Flexible Approaches to Environmental Measurement – The Evolution of the Performance Approach

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Assuring the quality of environmental measurements is essential to implementation of EPA's environmental programs, both regulatory and voluntary. In a 1997 Notice of Intent, the Agency outlined a "Performance Based Measurement System" concept that would "have the overall effect of improving data quality and encouraging advancement of analytical technologies." Ten years later, EPA has revisited the 1997 concept, gauged Agency progress towards achieving its goals, and redefined steps needed to ensure continued progress.

The Agency now believes that while it may be possible to specify performance criteria in a manner that is independent of methods, techniques, or instruments, the development of a single protocol for the validation of these measurements that could be applied to all measurements, including measurements made with techniques yet to be invented, is simply not possible. Accordingly, EPA is introducing flexible approaches in environmental measurement which capture the Agency's experience of the past ten years and sets the stage for future progress.

Key goals for these flexible approaches are as follows:

1) Increased emphasis on flexibility in choosing sampling and analytical approaches to meet regulatory requirements for measurements;
2) Development of processes for validation that confirm that measurements meet quality requirements;
3) Increased collaboration with stakeholders to develop validation processes for new measurement technology; and
4) Rapid assessment of new or modified technologies, methods and procedures.

These goals are discussed in more detail below.

1) Increased emphasis on flexibility in choosing sampling and analytical approaches to meet regulatory requirements for measurements.

The process for setting measurement requirements begins with identification of goals, considering such things as action levels, technology performance and mandates or limitations of the program or project. These goals may be set broadly across a program and set by a program office, or may be specific to a project or permit.

Goals are translated into measurement requirements which may take a variety of forms. In some applications, there may be a general requirement on accuracy; while in others, these requirements may be coupled to a technology, method or procedure (e.g. criteria for evaluating modifications to published reference methods).

The Agency acknowledges that many of its measurement quality requirements that appear throughout its regulations are more specific than are absolutely necessary, and intends to make these requirements more flexible as time and resources allow.

2) Development of processes for validations that confirm that measurements meet quality requirements.

A validation process should provide evidence that measurement quality requirements are achieved. According to ISO 17025[1], "validation is the confirmation by examination and the provision of objective evidence that the particular requirements for specific intended use are fulfilled." Validation is typically performed in two phases. The first phase provides evidence on both general performance of a measurement system on a range of materials that define a matrix class; while the second phase (often called verification) demonstrates that the requirements for a specific use are met. Both phases are important for scientific and legal defensibility.

The more general a measurement requirement, the more specific a validation process must be. A general requirement on accuracy that is specified in a manner independent of technique, method, or instrument must be accompanied by detailed validation for each method of measurement. On the other hand, a measurement quality requirement to use a particular procedure can require essentially no validation, as a detailed procedure often includes a complete specification of required quality control activities.

EPA intends to develop processes for validation that allow for an appropriate choice of specificity. For some applications, this may continue to be the use of defined procedures with ongoing quality control, while other applications may place emphasis on greater flexibility and include verification that the requirements for a specific use are achieved.

3) Increased collaboration with stakeholders to develop validation processes for new measurement technology.

It is difficult to specify in advance the validation that is required for new technology due to the wide variety of performance issues that may be encountered. The Agency anticipates that development of validation processes for applications of new technology will require collaboration with stakeholders to ensure timely development of these processes, and that the Agency must continue to play a key role in their development.

4) Rapid assessment of new or modified technologies, methods and procedures.

In the event that the measurement requirements in a program are specific to a technology, method, or procedure, the Agency is committed to rapid assessment of proposed alternatives to these requirements and to timely approval of these alternatives when approval is sought.

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[1] ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories.