Quality Control
Built in, or Added on?

Two common approaches in methods for environmental monitoring and the challenges involved

Harry McCarty and Kevin Roberts

General Dynamics Information Technology

Disclaimer

This material has not been subjected to review by EPA and does not reflect Agency policy.

Neither does it reflect the views of USACE Corp

Rather, these are the observations of the authors over a lengthy period of support to various environmental programs.

In the Beginning …

- The U.S. Geological Survey, formed in 1876, was responsible for early water monitoring efforts
- The American Public Health Association published the first edition of *Standard Methods for the Examination of Water and Wastewaters* in 1905
- The ASTM D-19 Committee on water monitoring was created in 1932
- The National Sanitation Foundation was established in Michigan in 1944.

There were methods …

- And they were good,
- Because they were run by skilled scientists trying to protect human health,
- There was little profit motive,
- And where were no regulations to speak of.

Open a savings and loan, I said. It's the perfect crime! But no, you had to go and open an environmental laboratory!

U.S. Environmental Protection Agency

- Formed in 1970
  - The Clean Water Act was enacted in 1972
  - The Safe Drinking Water Act was enacted in 1974
  - RCRA was enacted in 1976
  - CERCLA was enacted in 1980
- All those programs had monitoring methods
- Problem solved, right?

Not quite ...

Clean Water Act Methods

- When the Office of Water (OW) first proposed methods for wet chemistry, metals, and organic “parameters” at 40 CFR Part 136 in 1979, questions were raised about quality control (QC) procedures.
- OW issued the *Handbook for Analytical Quality Control in Water and Wastewater Laboratories* (EPA-600/4-79-019) in an attempt to consolidate QC information in one place.
- OW asked the EPA Science Advisory Board (SAB) to review its approach to quality control and SAB responded that OW should use a consistent approach across all methods.
- In the 1984 final promulgation of the first set of EPA methods for NPDES compliance monitoring, OW did attempt to build in a consistent set of required QC operations and samples across those methods, where they applied.

They’re not goals, they’re requirements!

Clean Water Act Methods (continued)

- Unfortunately, the recommended consistency was lacking
- The “new” methods for organics tended to be consistent with one another
- The “new” multi-analyte methods for metals also were consistent with one another, but not completely consistent with the organics methods
- The older methods in Methods for Chemical Analysis of Waters and Wastes (MCAWW) for wet chemistry parameters (e.g., nutrients) and the single-analyte metals methods were not necessarily revised and republished with built-in matching QC, and relied on the 1979 “Handbook” as an add-on

Clean Water Act Methods (continued)

- The result was years of questions from labs, dischargers, regulators, and others
- OW invested in hotlines and outreach efforts at local and national meetings (Norfolk, Pittcon, WTQA, etc.)
- But before the internet, there was no good way to distribute “FAQs” or guidance documents to a wide audience
- OW built in a lengthy QC section in all of its new methods promulgated after 1984
- However, many methods from other sources were approved at Part 136 that did not have QC built in
- Therefore, OW also used regulations to promote consistent QC

Methods Update Rules

- In April 2004, OW proposed withdrawing a large number of MCAWW methods, where suitable newer alternatives existed. Many of those older methods lacked adequate QC. That rule was finalized in 2007.
- In September 2010, OW proposed adding language to Section 136.7 to:

  " …specify "essential" quality control at § 136.7 for use in conducting an analysis with an approved method and when insufficient instructions are contained in an approved method. Auditors, coregulators, laboratory personnel, and the regulated community have noted the different amounts and types of quality assurance (QA) and quality control (QC) procedures practiced by laboratories that use 40 CFR part 136 methods. …"

Methods Update Rules (continued)

- OW added:

  "twelve essential quality control checks that must be in the laboratory's documented quality system unless a written rationale is provided to explain why these controls are inappropriate for a specific *analytical method or application."*

- Those 12 QC checks applied not only to EPA methods, but to methods from Voluntary Consensus Standards Bodies (VCSBs) such as Standard Methods and ASTM.
- At the time, OW noted that the VCSB methods compendia may list QC requirements in a specific method, or elsewhere in the compendium.
- That rule was finalized in 2012.

12 Essential QC Elements added to 136.7

- Demonstration of Capability (DOC)
- Method Detection Limit (MDL)
- Laboratory reagent blank (LRB) or method blank (MB)
- Laboratory fortified blank (LFB) or laboratory control sample (LCS)
- Matrix spike (MS) and matrix spike duplicate (MSD)
- Internal standards, surrogate standards or tracers
- Calibration (initial and continuing)
- Control charts (or other trend analyses of quality control results)
- Corrective action (root cause analysis)
- QC acceptance criteria
- Definitions of preparation and analytical batches that may drive QC frequencies, and
- Minimum frequency for conducting all QC elements.

(Not all of these elements apply to every type of analysis)

Other EPA Programs

- Methods required for use under the Safe Drinking Water Act are promulgated at 40 CFR Part 141
- Most have included a fairly consistent set of QC operations built in, although the names of the QC samples often differ from other EPA programs
- However, the SDWA laboratory certification program includes QC requirements that may overlap, add on, or supersede some of the information in the approved methods from both EPA and VCSBs
- The RCRA program took an altogether different approach

SW-846 Methods

- The Office of Solid Waste (now ORCR) developed the SW-846 methods manual as a compendium of methods that could be used to demonstrate compliance with various RCRA regulations
- Many of the original methods were repackaged versions of OW's 200-Series and 600-Series methods that were:
  - Reformatted and divided into preparative, cleanup, and determinative procedures
  - Overall QC requirements were aggregated in Chapter One of the manual with some specifics included in the preparative procedures and others in the determinative procedures
  - Mostly importantly, almost all of the methods were issued as guidance, with QC being a project-specific issue

Superfund

- When the Contract Laboratory Program (CLP) was founded in 1980, they developed lengthy contractual statements of work (SOWs) that included QC operations and requirements specific to the limited analyses of interest to Superfund at the time.
- Methods in the early SOWs were based on the OW wastewater methods and the early SW-846 implementations of them for soils
- QC was built into the methods, but the early SOWs did not readily separate the different procedures for specific analytes, and as a result, the QC sections were not easy to follow
- Over time, CLP SOWs were revised and reorganized, and the extensive QC requirements are built into each procedure

VCSBs

- As noted earlier, some VCSBs include QC discussions in a separate section of their methods compendia
- Standard Methods Part 1000 includes a moderately lengthy discussion of QA and QC
- Beginning in 1989, the 17th edition of Standard Methods noted that additional QC discussions were added to the “Parts” devoted to different types of analyses (e.g., Part 3000 for metals, Part 4000 for non-metal inorganics, etc.)
- Those discussions were all Part “XX20” and originally were perhaps 1 to 2 pages in length.
- More recently, Standard Methods has expanded the summary level information in each Part XX20, with more details included in individual methods

VCSBs (continued)

- ASTM methods are issued as a series of interrelated "Standards" designed to address both the specifics of a given analysis as well as the broader issues associated with many different analyses (e.g., D1193 Specification for Reagent Water and D3370 Practices for Sampling Water)
- As late as 1988, and perhaps later, ASTM Standards for many common analyses made no mention of QC operations or acceptance criteria at all, nor referenced any obvious other QC "Standard"
- More recently, individual Standards include both QC operations and acceptance criteria

So What?

- As long as there are QC operations and specifications, who cares?
- Everybody knows what to do, right?

Reality Check

- Contrary to what some people think, analysts at the bench are not working from a copy of a given EPA or VCSB method
- They are likely using the lab's SOP to guide their work
- That's usually a good thing, since the SOP should be tailored to their lab layout, their supplies, their implementation of the procedure, etc.
- If the analysts are any good and are trained properly, they are not even walking through the SOP line by line every day
- Quality assurance is handled by a different part of the laboratory organization, independent from the generation of the sample results
- Clients for specific projects may have their own QC requirements

Challenges – As a Client

- How are you supposed to figure out if your QC requirements can be met using a specific analytical method?
- How many different documents do you need to find, read, and digest?
- How do you know what to put into a QAPP?
- How can you tell if your requirements are reasonable and readily achievable?
- How do you ensure that the laboratory you are using is implementing the method requirements and your project-specific requirements?

Challenges – As a Lab

- How do you figure out what the real QC requirements are?
- How many different documents do you need to find, read, and digest?
- How can you prepare SOPs that address each set of requirements?
- Can you even hope to have one SOP for similar methods from different sources (e.g., NPDES, RCRA, and SDWA)?
- How many parts of your organization need to review the SOPs to make sure that the QC requirements are covered?
- How do you transmit the project-specific requirements to your staff?
- How do you make sure that your internal review of the results is adequate?
- How do you bid on projects for different clients if the QC requirements are not clear?

Challenges - As an auditor or regulator

- Where do you find QC requirements and acceptance criteria for a given method?
  - In the approved version of the method?
  - In the method compendium?
  - In the laboratory's SOP?
  - In some other document?
- When a method does not contain QC requirements or acceptance criteria, how do you know which requirements and acceptance criteria apply?
  - What if the approved version of a VCSB method appears in more than one edition of a methods compendium and there are differences between the requirements in each edition?
- What about older methods from vendors that have been determined to be acceptable versions of approved methods?

Possible Solutions

- Read everything you can get your hands on!
- Read it again!
- Ask questions within your organization
- Ask EPA – but choose the relevant Program Office
- Ask the VCSB – is there even a mechanism?
- Write down the answers!
- Don’t expect every answer to be simple or universal

Possible Solutions (continued)

- Collaborative efforts among:
  - EPA Programs
  - EPA and VCSBs
  - EPA and States
  - Auditors/accrediting bodies and EPA and VCSBs
  - Auditors/accrediting bodies and labs
- Can QC be made more clear?
- Can we even agree on what QC operations are essential?
- Stop blaming the labs for everything, but hold their feet to the fire where they are responsible for quality

Possible Solutions (continued)

- Outreach, outreach, outreach!
- Webinars and conference calls can only achieve so much
- Face-to-face interactions are critical to solving the bigger problems and overcoming the disconnects, so fight to go to conferences, organize sessions, participate in VCSB workgroups, and stay involved
- Recognize that there is no single solution or approach that will cover everything, no matter what some committee says
- Respect the collective efforts of all of the organizations involved
- It *can't be* your way or the highway!