EPA REGION III BROWNFIELDS QUALITY ASSURANCE PROJECT PLAN TEMPLATE ADDENDUM April 28, 2016

The following guidance is an addendum to **EPA Region III's *Brownfield's Quality Assurance Project Plan Template,* Interim Final, March 2001**.

Region III recently discovered that Section A3 in the above guidance document/template was unclear and may be a contributing factor in the development of inadequate Quality Assurance Project Plans (QAPPs). Section D2 refers to a Data Validation procedure that has been updated to better reflect the procedures used across the Agency. Region III seeks to clarify these two sections with the information below.

Furthermore, in order to comply with the Agency's policy on environmental measurement competency, Documents about Measurement Competency Under Assistance Agreements at https://www.epa.gov/measurements/documents-about-measurement-competency-under-assistance-agreements, an additional section entitled **A4 ASSURING COMPETENCY FOR ENVIRONMENTAL DATA MEASUREMENT** shall be included. This section shall discuss the organization's procedures and processes for documenting competency of personnel prior to beginning any work involving the generation or use of environmental data. This includes the performance of environmental sampling, field measurements, and/or laboratory. Guidance on how to accomplish this is also described below.

Please disregard the information provided in the existing Sections A3 and D2 of the March 2001 version of the Brownfields QAPP Template cited above. Please use the guidance below for developing Data Quality Objectives (Section A3); documenting environmental data measurement competency (Section A4) and performing Data Validation (Section D2). All other sections in the template/guidance are still valid.

A3 QUALITY OBJECTIVES AND CRITERIA FOR MEASUREMENT DATA

The DQO Process is used to establish performance or acceptance criteria, which serve as the basis for designing a plan for collecting data of sufficient quality and quantity to support the goals of a study. The DQO Process consists of seven iterative steps that are documented below. The nature of the DQO Process allows one or more of these steps to be revisited as more information on the problem is obtained.

Each step of the DQO Process defines criteria that will be used to establish the final data collection design. The first five steps are primarily focused on identifying qualitative criteria, such as:

- the nature of the problem that has initiated the study and a conceptual model of the environmental hazard to be investigated;
- the decisions or estimates that need to be made and the order of priority for resolving them;
- the type of data needed; and
- an analytic approach or decision rule that defines the logic for how the data will be used to draw conclusions from the study findings.

The sixth step establishes acceptable quantitative criteria on the quality and quantity of the data to be collected, relative to the ultimate use of the data. These criteria are known as performance or acceptance criteria, or DQOs. For decision problems, the DQOs are typically expressed as tolerable limits on the probability or chance (risk) of the collected data leading you to making an erroneous decision. For estimation problems, the DQOs are typically expressed in terms of acceptable uncertainty (e.g., width of an uncertainty band or interval) associated with a point estimate at a desired level of statistical confidence.

In the seventh step of the DQO Process, a data collection design is developed that will generate data meeting the quantitative and qualitative criteria specified at the end of Step 6. A data collection design specifies the type, number, location, and physical quantity of samples and data, as well as the QA and QC activities that will ensure that sampling design and measurement errors are managed sufficiently to meet the performance or acceptance criteria specified in the DQOs. The outputs of the DQO Process are used to develop a QA Project Plan and for performing Data Quality Assessment.

The DQO Process may be applied to all programs involving the collection of environmental data and apply to programs with objectives that cover decision making, estimation, and modeling in support of research studies, monitoring programs, regulation development, and compliance support activities. When the goal of the study is to support decision making, the DQO Process applies systematic planning and statistical hypothesis testing methodology to decide between alternatives. When the goal of the study is to support estimation, modeling, or research, the DQO Process develops an analytic approach and data collection strategy that is effective and efficient.

Summary of the DQO Seven Steps:

Step 1. State the Problem. Define the problem that necessitates the study; identify the planning team, examine budget, schedule.

Step 2. Identify the Goal of the Study. State how environmental data will be used in meeting objectives and solving the problem, identify study questions, define alternative outcomes.

Step 3. Identify Information Inputs. Identify data & information needed to answer study questions.

Step 4. Define the Boundaries of the Study Specify the target population & characteristics of interest, define spatial & temporal limits, scale of inference.

Step 5. Develop the Analytic Approach. Define the parameter of interest, specify the type of inference, and develop the logic for drawing conclusions from findings. Decision making (hypothesis testing), estimation and other analytic approaches**.**

Step 6. Specify Performance or Acceptance Criteria
Specify probability limits for false rejection and false acceptance decision errors. Develop performance criteria for new data being collected or acceptable criteria for existing data being considered for use.

Step 7. Develop the Plan for Obtaining Data Select the resource-effective sampling and analysis plan that meets the performance criteria.

The DQO Process is flexible to meet the needs of any study, regardless of its size. Reflecting the common-sense approach to systematic planning, the depth and detail to which the DQO Process will be executed is dependent on the study objectives. For example, on a study having multiple phases, the DQO Process will allow the planning team to clearly separate and delineate data requirements for each phase.

PROCESS EXAMPLE FOR DETERMINING DQO'S

Data Quality Objectives (DQO) are further defined and illustrated in EPA's *Guidance on Systematic Planning using the Data Quality Objectives Process,* (**QA/G-4**), EPA/240/B-06/001 February 2006. The seven step process outlined above, as taken from the QA/G-4, document should be followed. Particular emphasis needs to be placed on the decision threshold, which will determine the applicability of the proposed analytical methods and their ability to achieve the necessary sensitivity for this sampling event. As part of the DQO process the sampling event should have its sampling goals clearly delineated. Examples of sampling goals, include but are not limited, to:

- ascertain whether there is a threat to public health or the environment.
- locate and identify potential sources of contamination. Sampling data will be used to formulate remediation strategies, and estimate remediation costs.
- determine treatment and disposal options. Characterize soil for on-site or off-site treatment.
- verify attainment of clean-up goals. Ascertain if additional remediation is required.

The order and sequence for organizing the project is based on the DQOs. To determine the project specific analytical method(s):

a. Set the decision threshold, based on the sampling goal, for each analyte in the event. Usually this is driven by the appropriate toxicological levels, Preliminary Remediation Goals (PRGs), Screening Levels or Maximum Contaminant Levels (MCLs) or whatever limit is best suited for your project, matrix and analyte of concern.

b. Determine what analytical method, including the extraction and cleanup methods which will work in the matrix of interest to the level of interest to meet the requirements for the decision thresholds as developed in step a. Whenever possible, the level of reporting should be 10x below the decision level.

c. Determine the accuracy and precision needed for your project. Typical values range around ±20%. Establish those values to support the analytical method chosen. These are the Data Quality Indicators (DQI), also known as PARCC (precision, accuracy, representativeness, completeness, and comparability). Data Quality Objectives are typically assessed by evaluating PARCC of all aspects of the data collection process (field and laboratory). PARCC is defined as:

- Precision is a measure of the reproducibility of analyses under a given set of conditions.
- Accuracy is a measure of the bias that exists in a measurement system.
- Representativeness is the degree sampling data accurately and precisely depict selected characteristics.
- Completeness is the measure of the amount of valid data obtained from a measurement system compared to the amount that was expected to be obtained under "normal" conditions.
- Comparability is the degree of confidence with which one data set can be compared to another.

This information is most easily compiled into a table, such as:

Analyte	CAS #	Extraction method	Analysis method	Reporting level	Matrix
PCB		5035	8081A	0.02mg/Kg	Fish Tissue (filet)
1,1,1-Tri	5361	5030	524.0	0.02 µg/L	Water

Upon completion of the above steps, the analyte of interest will be determined at the level of interest in the matrix of interest. In other words, the number of samples and locations, containers, preservatives, holding times, etc. should be determinable from the data above. This is the starting point for selecting a competent laboratory to do the work.

The above outline illustrates that the DQI (or PARCC) are established by the DQO requirements of the project; the laboratory is then required to meet those DQI. To assess if environmental monitoring measurements are of an appropriate quality, the general PARCC requirements found in Section D3, of EPA Region III's *Brownfield's Quality Assurance Project Plan Template*, Interim Final, March 2001 document, should be compared to the site-specific Data Quality Objectives.

When this process has been completed it should lead to decision thresholds with resulting actions which can be described in "If...Then" statements. For example, *If the concentration is found to be below the decision threshold of x, then, no further action is expected at the site*. Following the above steps should lead to the information that must be recorded in the QAPP before sampling begins.

A4 ASSURING COMPETENCY FOR ENVIRONMENTAL DATA MEASUREMENT

To comply with Agency Policy Directive Number FEM-2012-02, *Policy to Assure the Competency of Organizations Generating Environmental Measurement Data under Agency-Funded Assistance Agreements* effective 10/01/2013, the following will be considered acceptable as adequately

demonstrating competency and meeting the requirements of this Policy for assistance agreements which include the generation and/or use of environmental data and exceed a total of $200,000 in federal funds.

Documentation required to demonstrate competency can include, but not be limited to, any of the options or combination of options listed below:

For personnel:

- A description of any training program for staff collecting samples or field measurements that includes a review of relevant procedures and methods, a commitment from staff to comply with said procedures and methods, on-the-job field training, and documentation of successful completion of that training. How successful completion of the training will be documented, who will be responsible for ensuring completion of the training, and how it will be ensured personnel competency is maintained needs to be included.
- A description of the processes in place for the hiring of personnel relevant to the project and how it will be ensured that relevant personnel are in place prior to environmental data activities.
- A description of any formal personnel certifications and/or accreditations, proficiency testing (PT), or other EPA accepted audits/assessments of proficiency demonstration relevant to the project including the source(s) of such personnel proficiency demonstration, how this is documented, and how it will be ensured the proficiency demonstration is maintained.

For laboratories:

- A description of any formal laboratory certifications and/or accreditations, PT testing, or other EPA accepted audits/assessments of proficiency demonstration relevant to the project including the source(s) of such laboratory proficiency demonstration, how this is documented, and how it will be ensured the proficiency demonstration is maintained.
- A description of the processes in place for the selection of a laboratory to perform environmental data activities relevant to the project and what quality system documentation is required, such as laboratory quality manuals or Quality Management Plans (QMPs) that describe the organization's quality practices and detailed standard operating procedures, and who will be responsible for ensuring such quality system requirements and documentation are in place.

For pass-through funds to sub-recipients and/or sub-contractors, the State will have the burden of proof and responsibility for meeting the demonstration of competency in compliance with the Policy. At any time, the EPA Project Officer may request that a copy of the competency documentation described above be submitted.

D2 DATA VALIDATION

To ensure that measurement data generated when performing this Brownfields investigation are of an appropriate quality, all data will be validated. Data validation is a systematic procedure of reviewing a body of data against a set of established criteria to provide a specified level of assurance of its validity prior to its intended use. It requires that the techniques utilized are

applied to the body of the data in a systematic and uniform manner. The process of data validation must be close to the origin of the data, independent of the data production, and objective in its approach.

All data from this project will be validated in accordance with EPA National Functional Guidelines for Inorganic and Organic Superfund Data Review, August 2014, available at Contract Laboratory Program National Functional Guidelines for Data Review at http://www.epa.gov/clp/contract-laboratory-program-national-functional-guidelines-data-review.