



# **Demonstration of Competency Using the NEFAP-TNI Accreditation Program for a Field Sampling and Measurement Organization (FSMO)**

July 2015

Presented by Kim B. Watson

2015 Environmental Measurement Symposium, "Big Data: Environmental Measurement and Monitoring Data in the 21st Century."

# Field Sampling and Measurement Organization

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## Accreditation Process

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Definitions

Sample Planning

Demonstration of Competency

What is NEFAP?

Getting Accredited

Standard Operating Procedures

Quality Systems Manual





# Field Sampling and Measurement Organizations

## Environmental Data:

**Any measurements or information that describe environmental processes, help environmental processes, any manufactured or natural processes that produce discharges to, or that impact, the ambient environment, location, or conditions; ecological or health effects and consequences; or the performance of environmental technology. For EPA, environmental data include information collected directly from measurements, produced from models, and compiled from other sources such as data bases or the literature.**

EPA CIO 2105-P-01-0 - EPA Quality Manual for Environmental Programs Glossary



# Field Sampling and Measurement Organizations

## Definitions

**Field:** Any location outside the controlled environment of a laboratory

**Field Sampling:** The process of obtaining a representative portion of an environmental matrix suitable for laboratory or field measurement or analysis

**Field Measurement:** The quantitative determination of physical, chemical, biological or radiological properties of a matrix by measurements made in the field





# The History behind Environmental Data?

Environmental Data. What is it?

Environmental data used in the public and private sector are the foundation upon which many environmental decisions are made.

1970's

1980's

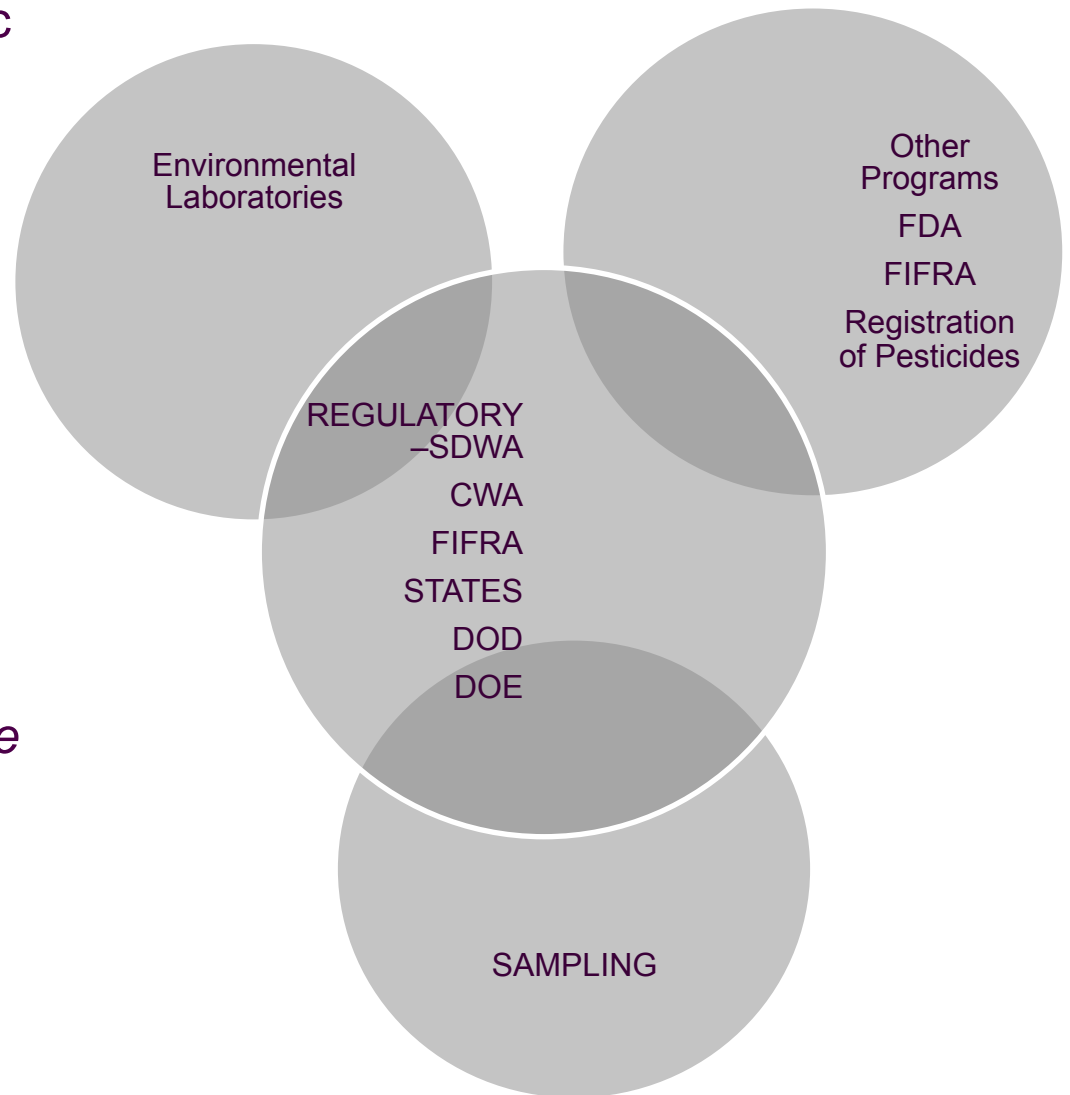
1990's

2000's

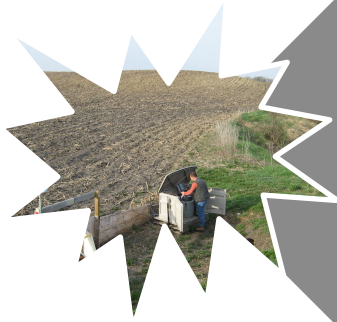
2010's

*"The quality assurance unit shall inspect each study at intervals adequate to ensure the integrity of the study."*

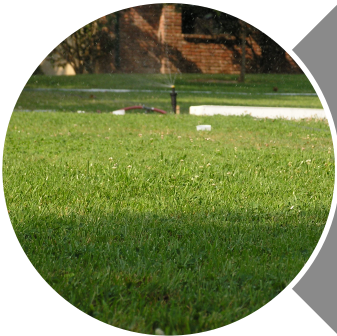
-40 CFR Part 160 § 160.35



# Decision Making and Planning



The critical nature of these decisions requires the underlying data to be of known and documented quality



Decisions on environmental impact, regulatory compliance, financial and economical considerations are among the many derived from environmental Field Sampling and Measurement Organizations (FSMOs)



Sample planning, collection techniques, preservation and transportation all have a significant impact on the final results

# Decision Making and Planning

**The quality of the final data is only as high as the quality of the sample collected or field measurement taken.**

Whether a project is complex, involving both field-testing procedures and analyses, or a basic field sampling and/or measurement event, it is critical that the quality of the samples and measurements/data and the competency of those collecting the samples and measurements be **known, documented, and traceable.**



# Decision Making and Planning

Environmental sampling and testing processes vary significantly depending on the scope of the project or objectives but one common keystone is that data are generated initially through sample collection, field measurements or by analysis of samples.

The fieldwork, whether collecting samples or measurements/data, is one of the core steps in generating environmental data.

Fieldwork is also one of, if not the most significant sources of data variability and error in the data collection process.

# Guidance, Directives, Regulations

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## INSPECTOR GENERAL

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September 5, 2001

Open Letter to the Environmental  
Analytical Laboratory Community

Attention to issues of misconduct or  
unethical practices in analytical  
laboratories, related to inappropriate  
manipulation of laboratory data...

“I encourage you to evaluate your  
Quality Systems, with particular  
attention to the detection and  
prevention of improper laboratory  
activities”





























Contract Laboratory Programs  
State Regulatory Programs  
DOD Regulatory Programs  
ACCREDITATIONS

PROFICIENCY TESTING

REGULATE

ACCREDIT

# SYSTEMATIC PLANNING

 5360	8/27/2001
 5360-1	8/27/2001
 Checklist for QMPs	8/27/2001
 Checklist for Quality Concerns	8/27/2001
 G-1, Final	2/18/2003
 G-3, Final	5/28/2003
 G-4, Final	8/27/2001
 G-4D, Final	6/22/2002
 G-4HW, Final	8/27/2001
 G-5, Final	2/18/2003
 G-5G, Final	5/28/2003
 G-5i, Peer Review Draft	6/22/2002
 G-5M, Final	2/18/2003
 G-5S, Final	2/18/2003
 G-6, Final	8/27/2001
 G-7, Final	8/27/2001
 G-8, Final	2/18/2003
 G-9, Final	8/27/2001
 G-9D, Final	8/27/2001
 G-10, Final	8/27/2001
 OCP Fact Sheet	8/9/2003 4
 OSWER Directive 9272-0-17	7/8/2005 1
 Overview of EPA Quality Systems, Final	2/18/2003
 R-2, Final	8/27/2001
 R-5, Final	8/27/2001
 TF Example	2/18/2003
 Triad Fact Sheet	8/9/2003 5
 Triad Resources Fact Sheet	8/9/2003 6





# Systematic Planning and Sampling

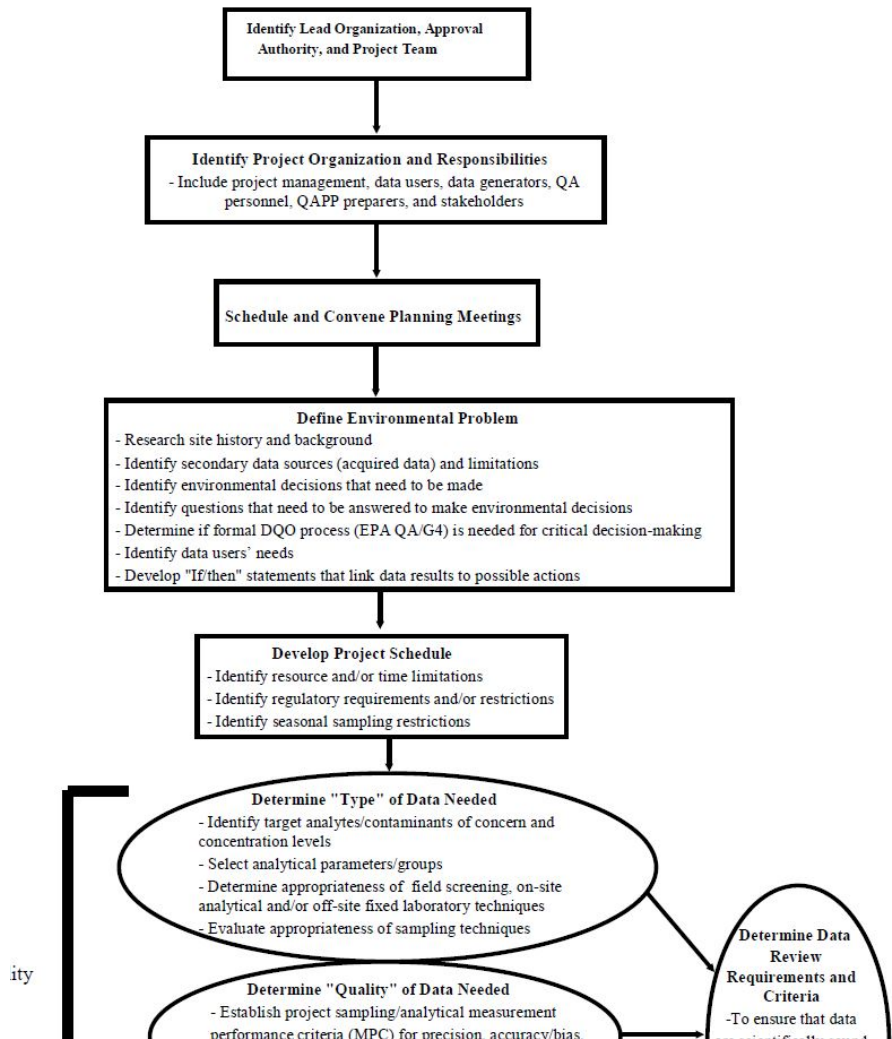
SW846 1986

EPA Region 1 "EPA NEDRP 4/22/2013

Figure 1. EPA NE Systematic Planning Process

## Section

1.0	INTRODUCTION . . . . .
2.0	QA PROJECT PLAN . . . . .
2.1	DATA QUALITY OBJECTIVES . . . . .
2.2	PROJECT OBJECTIVES . . . . .
2.3	SAMPLE COLLECTION . . . . .
2.4	ANALYSIS AND TESTING . . . . .
2.5	QUALITY CONTROL . . . . .
2.6	PROJECT DOCUMENTATION . . . . .
2.7	ORGANIZATION PERFORMING FIELD OR LABORATORY OPERATIONS . . . . .
2.7.1	Performance Evaluation . . . . .
2.7.2	Internal Assessment by QA Function . . . . .
2.7.3	External Assessment . . . . .



# EPA FIFRA, TSCA, FDA PROGRAM

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## 40 CFR Part 160, Part 792, 21 CFR Part 58

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Requires third party inspections of all critical phases of a STUDY

Performed by a qualified

Study Objective-Protocol

Quality  
Assurance  
Unit

Field Phase

Sampling Phase

Professional

Reporting Phase

*“The quality assurance unit shall inspect each study at intervals adequate to ensure the integrity of the study.”*

-40 CFR Part 160 § 160.35

# REGULATORY PROGRAMS

## Guidance Documents



OSWER 9240.0-47  
EPA 540-R-09-03

January 2011

Office of Superfund Remediation and Technology Innovation



**Sampler's  
Guide**



**Contract Laboratory Program  
Guidance for Field Samplers**

**Disclaimer:** This version of the document replaces any prior versions of the document in their entirety.





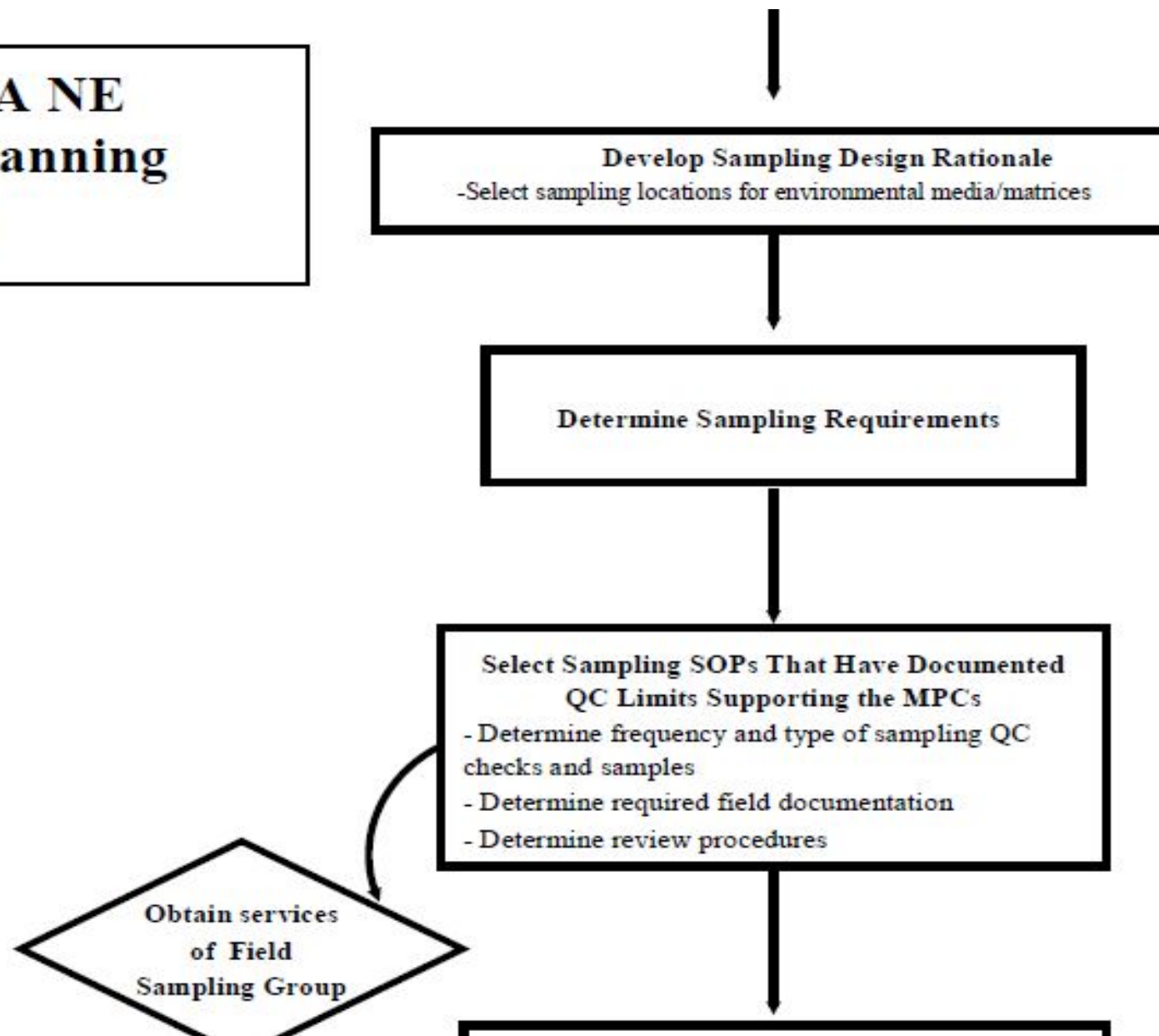


**Figure 2. QAPP Process Elements**

The four basic element groups of a QAPP present a framework consistent with *EPA Requirements for Quality Assurance Project Plans* (EPA QA/R-5), which requires use of a systematic planning process. The inconsistencies in language between the UFP-QS and the UFP-QAPP Manual are due to the different purposes of the documents. The UFP-QS, which outlines a six-step process, serves as a high-level policy document for implementing quality systems, as defined in ANSI/ASQ E4. Thus, it describes the systematic planning process at a conceptual level. This UFP-QAPP Manual is an implementation guide that significantly expands on the UFP-QS. Table 1 identifies how the four QAPP element groups outlined in the UFP-QAPP Manual and the detailed systematic planning process shown in Figure 13 (Section 2.6.1) address the six planning process elements outlined in the UFP-QS Section 7.2.

**Table 1. Comparison of UFP-QS and UFP-QAPP Systematic Planning Process**

**EPA NE  
c Planning  
ont.**



# WHY a FSMO Should Seek Accreditation

## POLICY TO ASSURE THE COMPETENCY OF ORGANIZATIONS GENERATING ENVIRONMENTAL MEASUREMENT DATA UNDER AGENCY-FUNDED ASSISTANCE AGREEMENTS

*Agency Policy Directive Number  
FEM-2012-02*

*Revision 1; Approved: March 13,  
2013*

## PURPOSE

This document establishes the U.S. EPA's policy requiring organizations generating or using environmental data under certain Agency-funded assistance agreements to **submit documentation of their competency** prior to beginning any work involving the generation or use of environmental data under the agreement. **This includes organizations performing environmental sampling, field measurements, and/or laboratory analyses under Agency-funded agreements.**



# WHY a FSMO Should Seek Accreditation

## Competence –

As defined in ISO 9000, competence is the demonstrated ability to apply knowledge and skills.

Documentation of competency may include:

Current participation in accreditation or certification programs that are applicable to the environmental data generated under the Agency-funded assistance or interagency agreement;

Ongoing participation by the organization in proficiency testing (PT) or round robin programs conducted by external organizations;

Ongoing U.S. EPA accepted demonstrations and audits or assessments of proficiency; and

Other pertinent documentation (e.g., statement of work [SOW]).

# WHAT IS NEFAP?

FSMO-V1-ISO-2014-Rev.2.0



## FIELD SAMPLING AND MEASUREMENT ORGANIZATION SECTOR

### VOLUME 1

## GENERAL REQUIREMENTS FOR FIELD SAMPLING AND MEASUREMENT ORGANIZATIONS

### TNI Standard

P.O. Box 2439  
Weatherford, TX 76086  
817-598-1624  
[www.nelac-institute.org](http://www.nelac-institute.org)

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# WHAT IS NEFAP?

## About NEFAP

The purpose of the National Environmental PT Field Activities Program (NEFAP) Executive Committee is to **establish and implement an accreditation program for field sampling and measurement organizations (FSMOs).**

[Learn more...](#)





# WHAT IS NEFAP?

## NEFAP Program Structure

NEFAP is not part of the National Environmental Laboratory Accreditation Program (NELAP). While both programs are based on similar ISO/IEC foundations and both have similarities, there are distinct differences between the two programs and they are operated independently of each other. **The NEFAP program is designed and developed specifically for those organizations performing field activities.**





# GET ACCREDITED USING THE NEFAP STANDARD!!

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## Taken From The TNI-NELAC Website:

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### How to Become an Accredited FSMO

Become familiar with the [General Requirements for Accreditation Bodies Accrediting Field Sampling and Measurement Organizations](#) (FSMO-V1-2008), and implement the program to comply with the requirements. Check back early February 2015 for new tools that will help an FSMO implement the Standard.

The new Standard (FSMO-V1-2014) goes into effect on March 15, 2015.

The 4 Accreditation Bodies (ABs) now accepting Field Sampling and Measurement Organization (FSMO) applications are:

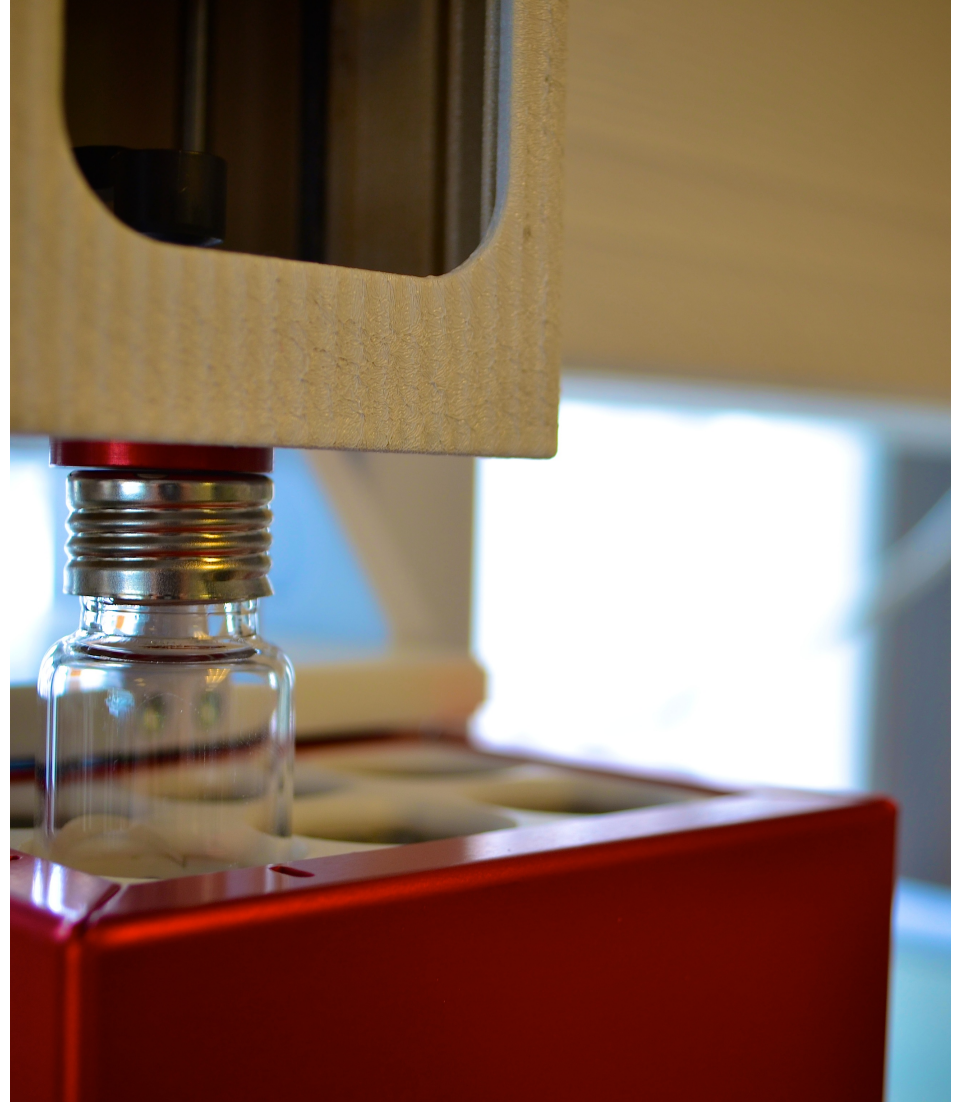
[ANSI-ASQ National Accreditation Board](#)  
[American Association for Laboratory Accreditation \(A2LA\)](#)  
[Laboratory Accreditation Bureau \(L-A-B\)](#)  
[Perry Johnson Laboratory Accreditation, Inc. \(PJLA\)](#)

An [FSMO Checklist](#) is available to help you prepare. You must own a copy of Volume 1 of the TNI NEFAP Standard that includes the ISO language, or own a copy of the Standard, in order to download the checklist.

**Questions?** Contact Ilona Taunton, NEFAP Program Administrator, at [ilona.taunton@nelac-institute.org](mailto:ilona.taunton@nelac-institute.org) or Kim Watson, NEFAP Executive Committee Chair, at [kwatson@stone-env.com](mailto:kwatson@stone-env.com).

# STANDARD OPERATING PROCEDURES

## Lab and Field Measurements





# STANDARD OPERATING PROCEDURES



## Field Measurements

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### STANDARD OPERATING PROCEDURE

SEI-6.43.4

### ***GROUNDWATER PROFILING AND KPRO TESTING***

SOP Number: SEI-6.43.4

Revision Number: 4

Date Issued: 08/13/02

Date of Revision: 7/8/2014

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#### **1.0 OBJECTIVE**

Groundwater profiling is conducted to assess the distribution of contaminants and hydrogeologic conditions of a given aquifer at a scale much smaller (several centimeters) than the conventional monitoring well system. This method uses the Waterloo<sup>APS</sup> (Advanced Profiling System) to collect groundwater samples at multiple discrete depths as the profiler is advanced vertically through unconsolidated, saturated porous media at a given location. The Waterloo<sup>APS</sup> is a direct push tool used to collect samples and other data at

# DATA INTEGRITY

## DATA Integrity

**In-teg-ri-ty** n.

1. Strict adherence to a standard of value or conduct.
2. Personal honesty and independence.
3. Completeness: unity
4. Soundness

Source: Webster's II New Riverside Dictionary,  
Based on the Webster's II New College  
Dictionary (1996)





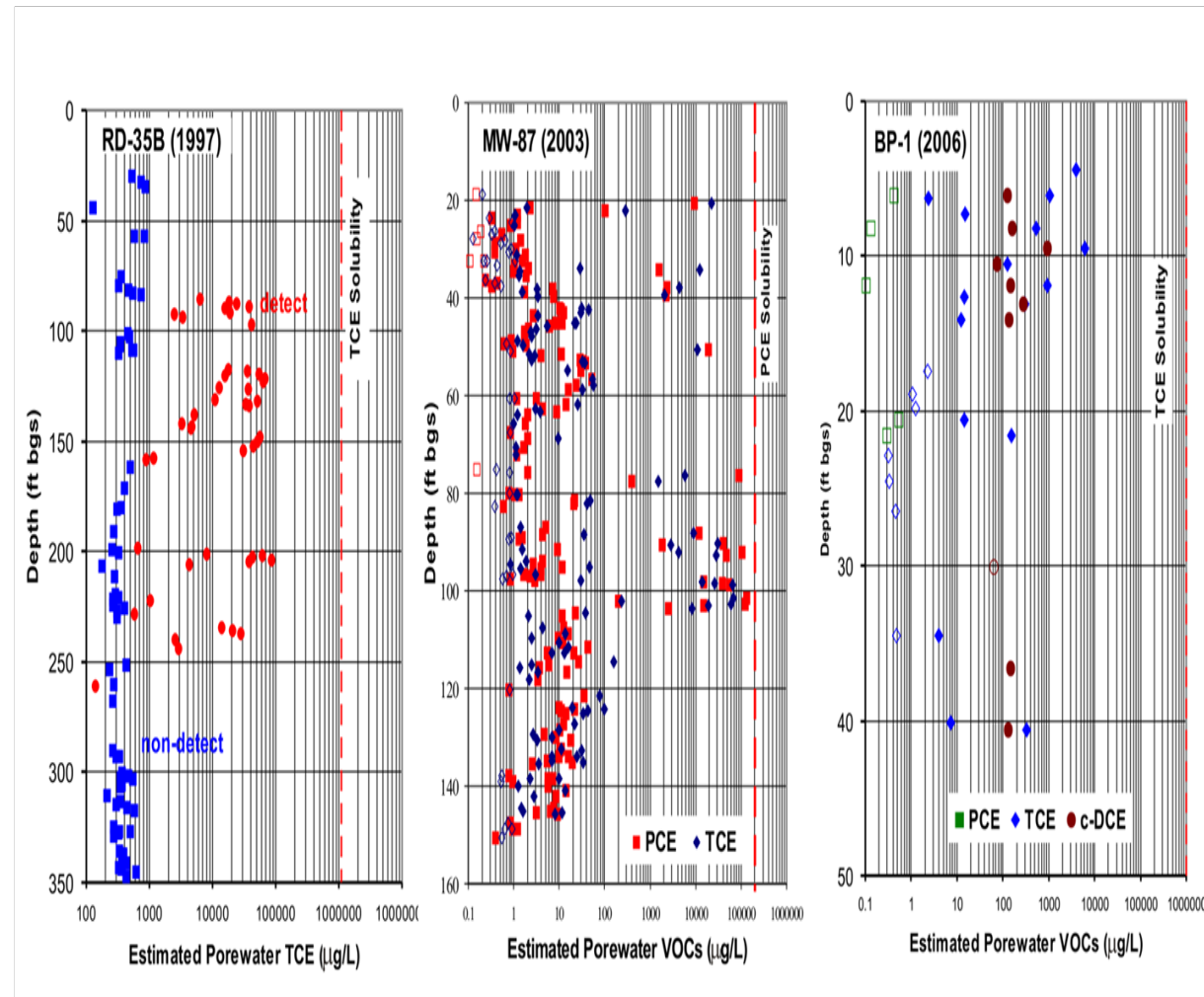
# DATA ETHICS

## Ethics

1. A principle of right or good conduct.
2. A system of moral values
3. The branch of philosophy dealing with the rules of right conduct.

The word ethics finds its root in the Greek word ethos, meaning habit.

Source: Webster's II New Riverside Dictionary, Based on the Webster's II New College Dictionary (1996)



# QUALITY SYSTEMS MANUAL

## WHAT IS IT?:

The quality manual shall include or make reference to the supporting procedures including technical procedures.

It shall outline the structure of the documentation used in the management system.

## LABORATORY and FIELD SAMPLING QUALITY SYSTEMS MANUAL

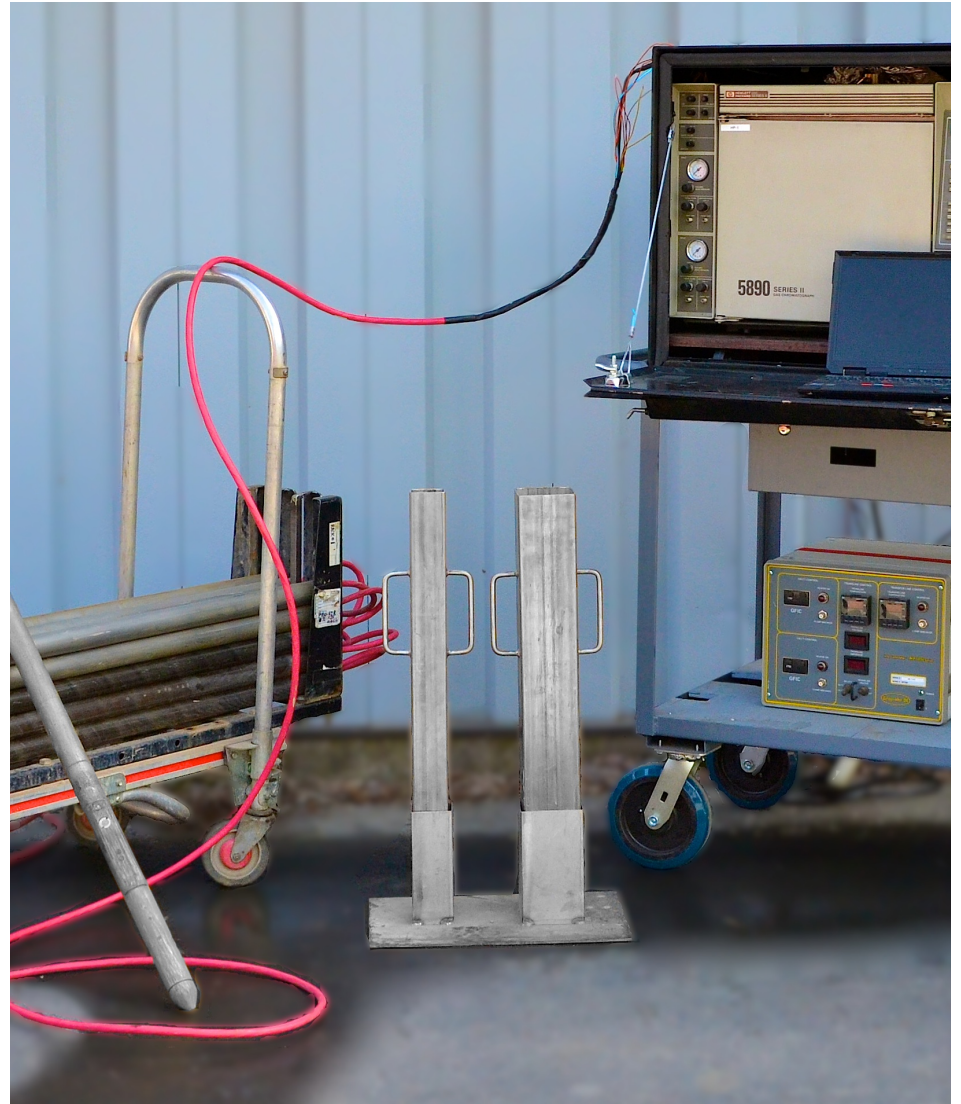


# GET ACCREDITED

## NEFAP

Is this program required?

The NEFAP Program is a voluntary program and is not required by regulation. The program may be required in contractual agreements or for work under programs or contracts in which the contracting organizations want to assure there is documented competency to a known standard.





***“Quality means doing it right when no one is looking.”  
— Henry Ford... Thank You, Questions???***

