

NCER's Guidance for Quality Management Plans (QMPs)

General Guidance for Writing and Reviewing QMPs

For EPA/NCER and the STAR Grant Program

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.html¹.

- (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)" [\[http://www.epa.gov/quality/qs-docs/r5-final.pdf\]](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) **Qualifications and Training:** Describe the process for ensuring and documenting that personnel have necessary quality-related qualifications and training.

¹Note: The STAR program has tailored the Agency elements to meet the needs of this grant program. Therefore, all the information contained in this guidance may not be applicable to your grant.

- (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>.