

**Ensuring the Validity of Agency
Method Validation and Peer Review Guidelines:
Microbiological Methods of Analysis** *Agency
Policy Directive Number FEM-2009-01*

Purpose

This document establishes the U.S. Environmental Protection Agency's (EPA's) policy with respect to the validation and peer review of microbiological methods of analysis.

Effective Date

This policy becomes effective upon December 7, 2009. After review, this Policy is being reissued with minor updates for five years from December 21, 2016.

Applicability

The policy applies to the evaluation of the performance and suitability of new environmental microbiological methods of analysis, which are to be: (1) published as serially numbered US EPA methods, (2) published as regulations, or (3) incorporated by reference in regulations.

Background

The EPA Science Policy Council established the Forum on Environmental Measurements (FEM) as a standing committee of senior EPA managers who provide EPA and the public with a focal point for addressing measurement and methods issues with multi-program impact. In October 2003, the FEM established the Method Validation Team to develop an Agency-wide policy to ensure the validity of new analytical methods prior to their publication for general use. One of the results of this effort was the development of this policy and a technical document titled, "*Method Validation of U.S. Environmental Protection Agency Microbiological Methods of Analysis*." The document describes general principles for determining and demonstrating that a microbiological method of analysis is suitable for its intended purpose (i.e., yields acceptable accuracy for the analyte, matrix, and concentration range of concern).

Policy

It is EPA's philosophy that all methods of analysis should be validated prior to issuance as an Agency method. This policy directive addresses the validation of microbiological methods of analysis, which should be validated by a process that, at a minimum, follows the guidelines in *Method Validation of U.S. Environmental Protection Agency Microbiological Methods of Analysis (FEM Document Number 2009-01, October 7, 2009; REVISION: December 21, 2016)*.

Any EPA organization that proposes to issue a microbiological method of analysis should ensure and document that the method has been validated according to this policy.

Each Program Office is responsible for establishing and documenting that its microbiological methods of analysis have been validated and peer reviewed in accordance with the above document. A Program Office may determine that an alternative validation and peer review process is equivalent to this policy for a method referenced and/or used. Prior to formal issuance as official EPA methods, by publication in the *Federal Register*, the Program Offices should provide documentation that the methods are consistent with the guidance document as part of the formal Agency concurrence procedures and records management policy.