

# ADVANCED LABORATORY QA/QC PRACTICES

## COURSE OBJECTIVES AND COURSE OUTLINE

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“Advanced Laboratory QA/QC Practices” course objectives:

- Describe applicability of laboratory QMS
- Discuss laboratory QA programs
- Describe QMS requirements
- Determining valid requirements
- Method validation
- Determining QC check standard concentration
- Developing control charts
- Inter-Intra-laboratory programs
- Significant digits
- Stating uncertainty
- Determining LOD / LOQ / MDL / UQL
- Reporting data at or near detection

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### 1.0 Introduction

- 1.1 Applicability to Power Plants
- 1.2 Basis for a Laboratory Quality Assurance Program
- 1.3 Overview
- 1.4 Quality Management System (QMS) Requirements
  - 1.4.1 Organization
  - 1.4.2 Quality Management System
  - 1.4.3 QMS Non-Conformances, Corrective and Preventative Actions
  - 1.4.4 Valid Requirements
  - 1.4.5 Document Control
  - 1.4.6 Test Methods and Method Verification/Validation
  - 1.4.7 Equipment
  - 1.4.8 Measurement Traceability and Quality Control Checks
  - 1.4.9 Personnel
  - 1.4.10 Accommodation and Environmental Conditions
  - 1.4.11 Sampling and Sample Handling
  - 1.4.12 Control of Data
  - 1.4.13 Reports
  - 1.4.14 Control of Records
  - 1.4.15 Purchasing Services and Supplies
  - 1.4.16 Internal Audits
  - 1.4.17 Management Reviews
- 1.5 Summary
  - 1.5.1 Quality Management System (QMS) Requirements

### 2.0 Laboratory QA/QC Program Requirements

- 2.1 Valid Requirement
  - 2.1.1 General
  - 2.1.2 Determining Valid Requirements
  - 2.1.3 Selecting Suitable Analytical Methods
  - 2.1.4 Regulatory Considerations
  - 2.1.5 Stating Valid Requirements
  - 2.1.6 Example, Determining Valid Requirements
  - 2.1.7 Example for the Comparison of Valid Requirements to Several Proposed Analytical Methods
- 2.2 Method Verification
  - 2.2.1 General
  - 2.2.2 Verification of Calibration Curve (Number of Standards, Linear, non-linear, etc.)
  - 2.2.3 Verifying Method Limit of Detection (LOD) and Upper Limit of Quantification (ULQ) Are Determined
  - 2.2.4 Determining Matrix Interference Using Spiked Sample Analysis
  - 2.2.5 Determining Blank Interferences
  - 2.2.6 Comparison to Existing Methods
  - 2.2.7 Method Re-Verification

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- 2.3 Basis for Control Charts
  - 2.3.1 Control Chart Theory
  - 2.3.2 Analysis of Stable Standards
- 2.4 Developing Control Charts
  - 2.4.1 General
  - 2.4.2 QC Check Concentration
    - 2.4.2.2 Background
    - 2.4.2.3 Objective of a QC Check Standard
    - 2.4.2.4 QC Check Standard Concentration
    - 2.4.2.5 Periodic Verification of Calibration at Concentrations Near LOD
  - 2.4.3 Collecting Data
  - 2.4.4 Characterization of Uncertainties
    - 2.4.4.1 Precision and Accuracy
    - 2.4.4.2 Random and Systematic Uncertainties
  - 2.4.5 Central Tendency and Dispersion
    - 2.4.5.1 Distributions
    - 2.4.5.2 Characterization of Random Uncertainties
  - 2.4.6 Evaluating Data Normality
  - 2.4.7 Statistical Models
    - 2.4.7.1 The Binomial Distribution
    - 2.4.7.2 The Poisson Distribution
    - 2.4.7.3 The Normal or Gaussian Distribution
  - 2.4.8 Tests for Non-Normal Data
    - 2.4.8.1 Introduction
    - 2.4.8.2 Rejecting Outliers
    - 2.4.8.3 The Kolmogorov Test for Goodness of Fit
  - 2.4.9 Evaluating Data Precision
    - 2.4.9.1 The “F” Distribution
  - 2.4.10 Evaluating Data Accuracy
    - 2.4.10.1 The “t” Distribution
    - 2.4.10.2 Testing for a Bias
    - 2.4.10.3 Determination of Persuasive Bias
  - 2.4.11 Setting Limits and Centering Control Charts
    - 2.4.11.1 Setting Statistically Based Limits
    - 2.4.11.2 Setting Non-Statistically Based Limits
    - 2.4.11.3 Centering a Control Chart
- 2.5 On-Going User of Control Charts
  - 2.5.1 General
  - 2.5.2 Frequency of QC Check Standard
  - 2.5.3 On-Going Checks
  - 2.5.4 Long-Term Trends

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- 2.6 Summary of Steps
- 2.7 Analysis of Duplicate Samples or Standards
- 2.8 Spiked Samples
- 2.9 On-Line Instrumentation QA/QC Practices Program Overview
  - 2.9.1 Reference Standard Method
  - 2.9.2 Line Sample Method
  - 2.9.3 Continuous Comparison of On-Line Analyzers
  - 2.9.4 On-Line Standard Injection
- 2.10 Interlaboratory and Intralaboratory Programs
  - 2.10.1 General
  - 2.10.2 Interlaboratory Programs
  - 2.10.3 Intralaboratory Programs
  - 2.10.4 Comparative Laboratory Testing
- 2.11 Significant Digits
  - 2.11.1 General
  - 2.11.2 Significant Digits Calculations
  - 2.11.3 Significant Figures
- 2.12 Analytical Uncertainty
  - 2.12.1 General
  - 2.12.2 Uncertainty Calculations
- 2.13 Propagation of Uncertainties
  - 2.13.1 Random Uncertainty Components
  - 2.13.2 Propagation Systematic Uncertainties
- 2.14 Reporting of Data
  - 2.14.1 Overview
  - 2.14.2 Dimensioning
  - 2.14.3 Reporting of Data and Uncertainty
  - 2.14.4 Expressing Data Uncertainty
- 3.0 Detection Limits**
  - 3.1 Introduction
  - 3.2 Statistical Basis for Detection Limits in Analytical Chemistry
    - 3.2.1 Other Definitions of LLD or MDL
  - 3.3 Detection Limit Definitions for Radiochemistry
  - 3.4 Detection Limits Applied to Gross and Liquid Scintillation Counting
    - 3.4.1 Minimum Detectable Count Rate (MDCR)
    - 3.4.2 Minimum Detectable Activity (MDA)
  - 3.5 Detection Limits Applied to Gamma Spectrometry Systems
  - 3.6 Summary