

**Ensuring the Validity of Agency Methods  
Methods Validation and Peer Review Guidelines:  
Sampling Methods for Chemical and Radiochemical Parameters**

*Agency Policy Directive Number FEM-2007-02*

**Purpose**

This document establishes the U.S. Environmental Protection Agency's (EPA's) policy with respect to the validation and peer review of sampling methods for chemical and radiochemical parameters used for environmental monitoring.<sup>1</sup>

**Effective Date**

This policy becomes effective upon December 3, 2007.

**Applicability**

The policy applies to the evaluation of the performance and suitability of new environmental sampling methods for chemical and radiochemical parameters, 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, "*Validation and Peer Review of U.S. Environmental Protection Agency Sampling Methods for Chemical and Radiochemical Parameters.*" The document describes general principles for determining and demonstrating that a sampling analysis method for chemical and radiochemical parameters 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 sampling methods for chemical and radiochemical parameters 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 Sampling Methods for Chemical and Radiochemical Parameters (FEM Document Number 2007-02, November 8, 2007)*.

Any EPA organization that proposes to issue a sampling method for chemical and radiochemical parameters 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 sampling methods for chemical and radiochemical 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

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<sup>1</sup> 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.

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.