

# 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



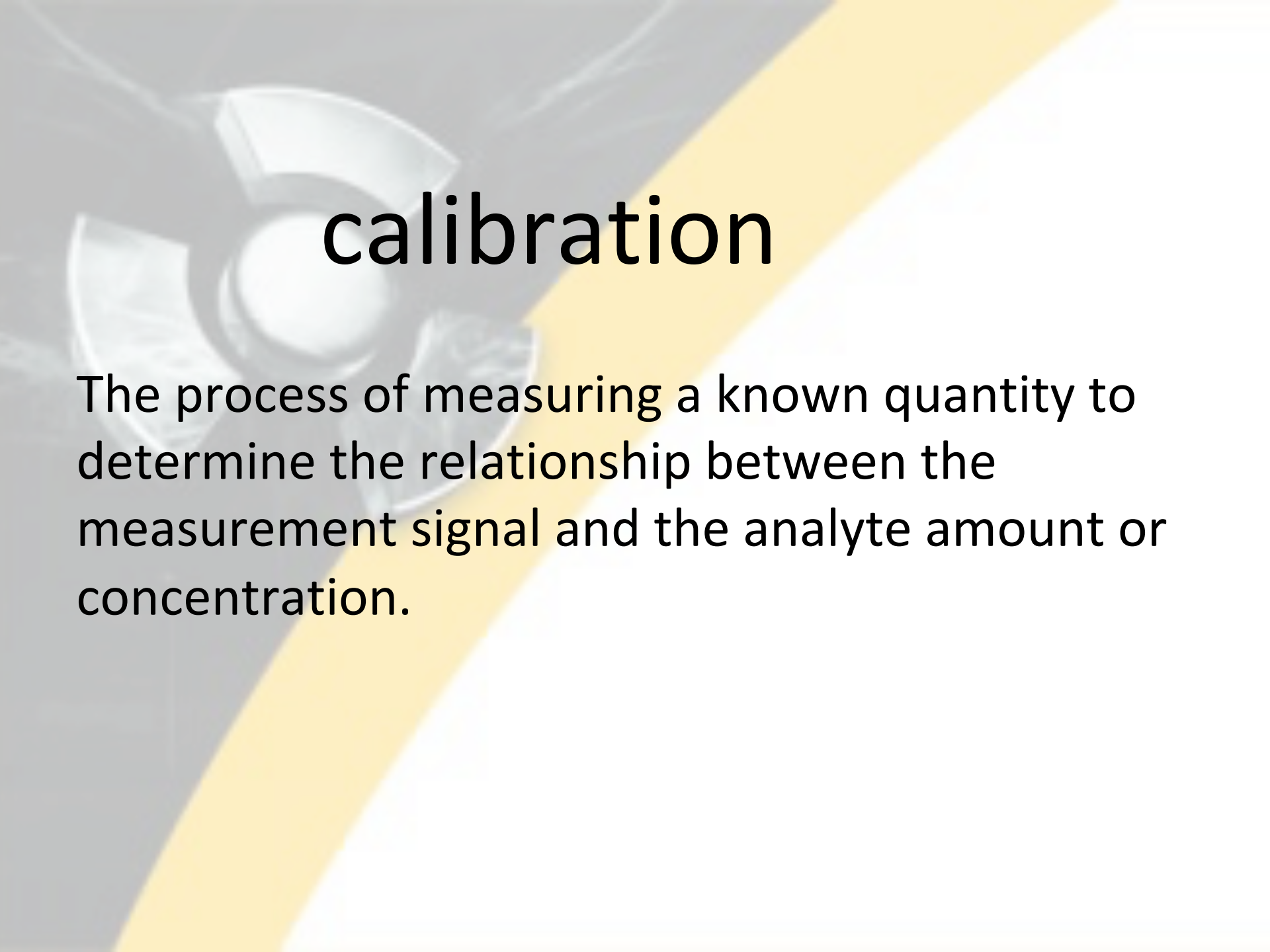
The background features a close-up, grayscale image of a mechanical component, possibly a valve or a connector, with a central circular opening and several curved, petal-like sections. A prominent, thick yellow diagonal stripe runs from the bottom-left towards the top-right, crossing the mechanical image.

# 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.

The background features a grayscale image of a mechanical component, possibly a valve or a part of a turbine, with a prominent yellow diagonal stripe running from the bottom-left towards the top-right.

# calibration

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

The background features a grayscale image of a mechanical assembly, possibly a valve or a similar component, with several curved, metallic-looking parts. A prominent yellow diagonal stripe runs from the bottom-left towards the top-right, crossing over the mechanical image.

# 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.

The background features a stylized globe with a yellow diagonal stripe running from the bottom-left to the top-right. The globe is rendered in a light grey color with some shading to suggest depth. The text is overlaid on this background.

# 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

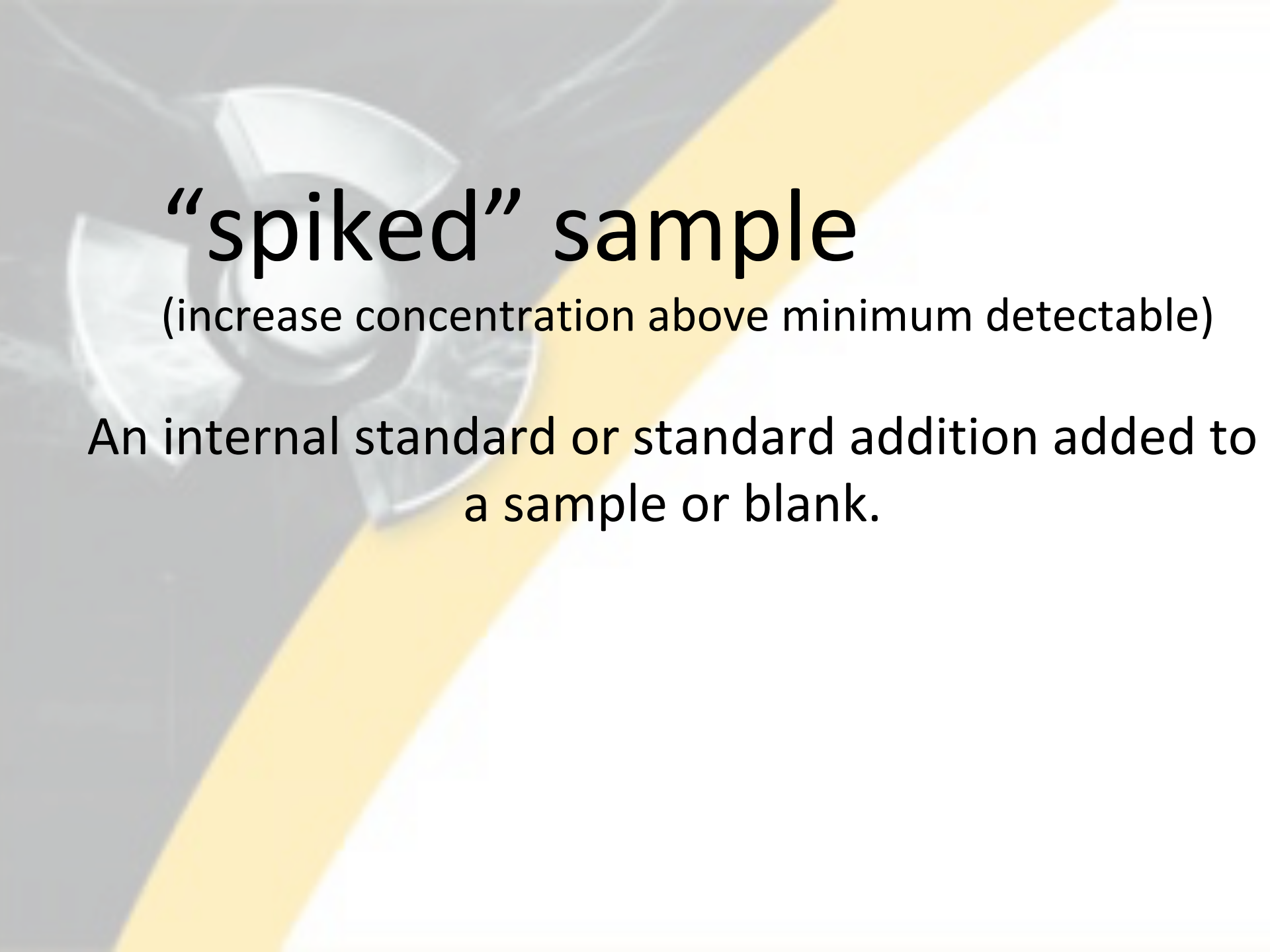
**Precision Calculation:**

$$\text{RPD} = 2 * [A - B] / A + B * (100)$$



# 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.

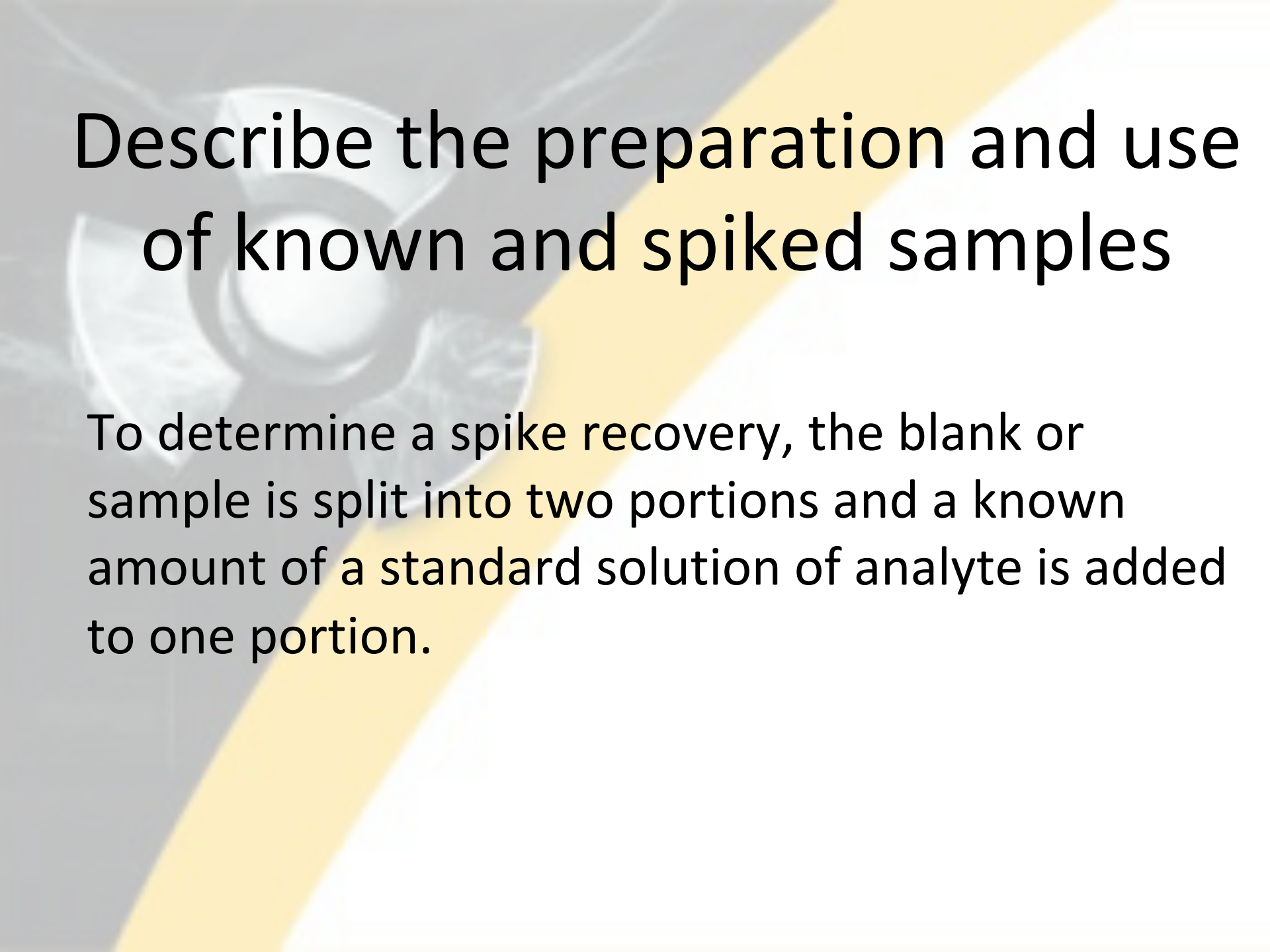


# Describe the preparation and use of known and spiked samples

- 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

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