

Ensuring the Validity of Agency Methods Methods Validation and Peer Review Guidelines

Agency Policy Directive Number FEM-2006-01

Purpose

This document establishes the U.S. Environmental Protection Agency's (EPA's) policy with respect to the validation of radiochemical methods of analysis used for environmental monitoring.¹

Effective Date

This policy becomes effective upon (insert date of signature).

Applicability

The policy applies to radiochemical methods of analysis, issued by the Agency, that are new, rational, quantitative, and intended for use in analytical laboratories.

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, "*Validation and Peer Review of U.S. Environmental Protection Agency Radiochemical Methods of Analysis*." The document describes general principles for determining and demonstrating that a radiochemical analysis method 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 radiochemical methods of analysis, which should be validated by a process that, at a minimum, follows the guidelines in *Validation and Peer Review of U. S. Environmental Protection Agency Radiochemical Methods of Analysis (FEM Document Number 2006-01, October 2006)*.

Any EPA organization that proposes to issue a radiochemical method 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 radiochemical methods 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.

¹ This document is a statement of Agency policy and does not constitute a rule. It is not intended, nor can it be relied upon, to create any rights enforceable by any party in litigation with the United States.