

ORGANIZATIONAL COMPETENCY WEBINARS

Compilation of Questions and Answers

Version 4.0 – December 4, 2013

Question: How does one judge a laboratory's competency and ensure that the data are reliable?

Answer: This question has been asked for years. In approximately 2005 to 2006, the U.S. Department of Energy (DOE) and U.S. Department of Defense (DoD) incorporated simple but carefully worded text into their contractual agreements to require a demonstration of competency as part of the application process and ongoing during multiyear efforts. EPA successfully tested this approach in Region 2. It was determined, however, that this approach was not applicable to all of the different types of funding agreements being used across the Agency. This led to the development of separate policy documents addressing the competency of environmental data under contracts (finalized March 2011) and other funding agreements (approved December 2012). The funding agreements policy has been posted and was scheduled for implementation beginning on May 15, 2013.

The policy is not intended to be burdensome or to require actions beyond what already was being done to ensure competency. The policy is intended as a check to ensure that entities are in fact doing what they have promised to do. Quality systems and Quality Management Plans (QMPs) already were in use; this policy is designed to ensure that they are being followed and updated as needed. Systems are to be in place up front and then followed at regular reporting intervals. Options for demonstrating this competency include providing copies of a current accreditation certificate for the work being done, annual management system review, external or internal audit, proficiency testing/evaluation results, etc. along with other routine reporting required for the project or program.

Question: How can regional office personnel tell whether what they are doing is consistent with this policy? For example, the state's drinking water programs are asked to submit their QMP and Quality Assurance Project Plan (QAPP) documents to the regional office for review and approval. These are to be renewed every 5 years and updated yearly or as changes occur. Is this sufficient?

Answer: When the groups perform their annual checkups, they should inform the regional office that the checkup has been performed and provide a brief summary of the results, including any deficiencies found or changes to be made. If annual reviews/updates are not being done, regional personnel should remind the groups to do them.

Question: State principal laboratories are audited every 3 years, often in association with the laboratory certification program, including the QMP and QAPP. This provides more detailed information every 3 years. Is this similar to what the policy requires?

Answer: That would be an excellent way to demonstrate competency and ensure compliance with the policy.

Question: The policy seems as though it will require much more coordination with regional office quality assurance (QA) personnel. Are these people ready to review the additional documents that may be required under this policy? Budgetary constraints and the like will result in additional burdens and challenges, especially because the competency check is required before work begins.

Answer: QA personnel across the Agency have been encouraged to become involved with and help support their Project Officers (POs) in this process. This encouragement will be ongoing. Lara

will explore the possibility of establishing a support network of QA people to help with the kickoff of this process.

Question: How can EPA ensure that conformance with the policy is not confused with the actual demonstration and documentation of competency? This documentation should be included in the QMP or QAPP; but simply having a QMP or QAPP is not necessarily sufficient to demonstrate competency. The documents must include a demonstration of competency that is appropriate to the work being performed. The FAQs may need to be tweaked to reflect this.

Answer: This idea will be emphasized in the webinars. Other thoughts or hints are welcome as well.

Question: What type of demonstration of competencies is expected? Is approval of the QMP or QAPP by a state examination officer sufficient?

Answer: The demonstration of competency is case specific and varies with the type of work being performed. Whatever the circumstance—e.g., field versus laboratory work, air versus water or other media—the entity involved must demonstrate the competency to assess the quality of its work to meet the project requirements. The QMP and QAPP set the basis, and proficiency testing of samples can help to demonstrate this. State certification of accreditations that are relevant to the work to be performed is sufficient. It becomes more difficult when such certifications/accreditations do not exist or are not available.

Additional points to note: The policy applies beyond laboratories and covers organizations that collect field samples or take field measurements as well. In addition, it may be more difficult to implement the policy for smaller grantees such as Tribes and universities. Such organizations, for example, may not be part of an accreditation program or may not have a QMP.

Question: The policy implies that the grantee is responsible for ensuring that its subgrantees or subcontractors meet the same competency requirements, but this is not how the revised FAQ reads.

Answer: The wording of the FAQ continues to be discussed with the Office of Grants and Debarment. The same expectation of quality applies to the grantee and its subgrantees, subcontractors and so forth. This creates an immediate issue for implementation and will be addressed accordingly.

Question: In general, should the state partners be able to examine a document and know what should be submitted to the PO?

Answer: Yes, if asked, they should be able to show a demonstration of competency for the work they are doing.

Question: If EPA gives grants to itself, how would EPA entities demonstrate their competency? Most regional offices do not have something in writing attesting to their competency in field work.

Answer: A regional office could demonstrate competency using a proficiency testing sample, proficiency evaluation sample, training, audits and/or other means. Regional offices thus far have not been held to the Field Operations Group (FOG) standards, but once those standards become applicable to regional offices, it will be easier for those offices to demonstrate their competency in this area. Demonstration of competency in field work will be required by 2016. In addition, the field operations of Region 4 and of the National Enforcement Investigations Center (NEIC) have been accredited for conformance to ISO 17025 requirements, and the NELAC Institute (TNI) offers a field accreditation program. Other programs are available as well.

Question: State grantees are asking how EPA can require them to do something that has been voluntary in the past and, because of state-level financial constraints, will EPA provide monies for accreditation?

Answer: Certification/accreditation are options for demonstrating competency, but neither is required. Grantees should already be taking steps to ensure competency for the work that they are performing. No additional costs should be required.

Question: Region 6 has been receiving QMPs from every organization that performs environmental grant work since the early 1990s. Does having a history of approved QMPs, QAPPs and the like demonstrate competency?

Answer: It helps, but regional offices must ensure that competency is demonstrated in the areas of work being performed. This should be done via documentation that is provided to the regional office on a regular basis that demonstrates an ongoing effort to show competency.

Question: What if such documentation is not being provided, for example, in a state that does not require laboratory accreditation? Or, what if the organization is a Tribe, which is sovereign?

Answer: EPA is in the process of addressing how Tribes can demonstrate competency under this policy. FAQs that specifically address Tribes will be added soon.

Question: If a specific certification or accreditation is not required and an organization demonstrates its competency to the PO, can the PO put a statement in the organization's grant file to that effect?

Answer: Absolutely.

Question: Is it correct that the PO does not have to submit all documentation to regional QA personnel for review—only on an as-needed basis?

Answer: Absolutely. If the PO is comfortable with what is received, that is sufficient. If, however, the PO would like help from regional personnel, he or she should ask for it.

Question: The idea of competency requirements has been included in the EPA Quality Management Structure for a long time. To ensure that the auditing and checking requirements are followed, why not just improve your implementation of your quality system? The additional grant paperwork is a concern. Is this duplication necessary?

Answer: We worked closely with the quality assurance (QA) staff and agreed that Quality Management Plans (QMPs) and QA plans are required and were being produced. However, a check for competency to ensure that people were capable of doing their environmental work and actually following the guidelines was not consistently happening. This policy called that to everyone's attention. This policy provides a check-and-balance to ensure the pieces are connected, and the policy will be referenced in policy documentation in the future. It adds a couple of more pages to the file. We are creating a one-page checklist showing possible combinations of information to help streamline this.

Question: How does this impact our work with external laboratories? Is anything required of those laboratories?

Answer: EPA's agreement is with the grantee. Grantees are responsible for their subcontractors and consultants and should indicate their comfort level with the laboratories' following and reporting of competency. The grantee is responsible for determining how best to pass down the requirement to their subcontractors and consultants.

Question: What type of demonstration would the grantee need to provide in an application for those instances when a subcontractor (e.g., laboratory) is not yet identified?

Answer: In instances where it does not make sense, is not practical or would delay award, the documentation should be provided before an analytical and/or measurement event occurs.

Question: Can this competency requirement be addressed with states during audits?

Answer: Audits generally do not occur frequently enough to ensure the competency requirement. Audits often occur every 3 years, and EPA is requesting continuous competency to be completed on an annual basis.

Question: Other than providing a certification, what types of assurance can be provided? How much detail should be included in the documentation?

Answer: EPA trusts that its grantees will provide honest assurance(s) in providing a statement and some documentation. The information can be checked during the QA/QMP review and/or audit process. EPA prefers that the information be provided up front to the Project Officer, but the Agency does not intend for provision of this information to interfere with the award of grants. EPA requests that the documentation be submitted before the measurement and/or analytical work occurs.

Question: Please explain how we can demonstrate competency in how we **use** data.

Answer: The policy says “generating or using” environmental data. Generating data (i.e., collection or analysis) is more common; using data would generally be a secondary application (e.g., data manipulated through modeling or analysis). EPA is preparing a document to provide more details about this.

Question: Are any states involved in the Work Group that is preparing the policy document?

Answer: EPA welcomes input regarding any of the FAQs or its other tools. These resources are posted on EPA’s website, and comments are welcome on all documents.

Question: What type of information will satisfy this policy at the project level? Are certifications of classes sufficient?

Answer: Training documentation to show recent training and/or certification is acceptable. There are many organizations (e.g., Source Evaluation Society, The NELAC Institute, ISO) that offer training and accreditation regarding field measurement as well as certain types of analysis and methods being used. Completed EPA courses also are acceptable.

Question: Our QMP fully describes our hiring policy and criteria. Must we include similar information for each of our cooperative agreements?

Answer: It is acceptable to reference it as being provided in your QMP.

Question: Will this impact every stat test that is done in the state? Are we required to demonstrate that the people doing the test(s) are truly competent for each testing activity?

Answer: EPA’s competency requirement is mandated only for Agency agreements. States have their individual policies. Currently, there are only a few instances where an accreditation and/or certification requirement is in place for field measurement and sampling.

Question: Are QA staff in EPA Regions knowledgeable about the policy?

Answer: The policy has been widely circulated within the Agency, and all QA groups have been involved. A small group of QA experts might be identified to assist with questions.

Question: Has the policy undergone any tribal review?

Answer: Two tribal members helped develop the policy, which recently was shared with the Tribal Council. In addition, two tribal webinars (dates TBD) are planned to ensure that tribal concerns are addressed.

Question: This is the first time that some EPA staff are seeing the policy.

Answer: We have representation on four measurement areas across regions and topical areas. It was approved by the Science and Technology Policy Council (STPC), which has representation from every region and area. We apologize that we are surprising anyone, as we have done our utmost to disseminate this to everyone.

Question: Because some grantees experience a long process to receive approval of their QMPs, they would appreciate having to meet only one set of quality requirements for EPA and would encourage Agency departments to coordinate better. “Quality” and “competency” appear to describe the same idea.

Answer: The competency requirement, which does not require changes in developing a QMP, simply asks grantees to confirm in their reporting (e.g., quarterly, semi-annually, annually) that they are following the QMP/QA plan and provide basic documentation to show this (e.g., staff were trained for methods, performance evaluation samples were completed competently).

Question: Can EPA adopt a policy to require mandatory laboratory accreditation or certification?

Answer: Only two parts of EPA have statutory authority to require certification or accreditation in their respective areas: the Office of Ground Water and Drinking Water Program, and the Asbestos and Lead Testing Program. No other part of EPA has statutory authority to allow the Agency to implement such a mandate. An accreditation certificate might make it easier for grantees, but it is not required. EPA is developing a basic checklist that will be available on the Agency’s website to facilitate meeting the competency requirement.

Question: Does the policy impact third-party laboratories for work performed that is not tied to grant dollars?

Answer: No.

Question: What is the policy impact for a stat testing group that observes but does not generate the data?

Answer: Grant recipients who have stat testing groups doing the work need to show that they are competent for the data that they are generating for the assessment.

Question: Is competency demonstration needed for a laboratory partner that sends information that was not paid for with grant funds?

Answer: No. The grantee who uses grant funds to analyze data would need to ensure that the data are being used appropriately but does not need to be concerned about showing the competency of the collector or source of information if the collection was not obtained through grant funds.

Question: We are responsible for documenting that our field people collecting the samples were trained adequately and that entities analyzing samples were following the QMP. Do we also have to document that users of data were trained?

Answer: Grantees should document that users of data were adequately using the data.

Question: Does this apply to laboratories that generate data or to the use of data?

Answer: It applies to laboratories that would generate and/or use data. It also applies to any measurement organization and field sampling.

Question: Example 3 refers specifically to an organizational chart. Would such a chart by itself demonstrate competency?

Answer: No, an organizational chart by itself is not sufficient. The position description, qualifications and competency of the staff to conduct the work and analysis should be demonstrated.

Question: Does this require certification of the field sampling teams that are collecting the data or just those taking measurements in the field?

Answer: It applies to those who are taking measurements and/or handling the samples. Qualifications of the proficiency of personnel involved—for example, in collecting samples properly—should be demonstrated.

Question: Is documentation kept in an organization's files that all of the staff and contractors are trained and qualified to take the samples adequate to show competency?

Answer: Yes. Documenting the level of training in one's quality management plan (QMP) and quality assurance project plan (QAPP) is sufficient.

Question: Is accreditation or certification necessary?

Answer: EPA is not requiring anyone to be accredited or certified. It is one way to demonstrate competency.

Question: Where does the documentation about competency need to be captured?

Answer: EPA encourages recipients, through their terms and conditions, to provide the documentation when one receives assistance agreements or, to not hold up the process, to send to the EPA Project Officer a short report and/or the pertinent training records for the personnel involved in data generation.

Question: Is the EPA Project Officer responsible for requesting the required competency information and ensuring that their projects meet this requirement in addition to other quality requirements? The material does not need to be sent to other EPA staff, right?

Answer: Grantees should submit their ongoing competency information directly to their Project Officer.

Question: If this information already is in an organization's QAPPs and QMPs, why is more action needed?

Answer: The QAPP and QMP are not themselves a demonstration of competency.

Question: With respect to personal qualifications, in the absence of a formal external training program, is documented, internal proficiency training adequate to satisfy the policy?

Answer: Yes, provided that the training program is outlined in the QMP and other documents to show that this is how one is ensuring that staff are qualified to complete the work.

Question: What type of qualification would an instructor need? Would 30 years of field experience be adequate, or is a formal certification necessary?

Answer: Long-term field experience, such as 30 years, would be sufficient.

Question: If an assistance agreement proceeds without the competency demonstration, is the information still required for that agreement?

Answer: Yes, the information still must be sent. The policy will be in effect starting with packages on October 1, 2013. Individuals may choose to send in their competency demonstration earlier.

Question: How are Project Officers coordinating with the regional QA staff? Can we at the state level expect to see more detailed direction and guidance from the Project Officer and regional QA staff?

Answer: Many EPA Quality Assurance Officers are discussing among themselves how to attain greater consistency in implementing the competency policy. The extension in implementation was partly to ensure adequate time for them to accomplish this. If a Project Officer is comfortable with his or her review of documentation to satisfy competency, then EPA is satisfied. The Project Officer also is encouraged to rely on the support of their program and regional Quality Assurance Officers. EPA is trying to facilitate such connections and as many useful tools as possible to support the implementation of this policy.

Question: Regarding the provision of a statement of competency, item 5 appears important. States undergo periodic audits of our quality system by EPA—would it be possible for EPA departments and offices to share that information internally rather than require grantees to duplicate the submission of information?

Answer: All QA and QMPs are supposed to have an annual assessment of how that program is doing and whether any changes to the quality system are needed because of any changes within the organization. Competency would need to be demonstrated for the years that the Agency is not conducting the audits. Reference to the Agency assessment could be made for those years when EPA conducts an audit.

Question: A state grantee has several partnership agreements in place, as well as an accredited laboratory, a QA plan and QMPs. Is it correct that, by themselves, these do not demonstrate competency and that additional reporting to the EPA Project Officer is needed to demonstrate competency?

Answer: Yes, that is correct.

Question: This competency policy is applicable to grants and agreements that are more than \$200,000. Does that amount refer to the entire grant or the amount that is apportioned for environmental data collection?

Answer: The policy is applicable to all grants that total \$200,000 or more, even if only a small portion is used for data collection and field work.

Question: If an ongoing program has a QMP and a cooperative agreement and also has completed audits on an annual basis, is that enough information to demonstrate competency?

Answer: Yes. A recipient should be able to show that he or she has followed his or her organization's quality system and agreement's reporting requirements.

Question: Please clarify regarding cooperative agreements for subcontracts. Those documents often do not arrive for several weeks or months afterwards. Also, the subcontractors provide information regarding their activities to show their competency. Is anything additional needed from them?

Answer: The policy is to rely on the grantee to determine what information might be asked and/or required from a subcontractor to ensure that the grantee is comfortable with the subcontractor's competency. EPA holds the recipient of the agreement responsible.

Question: What about independent consultants who provide data?

Answer: This is the same as subcontractors. EPA holds the recipient of the agreement responsible.

Question: Who should be included in the demonstration of competency? How far "up the food chain" should this go? Should it be anyone who physically touches the data? How far and broad

should this policy be implemented? The policy appears to be that anyone who touches the data should have some certification and competency attached to their ability to use the data. This could reach the state governor level. Management should be qualified to do their job and this competency should be addressed in QMPs, even generically.

Answer: The recipient should show that training is in compliance with the QA plan, including the qualifications of the team that will be working under the assistance agreement. These are the ones whom EPA would expect to see qualifications for to judge competency. EPA will provide further clarification to this issue soon.

Question: How does the competency policy relate to data handling—specifically, databases?

Answer: Competency should be demonstrated for the data entry person. It is not expected for anyone using the database once the data are input.

Question: Some partnership agreements (e.g., those that operate under 305B and 303D), require the recipient to use all available data. How does “secondary data”—that is, using data that one has not generated—apply to the competency policy?

Answer: EPA will need to provide further clarification on this issue. The recipient is responsible for ensuring that the secondary data used are appropriate for the intended purpose and that the users are qualified.

Question: How should one document when data are determined not to be appropriate for use?

Answer: If upper management levels made such a determination, it would have been excluded from the work performed under the EPA assistance agreement.

Question: Based on earlier questions, it would help if EPA would describe the limitations and parameters for the competency policy (e.g., as it affects laboratories, secondary data, some metadata; does not affect governors, etc.).

Answer: Thank you for the comment.

Question: What about instances when competency is difficult to demonstrate for a single person?

Answer: This would involve a corrective action, such as through additional training or replacement. EPA will consider identifying examples to clarify this.

Question: As a follow-on to the above question, this concerns the determination of usability. The policy should address all personnel who work from the project planning and sampling through the determination of the usability of the data collected and/or generated. These personnel will be making scientific determinations.

Answer: Great points. The EPA policy work group will consider these.

Question: This policy is focused on an organization’s competency. Defining an organization’s competency should encompass the training of personnel involved in the activity.

Answer: Agreed.

Question: Nearly all of the samples for the [Colorado] drinking water program are collected by parties that are regulated entities. Does the competency policy extend to these parties in their collection of the samples?

Answer: The requirements for competency lie directly with the recipient of the grant.

Question: Please provide examples of programs that could serve as a model in complying with the competency policy.

Answer: Thank you. Examples will be included on the website as they are developed.

Question: Part of the desire is to have a roadmap on how to handle unique and complex situations. The ISO 17025 standard for laboratories provides some answers.

Answer: EPA will provide a link to the resource.

Question: Has each subsequent webinar presented different content, or has the content been the same for all of the webinars?

Answer: The webinars all begin with the same information. If new information has been added to the EPA.gov/FEM General Laboratory Competency website (http://www.epa.gov/fem/lab_comp.htm) since the previous call (e.g., additional questions and answers), that information is made known to participants in subsequent webinars. Version numbers on the website indicate that updates have occurred.

Question: Please explain the *Federal Register* notice that was issued on July 1, 2013, and delayed implementation of the new organizational competency policy until October 1, 2013, and allowed EPA regional offices to use their discretion in determining when to implement the policy.

Answer: That *Federal Register* notice was published in response to feedback received during the initial webinars and outside of the webinars. Implementation in May proved problematic for many because of budget timing, additional questions and other issues. The notice extends the implementation period to October 1, 2013. Some programs were ready to implement the policy prior to October 1, and still can do so. New solicitations or awards made on or after October 1, 2013, are required to include a term and condition to the effect that, if generation or use of environmental data is involved and the award will be for more than \$200,000, the recipient organization is required to demonstrate its competency in accordance with the Policy to Assure the Competency of Organizations Generating Environmental Measurement Data Under Agency-Funded Assistance Agreements. This is not required until October 1, 2013, but EPA regional offices can require it sooner if they so choose.

Question: For grants that are awarded before October 1, 2013, does this mean that the requirement to demonstrate competency in some cases will not be implemented until whenever the next grant cycle starts—even if that is not for another year or two?

Answer: Yes.

Question: For grants that already have been awarded prior to October 1, 2013, would this policy become applicable during subsequent reviews or extensions?

Answer: If a grant is extended beyond its original award, then it would become subject to the new policy at that point; otherwise, the grant would not necessarily become subject to the policy until a new award is made.

Question: How far into sampling does this policy apply?

Answer: The policy applies whenever environmental data are being used or generated. This applies to laboratories, field sampling entities and other organizations.

Question: If we contract with other companies as part of a grant, are we required to obtain competency information from them?

Answer: Yes, but at the grantee's discretion. The recipient is responsible for any subgrantees or subrecipients. This policy is between EPA and the grantee, and it is the grantee's choice as to how the policy is carried out with any subrecipients.

Question: How is "environmental data" defined in this policy?

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

Question: Why is this policy referred to as the “laboratory competency policy” when laboratories are not always involved in the generation of environmental data?

Answer: Currently, the FEM website refers to laboratory competency. The website is in the process of being revised and eventually will refer to competency in general, but right now it refers to laboratory competency.

Question: We have a number of grants with EPA. Would it be possible for us to submit a package to demonstrate competency along with our annual grant certification and then be covered for any application we would submit during the year—instead of generating a new package with each application?

Answer: A single package would be fine. If multiple Project Officers (POs) are involved with the grants, each PO would need to receive a copy of the package.

Question: We submit an annual grant certification package to EPA. Could EPA share the competency demonstration information among the appropriate personnel? Would that be a more efficient way to meet the policy requirements, rather than submitting the competency information with each application?

Answer: If the package is set up for sharing, EPA could distribute it as needed. Different entities use different types of agreements; although a single package might work for some entities, it might not be appropriate in all situations. EPA regional offices are in the process of exploring ways in which the policy might be applied across routine grants. It was suggested that this be discussed with Howard Corcoran in the Office of Grants and Debarment as well.

Question: How does the policy apply when monies are taken off the top of a grant and given to an EPA-run national contract, as in the air program? This would include the audit program and other contracts that EPA actually manages. How would competency be demonstrated for these programs?

Answer: Discussions are ongoing with Mike Papp in the Office of Air and Radiation to ensure that such situations are handled consistently and in a nonburdensome manner. The result of these discussions will be disseminated broadly once conclusions have been reached.

Question: What caused this policy to be written?

Answer: This policy has been discussed for the past 10 to 15 years as a matter of continually ensuring that data of known and documented quality are being procured and that quality systems, rules and guidelines are being implemented as effectively and efficiently as possible. The policy is the culmination of years of effort and conversation about ensuring checks and balances and adherence to identified Quality Management Plans (QMPs) and Quality Assurance Project Plans (QAPPs) without creating an undue burden on anyone involved.

Question: We collect data and samples using state monies, but the evaluation is performed using EPA funds. Does the competency requirement apply to these situations?

Answer: Yes.

Question: Is it likely that this kind of policy will lead to EPA requiring more accreditations in the future?

Answer: Throughout the history of EPA, only three programs have been known to have the statutory authority to require certification and/or accreditation. This has not changed, and such a change is not expected in the near future.

Question: How is this policy expected to affect Performance Partnership Grants (PPGs) in which the different components (e.g., under Clean Water Act Section 106) may fall under the \$200,000 level, but collectively the PPG may be above the \$200,000 level—but only the monitoring is being done under the 106 component?

Answer: The requirement applies to grants that total \$200,000. Clarification is being sought from the grants office on how the policy applies when components of a grant may fall under the \$200,000 level as in the case of PPGs. This will be addressed in an FAQ posted on the FEM website as soon as clarification is received.

Question: How do participants contact Lara Phelps with additional questions or concerns?

Answer: Ms. Phelps will receive emails sent through the Contact Us link in the upper left corner of the FEM General Laboratory Competency website (http://www.epa.gov/fem/lab_comp.htm). She also can be reached directly at phelps.lara@epa.gov or at 919-541-5544.

Question: It sounds as though following a QMP that has been approved by an EPA regional office meets the new competency requirement. Is this basically correct?

Answer: Yes. All that is being asked is that, at the start of a new grant or cooperative or assistance agreement, a statement be provided that the QMP is being followed, along with an example of how that is being done that is relevant to the type of work being performed under the grant. Examples of appropriate documents include training records of key personnel, results of a former QAPP from a relevant project, and results of an internal assessment against the QAPP.

Question: Question 12 of the 02/21/2011 FAQ document on the website includes four bullets that state what is required to demonstrate competency. The first bullet refers to QMPs. It would be difficult to apply any of the other three bullets to Tribal partners that may receive grants in excess of \$200,000 over a 3-year period. Some Tribal organizations, however, do not have QMPs but may provide QAPPs. Would a QAPP satisfy the requirements of the first bullet?

Answer: The results from a QAPP that had been followed previously and was relevant to the work to be performed under the current project would be adequate to demonstrate competency in the absence of a QMP. In addition, General Assistance Program (GAP) grants that are given to Tribal organizations to provide training of personnel to take measurements or develop other skills do NOT fall under this competency policy.

Question: To clarify, is it correct that the above-referenced Question 12 refers to organizations that rely on accreditation/certification to demonstrate their competency, and that Question 14 applies to organizations that do NOT rely on accreditation/certification for these purposes?

Answer: Yes.

Question: In addition to the posting of the additional FAQs, etc. on the FEM website, is there a LISTSERV to provide additional information?

Answer: No such LISTSERV exists at this time, although it is under consideration. If one is created, it will be announced on the FEM website, and those who are interested will be able to sign up on the website as well.

Question: Is the webinar outreach considered to be consultation with Tribes?

Answer: The webinars, including webinars held solely for Tribal personnel, are the means that EPA is using to provide additional information about the implementation of the competency policy. It is understood that Tribal communities encounter unique situations with regard to grants and agreements, and the Tribal-only webinars are being held to allow personnel to ask questions about their special situations. EPA is very interested in Tribal feedback and interaction so as to

make this process as easy as possible. EPA also is open to conducting state-only or additional targeted webinars if requested.

Question: This is an additional requirement being put on Tribal environmental departments when budgets are being squeezed and additional reporting requirements have been put in place. In addition, there is a movement toward streamlining policies for awarding Tribal grants and reporting requirements. Implementation of this competency policy seems to go against those trends. Also, QAPPs often are good for 5 years. Can successes achieved during a QAPP's earlier years be used to justify successive years of a grant?

Answer: Yes. EPA is trying hard not to make this process more burdensome on Tribes or other organizations and therefore is not requiring any new documentation to be developed if appropriate documentation already exists. Pointing to success in previous related work is acceptable to satisfy the competency policy requirements.

Question: Will implementation of this policy be discretionary at the PO level, with some POs accepting simple statements and others requiring additional detail and proof?

Answer: EPA will do its best to ensure consistency in this process and to keep it as simple as possible.

Question: We have a Memorandum of Agreement with our state department of health laboratory, which is required to maintain safe drinking water laboratory certification with the state and meet the requirements of the federal safe drinking water program. Is this certification sufficient to meet the requirements of the competency policy?

Answer: Yes.

Question: Basically, does the policy mean that if an organization is the recipient of an EPA grant of \$200,000 or more to gather or use environmental data, then this policy must be reflected somewhere in the agreement? If that is true, does the policy not apply if data are gathered or used using funds other than EPA funds? And, will these same policy issues apply if data gathered under other agreements are used in EPA-funded projects?

Answer: The answer to the first question is yes. As for the second question, EPA's agreement is with the recipient organization, and EPA expects the recipient to have confidence in the data being used/reported back to EPA. How the recipient reaches that level of confidence is not specified by EPA if the data are collected via other than EPA-funded means.

Question: Are we expected to apply the competency policy to discharge monitoring report (DMR) data that we receive from facilities across the state and report to EPA under the National Pollutant Discharge Elimination System (NPDES) program?

Answer: This again is a choice of the recipient organization because EPA did not include subrecipient criteria in the policy. The burden is on the recipient of the EPA award to ensure that it has confidence in the information being provided to EPA, regardless of the source of that information. The recipient can apply the checks and balances it chooses to its subrecipients. EPA relies on its awardees to ensure that they are supplying EPA with data of the best known and documented quality that they can.

Question: To clarify, our permits typically involve monthly or more frequent monitoring, and we have more than 10,000 facilities that monitor their own discharges. Would it be adequate to include in the permit that the facilities must follow the methods in the CFR, and we will audit a sample?

Answer: Those two things together are sufficient.

Question: I want to confirm that the burden is on the recipient to identify and implement the competency requirements and that the expectation is that the recipient acknowledges the demonstration of competency, whether it be through an attachment such as a Quality Assurance Project Plan (QAPP), Quality Management Plan (QMP), or the like. It does not mean that the recipients must start submitting to EPA quality or project personnel all of the demonstrations of individual or organizational competencies for EPA approval. The recipient is not required to submit any new information that has not been requested otherwise. Is this correct?

Answer: That is correct.

Question: We receive funding from EPA Region 4 under our state circle program. We occasionally use a third-party contractor to conduct investigation and cleanup activities, including taking samples. In such cases, the contractor must follow guidance in the QAPP and QMP and, for the sample taking, the contractor would demonstrate to us that it is in compliance with the policy with regard to the quality of the sample collection and laboratory data. Is that correct?

Answer: That is EPA's recommendation to you. Because a third party is involved and EPA's agreement is with the recipient of EPA funds, however, how a third party demonstrates its competency is to be determined by the recipient of the EPA funding. Ultimately, the competency policy applies between EPA and the recipient of EPA funds. The grantee chooses if and how to apply the policy to any subawardees. It would appear to be in the best interests of grantees to apply the policy in some form to any third parties.

Question: Is it correct that EPA has until 2016 to implement the Field Operations Group (FOG) Operational Guidelines based on a policy signed by the Deputy Administrator? And, are grantees being asked to implement this competency policy after October 1, 2013, 3 years earlier?

Answer: EPA has given itself 3 years to implement what essentially is a certification program for all EPA field activities. EPA already has to demonstrate competency, whether for a laboratory, field exercise, or similar operation. The FOG guidelines take competency one step beyond having a QAPP or QMP in place.

Question: In this webinar as opposed to others, there has been considerable discussion of work relating to laboratories. To clarify, does this policy apply to nonlaboratory-related field work as well?

Answer: Yes, the policy applies to laboratory work as well as field sampling measurement/use of data/overall organization. If environmental data are being used or generated, the policy is applicable.

Question: We recently worked on identifying methods of training/certifying those conducting field sampling activities. A question arose concerning recent college graduates who have taken classes that involve field sampling. Would that be acceptable for certification as long as they then become familiar with standard operating procedures (SOPs) and go into the field with an experienced sampler?

Answer: It would be acceptable, but the grantee organization would want to ensure that the person has been trained in the type of measurement work that he or she will perform under the agreement.

Question: We perform watershed management work and sometimes consider implementing innovative activities to address water quality issues. This can involve practices that go beyond the "norm." In these situations, we do not always have someone available who has been trained in the exact activity to be performed. People may have related training, however, or may have been trained in parts of the activity. How would the competency policy apply to these types of situations?

Answer: If an organization can show that it has a demonstrated quality system in place (e.g., reviews its QMP annually and makes necessary changes to it, has an appropriate QAPP in place), this is what would be relied on in these types of situations.

Question: We are part of the air monitoring program, and we usually work with grants from EPA on a renewing schedule. I would assume that the competency policy would apply to us when the new grant cycle occurs. Is that correct? What would be the easiest way to demonstrate compliance—could we say we do a technical systems audit with EPA every 3 years and have had good results from that, or would we need to get into our annual internal audits, proficiency samples, etc.?

Answer: When an organization first receives an award, it should highlight the most recent audit or competency-related factor that is 2 or 3 years old. Maintaining competency over the life of the agreement can be demonstrated in the organization's annual report to EPA.

Question: It seems that it would be helpful for EPA to specify what is needed to demonstrate competency when a grant is being written.

Answer: This idea is under discussion, although nothing definite has been developed to date. It is possible that a template of terms and conditions may be developed, with parts to be inserted in specific grants, but it does not exist yet.

Question: Please clarify what is required to be submitted to EPA with regard to the answer given to question 10 of the FAQs related to what the Project Officer would use in deciding that a grantee meets the competency requirements. Would attaching a copy of an organization's updated QMP and most recent report on efforts made to demonstrate competency be sufficient?

Answer: An organization could make a statement as part of its statement of work in its grant receipt package attesting to its competence and referencing existing documentation that already was supplied. Or, the organization can attach additional information if it prefers to reference something other than what already was provided to EPA. Attaching a copy of the most recent report as described above would be sufficient.

Question: If a laboratory is drinking-water certified but is involved in analyses other than drinking water, could that EPA certification be used at least as supporting documentation of competency?

Answer: It can be used as supporting documentation, but if the laboratory will be involved in activities that are unrelated to that certification, something else will be needed as well.

Question: Did the discussion of the FOG Operational Guidelines refer to the original issue of those guidelines?

Answer: Yes, although some clarifications have been made subsequently. These guidelines cover 10 areas: Personnel and Training, Document Control, Records Management, Sampling Environmental Data Management, Field Documentation, Field Equipment, Field Inspections and Investigations, Reports, Internal Audits, and Corrective Action. The FOG guidelines are not posted on the FEM website because they do not apply to organizations outside of EPA. Anyone interested in exploring these guidelines further can email Lara Phelps at phelps.lara@epa.gov for a copy.

Question: EPA recently responded to some questions from Michigan, and one question asked why the laboratory competency and QA requirements had not been combined. The answer was that they had begun as independent projects, but it was unclear whether consolidation might be considered in the future. Has this been given any consideration, and is it a possibility? It might

be advantageous to incorporate the laboratory competency issue into the QMP so that two separate documents, sets of communications, etc. would not have to be referenced.

Answer: Discussion of this topic is ongoing. At a minimum, it is likely that the topic will at least be referenced, and efforts will continue to make this process as easy as possible.

**U.S. Environmental Protection Agency (EPA) Organizational Competency
Webinar – EPA QA Community
November 6, 2013**

Question: Is there suggested language regarding the demonstration of competency to be included in contracts and assistance agreements?

Answer: EPA has provided examples of ways in which entities could demonstrate their competency but has not provided specific wording to be used. This was done to accommodate the many different programs and their different templates and structures. EPA will serve as a conduit for any examples that participants might wish to share with others.

Question: EPA now has a decade of experience with implementing the March 2004 policy directive on assuring and documenting the competency of EPA laboratories. It would be informative to hear about the costs and benefits of implementing the policy and where we go from here.

Answer: EPA has not conducted a formal cost-benefit analysis of how this policy will work for agencies that receive funding from EPA. EPA has gained considerable internal experience, however, and a recent update for the scientific integrity report showed that EPA laboratories are keeping up with the policy. EPA anticipates that the cost will be minimal for outside entities to comply with the policy and ensure the receipt of data of known and documented quality.

Question: To what specific EPA organizations are assistance recipients required to demonstrate their competency?

Answer: Laboratories currently are required to demonstrate their competency (required since 2004). Field sampling and measurement organizations are in the process of complying with the field operations guidelines to demonstrate their competency by February 2016. The contracts policy that took effect in March 2011 and this policy for assistance agreements (effective October 1, 2013) require a demonstration of competency for any work that involves environmental data activities performed with EPA funds. This applies to new work; extended efforts are not required to comply with these policies unless they involve the generation or use of environmental data and the award will be for \$200,000 or more.

Question: Who judges competency?

Answer: The judges are the Project Officers (POs), alone or in consultation with their Quality Assurance (QA) officers.

Question: How does this policy apply to continuous monitors such as air monitors? In many cases there are no certification programs for continuous monitors, although in some cases there could be audits.

Answer: QA plans typically require periodic calibration checks and performance evaluation tests when practical. Also, field sampling and measurement accreditation programs exist for those performing those tasks. EPA suggests ensuring that QA/Quality Control (QC) processes assess an entity's history of having a Quality Assurance Project Plan (QAPP) in place; carrying out continuous QA/QC checks, even for continuous monitors; and reviewing reported results to establish that an entity is continuing to function and operate properly. EPA is willing to disseminate additional examples as they become available.

Question: Why should EPA judge the competency of laboratories that are external to the Agency? Why are we taking ownership of external laboratories?

Answer: If EPA chooses to provide funds to outside organizations to conduct analyses and other work on behalf of the Agency and will use those data in making decisions, the Agency needs to know that quality information is being provided. If the organization already is accredited and that accreditation seems appropriate to the work to be performed, that could be sufficient. If, for example, it is a state organization with a long history of providing services to EPA and the QA personnel involved are satisfied with the QAPP, reporting, history and the like, that also could be sufficient. These requirements are intended to ensure that properly trained staff are using suitable equipment and following the appropriate methodology in conducting EPA-funded work and providing data that will be the basis for EPA decision making.

Question: If the Agency provides a grant under an approved Quality Management Plan (QMP) or QAPP and some of the work is delegated to external laboratories, how does the competency policy impact this project? Will the competency policy directly apply to delegated laboratories, or will the policy apply only at the grantee level? If the competency policy applies to the delegated laboratories, what should EPA expect to receive?

Answer: The competency policy applies to the entity that receives EPA funds. The recipient entity is responsible for the EPA funds received and for determining whether and how it will apply the policy to any other entities that it hires to perform work under the project.

Question: What are the mechanisms for denying grant monies to laboratories that obviously are incompetent?

Answer: The entity that receives funding from EPA could refuse to award funds to an incompetent laboratory on the basis that the laboratory was found not to meet the necessary criteria to perform the work.

Question: We fund Indian tribes that hire laboratories. Who must demonstrate the laboratories' competency? Tribes seldom have technical staff, and our POs are not in a position to pass judgment. Are EPA QA staff members responsible for evaluating the laboratories that tribes hire?

Answer: This is similar to the previous question about delegated external laboratories. EPA understands that many tribes do not use QMPs and often have a history with laboratories on a project-by-project basis. They might have created QAPPs and the accompanying reports. EPA would rely on the entire package and interaction in such cases. In addition, some tribal communities work with other organizations for training purposes and might be learning a skill that involves data gathering. This policy does not apply to such training situations. Some tribes might be interested in being trained to implement the competency policy in the tribal context.

Question: To what degree should the EPA regional offices' contracts branches, which actually award contracts, be involved in the competency policy? Has guidance been provided to them on minimum requirements for laboratories that are being awarded contracts?

Answer: Guidance has been provided in the FAQs and in the examples of possible means to demonstrate competency. EPA is willing to expand the list of examples and suggested language that could be used as new ideas are submitted.

Question: Our regional office enters into regional contracts with laboratories. When the contracts branch issues a Request for Quote (RFQ), have they been directed to include language stating that laboratories must meet certain requirements with respect to quality systems?

Answer: If the contract will involve environmental data activity, the RFQ should include language addressing quality systems. The contract-related competency policy has been in effect since March 2011. Because the policy has not yet been integrated into the contracts manual, however, adoption has been slow in some areas, but such language should be included in relevant RFQs.

Question: When environmental data-related activities involve subcontractors, have those contracts been amended to state that subcontracted laboratories must meet the policy requirements?

Answer: Again, the entity that receives EPA funds carries the ultimate responsibility for the quality of the data produced. The EPA-funded entity can determine how it wishes to apply the data competency requirements to its subawardees. EPA is encouraging the integration of the policy into existing agreements as appropriate (e.g., with new grants and in the terms and conditions). This applies to contracts as well. The policy is still filtering through the system, and EPA is developing ways to track compliance.

Question: How does this policy apply to assistance agreements with state agencies for implementing EPA-delegated programs that entail decision making based on environmental data collected by regulated facilities?

Answer: The policy is applicable to state agencies in the same manner that it applies to any outside organization that enters into an assistance agreement with EPA. Many state agencies have had longstanding relationships with EPA and have a known history/documentation based on those relationships.

Question: What type of competency statement is required from state agencies with delegated programs? What templates or formats can be shared with grantees?

Answer: No specific templates or formats have been developed to date. EPA welcomes and will facilitate the sharing of examples that have been developed. EPA has been hesitant to create examples so as to avoid potential confusion. The examples that have been posted include language that could be useful to others. A simple suggestion might be to use language such as “I hereby certify that we maintain our competency through the following,” and cite specific examples of documents that were supplied already.

Question: What efforts have been made to coordinate with the Office of Environmental Information (OEI) QA staff to modify EPA requirements documents, specifically documents EPA QA-R/2 and EPA QA-R/5, to provide specific criteria for grantees to meet to ensure that they comply with the competency requirements?

Answer: No efforts have been made to date to modify specific documentation items, but consideration will be given to doing so in the future.

Question: The QA requirements are mandated by the applicable portions of the Code of Federal Regulations (CFR), but the organizational competency policy is an EPA-wide policy. Has consideration been given to defining the organizational competency requirements in the CFR rather than only as an internal EPA policy?

Answer: Announcements were placed in the *Federal Register* to increase awareness of the policy and its posting on external websites to facilitate access. No further thought has been given to publishing the policy in the *Federal Register*.

Question: In the future, how will the adequacy of these competency statements be evaluated, and who will be the ultimate arbiter?

Answer: The Forum on Environmental Measurements (FEM) is developing a way to better interact with its customers and clients across the Agency to ascertain successful/unsuccessful aspects of the policy implementation, the effectiveness of communications and evaluation tools, and so forth. A survey has proven to be an effective evaluation tool. The intent is to revisit the policy during the coming years to determine how well it is working. Interactions and feedback (e.g., through future webinars) will be vital in this process so that policy users can share their experiences. EPA looks forward to receiving ideas and creating helpful tools and templates based on user feedback.

Question: Does a PO receiving certification of competency from states and tribes need to consult with EPA regional office QA staff to validate the information provided, or is the information that the grantee submits acceptable?

Answer: EPA has encouraged POs who do not have an extensive QA background to work with their QA officers and to contact them any time they have a question about the information they have received. Such interaction is very much encouraged as needed.

Question: Although there is a need for flexibility, the wide range of ways that grantees can demonstrate their competency might make it difficult for POs across the Agency to apply this standard

consistently for similar projects. Are there plans to provide more program-specific guidance about the implementation of this policy?

Answer: The EPA will share any information that it receives. Some communities have discussed creating templates for use within their regional or program offices but have not shared it with EPA. EPA will share any such material that comes to its attention. Lara Phelps (OSA) also is willing to work with any programs that want to create more specific tools and templates and to share those materials either through the Intranet site or on the Internet site if the material is more broadly applicable.

Question: Questioning state competency could jeopardize the working partnerships that EPA has been establishing with states in recent years. What materials (e.g., templates, guidelines for statements of competency) are available for state partners to facilitate communication and help provide nationwide consistency?

Answer: This concern has prompted the capture and sharing of information (obtained, for example, through the webinar series) through the FEM website. Again, Ms. Phelps is willing to help groups create additional materials upon request. She had received no such requests to date.

Question: What can be done to foster consistency, which is particularly important when working with states?

Answer: States do communicate with one another, and inconsistencies can become problematic. If contacted by a state, Ms. Phelps refers the state personnel to their regional EPA representatives. She is willing to become involved in such discussions if asked to do so. If there is interest in establishing a group to develop specific tools/templates to help ensure consistency, Ms. Phelps is willing to facilitate the formation of such a group, to begin meeting in early 2014.

Question: It would be useful to have information about outreach to states. Could EPA issue a list of the states (and the specific programs) that have participated in previous competency policy webinars?

Answer: All states, except perhaps Hawaii, have participated in previous calls and/or webinars.

Question: In situations in which state, private or tribal laboratories have been decertified but still are receiving cooperative agreement funding through their grants, assigning the responsibility of enforcing this policy to EPA regional office personnel can create significant difficulties because the QMP or QAPP still might indicate that the laboratory is competent. It would be preferable to shift the responsibility to the states to certify their own laboratories and to inform their EPA representatives of how they are ensuring laboratory competency so that the information can be included in EPA's files. Specifying minimum requirements for ensuring competency would be helpful in such situations.

Answer: If the grant award is with the state itself and not directly with the laboratory, then the state is responsible for ensuring the competency of its subawardees. Creating a template that could be integrated into state grants could be helpful in these situations. Ms. Phelps is willing to work

with groups to explore this possibility and to bring it to the attention of higher management levels at EPA if needed. It also has been suggested that personnel from different regional offices be brought together to discuss how they address these kinds of situations to promote consistency across regional offices.

Question: It has been said that the policy requires documentation of competency but that QA staff are not required to evaluate that competency. What is the distinction between these two concepts? It seems that we accept the documentation provided at face value and that the burden is on the grantee to meet the conditions, but there is no follow up to ensure competency.

Answer: The policy is intended to provide justification for considering the documentation of competency that is provided as inadequate if appropriate. It has been suggested that the demonstration of competency should: come from an outside organization and that contact information for that organization be provided, be integrated into the terms and conditions of grants, and be provided on some regular basis as part of the routine reporting that is required.

In addition, language can be added to stipulate that if an entity becomes decertified or if any changes are made to its certification, it is required to notify EPA in writing of those changes or of that decertification. If a grantee is not complying with the terms and conditions and has not been demonstrating the competency to perform the work, then that grantee should not be paid for the work.

Question: If an EPA regional office is behind schedule with certifying and/or auditing state drinking water laboratories, and this is part of the competency assessment for the state to obtain a grant, how should this be documented, and what impact does it have on the competency determination?

Answer: This can be a challenging situation, but the laboratories should be prepared to supply the competency documentation information in the interim upon request.