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DEPARTMENT OF ECOLOGY
QUALITY ASSURANCE SECTION

REPORT ON

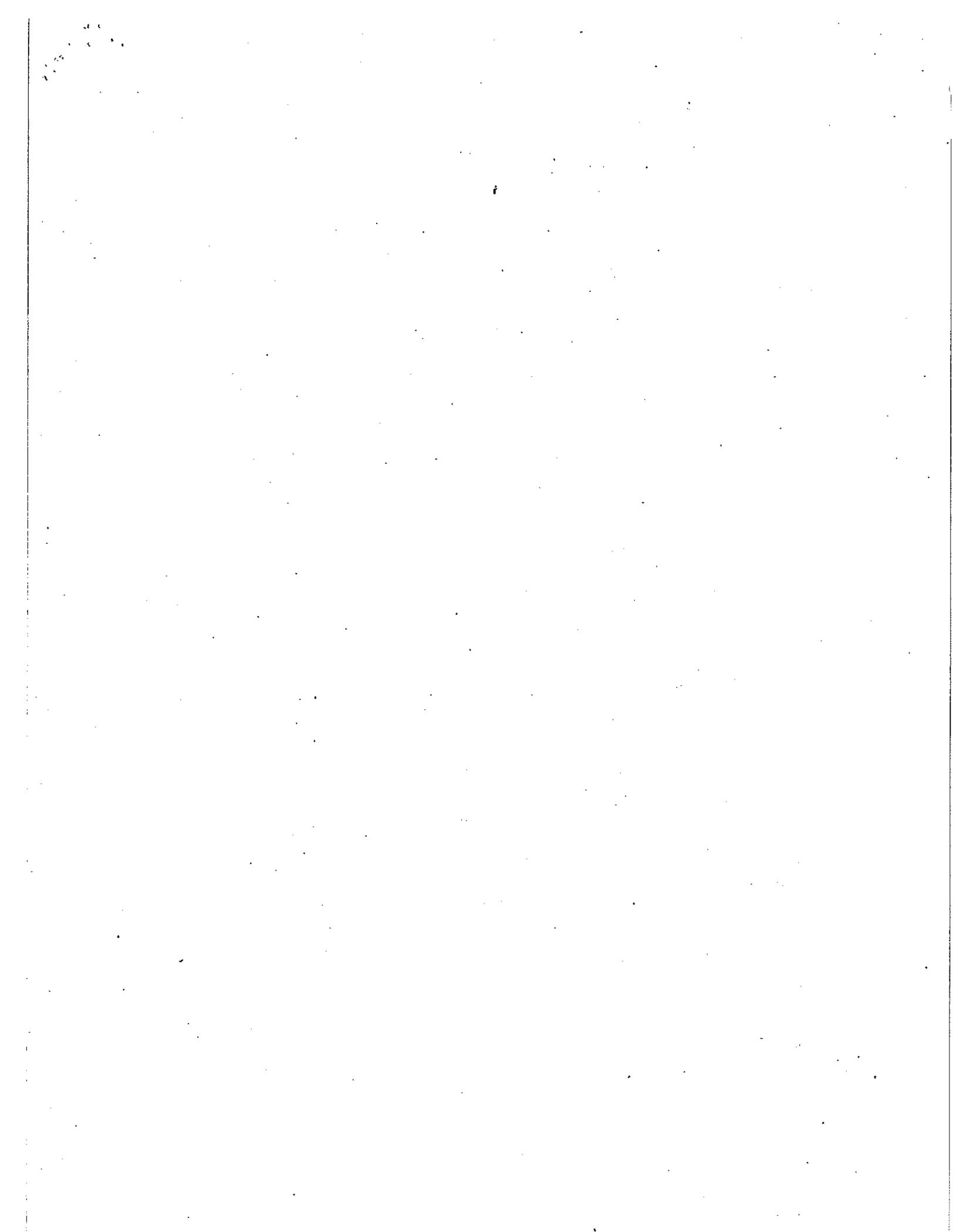
QUALITY ASSURANCE ISSUES

WITHIN ECOLOGY

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QUALITY ASSURANCE WITHIN ECOLOGY

ISSUE STATEMENT

A number of problems have recently surfaced related to the quality assurance of environmental data and to the quality of agency reports and documents. This has raised concerns that there are shortcomings in the manner in which Quality Assurance methods are presently being applied to maintain the quality of agency products.

These issues are important because much of the success of the agency depends upon maintaining credibility and public confidence. That confidence can only be maintained through continued diligence to the validity and accuracy of the data and analyses upon which Ecology managers make decisions.

Because of concerns about the quality of data and reports, the Executive Management Team appointed a committee to examine two basic quality assurance issues. Those two issues were posed in the form of questions:

First, should the Quality Assurance Units remain housed at their present locations, or is it more appropriate to place them in an independent location, such as under the Assistant Director for Quality Control, Information Management and Comprehensive Planning?

Second, should the Unit's efforts be focused on the quality of environmental data, or should it also have a hand in reviewing the quality of written reports and documents?

This report contains the information gathered by the committee, identifies options for addressing quality assurance issues, lists pros and cons for each option, and presents the recommendations from the committee.

METHOD OF ANALYSIS

To answer the questions posed by the Executive Management Team concerning Quality Assurance (QA), information was gathered from a variety of sources. Those sources included:

Reviewing the existing operation and organizational structure of the two Quality Assurance Units associated with environmental data (QA Section in EILS and the QA Unit in the Air Program)

Reviewing the organizational structure and placement of the QA group within EPA

Meeting with Kim Kenney of Sterling Associates to get a management perspective on the role and placement of the Quality Assurance Group within an organization

Reviewing the manner in which technical/peer review methods are applied to reports and documents at Pacific Northwest Labs (Battelle)

Conducting interviews with Ecology technical staff to better understand how QA is currently being performed on permits, reports and documents produced by the various sections in the agency.

Q U A L I T Y A S S U R A N C E C O N C E P T S

Before proceeding with an analysis of the issues and current problems, it would be helpful to define some commonly used terms and to discuss some of the basic quality assurance concepts.

DEFINITION OF TERMS

Quality Control and Quality Assurance terms are often used interchangeably. The terms pertinent to this report are defined here because the differences between "Control" and "Assurance" translate to "internal to the work unit" and "external to the work unit" respectively and have direct implications on organizational structure.

Quality Assurance Function - "All those planned or systematic actions necessary to provide adequate confidence that a product or service will satisfy given needs" (1).

Quality Control - Activities and procedures performed on a routine basis within a work unit (internal) to maintain and control the quality of products.

Quality Assurance - Activities and procedures used to review and approve, oversee, or audit the products from a work unit. These tasks are performed by personnel external to the work unit.

Technical Review - A review of the technical correctness of analyses and/or conclusions of a document. This review is conducted by personnel internal to the work unit that produced the document.

Peer Review - A review of the technical correctness of analyses and/or conclusions of a document. This review is conducted by personnel external to the work unit/program/organization that produced the document.

1 Juran, J.M., Quality Control Handbook, 3rd Ed. McGraw Hill, 1974

QUALITY ASSURANCE CONCEPTS

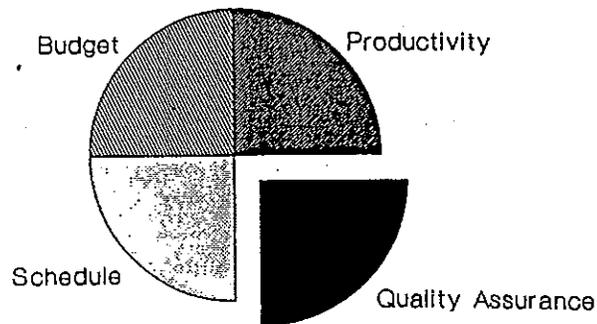
There are a number of basic management precepts that are directly applicable to the organizational location and operation of a Quality Assurance Group.

1. *Regardless of the industry or governmental body, Quality Assurance interests are subject to being in conflict with productivity, budget and scheduling interests.*

APPLICATION OF QA MANAGEMENT PRECEPT - The group responsible for QA should be organizationally and budgetarily independent of those line managers responsible for productivity, and meeting budgets and schedules.

This scheme provides a proper separation between the four functions and prevents quality from being sacrificed to meet quotas, budgets or schedules. When trade-offs are necessary, the organizational independence of QA ensures that the QA interest, along with the other three interests, are accurately presented to upper management for a decision.

POTENTIAL CONFLICTS - QUALITY ASSURANCE



2. *When problems/conflicts involving Quality Assurance occur, the group responsible for QA must have sufficient independent authority (leverage), or have direct access to leverage, to resolve the problem.*

APPLICATION OF QA MANAGEMENT PRECEPT - Resolution of conflicts can only be achieved if the QA Group has its authority clearly defined by upper management.

This clarification of authority should identify the types of issues which should be resolved by the QA Group and which issues should be brought to upper management for resolution. An organizational location which is independent of the line managers can be very helpful in providing the leverage needed to resolve conflicts.

3. *If a Quality Assurance Program is to be effective; it must be a "cradle to grave" activity.*

In simple terms, quality cannot be "inspected into" a product at the end of the line. Quality is a line function and each employee involved has a responsibility for product quality.

Specifically, achieving quality in the final product is obtained by:

- ※ Proper design and planning of the project - QA Project Plan
- ※ Adherence to the QA Project Plan and execution of the daily/routine Quality Control tasks by work unit staff
- ※ Review or auditing, as appropriate, by independent staff to confirm the validity, technical accuracy, consistency, and acceptability of the final product.

4. *The sophistication of approach and effort applied to QA activities for environmental data should be commensurate with the intended use of the data. Likewise, those analyses, conclusions, reports and policies that are controversial, politically sensitive and/or have long range policy implications should receive greater QA oversight.*

QA is a critical element in maintaining credibility and public confidence. It also provides confidence to the agency's upper management when decisions are required involving enforcement actions, monetary fines and when there is liability exposure.

Environmental Data - QA Project Plans for collection and measurement of environmental data should satisfy the needs of the intended use and be legally defensible. For projects associated with, or funded by EPA, the QA/QC standards or guidelines are usually set by EPA.

Reports and Documents - The issuance of simple, non-controversial permits can normally be accomplished with minimal technical review. At the other extreme, preparation of reports/documents which address complex issues, contain the results from detailed technical analyses and are subject to intense public or industry scrutiny should receive comprehensive technical/peer review and QA oversight.

O V E R V I E W O F C U R R E N T S I T U A T I O N

There are two basic subject areas within Ecology where Quality Assurance Functions are necessary.

First, QA/QC methods and procedures are critical components in the collection and measurement of environmental data. They are essential to achieve continued validity, accuracy and consistency of measurement data.

Second, QA is an important component for the preparation of reports and other documents. It is necessary to assure the validity and technical accuracy of the analyses and conclusions which are contained within, or support, agency documents. QA procedures are particularly relevant to Ecology because of the need to maintain consistency of similar products developed by various staff/regions.

QUALITY ASSURANCE OF ENVIRONMENTAL DATA

There are several work units presently performing tasks for quality assurance of environmental data. Most are located within Central Programs.

EILS - The primary group presently involved with Quality Assurance is located at the Section level in the Environmental Investigation and Laboratory Services (EILS) Program. The QA Section head in EILS is the designated QA officer for Ecology. This Section is responsible for:

- ✱ Review of QA Project Plans for those agency projects which have a data collection and measurement component
- ✱ Accreditation of laboratories.

EILS - The Data Management Unit is another group which has QA/QC responsibilities. It is housed at the Manchester laboratory and is located at the Unit level within the Laboratory Services Section in EILS. This Unit is responsible for review and validation of the quality of data for:

- ✱ Samples collected by Ecology and analyzed at the Manchester lab
- ✱ Samples collected by Ecology but analyzed by private laboratories

AIR PROGRAM - The primary group for Quality Assurance in the Air Program is located at the Unit level. This Unit is responsible for oversight and auditing of data measurement activities of the:

- ✱ Air monitoring program
- ✱ Vehicle emissions program
- ✱ Industry emission inventory.

HAZARDOUS WASTE - There is one staff person in the Cleanup Program who reviews proposed QA/QC Project Plans submitted by Engineering Consultants.

Current Problems and Symptoms

There are a number of unresolved problems currently plaguing the QA groups. Those problems include:

- ※ In 1983, the agency developed and adopted a Quality Assurance Management Plan for the collection, measurement and validation of environmental data. That plan has generally been ignored and sufficient staff to implement that Plan were never available. Attempts by EILS to update the Plan and get concurrence on procedures among the three major programs (Central, Water and Waste) have been generally met with resistance or malaise. After 9 months of effort, a mutually acceptable plan has not been adopted.

This is symptomatic of problems identified in QA Precepts 1 & 2 above, where the current organizational structure limits the ability to resolve cross-program conflicts and issues.

- ※ Because of problems in implementing the 1983 Quality Assurance Management Plan, the primary focus of the QA group in EILS has been on the review of the planning aspects for data collection and measurement (QA Project Plans). With limited staffing, few QA activities are possible to confirm that QA Project Plans are being properly implemented. In some instances, data collection projects are conducted by Ecology staff without the benefit of assistance or overview from the QA Section.

This is symptomatic of problems where cradle to grave tasks cannot be performed because of organizational impediments and inadequate staffing.

- ※ The QA Unit in the Air Program has had difficulty resolving problems when conflicts have occurred over the usability/validity of some Air Program databases. In one instance, a number of questions arose concerning the sampling and measurement procedures used in an acid-rain study. Because of the uncertainty, the QA Unit concluded that the reliability of the data was outside accepted limits. This finding was overruled by upper managers in the Air Program and the questionable acid-rain data was released to the Canadian Government.

This is symptomatic of problems where organizational structure, and no clear definition of authority, limits the ability of the QA Unit to resolve conflicts.

- ※ The QA Unit in the Air Program has recently had two vacancies open up on the staff. One vacancy has been taken and shifted to a planning task outside of QA. The other vacancy has not been filled but will likely be lost to non QA duties.

This is symptomatic of problems where QA is in competition, or conflict, with other program interests (QA Precept 1).

QUALITY ASSURANCE OF REPORTS AND DOCUMENTS

Assurance of the quality and consistency of permits, reports and documents is currently being accomplished on a hit and miss basis throughout the agency. Some sections have detailed technical review procedures, while other sections have little or no controls. Several ad-hoc groups are currently in place which provide technical or peer review on permits and reports involving both intra-program or cross-program issues. In most cases, however, review procedures are not written and are subject to change or elimination with the inevitable changes in staffing and management.

It was the consensus of those technical staff interviewed that there was a definite need for improved technical and peer review of agency documents. The need for adequate peer review and the QA function is accepted by most professional staff as evidenced by the number of sections with self-initiated review procedures.

Current Problems and Symptoms

No organized or comprehensive agency approach is currently being conducted to maintain the quality and consistency of reports and documents. Problems in maintaining consistency and quality of permits, reports and documents have occurred in the past. These problems will continue and possibly expand in the future as a result of:

- ※ Non-existent or unwritten technical and peer review procedures
- ※ Difficulties in maintaining consistency between regions and/or between regions and headquarters
- ※ Normal changes in personnel and the addition of less experienced professional staff in the various sections
- ※ No guidance from upper management that there is an emphasis on quality. In particular, which documents should receive the greater technical scrutiny during analysis and report preparation.

Possible Applications for Formal QA Review Procedures on Agency Documents

It would seem appropriate that Programs should have a major role in identifying the level of QA which is applied to a given type of permit, report, etc. It is also logical that the actual technical review be conducted by the resident experts within the programs. The quality assurance role would be to provide concurrence on proposed review procedures and to provide oversight and auditing. Formal QA procedures of varying sophistication could be applied to a number of documents including:

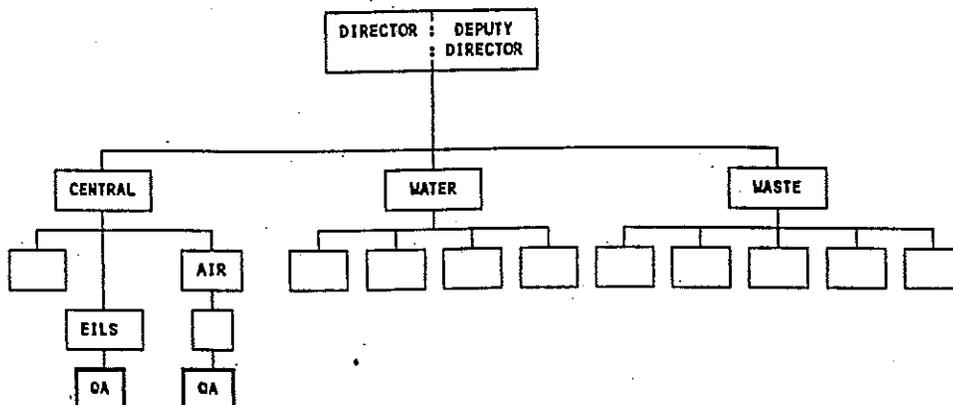
- ※ Findings and conclusions based on environmental data collected by Ecology staff.
- ※ Reports prepared by the agency based on either agency data or data collected by other sources.

- ※ Issuance of permits and approvals.
- ※ Recommendations for enforcement actions.
- ※ Review of consultant's reports and/or construction plans and specifications for which an agency permit or approval is issued.
- ※ Review of proposed Statutes and Rules which have a significant technical component.

In summary, some of these documents are currently receiving technical and peer review. However, there is no organized or comprehensive agency sanctioned approach to maintaining quality and consistency.

OPTIONS FOR REORGANIZATION

OPTION 1 -- STATUS QUO - MAINTAIN QA SECTION WITHIN EILS
 - MAINTAIN QA UNIT IN AIR PROGRAM



CURRENT FUNCTIONS AND STAFFING LEVELS - EILS

Quality Assurance Section

Accreditation of Laboratories 4.3 FTEs

Review of QA Project Plans for
 Investigations which Require Collection
 and Analyses of Environmental Data 1.7 FTEs

Proposed Adds for FY 92-93 None

CURRENT FUNCTIONS AND STAFFING LEVELS - AIR PROGRAM

Quality Assurance Unit

Air Monitoring 3.0 FTEs

I & M Program, Emission Inventory 2.0 FTEs (recently transferred)
 (Currently vacant or transferred to
 other non QA Air Program section)

Proposed Adds for FY 92-93 None

OPTION 1 - PROS:

- ※ QA Section in EILS has some similarities to the EPA Region X organizational structure. The EPA structure has been effective due to strong QA policies and management support.
- ※ Close association with laboratory and with Environmental Investigations technical staff.

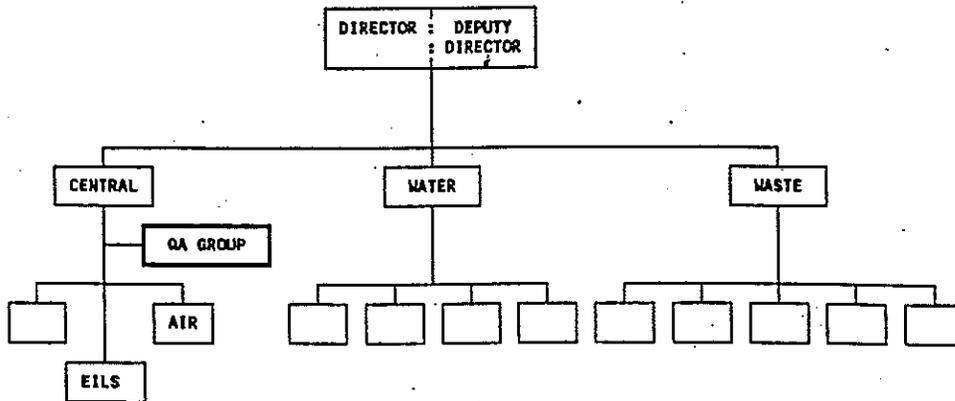
OPTION 1 - CONS:

- ※ Low position in organizational structure limits ability to resolve both intra-program and cross-program problems.
- ※ Does not provide for coordinated effort on QA of environmental data within Water and Waste Programs.
- ※ No direct/independent reporting to upper management on QA issues
- ※ Potential for conflicts on staffing levels for QA - versus productivity, budget and scheduling interests.
- ※ Questions of objectivity and perceived objectivity in dealing with Manchester laboratory when organizationally tied to the laboratory.
- ※ Organizational structure not easily adaptable to expanded role of QA for oversight of review procedures for agency reports and documents.

COMMENTS:

A very strong QA Executive Policy statement and continued commitment from the Director and Deputy Director would be needed if this structure is to have a chance to function properly. Dual reporting could be added to this scheme (both to Program Manager and to Director) but would place an added burden directly on the Directors' office. Future success would likely be dependent upon the individual personalities involved rather than be supported by the organizational structure.

OPTION 2 - CONSOLIDATE QA UNITS AND MOVE QA GROUP TO AN INDEPENDENT LOCATION WITHIN CENTRAL PROGRAMS



OPTION 2 - PROS:

- ✘ Consolidation of QA functions for environmental data aspects.
- ✘ Somewhat more independent location for QA of environmental data.
- ✘ Potential for improved reporting to upper management on QA issues.
- ✘ Reduces QA budget and staffing conflicts with line managers within Central Programs by having QA report to Assistant Director level.

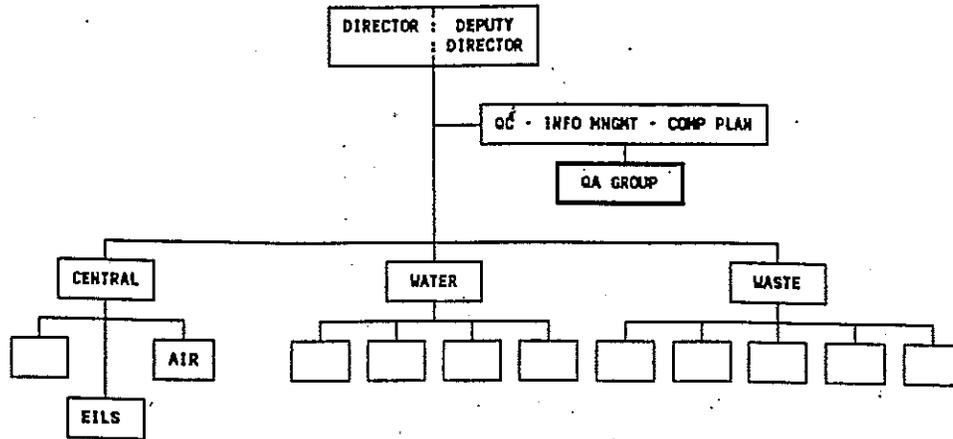
OPTION 2 - CONS:

- ✘ Position in organizational structure limits ability to resolve cross-program problems.
- ✘ Does not provide for coordinated effort on QA of environmental data within Water and Waste Programs.
- ✘ Organizational structure not easily adaptable to expanded role of QA for oversight of review procedures for agency reports and documents.

COMMENTS:

Some restructuring within the new QA Group would be needed to consolidate the present EILS and Air QA Units. Like Option 1, a very strong QA Executive Policy would be needed if this structure is to work.

OPTION 3 - CONSOLIDATE QA UNITS AND MOVE QA GROUP TO AN INDEPENDENT LOCATION OUTSIDE OF CENTRAL, WATER AND WASTE PROGRAMS



OPTION 3 - PROS:

- ✦ Consolidation of QA functions for environmental data aspects.
- ✦ Neutral position within organization for resolving cross-program problems.
- ✦ More direct reporting to upper management on QA issues.
- ✦ Separates budget and staffing issues for the QA Group from issues of productivity, budget and scheduling within the three major programs.
- ✦ Achieves actual independence, as well as perceived independence, from three major programs.
- ✦ Amenable to expanded QA role for oversight of review procedures for agency reports and documents.

OPTION 3 - CONS:

- ✦ Some reduction in ability to communicate with former colleagues in Central Programs and at the laboratory.
- ✦ Somewhat more formalized relationships with all three major programs.

COMMENTS:

- ✦ Requires restructuring, movement of personnel and budget to Assistant Director for Quality Control, Information Management and Comprehensive Planning. QA Executive Policies and a well defined QA Management Plan are also necessary for this structure to function properly.

RECOMMENDATIONS

It was the consensus of the committee that the existing QA Units located within EILS and Air Programs should be consolidated into one QA Group. This new QA Group should have an independent oversight role and be placed in an organizational location separate from those units, sections and programs where quality is to be maintained and where the actual Quality Control work is being performed. It is recommended that this QA Group be moved to the Assistant Director for Quality Control, Information Management and Comprehensive Planning as indicated in Option 3.

It was also the consensus of the committee that there is a strong need for a coordinated and consistent approach for review of agency reports and documents. Application of the procedures for the actual technical and peer review of agency documents should be conducted by the technical experts at the unit/section/program level. The QA Group would have an oversight role in these matters and would also coordinate the development of plans and procedures to be used in the review of documents produced by the agency.

Executive Policies on Quality Assurance are needed which emphasize a continued commitment to the quality of environmental data and to the quality of reports and documents produced by the agency.

SUMMARY

Consolidation and reorganization of the QA Units should not be viewed as a panacea for solving all of the Quality Assurance problems. If a Quality Assurance Program is to be successful at Ecology, it must be supported by four elements:

1. An Agency ethic must be fostered which makes quality a basic goal and responsibility at all levels of the Agency. This ethic starts with Executive Policies which place an emphasis on achieving and maintaining the quality of Agency products.
2. A QA Management Plan is needed which describes how the QA Executive Policies are to be implemented. The QA Management Plan should also clearly define the authority and responsibilities of the QA Group and applicable units/sections/programs. The Plan should be developed in a manner which promotes teamwork, minimizes finger pointing and emphasizes problem solution.
3. An organizational structure is needed which allows the QA Group to: properly perform its duties; resolve cross-program conflicts from a neutral position; and which provides for independent reporting to upper management on QA issues.
4. Additional resources will be needed within the QA Group. Affected programs may also need additional staff or may be able to accommodate QA requirements through internal reassignment of duties.

OTHER CONSIDERATIONS

STAFFING - COSTS

Staff increases will be needed to implement these recommendations. An assessment of the staffing requirements and budgetary impacts have not been made.

The issue of QA staffing levels should be addressed during development of the QA Management Plan after decisions are made on issues of organizational location and QA Group responsibilities.

IMPLEMENTATION

Implementation of these recommendations will undoubtedly result in some changes in the way business is conducted. It is recommended that actual implementation of new QA policies and procedures be accomplished in phases to allow adjustments and adequate time for evolution of the new QA programs.

QA Management Plan

A Quality Assurance Program, like other programs, can become overly bureaucratic and authoritarian at the expense of efficiency. This tendency should be considered when developing the QA Management Plan.

The QA Group must balance two responsibilities which can potentially be in conflict. It must maintain its independence from the line managers and programs for proper auditing and it must also act to educate on QA matters and to facilitate problem resolution. These demands for being independent and authoritarian and at other times to be educators and facilitators requires special "people skills". These considerations should be recognized when developing the QA Management Plan and when staffing the QA Group.

HOUSING LOCATION versus ORGANIZATIONAL LOCATION

Some elements of the recommendations can be accomplished without physical moves of personnel. There are elements of QA where there is a need for close and frequent coordination and a detailed understanding of the ongoing work. In these instances, it is often desirable to house those QA staff near the working units - although the QA staff should be organizationally aligned independent of the working units. These issues should be addressed in conjunction with the development of the QA Management Plan.