ASSURING THE COMPETENCY OF ENVIRONMENTAL LABORATORIES
AGENCY POLICY DIRECTIVE

Approved: February 23, 2004; Reaffirmed: November 20, 2015
Revised & Approved: August 25, 2025[1]

To assure the competency of the Agency's laboratories, all laboratories operated by US Environmental Protection Agency (EPA), including government owned contractor operated laboratories, will be required to maintain a documented Quality Program (e.g., Quality Manual, accreditation, Quality Management Plan [QMP], facility manual). At a minimum, laboratories must comply with the requirements of the EPA Quality Program as defined by the current versions of the EPA Environmental Information Quality Policy and Environmental Information Quality Procedure plus contain the specific components listed here under Laboratory Quality Program Components. In addition, documentation of competency through independent assessments and participation in inter- laboratory comparisons or programs is required as specified below. Program oversight will be provided through annual reports by laboratory organizations though the Office of Mission Support (OMS) to the Science Technology Policy Council (STPC).

DEFINITIONS

Accreditation – As defined by the International Organization for Standardization (ISO) https://www.iso.org/certification.html, accreditation is the formal recognition by an independent body, generally known as an accreditation body, that a certification body operates according to international standards.

Certification – As defined by the ISO (https://www.iso.org/certification.html), certification is the provision by an independent body of written assurance (a certificate) that the product, service or system in question meets specific requirements.

Competence – The demonstrated ability to apply knowledge and skills. Some examples for specific discipline areas can be found using the ISO Online Browsing Platform (OBP), Terms & Definitions, https://www.iso.org/obp/ui.

LABORATORY QUALITY PROGRAM COMPONENTS

- Staff training

[1] In 2004, EPA's Science and Technology Council (STPC) established and chartered the Forum on Environmental Measurements (FEM) to develop and issue policy documents ensuring that organizations are technically competent and have effective Quality Program management. While the FEM was dissolved in 2019, in 2025, the STPC convened and charged an ad hoc working group to review the policies, and either reaffirm or revise them, as appropriate. As a result, this policy is being reaffirmed.

- Initial and continuing demonstrations of laboratory capability
- Demonstration of individual staff capability and competency demonstrations of individual staff capability and competency
- Active internal Quality Program including routine internal audits and management reviews, as required
- Validation/verification of method performance
- Systematic planning of work
- Correction of deficiencies identified during audits
- Controls on subcontracting to ensure data quality
- Laboratory standard operating procedures
- Laboratory control charts

DEMONSTRATING LABORATORY COMPETENCY

- Independent external assessments. All laboratories must have routine independent external assessments to demonstrate and document the laboratory is adhering to the procedures and policies described in its documented Quality Program.
- Accreditation. Where an appropriate recognized accreditation program is available for all or part of a laboratory's operation (e.g., NELAP, ISO), the laboratory will participate in that program. In the absence of appropriate recognized accreditation program(s), laboratories must be assessed by qualified independent assessors. A routine external assessment/audit of each of the laboratory's functional areas (e.g., analytical, toxicity testing, modeling) will be performed as required. Assessments include evaluating the laboratory's Quality Program and audits of its products and data. This may require a combination of assessments, audits, and accreditations to assure thorough evaluation of all laboratory operations including multiple accreditations where necessary or appropriate.
- Participation in inter-laboratory comparison studies/programs. These can be either existing Proficiency Evaluation Programs or Round Robin Studies or a combination of programs and studies to assure evaluation of all laboratory operations.

PROGRAM IMPLEMENTATION AND OVERSIGHT

Implementation of this policy by the laboratory's parent organization will be documented in their QMP and submitted to OMS following the Agency's regular 5-year cycle or as required by the current versions of the EPA Environmental Information Quality Policy and Environmental Information Quality Procedure.

OMS will annually document and report the implementation of this policy to the STPC and each organization's management by:

1. Reviewing each organization's QMP as it is submitted (Quality EPA Quality Management Plan Standard);

2. Compiling the Quality Assurance Annual Report and Work Plan (QAARWP) submittals from each organization; and
3. Checking on the status of implementation during the Quality Program Assessment (QPA) process, as appropriate.