United States Environmental Protection Agency
Office of Environmental Information
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Guidance on Satisfying EPA Quality System Requirements for STAR Grants

EPA QA/G-1STAR

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United States Environmental Protection Agency
Office of Environmental Information
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FOREWORD

This document, EPA QA/G-1STAR, is one of the U.S. Environmental Protection Agency's (EPA's) Quality System Series requirements and guidance documents. This document is designed both to summarize the quality assurance (QA) requirements and to provide guidance to an academic researcher (extramural grant applicant) preparing to submit a Science to Achieve Results (STAR) research grant application. This document guides the applicant through the concept and development of a Quality System and describes how that system can be documented through the required quality statement and the quality management project plan (QMPP), which may be required in some cases before an approved grant application is funded.

The Quality System Series documents describe EPA policies and procedures for planning, implementing, and assessing the effectiveness of the quality system. Requirements documents (identified as EPA QA/R-x) establish criteria and mandatory specifications for QA and quality control (QC) activities. Guidance documents (identified as EPA QA/G-x) provide suggestions and recommendations of a nonmandatory nature for using the various quality system components. This document, QA/G-1STAR, contains the governing policy for the STAR program. Information on other Quality System Series documents is provided for supplemental reference.

Questions regarding this document or other Quality System Series documents may be directed to:

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All requirements and guidance documents are available on the Quality Staff's World Wide Web (www) site at

http://www.epa.gov/quality

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ACRONYMS AND ABBREVIATIONS

ANSI	American National Standards Institute
ASQ	American Society for Quality [formerly American Society for Quality Control (ASQC)]
CFR	Code of Federal Regulations
NCER	National Center for Environmental Research
QA	quality assurance
QAS	quality assurance statement
QC	quality control
QMPP	quality management project plan
RFA	Request for Application
SOP	standard operating procedure
STAR	Science to Achieve Results (environmental research grants program)

Guidance on Satisfying EPA Quality System Requirements for STAR Grants

1 INTRODUCTION

1.1 BACKGROUND

The U.S. Environmental Protection Agency's National Center for Environmental Research (NCER) promotes and advances environmental science in the United States by competitively awarding grants for research focusing on reduction of risks to human health and ecosystems and on reduction of uncertainty associated with risk assessment. This is done through the Science To Achieve Results (STAR) program. The preponderance of the research supported by the STAR program is funded through financial assistance agreements awarded through competitive Requests for Applications (RFAs). These RFAs are developed from the Strategic Plan of EPA's Office of Research and Development (ORD) and from specific topical research plans developed by ORD. The RFAs are prepared in cooperation with other parts of the Agency and focus research on areas of particular importance to the Agency and/or on areas that complement the ORD intramural research programs and the programs of research partners in other Agencies. From time to time, NCER will also establish larger research centers and programs competitively in specific areas of national concern requiring long-term or multi-disciplinary approaches.

The most recent information about STAR programs, including grant opportunity announcements, can be found on the NCER web site:

http://www.epa.gov/ncer

1.2 PURPOSE OF THIS DOCUMENT

This document is intended to assist potential applicants and grantees in meeting the EPA quality requirements for the STAR Program. It provides information for you, the applicant, in documenting the quality assurance approach to be used in the proposal and additional information for grantees when the award document states that more detailed information is needed. Grants for larger, often multi-university, research programs and centers will require further and/or different detail than is included here, but directions on the required approach will be provided in the individual solicitations and in other EPA guidance documents.

This document is designed to provide the grant applicant with minimum required information on the concepts of quality assurance (QA) and quality control (QC) and their appropriate application to the STAR program. EPA hopes it will help applicants to prepare proposals that will result in data or procedures that can be interpreted or applied with confidence. Following this introductory Section, subsequent Sections present the following information:

- SECTION 2 presents the general EPA QA requirements for research involving data collection and analysis. It discusses what QA is and its importance in any type of research or production and a description of the two types of QA documentation needed for STAR research grants: the Quality Assurance Statement (QAS), required of all applicants, and the Quality Management Project Plan (QMPP), which will be required for certain types of projects.

- SECTION 3 provides expanded information about the QAS.

- SECTION 4 provides expanded information about the QMPP, its ten elements, and examples.

- SECTION 5 briefly describes the QA requirements that should be implemented following grant award.

- Appendix A provides an overview of the EPA Quality System.

- Appendices B and C provide lists of sources of additional information, Appendix B – Internet addresses; Appendix C – Bibliography of R and G Series documents.

- Appendix D is a Glossary of terms used in this document and their definitions.

2 ENVIRONMENTAL PROTECTION AGENCY QUALITY ASSURANCE REQUIREMENTS

2.1 QUALITY ASSURANCE AND QUALITY SYSTEM REQUIREMENTS

Basic quality terms used in this guidance are defined as follows:

> *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 [American Society for Quality (ASQ), 1994].

> *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.

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 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 undertaken. Accordingly, EPA has established quality system requirements that must be followed within EPA and by extramural contractors and financial assistance recipients for all work performed that involves environmental data production and use.

EPA assistance agreement recipients must implement or have implemented a quality system 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). The National Technology Transfer and Advancement Act (NTTA) requires Federal Agencies to use technical standards developed by voluntary consensus standards bodies whenever possible. EPA defers to ANSI as the U.S. standards setting body in this area. The national standard provides the basis for planning, implementing, documenting, and assessing a quality system. It includes segments on Management Systems, Environmental Data, and Environmental Technology. 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 policy is to require that the quality system be applied to all "environmental programs" within the scope of the assistance agreement in accordance with the principle of *graded approach*; that is, the level of detail needed to document quality practices for proposed work depends on the type of work and the intended use of the results. The simpler the project, the less detail will be needed to adequately document the quality practices for the project. However, the intended use of the results will also dictate the extensiveness of the QA and QC documentation needed to substantiate the work performed. The *graded approach* reflects the importance of the work, not just its complexity. This policy is consistent with all environmental programs operating under the EPA quality system as defined by EPA Order 5360.1 A2, May 2000 (U.S. EPA, 2000a).

Customarily, the EPA requirements for extramural agreements include documentation of (1) the

organization's quality system via a detailed Quality Management Plan, and (2) the application of quality assurance and quality control activities to specific efforts via a QA Project Plan. However, following the graded approach, and in acknowledgment that research is often conducted simply to obtain data rather than to be used in decision making, with peer-reviewed publications as a result, the STAR program allows more flexibility. The quality system documentation for the typical STAR research grant application will consist of a written "Quality Assurance Statement" (QAS), which accompanies the application and is described in Section 2. In some cases, EPA will require further documentation via a "Quality Management Project Plan" (QMPP), which is described in Section 3.

2.2 BENEFITS OF QUALITY ASSURANCE TO GRANT APPLICANTS

As a university researcher, you are familiar with the peer review process as it applies to selection of research grants and to the publication of journal articles. 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 very 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 designed QMPP 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. (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.) Similarly, an uncalibrated (or 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. The cost to repeat the experiment may be prohibitive.

Introducing student researchers to QA and QC practices can be part of the educational process they must have to compete in today's job market. Quality is a leading force enabling businesses to compete effectively in national and international markets. People entering the business world are being increasingly expected to understand basic QA and QC principles and practices and to be proficient in their use. While we recognize that quality requirements may be viewed as being unnecessary burdens to the conduct of the experiment, experience has demonstrated that QA and QC practices provide prudent safeguards against the occurrence of problems and the introduction of error into the data produced which could have dramatic adverse impacts on the results and the conclusions made from them.

Many research projects are so novel that the chances of failure are higher than for other types of research. However, establishing a quality system in the beginning should help lead to successful completion of the project with data of known quality. Such a quality system would provide a framework for the early detection of errors and for the documentation of the steps in the experiment to help to assure the reproducibility of the research.

2.3 REQUIRED DOCUMENTATION FOR QUALITY ASSURANCE

Any project involving the work listed below must be supported by sufficient QA and QC practices to assure that the results will be of the type and quality needed and expected for their intended use. This work includes:

-- 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.

For STAR grants, one or both of two forms of QA documentation will be required:

- Quality Assurance Statement (QAS) (mandatory)
- Quality Management Project Plan (QMPP) (may be requested).

The purpose of the QAS and QMPP is to provide information to the U.S. Environmental Protection Agency Project Officer (PO), Quality Assurance Manager, and award official on an applicant's capabilities to provide minimum required quality assurance (QA) and quality control (QC) 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.

For awards that involve measurements or data collection (generation), a quality system that complies with the requirements of ANSI/ASQC E4-1994, *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs*, must be in place. ANSI/ASQC E4 is available for purchase from the American Society for Quality (Phone 1-800-248-1946 and ask for item T55.) Only in exceptional circumstances should it be necessary to consult this document. There are EPA requirements documents (R-series) and guidance documents (G-series) available for potential applicants which address in detail how to comply with ANSI/ASQC

E4. Copies of these documents can be downloaded from the EPA Quality Staff web site at:

http://www.epa.gov/quality

These documents are in PDF format and may be retrieved using ADOBE Acrobat Reader and printed.

3 QUALITY ASSURANCE STATEMENT

3.1 WHAT IS A QUALITY ASSURANCE STATEMENT?

The 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. Typically, the QAS is presented as a narrative; there is no prescribed format required. Each STAR grant applicant must provide this statement. The QAS usually will not exceed two consecutively numbered, 8.5x11-inch pages of single-spaced standard 12-point type with 1-inch margins.

3.2 COMPONENTS OF THE QUALITY ASSURANCE STATEMENT

EPA requires that, for each item listed below, the QAS either present the requested information, reference (by page and paragraph number) the specific relevant portion of the project description containing the information, or provide a clear logical justification as to why the item does not apply to the proposed research.

1. Discuss the activities to be performed or hypothesis to be tested *(see above)* and the criteria for determining acceptable data quality. (Note: Such criteria may be expressed in terms of precision, accuracy, representativeness, completeness, and comparability, or in terms of data quality objectives or acceptance criteria. Furthermore, these criteria must also be applied to determine the acceptability of existing or secondary data to be used in the project. In this context secondary data may be defined as data previously collected for other purposes or from other sources, including the literature, compilations from computerized data bases, or results from models of environmental processes and conditions.)

2. Describe the study design, including sample type and location requirements, all statistical analyses that were or will be used to estimate the types and numbers of physical samples required, or equivalent information for studies using survey and interview techniques.

3. Describe the procedures for the handling and custody of samples, including sample collection, identification, preservation, transportation, and storage.

4. Describe the procedures that will be used in the calibration and performance evaluation of all analytical instrumentation and all methods of analysis to be used during the project. Explain how the effectiveness of any new technology will be measured and how it will be benchmarked to improve existing processes, such as those used by industry.

5. Discuss the procedures for data reduction and reporting, including a description of all statistical methods, with reference to any statistical software to be used, to make inferences and conclusions; discuss any computer models to be designed or utilized, with associated verification and validation techniques.

6. Describe the quantitative and/or qualitative procedures that will be used to evaluate the success of the project, including any plans for peer or other reviews of the study design or analytical methods prior to data collection.

If you believe that parts of the QAS are inappropriate or not applicable to the project, a brief statement of justification should be substituted for that element of the QAS. This is expected to occur rarely.

4 QUALITY MANAGEMENT PROJECT PLAN

4.1 WHAT IS A QUALITY MANAGEMENT PROJECT PLAN?

If the scope of the project involves significant and complex environmental data operations or environmental technology development, applicants for STAR research grants may be required to submit a more detailed explanation of the quality assurance and quality control practices to be used in the project. A Quality Management Project Plan (QMPP) is a document that includes elements of the QA Statement but generally contains more information and details about the QA and QC activities planned. The QMPP may also be applied to small data collection tasks, small assistance agreements for basic or exploratory research, and similar work of limited scope and duration, at the recommendation of the Project Officer or EPA Quality Assurance Manager. You will be advised by the Project Officer if your project will require a QMPP.

The QMPP should be prepared in accordance with the guidance provided in this section and 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. This is basically an enhancement of the QAS, without a page limit. The QMPP must be submitted for review and approval by the EPA Project Officer and QA Manager before beginning any work.

Below are several questions to consider and answer as part of planning the QMPP:

- What is the intended use of the data and what decisions may be made as a result of this research? (Basis for the hypothesis)
- What quantity and quality of data are needed to be able to make the decision (test the hypothesis)?
- What procedures or methods will be used to sample and analyze environmental or laboratory media ?
- What analytes are planned to be measured, and what are the performance criteria for any type of measurements planned?

4.2 COMPONENTS OF THE QUALITY MANAGEMENT PROJECT PLAN

The following information should be included in the QMPP in appropriate sections:

- Project description;
- Statement of the project objectives ~~and statistical hypotheses;~~
- Proposed schedule with start and end dates and milestones for the project;
- Description of the experimental design;
- Description of the process for sample handling and custody;
- Description of the sampling and analytical methods, and equipment;
- List of key project staff;
- Description of how quality will be ensured during the project; ~~and~~
- ~~Identification of any needed special reports on the QA and QC activities performed, as appropriate.~~
- Description of data reduction methods and procedures; and
- Description of data evaluation, validation, and verification

If any of these items have been covered in detail in the text of the application, they may be included in the QMPP by reference to the specific page number in the project narrative of the original application, although we would prefer a stand-alone document. The content needed for each of these ten items is described below, and we have provided brief examples of text and tables. Science and engineering topics for STAR grants are so numerous that only a few selected examples can be included; however, not all components may apply to a particular STAR grant topic. If a component does not seem to apply, state this and indicate why in a brief discussion in the text.

The specific elements of the QMPP are as follows:

(1) Project Description

A brief synopsis of the project (e.g., a few concise paragraphs) should describe the purpose of the study, including the hypothesis to be tested and the unique research aspects of the project. Also note other anticipated uses of information or data generated in the project. Particularly important is a

description of how the data collection activities will be performed, including the process or environmental system that will be tested. If the project is part of a larger EPA program, describe how it fits in the program. The abstract included in your application may be adequate for this section.

(2) Statement of the Project Objectives

Project objectives of the research or test(s) should be summarized in this section. Clearly identify the primary goals of the project in quantitative terms, if possible, and state how the anticipated results will achieve the research objectives of the project. For example, a project objective may be stated as:

> *The objective of this project is to demonstrate a removal efficiency of 90 percent or higher with a confidence level of 95 percent for the heavy metals identified in the top 5 centimeters of estuarine sediment.*

Some objectives may not be stated entirely in quantitative terms. The criteria for successful completion of the work should be described; that is, how will one know the objectives of the project have been met?

(3) Proposed Schedule with Start and End Dates and Milestones for the Project

The actual start and expected end dates of the project, including intermediate milestones and results, should be identified. A milestone chart or table indicating start or end dates for major milestones may be helpful. If your project involves sampling, you should also address the schedule for collecting samples and the laboratory analysis of the samples.

(4) Description of the Experimental Design

Describe the experimental design of the project with emphasis on the critical and noncritical measurement aspects of the project. Critical measurements are those necessary to achieve the project objectives; noncritical measurements are those used for process control or general background measurements. What must be accomplished or what measurements taken to achieve those objectives? Discuss the sampling design, including sample type and location requirements, how randomness was achieved in the sampling design and any statistical analyses that were used to estimate the types and numbers of samples required. The experimental design should be linked (as much as possible) to the quantitative project objectives discussed in a previous section.

(5) Description of the Process for Sample Handling and Custody

Describe the system for identifying (or numbering) samples, sample containers, required sample volume or mass, avoidance of contamination, preservation, transportation (if applicable), holding times,

storage times and conditions (if applicable), and safe final disposal of samples. Samples may be attached as documentation for sample labels. Describe the procedure for recording sample history, sampling conditions, and any other pertinent information. Formal sample custody is usually not necessary but samples must still be tracked in some manner, especially those that are toxic or radioactive. Not all environmental samples are physical samples that can be tracked. For instance, real-time air samples from continuous emission or ambient air monitors will not require sample labels, preservation, or transportation. It is important to note, however, how a gaseous sample will be brought from the point of sampling to the monitor. It also is important that a system be in place to accurately match data to the time and place of the air sampling.

(6) Description of the Sampling and Analytical Methods, and Equipment

The sampling and analytical methods (for each analyte provide instrument and method detection limits) that will be used should be described. When standard methods, such as those published by EPA, ASTM, or the American Public Health Association, are used, a reference to the method with any deviations or choices specifically noted is sufficient documentation. Who will test proposed new industrial equipment or processes and how will their accuracy and effectiveness be demonstrated? What types of QC samples will be included in the sampling and analysis routines (for example, spikes, duplicates, matrix spikes, matrix spike duplicates, and identify surrogates that will be used and why they were chosen). What methods of calibration for instruments will be used and how frequently will they be calibrated? What standards will be used for calibration, how they are prepared, how are they stored, and do they provide traceability to higher accuracy standards? What are the relevant performance criteria? Consider analytical blanks, instrument response check samples, interferences, and effects of temperature or pressure on the analytical method.

(7) List of the Key Project Staff

All key personnel and their assigned responsibilities should be listed in this section. The list should include geographic locations, telephone and fax numbers, and electronic mail addresses. For managerially complex projects, an organizational chart or communications plan may be helpful. Any subcontractors or consultants (if used) and their responsibilities should be included. In addition, any special skills or need for training should be determined and steps to provide those skills or training identified. Project personnel and organization may be shown in tabular form, if desired.

(8) Description of How Quality Will be Ensured During the Project

The process by which quality will be ensured during the project should be described. Overall, we are interested in the quality of information (including environmental data) that your project requires and how the necessary quality will be obtained and documented. Some of the key questions that may be asked in developing an appropriate description are:

- Can quantitative objectives be established for quality? Will only qualitative objectives be possible?

- How will the data comparability and representativeness be determined?

- What calculations will be performed and how will the correctness of calculations be ensured?

- What statistical procedures will be used to analyze the data (identify the commercial source of all programs)?

- Can the quality of the information or data be independently verified, and how?

- How will success be measured (measurement performance criteria) and how is it related to the project's objectives?

(9) Description of Data Reduction Methods and Procedures

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. 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. Provide a complete citation of these data sources so that these data can be reviewed if necessary.

(10) Description of Data Evaluation, Validation, and Verification

In this section a complete discussion should be provided on how data are collected and by whom. Identify who is responsible for verifying the accuracy of the original data and whether or not the data met measurement quality objectives. The performance criteria of the project should be discussed and the process that will be used to ensure the performance criteria have been met. In addition, any performance evaluations, audits, surveillance, and other assessment procedures planned should be described, including the procedures to be used for data validation and verification. Also, there should be a discussion of how any corrective actions will be implemented and documented and their effectiveness confirmed for any audits performed.

There should also be a discussion of any plans for peer or other reviews of the design or analytical methods prior to data collection.

If the project involves the development or use of a model, your plan should also include a description of the project configuration; management; key assumptions; quality control procedures for data requirements and acceptance/rejection criteria; how the code will be maintained; the mechanism for transferring the code to the Project Officer and potential users; and the model evaluation and testing, including limitations of the model and its intended application. (Note: your award document will contain requirements for further information on models to be provided in your reports.)

For projects generating or using GIS/Remote Sensing data, discuss in the QMPP (and reports) how these elements will be addressed: positional accuracy; attribute accuracy; logical consistency; time; lineage; resolution accuracy; and the completeness of coverage, classification, and verification. See Appendix D for definitions.

5 QUALITY ASSURANCE REQUIREMENTS FOLLOWING GRANT AWARD

5.1 POSSIBLE QUALITY ASSURANCE PROJECT PLAN REQUIREMENT

Although your STAR grant application may have been recommended for funding, there may be questions about the adequacy and suitability of the QA statement or QMPP resulting in the recommendation including a conditional QA approval. In this case, your grant's Project Officer or Quality Assurance Manager may require that a more comprehensive QA Project Plan be approved before you begin any research activities These individuals make the final decision about whether to require a QA Project Plan and then determine who will provide the EPA approval.

The QA Project Plan typically may be required for studies producing large volumes of data, or determined to be controversial by EPA, or of a highly complex nature that may need more extensive documentation of the planning process, and for major grants in terms of the impact of or funding for the work. If the approval is conditional, 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.

Often, a dialogue between the Principal Investigator (PI) and the Project Officer can resolve quality assurance requirements questions. For instance, after award, sections of the QMPP could be expanded, or a standard operating procedure or protocol for performing a certain task could be prepared and attached to the QMPP as an appendix to supply additional information. This action must be approved by the Project Officer or the Quality Assurance Manager for NCER and documented prior to the initiation of research.

5.2 IMPLEMENTATION AND REPORTS

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 as well as 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, QMPP (if required) and QA Project Plan (if required), 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 briefly discussed in your annual and final reports.

REFERENCES

ASQ (American Society for Quality). 1994. *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs.* ANSI/ASQC E4-1994. Milwaukee, WI.

U.S. EPA (Environmental Protection Agency). 1994. *Guidance for the Data Quality Objectives Process* (QA/G-4).

U.S. EPA (Environmental Protection Agency). 1999. *EPA Requirements for Quality Assurance Project Plans* (QA/R-5).

U.S. EPA (Environmental Protection Agency). 2000. EPA Order 5360.1 A2, May 2000. *Policy and Program Requirements for the Mandatory EPA Quality System*.

APPENDIX A

OVERVIEW OF THE ENVIRONMENTAL PROTECTION AGENCY QUALITY SYSTEM

The EPA Quality System has been in place since 1979. The EPA Quality System operates under the authority of Order 5360.1 A2, *Policy and Program Requirements for the Mandatory EPA Quality System* (May 2000). The quality system is applicable to work done by EPA employees as well as by contractors and grant recipients. The quality system provides the management and technical practices needed to ensure that environmental data are of adequate quality and usable for their intended purposes.

Figure A-1 illustrates the components of the EPA Quality System. This rather elaborate diagram can be broken down into three interactive structural levels: policy, organization or program, and project.

A.1 QUALITY SYSTEM — POLICY LEVEL

The top level of Figure A-1 illustrates the policy section. It is described here for background information only. Each STAR grant applicant or grant holder need only be aware of the policies and standards; it is not necessary to review them to establish a quality system. The policy section may be thought of as the by-laws or reference library of the quality system. The internal and external EPA quality policies are described here, including 40 *Code of Federal Regulations* (CFR) Part 30, *Grants and Agreements With Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations*, which applies to nonprofit organizations working under EPA grants. Each policy reflects the consensus American National Standard, ANSI/ASQC E4, *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs* [American Society for Quality (ASQ), 1994]. This American National Standard was authorized by the American National Standards Institute (ANSI) and developed by the American Society for Quality (ASQ). EPA played a significant role in creating and writing the standard.

A.2 QUALITY SYSTEM — ORGANIZATION/PROGRAM LEVEL

The second level of the quality system diagram shows the organization and program elements – that is, the management structure. A quality management plan (QMP) is the focus of this section. Please consult *EPA Requirements for Quality Management Plans (QA/R-2)* (U.S. EPA, 1999) for more information on QMPs. The QMP is one of the requirements for organization and research center grants, but not for STAR grants. For STAR grants, the Quality Management Project Plan (QMPP) is sufficient. The QMPP combines the organizational, program management, and training aspects of the QMP with the technical details usually found in the QA Project Plan. The content of a QMPP is determined by applying the principle of the graded approach to the guidelines given in the main text.

A.3 QUALITY SYSTEM — PROJECT LEVEL

The third level of the quality system diagram, Figure A-1, shows QA and QC activities at the project or grant work level. This is where a systematic plan for the work is documented in a QA Project Plan (or, in the case for a STAR grant, in the QAS or QMPP), the work is implemented according to the plan and any standard operating procedures (SOPs), and critical assessments of the experimental results and conclusions are made. This process leads to defensible products (data of known quality) and conclusions (decisions) that are communicated through reports, journal articles, and presentations at symposia or seminars.

> Consult the following documents for further information on preparing and using the QA Project Plan. Both are available on the Quality Staff's home page (http://www.epa.gov/quality/qa_docs.html): *EPA Requirements for Quality Assurance Project Plans (QA/R-5)* (U.S. EPA, 1999) and *EPA Guidance on Quality Assurance Project Plans (QA/G-5)* (U.S. EPA, 1998).

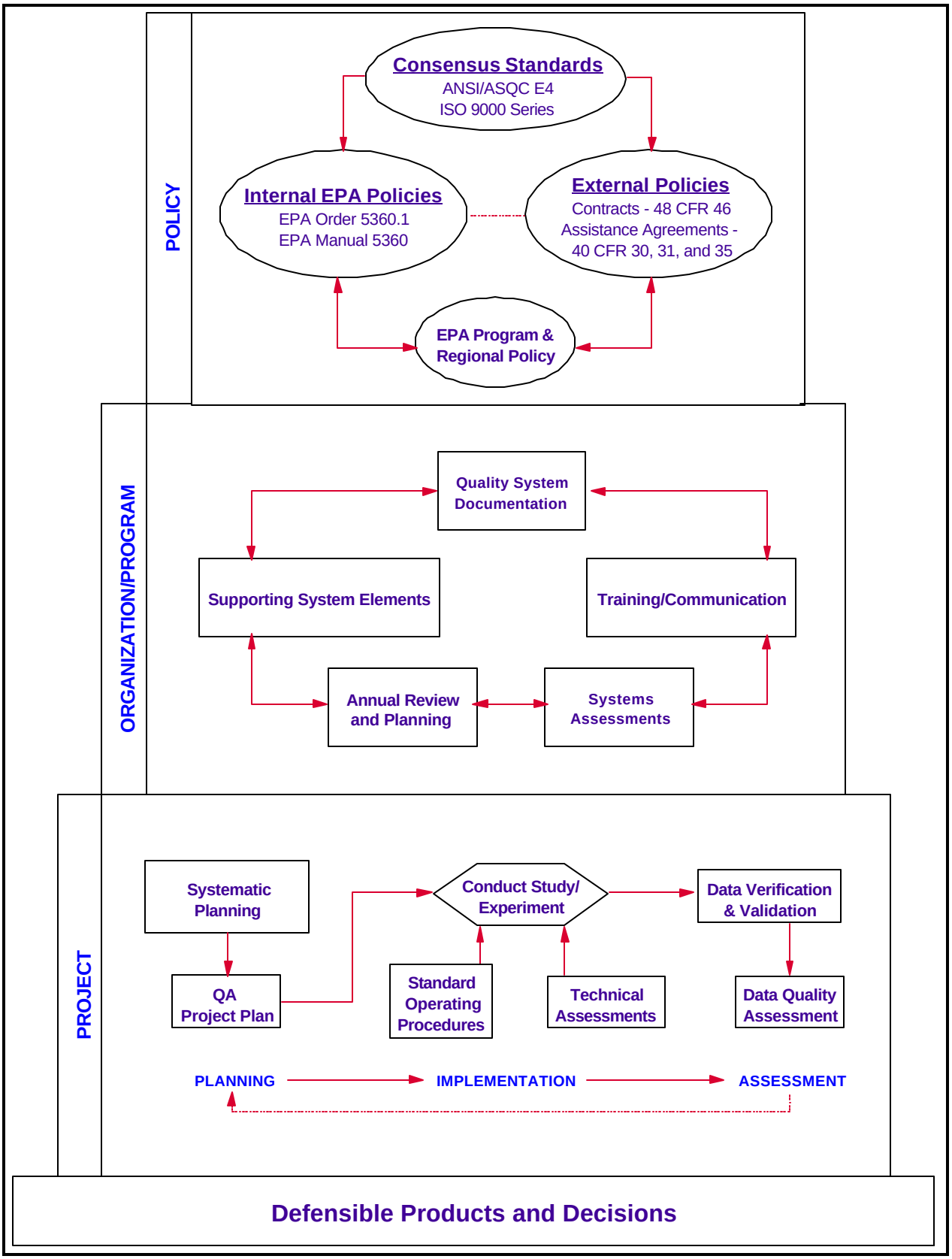

Figure A-1 EPA Quality System Components

APPENDIX B

BIBLIOGRAPHY OF USEFUL INTERNET ADDRESSES

1. Air and Waste Management Association
   http://www.awma.org

2. American Chemical Society, Division of Environmental Chemistry
   http://www.envirofacs.org/

3. American Society for Quality
   http://www.asq.org

9. American Society for Quality, Energy and Environmental Division
   http://www.envnet.org/

10. EPA Grants Information
    http://www.epa.gov/epahome/grants.htm

11. EPA Peer Review Program
    http://www.epa.gov/osp/spc/2peerrev.htm

12. International Organization for Standardization (ISO 9000 and ISO 14000)
    http://www.iso.ch

13. National Academies of Science and Engineering, and Institute of Medicine
    http://www.nas.edu

14. National Center for Environmental Research (Office of Research and Development, U.S. Environmental Protection Agency)
    http://www.epa.gov/ncer

15. U.S. EPA Quality Staff
    http://www.epa.gov/quality

APPENDIX C

BIBLIOGRAPHY OF R AND G SERIES EPA QUALITY SYSTEM DOCUMENTS

The EPA has the following requirements (R-series) and guidance (G-series) documents to assist research grant applicants and recipients in complying with quality assurance (QA) requirements:

- *EPA Requirements for Quality Management Plans (QA/R-2)*
- *EPA Requirements for Quality Assurance Project Plans (QA/R-5)*
- *Guidance for the Data Quality Objectives Process (QA/G-4)*
- *Guidance on Quality Assurance Project Plans (QA/G-5)*
- *Guidance for the Preparation of Standard Operating Procedures for Quality-Related Documents (QA/G-6)*
- *Guidance on Technical Audits and Related Assessments (QA/G-7)*
- *Guidance for Data Quality Assessment: Practical Methods for Data Analysis (QA/G-9)*
- *Data Quality Assessment Statistical Toolbox (DataQUEST) (QA/G-9D)*

These documents and others may be downloaded from the EPA Quality Staff Home Page at:

http://www.epa.gov/quality

The home page documents are available in the Adobe Acrobat PDF format and may be printed using the free Adobe Acrobat Reader, which is available on the Internet.

APPENDIX D

GLOSSARY OF TERMS AND DEFINITIONS

calibration – comparison of a measurement standard, instrument, or item with a standard or instrument of higher accuracy to detect and quantify inaccuracies and to report or eliminate those inaccuracies by adjustments.

data of known quality – data for which the qualitative and quantitative components associated with their derivation are documented appropriately for their intended use; such documentation must be verifiable and defensible.

environmental data – any measurement or information that describes environmental processes, locations, or conditions; ecological or health effects and consequences; or the performance of environmental technology. For EPA, environmental data include information collected directly from measurements, produced from models, and compiled from other sources such as databases or the literature.

environmental technology – an all-inclusive term used to describe pollution control devices and systems, waste treatment processes and storage facilities, and site remediation technologies and their components that may be utilized to remove environmental pollutants or contaminants from or prevent them from entering the environment. Examples include wet scrubbers (air), soil washing (soil), granulated activated carbon units (water), and filtration (air, water). Usually, this term applies to hardware-based systems; however, it also applies to methods or techniques used for pollution prevention, pollutant reduction, or containment to prevent further movement of the contaminants, such as capping, solidification or vitrification, and biological treatment.

GIS definitions –

Attribute Accuracy--the accuracy of the variables describing a map feature

The completeness of:

-- Classification--assessment of how well the chosen classification is able to represent the data

-- Coverage--proportion of data available for the area of interest

-- Verification--the amount and distribution of field measurements or other independent sources of information that were used to develop the data

Lineage--the history of the data set, including its sources and processing steps.

Logical Consistency--the logical relations among data elements.

Positional Accuracy--the deviation of a mapped object from its true ground position.

Resolution Accuracy--the smallest discernible unit or object represented in the GIS

Time--whether the data is up-to-date enough for its intended use

graded approach – the process of basing the level of application of managerial controls applied to an item or work according to the intended use of the results and the degree of confidence needed in the quality of the results.

guideline – a suggested practice that is nonmandatory in programs intended to comply with a standard.

QA manager – the individual designated as the principal manager within the organization having management oversight and responsibility for planning, coordinating, and assessing the effectiveness of the quality system for the organization.

quality management – that aspect of the overall management system of the organization that determines and implements the quality policy. Quality management includes strategic planning, allocation of resources, and other systematic activities (e.g., planning, implementation, and assessment) pertaining to the quality system.

quality system – a structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring quality in its work processes, products (items), and services. The quality system provides the framework for planning, implementing, and assessing work performed by the organization and for carrying out required QA and QC activities.