

Assuring the Competency of Environmental Protection Agency Laboratories
Agency Policy Directive
Approved: February 23, 2004
Reaffirmed: November 20, 2015

To assure the competency of the Agency's laboratories, all laboratories operated by EPA, including government owned contractor operated laboratories, will be required to maintain a documented Quality System that at a minimum complies with the requirements of the EPA Quality System as defined by EPA Order 5360.1 A2 May 2000, *Policy and Program Requirements for the Mandatory Agency-wide Quality System* and contains the specific components listed here under Laboratory Quality System Components. In addition, documentation of competency through independent assessments and participation in inter-laboratory comparisons or programs is required as specified below. System oversight will be provided through annual reports by laboratory organizations to the Office of Environmental Information (OEI); OEI will report to the Forum on Environmental Measurement (FEM), the Science Technology Policy Council (STPC), and the Quality Information Council (QIC).

Laboratory Quality System Components

- staff training
- initial and continuing demonstrations of laboratory capability demonstration of individual staff capability and competency
- active internal quality assurance system including periodic internal audits periodic management reviews
- validation/verification of method performance documentation of procedures used and results obtained systematic planning of work
- correction of deficiencies found 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 periodic independent external assessments to demonstrate and document that the laboratory is adhering to the procedures and policies described in its documented Quality System.
- Where an appropriate recognized accreditation program is available for all or part of a laboratory's operation, the laboratory will participate in that program. In the absence of appropriate recognized accreditation programs, laboratories must be assessed by qualified independent assessors. A periodic external assessment/audit of each of the laboratory's functional areas (e.g., analytical, toxicity testing, modeling) will be performed at least once every three years. Assessments include evaluating the laboratory's Quality System 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.

System Implementation and Oversight

- Implementation of this policy by the laboratory's parent organization will be documented in their Quality Management Plan (QMP) and submitted to OEI following the Agency's regular 5 year cycle or as called for in EPA Order 5360.1 A2.
- OEI will assess implementation of this policy by: (1) reviewing each organization's QMP as it is submitted (Quality Manual Section 3.2.4) or on a 5 year cycle; 2) checking on the status of implementation during the Quality System Assessment (QSA) process on a 3 year cycle; and (3) reviewing every year the Quality Assurance Annual Report and Work Plan (QAARWP) submittals from each organization.
- OEI will report annually to FEM, STPC, and QIC.