Validation/Verification of New Instruments in the Laboratory

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Validation or Verification?

• Most likely a verification if...
  – EPA approved method
  – You are familiar with the method
  – The method has already been validated
Validation

- New method
- Not EPA validated
- ATP method
- Method Modified

Procedures for Approvals listed in 40 CFR 136.5 and 40 CFR 136.6
New Equipment in the Lab?

• What do I need to do?
• What records do I need to have available?
• When do I know when it’s ok to run routine samples?
Once the Instrument is installed...

- Have the service engineer run the method(s) with QC samples to demonstrate the instrument can provide accurate and precise results at the quat levels required for the compliance samples you are running.
- Get documentation of the instrument meeting method specifications.
- Use this opportunity to train staff – document.
Once the Service Engineer Leaves...

• Follow procedures in SM XX20 B or EPA Method QC Section.
• Have all staff who run the instrument perform their Demonstration of Capability (DOCs)
• If you have the old system up and running, perform some comparisons of QC samples for both instruments to make sure the results are comparable
• If you traded in the old system or it is not functional, run QC samples on the new instrument and evaluate the accuracy and precision at different concentrations and with all applicable sample matrices.
Example of EPA QC Section

• 9.0 QUALITY CONTROL
• 9.1 Each laboratory using this method is required to operate a formal quality control (QC) program. The minimum requirements of this program consist of an initial demonstration of laboratory capability, and the periodic analysis of laboratory reagent blanks, fortified blanks and other laboratory solutions as a continuing check on performance. The laboratory is required to maintain performance records that define the quality of the data that are generated.
• 9.2 INITIAL DEMONSTRATION OF PERFORMANCE
• 9.2.1 The initial demonstration of performance is used to characterize instrument performance (determination of LCRs and analysis of QCS) and laboratory performance (determination of MDLs) prior to performing analyses by this method.
• 9.2.2 Linear Calibration Range (LCR) -- The LCR must be determined initially and verified every six months or whenever a significant change in instrument response is observed or expected. The initial demonstration of linearity must use sufficient standards to insure that the resulting curve is linear. The verification of linearity must use a minimum of a blank and three standards. If any verification data exceeds the initial values by ±10%, linearity must be reestablished. If any portion of the range is shown to be nonlinear, sufficient standards must be used to clearly define the nonlinear portion.
• 9.2.3 Quality Control Sample (QCS) -- When beginning the use of this method, on a quarterly basis or as required to meet data-quality needs, verify the calibration standards and acceptable instrument performance with the preparation and analyses of a QCS. If the determined concentrations are not within ±10% of the stated values, performance of the determinative step of the method is unacceptable. The source of the problem must be identified and corrected before either proceeding with the initial determination of MDLs or continuing with on-going analyses.
• 9.2.4 Method Detection Limit (MDL) -- MDLs must be established for all analytes, using reagent water (blank) fortified at a concentration of...
Necessary Items from SM 4020B

- Calibration (Sec. 1) – I/P
- Operational Range (Sec. 2) – I/P
- Method Detection Limit (Sec. 2) – I/P
- Initial Demonstration of Capability (Sec. 3) – A

I/P = Instrument/Procedure must be completed for each I/P
A = Analyst must be completed for each person
Evaluate Accuracy, Precision and Sensitivity

• Use QC to establish new control limits for QC charts

• Measure duplicates and establish limits for RPDs

• Determine MDL if possible – Make sure new instrument can meet the required sensitivity for the method
SOP and Validation/Verification Package

• Make sure you have your SOP up to date, approved and signed

• Combine your accuracy, precision, MDL and comparisons into a package to provide auditors, IDNR, or EPA if requested.
Perform a Proficiency Testing Sample

- Pass a PT for each matrix
- Back-up analyst can run the PT after it has been reported to demonstrate capability
- Document for each analyst
Once you have all of this done...

• You are ready to run routine samples
Examples

• Moving to a new Lab
• The Lemon
• Others??