

Demystifying Methods Development: Methods Development and Validation for Use in Regulatory and Other Programs

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There seems to be an impression among methods developers and the regulated community that there is some esoteric or mystical process that must be followed in order to get an analytical method "approved" by regulatory agencies like the U.S. EPA. Actually, there is no difference in developing methods for these Agencies and those methods to be used in any other area of chemistry, either in the public or private sector.

This training, is designed to dispel these misconceptions, identify some basic principles, and present a logical approach to methods development that is currently followed by OSW in developing methods for SW-846 and for other general applications.. This approach is based on sound scientific principles, and methods developed according to this process would be acceptable for use in other regulatory and industrial programs, and be legally defensible.

The training covers the basic elements that must be addressed for a successful methods development project, how to generate a viable project plan, and what to include in the supplemental documentation supporting the method submission. It includes an interactive workshop atmosphere where attendees will be able to develop actual project plan outlines to address real analytical problems and learn from actual case studies.

Two levels of methods development are covered in this training, initial "proof of concept" and a formal validation. This guidance is applicable to both new methods or for adapting existing methods for additional applications. Additional coverage of this training includes basic principles for site-specific method validation, or "demonstration of applicability" of a method for its intended use.

The basic method development approach in this course utilizes three basic principles for either demonstrating "proof of concept" or for use in a formal validation. These basic scientific principles are:

- 1) Identify the scope and application of the proposed method, (What is this method supposed to accomplish?)
- 2) Develop a procedure that will generate data that are consistent with the intended scope and application of the method, and

- 3) Establish appropriate quality control procedures which will ensure that when the proposed procedure is followed, the method will generate the appropriate data from Step 2 that will meet the criteria established in Step 1.

An additional portion of this training addresses “Analytical Strategy”, which involves how to put together a project or study plan to use these methods in actual practice

BARRY LESNIK

Barry Lesnik is a Chemist with more than 39 years of methods development and chemical problem solving experience. For more than 20 years, he was with the Methods Team of EPA's Office of Solid Waste (OSW) where he was the RCRA Organic Methods Program Manager. His other responsibilities for OSW included dealing with RCRA regulatory issues involving analytical methods, serving as the OSW technical representative on cross-Agency and inter-Agency issues and Workgroups, serving as the OSWER voting representative to the National Environmental Laboratory Accreditation Conference (NELAC), and dealing with mixed waste issues. He also served as the leader of the Chemistry Workgroup for the EPA Homeland Security Methods Manual, SAM. Barry was with EPA from 1987 until his retirement at the end of 2007, except for ten months in 1991, when he was with DOE's Laboratory Management Branch. His responsibilities as Analytical Support Program Manager at DOE included the DOE Methods Compendium, as well as development of field and mixed waste methods.

Barry received his B.S. in Chemistry from Drexel University in Philadelphia. He did graduate work at the University of Pennsylvania. In addition to his 20 plus years of government experience, Barry has over nineteen years of industrial experience as a chemist and laboratory manager in a variety of industries including environmental consulting, food, aerospace, detergents, and fats and oils. He has also managed a commercial environmental analytical laboratory and a laboratory for a RCRA waste handling facility.

In 2000, Barry received one of the 12 National Excellence Awards for public service awarded annually by the Canadian government as a member of an international methods development team which included members from both Environment Canada and the U.S. EPA.