

Laboratory Quality Systems
Unit II: Quality Assurance and Quality Control
(Weeks 3 - 5)

If you need help, please e-mail prabha@otsc.tamu.edu

Learning Objectives

- Understand the use of statistical process control within a laboratory quality system
- Explain the use of quality control procedures in laboratory with an emphasis on ISO accreditation
- Understand the importance of traceability, proficiency testing and uncertainty in producing reliable and defensible results

Topic # 1 - Statistical Techniques

Presentations

- [Statistical Process Control – Sources of Variability](#) (17 min.) | [PDF](#)
- Statistical Process Control - Histograms and Variable Control Charts [Part 1](#) (15 min.) | [Part 2](#) (18 min.) | [PDF](#)
- [Statistical Process- Diagnostic Tools](#) (15 min.) | [PDF](#)
- [SPC Attribute Control Charts p-chart, np-chart, c-chart](#) (7 min.) | [PDF](#)

Excel Demonstrations

How to Guides	Example Files
How to Install the Data Analysis ToolPak in Microsoft Excel - YouTube – Required to run Descriptive Statistics Descriptive Statistics in Excel Using the Data Analysis Tool - YouTube Descriptive Statistics in Excel - Easy Excel Tutorial How to calculate Correlation Coefficient	Demo 1 practice file.xls (Includes Descriptive Statistics, Histogram and Cluster Diagram)
Histograms Histogram in Excel How To Create A Histogram in Excel (& change the bin size) - Youtube	Demo 1 practice file.xls (Includes Descriptive Statistics, Histogram and Cluster Diagram) Statistical Process Control Macro: Histogram and Control Charts <i>(Important: How to enable Excel macros)</i> Instructions for Creating Histogram and Control

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Create a Histogram with Excel - Youtube	Charts in Excel Excel File – histogram.xls use for creating histogram)
Cluster Diagram Making Scatter Plots/Trend lines in Excel How to Create a Scatter Plot in Excel How to make a scatter plot in Excel How to add trendline	Demo 1 practice file.xls (Includes Descriptive Statistics, Histogram and Cluster Diagram)
Variable Control Chart Control Charts in Excel	Instructions for Creating Histogram and Control Charts in Excel Excel File – cc.xls use for creating control charts) Statistical Process Control Macro: Histogram and Control Charts <i>(Important: How to enable Excel macros)</i> Demo 2 Statistical Process Control Macro.xls – Example (Data is highlighted)

Note: You can find a variety of sources on how to use Excel on the web using a simple google search

Readings

- [Montgomery. 2009. 6th Edition. Introduction to Statistical Quality Control](#) (pg. 226-245)
- [Montgomery. 2009. Appendix VI](#)
- [Wheeler & Chambers. 2010. 3rd Edition. Understanding Statistical Process Control, Ch. 12](#)
- [Amsden & Butler. 1998. 2nd Edition. SPC Simplified Practical Steps to Quality, Ch. 2](#)
- [NCSS Statistical Software. Chapter 241 Individuals and Moving Range Charts](#)
- [Amsden & Butler. 1998. 2nd Edition. SPC Simplified Practical Steps to Quality, Ch. 4](#)

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Assignments

- Homework #2- Statistical Process Control - Due by Midnight on Monday, February 26, 2024 (See [Course Webpage : Unit II Page](#) - 10 pts)
Submit via E-mail: outreach@otsc.tamu.edu

Topic # 2 - Quality Control

Presentations

- [Quality Assurance and Quality Control](#) (15 min.) | [PDF](#)
- [Uncertainty](#) (14 min.) | [PDF](#) | [Excel Sheet](#)
- [Analyst Qualification](#) (12 min.) | [PDF](#)
- [Proficiency Testing](#) (21 min.) | [PDF](#)
- [Reference Material](#) (18 min.) | [PDF](#)
- [Control of Non-conforming Work](#) (8 min.) | [PDF](#)
- [Records and Reporting for Quality Assurance](#) (16 min.) | [PDF](#)

Excel Demonstrations

Demonstration	Associated Excel Files and other files
Homogeneity (3 min.) Demo Excel File	Homogeneity Excel File Homogeneity (Annotated Example)
Stability (2 min.) Demo Excel File	Stability Excel File Stability (Annotated Example)
Dixon Outlier : (6 min.) Note: The SD of control data mentioned in this presentation can be found in: OTSC Uncertainty of Measurement Estimation	Dixon Outlier: Use in Analyst Qualification Excel File Dixon Q-Test Outlier Annotated Example

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Uncertainty (14 min.) PDF (Also listed above)	Uncertainty - Excel Sheet
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Readings

Quality Control Procedures

- [Quality Control Reference Material and Benchmarking Instrument Performance](#)
- [Human and Animal Food Testing Laboratories Best Practices Manual](#)

Proficiency Testing

- [International Harmonized Protocol for the Proficiency Testing of Analytical Chemistry Laboratories](#)
- Review [OTSC – TAMU AgriLife Research Aflatoxin Proficiency Testing and Control Program](#)

(Login Information: Lab Number-101 ; Password –password)

Uncertainty

- [A Beginner's Guide to Uncertainty of Measurement](#)
- [Analytical Measurement Uncertainty ISO/IEC 17025: 2005 \(APHL, AFDO, AAFCO\)](#)
- [P103B-Annex- Policy on Estimating Measurement Uncertainty for Life Sciences Testing Labs](#)

Assignments

- Homework #3 – Uncertainty - Due by Midnight on Monday, March 4, 2024 (See [Course Webpage : Unit II Page](#) - 10 pts)
Submit via E-mail: outreach@otsc.tamu.edu
- Homework #4 – Non-conforming work Due by Midnight on Monday, March 11, 2024 (See [Course Webpage : Unit II Page](#) - 10 pts)
Submit via E-mail: outreach@otsc.tamu.edu

Discussions

- Graded Discussion # 2: Proficiency Testing -Due by Midnight on Monday, February 26, 2024 (See below for more information - 5 pts) **Submit to google group**

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Review the following 2018 Round 1 and Round 2 reports for Total and B1 Aflatoxin Results respectively from the [OTSC – TAMU Agrilife Research Aflatoxin Proficiency Testing and Control Program](#) ((Login Information: Lab Number-101 ; Password –password))

Compare the Round 1 and Round 2 results for Total and B1 Aflatoxin respectively and address the following:

1. Presence of Outliers
2. # of Labs that had satisfactory results
3. What should a lab do if their results is not satisfactory?
4. Why should a laboratory participate in a Proficiency Testing Program?

Graded Discussion # 3 Due by Midnight on Monday, March 11, 2024 (See below for more information - 5 pts) **Submit to google group**

All laboratory results need to account for a level of uncertainty. What are sources of uncertainty in laboratory results? What types of information should accompany laboratory results to account for this uncertainty. (5 pts)

References

Quality Control Procedures

- [One Sample Strategy Handbook](#)
- [OTSC SOP Aflatoxin in Feeds \(Corn and Cottonseed Meal Product\) by HPLC/PHRED](#)
- [OTSC SOP Aflatoxin in Feeds by UHPL/FLD](#)
- [OTSC SOP on Analyst Qualification](#)
- [OTSC SOP on Dixon Outliers](#)
- [OTSC Analyst Qualification Example](#)
- [Assuring the Quality of Test Results from ORA-FDA Laboratory Manual of Quality Policies \(Pg.41\)](#)

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- [Control of Non-Conforming Work from ORA - FDA from ORA-FDA Laboratory Manual of Quality Policies \(Pg.17\)](#)
- [Corrective Action Procedure from ORA - FDA from ORA-FDA Laboratory Manual of Quality Policies \(Pg.18\)](#)

Uncertainty

- [ISO/IEC Guide 98-3: Uncertainty of Measurement –Part 3: Guide to the expression of uncertainty in Measurement](#)
- [Sources of Uncertainty in Measurement for Every Uncertainty Budget](#)
- [OTSC Uncertainty of Measurement Estimation](#)