USEPA Equivalency Question 6:

What must the laboratory staff do to meet regulators requirements?

MilliporeSigma is a business of Merck KGaA, Darmstadt, Germany

MilliporeSigma

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The checklist list all the requirements from the Equivalency study and the requirements of 40 CFR part 136.7 which is quality control for the method provided. See the following example:

- **Millipore Sigma has made available**:
  - Certificate Letters
  - Method Equivalency Reports
  - Equivalent Methods in EPA Format
  - Method Equivalency Checklist for Laboratory Management (Auditor)
  - Method Equivalency Checklist for the Laboratory
- **For Example: Ammonia by Indophenol Reaction and Photometry**
  - Ammonia (Ammonium) Spectroquant® Test Kits Certificate Letter USEPA 2017
  - Ammonia (Ammonium) Spectroquant® Test Kits Method 2017
  - Ammonia (Ammonium) Spectroquant® Test Kits Equivalency Report 2017
  - Ammonia (Ammonium) Spectroquant® Test Kits Equivalency Checklist Laboratory Management (Auditor) 2017
  - Ammonia (Ammonium) Spectroquant® Test Kits Equivalency Checklist for Laboratories 2017

What Is Required In the Equivalency Checklist??

1. Concentrations of calibration standards. Document the range of the concentrations of material used to establish the relationship between response of the measurement system and analyte concentration.
2. %RSD or correlation coefficient of calibration regression.
3. Performance range tested with units.
4. Sample(s) used in initial demonstration have the recommended preservative, where applicable.
5. Sample(s) used in initial demonstration met recommended holding times, where applicable.
6. Interferences.
7. Document the qualitative identification criteria used.
8. Performance evaluation studies performed for analytes of interest, where available.
9. Latest study sponsor or title
10. Latest study number.
11. Analysis of external reference material
12. Results of analyses on reference material from a source different from that used to prepare the calibration standards, if applicable.
13. Sources of external reference material, if applicable.

Equivalency Checklist (cont.)

14. Surrogates used, if applicable.
15. Concentrations of surrogates, if applicable.
16. Recoveries of surrogates appropriate to the proposed use, if applicable.
17. Sample preparation.
18. Clean-up procedures.
19. Method blank result.
20. Matrix (reagent water, drinking water, effluent)
21. Matrix spikes.
22. Spiking system, appropriate to the method and application.
23. Spike concentrations (with units corresponding to the final sample concentration) and recoveries.
24. Source of spiking material.
25. Number of replicate spikes
26. Initial demonstration of capability.
27. Precision (analyte by analyte) Duplicates.

Equivalency Checklist (cont.)

28. Bias (analyte by analyte).
29. Detection limit (with units; analyte by analyte).
30. Confirmation of detection limit, if applicable.
31. Quantitation limit (with units; analyte by analyte) Minimum level (ML), practical quantitation level (PQL) or limit of quantitation (LOQ).
32. Qualitative confirmation.

With these details and the documentation of the data the laboratory will be able to explain why their used method is equivalent and show the results accordingly.