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Guidance on Satisfying EPA Quality Requirements for STAR Grants

NCER G-1 STAR

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FOREWORD

The Environmental Protection Agency's National Center for Environmental Research's Science to Achieve Results or STAR program funds research grants and graduate fellowships in numerous environmental science and engineering disciplines through a competitive solicitation process and independent peer review. The program engages the nation's best scientists and engineers in targeted research that complements EPA's own outstanding intramural research program and those of our partners in other federal agencies. In addition, through this same competitive process, NCER periodically establishes large research centers in specific areas of national concern. The most recent information about STAR programs, including grant opportunity announcements, can be found on the NCER web site:

http://www.epa.gov/ncer

This document assists potential applicants and grantees in meeting the EPA's quality requirements for the Science to Achieve Results (STAR) Program, both before and after award. It provides information for you, the applicant, in documenting the quality assurance approach to be used in the proposal and after award when the award document requires more detailed information is needed. Quality assurance documentation for the STAR Program includes Quality Assurance Statements (Section 2), Quality Assurance Project Plans (Section 3), and Quality Management Plans (Section 4).

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Guidance on Satisfying EPA Quality Requirements for STAR Grants

1. BACKGROUND

1.1 Why is Quality Assurance Necessary for Research Grants?

Quality assurance (QA) and quality control (QC)[1] practices provide prudent safeguards against the occurrence of problems and the introduction of error into the data produced which could adversely impact the results and the conclusions made from them. EPA believes that as a potential grant applicant considers the approaches to be taken to successfully complete the research project and obtain documented quality data, the applicant should also identify and document the activities that will ensure that the product of the research is of adequate quality to be used as planned. Such documentation is beneficial when a grant application is peer reviewed or a manuscript is submitted for publication. Documents demonstrating that the data meet applicable and appropriate quality standards or criteria are critical and are positively received by many reviewers.

A well-written quality plan may also help detect problems or incorrect assumptions before work begins and, thus, avoid false starts or generation of questionable or unusable data sets. Results of a well-designed experiment can be invalidated by simple things such as misunderstanding verbal directions that could have been included in standard operating procedures (SOPs) or research protocols.[2] Similarly, an improperly calibrated sensor, such as a pH electrode, can result in data gathered at great expense of time and money being unusable by the researchers. Finally, many research projects are so novel that the chances of failure are higher than for other types of research. Developing a framework for the early detection of errors and for the documentation of the steps in the experiment will help to assure the reproducibility of the research and lead to successful completion of the project with data of known quality.

The EPA believes strongly in the application of QA and QC principles to all types of environmental studies. In science and engineering research studies, products may range from a clear-cut identification of a fundamental photochemical reaction mechanism (which may lead to a better understanding of ozone formation) to a realistic assessment of the efficiency and longevity of a novel catalytic converter for reducing automobile tailpipe emissions. To ensure that such products are of sufficient and adequate quality for their intended use, the application of QA and QC is both prudent and necessary regardless of the level of complexity of the work.

[1] EPA Order 5360.1 defines *Quality assurance (QA)* is an integrated system of management activities involving planning, implementation, documentation, assessment, reporting, and quality involvement to ensure that a process, item, or service is of the type and quality needed and expected by the customer and *Quality control (QC)* is the overall system of technical activities that measures the attributes and performance of a process, item, or service against defined standards to verify that they meet the stated requirements established by the customer; the operational techniques and activities used to fulfill quality requirements.

[2] In this context, SOPs are defined as *written* and officially approved documents that detail the preferred method for performing an operation such as sample collection, analysis, equipment use or other routine tasks with thoroughly prescribed techniques and steps to ensure consistency. Research protocols are written directions that describe the plan of a scientific experiment such as the experimental design and data collection activities, and they may be adapted or modified as the experiment progresses or when an experiment is added to the project.

Accordingly, EPA has established quality requirements that must be followed within EPA and by extramural contractors and financial assistance recipients for all work performed that involves environmental data collection, use or reporting (including both primary and secondary data).

1.2 What are EPA's Quality Assurance Requirements for Research Grants?

EPA assistance agreement recipients that conduct environmental programs must implement or have implemented a quality program that conforms to the American National Standard ANSI/ASQC E4-1994, *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs* (ASQ, 1994). This requirement is defined in 40 *Code of Federal Regulations (CFR)* Part 30, *Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations*, as applied to the STAR program (Parts 30.45 and 30.54). Any awards made to State, Tribal, or local governments would be covered by quality requirements defined in 40 CFR Part 31, *Uniform Administrative Requirements for Grants and Cooperative Agreement to State, Tribal, and Local Governments*.

EPA's quality requirements apply to projects that include:

- data collection or processing, including the use of secondary data;
- conducting surveys;
- making environmental measurements;
- describing processes or conditions;
- describing ecological or health effect and consequences
- creating or modifying models; and
- developing environmental technology (whether hardware-based or via new techniques and methods) for pollution control and waste treatment.

Customarily, the EPA requirements for extramural agreements include:

1. documentation of the organization's quality program (usually in a Quality Management Plan) and

2. documentation of quality assurance and quality control activities to specific efforts (usually in a QA Project Plan).

The level of detail needed to document quality practices depends on the type of work and the intended use of the results. For more information on EPA's quality program, see http://www.epa.gov/quality.

1.3 What are EPA's Quality Assurance Requirements for STAR Research Grants?

Research is often conducted simply to develop information rather than to be used in decision making, with peer-reviewed publications as a result. As a result, the STAR program has tailored the customary EPA quality documentation to allow more flexibility. Potential quality documentation for STAR research grant application includes:

- QA Statement (Section 2): A brief description of the QA and QC activities for a specific project and identifies the individual responsible for ensuring these activities are performed. A QA Statement is typically requested for **all** STAR grant applications (usually in the RFA), and is usually provided by the applicant as part of the proposal. This documentation usually satisfies EPA requirements (1) and (2) in Section 1.2.

- QA Project Plan (Section 3): A detailed description of the QA and QC activities for a specific project. After an award decision is made, a QA Project Plan **may be requested as part of the terms and conditions of an award** to supplement the QA Statement. This documentation satisfies EPA requirement (2) in Section 1.2.

- Quality Management Plan (Section 4): A description of an organization's quality program. A Quality Management Plan **will be requested as part of the terms and conditions of awards** for Research Centers or for STAR grants that are extremely large or have direct regulatory impacts. This documentation satisfies EPA requirement (1) in Section 1.2. Research Centers then develop their own procedures for the development, review, and approval of documentation to satisfy EPA requirement (2) in Section 1.2.

The purpose of these documents is to provide information to the EPA Project Officer, Quality Assurance Manager, peer reviewers, and award officials on an applicant's capabilities to provide minimum required quality assurance and quality control for the proposed work. These documents should demonstrate that QC procedures are in place to ensure that each project is successfully completed and the objective is achieved. Assistance recipients are encouraged to create written standard operating procedures (SOPs) and protocols, and reference them in these documents.

2. QUALITY ASSURANCE STATEMENT

A Quality Assurance Statement (QAS) is a brief description of the quality assurance and quality control practices that will be applied during a research project to assure that the results obtained satisfy the project objectives. The majority of the Requests for Applications require that the grant applicant provide this statement as part of the proposal. The QAS usually does not exceed three pages and should either include the requested information, reference (by page and paragraph number) the specific relevant portion of the research plan containing the information, or provide a clear logical justification as to why the item does not apply to the proposed research.

The elements of a QA Statement are:

Quality Assurance Statement (1 to 3 pages in addition to the 15-page research plan)
For projects involving environmental data collection or processing, conducting surveys, modeling, method development, or the development of environmental technology (whether hardware-based or via new techniques), provide a Quality Assurance Statement (QAS) regarding the plans for processes that will be used to ensure that the products of the research satisfy the intended project objectives. Follow the guidelines provided below to ensure that the QAS describes a system that complies with ANSI/ASQC E4, *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs*. Do not exceed three consecutively numbered, 8.5x11-inch pages of single-spaced, standard 12-point type with 1-inch margins.

NOTE: If selected for award, applicants will be expected to provide additional quality assurance documentation if requested by the terms and conditions of the agreement.

Address each *applicable* section below by addressing the following points or referencing the specific location of the information in the Research Plan. **(Not all will apply.)**

(1) Identify the individual who will be responsible for the quality assurance (QA) and quality control (QC) aspects of the research along with a brief description of this person's functions, experience, and authority within the research organization. Describe the organization's general approach for conducting quality research. *(QA is a system of management activities to ensure that a process or item is of the type and quality needed for the project. QC is a system of activities that measures the attributes and performance of a process or item against the standards defined in the project documentation to verify that they meet those stated requirements.)*

(2) Discuss project objectives, including quality objectives, any hypotheses to be tested, and the quantitative and/or qualitative procedures that will be used to evaluate the success of the project. Include any plans for peer or other reviews of the study design or analytical methods.

(3) Address each of the following project elements as applicable:

(a) Collection of new/primary data:
*(**Note:** In this case the word "sample" is intended to mean any finite part of a statistical population whose properties are studied to gain information about the whole. If certain attributes listed below do not apply to the type of samples to be used in your research, simply explain why those attributes are not applicable.)*

(i) Discuss the plan for sample collection and analysis. As applicable, include sample type(s), frequency, locations, sample sizes, sampling procedures, and the criteria for determining acceptable data quality (e.g., precision, accuracy, representativeness, completeness, comparability, or data quality objectives).
(ii) Describe the procedures for the handling and custody of samples including sample collection, identification, preservation, transportation, and storage, and how the accuracy of test measurements will be verified.
(iii) Describe or reference each analytical method to be used, any QA or QC checks or procedures with the associated acceptance criteria, and any procedures that will be used in the calibration and performance evaluation of the analytical instrumentation.
(iv) Discuss the procedures for overall data reduction, analysis, and reporting. Include a description of all statistical methods to make inferences and conclusions, acceptable error rates and/or power, and any statistical software to be used.

(b) Use of existing/secondary data (i.e., data previously collected for other purposes or from other sources):

(i) Identify the types of secondary data needed to satisfy the project objectives. Specify requirements relating to the type of data, the age of data, geographical representation, temporal representation, and technological representation, as applicable.
(ii) Specify the source(s) of the secondary data discuss the rational for selection.
(iii) Establish a plan to identify the sources of the secondary data in all deliverables/products.
(iv) Specify quality requirements and discuss the appropriateness for their intended use. Accuracy, precision, representativeness, completeness, and comparability need to be addressed, if applicable.
(v) Describe the procedures for determining the quality of the secondary data.
(vi) Describe the plan for data management/integrity.

(c) Method development:
*(**Note:** The data collected for use in method development or evaluation should be described in the QAS as per the guidance in section 3A and/or 3B above.)*

Describe the scope and application of the method, any tests (and measurements) to be conducted to support the method development, the type of instrumentation that will be used and any required instrument conditions (e.g., calibration frequency), planned QC checks and associated criteria (e.g., spikes, replicates, blanks), and tests to verify

the method's performance.

(d) Development or refinement of models:

*(**Note:** The data collected for use in the development or refinement of models should be described in the QAS as per the guidance in section 3A and/or 3B above.)*

(i) Discuss the scope and purpose of the model, key assumptions to be made during development/refinement, requirements for code development, and how the model will be documented.
(ii) Discuss verification techniques to ensure the source code implements the model correctly.
(iii) Discuss validation techniques to determine that the model (assumptions and algorithms) captures the essential phenomena with adequate fidelity.
(iv) Discuss plans for long-term maintenance of the model and associated data.

(e) Development or operation of environmental technology:

*(**Note:** The data collected for use in the development or evaluation of the technology should be described in the QAS as per the guidance in section 3A and/or 3B above.)*

(i) Describe the overall purpose and anticipated impact of the technology.
(ii) Describe the technical and quality specifications of each technology component or process that is to be designed, fabricated, constructed, and/or operated.
(iii) Discuss the procedure to be used for documenting and controlling design changes.
(iv) Discuss the procedure to be used for documenting the acceptability of processes and components, and discuss how the technology will be benchmarked and its effectiveness determined.
(v) Discuss the documentation requirements for operating instructions/guides for maintenance and use of the system(s) and/or process(s).

(f) Conducting surveys:

*(**Note:** The data to be collected in the survey and any supporting data should be described in the QAS as per the guidance in section 3A and/or 3B above.)*

Discuss the justification for the size of the proposed sample for both the overall project and all subsamples for specific treatments or tests. Identify and explain the rational for the proposed statistical techniques (e.g., evaluation of statistical power).

4.) Discuss data management activities (e.g., record-keeping procedures, data-handling procedures, and the approach used for data storage and retrieval on electronic media). Include any required computer hardware and software and address any specific performance requirements for the hardware/software configuration used.

3. QUALITY ASSURANCE PROJECT PLAN

In some cases, the QA Statement may not contain sufficient quality assurance and quality control information for a particular application and EPA may require that a more comprehensive QA Project Plan be approved before you begin your research activities. The QA Project Plan typically may be required for studies producing large volumes of data, determined to be controversial by EPA, of a highly complex nature that may need more extensive documentation of the planning process, or be significant in terms of the impact of or funding for the work. In this case, a term and condition statement will be added to the award document which specifies that more documentation is necessary, and that work involving environmental data generation may not begin until the EPA Project Officer or Quality Assurance Manager provides you written notification that the quality assurance plan is approved.

The terms and condition statements in the agreement will indicate whether the QA Project Plan should be prepared in accordance with guidance that will be provided by the EPA Project Officer *or* in accordance with the full *EPA Requirements for Quality Assurance Project Plans* (EPA, 2001) (available at http://www.epa.gov/quality/qs-docs/r5-final.pdf) and EPA's *Guidance for Quality Assurance Project Plans* (EPA, 2002) (available at http://www.epa.gov/quality/qs-docs/g5-final.pdf).

The QA Project Plan should describe the QC and QA practices to be implemented by the applicant for the proposed project in sufficient detail to present a clear picture of what is to be done and when. Before writing your QA Project Plan, check with the EPA Project Officer to determine which elements are applicable for your grant. In addition to the examples and guidance found on NCER's website, additional information on QA Project Plans, including examples and answers to frequently asked questions, is contained at epa.gov/quality/qapps.html.

Although guidance for writing a QA Project Plan may be customized for a specific project by the EPA Project Officer and the NCER Quality Assurance Manager, the guidance that they will provide if indicated by the terms and conditions of the agreement is likely to resemble the following:

Quality Assurance Project Plans (QAPPs)
General Guidance for Writing and Reviewing QAPPs For EPA/NCER and the STAR Grant Program

General Information about QAPPs –
The purpose for writing a QAPP is to ensure that the activities associated with the collection, generation, use, and/or reporting of data will provide information suitable for answering a question or making a decision, such as:

- a hypothesis is correct, or not;
- a method works, or not;
- a new technology is beneficial, and it is "this much" better than the old standard;
- this model can tell us "XYZ", but with these limitations.

Basically, state what you are going to do, how you are going to do it, and how you will know that you have done it "right". In the QAPP, *you* will define what "right" is for *your* research. For example, when you provide specific criteria for some measure of accuracy, then also explain the reasons for needing that level of accuracy (or inaccuracy, as the case may be). The goal is to be specific enough about how you will conduct the research that it could be reproduced by another team of researchers with reasonably similar results. Assume that the reader has already read your proposal, and refer to specific sections of it as necessary.

The QAPP must cover all areas / phases of your research, so ensure that the plan is complete. If necessary, break it into logical sections for different activities. If the details of later phases depend on information gleaned in the early ones, provide the information you have now, and provide your EPA PO with an addendum with the remaining information at a later date. However, all research activities must be covered under a QAPP approved by your EPA PO before you can begin working on those activities. So ensure timely submission of your plans for the next phase. Failure to obtain EPA approval on the requisite documentation in a timely manner may result in a freeze on your funding.

QAPPs must be written in active language indicating exactly what will be done during the course of the project and not in terms of "may", "should", or "could" as might have been done during the proposal stage of the research. Now that the research has been funded, write in concrete terms of what will be done with the money. The QAPP must be significantly more detailed than the Quality Assurance Statement that was submitted with the proposal. There is no page limit; but short, to the point, yet complete is preferred.

This summary guidance provides information on the general content to be provided in QAPPs, but **it is not a requirement to follow the format described below**. It is far more important to cover all of the required details in a format that makes sense for the type of research project in question. The EPA QA/R-5 document (referenced below) provides a generally accepted, formalized structure that many people are already familiar with and may wish to use.

This information is a short summary of EPA's "Guidance for Quality Assurance Project Plans (EPA QA/G-5)" (http://www.epa.gov/quality/qs-docs/g5-final.pdf) and "EPA Requirements for Quality Assurance Project Plans (EPA QA/R-5)" (http://www.epa.gov/quality/qs-docs/r5-final.pdf). If necessary, additional details can be found within these online documents.

The first part of this guide present general guidance that would be applicable to almost any type of research. Then the following section covers additional issues that are specific to certain types of data and/or specific types of research (e.g. modeling, technology development, analytical method development, surveys, etc.). One or more of the issues discussed may apply to any given project, but it is not necessary to read the ones that obviously do not apply.

Parts of a QAPP are:

Background/purpose: Lay out the question to be answered and/or decision to be made.

Experimental Design: Describe what will be done.

Data Gathering Methods: Connect what will be done with how it will be done.

Data Quality: Show how we can be sure it will be done well enough (acceptance criteria).

Data Reduction: Discuss the procedures that will make the data meaningful.

Interaction of the Players: Show the responsibilities of each organization / researcher.

Each of these segments is discussed on the following pages.

NOTE: ***It is not necessary to repeat information that is in the Research Plan (RP) that was submitted with the proposal. Simply make reference to pages in the RP as necessary.***

Background/Purpose - Lay out the question to be answered and/or decision to be made.

- State explicitly the *question to be answered and/or the decision to be made*. (This must be clear if we are to evaluate the usefulness of methodologies.) Indicate the reasons why this research is important.

- Describe *how the research group will obtain the data necessary to provide the information needed* to answer the question or make the decision, so that the Project objectives are connected with the Data objectives. (i.e., how will the methods be used to get you the data you need?) Show what general kind of information is needed (e.g. sampling, monitoring, analysis, compilation of secondary data, etc.)

Design - Describe what will be done.

- Provide a summary of *all* technical work to be performed and/or products to be produced.

- Describe the connections between your stated purpose and what will be done to successfully achieve it. [*AND* define the criteria for "success" for the research].

- Describe the scheme for different types of data collection (or compilation) activities to be used (include conditions and assumptions). Explain the reasons for designing the project in such a way, and **provide explanation for any quality control (QC) criteria you set in this section.**

- Show how this scheme will produce the group of results needed to answer the question, etc. from above. (This is essentially the Data Quality Objectives (DQO) Process, which is a QA system name for a set of steps that mirror the scientific method. The bigger the project, the more important it is to utilize true DQOs in developing the QAPP. For additional information see http://www.epa.gov/quality/qs-docs/g4-final.pdf.)

Data Gathering Methods - Connect what will be done with how it will be done.
(Includes analytical work, secondary data, meta-data, surveys, modeling efforts, etc.)

- Describe what specific types of data need to be gathered, how they will be gathered or produced, and how each one connects with and/or supports the stated purpose and criteria for success of the research.

- Describe the specific methods and equipment to be used. If established methods are to be used cite them and attach copies if they are not readily available. (Use of tables may be helpful.)

- Include operating procedures for major analytical work and/or unique research procedures, and provide a table listing all other repetitive operating procedures that are followed in the process of the research. (It is important to show that the research is repeatable.)

Data Quality - Show how we can be sure it will be done well enough (acceptance criteria).

- **Data quality encompasses both Quality Control (QC) and Quality Assurance (QA) practices.** QC is the system of technical activities used in data gathering activities/methods to ensure the quality of each individual data point (as applicable: precision, accuracy, representativeness, completeness, & comparability); and Quality Assurance (QA) is the overall program that includes planning, QC, documentation, and Assessments or audits.

- List the QC, QA, and Assessment activities that will be part of the project, to show how the required data quality will be achieved. (What will the numbers represent and what will we do with them?)

- Explain the reasons for the research design, and provide explanation for any quality control (QC) criteria you set in this section.

- *For each activity*, state appropriate acceptance limits/criteria. Include all QC parameters for each type of laboratory analysis, secondary data sources, model validation, statistical procedures, etc. Indicate how each will be documented and what corrective actions will be taken if QC criteria are not met. (Again, use of tables may be helpful.)

- *For each QC parameter* (Precision, Accuracy, Representativeness, Completeness, Comparability), state the how conformance with the stated limits will be determined, and *the consequences of failure* --such as for precision, what is the acceptable range, how will it be determined (average of 3 lab duplicates prior to the start, etc.), if fail, recalibrate and repeat until satisfactory, etc. Who makes the decisions if some parameters fail?

- *For each assessment type* (field audit, lab audit, data quality assessment, etc.), state the type and acceptance level, if any, and the consequences of failure.

- Of all of the data quality parameters (Precision, Accuracy, Representativeness, Completeness, Comparability), *the most important is Representativeness*. Describe the representativeness of the sample(s) in the plan. How is the statistical network designed? (If the research does not use representative data, it doesn't matter how good it is, or how good the use of it is. This is the main connection between the science and the politics: making sure that the right samples will be collected to validly address the issue at hand.)

Description of Data Reduction Methods and Procedures - Discuss the procedures that will make the data meaningful.

- Describe all data reduction methods and procedures.

- Identify the specific descriptive statistical methods (for example, regression analyses, analysis of variance, or multivariate analyses) that will be used to present results. Discuss how raw and processed data that are used in statistical analyses will be verified after statistical analyses have been completed. Also include a complete citation of software programs that will be used for these statistical analyses and to present results.

- When using secondary data, include a discussion of the quality of these data and how the data will be transferred into computer files for various analyses and how they are verified through these processes. Discuss how the quality of these secondary data affect the results being reported. Indicate that a complete citation of these data sources will be complied during data collection so that these data can be reviewed later if necessary.

- Discuss how original or raw data measurements will be verified after they have been transferred from instrument data recording devices and/or floppy diskettes or laboratory notebooks and processed by computer or manually.

Interaction of the Players - Show the responsibilities of each organization / researcher.

- Need clear *organizational charts* for the project, showing who is responsible for what, and who reports to whom. This must include *every organization* involved in the project: management, project management including co-PIs, field groups, lab workers, QA, contractors, consultants. Indicate how each party will interact to achieve the end result.

- Plan must include statements of who has the authority to change it or the operating procedures.

- It should be *signed* by a representative of each organization *to confirm their involvement*, understanding, and acceptance of the stated roles, responsibilities, and authorities. (A common flaw is that one group writes and signs the Plan and sends it to EPA without the concurrence of all parties.)

Special Topics:

GIS/Remote Sensing data: Discuss how the following elements will be addressed: positional accuracy; attribute accuracy; logical consistency; time; lineage; resolution accuracy; and the completeness of coverage, classification, and verification.

Conducting surveys: Discuss the justification for the size of the proposed sample for both the overall project and all subsamples for specific treatments or tests. Identify and explain the rational for the proposed statistical techniques (e.g., evaluation of statistical power).

Development or refinement of models:

(i) Discuss the scope and purpose of the model, key assumptions to be made during development/refinement, requirements for code development, and how the model will be documented.
(ii) Discuss verification techniques to ensure the source code implements the model correctly.
(iii) Discuss validation techniques to determine that the model (assumptions and algorithms) captures the essential phenomena with adequate fidelity.
(iv) Discuss plans for long-term maintenance of the model and associated data.

Development or operation of environmental technology:

(i) Describe the overall purpose and anticipated impact of the technology.
(ii) Describe the technical and quality specifications of each technology component or process that is to be designed, fabricated, constructed, and/or operated.
(iii) Discuss the procedure to be used for documenting and controlling design changes.
(iv) Discuss the procedure to be used for documenting the acceptability of processes and components, and discuss how the technology will be benchmarked and its effectiveness determined.
(v) Discuss the documentation requirements for operating instructions/guides for maintenance and use of the system(s) and/or process(s).

Secondary Data Collection:

(Secondary data is data that will be used for purposes other than those for which they were originally collected. They may be obtained from many sources, including literature, industry surveys, compilations from computerized databases and information systems, and computerized or mathematical models of environmental processes. This includes purchased data sets, too.)

(i) Identify the types of secondary data needed to satisfy the project objectives. Specify requirements relating to the type of data, the age of data, geographical representation, temporal representation, and technological representation, as applicable.
(ii) Specify the source(s) of the secondary data discuss the rational for selection.
(iii) Establish a plan to identify the sources of the secondary data in all deliverables/products.
(iv) Specify quality requirements and discuss the appropriateness for their intended use. Accuracy, precision, representativeness, completeness, and comparability need to be addressed, if applicable.
(v) Describe the procedures for determining the quality of the secondary data.
(vi) If no quality documentation exists or if the quality of the secondary data will not be evaluated under the grant, the QAPP shall require that a disclaimer be added to all deliverables/products (including models and other decision support tools). The wording for the disclaimers shall be defined. (Use of disclaimers must receive prior approval from the EPA Project Officer.)
(vii) Describe all data reduction procedures including calculations, equations, scripts, and statistical analysis. At some point, relate these back to satisfying the project objectives.
(viii) Include a plan for data management / integrity.

4. QUALITY MANAGEMENT PLAN

Quality Management Plans (QMPs) are typically required for Research Centers and other grants with multiple distinct projects. A QMP is a document that describes an organization/program's quality system in terms of the organizational structure, policy and procedures, functional responsibilities of management and staff, lines of authority, and required interfaces for those planning, implementing, documenting, and assessing all activities conducted across multiple projects. [*This is in contrast to project-specific documentation, such as a Quality Assurance Project Plan (QAPP), that describes the necessary QA, QC, and other technical activities that must be implemented to ensure that the results of the work performed will satisfy the stated performance criteria.*] The elements of a QMP are described below. Your QMP must be signed and dated by senior manager, senior line management, and QA Manager. Additional information on QMPs, including examples and answers to frequently asked questions, is contained at epa.gov/quality/qmps.html[3].

(1) **Management and Organization:** State the organization's QA policy and how management assures that all programs and PIs understand and implement QA and QC activities. Identify all components of organization, the position of QA Manager, and the lines of reporting of the QA Manager. (This may be done through an organizational chart.) Discuss the authorities of the QA Manager and staff and demonstrate that the QA Manager is both qualified **and** independent of data collection or use activities. Discusses technical activities or programs that require quality management and where internal coordination of QA and QC activities among organizations or co-PIs is needed. **The Center QA Manager cannot be one of the co-PIs or research personnel for the projects covered by scope of the agreement.**

(2) **Quality System Components:** Describes principal quality components (e.g., quality program documentation, annual reviews, project-specific quality documentation) along with the responsibilities of management and staff for each component. The Center QMP *must* indicate the requirement for each project to develop a Quality Assurance Project Plan (QAPP) that is compliant with "EPA Requirements for Quality Assurance Project Plans (EPA QA/R-5)" *{http://www.epa.gov/quality/qs-docs/r5-final.pdf}*. Additional guidance for developing QAPPs can be found at http://www.epa.gov/quality/qs-docs/g5-final.pdf. The QMP *must* also state the following requirements: 1) any type of planned work with environmental data may not begin until the QAPP has been written and 2) the QAPP has been reviewed and approved for completeness and compliance with the R-5 document by the Center's QA Manager. The QMP must describe the process for submission, review, documentation of approval, revision control, distribution, and implementation of QAPPs.

[3]Note: The STAR program has tailored the Agency elements to meet the needs of this grant program. Therefore, all the information contained on this web page may not be applicable to your grant.

(3) **Qualifications and Training:** Describe the process for ensuring and documenting that personnel have necessary quality-related qualifications and training.

(4) **Procurement of Items and Services:** Describe the process for review and approval of extramural agreements (e.g., grants and contracts) and responses to solicitations to ensure that they satisfy all technical and quality requirements. Describe the process to ensure the quality or acceptability of Suppliers' products.

(5) **Documents and Records:** Describe the process for preparing, reviewing, approving, issuing, using, and revising documents and records. Describe the process for maintaining documents and records including retention, access, preservation, traceability, removal of obsolete documentation, and disposition.

(6) **Computer Hardware and Software:** Describe the process for developing, installing, testing, using, maintaining, controlling, and documenting computer hardware and software.

(7) **Planning (This element is particularly important for Research Centers):** Describe the process for developing, reviewing, approving, implementing and revising project-level QA and QC documentation. This documentation should include: project goals, objectives, and questions to be addressed; the project schedule, resources, and milestones; the type and quantity of data needed and how the data will be used to support the project's objectives; performance criteria for measuring quality; QA and QC activities to assess the performance criteria; and a description of how, when, and where the data will be obtained (including secondary/existing data) and identification of any constraints on data collection.

(8) **Implementation of Work Processes:** Describe the process for ensuring that work is performed according to planning and technical documents (e.g., project narrative, Standard Operating Procedures, etc.). Describe the process for identifying operations which need standard procedures for uniformity (e.g., SOPs) and the process for preparing, reviewing, approving, revising, and withdrawing these procedures.

(9) **Assessment, Response, and Improvement:** Describe the process for reviewing the organization's quality program, at least annually. Describe the process for planning, implementing and documenting assessments of QA/QC across projects, and how the findings of these assessments will be addressed by management. Describe the process for ensuring that conditions adverse to quality are identified and promptly corrected and/or prevented. The Center QA Manager/Officer must conduct Technical Systems Assessments (TSAs) on-site for each project during the first year research is being performed and at least every-other year thereafter. On the years in-between on-site TSAs, the QA Manager/Officer must go through the TSA checklist by conference call. TSA reports and completed checklists must be maintained as part of the Center's records. The QMP must also describe procedures for Data Quality Assessments and any other types of

assessments/audits to be conducted. EPA guidance on different types of assessments (including TSAs) can be found at: http://www.epa.gov/quality/qs-docs/g7-final.pdf.

5. REPORTS AND IMPLEMENTATION

While summaries of QA and QC results may be included as an appendix to the final report, specific QA and QC text descriptions are required by your grant's terms and conditions to be addressed as part of annual and final reports. We suggest you contact your sponsored programs/business office to obtain a copy of the terms and conditions, as they are legally binding on a recipient. In your reports, be sure to note your laboratory's QA and QC plans, assessment activities, and any calibration and verification services performed outside your research unit (for example, verification of a microbalance, calibration of a flow meter, or tuning of a spectrophotometer). Also, any secondary data used in the project must have a complete citation.

Following the grant award and approval of the QAS, QA Project Plan, and/or Quality Management Plan, (if required by the terms and conditions of the agreement) EPA expects that the elements of the applicable document will be implemented as part of the agreement. If you need to alter your approach as the research progresses to improve the integrity of the work or the validity of the results, these changes should be discussed in your annual and final reports.