EPA Method Equivalency

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Method Equivalency (Flexibility)

- DO YOU KNOW WHAT IT IS ??
  (Are the Auditors Listening ??)

Equivalency ≠ ATP

- Requires specific test procedure:
  - *Protocol for Review and Validation of Alternate Test Procedures for Regulated Organic and Inorganic Analytes in Wastewater Under EPA's Alternate Test Procedure Program*
- **Once recommended, must be promulgated to be a rule!!!**

- Follow 40 CFR 136.6
- Refer to Redding Memo
- **Complete**

ATP

Equivalency

We Don't Need No Stinking Equivalency

- Question 1: What type of DO probe do you use for BODs?
  - What method allows you in writing to use an optical DO probe??
    - SM 5210 B
    - Footnotes (Hach or InSitu)
- Question 2: What method do you use for CODs?
  - What method allows the use of Silver Sulfate??
    - SM 5220 D
    - EPA 410.4 Revision 2

EPA Approval Letter from the 1990s

- Auditor-Laboratory
  What Should I Look For In My Test Kit ????

Supplier's Claim: *Procedure is equivalent to USEPA and Standard Method 4500-P E for wastewater*

- Fill a sample cell with 10 mL of sample.
- Add the contents of one Reagent Powder Pillow to the cell. A blue color develops if phosphorus is in the sample.
- Immediately close the sample cell. Shake vigorously for 20-30 seconds.

Old Test Kit EPA Letter **1996 & 1999**
EPA Approval Letter only for EPA Methods 365.1& 365.2

- Add 5.0 mL of sample to a vial. *(Vial contains 5 mL liquid reagent)*
- Cap and invert to mix.
- Using a funnel, add the contents of one dry packet to the vial.
- Cap the vial tightly and shake for 10-15 seconds.
- *Note: The powder will not completely dissolve.*

New Test Kit 2017

What is EQUIVALENCY

- 40 CFR part 136.6

40 CFR part 136.6 Method Equivalency for Clean Water Act Methods: EPA Website

Flexibility to Modify Methods – 40 CFR 136.6

https://www.epa.gov/cwa-methods/alternate-test-procedures

- If you use a modification to an approved **40 CFR Part 136** method and document the modification as described at **40 CFR 136.6** , you will no longer receive or require a letter from EPA.
- The promulgated § 136.6, as modified by the **May 18, 2012 Methods Update Rule** allows the regulated community more flexibility to modify approved methods without EPA review, provided certain requirements are met.
- This regulation allows the analytical community greater flexibility to modify approved methods to lower the costs of measurements, overcome matrix interferences, or otherwise improve the analysis without EPA review. Laboratories that modify Part 136 methods may be private, public or commercial and may conduct analyses for one or more clients or facilities.

DETAILS ??????

- My Auditor Is ONSITE !!!!

What Is An Allowed Modification As Per 40 CFR part 136.6

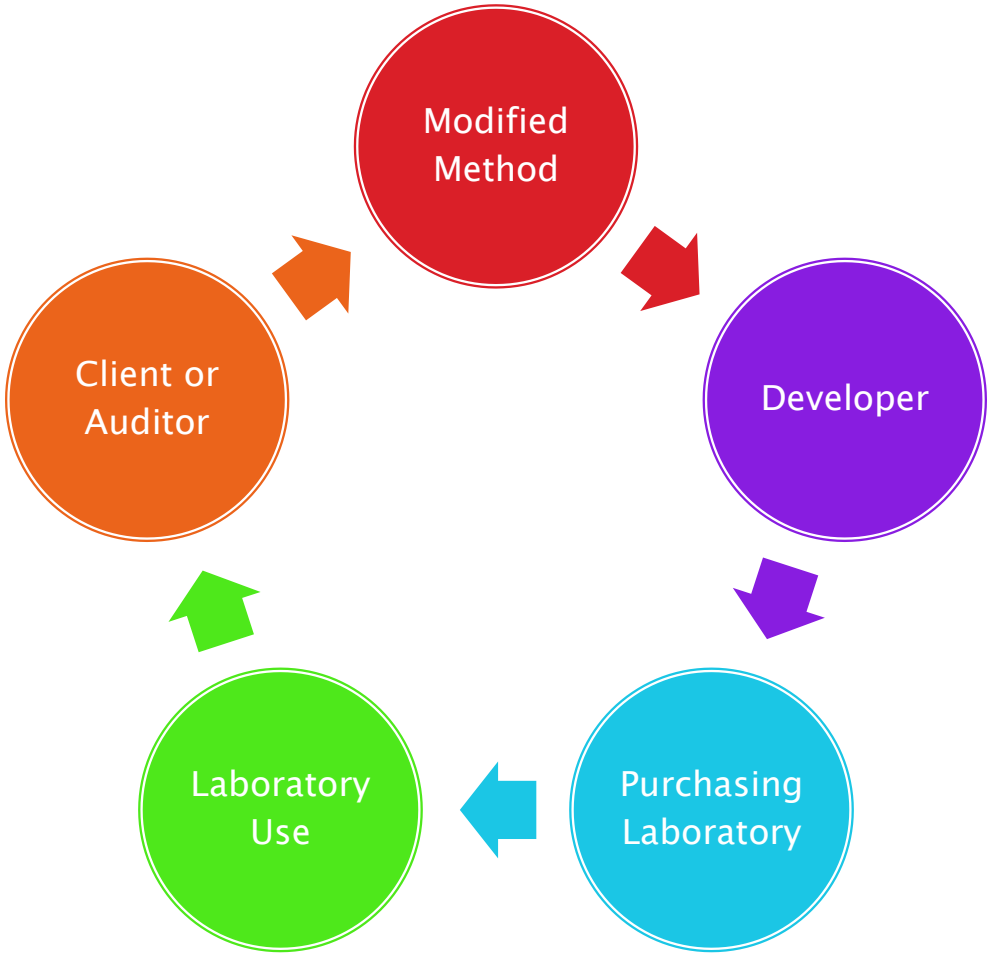
- **Method modifications**:

- If the underlying chemistry and determinative technique in a modified method are essentially the same as an approved part 136 method, then the modified method is an equivalent and acceptable alternative to the approved method provided the requirements of this section are met.
- However, those who develop or use a modification to an approved (part 136) method must document that the performance of the modified method, in the matrix to which the modified method will be applied, is equivalent to the performance of the approved method.
- Supporting documentation must, if applicable, include the
  - Routine initial demonstration of capability and
  - Ongoing QC including
    - Determination of precision and accuracy,
    - Detection limits,
    - Matrix spike recoveries.

MORE DETAIL

- My Auditor Wants More Information About The Modified Method's Use For Regulatory Reporting Under the CWA

Modified Method Cycle



Who Is The Developer??

The Supplier

The Laboratory

Clarification of 40 CFR part 136.6 Requirements

- **Richard Redding Memo: Flexibility to Modify CWA Methods, November 20, 2007**
- https://www.epa.gov/sites/production/files/2015-08/documents/cwa-method-flexibility_memo_11-20-2007.pdf
  - Developer Responsibilities

- Provide the laboratory with a side-by side method comparison table
- The developer should provide to its customers an in-depth comparison of the modified method with the EPA approved method, and document the comparison in a two-column method comparison table. The two-column method comparison table shall include the number and title of each method, the latest revision date of the modified method and a detailed discussion of each of the 17 topics required by the standard EPA method format.

- The developer should provide to their clients the modified method written in the standard EPA format: http://www.epa.gov/waterscience/methods
- Provide a copy of the data comparing the modified method performance to the approved method to demonstrate that the method is capable of yielding reliable data for compliance monitoring purposes. Test results from validation of a modified method are used to demonstrate that the modified method produces results are equivalent to results produced by the EPA-designated approved method. Equivalency is established by demonstrating that the modified method produces results that meet or exceed the QC acceptance criteria of the EPA-designated approved method.
- Verify that all items of the "Equivalency Checklist" are met:

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.**
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)**
28. **Duplicates.**
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.

So Where Do You Find These??

- My Auditor is Breathing Down My Neck!!

Product Insert or Instrument Manual

Substance	Interference Level and Treatment
Aluminum	200 mg/L
Arsenate	Interferes at any level.
Chromium	100 mg/L
Copper	10 mg/L
Iron	100 mg/L
Nickel	300 mg/L
Silica	50 mg/L
Silicate	10 mg/L
Sulfide	90 mg/L
Turbidity (large amounts)	May cause inconsistent results because the acid present in the powder pillows may dissolve some of the suspended particles and because of variable desorption of orthophosphate from the particles.

What I Didn't Find in the Product Insert or Instrument Manual

- %RSD or correlation coefficient of calibration regression.
  - No
- Performance evaluation studies performed for analytes of interest, where available.
  - No
- Analysis of external reference material
  - No
- Results of analyses on reference material from a source different from that used to prepare the calibration standards, if applicable.
  - No
- Sources of external reference material, if applicable.
  - No

- Method blank result.
  - No
- Matrix (reagent water, drinking water, effluent)
  - No
- Matrix spikes.
  - No
- Spiking system, appropriate to the method and application.
  - No
- Spike concentrations (with units corresponding to the final sample concentration) and recoveries.
  - No
- Source of spiking material.
  - No

- Number of replicate spikes
  - No
- Initial demonstration of capability.
  - No
- Duplicates.
  - No
- Bias (analyte by analyte).
  - No
- Detection limit (with units; analyte by analyte).
  - Estimated
- Confirmation of detection limit, if applicable.
  - No

NOW, What Do I Do ???

- Auditor Has The Checklist Out!!!

Thing You Should Have Done

- Require Supplier to Provide:
  - Equivalency Report that Answers ALL requirements in 40 CFR 136.6 and Richard Redding's Memo!!
    - https://www.epa.gov/sites/production/files/2015-08/documents/cwa-method-flexibility_memo_11-20-2007.pdf
  - Method in EPA Format
    - **Product Insert Does Not Do This!!!!**
  - Additional Nice Items to Have:
    - **Check List for Laboratory Management/QC Staff**
    - **Check List for Laboratory Staff**

Laboratory Staff Checklist Example

Table 1: Laboratory Method Equivalency Checklist	
Item from Reding Memo	**Check Off (Yes/No)**
➢ **Have a detailed Standard Operating Procedure (SOP) available**. (Guidance provided in Spectroquant® method)	
➢ Performing and document an initial demonstration of capability. (Required in Spectroquant® method)	
➢ Verify the modified method by analyzing and documenting 3-7 representative effluents (QC in the Spectroquant® method meets this requirement as per 40 CFR part 136.6(b)(2)(i)(A)).	
➢ The facility/lab is to show they can get the modified method to work and that it gets comparable results for their effluent. (QC in the Spectroquant® method meets this requirement as per 40 CFR part 136.6(b)(2)(i)(A))	
➢ A demonstration of calibration linearity or use of a calibration curve. (required in Spectroquant® method)	
➢ Periodic calibration verification (Required in Spectroquant® method)	
➢ An ongoing demonstration of performance (ongoing precision and recovery (OPR) and a blank with each sample batch (Required in Spectroquant® method)	
➢ A demonstration of the method detection limit (MDL) (Required in Spectroquant® method)	
➢ Matrix spike and matrix spike duplicate for each discharge the first time that the sample of the discharge is analyzed and at a frequency of 5% thereafter (Required in Spectroquant® method)	
➢ Meeting the quality control (QC) specifications of the method. (See Spectroquant® method)	
➢ Keep on hand the modified method manufacturer's supporting data available for review when the manufacturer has developed the method modification.	

Examples

- MilliporeSigma
  - http://www.emdmillipore.com/USEPA
- Environmental Express
  - http://www.envexp.com/products/1-Wet_Chemistry/PW-Solids_Testing/TDSSW-StableWeigh_for_TDS

Questions ??????