FREQUENTLY ASKED QUESTIONS:
Policy to Assure Competency of Organizations Generating Environmental Measurement Data under Agency Funded Assistance Agreements or Interagency Agreements

Version 12/13/12

The Forum on Environmental Measurements (FEM) recently drafted a policy requiring organizations (e.g., laboratories, field sampling and measurement organizations) to provide documentation of their competency when they generate environmental data[1] through measurement under U.S. Environmental Protection Agency (i.e., U.S. EPA or Agency) funded assistance agreements or interagency agreements. The following are frequently asked questions and answers about the impact of this policy for all U.S. EPA programs (e.g., Program Offices, Regional Offices, Laboratories). This document will be updated as necessasry.

DEFINITIONS

Q1: What is competency?

A: Competency, according to ISO 9000, is the demonstrated ability to apply knowledge and skills.

Q2: The *U.S. Environmental Protection Agency Quality Policy* (CIO 2106.0; 10/20/08) definition for "environmental data" includes data produced from models and compiled from sources such as databases as well as those generated directly from measurements. Does this policy apply to organizations proposing to conduct dispersion modeling or to compile emission inventories under assistance agreements or interagency agreements?

A: Under this policy, only organizations generating environmental data directly through measurements under assistance agreements or interagency agreements (if applicable) will be covered (i.e., laboratories and field sampling organizations). This is clarified in the purpose statement of the policy and the title of the policy itself: POLICY TO ASSURE THE COMPETENCY OF ORGANIZATIONS GENERATING ENVIRONMENTAL MEASUREMENT DATA UNDER AGENCY FUNDED ASSISTANCE AGREEMENTS OR INTERAGENCY AGREEMENTS.

Q3: What do the terms assistance agreement, cooperative agreement, and interagency agreement mean?

A: **Assistance Agreement:** As defined in the *Grants and Debarment Glossary*, 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: budget and project periods, the federal share of eligible project costs, a description of the work to be accomplished, and any terms and conditions.

Cooperative Agreement: As defined in the *Grants and Debarment Glossary* (see also "Assistance Agreement") the legal instrument used when the principal purpose of the

[1] As defined in the *U.S. Environmental Protection Agency 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.

relationship is the transfer of money, property or anything of value to a state or local government or other eligible recipient to accomplish a public purpose of support or stimulation authorized by federal statute, in which substantial involvement is anticipated between the U.S. EPA and the recipient during performance of the contemplated activity.

Interagency Agreement: As defined in the *Grants and Debarment Glossary*, an interagency/intergovernmental agreement/international agreement (IAG) is: (a) a written agreement between federal agencies under which goods and services are provided in exchange for funds, or where services are provided without payment; (b) a written agreement between a federal agency and a state or local government under which the state or local government reimburses the federal agency for the costs of providing a specific technical service, e.g., statistical studies and compilations, technical tests and evaluations, training, surveys, reports, documents and data; (c) a written agreement between a federal agency and a foreign government under which work will be conducted for, or services provided to, a foreign government or international organization.

Q4: What do the terms accreditation and certification mean?

A: 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. Similarly, as defined in various ISO publications and glossaries, certification is the recognition provided by an independent body related to products, processes, systems or persons.

APPLICABILITY

Q5: The policy covers only assistance agreements and interagency agreements. Is there a similar policy for measurement data collected under acquisitions?

A: Yes. A link has been provided under the "References" section to the *Policy to Assure Competency of Organizations Generating Environmental Measurement Data under Agency Funded Acquisitions*, http://www.epa.gov/fem/pdfs/fem-lab-competency-policy.pdf.

BACKGROUND/AUTHORITY

Q6: Do any EPA regulations specifically require participation by laboratories in certification or accreditation programs?

A: Yes, the **Safe Drinking Water Act (SDWA)** requires laboratories that perform drinking water analyses to be certified by either the U.S. EPA or by a state with a U.S. EPA SDWA certification program (40 CFR 141.28). More information about the SDWA laboratory certification programs can be found at: http://water.epa.gov/scitech/drinkingwater/labcert/index.cfm. Other U.S. EPA regulations do not have similar requirements; however, other U.S. EPA regulations allow for more stringent implementation by states, tribes or local agencies, which may require participation in an accreditation/certification program and/or regular participation in a U.S. EPA, state-run or external proficiency testing (PT) program. Such requirements may be found in federal/state regulations and environmental permits, among other locations. Here are some additional examples by U.S. EPA regulation:

- **Clean Water Act (CWA):** Although the CWA does not have a certification or accreditation program requirement, some states that are authorized to run their own National Pollutant Discharge Elimination System (NPDES) programs require

participation in the state's certification/accreditation program. NPDES permittees are required to use methods approved by the U.S. EPA for wastewater analyses at 40 CFR Part 136. In most cases, those (CWA) methods include both the traditional suite of quality assurance/quality control (QA/QC) operations (e.g., MDLs, IPR or IDC, blanks, spikes, calibrations) and required acceptance criteria for the results. However, where these acceptance criteria are not contained in a method for a given analyte, guidance is given on how to develop acceptance criteria through the use of laboratory control charts or as specified in the "Protocol for EPA Approval of New Methods for Organic and Inorganic Analytes in Wastewater and Drinking Water" (EPA-821-B-98-003), March 1999. http://water.epa.gov/scitech/methods/cwa/atp/upload/2007_02_06_methods_atp_EPA821B98003.pdf. Major and select minor NPDES permittees also are required to participate in the annual Discharge Monitoring Report–Quality Assurance (DMR–QA) studies via CWA 308 Request for Information. These studies are conducted by the U.S. EPA Office of Enforcement and Compliance Assurance's (OECA) Office of Compliance–Monitoring, Assistance, and Media Programs Division. More information about DMR-QA may be found at: http://www.epa.gov/compliance/monitoring/programs/cwa/dmr/.

- **Superfund–Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA)/Superfund Amendments and Reauthorization Act (SARA):** Although no certification program exists under Superfund, contractors under the U.S. EPA's Contract Laboratory Program (CLP) are required to participate in ongoing PT studies administered by the U.S. EPA Office of Solid Waste and Emergency Response (OSWER) Analytical Services Branch. More information about the U.S. EPA CLP can be found at: http://www.epa.gov/superfund/programs/clp/index.htm.
- **Federal Insecticide, Fungicide and Rodenticide Act (FIFRA):** There is no PT or laboratory accreditation/certification program required under FIFRA; however, to assure the quality and integrity of data submitted to the Agency, the U.S. EPA prescribes compliance with the FIFRA Good Laboratory Practices Standards (GLPS, 40 CFR Part 160) for those laboratories conducting studies that support or are intended to support applications for research or marketing permits for pesticide products regulated by the Agency. The U.S. EPA conducts inspections of these laboratories and data audits to monitor compliance. States have primary authority for compliance monitoring and enforcement against the use of pesticides in violation of the labeling requirements. The state agency with primary responsibility for pesticides differs from state to state and may be the state's department of agriculture, environmental agency or another agency. For more information about FIFRA GLPS, go to: http://www.epa.gov/compliance/monitoring/programs/fifra/glp.html.
- **Toxic Substances Control Act (TSCA):** GLPS also are prescribed by the U.S. EPA for laboratories submitting certain industrial chemical data to the Agency under TSCA. For more information on TSCA GLPS (40 CFR Part 792), go to: http://www.epa.gov/compliance/monitoring/programs/fifra/glp.html.
- **Resource Conservation and Recovery Act (RCRA):** There is no PT or laboratory accreditation/certification program required under RCRA. Analytical methods under RCRA ("Test Methods for Evaluating Solid Waste, Physical/Chemical Methods," also known as SW-846) are issued as guidance, with the exception of those methods that are required to be used by regulations. A complete list of required methods can be found in 40 CFR Part 260.11. The analytical methods issued as guidance under RCRA methods include general QA/QC operations and recommended performance criteria.

Given the wide range of sample matrices to which the methods may be applied, these criteria may be modified to satisfy data quality needs on a project-specific basis. Chapter One (Project Quality Assurance and Quality Control) of SW-846 contains guidance on how to ensure data are of sufficient quality for their intended use. This chapter can be found at: http://www.epa.gov/epawaste/hazard/testmethods/sw846/pdfs/chap1.pdf.

- **Clean Air Act (CAA):** The U.S. EPA Office of Air and Radiation (OAR), Office of Air Quality Planning and Standards' (OAQPS) implementation and oversight of the Ambient Air Monitoring Program includes a National Performance Evaluation Program (NPEP). The NPEP includes: a National Performance Audit Program for O_3, NO_2, SO_2 and CO; Ambient Air Protocol Gas Verification Program; Ozone Standard Reference Photometer Program; Lead (Pb) Performance Evaluation Program; and a PM 2.5 Performance Evaluation Program. Ambient air monitoring organizations, including their laboratories, are responsible for participating in these programs either directly with the U.S. EPA, states and/or Indian tribal governments. More information about NPEP can be found at: http://www.epa.gov/ttn/amtic/npepqa.html.
- **Clean Air Act (CAA):** The U.S. EPA Office of Atmospheric Programs (OAP), Clean Air Markets Division (CAMD), provides oversight and implementation support for emission reduction programs such as the Acid Rain Program (ARP) and the Clean Air Interstate Rule (CAIR). Both the ARP and CAIR include an Emission Protocol Gas Verification Program (PGVP) and minimum competency requirements for Air Emission Testing Bodies (AETB). The Emission PGVP and AETB programs will strengthen emission measurement data and better ensure the accuracy of calibration gases and the competency of emission stack testers. For more information on PGVP and AETB, go to: http://www.gpo.gov/fdsys/pkg/FR-2011-03-28/pdf/2011-6216.pdf#page=1.
- **Title X Lead-Based Paint Hazard Reduction Act of 1992 Sections 405(a) and (b):** The U.S. EPA Office of Chemical Safety and Pollution Prevention's (OCSPP) Office of Pollution Prevention and Toxics (OPPT) established the National Lead Laboratory Accreditation Program (NLLAP) to recognize laboratories that demonstrate the ability to accurately analyze paint chip, dust or soil samples for lead (Pb). Fixed-site laboratories, mobile laboratories or testing firms that operate portable equipment are eligible for U.S. EPA recognition through the NLLAP. The U.S. EPA recognizes four organizations as accrediting bodies for the NLLAP that accredit for lead sample analysis. More information on the NLLAP can be found at: http://www.epa.gov/lead/pubs/nllap.htm.

Q7: Do other federal agencies require their contractors or assistance or interagency agreement partners to participate in accreditation/certification programs?

A: Yes. The Department of Defense (DOD) established the DOD Environmental Laboratory Accreditation Program (DOD ELAP) in 2008 to accredit laboratories that perform environmental testing in support of DOD. The program uses third-party accrediting bodies to assess laboratories on meeting requirements specified in DOD's Quality Systems Manual for Environmental Laboratories (DOD QSM). The U.S. Food and Drug Administration (FDA) requires third-party accreditations to ISO/IEC 17025.

Q8: Who defines the areas of competency or capability? Do they differ among organizations?

A: The areas of competency or capability are established by the organization offering accreditation or certification, which can vary between institutions. Some examples of

organizations that provide accreditation or certification can be found at http://www.epa.gov/fem/accredit.htm, which does not exclude other opportunities that are available.

Q9: Who at U.S. EPA makes the decision that an organization meets the competency requirements of this policy?

A: The U.S.EPA project officer, in consultation with the appropriate U.S. EPA QA personnel, makes the decision that an organization meets the competency requirements of this policy.

Prior to the generation or use of environmental data, provision by the grantee and subsequent approval of acceptable quality, system documentation is required in accordance with the soon-to-be-issued U.S. EPA Quality Policy, CIO Policy 2106; U.S. EPA procedure for Quality Policy, CIO Procedure 2106-P-01; Quality Standard for Environmental Data Collection, Production, and Use by EPA Organizations, CIO Standard 2106-S-01; and/or Quality Standard for Environmental Data Collection, Production and Use by Non-EPA (External) Organizations, CIO Standard 2106-S-02. In addition, provision of the demonstration of competency in the fields of expertise is required.

POLICY OR REQUIREMENT

Q10: If an organization relies on accreditation/certification to demonstrate its qualifications in the field of sampling or analyses to be conducted, what documentation should it provide to U.S. EPA?

A. At a minimum, the documentation must include:

- A copy of the organization's quality system documentation. It may be called a Quality Management Plan (QMP), a quality manual, or some other name, depending on the organization. It should describe how the organization will plan, implement and assess the effectiveness of its QA/QC operations applied to environmental programs. It should conform to ANSI/ASQ E-4 2004, *"Quality Systems for Environmental Data and Technology Programs: Requirements with Guidance for Use,"* as well as the U.S. EPA Quality documents listed in the answer to FAQ #9 and their referenced guidance. In some cases, analytical laboratories are now following ISO Guide 17025.
- Copies of the dated certificate(s) of accreditation/certification from those accrediting bodies indicating the applicable field(s) of sampling or analysis, and the period for which the accreditation/certification is valid.
- If the accreditation/certification is limited to specific sampling techniques, analytes or laboratory instrumentation, then a complete list of those techniques, analytes or instruments must be provided.

Q11: What are the responsibilities of an organization that relies on accreditation/certification to demonstrate its qualifications in the field of analyses to be conducted (as described in FAQ #10)?

A. The organization is responsible for:

- providing documentation of its accreditation/certification as required by EPA;
- maintaining its accreditation/certification status throughout the period of performance;
- immediately notifying the U.S. EPA project officer if the status of its accreditation/certification changes (i.e., is suspended, lapses, or is revoked in part or in full) any time during the period of performance; and

- ensuring the qualifications of the organization's partners under the assistance agreement or interagency agreement.

Q12: What are some examples of documentation (i.e., in addition to or *in lieu* of accreditation/ certification) that organizations can provide to demonstrate their qualifications in their fields of analysis?

A. Some examples of documented activities that competent organizations should be able to provide include:
   - Results from ongoing participation by the organization in PT or round-robin programs conducted by external organizations;
   - Reports of technical and quality system assessments of the organization conducted by external organizations;
   - Quality documentation, such as laboratory quality manuals or QMPs that describe the organization's quality practices and detailed standard operating procedures (SOPs); and
   - Descriptions of applicable instrumentation, sampling, equipment, method sensitivities, reporting practices, capacity, experience, staffing (e.g., education, job experience, training) and references of past performance (i.e., EPA QA/R-2; EPA QA/R-5; EPA QA/G-5; and soon-to-be-issued Quality Standard for Environmental Data Collection, Production and Use by Non-EPA (External) Organizations, CIO Standard 2106-S-02).

   The list above is not exhaustive; other documentation may be useful. More importantly, no single piece of documentation, including accreditation or certification, is a guarantee that data generated by an organization will meet the needs of a specific project. Thus, this policy does not eliminate the existing U.S. EPA requirements regarding developing a quality assurance project plan (QAPP) for all projects involving collection of environmental measurements.

Q13: How and where should competency be addressed in project-level quality documentation (e.g., QAPPs) that may be required to satisfy quality terms and conditions of the assistance agreement or interagency agreement throughout the life of the agreement?

A: The QAPP (or other required project-level quality documentation) should summarize all of the organization's competency documentation presented and its responsibilities with respect to ongoing accreditations/certifications during the lifetime of the agreement (i.e., FAQ #11). This information should be included under appropriate sections of the QAPP. Currently, per requirements in EPA QA/R-5 and soon-to-be-issued Quality Standard for Environmental Data Collection, Production and Use by Non-EPA (External) Organizations, CIO Standard 2106-S-02, the sections would include: Group A Project Management: A8 Special Training/Certifications (to address any applicable accreditations/certifications)
   - Group C Assessment and Oversight: C1 Assessments and Response Actions and C2 Reports to Management. Both sections would address the organization's ongoing participation in and results from: proficiency testing, round-robin programs, technical audits, quality program assessments, revisions of key quality documentation such as QMPs, laboratory manuals, SOPs used in conjunction with the project, etc. The status of the organization's certifications/accreditations also is reported, including any changes thereto.

Q14: The policy states that accreditation must be maintained for the entire assistance agreement or interagency agreement. Must this be stated in the assistance agreement or interagency agreement

itself to be enforced? Is there a standard assistance agreement or interagency agreement clause that addresses this?

A: Yes. If accreditation is used to demonstrate the organization's competency, the status of the organization's accreditation must be maintained throughout the assistance agreement or interagency agreement, and this requirement shall be stated in the assistance agreement or interagency agreement to be enforced. It is the organization's responsibility to immediately inform the project officer of any changes to accreditation status at any time during the period of performance. At this time, there is no standard assistance agreement or interagency agreement clause, but one will be developed as necessary.

IMPLEMENTATION ISSUES

Q15: If we use accredited laboratories, is it still necessary for us to review data?

A: Yes, you must still review data. Accreditation is one tool that may help in obtaining data of the quality needed for a project; however, it is not a guarantee. The overall goal of having "data of known and documented quality" still requires reviewing the data so that their quality can be evaluated objectively. Laboratories or field sampling organizations with accreditation/certification have demonstrated to an organization that they have a system in place to produce appropriate quality data, but that does not mean that they always do, or that they can meet the specific needs of a particular project.

Q16: Is there a catalog of accreditation or certification programs? Is there a centralized source to determine if a laboratory is accredited/certified and for what? How would a program be able to determine a laboratory's status before an award is made? What is to stop an organization from claiming an accreditation that it does not hold or that does not exist?

A: Currently, there is no catalog of accreditation/certification programs or centralized sources to determine if a laboratory is accredited/certified and for what field of analyses. Some organizations, including The NELAC Institute (TNI), recently have completed a database for accredited laboratories and their fields of analyses under their respective programs, which should be available soon. A project officer is responsible for using the information on the accreditation/certification certificate provided by the organization to look up the list of accredited laboratories established by the associated accreditation or certification program to determine the status of the organization's accreditation/certification. This also will allow the project officer to verify that the organization is making a legitimate claim of its accreditation and/or the current status of its recognition. Most accreditation bodies also include a listing of organizations that they have accredited on their website. If an organization has made a false claim, the project officer should no longer consider the organization a viable candidate for award.

Q17: How can a project officer ensure that a subgrantee maintains accreditation for the life of the assistance agreement or interagency agreement, when recourse is only to the prime grantee?

A: The Office of Grants and Debarment (OGD) will work to develop with affected offices.

Q18: What provisions would be included in grant solicitations alerting applicants of the requirements? What about terms and conditions in assistance agreements and IAs?

A: The OGD will work to develop with affected offices.

Q19: Given that the cost of accreditation or certification may be prohibitive for some organizations, what should be considered when evaluating competency?

A: The competency of an organization that performs sampling or analysis can be evaluated in a number of ways. As noted in the response to FAQ #15, accreditation or certification is one tool that may be useful in evaluating competency. Many competent organizations may not hold an accreditation or certification, yet they can and do play important roles in the generation of environmental data. Some other considerations for evaluating competency include:

- **Past Performance –** A well-qualified organization should be able and willing to provide the names of past clients who can attest to the organization's past performance.
- **Sampling Access and Compliance –** The organization must comply with all regulations that apply to U.S. EPA field operations on public and private land, such as sampling permits and regulations, and obtaining right-of-way permission.
- **Capacity and Experience –** How many samples of "X" *does* the organization collect every year or month? How many analyses of "Y" *does* the laboratory perform every year or month? How many *can* the organization perform under routine circumstances? Even accredited/certified organizations might not collect specific types of samples or perform a given analysis very often, so it might be important to consider the organization's capacity to collect or analyze all samples in the required time frame. Likewise, does the organization have demonstrated experience with the matrices of interest? For example, not all solid matrices are the same, such that a laboratory with extensive experience in soil analysis might not be familiar with analyses of waste samples for the same analytes, or might not be familiar with soil types from other geographic regions (e.g., calcareous soils from the arid southwestern United States are very different from sandy loams from the East Coast).
- **Leave No Trace –** Currently, the Agency is focusing on appropriate field sampling practices. One practice highlighted in the Agency's Environmental Management System is a program called "Leave No Trace," which requires that any group involved in field sampling must leave its field site as it was found and not allow its sampling activities to have a negative environmental impact.
- **Quality Assurance –** Refer to the Agency's Quality System web page "Doing Business with EPA: Quality Specifications for non-EPA organizations."
- **Additional Staff Availability –** As with instrumentation and sample collection equipment, does the organization have additional staff that can be tasked to complete the work as scheduled?
- **Sampling Equipment –** If an organization is being evaluated for its capability to collect field samples, the availability of sampling equipment to that organization is an important consideration. Some organizations own all of the equipment to collect samples, and other organizations may rent or lease specialized sampling equipment for the duration of a project. The project officer should verify exactly what equipment the grantee organization or its subgrantee owns versus what it may rent or lease. The organization's procedures for cleaning and preparing equipment also are important sampling considerations, and copies of any relevant SOPs should be made available for the project manager's consideration.
- **Instrumentation –** Does the organization possess all of the equipment needed to analyze samples for the project? As many analytical methods include optional equipment and procedures, it is important to ensure that the specific equipment needed for a given project is available in those cases. For large projects (e.g., many samples over a short time frame), redundant instruments may be important for the grantee organization or its designee to have available in the event that the primary instrument fails.

- **Method Sensitivity and Reporting Practices –** Establishing that a laboratory can produce quality-assured measurements of sufficient sensitivity may be an essential component of deciding whether the organization can fulfill the project objectives. Regardless of the term or procedure that the organization uses to describe the sensitivity of its analytical methods, a competent laboratory should be able to provide an analyte-specific table describing its application of Method X in Matrix Y under ideal conditions. The organization also should be able to describe its routine reporting practices for results, including whether it censors results below a particular concentration (e.g., below some reporting limit, quantitation limit or detection limit), and whether it is willing and able to modify its reporting scheme to meet any project-specific requirements.
- **Assessment Program –** All laboratories must have procedures for assessing or auditing their analytical capabilities, generated data and staff competency. Does the organization address these procedures and provide demonstrated compliance with U.S. EPA requirements?
- **Miscellaneous –** Other areas to consider may be the timely manner of providing results, providing consistent results, understandable or consistent data formats and processes for identifying and communicating problems, corrective actions including implementation and validation of solutions, and dispute-resolution practices.

Q20: How should one evaluate alternative means of demonstrating capabilities other than accreditation/certification?

A: As noted in FAQ #6 and FAQ #7, many federal programs do not require accreditation/certification. More importantly, many accreditations/certifications often are specific to the scope of a program. For example, a laboratory may be certified by the U.S. EPA or a state for certain drinking water analyses, but the certification is not relevant to the laboratory's competence to perform analyses of hazardous wastes, wastewaters or even other analytes in drinking water. Likewise, an organization may have an accreditation for stack gas sampling, but that does not mean that it is competent to sample ambient waters for trace level metals to assess water quality criteria. Accreditation/certification typically is specific to the area of work (e.g., method, matrix, analyte) for which the organization has applied and been approved.

As noted in the answers to FAQ #10, FAQ #12, FAQ #13 and FAQ #19, considerations other than accreditation/certification may be relevant in evaluating the competency of a given organization. Considerations such as whether the organization is capable of meeting program or project objectives may be combined with a thorough review of the organization's quality system documentation, thereby providing much of the information that would be evaluated by an accrediting body.

In addition, a review of the organization's results for *relevant* PT samples (i.e., for the appropriate methods, matrices and analytes) may provide additional supporting information to demonstrate that the organization can produce acceptable results when it knows that it is being tested. For projects of particularly critical significance or with very high visibility, more stringent evaluation and monitoring of laboratory performance may be warranted, such as the following:

- The grantee laboratory is required to analyze relevant PT samples prior to the assistance award, before submitting any field samples from the project, and/or periodically during the assistance period; and/or

- The grantor organization performs an in-depth, onsite evaluation of the grantee prior to or during the course of the project, whether that involves sampling or laboratory analyses.

These last two steps require specialized skills that may be beyond the capabilities of the grantor organization's project staff, but they are worth considering in some circumstances. All alternative means implemented by the project officer must be documented thoroughly.

Q21: How can the policy be integrated into programs that use a pass/fail system? If a laboratory has accreditation that is not applicable to the data requirements, would that laboratory fail under a pass/fail system?

A. For those U.S. EPA programs that use a "pass/fail" system, the U.S. EPA staff incorporating this policy will have to consider the overall submitted documentation in the same fashion (i.e., pass or fail). Thus, it becomes *critical* for such U.S. EPA programs to establish these requirements *beforehand* if relevant accreditation/certification programs exist for the data-generation activities involved.

Q22: What are the expectations for small organizations as grant recipients to demonstrate their conformance to U.S. EPA quality requirements and their competency?

A: All organizations, regardless of size, must document conformance to U.S. EPA quality system requirements for the entire project. This may include but is not limited to the collection and/or use of environmental data, field sampling, data analysis and data management, as applicable to each situation. In addition, all organizations must demonstrate competency in all fields of sampling and analysis applicable to their project(s). The level of conformance and the competency requirements should be scaled/graded as applicable but must meet the needs of the program and/or project.

Pre-award conformance may be documented in a QA Narrative Statement, QMP, QAPP, laboratory manuals and SOPs, descriptions of laboratory and field sampling equipment, other QA documentation, or a combination of these. Pre-award evaluation of competency may be demonstrated through accreditations, certifications or a combination of successful participation in PT programs, demonstrations of competencies, experience, past performance and the like (see FAQ #19).

Please note that as a rule no work may be performed without adequate QA documentation that has been approved by the U.S. EPA or the delegated approving authority. Generally, this is a programmatic Term and Condition (T&C) of each award.

During the post award phase (i.e., the project/budget period), the organization must continue to demonstrate that it meets the aforementioned conformance and competency requirements. This may be accomplished through a variety of means, including but not limited to QA progress reports to the U.S. EPA, internal or external/independent QA audits and audits by the U.S. EPA.

Q23: How does the policy pertain to volunteer monitoring/citizen science, in particular to those groups performing air and water quality monitoring or working with data collected at least in part by others, published, and so forth? How can an organization ensure that the conformance and competency requirements meet the needs of the project?

A: For citizen science/volunteer recipients of U.S. EPA grants, if the project collects and/or uses environmental data, then the expectations are the same as those for small businesses (see FAQ #22). To ensure that the conformance and competency requirements are met, the U.S. EPA encourages the organizations to address QA requirements as much as possible during the pre-award phase and to consult with the U.S. EPA contact or U.S. EPA Project Officer in developing, implementing and documenting the appropriate QA aspects of the work.

Under the Voluntary Partners Program, environmental data may be collected and submitted to the Agency for use through voluntary partner programs with non-governmental organizations, industry groups and other interested parties. To maximize the utility of this data, to the extent possible and practicable, the effort should be planned, documented in a QAPP or equivalent planning document, and implemented to ensure that the quality of the items and services is specified, documented and meets the technical requirements for their intended use. U.S. EPA approval may be required if the Agency is expected to use such data for its environmental decisions at the time or in the future. CIO Standard 2106-S-02 and the U.S. EPA environmental data standards may be useful to such programs in implementing needed quality practices.

Depending on the funding source, recipients may have to meet QA requirements imposed by state or local governments or other funding organizations. For those projects that are funded in part by the U.S. EPA, recipients have to meet QA requirements of both the U.S. EPA and their other funding source(s). For projects that are not funded by the U.S.EPA, Agency conformance and compliance cannot be required of the citizen scientists/volunteer monitoring organizations. However, even if no QA requirements are imposed by the funding organization(s), the U.S. EPA encourages incorporating competency, QA and, as appropriate, conformance requirements that meet the needs of the project.

Headquarters and Regional guidance are available to assist citizen scientists/volunteer monitoring groups in these situations. Some links to the guidance and contacts may be found at: http://water.epa.gov/type/watersheds/monitoring/vol.cfm