# FREQUENTLY ASKED QUESTIONS (FAQs)

POLICY TO ASSURE COMPETENCY OF ORGANIZATIONS CONDUCTING ENVIRONMENTAL INFORMATION OPERATIONS AND GENERATING ENVIRONMENTAL INFORMATION UNDER AGENCY-FUNDED ASSISTANCE AGREEMENTS

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The Forum on Environmental Measurements (FEM)<sup>1</sup> issued a policy to require grantee organizations (e.g., laboratories, field sampling and measurement organizations) to provide documentation of their competency when they conduct environmental information operations<sup>2</sup> and generate environmental information through measurement under U.S. Environmental Protection Agency (i.e., EPA or Agency) funded assistance agreements. The following are frequently asked questions and answers about the impact of this policy for all EPA programs (e.g., Program Offices, Regional Offices, Laboratories).

### **DEFINITIONS**

Q1: What is competency, accreditation, and certification mean?

A: The term *competency* refers to the aggregate of skills, knowledge, and attitudes that enable an individual to perform a job effectively. According to the International Organization for Standardization) ISO, laboratory competency, as outlined in ISO/ International Electrotechnical Commission (IEC) 17025, means the ability of a laboratory to perform specific tasks and deliver reliable results, demonstrated through a robust quality management system and adherence to international standards. Here is a link to the ISO Online Browsing Platform (OBP), Terms & Definitions, <a href="https://www.iso.org/obp/ui">https://www.iso.org/obp/ui</a>.

Accreditation, as defined by the International Organization for Standardization (ISO) <a href="https://www.iso.org/certification.html">https://www.iso.org/certification.html</a>, 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 (<a href="https://www.iso.org/certification.html">https://www.iso.org/certification.html</a>), is the provision by an independent body of written assurance (a certificate) that the product, service or system in question meets specific requirements.

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

<sup>&</sup>lt;sup>1</sup> 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.

<sup>&</sup>lt;sup>2</sup> As defined in the *US Environmental Protection Agency Environmental Information Quality Policy* (CIO 2105), environmental information operations is a collective term for work performed to collect, produce, evaluate, or use environmental information and the design, construction, operation or application of environmental technology, and environmental information includes data and information that describe environmental processes or conditions which support EPA's mission of protecting human health and the environment.

under assistance agreements?

- A: Under this policy, only organizations generating or using environmental data directly through measurements under assistance agreements will be covered (i.e., grantee organizations that conduct laboratory work in house ["grantee laboratory"] 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 CONDUCTING ENVIRONMENTAL INFORMATION OPERATIONS AND GENERATING ENVIRONMENTAL INFORMATION UNDER AGENCY-FUNDED ASSISTANCE AGREEMENTS.
- Q3: What do the terms assistance agreement, cooperative agreement, and grant mean?
  - A: Assistance agreement means the legal instrument of financial assistance between the EPA and the recipient to transfer anything of value to carry out a public purpose and not to acquire property or services for the EPA's direct benefit or use. 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 and special conditions.

Cooperative agreement means an assistance agreement in which substantial EPA involvement is anticipated during the performance of the project (does not include fellowships).

Grant means an assistance agreement in which EPA does not provide substantial involvement during the performance of the project. The term does not include technical assistance which provides services instead of money, or other assistance in the form of revenue sharing, loans, loan guarantees, interest subsidies, insurance, or direct appropriations.

- 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: What organizations are subject to this policy?
  - A: Organizations that are recipients of an EPA assistance agreement expected to exceed a total maximum value of \$200,000 (in federal funding) and that are generating or using environmental data under the agreement must demonstrate competency to EPA.
- Q6: The policy covers only competitive and non-competitive assistance agreement expected to exceed a total maximum value of \$200,000 (in federal funding). What if the original award does not exceed \$200,000 (in federal funding) and subsequently an award does exceed \$200,000 (in federal funding)?
  - A: The \$200,000 threshold is based on a best estimate of the dollar expectation at the time of solicitation issuance or award. If at the time a solicitation is issued for a competitive award, or when a non-competitive award is made, the project officer does not expect the award(s) to exceed \$200,000, then they do not need to address this Policy at that time. If,

however, subsequently an award does exceed the \$200,000, the project officer should get a competency determination during the award period as soon as they realize the award will exceed the \$200,000 threshold.

# BACKGROUND/AUTHORITY

Q7: Do any EPA statutes specifically require participation by laboratories in certification or accreditation programs?

A: Yes.

- Safe Drinking Water Act (SDWA) requires laboratories, which perform drinking water analyses, to be certified by either EPA or by a state with an EPA SDWA certification program. Certification of Laboratories that Analyze Drinking Water Samples to Ensure Compliance with Regulations | US EPA
- Clean Water Act (CWA): EPA protects drinking water by requiring that laboratories become certified to analyze drinking water samples that that they use analytical approved by EPA. <u>Certification of Laboratories that Analyze Drinking Water Samples to Ensure</u> <u>Compliance with Regulations | US EPA</u>
- Superfund CERCLA/SARA: The Contract Laboratory Program (CLP) supports EPA's
   Superfund program created under the 1980 Comprehensive Environmental Response,
   Compensation, and Liability Act (CERCLA) and the 1986 Superfund Amendments and
   Reauthorization Act (SARA). The Superfund CLP's mission is to provide analytical data of
   known and documented quality to support the 10 EPA Regional Offices in their Superfund
   activities. Superfund Contract Laboratory Program | US EPA
- Federal Insecticide and Rodenticide Act (FIFRA) and Toxic Substances Control Act (TSCA):
   EPA's Good Laboratory Practice Standards (GLPS) compliance monitoring program
   ensures the quality and integrity of test data submitted to the Agency in support of a
   pesticide product registration under FIFRA, section 5 of the TSCA, and pursuant to testing
   consent agreements and test rules issued under section 4 of TSAC. Good Laboratory
   Practices Standards Compliance Monitoring Program | US EPA
- Resource Conservation and Recovery Act (RCRA): There is no PT or laboratory accreditation/certification program under RCRA. For more information on RCRA SW-846, go to: <u>Hazardous Waste Test Methods / SW-846 | US EPA</u>
- Clean Air Act (CAA): The 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<sub>3</sub>, NO<sub>2</sub>, SO<sub>2</sub>, and CO; Ambient Air protocol Gas Verification Program; Ozone Standard Reference Photometer Program; Lead (Pb) Performance Evaluation Program; and a PM2.5 Performance Evaluation Program. Ambient air monitoring organizations, including their laboratories, are responsible for participating in these programs either directly with EPA, states, and/or Tribal governments. Ambient Monitoring Technology Information Center (AMTIC) | US EPA
- 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). EPA issued the final rule Protocol Gas Verification Program and Minimum
  Competency Requirements for Air Emission Testing to establish the Protocol Gas
  Verification Program (PGVP) and the Air Emission Testing Body (AETB) program. These are
  ongoing programs to ensure the accuracy of calibration gases and the competency of

- emission stack testers. Both programs enhance the quality of the emissions data reported to the Acid Rain Program, Cross-State Air Pollution Rule, and the Agency's other regional emission reduction programs.
- 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: <a href="https://doi.org/10.1001/jhc.2001/
- Q8: Do other federal agencies require their contractors or assistance 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, which 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.
- Q9: 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: Resources for Assessing Measurements | US EPA.

- Q10: Who at EPA makes the decision that a recipient organization meets the competency requirements of this policy?
  - A: From CIO 2105-P-01-0, All environmental information operations performed under extramural agreements shall comply with the Agency-wide Quality Program requirements as defined by the relevant regulations. Accordingly, all assistance agreements must be reviewed by an authorized Quality Assurance (QA) Manager, Officer, or designee, as specified in the organization's Quality Management Plan (QMP), to determine if environmental information operations are to be performed and, if so, to ensure that appropriate QA and Quality Control (QC) specifications are included or identified in the acquisition and assistance agreement solicitation package. Upon their receipt in response to the solicitation, proposals or applications must be reviewed by the QA approval authority to evaluate the adequacy with which the offeror or applicant addressed stated specification, as well as the adequacy of the QMPs and QA Project Plans, when submitted.

## POLICY OR REQUIREMENT

Q11: If an organization relies on accreditation/certification to demonstrate their qualifications in the field of sampling or analyses to be conducted, what documentation should they provide to EPA?

A: At a minimum, the documentation of accreditation/certification must include:

- A copy of the organization's quality program documentation. It may be called a 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 quality
  assurance and quality control operations applied to environmental programs. It should
  conform to the most current version of <u>ASQ/ANSI E4: Quality Management Systems for Environmental Information & Tech.</u>
- A signed narrative statement from a responsible corporate official affirming that the organization holds relevant accreditation/certification from a specific accrediting body. This statement could be part of an overall proposal, or bid response, or it could be a separate requirement.
- 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.
- Q12: What are the responsibilities of an organization that relies on accreditation/certification to demonstrate their qualifications in the field of analyses to be conducted (as described in Q11)?
  - A: The organization is responsible for:
    - providing documentation of their accreditation/certification in response to the solicitation.
    - maintaining their accreditation/certification status throughout the period of performance.
    - immediately notifying the EPA contracting personnel in consultation with the organization sponsoring the work if the status of their accreditation/certification changes (i.e., is suspended, lapses, or is revoked in part of full) any time during the period of performance.
    - ensuring the qualifications for the organization's subcontractors under the contract.
- Q13: What are some examples of documentation (i.e., in addition to or in lieu of accreditation/certification), which organizations can provide to demonstrate their qualifications in their fields of analysis?
  - A: Some examples of documented activities, which competent organizations should be able to provide, include:
    - Results from on-going participation by the organization in proficiency testing (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, QMPs, which describe the organization's quality practices and detailed standard operating procedures (SOPs).
    - Descriptions of applicable instrumentation, sampling, equipment, method sensitivities, reporting practices, capacity, experience, staffing (e.g., education, job experience, training), and reference of past performance.

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 your specific project. Thus, this policy does not eliminate the existing EPA requirements regarding developing a quality assurance project plan (QAPP) for all projects involving collection of environmental

measurements.

- Q14: 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 throughout the life of the agreement?
  - A: The QAPP (or other required project-level quality documentation) should summarize all the organization's competency documentation presented and its responsibilities with respect to ongoing accreditations/certifications during the lifetime of the agreement. 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.

- Q15: The policy states that competency must be maintained for the entire assistance agreement. Is there a standard assistance agreement term and condition 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. It is the organization's responsibility to immediately inform the contracting personnel in consultation with the organization sponsoring the work of any changes to their accreditation status at any time during the period of performance.

QAPP Standard (CIO 2105-S-02), B3 requirement: If the environmental information operations include laboratory analyses, the QAPP shall identify each laboratory to be used as well as a back-up laboratory if identified as required in systematic planning, contract statements of work, or workplans. The QAPP shall also describe the processes for ensuring the laboratory maintains current accreditation and/or certification for applicable analytes and matrices.

### **IMPLEMENTATION**

- Q16: How will EPA notify applicants for grant solicitations about this policy where an award under the solicitation is expected to exceed the \$200,000 threshold (in federal funding) and involve the generation or use of environmental data?
  - A: EPA Program Offices issuing grant solicitations for awards that will be subject to this policy will include a provision on Competency of Organizations Generating Environmental Measurement Data incorporated by reference in Notice of Funding Opportunity (NOFO) so that applicants will be aware of this policy and its requirements.

- Q17: How will recipients of EPA assistance agreements be on notice of what is required to comply with the policy?
  - A: Recipients of EPA assistance agreements that are expected to exceed a total maximum value of \$200,000 in federal funding and involve the generation or use of environmental data will be subject to a term and condition implementing this policy that will be included in their grant award document.

    Recipients should contact their project officer if they have any questions about this policy.
    - Recipients should contact their project officer if they have any questions about this policy or the term and condition implementing this policy.
- Q18: If the recipient's laboratory is accredited, is it still necessary for the organization sponsoring the work to review data?
  - A: Yes, you must still review data. Accreditation is one tool that may help you obtain data of the quality needed for your project. However, it is not a guarantee. The overall goal of having "data of known and documented quality" still requires that you review the data so that you "know" its quality. 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 project.

By way of analogy, consider accreditation to be like a driver's license issued by a given state. Holding a valid driver's license indicates that the individual demonstrated acceptable driving skills to some official body at some point in the past. However, lack of a valid license does not mean that an individual is physically incapable of operating a motor vehicle. Conversely, anyone who travels the nation's roadways knows that not all licensed drivers are competent drivers.

Before a company hires someone to drive a vehicle, they certainly ask if the applicant has a valid driver's license. However, they also will ask if the license is valid for the type of vehicle to be driven (e.g., a tractor-trailer rig license versus a simple passenger vehicle license). The company is likely to investigate that applicant's actual driving record, looking for citations, accident claims, or other infractions. Also, anyone driving for a living in such a situation is likely to have their performance as a driver reviewed periodically by that employer (e.g., the familiar bumper sticker "If you see this vehicle being driven unsafely, call 1-800 ...").

As described in the policy statement, an organization's accreditation or certification status is analogous to holding a valid license for the type of vehicle of interest. Thus, accreditation/certification status is at best the first step in achieving data of known and documented quality for a given project.

- Q19: 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 they do not hold, or that does not exist?
  - A: Currently, there is neither a catalogue of accreditation/certification programs nor centralized sources to determine if a laboratory is accredited /certified and for what field of analyses. Some organizations, like The NELAC Institute (TNI), have recently completed a database for accredited laboratories with their fields of analyses under their respective programs, which should be available soon. P ersonnel in consultation with the organization

sponsoring the work can use 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 their accreditation/certification. This will also allow you to verify the organization is making a legitimate claim of their accreditation and/or the status of their recognition.

- Q20: Given that accreditation and certification does not exist for all fields of sampling and analysis, and 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 several ways. Accreditation or certification is one tool that may be useful in evaluating competency, but many competent organizations may not hold an accreditation or certification, yet they can and do play important roles in the generation of environmental information. Some other considerations for evaluating competency include:
    - Instrumentation Does the organization possess all the equipment needed to analyze samples for your specific project? Since many analytical methods include optional equipment and procedures, it is important to ensure that the equipment needed for your project is available in those cases. For large projects (e.g., many samples over a short time frame), you may need to ask about redundant instruments if their primary instrument fails
    - Sampling equipment If you are evaluating an organization that will collect your samples, you need to ask about the availability of sampling equipment. Some organizations own all the equipment to collect samples, while other organizations may rent or lease specialized sampling equipment for the duration of a project. Make sure you know what equipment they own versus what they may rent or lease. Field work is often unpredictable. Ask about their procedures for cleaning and preparing equipment, and request copies of any relevant SOPs they may cite.
    - Method sensitivity and reporting practices There are various ways to demonstrate the analytical sensitivity that a given laboratory can achieve, many of which are poorly understood. However, whichever term or procedure that the organization uses to describe the sensitivity of its analytical methods, a competent laboratory should be able to provide you with an analyte-specific table describing their application of Method X in Matrix Y under ideal conditions. They should also be able to describe their routine reporting practices for results, including whether they censor results below a particular concentration (e.g., specifically telling you if they censor below some reporting limit, quantitation limit, or detection limit), and whether they are willing and able to modify their reporting scheme to meet your specific requirements. The challenge for you is to determine if their demonstrated sensitivity and reporting practices meet your project needs.
    - 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 they perform under routine circumstances? Even organizations with accreditation/certification may not collect specific types of samples or perform a given analysis very often, so you may need to consider their capacity to collect or analyze all your samples in the required time frame. Likewise, do they have demonstrated experience with your matrices of interest? For example, not all solid matrices are the same, such that a laboratory with extensive experience in soil analysis may not be familiar.

with analyses of sediment samples for the same analytes or may not be familiar with soil types from other geographic regions (e.g., calcareous soils from the arid Southwest are very different from sandy loams from the East Coast).

- Staff redundancy As with instrumentation and sample collection equipment, do they have additional staff that can be tasked to complete the work as scheduled?
- Past performance A well-qualified organization should be able and willing to provide the names of one or two past clients who can attest to the organizations past performance.

Whatever considerations you choose to use, they must be requested in your solicitation and evaluation of each criterion must be thoroughly documented in your project files.

- Q21: How should one evaluate alternative means of demonstrating capabilities other than accreditation/certification?
  - A: Many federal programs do not require accreditation/certification. More importantly, many accreditation/certifications are often specific to a program. For example, a laboratory may be certified by EPA or a state for certain drinking water analyses, but that certification has absolutely no bearing on their competence to perform analyses of hazardous wastes, wastewaters, or even other analytes in drinking water. An organization may have an accreditation for stack gas sampling, but that does not mean they understand the rigors of sampling ambient waters for metals at the ultra-low levels needed to assess water quality criteria.

Other considerations can be used to demonstrate the capabilities of a given organization. Combining those considerations with your review of the organization's quality system documentation provides much of the information that would be evaluated by an accrediting body.

In addition, you can review the organization's results for *relevant* PT samples (i.e., relevant meaning that the methods and matrices are like yours) to see if the organization can produce acceptable results, when they know that they are being tested. For projects of particularly critical significance or with very high visibility, you may even wish to take two further steps:

- Providing relevant PT samples to the laboratory for analysis prior to contract award, before submitting any field samples from your project, and/or periodically during the contract period; and/or
- Conducting an in-depth on-site evaluation of the organization prior to, or during the project, whether that involves sampling or laboratory analyses.

These last two steps require specialized skills that may be beyond the capabilities of your project staff but are worth considering in some circumstances. Whatever alternative means you choose to use, they must be thoroughly documented in your project files.

- Q22: How can the policy be integrated into those 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 EPA programs that use a "pass/fail" system, the EPA staff incorporating this policy will have to consider the overall submitted documentation in the same fashion (i.e. pass or

fail). For example, if the accreditation/certification requirements are incorporated in solicitations as part of the QA requirements, then accreditation/certification will have to be considered as either passing or failing the QA requirement. Thus, it becomes *critical* for such EPA programs to establish *beforehand* if relevant accreditation/certification programs exist for the data generation activities involved. If such programs exist, then the contract or grant solicitation should include a *technical* requirement that the respondents have and maintain such certifications, and the solicitation should assign importance to that requirement, so that each respondent's accreditation/certification information can be judged on its overall merits.

If relevant accreditation/certification programs do *not* exist, then information provided by respondents regarding any non-relevant accreditation/certification is not useful in evaluating the bids or proposals and should be ignored. As noted earlier, accreditation/certification in one field of environmental measurement may have no relevance to another field.

- Q23: What are the expectations for small organizations as grant recipients to demonstrate their conformance to EPA quality requirements and their competency?
  - A: All organizations, regardless of size, must document conformance to 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.

Please note that no work may be performed without adequate QA documentation that has been approved by the QAM or the delegated approving authority as required by the 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 conformance and competency requirements. This may be accomplished through a variety of means, including but not limited to QA progress reports to the EPA, internal or external/independent QA audits and audits by the EPA.

Q24: How does the policy pertain to volunteer monitoring/citizen science, 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 EPA grants, if the project collects and/or uses environmental data, then the expectations are the same as those for small businesses. To ensure that the conformance and competency requirements are met, the EPA encourages the organizations to address QA requirements as much as possible during the pre-award phase and to consult with the EPA contact or EPA Project Officer in developing, implementing and documenting the appropriate QA aspects of the work. A link to EPA's Quality Assurance Handbook and Toolkit for Participatory Science Projects may be found at: Quality Assurance Handbook and Toolkit for Participatory Science Projects | US EPA

Under the Voluntary Partners Program, environmental data may be collected and submitted to the Agency for use through voluntary partner programs with nongovernmental 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. 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 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 EPA, recipients must meet QA requirements of both the EPA and their other funding source(s). For projects that are not funded by the 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 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: <a href="http://water.epa.gov/type/watersheds/monitoring/vol.cfm">http://water.epa.gov/type/watersheds/monitoring/vol.cfm</a>

- Q25: What language must be incorporated in a Notice of Funding Opportunity (NOFO) where awards are expected to exceed the \$200,000 maximum value threshold (in federal funding) and involve the generation or use of environmental data?
  - A: EPA Program Offices issuing a NOFO that may result in awards subject to the Policy to Assure Competency of Organizations Conducting Environmental Information Operations and Generating Environmental Information Under Agency-Funded Assistance Agreements (Policy) (i.e., when the total maximum value of an award under the solicitation is expected to exceed \$200,000 in federal funding and involve the generation or use of environmental data) must ensure that the solicitation incorporates the following provision ::

Competency of Organizations Generating Environmental Measurement Data In accordance with EPA's <u>Policy to Assure the Competency of Organizations Generating Environmental Measurement Data under Agency-Funded Assistance Agreements</u>, successful applicants/recipients for awards under this competition that are expected to

exceed \$200,000 in federal funding that involve the generation or use of environmental data must demonstrate competency to perform such work either prior to award, or if that is not practicable or will delay the award, prior to beginning any work involving the generation or use of environmental data under the agreement. Applicants that demonstrate competency prior to award must maintain competency, as appropriate, during the award period. Applicants that do not address competency prior to award must demonstrate competency prior to beginning any work involving the generation or use of environmental data under the agreement and maintain competency, as appropriate, during the award period. A copy of the Policy is available online at <a href="http://www.gpo.gov/fdsys/pkg/FR-2013-04-29/html/2013-10043.htm">http://www.gpo.gov/fdsys/pkg/FR-2013-04-29/html/2013-10043.htm</a> or a copy may also be requested by contacting the person listed in Section VII of the announcement. This provision and other boilerplate solicitation provisions applicable to solicitations are available on the OGD intranet at: <a href="http://intranet.epa.gov/OGD/competition/compet/competition\_announcement\_boiler\_plate\_provisions\_and\_guidance.htm">http://intranet.epa.gov/OGD/competition/compet/competition\_announcement\_boiler\_plate\_provisions\_and\_guidance.htm</a>.

Q26: What programmatic terms and conditions must project officers incorporate in assistance agreements to implement this policy?

- A: There are two clauses, depending on whether it is known, or uncertain, at the time of award whether the award is expected to exceed a maximum value of \$200,000 in federal funding and expected to involve the use or generation of environmental data. The first term and condition below must be incorporated in assistance agreement awards that will, or are expected to, involve the generation or use of environmental data and exceed \$200,000 in federal funding. The second term and condition are for when it is uncertain:
  - Project officers must ensure that the following programmatic term and condition is included in awards (made starting October 1, 2013) exceeding, or expected to exceed, a total maximum value of \$200,000 in federal funds that will or are expected to involve the generation or use of environmental data: Competency of Organizations Generating Environmental Measurement Data In accordance with Agency Policy Directive Number FEM-2012-02, Policy to Assure the Competency of Organizations Generating Environmental Measurement Data under Agency- Funded Assistance Agreements, Recipient agrees, by entering into this agreement, that it has demonstrated competency prior to award, or alternatively, where a pre-award demonstration of competency is not practicable, Recipient agrees to demonstrate competency prior to carrying out any activities under the award involving the generation or use of environmental data. Recipient shall maintain competency for the duration of the project period of this agreement and this will be documented during the annual reporting process. A copy of the Policy is available online at http://www.epa.gov/fem/lab\_comp.htm or a copy may also be requested by contacting the EPA project officer for this award.
  - Project officers must ensure that the following programmatic term and condition is included in awards (made starting October 1, 2013) where at the time of award it is uncertain whether the total maximum value of the agreement will exceed \$200,000 in federal funding and/or the project will involve the generation or use of environmental data:

Competency of Organizations Generating Environmental Measurement Data (Alternate 1)

In accordance with Agency Policy Directive Number FEM-2012-02, <u>Policy to Assure the Competency of Organizations Generating Environmental Measurement Data under Agency- Funded Assistance Agreements</u>, Recipient agrees that if the total federal funding obligated on this award exceeds \$200,000 and will involve the use or generation of environmental data it will (unless it has otherwise done so) demonstrate competency prior to carrying out any activities involving the generation or use of environmental data under this agreement.

Recipient shall then maintain competency for the remainder of the project period of this agreement and document this during the annual reporting process. A copy of the Policy is available online at <a href="http://www.epa.gov/fem/pdfs/competency-policy-aaia-new.pdf">http://www.epa.gov/fem/pdfs/competency-policy-aaia-new.pdf</a> or a copy may also be requested by contacting the EPA project officer for this award.

- Q27: How should EPA implement the Policy for a proposed grant where an on-going continuing environmental program (CEP) relationship exists between EPA and the applicant and where the scope of work for the use or generation of environmental data is like that in the previous CEP award and the recipient has an approved Quality Management Plan (QMP) in place?
  - A: The applicant should include in the proposed grant workplan a statement explaining the similar nature of the scope of work and the existence of an approved QMP. If the EPA Project Officer (PO) concurs in the applicant's explanation, and determines that the applicant's performance under the previous, similar scope of work was satisfactory, the PO will document the competency demonstration by indicating the existence of an approved QMP in Section B.6a of the IGMS Funding Recommendation and including the following statement in Section M: "In accordance with the Competency Policy, as Project Officer, I have determined that the recipient meets the requirements for demonstration of competence through ongoing successful past performance to similar statement of work" for this continuing environmental program."

B.6. Quality Assurance: Does this program or project include generation of environmental data, or use of existing environmental data?	Yes
B.6.a. Are the proposed measurement activities covered by an existing or draft	Yes
Quality Management Plan (QMP), or Quality Assurance Project Plan (QAPP)?	
B.6.b. Are the QA Plans or QA documents required for this assistance award	No
approved?	
Enter appropriate Terms and Conditions in Section F.	

Section M Attachments:

"In accordance with the Competency Policy, as Project Officer I have determined that the recipient meets the requirements for demonstration of competence through ongoing successful past performance to similar statement of work" for this continuing environmental program."