Quality Assurance
Key Practices for Your Lab

September 2017

Iowa's Environmental & Public Health Laboratory

Agenda

- Introduction
- Pre-Quiz
- Key Practices
- Post-Quiz
- Questions

60 Minute Schedule

- Introduction 5 min
- Pre-Quiz 5 min
- Key Practices
  - Standard Work 20 min
  - Quality Control 15 min
- Post-Quiz 5min
- Questions (10 min float)

Introduction

Mark Pendergast

- 15 years as an analytical chemist
  - GCMS, HPLC, Nutrients
  - Microscopist
- 2015 to Present
  - Manager, Quality Systems
  - Advisor to SHL Director
- Contact Information
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Standard Work

- Hand Out and Exercise

Quality Control

1. DOC
2. MDL
3. LRB
4. LFB
5. MS/MSD
6. ISTD
7. CCV
8. Control Charts
9. Corrective Action
10. QC Acceptance Criteria
11. Definitions
12. Minimum Frequency for QC

Quality Control

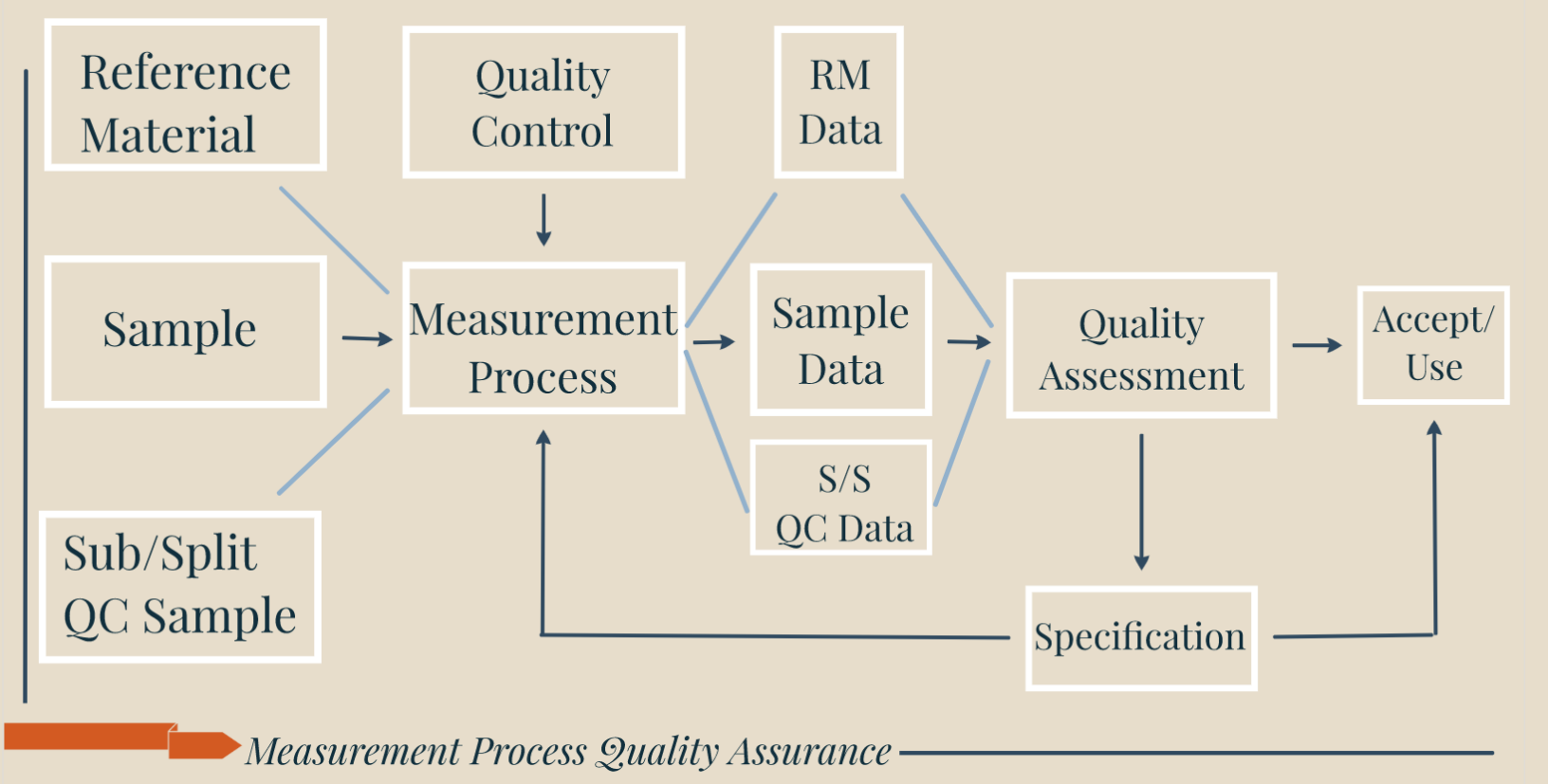
1. **DOC**
2. MDL
3. LRB
4. LFB
5. MS/MSD
6. ISTD
7. CCV
8. **Control Charts**
9. **Corrective Action**
10. **QC Acceptance Criteria**
11. Definitions
12. **Minimum Frequency for QC**

Process

- **Document Hierarchy**

Process

- **Measurement Process**



Quality Assurance of Chemical Measurements – John Keenan Taylor

Quality Control

Meet the needs of the users

- **Satisfactory**
- **Adequate**
- **Dependable**
- **Economic**

Quality Control

40 CFR 136.7

The permittee/laboratory shall use suitable QA/QC procedures when conducting compliance analyses with any part 136 chemical method or an alternative method specified by the permitting authority. These QA/QC procedures are generally included in the analytical method or may be part of the methods compendium for approved Part 136 methods from a consensus organization. For example, Standard Methods contains QA/QC procedures in the Part 1000 section of the Standard Methods Compendium. The permittee/laboratory shall follow these QA/QC procedures, as described in the method or methods compendium. If the method lacks QA/QC procedures, the permittee/laboratory has the following options to comply with the QA/QC requirements:

12 Elements

Quality Control

40 CFR 136.7

- **Use suitable QA/QC procedures**
- **Standard Methods contains QA/QC procedures (part 1000)**
- **The permittee/laboratory shall follow these QA/QC procedures, as described in the method or methods compendium.**
- **If the method lacks QA/QC procedures, the permittee/laboratory has the following options to comply with the QA/QC requirements:**
  - **12 Elements**

Quality Control

Standard Method 1020 B.

Include in each analytical method or SOP the minimum required QC for each analysis.

14 Elements

Control Charts & QC Limits

1. **Percent Recovery** **(unknown compared to known)**
2. **Relative Percent Difference** **(duplicate samples comparing two values)**
3. **X Control Chart**

Control Charts & QC Limits

X Control Chart

1. **Mean (establish from 20 data points)**
2. **Warning Limits (2 standard deviations)**
3. **Control Limits (3 standard deviations)**

Control Charts & QC Limits

Control Limits

- **Control charts utilize a central line to define and provide the best estimate of the variable plotted.**
- **Control limits define the bounds of virtually all values produced and in statistical control.**

Control Charts & QC Limits

Standard Deviation

- **Standard deviation is only an estimate based on limited data.**
- **Represents the spread around the mean. Is used to establish control of a measurment.**

QC Frequency

- **Follow your method requirements**
- **If in doubt contact lab certification program**

Corrective Action

Culture

- **Create a culture to discover and report nonconforming events**
- **Nonpunitive**
- **link events to process improvement**
- **provide education open communication**

Corrective Action

A Just Culture

- **Unintended, honest human error -** error was not intended but resulted from distractions and system problems; most common.
- **At-risk behavior -** employee thinks actions are sufficient, but are not (shortcutting)
- **Reckless behavior -** employee knows the risk but does it anyway

Corrective Action

Nonconforming Event (NCE) Management

- Detect and Discover
- NCE Reporting Mechanism
- Action to the NCE

Corrective Action

Not all actions are the same

- Remidial Action - action taken to rectify a recongnized NCE
- Corrective Action - action taken to remove the root cause of the NCE
- Preventive Action - action taken to eliminate the cause of a potential NCE

Corrective Action

Investigate

Review your lab's workflow

- Pre-analytical
- Analytical
- Post-analytical

The what, how, and why

Corrective Action

Document

Record of action relating to NCE

Corrective Action

Assistance

Forms and assistance available, just ask.

Demonstration of Capability (DOC)

Initial

Can the lab and the analyst perform the method and obtain acceptable results for each analyte?

What the SHL does for documenting initial DOCs:

- **Four Blind Spikes**
- **Each analyst before performing testing**

Demonstration of Capability (DOC)

Ongoing

Demonstrates laboratory performance versus method performance (Also known as the laboratory control sample)

What the SHL does for documenting ongiong DOCs:

One of the following is used:

- **Acceptable performance of a blind sample (PT)**
- **Another initial DOC**
- **Four consecutive analytical runs of acceptable control samples**
- **Duplicate analyst analysis (when other options are unavailable)**

Next Steps

Plan, Do, Check, Analyze

1. **Review your policy, process, procedure, and forms**
2. **Improve and Repeat**

QUESTIONS?

Acknowledgements

- **CFR**
- **Standard Methods**
- **Quality Assurance of Chemical Measurements – John Keenan Taylor**
- **CLSI – QMS11-A Management of Nonconforming Laboratory Events; Approved Guideline**
- **BD Medical and Life Sciences**
- **Google**