

*Procurement of Standards, Reagents &
Reference Materials and Maintaining
Proper Traceability*

{ TNI Assessment Forum, Crystal City, VA
{ February 4, 2015

- & Purchasing
- & Receiving
- & Labeling & Documenting
- & Traceability

Overview

- ⌘ Accountability for Materials Used in Testing
- ⌘ Reproducibility
- ⌘ Defensibility of Generated Data
- ⌘ Management Tool
- ⌘ Quality Control
- ⌘ Troubleshooting Tool
- ⌘ Required for Standards by Regulation
- ⌘ Required by Standard Methods (SM)

Why?

⌘ **4.6 Purchasing Services and Supplies (ISO/IEC 17025:2005(E), Clause 4.6)**

⌘ *4.6.1 The laboratory shall have a policy and procedure(s) for the selection and purchasing of services and supplies it uses that affect the quality of the tests and/or calibrations. Procedures shall exist for the purchase, reception and storage of reagents and laboratory consumable materials relevant for the tests and calibrations.*

TNI 2009 Standard Review
EL-V1M2, Section 4.6

- ⌘ Contracts for acquiring Standards, Reagents and Reference Materials
 - ⌘ Piggy Backing
 - ⌘ Low Bid
 - ⌘ Sole Source
 - ⌘ Blanket Contract
- ⌘ Procurement/Finance Departments
- ⌘ Credit Card Authorized Purchases
 - ⌘ Limits to amounts?
 - ⌘ Reimbursements
 - ⌘ PayPal used
- ⌘ Renewals at a specified frequency – annually?
- ⌘ Written Policy & Procedures

Procuring

⌘ 4.6.2 *The laboratory shall ensure that purchased supplies and reagents and consumable materials that affect the quality of tests and/or calibrations are not used until they have been inspected or otherwise verified as complying with standard specifications or requirements defined in the methods for the tests and/or calibrations concerned. These services and supplies used shall comply with specified requirements. Records of actions taken to check compliance shall be maintained.*

TNI 2009 Standard Review
EL-V1M2, Section 4.6

- ⌘ Sign Certificate of Analysis (CofA) as “received on” date/initials.
- ⌘ Label chemicals with “received on” & “opened on” dates with initials.
- ⌘ Inspect CofA’s to ensure they include certificates that meet the method criteria.
 - ⌘ May still need to verify values prior to using.
 - ⌘ Must verify the concentration of titrants affecting the quality of test and/or calibration.
- ⌘ Who is responsible for maintaining the shipping documentation as received?

Receipt

⌘ 4.6.3 *Purchasing documents for items affecting the quality of laboratory output shall contain data describing the services and supplies ordered. These purchasing documents shall be reviewed and approved for technical content prior to release.*

NOTE: The description may include type, class, grade, precise identification, specifications, drawings, inspection instructions, other technical data including approval of test results, the quality required and the management system standard under which they were made.

TNI 2009 Standard Review
EL-V1M2, Section 4.6

⌘ 4.6.4 *The laboratory shall evaluate suppliers of critical consumables, supplies and services which affect the quality of testing and calibration, and shall maintain records of these evaluations and list those approved.*

TNI 2009 Standard Review
EL-V1M2, Section 4.6

- ⌘ Contract Renewals – Time for Review
- ⌘ QA, Supervisors or Manager – Who Reviews?
- ⌘ Techs/Chemist can provide Valuable Input as to the Usability of the Standard/Reagent/Reference Standard.

Contract Reviews

⌘ 5.6.4.2 Documentation and Labeling of Standards, Reagents, and Reference Materials

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

- a) The laboratory shall retain records for all standards, reagents, reference materials, and media, including the manufacturer/vendor, the manufacturer's Certificate of Analysis or purity (if available), the date of receipt, and recommended storage conditions.
- b) For original containers, if an expiration date is provided by the manufacturer or vendor it shall be recorded on the container. If an expiration date is not provided by the manufacturer or vendor it is not required.

TNI 2009 Standard Review
EL-V1M2, Section 5.6.4.2

- ⌘ Many labs place an arbitrary expiration date when the vendor does not provide one.
- ⌘ Safety Data Sheets (SDS) will also be provided and would require retention as well.
- ⌘ Don't rely on the company's website to store CofA's that should be downloaded when acquired. Keep your own copies.

Documenting & Labeling

Continued...5.6.4.2 Documentation and Labeling of Standards, Reagents, and Reference Materials

- c) Records shall be maintained on standard, reference material, and reagent 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 standards, reference materials, and reagents shall bear a unique identifier and expiration date.
- e) Procedures shall be in place to ensure prepared reagents meet the requirements of the test method.
- f) Standards, reference materials, and reagents shall not be used after their expiration dates unless their reliability is verified by the laboratory.

TNI 2009 Standard Review
EL-V1M2, Section 5.6.4.2

- ⌘ A Unique Identifier; Lot Number, but need System for Intermediate & Working Standards
- ⌘ Written Standards Logbook
- ⌘ Laboratory Bench sheets include Traceability
- ⌘ Electronic Forms or Logbooks
 - ⌘ LIMS used for Standard/Reagent Traceability

Traceability

PH Buffer Manufacture	PH Buffer Lot #	Received Date	Received Date	Expiration Date
FISHER PH4	R206298 AOT 121125	06-27-12 ED	07-05-13 ED	03-2014
FISHER PH7	R205154 120143	05-03-12 JVR	03-12-13 JD	01-2014
FISHER PH10	R305038 130533	03-29-13 SM	05-10-13 JVR	02-2015
RICCA PH6	R302342 1211572	02-28-13 JVR	08-08-13 SD	11-2014
FISHER PH4	R404004 130155	03-29-13 SM	03-14-14 JKV 04-14-14 JH	01-2015
FISHER PH7	R309214 130534	03-29-13 SM	04-14-14 LS 12-14-14 LS	01-2015
FISHER PH10	R305088 130533	03-29-13 SM	12-19-13 SA	02-2015
RICCA PH6	R400182 1401960	06-16-14 ED	06-12-14 JAR 12-14-14 SA	01-2016 05-2016
RICCA PH6	R400192 1405967	06-16-14 ED	08-11-14 SA	05-2016
FISHER PH10	R400164 141488	06-12-14 JRV	10-09-14 LS	03-2016
FISHER PH4	R406163 141956	06-12-14	01-20-15 SA	04-2016

PREPARATION BENCH SHEET

B501300














RWRD CRAO Laboratory

Printed: 1/22/2015 12:03:59

Matrix: Water

Prepared using: Inorganic - No Prep - Inorganics

(No Surrogate)

Lab Number	Analysis	Prepared	Initial (mL)	Final (mL)	Spike ID	Source ID	ul Spike	ul Surrogate	Code 128	Extraction Comments
1501041-06	Ammonia Probe	01/22/2015 11:57	50	50						
1501055-02	Ammonia Probe	01/22/2015 11:57	50	50						
1501080-01	Ammonia Probe	01/22/2015 11:57	50	50						
1501081-01	Ammonia Probe	01/22/2015 11:57	50	50						
1501121-01	Ammonia Probe	01/22/2015 11:57	50	50						
1501122-01	Ammonia Probe	01/22/2015 11:57	50	50						
B501300-BLK1	QC	01/22/2015 11:57	50	50						
B501300-BS1	QC	01/22/2015 11:57	50	50.75	R410270		750			
B501300-BS2	QC	01/22/2015 11:57	50	50.75	R410270		750			
B501300-BS3	QC	01/22/2015 11:57	50	50.75	R410270		750			
B501300-BS4	QC	01/22/2015 11:57	50	50.75	R410270		750			
B501300-MS1	QC	01/22/2015 11:57	50	50.75	R410270	1501122-01	750			
B501300-MSD1	QC	01/22/2015 11:57	50	50.75	R410270	1501122-01	750			

Reagents & Standards

Standard ID	Description	Prepared Date	Expiration Date
R410270	AMMONIA 1000 PPM SECOND SOURCE	10/28/2014 00:00	08/31/2019 00:00
R405190	Ammonia pH Adjusting ISA	09/27/2013 00:00	09/27/2028 00:00

ANALYSIS SEQUENCE

SS01052

Instrument: Orion ISE #1

Calibration ID: UNASSIGNED

Printed: 1/22/2015 15:40:06

Lab Number	Analysis	Container	Order	Position	STD ID	ISTD ID	Client	Comments
SS01052-CAL1	QC		1		R412284			
SS01052-CAL2	QC		2		R412283			
SS01052-CAL3	QC		3		R412282			
SS01052-ICV1	QC		4		R412285			
SS01052-SCV1	QC		5		R412286			
B501300-BS1	QC		6					
B501300-BS2	QC		7					
B501300-BS3	QC		8					
B501300-BS4	QC		9					
B501300-BLK1	QC		10					
1501041-06	Ammonia Probe	A	11				Sub-regional Facilities	
1501055-02	Ammonia Probe	D	12				PC Department of Environmental Quality	
1501080-01	Ammonia Probe	A	13				CRAO	
1501081-01	Ammonia Probe	A	14				CRAO	
1501121-01	Ammonia Probe	A	15				CRAO	
1501122-01	Ammonia Probe	A	16				CRAO	
B501300-MS1	QC		17					
B501300-MSD1	QC		18					
SS01052-CCV1	QC		19		R412285			
SS01052-CCV2	QC		20		R412285			

LIMS
Traceability
Example

- ⌘ Tracking Reagents, Standards, and Reference Material from Date of Receipt throughout the Laboratory is an Essential Quality Control Practice
- ⌘ Lends Legal Defensibility and Accountability to the Data Generated by the Laboratory
- ⌘ Can Help your Laboratory Maintain a Cost Efficient System for their Use in Testing
- ⌘ Part of a Reliable Quality Assurance Program

Summary