FREQUENTLY ASKED QUESTIONS (FAQS)

POLICY TO ASSURE COMPETENCY OF ORGANIZATIONS CONDUCTING ENVIRONMENTAL INFORMATION OIPERATIONS AND GENERATING ENVIRONMENTAL INFORMATION UNDER AGENCY-FUNDED ACQUISITIONS

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The Forum on Environmental Measurement (FEM)[1] issued a policy to require organizations (e.g., laboratories, field sampling and measurement organizations) to provide documentation of their competency when they conduct environmental information operations[2] and generate environmental information through measurement under U.S. 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, 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, https://www.iso.org/obp/ui.

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

Q2: What do the terms assistance agreement, cooperative agreement, interagency agreement, and contract mean?

A: *Assistance agreement* means 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

[1] 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.

[2] 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.

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).

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

Contract means a mutually binding legal relationship obligating the seller to furnish supplies or services and the buyer to pay for them. Contracts are acquisition agreements, while Assistance, Cooperative and Interagency agreements are not.

Q3: 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

Q4: The policy covers only acquisition agreements. Is there a similar policy that covers assistance agreements (i.e., grants, cooperative agreements, and interagency agreements)?

A: Yes. It is titled: POLICY TO ASSURE THE COMPETENCY OF ORGANIZATIONS CONDUCTING ENVIRONMENTAL INFORMATION OPERATIONS AND GENERATING ENVIRONMENTAL INFORMATION UNDER AGENCY-FUNDED ASSISTANCE AGREEMENTS.

BACKGROUND/AUTHORITY

Q5: Do any EPA regulations 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. Certification of Laboratories that Analyze Drinking Water Samples to Ensure Compliance with Regulations | US EPA
- 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: Hazardous Waste Test Methods / SW-846 | US EPA
- 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 Tribal governments. Ambient Monitoring Technology Information Center (AMTIC) | US EPA

Q6: 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).

Q7: 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 Acquisition Policy EPAAR | Acquisition.GOV. Chapter 7, Acquisition Planning, and Chapter 46, Quality Assurance, require application of quality requirements to all solicitations that involve environmental information operations.

Q8: 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 to be awarded work but allows other ways to demonstrate performance (see Q10 and Q13). In those cases, a pass/fail evaluation is not recommended.

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 an organization meets the competency requirements of

this policy? And what is the process?

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 acquisitions and 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. See also EPAAR | Acquisition.GOV, Chapter 46, Quality Management.

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 ASQ/ANSI E4: Quality Management Systems for Environmental Information & Tech.
- 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?

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; and
- 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: 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 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.

Currently, there is no contract clause. PART 1552 - SOLICITATION PROVISIONS AND CONTRACT CLAUSES | Acquisition.GOV

IMPLEMENTATION ISSUES

Q15: 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 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.

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 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 contracting personnel 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.

Q17: How can a contracting personnel in consultation with the organization sponsoring the work 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 contracting personnel in consultation with the organization sponsoring the work 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 contracting personnel in consultation

with the organization sponsoring the work. In addition, the contracting personnel in consultation with the organization sponsoring the work can also monitor the accreditation/certification database, if one is established and available, for the status of the subcontractor's accreditation/certification status.

As part of the prime contractor's offer, the contract office must request the prime contractor also submit the subcontractor accreditation. Retention of their accreditation must be reported with the prime's status on a yearly basis.

Q18: How would an RFP or RFQ require organizations to demonstrate competency for sample collection and field measurements?

A: An 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.

Q19: 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.

Q20: 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.

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 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.

Q21: 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.