CHAPTER 4
QUALITY ASSURANCE ANNUAL REPORT AND WORK PLAN

4.1   Background

Careful annual planning is necessary to the success of the Agency-wide Quality System. In order for management to budget adequate resources to implement the quality system for an organization, estimates of the quality system workload are needed. Moreover, management must give priority to quality system resource needs with respect to other mission requirements.

All Agency organizations subject to the requirements of EPA Order 5360.1 A2 shall submit a Quality Assurance Annual Report and Work Plan (QAARWP) annually. The QAARWP shall summarize the results of having implemented the quality system the previous fiscal year and describe QA activities planned for the fiscal year beginning in October. The QAARWP may be used to identify limited changes or updates to the organizations's approved Quality Management Plan (QMP) (see Chapter 3). The QAARWP should provide helpful information to management by documenting the past fiscal year's activities and estimating the current year's workload based on the prior year and the expected activities in the current year.

4.2   Use of QAARWP Submissions

The contents of the QAARWPs shall be used by the Quality Staff to evaluate the overall effectiveness of the Agency-wide Quality System. As problems related to QA are identified by EPA organizations, the Quality Staff shall use the QAARWP information to identify systemic or Agency-wide problems and shall initiate plans to address such problems. The QAARWPs shall not be approved as are QMPs.

4.3   Requirements

The QAARWP must be submitted under the signature of the senior manager for the organization to the AA/OEI. Organization is defined here as an ORD Center, Laboratory, or Office; individual Program Office one level under an AA-ship; or Region. In order to simplify the submittal, the QAARWP and its attachments may be submitted electronically to the OEI Quality Staff Director along with a copy of the original signature page. The QAARWP has two parts, the annual report for the previous fiscal year and the proposed work plan for the new fiscal year. Specifications for the QAARWP are contained in Sections 4.3.1 - 4.3.2.

4.3.1   QA Annual Report

4.3.1.1   Quality Management Resources

Resources provided here may be estimated if not strictly accounted for by position or expense tracking. For example, if 10% of the time of all project officers is spent on quality assurance activities, then an estimate can be made by multiplying 10% times the number of project officers. If such an estimate is made, the algorithm should be provided to clarify the response.

- Provide a current estimate of the organization's filled FTE positions.

- State the total EPA (and other Federal) FTE (to the nearest tenth of an FTE) involved in the management of QA/QC activities. Examples of these activities include providing input to management on the need for and use of QA resources, disseminating Agency QA policy, developing and ensuring the implementation of the organization's QMP (including document tracking, auditing, and training), and acting as a liaison with the Quality Staff. Vacancies should be listed separately.

- State the total EPA (and other Federal) FTE involved in QA/QC support activities. Examples of these activities include writing and reviewing QAPPs and Standard Operating Procedures (SOPs) and validating data.

- If your organization uses contractor support to implement the quality system, state the total contractor FTEs involved in QA/QC support activities. Include the technical QA/QC support of Senior Environmental Employment Program (SEEP) grantees or other grantees.

- State the total FTEs involved in other non-technical QA/QC support activities. This category would include the non-technical SEEP employees and clerical staff.

- State the total dollar amounts (rounded to nearest $K) of other QA supporting funds, not including travel funds or training.

- State the total dollar amounts of travel funds used for QA activities such as oversight, surveillance, and audits/assessments.

- State the total dollar amount of funds used for QA/QC training, including travel for training, and the total number of people who attended the training. Include training for QA staff.

- Discuss the adequacy of the above listed resources in relation to their impact on your quality system, including the ability to implement last year's work plan.

4.3.1.2 Training

- Briefly describe the method used to assess the organization's QA training needs and the results of the assessment; i.e., what needs were identified. Discuss separately any needs assessment made of other organizations participating in your quality system (i.e., States, Tribes, Regions).

- List courses and name the supplier(s) for QA/QC courses given to your organization and other non-EPA organizations participating in your quality system. The courses attended by the QA staff, while critically important for educating new QA staff members, are not the primary concern of the Quality Staff. For example, contract administration and field/lab equipment techniques are not considered QA courses. Statistics courses, however, are considered related to QA in terms of project planning and data analysis.

- List the attendance for each course. If course attendees included persons from outside your organization, identify the total attendance by each organization represented.

- For each course, indicate whether the course goals were achieved; that is, were the training needs fulfilled? If not, please indicate why and what you believe needs to be done to satisfy the remaining needs.

4.3.1.3 Management Accomplishments

- Discuss any innovative quality management practices you have developed and used in planning, implementing, or assessing your quality system. Include any proposed revisions to your Quality Management Plan reflecting changes to your operating practices for QA/QC.

- Summarize the technical assessments that were performed by your organization on itself and others participating in your quality system. For each assessment, identify the type of assessment performed, the organization and project which were the subject of the assessment, when the assessment was performed, and who did the assessment. Also provide a general statement of the assessment results and any corrective actions. For example, the QA staff members performed technical systems audits of these projects:

(list). Note, if this information is indicated on an attached quality system tracking program output, give the totals here.

• Summarize the technical assessments that were performed on your organization by others. For each assessment, identify the type of assessment performed, the organization and project which were the subject of the assessment, when the assessment was performed, and who did the assessment. Also provide a general statement of the assessment results and any corrective actions.

• Summarize technical assistance given on planning, data review, etc. For QAPPs, the numbers of QAPPs reviewed (or re-reviewed) and an indication of average turnaround time is sufficient. Note, if tracking program outputs are attached, give totals for intramural and extramural projects. Include QA assistance given by the organization or individuals to non-EPA organizations, including states, private industry, and foreign countries. Organizations participating in your quality system that have QMPs reviewed and approved by you should also be listed.

• List any new or revised QA guidance developed by your organization. It is not necessary to list SOPs written and revised during the past year. The numbers of both new and revised SOPs is sufficient.

• List any publications and presentations concerning QA/QC practices and results by your organization. QA guidance listed above need not be repeated. Internet or other electronic document forms should be included.

• List any awards or recognition related to QA given to your organization or to individual staff members.

4.3.1.4   Management Assessment of the Approved Quality System

• Summarize the management assessments (i.e. management systems reviews) that were performed by your organization on itself and others participating in your quality system. Include the part of the implemented program that was examined and what was learned (including positive findings). If corrective actions were indicated, summarize the response actions taken, and discuss progress toward their implementation. Report on their effectiveness, if known.

• Summarize the management assessments that were performed by others (including the Quality Staff) on your quality system. Include the part of the implemented program that

was examined and what was learned. If corrective actions were indicated, briefly summarize the response actions taken, and discuss progress toward their implementation. In particular, highlight any incomplete corrective actions resulting from the Quality Staff's assessments. Report on the effectiveness of the corrective actions, if known.

4.3.2   Work Plan

4.3.2.1   Quality Management Resources

- State the total EPA (and other Federal) FTE (to the nearest tenth of an FTE) proposed for supporting quality management activities in your organization. Examples of these activities include providing input to management on the need for and use of QA resources, disseminating Agency QA policy, developing and ensuring the implementation of the organization's QMP (including document tracking, auditing, and training), and acting as a liaison with the Quality Staff. Vacancies should be listed separately.

- State the total EPA (and other Federal) FTE proposed for QA/QC support activities. Examples of these activities include writing and reviewing QAPPs and SOPs and validating data.

- If your organization uses contractor support to implement the quality system, state the total contractor FTEs proposed for the QA/QC support activities.

- State the total FTEs proposed for other non-technical QA/QC support activities. This category would include Senior Environmental Employment Program employees, other grantees, and clerical staff.

- State the total dollar amounts (rounded to nearest $K) of proposed QA/QC support funds, not including travel funds or training.

- State the total dollar amounts of proposed travel funds for QA activities such as oversight, surveillance, and audits.

- State the total dollar amounts of proposed funds for training, including travel.

4.3.2.2   Activities

- List and briefly describe anticipated major QA/QC activities expected during the year including QA/QC-related training to be given, taken, or developed, guidance to be developed or revised, technical and management assessments of your organization and others participating in your quality system, and implementation of corrective actions from prior MSRs of your quality system.