

The Official Method – is it time for a new approach? If so, it's time to PERFORM!

An Officially recognized method is the gold standard when it comes to analytical test methods, and we all know that data produced using an Official method is less likely to be challenged and is easily defended when disputes arise over test results. We know what we like about them, and we also know that the journey to produce these officially recognized procedures takes a long time, involves a lot of support and is expensive! Many really great methods never achieve this much sought-after status. Perhaps we can also agree that for ISO 17025 accredited labs, use of an Official method is not as critical as it once was; we are verifying the performance of the test methods that we use on the samples that we are testing, whether we are using an Official method or not. Many Official methods are being adapted for use well beyond the initial scope of the original procedure. Perhaps the best example of this is AOAC 2007.01, "QuEChERS". The extraction procedure used in this test method has been applied successfully to countless applications, well beyond the 26 pesticides and three fruit and vegetable matrices of the Official Method. We are consummate modifiers, and in doing so we are improving the performance, and expanding the applicability of the methods while making efficient use of our resources. We can demonstrate that the methods perform as well for these new applications, but they no longer have the same status as the Official method. **What if we develop an Official process to demonstrate equivalent performance of the method you used to the performance required of an Official method?** Could we get regulators on-board? What would be involved?

Let's take a look at the key elements involved in the current process for developing an Official method.

Support – there is a recognized need for the method, and people are willing to invest resources (time, technical expertise, supplies and money) in the method

Performance criteria – requirements that are specific to the use of the data; agreed upon by experts

Single lab validation (SLV) – data that demonstrate potential method suitability that has been put together in a format for review

Assessment of performance – collaborative study with a single sample set or use of reference material; expert review of the data produced

Publication – performance criteria, SLV and collaborative study data are published; the method itself is written in the specified format and published

Can we demonstrate method suitability in a different, streamlined, efficient and less costly manner? An Official process can include many of these elements, but also would provide flexibility and allow tailoring to meet specific needs. Let's talk about the resources needed for these elements. Support and contribution come from all stakeholders including laboratory personnel, policy regulators, instrument vendors, consumable manufacturers from government, academia, and industry representing the Residues and Contaminants Community. We need subject matter experts (SMEs) that have been vetted to ensure they have appropriate credentials. Developing and publishing templates for performance criteria, SLVs, and data packets to document performance assessment will be essential. Reference materials (RMs) are an absolutely critical component of this process. Development of suitable materials and provision of guidance on assessment of your performance using RMs is likely to be the most costly part of this enterprise, but will be extremely valuable.

NACRW has established the **PERFORM Working group** – Proficient, Equivalent, Reliable, Flexible, Officially Recognized Method – to explore development of such a process. The idea is to utilize the available published guidance to provide resources and tailored instructions to allow labs to demonstrate that their test methods meet Official performance criteria. We'll be developing a pool of vetted SMEs, custom document templates and sourcing suitable reference materials.

Please contact us to volunteer for the Working Group at PerformWGNACRW@gmail.com

Victoria Siegel and Jon Wong, PERFORM Co-chairs and Jo Marie Cook, NACRW working groups