

Controls and Control Charting

APHL Quality Management System (QMS) Competency Guidelines

This course will help staff understand what is important for selecting controls and performing control charting.

Objectives:

1. Participant will understand the need for control charting.
2. Participant will comprehend which tests require control charting.

ISO/IEC 17025, 7.7.3 If the results of the analysis of data from monitoring activities are found to be outside pre-defined criteria, appropriate action shall be taken to prevent incorrect results from being reported.

Control charts...

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- Are used to meet the requirements of the ISO/IEC 17025 standard by providing a way for laboratories to monitor the validity of test performed
- Use RM, spiked samples, laboratory characterized materials, percent/absolute difference in duplicate samples
- Make it possible for the laboratory to track trends in analysis

Public health laboratory competency guidelines:

General (GEN) domain

GEN 1.00 General technical and laboratory practice knowledge: demonstrates general knowledge and skills related to the scientific and technical components of laboratory testing (including technical, troubleshooting, mathematical and statistical skills). Documents actions and results using established paper or electronic systems

GEN 5.00. Examination: performs steps in the examination phase of testing

GEN 5.03. Quality control (QC)* analysis

GEN 6.00. Postexamination: performs steps in the postexamination phase of testing

GEN 6.01. QC evaluation

Bioinformatics (BIO) domain

BIO 3.00. Data analysis: analyzes biological data

Informatics (INF) domain

INF 2.06. Data verification



INF 15.00. QC and QA management: manages quality control and quality assurance processes

Microbiology (MCB) domain

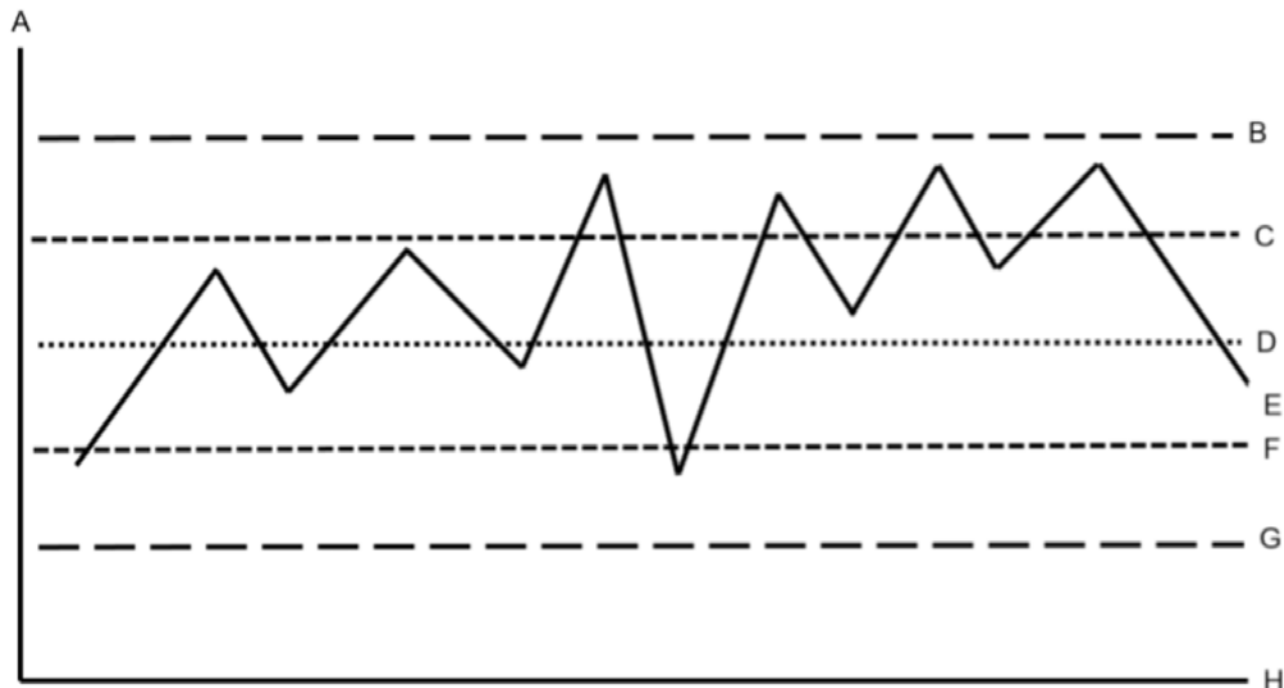
MCB 4.12. Quality control (QC) analysis

Chemistry (CHM) domain

CHM 1.03. Laboratory statistics

CHM 4.03. Quality control (QC) analysis

Typical Control Chart



X-axis=H

Y-axis=A

Plotted control data=E

Upper control limit=B

Upper warning limit=C

Lower control limit=G

Lower warning limit=F

Mean=D