



Standard Methods and QA/QC Updates to Drinking Water and Wastewater- The Balancing Act of Regulatory Constraints



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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 Methods Update Rule (MUR)



22nd edition (2012) – significant QC clarifications included

Uh oh.... Now everyone wants to know where to go for QC when using different versions of Standard Methods for compliance

Will this presentation answer that question?

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

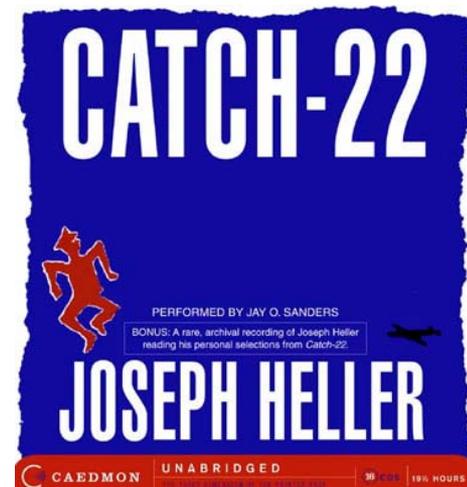
Safe Drinking Water Act interpretation was that cited methods could not be changed at all (not even to update QC) without review and then publication in the FR for proposal/promulgation

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

(Wait for Glynda Smith's presentation in an hour...)

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 New 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 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.



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 at a minimum use that QC”

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

Why Wasn't it Phrased this Way in the Final MUR?



Timing, timing, timing....

EPA could not add things to the final MUR that were not in the proposed MUR... and the latest version of the QC was not yet finalized by the deadline for getting things to EPA for review for the MUR (yes, we still need to provide that material for review...)

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

Where Can You Find Our Policy?



We were waiting for the dust to settle from this meeting, but within a week, our position as articulated here, will be on line for citation at:

www.standardmethods.org

Oh, and One More Thing We Feel Strongly About



Method modifications

Although most of the issues with Standard Methods and the MUR 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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