

Guidelines for Ensuring the Validation and Peer Review of Agency Methods: Environmental Sampling Techniques that Support the Detection and Recovery of Microorganisms

Agency Policy Directive Number FEM-2012-01

Purpose

This document establishes the U.S. Environmental Protection Agency's (EPA's) policy with respect to the validation and peer review of environmental sampling techniques that support the detection and recovery of microorganisms from the environment.

Effective Date

This policy becomes effective upon December 12, 2012.

Applicability

The policy applies to the evaluation of the suitability of new environmental sampling techniques that support the detection and recovery of microorganisms from the environment. The policy specifically addresses methods that are to be: (1) published as 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 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, "*Validation of U.S. Environmental Protection Agency Environmental Sampling Techniques that Support the Detection and Recovery of Microorganisms.*" The document describes general principles for determining and demonstrating that an environmental sampling technique that supports the detection and recovery of microorganisms from the environment is suitable for its intended purpose (e.g., yields acceptable accuracy for the analyte, matrix, and concentration range of concern).

Policy

It is EPA's policy that all methods of analysis should be validated and peer reviewed prior to publication as an Agency method. This policy directive addresses the validation and peer review of environmental sampling techniques that support the detection and recovery of microorganisms from the environment. These techniques should be peer reviewed and validated by a process that, at a minimum, follows the guidelines in *Validation of U.S. Environmental Protection Agency Environmental Sampling Techniques that Support the Detection and Recovery of Microorganisms (FEM Document Number 2012-01, December 2012)*.

Any EPA organization that proposes to publish an environmental sampling technique that supports the detection and recovery of microorganisms from the environment is responsible for ensuring and documenting that the method has been validated and peer reviewed according to this policy. An EPA organization may determine that an alternative validation and peer review process is equivalent to this policy. Prior to formal publication as official EPA methods the EPA organization should provide

documentation that any alternative process used is consistent with the guidance document as part of the formal Agency concurrence procedures and records management policy.