The Development of a Quality Assurance Project Plan for the USEPA Dioxin Exposure Initiative Program

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Introduction

All projects planned and implemented under the United States Environmental Protection Agency (USEPA) Dioxin Exposure Initiative are required to have completed Quality Assurance Projects Plans (QAPPs). EPA Order 5360.1 A2 [1] states, "All work funded by the United States Environmental Protection Agency (EPA) that involves the acquisition of environmental data generated from direct measurement activities, collected from other sources, or compiled from computerized data bases and information systems are implemented in accordance with an approved QA Project Plan . . . except under circumstances requiring immediate actions to protect human health and the environment or operations conducted under police powers". This policy is based on the newly revised national consensus standard, ANSI/ASQC E-4-2004 [2].

These QAPPs have proven invaluable in the development and improvement of analytical methodology for dioxin-like compounds over the intervening years and in the verification and validation of the results of dioxin exposure studies.

Methods & Materials

The EPA's Quality System is composed of three levels: Policy, Organization/Program, and Project (Figure 1). Within the Project Level of the system, the principal quality assurance project tool is the Quality Assurance Project Plan (QAPP). As is explained in EPA Order 5360.1 A2, "The QA Project Plan integrates all technical and quality aspects of a project, including planning, implementation, and assessment. Its purpose is the documentation of the planned results of environmental data operations and the development of a project-specific document for obtaining the type and quality of the environmental data needed for a specific decision or use. This document also includes how the quality assurance (QA) and quality control (QC) are applied to environmental data operations to ensure that the results of the project satisfy the stated performance criteria."

At the start of a Dioxin Exposure Initiative project, the Project Level is initiated. This begins with a systematic planning process, undertaken by all individuals/ organizations involved in any aspect of the project (e.g., sample collection, logistics, sample storage, sample extraction, sample analysis, data reduction, data implementation, data assessment, etc.). This process is referred to as the Data Quality Objectives (DQO) process[3]. This is the preferred planning process in the EPA and enables all individuals involved in the project the opportunity to discuss and

understand the purpose, expectations, and limitations of the project and the key personnel involved in the project. The Dioxin Project Manager, contractual Team Leader for Sampling, Dioxin Team Leader for Analysis, and the Data Risk Assessors meet and discuss all pertinent aspects of the project, interactions among each other, and establish the objectives to be met that would constitute success for the project. It has been determined that when individuals are excluded from the planning process by design or omission, the quality of the project suffers through lack of orderly integration of focus, effort, and information.

After the DQO process is completed, then the QA Project Plan document is assembled. Guidance on the preparation of the QA Project Plan can be found in the EPA Guidance and Requirements for Quality Assurance Project Plan [4,5]. The QAPP is comprised of standardized, recognizable components covering the entire project from planning, through implementation, to assessment. These subjects are presented and have been arranged into four basic element groups. The four groups and their intent are summarized as follows:

a. Project Management. Addressing the basic area of project management, including the project history and objectives, roles and responsibilities of the participants, etc. and ensuring that the project has a defined goal, that the participants understand the goal and the approach to be used, and that the planning outputs have been documented.
b. Data Generation & Acquisition. Addressing all aspects of the project design and implementation. Implementation of these elements and ensuring that appropriate methods for sampling, measurement, and analysis, data collection or generation, data handling, and QC activities are employed and are properly documented.
c. Assessment & Oversight. Addressing the activities for assessing the effectiveness of the implementation of the project and associated QA and QC activities and ensuring that the QA Project Plan is implemented as prescribed.
d. Data Validation & Usability. Addressing the QA activities that occur after the data collection or generation phase of the project is completed and ensuring that the data conform to the specific criteria, thus achieving the project objectives.

Table 1 outlines the twenty-four elements of the four groups of the QA Project Plan.

The QA Project Plan is developed using a systematic planning process based on the graded approach. This “graded approach” is based on a common sense method that establishes QA and QC activities commensurate with the importance of the work, the availability of resources, and the unique needs of the organization. Therefore, QAPPs will vary in their complexity and length of details as is required to describe the project’s objectives.

Results and Discussion

The QAPP is implemented and the experiment started. After the completion of the experiment, a Data Quality Assessment (DQA)[6] is performed on the data from the environmental data operations of the project. This process is a scientific and statistical evaluation of the data to determine its value as to its intended use and also the potential future use of the environmental data operations of the project. In the first case, the immediate value of the data can be assessed to enable a decision maker the confidence of a decision based upon clearly defined data. In the second case, future investigations based on this data might be considered and the use of parts of the QA Project Plan (e.g., sampling design, analytical methods, detection limits, etc.) might be evaluated in

relationship to the findings of the assessment. A properly executed DQA will provide valuable confirmation of the purpose and decisions resulting from the project and validation of the project's applicability in future decision making needs.

The need for comprehensive, systematic documentation of the processes and procedures used in the strategic planning, sample collection, sample extraction, sample analysis, data reduction/ tabulation, and data utilization in the investigation of polychlorinated dibenzo-p-dioxins (PCDDs), -furans (PCDFs), and co-planar biphenyls (PCBs) is vital. Without an adequate QA Project Plan, there may be little or no documentation of the history and details of the project and the significance of the findings of a project may be jeopardized, resulting in additional cost, lost time, and reduced data usefulness or possible data uselessness.

These quality assurance documents can be obtained from the Quality Staff of the Office of Environmental Information, United State Environmental Protection Agency Website: www.epa.quality.

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Disclaimer: This paper reflects the views of the authors and does not necessarily reflect the views of the Environmental Protection Agency and no official endorsement should be inferred. The mention of trade names or commercial products constitutes neither an endorsement nor a recommendation of use.

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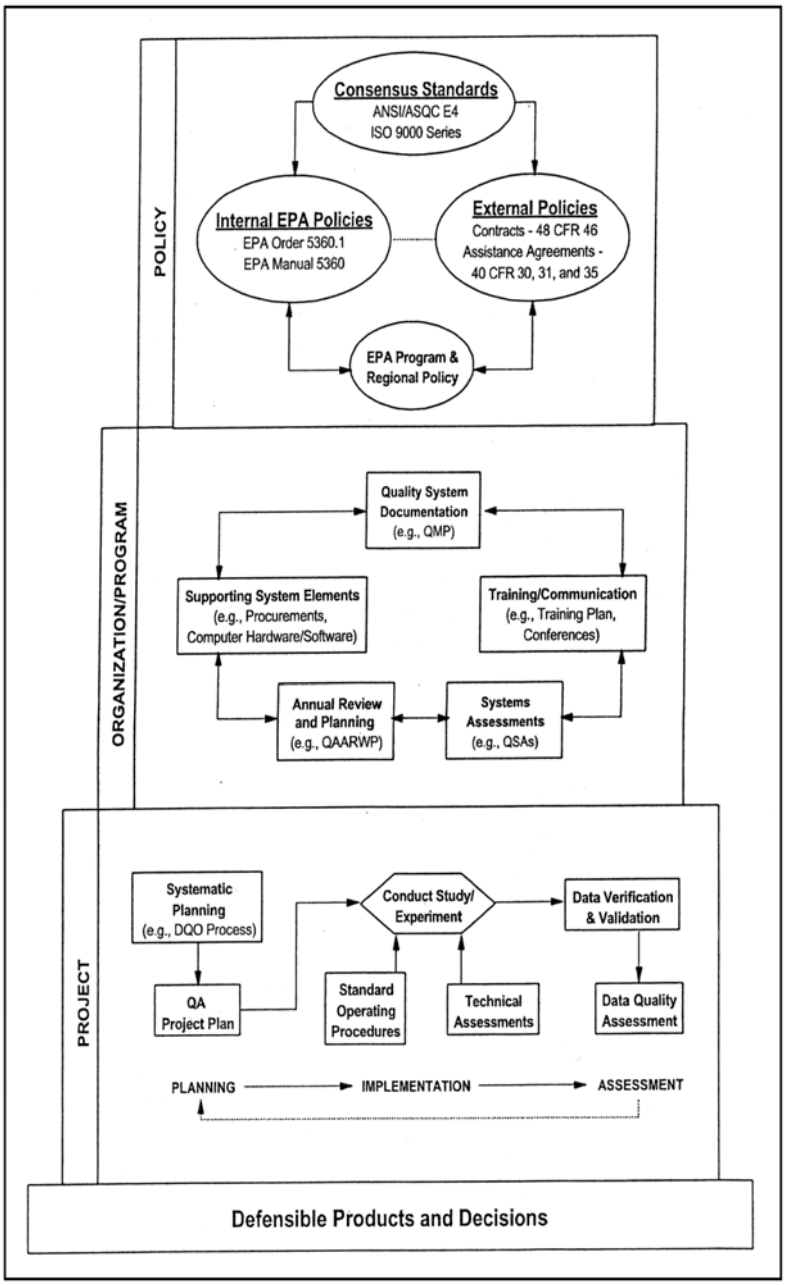

Figure 1. EPA Quality System Components and Tools

Table 1. Elements of the QA Project Plan

Group A:	Project Management Elements
A1	Title & Approval Sheet
A2	Table of Contents
A3	Distribution List
A4	Project/Task Organization
A5	Problem Definition/Background
A6	Project/Task Description
A7	Quality Objectives and Criteria
A8	Special Training/Certification
A9	Document & Records
Group B:	Data Generation & Acquisition Elements
B1	Sampling Process Design (Experimental Design)
B2	Sampling Methods
B3	Sample Handling and Custody
B4	Analytical Methods
B5	Quality Control
B6	Instrument/Equipment Testing, Inspection, & Maintenance
B7	Instrument/Equipment Calibration and Frequency
B8	Inspection/Acceptance of Supplies and Consumables
B9	Non-direct Measurements
B10	Data Management
Group C:	Assessment & Oversight Elements
C1	Assessments and Response Actions
C2	Reports to Management
Group D:	Data Validation and Usability Elements
D1	Data Review, Verification, and Validation,
D2	Verification and Validation Methods
D3	Reconciliation with User Requirements