UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAR 10 2004

MEMORANDUM

SUBJECT: New Policy Directive on Assuring and Documenting the Competency of Agency Laboratories

FROM: Paul Gilman
Science Advisor to the Agency (8101R)

TO: Assistant Administrators
Regional Administrators
Deputy Assistant Administrators
Deputy Regional Administrators

On February 23, 2004, the Agency's Science Policy Council issued a new Agency Policy Directive, *Assuring the Competency of Environmental Protection Agency Laboratories* (see attached policy). To assure the quality of data generated by our laboratories, all the laboratories operated by EPA, including Agency owned, contractor operated facilities, will need 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 items listed in the Laboratory Quality System Components section of the Policy Directive. All laboratories will document adherence to their quality system through periodic independent assessments and by participation in inter-laboratory comparisons. In addition, where appropriate accreditation programs are available for one or more components of a given laboratory's operations (e.g., environmental sample analysis, animal husbandry, microbiology), the laboratory will seek accreditation for those components. The Office of Environmental Information (OEI) will provide oversight of policy implementation through the existing Quality Assurance Annual Report and Work Plan, and Quality Management Plan review processes. OEI will report annually to the Forum on Environmental Measurement (FEM), the Science Policy Council (SPC), and the Quality Information Council (QIC) on the results of their oversight. Implementation of this policy will go a long way toward protecting the Agency against any challenges to the data that we generate.

As a first step in implementing the new directive, each laboratory will submit to the FEM, by the end of August, 2004, a description of the approach they will use in implementing the policy and an implementation timetable. The FEM Laboratory Competency Action Team will remain active to provide assistance on policy implementation. The Action Team will also review and evaluate the implementation plans that are submitted to the FEM and identify any implementation or clarification issues that may need to be addressed by the FEM.

We urge you to appoint appropriate members of your laboratory staff to this Action Team. Please notify David Friedman, FEM Executive Director, of the members of your organization that will be participating on the Action Teams so that they can be notified of upcoming meetings. In addition, if you have any questions about the new policy, please contact David. He can be reached at: friedman.david@epa.gov or 202-564-6662.

Attachment

Assuring the Competency of Environmental Protection Agency Laboratories

Agency Policy Directive

Approved: February 23, 2004

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 Policy Council (SPC), 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

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.

  - As an interim implementation step, the first external assessment performed as a result of this policy may utilize assessors that are Agency employees but independent of the laboratory being assessed. All subsequent assessments must be performed by independent assessors who are not agency employees and are free of any perceived conflict of interest in assessing the specific agency laboratory being assessed.

- **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

- As a first step in implementing this directive, each laboratory will submit to the FEM, within six months of the policy's effective date, a description of their approach and timetable for implementing the policy.

- 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, SPC, and QIC.