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Los Alamos
Los Alamos National Laboratory
Los Alamos, New Mexico 87545

November 4, 1987
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G736
(505)-667-0030
FTS 843-0030

James E. Kennedy
U.S. Nuclear Regulatory Commission
7915 E Avenue
Mail Stop: 623-55
Washington, D.C. 20555

Dear Mr. Kennedy:

Subject: Minutes of the meeting of September 15, 1987

A meeting of the ASQC Research and Development Committee was held in Las Vegas, Nevada in conjunction with the 14th Annual National ASQC Energy Division Conference. Members attending were:

G. W. Roberts
R. R. Geoffrion
T. S. Baer

Guests in attendance were:

R. K. Gill	Babcock & Wilcox
Dennis Arter	TICOMP
Gene Caveness	Dupont
Raymond Camp	Princeton Plasma Physics Lab.
Tommy Ambrose	Battelle
Robert Thomas	Brookhaven Natl. Lab.
Cecil Hughey	Battelle, PNL
Pete Bussolini	Los Alamos Natl. Lab.

The chairman gave a brief discussion on the charter of the committee and reviewed problems and progress of the committee in the recent past for the benefit of the guests.

George Roberts also discussed a request received from a scientist in Korea that was interested in information that has been generated by the committee.

A review of the transpiring of the last meeting was held. Teresa Baer has not received enough support from committee members to do trend forecasting. The project will be phased out until George gets further information from National.

Ray Vurpillat was present at part of the committee meeting. He requested that the committee goals and objectives be put into a written format. He would like the

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committee to track and report on the progress of completion of these goals on a yearly basis (either by conference year or by calendar year).

Robin Gill reported that she has not received many comments from committee members on the draft ASQC Research and Development Guidelines Document. A copy of the draft is attached to these minutes. Committee members should get their comments to Robin at Babcock and Wilcox (1562 Beeson St., Alliance, OH 44601) by November 30.

Due to problems at the last committee meeting, no topic of discussion was selected for this meeting. However, committee members should come to the Dallas meeting in May prepared to discuss how research data reporting and peer review are conducted at their facilities.

It was pointed out at the meeting that it might be necessary for the committee to meet more often. It was suggested that another meeting could be held in January. If you are interested and willing to meet at that time please call George at (216) 821-9110 or me at (505) 667-0030. If enough members are interested, we can plan a session at a mutually convenient location.

It was suggested that the committee get someone from the NQA-3 committee to give a brief presentation to us on the definition of Surveillance. I talked with Mike Nicol of ORNL at the conference after our committee meeting. He said he would be more than happy to make such a presentation to our committee in Dallas.

Our committee was also asked to provide a session at next year's conference. I will take on the task of securing papers and will moderate the session.

Committee members will be given information on the time and date for the next meeting in Dallas at a later date.

Sincerely,

R. Ronald Geoffrion

R. Ronald Geoffrion

RRG:sab

Attachment - ASQC R&D Guidelines - Draft

Cy: P. L. Bussolini, w/o att.
R. R. Geoffrion, w/o att.
CRM-4 (2), w/o att., MS A150
MEE-9 File

ASQC Quality Assurance
Guidelines Document

INTRODUCTION

This Guidelines Manual is intended to provide guidance in the application of Quality Assurance practices to research and development activities. Researchers in all scientific disciplines have inherited "good laboratory practices "from the multitude of scientist and researchers which have gone before them. These good laboratory practices resulted from the lessons learned in the quest for valid, accurate, reproducible data. The practices give control over the various sources of loss and failure that can occur at any time in any experiment. Good laboratory practices are used by the researcher to help assure that all research activities are properly planned and executed resulting in reliable data.

A research environment is quite distinctive, not at all like the manufacturing environment of which it is sometimes a part. Researchers tend to be highly educated and highly self motivated people. Creativity and individuality are not only encouraged but are requirements of the job. Mistakes, not tolerated in the manufacturing environment, are commonplace. Research is trial and error. Failure after failure after failure may occur until the correct solution is arrived at. Newton, Tesla, Einstein, Wang to name a few exemplify the boundless creativity of the researcher. This type of person resists any attempt at being placed into a "straight jacket" of conformity. However, a comparison of quality assurance procedures to good engineering practices shows that the two are not mutually exclusive and that researchers have in reality been using some quality assurance procedures all along.

For any Quality Program to succeed it must have the support of management. The proper culture must be set. Employees must know that management truly and enthusiastically believes in the Quality Program. This belief is demonstrated when management helps to set the goals of the quality program, authorizes and then gives full support to quality improvement projects and periodically evaluates adherence to and effectiveness of the quality program. When upper management shows this much concern and commitment to quality it doesn't take long for middle managers, researchers, and others in the organization to realize that quality is of great importance and is not to be taken lightly. Management's actions far outweigh it's words. If quality is only given lip service by management then the quality program is doomed to mediocrity. Employees will realize that quality is not important to management and is therefore not important to them. The best quality assurance program in the world will have no effect on quality in this type of culture. A culture which promotes the performance of work of high quality will produce work of high quality.

ASQC Quality Assurance
Guidelines Document

The end product of most research efforts is data. The goal of the quality program should be to ensure that the work performed achieves the intended objectives of the research project and that the work can be understood and if necessary, reproduced successfully by others. The quality program should ensure the integrity, adequacy, accuracy, precision, reproducibility, and retrievability of the data. With support from both management and researchers the goal of the quality program can be achieved.

One quantity of a documented, active, management supported quality program will be the customer's perceived value received. A quality program will go far to increase the customer's opinion of the laboratory as doing good quality work.

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I. Responsibility

The responsibility of ensuring that proper quality controls and checking activities are carried out should be placed upon the individual project leader. The individual project leader is best able to decide which elements of the quality program apply to the particular project being conducted. It should also be the responsibility of the project leader to ensure that all special customer requirements, such as material certifications, inspections, special tests or instrument calibrations are performed and appropriate documentation on file. Further, it should be the responsibility of the project leader to identify appropriate resources, technical and managerial, that are needed to meet the customer's requirements. And finally the project leader is accountable to Laboratory Management for the successful completion of the project.

II. Front End Planning

It has been shown that the successful completion of a research project is directly proportional to the amount of front end planning which is performed. The project leader should in all cases discuss with the customer and come to an agreement with the customer on the workscope of the proposed project. Areas which should be discussed during the front end planning stage include customer's needs, project objectives and goals, applicable codes and standards, quality requirements, schedule, cost and deliverables. Once details of the project have been agreed upon they should be documented on some type of project authorization form. All authorizations should define the workscope, funding, schedule and quality requirements.

As a first task for any project a detailed work plan should be developed to cover the project. The work plan can be a separate stand alone document, a contract statement of work or some other project authorization document as long as it meets the following criteria. To be considered a detailed work plan the document must be detailed enough that a technically competent person can understand and perform the required work without recourse to project personnel for clarification. When writing the work plan the project leader should consider the design of experiment and the analysis required, test planning, pre-test reviews, limitations of the approach and probability of success, parameters to be investigated, test apparatus required, acceptable measurement uncertainty, whether formal inspections are required, whether customer approval of material substitutions is required, data evaluation methods required, reports required and any other deliverables. Preparation and submission of this work plan to the customer should be the the first milestone of the project. The purpose of submitting the detailed work plan to the customer is to provide the customer with the details of

the project as understood by the project leader. If the customer disagrees with any item of the test plan this allows him ample opportunity to clarify the work required.

Front end planning should include that the project leader ensures facilities requirements are known and available when needed. Such items as buildings, utilities, space and temporary project labor may be needed to fulfill project requirements. It is best that facilities personnel be informed of the project's requirements at the outset of project planning in order to avoid costly delays later.

Included in front-end planning should be safety considerations of the project. The project leader should assure that all work activities of the project will be performed according to applicable safety rules, approved procedures, and government safety standards. The project leader should know the hazards and the approved procedures related to the work which will be performed.

The project leader should be aware of such safety concerns as personal protective equipment, hazardous chemical use, storage and disposal, and radiation hazards. Safety concerns should be discussed with the Laboratory's Safety Officer at the outset of project planning to avoid hazardous or life threatening situations latter in the project.

III. Design of Experiment

Statistically designed experiments are recommended both for projects investigating parameters and their interactive effects, and for experiments seeking optimum conditions. Design of experiment techniques should also be used when the outcome of an experiment is to be defined by an equation.

The documented design should include a statement of the test objectives and a design matrix. The statement of the test objectives may be in the form of questions to be answered, the hypotheses to be tested, or the parameter effects to be estimated. The design matrix should consist of the parameter combinations to be tested to meet the test objectives.

The analysis and the interpretation of the experimental results should be performed mainly in relation with the design of experiment. Where possible, statistical computer software should be used in the analysis of the test results.

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IV. Design Reviews/ Control

Design Reviews

The purpose of a design review program is to assure high quality, reliable, cost effective products or processes being developed or remodeled by the Laboratory. Design reviews can also be extended to new or redesigned experimental facilities within the Laboratory. Need for a design review may be dictated by the customer. In those cases where the customer has no requirement for a design review the "need" for a design review should be considered on a case-by-case basis by the appropriate Laboratory manager. Design reviews dealing with experimental facilities may not need to meet all the suggested requirements which follow and should be conducted at a level appropriate to meet the requirements of the particular situation.

It is recommended that at least two reviews be performed. The first should be during the initial stages of planning to concur with design specifications. The second review is recommended prior to transferring the new product to the customer for use or manufacture.

The first review should be performed by technically experienced and skilled personnel from within the laboratory. Selection of these participants should be the responsibility of the appropriate Laboratory Manager. The recommendations, based on a consensus of the review participants, should be documented and signed by the participants.

The second review should be performed after the design has been finalized and before transfer of the product or process to the customer or construction of the facility takes place. This second review should be performed in a formal documented meeting having a formal agenda. The chairperson of this meeting can be the appropriate Section Manager or the project leader responsible for the new or remodeled product or process or facility. This review should be conducted by technically experienced and skilled personnel from within the Laboratory who are not directly associated with the development of the design being reviewed. The agenda should encompasses such considerations as design objectives, design alternates (including associated costs), and comments from special government or industry review committees. The recommendations, based on a consensus of the review participants, should be documented in a formal design review report. All participants should sign this document denoting understanding of the recommendations. Opinions of participants disagreeing with the recommendations should be attached to the report. Should the customer take the responsibility of performing the design review, Laboratory personnel should follow the design review procedures of the customer.

Drawing Control

Engineering drawings are defined as representations of mechanical or electrical equipment, test facilities, etc. that are produced on drawing media with formatted borders and title blocks. Sketches are defined as representations of equipment, test facilities, etc. that are used to communicate temporary, preliminary, or intermediate engineering information pertaining to a project. Sketches are usually not to scale. Engineering drawings are recommended for:

a. Documentation or long-term retention of design and/or construction of test articles necessary for reproduction of the experiment.

b. All applications such as construction of equipment, test facilities, etc. requiring any type of Code conformance.

c. Design or construction of equipment, test facilities including buildings, utility systems (i.e. air, water, steam, gases, electrical, etc.), or other reasonable permanent installations, or that require documentation for insurance purposes.

d. Documentation of electrical circuits for construction or modifications to reasonably permanent equipment or test facilities.

All drawings should be checked by an individual other than the drafter and approved by the project leader prior to release for use. Revisions to drawings should be reviewed and approved in the same manner as the original.

Drawings and drawing revisions should be controlled to ensure that incorrect or obsolete drawings are not inadvertently used.

Independent Technical Review

Independent technical reviews should be performed on projects which involve the taking and/or analyzing of data. The reviews should be performed by a person or persons knowledgeable in the subject of the research, but who had no responsibility in the project being reviewed. The project leader may select the reviewer or reviewers and inform them of the purpose of the project and of the funding limitations.

Prior to the fabrication of a test article or the set-up of a complicated test structure, critical characteristics specified in the detailed work plan or by the project leader should undergo an independent review. These characteristics may include calculations for scaling, test performance, dimensional stability and Code and design interfaces.

During the course of the project or during the final review at the completion of the project, the following questions concerning the project should be considered by the reviewer commensurate with their effect on the quality or the validity of the data:

a. Project performance with customer specifications and requirements;

b. Results of analysis; that is, do the results obtained meet the objectives established in the detailed test plan; and

c. Were specified quality standards, calculations, and/or computer programs checked for adequacy and accuracy.

Independent reviews should be legibly documented. Reviewers should indicate the approach used for performing the review and the results of the review (i.e. acceptability of the data reviewed). Questions concerning the data should be reviewed with the originator and answered to the satisfaction of the reviewer. The reviewer should sign and date the review documentation and present it to the project leader for inclusion in the project records.

V. Calculations

Calculations which should be documented are those required to substantiate the design of a test article and those made during test data reduction and analysis. Calculations can be documented on a designated form, laboratory notebooks, computer output sheets or magnetic media. Calculations should be legible and sufficiently detailed such that a person qualified in the subject can understand the calculation without contacting the originator.

To make calculations suitable for filing, retrieving and reproduction, the first page of the calculation should contain the project title, project identification number, page number, name of the person making the calculation, date the calculation was made, and a cross reference to the drawing specification or the system or test phase to which the calculations apply. Project identification number and page numbers should be included on each page of the calculation.

Calculation detail should typically include identification of the objective or purpose of the calculation, design inputs and their sources, methods used and assumptions made, including identification of those assumptions requiring verification, parameters to be investigated, any references used, units, results of the analysis and conclusions, if any.

The project leader in conjunction with a superior should determine if calculations for the project require an independent review. The decision for this review should be based on the risk inherent in the use of the calculations. Calculations which may require review include calculations based on customer inputs, design engineer's calculations for test article fabrication, calculations used for analysis of test data, and calculations required to complete a final report. After the reviewer has completed the review the calculation should be dated and signed by the reviewer to indicate the review was performed. The reviewer should document the results of the review and note any discrepancies.

VI. Software

Whether using an existing program, commercially acquired software or developing software internally, a risk assessment associated with the use of the software should be made. The following are suggested definitions of risk.

a. High Risk - Errors in the software could result in significant cost, product liability or impaired customer relations.

b. Medium Risk - Software which effects company product but not to the extent that a significant cost or product liability could be incurred.

c. Low Risk - Software which does not affect the company product or results produced by the software will be verified in developing the product

The project leader should be held responsible for all data and other information produced with computers. Prior to using existing software, whether it has been purchased or developed internally, the project leader should review the software in sufficient detail to ensure that the methods used by the software and the results obtained from the software are correct for the intended application.

A software development project should be planned carefully including reviews and tests to ensure that the program is an accurate implementation of the required method and that the correct results are being obtained. A risk assessment should be performed prior to starting software development.

Documentation should be developed during each phase of a development program as appropriate. As a minimum, documentation should include the program identification, a

brief description of significant limitations, capabilities, intended use, and a permanent record of the source code listing. Documentation should increase as risk level of using the software and required effort to produce the software increases. A minimum level of document control includes the assignment of software identification and revision level or date to be included on all software output. Additional controls should be performed as risk level of using the software and required effort to produce the software increases.

VII. Procurement Control

Records for procurements for a project should be maintained by the project leader in the project files.

Purchase requisitions should contain a clear statement of what is required, date required, approximate cost estimate, necessary department approvals, quality assurance/code requirements, charge numbers and the name of the requisitioner.

The project leader should identify those procurements affecting the quality or validity of data, code materials, and instrumentation. Quality assurance requirements should be documented on the purchase requisition. Purchase requisitions for code materials, instrumentation and any other items affecting the quality or validity of data should be reviewed and approved by the Quality Assurance department for appropriate quality assurance requirements. Purchase requisitions for instrumentation should also be approved by the laboratories Instruments Department.

The laboratory should conduct its purchasing practices to reflect experience with supplier performance. The Quality Assurance department should maintain experience records for selected vendors meeting prescribed quality requirements. In specifying equipment purchases the project leader should consider the experience records maintained by quality assurance and the importance of the equipment to the quality and validity of the data in specifying the extent of supplier certification and qualification testing needed. All researchers should assist in gathering experience information by reporting significant performance failures as well as outstanding performances to Quality Assurance for inclusion in its supplier experience records.

VIII. Inspections

Receiving Inspection

Once a purchased item is received, it should be immediately inspected to verify that the material does, in fact, meet the purchase order requirements. This inspection

may be performed by the Quality Control personnel or by the project leader or his designee. The inspection can be documented on a copy of the purchase order, in the project logbook, instrumentation records for an instrument or a formal receiving inspection report if one exists.

Inspection documentation should include the name and other identification of the item inspected, purchase order number, item number, characteristics inspected, certifications received, deficiencies noted, whether the item is accepted or rejected, the inspector's signature and the date the inspection was performed.

Immediate corrective action should be taken if the material is discrepant. Appropriate identification should be used to identify material which is being held for inspection, that which has been inspected and accepted, and that which is discrepant.

Material furnished by the customer should also receive a documented receiving inspection to assure that the material is complete, undamaged, and meets all specifications previously agreed to by the Laboratory and the customer.

In-Process

Inspections are usually performed for those physical characteristics identified by the project leader as critical to the test results. The need for inspections can be identified on receiving copies of Purchase Orders, Route Sheets, Test Procedures, Inspection Checklists. The project leader should be held responsible for all inspections performed on his project. Inspections can be performed by shop personnel, quality control personnel, or technical section personnel.

Critical dimensions should have a corresponding checklist or route sheet prepared by the project leader or his designee to direct the inspection of critical dimensions. If there are construction codes involved with test apparatus fabrication, the inspection of the attributes required by Code can be handled in a similar manner. The following guidelines may be helpful.

a. Inspection checklists should be used if the inspection is fairly simple and if all the characteristics can be inspected at one time.

b. Inspections of manufacturing operations that are more complicated (many inspections required at different times) should be controlled by a route sheet.

c. All inspections performed by the technical section regarding the condition of the test article during and after test should be documented in the project logbook.

d. Occasionally the customer may want to witness inspection or testing operations. These witness or hold points can be included on Route Sheets or Test Procedures. The customer's representative should be asked to sign and date the above records verifying his witness of the test or to provide written authority to proceed if the hold point is waived.

Inspections can be performed by any person familiar with the operation. Inspections performed during test are usually done by the project leader or his designee. Shop inspections may be performed by the operator responsible for making the part or, if required, by an independent inspector. The project leader should determine if an independent inspector is required or if the person responsible for performing the operation can perform his own inspection. The Laboratory may wish to maintain a list of inspectors who may be called upon to perform special inspections. This list may be maintained by the Quality Department

The person performing the inspection should be responsible for the inspection documentation. Inspection documentation should include the type of inspection performed (i.e., visual, dimensional, or type of NDE used), results of the inspection, deficiencies, whether the item was accepted or rejected, reference to corrective action documentation, the inspector's signature and the date the inspection was performed.

Nonconformances detected during fabrication of the test article should be identified on a corrective action report. The article itself should be identified as discrepant and segregated until the project leader has reviewed the nonconformance and any adverse effects it may have on the test results. Nonconformances discovered during test should be documented in the project logbook. A nonconformance report may also be used. The project leader should be responsible for determining the necessary corrective action. This may require customer approval.

IX. Material Identification and Control

The project leader should be held accountable for assuring that all project materials affecting test results are identified and controlled. Usually the person most likely to be involved with project materials is the project leader. Project leaders will usually prefer to maintain their own controlled area for their project materials and keep them segregated from other project materials. Therefore, there may

be several storage areas throughout the Laboratory maintained by the various technical sections or project leaders. These "private stores" assure the project leaders that their materials are separate and available when needed.

The project leader should implement material controls. These controls can be accomplished by maintaining identification tags and markings on the materials so that they cannot be mixed in or confused with unidentified stock or materials from another project. Standard quality control tags such as "Hold for Inspection" tags, "Material/Part Identification" tags, green "Accepted" tags and red "Discrepancy" tags are available and can be used by the project leader to segregate and identify his material.

If materials will be needed by a support group such as a machine shop or weld shop the project leader may want to set some type of central storage area so that when the support group needs to withdraw materials they are available and appropriately protected.

The project leader may choose to delegate the responsibility for material control and identification to another section within the Laboratory. The project leader should transmit all material control and identification requirements to the delegated section. The delegated section, in turn, has a responsibility to the project leader to ensure that all material control and identification requirements are adhered to for as long as the material is in their possession.

The project leader should maintain a list of materials or parts, and components that affect the validity of the test results. The list should indicate if certified test reports or certificates of conformance are required. Any additional tests to be performed by the Laboratory to verify material identity should be specified. The project leader should maintain any test reports or material certifications in the project files. Copies of material test reports should be on file in the Quality Department for those materials used on a project or test facility which may, at the least, become a semi-permanent part of the Laboratory. Decisions on material substitutions should be based on the effect the substitution will have the test results. State and local codes may influence or determine what substitutions if any are allowed. The project leader may have to obtain customer approval of any proposed material substitutions prior to utilizing the substitute material. This requirement should be made clear during initial project planning.

X. Nonconformances

Nonconformances will occur in the areas of fabrication of test specimens or fixtures and quality systems. Nonconformances should be documented on an appropriate nonconformance report. If the nonconformance is on a specimen or fixture the item should be tagged with a discrepancy tag and segregated to prevent inadvertent use whenever possible. The project leader should review the nonconformance and determine what if any adverse effects the nonconformance will have on test data. The project leader should determine what corrective action to take whether it be "use as is", "repair", or "scrap". If a "use as is" or "repair" decision is reached the project leader must determine whether the decision will cause a deviation to any of the customer specifications or commitments agreed to during the up-front planning or detailed test plan. The project leader may have to obtain customer approval of proposed corrective actions. Once a nonconformance is satisfactorily resolved the discrepancy tag may be removed.

Nonconformances to a quality system, such as a deviation to a test plan or procedure, should also be documented on some type of nonconformance report. At the very least the nonconformance should be documented in the project logbook or somewhere in the project records. Again, the nonconformance may require customer approval.

QA should receive copies of nonconformance reports. This allows QA to gather noncompliance data and perform long term collective analysis of various research projects so that undesirable trends or chronic violations can be detected and corrected. Allowing QA to be involved in the corrective action process brings their particular skills into the problem solving aspects of the quality program.

XI. Test Control

Tests should be specified in the detailed work plan developed at the start of the project. Suggested Work plan contents have been discussed in Section II. After the work plan has been agreed to the test program itself may begin. Control of specific tests may be achieved by individual test procedures. Some of these may be standardized procedures such as those published by the American Society of Mechanical Engineers (ASME) or the American Society of Testing and Materials (ASTM). These can be identified by number and revision in the work plan or somewhere in the project files, such as in the project logbook. Some procedures may have to be written specifically for the test. Details of performing the test may not be known at the start of the test and will be developed as the testing proceeds. These procedures can be written very open ended so that they can be developed as the

test proceeds. The procedure would contain only those steps and acceptance criteria known at the start of the test. As testing continues and details of the test become more solidified the test procedure would be amended to reflect the actual testing perform. In the case where a phenomena is being characterized there is no acceptance criteria. Therefore, the test procedure should only state how the test data is to be recorded. In some cases the detailed work plan may contain enough detail that a separate test procedure is not required.

Detail contained in test procedures should include test prerequisites, such as special operator training or certification requirements and test conditions that should be verified prior to beginning the test. If tests are sequenced or require specified inspections or independent verification of test the procedure should require verification of the requirement prior to proceeding to the next step of the test. The procedure should contain a listing of typical test equipment to be used. Reference to specific instrumentation or equipment by serial number should be avoided since if substitute equipment is used the procedure would have to be revised. Actual equipment set-ups, including serial numbers should be documented in the project records.

Test data not processed directly through a computer or documented on computer output sheets should be recorded on formal data sheets or logbooks. All recorded data should reference the project title, date, time, data taker and facility used. This data should reference, if not included elsewhere, other documentation that describes how the test was performed, a description of the test facility, and test article, including sketches or drawings utilized, instrumentation used, test procedure and revision number or standard method used, actual parameters used and deviations from the test procedure.

Test results should be reviewed by the project leader. Calculations and/or computer programs used in the analysis and interpretation of data should be independently reviewed. The review should determine not only the mathematical correctness of the calculation but also whether the experimental objectives were met and whether the effect or interactions were interpreted correctly.

XII. Instrumentation

Researchers have learned that an accurately calibrated instrument traceable to NBS does not always give a measurement of the desired accuracy for the project. It is, however, an important component. Environmental conditions or operator error can have a devastating effect on the accuracy of an measurement. Total measurement uncertainty, random

error as well as systematic error, determines whether or not a measurement is accurate. A documented calibration program clearly defining the responsibilities of the technical and support sections using calibrated equipment is the first step a Laboratory can take in the effort of determining the total measurement uncertainty associated with its various instrumentation. And, is the first step to providing measurement quality assurance.

The program should include all measuring devices in the Laboratory. Some type of physical identification should be given to each instrument identifying it immediately as to its calibration status. That is, is it within its calibration interval or is it in need of calibration or perhaps it doesn't require calibration as it is used for rough indications only. This identification should also identify the history files for the instrument, which indicate its accuracy.

It is recommended that a centralized calibration group be established. This group would have the authority to "certify" the calibration status of an instrument and the technical expertise to oversee the calibration function. This group should have the power to perform the initial evaluation and assignment of an instrument status or category, approve calibration procedures, calibration set-ups, calibration personnel qualifications, and calibration data (whether generated by its own people, other technical sections of the Laboratory, or calibration suppliers). After evaluating calibration data the centralized control group can reject or accept the data. If the data is rejected the appropriate project personnel should be contacted so that the impact of the out-of-calibration condition can be evaluated for the project data. Activities of this centralized calibration control group should be evaluated by Quality Assurance.

Even with all these controls in place it is still the project leader's responsibility to assure that the proper instrumentation is used to meet the accuracy requirements of the project. The project leader should document the actual instrumentation used on the project in the project records. If the facility being used to perform the test has its own list of instrumentation this list may be referenced in the project records. However, the project leader should be aware of instrument substitutions made on the facility during the test and update his records appropriately. All instruments used for taking data during the test should be calibrated. Instruments which have been designated as "indication only instruments" should be used for indication purposes only and not for acquiring data on the project. Instruments not calibrated should not be used for taking data. The project leader should also ensure that the instrumentation used is within its calibration interval throughout the time frame of the test.

XIII. Reports

Reports will vary with regard to type, size, complexity, timing and format. Latitude should be given the project leader in choosing the particular style of report, whether it be a letter report or a more formal report, to suit the circumstances and the customer requirements agreed to during the up-front planning. The project leader should be aware that a report published by the Laboratory is the principle evidence of the quality of its performance and ability. Personnel of the Laboratory will be judged by the contents of their reports, therefore their writing ability must match their research ability. The production of effective reports is a major part of their professional performance.

XIV. Project Records

Complete documentation of the work performed by the Laboratory is quite important. Any information, memos, meeting minutes or special references that have a bearing on the direction the project has taken, the data required, or the interpretation of results should be included in the project records. Suggested records which should be maintained include work authorizations and any revisions to work authorizations, all customer communications, purchase requisitions, purchase orders, receiving inspection documentation of purchased items and customer furnished materials, inspection documentation of inspections performed in the shop on "critical dimensions," design reviews, sketches, drawing or drawing list, instrumentation list, calculations, calculation reviews, reference to computer programs used, computer program reviews, computer printouts, characteristics of the test facility and test article, procedures used and all test data. Results such as preliminary plots or data should be subject to the same traceability requirements as calculations. The project leader should be held responsible for maintaining all project records.

All project records should be identified in enough detail that they can be easily reproduced, filed and retrieved at a later date. The Laboratory as a whole or the individual technical sections should devise and maintain a standard system by which all project records within the individual section of the Laboratory are retrievable.

XV. Audits

Quality Assurance should perform general surveillance over all projects being conducted to the general quality guidelines of the Laboratory. A more detailed review or audit should be performed periodically. The purpose of auditing projects performed under standard laboratory practice is to

characterize how projects are being performed with respect to general Laboratory guidelines. A statistical sample giving the desired level of confidence in the data should be selected from the total number of projects being conducted at the time of the audit. Checklists for these audits should be taken from the guidelines and requirements for the various administrative systems utilized during the course of a project. A checklist of standard questions applicable to any project audited should be designed. For support systems which may or may not be used by the projects, such as the purchasing function, a separate checklist should be developed and used when applicable to the project being audited. The auditor should feel free to deviate from the checklist and pursue an independent line of questioning when answers given appear to warrant this type of questioning.

The audit report should be written to the upper management of the Laboratory and should include an introduction, summary of significant results, conclusions, recommendations and detailed analysis of the audit results. The audit report should be written to summarize the results of the entire lab. However, supplemental reports can be written to summarize the results of each individual technical section if the section manager should request it. Audit data should be summarized statistically so that the reader of the audit report can make up his own mind as to the importance of the statistic to the laboratory or to his individual technical section and whether corrective action is required.

Statistical sampling can also be used when conducting a generic systems audit. Major systems, such as purchasing and drawing control, have an enormous data base to audit. To audit 100% would be time consuming and impractical. Because a generic system usually involves only a handful of controlling procedures, a checklist which covers all aspects of the procedures is more easily designed and a very good degree statistical inference can be made as to the degree of actual compliance. Again a statistical report showing significant trends using percentages and graphics, allowing the numbers to speak for themselves is best. Variations and the approach to corrective action are dependent upon the seriousness of the noncompliance found. Serious noncompliances should not go uncorrected just because there is a lack of sufficient statistical data to prove a trend exists. The auditor's judgement and experience should take over from the unbiased objectivity of the pure numbers presented.

Audits of suppliers are similar to audits of any other Laboratory process. Audits of instrumentation and calibration suppliers should be of particular importance to the Laboratory. Like other audits, supplier audits should be performed periodically, and like other audits, a checklist is designed to meet the requirements of the activity being audited. It may be beneficial to the Laboratory for its audit

teams to include not only a QA auditor but also a technical expert in the area being audited. An audit team composed of a technical expert and QA Auditor can perform a more through audit thus giving the audit more credibility. An audit report should be written and transmitted to the supplier within one week of performing the audit. Noncompliances should be addressed by the supplier and a response returned to the Laboratory within two weeks. Responses received from the supplier should be evaluated. A decision should be made as to the acceptability of the response and whether the supplier will be approved. Final verification of implementation of the committed action items may be held off until the next regularly scheduled audit if the findings are relatively minor, or they may be the subject of a special follow-up action or reaudit if they are major.

XVI. Training

Introduction of a Quality Program to a Research Laboratory will require some employee indoctrination. One way this can be accomplished is by the Quality Department presenting mandatory training seminars. However, a better way would be for upper managers to train lower managers in the quality practices to be followed and the lower mangers in turn then train the researchers. This approach again shows management ownership of the Quality Program and gives more meaning to the training received by the researchers. Many laboratories are divided into various disciplines. This approach allows the management of the various disciplines to emphasize the quality procedures it feels most important to the type of research it performs thus allowing a tailor fit quality program.

XVII. Quality Cost

There are many ready references detailing how to collect quality costs in a manufacturing environment. However, no such references exist for the research laboratory. Collecting accurate, reliable quality costs can be difficult. Unlike a manufacturing facility where the same process is performed repeatedly, research projects tend to be unique and one of a kind. It is suggested that the traditional quality costs, prevention, appraisal and failure, be evaluated on a Section basis. This can be done by having the Section perform an evaluation to determine what percentage of their project dollars as well as overhead budget, is spent on these costs. Actual dollars spent by the Section can be obtained from accounting and used to produce a quality cost report for the Section on a monthly or quarterly basis. The Section reports can then be combined to produce a report of quality cost for the Laboratory. Over time the percentages stated by the Sections will become more refined and a very accurate report will be produced. Quality

costs for such functions as accounting, purchasing and personnel can also be obtained and added to the Laboratory's quality cost report for a complete picture of quality related costs.