AMERICAN SOCIETY FOR QUALITY CONTROL

ENERGY DIVISION

March 1, 1988

To: Distribution

Subject: Meeting of Energy Division Committee for R&D

The next meeting of the R&D Committee is scheduled for March 14, 1988 from 9:00 a.m. to 12:00 noon in the Pennsylvania Room at the Resorts International Hotel in Atlantic City, New Jersey. This will be in conjunction with the ASQC Energy Division Eastern Regional Conference.

The purpose of this meeting will be to work on the Quality Assurance Guidelines Document. Attached are general and specific comments received to the document. The spiral bound copy of the guidelines document contains the specific comments. Specific comments have been placed opposite the page and in most cases opposite the paragraph that they apply to. The general comments have been printed separate from the specific comments to avoid confusion. Grammatical corrections to the text of the document are not included in these comments. These will be dealt with later.

G. W. Roberts
Chairman

tlb

Attachment

405
NH01

General Comments to ASQC Quality Assurance Guidelines Document
Draft 0 Dated 4/27/87

Overall, the thrust of the document is correct, in attempting to show researchers that some degree of control is beneficial to the direction of their work and to assuring the quality of its output. A criticism I foresee is that once one gets beyond the introduction there is a large proportion of the document which appears to be very similar to manufacturing program standards, examples being procurement control, inspections, material identification and control. Different terminology might help dispel any feeling that this guideline is little more than a manufacturing quality program. (W.J. Langford)

Reviews, calculations and other key documents/media should be assigned unique identification and be issued through a controlled system. (P.C. Payne)

Should cover project note books - serial number control, each page signed and dated for legal reasons. (D. Maxwell)

The failure reporting systems and the statistical sampling system seems to complicated for most R&D efforts. (D. Maxwell)

This write-up could apply to a large DOE/DOD/NASA program/project but not to small R&D projects. Far to complicated. (D. Maxwell)

First, I believe that the intended message can be given in a shorter document. The document was intended to give guidelines for research managers. It has been our experience that most research managers will not take the time to read a quality assurance document that is this long. I suggest a document that is briefer, more direct, and outlines quality assurance requirements, or guidance, that is necessary for research activities (understanding, of course, that these points still need to be formulated). I feel that a document with this information and considerable less verbiage would be more useful to the research manager.

Secondly, I feel that the document sounds as though the author(s) are lecturing. If this document is to be truly a guidance document, we need to soften the approach. Reading the document as though I were a research manager, I would say that the document might even be somewhat patronizing. This will not help us sell a quality program to technical personnel. (R. Geoffrion)

Overall, the document appears to be oriented to applied research (or development), as opposed to basic research. Although there is some degree of "fabrication" in any research this document seems to assume more than is typically found. Additionally, the document seems to lack a sense of those controls which are necessary and those which are nice.

Its usefulness is thus limited to the component development labs typically found performing work for NASA, DOD, and DOE.

I would like to suggest that the document become more global in application by listing the fundamental controls to be supplied in any situation, basic or applied, and then include the more detailed and sometimes more stringent controls which may be applicable in the development of scientific principles. The work I did last year in developing my thesis on the shortcomings of NQA-1 lead me to propose a framework for the establishment of a quality assurance program for research:

1. Identify the products and the customers
2. Identify the organizations performing the research effort
3. Identify the areas of risk
4. Choose traditional "control" methods to minimize risks
5. Identify and produce records keyed to deliverable products
6. Monitor the above and improve through feedback

While these steps are nice in theory, I don't believe they address the practical issue of providing guidance to the scientist on how to apply QA to the discovery process.

Further digging into this matter of QA for Research has led me to two works by a local colleague, Wayne Delvin of Westinghouse Handford. In 1984, he published a study which discussed the concept of data quality and outlined eight suggested practices to assure the quality of the data. This was followed by an unpublished study which explained the principles of the traditional 18 criteria elements and then showed how these could be incorporated into the eight practices suggested in the earlier paper. Having examined both of these works in considerable detail, I believe Mr. Delvin is right on track. I suggest that the committee build upon his work. I've taken the liberty of enclosing a copy of portions of the second document for your use. (copy attached) Unfortunately, the entire work lies languishing somewhere within the offices of the DOE in Washington, DC, and has not been approved for publication.

Delvin has suggested that the quality of data is assured by the application of the following practices:

A. Planning and Organization of Projects
B. Training and Qualification of Personnel
C. Preparation and Control of Procedures
D. Peer Review of Work
E. Acquisition, Protection, and Evaluation of Data
F. Use and Control of Records

G. Control and Handling of Equipment and Materials
H. Identification and Correction of Deficiencies

When arranged like this, few scientists can argue with the value of these practices to the research environment, whether it be basic or applied. Thus, one component of opposition to QA is removed-the difference in language.

How does all of this apply to the draft ASQC committee document, you might be asking. I believe that Delvin's practices should form the framework for the guidance document, with the draft committee methods placed as details within the framework. This might be accomplished as follows:

Committee Draft Section	Delvin's Practices
Responsibility	Planning/Organization
Front End Planning	Planning/Organization
Design of Experiment	Procedures
Design Reviews	Peer Reviews
Drawing Control	Procedures
Independent Tech Review	Peer Review
Calculations	Data
Software	Data
Procurement Control	Equipment/Materials
Receiving Inspection	Equipment/Materials
In-Process Inspection	<not addressed>
Material ID	Equipment/Materials
Nonconformances	Deficiencies
Test Control	Data
Instrumentation	Equipment/Materials
Reports	Records
Project Records	Records
Audits	Deficiencies
Training	Personnel
Quality Cost	<not addressed>

Since no doubt, you will be receiving many comments on the individual sections of the draft guidelines, I will not repeat that effort here. Rather, I have limited myself to the global issues of what the document is designed to do and how can it reach its intended audience. As presently structured, I believe it will be rejected by most scientist as not applicable to their situation and too full of controls. That's not to say that such controls are not necessary in a development environment; they are. But I feel that the "base" of the document should be Basic Research, with filler added to meet the needs of the Applied Research community. I think Delvin's approach is closer to that mark. (D. R. Arter)

Wayne L. Delvin
"Report on Quality Assurance in Research and Development
Sept. 1986

3.0 QUALITY GUIDES FOR RESEARCH AND DEVELOPMENT

Scientists and engineers have established work practices to assure the success of their work. Those practices are often called good scientific or engineering practices, and they control the process through which technical work is done. This is also the objective of quality assurance practices, i.e., to control the work process. The principles that govern both sets of practices are basically the same, which means that scientific and engineering practices are similar to quality assurance practices. Both sets of practices are used to evaluate, control, and improve the work process.

The purpose of the section is to present a set of guides that relate scientific and engineering practices to quality assurance practices, which in turn are related to the requirements found in the NQA-1 standard discussed in Section 2.0. These guides, adapted from a document on the quality of data,[3] should help make quality assurance more relevant to the technical community. The guidance that they provide can be used in the application of quality assurance to research and development. The guides are grouped into seven categories. Table 1 shows the relationship between the categories and the requirements in NQA-1.

3.1 PLANNING AND ORGANIZATION OF PROJECTS

Planning and organization is a key to the success of research and development projects. The primary purpose of planning and organizing is the clear and specific identification of work requirements and objectives. Work requirements should include participants, organizational interfaces, responsibilities, limitations, and the anticipated results of the project. The need for planning unfortunately can be too easily de-emphasized or overlooked, especially during those stages where cost and schedule are most critical. Szankonyi recommends that assumptions for planning and organizing be continually evaluated to assure that the R&D project does not go off track. He stated: "A project can be meeting the technical objectives as originally defined, but the technical premises may have changed."[4]

3.1.1 Establishing Work Objectives

Establishing work objectives may appear deceptively straightforward and simple. This particular step in planning and organizing may, therefore, receive little attention and consequently may be inadequately performed, yet it is perhaps the most important part of planning. A clear statement and understanding of the objectives is required. Particular emphasis should be given to assuring participation by all organizations and disciplines affected by or interfacing with the planned work, including sponsoring organizations. Appropriate review and approval should be obtained. The use of peer review is often effective if care is taken to ensure appropriate multi-discipline participation. Once established, the work objectives should be clearly communicated to all affected parties.

3.1.2 Defining Work Tasks

Defining work tasks normally follows the establishing of work objectives, although there may be modification to work tasks as the work progresses. The suitability of work tasks, much like work objectives, depends on participation by the appropriately involved and affected organizations and disciplines. When defined, work tasks should receive sufficient review and approval to assure technical adequacy, identification of constraints, and description of any unusual or special requirements. The most common result of this element is a project or work plan, which would include established work objectives.

3.1.3 Designing Experiments

Designing experiments requires input from established objectives and defined work tasks (work plan). The statistical design of experiments can enhance significantly the success of a project, not only by making the experiments more cost effective, but also by optimizing the acquisition of data to maximize the information obtained from the statistical evaluation of that data. As stated by one author: "A good experimental design is one which furnishes the required information with the minimum of experimental effort. To do this, three things are required: first, the questions to be answered by the experiments must be correctly formulated; second, a correct choice of experimental method must be made in the light both of the accuracy required and of the various experimental pitfalls which are likely to be encountered; and third, the general pattern of the experiments, i.e. the number, spacing, and interrelation of the individual observations, must be correctly chosen."[5] The use of statistical design of experiments should be carefully considered when planning a research project. The factors that are considered in designing experiments are the hypothesis to be tested, the dependent and independent variables, and the required discriminatory power of the test.

3.1.4 Assigning of Responsibilities

Planning and organizing should include and emphasize clear and specific assignment of responsibility. This should be defined in writing. All affected organizations and individuals should be notified and concurrence or agreement acknowledged by appropriate organizational representatives. The assignment of responsibility should be defined for reporting, monitoring, and reviewing progress of the work and for assessment of performance. Interfaces between associated organizations should be well defined. The degree to which the above guidance would be used will depend on the scope of the work task.

3.2 QUALIFICATION OF PERSONNEL

An important factor affecting all work activities is the qualification of those doing the work. Qualifying includes the review and verification of applicable education and experience. Using adequately qualified people should be a requirement for all research or development projects. In addition, training may be required for some personnel.

3.2.1 Qualification

The concept of qualifying scientists, engineers, and technicians to perform specific tasks implies that qualification requirements are established for each task. Management is responsible for the qualifying process, which can range from a simple verification that a person is qualified by reason of education, experience, and job knowledge to a system requiring demonstrated proficiency in required job skills. Qualification should be documented in some way for verification should that action be required later.

3.2.2 Training

Providing training is a basic management responsibility. The need for training and the type of training required is a management decision. Management should establish a training system to assure that technicians are adequately trained and that they are retrained as changes in work practices occur. Such a system should be developed based on job requirements relating to skills, knowledge, and levels of competency required for adequate job performance. Training records should be maintained that give visibility to the training system and that show the past and current training status of each person, which may include scientific and engineering personnel. Training provided to technical personnel should be documented.

3.3 PEER REVIEW OF WORK

The review of research and development work by scientists and engineers not involved with the work and who have at least the same level of expertise as those doing the work is often called peer review. Peer review is perhaps the practice most used for verifying the technical adequacy of work. One of the most frequent forms of peer review occurs when technical work is submitted for publication in a technical journal or for presentation at a technical meeting.

Research and development organizations often establish a peer review system for their own work. Generally, in-house reviewers are used. For the more important work, however, an organization may go outside for reviewers, particularly for reviewers with levels of expertise higher than available inhouse or with established reputations in a particular field. In addition, the use of outside reviewers supports the concept of independence of reviewers alluded to above.

3.3.1 Responsibility

Peer reviews should be planned and conducted by the organization responsible for the work. That organization is also responsible for following up on recommendations and comments coming from a peer review, including the verification and documentation that all issues raised have been addressed.

3.3.2 Types

Peer review can be typed as informal or formal. An informal review can take place as follows: a review of work by noninvolved co-workers, a review by persons outside of the work group, and the publication and presentation of

papers that are subject to peer review within the scientific community. Formal reviews, on the other hand, are characterized by the following: a formal review plan is established; experts outside and independent of the organization are used; a notification letter is issued identifying time, place and participants; a meeting is held in which presentations about the work are made to the participants; a detailed report of the review is issued; and a written response from the organization is required regarding recommendations and comments made by the reviewers.

3.3.3 Use

Peer reviews should be used to evaluate program or project planning and to verify the technical adequacy of procedures and techniques, particularly when there is a unique application of a routine or standard technique. They should always be used when the work goes beyond the state-of-the-art and when new or unusual experimental techniques are used. Formal peer reviews should be used when any of the following actions occur: major changes are being made in an investigation, significant reports are being issued that will have major impact on a project, a major milestone has been reached, or corrective actions are being recommended for deficiencies (including accidents) having major impact on a program or project.

3.3.4 Criteria

Peer reviews should be planned and conducted using the following criteria: reviewers are not directly involved with the work; reviewers have technical expertise in the field; reviewers are provided with sufficient information about the work, including purposes and objectives, to adequately evaluate the work; and results of the peer review are documented.

3.3.5 Documentation

The extent of documentation should depend on the type of review. Documentation of an informal review could be simply the signing and dating by the reviewer of a page in a data record. It could be a dated and signed letter from the reviewer to the manager of the organization stating what was reviewed and giving comments on the work. The publication of a paper in a scientific journal is a form of documentation since papers submitted to most journals are reviewed before being accepted and published. Formal peer reviews should be documented with a report that includes, in detail, the following kinds of information: date of review, place, participants, activities reviewed, evaluation process used, results of evaluation, and recommendations. These reports, including any notification letters and responses from the organization, should become a part of the records associated with the research project.

3.4 ACQUISITION, PROTECTION, AND EVALUATION OF DATA

The practices used to acquire, protect, and evaluate data are crucial to research and development projects. They should be appropriately documented in the form of written instructions, procedures, or data sheets or in some other

form such as a computer program. In this way, requirements relating to the acquisition, protection, and evaluation of data are established and readily available to help assure that mistakes are not made or that data are not lost. The elements of this guide define the type of practices required.

3.4.1 Technical Adequacy of Practices

Many practices and techniques used regularly by scientists and engineers are established and recognized by the technical community as being technically adequate when applied properly. A common practice used to establish the adequacy of technical activities is to reference published work that has a relationship to the work being done. The references should support the technical adequacy of practices used and verify their applicability. References should be documented in the laboratory records system and in technical reports as appropriate. Peer review can also be used to verify technical adequacy. Of course, once the technical adequacy of a practice has been established, the users should adhere to it, or if changes are made, those changes should be carefully documented.

3.4.2 Control and Calibration of Measuring Equipment

The adequacy of data is highly dependent on how measuring equipment used to produce data is selected, calibrated, and used. Technically sound practices should be established and used to provide appropriate selection, calibration, adjustment, maintenance, identification, handling, and storage of measuring equipment. Calibration procedures should include criteria that indicate when equipment is out-of-calibration and actions required to reestablish calibration, as well as frequency of calibration. The selection, use, and maintenance of calibration standards should be included as part of calibration procedures. A well-documented record system should be maintained so that the calibration status of individual items of measuring equipment is readily verifiable.

3.4.3 Data Records

Data must be recorded in some manner when they are produced; otherwise, they will be lost. Recording may be done manually in a laboratory notebook, in a log book, or on data sheets; or it may be done by an automatic recording or computerized instrumentation system. Regardless of the recording method used, provisions should exist to permit the recording of observations, ideas, or other kinds of information that the researcher or developer becomes aware of during an experiment or study, including changes made in steps taken and conditions used. Data records must be protected to avoid loss and controlled to permit retrievability.

3.4.4 Identification of Data

Practices should be established to assure that all data are clearly identifiable and traceable to the experiment, study, or project from which the data were produced. It is very important that this identification and traceability be maintained (protected) throughout the needed lifetime of the data.

3.4.5 Control of Erroneous Data

Practices are needed for controlling data that are erroneous, rejected, superseded, or otherwise unsuited for their intended use. The practices should provide for the identification and segregation or disposal of inadequate data to avoid their inadvertent use. For example, rejected data recorded in a laboratory notebook is often crossed out, dated, and signed by the person taking that action.

3.4.6 Evaluation

The statistical methods used to evaluate data depend upon the amount of planning that preceded the data collection and on whether a formal statistical design was followed when the data were collected. Examples of experimental designs that have been used in industrial or scientific applications are: randomized block, Latin square, factorial, and fractional factorial designs. In general, methods of data analysis include techniques such as the analysis of variance, the analysis of covariance, regression analysis, and the general linear model approach. When the data are collected according to a preplanned statistically designed experiment, the use of analysis of variance methods is appropriate. In some instances, it may be difficult or impossible to maintain all of the variables at the prescribed series of constant levels (or there may be serious economic penalties associated with such an approach). Under these circumstances, analysis of covariance, regression, or general linear model methods can be used to infer the relationships or factor effects. To insure that the best use can be made of experimental results it is important to preplan or design the entire experimental program so the data, when collected, will be suitable for analysis by one of the standard statistical methods.

3.4.7 Procedures

Much laboratory and test facility work, even in research or development, involves routine (repetitive) activities. The operation of instruments, the preparation of apparatus, the testing of equipment, and the analysis of materials are examples of routine laboratory activities that are usually done by technicians, but may also be done by scientists or engineers. Research and development is a blend of the routine (the repetitive, the known) and the new (the untried, the unknown). The degree of each depends on the particular research or development projects.

Nonrepetitive activities (the nonroutine, the untried, the unknown) are initially planned, but are subject to changes as an experiment or study proceeds. Procedures are not normally prepared for such activities. The steps taken and conditions used, including changes made during an experiment or study are documented.

Most routine activities are carried out in a planned, systematic, and controlled manner so that the end results will be based on proven and sound technology. The process used to produce such an outcome often involves discrete actions taken in a specific order. Any change in an action or in the order

without a valid reason will most likely result in an unsatisfactory outcome. To control the processes and avoid errors, procedures are written that provide guidance for those doing the work. To be effective and to help provide credibility to the activity being performed, procedures should be well-written, complete, and correct. Revision of procedures should be done on a planned basis to avoid changes that would cause errors in the work activities.

3.5 USE AND MANAGEMENT OF RECORDS

Records provide the supporting evidence for the technical interpretations, judgements, and decisions made regarding a research or development project. Records preparation and control should be an integral part of work activities. They should provide the historical information needed for later reviews or reevaluations, for future research and development, and for other activities that may be based on the results from the studies and experiments.

There can be many acceptable and varied methods for the use and management of records. The selected method or system should, however, include certain generally accepted features and practices. An effective system of records management will provide records that are legible, identifiable and retrievable.

3.5.1 Records System

At the earliest practical time, a system for managing records should be developed. Written instructions and other descriptions of the records system should be prepared and distributed to appropriate personnel. The practices established for management of data should include a documented records system that includes or references procedures for records generation, validation, indexing, distribution, identification, retention times, storage, preservation, safekeeping, retrieval, and disposition.

3.5.2 Record Validation

Data records (particularly those in the form of logbooks, data sheets, workbooks and calculations) may be subject to reviews and evaluations, which may occur several years after a record was produced. The authentication practices; which may include stamping, initialing, signing, dating, and transmittal statements; should result in records that are clearly traceable and identifiable as the valid product of the responsible organization, individual, or project.

3.5.3 Records Identification, Indexing, and Retention

Practices of record identification, including an appropriate indexing system, should include sufficient information to permit identification of the record with the item or activity to which it applies. The indexing system must provide information that permits information retrieval. A very important part of this indexing/identification system is the records retention policy. The retention policy should have clearly established rules and instructions that permit disposal of data and other records when they are no longer needed. Selected raw data that may have significance in assisting future explanation and verification of the results should be retained on some long-term basis.

One problem is to determine what should be discarded and when, particularly with raw data. Some researchers and developers tend to discard raw data soon after they have been evaluated, compiled, and reported. The availability of raw data can be important, however, if a problem surfaces after the completion of a research or development project. That can be particularly true if the person who produced the data is no longer available. Lack of retrievability may create suspicion about the quality of data.

3.5.4 Records Distribution and Storage

The records management system should clearly define records distribution and handling practices. Individuals or the organization responsible for distribution, receiving, and storage of records should be identified. It may be important that the practices followed provide for interim or work-site handling and storage prior to transfer to central storage facilities. Interim and final storage instructions should be established to provide necessary retrieval capability, physical preservation, and safekeeping. Facilities required for records storage should be identified.

3.6 CONTROL AND HANDLING OF EQUIPMENT AND MATERIALS

The suitability of equipment and materials can play a significant part in the acceptability of data. Control over the handling and use of equipment and materials should be established and maintained throughout the course of a project. The elements of this principle indicate the types of control that should be incorporated into the research or development process.

3.6.1 Maintenance of Equipment

Equipment must be maintained in proper working order. There should be provisions for identifying equipment items not working properly and for controlling their use until they have been repaired. In some laboratories, a maintenance and repair log is maintained for each item of equipment. Such a log documents the status of each item.

3.6.2 Quality of Materials

Quality requirements for materials should be established and specified. When possible, there should be provisions for identifying and verifying the quality of materials before they are used, particularly if the use of deficient materials would have a significant adverse affect on a research or development project.

3.6.3 Labeling

Labels should include appropriate information relating to identity, composition, safety hazards, stability, and storage and handling requirements. When possible, established industrial labels should be used, particularly for bulk chemicals. Requirements should be established for corrective actions when a label is missing or found to be incorrect.

3.6.4 Storage of Materials

Storage containers should protect materials from contamination and other adverse effects. Storage conditions should meet special requirements such as limits of exposure to light, humidity, and temperature. Those requirements should be stated in the appropriate procedures.

3.6.5 Acceptance of Equipment and Materials

When the purchase of equipment and materials is required, specifications and other requirements that define the desired characteristics should be clearly established and included in procurement documents. Control over those documents should be established to assure that changes in specifications and other requirements are not made without proper review and approval. Acceptance of equipment and materials should be based on verification that specifications and other requirements have been met through inspection upon receipt or through supplier's certification. In some cases, acceptance by inspection at the supplier's plant may be necessary.

3.7 RESOLUTION OF PROBLEMS

The unpredictability associated with research and development means that mistakes and failures will occur. Such problems, from which new knowledge is often obtained, are anticipated by scientists and engineers. Even mistakes and errors occurring in the routine and established aspects of research and development might lead to new knowledge. But, too frequently, such mistakes and errors, or deficiencies, adversely affect the success of a project or an experiment. Szakonyi stated: "Recognizing that an R&D project is off track often means seeing things that were always there, but that one did not want to see."[4] In other words, problems in a system can cause a project to go off track. If not found and corrected, these problems can lead to loss of data, erroneous data, or even incorrect conclusions. Problems can result from something as simple as the operation of a piece of equipment by an improperly trained technician. A system to identify and evaluate problems and to correct them in a way that minimizes recurrence should be established and used by research and development organizations.

3.7.1 Identification

Most problems are found during the normal performance of work. Defective equipment and materials are often found through inspections and test when received from suppliers. Defective equipment and inadequate data can be found through calibration activities. Inadequate data may also be found by peer reviews and through statistical evaluations. Tags, markings, or other means of positive identification should be used on defective materials and equipment to prevent their improper use. Problems can occur in operational and administrative activities associated with the technical work. Those problems are often found by auditing and surveillance. Prompt reporting of problems will assure that corrective actions can be taken before more serious consequences occur.

3.7.2 Evaluation

Problems should be evaluated to determine the true causes. The important part of an evaluation is identifying the required actions for correction, including the actions required to preclude recurrence. A peer review process should be used, when justified, to assure technical adequacy of the evaluations.

3.7.3 Correction and Follow-Up

Responsibilities for taking corrective action should be identified and a schedule for correction established. The assigned actions and schedules should be recorded and reported to responsible technical or project management. The final actions taken should be documented and reported. It is important that actions taken be reported and communicated to the responsible and involved technical and managerial participants. Follow-up is a necessary action to assure that prescribed corrective actions have been taken.

TABLE 1

QUALITY GUIDES AND RELATED NQA-1 REQUIREMENTS

Guides	NQA-1 Requirements																	
	1*	2*	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17**	18*
3.1 Planning and Organization of Projects	X	X	X			X												
3.2 Qualification of Personnel		X							X						X			
3.3 Peer Review of Work	X	X	X														X	
3.4 Acquisition, Protection, and Evaluation of Data			X		X	X						X			X	X	X	
3.5 Use and Management of Records																	X	
3.6 Control and Handling of Equipment and Materials		X		X			X	X		X	X	X	X	X				
3.7 Resolution of Problems															X	X		X

*In a general way, these Requirements apply to all Guides because Organization (1), Quality Assurance Program (2), and Audits (18) affect all work activities in terms of initial planning and organizing and in providing ongoing surveillance.

**This Requirement applies to all Guides in which quality assurance records are generated.