

IMPLEMENTATION OF QUALITY ASSURANCE IN THE ENVIRONMENTAL ARENA WITH CHANGING PROGRAM REQUIREMENTS

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ABSTRACT

WESTON is following a formal process in order to implement a full scope Quality Assurance Program for environmental projects for the U.S. Department of Energy, including those with overview or regulation by the Environmental Protection Agency. The program consists of a corporate level program description document that includes top-level requirements applicable to all WESTON activities regardless of contract source; a Quality Assurance Management Plan, which is the primary subject for this paper; and the supporting procedures. Care has been taken to design documents that allow for the matrix management system used in the corporation and to include the existing processes in use in the organization that meet the new requirements or can easily be made to meet these requirements. The goal is to provide a program that meets requirements from various sources, meets project needs and requires a minimum of changes to existing activities for implementation.

INTRODUCTION

At WESTON, we are involved in the implementation of a multi-tiered Quality Assurance (QA) Program applicable to a wide variety of DOE-sponsored environmental activities. This is being done in a climate that is undergoing as much or more change than at any time since the introduction of formal full function Quality Assurance Programs. The drivers for the changes are provided by the following:

1. DOE Programs are undergoing a transition from DOE Order 5700.6B (1) to DOE Order 5700.6C (2). This includes a program format change and the addition of Total Quality Management concepts to the program.
2. The acceptance of ISO 9000 series requirements by service industries and manufacturing organizations interested in doing work internationally. Many defense contractors are in this group.
3. ANSI/ASQC-E4-19xx (3) is expected to be finalized and released late this winter or early spring. It is assumed that the requirements of this document will be met by meeting requirements of NQA-1 (4).
4. It is expected that QAMS-005/80 (5) will be revised in the near future.

The changes require the determination of real quality needs based on the concept of data quality objectives and the introduction of the concepts of Total Quality Management and Continuous Quality Improvement. In addition, programs and program evaluations are becoming more performance based, requiring changes in the way activities are evaluated. These changes must be implemented in an industry that has a highly technical environment and one that may include experimental or innovative approaches. The environmental industry is, in part, service oriented but also requires many production- or manufacturing-type control functions. Many environmental service organizations, including ours, are strongly matrix organized and managed. This provides an added measure of complexity for planning and implementing the QA Program. Projects often include support and staff provided by several offices, multiple organizations, and several corporations. Organizational structure must be considered as a constraint to QA Program Development and flexibility is required in program level documents to allow for

the participation of numerous organizational groups in the meeting of requirements. Program level documents must also provide sufficient flexibility to be applicable to a wide variety of sites and to provide sufficient controls for a wide variety of tasks. QA program documents must interface with a wide variety of Work Plans, Health and Safety Plans, and Sampling and Analysis Plans.

In order to remain competitive and have time for appropriate evaluation and implementation, QA Program development must be accomplished at a time when formal requirements are not fully defined. The consensus program requirements standard for environmental activities has not been released. Fortunately, the document (3) containing these requirements is expected to be finalized in the near future. The contents of this document appear to be sufficiently well defined that we are using the draft prior to its formal release in writing our program and implementation documents. The requirements from NQA-1 (4) and from DOE Orders 5700.6C (2) and 5480.19 (6), and from QAMS-005/80 (5) are sufficient to plan and implement many aspects of a full scope QA Program.

Weston currently has many aspects of the full program in place. These processes and procedures have been used in the corporation for a number of years. In addition, Weston has projects with dedicated staff working to full QA Programs currently in place and applicable to that specific activity. These conditions have led to the determination that the scope of the program discussed here must be applicable to all DOE-funded projects carried out by WESTON where the staff was not dedicated. The Program described here may be adopted for any new-start DOE-funded activity. This program also must meet the requirements of the new consensus standard and must be easily extendable for programs funded by other agencies. It is intended that, in areas where there is existing compliance with requirements, activities be incorporated into the QA Program with as little additional change as possible. To provide this flexibility, the decision was made to develop a multi-tiered program that utilizes as many of the good technical practices currently in use as possible. To do this a full evaluation of the existing activities for formal compliance and adequacy of procedures was completed. Areas where requirements are currently met but not formalized by

procedures were identified. Also identified were the activities where requirements have not been met such as inspection and testing, and where there is partial compliance with requirements in areas such as records. These last activities are those that require additional analysis and full implementation.

APPROACH

The approach chosen to provide a full QA program includes a Quality Assurance Program Description (QAPD). This document is complete and released. The QAPD provides the corporate commitment to quality and defines upper level management responsibilities. The QAPD is consistent with NQA-1 requirements that are applicable to all WESTON activities. The document describes basic controls for all areas of WESTON corporate activity. Corporate direction for activities are described in the corporate Operating Practices. The QAPD is the document that provides for the development of specific QA programs as needed for WESTON activities. These include those for existing dedicated programs whether authored by WESTON or authored by other organizations and used by WESTON staff, and the programs described by the Quality Assurance Management Plan for U.S. DOE Activities (QAMP), described in this paper. If necessary, additional plans for future projects with other requirements or other activities may be written. These other plans may include essentially the same requirements as those for DOE activities but could include the appropriate references to funding or regulating organization's requirement documents and any additional requirements imposed by those organizations. It is expected that the release of the E4 consensus standard document will minimize the need for changes to the existing QAMP. One possibility might be the requirement to track the QA costs for corrective actions. The relationships between the documents in this multi-tiered hierarchy are shown in Fig. 1. This diagram indicates the requirements flow down and document interfaces.

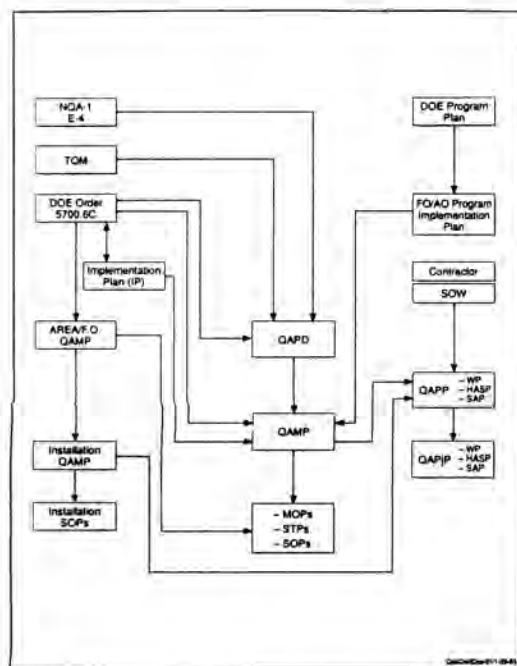


Fig. 1. Documents hierarchy/requirements flowdown.

PROGRAM ORGANIZATION AND DEVELOPMENT

The format for the QAMP is based on (2) DOE Order 5700.6C. The sections of the document for Construction and Operation are currently identified as RESERVED since no activities in these areas are currently planned. The document provides for controls for training and certification of personnel including audit and test and inspection. Also provided are the requirements for the quality assurance elements that include deficiencies, nonconformances, corrective actions and trending. These are described as parts of the *continuous improvement process*. Quality Assurance and Quality Control functions are described in the context of the rolls and responsibilities for independent activities associated with review, approval, assessment, audit and independent support. Also described are the Quality Assurance and Quality Assurance for which independence from the work activity is not required and is probably not most appropriate. These include the day-to-day support for field activities and analysis as well as the implementation of many requirements described in QA Project Plans.

The requirements for document preparation are identified and discussed. Currently, document preparation is controlled by a Reports Manual that is used at the same level as a procedure but with greater scope. The manual provides the content and scope for the more common documents typically generated on environmental projects. This manual is being revised to include additional documents and to include the requirements not fully covered. Added review by Quality Assurance and Health and Safety will be included as required. The guidelines and specifications for QA Project Plans given in QAMS-005/80 are included in the Reports Manual and are included in the (5) QAMP.

The QAMP leads to a series of Management Operating Procedures (MOPs) applicable to general program staff activities. These procedures include such topics as records, document control, nonconformance, audit, training, calibration, procedures, document change control, and notebook use and control. Some of these procedures are in-place and in use and some are still in the development phase. There is further discussion of implementation in the section of this paper titled Program Implementation found below. For field activities, a set of Standard Operating Procedures (SOPs) and Standard Technical Procedures (STPs) have been written. WESTON has controlled field activities by the use of procedures for many years. These procedures have been revised to reflect additional requirements for procedure content and review provided by the QAMP. Standard Operating Procedures are those procedures applicable to WESTON activities alone and reflect corporate processes or requirements. Standard Technical Procedures are procedures of a more generic nature. These contain directions that could be done by WESTON or other organizations. These procedures may be used by organizations under contract to WESTON or by other organizations. The format of the SOP and STP procedure sets is the same and there is no duplication of the numbering between the two sets of procedures. They may be intermingled on any specific project to provide control of all necessary activities.

CONTENT OF THE QUALITY ASSURANCE PROJECT PLANS

Currently QA Project Plans meet QAMS-005/80 (5) requirements but do not include all program level requirements for records, document control, or training. Added

information on these elements will be provided in the planning documents at a level of detail needed for project implementation. In addition, at the time of project start, specific delegations of authority and records management requirements are to be specified. Much of the job-start process is in place and includes the establishment of cost accounting and project planning and management functions. Additions will be made to include other decisions and delegations of responsibility and authority best made at the time of actual project start. These will become part of the project records.

PROGRAM IMPLEMENTATION

The formal method of QAMP implementation has followed the following steps.

First a list of requirement or closely related requirements were made from the QAMP. One hundred seventy-six requirements were identified. At the same time the QAMP was evaluated for completeness and consistency against 5700.6C (2), NQA-1 (4), NQA-2 part 2.7 for computer software, (7), and QAMS-004/80 (5) and QAMS-005/80. Questions concerning requirements flow down were identified. These are to be addressed during the implementation phase.

The second step was to evaluate the requirements against current WESTON practice on DOE and other activities and to determine what requirements could be grouped into addressable action items. The 176 items were grouped into 18 action items.

Third, activity priorities were assigned based on the need to implement that activity and whether any other item served as a prerequisite. Upper management also provided schedule constraints for the implementation. Eleven of the 18 items were high priority and represented 127 of the identified 176 requirements. For the high priority action items, a responsible senior staff member or members were identified, as well as the senior technical reviewer.

Fourth, the responsible party or parties and the reviewer completed a preliminary evaluation of the action area determined the approach needed, and identified the schedule to be followed for the implementation that met management guidelines.

Fifth, this information has been included in a formal QAMP Implementation Plan. Progress is to be tracked on a monthly basis.

Potentially, an action item includes an evaluation of which specific requirements are currently met and the determination of whether sufficient procedures exist for day-to-day activities in a given area. If a procedure is needed this is to be written, reviewed, and approved. If the activity area is sufficiently open to require the development of processes and process activity flows or interaction with other major areas for implementation, a planning document may be required before implementing procedures can be written.

SUMMARY AND CONCLUSION

WESTON has put into place the formal documents that lead to the implementation of a full scope QA Program. These include a corporate level description document that governs all WESTON activities. Tiered to this is a QA Management

Plan that is intended to meet DOE and EPA requirements and is expected to meet those of other agencies. Tiered to this are Management Operating Procedures and Standard Technical Procedures that are split into two categories. The program is written to account for the matrix management system used within the corporation as well as the use of multiple offices participating on a project. In addition, the QAMP is applicable to a broad spectrum of activities carried out on multiple sites.

Even without full Quality Assurance Program implementation, we are starting to see changes in the way projects function. Many, if not all, employees embrace these changes.

WESTON, both as a corporation and as individual employees, has traditionally had strong feelings about the quality of the work done and the satisfaction of its customers. The formal approach to Quality Assurance provides a better understanding of how to reach these goals. The change in culture brought on by this more formal approach leads to changes in how the QA staff functions and interfaces within the corporation. The use of liaison QA staff results in a better coordination between the field staff, other project team members and the analytical laboratories. Line staff are becoming more fully responsible for the quality of the activity. This leads to more rapid identification of problems and to solutions that really do prevent recurrence. This also provides for better communications of lessons learned. Field teams are being trained in the QA program as well as individual field requirements and field procedures. Data quality objectives are being used in the ongoing decision process associated with the field activities. Independent QA staff are better able to do evaluations, assessments or audits and are able to recommend and implement program improvements.

We are seeing better documentation of field activities and this in turn not only provides for more information available for technical interpretation and inclusion in reports but also provides more information concerning the use of the procedures themselves that will be used when it is required to revise and improve the field procedures.

REFERENCES

1. DOE Order 5700.6B, "Quality Assurance," September 23, 1986.
2. DOE Order 5700.6C, "Quality Assurance," August 21, 1991.
3. ANSI/ASQC-E4-199x, "Quality Assurance Program Requirements for Environmental Programs [DRAFT]."
4. ASME/NQA-1-1989 Edition, "Quality Assurance Program Requirements for Nuclear Facilities."
5. QAMS-005/80, "Interim Guidelines and Specifications for Preparing Quality Assurance Project Plans," December 29, 1980.
6. DOE Order 5480.19, "Conduct of Operations Requirements for DOE Facilities," July 9, 1990.
7. ASME/NQA-2a-1989 Edition and NQA-2a-1990 Addendum, "Quality Assurance Requirements for Nuclear Facilities Application."
8. QAMS-004/80, "Guidelines for Preparing Quality Assurance Program Plans," July 1980.