FREQUENTLY ASKED QUESTIONS:
Policy to Assure Competency of Organizations Generating Environmental Measurement Data under Agency Funded Acquisitions
Version 02/21/2011

The Forum on Environmental Measurement (FEM) recently drafted a policy to require organizations (e.g., laboratories, field sampling and measurement organizations) to provide documentation of their competency when they generate environmental data[1] through measurement under US Environmental Protection Agency (i.e., EPA or Agency) funded acquisitions. 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?

A: The Oxford English Dictionary defines competency as "the ability to do something successfully or efficiently." In the context of this policy, competency means that an organization has the equipment, instrumentation, staff, and demonstrated experience needed to generate valid environmental measurement data that meet the project needs.

Q2: The *US 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 that generated directly from measurements. Does this policy apply to organizations bidding on contracts to conduct dispersion modeling or to compile emission inventories?

A: Under this policy, only organizations bidding on contracts to generate environmental data directly through measurements will be covered, for example laboratories and field sampling organizations. This is clarified in the purpose statement of the policy and the title to the policy itself: POLICY TO ASSURE COMPETENCY OF ORGANIZATIONS GENERATING ENVIRONMENTAL MEASUREMENT DATA UNDER AGENCY FUNDED ACQUISITIONS.

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

A: Assistance agreement: the legal instrument 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 and special conditions.

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

Interagency agreement: a written agreement between Federal agencies under which goods and services are provided in exchange for funds or where services are provided without payment.

[1] As defined in the *US 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.

Contract: a mutually binding legal relationship obligating the seller to furnish supplies or services and the buyer to pay for them. Contracts do not include grants and cooperative agreements.

Q4: What is meant by organizational competency for a Request for Proposal (RFP) or a Request for Quotation (RFQ) for analytical services?

A: Organizational Competency is defined by the policy as the demonstration by the organization (e.g., laboratories, field sampling and measurement organizations) of their qualifications in the fields of analyses that are stated or required in or by an issued RFP or RFQ.

APPLICABILITY

Q5: The policy covers only acquisition agreements. Are there plans to develop a similar policy for measurement data collected under assistance agreements (i.e., grants, cooperative agreements, and interagency agreements)?

A: The FEM workgroup determined that due to the complex nature and variety of assistance agreements that the Agency funds, further study on how to address them in an overarching policy is needed. The workgroup plans to write a white paper identifying the challenges and opportunities in the area of organizational competency under assistance agreements. The white paper will be presented to the FEM membership, who will decide next steps.

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, which perform drinking water analyses, to be certified by either EPA or by a state with an EPA SDWA certification program. More information about the SDWA lab certification programs can be found at: http://water.epa.gov/scitech/drinking water/labcert/index.cfm. Other EPA regulations do not have similar requirements, however, other 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 an EPA, state-run, or external PT program. Such requirements may be found in federal/state regulations, environmental permits, among other locations. Here are some additional examples by EPA regulation:

- **Clean Water Act (CWA)**: While the CWA does not have a certification or accreditation program requirement, some states, which are authorized to run their own National Pollution Discharge Elimination System (NPDES) programs, require participation in the state's certification/accreditation program. NPDES permittees are required to use methods approved by EPA for wastewater analyses at 40 CFR 136. Those methods include both the traditional suite of QC operations (e.g., blanks, spikes, calibrations) and required acceptance criteria for the results. A listing of EPA approved CWA methods can be found at: http://water.epa.gov/scitech/swguidance/methods/index.cfm. Most major and select minor NPDES permittees are also required via CWA 308 Request for Information to participate in the annual Discharge Monitoring Report – Quality Assurance (DMR-QA) studies, which is conducted by the EPA Office of Enforcement and Compliance Assurance's (OECA) Office of Compliance – Agriculture Division. More information about DMR-QA may be found at: http://www.epa.gov/compliance/monitoring/programs/cwa/dmr/.
- **Superfund – CERCLA/SARA**: While no certification program exists under Superfund, contractors under EPA's Contract Laboratory Program (CLP) are required

to participate in on-going PT studies administered by the EPA Office of Solid Waste and Emergency Response (OSWER) Analytical Operations Branch. More information about the EPA CLP can be found at: http://www.epa.gov/superfund/programs/clp/index.htm.

- **Federal Insecticide and Rodenticide Act (FIFRA)**: To assure the quality and integrity of data submitted to the Agency, EPA prescribes Good Laboratory Practices (GLPs) for those labs conducting studies that support or are intended to support applications for registration of pesticide products. 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 are also prescribed by EPA under TSCA for laboratories for situations described earlier for FIFRA. For more information on TSCA GLPs, 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 under RCRA. Analytical methods under RCRA SW-846 are issued as guidance with the exception of those methods which are required to be used to determine RCRA hazardous waste characteristics. RCRA methods include traditional QC operations, but do not include required acceptance criteria. Rather, given the wide range of sample matrices to which the methods may be applied, acceptance criteria are considered a project specific issue. For more information on RCRA SW-846, go to: http://www.epa.gov/epawaste/hazard/testmethods/index.htm.
- **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_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 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 Indian tribal governments. More information about NPEP can be found at: http://www.epa.gov/ttn/amtic/npepqa.html.

Q7: Do other federal agencies require their contractors 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).

Q8: The apparent mechanism for including this policy is to incorporate it in the "Higher Level Contract Requirements." Do those only apply to larger procurements?

A: No, the Higher Level Contract Requirements refer to procurements of complex items/services, not to a dollar amount. EPA Manual 1900 *Contract Management Manual*,

Chapters 7 and 46 require application of quality requirements to all solicitations that involve environmental data operations.

Q9: Incorporating this policy through the Higher Level Contract Requirements and the overall Quality System requirements could mean that an offeror could be evaluated on a Pass/Fail basis only. Does the FEM recommend Pass/Fail as a good practice to address laboratory competency? Must I fail an offeror if no accreditation is provided as part of the offer?

A: This should be determined by the program office during procurement planning. If accreditation/certification is required in regulation (e.g., drinking water compliance) for the work being performed, a pass/fail evaluation could be appropriate. However, the policy does not mandate that an offeror be accredited in order to be awarded work, but allows other ways to demonstrate performance (see Q #11 and Q #14). In those cases, a pass/fail evaluation is not recommended.

Q10: 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.

Q11: Who at EPA makes the decision that an organization meets the competency requirements of this policy? And what is the process?

A: From CIO 2105-P-01-0: All environmental data operations performed under extramural agreements shall comply with the Agency-wide Quality System requirements as defined by the relevant regulations. Accordingly, all acquisitions and assistance agreements must be reviewed by an authorized Quality Assurance (QA) Manager, Officer, or Coordinator, as specified in the organization's Quality Management Plan (QMP), to determine if environmental data 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. See also Section 46.1.5.2 of the Contract Management Manual.

POLICY OR REQUIREMENT

Q12: 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 system 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 ANSI/ASQ E-4 2004, *"Quality Systems for Environmental Data and Technology Programs: Requirements with Guidance for Use."*
- 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.

Q13: 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 Q #12)?

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 project officer 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; and
- ensuring the qualifications for the organization's subcontractors under the contract.

Q14: 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); and
- Descriptions of applicable instrumentation, sampling, equipment, method sensitivities, reporting practices, capacity, experience, staffing (e.g., education, job experience, training), and reference of past performance (see Q #20).

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.

Q15: The policy states that accreditation must be maintained for the entire contract. Must this be stated in the contract itself to be enforced? Is there a standard contract 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 contract and this requirement shall be stated in the contract to be enforced. It is the organization's responsibility to immediately inform the project officer of any changes to their accreditation status at any time during the period of performance. At this time, there is no contract clause.

IMPLEMENTATION ISSUES

Q16: If we use labs with accreditations, is it still necessary for us 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 similar to 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.

Q17: 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. A project officer 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 current status of their recognition.

Q18: How can a project officer ensure a subcontractor maintains accreditation for the life of the contract, when recourse is only to the prime contractor?

A: It is the responsibility of the prime contractor to ensure their contract performance, as well as that of their subcontractor(s). The project officer shall require the contractor to monitor the accreditation/certification status of their subcontractor(s) with their subcontractor(s) required to report immediately to the contractor when there is change in their accreditation status (i.e.,

be suspended, or revoked) during the whole period of performance, which the prime contractor is responsible for reporting to the project officer. In addition, the project officer can also monitor the accreditation/certification database, if one is established and available, for the status of the subcontractor's accreditation/certification status.

Q19: How would a RFP or RFQ require organizations to demonstrate competency for sample collection and field measurements?

A: A RFP or RFQ could require organizations to provide documentation demonstrating their adherence to or compliance with national or international standards for field measurement organizations (e.g., The NELAC Institute [TNI] standards, ISO standards) or by data that meets the technical requirement of the required work/project. Laboratories, if not accredited, should be able to indicate in their QMP their proficiency for the project, as well.

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 a number of ways. As noted in response to Q #16, 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 data. Some other considerations for evaluating competency include:

- **Instrumentation** - Does the organization possess all of 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 in the event that 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 of 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 criteria must be thoroughly documented in your project files.

Q21: How should one evaluate alternative means of demonstrating capabilities other than accreditation/certification?

A: As noted in Q #6, many federal programs do not require accreditation/certification. More importantly, many accreditation/certification 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.

As noted in the answers to Q #6, Q #19, and Q #20 some 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 (see Q #12) 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 similar to 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 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 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.