POLICY TO ASSURE THE COMPETENCY OF ORGANIZATIONS GENERATING ENVIRONMENTAL MEASUREMENT DATA UNDER AGENCY-FUNDED ASSISTANCE AGREEMENTS

Agency Policy Directive Number FEM-2012-02 Revision 1; Approved: March 13, 2013

PURPOSE

This document establishes the U.S. Environmental Protection Agency's (U.S. EPA's or the Agency's) policy requiring organizations generating or using environmental data under certain Agency-funded assistance agreements¹ to submit documentation of their competency prior to award of the agreement or if that is not practicable prior to beginning any work involving the generation or use of environmental data under the agreement. This includes organizations performing environmental sampling, field measurements, and/or laboratory analyses under Agency-funded agreements.

EFFECTIVE DATE

This Policy was originally approved on December 12, 2012 by the Science Technology Policy Council (STPC) and will be effective on May 15, 2013. As further described below, the Policy will apply to competitive and non-competitive assistance agreements expected to exceed a total maximum value of \$200,000 (in federal funding) that will involve the generation or use of environmental data. The Policy will be reviewed against experience and feedback within two years after its effective date and will either be reissued without revision, reissued with revisions, or rescinded.

DEFINITIONS

For purposes of this Policy, the following definitions apply:

Accreditation – As defined in various International Organization for Standardization (ISO) publications and glossaries, accreditation is a procedure by which an authoritative body gives formal recognition that an entity is competent to carry out specific tasks.

Assistance agreement – As described in the U.S. EPA Grants and Debarment Glossary (<u>http://www.epa.gov/ogd/recipient/glossary.htm</u>), an assistance agreement is the legal instrument that the U.S. EPA uses to transfer money, property, services, or anything of value to a recipient to accomplish a public purpose. It is either a grant or a cooperative agreement and will specify certain things including: budget and project periods; the federal share of eligible project costs; a description of the work to be accomplished, and any terms and conditions/special conditions.

¹ Interagency agreements (if applicable) were included in the original policy, but removed in revision 1 due to the determination by the Office of General Counsel that a competency review would not need to be performed on a Federal Agency since all agencies must comply with fiduciary management rules and regulations.

Competence – As defined in ISO 9000, competence is the demonstrated ability to apply knowledge and skills.

Certification – As similarly defined in various ISO publications and glossaries, certification is the recognition provided by an independent body related to products, processes, systems or persons.

Environmental data – As defined in the U.S. EPA Quality Policy (CIO 2106.0; 10/20/08), environmental data include any measurements or information that describe environmental processes, location or conditions; ecological or health effects and consequences; or the performance of environmental technology.

APPLICABILITY

This Policy applies to all U.S. EPA programs (e.g., Program Offices, Regional Offices, and Laboratories) responsible for evaluating, issuing, and/or managing Agency assistance agreements involving organizations generating or using environmental data through environmental sample collection, field measurements and/or laboratory analyses. It applies to new competitive and non-competitive awards that at the time of solicitation issuance or award are expected to exceed \$200,000 (in federal funding) in total maximum value (including any amendments).² This is an additional award requirement to be implemented by the project officer(s) and overseen by the project officer(s) or their technical designee(s). This Policy does not replace any existing requirements (e.g., general information, quality system requirements documentation) or prohibit an Agency program from placing additional requirements or stipulations on an organization receiving an award. Project officers are responsible for implementing the requirements under this Policy and ensuring that appropriate solicitation provisions and programmatic terms and conditions, if necessary, are included in solicitations and assistance agreements.

This Policy applies to:

- Awards made under competitive solicitations issued after May 14, 2013 that are expected to exceed \$200,000 (in federal funding) in maximum total value and involve the use or generation of environmental data; and
- Non-competitive assistance agreements awarded after May 14, 2013 that are expected to exceed \$200,000 (in federal funding) in total maximum value and involve the use or generation of environmental data.

BACKGROUND/AUTHORITY

The U.S. EPA Science Policy Council (now U.S. EPA Science and Technology Policy Council) established the Forum on Environmental Measurements (FEM) as a standing committee of senior U.S. EPA managers who provide the Agency and the public with a focal point for addressing measurement, monitoring and laboratory issues with multi-program impact. Since the inception of the FEM in April 2004, an action item has existed for the FEM to assure the competency of

 $^{^{2}}$ While this Policy does not apply to existing awards, or awards under the dollar threshold, offices are encouraged to apply this Policy to those awards as deemed appropriate.

organizations funded by the Agency under acquisition and/or assistance agreements to generate environmental data through measurement activities. The goal is to assure that, nationwide, organizations performing environmental data operations have effective quality management systems and technical competence, and thus have the capability to generate valid environmental data.

In 2004, the Agency issued a policy to assure the competency of U.S. EPA laboratories. In 2011, the Agency issued a second policy to assure the competency of organizations (e.g., laboratories, field sampling and measurement) generating environmental data under Agency-funded acquisitions (i.e., contracts).

This Policy was developed to ensure the use of competent organizations for performing activities involving the use or generation of environmental data under Agency-funded assistance agreements. As explained below, these organizations will have to demonstrate competency either prior to award or prior to beginning such activities. Project officers are responsible for implementing this requirement.

A Frequently Asked Question document is available with further details on implementing this Policy³. This will be revised and updated as necessary. Questions as to whether activities involve the use or generation of environmental data and are covered by this Policy should be referred to the FEM (<u>http://www.epa.gov/fem/lab_comp.htm</u>).

REQUIREMENTS

Organizations performing activities involving the use or generation of environmental data under covered assistance agreements shall provide the Agency with:

- Quality documentation such as a quality management plan (QMP), and/or other documentation that demonstrates conformance to U.S. EPA quality program requirements⁴; and
- Demonstration of competency in the field(s) of expertise.

Demonstration of competency may include (but not be limited to):

- Current participation in accreditation or certification programs that are applicable to the environmental data generated under the Agency-funded assistance;
- Ongoing participation by the organization in proficiency testing (PT) or round robin programs conducted by external organizations;
- Ongoing U.S. EPA accepted demonstrations and audits/assessments of proficiency; and
- Other pertinent documentation that demonstrates competency (e.g., past performance to similar statement of work [SOW]).

Assistance agreement solicitations and agreements will include applicable provisions and terms and conditions. Examples will be contained in the FAQ document.

³ See http://www.epa.gov/fem/lab_comp.html

⁴ See http://www.epa.gov/quality

IMPLEMENTATION

Competitive awards and solicitations: Program offices that issue competitive solicitations expected to result in awards exceeding \$200,000 (in federal funding) in total maximum value that will involve the generation or use of environmental data must include a provision in the solicitation indicating that applicants for these awards must demonstrate competency (i) prior to award or (ii) if that is not practicable or will unduly delay the award prior to beginning such activities under the award. For awards covered by (i) above where the Project Officer obtains the competency demonstration prior to award the Project Officer will include the demonstration in their file. For awards covered by (ii) above, where the competency demonstration will be made after award, the Project Officer will include a programmatic term and condition in the grant requiring the grantee to demonstrate competency prior to performing any work involving the use or generation of environmental data. This competency demonstration should be documented in the project officer's file. Sample clauses will be provided in the FAQ document.

Non-competitive awards: Program offices that make non-competitive awards expected to exceed \$200,000 (in federal funding) in total maximum value that will involve the generation or use of environmental data should ensure that the applicant demonstrates their competency to perform such activities prior to award. This will be documented by the Project Officer in their file. However, if obtaining the competency demonstration prior to award is impracticable or will cause a significant delay of the award, project officers must include a programmatic term and condition in the grant requiring the grantee to demonstrate competency prior to performing any such activities. This competency demonstration should be documented in the project officer's file. Sample clauses will be provided in the FAQ document.

Note: If, at time of award, it is uncertain whether the award will exceed \$200,000 (in federal funding) in total maximum value and involve the generation or use of environmental data, the project officer will include a term/condition in the award that the recipient must demonstrate competency prior to performing any such activities (an example will be put in the FAQ document).

REFERENCES

- US EPA Grants and Debarment, <u>http://www.epa.gov/ogd</u>.
- US EPA CIO 2106.0 U.S. EPA Quality Policy, October 20, 2008, <u>http://www.epa.gov/irmpoli8/policies/21060.pdf</u>
- U.S. EPA CIO 2105-P-01-0 EPA Quality Manual for Environmental Programs, May 5, 2000, <u>http://www.epa.gov/irmpoli8/policies/2105P010.pdf</u>
- U.S. EPA Agency Policy Directive Assuring the Competency of Environmental Protection Agency Laboratories, February 23, 2004, <u>http://www.epa.gov/fem/pdfs/labdirective.pdf</u>
- U.S. EPA Agency Policy Directive FEM-2011-01 Policy to Assure Competency of Organizations Generating Environmental Measurement Data under Agency Funded Acquisitions, March 28, 2011, http://www.epa.gov/fem/pdfs/fem-lab-competency-policy.pdf