What's New in Standard Methods?

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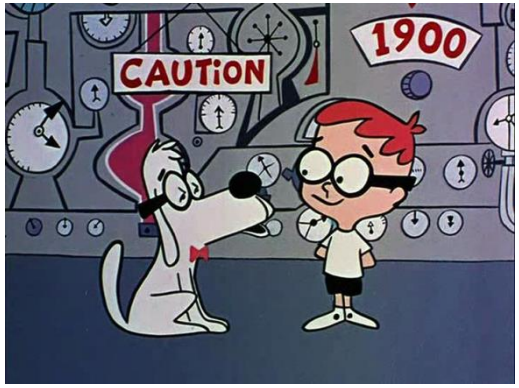
Presentation Topics

- Standard Methods history
- What's imminent in terms of new material?
- Standard Methods in the regulatory arena
- The QC condundrum
- Questions

A Bit of Standard Methods History

1905 – First Edition

guidance document
no regulatory requirements!



PUBLISHED EVERY 3 TO 7 YEARS AS HARDCOPY BOOK

13th edition – (1971) EPA began referencing Standard Methods for regulatory compliance

20th edition (1998) – first electronic version (CD)

21st edition (2005+) – first truly "on line" version

And Along Came 2012…and the Last Methods Update Rule (MUR)

22nd edition (2012) – We included significant QC clarifications and expanded requirements.

This apparently confused people because now all the questions are about QC.

(or BOD)..

So QC changes continue.

4020 QUALITY ASSURANCE/QUALITY CONTROL*

4020 A. Introduction

Without ~~both~~ quality control (QC) ~~and sample results~~, there is no confidence in the results of analytical tests. ~~As described in Part 1000, a~~ **E**ssential QC measures **may** include method calibration **or** ~~,~~reagent standardization~~,~~; assessment of each analyst's capabilities~~,~~; analysis of blind check samples~~,~~; determination of the method's sensitivity (method detection level or quantification limit~~),~~); and daily evaluation of bias, precision, and the presence of laboratory contamination or other analytical interference **(see Part 1000 for a detailed QC discussion)**. The details of these procedures, their performance frequency, and expected ranges of results **vary by analytical method and** should be formalized in a written quality assurance **(QA)** manual and standard operating procedures **(SOPs)**.

Some ~~of the~~ methods in Part 4000 include specific QC procedures, frequencies, and acceptance criteria. These are considered ~~to be~~ the minimum quality controls needed to perform the method successfully~~. A~~; additional QC procedures can and should be used. Some regulatory programs may require additional QC or have alternative acceptance limits.

Each method typically includes acceptance-criteria guidance for precision and bias of test

The Next Print Version

- Expected out in 2017
- 23rd Edition (we just can't get away from that terminology…)
- It will be a print version of the online methods that are most current at the time.
  - Lots of updates in process.

Part 1000- Quality Assurance "New and Improved" in 2016-2017

- 1020- QA/QC guidance is heavily rewritten
- 1030- Data quality will be updated
- 1040- Method development updated
- 1090- Lab safety (likely updates)

  - Preservation table in 1060 is always a challenge…

    when in doubt, see 40CFR136…

Part 2000 & 3000- Physical and Metals "New and Improved" in 2016-2017

- 2330 – Calcium carbonate saturation - errors
- Things that won't make the 23rd Edition
  - 2150-Aroma intensity
  - Updates to 2540 solids (measurement levels)
  - No changes anticipated in 3000

Part 4000 – Inorganics
"New and Improved" in 2016-2017

- 4020 – continued revisions….
- Nitrate updates
  - And hoping to include enzymatic reduction
- Cyanide!!
  - Lots of changes
- Total nitrogen – maybe… pending validation data
- DO – optical probe method

Part 5000 & 6000 - Organics "New and Improved" in 2016-2017

- 5210- BOD updates (continued clarifications)
  - Also see SM interpretations on website
- 5310 – TOC revised with clarifications
- 5910 – UV absorbance – revised with clarifications
- 6850 – PPCPs – already in online version

- In the works, maybe (need volunteers)
  - PAHs by SIM, Pyrethroids

Part 7000 - Radiochemistry
"New and Improved" in 2016-2017

- 7010/7020 QC and counting just revised
- 7110 – alpha/beta. Look for tweaks (also EPA is updating 900.0…)
- Other changes in process, but not imminent

Part 8000 – Toxicity, etc.
"New and Improved" in 2016-2017

- **Updates are too numerous to list**
  - **Lots of sections have been balloted, with few negatives**

Part 9000 – Microbiology
"New and Improved" in 2016-2017

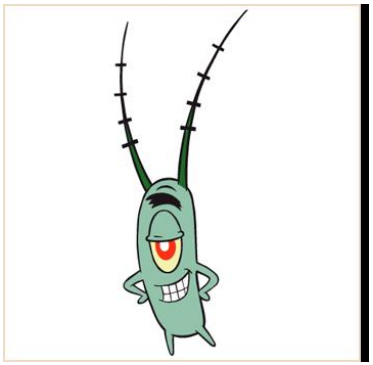
- Updates will be numerous
  - Lots of sections have been balloted already, with a lot of negatives/comments….
- 9020 - QA. Lots of discussion in Joint Task Group… it's QC so everyone has opinions. Going out for general ballot soon.
- 9030 – Apparatus. Negatives…
- 9040, 9060. Negatives (resolved)

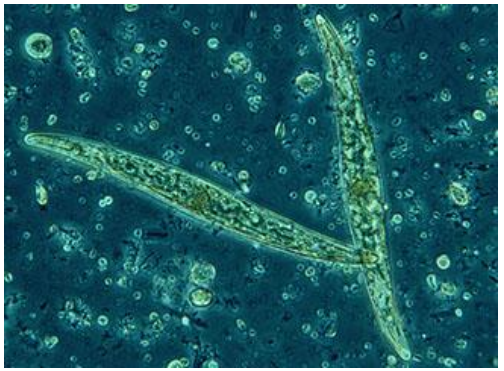
Part 9000 – Continued
"New and Improved" in 2016-2017

- **9215 – Plate Count. Ignore the last version. It is being rewritten and reballoted…**
- **9222 – Coliforms by MF. Going out to ballot soon**
- **9223 – Coliforms by chromogenic substrate. Going out to ballot soon**
- **Lot of other sections in process – whether they are ready for the 23rd Edition remains to be seen.**

Part 10000 – Biological Examination "New and Improved" in 2016-2017

- No more drawings of plankton – there will be real photos!





- Updating chlorophyll section
- Microcystins – maybe….

Regulatory Drivers for Standard Methods

Beginning with the MUR (drinking water and wastewater) in the mid 90s, Standard Methods began seeing sales significantly impacted by the status of regulatory approval

earlier editions sold 30,000+ copies …

Even as Standard Methods made changes to improve methods and add/clarify QC, the demand was still for the latest "approved" edition

EPA approved individual methods by Edition

Wastewater Method Approval Process – the Past

The approval cycles and mechanisms for drinking water and wastewater were (and still are) different

Only mechanism for updating methods was a MUR

…. And we know how cumbersome those are

ANY change in a method required review and approval by EPA and its contractors

Redline/strikeout versions of all balloted methods provided to EPA and its contractors

EPA took a very conservative view of changes….. (lawyers rule….)

Drinking Water Approval Process- the Past

Almost more cumbersome than wastewater

Again required redline/strikeout review.

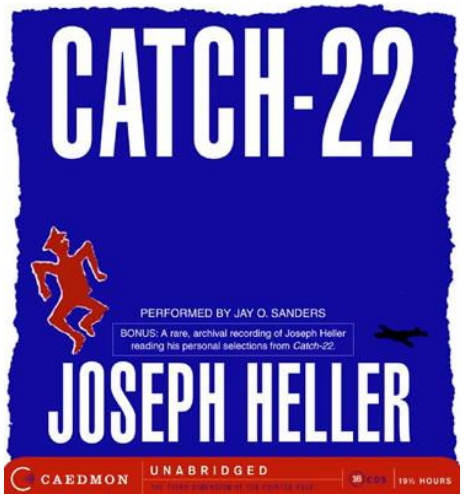
Could not submit methods till they were final – hence after a new edition was published

Safe Drinking Water Act interpretation was that cited methods could not be changed at all (not even to update QC) without review and then publication in the FR for proposal/promulgation

So What Did This Mean For Standard Methods?

Since sales were tied to approval, there was no incentive to update methods (or improve QC) because the newer book would not sell well…

Meantime EPA (WW and DW) kept asking us to update QC in the methods… so there was a



Solution #1

Our first “end run” was via part 1000 and early versions of the 020 sections, which we thought gave EPA a way to cite unchanged methods (the basic method) while we did update QC, as long as EPA did not have to cite QC directly…

This didn’t work…

Problems with That Approach

If the QC sections are just guidance, they can't be enforced

OR

EPA would look carefully at the 020 sections and consider them to be part of the method (our ultimate goal) and not be able to approve the new method without a MUR.

EPA viewed the 020 and 1000 as fundamental parts of methods and thus in some cases "disapproved" a method because of perceived reduction of QC.

Solution #2: So It Was Back to the Drawing Board and Collaboration

And EPA changed lawyers….

Safe Drinking Water Act - the Expedited Methods Rule

provided a mechanism for approval of newer methods (and hence better QC) without proposal/promulgation

WW – Dick Reding memo

re basic QA/QC elements when there were not any

And We Also Tried to Get Around the “Edition” Conundrum

We reached an agreement (we thought….) with EPA to change the method of citation

Once there was a mechanism for more rapid approval of methods we had an incentive to move to the on-line publication to get methods out more rapidly.

The SM Approach to Citation

EPA could cite online methods in addition to the printed methods (which would usually just be the printed version of the online method once we had established a date for printing a new hardcopy)

But what edition do you reference for the "online versions"?

Answer: Cite by year of approval

This has been adopted inconsistently so far by EPA

How Does QA/QC Play Into This?

Standard Methods is always trying to be sure we are responsive to regulatory demands (even though the book did not start out that way…)

In the early 2000s we began a 10+ year journey to get to the QC that is initially enshrined in the 22nd edition. This was designed in part to address concerns from OW and OGWDW and state regulators

Made more urgent when the last MUR eliminated many EPA methods from use for compliance

Our Policy re Using the Latest Version

Our view has always been that we want people to use the most current version of a method because we….

a) are seeking to be sure we resolve issues identified with old methods

b) don't have resources to support methods that are outdated

(where the author may have long since died…..)

c) with greater emphasis on regulatory use of Standard Methods it is essential that our built in QC be rigorous and clear enough to make audits objective.

Standard Methods and the MURs

The basic challenge for us and EPA has been how to ensure that people don't method shop based on perceived QA/QC

Lem Walker memo to States and Standard Methods

> **"If a method does not have QC in it, default to the 12 steps we identified…… If a method has QC <u>at a minimum</u> use that QC"**

This obviously directly impacts Standard Methods and the approval of the latest versions of methods.

Some Folks Are Taking SM QC in an Interesting Direction….

- **VDCLS: Why was the Fixed Limits Table needed?**

The 2012 40 CFR 136 Methods Update Rule (MUR) caused the Standard Methods 18th edition, published in 1992, to no longer be an option for laboratories. SM 18th edition included a table of fixed limits which were used as evaluation criteria for duplicates and for known additions.

TABLE 1020:I. ACCEPTANCE LIMITS FOR DUPLICATE SAMPLES AND KNOWN ADDITIONS TO WATER AND WASTEWATER

Analysis	Recovery of Known Additions* %	Precision of Low-Level Duplicates*† ± %	Precision of High-Level Duplicates*†‡ ± %
Metals	80–120	25	10
Volatile organics	70–130	40	20
Volatile gases	50–150	50	30
Base/neutrals	70–130	40	20
Acids	60–140	40	20
Anions	80–120	25	10
Nutrients	80–120	25	10
Other inorganics	80–120	25	10
Total organic carbon	80–120	25	10
Total organic halogens	80–120	25	15
Herbicides	40–160	40	20
Organochlorine pesticides	50–140	40	20
Captan	20–130	40	20
Endosulfans	25–140	40	20
Endrin aldehyde	25–140	40	20
Organophosphorus pesticides	50–200	40	20
Trichlorophon	20–200	40	20
Triazine pesticides	50–200	40	20
Carbamate pesticides	50–150	40	20

- **The referenced table was developed by two of us in the mid 80s. It was based on best judgment at the time.**

SM Dropped the Table Because We Could not Justify the Choice of Limits

- Virginia's table is interesting….
- But codifies the same condundrum we faced. It has some elements of being "arbitrary and capricious."
- Where there are limits in existing methods, there is justification, but each one needs to be thought through based on experience, which is why we have generally avoided specific limits in the 020 sections.

What Does This All Mean for Standard Methods and QA/QC?

SM positions

1) the QC articulated in the latest online and 22nd editions is essentially the same as what existed previously…. All we have done is to make it easier to find

2) the QC in Standard Methods is consistent with the 12 QC steps from Dick Reding's memo and the more recent guidance from Lem Walker

Oh, and We Need to Reiterate Something I Said a Few Years Ago

Method modifications

Although most of the issues with Standard Methods and the MURs have related to how to encourage the latest version of QC, there have also been questions about method modifications….

We have no objection to someone modifying a method beyond what is spelled out in the method as allowable modifications….AS LONG AS THEY DON'T CALL IT STANDARD METHODS….OR ASK US TO DEFEND IT…

Any Questions?

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