Method Modification

When is a Method Modified? Can we define this?

- Determinative Methods:
  - detector
  - column
  - wavelength
  - chemistry
  - analyte list
  - instrument type
- For Preparation Methods:
  - time and cycles
  - mass
  - stoichiometry
  - temperature
  - volume
  - Automation

Should Validation Protocol be based on Modification? Or

- Procedure mandated by certain EPA methods
- Protocol and Procedure given in NELAC C.3.3
- EPA Tier 1 protocol given in the ATP Manual
- Section 1040 B of the 20th ed. of SM
- ASTM Guide D 6956-03

What Performance Data is Necessary to Justify the Modification?

- Estimate of Bias
- Statement of Precision
- Demonstration of Sensitivity
- Demonstration of Selectivity (freedom from interference)

Current Guidance 40 CFR Part 136.6

Potentially Acceptable Modifications

- Changes between manual discrete & automated instrumentation
- Changes in calibration ranges
- Use of similar equipment from a different manufacturer
- Use of capillary GC columns vs. packed columns
- Changes in equipment operating parameters
  - Changing colorimeter monitoring wavelength
  - Modifying GC oven temperature program
  - Increases in purge-and-trap sample volumes
- Use of salts or inert surfactants to enhance recovery of organic analytes

Current Guidance 40 CFR Part 136.6

Documentation Requirements

- Method write-up or addendum must describe the modification(s) made to the approved method
  - Includes reference #, revision #, & revision date
- QC test results must be documented & retained