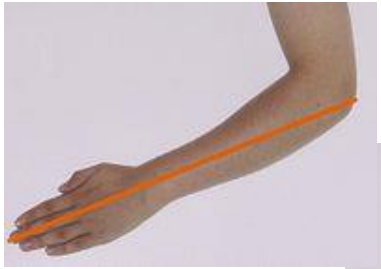
Creating a Robust and Sustainable Quality Assurance Program

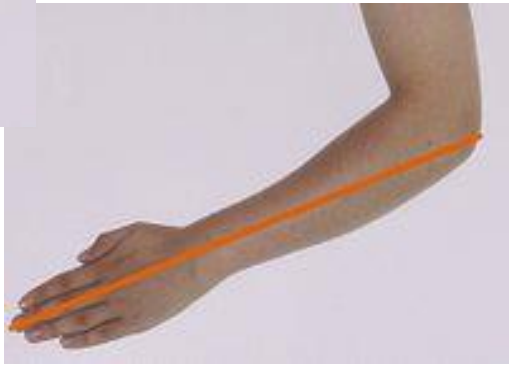
Kevin Thompson
Sr. Manager, Engineering & Technical Team

Outline

- History of measurement
- Definition of Certified Reference Material (CRM)
- Basics of quality assurance
  - Method development
  - Staff training
  - Ongoing performance
  - Corrective action
- Proficiency Testing (PT)
- Summary

Historical measurement





- Measurement of goods such as cloth used the ell
  - The combined length of the forearm and extended hand
  - Your ell is different to my ell!

- How did they standardise the ell/cubit?
  - Hanseatic league agreed to use a statue on the market place as a reference
  - Roland statue - one Bremen ell is the distance between his knees
  - Frankfurt still has the Frankfurter Elle in old town

- Not very scientific and not very accurate!

http://en.wikibedia.ru/wiki/Ell: https://whc.unesco.org/en/documents/137978
https://commons.wikimedia.org/wiki/File:Frankfurt_Leinwandhaus_Frankfurter_Elle.jpg

Metrology in chemistry – Why is it so important?

- Chemical measurements are used to make important decisions:
  - Food safety
  - Water quality
  - Environmental quality
  - Occupational health & safety
  - Safety and quality of medicines
  - Clinical diagnoses
  - Criminal investigations & legal proceedings
  - Authenticity
  - International trade
  - New products, materials, pharmaceuticals
- Metrology in quality assurance - quality can be defined as the degree to which an item satisfies the given need it was designed to fulfill, i.e. its fitness for the purpose.

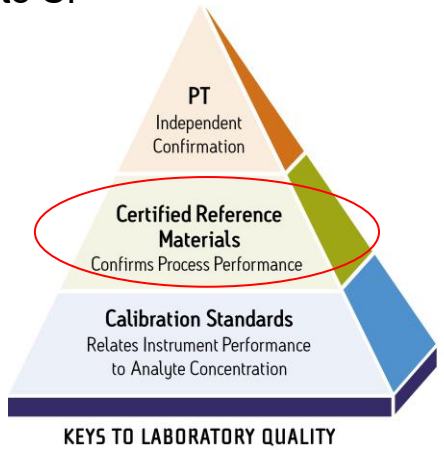
Definition of Certified Reference Material

ISO 17034:2016 Sect 3.1

"Reference material characterized by a metrologically valid procedure for one or more specified properties, accompanied by a reference material certificate that provides the value of the specified property, its associated uncertainty, and a statement of metrological traceability".

Certified Reference Materials - CRMs

- Characteristics of Certified Reference Materials:
  - Known concentrations (assigned values)
  - Known uncertainty, homogeneity and stability
  - Assigned values are traceable through an unbroken chain of comparisons to SI
  - Includes a certificate of analysis (CofA)
- Uses
  - Method development and validation
  - Analyst training and demonstration of capability
  - Routine quality control
  - Calibration
  - Corrective action/troubleshooting



CRMs are used to evaluate measurement accuracy on a routine basis

ERA certified reference material CoA details

Actual “made-to” value verified by ERA analytical testing

Expanded uncertainty at ~95% confidence interval

Fixed acceptance limits (per NELAC) from the PT round

Based on historical data collected in ERA PT studies. Use to evaluate performance to your peers

Certified Reference Material

▪ Certificate of Analysis ▪

Product: WatR™ Pollution PFAS in Wastewater
Catalog Number: 404
Lot No. P336-404
Certificate Issue Date: March 13, 2023
Expiration Date: December 12, 2024
Revision Number: 1.0
Revision Date: April 18, 2023

Product use instructions are included as part of the certification packet and are paginated separately from this Certificate of Analysis. Please reference the product use instructions for catalog #404 revision 123022.

CERTIFICATION

Parameter	Certified Value[1]	Uncertainty[2]	QC Performance Acceptance Limits[3]	PT Performance Acceptance Limits[4]
	ng/L	%	ng/L	ng/L
11-chloroeicosafluoro-3-oxaundecane-1-sulfonic acid (11Cl-PF3OUdS)	300	9.5	254 - 363	219 - 372
9-chlorohexadecafluoro-3-oxanonane-1-sulfonic acid (9Cl-PF3ONS)				
4,8-dioxa-3H-perfluorononanoic acid (DONA)				

ERA certified reference material CoA details

Waters™ | ERA

Actual “made-to” value verified by ERA analytical testing

Analytical traceability to a NIST SRM where available

Certified Reference Material

▪ Certificate of Analysis ▪

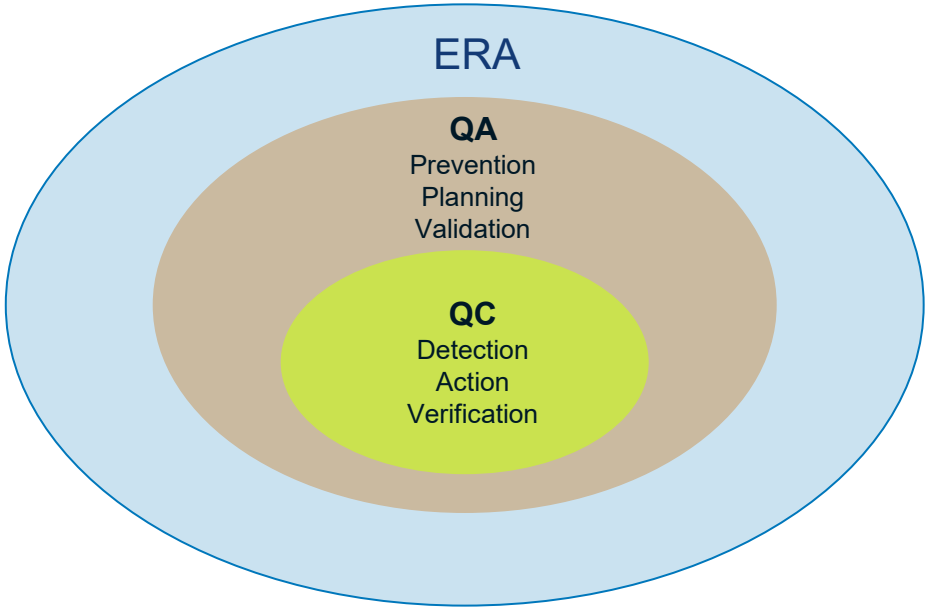
ANALYTICAL VERIFICATION

Parameter	Certified Value[1]	Proficiency Testing Study			NIST Traceability	
		Mean	Recovery[5]	n	SRM Number[6]	Recovery
	ng/L	ng/L	%			%
Perfluorobutanesulfonic acid (PFBS)	176	162	91.4	49	-	-
Perfluorobutanoic acid (PFBA)			93.5	46	-	-
Perfluorodecane sulfonic acid (PFDS)			92.5	44	-	-

Study mean, recovery and number of participants per analyte

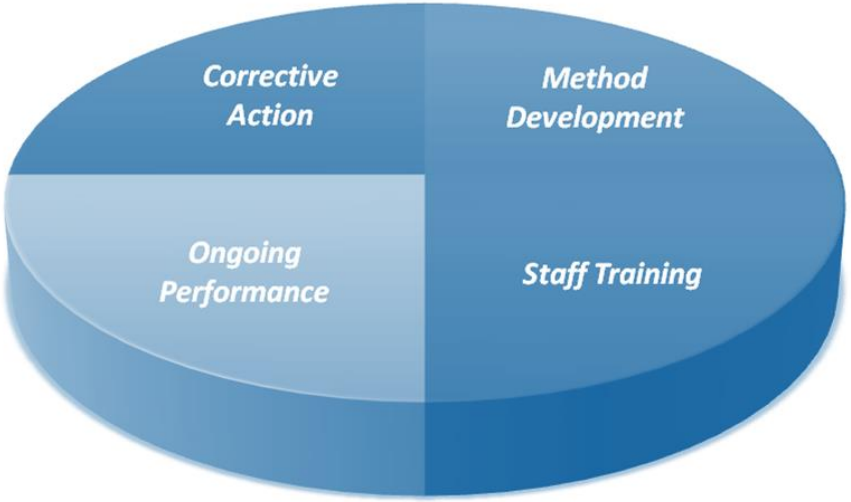
The difference between Quality Control and Quality Assurance

- Quality Control is *Product* Focused
  - Focused on fulfilling the quality requirements
  - Goal is to detect defects
  - Think: Testing
- Quality Assurance is *Process* Focused
  - Provides confidence that quality requirements will be fulfilled
  - Goal is to prevent defects
  - Think: Audits



Basics of Quality Assurance

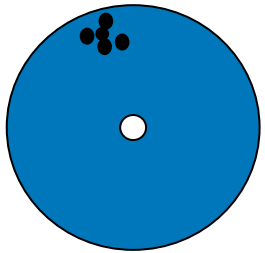
- Laboratory responsibilities with the aid of CRMs
  - Method development
  - Staff training
  - Ongoing performance
  - Corrective action



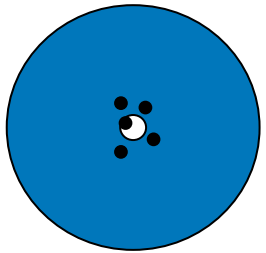
Method development and validation

- Method limitations
- Ruggedness
- Sensitivity and linear range
- Precision
  - “Degree of agreement between independent measurements under controlled conditions”
  - How close repeated measurements are to each other
  - Represented by standard deviation
- Accuracy
  - “Degree of agreement of a measured value with the true or expected value”
  - How close measurements are to the “true” value
  - Represented by the percent recovery

METHOD VALIDATION



Precise but not accurate



Accurate but not precise

Staff training

- Initial training
  - Communicating procedures
  - Hands on training
  - Observe a newly trained analyst
  - Lab safety rules
  - Importance of ethics

- Ensure that the training was effective
  - CRMs are effective tools
  - Document precision and accuracy

Ongoing performance

- Many variables in a laboratory
  - Analysts
  - Instruments
  - Standards and reagents
  - Laboratory environment
  - Sample matrix
  - Random errors
- Routine use of CRMs
  - Extraction efficiency
  - Calibration
  - Continuing calibration verification (CCV)
  - Independent calibration verification (ICV)

INTERNAL DIGESTION AND EXTRACTION EFFICIENCIES

CALIBRATION / VERIFICATION

Corrective action

- Corrective action indicators
  - Failed proficiency test
  - Calibration failure
  - Data outside control chart limits
- Corrective action process
  - Root cause analysis
    - Machine
    - Material
    - Method
    - Analyst
  - Implement corrections
  - Confirm corrections are appropriate and effective
    - Analyze CRM
    - Long term control charting

Benefits of using CRMs

- CRMs provide the reference, or traceability to a known value
- The quality (accuracy, reliability and appropriateness) of the CRM directly affects the value of the data a laboratory provides
- A questionable CRM is a broken link

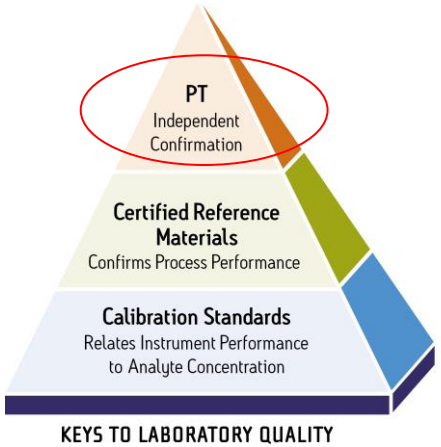
Analysis

Data

Without a quality CRM, any analysis is only an opinion

What is proficiency testing?

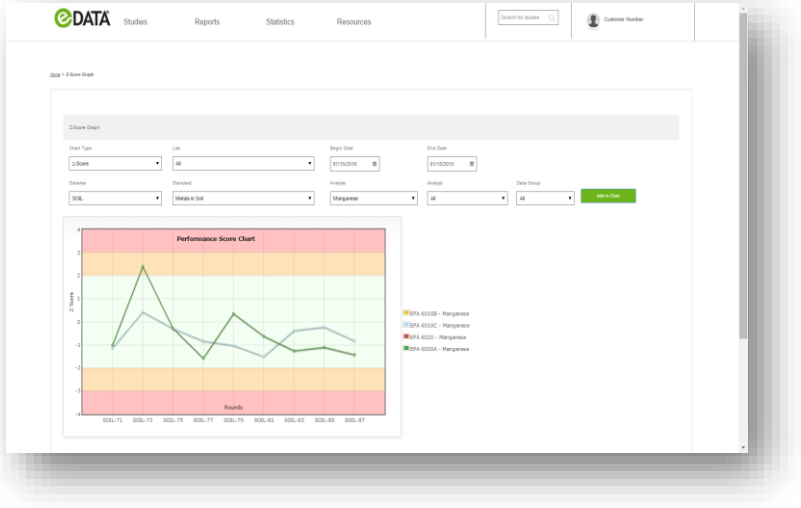
- Proficiency testing is the use of interlaboratory comparisons as part of an assessment of performance.
  - Proficiency testing programs require the laboratory to analyze unknown samples using a standard, national, or specified method within a specific timeframe.
  - Participation in many cases is a requirement for license or accreditation of the laboratory and often required by customers of laboratory data
  - One of the primary uses of PT schemes is to assess laboratories' ability and competency to perform analytical tests
  - PT is globally recognized as a critical component to qualifying laboratory data quality and comparability



PT equals independent evaluation of performance and a way to demonstrate your labs expertise

Additional uses of PT – more than just accreditation

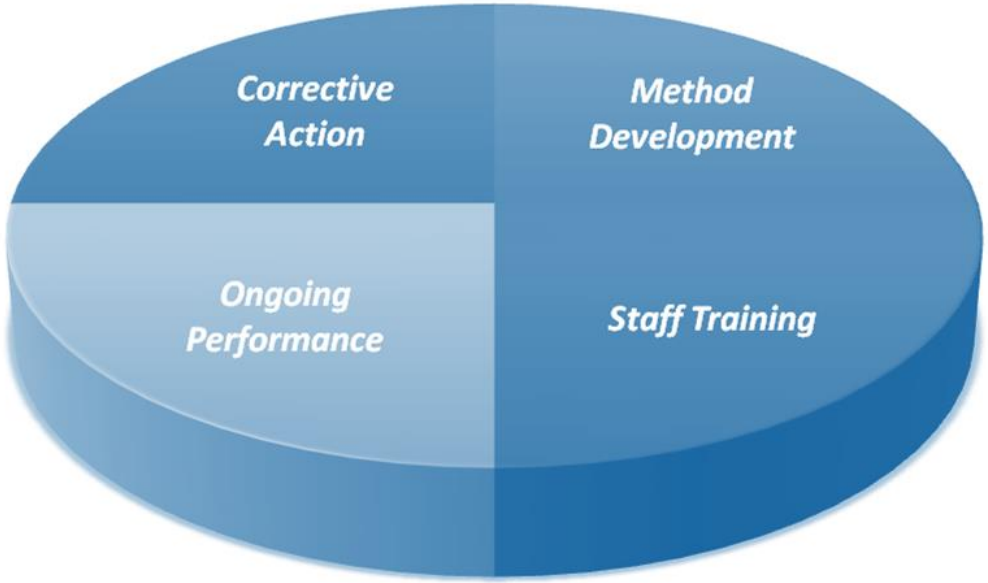
- Quality improvement tool
  - Key element of Quality Management System
  - Initial demonstration of capability
  - Analyst training, certification
- Data reporting/management
  - Risk analysis
  - Root cause analysis
  - Method optimization
  - Monitor performance over time
  - Track by analyst
  - Compare to other labs/methods



Quik™ Response

- What is Quik Response?
  - Proficiency testing on demand
  - A CRM that is has already gone through a PT Study is relabeled so it is blind to the participant
  - Participant tests the samples, reports results in eDATA and results are immediately issued
  - QR results are evaluated against the results of the PT round from which the sample came
- Why use QuiK Response?
  - Comply with deadline-driven corrective action requirements
  - Swiftly expand your scope of accreditation
  - Document and validate the effectiveness of corrective actions
  - Instantaneous results

Basics of Quality Assurance



Summary

- Accurate measurements are important and require an agreed upon common system
- CRMs and PTs can help improve laboratory performance and are essential for a sustainable QA program
- QA program requires thoughtful consideration for implementation, execution and monitoring – continual improvement
- Data supports the value and importance of structured testing to improve laboratory performance – ensure customer confidence
- Make quality an integral part of everyday activities

Acknowledgements

- Christy Abbas
- Nicole Cotta
- Craig Huff
- Matt Graves


Waters™
ERA™