QUALITY CONTROL PROGRAM

ACADs (08-006) Covered

4.30.2.1	4.30.2.2	4.30.2.3	4.30.2.4	4.30.2.5	4.30.2.6	4.30.2.7	4.30.2.8
4.30.2.9	4.30.2.10	4.30.2.11	4.30.2.12	4.30.4			

Keywords

Accuracy, blank, calibration, calibration check, calibration curve, check source, functional check, performance check, precision, quality control chart, spiked sample, preparation and use of known and spiked samples

Description

Explain and apply the concepts related to the quality control program.

Supporting Material

RCNET
Regional Center for Nuclear Education & Training

accuracy

The closeness of an experimental measurement to the true value.

blank

A standard that contains no analyte.

i.e., a concentration of 0.0.

calibration

The process of measuring a known quantity to determine the relationship between the measurement signal and the analyte amount or concentration.

calibration check

Confirmation that the calibration of the instrument, kit, or test system has remained stable.

calibration curve

A plot of signal versus analyte amount or concentration for multiple standards. Used to calibrate a measurement over an extended range.

check source

Assesses the sensitivity and consistency of a source.

functional check

Reveals whether the subject being examined is functioning properly.

performance check

Performance tests reveal details regarding quality.

precision

Ability to produce the same result in repeated tests of the same sample.

precision

Precision Calculation:

RPD = 2 * [A - B] / A + B * (100)

quality control chart

Easily interpreted picture of the statistical state of an analysis

“spiked” sample

(increase concentration above minimum detectable)

An internal standard or standard addition added to a sample or blank.

“spiked” sample

Spike Accuracy Equation

%R = 100 * (OV - BV / KV)

standard

A sample of known composition prepared from a certified reference material.

Describe the preparation and use of known and spiked samples

- Used during method validation to demonstrate many of the required elements such as accuracy, precision and stability.

- Subsequently used during the conduct of the study to provide batch-level quality control.

Describe the preparation and use of known and spiked samples

- QC samples must achieve a pre-defined level of accuracy for the associated batch to be considered acceptable.

- Represent the matrix of the samples with known amounts of the analyte.

Describe the preparation and use of known and spiked samples

- Process QC Samples in the Same Manner as Study Samples

- Invalid if the study samples are processed in a different manner or sequence than the QC samples.

Describe the preparation and use of known and spiked samples

To determine a spike recovery, the blank or sample is split into two portions and a known amount of a standard solution of analyte is added to one portion.

Describe the preparation and use of known and spiked samples

The concentration of the analyte is determined for both the spiked, F, and unspiked portions, I, and the percent recovery, %R, is calculated as

$$\%R = (F-I)/A \times 100$$