EPA

Office of Wastewater Management Common Sense Guide to Quality Management

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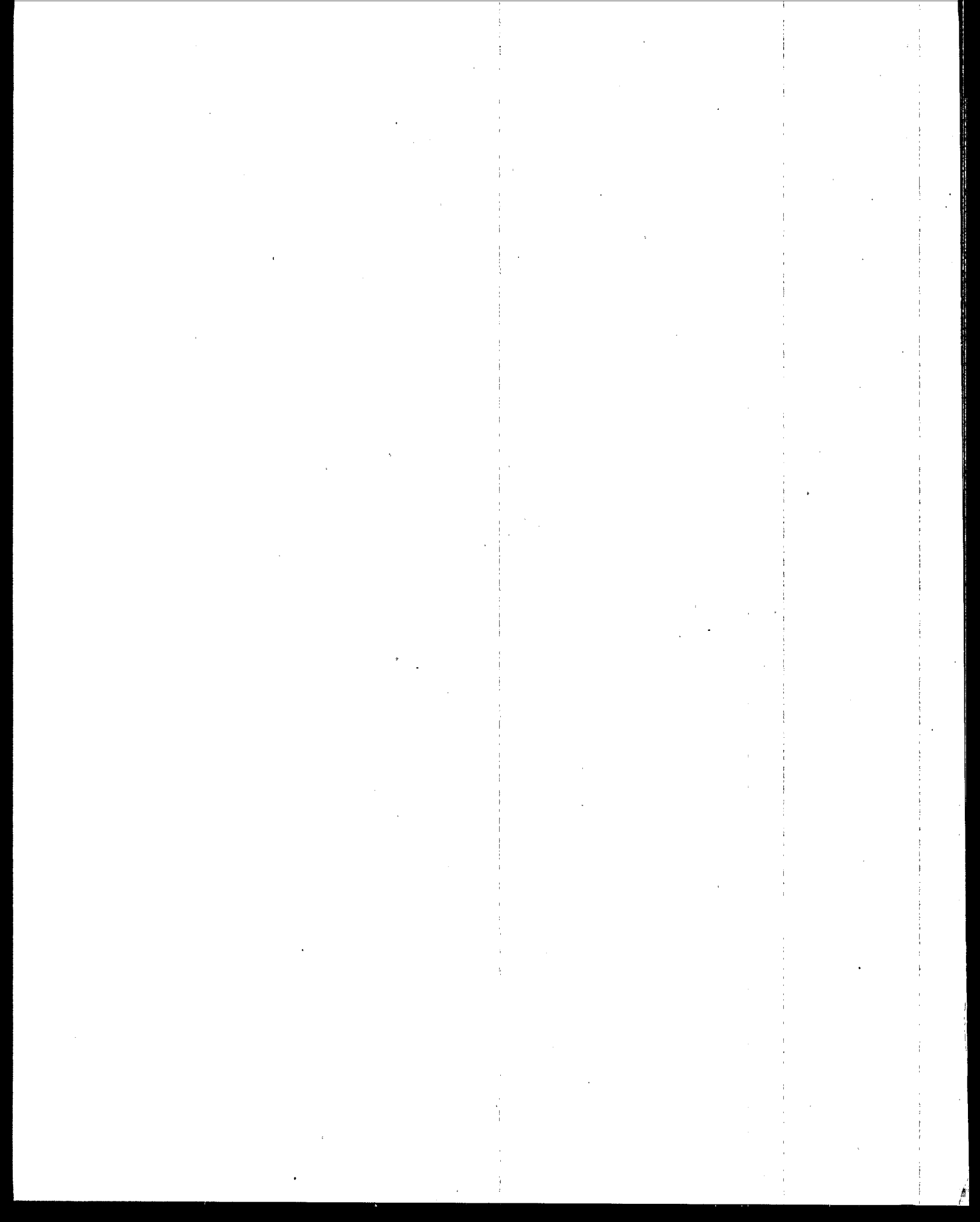QM

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PILOT TEST DRAFT: July 2000

Office of Wastewater Management
Common Sense Guide to
Quality Management
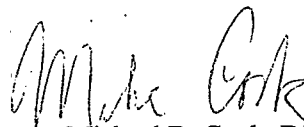
Foreword

The U. S. Environmental Protection Agency (EPA) has an Order 5360.1 CHG 1, July 1998, entitled *"Policy and program requirements for the Mandatory Agency-Wide Quality System"*, directs that all Agency organizations to develop and implement a quality system to support its mission and that conforms to requirements in the Order and in applicable extramural agreement regulations. All Offices within EPA must comply with this order.

As part of the Office of Wastewater Management's (OWM's) commitment to providing high quality products and complying with this order, we have developed a guide that provides a common sense approach to quality management for managers and staff. This guide contains examples from OWM's ongoing activities showing how they can be improved by adhering to sound principles of quality management. The guide also contains check lists that if followed should help individuals provide improved management of the quality of their activities. These check lists should also help document these activities in a manner that is not overly burdensome.

We hope that you will use this guide to improve the quality of all your activities and encourage your feedback so that we might improve the usefulness of this document in the future.

Michael B. Cook, Director
Office of Wastewater Management

Acknowledgments

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Chapters

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Chapter 1

Purpose and Overview of the Guide

Applies to Virtually All Office of Wastewater Management (OWM) Activities

This *Common Sense Guide to Quality Management* is for OWM managers and staff. It provides simple, clear guidance on how each person can use quality management (QM) principles to improve his or her work. It also provides practical, straightforward guidance on how to comply with the U. S. Environmental Protection Agency (EPA) and the Office of Water (OW) quality assurance policies and how to document the steps taken to achieve quality outputs. The procedures provided in this guide apply to virtually all OWM activities. These activities include, but are not limited to:

- Developing policies
- Developing regulations
- Developing and using database management systems
- Evaluating technologies
- Preparing strategies
- Sampling and analysis activities
- Managing primary or secondary data
- Office or Division-level strategic planning
- Preparing fact sheets
- Preparing guidance documents
- Preparing briefing documents
- Preparing scientific documents or documents for the public
- Preparing reports for Congress
- Preparing correspondence for your signature or that of management, and
- Serving as project officer, task manager, or work assignment manager for contracts or grants

What Is Quality Management?

Quality management (QM) can be thought of as an organization's "culture" with respect to managing the quality of its products. More specifically, it is that aspect of OWM's overall management system that determines the requirements for quality up front and implements the policies and procedures needed to ensure that the quality requirements for its products are continuously met. OWM's commitment to quality management includes:

- Development of policy regarding quality,
- Development of this guidance, and
- Commitment of funds to train staff and implement quality management.

Quality management as outlined by Deming's[1] Total Quality Management model is to *Plan – Do – Check and Act*.

- *Planning* – Define the quality requirements as well as all other project requirements up front including objectives and goals, budget, schedule, milestones, and work product application.
- *Doing* – Implement the project with the appropriate documentation and document control for quality assurance; including other critical quality management implementation requirements such as roles/responsibilities, training, communication, operational procedures/protocols and contingency.
- *Checking* – Periodically measure progress and evaluate conformance with requirements, including quality requirements of the project; take corrective and preventive actions as required to meet project quality requirements.
- *Reviewing* – At the end of the project, review how well the quality requirements were satisfied, apply lessons learned to continuously improve the quality management of future projects.

> **A COMPANY CAN NOT BUY ITS WAY INTO QUALITY – IT MUST BE LED INTO QUALITY BY TOP MANAGEMENT – Deming**

Quality assurance (QA) can be thought of as the entire set of management strategies, controls, and activities used to deliver a product that meets user expectations regarding quality. Quality control is no longer used in modern

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[1] Deming, W.E. Out of Crisis, MIT Center for Advanced Educational Services, Cambridge, MA, 1986.

quality management systems because of its negative connotations. As used historically, quality control assumed that a certain level of defects (mistakes and errors) were unavoidable and needed to be caught at the end of the factory, project, etc. Today the quality control concept has been replaced with quality management and quality assurance that defines quality requirements up front and manages the quality throughout so quality requirements are met at the end. Quality assurance measures and checks are used throughout and at the end to provide this assurance.

The purpose is not to ensure OWM staff can recite quality definitions, rather

> ## THE PURPOSE OF THIS GUIDE IS TO HELP OWM MANAGERS AND STAFF IMPROVE THE QUALITY OF THEIR WORK.

What Level of Effort Must I Use to Obtain the Quality Needed for Each Activity?

The level of effort needed to control quality depends on the project's purpose, complexity, and nature.

In general, the highest level of quality is needed for those work products that (1) support regulatory decisions, (2) will have widespread use or widespread impacts, (3) are highly innovative in approach or design, (4) involve the work of multiple organizations, or (5) span many months or years. Another way of saying this is that the activities required to control quality are likely to be more intense if your project fits any of these criteria.

Lower quality would likely be acceptable for an E-mail note. In this case, the note sender would need to think about what he or she is saying in the note, and would likely provide the only review.

What is Quality?

It is important to say a bit more about what quality is before proceeding with a discussion of the tools that are useful for achieving quality. A dictionary definition of quality is the "degree of or grade of excellence." Another definition is conformance with requirements.

Chapters 2 and 3 of this guide provide a series of procedures and tools to help make and implement the determination of the degree of excellence or quality needed, i.e., the quality requirements for any given effort.

What's in the Rest of the Guide?

Documentation Checklists

Chapter 4 of this guide provides a documentation checklist and a straightforward discussion of simple, effective ways OWM staff can document their QM activities without adding cumbersome paperwork. Examples of QM documentation in actual OWM projects are provided in Appendix C.

Primary and Secondary Data Management

This document also suggests approaches for managing different forms of data that normally are used to develop OWM work products. It will, by example and reference, discuss ways of managing the quality of *primary data* (original new data gathered by or for the project manager to address specifically an issue

at hand) and, similarly, it will discuss the management of *secondary data* (data that were originally gathered by others for one purpose that are now being used by the project manager, his or her contractor or grantee for a different, or secondary, purpose). Examples that illustrate how QM has been applied to different projects and different forms of data within OWM are included in Chapter 5 of this Guidance.

Questions and Answers

Answers to commonly asked questions regarding QM are provided in Chapter 6.

References to QM

A list of suggested references is provided in Appendix A for those readers who wish to learn more about QM.

Peer Review Policy

EPA has a Handbook on Peer Review (EPA-100-B-98-001). Important parts of the Agency's Peer Review policy are provided in Appendix B.

An Example Documentation File

An example Documentation File comprises Appendix C.

Finally, this guidance provides a straightforward discussion of the steps needed to comply efficiently and effectively with EPA and Office of Water (OW) QA policies.

This Document Is Meant to be Dynamic

This is a dynamic document intended to provide you with up-to-date information and examples that will help you and other OWM staff implement QM strategies in your daily activities. Therefore, we strongly encourage you to provide feedback and examples of QM to your QA Coordinator for inclusion in future updates to this guide.
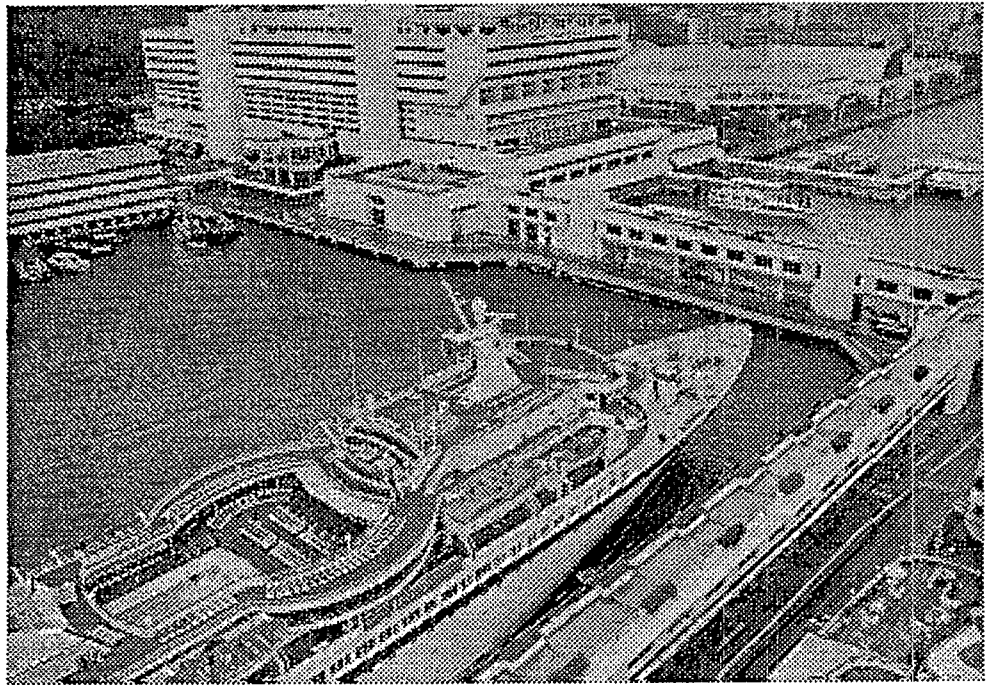
Chapter 2

Quality Tools

Stages of a Quality Management Effort

Stages of QM that should apply to any OWM activity or effort include:

- planning the effort
- determining the quality requirements
- producing the product
- assuring that the product meets the quality requirements
- documenting how the quality was assured

Several tools are available to aid OWM staff in ensuring that the desired results are achieved. These tools, which are summarized below, may be used by themselves or in combination with others, depending on the nature, size, importance, and visibility of the project. Additional information about these tools can be found in the sources cited in the footnotes and the remainder of this Chapter. Chapter 3 describes more fully the application of these QM tools to OWM projects.

Introduction to Quality and Peer Review

Two of the most useful tools to define, ensure, and improve the relevance and quality of your work products are quality review and peer review. The phrase "quality review" has been used in this guide in addition to the phrase "peer review" to facilitate a more comprehensive description and thorough understanding of the steps that you can take to meet needed quality goals.

Quality Review
Quality review entails the use of knowledgeable individuals to assist in determining, for all OWM work products and processes, the relevance to customer needs and the level of quality needed, and later, to evaluate the work product to determine if the level of quality is being obtained. Quality review, as it is defined

in this guide, includes both technical or nontechnical review and input by all stakeholders in OWM activities.

Peer Review

Peer review is a more formal Agency process that uses technically qualified peers (persons of equal or greater skill to your own) to ensure independently the quality of all major, technical work products (the criteria for "major" products are listed on Pages 2.4 and 2.5.)

Exhibit 1 highlights the similarities and differences between quality and peer concepts. Additional descriptions are provided below.

Exhibit 1
Quality Review vs. Peer Review

Quality Review	Peer Review
★ Can be performed at any phase of a project?	★ Can be performed at any phase of a project?
★ Involves active outreach to and participation of scientific and technical experts inside and outside EPA	★ Involves active outreach to and participation of scientific and technical experts inside and outside EPA
★ Reviewers may or may not be independent of the work product	★ Reviewers are independent of the work product
★ Recommended for all work products or activities	★ Required for all "major, technical work products" (defined on pages 2.4 & 2.5.)
★ In-depth assessment of the quality objectives, quality strategies, or final product associated with the project	★ In-depth assessment of assumptions, calculations, extrapolations, alternate interpretations, methodology, acceptance criteria, and conclusions pertaining to the work product
★ Non-technical stakeholders may be used to evaluate if a work product is clearly presented and meets user needs.	★ Most peer reviewers are technical experts
★ The focus is on planning, monitoring, and/or evaluating quality	★ The focus is to ensure that activities are technically adequate, competently performed, properly documented, and satisfy established quality requirements.

Implementing Quality Review

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Exhibit 2
Implementation of Quality Review

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At the beginning!

A quality review of planned activities is especially important <u>at the beginning</u> of the activity. It helps determine:

1. The appropriateness and relevance of the task. *If the planned task is not relevant, change it so that it is or do not do it.*

2. The quality requirements for each of the activities required during the project.

3. The ability to meet the quality requirements, given the resources and time available.

4. What to do if the quality needed is greater than available resources allow: *(i) change the approach which might include ways to leverage and/or change the level of resources; (ii) tell managers that the level needed cannot be attained and identify what level can be attained with what shortcomings, or (iii) do not do the task.*

In the middle!

Quality review by peers <u>during the task</u> will help assure that the level of quality you determined was necessary and possible is being attained. When coupled with peer input, it also can provide an opportunity to obtain suggested midstream corrections to address unforeseen problems. (<u>Note</u>: Although this is a helpful strategy in some projects, please remember that any consolidation of peer input and quality review functions during project implementation may preclude the quality reviewers from serving as independent peer reviewers of the final product). This could result in project delay or retraction.

And at the end!

Quality review <u>at the completion</u> of the final draft of a report or project further helps ensure that a relevant quality product has been attained and may also be useful in interpreting peer reviewers' comments.

More About Quality Review

Quality Review Involves Peer and/or Stakeholder Input and Consultation
Quality review during the planning, development, and at the completion of a project requires the assistance of recognized, qualified peers who also adequately represent stakeholder concerns. This consultation or input of peers during the development of an evolving Agency work product, which also includes

the open exchange of data, insights, and ideas, is sometimes referred to as peer input or peer consultation.

- A good example of peer input is the input received from workgroup members during development of a product. These workgroup members have an active, ongoing participation in developing the work product.

- Another example of peer input is that received from stakeholder representatives who have been asked for general comments on a draft work product by an OWM project manager. (Stakeholder representatives often include experts who could be considered "peers.")

- Peer input or peer consultation can be thought of as a subset of the quality review process.

Eligibility of Quality Reviewers for Peer Review
Peers or stakeholders who provide active ongoing input and participation during the development of a work product <u>are not</u> eligible to undertake a peer review of that work product because of their lack of independence from its development.

More About Peer Review (See also Appendix B).

Peer review is an essential Agency requirement for review of technical products and the *scientific and technical* aspects of *major* products. This documented critical review is conducted to ensure that activities are technically adequate, competently performed, properly documented, and satisfy established quality requirements. The peer review is an in-depth assessment of the assumptions, calculations, extrapolations, alternate interpretations, methodology, acceptance criteria, and conclusions pertaining to the specific major scientific and/or technical work product and of the documentation that supports them.[2]

Peer review is a critical and, most often, final evaluation of the work product. Like quality review, it may also be used as an interim evaluation of a work plan, preliminary draft or the like, and it constitutes active outreach to and participation of the broad scientific, engineering, and economics communities external to as well as within the Agency.

Major Product
The determination that a scientific or technical product is *major* is based on consideration as to whether it meets at least one of the following criteria:

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[2] Defined in the *Science Policy Council Handbook for Peer Review*, EPA\100-B-98-001, January 1998.

- Does it support major regulatory decisions or policy/guidance of major effect?
- Does it establish a significant precedent, model, or methodology?
- Does it address controversial issues?
- Does it focus on significant emerging issues?
- Does it have significant cross-Agency/inter-Agency implications?
- Does it involve a significant investment of Agency resources?
- Does it consider an innovative approach for a previously defined problem/process/methodology?
- Does it satisfy a statutory or other legal mandate for peer review?

The Assistant Administrators and Regional Administrators are the ultimate decision makers and are accountable for implementing Peer Review Policy within their organizations. They may designate Office directors and Division Directors of other appropriate level line-managers as the front line decision makers. The principal agency staff are decision makers and their line-managers – peer review leaders, and peer review coordinators and certain staff within ORD. The decision makers decide whether a work product is major and needs peer review, and what peer review mechanism to use. They also commit resources and ensure that peer reviews are properly performed and documented. The decision makers also designate a peer review leader to organize the peer review.

Who Are Peer Reviewers?

The peer review is conducted by qualified individuals (or organizations) who are independent of those who performed the work, but who are collectively equivalent to them in technical expertise (i.e., peers). These subject-matter experts will have had no previous *substantial* participation in the development of the work product. These individuals may be both from inside and outside of EPA.

Caution!

"Peer review" is not the same as quality review, stakeholder review, or public comment. Neither stakeholder involvement nor public comment are considered adequate substitutes for formal peer review.

Although independent peers can be employed for review during the initial planning stages in addition to the final review, considerable care is needed to avoid the perception or fact that these peers have become an actual part of the planning and production process. If this happens, these peers run the risk of being perceived as incapable of giving an independent final review, and the final product could be delayed or retracted.

Other Benefits of Peer Review

Peer Review helps to ensure better acceptance of your document by improving the way it is presented and the conclusions and recommendations it reaches. Peer review allows the Agency to determine if the work is judged as credible by relevant experts who deal with the Agency and that the scientific and technical underpinnings of its decisions are based upon the best current knowledge from science, engineering, and other domains of technical expertise.

> **WHETHER "OFFICIAL AGENCY PEER REVIEW" IS REQUIRED OR NOT, YOU WILL HAVE A MUCH MORE RELEVANT, USEFUL AND ACCEPTABLE PRODUCT -- USUALLY WITH LESS PERSONAL STRESS AND MORE SELF-SATISFACTION -- IF YOU FOLLOW THE QUALITY REVIEW PROCESS OUTLINED ABOVE.**

Additional information regarding the official Agency peer review process can be found in Appendix B.

Quality Review and Peer Review Mechanisms

Quality review and peer review support can be provided by groups or individuals, or a combination of the two. The most common approaches are to use workgroups, committees, individual experts from universities, contractors, or professional organizations in addition to experts within the Agency.

Workgroups

Workgroups are interdisciplinary teams of individuals with an interest and experience in aspects of a project and who work together to plan and conduct a particular project. The participants in the workgroup typically represent a variety of program offices and missions. Workgroups can be used as a tool for obtaining peer input, quality review, and/or peer review services from more than one individual. Note, however, that if a workgroup has had substantial involvement in the development of the product, neither the workgroup nor its members can serve as formal Agency peer reviewers. Therefore, it may be desirable to create more than one workgroup for OWM projects that require both cross-program development and cross-program review.

Teams

The use of cross-functional, multi-skilled teams is a strong quality management concept and has become increasingly important at EPA. Teams are often being used to plan and carry out specific tasks. However, teams can also be a good mechanism for improving communication and coordination and for managing quality. Some teams are fairly similar to workgroups while others are more

formally established and tend to take on tasks as a group rather than as individuals. Similar to workgroups, the team participants are often interdisciplinary in nature and sometimes are structured to represent a variety of program offices and missions. Teams can also be used as a tool for obtaining peer input, quality review, and/or peer review services from more than one individual. As with work groups, if the team has had substantial involvement in the development of the product, neither the team nor its members can serve as formal Agency peer reviewers.

Federal Advisory Committee Act (FACA) Committees
The Federal Advisory Committee Act of 1972 established a system governing the creation of advisory committees in the executive branch of the federal government. Advisory committees are to be established only when necessary and must be established under standard procedures. These committees also must be reviewed on a routine basis and terminated when they are no longer accomplishing their purpose. Examples of FACA committees include the statutorily required National Drinking Water Advisory Committee, the discretionary Urban Wet Weather Flows Advisory Committee, the Science Advisory Board, and the FIFRA Science Advisory Council.

Federal Advisory Committee Act (FACA) committees, like workgroups, may be used to provide peer input, peer review, or quality review services from more than one individual. Because rules regarding FACA committee meetings and membership are typically more cumbersome than those involving workgroups, use of a workgroup instead of a FACA committee is recommended for most OWM projects. Use of a FACA committee is generally limited to large, highly complex or controversial projects, or when it is desirable to obtain a consensus recommendation from a group of individuals rather than a variety of individual perspectives. There are very specific rules that apply to the need for and operation of FACA committees and advice from the Office of General council might be helpful to resolve any uncertainty.

Other Quality Management Tools

The remainder of this chapter describes other tools that OWM staff and managers can use to plan, implement, monitor, and improve the quality of their activities. Specific ways in which these other tools can be used are also described in Chapter 3.

Standardized Processes

Standardized processes, which can range from well-documented methods, to standard operating procedures, to flow charts, are designed to reduce the variability in activities that are performed repeatedly by numerous staff. Standardized and documented procedures are particularly useful tools for data gathering activities (such as sampling and analysis) or data management activities (such as data review, database access, storage, and retrieval) that will be performed by more than one individual or organization. In such cases, the up-front investment of resources to document and apply these procedures can offer the following benefits to OWM project managers:

- Consistency in performance
- Improved data comparability, credibility, and defensibility
- Reduced errors
- Increased efficiency in performing tasks, thus lowering costs
- A historical record of the processes used.

Standard or Widely Accepted Tools

Widely accepted or standardized tools, such as models, statistical analysis software, data management software, or even word processing software can greatly improve the quality of OWM products because these tools have been tested already and evaluated by other organizations performing similar activities. Some questions to ask when selecting such tools are:

- Is it readily available to all project participants?

- Will it meet the needs of the project?
- Do all project participants have access to the same version of the tool?
- If an update is issued during the lifetime of this project, will participants begin using the updated version?

Because standardized tools can provide valuable benefits, it pays not only to consider the use of standardized tools but also the ways in which these tools will be used. Word processing software is the most obvious (and frequently overlooked) example of the benefits of using standardized tools in standardized ways. For example, newer versions of WordPerfect offer extensive document management capabilities that, when used properly by all parties, can be a valuable resource for controlling document quality, tracking document revisions, and tracking workgroup comments. However, these same features can become a burdensome nightmare if used improperly or inconsistently.

Quality Assurance Measures and Acceptance Criteria

Within EPA, QA is traditionally thought of as a series of procedures used to monitor and control the quality of sampling and analysis data. In reality, QA measures can be applied to all projects, including those that do not involve sampling and analysis. Exhibit 3 highlights ten QA measures that allow full characterization of the quality of primary data that are being collected, and, if appropriate parameters are available, which can be used to help determine the quality of data that have previously been collected for similar or different purposes by other persons.

Exhibit 3
Quality Management Requirements Applicable to Sampling and Analysis Activities

- Calibration linearity
- Calibration verification
- Absolute and relative retention time precision (for chromatographic analyses)
- Initial precision and recovery
- Ongoing precision and recovery
- Analysis of blanks
- Surrogate or labeled compound recovery
- Matrix spike and matrix spike duplicate precision and recovery (for non-isotope dilution analyses)
- Method detection limit demonstration
- Analysis of reference samples

Primary and Secondary Data

There are different ways of controlling and evaluating primary and secondary data. If you are conducting any sampling and analysis activities for your project, (i.e., collecting primary data), you should consider using all the QM elements shown in Exhibit 3. Reasons for omitting any of these measures should be documented in your QM file.

If you are gathering secondary sampling and analysis data to support your project (e.g., analytical results that have been generated for another project or purpose), you should attempt to obtain and evaluate any and all QA results associated with those samples. If QA results are unavailable with secondary data, it may be difficult, if not impossible, to define the quality of your data. Several options are available to help determine the relevance and appropriateness of the secondary data. These are:

■ Evaluate the data against historical results and other data sources in order to determine if they are within the "realm of reasonable expectations"

■ Consult with experts (e.g., peer input or quality review) who are familiar with your type of data,

■ Request results from any performance evaluation samples that may have been performed by the involved laboratories during the initial data gathering time frame, or

■ Audit the facilities and staff involved in gathering the data to assess the quality of their data gathering (if the same facilities, staff, and processes still exist).

Evaluate Sampling and Analysis Activities Against Project Requirements

QA results from sampling and analysis activities should be evaluated against your project requirements. As a rule, it is simplest to rely on method-defined QA acceptance criteria (i.e., performance specifications) for each of the measures shown in Exhibit 3. However, it may be worthwhile to relax these acceptance criteria when significant savings can be realized by doing so and when such changes do not compromise project objectives. Similarly, it may be worthwhile to relax your criteria if the secondary data you obtain do not meet method-defined QA acceptance criteria but are sufficient to meet your needs.

Non-Sampling and Analysis Activities

All projects, including those that involve sampling and analysis, can benefit from such simple QA measures as defining project timelines, milestones, and budgets (see Exhibit 4.) More complex projects also can benefit from early

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testing or review (e.g., alpha testing, quality review, and peer review) and testing or review of final drafts (e.g., beta tests, pilot tests, and peer review).

Exhibit 4
Quality Management Requirements Applicable to Non-Sampling and Analysis Activities

- Identification of key project milestones
- Identification of target dates and budgets for completing each milestone
- Monitoring project status against project schedules and budgets
- Alpha testing to provide early assessment of the project
- Beta testing of the final draft product
- Pilot studies

Surveys
Surveys can be designed and implemented for several reasons. For example, they are useful for collecting data needed to complete a project (e.g., a survey of data resources available) and for determining the project scope (e.g., a survey of customer needs). They can also be useful for evaluating project quality (e.g., a survey of product users to determine if the planned task will adequately meets the users needs) and to identify areas for improvement.

Alpha Testing (analogous to Quality Review)
Alpha testing is a quality control process originally designed to test computer hardware or software; it is increasingly being used for initial testing of any type of project. During an alpha test, a limited number of experienced users, both internal and external to the developer's (project manager) organization, advise the developer on the needs of the customer, the design of the interface, and the selection of technology.

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Beta Testing (more like Peer Review)
Beta testing is typically applied to software products prior to public release.
Beta testing is the last stage of testing, and normally involves sending the
product to a number of users external to the developers organization for real-
world testing to determine if the product meets user requirements and
expectations. Beta testing is often preceded by a round of testing called alpha
testing.

Pilot Studies
Pilot studies are similar in concept to beta testing, but normally apply to non-
software related products, such as guidance documents and pollution control or
treatment techniques. Pilot studies typically involve implementation of the
product on a small scale. Pilot studies should be designed to capture as many
variables as possible within a small budget and time frame.

Quality Assurance Project Plans (QAPPs)
Although quality assurance project plans (QAPPs) have been used historically
for primary data gathering activities, they, like most other QM tools, can be
valuable in improving the quality of any project. This is particularly true of
large projects that involve multiple organizations and activities because the
QAPP describes the purpose of the project, quality objectives, roles and
responsibilities in implementing the project, resources needed, strategies for
implementing the project, and procedures for evaluating the quality of any data
used in the project. As a result, the QAPP provides a mechanism for
documenting the results of the quality planning process and serves as a tool to
ensure that all project participants understand project requirements, (i.e., that
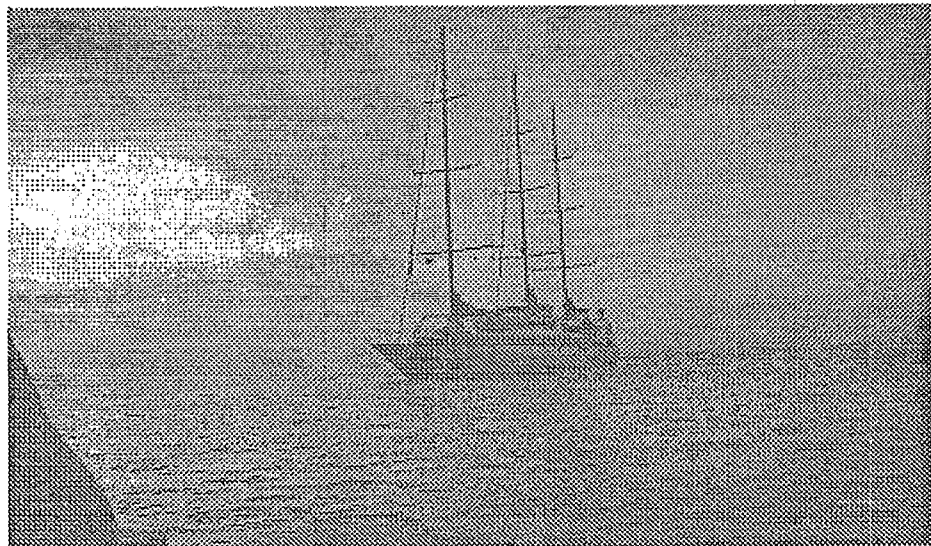
everyone is following the same procedures and that the procedures are clear). Requirements for a QA Project Plan (QAPP) are outlined in EPA QA/R-5, *EPA Requirements for Quality Assurance Project Plans*, Draft Final, October 1997. Guidance for preparing a QAPP is outlined in EPA QA/G-5, *Guidance on Quality Assurance Project Plans*, EPA/600/R-98/018, February 1998.
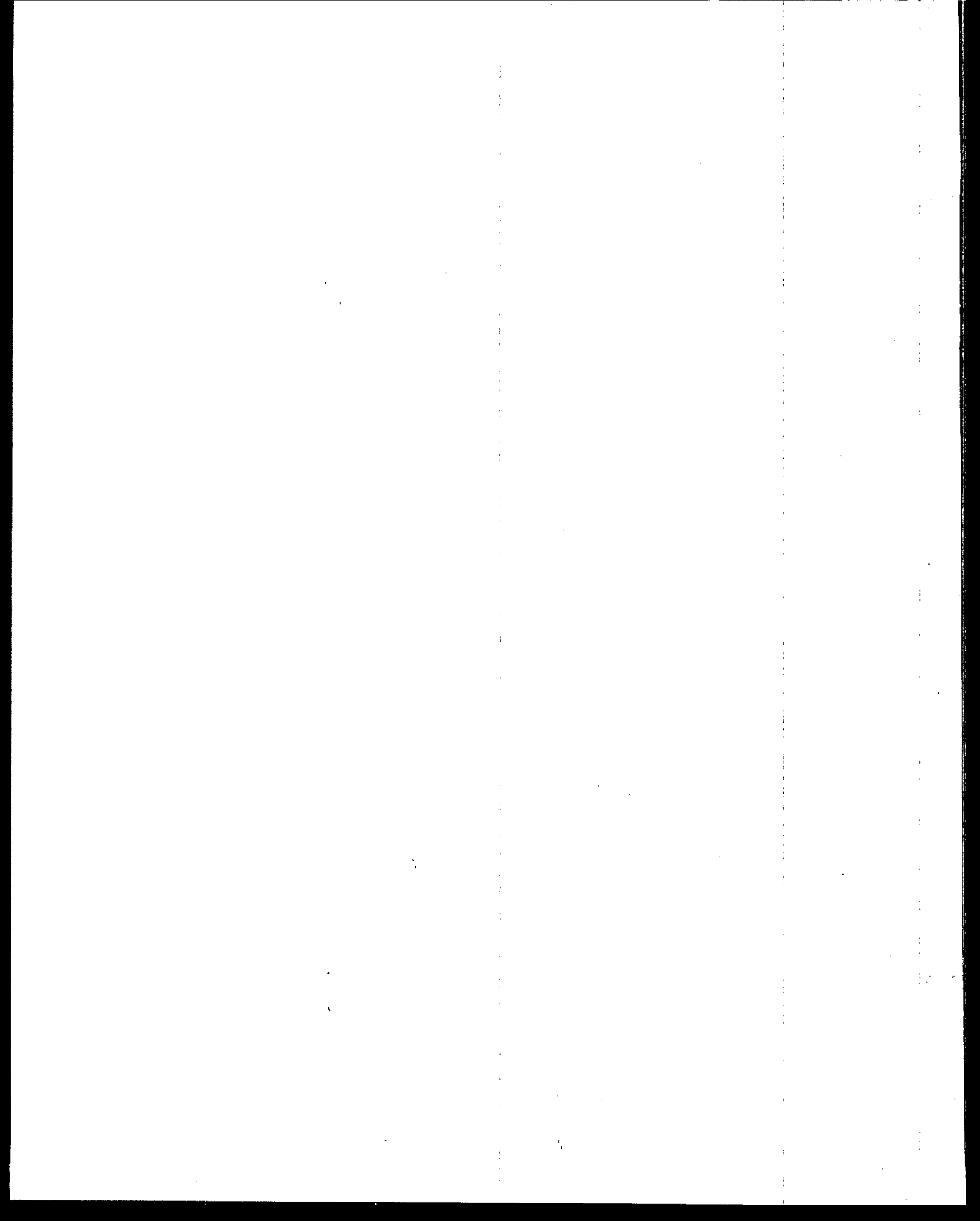
Chapter 3

Applying QM tools to OWM Projects

Planning is One of the Most Important Aspects of QM

Careful planning can save you thousands of dollars as well as weeks, months, and even years of wasted effort. Although projects vary greatly in scope and importance, each project should be started in essentially the same way—by determining the relevance of the project, the level of quality required, and by planning accordingly. The nature of each OWM project drives the level of quality needed on the project. Two very important things to realize are:

(1) The same level of effort is likely to be involved in doing a relevant or a non-relevant task. However, the usefulness to your customers and your ultimate self-satisfaction will be much greater for the relevant task, even if the relevant task was not conducted in an optimum manner.

(2) Poorly planned projects often have flawed results and are more difficult to do than projects that are carefully planned.

Planning Questions
The planning process should address the following questions:

- What are the quality requirements for my project?

- Can I achieve these requirements within a reasonable time frame with available technical, financial, and staffing resources?

- Can I modify my project design or scope to ensure that my product will meet quality requirements?

Additional issues that should be considered when addressing each of these questions are shown in Exhibit 5.

Exhibit 5. Quality Management Issues to Consider When Planning Projects

What level of quality do I need? Is this level of quality achievable? Should I modify my project design?

- What is the primary purpose of the project?

- How is the project relevant to OWM's mission, and why is it important to proceed?

- Who is the project customer (e.g., Senior EPA management, the public, Congress, the regulated community, etc.)?

- What are the customer's requirements?

- What are the project goals?

- How can I measure the success of my project (e.g., through quantitative measures, surveys, peer review, etc.)?

- What activities must be performed to meet project goals?

- What staff members are needed to complete these activities? Are these staff available? If not, what other options exist (e.g., will staffing limitations dictate achievable project quality or project design?)

- What resources and materials are needed to complete project activities? Are these resources/materials available? If not, what other options exist (e.g., will resource limitations dictate achievable project quality or project design)?

- What is the required project completion date (e.g., will the targeted completion date dictate project quality or project design?)

- What QM tools and requirements are appropriate for the project?

- What possible problems might arise during the project and what up-front actions can I take to mitigate them?

- If time, budget, staffing, or other resource limitations do not allow the required project quality to be achieved, can I redefine the study, scope, or design? Can I postpone the project? What other solutions can I take to address the problem?

Expert Assistance

In many cases, OWM Project Managers may find it helpful to seek expert assistance in answering these questions. Expert assistance may be provided through informal meetings and discussions with staff. These persons may be within or outside of EPA. Expert assistance may also be gained from appropriate individuals in trade associations, environmental groups, interoffice workgroups or FACA committees assembled to provide quality review, technical oversight, and/or peer review support to the project.

> Q: Who are the experts, and how do I find them?
>
> A: Suggestions for finding experts include: seeking recommendations from fellow co-workers, reviewing the public literature for widely published authors, your quality assurance coordinator, or contacting stakeholder organizations for recommendations.

Quality Gaps

Quality review at the planning stage can help identify any potential gaps in quality requirements for each project. To address these gaps, quality reviewers may provide solutions or suggest advisors to the Project Manager. Typically, such gaps occur when insufficient resources are available to meet project objectives, but they also may occur when technology is not sufficient to support project needs. The Project Manager can address these problems by:

- leveraging additional resources,

- modifying the project design and scope to reduce the level of resources or type of technology needed, or

- clearly identifying to senior management that the level of quality needed cannot be attained. Managers can then decide to accept the level achievable with limited resources and technology or to cancel the project.

A real-life example of this situation is Example 6 "1998 Biosolids Quality Survey" in Chapter 5. Quality review meetings during the planning stage of this activity convinced the Project Manager that the original project objectives could not be met within the predefined budget. In subsequent meetings, the quality review team assisted the project manager in identifying alternative solutions that could be presented to the Assistant Administrator (AA). Later, they assisted in designing a study to meet refined project objectives that were approved by the AA after having learned of the resource constraints.

Additional Quality Tools During Planning
Depending on the level of quality needed for the project, the OWM Project
Manager may want to consider the use of these additional tools during the
planning phase:

- Use of internal or external peer reviewers to review the final
  project plan, quality assurance project plan, grant proposal, or
  other planning document. This is advisable when the project is
  likely to be costly, highly controversial, or highly innovative.

- Assembly of a FACA committee or an interoffice workgroup to
  provide oversight, recommendations, or peer input into the
  overall project.

- Development of a formal QA Project Plan (QAPP) in
  accordance with requirements.
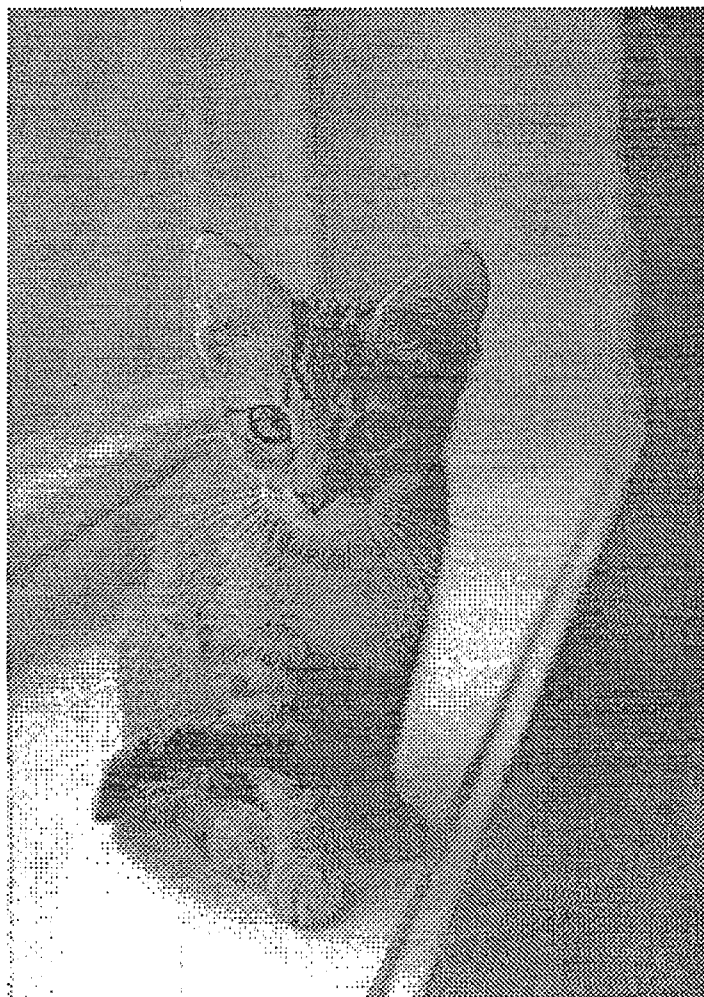
A QA Project Plan (QAPP) is Required for Collection of Primary Environmental Data. EPA policy requires that all work performed by or on behalf of EPA that involves the collection and use of primary environmental data be implemented in accordance with an Agency approved QAPP. The QAPP is a critical planning document used to define and record how QA activities will be implemented and assessed on the project. Requirements for a QAPP are outlined in EPA QA/R-5, *EPA Requirements for Quality Assurance Project Plans*, Draft Final, October 1997. Guidance for preparing a QAPP is outlined in EPA QA/G-5, *Guidance on Quality Assurance Project Plans*, EPA/600/R-98/018, February 1998.

QA Tools Are also Needed for Project Documentation

Effective management of your product's quality does not end with project planning. To make the most of your resources, you should implement QM tools throughout the duration of your project, evaluate the success of your product against your quality objectives, and, where appropriate, refine your management strategy to improve the quality of your product. For example, a long-term regulation development effort involving the use of highly innovative data could benefit from continuous involvement and oversight of external reviewers who review the project plan during the planning stage, review the quality of data gathered by OWM to develop the regulation, and OWM's technical methods and assumptions for analyzing and interpreting the data, and review OWM's presentation of its findings (e.g., its technical support document). Examples 1 through 5 in Chapter 5 all illustrate these principles.
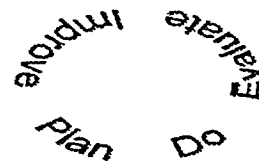
QM Tools During Task
QM tools that can be used to monitor and evaluate project quality during project implementation include:

- Workgroup or committee oversight of technical activities

- Internal or external peer review of interim products and drafts

- Using widely accepted, peer-reviewed data, models, approaches, or other tools when developing the product

- Verification that assumptions during project planning were valid

- Monitoring of actual schedules and budgets against planned schedules and budgets.

- Alpha testing (defined in Chapter 2) to obtain advice on the needs of the customer, the design of the interface, and the selection of technology.

QM Tools at End of Task

The last component of the QM cycle is to improve the quality of your current product, or even of your next product by incorporating comments, recommendations, and other improvements into your project activities. Midstream improvements designed to address deficiencies or problems identified during the course of project implementation can often save the Agency months or years of wasted efforts and needless embarrassment or litigation.
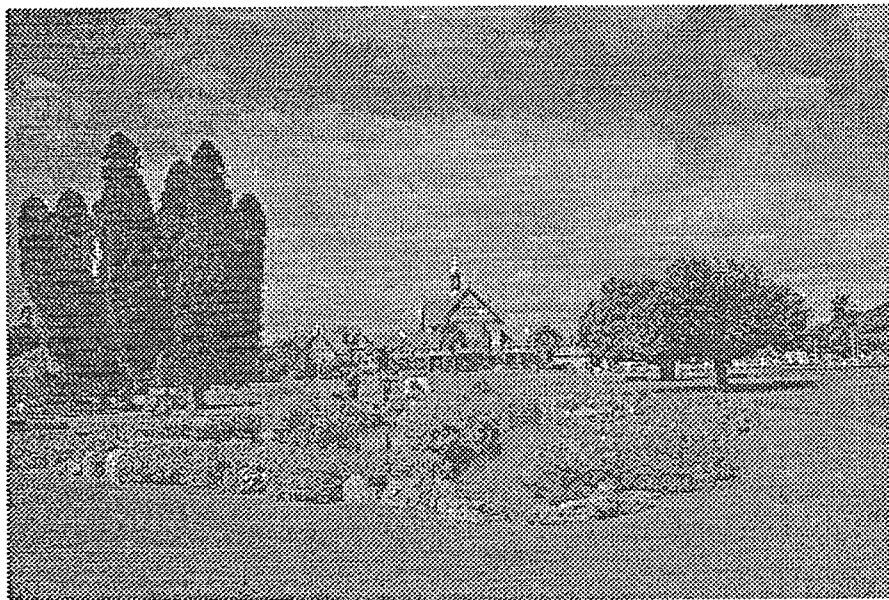
Some quality management tools you might use to evaluate and improve the quality of your final work product or your next work product include:

- External peer review to ensure that your final product meets original project objectives, is clearly presented, and is technically accurate

- User/reader/stakeholder surveys designed to determine if the product is useful, if it meets its intended purpose, and if additional activities, guidance, clarification, are needed

- Formal and informal public comments about the usability of the product, the technical approach to developing the product, and recommendations regarding further activities.

- Beta testing (defined in Chapter 2) or pilot studies to determine if the product meets user requirements and expectations.

Example 5, the 40 CFR Part 503 Biosolids Rule case study in Chapter 5, illustrates the concept of quality improvement for a situation in which a second formal peer review process was undertaken two years after project completion. In this case, the second peer review was used to further verify the extent to which the science and approach used in the rule-making process was valid, (i.e., as a means of evaluating the performance of the final product and identifying further areas of improvement.)
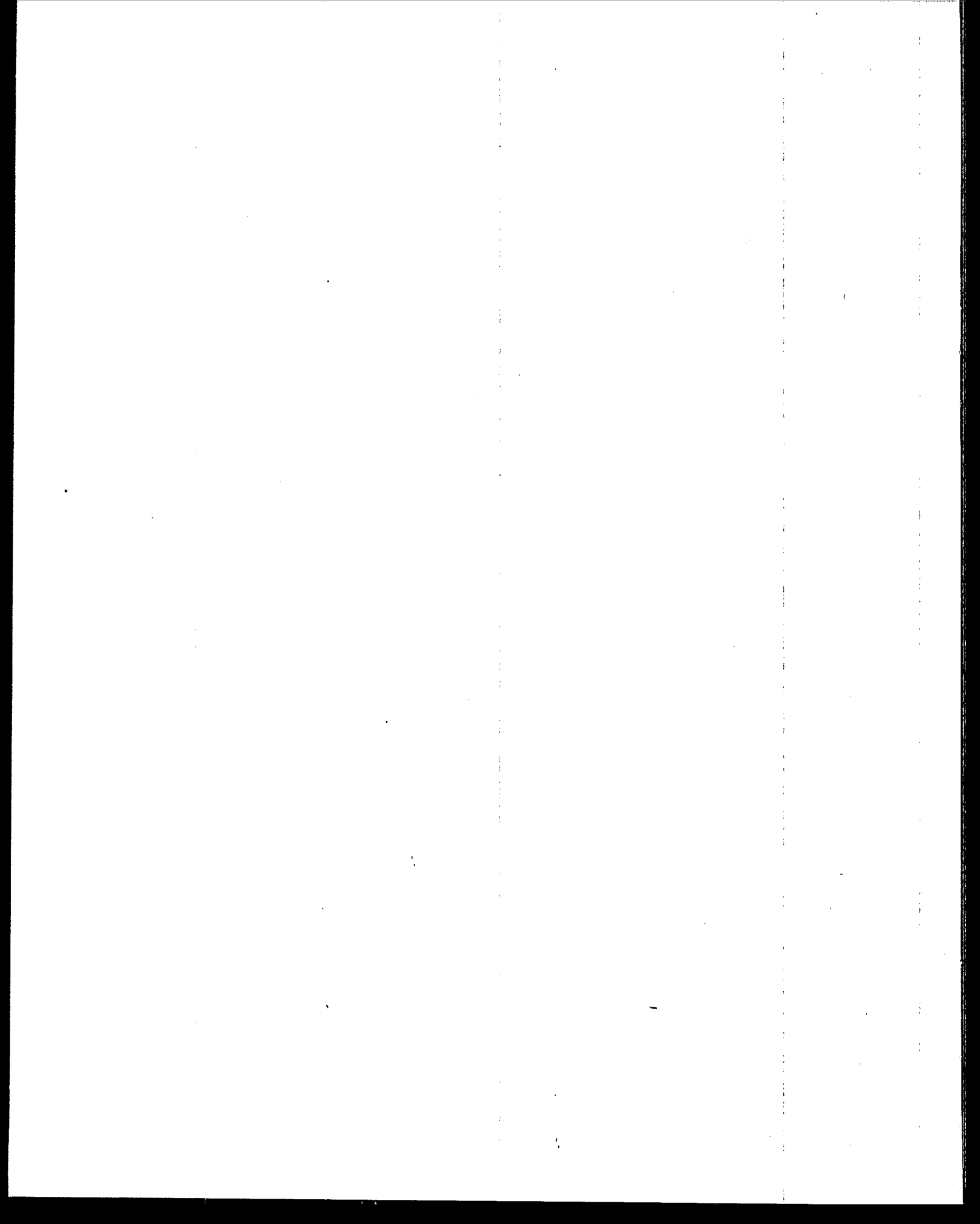
Chapter 4

Documenting Your Quality Management

Document as You Go

Documentation is not a distinct phase of quality management. It is an ongoing requirement throughout all phases of the quality management process.

> **IT IS OFTEN ARGUED THAT IF YOU DID NOT DOCUMENT YOUR QUALITY MANAGEMENT ACTIVITIES, YOU DID NOT PERFORM THEM.**

Documentation Benefits

Documentation helps you:

- Inform managers, team members, and stakeholders of project objectives, design, and limitations

- Defend the quality of your data against criticism

- Defend your work product against litigation

- Ease the transition of new project managers and staff brought into the project midstream

- Demonstrate that you fulfilled Agency requirements concerning quality management

- Identify areas for future improvement and build on lessons learned

Documentation is also a technique for monitoring and measuring technical and financial progress. It also serves as a source of good backup information on performance--past and present, and can ease transitions of new project managers and staff brought into the project midstream.

Tip: Protect your project and ensure all staff members understand requirements by documenting your activities throughout project duration!
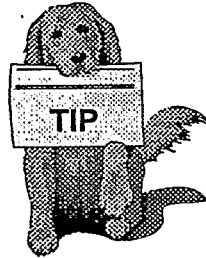
"It is characteristic of committee discussions and decisions that every member has a vivid recollection of them and that every member's recollection differs violently from every other member's recollection" — Jonathan Lynn and Anthony Jay, *Yes, Prime Minister*

Documentation Aids

Documentation does not have to be difficult. This chapter is designed to provide you with several options for documenting quality management activities *without adding to your paperwork burden.* Several different approaches and checklists are provided in Exhibit 6-9. **You may use some, all, or none of these checklists,** but you are required to document your QM activities in some way. Three possible documentation options are:

- A checklist designed to help you reference documentation that already exists in other sources

- A checklist designed to help you document, in brief bullets, answers to the quality management planning, implementation, assessment, and improvement questions raised in Chapter 3, and/or

- A checklist designed to aid you in planning and documenting your peer review activities.

These checklists were created to assist you. Exhibit 6 also provides recommendations regarding minimum documentation requirements for specific QM activities. Finally, Appendix B provides examples of QM documentation for some of the case studies provided in Chapter 5, including completed versions of the checklists provided in this chapter. *[It is important to document pertinent information about roles, responsibilities, training, communications, operational controls, and inspections.]*

Exhibit 6. Documentation of QM Activities

Quality Review

1. A list of peers and their affiliations that helped plan the task with several words about why selected.

2. A brief statement of the quality needed and attainable with available resources.

3. A list of peers that are involved in oversight plus affiliations and why they were selected (may be the same as the planner peers).

4. (Optional). A copy of the written "charge" given to reviewers.

Peer Review

1. A list of knowledgeable peers who have reviewed the product. Give peer reviewer affiliations and several words about why they were selected.

2. A copy of the "charge" given to peer reviewers. The charge provides specific instructions for the areas which the reviewer should focus on during the review.

3. The major points made by the reviewers and how these were addressed.

4. Written justification for any major work products that did not undergo peer review, including signature approval from the AA.

Other QM Tools

1. Copies of any standardized processes (e.g., methods, flow charts, SOPs, etc.) used in the project.

2. Copies of any surveys and survey results used to determine project scope or evaluate project quality

3. Description of any pilot testing, alpha testing, or beta testing performed on an interim product. Include names of testing participants, test results, and changes made as a result of test.

4. Copies of any QAPPs prepared for the activity.

Contractor/Grantee Support

1. Document all important events included in the pre-award, award, management, and closeout phases of the agreement and include this information in the project file.
   - Identifying Information: agreement identification number, title, program office, project manager and their telephone number and mail code; and
   - Management Personnel: names, title, telephone number, and mail code of the project officer's management chain-of-command through the approval official.

2. OWM project managers should establish a routine practice of reporting to the file as soon as the agreement has been activated. This reporting may take the form of a memorandum to the file or a brief note. The key to effective post-award assistance management is documentation; a paper trail in case of a problem, or in other unforseen situations. A good post award management plan as required by OWM for grants should meet these documentation requirements.

3. Include information regarding contractor or grantee performance in the file. Examples of such documentation include: award fee evaluation results, commendations and awards for superior performance, and cure notices or other written correspondence to direct specific corrective actions for performance problems. Other examples include records of all meetings, conferences, site visits, and phone calls related to the quality of the contractor or grantees performance.

4. Maintain all documentation regarding the financial performance. This includes documentation of original and revised cost estimates, as well as documentation of actual costs. Documentation that explains any significant deviation between estimated and actual costs also should be included in the file.

OPTIONAL OWM CHECKLIST FOR DOCUMENTING QM ACTIVITIES

No.	Action Item	Completed/ Not Completed/ N/A	Location of Documentation (circle all that apply)
1	Clearly state the *primary* purpose of this project		*Grant application Peer Review Charge Quality Review Charge Study plan QA Plan Congressional Appropriation Contract Work Assignment Task Order Written Correspondence (cite date, parties)_____ Other_____*
2	State the relevance of this project to the program mission		*Grant Application Peer Review Charge Quality Review Charge Study Plan Contract Work Assignment Task Order Written Correspondence (cite date, parties)_____ Other_____*
3	State customer (internal or external) needs and specific requirements		*Status Report QA Plan Peer review Charge Quality Review Charge Study Plan Written Correspondence (cite date, parties)_____ Other_____*
4	State the goals of the project ▲ Are they measurable?		*Grant Application Peer Review Charge Quality Review Charge Study Plan Written Correspondence (cite date, parties)_____ Other_____*
5	State specific staff roles/responsibilities for this project ▲ Are in-house staff and staff responsibilities identified? ▲ Are staff and corresponding responsibilities from other offices identified? ▲ Are contractor staff and responsibilities identified?		*Organizational Chart (cite date and source)_____ Grant Application QA Plan Study Plan Work Plan Other_____*
6	State specific resources and materials necessary for this project; for example, ▲ Data to be used ▲ Hardware & software		*Grant Application Study Plan Work Plan Other_____*

Planning

4.5

OPTIONAL OWM CHECKLIST FOR DOCUMENTING QM ACTIVITIES

No.	Action Item	Completed/ Not Completed/ N/A	Location of Documentation (circle all that apply)
Planning			
7	Identify appropriate quality tools; for example, ▲ Are peer reviews required? ▲ Are teams required? ▲ Are workgroups required?		*QA Plan* *Annual Peer Review Submission (cite date)* _____ *Written Correspondence (cite date, parties)* _____
8	Describe the time line for this project: ▲ Based on the most *realistic* assumptions ▲ Broken down by task		*Grant Application Peer Review Charge Quality Review Charge* *Study plan QA Plan Congressional Appropriation* *Contract Work Assignment Task Order* _____ *Written Correspondence (cite date, parties)* _____ *Other* _____
9	Determine anticipated problems that might arise during this project, with possible solutions. ▲ Are alternate personnel identified? ▲ Are contingency plans made for unavailable or inadequate secondary data? ▲ Have impacts of schedule slippages been addressed?		*Grant Application Study Plan QA Plan* *Written Correspondence (cite date, parties)* _____ *Other* _____
10	Determine how quality and relevance of secondary data can be assessed		*QA Plan Work Plan* *Other* _____
11	Clearly state the budget for this project ▲ Does budget account for every resource, material, and individual identified above? ▲ Does budget include the costs of contingency plans/solutions described above?		*Grant Application Congressional Appropriation Work Assignment* *Work Plan Task Order QA Plan* *Written Correspondence (cite date, parties)* _____ *Other* _____

OPTIONAL OWM CHECKLIST FOR DOCUMENTING QM ACTIVITIES

No.	Action Item	Completed/ Not Completed/ N/A	Location of Documentation (circle all that apply)
12	Assess the plan's achievability with existing resources ▸ Staff ▸ Funds ▸ Time		*Explain or cite location of explanation*
13	Discuss project plans with your QA Coordinator		*Cite any written documentation of any conversation or internal correspondence with QAC* _____
14	Describe the use of quality review ▸ Were quality reviews used during project planning? ▸ Was quality review used on completed drafts or on parts as produced?		*Final Report (document date and title)* _____ *Status Report (cite reference)* _____ *Other* _____
15	Describe the use of peer review ▸ How was the extent of peer review needed determined?		*Final Report (document date and title)* _____ *Status Report (cite reference)* _____ *Annual Peer Review Submission* _____ *Other* _____
16	Describe the quality assessment of the data used		*Final Report (document date and title)* _____ *Other* _____
17	Describe project technical monitoring; for example, ▸ Site visits ▸ Conference calls ▸ Review of progress reports		*Final Report (document date and title)* _____ *Status Report (cite reference)* _____ *Other* _____
18	Describe any problems that arose on the project		*Final Report (document date and title)* _____ *Status Report (cite reference)* _____ *Other* _____

Assessment that Quality Has Been Achieved

4.7

OPTIONAL OWM CHECKLIST FOR DOCUMENTING QM ACTIVITIES

No.	Action Item	Completed/ Not Completed/ N/A	Location of Documentation (circle all that apply)
19	Describe any substitutions in proposed staff		*Amended QA Plan Amended Work Plan* *Other (describe)*_____
20	Describe any substitutions in proposed resources and materials		*Amended QA Plan Amended Work Plan* *Other (describe)*_____
21	Describe project cost monitoring		*Describe:*

4.8

OPTIONAL OWM PROJECT PLANNING DOCUMENTATION FORM

Project Title:

OWM Contact:

Primary purpose of project

Relevance of project to program mission

Project Goals	**Measures used to determine if goals can be met**

Staff Roles and Responsibilities *(list or attach org chart)*

Does the project rely on data? *(Circle all that apply)* Primary data Secondary data No data	**Describe how quality and relevance of data will be assessed**

Other resources and materials necessary for project *(internal and external)*

Project Budget	**Project time line** *(list key milestones or attach project schedule)*
Anticipated problems meeting project objectives or schedules	**Possible solutions to mitigate problems**

Anticipated Quality Management Tools (circle all that apply)

Quality review   Internal peer review   External peer review   QA Plans
Data review and data quality assessment
Other (describe):

Discussion of Project Plans with QA Coordinator *(document dates of discussion and major issues/recommendations)*

OPTIONAL OWM PEER REVIEW DOCUMENTATION FORM

PART I - DOCUMENT IDENTIFICATION

Title of Material to be Reviewed: _____

Primary Author or Manager Responsible for Document: _____

Type of Document (circle one):   **Guidance**   **Report**   **Regulation**

                                   Other (if other, explain) _____

PART II - PEER REVIEW OBJECTIVES

Type(s) of Peer Review to be Conducted (circle one or more):

Internal Agency Expert(s)   **Internal Panel of Experts**   **External Expert(s)**

External Panel of Experts   **Agency-Appointed Special Board or Commission**

Science Advisory Board   **Other Agency-Based Federal Advisory Committee**

Interagency Committee   **EPA-Sponsored Peer Review Workshop**

National Academy of Science   **National Research Council**

Committee of Another Agency   **Other** (please explain) _____

Summarize Mission/Charge to be Provided to Peer Reviewers (attach if desired):

Name of Person Approving Mission/Charge: _____

Peer Reviewer Qualifications and Diversity (Describe the minimum qualifications and diversity required of individuals selected to review the document. Attach if necessary):

 Are Funds Available for Peer Review?   **Yes**   **No**
If yes, describe (e.g., contract funds, travel funds, grant funds, etc.) _____
_____

PART III - PEER REVIEWER INFORMATION

Peer Reviewer Name(s) and/or Organization:

_____	_____	_____
Name	Affiliation	Date of Review
_____	_____	_____
Name	Affiliation	Date of Review
_____	_____	_____
Name	Affiliation	Date of Review
_____	_____	_____
Name	Affiliation	Date of Review
_____	_____	_____
Name	Affiliation	Date of Review
_____	_____	_____
Name	Affiliation	Date of Review

PART IV - Peer Review Recommendations

Was peer review conducted throughout document development?   **Yes   No**

If yes, were comments incorporated into document before proceeding to next level?   **Yes   No**

Summarize nature of peer review comments and recommendations (attach if necessary):

Was a response written to address peer review comments?   **Yes   No**

If yes, please cite document and author or attach. If no, please explain.

Summarize overall benefit/improvements of the peer review process below:

4.11
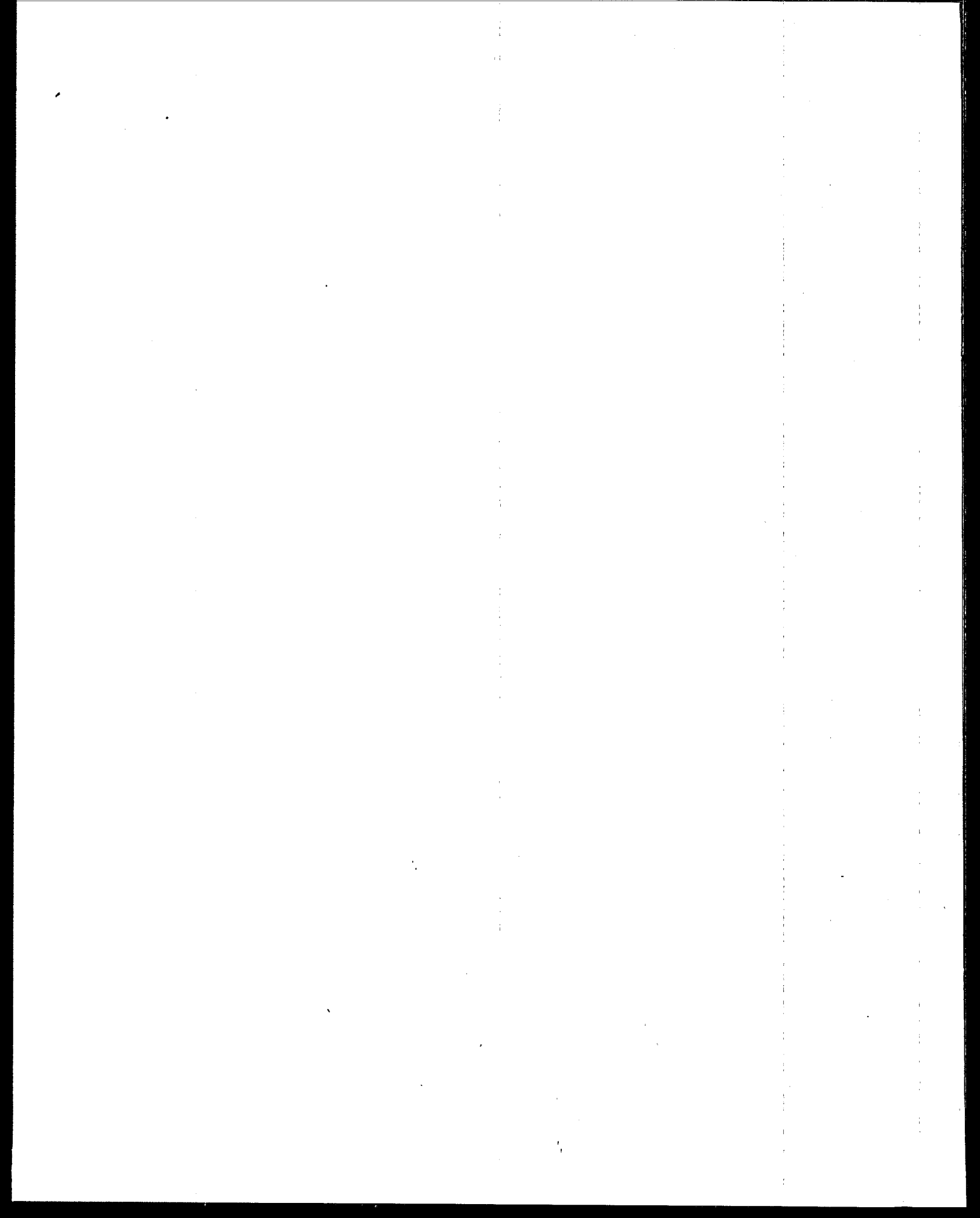
Chapter 5

Examples of Quality Management

This chapter provides examples of actual OWM projects in which the quality management tools and techniques described in Chapters 2 through 4 were applied. These examples are intentionally diverse in scope and quality management approach, and were selected to help OWM project managers understand the importance of quality management and its application to OWM projects. Some of the tools presented in these case studies were identified at the beginning of the project; others were incorporated into the project as it progressed.

Each example is divided into the following sections:

What can be learned from this example? This section summarizes the reason we have included the example in this guide.

Project Background. This section provides a brief history of the project, including the parties involved, major project objectives, and final work product.

Quality Management Challenges. Each project is unique in terms of potential obstacles for successful completion while accomplishing its goals. Possible difficulties are listed in this section.

OWM's Quality Management Strategy. The basic processes for implementing the use of quality management tools are summarized in this section. Description of any workgroups formed and plans for peer input, quality review, and peer review will be found here.

Final Work Product/ Current Project Status. Depending on whether or not the project has reached completion, the title of this section will differ. If it has been completed, then the final work product

will be described briefly, and any future plans resulting from the product will be described briefly. If the project has not yet reached completion, future project plans will be noted, along with anticipated work products and outcomes.

Quality Management Tools Used to Implement the Strategy. The tools utilized in implementation of the strategy described in a previous section are organized in this section by the type of tool used. Three general categories are used to ease readability: Quality Review, Peer Review, and Other QM Tools.

Documentation Notes. This section summarizes the type of quality documentation maintained in the project file. These items may include, but are not limited to drafts of project plans, sampling plans, peer reviewer charges, comments from reviewers, and responses to omments documents.

Quality Management Lessons Learned (if applicable). Continuous improvement, by building on lessons learned, is a key component of quality management. This section summarizes any comments made by Project Managers concerning activities or processes they would like to apply to future projects or wish they had considered during project implementation to improve the quality or efficiency of their project.

5.3
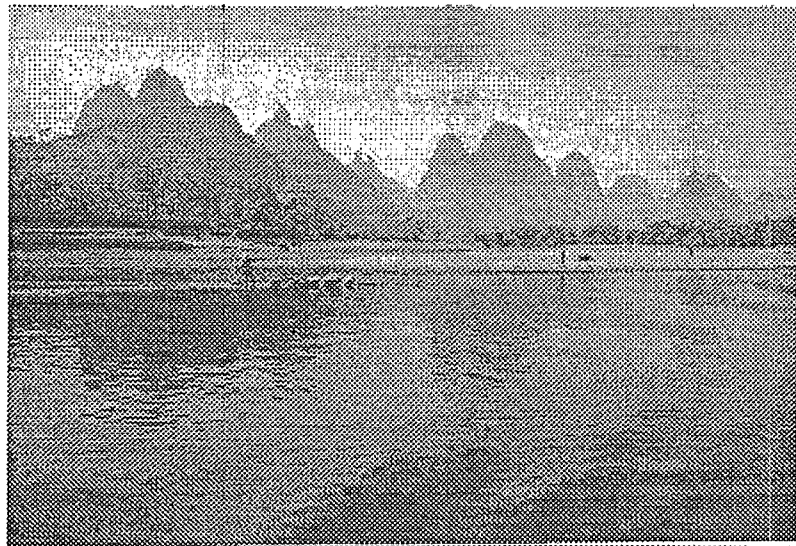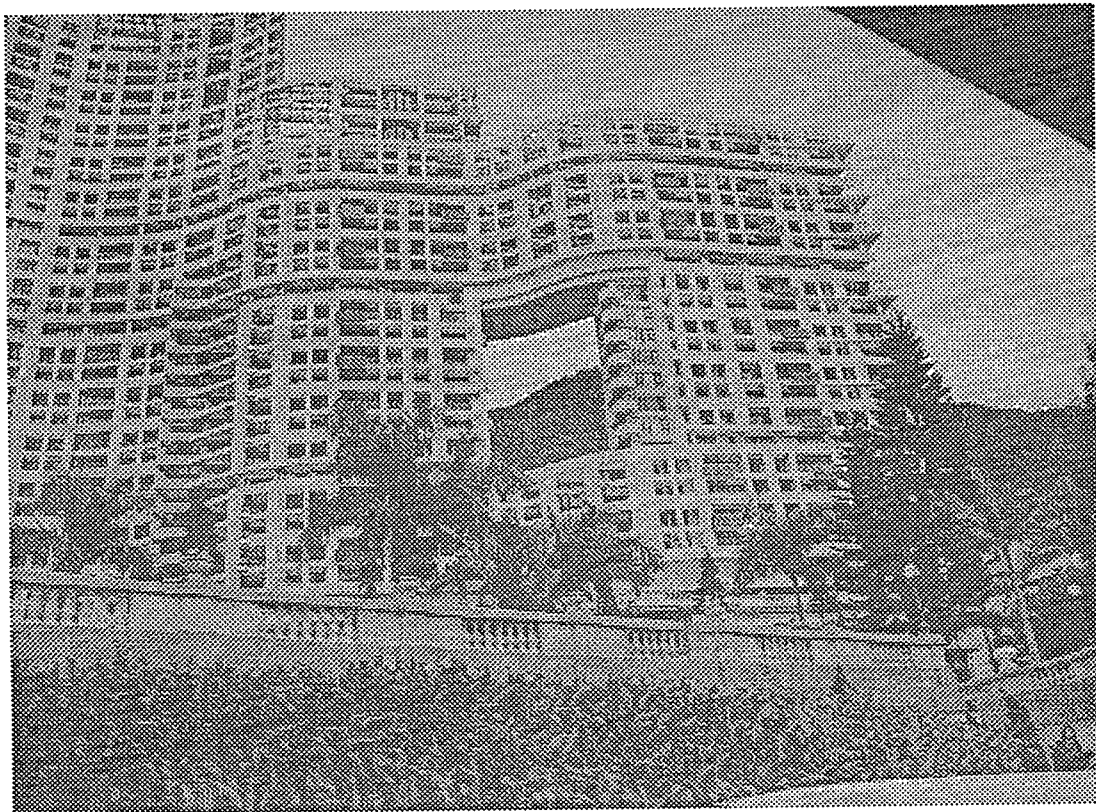
Example 1
Response to Congress on
Use of Decentralized Wastewater Treatment Systems

What can be learned from this example?

An interoffice workgroup can be utilized successfully for quality review and peer input.

Project Background

In 1996, the Congressional House Appropriations Committee requested that EPA analyze and report on the use of decentralized wastewater treatment systems as an alternative to current centralized systems. EPA's analysis was to include an assessment of 1) the benefits of the alternative approaches, 2) the potential savings and/or costs associated with these approaches, 3) the Agency's ability to implement these alternatives within the current statutory and regulatory structure, and 4) any Agency plans to implement such alternatives using funds appropriated in FY97.

Quality Management Challenges

- Completing project goals within established time constraints
- Determining what information was necessary and whether it could be obtained with available resources
- Finding appropriate experts
- Presenting technical information to a Congressional audience with varied levels of technical understanding

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OWM's Quality Management Strategy

OWM formed a workgroup comprised of experts throughout OW and ORD. The workgroup assisted in planning the project and implementing project activities. OWM submitted the draft product for external peer review to evaluate the adequacy of the project against project objectives and recommend product improvements.

Final Work Product

OWM coordinated the required analyses, report development, and submission to the Congressional committee. As a next step, OWM plans to use the analyses and recommendations described in the report to prepare an implementation plan and guidance to states and municipalities regarding the use of alternative wastewater treatment technologies.

Quality Management Tools Used to Implement the Strategy

Quality Review

At the Beginning:
An initial brainstorming session with workgroup members was used to:
- Determine quality needed for the project
- Develop a strategy for project implementation
- Identify data and data quality needs
- Recommend existing sources of relevant data
- Identify tasks for a contractor

During:
- The workgroup completed quality review of data and first draft from contractor
- Plan for peer review of final drafts

At the End:
- The workgroup evaluated and integrated, where applicable, all comments from the peer reviewers

Peer Review

At the End:
The workgroup submitted the final draft report from the contractor for external peer review by:

- Technical staff from EPA Regional Offices
- Several states and universities
- Water Environment Federation
- Small Flows Clearinghouse
- Association of State and Interstate Water Pollution Control Agencies

Where applicable, all peer reviewer comments were integrated into the report before submitting it to Congress.

Other QM Tools

- The OWM PM maintained control of the electronic drafts to ensure all relevant comments were integrated into the draft
- Most data used were from published, peer reviewed sources, and all secondary data were evaluated by a contractor for relevance to project needs
- A widely accepted computer cost model described in peer reviewed journals was used for cost analyses

Documentation Notes

The Project Manager retained copies of:
- Documentation of the initial workgroup meeting, including a basic strategy and report outline
- The written charge with specific instructions for each peer reviewer
- All internal and external peer reviewer comments
- All drafts of the report

Example 2
Investigation of Best Management Practices for Photo
Processors via Draft Code of Management Practices

What can be learned from this example?

Stakeholders can offer technical and resource support in defining and managing the quality of the project.

Project Background

OW is streamlining the National Pretreatment Program by simplifying regulatory and administrative requirements applicable to POTWs and the facilities that discharge to them. As part of this initiative, EPA has funded the Association of Metropolitan Sewerage Agencies (AMSA) and The Silver Council (TSC) to demonstrate that a newly developed Code of Management Practice (CMP) can be used by the photo industry as an alternative to existing compliance mechanisms for controlling wastewater discharges. The CMP was developed by AMSA and TSC. This project seeks to demonstrate to all stakeholders that the CMP alone or in combination with innovative regulatory options can help attain environmental goals more effectively and efficiently than traditional approaches. More specifically, the purpose of the demonstration project is: 1) demonstrate continuous progress toward meeting program goals for clean water and efficient operation of POTWs by reducing the headworks loadings of silver, 2) deliver cost savings (silver recovery, operating efficiencies) and generally mitigate the cost to industrial users of achieving environmental objectives, and 3) simplify POTW program administration.

Quality Management Challenges

- Definition of project objectives that met the needs of both government and industry representatives
- Designation of proper representatives of the various organizations to the three committees
- Determination of the data collection and data quality needs, in order to design a statistically suitable sampling and analysis plan

OWM's Quality Management Strategy

Three groups comprised of both government and industry were formed. The Steering Committee was developed to oversee the project as a whole. A Technical Project Committee was responsible for development of the work plan and final report and for responding to technical inquiries arising during data collection and analysis. A Quality Review Team was developed to provide external review of the work plan and final report. Both the Steering Committee and Quality Review Team will review and offer improvements for the final report.

Current Project Status

At this point, baseline data are being collected. Data collection, analysis and model development will proceed as designated in the work plan. The final report will be used as a demonstration to states and cities of options available and the corresponding success rates and cost analyses.

Quality Management Tools Used to Implement the Strategy

Quality Review

At the Beginning:
A meeting with Steering Committee members was used to:
- Define clear project objectives
- Determine the quality needed for the project
- Determine data and data quality needs
- Develop a statistically-based sampling and analysis plan
- Identify tasks for a contractor
- Plan for peer review of the work plan and final report

During:
- The Technical Project Committee completed quality review of initial contractor data
- The Technical Project Committee will perform a quality review of the draft report from contractor

At the End:
- The Steering Committee will perform a quality review of the final report
- The Technical Project Committee will evaluate, and integrate, where applicable, all comments from the Steering Committee and Quality Review Team

Peer Review

During:
The Technical Project Committee submitted the work plan for external peer review by the Quality Review Team, comprised of members of:
- EPA Offices
- State and City Offices
- Industry

At the End:
- The Technical Project Committee will submit the final report for external peer review by the Quality Review Team

Other QM Tools
- A cost analysis model will be developed for estimating financial implications among approaches. This model will be tested and refined based on real world data and experience.

Documentation Notes

The following have been documented by the Project Manager:
- The charge given to each of the three committees
- All committee meeting minutes
- Draft workplan, comments on draft, and final workplan
- Quarterly progress reports

Quality Management Lessons Learned

The Project Manager realized the importance of defining clear data quality requirements, especially when numeric data are being generated. At the outset of the project, some participants did not see a need for a statistical sampling and analysis design as a part of the work plan. Once the data quality requirements were defined, however, it was realized that in order to obtain the specified level of quality in the data and its interpretation, a clear sampling and analysis plan must be defined before sampling begins. The plan was developed and incorporated into the work plan.

Example 3
Storm Water Phase I Model for 1996 Clean Water Needs Survey

What can be learned from this example?

Quality and peer review of the data and the models in the Clean Water Needs Survey assisted in the ability to estimate costs of the storm water treatment required by Storm Water Phase 1. Review of the the up-front planning of budget, and timelines facilitated full completion with quality needed.

Project Background

EPA's Clean Water Needs Survey (CWNS) is required by Sections 205(a) and 516(b)(1) of the Clean Water Act. The CWNS is a summary of the estimated capital costs for water quality projects and other activities eligible for State Revolving Fund (SRF) support. In 1987, Congress amended the CWA to add Section 402(p), which directs EPA to establish phased National Pollutant Discharge Elimination system (NPDES) permit requirements for Storm Water (SW) discharges. EPA was directed to prepare a Report to Congress detailing SW management costs, with special attention to 1) costs for structural controls and BMPs that might be eligible for SRF funding, and 2) the costs of implementing NPDES municipal storm water programs on a national basis.

Quality Management Challenges

- Obtaining the desired work product while working under time and financial constraints
- Finding persons knowledgeable in SW management for input in project planning
- Determination of data and data quality needs, so a model could be properly developed
- Presenting technical information in way that could be understood by Congressional staff

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OWM's Quality Management Strategy

A contractor held several workgroup sessions around the country, inviting persons knowledgeable in SW management. The contractor used recommendations and concerns voiced in these sessions to develop appropriate BMPs and controls to define criteria for categorizing the cities where data would be collected. All data were collected and reviewed by the contractor. A model was developed and refined, and a draft report was prepared to discuss the modeling process and its results. A group of three external reviewers conducted a peer review of both the modeling process and the report. The comments were reviewed by the Project Manager and the contractor, and where applicable, the Project Manager incorporated the comments into the report. The ultimate decision to incorporate a comment was made by the Project Manager.

Final Work Product

The results of the model have been released. Also, a draft final report was written. Because of financial constraints, the report will remain in its current draft form. One chapter remains unwritten, and funds are not likely to be allocated for completion of this chapter.

Quality Management Tools Used to Implement the Strategy

Quality Review

At the Beginning:
Several workgroup sessions were held to:
- Determine what processes were available to control SW discharges
- Develop an implementation strategy for testing the chosen BMPs and controls
- Identify data and data quality needs for the model
- Identify data collection and other tasks for the contractor

During:
- Initial model outputs were reviewed by the contractor. Questionable data were reviewed with the corresponding community in order to determine the correct data.

At the End:
- Peer review comments were evaluated by the contractor and the PM, and incorporated where applicable.

Peer Review

At the End:
- The modeling process and draft report were submitted for external peer review by three individuals: one academic, one practitioner, and one designer/engineer.

Other QM Tools

- The PM maintained control of the drafts to ensure that the appropriate comments were integrated into the final draft report.
- A model analyzing SW discharges was developed, tested, and refined based on real world data.

Documentation Notes

- Copies of the charge to peer reviewers, names, and affiliations of the peer reviewers.
- All peer reviewer comments were addressed in a Response to Comments document, available through the Freedom of Information Act.

Quality Management Lessons Learned

Peer review was not a planned part of the project. The decision to peer review was made late in the project. In retrospect, the PM would have chosen to plan for peer review at the outset, and to conduct peer review as the project progressed. In this manner, time would have been available to review thoroughly all candidates and choose among them. Also, time and financial constraints forced the publication of the model without completion of the final report. Once the model had been published, less interest in the discussions of the final report remained. A time line and budget planning for other options when obstacles arose may have avoided this outcome.

Example 4
Assessment of "Solar Aquatics" Technology for
Treating Wastewater

What can be learned from this example?

1) Application of quality management strategies to a primary data collection effort
2) Extensive planning, quality review, and peer review throughout all stages of this project produced defensible results in a politically sensitive project.

Project Background

This project provided annual grant proposals to fund the demonstration of the benefits of a wastewater treatment technology involving the use of natural processes that occur in ponds, wetlands, and land treatment systems under controlled conditions by establishing natural ecosystems in a series of tanks in a greenhouse. The technology is generally referred to as "Solar Aquatics", "Advanced Ecological Engineered Systems", or "Living Machines". This technology has been supported by Congressional add-on funds to EPA's budget to demonstrate the technology at four sites. The project involves full-scale demonstration facilities to evaluate the grantee's technical and cost claims regarding their biological wastewater treatment process while operating at full design capacity and under steady state conditions

Quality Management Challenges

* Development of procedures to verify that project outputs and work products were of the desired quality.
* Identification of the appropriate personnel to provide technical assistance
* Mid-stream technological improvements made by the grantee that could affect data interpretation

OWM's Quality Management Strategy

Two technical advisory committees were formed, one by EPA and one by the grantee. EPA's technical committee reviewed the grantee's proposal package, which included a QAPP, against project objectives. During the project, and independent evaluation effort was conducted by an EPA contractor with funding connected with the Congressional add-on at the request of the grantee involving separate samples and data collection as well as split samples that were analyzed by an EPA contract laboratory, the grantee's laboratory, and the demonstration site laboratory to verify that the data produced by the grantee were reproducible and defensible. The quality of the grantee's work products were also evaluated independently. EPA's draft reports were submitted for quality review and peer review by EPA's technical advisory committee, the grantee's technical advisory committee, and other individuals expressing an interest in the project.

Final Work Product

Comments from the external peer review process were integrated, where applicable, into EPA's Interim Report to Congress, and Final Technology Assessment Report. The grantee used OWM's feedback to refine its system and adjust some of its claims for the system. This allowed OWM to focus on what the technology could do rather than on what it could not do.

Quality Management Tools Used to Implement the Strategy

Quality Review

At the Beginning:
Two Technical Advisory Committees, one formed by EPA and one formed by the grantee, communicated to:
- Review the grantee's proposals, project objectives, and study design
- Determine data and data quality needs
- Review grantee's sample collection plan, QAPP , data and draft reports
- ORD reviewed the grantee's QAPP in accordance with ORD's approach for research and development (R&D) data gathering projects
- EPA's technical advisory committee reviewed the grantee's proposal package against project objectives

During:
- Split samples were analyzed by an EPA contract laboratory and the demonstration site laboratory, in order to verify that the data produced by the grantee's laboratory were reproducible and defensible

Peer Review

During:
- OWM sought an independent evaluation of the cost data, biological and chemical data submitted by the grantee

At the End:
- Draft reports were submitted for peer review to individuals expressing an interest in the project
- Both EPA's and the grantee's technical advisory committees completed assessments of the draft reports and offered improvements
- Comments from the peer review and quality review processes were evaluated and integrated, where applicable, into EPA's Interim Report to Congress, and Technology Assessment Report

Documentation Notes

The Project Manager has retained documentation of the following, both for the overall demonstration project and the independent field sampling/analyses activities:
- Development, submittal, review, and approval of the QA/QC plan
- Memo to outside reviewers requesting their review of the above mentioned plan
- Outside reviewers comments
- Memo providing feedback on the draft QA/QC plan
- Final QA/QC plan
- Progress reports, draft and final reports, and data generated

Quality Management Lessons Learned

Because the project was based on a technology that still was being developed and improved, the PM believes that the project should have been categorized as an R&D project rather than a demonstration project. Realizing during the planning stage that some changes were possible; however, the PM did allow for the planning of R&D type QC requirements that were a key success for the project. Also, using quality and peer review throughout the project allowed for the grantee to receive feedback and to refine its technology and its claims.

Example 5
40 CFR Part 503 Biosolids Rule

What can be learned from this example?

The value of peer input and peer review in managing secondary data.

Project Background

In February 1989, EPA proposed regulations concerning the use and disposal of municipal sewage. Development of these regulations was an extensive effort involving several EPA divisions and staff, the collection and analysis of secondary data (e.g., data originally collected for other purposes), and the collection of primary data through a long-term survey of statistically-selected POTWs. The proposed rule included an Agency commitment to submit the proposal through a formal peer review process. Peer reviewers and stakeholders commenting on the proposed rule criticized specific aspects of the Agency's use and interpretation of secondary data. EPA then embarked on an extensive effort to revise the proposed regulations to address these concerns.

Quality Management Challenges

- Evaluating the technical validity of the public comments received (i.e., distinguishing comments that were "politically motivated" from those that were "technically valid").
- Ensuring that the quality of secondary data used to develop final regulations would be sufficient to withstand legal challenge
- Ensuring that the Agency's use and interpretation of secondary data was technically valid.

OWM's Quality Management Strategy

A three-day peer review meeting involving 35 peer reviewers was convened to fulfill EPA's commitment to have a formal peer evaluation of the proposed rule. This peer review meeting was facilitated and financially supported by the Association of Metropolitan Sewerage Agencies, the Association of State and Interstate Water Pollution Control Administrators, the National Association of Counties, the National League of Cities, the U.S. Conference of Mayors, and the Water Environment Federation. Peer reviewers attending the meeting represented diverse cross-section of interests, expertise, and perspectives on the diverse and highly technical issues relating to sludge management and disposal practices. In response to peer review comments that inappropriate use of the secondary data in EPA's model created an unrealistic worst-case scenario for a protection benchmark. Twelve experts (including some of the 35 peer reviewers) were asked to provide assistance (peer input) in revising the rule, especially in the appropriate selection and use of secondary data, models, and in the simplification of the rule, based on knowledge from research involving protection against potential harm. A smaller number of independent experts, primarily representing various EPA offices, reviewed the final draft of the rule. A third peer review was initiated two years after promulgation of the final regulations as a means of verifying that the regulations met expectations and for identifying areas for further improvement.

Current Project Status

The final rule was published after a two year effort to revise the proposed rule. OWM is now assisting Regions, states, and municipalities with implementation of the final rule.

Quality Management Tools Used to Implement the Strategy

Quality Review

During:
- Twelve experts, some of whom were involved in a peer review of EPA's proposed rule, were asked to assist EPA in revising the rule to address peer review comments.
- Experts provided assistance in selecting appropriate secondary data for use in the rule, appropriate use of these data in EPA models, and simplifying the rule

Peer Review

At the End:
- The revised draft of the final rule was reviewed by several experts who were completely independent of the quality review process activities or the regulatory development process. Most of these experts represented various EPA offices.
- An internal review of the final rule was coordinated in accordance with the formal peer review procedures used by the National Academy of Science.
- A follow-up peer review was performed two years after promulgation of the rule. Comments from this review were used to identify further OWM priorities related to management and regulation of biosolids.

Documentation Notes

- A formal docket was assembled to support both the proposed and final rulemaking activity. The docket included copies of all data used to support the regulation, all assumptions used to interpret the data, all comments received, a formal response to those comments, and records of the peer review process.

Quality Management Lessons Learned

- The inclusion of expert quality and peer reviewers earlier in the regulatory development process would have prevented EPA from developing a proposed rule that was based, in part, on a flawed interpretation of the data.

Example 6
1998 Biosolids Quality Survey

What can be learned from this example?

The importance of up-front planning and involvement of experts when project budgets are not sufficient to meet project goals.

Project Background

In FY 1998, the Assistant Administrator for Water directed OWM staff to gather data necessary to evaluate the quality of biosolids (municipal sewage sludge) that are being beneficially used in accordance with the 40 CFR 503 regulations. The AA provided a five year budget of $350,000/year to address the specific question, "Is the quality of biosolids generated today the same, better, or worse than the quality of biosolids generated in 1988?" (EPA conducted a National Sewage Sludge Survey and other data gathering activities in 1988.)

Quality Management Challenges

- Designing a study that answers the AA's question within the specified budget and time period.
- Including in the planning process an awareness of new sampling and analysis methodologies that allow determination of pollutants at lower concentrations than could be measured in 1988
- Finding appropriate experts
- Building on lessons learned in the 1988 data gathering activities

OWM's Quality Management Strategy

OWM consulted with statisticians, chemists and other staff from OST regarding sampling and analysis costs, statistical design, and methodology that might be appropriate for the study. The statisticians cautioned that it would not be possible to answer statistically the question posed with the funds provided. The statisticians indicated it was necessary to survey 19,000 entities to determine whether a statistically significant difference exists between biosolids today and in 1988, whereas cost estimates suggested that only 200 entities could be surveyed.. OWM then conducted several meetings with technical and statistical experts to determine options. Options included re-framing the project objectives, narrowing the scope of the question to address self-reported data, and requesting a larger budget. After briefing the AA on the challenges, the AA re-directed OWM to eliminate the need for statistical comparison to 1988 and instead answer the question, "Are biosolids generated today still of sufficient quality to meet the risk assessment objectives used to develop the current regulations?"

Current Project Status

OWM staff are working with a group of internal and external experts to design a study that meets new project objectives within the allotted budget.

Quality Management Tools Used to Implement the Strategy

Quality Review

At the Beginning:
Meetings were held to:
- Determine project objectives
- Develop a strategy for project implementation
- Identify financial resources
- Determine data and data quality needs
- Develop a statistically-based study design based on those needs

During:
Because financial constraints prohibited the implementation of a statistically-based study design, additional meetings were held to:
- Develop alternatives to the initial project objectives
- Decide if implementation of alternatives would offer significant, useful information
- Determine data and data quality needs for implementation of options generated
- Determine if alternative approaches could be implemented with available resources

Peer Review

- The initial draft of the study plan was submitted for formal review by external experts experienced in the collection and management of biosolids. Results of this review are being used to revise the study design.
- The final study plan also is scheduled for external peer review.

Other QM Tools

- Standardized sampling and analysis methods will be used to ensure consistency across sampled facilities and analytical laboratories.
- All of the QC measures shown in Chapter 2, Exhibit 2-2 will be applied to sampling and analysis activities.
- State and Regional sampling personnel will be provided with sampling guidance and sampling kits to control variability between sample collection processes and sampling containers.

Documentation Notes

- Documentation of initial charge issued (verbally) by the Assistant Administrator
- Notes, agendas, and internal correspondence from the initial project planning meetings (including cost estimates, statistical scenarios, and information on data needs and existing data,)
- Copies of materials used to brief the AA on the difficulty answering the initial question and notes from that meeting that document the revised charge
- Notes, agendas, and internal correspondence from the subsequent planning meetings being held to discuss study designs needed to answer the new question.

Quality Management Lessons Learned

The process of determining project objectives and resources available at the outset may sometimes appear to be burdensome, but it can save a large tremendous amount of time and money. In this case, OWM's investment of up-front planning ensured that a $350,000 annual budget would not be spent in gathering data that failed to answer scientifically the question these funds were directed to address.

Example 7
CSO Monitoring and Modeling Guidance

What can be learned from this example?

It is never too late to add new QM strategies to a project. In this example, an unplanned peer review phase was added, and dramatically improved the quality of the final work product.

Project Background

In 1994, EPA issued the final Combined Sewer Overflow (CSO) Control Policy. The policy establishes a consistent national approach for controlling discharges from combined sewer systems to the Nation's waters through the National Pollutant Discharge Elimination System (NPDES) permit program. In support of EPA's commitment to providing the required tools for effective implementation of the policy, EPA has issued several guidance documents. The *CSO Monitoring and Modeling Guidance* was developed to provide a set of guidelines that provides flexibility for municipalities to develop site-specific strategies for characterizing their combined sewer system operation and impacts, and for developing and implementing comprehensive CSO control plans. The guidance includes low cost monitoring and modeling techniques that should be useful to communities of all sizes.

Quality Management Challenges

- Defining project goals and scope of the document to be produced
- Completing project goals within established resource constraints
- Identifying available relevant models
- Ensuring the guidance was applicable to communities of all sizes
- Assignment of a new Project Manager mid-way through the project
- Finding appropriate experts to peer review draft manual, and to address comments from peer reviewers and stakeholders
- Determining the level of peer review to utilize in the project

OWM's Quality Management Strategy

Because he took this multi-year project over midstream, the project manager was faced with the challenge of reconciling initial project plans with more recent developments in CSO monitoring and policy. The project manager also was faced with a challenge of applying the Agency's newly refined peer review policy and procedures to this guidance document. The project manager addressed these challenges by 1) seeking multiple rounds of internal review prior to external review and public release, 2) consulting with other EPA and Water Environment Federation staff to identify appropriate peer reviewers, 3) submitting the final draft to three external organizations for formal peer review, and 4) releasing the document to stakeholders for informal comment concurrent with the formal peer review process. All comments received from the stakeholders and from formal peer reviewers were documented and addressed in a formal "response to comments" document. In addition, all comments were evaluated by three people and integrated, where applicable, into the manual.

Current Project Status

A draft final document has been produced submitted to the Branch Chief, Division Director, and Office Director for final review. Once comments are received and addressed, the final document will be published, providing guidance to all communities, regardless of size, on development of monitoring/modeling programs commensurate with their CSO problems.

Quality Management Tools Used to Implement the Strategy

Quality Review

During:
- Drafts of the guidance were reviewed several times internally before release to public.
- Discussions were held to find resources for potential peer reviewers. They were chosen based on the recommendations of EPA staff and the Water Environment Research Federation.

At the End:
- Concurrent with formal peer review, the draft manual was released to stakeholders for review and informal submission of comments.
- Stakeholder comments were evaluated by three people and, where applicable, integrated into the manual.

Peer Review

At the End:
- The draft manual was submitted for external peer review by three independent organizations.
- Peer review comments were reviewed by three people and, where applicable, integrated into the manual.

Other QM Tools

- Existing data models were referenced planning data gathering and analysis.

Documentation Notes

The Program Manager has retained copies of the following:
- The charge sent to external peer reviewers
- Comments received from reviewers
- Decisions and explanations regarding the acceptance or rejection of comments
- A Response to Comments document

Quality Management Lessons Learned

Although the Project Manager had not planned on peer review of the draft work product, it was selected for peer review by OWM management in response to EPA's new peer review policy. The Project Manager was pleased with the results of the review and would incorporate it during the planning stages of future projects. Also, the manual changed dramatically in scope and organization as the project proceeded. In future projects, the Project Manager believes that it would be beneficial to define clearly the scope and objectives of the project, and a basic outline of the final work product.
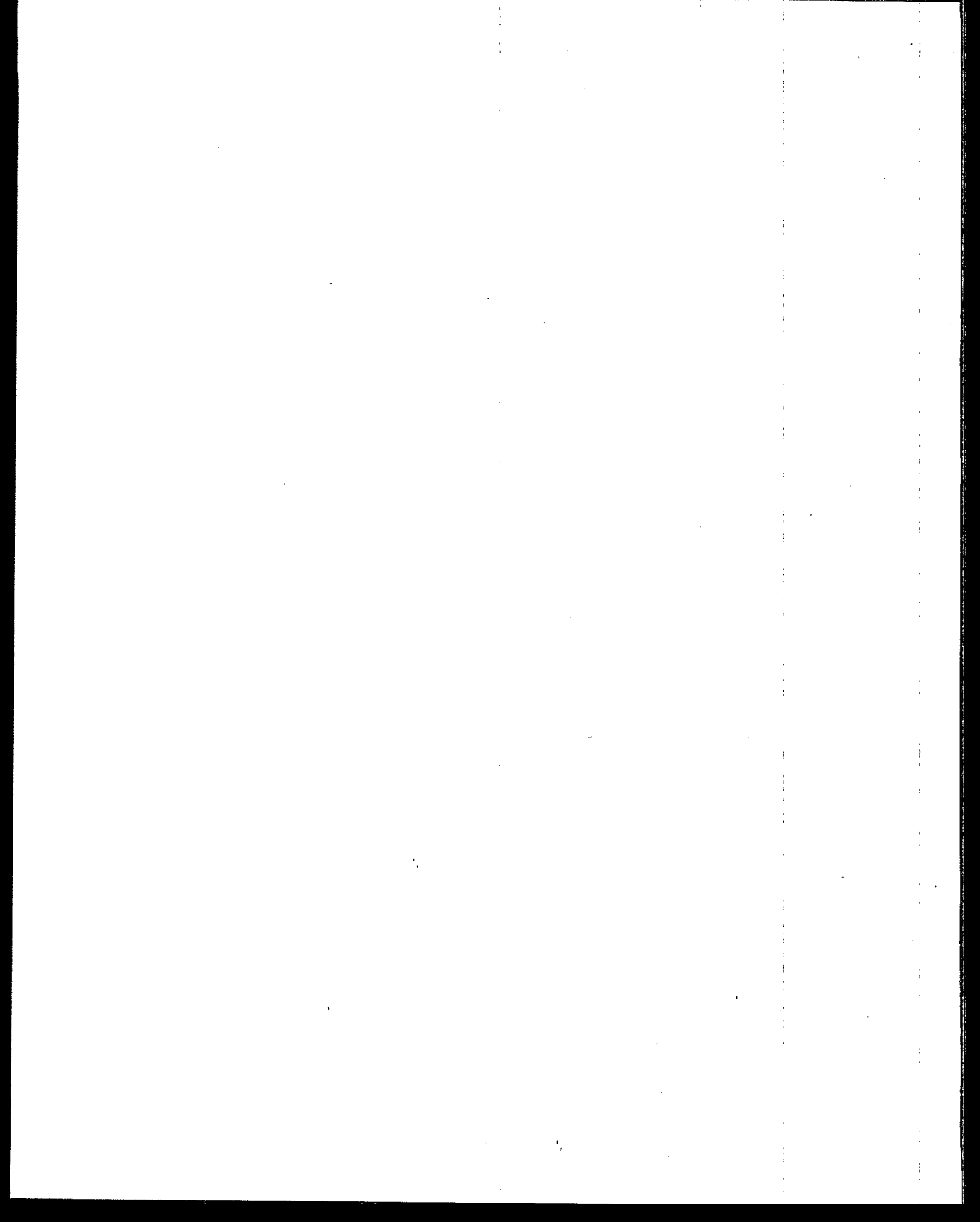
Chapter 6

Answers to Commonly Asked QM Questions

A number of questions are often asked about quality management. This chapter poses many of these questions and answers them. Additional discussion concerning many of these issues may be found elsewhere in this guide.

Needed Quality Requirements

Q: How do I determine the quality requirements that I need for the project?

A: All EPA work products should be of high quality, but in general, the highest quality requirements are needed for those work products that: (1) support regulatory decisions, (2) will have widespread use or widespread impacts, or (3) are highly innovative in approach or design. OWM staff members should attempt to design all their activities in a way that maximizes quality within given resource budgets and project time lines, and are strongly encouraged to incorporate quality review into the planning stage of any project that demands the highest level of quality. Quality reviewers can then assist in determining the overall level of quality needed and capable of being achieved.

Controlling Quality

Q: What are some of the ways I can control quality?

A: The most valuable ways to control quality are:

- ► to consider your quality needs up-front during the project planning process and design your project accordingly,
- ► to follow through on your planned project design,
- ► to monitor your project continuously to ensure you are meeting your planned schedules, budgets, and objectives, and
- ► either to revise your plan or to seek additional resources as soon as you encounter unanticipated difficulties that may impact your schedules, budgets, or objectives.
- ► to document how the quality was assured.

Q: How do I control the quality of primary data?

A: Specific ways of controlling the quality of primary data include: defining data needs, using standardized methods to collect data, and using QA measures such or those shown in Exhibit 3 of Chapter 2. Detailed information regarding the control of primary data may be found in EPA's guides pertaining to Data Quality Objectives, listed in Appendix A.

Q: How do I control the quality of secondary data?

A: Specific ways of controlling the quality of secondary data include: (i) using experts to assist you in finding the most relevant data available, (ii) using experts to assist you in determining if the data obtained are, in fact, suitable for your project, (iii) using experts to assist you in determining data limitations, and (iv) testing any conclusions you reach with secondary data against "real world expectations." (This might include, for example, performing a pilot study or bench-scale test to determine the accuracy of model outputs resulting from assumptions made with secondary data).

Quality Control Tools

Q: What are some of the tools I can use to control quality?

A: Some examples of quality management tools include the use of: (see also chapter 2)

- ■ Experts to assist in defining quality needs and devising plans to obtain the desired level of quality (quality review and peer input);

- Experts to review interim and final work products (quality review and peer review);

- Standard operating procedures or methods to ensure that a process is applied consistently over time and by multiple individuals;

- Peer review or widely accepted data management tools or strategies (e.g., a cost/benefit model, a statistical approach, or an analytical database);

- Pre-defined data quality objectives, stringent QM measurements, and QM acceptance criteria for data gathering projects;

- Data whose quality already has been defined for other projects; and

- Centralized process control strategies (e.g., Word Perfect document management features that track all edits made and by whom, or strategies to control decision making by establishing a hierarchy of decision makers).
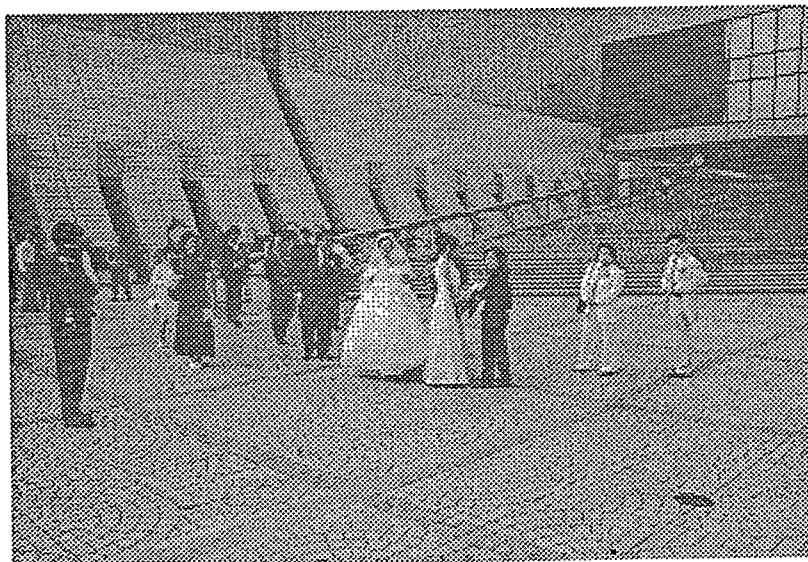
Quality Management Applies to

Q: To which OWM activities does QM apply?

A: Everything! QM is not limited to activities involving the collection of data. It applies to the development of regulations, guidance documents, briefing packages, and more. See Chapter 1 for a list of other examples to which QM principles apply.

Documenting Quality Management

Q: If I do an excellent job of quality management, but I did not document anything, did I really do Quality Management?

A: Not really. Without documentation, you cannot demonstrate that you have considered aspects of project or data quality. A lack of documentation also deprives other OWM staff of the opportunity to build on your products, your processes, or your activities. This contradicts a key concept of quality management—continuous improvement.

Why bother with Quality Management?

Q: I already have more than enough work to do. Why should I bother with quality management?

A: See Exhibit 7.

Exhibit 7
Top 10 reasons why you should practice quality management

10. Because it can save hundreds, thousands, and even millions of taxpayer dollars.
9. Because it could save you weeks or months--you'll have time to go on vacation.
8. Because your QM documentation will facilitate transferring the project to someone else so you can move on to bigger and better things.
7. So you can survive a QA audit.
6. Because it helps defend against adverse comment or litigation.
5. To ensure your data are available and usable for the future.
4. So you can achieve Agency recognition for a well-managed project.
3. Because your QA Coordinator says so.
2. Because your QA Manager says so. And if that's still not enough . . .
1. Because the Administrator says so!

Quality Control, Quality Requirements, Quality Assurance, and Quality Management

Q: What is the difference between *quality control (QC)*, *quality requirements, quality assurance (QA)*, and *quality management (QM)*?

A: *QC* is the term now generally associated with end of the pipe inspections to identify any defective products. It is no longer used by most quality managers because it implies that there will be defects. The current quality management system is designed to control quality from the beginning

Quality requirements are the standards that are necessary for the work product/effort under consideration.

QA is the collective system of processes used to control quality. The level of effort needed to control quality depends on the project's purpose, complexity, and nature.

QM describes an organization's commitment to quality by its management. *QM* involves the development of policies and the provision of resources and rewards to ensure that have been met. QM as outlined by Demming's Total Quality Management model is to *Plan – Do – Check and Act.*

Because "quality management" is a more recent term that was developed to equate QA with total quality management (TQM) principles, it is widely confused with QA, and the words are often used interchangeably. This guide seeks to promote OWM's QM culture by illustrating the ways in which QM can benefit OWM staff and products and by providing straightforward ways (and examples) of implementing QM principles into projects through development of QA systems and tools.

Primary and Secondary Data

Q: What is the difference between *primary data* and *secondary data*?

A: *Primary data* are original new data actively collected by or for the project manager to address specifically an issue at hand. Examples of primary data include sampling and new analytical measurements, new survey results, and comments to proposed regulations collected by EPA or by EPA's contractors to address an immediate need.

Secondary data consist of data that were originally gathered by others for one purpose and that are now being used by the project manager, and his or her contractor or grantee for a different, or secondary, purpose. This may include previously collected analytical data from scientific literature and state program monitoring programs, historical information, etc., that is now being assembled for

use in a current EPA project.

Q: Does Quality Management apply only to the collection of primary data?

A: No. Quality Management applies to the collection of both primary and secondary data. OWM staff using secondary data must assess the quality and appropriateness of the secondary data, including how it was collected originally, the purpose for which it was collected, and the limitations on its use.

Q: If we have had no opportunity to plan for the quality of the secondary data that we are using, how do we assure that the data are appropriate for our projects?

A: Although you may not have been involved in planning the quality of data gathered by others, *you can plan how you will use such secondary data* in your study. When using secondary data, it may be advisable to consult experts familiar with the generation and use of the data (or similar types of data) to help evaluate the applicability of the data to your project, identify its limitations, and determine how it can be used properly in your project. See Example 5 in Chapter 5 as a case study in which problems occurred because experts were not consulted prior to using secondary data. The quality review and peer review tools are particularly well-suited to evaluating the adequacy of secondary data.

Q: Who are the experts, and how do I find them?

A: Suggestions for finding experts include: seeking recommendations from fellow co-workers, reviewing the public literature for widely published authors, your quality assurance coordinator, or contacting stakeholder organizations for recommendations

Hey! I Just Got Someone Else's Project

Q: Can quality management techniques that are not planned for and implemented at the start of a project be added part way through the project?

A: Yes. Quality management is a highly dynamic process that can be thought of as a cycle involving planning of the project and project quality, implementation of the plan, assessment of whether the plan is working or has worked, and refinement of the plan to improve the product or project process. If a project becomes technically more complicated than originally anticipated, for example, a workgroup of additional experts may be formed to work through the issues. Or the project may become more controversial than at the start, and more extensive peer review may be added.

Example 7 in Chapter 5 illustrates a situation in which a requirement for formal peer review was added just prior to completion of the final work product. *Example 5* in Chapter 5 illustrates a situation in which unanticipated complexities of the project led to difficulties and required previously unplanned levels of quality and peer review.

Quality Review (See also Chapter 2)

Q: What is Quality Review?

A: *Quality review* entails the use of knowledgeable individuals to assist in determining the level of quality needed of all OWM work products or processes, and later, to evaluate the work product to determine if the level of quality is being obtained. Quality review, as we are defining it in this guide, includes both technical or nontechnical review and input by all stakeholders in OWM activities.

Q: What is one of the most important parts of quality review?

A: A quality review of planned activities is especially important <u>at the beginning</u> of the activity. It helps determine:

- The appropriateness and relevance of the task. *If the planned task is not relevant, either change it so that it is or do not do it.*
- The level of quality needed for each of the activities required during the project.
- The level of quality that is possible, given the resources and time available
- What to do if the quality needed is greater than available resources allow: *(i) change the approach which might include ways to leverage and/or change the level of resources; (ii) identify clearly to managers that the level needed cannot be attained and identify what level can be attained with what shortcomings, or (iii) do not do the task.*

Q: What are other important times for quality review?

A: Quality review by peers <u>during the task</u> will help assure that the level of quality you deemed necessary and possible is being attained. When coupled with peer input, it also can provide an opportunity to obtain suggested mid-stream corrections to address unforeseen problems. (<u>Note</u>: Although this is a helpful strategy in some projects, OWM staff members need to remember that any consolidation of peer input and quality review functions during project implementation may preclude the quality reviewers from serving as independent peer reviewers of the final product).

Quality review <u>at the completion</u> of the final draft of a report or project further helps ensure that a relevant quality product has been attained and may also be useful in interpreting peer reviewers' comments.

Peer Review

Q: Whom do I go to for peer review?

A: Peer review should be performed by individuals who are technically qualified to perform the work, are free from real or perceived bias concerning the work product, and are independent of the work product (i.e., they were not substantially involved in its development). Qualified peer reviewers may be found within OWM, within OW, within other EPA offices or EPA Regions, or external to EPA (e.g., states, municipalities, stakeholder organizations, private citizens, or contractors).

Q: Do all peer reviewers have to be "technical" people?

A: Generally, peer reviewers should be selected to meet the objectives of your peer review. If your work product involves guidance or analysis of engineering practices, for example, your work plan or product should be reviewed by a qualified engineer. If the work product is intended for a wide, non-technical audience, however, it also may be desirable to include a non-technical peer reviewer whose purpose is to evaluate whether the product is clearly presented to its intended audience.

Q: How much will I have to pay for external peer review services?

A: In a great many cases other technical experts will serve as peer reviewers as a professional courtesy to those persons who have produced the product. They will often do this because they also have an interest in having and using a product like that being produced and/or they have an interest in assuring that it is a good product as it may ultimately apply to them. They are more likely to come if they do not have to pay their own way, but instead have their travel and lodging expenses paid for them.

When you find that you will need to pay for peer review -- either because of the short time frame in which you need to get the work done, or because of the considerable amount of work that needs to be done – you should estimate the time involved in conducting a peer review of each of your products. Then multiply that time figure by the number of reviewers who will be required to review your product and multiply that by the estimated hourly rates for individuals with expertise in your subject area. Arrangements for pay are generally made by contract.

Q: How do I initiate the peer review process?

A: You begin by writing a "charge" to peer reviewers that documents specific issues or questions you would like them to address and invites comments on the entire product. Additional information can be found in the *Science Policy Council Handbook for Peer Review*, EPA 100-B-98-001, January 1998.

Q: Once peer review comments are received, what is the procedure for incorporating them into my final work product?

A: All peer review comments received must be evaluated. This evaluation may include consultation with other experts or staff within the Agency. All comments must be either addressed in the revised work product, or must be documented in the QM file to indicate why the comment was not addressed.

Q: Does peer review have any role in regulatory negotiations?

A: Regulatory negotiations are not candidates for peer review. However, to ensure that decisions are based on sound and credible science, the major scientific and technical work products that support the negotiation need peer review before the negotiation takes place.

Q: Are there any circumstances when a major work product may not be subjected to a peer review?

A: Yes, there may be situations when a decision to eliminate the peer review process can be justified. For example:

- Additional peer review is not required with work that has been previously reviewed by recognized experts or an expert body.
- Additional peer review is not required when the scientific and/or technical methodologies or information being used are commonly accepted in the field of expertise.
- A major work product would not receive peer review when the regulatory activity or action which the work supports is terminated or canceled. No further action is necessary
- Statutory and court ordered deadlines may limit or preclude peer review.
- Rarely, resource limitations may restrict peer review. These should be evaluated on a case by case basis.

If peer review of a major work product is not conducted, written justification, signed-off by the appropriate decision maker, must be documented.

Q: Can work products that are not determined to be major still be subjected to peer review?

A: Yes, peer review may be warranted if it adds substantial value to the work product. Another alternative is to use the less formal "quality review" process for such final work products because:

- the formal Agency "peer review" requires each office annually to prepare and submit to the Administrator records of its peer review activities, and
- the peer review process requires that reviewers be completely independent of the work product. The quality review mechanism imposes neither the added level of documentation nor the added level of independence.

Q: How does one determine the appropriate Peer Review Mechanism?

A: Arranging for the most appropriate and feasible peer review will involve consideration of substance, time, and resource trade-offs. Essentially, the level of peer review matches the impact and complexity of the major work product. The greater the possible impact or complexity, the stronger the indication for a more extensive and involved peer review and for external peer review, in particular. The choice of mechanism will depend upon the experience and assessment of the Decision Maker.

How Is Peer Review Different From?

Q: How does peer review different from quality review?

A: Peer review is more formal than quality review and involves the use of qualified peers who have had very little involvement in the activity, (e.g., except perhaps for review of the project's plans). Peer review is a required Agency process that uses technically qualified peers (persons of equal or greater rank) to ensure the quality of all major, technical work products.

Quality review does not require the independence of peers who assist in the conducting and review of an activity.

Q: How does peer review different from stakeholder involvement?

A: Stakeholder involvement occurs when the Agency works with external interest groups that have some stake or concern over the outcome of the technical work product or regulatory position. This is an interactive process, working with other agencies, industry groups, regulated-community experts, environmental groups, and other groups that represent a broad spectrum of the regulated community. This process usually strives for a consensus approach. The goal of peer review, on the other hand, is to obtain an independent, third-party review. Stakeholder involvement does not substitute for peer review even though it adds value to the work product.

Q: How does public comment differ from peer review?

A: The critical distinction is that public comment does not necessarily draw the kind of independent, expert information and in-depth analyses expected from the peer review process. Public comment is open to all issues, whereas the peer review process is limited to the consideration of technical issues. While it may be an important component of the review process, public comment does not substitute for peer review.

Federal Advisory Committee Act (FACA) as a Quality Management Tool

Q: I have heard that there are a lot of rules regarding the use of Federal Advisory Committee Act (FACA) committees and that workgroups are considered FACA Committees. Where do I find more information about these requirements, and when would I want to use such a cumbersome tool?

A: Peer review carried out by formal and established (chartered) Federal advisory committees (such as the Science Advisory Board) is always subject to FACA requirements. If, however, EPA conducts a peer single review meeting for the purpose of obtaining advice from the individual attendees (as opposed to consensus advice from the group), the meeting would not be subject to FACA. Questions concerning the applicability of FACA to peer review meetings should be addressed to the FACA experts in the Cross-Cutting Issues Division of Office of General Council.

Often, the choice to use a FACA committee is dictated through a Congressional, Presidential, or Administrator's directive to address complex or controversial projects and issues. At other times is may be a recommendation of the program office.
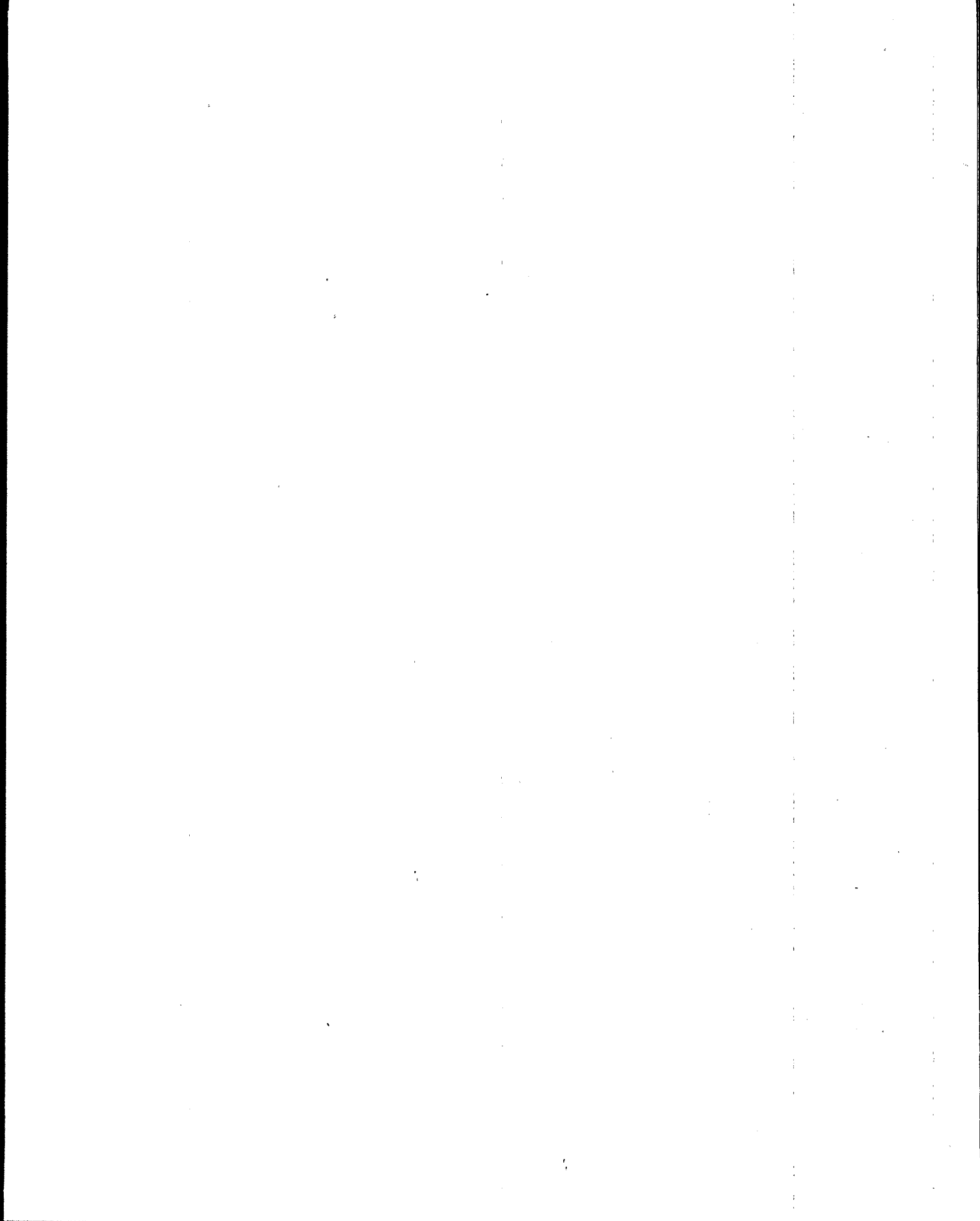
Appendix A

EPA Quality Assurance Requirements and Guidance Documents

[NOTE: Many of the following documents are available to download from EPA's Quality Assurance Division Internet pages at the following address: *http://es.epa.gov/ncerqa/qa/qa_docs.html*]

EPA QA/G-0, *EPA Quality System Description*

QA/G-0 provides an overview of the EPA Quality System and describes the various quality assurance (QA) and quality control (QC) policies and practices comprising the Quality System. This document provides a brief history of the evolution of the EPA Quality System and why it plays a critical role in Agency operations. This document was placed into the Agency's directives clearance process in December 1997.

EPA QA/R-1, *EPA Quality Systems Requirements for Environmental Programs*

QA/R-1 is the external policy document by which EPA will announce its implementation of the American National Standard ANSI/ASQC E4-1994, *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs*. An internal preliminary draft has been completed and is awaiting formal adoption of the standard by EPA. The same information will be part of the EPA *Quality Manual for Environmental Programs*, an internal policy manual. When E4 has been formally adopted by EPA, the draft will be distributed for comment.

EPA QA/G-1, *Guidance for Developing Quality Systems for Environmental Data Operations*

QA/G-1 provides non-mandatory guidance to help organizations develop a QA program that will meet EPA expectations and requirements. There is no draft currently available.

EPA QA/R-2, *EPA Requirements for Quality Management Plans*

QA/R-2 is the policy document containing the specifications and requirements for Quality Management Plans (QMPs) for organizations with which EPA has extramural agreements. A Draft Final version is awaiting Agency approval for release. QA/R-2 is the intended replacement

for QAMS-004/80. The same information contained in this document is found in the EPA *Quality Manual for Environmental Programs*, an internal policy manual. Current Draft Version: August 1994.

EPA QA/R-2A, *EPA Requirements for Quality Management Plans for Analytical Laboratories and Facilities*

QA/R-2A will provide detailed requirements for environmental analytical labs. Since there may be a national consensus standard for labs, the content of this document is unclear at present.

EPA QA/G-2, *Guidance for Preparing Quality Management Plans*

QA/G-2 provides non-mandatory guidance to help organizations develop Quality Management Plans (QMPs) that will meet EPA expectations and requirements. The document will contain tips, advice, and case studies to help users develop improved QMPs. There is no draft currently available.

EPA QA/G-2EA, *Guidance to Implementing Quality Assurance in Extramural Agreements*

The G-2EA document is intended for use by EPA project officers and contains one section each on steps needed to determine and implement QA requirements for contracts, work assignments, cooperative agreements, and interagency agreements. The text will be written from the perspective of the project officer and will present the step-wise process for each extramural agreement mechanism in one document. There is no draft currently available.

EPA QA/G-2C, *Guide to Satisfying EPA Quality Assurance Requirements for Contracts and Work Assignments*

The G-2C document is intended for use by contractors performing work on behalf of EPA and contains sections on the steps needed to identify, document, and implement QA requirements for proposals, awarded contracts, work assignments, and technical directives (or similar mechanisms). The text will be written from the perspective of the contractor and will present the step-wise process for each contract mechanism in one document. There is no draft currently available.

EPA QA/G-2F, *Guide to Satisfying EPA Quality Assurance Requirements for Financial Assistance Agreements*

The G-2F document is intended for use by organizations receiving financial assistance from EPA and contains sections on the steps needed to identify, document, and implement QA requirements for research grants, state and local government grants, cooperative agreements, and other financial assistance agreements. The text will be written from the perspective of the applicant or awardee for assistance and will present the step-wise process for each extramural agreement mechanism in one document. There is no draft currently available.

EPA QA/G-3, *Guidance for the Management Systems Review Process*

QA/G-3 provides non-mandatory guidance to help organizations plan, implement, and evaluate management assessments of their quality systems. The guidance will present a step-by-step description of the MSR process. Current Draft Version: January 1994.

EPA QA/G-4, *Guidance for the Data Quality Objectives Process,* **EPA/600/R-96/055, September 1994**

> QA/G-4 provides non-mandatory guidance to help organizations plan, implement, and evaluate the Data Quality Objectives (DQO) process, with a focus on environmental decision-making for regulatory and enforcement decisions. The guidance presents a step-by-step description of the DQO process.

EPA QA/G-4D, *Data Quality Objectives Decision Errors Feasibility Trials (DEFT) Software,* **EPA/600/R-96/056, September 1994**

> QA/G-4D provides non-mandatory guidance for using the Decision Error Feasibility Trials (DEFT) software to help organizations plan, implement, and evaluate the Data Quality Objectives (DQO) process. The guidance presents a step-by-step description of the use of the PC-based DEFT software DQO process.

EPA QA/G-4R, *Guidance for the Data Quality Objectives Process for Researchers*

> QA/G-4R provides non-mandatory guidance on the application of the Data Quality Objectives (DQO) Process for researchers and experimenters. The guidance integrates the DQO Process with statistical design of experiments. There is no draft currently available.

EPA QA/G-4HW, *Guidance for the Data Quality Objectives Process for Hazardous Sites*

> QA/G-4HW provides non-mandatory guidance to help organizations plan, implement, and evaluate the statistics-based Data Quality Objectives (DQO) process as applied to hazardous waste sampling activities. The guidance will present a step-by-step description of the DQO process and its application to environmental remediation and waste management activities. There is no draft currently available.

EPA QA/G-4CS, *The Data Quality Objectives Process: Case Studies*

> QA/G-4CS will be a collection of case studies that illustrates applications of the DQO process to environmental situations. These case studies will be adapted from actual investigations and several lead to complex applications of the DQO process. There is no draft currently available.

EPA QA/R-5, *EPA Requirements for Quality Assurance Project Plans*

> QA/R-5 is the intended replacement for QAMS-005/80. This external policy document will establish the requirements for QA Project Plans prepared for activities conducted by or funded by EPA. It is intended for use by organizations having extramural agreements with EPA. Current Draft Version: October 1997. This document was placed into the Agency's directives clearance process in October 1997.

EPA QA/G-5, *Guidance on Quality Assurance Project Plans,* **EPA/600/R-98/018, February 1998**

> QA/G-5 provides non-mandatory guidance to help organizations develop a Quality Assurance Project Plans (QAPPs) that will meet EPA expectations and requirements. The document provides a linkage between the DQO process and the QAPP. It contains tips, advice, and case studies to help users develop improved QAPPs.

EPA QA/G-5S, *Guidance on Sampling Designs to Support QA Project Plans*

> QA/G-5S provides non-mandatory guidance on the practicality of constructing sampling plans to meet the guidelines outlined in the statistics-based DQO Process (QA/G-4), and the QAPP (QA/G-5). Different sampling schemes are discussed and the relative strengths and weaknesses outlined. There is no draft currently available.

EPA QA/G-5T, *Guidance on Specialized Topics in Quality Assurance*

> QA/G-5T is a collection of discussion papers on some of the more advanced topics in Quality Assurance. These papers reflect some of the latest research results in QA and is also a forum for discussion of QA policy issues. There is no draft currently available.

EPA QA/G-6, *Guidance for the Preparation of Operating Procedures for Quality-Related Operations,* **EPA/600/R-96/027, November 1995**

> QA/G-6 provides non-mandatory guidance to help organizations develop and document Standard Operating Procedures (SOPs). The document contains tips, advice, and case studies to help users develop improved SOPs.

EPA QA/G-7, *Guidance on Technical Assessments for Environmental Data Operations*

> QA/G-7 will provide non-mandatory guidance to help organizations plan, conduct, evaluate, and document technical assessments for their programs. Such technical assessments include Technical Systems Audits (TSAs), surveillance, readiness reviews, and Performance Evaluations (PEs). The document will contain tips, advice, and case studies to help users develop improved processes for conducting technical assessments. This is currently a planning item. QAD expects to use a Work Group process to develop this guidance.

EPA QA/G-8, *Guidance on Environmental Data Validation and Verification*

> QA/G-8 will provide non-mandatory guidance to assist users in validating and verifying environmental data. The guidance will discuss alternative approaches to data validation, including examples of statistics-based validation techniques, and options for verifying that the validated data satisfy relevant claims about their authenticity and quality.

EPA QA/G-9, *Guidance for the Data Quality Assessment Process: Practical Methods for Data Analysis,* **EPA/600/R-96/084, January 1998**

> QA/G-9 provides non-mandatory guidance for planning, implementing, and evaluating retrospective assessments of the quality of the results from environmental data operations. DQA is a statistically-based, quantitative evaluation of the extent to which a data set satisfies the user's needs (or DQOs). This particular document is aimed at the project managers who are responsible for conducting the environmental data operations and assessing the usability of the results.

EPA QA/G-9D, *Data Quality Evaluation Statistical Toolbox (DataQUEST),* **EPA/600/R-96/085, December 1997**

> QA/G-9D provides non-mandatory guidance for planning, implementing, and evaluating retrospective assessments of the quality of the results from environmental data operations using the PC-based software, DataQUEST.

EPA QA/G-10, *Guidance for Determining Quality Training Requirements for Environmental Data Operations*

> QA/G-10 will provide non-mandatory guidance to help organizations determine and develop training requirements for their programs. The document contains an overview of all of QAD's QA publications together with how the documents interact with the Agency's QA System. In addition, the document outlines all the training courses in QA developed by QAD, a description of all the individual modules constructed by QAD, and directions for downloading these from Agency's QA home page. This document has not been reviewed internally by all Agency program or regional offices and is subject to change or revision. External Review Draft versions were released at the EPA National Quality Assurance Meeting held in August 1997.

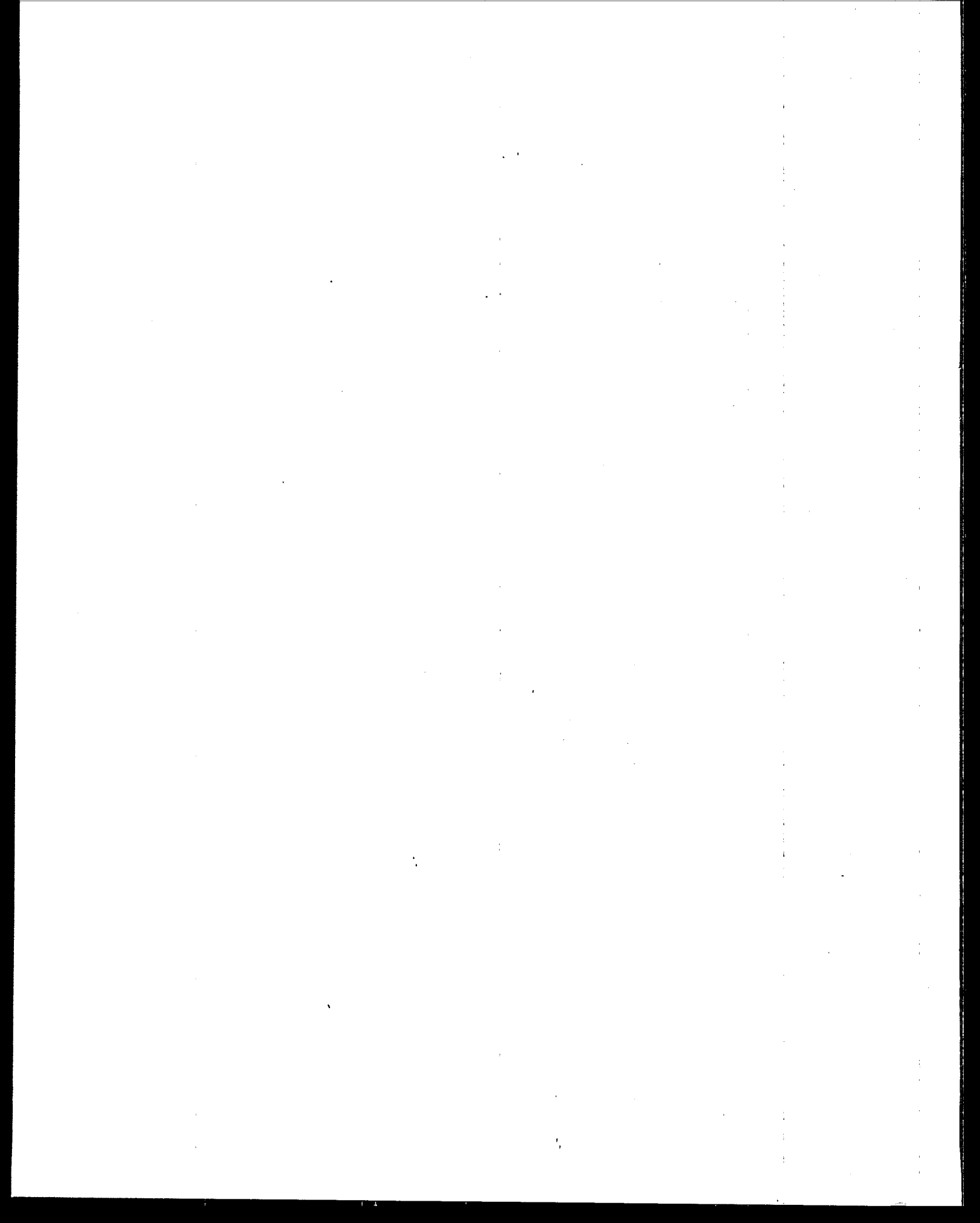**EPA QA/G-11,** *Guidance on Decision Quality Planning for Project Managers*

> QA/G-11 will provide non-mandatory guidance for assuring quality in the planning of environmental programs and projects. Its intention is to help project managers integrate quality management principles and practices into all of their project activities. There is no draft currently available.

EPA QA/G-12, *Quality Assurance for Environmental Technology Design, Construction, and Operation*

> QA/R-12 will provide non-mandatory guidance for assuring quality in the design, construction, and operation of environmental technology. This guidance will describe how to apply Part C requirements of ANSI/ASQC-E4-1994 to various environmental technology scenarios and how to demonstrate conformance to that American National Standard. There is no draft currently available.

EPA 100-B-98-001, *Science Policy Council Handbook on Peer Review*

Deming, W.E. Out of Crisis, MIT Center for Advanced Educational Services, Cambridge, MA, 1986.

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Appendix B

Peer Review

Policy Overview
Major scientifically and technically based work products related to Agency decisions should normally be peer reviewed. **Agency managers within headquarters, Regions, laboratories, and field components determine and are accountable for the decision whether to employ peer review in particular instances** and, if so, its character, scope and timing. These decisions are made in conformance with program goals and priorities, resource constraints, and statutory or court-ordered deadlines. For those work products that are intended to support the most important decisions or that have special importance in their own right, external peer review is the procedure of choice. Peer review is not restricted to the penultimate version of work products; in fact, peer review at the planning stage can often be extremely beneficial. (From the forward of the Science Policy Council Handbook on Peer Review EPA 100-B-98-001)
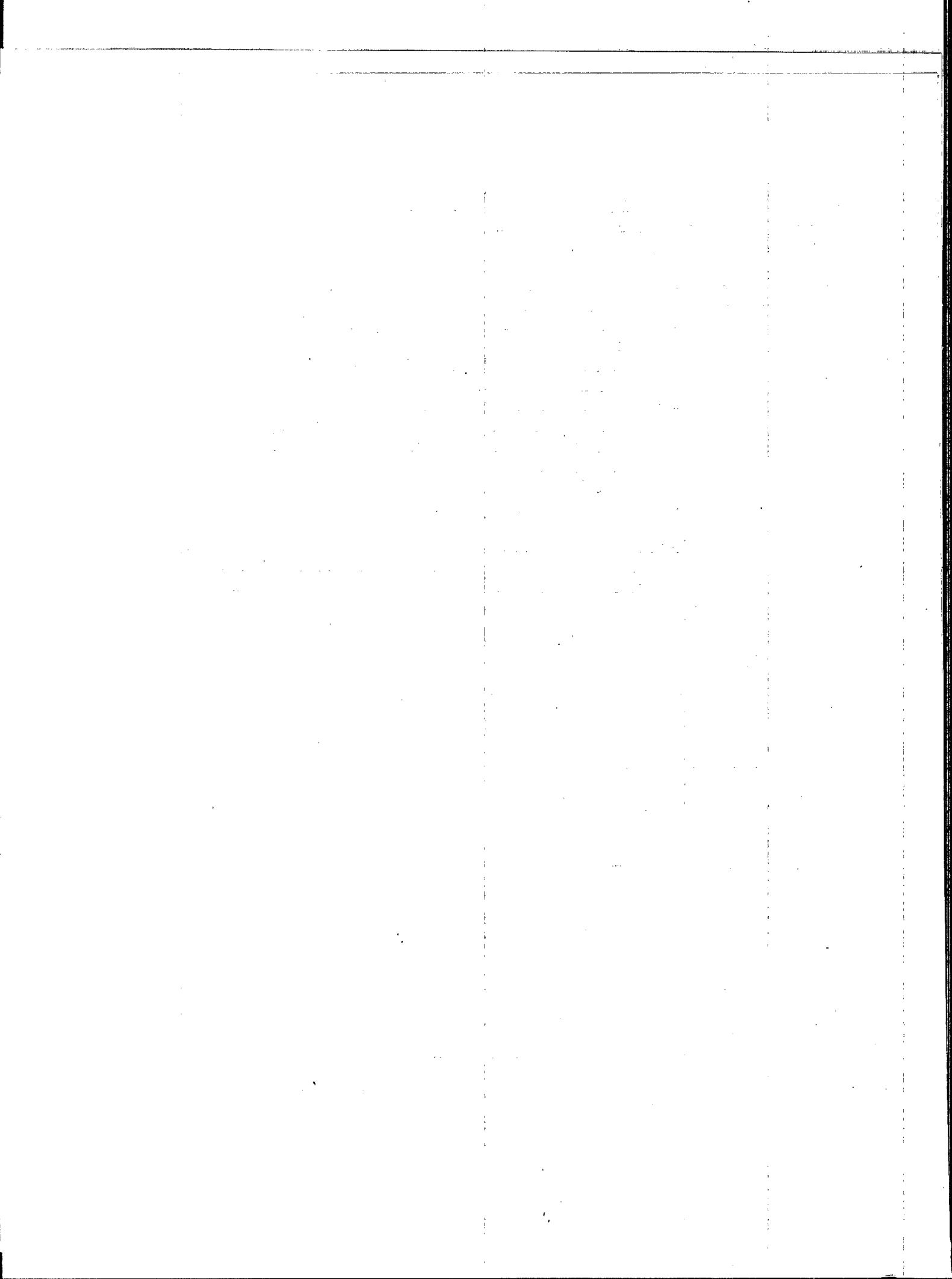
Why Do We Do a Peer Review?
The Agency strives to ensure that the scientific and technical underpinnings of its decisions meet two important criteria:

- They should be based upon the best current knowledge from science, engineering, and other domains of technical expertise, and

- They should be judged credible by relevant experts who deal with the Agency.

What Products Need Review?
- *Major scientific and technical work products* as defined in Chapter 2.

- A *rule or regulation itself* is not subject to Peer Review Policy. However, if the rule is supported by major scientific and/or technical work products, those work products should be peer reviewed. prior to use in the rule. Tier 1 and 2 rulemakings are significant because they have an economic impact of $100 million or more. Analytical blueprints are required for Tier 1 and 2 rulemakings. The analytical blueprint is the process whereby the project manager identifies the supporting scientific and technical work products and identifies needed peer

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Comments Received and Addressed

Most individuals that received the document for peer review did not respond. Substantial review was received from Pat Bradley, Ben Lesser, and Glen Nestel. Less comprehensive reviews were received from Mike Cook and Jim Wheeler. Mike Cook indicated his belief that the document would be very useful to OWM, Individual staff corrected the examples in Chapter 5. Ben Lesser and Pat Bradley gave comments that were useful in improving the document and were for the most part incorporated. Glen Nestel, gave the most thought provoking comments and indicated the need to drop the term Quality Control. He stated that the term quality control has a negative connotation because it is based upon the concept that control is needed in the end of an activity because there will be mistakes. This is in contrast with the more modern concept of Quality Management that takes place throughout the entire development of the work products. Glen Nestel also indicted the desirability of including TQM concepts in the draft in addition to the considerable focus already present on quality and peer review tools. His comments were incorporated. Copies of those reviews are included in a supplemental file. The peer review comments were incorporated into this final draft for pilot testing by the peer review leader.

Contract Management

The peer review leader served as the Task Manager for the development of the Guide. Wendy Blake-Coleman was the Project Officer for the DynCorp contract. My control of the project was predominately through having submitted chapers and parts of chapters throughout the development of the draft document so that they could be corrected and placed in a user friendly format.

Supplemental Project File

Additional quality and peer review information is contained in a supplemental project file. This information includes a number of draft pieces of the report as well as communication with the OW Project Officer. Also present in this supplemental file are four peer reviewed copies of the guide and a copy of the revised OWM pilot test copy.

[Propose to Add about two more example documentation files]

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review. It also shows the schedule of peer review. If significant change based upon public comment, additional peer review may be required.

Work products supporting Tier 3 rulemaking may also be considered major and thus candidates for peer review.

- *Economic work products* that need peer review include:

    - Internal Agency guidance for conducting economic analysis.
    - New economic methodologies or unique or novel applications of existing economic methodologies, particularly those that are path breaking.
    - Broad-scale economic assessments of regulatory programs, such as the Congressionally-mandated study of the costs and benefits of the Clean Air Act.

Is Peer Review by a Refereed Scientific Journal Adequate?
Peer review by a refereed scientific journal is a satisfactory form of peer review for EPA purposes. EPA employees are encouraged to have an article they produce internally peer reviewed prior to submission to a peer reviewed scientific journal. However, journal peer review <u>may not</u> cover issues and concerns that the Agency would want peer reviewed to support an Agency action.

> # SOMETIMES MORE THAN ONE PEER REVIEW OF A PRODUCT MAY BE DESIRABLE

Roles of People and Organizations in Peer Review
- The *Assistant Administrators and Regional Administrators* are the ultimate *decision makers* and are accountable for implementing Peer Review Policy within their organizations.

    - They may designate Office directors and Division Directors of other appropriate level line-managers as the front-line decision makers.

- *Decision makers*

    – Decide whether a work product is major and needs peer review, and what peer review mechanism to use.
    – Commit resources and ensure that peer reviews are properly performed and documented.
    – Designate a peer review leader to organize the peer review.

- By signature document the decisions made that are reported in the peer review annual report including the peer review summary report
- Certify any decision not to peer review.

- Agency staff involved in peer review are the decision makers and this includes line-managers, peer review leaders, peer review coordinators and certain staff within ORD.

- The *peer review leader*

  - Organizes, conducts, and completes the peer review.
  - Selects the peer reviewers unless there is a contract or some other group be available for conducting peer review.
  - Keeps the record and initiates the peer review summary.
  - Advises the peer reviewers of their responsibilities.
  - Provides decision-makers information on the charge to the reviewers, their profile, their comments and how they are to be used.
  - The peer review leader must carefully evaluate and analyze the objectivity of all peer review comments and recommendations and document how they have been used.
  - Appropriately archives the peer review record.
  - Advises the peer review coordinator regarding the status of the peer review for purposes of the annual peer review report.

- The *peer review coordinator* is the main contact peer review matters. The peer review coordinator for OW is currently Arnold Kuzmack and for OWM is Barry Benroth. The peer review coordinator:

  - Provides advice, guidance and support to the various peer review leaders and helps mediate difficult peer review issues
  - Participates in Agency peer review training, workshops, etc., as requested and disseminate this information to the organization
  - Coordinates and/or presents training within the organization
  - Establishes procedures to assure that the required work product peer review documentation (peer review record) is filed and maintained in an appropriate manner and keeps the annual peer review report.

Where do you find Peer Reviewers?

- References from special and public interest groups, professional societies, trade organizations, professional societies, tribes, colleges and universities, the national Research Council, other Federal Agencies, Science Advisory Board and Regional and Program Offices.

- Ask them if they have a real or perceived conflict of interest. If needed, speak with the Office of General Council (OGC) for assistance.

Peer Reviewer Selection
Selection criteria for peer reviewers include that the persons have expertise in the scientific and technical subject matter and that the persons disclose conflicts of interest, real or perceived. Independence (i.e., freedom from institutional, ideological, or technical bias) is necessary for objective, fair, and responsible peer review. Some peer reviewers may have conflicts of interest. This is okay as long as this fact is disclosed up front and in the peer review, and that the peer reviewer tries to be objective as possible. It is also important that the resulting group of peer reviewers be balanced in terms of differing expertise, backgrounds, and perspectives on the subject matter.

The person or group doing the selection of the peer reviewers depends upon how the peer review is handled. If it a contractor, the contractor selects the peer reviewers. Likewise if it is done by the Science Advisory Board (SAB), the SAB makes the selection, or it could be the peer review leader.

Peer Review Funding
Senior managers (including decision-makers and budget officers) need to be sure that budget requests include anticipated resources for peer review. Peer review needs to be considered a normal part of doing business.

Peer Review Charge
The *peer review charge is prepared by the peer review leader*. This very important element of peer review should include:

- An introduction saying what work product is, how it was developed, and how it is to be used.
- A brief listing and description of background materials provided to the reviewers, and
- The issues or questions to be addressed by the peer reviewers.
- A statement requesting that draft materials not be disclosed to public
- A request for written comments
- A request that the prospective peer reviewer advise the Agency of any real or perceived conflict of interest.

Note: If doing the peer review without charge, the peer reviewer should sign a statement saying that he or she has no expectation of compensation from EPA.

How Do I Incorporate Peer Review Comments into the Final Work Product?
The peer review leader must carefully evaluate and analyze the objectivity of all peer review comments and recommendations. Adequate documentation is required to show that comments are accepted or rejected. Documentation can be brief, bust must address the legitimate, valid comments. A carefully crafted charge to the peer reviewers helps simplify organizing and analyzing comments.
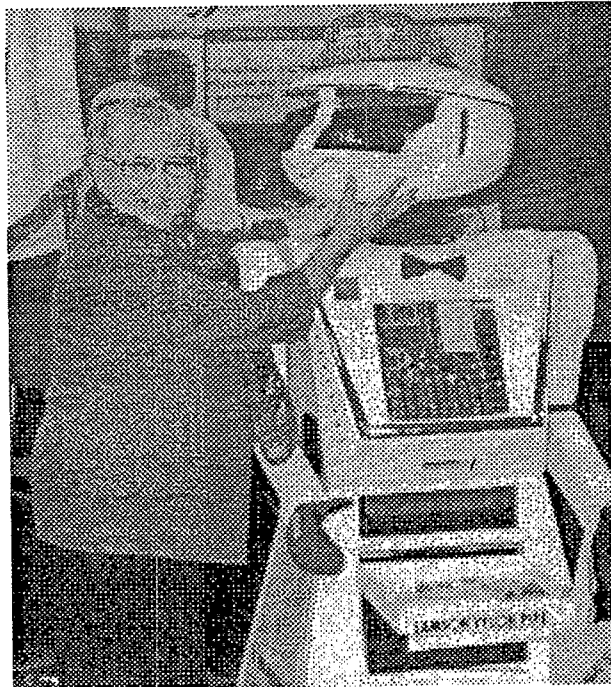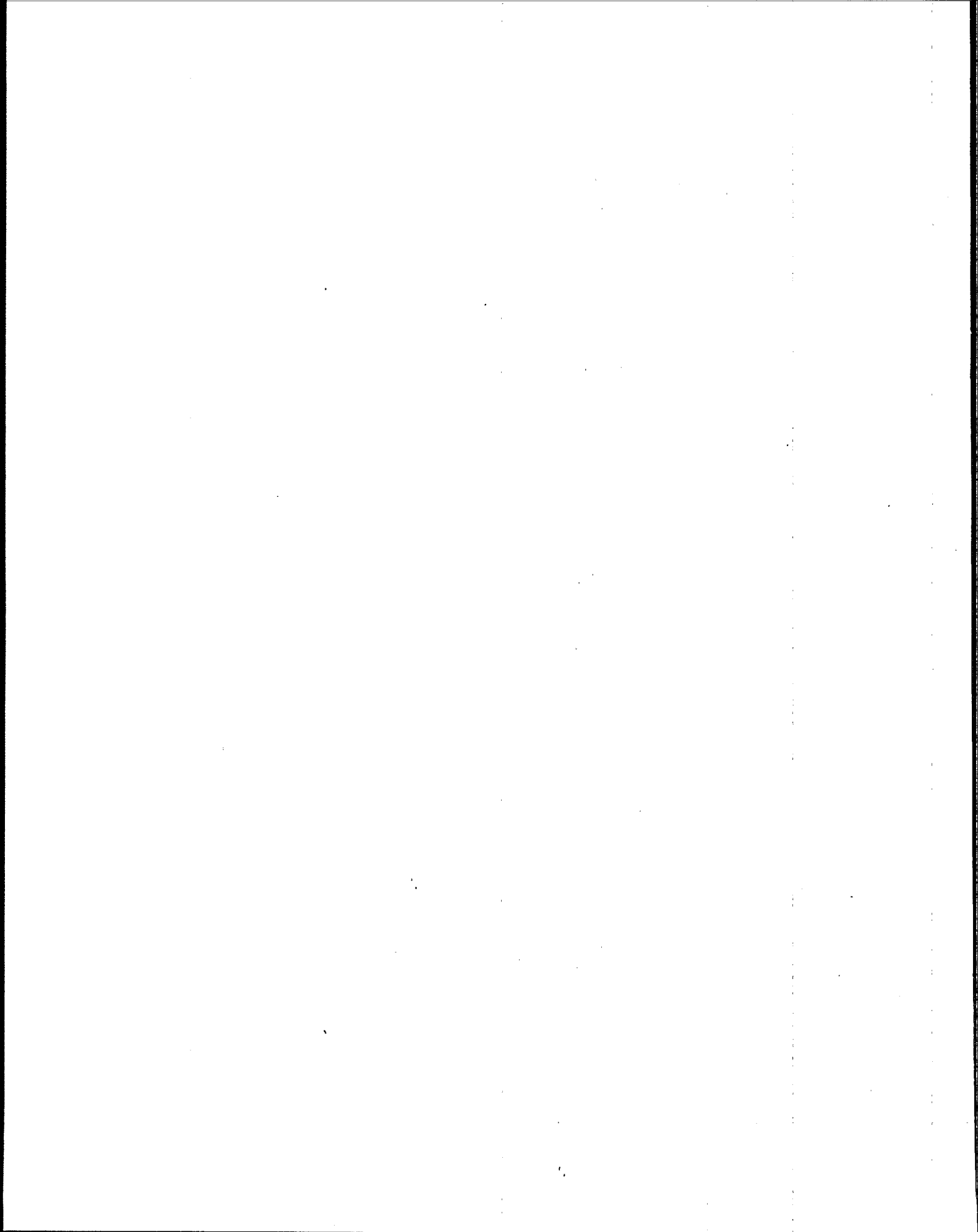
Documentation
- The *peer review record* contains the type of peer review and a summary of the outcome of the peer review. It includes sufficient documentation for an

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uninformed person to know what actually happened and why. *The peer review leader is responsible for keeping the peer review record.* The record should contain:

- The draft work product submitted for peer review whether a near final document or and early draft of plans.
- Materials and information including the charge given to the peer reviewers.
- Information about the peer reviewers – names, affiliations, and identified potential conflicts and their resolution.
- Times and locations of meetings.
- A memorandum or other written record responding to the peer review comments specifying acceptance or, where appropriate, rebuttal and nonacceptance.
- The final product.
- The summary report on the outcome of the peer review.

■ *Peer review leaders should maintain the peer review record with themselves until the peer review is totally completed.* Minimally, the record should be kept one year after the completion of the peer review, for example in an archive.

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Appendix C

Example Project File Showing the Kind of QA Documentation that Should Be Retained

Example Documentation for the Production of the Office of Wastewater Management (OWM) Common Sense guide to Quality Management

Project Background
In 1996, during the preparation for and the Office of Research and Development (ORD) Management System Review of OWM, it became readily apparent that a Commonsense Guide to QM could be very helpful to OWM management and staff. During that time period, there also was considerable emphasis on the need for peer review within the Agency. In response to this need, OWM prepared and conducted training on both quality and peer review. The training featured presentations by individual staff members regarding their projects and their review activities. The development of the Guide was envisioned that would. incorporate important elements of the quality and peer review training and provide user-friendly quality management guidance dealing with all OWM efforts including the collection and use of both secondary and primary data.

A limitation of the existing ORD QM guidance for OWM is its focus on the collection of primary data and lack of applicability to all aspects of OWM effort. The hope for this guide was to include examples that are relevant to OWM and to provide check lists to help persons do a good job of QM including documenting their QM efforts. The OWM Office Director endorsed the need for the development of this Guide.

Purpose
The purpose of this guide is to help OWM managers and staff improve the quality of their work. It provides simple, clear guidance on how each person can use quality management (QM) principles to improve his or her work. It also provides practical, straightforward guidance on how to comply with the U. S. Environmental Protection Agency (EPA) and the Office of Water (OW) quality assurance policies and how to document the steps taken to achieve

quality outputs. The procedures provided in this guide apply to virtually all OWM activities.

Quality Review

A series of meetings were held to gain the input of a broad spectrum of Agency QM expertise. This included meetings with Wendy Blake-Coleman, Quality Assurance Officer for the Office of Water (OW) and the Quality Assurance Officers from each of the OW offices. In addition, members of the OW QM contractor DynCorp (Jim King, Karen Elm, and Maggie Jones) were present and provided assistance for the planning of this document.

Planning for this document proved to be no easy task. Several initial partial drafts of outlines and skeletal development of the document were reviewed and rejected by the peer review leader for this effort (John Walker). Part of the initial planning involved the need to determine just who the document was being developed for – all OW offices or just OWM. Finally, with $20,000 in contract dollars being provided by OWM with some additional funding by OW, it was decided that this guide would be developed as an OWM document, and that other offices might use or adapt parts of it later if it was found to be useful to them. Another possible output subsequent to the issuance of the Guide was the development of a training program for OWM by ORD and OWM.

During this development period, it was decided that Lynn Riddick and Kim Conmy of Dyncorp would work with OWM to prepare the draft Guide. Drafts of the various chapters and of the examples were reviewed by the peer review leader and other selected Agency QM and management staff to obtain user-friendly format. Ultimately, each chapter was reviewed by the peer review leader and individual sections were reviewed by the staff responsible for each example and/or familiar with concepts in individual chapters. Once this level of quality review had been obtained, a peer review draft was put together by the Peer Review Leader for peer review. This effort in preparing the draft involved putting the guide into a format that would be used in the publication.

Peer Review

Peer Reviewers were selected and a charge letter prepared. A copy of this letter is given below.

Charge

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

September 2, 1998

MEMORANDUM

SUBJECT: Request for Review of *Common Sense Guide to Quality Management*

FROM: John Walker (4204)
Quality Assurance Officer for the
Office of Wastewater Management

TO: Reviewers (see list below)

Please find attached a draft copy of a new Guidance of Quality management for the Office of Wastewater Management (OWM) at the U.S. Environmental Protection Agency (EPA) which I have been developing with the assistance of a contractor (DynCorp). This draft has resulted after a number of iterations of guidance with all parts present except Appendix C. I took the last draft from the contractor and changed its wording and some of its order in the text. In addition, I have put it into what I hope is a user-friendly format into which I have inserted a lot of headings and subheadings. I also put the text into a three-quarter-width page format. The ultimate plan is to insert additional illustrative material. This would include several photographs and even a cartoon if we knew of one that is appropriate and one that the cartoonist would give permission for use. There are several quotes, some of which may not be very appropriate. Please comment if you like and suggest any additional such information you might like.

Your assistance in providing a peer review _____ or quality review ____ (whichever is checked) of this draft guidance would be most appreciated. I specifically would like your review to see if the material is presented in a way that is easy to read and understand. I would like you to see if anything is incorrect. I would like for you to suggest, where you think appropriate, the insertion of any additional topics of material. I would like you to look at the questions and answers to see if they are correct and if there are any that you think would be useful to add. I would like you to look at the examples of OWM quality and peer review in Chapter 5 to see if they are understandable and if they add useful information and in the process make the ability to do quality management more easily.

I have asked you to do a number of things in a generic sense. Please actually only do those parts of the review for which you have time and expertise. Again, I greatly appreciate your willingness to assist us in making this review. I request that you send me you comments by September 15. If you are unable to do the review by that time, please just let me know. I believe that you will find that this guidance is really not very long and I would recommend that you approach it by reading Chapter 1 first followed by Chapters 2 and 3. Then, the fourth Chapter contains documentation checklists. Please look these over briefly to see if they are helpful, and if not, any comments for improvement. Chapter 5 contains examples of QM within OWM. Only spend time on this chapter to the extent you see if the examples add useful meaning and.or if they are presented in an understandable form, and/or if some other form might be more helpful. The plan is to have each example on facing pages in the printed document. I have packaged Appendices A and B separately. Please glance at these and comment on the ease of understanding the peer review memo (App. A) and for those that know, the relevance of the cited references (App. B).

My plan is to do this round of peer or quality review and work to address any issues and questions, etc. that you raise. Then, after this revision possibly a second peer review by others.

List of Reviewers: (Internal and external to EPA)

Barry Benroth, Quality Assurance Coordinator, Municipal Support Division
Tony Smith, Quality Assurance Coordinator, Permits Division
Ben Lesser, OWM
Pat Bradley, PD
Jim Wheeler, MSD
Bob Lee, Chief, Municipal Technology Branch
Fred Lindsey, Deputy Director OWM
Wendy Blake-Coleman, Quality Assurance Officer for the Office of Water
Arnold Kuzmack, Office of Water Peer Review Officer
Tom Dixon, Quality Assurance Division, ORD
Mary Fraker, Powell Tate
Glenn Nestel, Hager Bailly

Note comments by those receiving information copies are welcome. I thought that I would give you another chance after a more formal review by those listed above and subsequent revision.
Information Copies to
All OWM Branch Chiefs
OWM Division Directors
Mike Cook, Director OWM
OW Quality Assurance Officers

Attachment
bcc. Lynn Riddick, Dyncorp, Kim Conmy, DynCorp

Comments Received and Addressed
Most individuals that received the document for peer review did not respond. Substantial review was received from Pat Bradley, Ben Lesser, and Glen Nestel. Less comprehensive reviews were received from Mike Cook and Jim Wheeler. Mike Cook indicated his belief that the document would be very useful to OWM, Individual staff corrected the examples in Chapter 5. Ben Lesser and Pat Bradley gave comments that were useful in improving the document and were for the most part incorporated. Glen Nestel, gave the most thought provoking comments and indicated the need to drop the term Quality Control. He stated that the term quality control has a negative connotation because it is based upon the concept that control is needed in the end of an activity because there will be mistakes. This is in contrast with the more modern concept of Quality Management that takes place throughout the entire development of the work products. Glen Nestel also indicted the desirability of including TQM concepts in the draft in addition to the considerable focus already present on quality and peer review tools. His comments were incorporated. Copies of those reviews are included in a supplemental file. The peer review comments were incorporated into this final draft for pilot testing by the peer review leader.

Contract Management
The peer review leader served as the Task Manager for the development of the Guide. Wendy Blake-Coleman was the Project Officer for the DynCorp contract. My control of the project was predominately through having submitted chapers and parts of chapters throughout the development of the draft document so that they could be corrected and placed in a user friendly format.

Supplemental Project File
Additional quality and peer review information is contained in a supplemental project file. This information includes a number of draft pieces of the report as well as communication with the OW Project Officer. Also present in this supplemental file are four peer reviewed copies of the guide and a copy of the revised OWM pilot test copy.

[Propose to Add about two more example documentation files]