UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

July 24, 1998

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OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

Honorable Carol M. Browner
Administrator
U.S. Environmental Protection Agency
401 M Street, SW
Washington, DC 20460

Subject: Science Advisory Board Review of the Agency-Wide Quality Management Program

Dear Ms. Browner:

In response to a request from the National Center for Environmental Research and Quality Assurance (NCERQA) of EPA's Office of Research and Development (ORD), the Environmental Engineering Committee (EEC) of the Science Advisory Board (SAB) reviewed the Agency-wide Quality Management System in Washington, DC on April 27-29, 1998.

The Committee believes that the Agency should be complimented for developing its Quality Program and the precedent-setting work performed by the Quality Assurance Division (QAD) including:

a) The updating of policy, which further defines the Agency's policy and requirements for the preparation and implementation of quality management systems;

b) The generation of widely accepted project-level guidance and requirements for data collection activities;

c) A successful outreach and training effort regarding quality in the data collection process; and

d) The use of the peer-review process, which has undoubtedly contributed to the quality of its guidance and requirement documents.

The Subcommittee also found issues that require the attention of the Agency's management such as:

a) The need to include all activities, which have the potential to affect the quality of the Agency's products and services, under the auspices of the Quality System;

b) The need for Agency management to review the appropriateness of the reporting status of the Quality System function within the Agency organization. The Subcommittee recognizes that this recommendation is of a policy nature. However, the Subcommittee believes this recommendation is justified due to the impact of reporting status on the efficacy of the Quality System;

c) The lack of an Agency-wide focal point for quality issues and needed corrective actions;

d) The need for Quality System training to be expanded to include the training of senior management;

e) The need to identify metrics for "bench marking" existing levels of quality and changes over time;

f) The need for guidance appropriate for the development and use of mathematical/computer models and the associated data; and

g) The need to determine if budgeted resources for QAD are sufficient to meet the increased demand for its services.

These findings and others are discussed in more detail on the following pages.

The QM review consists of three parts. The first part addresses the first two levels of the EPA's Quality System (Policy & Organization). The second part examines the third level of the Agency's Quality System (Project). The first two parts were addressed during the April meeting and are summarized in this letter. The third part of the review, which is tentatively scheduled for September 1998, will consider implementation of the Quality System. A more detailed charge is presented in Appendix A.

As part of the review, QAD and its management gave a detailed description of its past, present and planned activities. The Subcommittee was impressed with the high-level of professionalism, knowledge and obvious dedication of the QAD Staff, yet not surprised in light of the significant and positive impact this small group of scientists has had not only across the Agency but across other Federal agencies and the regulated community.

1. Part 1 -- Policy & Organizational Component Levels of the Agency's Quality System

The first part of the review focused on relevance, completeness and practicality of the Agency's quality policy as defined in EPA Order 5360.1, the Quality Manual and the organizational components designed for policy implementation as described by the Agency's Quality System (EPA QA/G-0).

a) Relevance

(1) The Subcommittee found the proposed revision to Order 5360.1 and the requirements in the Quality Manual to be relevant to the achievement of Agency goals. These documents establish a quality assurance (QA) management structure which encourages Agency personnel and recipients of EPA funding to collect data of known and sufficient quality adequate to support the decisions for which the data were collected.

(2) The Subcommittee found the existing organizational component guidance (EPA QA/R-2 - Quality Management Plans and EPA QA/G-3 - Management System Reviews) to be relevant to the achievement of Agency goals and to the control of certain activities specified by the Quality Manual. Documentation for the training component is not yet available, but as outlined during the review by QAD personnel and as implemented in QAD's existing training programs, the training component should be relevant to the successful implementation of the Quality System.

(3) The Subcommittee recommends that EPA periodically review the policy and associated organizational components to determine whether they remain relevant and, if necessary, revise them. QAD staff noted that documents are now issued with a five year "sunset" provision which requires documents to be either reissued, revised or revoked.

(4) The Agency's mission statement contains two responsibilities, protection of human health and safeguarding the environment, which are not clearly

reflected in EPA Order 5360.1. While the Agency's work culture and practices may include "health" under "environment", the outside reader has no way of understanding this integration from the Agency's Quality System documentation. Because health protection is a major responsibility of the Agency, the Subcommittee recommends that the inclusion of health data in the Quality System be clearly stated and visible throughout all quality system documentation.

b) Completeness

(1) The overall success of the Agency's Quality System will depend upon oversight of all pertinent activities with the potential to affect the quality of the Agency's services and products. Agency policy (as defined by 5360.1) and the Quality Manual focus on environmental measurement programs. Neither document identifies the universe of Agency activities that need to be monitored under the Agency's quality system. This may result in spotty coverage of quality issues.

The Subcommittee recommends that the Agency: (a) identify all Agency services and products; (b) identify all activities critical to the quality of these services, products and the achievement of Agency goals; © identify which of these activities are presently subject to the auspices of the Agency's Quality System; and (d) identify any remaining activities that are not presently covered by the Quality System (e.g., models) and modify the Policy and requirements to incorporate the activities under the auspices of the Quality System. (Refer to Figure 1 for a graphical depiction of covered and non-covered activities.)

(2) The Quality System documentation lacks an organizational chart detailing the formal authority, responsibility, reporting and communication lines that must be understood across the Agency to ensure success of the Quality System. The Subcommittee recommends that the role of the QAD and any other organization responsible for the Quality System be explicitly portrayed in Agency documents such as the Quality Manual and EPA QA/G-0.

(3) The Subcommittee recommends that the Quality System policy require development of metrics for "bench marking". Qualitative, and where possible quantitative, metrics will establish existing levels of quality and

identify changes in quality over time. Such metrics could be used across the Agency to measure understanding of, and commitment to, the Quality System.

(4) The quality system organization/program appears to be conceptually complete. One key organizational component, the training guidance, is not yet final and was not reviewed. The Subcommittee suggests that QAD develop a comprehensive training strategy with effective target audience, needs assessment and evaluation components to ensure the ongoing success of the training program. Regarding the presently incomplete training guidance, the Subcommittee recommends that, when complete, the training documentation address the training of senior managers since their understanding of the Quality System and their role are key to its success.

(5) The Subcommittee recommends that QAD update its mission statement and clearly identify its customers. The Subcommittee believes this will allow QAD to appropriately allocate its resources as demand for its services increases as well as make QAD's role more clearly understood within and outside of the Agency.

c) Practicality

(1) The success of the Quality System is, in part, dependent upon access to the proper level of authority by those who lead the QA management efforts. The Subcommittee believes that the Agency's organization does not appropriately accommodate this Quality Management need, since the first presence of a Quality Management function within the Agency occurs at the 4th or 5th tier. The Subcommittee recommends that: (a) the Agency identify a lead Quality Management organization; (b) incorporate the Quality Management organization at an elevated position within the Agency's organization such that it would have the appropriate level of authority; and © define the senior management position for the Quality Management organization such that it would be free from the turnover of appointed positions. The Subcommittee recognizes that this recommendation is of a policy nature. However, the Subcommittee believes this recommendation is justified due to the impact of reporting status on the efficacy of the Quality System.

(2) The Policy does not identify an Agency-wide focal point for quality issues and needed corrective actions that could be approached by both those internal and external to the Agency. For example, during its review, the Subcommittee examined a letter, which alleged that proposed regulatory standards may have been based on poor-quality data. After reviewing this letter, the Subcommittee could not identify an Agency organization having the authority to investigate such quality issues and initiate corrective actions.

(3) Although the revised EPA Order 5360.1 designates QAD as the "central management authority", section 7.a.(1) limits this authority to four requirements the development of training, management assessments, QMP review and approval and review and revision of Quality System policy. As a consequence, QAD's role is ambiguous and needs to be clearly defined.

(4) The external pressures for increased quality, growing acceptance of existing QAD requirements and guidance, and the planned release of new guidance documents will increase demands on the already oversubscribed QAD staff. Due to QAD's critical role in the Agency's Quality System, the Subcommittee recommends that the Agency consider whether sufficient resources are available. Among other critical responsibilities, QAD must support the Performance Based Measurement System (PBMS), use of secondary data, training and management system reviews.

(5) The QAD implemented Management System Reviews (MSRs) have offered both a front line perspective and a metric of how the Quality System has been implemented. MSRs have detected inconsistent implementation across the Agency's regions and program offices and have also uncovered issues that influence successful implementation (e.g., the management levels to which Quality Assurance Managers (QAMs) report). The Subcommittee recommends that the Agency investigate whether more frequent use of MSRs would facilitate acceptance of the Quality System.

(6) The policy specified reporting structure and authority for quality assurance managers (QAM) are vague. QAMs are most effective when they report to the highest career professional in an organization. EPA

does not appear to apply this finding to policy or practice. To improve the overall Quality System, the Subcommittee recommends that EPA rewrite the Quality Management Plan (QMP) requirements document (EPA QA/R-2) to reflect this and other findings (e.g., the need for QAM backup to prevent disruptions resulting from QAM travel or vacations).

2. Part 2 -- Review of the relevance, completeness and practicality of the Agency's project-level requirements and guidance for data collection activities

The second part of the review focused on the relevance, completeness, and practicality of the "project" level of the Agency-wide Quality System as defined by existing requirement and guidance documents (G-4, R-5, G-5, G-6 and G-9) and future activities and planned documents as described by the QAD staff.

a) Relevance

(1) The Subcommittee found the existing project-level requirements and guidance (G-4, R-5, G-5, G-6 and G-9) and the planned guidance (G-7 and G-8) to be relevant to the achievement of Agency goals. These documents establish project level guidance that encourages Agency personnel and recipients of EPA funding (including contractors, researchers, state and local agencies, and Tribes) to collect data of known and sufficient quality adequate to support the decisions for which the data were collected.

(2) The Subcommittee encourages QAD to continue its plans to develop program and matrix specific guidance such as QA-G4HW. The pedagogic value of these guidance documents will highlight the relevance of the planning process to specific programs and facilitate acceptance of the Quality System.

b) Completeness

(1) The existing and planned project-level requirements and guidance provide a comprehensive blueprint for the planning, implementation and assessment of the data collection operation.

(2) According to Agency policy, the Quality System covers data collection activities and the design, construction and operation of environmental

technology. Pertinent guidance does not now exist for technology. QAD plans to develop guidance for environmental technology (G-12) based on existing US Army Corps of Engineers guidance. The Subcommittee agrees that this is a logical approach to the development of guidance and urges QAD to obtain peer review of this guidance document as was done with the previous documents.

(3) The Agency's plans for defining quality system requirements and guidance for the review and use of mathematical and computer models are unclear. Over time the Agency has increased the use of models to "generate" data and in some cases the results are used for regulatory purposes. In 1992 the Agency Task Force on Environmental Regulatory Modeling (ATFERM) developed guidance for conducting external peer review of regulatory models.

Recently, EPA hosted the Models 2000 conference and established an internal Committee on Regulatory Environmental Modeling (CREM) under the direction of the Agency's Science Policy Council (SPC).

The SAB also finds modeling to be an important issue. The SAB has long been interested in the scientifically appropriate use of models at EPA. In 1989 the SAB issued the Resolution on the Use of Mathematical Models by EPA For Regulatory Assessment and Decision-making (EPA-SAB-EEC-89-012), in 1993 it reviewed Draft Agency Guidance for conducting External Peer Review of Environmental Regulatory Modeling (EPA-SAB-EEC-LTR-93-008), and in the last five years the SAB has reviewed several models for EPA. SAB members participated in the Models 2000 workshop and the Environmental Models Subcommittee (EMS) of the SAB's Executive Committee is presently investigating the Agency-wide use of models and the use of data generated from the models.

At this time, QAD is unsure about how to incorporate models into the Quality System. The Subcommittee recommends that models and model-generated data be covered by the Agency's Quality System in accordance with the Quality Manual (page 1-3 Section 1.3.1) and the new draft order 5360.1 (p. 3 Section 5b(3)) and in a manner, that is specific and appropriate for computer/mathematical models and associated data. In

developing guidance for models and model-generated data, QAD may wish to consider the ATFERM and existing SAB guidance on model use and peer review. Such documents may help because they were written with the intent of having models provide "quality" information. QAD will also find it helpful to consider the activities and reports of the SAB's new Environmental Models Subcommittee.

(4) The Subcommittee recommends that guidance for Step 3 of the Data Quality Objective (DQO) planning process be rewritten to address the problem of linking EPA-generated data bases with externally generated data bases. For example, answering many health-related questions frequently requires linking environmental data with census, cancer or birth defect registry data, or other data systems (such as water distribution maps) to determine whether there is a relationship between the environmental measurements and health. Without identifying some mutually-agreed linking variable (perhaps latitude-longitude, block number, etc.) or strategy, critical questions cannot be answered regarding health, risk assessment and standard-setting. It is imperative that the linking issue be addressed in the planning stage so all parties will be aware of what needs to be done or can't be done to link data systems. This early consideration will reduce the probability of later frustration and dissatisfaction.

(5) The intent of the DQO planning process is to be inclusive regarding key stakeholders. The Subcommittee recommends that the next revision of Step 1 of the G-4 guidance acknowledge that many projects will have multiple stakeholders. As a result many questions need to be addressed collectively and when possible consensus built before data are collected. The revised guidance needs to assist staff in identifying the appropriate range of stakeholders, discuss the potential need to obtain acceptable answers to more than one question and discuss how quality is not bargained away by proceeding with a consensus-based plan.

c) Practicality

(1) The Subcommittee finds that the structural form of QAD's project-level guidance is an appropriate and practical consequence of addressing the policy and program requirements set forth in ANSI/ASQC E-4.

(2) The Subcommittee finds the structured planning process, the detailed documentation of its outputs in a Quality Assurance Project Plans (QAPP), and the mandatory requirement that all QAPPs be approved by the Agency prior to project initiation provides confidence that all pertinent data collection issues have been addressed.

(3) The Subcommittee recommends that revised guidance require that, where the DQO process was not employed, the QAPP discuss how the objectives were identified.

(4) QAD has been a leader in defining terminology and thus improving communications about data collection activities. The Subcommittee suggests two areas for further improvement:

(a) First, due to the increasingly multi-disciplinarian audience for QAD documents, it would be helpful, when possible, to employ more universally understood terms or in those many cases when a term having more than one meaning (e.g., population, stakeholder, sample) must be employed that it be defined within the document.

(b) Second, minimize the unnecessary use of synonymous terms so that the reader will not incorrectly assume additional levels of complexity (For example, the trail from DQOs to the documentation of Data Quality Indicators in a QAPP is littered with terms such as quality objectives, quality standards, quality criteria, criteria for measurement criteria, quality control, quality control requirements, QC procedures, acceptance criteria, measurement performance criteria and PARCC.).

The Subcommittee commends the NCERQA and QAD management for their commitment to quality improvement as evidenced by their request for a review of the Agency-wide Quality Management Program. The Subcommittee recognizes the importance of the Agency's Quality Management Program and QAD's role in developing the Quality System to its present state. The Subcommittee believes the Agency has benefitted greatly from the dedicated efforts of the QAD staff and that further benefit could be obtained by increasing support for more of the same type of effort.

The above findings and recommendations reflect an appreciation for the significant contributions made towards the quality of data collection activities while recognizing that the job

is not nearly done. Continued and increased attention from senior management is needed to implement the Quality System uniformly to all activities on an Agency-wide basis.

We look forward to your response to the advice contained in this report.

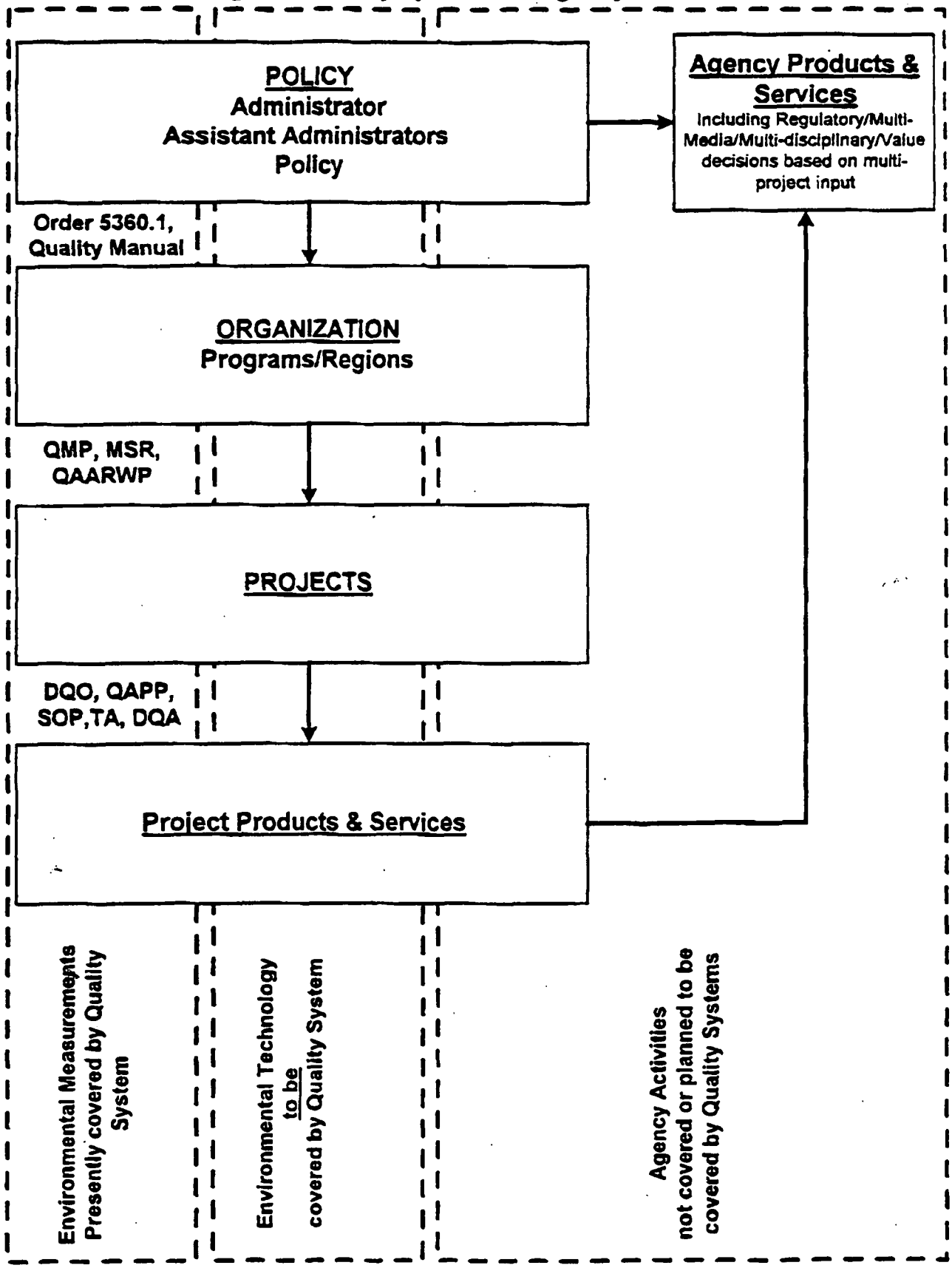
Sincerely,

Dr. John Maney, Chair
Quality Management Subcommittee
Environmental Engineering Committee

Dr. Hilary Inyang, Chair
Environmental Engineering Committee
Science Advisory Board

Dr. Joan Daisey, Chair
Science Advisory Board

Figure 1. Quality System and Agency Activities



APPENDIX A -- Proposed Charge for QM Review

The QM review consists of three parts. The first part addresses the first two levels of the EPA's Quality System (Policy & Organization). The second part examines the third level of the Agency's Quality System (Project). (Refer to Figure 0-2 of EPA QA/G-0 for a depiction of the 3 Quality System levels and Section 1.3 of the Quality Manual for covered activities.) The third part of the review will consider implementation of the Quality System. This review also ties the QM review in with EPA's mission statement and goals, a driver that should be behind all Agency activities.

1. A Proposed Charge for Part I of the Quality Management Subcommittee Review -- To evaluate the relevance, completeness, and practicality of the "policy" and "organizational" components of the Agency-wide Quality System.

   a) Relevance: Evaluate whether the "policy" and "organizational" components of the Agency's Quality System are applicable to the Agency's mission statement, goals (EPA/190-R-97-002) and those activities identified in Section 1.3 of the Quality Manual.

   b) Completeness: Evaluate whether the "policy" and "organizational" components of the Agency's Quality System are structured such that the quality of all Agency activities needed to comply with the Agency's mission statement and goals will be monitored and assessed versus performance measures.

   c) Practicality: Is the present structure of the "policy" and "organizational" components of the Agency's Quality System designed for success (i.e., will the policy and organizational levels of the Quality System properly assess and control pertinent activities and facilitate achievement of EPA goals).

2. A Proposed Charge for Part II of the Quality Management Subcommittee Review -- To evaluate the relevance, completeness, and practicality of the "project" level of the Agency-wide Quality System.

   a) Relevance: Evaluate whether the "project" level of the Agency's Quality System is applicable to the Agency's mission statement and goals (EPA/190-R-97-002) and the covered activities identified in Section 1.3 of the Quality manual.

   b) Completeness: Evaluate whether the "project" level of the Agency's Quality System is structured such that of all project activities needed to comply with the

Agency's mission statement and goals will be monitored and assessed versus performance measures. Evaluate whether the project level guidance documents consider all essential aspects necessary to monitor and measure the quality of environmental measurement data.

c) Practicality: Is the present structure of the "project" level of the Agency's Quality System designed for success (e.g., are they cost-effective, efficient to implement, understandable by the intended audience, will the project level of the Quality System facilitate achievement of EPA goals).

3. A proposed charge for Part III of the Quality Management Subcommittee Review -- To use available information to evaluate the Agency's success in implementing the Agency-wide Quality System.

U.S. ENVIRONMENTAL PROTECTION AGENCY
Science Advisory Board
Environmental Engineering Committee
Quality Management Subcommittee
July 21, 1998 Meeting

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