

**Ensuring the Validity of Agency
Methods Validation and Peer Review Guidelines:
Methods of Analysis Developed for Emergency Response Situations**
Agency Policy Directive Number FEM-2010-01

Purpose

This document establishes the United States Environmental Protection Agency's (EPA's) policy with respect to the validation¹ and peer review² of all environmental methods of analysis (e.g., chemical, radiochemical, microbiological) developed for emergency response³ situations. All methods of analysis must have documentation to support their utilization.

Effective Date

This policy became effective on July 21, 2010. This policy was reaffirmed on October 25, 2016.

Applicability

This policy applies to the evaluation of the performance and suitability of new environmental methods of analysis that are used in emergency response situations (e.g., natural disaster, homeland security).

Background

The EPA Science and Technology Policy Council (STPC)⁴ 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 method issues with multi-program impacts. The FEM has established a team devoted to the Improvement of the Quality of Agency Methods for the development of Agency-wide policy to ensure the validity of new analytical methods prior to their publication for general use. Although several policy and technical guidance documents have been developed (e.g., Chemical Methods, Radiochemical Methods, Sampling for Chemical and Radiochemical Methods, Microbiological Methods), they are not well-suited to evaluate

¹ Consistent with EPA method validation guideline documents (e.g., *Method Validation of U.S. Environmental Protection Agency Microbiological Methods of Analysis*) and *Guidance on Environmental Data Verification and Data Validation*, validation is the confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use are fulfilled.

² EPA Science Policy Council, *Peer Review Handbook*, 3rd ed.; EPA/100/B-06/002; U.S. Environmental Protection Agency, Office of Science Policy, Office of Research and Development, Washington, DC, December 2006.

³ In 40 CFR Part 68, "response" has the same meaning as that term has under OSHA's Hazardous Waste Operations and Emergency Response (HAZWOPER) Standard (29 CFR 1910.120). OSHA defines emergency response as "a response effort by employees from outside the immediate release area or by other designated responders ... to an occurrence which results, or is likely to result, in an uncontrolled release of a hazardous substance."

⁴ Prior to July 2010, the STPC was the Science Policy Council (SPC).

the performance and suitability of environmental methods of analysis that must be developed and utilized expeditiously for emergency response situations. This policy is intended to establish a process for use in these emergency response situations only.

Policy

It is EPA's policy that all methods of analysis (e.g., chemical, radiochemical, microbiological) must be validated and peer reviewed prior to issuance as Agency methods. There are emergency response situations that require methods to be developed and utilized, which may or may not have previously been validated or peer reviewed prior to use. This policy directive addresses those situations in which a method must be developed, validated, and/or peer reviewed expeditiously for utilization in an emergency response situation. Also, in such emergency response situations only, an analytical method may be employed that has been validated by another established laboratory network (e.g., the Center for Disease Control and Prevention's Laboratory Response Network, the U.S. Department of Agriculture/Food and Drug Administration's Food Emergency Response Network). In those instances, the responsible federal agency will indicate that the level of validation and/or peer review that their analytical method underwent is consistent with the Integrated Consortium of Laboratory Networks (ICLN) *Guidelines for Comparison of Validation Levels between Networks*⁵. The responsible federal agency may also refer to the *Validation Guidelines for Laboratories Performing Forensic Analysis of Chemical Terrorism*⁶ in order for the receiving federal agency to determine if the analytical method meets the intended purpose.

Any EPA regional or program office that proposes to utilize a method in an emergency response situation is responsible for establishing and documenting to what level and by what process the method has been validated and/or peer reviewed in accordance with this policy. A regional or program office may determine the level of validation and/or peer review that is necessary to provide the objective evidence that a method is suitable for its intended purpose; however, the office must document the validation and/or peer review information supporting use of the method. All documentation should be preserved in accordance with the Agency's records management policy.

⁵ U.S. Department of Homeland Security, Integrated Consortium of Laboratory Networks (ICLN), *ICLN Guidelines for Comparison of Validation Levels between Networks*, Original Version, <http://www.icln.org/docs/sop.pdf>.

⁶ Federal Bureau of Investigation (FBI), Scientific Working Group on Forensic Analysis of Chemical Terrorism (SWGFACT), *Validation Guidelines for Laboratories Performing Forensic Analysis of Chemical Terrorism*, Forensic Science Communications, Volume 7, Number 2, April 2005.