MS
VOCs	soil	Volatile Organic Compounds	EPA 8260	GC/MS
VOCs	water	Volatile Organic Compounds	EPA 8021	GC
VOCs	soil	Volatile Organic Compounds	EPA 8021	GC
BNAs	water	Semivolatile Organics	EPA 8270	GC/MS
BNAs	soil	Semivolatile Organics	EPA 8270	GC/MS
Pest	water	Pesticides	EPA 8081	GC
PCBs	water	Polychlorinated Biphenyls	EPA 8082	GC
PCBs	soil	Polychlorinated Biphenyls	EPA 8082	GC
Metals	water	TAL Metals (23 Metals)	EPA 6010/7000 series	ICP/AAGF
Metals	soil	TAL Metals (23 Metals)	EPA 6010/7000 series	ICP/AAGF
TPH*	water	Total Petroleum Hydrocarbons	EPA 8015	Documentation/ On-site Review*
TPH*	soil	Total Petroleum Hydrocarbons	EPA 8015	Documentation/ On-site Review*

*There is much variability in state method protocol, therefore the review process shall require state certification and include a review of the method and laboratory SOP during the on-site assessment.

4.0 Analysis of PT Sample

The laboratory shall use contract-required analytical methods for all PT sample analyses. The assessor, in coordination with the EFD/EFA must preapprove any changes in analytical methods from the contract-required analytical methods.

The laboratory shall maintain copies of all written, printed, and electronic records, including but not limited to, bench sheets, instrument strip charts or printouts, data calculations, and data reports resulting from the analysis of any PT sample analyzed in support of the Navy IR Program as specified by the Navy. These laboratory records shall be made available to assessors during on-site assessments of the laboratory.

4.1 Internal Quality Control (QC) Analyses

A laboratory shall conduct and report all method-required internal quality control (QC) analyses. Supplemental to the method required QC, the minimum internal QC analyses required for PT samples include:

- Method blanks for all PT sample analyses
- Surrogate spikes for all organic PT sample analyses
- Laboratory control samples (LCS), second column confirmation, etc., whenever applicable
- Replicates, matrix spikes, and matrix spike duplicates for all soil/sediment PT sample analyses
- Replicates, matrix spikes, and matrix spike duplicates for all water PT samples

5.0 Reporting of PT Sample Results

The laboratory shall submit PT results no later than 30 calendar days from the date of sample receipt, unless the PT provider specifies otherwise.

5.1 Data Reporting Package

A data reporting package shall be generated and forwarded to the assessor for review. A laboratory may use its standard data package to report PT sample results, however, the data package submitted should be reflective of packages that will be submitted for Navy IR projects. In addition, the package shall be sequentially numbered and contain at least the following information:

- Table of contents
- Case narrative including a list of PT samples analyzed/reported and problems encountered with PT sample analysis
- Chain-of-custody (CoC) report
- Sample preparation information including sample preparation date, method citations for sample digestion, extraction, solvent exchange, concentration, clean-up, etc.
- Analytical results for all target analytes plus method citations and laboratory RLs

- Summary of method-specific QC results and assessments of precision and accuracy;
- Raw data including sample preparation and run logs, calibrations, chromatograms, calculations, etc.
- Phone conversation records on major issues related to PT sample analysis

The analysis results shall identify and quantify all target analytes listed in the required analytical method, including estimated values and the quantitation limits for target analytes not detected.

6.0 PT Evaluation

6.1 Data Reporting by PT Providers

The PT provider shall evaluate the results submitted by the laboratory according to the applicable sections of this manual and return the results within 21 calendar days of the close of each study. The PT provider shall report laboratory PT performance results to the assessing organization at the same time that it reports the results to the laboratory.

All data developed by the provider in support of verification testing, homogeneity testing, and stability analysis must be provided to the laboratory upon request, after the close of the study.

6.1.1 Failed Studies

If a laboratory has a "not acceptable" result, it shall determine the cause for the failure and take necessary corrective action. It shall then document in its own records both the investigation and the action taken. Copies of the documentation shall be provided to the PT provider as necessary to reconcile the result, and a copy shall be provided to the assessor for review.

If a laboratory fails two consecutive studies for a given field of testing, its performance is considered unacceptable for that field.

7.0 Application of PT Information to the Assessment

PT results for the laboratory assessment will be considered along with the other elements of the assessment process when determining a laboratory's compliance with the requirements of the Navy IR QA Program.

8.0 Ongoing PT

After a laboratory has been accepted (by Navy) to perform analyses, they must participate in the Navy's ongoing PT program, administered by NFESC. Every six months, participating laboratories are required to submit their results from nationally recognized PT studies (e.g., copy of the letter that presents the results, issued by the study administrator). The results shall be reflective of the tests for which the laboratory has been accepted. If a laboratory does not have results available for Navy review, NFESC reserves the option of sending PT samples to the laboratory as needed. Navy samples for the ongoing PT program are typically generated and

evaluated by the Army Corps of Engineers Hazardous, Toxic & Radioactive Waste, Center of Expertise (ACE HTRW-CX). Specific information pertaining to the analysis, reporting and scoring for these PT samples is found in the Army Corps of Engineers (ACE) document Validation of Analytical Chemistry Laboratories (EM 200-1-1, dated 1 July 1994 or the latest version). Samples may be single or double blind.

8.1 Failed Studies

The following protocol is applicable to failed studies associated with PT samples sent by the ACE HTRW-CX , in support of the Navy's ongoing PT program:

- If a laboratory has a "not acceptable" result, it shall determine the cause for the failure and take necessary corrective action. It shall then document in its own records both the investigation and the action taken.
    - Copies of the documentation shall be provided to ACE HTRW-CX. Upon review, ACE HTRW-CX will consult with the EFD/EFA to determine the next appropriate action which may be to accept corrective action, elect to send a remedial PT, or investigate the nature of the failure in more detail (i.e., review more documentation or on-site review).
- If a laboratory fails two studies for a given field of testing, its performance is considered unacceptable for that field and its acceptance for that field may be revoked.

Appendix E
Field Sampling Requirements

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Enclosure

OPNAVINST 5090.1B, Chapter 25 Enclosure 1

General Information

Enclosure (1) is Chapter 25 of the Navy Environmental And Natural Resources Program Manual (OPNAVINST 5090.1B, change 1, dated 2 Feb 98). This document provides policy and guidance applicable to environmental sampling and laboratory testing for Navy shore facilities. Enclosure (1) is primarily provided to supply basic information regarding sampling. Detailed information regarding laboratory testing requirements is presented in Appendix C.

Enclosure 1

Navy Environmental And Natural Resources Program Manual OPNAVINST 5090.1B, CH-1 dated 2 Feb 98
Chapter 25 – Sampling and Laboratory Testing

CHAPTER 25

SAMPLING AND LABORATORY TESTING

25-1 Scope

25-1.1 This chapter contains policy and guidance applicable to environmental sampling and laboratory testing for Navy shore facilities. It identifies requirements and responsibilities to ensure that measurements and collected data are accurate, that they meet requisite data quality objectives, and are appropriate for use by the Navy in making decisions concerning the environment. The provisions of this chapter apply to all organizations, public and private, that perform environmental sampling and testing for the Navy. Chapter 19 discusses afloat issues.

25-1.2 This chapter sets uniform standards to ensure high quality, timely, and cost effective environmental sampling and testing for Navy.

25-1.3 For the purposes of this chapter, environmental sampling and testing is defined as sampling and testing performed to comply with, or to determine the need to comply with, regulatory requirements. This chapter does not supersede more stringent requirements that may be invoked by other documents issued by the Environmental Protection Agency (EPA), the Navy Occupational Safety and Health Program (NAVOSH), the Navy Installation Restoration (IR) and Base Realignment and Closure (BRAC) Cleanup Program, other Federal, State and local regulations, or the Navy Nuclear Propulsion Program.

25-1.4 References. Although this chapter deals primarily with guidance on environmental sampling and testing, an effective program for the management and control of these activities must also integrate sampling and testing requirements with other policies provided in references (a) through (cc):

a. ISO Guide 25, "General Requirements for the Competence of Calibration and Testing Laboratories" 1990;

b. 29 CFR 1910.1200, Occupational Safety and Health Administration (OSHA) Hazard Communication Standard;

c. 29 CFR 1910.1450, OSHA Occupational Exposure to Hazardous Chemicals in Laboratories;

d. NFESC Interim Guidance Document, Navy Installation Restoration Laboratory Quality Assurance Guide (Feb 1996);

e. OPNAVINST 5100.23D, Navy Occupational Safety and Health Program Manual;

f. 40 CFR 141-143, National Primary Drinking Water Regulations;

g. 40 CFR 150-186, Federal Insecticide, Fungicide, and Rodenticide Act Regulations;

h. 40 CFR 260-270, Resource Conservation and Recovery Act Regulations;

i. 40 CFR 279, Standards for Management of Used Oil;

j. 40 CFR 300, National Oil and Hazardous Substances Pollution Contingency Plan;

k. 40 CFR 350, 355, 370, and 372, Emergency Planning and Community Right-To-Know Act Regulations;

l. 40 CFR 401 - 433, Effluent Guidelines and Pretreatment Guidelines for Wastewater;

m. 40 CFR 700-763 and 790-799, Toxic Substances Control Act Regulations;

n. 40 CFR 792, EPA Good Laboratory Practice Standards;

o. 40 CFR 797, EPA Environmental Effects Testing Guidelines;

p. 49 CFR 100 - 199 Department of Transportation (DOT) Hazardous Materials Regulations; particularly 49 CFR 172-199;

q. EPA SW-846, Test Methods for Evaluating Solid Waste Physical/Chemical Methods;

r. EPA 540/G-93/071 Data Quality Objectives Process For Superfund, Interim Final Guidance;

s. International Standardization Organization (ISO) Guide 2, "General Terms and Their Definitions Concerning Standardization and Certification" 1990;

t. ASTM E 548-91, "Standard Guide for General Criteria Used for Evaluating Laboratory Competence;"

u. ASTM E 1187-90, "Standard Terminology Relating to Laboratory Accreditation;"

v. 40 CFR 50-80 Clean Air Act Regulations;

w. 40 CFR 110-140, Clean Water Act Regulations; particularly 40 CFR 136, Guidelines Establishing Test Procedures For the Analysis of Pollutants;

x. Department of the Navy Report, "Study on Navy Environmental Testing Costs and Environmental Laboratory Improvements," July 1994;

y. EPA, QAMS, Quality Assurance Glossary and Acronyms (11 Feb 1991);

z. EPA PB83-124503, Handbook for Sampling and Sample Preservation of Water and Wastewater, Sept 82;

aa. EPA 833-B-92-001, NPDES Storm Water Sampling Guidance Document, July 92;

bb. EPA/600/4-85/013, Methods for Measuring the Acute Toxicity of Effluents to Freshwater and Marine Organisms, March 85;

cc. Navy Environmental Compliance Sampling and Field Testing Procedures Manual, NAVSEA T0300-AZ-PRO-010.

25-2 Legislation

25-2.1 The Navy requires sampling and testing to determine compliance with environmental regulations. States and local agencies may invoke more stringent laws and regulations including requirements such as certification for sampling and testing. It is imperative that managers consult the applicable regulations and/or regulatory agencies in order to identify specific requirements.

25-3 Terms and Definitions

These terms and definitions come principally from ISO Guide 25, reference (a). Other documents may provide more specific detail than the following general definitions. Where the terms are defined in laws, regulations, and associated test methods, those definitions take precedence.

25-3.1 Accreditation. A formal recognition that an organization (i.e., laboratory) is competent to

carry out specific tasks (i.e., tests) or specific types of tasks.

25-3.2 Calibration. The set of operations, which establishes, under specified conditions, the relationship between values indicated by a measuring instrument, measuring system, or values represented by a material measure, and the corresponding known values of a measurand.

25-3.3 Certification. Procedure by which a regulatory agency or third party gives written assurance that a product, process or service conforms to specified requirements.

25-3.4 Data Quality Objectives. (DQOs). Qualitative and quantitative statements that specify the study objectives, domain, limitations, the most appropriate types of data to collect, and specifies the levels of decision error that will be acceptable for the decision.

25-3.5 Laboratory. A body that calibrates and/or tests. In cases where a laboratory forms part of an organization that carries out other activities besides calibration and testing, the term "laboratory" refers only to those parts of the organization that are involved in the calibration and testing process. As used herein, the term "laboratory" refers to a body that carries out calibration or testing at or from a permanent location, at or from a temporary facility, or in or from a mobile facility. Specifically, the Navy defines an environmental laboratory as any fixed or mobile facility, in whole or in part, that performs testing for the purpose of environmental regulatory reporting and/or to determine compliance with federal, state, regional and/or local environmental laws and regulations. Note: This excludes process environmental control laboratories, provided none of the results are reported to a regulatory agency to determine compliance.

The Navy has both single service and multi-service laboratories. Single service laboratories are defined as those laboratories that exist to perform testing in support of a particular function at an activity, such as wastewater treatment. Multi-service laboratories are defined as those laboratories that exist to perform testing in support of multiple functions at an activity (i.e., hazardous waste disposal, drinking water monitoring, wastewater treatment, etc.).

25-3.6 Method. (reference method) A sampling or measurement procedure that has been officially specified by an organization as meeting its data quality requirements.

25-3.7 Procedure. A set of systematic instructions for performing an operation.

25-3.8 Proficiency testing. Determination of field or laboratory testing performance by means of inter-laboratory comparisons.

25-3.9 Quality Assessment. The evaluation of data to determine if they meet the quality criteria required for a specific application.

25-3.10 Quality Assurance. An integrated system of activities involving planning, quality control, quality assessment, reporting and quality improvement to ensure that sampling and testing meet defined standards of quality with a stated level of confidence.

25-3.11 Quality Control. The aggregate of activities whose purpose is to measure and control the quality of sampling and testing so that it meets the needs of users and provides assurance that the appropriate level of confidence is achieved.

25-3.12 Quality Manual. A document stating the quality policy, quality system, and quality practices of an organization. The quality manual, however named, may call up other documentation relating to the operation's quality arrangements.

25-3.13 Quality System. The organizational structure, responsibilities, procedures, processes,

and resources for implementing quality management.

25-3.14 Raw data. Any worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and/or activities of a study and are necessary for the reconstruction and evaluation of the report of that study. Raw data may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments.

25-3.15 Reference substances. Any chemical substance, mixture, analytical standard, or material other than a test substance administered or used in analysis for the purpose of establishing a basis of comparison with the test substance of a known chemical or biological measurement.

25-3.16 Test. A technical operation that consists of the determination of one or more characteristics or performance of a given product, material, equipment, organism, physical phenomenon, process or service according to a specified procedure. A document sometimes called a test report or a test certificate normally records the test result.

25-3.17 Traceability. The property of a sample or measurement relating it to appropriate international or national standards through an unbroken chain.

25-3.18 Verification. Confirmation by examination and provision of evidence that specified requirements have been met.

25-4 Requirements

25-4.1 General

a. Navy activities shall perform environmental sampling and laboratory testing per Federal, state and local regulatory requirements, and Navy policy and procedures. Individuals and/or laboratories involved in sampling and testing shall have appropriate certifications, accreditations or evaluations as required by the applicable regulation, policy, or procedure.

b. Requirements and interpretations of requirements vary widely, and some regulations provide advisory or recommended guidelines for sampling and testing. To ensure consistent quality in the test data collected for environmental determinations, all commands shall ensure that sampling and testing are performed per regulatory requirements.

25-5 Navy Policy

25-5.1 Conformance with Uniform Standards. Navy activities shall perform sampling and testing per a documented quality system. The quality system shall be appropriate to the type, range, and scope of sampling and testing performed. As a minimum, sampling and testing programs shall meet the following Uniform Standards. A quality system that meets the requirements of ISO Guide 25, reference (a) meets the intent of this chapter.

25-5.2 Uniform Standards for Sampling

a. **Quality System.** Activities shall document, implement, communicate, and make understood to all personnel concerned, the elements of the quality system. Documentation may be in the form of a sampling quality assurance manual or other written instruction.

b. **Organization and Management.** Sampling operations shall have an organizational structure that allows it to maintain satisfactory sampling functions. Activities shall clearly define

and document overall authority and responsibility.

c. **Personnel.** The sampling operation shall have a sufficient number of personnel who have the necessary education, training, technical knowledge and experience relative to their assigned functions. Keep training of personnel up-to-date, and maintain records on their relevant qualifications, training, skills, and experience. See paragraph 25-5.8 for specific requirements.

d. **Quality Assurance/Quality Control (QA/QC) Coordinator.** There shall be a designated QA/QC coordinator, however named, who has responsibility for the quality system. The QA/QC coordinator shall continually monitor operations to ensure conformance with the documented quality system. This function should be separate from, and independent of, personnel engaged in the performance of the work although the assignment may involve collateral duties. When staffing does not allow for an independent function, the activity shall ensure that an individual does not perform QA/QC oversight of his or her own work. Activities must document the separation of QA/QC functions from work performed.

e. **Environment**. The environment in which sampling activities are undertaken shall not invalidate the subsequent results or adversely effect the representativeness of the sample. (Take particular care when undertaking such activities at sites other than permanent facilities). The sampling operation shall provide for the effective monitoring, control and recording of environmental conditions as appropriate. Note: it is the sampling operation's responsibility to comply with the relevant health and safety requirements as defined in references (b), (c), (d) and (e).

f. **Equipment, Instruments, Reference Materials and Supplies.** All equipment, instruments, reference materials, and associated supplies shall be available for the correct performance of work. Label, mark, or otherwise identify each instrument or item of sampling equipment used for measuring to indicate calibration status. Maintain instruments to meet the requirements of the manufacturer's specifications and/or approved maintenance procedures.

g. **Measurement Traceability and Calibration.** Activities shall calibrate, standardize, and verify at appropriate intervals all measuring devices having an effect on the validity of a sampling event before placing them into service. The calibration of instruments and equipment shall meet the requirements of the manufacturer, applicable regulations, or specific methods, whichever is more stringent. As applicable, the calibration of instruments and equipment shall also meet the requirements of the Navy Metrology Calibration Program. Measurements made shall be traceable to national or international standards of measurement or physical constants, where such standards exist. Retain for the same period as the field or laboratory analytical data, all calibration and standardization records for sampling instruments and equipment.

h. **Reagents and Solutions.** Activities shall label all reagents, solutions, preservatives, (including water type) to indicate identity, concentration (where applicable), and the grade or quality of the material. Labeling shall also indicate the preparation or receipt date and the shelf life. Document working reagents and solutions as to their preparation, traceability to lot or batch of stock solution and protected from deterioration and contamination. Do not use outdated reagents and solutions unless their integrity is verified by testing. In certain instances, pre-authorization by appropriate program managers may be required in order to use outdated reagents or standards.

The operation must comply with waste disposal requirements as defined by Resource

Conservation and Recovery Act (RCRA) regulations, and state, local and Navy requirements.

i. **Sampling Procedures and Methods.** Activities shall perform sampling in compliance with written procedures based on approved methods issued by environmental regulations where applicable. They shall document routine sampling operations in step by step procedures to provide for consistent and uniform sampling operations. Activities shall maintain an historical file of SOPs, and all revisions thereto, including the dates of such revisions so that the procedure used is retrievable for correlation with the sampling event. They shall retain this file for the same period of time as the analytical data.

j. **Handling of Samples or Test Items.** A documented system for uniquely identifying samples or test items shall be established. Document sample preparation, storage, and handling including any departures from documented procedures or standard conditions. They shall maintain, monitor, and record storage conditions where necessary.

Activities shall perform sample tracking using chain of custody documentation. Include a chain-of-custody (COC) document with all samples taken for environmental determinations. COC and sample tracking shall be maintained from the time the sample is taken, until the time the analyses are complete.

49 CFR 172 applies when samples are shipped by common (commercial) carrier or sent through the United States mail. The person offering such material for transportation is responsible for ensuring compliance. 49 CFR 172 also provides some exemptions for regulating transportation of preserved samples, (i.e., reference Table II of 40 CFR 136). When shipping samples from overseas locations, ensure applicable host nation regulations are followed.

Samples must be traceable from collection to disposal. Sample disposal shall comply with Federal, State and local requirements relative to environmental compliance and protection of human safety and health.

k. **Records and Documentation.** The sampling operation shall maintain all records as required to comply with any applicable regulations. Sampling records will contain the following information: sampling date, sampling time, location sampled (supported by tables, graphs, sketches and photographs as appropriate), name of individual(s) collecting sample, number/unambiguous identification of sample, type of sample, description of sample, reference to sample collection procedures used, preservation used, COC documentation, measurements, examinations and derived results, and records of calibration relative to equipment used. Record and document data in a system that provides for the ability to retrieve and trace the sample source, associated sample collection, and test data.

l. **Data Verification and Retention.** Activities shall record and report sampling data with sufficient figures to be statistically significant. Review field records for accurate reporting and adherence to documented procedures. Duly note any record modifications or amendments. (At a minimum include date, the person making the change, and the reason.) Retain as required by specific regulations, contract requirements, or for at least 3 years, all field records including raw data. Field records will be retrievable within a reasonable time.

m. **Sampling Reports.** Activities shall report accurately, clearly, and objectively within the guidance of any procedures or instructions for the operation, all sampling data for each sampling event. Reports may be in the form of field log book notes, standardized field form

records or formal consolidated reports describing the sampling operation or event.

(1) Each report will include at least: the identification of the operation; location where the sampling was carried out; unique identification of the report (such as serial number) and of each page, the total number of pages and the date of issue; name and address of customer; description and unambiguous identification of the sample; characterization and condition of the sample; information on the sampling event including environmental conditions; date of sampling event; unambiguous description of any non-standard method used; reference to sampling procedure; reported measurements and units of measure; and a signature and title, or equivalent, of the person(s) accepting responsibility for the content of the report.

(2) Where subcontractors are used they shall be clearly identified.

(3) Formally document in the form of an amended report, all amendments to a sampling report. The project manager will notify customers promptly, in writing, with an explanation of any event (such as the identification of defective measuring equipment) that casts doubt on the validity of results given in a report or amendment to a report.

n. **Contracting and/or Sub-contracting of Sampling.** Place, with a sampling operation complying with the requirements of this chapter, any sampling operation contracts, sub-contracts, or any part of its sampling responsibilities. All contractors and sub-contractors involved with the sampling event must demonstrate proficiency and the ability to perform sampling by prescribed procedures through a documented training program. Maintain records and details of the investigation regarding the proficiency and conformance of the contractor/sub-contractor to the requirements of this chapter.

o. **Complaints.** The sampling operation shall have a documented procedure for the resolution of complaints or circumstances raising doubt concerning the sampling. Make a record of the complaint or circumstance. It shall include the substance of the complaint and its resolution.

p. **Audits.** Organizations responsible for sampling work performed for the Navy shall arrange for and/or submit to audits of its activities at appropriate intervals. Audits shall verify that the operations continue to comply with the requirements of the quality system. Sampling operations shall be subject to evaluation as part of the Navy's Environmental Compliance Evaluation (ECE) program and/or Installation Restoration and BRAC Cleanup Laboratory Evaluation Program, as appropriate. Conduct and document on a continual basis, and at least once per year for repeat sampling events, all internal audits by the QA/QC Coordinator.

25-5.3 Uniform Standards for Laboratory Testing

a. **Quality System.** Laboratories shall document, implement, communicate to, and make understood by all personnel concerned, the elements of the quality system. Documentation may be in the form of a laboratory quality assurance manual or other written instruction.

b. **Organization and Management.** The laboratory shall have an organizational structure that allows it to operate and maintain satisfactory testing functions. Clearly define overall authority and responsibility.

c. **Personnel.** The testing laboratory shall have a sufficient number of personnel having the necessary education, training, technical knowledge and experience relative to their assigned functions. The laboratory shall ensure that the training of its personnel is kept up-to-date. The laboratory shall maintain records on the relevant

qualifications, training, skills and experience of the technical personnel. See paragraph 25-5.8 for specific requirements.

d. **Quality Assurance/Quality Control (QA/QC) Coordinator.** There shall be a designated QA/QC coordinator, however named, who has responsibility for the quality system. The QA/QC coordinator shall continually monitor operations to ensure conformance with the documented quality system. This function shall be separate from, and independent of, personnel engaged in the performance of the work although the assignment may involve collateral duties. When staffing does not allow for an independent function, the activity shall ensure that an individual does not perform QA/QC oversight of his or her own work. Document all separation of QA/QC functions from work performed.

e. **Accommodation and Environment**. Each test facility shall be of suitable size and construction to facilitate the proper conduct of testing. Design testing facilities so that there is a degree of separation that will prevent any adverse effects on testing. The laboratory will provide facilities for the effective monitoring, control and recording of environmental conditions as appropriate. Note that it is the laboratory's responsibility to comply with the relevant health and safety requirements as defined in references (b), (c), (d) and (e).

f. **Equipment, Instruments, Reference Materials and Supplies.** All equipment, instruments, reference materials, and associated supplies shall be available for the correct performance of work. Label, mark, or otherwise identify each item to indicate calibration status of equipment (measuring instruments and reference materials). Maintain equipment to meet the manufacturer’s specifications and the requirements of approved calibration procedures and schedules.

g. **Measurement Traceability and Calibration.** Laboratories shall calibrate, standardize, and verify before being placed into service and at appropriate intervals thereafter, all measuring and testing equipment having an effect on the accuracy or validity of calibrations or tests. The calibration of instruments and equipment shall meet the requirements of the manufacturer, applicable regulations, or specific methods, whichever is more stringent. As applicable, the calibration of instruments and equipment shall also meet the requirements of the Navy Metrology Calibration Program. Measurements made shall be traceable to national or international standards of measurement or physical constants, where such standards exist. Retain calibration and standardization records for the same period as the field or laboratory analytical data.

h. **Reagents and Solutions.** Laboratories shall label all reagents, solutions, preservatives, (including water type) to indicate identity, concentration (where applicable), and the grade or quality of the material. Labeling shall also indicate the preparation or receipt date and the shelf life. Document working reagents and solutions as to preparation, traceability to lot or batch of stock solution and protected from deterioration and contamination. Do not use outdated reagents and solutions unless their integrity is verified by testing. In certain instances pre-authorization, by appropriate program managers, may be required in order to use outdated reagents/standards.

The operation must comply with waste disposal requirements as defined by Resource Conservation and Recovery Act (RCRA) regulations, and state, local and Navy requirements.

i. **Test Methods.** Perform laboratory testing in strict compliance with the test methods approved by environmental regulations. The

laboratory will establish step by step "bench procedures" for the analyst, such as standard operating procedures (SOP). These procedures will establish the exact steps to be taken by the laboratory where one or more options is available in the method. Maintain, a historical file of SOPs, and all revisions thereof, including the dates of such revisions so that the method used is retrievable for correlation with reported data.

j. **Handling of Test Items.** The laboratory shall have a documented system for uniquely identifying the sample to be tested. Upon receipt, record the condition of the sample including any departures from standard conditions. Maintain, monitor, and record appropriate storage conditions where necessary.

The laboratory shall have documented procedures for the receipt and retention of samples. Include a chain-of-custody (COC) document with all samples taken for environmental determinations. COC and sample tracking shall be maintained from the time the sample is taken, until the time the analyses are complete.

49 CFR 172 applies when samples are shipped by common (commercial) carrier or sent through the United States mail. The person offering such material for transportation is responsible for ensuring compliance. 49 CFR 172 also provides some exemptions for regulating transportation of preserved samples, (i.e., reference Table II of 40 CFR 136).

Laboratories shall establish sample disposal procedures and dispose of unused samples as agreed upon with sample originators. Sample disposal shall comply with Federal, State and local requirements relative to environmental compliance and protection of human safety and health.

k. **Records and Documentation.** The laboratory shall maintain all records as required to comply with any applicable regulations, pursuant to the work performed. Record and document data in a system that provides for the ability to retrieve and trace the sample source and associated sample collection and test data. (Sampling and test data may be stored separately; however, all data associated with a sample must be documented and retrievable.)

Testing records will contain the following information: sampling date, sampling time, location sampled (supported by tables, graphs, sketches and photographs as appropriate), name of individual(s) collecting sample, number/unambiguous identification of sample, type of sample, description of sample, reference to sample collection procedures used, preservation used, laboratory verification of preservation, COC documentation, analytical method(s) used, name of person(s) performing each test, date and time of test, measurements, examinations and derived results, and records of calibration relative to equipment used.

l. **Data Verification and Retention.** Laboratories shall record and report test results with sufficient figures to be statistically significant. Review data for accurate reporting and adherence to documented procedures. Duly note all data modifications or amendments. (At a minimum include date, the person making the change, and the reason.) Retain records as required by specific regulations, contract requirements, or for at least 3 years including raw data. Records will be retrievable within a reasonable time.

m. **Reports.** Laboratories shall report accurately, clearly, unambiguously, objectively, and within the guidance of any instructions within the test methods, the results of each test or series of tests.

(1) Each report will include at least: the identification of the laboratory and the location where the test was carried out if different from the address of the laboratory; unique identification of

the test report (such as serial number) and of each page, the total number of pages and the date of issue; name and address of customer; description and unambiguous identification of the item tested, characterization and condition of the item(s) tested; date of receipt and date(s) of performance of test; identification of the test method used, unambiguous description of any non-standard method used; reference to sampling procedure, where relevant, reported measurements and units of measure; and a signature and title, or equivalent, of the person(s) accepting responsibility for the content of the report.

(2) Where the report contains results of tests performed by sub-contractors the results shall be clearly identified.

(3) Formally document amendments to a test report in the form of an amended report. The laboratory will notify customers promptly, in writing, with an explanation, of any event (such as the identification of defective measuring or test equipment) that casts doubt on the validity of results given in a test report or amendment to a report.

n. **Sub-contracting of Testing.** When any laboratory sub-contracts any part of the testing, place this work with a laboratory complying with the requirements of this chapter. The laboratory shall ensure and be able to demonstrate that its sub-contractor(s) is able to perform the activities in question, and able to comply with the same criteria of competence as the laboratory sub-contracting the work. The Navy shall approve, in advance, any sub-contracting by private laboratories.

o. **Complaints.** The laboratory shall have a documented procedure for the resolution of complaints or circumstances raising doubt concerning the data. Make a record of the complaint or circumstance and include in the file the substance of the complaint and its resolution.

p. **Audits.** All laboratories performing work for the Navy shall arrange for and/or submit to audits of its activities at appropriate intervals to verify that its operations continue to comply with the requirements of the quality system. Laboratories (in-house and private) shall be subject to evaluations as part of the Navy's Environmental Compliance Evaluation (ECE) program and/or Installation Restoration Laboratory and BRAC Cleanup Evaluation Program, as appropriate. Conduct and document on a continual basis (at least once per year) internal audits by the QA/QC Coordinator.

q. **Field and Mobile Facility Testing Requirements.** Testing performed in the field or in a mobile facility is subject to the same requirements as testing performed in a permanent laboratory facility.

25-5.4 Environmental Laboratory Advisory Council. The Navy has established an Environmental Laboratory Advisory Council, (ELAC) under the auspices of the CNO (N45), to provide overall guidance and direction for environmental sampling operations and laboratory testing improvement initiatives. The Council shall coordinate efforts across commands. The Council shall provide a forum for continuous process improvement and cost efficiencies for Navy sampling and laboratory support services. The Council helps ensure compliance with the Navy's Uniform Standards as outlined in this document.

25-5.5 Laboratory Certification. Testing shall be performed by certified laboratories having appropriate credentials to perform testing, as required by the applicable regulatory agency. Require credentials for the specific type of regulatory testing (i.e., Safe Drinking Water Act (SDWA)), and for a specific test and/or parameter. Typically, credentials are obtained as certifications or accreditations from Federal, State or sometimes local regulatory agencies.

Certification in one program or State cannot be used as justification to perform testing in another program or State (unless reciprocity or equivalency of certification is recognized by the appropriate regulatory agency).

25-5.6 Laboratory Accreditation. In the absence of certification requirements, laboratories shall demonstrate competency to perform environmental testing, required by their customers, through accreditation. All laboratories shall acquire the required accreditation from a Federal (including Navy), State, or third party, nationally recognized accreditation system, for all environmental testing performed by the laboratory. Accrediting agencies shall evaluate laboratories performing IR and BRAC Cleanup testing by means of the IR and BRAC Cleanup Laboratory Quality Assurance Program before beginning work.

Accreditation requirements shall include laboratory site assessments, requirements for QC data, and participation in on-going proficiency testing. Process exemptions to this accreditation requirement as waivers from CNO (N45). All laboratories must either be accredited or have sought and obtained waivers within 2 years from the issuance of this chapter.

25-5.7 Contract Improvement. The Navy shall amend the technical requirements of contracts by incorporating the Uniform Standards and require Contracting Officers Representatives to be or to consult technically qualified personnel when providing contract support services. Use the source selection mechanism whenever practicable as a means of ensuring the quality and cost effectiveness of sampling and testing services provided by contract. The Navy shall document quality problems, identify poor performance, and execute default clauses, where appropriate.

25-5.8 Specific Training Requirements. Personnel involved in sampling and testing shall have the appropriate education, experience, and training to perform their assigned tasks. Laboratories shall document training and keep records up to date.

a. **Training Requirements for Navy Environmental Professionals, Specialists and Technicians**. Personnel acting as environmental program managers, who routinely request sampling and testing and/or develop sampling and testing plans as part of their management of a program(s) shall have the following minimum training, provided via a documented training plan:

(1) Environmental laws and regulations, relative to proper sampling (i.e., 40 CFR 136, 40 CFR 141, etc.);

(2) Basic determinations of Data Quality Objectives (DQOs);

(3) Training, applicable to the specific area(s) of program management relative to sampling plan development (i.e., sampling and testing for National Pollutant Discharge Elimination System (NPDES) compliance, hazardous waste management plan development, etc.).

b. **Training Requirements for Sampling Personnel.** A documented plan shall exist which, minimally, must include the following training:

(1) Basic sampling techniques (grab sampling, composite sampling, how to avoid contamination, use of preservatives, etc.);

(2) Specific sampling techniques as required (i.e., NPDES sampling, potable water bacteriological sampling, etc.);

(3) Completion of environmental

sampling paperwork including sample container labeling, sample field logs and sample notebooks, COC documentation;

(4) Field testing techniques. Certain tests (i.e., pH, chlorine residual, dissolved oxygen, turbidity, temperature, etc.) due to method requirements must be performed in the field. Sampling personnel performing field analyses are subject to the same requirements as laboratory analysts, and therefore, shall be properly trained. See the training requirements for laboratory technicians;

(5) Health and safety training.

c. **Training Requirements for Laboratory Personnel.** The laboratory shall have a policy and procedures for identifying training needs and providing training of personnel. Appropriately supervise personnel undergoing training.

Laboratory scientists and technicians shall have education or training appropriate to the tasks assigned. As a minimum, this shall include:

(1) Training in the laboratory quality system;

(2) Training in general laboratory operations;

(3) Specific training applicable to the tests to be performed;

(4) Health and safety training.

The laboratory shall have a written training plan and maintain documentation of all training including demonstrations of proficiency. Demonstration of proficiency must take place within established guidelines that are documented in the laboratory's quality manual or other referenced instruction.

The laboratory shall maintain records of the relevant competence, education and professional qualifications, training and experience of all personnel concerned with testing. These records shall include the date of authorization to perform particular types of tests, to authorize test reports and to operate particular types of equipment or to make professional judgment.

25-6 Responsibilities

25-6.1 CNO (N45) shall:

a. Chair the Navy's Environmental Laboratory Advisory Council (ELAC).

b. Issue policy/guidance, as appropriate, based on recommendations made by the ELAC.

c. Issue policy/guidance and approve, as appropriate, requests for waivers as outlined in this chapter.

25-6.2 Environmental Laboratory Advisory Council (ELAC) shall:

a. Coordinate claimant approval and implementation of ELAC recommendations.

b. Develop an integrated approach to environmental sampling and testing.

c. Recommend improvements in the Navy's sampling and testing program.

25-6.3 Major claimants shall:

a. Provide technical assistance and prepare appropriate manuals or other forms of guidance for implementing proper sampling and testing techniques at Navy activities.

b. Plan, program and budget for current and future environmental sampling and testing.

c. Provide a member to the Environmental Laboratory Advisory Council (only applies to major claimants that perform environmental sampling in-house, have environmental testing laboratories, or contract for at least $25,000 in laboratory services annually).

d. Ensure shore activities comply with the requirements of this chapter.

25-6.4 Commanding Officers of Shore Activities shall:

a. Ensure that in-house environmental sampling operations and laboratories, under their command, comply with the requirements of this chapter.

b. Ensure that mechanisms are in place so that environmental sampling and testing, contracted out by the shore activity, as a minimum, meet all baseline Uniform Standards set forth in this chapter, as well as Federal, State, local and other Navy sampling and laboratory testing requirements.

c. Ensure that Contracting Officers Representatives (CORs), under their command, involved in oversight of sampling and testing contracts, consult with or be technically qualified scientists or technicians.

d. Ensure that training programs are established and maintained for sampling and testing personnel under their command, and that training is performed and properly documented.

Appendix F
Project Document Assessment

Appendix F, Project Document Assessment

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1.0 General Information

1.1 Introduction

Independent project document assessments should be performed on every project, where environmental data is collected or evaluated in the decision making process. Assessments of project planning documents should be performed when the documents are in draft form. This is necessary to ensure that there is sufficient time to revise the document(s) and to resolve any problems identified during the assessment process.

In addition to addressing problems that would impact the planned project, the results of project document assessments should be used to identify and address Installation Restoration (IR) Program activities, systems, and practices that need process improvement. The organizations that prepare project planning documents should use the results of project document assessments as the basis for corrective actions to their internal quality systems. It is considered a serious and avoidable deficiency if an organization's project plans contain recurring deficiencies identified in previous project document assessments.

The Engineering Field Division/Engineering Field Activity (EFD/EFA) as the project manager decides who will conduct project document assessments. In this regard, the EFD/EFA may elect to perform project document assessments in-house or arrange for the Naval Facilities Engineering Service Center (NFESC) or a contractor to perform the assessment. It should be noted that the direction given in this section is typically presented using the term "should." The EFD/EFA shall determine if the information and guidance presented in this section shall be applied more stringently (i.e., "should" implemented as "shall").

1.2 Objectives

This document provides guidance for conducting technical assessments of project documents pertaining to the collection and handling of samples, evaluation of environmental data, and for proposed environmental field operations in support of the Navy Installation Restoration (IR) Program.

1.3 Scope

This document describes the scope, content, and approach for technical assessments of project planning documents (i.e., analytical plans and field operation plans) in support of IR and BRAC environmental programs (excluding compliance). This document is not intended to serve as a standard operating procedure (SOP) for project document assessments. It is applicable to assessments of all IR Program projects that include the collection or evaluation of environmental data.

Although the technical assessment process is generally applicable to environmental programs, the user is cautioned that the technical details in this document are not universally applicable. It is necessary to select and consider only those assessment elements that are relevant to the planned project.

1.4 Qualifications of Project Document Assessors

Assessors must possess technically appropriate educational credentials and environmental project experience that are commensurate with their responsibilities for assessing project documents. The EFD/EFA will determine the appropriate assessor qualifications. Qualifications must be forwarded to the EFD/EFA prior to beginning the project document review.

Personnel who perform project document assessments must be independent of the organizations that prepared or will implement the subject project plans.

1.4.1 Standards of Ethical Conduct

As detailed in Appendix A, Standards of Ethical Conduct, each assessor must be familiar with standards of ethical conduct and submit a signed statement declaring freedom from conflict of interest prior to conducting any project document assessments.

2.0 Conducting Project Document Assessments

The scope of the assessment should be commensurate with the scope of the planned field project. A single assessor with appropriate disciplinary expertise may complete project assessments of relatively small-scale projects (e.g., those with routine, limited, or infrequent sampling activities). Project document assessments of relatively large scale or long term projects will typically require comprehensive assessment by an interdisciplinary team of personnel.

Environmental data collection projects are subject to routine assessments to assess the effectiveness of the planning process (quality system). The planning process should include:

- Identification of technical and quality objectives for the project
- Development of a sampling and analysis strategy to meet project objectives
- Establishment of performance specifications or acceptance criteria for the data resulting from project implementation

Project documents are assessed to determine if they are:

- Effective at generating data which will satisfy project objectives
- Technically defensible
- Compliant with applicable quality standards and regulations[1]

2.1 Assessment Elements

Project document assessments include an assessment of four major elements:

- Project plans
- Proposed field operations
- Analytical plans
- Laboratory capability for the proposed work

Details regarding the assessment of each element are provided in the following sections.

2.1.1 Project Plans

The assessor must ascertain if each of these review elements is addressed in the planning documents (e.g., work plan, field sampling plan, sampling and analysis plan, or quality assurance (QA) project plan) in a manner that ensures that quality data is produced and is appropriate to the objectives of the project. Table F-1 presents the elements that are subject to review (for completeness, clarity, and technical merit) during the assessment process. Project planning documents describing field sampling (i.e., field sampling plan, sampling and analysis plan) should meet OPNAVINST 5090.1B, CH-1, Chapter 25 field sampling requirements as presented in Appendix E.

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[1] The Navy has specified minimum field sampling requirements in the latest version of OPNAVINST 5090.1B, CH-1, Chapter 25. These requirements must be considered when assessing project planning documents and proposed field operations. Appendix E details field sampling requirements presented in Chapter 25.

Table F-1: Review Elements for Project Planning Documents

Instructions to the field personnel responsible for sample collection
Description of project and sampling objectives
Technical basis for the proposed sampling approach and analysis activities
The intended data uses
Strategy for proposed sampling and analysis activities
Proposed controls to limit cross contamination
Chain of custody procedures
Proposed field quality control (QC) practices and samples to be collected
Data Quality Objectives
Background data and supporting information
Historical information and interpretation including validation, QC results, and support laboratory names/locations
Applicable regulatory thresholds, negotiated action limits, or project decision thresholds
Qualifications, roles, and responsibilities of all project personnel, including subcontractors and analytical laboratories participating in the project
Site maps, including sample collection locations
Number and type of samples from proposed sampling locations and depths
Technical basis for all planned sampling and analysis activities
Sample description by matrix, required analyses, quantity, preservative, storage conditions, and holding time
Sample collection techniques (sampling mechanisms, materials of construction, ability to collect desired sample)
In-situ or field measurements
Sampling and monitoring equipment, including calibration requirements
Number, criteria, and use of field QC samples
Laboratory QC sample requirements
Analytical quality criteria
Analytical methods and targeted analytes
Reporting limits, and method detection limits or quantitation limits
Accuracy and precision at specified concentration(s)

Content and format of data deliverables (hard copy and electronic)
Laboratory turnaround times for specified deliverables
Field contact for resolution of analytical problems
Scope, frequency, and conduct of data validation
Data analysis and interpretation
Conditions and procedures for suspension of or change in planned work
Procedures for handling investigation derived wastes

2.1.2 Proposed Field Operations

An assessment of planned field operations is accomplished by assessing the technical content of document(s) including:

- Work plans
- Field sampling and analysis plans
- SOPs
- Contract instructions

Field documents must include complete citations to laboratory and corporate quality manuals and plans, SOPs for field activities, and any other documents containing pertinent information. The citations must include revision or version number and promulgation or publication dates for each document or SOP.

Assessment of planned field operations documents includes review of:

- The proposed use of equipment
- The procedures for establishing sampling locations in the field
- Documentation of sample locations
- Decontamination processes
- Custody control
- Sample preservation
- The appropriateness of other sampling procedures which may include, but are not limited to, drying, sieving, mixing, compositing, splitting, labeling, storing, packaging, and shipping.

Proposed field operations documents should meet OPNAVINST 5090.1B, CH-1, Chapter 25, field sampling requirements as presented in Appendix E.

Table F-2 describes the scope of technical issues that are subject to review. Criteria and specifications to be assessed during the review are provided, but are not limited to those listed.

Table 2: Scope of Technical Issues Subject to Review

Element	**Criteria and specifications to be assessed during review.**

Water Sampling	– calibration, operation, and maintenance of water monitoring equipment
	– representativeness of each sampled media
	– appropriateness of sample collection operations to the intended analyses
	– unique sampling challenges posed by
	  – dense non-aqueous phase liquid (DNAPL)
	  – trace levels of volatile organics
	  – suspended particulates

Groundwater	– monitoring well installation – well development and purging – screen intervals – materials of construction – low-flow sampling techniques – use of bailers – use of peristaltic pumps – collection of samples for dissolved metals
Surface Water	– measurement of flow rates – collection from discrete depths – collection of surface films or discrete layers – collection from weirs – collection from static or turbulent sources

Element	**Criteria and specifications to be assessed during review.**

Soil and Sediment Sampling	– appropriate sampling techniques and equipment
	  – auger
	  – core sampler
	  – scoop
	  – lightweight, small volume grab samplers
	  – heavy, large volume grab samplers
	  – single gravity corers
	  – box corers
	  – multiple corers
	  – piston corers

Sediment	– nonpoint source – intermittent sources – bioassay – discrete depths
Surface and Subsurface Soil	– auger – split spoon – discrete depths – responses to refusal

Air and Subsurface Vapor	– procedures and practices for use of air sampling and monitoring equipment including
	  – combustible gas detectors
	  – hydrocarbon analyzers
	  – detector tubes
	  – solid sorbent cartridges
	  – reduced pressure canisters
	– calibration procedures
	– sample train construction
	– ambient air

Element	**Criteria and specifications to be assessed during review.**
	– screening soil vapor streams – soil vapor – selection, use, handling, and storage of canisters, Tedlar® bags, and syringes
Other Matrices	– containerized wastes drums – tanks – waste piles – liquids from surface impoundments – sludges – landfills – biota – radioactive materials – in-situ measurement techniques

Field Practices	– training and qualification of field operations personnel
	– record keeping and documentation
	  – field logbooks
	  – well development records
	  – equipment calibration checks
	  – sample management records
	– contamination control
	– decontamination procedures
	– change control
	– sample compositing
	– sample preparation, preservation, storage, and management
	– field organizations' QA program
	– housekeeping
	  – safety
	  – accident documentation

Element	Criteria and specifications to be assessed during review.
	– security – cleaning and storage of sampling equipment

2.1.3 Analytical Plans

Assessment of analytical plans includes assessing the appropriateness of planned analyses and methods to achieve the objectives presented in project documents. The assessor must determine:

- If the proposed analytical methods (preparation, clean-up, and determinative) are appropriate for determination of target analytes in the anticipated project matrices.
- If the laboratory appears capable of performing the methods as stated[1].
- If the proposed reference methods are theoretically capable of generating data of acceptable qualitative and quantitative confidence for the project.
- As appropriate to the project, whether the proposed analytical plans have effectively addressed matrix-specific analytical problems that may impact the ability of conventional off-the-shelf methods to meet project requirements. Examples include the known or suspected presence of ash, high salinity, elevated levels of non-target analytes, tars, or other analytical interferents.

2.1.4 Laboratory Capability

The laboratory should be assessed to determine their ability to comply with project requirements as well as Navy quality requirements. It should be noted that this element of the project review can not be performed in instances where the laboratory that will be supporting the project has not been selected. The laboratory capability assessment reports to the Navy whether the procedures performed by the laboratory are:

- Acceptably performed as specified in project data quality objectives
- Compliant with laboratory SOPs and reference method requirements
- Technically valid
- Completely and appropriately documented

A laboratory capability assessment is based on the analytical requirements specified in the project documents or supplied by the requesting EFD/EFA personnel. Information is requested of and supplied by the laboratory, is used to assess the laboratory's adequacy in relation to the project objectives. Information requested for review may include, but is not limited to:

- Previous audit reports
- A current list of instrumentation and method capabilities
- SOPs for specified methods

- Method performance data (e.g., MDL studies, proficiency test results, etc.).

2.1.4.1 SW-846 Methods

Two primary issues are reviewed when determining a laboratory's capability to acceptably perform SW-846 reference methods:

- Whether the laboratory has policies and procedures that comply with the requirements of the reference method.
- Whether the laboratory's performance, as evidenced by laboratory records, complies with written policies and procedures. Staff interviews (typically conducted via telephone) may be required in some cases to ascertain if the laboratory adequately addresses these issues.

The scope of an assessment is defined on a project basis to address the overall project objectives. In general, the assessment may include a review of the following as applicable to the method:

- SOPs
- Performance data (MDLs, accuracy, precision)
- Proficiency testing results (if available)
- A fully-validatable data deliverable (if available)
- Interviews with responsible analysts

2.1.4.2 Specialty Methods

An assessment of a laboratory's capability to perform specialty methods is analogous to the guidance provided in Section 2.1.4.1. Examples of these types of specialty methods include:

- Radiochemistry
- NOAA Status & Trends
- Determination of alkyltins
- Determination of dioxins/furans
- Analysis of biota
- Determination of contaminants at ultra-low trace levels
- Determination of high explosives

2.1.4.3 CLP SOW Methods

The primary objective of an assessment of CLP methods is to determine whether a laboratory has systems and practices in place to perform the project specified version(s) of the SOW without deviation. The assessor must ascertain the adequacy of the laboratory's systems for specification and communication of the particular SOW version(s) required for the project, and must determine whether the laboratory has written SOPs that are prescriptively compliant with the

applicable SOW. Inconsistencies between the SOW and the laboratory's procedures or practices must be identified.

2.2 Assessment Report

The results of project document assessments are summarized in a written report prepared by the assessor, and will identify and report issues of concern.

The assessment report must clearly indicate the title, version, date, and sections of documents assessed. As appropriate to the assessment comments, the origin of the comment should be clearly referenced (e.g., by page or section number). An example table of technical findings and a blank table are provided in Attachment 1, Table of Technical Findings. This table provides space for citation of each finding and discussion of the issues of concern.

2.3 Corrective Action

Each assessment finding should be resolved, with revision of the documents as appropriate, prior to issuing final approved versions of the project planning documents. The EFD/EFA shall designate the agency which will be tasked to work with the laboratory to resolve deficiencies. The resolution should address measures taken to prevent recurrences of deficiencies.

Appendix F
Project Document Assessment
Attachment 1
Table of Technical Findings

This is an example table of technical findings. There is a blank table provided on the next page.

TABLE OF TECHNICAL FINDINGS		
Section / Page	**Statement or Issue identified in the document**	**Comment**
General comment	Table of Contents.	The table of contents does not correspond to the document pages provided for review. It appears that not all pages of the document were submitted for review, but this cannot be categorically determined from the information provided.
S. 1.2, p. 1-5	Title "Data Quality Objectives (DQO) "	DQOs are not provided in this document.
Table 1-5	Control limits for Method 8260A.	The laboratory control limits for Method 8260A do not appear to be statistically derived as required by Navy QA
Table 2-1	Sample Container "Stainless steel Teflon® paper under plastic caps".	The design and function of this unusual type of container is not known.
Table 2-1 and 2-2	Storage of samples in the dark.	This is not a CLP requirement for metals.
Table 2-2	Preservation for Total Organic Carbon.	Method 9060 requires the pH of the sample to be adjusted to <2 with hydrochloric or sulfuric acid. Although there is a footnote regarding the addition of acid, the table should clearly state the method requirement for pH rather than addition of predetermined volumes of acid.
S. 4, p. 4-1	Field monitoring equipment which <u>may</u> be used.	The section must specify equipment which <u>will</u> be used.
S. 6, p. 6-1	QC for field analysis.	This section does not address QC for field analysis.

TABLE OF TECHNICAL FINDINGS		
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Appendix G
Field Assessment

Appendix G, Field Assessment

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1.0 General Information

1.1 Purpose

The purpose of this appendix is to provide information and guidance on conducting field assessments in support of the Navy's Installation Restoration (IR) Program. In this regard, it should be noted that the direction given in this section is typically presented using the term "should."

Field assessments are conducted to promote data quality and foster continuous improvement in the systems that support data collection. Contractors should perform routine field assessment as part of their internal quality assurance (QA) system. EFDs/EFAs may need to perform assessments beyond those performed by the Contractor. Such assessments shall be performed at the discretion of the EFD/EFA. The EFD/EFA shall determine if the information and guidance presented in this section shall be applied more stringently (i.e., "should" implemented as "shall").

1.2 Scope

All field assessments should include an assessment of general issues, including:

- Training and qualifications of personnel
- Quality control (QC)
- Record keeping and documentation
- Contamination control
- Change control
- Sample compositing
- Sample preparation
- Preservation, storage
- Management and related issues

Checklists for various field sampling activities are provided as attachments to this appendix.

It is not within the scope of a field assessment to address the scientific validity of sampling techniques, sampling and analytical design considerations, or health and safety issues. However, assessors may identify and report issues of concern in these areas that merit the attention of project or Navy management.

1.3 Objectives

Field assessments use on-site observations, interviews, and reviews of documentation and records to:

- Determine if sampling procedures, QC practices, and use of field equipment are being performed in an acceptable manner and in accordance with project and Navy requirements[1]
- Determine if project documentation is accurate, complete, and in compliance with project and Navy requirements
- Determine if quality systems are effectively implemented to identify, resolve, and prevent field problems
- Verify the identity and qualifications of field operations personnel
- Provide objective evidence on the effectiveness of field operations and the representativeness of samples

1.4 Frequency

The frequency and duration of field assessments should be determined by the project technical team to ensure quality work and attainment of DQOs. The number of site assessments and level of scrutiny will depend on the nature, length and complexity of the project, as well as past performance of the sampling team and the intended use of the data. Assessments of field sampling activities should be carried out on both an announced and unannounced basis. Assessments should be a priority during the first stages of a field sampling event and during sampling of critical locations or sample media.

An independent assessment of each contractor's media-specific sampling operations should be conducted each year. Each contractor's internal QA program should require internal assessments of all major types of sampling operations on a frequency not less than annually.

1.5 Assessor Qualifications

Assessors should possess technically appropriate educational credentials and environmental field experience that are commensurate with their responsibilities for conducting field assessments. The EFD/EFA will determine the appropriate field assessor qualifications. Qualifications should be forwarded to the EFD/EFA prior to beginning the field assessment.

1.5.1 Standards of Ethical Conduct

Each assessor should be familiar with standards of ethical conduct and submit a signed statement declaring freedom from conflict of interest as detailed in Appendix A, Standards of Ethical Conduct.

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[1] The Navy has specified minimum field sampling requirements in the latest version of OPNAVINST 5090.1B, CH-1, Chapter 25. These requirements shall be considered when assessing project planning documents and proposed field operations. Appendix E details field sampling requirements presented in Chapter 25.

2.0 Conducting Field Assessments

2.1 Preparation

As appropriate to the scope of the field assessment, the lead assessor should request advance copies of selected materials for review to familiarize the assessors with the relevant procedures and to prepare the assessors for interviews of project personnel. Documents reviewed should include, but are not limited to:

- Project planning documents (i.e., the approved sampling and analysis plan (SAP))
- Selected implementing procedures (at a minimum, one each of the following types of implementing procedures should be reviewed; sampling technique (one for each media sampled); data assessment (one for each major class of analysis subject to assessment); data management; field QC; custody control))
- Supporting information (e.g., a map to the field sampling locations, access instructions for assessment personnel, a current project organization chart, and a site-specific health and safety plan)

In addition to reviewing documents, the assessors should select and familiarize themselves with the checklists they will be using.

The assessment team will review these materials prior to the on-site assessment as a means of familiarizing themselves with the project, preparing for the assessment, and ensuring that the scope of the assessment is appropriately established to maximize the use of on-site time.

2.1.3 Safety Considerations

On-site assessments may require that assessors enter areas with known or potential hazards. Assessors are encouraged and expected to decline participation in activities which, based on their professional judgment and experience, present an unreasonable risk to their health or safety.

Assessors are required to comply with all applicable site-specific safety requirements, as defined by site management.

As experienced environmental professionals, assessors are expected to behave in a safe and responsible manner. At a minimum, assessors should wear whatever level of personal protective equipment appropriate for the site (including, but not limited to, wearing gloves when touching samples and using safety glasses and boots).

2.3 Team Assignments

The lead assessor should assign individual assessors areas of the review. All field assessors should assess procedures and practices for:

- Selection and documentation of sampling locations

- Execution and documentation of sampling activities (including compositing, preparation, preservation, storage, and handling)
- Custody control
- Collection of representative samples
- Use of equipment and containers (including cleaning and storage)
- Contamination prevention and control
- Adherence to the QA program and QC (including; collection and use of field QC samples)
- Training and qualification of field operations personnel
- Accuracy, completeness, and procedural compliance of documentation and records (including, field logbooks, well development records, equipment calibration checks, and sample management records).

2.4 On-Site Protocol

2.4.1 Orientation Tour

Upon arrival at the site, the assessment team should meet with the site supervisor to review the intended work schedule, and identify which personnel and operations should be involved in the assessment. In most cases, the on-site assessment should begin with a brief tour of the field area to provide the assessment team with a general orientation to the area subject to review and to introduce the assessors to the field operations staff.

2.4.2 Assessment

Assessors interview field personnel and observe field operations first hand to assess whether project documentation meets evidentiary requirements and provides a complete and accurate record that allows for after the fact reconstruction of field activities. The approved SAP, along with the appropriate field assessment checklists, should be used as the basis for conducting the field assessment.

The on-site assessment should assess and procedures and practices for the areas identified in Section 2.3.

2.4.3 Feedback

Feedback and corrective action, if appropriate, are the desired outcomes of the field assessment. For immediate correction of a problem, verbal feedback is acceptable followed by documentation in the field assessment report. Feedback should be provided in written form to the agency responsible for conducting the sampling effort.

2.5 Documentation

The documents and records which are generated, compiled, or reviewed during the assessment process (e.g., checklists, corrective action) should be managed and maintained in the QA program files. These files are Navy property, and should be provided to the cognizant

organization on request.

2.5.1 Files

For each assessment, the lead assessor should establish and maintain files for the correspondence, records, documents, copies, and supporting information that is generated, obtained, or reviewed during the course of the assessment. The assessment files are maintained by the assessing organization during the course of the assessment. The assessment files should allow after-the-fact reconstruction of the overall assessment process, from planning the assessment scope through final resolution of deficiencies based on corrective action documentation.

2.5.2 Notebooks

Each assessing organization should issue their assessors a controlled notebook for the purpose of recording observations and notes. The assessment notebooks should be used to record all relevant information and observations during an on-site assessment. The assessment notebooks should be written legibly in ink. Either the original notebooks, or copies of the notebooks, should be provided to Navy.

2.6 Report

The report should include the following information, as appropriate to the individual assessment:

- Date(s) and location(s) of the assessment
- Identification of assessment team members and observers
- Identification of opening meeting and exit brief participants
- Identification of persons interviewed or contacted during assessment (by name or title)
- All deficiencies or observations noted (see Section 2.6.1 and Section 2.6.2, below)
- Discussions held with sampling personnel and any corrective actions taken
- Unresolved questions from the Contractor
- Health and safety protocols and level of protection used
- General quality of the work observed
- Comments on overall adherence to the approved work plans

2.6.1 Deficiencies

Deficiencies identify those practices or procedures that represent a departure from scientifically sound practices, or would adversely impact data quality, or contribute to poor documentation. The assessment report should provide a description of each deficiency in sufficient detail that the deficiency may be clearly understood by the reader. In addition, the requirement that is associated with each deficiency should be stated or referenced.

2.6.2 Observations

Observations that reflect on the project but are not serious enough to constitute a deficiency should be documented in the observations section of the report.

2.7 Report Issuance

The assessment report, signed and distributed by the lead assessor, should be issued to the requestor (EFD/EFA or Contractor) within seven calendar days of completion of the on-site assessment. The lead assessor should review and approve the final version of the assessment report to ensure that the report is complete and accurate. The EFD/EFA should receive copies of all field assessments performed on Navy IR projects.

2.8 Action Resulting from the Assessment Report

The action to be taken in response to the information provided in the assessment report shall be at the discretion of the EFD/EFA.

Appendix G
Attachment 1
Field Assessment General Information

Field Assessment General Information

Project Name:	
Address:	
Facility Contact and Phone Number:	
Sampling Team:	
Affiliation:	
Address & Phone Number:	
Sampling Personnel:	
Field Assessment Personnel	
Affiliation:	
Date(s) of Assessment:	

Checklist enclosure(s) completed for this overview:

1. ☐ 2. ☐ 3. ☐ 4. ☐ 5. ☐ 6. ☐ 7. ☐ 8. ☐

Key:

1. General Procedures
2. Groundwater Sampling
3. Soil and Sediment Sampling
4. Surface Water Sampling
5. Waste Sampling
6. Storm Water Sampling
7. Air Sampling
8. Potable Water Sampling

Appendix G
Attachment 1, Enclosure 1
General Procedures Checklist

General Procedures

1. Type of samples collected:	
List:	
2. Were sampling locations properly selected?	Yes ☐ No☐
Comments:	
3. Were sampling locations adequately documented in a bound field logbook using indelible ink?	Yes ☐ No☐
Comments:	
4. Were photos taken and a photolog maintained?	Yes ☐ No☐
Comments:	
5. What field instruments were used during this study?	
List:	
6. Were field instruments properly calibrated and calibrations recorded in a bound field logbook?	Yes ☐ No☐
Comments:	
7. Was sampling equipment properly wrapped and protected from possible contamination prior to sample collection?	Yes ☐ No☐
Comments:	

8. Was sampling equipment constructed of Teflon®, polyethylene, glass, or stainless steel?	Yes ☐ No☐
Comments:	
9. Were samples collected in appropriate order (e.g. least suspected contamination to most contaminated)?	Yes ☐ No☐
Comments:	
10. Were clean disposable latex or vinyl gloves worn during sampling?	Yes ☐ No☐
Comments:	
11. Were gloves changed before each sample?	Yes ☐ No☐
Comments:	
12. Was any equipment field cleaned?	Yes ☐ No☐
13. Type of equipment cleaned:	
List:	
Comments:	
14. Were proper cleaning procedures used?	Yes ☐ No☐
Comments:	
15. Were equipment rinse blanks collected after field cleaning?	Yes ☐ No☐

Comments:	
16. Were proper sample containers used for samples?	Yes ☐ No☐
Comments:	
17. Were split samples offered to the regulatory agency representative?	Yes ☐ No☐
Comments:	
18. Was a receipt for samples form given to regulatory agency representative?	Yes ☐ No☐
Comments:	
19. Were any duplicate samples collected?	Yes ☐ No☐
Comments:	
20. Were samples properly field preserved?	Yes ☐ No☐
Comments:	
21. Were preservative blanks utilized?	Yes ☐ No☐
Comments:	
22. Were field and/or trip blanks utilized?	Yes ☐ No☐
Comments:	

23. Were samples adequately identified with labels or tags?	Yes ☐ No☐
Comments:	
24. Were coolers sealed with custody seals after collection?	Yes ☐ No☐
Comments:	
25. Were security measures used to insure custody of the samples after collection?	Yes ☐ No☐
Comments:	
26. Were chain-of-custody and receipt for samples forms properly completed?	Yes ☐ No☐
Comments:	
27. Were any samples shipped to a laboratory?	Yes ☐ No☐
Comments:	
28. If yes to # 27, were samples properly packed?	Yes ☐ No☐
Comments:	

29. What safety monitoring equipment, protection and procedures were used prior to and during sampling?	Yes ☐ No☐
List:	
30. Was safety monitoring equipment properly calibrated and were calibrations recorded in a bound field log book?	Yes ☐ No☐
Comments:	
31. Other comments or observations:	Yes ☐ No☐
Comments:	

Appendix G
Attachment 1, Enclosure 2
Groundwater Sampling Checklist

Groundwater Sampling

1. Type of wells sampled? (monitoring, potable, industrial, *etc.*)	Yes ☐ No☐
List:	
2. Were wells locked and protected?	Yes ☐ No☐
Comments:	
3. Were identification marks and measurement points affixed to the wells?	Yes ☐ No☐
Comments:	
4. What were the sizes and construction materials of the well casings?	
List:	
Comments:	
5. Were the boreholes sealed with a concrete pad to prevent surface infiltration?	Yes ☐ No☐
Comments:	
6. Was there a dedicated pump in the well?	Yes ☐ No☐
Comments:	
7. Was clean plastic sheeting placed around the wells to prevent contamination of sampling?	Yes ☐ No☐

Comments:	
8. Were total depth and depth to water determined before purging?	Yes ☐ No☐
Comments:	
9. What device was used to determine depth?	Yes ☐ No☐
Comments:	
10. Were measurements made to the nearest 0.01 ft.?	Yes ☐ No☐
Comments:	
11. Was the measuring device properly cleaned between wells?	Yes ☐ No☐
Comments:	
12. Was the standing water volume in each well determined?	Yes ☐ No☐
Comments:	
13. How was the volume determined?	
Comments:	

14. Was a sufficient volume purged prior to sampling?	Yes ☐ No☐
Comments:	
15. What was done with the purged water? Was it collected for proper disposal, containerized until characterized or sent to an approved treatment facility?	Yes ☐ No☐
Comments:	
16. How many volumes?	
List:	
17. How was the purged volume measured?	
Comments:	
18. What was the method of purging?	
Comments:	

19. Were pH, conductivity, temperature, turbidity, and dissolved oxygen measurements taken and recorded during well-purging activities?	Yes ☐ No☐
Comments:	
20. Were pH, conductivity, temperature, turbidity, and dissolved oxygen readings stable prior to sampling?	Yes ☐ No☐
Comments:	
21. How many wells were sampled?	☐ Up gradient ☐ Down gradient
Comments:	
22. How were the samples collected?	☐ Bailer ☐ Pump ☐ Other:
Comments:	
23. If pump was used, what type?	
List:	
Comments:	

24. If a pump was used, was it properly cleaned before and/or between wells?	Yes ☐ No☐
Comments:	
25. What were the cleaning procedures?	
List:	
26. Did bailers have polytetrafluoroethylene (PTFE)-coated wire leaders to prevent rope from coming into contact with water?	Yes ☐ No☐
Comments:	
27. Were bailers open or closed top?	Yes ☐ No☐
Comments:	
28. Was a clean bailer and new leaders used at each well?	Yes ☐ No☐
Comments:	
29. Were samples properly transferred from the sampling device to the sample containers? (*i.e.*,	Yes ☐ No☐
Comments:	

30. Was pH of preserved samples checked to insure proper preservation?	Yes ☐ No☐
Comments:	
31. Were samples iced immediately after collection?	Yes ☐ No☐
Comments:	
32. For what analyses were the samples collected?	
List:	
Comments:	
33. If samples were split, what were the sample/station numbers?	
List:	
Comments:	
34. If samples were split, were they blind to the laboratory on the chain-of-custody form?	
Comments:	

35. Other comments or observations:	
Comments:	

Appendix G
Attachment 1, Enclosure 3
Soil and Sediment Sampling Checklist

Soil and Sediment Sampling

1. Type of samples collected:	
List :	
Comments:	
2. General sample description:	
Comments:	
3. How many samples were collected?	Number:
Comments:	
4. Were background and/or control samples collected?	Yes ☐ No☐
Comments:	
5. Were representative samples collected?	Yes ☐ No☐
Comments:	
6. Were grab or composite samples collected?	Yes ☐ No☐
Comments:	

7. Were composite samples areal or vertical?	☐ areal ☐ vertical
Comments:	
8. How many aliquots were taken for the composite sample?	Number:
Comments:	
9. What procedures and equipment were used to collect samples?	
Comments:	
10. Were samples thoroughly mixed prior to putting them into the sample containers?	Yes ☐ No ☐
Comments:	
11. Were samples properly placed into sample containers?	Yes ☐ No ☐
Comments:	
12. Were samples chilled with ice water immediately after collection?	Yes ☐ No ☐
Comments:	

13. For what analyses were the samples collected?	
Comments:	
14. If samples were split, what were the sample/station numbers?	
List:	
Comments:	
15. If samples were split, were they blind to the laboratory on the chain-of-custody form?	Yes ☐ No☐
Comments:	
16. Was a drilling rig, backhoe, *etc.*, used to collect soil samples?	Yes ☐ No☐
Comments:	
17. What was done with the soil cuttings from the drill rig or backhoe?	
Comments:	
18. Were the cuttings collected for proper disposal, or containerized until characterized?	Yes ☐ No☐
Comments:	
19. Were the drilling rig, backhoe, *etc.*, properly cleaned prior to arriving on site?	Yes ☐ No☐
Comments:	

20. What was the condition of the drilling and sampling equipment when it arrived on site? (cleanliness, leaking jacks, peeling paint)?	
Comments:	
21. Was a decontamination area located where the cleaning activities would not cross-contaminate clean and/or drying equipment?	Yes ☐ No☐
Comments:	
22. Was clean equipment properly wrapped and stored in a clean area?	Yes ☐ No☐
Comments:	
23. Was the drilling rig(s) properly cleaned between well borings?	Yes ☐ No☐
Comments:	
24. Were the cleaning and decontamination procedures conducted in accordance with the project plans?	Yes ☐ No☐
Comments:	
25. Other comments or observations	
Comments:	

Appendix G
Attachment 1, Enclosure 4
Surface Water Sampling Checklist

Surface Water Sampling

1. Type of samples collected?	Yes ☐ No ☐
Comments:	
2. General sample description	
Comments:	
3. How many samples were collected?	Number:
Comments:	
4. Were background and/or control samples collected?	Yes ☐ No ☐
Comments:	
5. Were grab or composite samples collected?	Yes ☐ No ☐
Comments:	
6. How many aliquots were taken for the composite sample?	
Comments:	
7. What procedures and equipment were used to collect the samples?	
Comments:	
8. Were samples collected directly into sample containers?	Yes ☐ No ☐
Comments:	
9. Did the sampler wade in the stream to collect the samples?	Yes ☐ No ☐
Comments:	
10. Were the samples collected upstream from the sampler?	Yes ☐ No ☐
Comments:	

11. Did the sampler insure that roiled sediments were not collected along with the water samples?	Yes ☐ No☐
Comments:	
12. Were representative samples collected?	Yes ☐ No☐
Comments:	
13. Was the pH of preserved samples checked to insure proper preservation?	Yes ☐ No☐
Comments:	
14. Were samples chilled with iced water immediately after collection?	Yes ☐ No☐
Comments:	
15. For what analyses were the samples collected?	
Comments:	
16. If samples were split, what were the sample/station numbers?	
List:	
Comments:	
17. If samples were split, were they blind to the laboratory on the chain-of-custody form?	Yes ☐ No☐
Comments:	
18. Other comments or observations:	
Comments:	

Appendix G
Attachment 1, Enclosure 5
Waste Sampling Checklist

Waste Sampling Checklist

1. Type of samples collected (oil, sludge, waste, wipe, chip, sweep)?	Yes ☐ No☐
Comments:	
2. Description of containers or sources sampled:	
Comments:	
3. How many samples were collected?	
Comments:	
4. What type of equipment was used to collect the samples?	
Comments:	
5. What procedures were used to collect the samples?	
Comments:	
6. For what analyses were the samples collected?	
Comments:	
7. If samples were split, what were the sample/station numbers?	
Comments:	
8. If samples were split, were they blind to the laboratory on the chain-of-custody form?	Yes ☐ No☐
Comments:	

9. Were any special safety measures taken during collection of the samples?	Yes ☐ No☐
Comments:	
10. What level of safety protection was required for collection of the samples?	
Comments:	
11. Other comments or observations:	
Comments:	

Appendix G
Attachment 1, Enclosure 6
Storm Water Sampling Checklist

Storm Water Sampling

1. Was outfall sampling point selection appropriate?	Yes ☐ No ☐
Comments:	
2. Was visual monitoring conducted and recorded?	Yes ☐ No ☐
Comments:	
3. Did the rainfall event produce a minimum of 0.1 inches of rain?	Yes ☐ No ☐
Comments:	
4. Was the rainfall event preceded by a period of at least 72 hours during which no more than 0.1 inches of rain occurred?	Yes ☐ No ☐
Comments:	
5. Was it a "normal" rainfall event (duration and total rainfall not more than 50% of the average storm event)?	Yes ☐ No ☐
Comments:	
6. Was runoff produced?	Yes ☐ No ☐
Comments:	
7. Types of samples collected (grab, flow-weighted composite)?	
Description:	
Comments:	
8. Were grab samples collected within the first 30 minutes after the on-set of runoff?	Yes ☐ No ☐

Comments:	
9. If grab samples were not obtained during the first 30 minutes, were they at least collected within the first 60 minutes of discharge?	Yes ☐ No☐
Comments:	
10. What analytical procedures are going to be conducted on the grab samples?	
Description:	
Comments:	
11. Were flow-weighted samples properly prepared (even time intervals)?	Yes ☐ No☐
Comments:	
12. What was the time duration over which the composite samples were obtained?	
List:	
Comments:	
13. Were composite samples composed of at least three discrete samples taken in each hour for the first three hours of discharge, or the entire storm if less than three hours in duration, with each sample being separated by minimum of 15 minutes?	Yes ☐ No☐
Comments:	
14. How was flow rate determined?	
Description:	

Comments:	
15. How was rainfall amount determined?	
Description:	
Comments:	
16. What analytical procedures will be conducted on the flow-weighted composited samples?	
Description	
Comments:	
17. What procedures and equipment were used to collect the samples?	
Description	
Comments:	
18. Were representative samples collected?	Yes ☐ No☐
Comments:	
19. Was adequate information recorded to document the sampling event?	Yes ☐ No☐
Comments:	
20. Was the pH of preserved samples checked to insure proper preservation?	Yes ☐ No☐

Comments:	
21. Were samples chilled with ice water immediately after collection?	Yes ☐ No☐
Comments:	
22. If samples were split, what were the sample/station numbers?	
Description:	
Comments:	
23. If samples were split, were they blind to the laboratory on the chain-of-custody form?	Yes ☐ No☐
Comments:	
24. Other comments or observations:	
Comments:	

Appendix G
Attachment 1, Enclosure 7
Air Sampling Checklist

Air Sampling

1. Is there a list of the air monitoring and meteorological stations?	Yes ☐ No☐
Comments:	
2. Is there a map(s) showing the location of air monitoring and meteorological stations?	Yes ☐ No☐
Comments:	
3. Is there a Contingency Plan addressing sampling failures caused by unpredicted meteorological delays?	Yes ☐ No☐
Comments:	
4. Does the sampling network agree with the project plan?	Yes ☐ No☐
Comments:	
5. Are there planned or required QC/QA samples scheduled?	Yes ☐ No☐
Comments:	
6. What are the contaminants of concern?	
List:	
Comments:	
7. What are the types of data collected (particulate, gaseous, meteorological, *etc.*)?	
Description:	

Comments:	
8. Are there project-specific SOPs for sampling?	Yes ☐ No☐
Comments:	
9. Are the correct methods being performed?	Yes ☐ No☐
10. What type(s) of air monitoring equipment are used?	
Comments:	
11. How many air monitoring stations are there?	Number:
Comments:	
12. Is there a data recording, reporting, and required data CoC plan?	Yes ☐ No☐
Comments:	
13. Are the air monitoring instruments locked and protected?	Yes ☐ No☐
Comments:	
14. Are there air monitoring calibration SOPs?	Yes ☐ No☐
Comments:	
15. Are the air monitoring instruments calibrated?	Yes ☐ No☐
Comments:	

16. Are calibration data and instrument serial numbers recorded in a log book?	Yes ☐ No☐
Comments:	
17. What meteorological data are being collected?	
Comments:	
18. How many meteorological stations are there?	Number:
Comments:	
19. Are the wind speed and direction sensors located at the recommended height in meters?	Yes ☐ No☐
Comments:	
20. What is the duration for wind speed and direction readings?	
List:	
Comments:	
21. Are the meteorological instruments calibrated?	Yes ☐ No☐
Comments:	
22. Are calibration data and instrument serial numbers recorded in a log book?	Yes ☐ No☐
Comments:	
23. Are any air monitoring or meteorological stations located where the data collected could be biased?	Yes ☐ No☐
Comments:	

24. Did the sampling time and total sample volume collected provide sufficient sample for analysis that meets the required detection limits?	Yes ☐ No☐
Comments:	
25. Other comments or observations:	
Comments:	

Appendix G
Attachment 1, Enclosure 8
Potable Water Sampling Checklist

Potable Water Sampling

1. Did the sampling team verify that the sample tap was not located after a household purification and/or conditioning system?	Yes ☐ No☐
Comments:	
2. Were name(s) of the resident or water supply owner/operator, mailing address, and phone number obtained by the field sampling team?	Yes ☐ No☐
Comments:	
3. Was clean plastic sheeting placed around the sampling point to prevent contamination of sampling equipment and containers?	Yes ☐ No☐
Comments:	
4. What were the preparatory purging procedures?	
Comments:	
5. Were aerator, strainer, and hose attachments removed from the tap prior to sampling?	Yes ☐ No☐
Comments:	
6. Were pH, specific conductance, and temperature readings stable prior to sampling? (pH ± 0.2 units, specific conductance ± 10%, temperature ± 0.5°C)	Yes ☐ No☐
Comments:	
7. Were the samples collected directly into the sample container?	Yes ☐ No☐
Comments:	

8. Were clean gloves used for each sampling location?	Yes ☐ No ☐
Comments:	
9. How many taps were sampled?	Yes ☐ No ☐
Comments:	
10. If dissolved metals are a parameter of concern, were the samples filtered in the field prior to preservation?	Yes ☐ No ☐
Comments:	
11. Was the pH of preserved samples checked to insure proper preservation, and was this check completed without contaminating the sample? (*i.e.*, pH test strips must not be put into the sample container)	Yes ☐ No ☐
Comments:	
12. Were samples iced immediately after collection?	Yes ☐ No ☐
Comments:	
13. For what analyses were the samples collected?	
Comments:	
14. If samples were split, what were the sample/station numbers?	Yes ☐ No ☐
Comments:	
15. If samples were split, were they blind to the laboratory on the chain-of-custody form?	Yes ☐ No ☐
Comments:	

16. Other comments or observations:	
Comments:	

Appendix H
Data Validation

Appendix H, Data Validation

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Attachments

Objective, Subjective, and Supporting Data Elements Reviewed During Data Validation Attachment 1

1.0 Introduction

Data validation is performed to determine how well project data meet project acceptance criteria. If potentially severe data quality problems are identified in a data review, then project management should consider a full-scale validation effort.

1.1 Purpose

This document provides guidance for the technical validation of analytical data generated and used in support of the Navy's Installation restoration (IR) program.

The Engineering Field Division/Engineering Field Activity (EFD/EFA), as the project manager, shall establish the required frequency and level of effort for data validation in project planning documents and should define the process through which the specific data intended for validation will be selected. It should be noted that the direction given in this section is typically presented using the term "should." The EFD/EFA shall determine if the information and guidance presented in this section shall be applied more stringently (i.e. "should" implemented as "shall").

1.2 Objectives

This document provides guidance for the scope, context, and approach for data validation. This document is not intended to serve as a standard operating procedure (SOP) for data validation activities.

1.3 Scope

This document describes the general elements of technical reviews of data generated using nonprescriptive methods such as the Environmental Protection Agency (EPA) SW-846 and highly prescriptive methods such as the EPA Contract Lab Program (CLP). It is applicable to reviews of chemical data generated using published reference methods. Although the data review process is generally applicable, the user is cautioned that the technical details in this document are not universally applicable to data generated using all published methods (e.g., they would not be applicable to bioassay, radiochemical or geological testing).

2.0 Data Review and Data Validation

Data review and data validation are not adequately defined in most procedures or guidance documents. For purposes of this document, data review is defined as a systematic approach for the review of laboratory data. Data validation is a thorough assessment of data and supporting QC documentation without making any assumption to the quality of the data provided.

2.1 Data Review

In a summary or low level review only the sample results and limited project documentation are typically reviewed. Summary or low-level reviews are best suited to cases in which some project data has been subjected to a high level or full-scale validation.

Typically, laboratory personnel and end users perform data reviews as a quality assurance/quality control (QA/QC) measure. It is the responsibility of end users to review 100 percent of laboratory data for completeness. This type of review is commonly referred to as "summary level" review. In summary level reviews, the following elements should be examined:

- Completeness: Determine if:
  - All requested analytes accounted for
  - All Project Data Quality Objectives (DQOs) or target/action levels met
  - Results correlate with historic data
- Holding times: Are they within limits
- Chain of custody: Is documentation complete and accurate
- Method and reporting limits: Are they within the scope of project DQOs
- Dilution factors/concentration units: Are they correct as reported
- Preparation/analysis methods: Were those identified on the report appropriate for the project
- Matrix spike results (if provided): Were they within specification
- Surrogate recoveries (if provided) within specification

The results of a summary level review may reveal inaccuracies or errors in the data that may require a more thorough assessment, such as data validation.

2.2 Data Validation

In a full level data validation, validators review and evaluate reported data, raw data, supporting information, and project documentation to make a determination as to whether the reported data are of sufficient quality to satisfy project objectives.

In many cases, project plans and management reviews do not specify the elements that must be reviewed for data validation. If specific project or program guidance (i.e., the

CLP) is not available to determine the elements necessary for data validation, then the guidance in the following sections may be applied.

2.2.1 Validation Scope

The appropriate scope for project data validation should be determined in consideration of project DQOs and established in project planning documents such as a QA Plan. Planning documents should specify:

- Which data set(s) will be subject to validation by sample type, location, or sampling period as appropriate
- The frequency or percentage of data to be validated
- The level or degree of validation required and the specific laboratory documents required to accomplish the validation
- The source or reference documents used to determine applicable technical performance (i.e., to qualify or "flag" the data)

The overall scope of a project's data validation effort may be relatively large for data that is critical to providing input for decisions involving high risk or low tolerance for risk. Conversely, limited or no validation may be required for routine project data.

Data validation may be scoped as a full-scale effort or limited to only a summary level review without data validation.

2.2.1.1 Navy QA Guidance

The Navy Installation Restoration Chemical Data Quality Manual (IR CDQM) provides or references QC requirements and criteria that must be adopted and implemented by a laboratory in the absence of project-specific instructions. A copy of the guidance document must be provided to the data validators for reference. However, data validation is not intended to assess a laboratory's compliance with the IR CDQM.

2.2.2 Validation Levels

All aspects of the data are reviewed and appropriate data "flags" assigned. The Navy understands that a consensus among agencies does not exist for the degree of documentation review required to "validate" data. Therefore, it is important that project plans specifically outline the areas of lab documentation that must be reviewed prior to validation of data.

Some agencies, such as EPA, create "levels" or "tiers" of review for data validation. An upper level or tier review may require extensive documentation and research including calibrations, standards traceability, contract review, statement of work review (SOW), and on-site lab audits.

As an end user of data, it is important to remember that the amount of documentation required to perform data reviews (level/tier I, II, III, etc.) is not consistent among agencies. Level II validation, for example, may not have the same meaning in various EPA regions or military components. Data validation reports must include as references any documents(s) that were used to determine the degree or level of validation required.

If project specific plans or responsible regulatory authority do not specify the required criteria for data validation, then the following will apply.

2.2.2.1 CLP

For data under the CLP, use as references:

- Applicable EPA Region Quality Assurance Project Plan Guidance
- EPA Regional Data Validation Functional Guidelines for Evaluating Environmental Analyses
- USEPA Contract Laboratory Program National Functional Guidelines for Organic Data Review
- USEPA Contract Laboratory Program National Functional Guidelines for Inorganic Data Review

For data generated outside the Contract Lab Program, the guidance provided in section 2.2.2.2 will apply.

2.2.2.2 Non CLP

After reviewing all elements of a data set, the validator will use professional judgement to generate an overall summary of the technical quality of the data. Data may be qualified or “flagged” based on the elements presented in the tables included in Attachment (1) to this appendix, or for other reasons as documented by the validators. Data must not be qualified if only a summary level review of the data set was performed. Final qualifiers for individual data points that have previously been flagged with multiple individual qualifiers may be increased in severity (e.g., a point which has been flagged with multiple “J”s on the basis of several different quality elements may be downgraded to an “R” flag). The validator must document any suspected biases in the data set.

The end user must determine the impact of all suspected biases or qualified data based on intended project use.

2.3 Frequency of Review and Validation

As stated in Section 2.1, end users must review 100 percent of the data for which they are responsible. For a given project a certain percentage of the data may require a more thorough assessment, or data validation. The frequency of validation should be

determined based on consideration of project DQOs. Each project's planning documents should establish the required data validation frequency, define the process through which specific data is selected for validation, and the level of detail in documentation required to validate the data.

3.0 Validator Qualifications

3.1 Education

The individuals who provide data validation services must have technically appropriate credentials that are commensurate with their responsibilities. The individuals who perform or review data validation must have a minimum of a Bachelor of Science (BS) or Bachelor of Arts (BA) in chemistry or a physical science. Validators who do not meet these requirements should provide documented evidence that demonstrates that they possess the disciplinary expertise, experience and theoretical knowledge necessary to validate data.

3.2 Knowledge and Experience

Each individual who provides data validation services must have a minimum of 2 years of professional bench level experience beyond a baccalaureate degree that is commensurate with their method specific responsibilities for data validation. For example:

- To validate data from volatile organic methods, an individual must have performed GC-MS analyses for the determination of trace level volatile organic contaminants.
- To validate data from semi-volatile organic methods, an individual must have performed GC-MS or HPLC analyses for the determination of trace level semi-volatile organic contaminants.
- To validate data from Pesticide/PCB methods, an individual must have performed GC analyses for the determination of trace level organics.
- To validate data from Dioxin methods, an individual must have performed GC-MS analyses and must have experience using high-resolution mass spectroscopy techniques.
- To validate data from metals methods, an individual must have performed analyses for the determination of trace metals using ICP, ICP-MS, AA, or GFAA.

To validate data from classical methods (e.g., CRVI, CN, ion chromatography, gravimetric, etc.) or radiochemical methods (gross alpha, beta, gamma, etc.) an individual must have performed analyses using the referenced methods.

Appendix H
Attachment 1
Objective, Subjective, and Supporting Data Elements Reviewed During Data Validation

1.0 Objective Data Elements Reviewed During Data Validation

The initial step in the data validation process is the review and evaluation of objective data elements. The objective data elements addressed in this section are independent of sample matrix, and provide objective, quantitative information regarding performance of the preparative and analytical methods and instrumentation (if applicable) during the measurement process. Compliance with individual method, project, or Navy acceptance criteria must be evaluated, as appropriate. Data associated with unacceptable QC may be of extremely limited use and must be carefully assessed and qualified if the data are not to be rejected. Table H-1 summarizes the objective data elements that must be reviewed during the validation process:

Table H-1.

Validation Element	Criteria and specifications to be assessed during validation
Initial Calibration	- number of standards used - range of calibration - algorithm used - samples analyzed and reported within calibration range
Initial Calibration Verification (ICV)	- independent, or second source standard - concentration - percent recovery - position in the analytical run sequence(s)
Initial Calibration Blank (ICB)	- composition of the blank - analytical result(s) - position in the run sequence(s)
Continuing Calibration Verification (CCV)	- concentration - percent recovery - position in the analytical run sequence(s) - frequency
Laboratory Control Sample (LCS)	- composition (matrix) - concentration - percent recovery - trends in LCS recovery (if possible)
Laboratory Control Sample Duplicate (LCSD)	- evaluation criteria, as for LCS - performance of LCSD appropriate - batch precision

Interference Check Standard (ICP, ICP/MS)	- composition - concentration - percent recovery - position(s) in the analytical run sequence(s)
Method Blank (MB)	- detection of target analytes - concentration of target analytes - percent recovery of compounds added (e.g., surrogates)
Instrument Blanks	- detection and concentration of target analytes - percent recovery of any compounds added (e.g., surrogates)
Process Blanks (e.g., trip blanks, holding blanks, and rinsate blanks)	- detection and concentration of target analytes - percent recovery of any compounds added (e.g., surrogates)
GC/MS Tunes	- compound used - amount analyzed - introduction technique - instrument operating parameters - spectrum generation procedure
GC Degradation Check	- compounds used - standard concentrations - algorithm for breakdown calculation - compliance with criteria
GC and LC Retention Time Windows	- number of standards analyzed - temporal spacing of analyses - algorithm for calculation of window size - procedure for centering windows - frequency of recentering
HRMS Resolution and Mass Accuracy (Dioxins)	- resolution - mass accuracy
Dioxin GC Column Performance Check	- resolution of 2,3,7,8-TCDD - retention times of analytes
Analytical Wavelength (ICP, spectrophotometric analysis)	- analytical wavelengths used - consistency with QC and method performance data
Method of Standard Addition (GFAA)	- spike concentrations - number of concentration levels - algorithm for calculation of sample concentration

High Calibration Standard (ICP)	- position in analytical run sequence - acceptance with criteria
Gel Permeation Chromatography (GPC)	- analytical results for the GPC blank - calibration check
Linear Range	- samples analyzed within linear range - reasonableness of linear ranges determined
Calculations	- confirmation of manual calculations
Samples	- assessment of results (i.e., detection, qualitative identification, and quantitation) with reference to all objective validation elements

2.0 Subjective Data Elements and Criteria

The second step in the data validation process is the review and evaluation of subjective data elements. The effect of these review elements on the integrity and usability of the data set must be assessed using professional judgment. Although some elements are assigned numerical values and acceptance criteria, the relationship of the numerical value to data validity, acceptability, accuracy, and precision cannot be precisely and predictably determined. The impact of these subjective data elements on data validity, usability, and defensibility must be assessed, and data qualified as warranted in consideration of project objectives. Table H-2 summarizes the subjective data elements that must be reviewed as part of the validation process:

Table H-2. Subjective Data Elements Reviewed During Data Validation

Validation Element	Criteria and specifications to be assessed during validation
Matrix Spike/Matrix Spike Duplicate (MS/MSD)	- concentration - percent recovery - precision - field duplicate precision
Duplicates (Laboratory and Field)	- precision - sample heterogeneity - subsample heterogeneity
Hold-Time	- verify to preparation and analysis dates, as appropriate
Serial Dilutions (ICP)	- appropriate sample diluted - percent difference between diluted and undiluted sample result
Post Digestion Spike (PDS)	- spike concentration - percent recovery
Surrogates	- surrogates used - calibration and quantitation procedures - concentrations - percent recovery
Internal Standard Responses	- internal standards used - concentrations in standards and extracts/digestates - instrument responses
Organic Internal Standard Retention Times	- retention times
GC and LC Confirmation Analyses	- procedures for confirmation analyses (e.g., initial calibrations, calibration verifications, etc.) - procedures for combining results from two analyses

Coeluting Compounds in GC and LC Analyses	- procedures for treatment of coeluting compounds
Qualitative Identification of GC/LC Target Compounds	- procedures for use of retention time windows or pattern matching
Qualitative Identification of GC/MS Target Compounds and TICs	- relative retention times (target compounds only) and spectra of reported compounds - closely eluting compounds with similar spectra
Qualitative Identification of Dioxins	- relative or absolute retention times - ion ratios - signal to noise ratios - lack of interference by chlorinated diphenyl ethers
Calculations	- spot checks of calculations for accuracy
Samples	- results (i.e., concentrations, qualitative identification, and quantitation) assessed with reference to all subjective validation elements

3.0 Supporting Data Elements and Criteria

The review and assessment of supporting data elements is an important part of the validation process. The supporting data elements are assessed for compliance with the appropriate standard, which may be the laboratory's project-specific SOW, reference methods, or Navy's chemical data QA guidance document. The effects of noncompliance on data validity, usability, and defensibility must be assessed, and data flagged as necessary. It is noted that assessment of these elements does always result in technical qualification of data, but may have significant impact on data usability, and technical acceptability. Table H-3 summarizes supporting data elements that are reviewed during the validation process:

Table H-3. Supporting Data Elements Reviewed During Data Validation

Validation Element	Criteria and standards to be assessed during validation
Narrative	- relevant information, e.g., date of sample receipt, date(s) of sample preparation, date(s) of sample analyses, sample matrix, results, and dilution factors - QC failures - initiation of corrective actions - basis of wet or dry weight reporting
Type and Frequency of QC Samples	- compliance with requirements of each reference method and other source documents
Standard Material Traceability and Quality	- traceable to manufacturer and lot number - within assigned and appropriate shelf lives - preparation and use of intermediate and working standards - unique, unambiguous identification of standard materials - preparation of all standard material documented
Reagent traceability and Quality	- traceable to manufacturer and lot number - within assigned shelf life
Analyte List	- complete and accurate target analytes
MDLs/RLs	- frequency of generation - technical acceptability of MDLs - reasonableness of MDLs/RLs - relationship to reporting limit or project required limit(s)
Sample Receipt Conditions	- cooler and individual sample container integrity - temperature - preservation - appropriate containers for analytes - head space

Chain of Custody (CoC)	- unbroken custody record from date and time of sampling through all analyses - internal custody control for extracts and digestates
Sample Storage Conditions	- temperature - preservation - segregation - first removal of volatile aliquots
Unique Identification for Individual Samples	- chain of custody (CoC) - preparative and determinative logs
Dilutions	- documentation - calculation algorithms - appropriate calibration range - correct reporting of results - diluted/undiluted results comparison
Batching Protocol	- batching practices for digestion/extraction and analysis - correlation of samples with associated QC samples and standards.
Pipette Verification	- pipet ID numbers documented - daily calibration check records
Support Equipment (e.g., pH meter, balance, ovens)	- calibration records - daily QC check records - traceability of reference materials and equipment
Corrections/Manual edits	- complete documentation
Corrective Actions	- documentation of nonconformances - nonconformances discussed in the narrative - evaluate laboratory's assessment regarding data quality and usability, if presented
Preparative/Analytical Method	- methods appropriate to sample matrix, analytes, and project requirements - methods can achieve required project limits - method version consistently and accurately specified
Percent Solids	- determined using appropriate protocol - samples reported on dry weight basis if required
Data Review	- scope and levels of review documented
Data Qualifiers	- applicability of data qualifiers assigned by the laboratory - qualifiers defined

Preparation Logs and Run Logs	- completeness - accuracy - analyst and reviewer signatures and dates
Instrument Printouts	- completeness - accuracy - analyst signature and date
Calculations	- calculations spot checked for accuracy
Samples	- results assessed with reference to the supporting elements listed above

Glossary

Glossary

algorithm	A formula which establishes the mathematical relationships between variables and fixed parameters.
action level	The numerical value that causes the decision maker to choose one of the alternative actions (e.g., compliance or noncompliance). It may be: a regulatory threshold standard, such as Maximum Contaminant Level for drinking water; a risk-based concentration level; a technological limitation; or a reference-based standard. The action level is specified during the planning phase of a data collection activity. It is not calculated from the sampling data.
analyte	The element, compound, or species detected and determined through analysis. Analytical methods require calibration for quantitation of specific analytes.
assessment	The evaluation process used to measure the performance or effectiveness of a system and its elements.
batch	Environmental samples prepared and/or analyzed together with the same process and personnel, using the same lot(s) of reagents.
blank	A QC sample used to detect and identify contaminants introduced to samples during the collection, transportation, storage, and measurement process. A laboratory blank is an analyte-free matrix carried through all or part of the analytical process for the purpose of identifying contamination introduced during analysis. Types of laboratory blanks include method blanks (carried through the entire preparation and analysis sequence), calibration blanks (matrix-matched reagent water used for calibration), and storage blanks (placed in sample storage areas). In the field, an analyte-free matrix is carried through a portion of the field process to identify contamination introduced during field or transportation operations. Types of blanks associated with the field are trip blanks (these accompany samples through the transportation process), equipment rinsates (collected after decontamination), and field blanks (collected on-site during the sampling event).
calibration	Comparison of a measurement standard, instrument, or item with a standard or instrument of higher accuracy to detect and quantify inaccuracies and to report or eliminate those inaccuracies by adjustments. The result of a calibration may be recorded in a document,

	sometimes called a calibration certificate or a calibration report. The result is sometimes expressed as a calibration factor or as a series of calibration factors in the form of a calibration curve.
calibration method	Defined technical procedure for performing a calibration.
certified reference material (CRM)	A reference material in which one or more of its property values are certified by a technically valid procedure and is accompanied by or traceable to a certificate or other documentation which is issued by a certifying body.
chain of custody (CoC)	An unbroken trail of accountability that ensures the physical security of samples, data, and records.
confidential business information (CBI)	Information considered "business sensitive" by the originating organization that must be controlled to prevent unauthorized review, distribution, or use.
contract required detection limit (CRDL)	Minimum level of detection acceptable under the contract statement of work (SOW). The inorganic SOW for the CLP gives CRDLs that should be attainable by the laboratory.
contract required quantitation limit (CRQL)	Minimum level of reliable quantitation acceptable under the contract SOW. Typically, for the CLP, a list of organic analyte quantitation limits that most laboratories are expected to be able to achieve. Used as the basis for reporting limits under CLP OLM protocols.
Contractor	The entity responsible for collection of field samples and contracting for analytical services. The Contractor may provide the Navy with services under a RAC or CLEAN contract. A Contractor may also be a Navy organization that contracts directly with a laboratory for analytical services. In this manual, Contractor refers to the Prime Contractor as opposed to the subcontractor.
control chart	A tool for using statistically derived control limits as the basis for real-time data quality analysis and long-term trend analysis.
control limits	Represent acceptance criteria for determining whether an analytical system is in control. Control limits may be specified in a reference method (either as mandatory or guidance limits) or developed by a laboratory using internal performance data.
control sample	A QC sample introduced to the analytical process to allow evaluation of the measurement system performance.
corrective action	An action taken to eliminate the causes of an existing nonconformance, deficiency, or other undesirable situation in order to prevent recurrence.
data quality assessment (DQA) process	A statistical and scientific evaluation of the data set to assess the validity and performance of the data collection design and

	statistical test, and to establish whether a data set is adequate for its intended use.
data quality objectives (DQOs)	Qualitative and quantitative statements derived from the DQO process which clarify study objectives, define appropriate type of data, and specify the tolerable levels of potential decision errors which will be used as the basis for establishing the quality and quantity of data needed to support decisions.
data quality objectives process	A systematic strategic planning tool based on the scientific process that identifies and defines the type, quality, and quantity of data needed to satisfy a specified use. The elements of the process include the following steps: • Define the problem concisely; • Identify the decision to be made; • Identify the key inputs to that decision; • Define the boundaries of the study; • Develop the decision rule; • Specify tolerable limits on potential decision errors; and • Select the most resource efficient data collection design. DQOs are the qualitative and quantitative outputs from this process.
data validation	A systematic process through which project data are compared to established criteria to provide assurance that the data are adequate for the intended use. The frequency and scope of the data validation process may vary, but shall always be consistent with project DQOs.
deficiency	An assessment conclusion which identifies a condition which represents a significant impact on an item or activity. A deficiency may be an unauthorized deviation from acceptable procedures or practices, or a defect in an item.
demonstration of method performance (initial demonstration of analytical capability)	Procedure to establish the laboratory’s ability to generate acceptable accuracy and precision required in many of the EPA's analytical methods. In general the procedure includes the addition of a specified concentration of each analyte (using a QC check sample) in each of four separate aliquots of laboratory pure water. These are carried through the entire analytical procedure. The percentage recovery and the standard deviation are then determined and compared to specified limits. Appendix C, Attachment 2, details demonstration of method performance.
double blind PT	A proficiency test sample introduced to the laboratory in such a manner that the entire analytical staff is unaware that the sample is

a proficiency test sample. A double blind PT sample is an effective means of assessing a laboratory's routine performance.

duplicate — A QC sample used to determine the precision associated with all or part of the sample collection and measurement process.

Field duplicates are used to determine the precision associated with the entire sample collection and measurement process. Field duplicates are two independent samples collected, as nearly as possible, from the same point in space and time. The two field duplicate samples are collected from the same source, using the same type of sampling equipment. Each field duplicate is collected and stored in separate sample containers and transported in the same shipping container. Field duplicates should not be used as a measure of laboratory performance.

Types of laboratory duplicates include matrix duplicates, and matrix spike duplicates. A matrix duplicate (typically called a laboratory duplicate) is used to determine the precision of the intralaboratory analytical process for a specific sample matrix. A laboratory sample and its associated matrix duplicate are prepared in the laboratory as split samples, and carried through the entire measurement process as independent samples. A matrix spike duplicate is also used to determine the precision of the intralaboratory analytical process for a specific sample matrix. A matrix spike sample and its associated matrix spike duplicate are prepared in the laboratory as split samples, and each are spiked with identical, known concentrations of targeted analyte(s).

equipment rinsate blank — A sample of analyte-free water poured over or through decontaminated field sampling equipment that is considered ready to collect or process an additional sample. The purpose of the equipment rinsate blank is to assess the adequacy of the decontamination process.

field blank — A sample of analyte-free water transferred, at the project site, into an appropriate container to distinguish ambient air contamination from in-situ sample contamination.

holding time — The elapsed time between time of sample collection and time of verified sample receipt by the laboratory, as defined by CLP methods. For non-CLP methods, the holding time is the elapsed time between sample collection and the execution of the determining activity in the laboratory, either preparation or analysis, as defined by the applicable method.

implementing procedures — The written, approved procedures that serve as the basis for implementation of a quality management system and its policies. In laboratories, these are usually referred to as standard operating

	procedures, or SOPs.
IR projects	The purpose of IR projects are to identify, investigate, or clean up hazardous waste sites. These projects may be funded by ER, N or BRAC. BRAC projects are considered IR projects if the purpose of the project is to remediate the site prior to closure. BRAC funded compliance projects are not subject to the requirements presented in this manual.
laboratory	A body that calibrates and/or tests. Specifically, the Navy defines an environmental laboratory as any fixed or mobile facility, in whole or in part, that performs testing for environmental regulatory reporting and/or to determine compliance with federal, state, regional and/or local environmental laws and regulations. This excludes process environmental control laboratories, provided none of the results are reported to a regulatory agency to determine compliance. The Navy has both single service and multi-service laboratories. Single service laboratories are defined as those laboratories that exist to perform testing in support of a particular function at an activity, such as wastewater treatment. Multi-service laboratories are defined as those laboratories that exist to perform testing in support of multiple functions at an activity (i.e., hazardous waste disposal, drinking water monitoring, wastewater treatment, etc.).
laboratory control sample (LCS)	A QC sample consisting of a known matrix spiked with a known amount of targeted analytes. The LCS is carried through the entire analytical protocol, including preparation, clean-up, and determinative procedures, and is used to monitor the overall accuracy of the analytical measurement process. Control limits for LCS recovery, typically expressed as % recovery, serve as acceptance criteria for determining whether an analytical run is in control, and are used for development of statistical control limits.
matrix (a.k.a., sample matrix)	The component or substrate containing the analyte(s) of interest. Examples include: groundwater, high clay content soil, concrete, drinking water, brine, sediment, and sludge. Matrix QC samples are used to assess the impact of the sample matrix on recovery of the analyte(s) of interest.
matrix spike (MS)	An aliquot of sample spiked with a known concentration of target analyte(s) prior to sample preparation. The recovery of target analyte(s) from the matrix spike sample is used to determine the bias of the method in the specific sample matrix.
matrix specific QC samples	Matrix specific QC samples are used to measure the impact of sample matrix on method performance, but, because matrix specific QC results are highly dependent on the nature of the sample matrix, they are not generally indicative of laboratory

	performance. Examples of matrix specific QC include: laboratory duplicate, matrix spike, matrix spike duplicate, and surrogate.
matrix spike duplicate (MSD)	Used to determine the precision of the intralaboratory analytical process for a specific sample matrix. A matrix spike sample and its associated matrix spike duplicate are prepared in the laboratory as split samples, and each are spiked with identical, known concentrations of targeted analyte(s).
method (a.k.a., reference method)	A body of procedures and techniques for performing an activity (e.g., sampling, chemical analysis, quantification) systematically presented in the order in which they are to be executed. Within the scope of this manual, the term "method" normally refers to a sampling or analysis procedure that has been officially specified by an organization, such as EPA, ASTM, AIHA, or state agencies.
method detection limit (MDL)	The minimum concentration of an analyte which can be measured and reported with 99% confidence that the actual analyte concentration in the sample is greater than zero. A matrix-specific MDL is experimentally determined through analysis of replicate samples containing the target analyte. The reference for determination of MDL is provided in 40 CFR Part 136, Appendix B.
Method Quantitation Limit(MQL)	The value at which the laboratory has demonstrated the ability to reliably quantitate target analytes for the method performed. In absence of project specific requirements, the MQL must be set using the lowest standard used by the laboratory for initial calibration (or initial calibration verification) for each target analyte.
observation	An assessment conclusion which identifies a condition which does not represent a significant impact on an item or activity. An observation may identify a condition that does not yet cause a degradation of quality.
performance based measurement system (PBMS)	A set of processes wherein the data quality needs, mandates, or limitations of a program or project are specified and serve as criteria for selecting appropriate methods to meet those needs in a cost-effective manner.
proficiency testing (PT)	Determination of field or laboratory testing performance by means of inter-laboratory comparisons.
project planning documents	Describe project plans for field activities and for sampling and analysis plans, and are submitted to the responsible Navy RPM for approval. Examples of planning documents include: site specific work plan, sampling and analysis plan, and QA project plan.
prime contractor	see definition of Contractor

project file	Records documenting activities, decisions, or directions regarding work on a specific Navy project. Laboratories and Contractors maintain project files.
quality assurance (QA)	An integrated system of management activities involving planning, QC, quality assessment, reporting, and quality improvement to ensure that a product or service (e.g., environmental data) meets defined standards of quality with a stated level of confidence.
quality assurance officer	As used in this manual, the individual responsible for development, documentation, and assessment of a laboratory's QA program.
quality assurance project plan (QAPP)	A formal technical document describing in comprehensive detail the necessary QA, QC, and other technical activities that must be implemented to ensure that the results of the work performed will satisfy the stated performance criteria.
quality control (QC)	The overall system of technical activities which measures the attributes and performance of a process, item, or service against defined standards to verify that they meet the stated requirements established by the customer.
quality manager	As used in this manual, the senior individual responsible for development, documentation, and assessment of an organization's quality program.
quality manual	A document stating the quality policy, quality system, and quality practices of an organization. The quality manual, however named, may call up other documentation relating to the laboratory's quality arrangements.
quality system	The organizational structure, responsibilities, procedures, processes, and resources necessary for implementing quality management.
quantitation limit (QL)	The concentration of an analyte which can be reliably quantitated to a known degree of accuracy in a particular matrix using the referenced method within specified limits of accuracy and precision. The QL is typically 3-10 times the MDL, and is highly matrix dependent. The samples used for MDL studies are typically spiked at the quantitation limit, and if all study criteria are met, may be used to document analyte recovery at the quantitation limit.
reference material	A material or substance one or more properties of which are sufficiently well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials.
reference method	The published method which serves as the basis for a laboratory's

	sampling and/or analysis procedure.
reference standard	A standard, generally of the highest metrological quality available at a given location, from which measurements made at that location are derived.
reporting limit (RL)	The threshold value below which the laboratory reports a result of “less than” or “not detected”.
requirement(s)	A translation of the needs into a set of individual quantified or descriptive specifications for the characteristics of an entity in order to enable its realization and examination.
sampling event	A sequential sampling campaign at a single contiguous site for a single matrix. A sampling event begins with collection of the first sample and ends when: sampling at a site is discontinued for an extended period (excluding weekends or routine days off); the ambient conditions at the site change; or an unanticipated change in the sample matrix is encountered.
single blind PT	A proficiency test sample that is known to be a proficiency sample by members of the laboratory staff, but the actual composition of the sample, in terms of types and concentrations of analytes, is unknown (i.e., "blind"). Single blind PT samples may not be a good indicator of routine laboratory performance, particularly when the laboratory has to reconstitute the sample from a concentrate.
split sample	A sample which may be used to assess intra- or inter-laboratory precision of the measurement process. Field split samples are obtained by preparing two (or more) individual sample aliquots after thorough homogenization of a single sample in the field. A field split sample may be used to determine intralaboratory precision if the split samples are submitted to a single laboratory. A field split sample may be used to determine interlaboratory precision if the split samples are submitted to different laboratories. The degree to which split precision data represent a true measure of laboratory precision is limited by the degree to which the sample is homogenized in the field. If the field sample is not effectively homogenized, the resultant data may not be used to assess laboratory precision.
standard materials	Neat chemicals or purchased stock standards that are used as the basis for analyte quantitation or for the preparation of QC samples.
standard operating procedure (SOP)	An approved, controlled document describing practices for a given procedure or activity, in sufficient detail which a qualified individual could use the SOP to conduct the procedure.
subject matter experts	Individuals whose academic training, theoretical knowledge, and practical experience in a particular subject matter qualify them as

	experts in the relevant subject matter.
surrogate	An analyte used to monitor method performance on a matrix-specific basis. A surrogate is a pure analyte added to the sample aliquot in known amount, prior to sample extraction. The surrogate, which is similar to the method target analytes in composition and behavior, is not ordinarily found in environmental samples. Because surrogates are generally added to each sample in a batch, they can be used to monitor recovery on a sample-specific, rather than batch-specific basis.
target analyte	The element, compound, or class of compounds detected and quantitated through the analytical measurement process.
test	A technical operation consisting of the determination of one or more characteristics or performances of a given product, material, equipment, organism, physical phenomenon, process or service according to a specified procedure. The result of a test is normally recorded in a document sometimes called a test report or a test certificate.
test method	Defined technical procedure for performing a test.
traceability	The property of a result of a measurement which can be related to appropriate standards, generally international or national standards, through an unbroken chain of comparisons.
trip blank	A blank used to identify the presence of volatile compound contamination attributable to transfer across a sample container septum during shipping and storage of samples. A trip blank is a sample of analyte-free matrix transported from the laboratory to the sampling site with the empty sample containers. The trip blank is stored on-site with the sample containers and field samples and then transported back to the laboratory with the samples for analysis. The trip blank is received and processed as a sample by the laboratory.
validation	Confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use are fulfilled.
validation (data)	A process used to determine if the available project data satisfy the project DQOs. The frequency and scope of the data validation process may vary, but should always be consistent with project DQOs. An appropriately qualified independent party that is not affiliated with the data generators or data users performs data validation.
validation (software)	The process of evaluating a software product to determine whether it provides a correct result within specified tolerance requirements.

verification	Confirmation by examination and provision of objective evidence that specified requirements has been met. In connection with the management of measuring equipment, verification provides a means for checking that the deviations between values indicated by a measuring instrument and corresponding known values of a measured quantity are consistently smaller than the maximum allowable error defined in a standard, regulation or specification peculiar to the management of the measuring equipment. The result of verification leads to a decision to: restore to service, perform adjustments; repair, downgrade, or declare obsolete. In all cases it is required that a written trace of the verification performed be kept on the measuring instrument's individual record.
verification (software)	The process of determining whether individual elements of a given software product are performing their intended functions or operations.

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Correlation of Electronic Files to the Printed Version of the IR CDQM

Section	Printed Version Page Numbers[2]	Electronic File Name
IR CDQM	1 -20	IRCDQM.pdf
Appendix A, Standards of Ethical Conduct	21-24	Appendix A.pdf
Appendix B, Laboratory Assessment	25-82	Appendix B.pdf
Appendix C, Laboratory Requirements	83-174	Appendix C.pdf
Appendix D, Proficiency Testing	175-182	Appendix D.pdf
Appendix E, Field Sampling Requirements	183-200	Appendix E.pdf
Appendix F, Project Document Assessment	201-216	Appendix F.pdf
Appendix G, Field Assessment	217-266	Appendix G.pdf
Appendix H, Data Validation	267-283	Appendix H.pdf
Glossary	284-294	Glossary.pdf

[2] Page references correspond to those found on the right lower corner of printed versions of this document.

Appendix B
Attachment 3
Initial Laboratory Assessment Package Requirements

Initial Laboratory Assessment Package Requirements

Laboratories that have been nominated to provide analytical support for Navy Installation Restoration (IR) or Base Realignment and Closure (BRAC) environmental programs shall supply the items listed below to the assessment organization. The assessors will use the information provided to make an initial assessment of the laboratory's capabilities to support IR and BRAC environmental projects.

Initial laboratory assessment package items shall be compiled/submitted in the following order:

1. *Navy Installation Restoration Laboratory Information Sheet*: Enclosure (1)
2. *Organization Chart*: An organization chart depicting the lines of authority for laboratory positions, with identification of individuals for key positions including:
   - Lab Director
   - Quality Manager
   - Quality Assurance (QA) Officer
   - Operations Manager
   - Inorganic Section Supervisor
   - Organic Section Supervisor
   - Classical Section Supervisor
   - LIMS Systems Manager
   - Data Reporting Section Supervisor
   - Sample Management Supervisor
3. *Resumes*: Resumes for the individuals in key positions, including those identified in number 2 above.
4. *Laboratory Facility(ies) Floor Plan*: A floor plan of the laboratory facility(ies) with general production areas identified including:
   - Organic and inorganic sample preparation laboratories
   - Inorganic instrument laboratories
   - Volatile organic instrument laboratories
   - Semi volatile organic instrument laboratories
5. *List of Major Analytical Instrumentation*: A list of major analytical instrumentation (limited to those instruments that are routinely applied to production analyses).
6. *Completed Laboratory Compliance Checklist*: The laboratory shall complete this checklist, Enclosure (2), to demonstrate its compliance with Navy requirements (detailed in IR CDQM Appendix C[1]). More information may be provided on additional sheets of paper as needed. The checklist is available electronically from the Navy QA contact. This checklist is based on the DOD QS document.
7. *Quality Manual:* The laboratory's current document(s) that describe the laboratory's QA program, typically called the QA manual, QA program plan, or QA plan.
8. *Methods Information*: A list of methods (by EPA or other method reference as appropriate) routinely performed by the laboratory, with the applicable matrices specified. The laboratory

[1] This checklist will be generated upon finalization of Appendix C.

must include initial demonstration of method performance certificates as detailed in Appendix C (Laboratory Requirements Appendix) and MDLs for applicable methods. Supporting data and documentation does not need to be included.

9. *SOPs*: A list of titles of the laboratory's currently approved standard operating procedures (SOPs), with SOP number, revision number, and date of approval. As applicable to the assessment, the laboratory shall submit at least one SOP associated with each of the following categories:

   - Organics
   - Inorganics
   - General Chemistry
   - Radiochemistry
   - QA Program and Operations

   Note: The laboratory shall compile a complete set of all applicable SOPs for assessor review. The assessors may also request additional specific SOPs.

10. *Proficiency Testing*: Copies of the results (including corrective actions as appropriate) from nationally recognized PT programs completed during the last two years, including as appropriate: EPA CLP Quarterly Blinds; EPA EMSL-LV Radiochemistry Intercomparison Program; and United States Army Corps of Engineers (USACE) PT Program; Air Force Center for Environmental Excellence (AFCEE) PT Program.

Navy Installation Restoration Laboratory Information Sheet

Legal Name of Laboratory: _____

Street Address: _____
_____
_____

Mailing Address: _____
(if different)
_____
_____

Fax Number: _____ Hours of Operation: _____

Name of Owner: _____

Owner Address: _____
(If different from above) _____
_____

	Name	Phone Number
Laboratory Director:		
Laboratory Quality Manager:		
Quality Assurance Officer:		

The undersigned persons understand and acknowledge that the laboratory will be assessed in accordance with the *Navy Installation Restoration Chemical Data Quality Manual*. The laboratory has received and reviewed this manual and is prepared to proceed.

The under-signed persons understand and acknowledge that the Navy or its Contractor will conduct an on-site assessment and may perform unannounced follow-up assessments.

I hereby certify that I am authorized to sign this form on behalf of the owner and that there are no misrepresentations in the information provided in the initial laboratory assessment package.

_____ _____
Signature of Quality Manager Date

_____ _____
Signature of Laboratory Director Date