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Letter Report—GAC/QA 3519.100

EVALUATION AND RECOMMENDATIONS

ON

U.C. LAWRENCE LIVERMORE LABORATORY

QUALITY ASSURANCE PROGRAM

P.O. 1309509

by

F. D. Carpenter
M. H. Horner

April 12, 1978

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I. INTRODUCTION

The University of California - Lawrence Livermore Laboratory Quality Assurance Office requested General Atomic Company to conduct an evaluation and make recommendations on specific areas of LLL's Quality Assurance Program. This request was made as a result of LLL's QA Office personnel visiting the General Atomic site to establish the capabilities of GAC/QA Division staff to implement cost effective QA programs in a Research and Development environment.

General Atomic's QA program also includes compliance with Federal, State, and Industry QA codes and standards. This integrated application of various codes and standards is established through levels of quality which are responsive to R&D projects and manufactured products. Verification of compliance has occurred by DOE, NRC, Utilities, ASME Boiler and Pressure Vessel, and other contractor auditors.

A specific area of interest to the LLL/QA Office personnel was the GAC/QA Division's capabilities in training personnel in Quality Assurance Technology. GAC/QA Division, through its own efforts to provide cost effective and uniform application of quality engineering principles by knowledgeable persons, developed a series of courses for training employees. These courses have been offered publicly and are well attended by quality oriented personnel from Utilities, NSS suppliers, component manufacturers, Federal and State employees. The courses have been developed and are presented by mature, well seasoned engineers and/or professionals in quality technology, course development, and teaching techniques. The combined capabilities of quality assurance programming and application, instructional development, and teaching in quality related technologies motivated LLL/QA Office personnel to establish a contract with key representatives of GAC/QA Division to review and make recommendations in training approaches and QA programs tailored to the work-mix in specific on-going LLL projects.

II. SUMMARY

A study was conducted of the University of California's Lawrence Livermore Laboratory Quality Assurance Program, which focused on training needs and recommendations tailored to the various on-going programs. Specific attention was directed to an assessment of the quality status for the MFTF facility and the capabilities of assigned quality project engineers.

Conclusions and recommendations are presented which not only address the purpose of this study, but extend into other areas to provide insight and needs for a total cost effective application of a quality assurance program.

III. PURPOSE

This study was made for the purpose of recommending a cost effective LLL QA program in the Mirror Fusion Test Facility and recommendations for training of QA project engineers.

The study was conducted at the University of California's Lawrence Livermore Laboratory Facility and involved a review of the existing generic QA plans, interviews of the LLL's QA/staff personnel, proposed level of QA activity, overall work mix by program phase, and other pertinent areas within the QA Program.

The activities associated with this study and the conclusions and recommendations are stated in the following sections of this report.

IV. QUALITY ASSURANCE PROGRAM REVIEW

1.0 Existing/Generic QA Program

The LLL's QA Office personnel are to be complimented on the well-organized and diversified interactions that were scheduled and conducted with selected operating personnel throughout the laboratory. The work mix by programs provided an excellent basis to establish the existing level of QA activity and, in particular, the existing knowledge of operating personnel in quality technology, criteria, and concepts.

The Lawrence Livermore Laboratory can be proud of its many years of achievement in science and technological development. The use of the matrix type of management system (Project/Resources) has been very successful. The achievements of the Laboratory have depended heavily upon the individual program managers. This individual dependence for project-related activities also results in various levels of quality of work--some very good, others not so good.

All research and development activities in today's world are viewed by our society in the light of their effect on our environment. Management of such activities must not only be concerned with achieving the objectives of the program, but doing it in a safe manner and with acceptable quality. The recent visualization of the LLL QA Program requirements by publication of the Quality Assurance Manual, Volume I, dated March 1, 1978, is an excellent start. The additional volumes 2, 3, and 4 should be published as soon as possible for guidance and implementation.

A review of this generic QA Manual indicates several quality assurance elements (criteria) that are not fully addressed. The following are examples.

Design Control - The manual does address the design review and design verification processes, but it is not clear in establishing the elements of design control which relate to establishing design basis (criteria), interface control and design change control.

Procurement Control - Two areas which are not addressed include how purchased equipment is controlled, and the identification and control of purchased materials and parts for which quality efforts have been expended and require separation from non-pedigreed materials or parts. In addition, uniform source evaluation methods should be established and an approved supplier listing for those suppliers surveyed or evaluated would be beneficial for cost effective applications involving outside procurement.

Records - The records requirements are addressed properly (e.g., documented QC/QA results, sufficient records, traceability and retrievability), but guidance is not given which establishes a uniform application of record control for the multi-program LLL operations. Requirements need to be clarified to establish the type of records, permanent or non-permanent, and the storage criteria.

Verification (Audits) - Two elements of an effective verification process need to be addressed. The timeliness of periodic audits should be stated, and the independent access of project quality engineers to higher levels of management for problem solving should be stated more clearly.

2.0 LLL/QA Staff Interviews

Staff interviews were conducted with four principal groups. These groups included: LLL QA Office staff; proposed project quality engineers from selected programs; the MFTF project manager, and key members of his staff; and project managers, test directors, technical leaders, and resource personnel from nonfusion programs. Two general questionnaires (guides) were developed to probe specific capabilities and quality knowledge of the selected quality project engineers, and to analyze the quality related activities for the MFTF and non-fusion programs. (The questionnaires are illustrated in the appendix to this report.) Along with the specific questions, an attempt was made to establish what they were doing, what their needs and concerns were, and what they expected of Quality Assurance.

The initial indoctrination period with the LLL QA Office staff included a presentation of the LLL QA program. The presentation was a replica of the QA Program indoctrination that had begun to introduce the concepts in the newly issued LLL/QA Manual.

The interviews with the pre-selected project quality engineers can be summarized in four main observations:

(a) The individuals had broad engineering backgrounds. Educational backgrounds varied from the non-professional (tradesperson) to the professional Engineer or physical scientist.

(b) Most had good or excellent R&D experience, especially motivated to make things work. Work elements which formally established planning or setting objectives, performance monitoring of the work, as well as documenting results, were deficient.

(c) The majority of individuals lack the knowledge or awareness of quality concepts (e.g., QA planning, design control, document control, quality records, audits, etc.).

(d) Most individuals were also not knowledgeable or aware of Federal or commercial quality standards or their application.

The interviews with the fusion and non-fusion managers, staff, and members of the resource groups also resulted in establishing several observations:

(e) All personnel are strongly oriented toward safety concepts. LLL management has been very successful in communicating safety consciousness in all employees and, in many such high safety risk operations, such a motivation also provides high quality control and assurance.

(f) As a result of the above statement, there is evidence of quality principles being integrated into the work elements.

(g) Some personnel were leery of QA. Statements such as "Project Planning didn't include QA activity costs," "Quality would only increase costs," "I don't have enough principals to accomplish the work," were symbolic of a misunderstanding of QA and its application and impact on a program.

(h) There were a few areas where a QA program was edicted. For these areas, the operating staff attempted to do the best job they knew how, but here again fell short in the concept of Quality Assurance. An example related to the statement that a "qualified person must be used to handle the controls on a hazardous operation." The person was only qualified, not by documented pre-established list of requirements that were certified by supervision and approved by management, but when the supervisor thought he was able to perform the operation safely.

The above observations should not be construed as a failure to provide good work programs, but emphasizes the lack of awareness or thought processes which focus on the application of a Quality Assurance Program to provide a total management system which can be much more effective in achievement of program objectives.

3.0 QA Activities - Work Mix/Program Phase

The review of work mix by program phase to evaluate the extent of QA activities was conducted by the interviews held with the project managers, their assigned staff and representatives of the resource groups. In addition, a select tour was arranged to view the physical facilities for the Laser/Neutral Beam and MFTF programs.

It was clearly visible by the tour and in subsequent discussions that the QA activities were dependent upon the assigned project manager and his individual application of any quality or safety related criteria. There was no uniform control from program to program or enforced management direction. As a result, the influence of believers or non-believers in the application of QA programming was mixed from project to project.

Several project or program managers did express some concerns in their ability to control all activities which could affect quality. This concern was expressed in two different areas. One area was in component quality. Variations of quality existed and were dependent upon whether the decision was made to fabricate the component in-house or to fabricate by an outside vendor. The second area involved decisions which could be made by resource group managers to fabricate components without the knowledge of the project manager. These decisions were outside the control of the project manager, and quality related activities could be established without their review and concurrence.

Generic to all operations of the LLL system, and one of the fundamentals of a quality assurance program for any level of quality, should be policy and procedures which describe how work is to be done. A quick search to establish the hierarchy of the LLL's procedural system to guide the management and operations within the laboratory was not very successful. Some procedural or policy manuals did exist, e.g., Safety Manual, Mechanical Engineering Department's Policy and Procedures Manual, but these were not current in content or issue.

Another important feature of establishing quality related activities is to indoctrinate or train all employees, especially new hires, in the various policies and operational requirements or constraints within the laboratory. There was no evidence of indoctrination of new employees in a formal manner, even in the Safety Manual. All indoctrinations appeared to be conducted by peers or the employees' immediate supervisor. This type of indoctrination lacks uniformity and impact.

V. CONCLUSIONS/RECOMMENDATIONS

1.0 Mirror Fusion Test Facility - QA Program Recommendations

A considerable portion of the review effort with LLL personnel was devoted to individuals and facilities of the Mirror Fusion Test Facility (MFTF). Several general recommendations derived from that effort are presented here as an introduction to specific Quality Assurance Program recommendations for MFTF project work.

1.1 General Recommendations

The Quality Assurance Program at LLL should be considered to include all activities that provide a system for control of work, including non-safety areas, even though formally designated quality assurance personnel are not used in that work, and QA plans are not written. An extensive system of controls is an essential need for projects such as MFTF. Much smaller projects will benefit from a minimum level of control and should be able to state that their quality assurance program is represented by an implemented system of procedures used "to minimize delays and costs due to deficiencies and failures of items and services."[1] Project managers and other senior managers must be seen by personnel as being active supporters of systematic work controls and of QA personnel efforts, where QA people are involved.

The Quality Assurance professional can and should help the project manager set up controls on a "team" basis where project personnel write procedures with effective guidance to make the procedures a useful product.

The absence of hardware or facility related control of work is clearly evident in the contrast between working areas in the MFTF Building 431 and the project office. Control of sponsor interfacing activity by the project office is apparently well managed with Management Plans, schedule formats, quality assurance planning, and other documents that serve as the basis for communication with DOE and with project management personnel. Very little control was observed for work performed in the MFTF facility. The project needs to provide a practical, common sense system of communication and control throughout the project organization in the form of project procedures. The procedures should define specifically how all project work is to be conducted and involve the use of any LLL procedures already in existence.

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[1]LLL QA Manual, page 1, Objective 2.

For MFTF, the LLL selection process involving failure consequences can be roughly approximated by evaluating accessibility for repair to determine which items should receive the most quality effort. The highest levels of quality assurance effort should be defined for the items that comprise the confinement vessel system, the superconducting magnet, and other internal vacuum chamber components, with less concern for power systems and facility construction unrelated to personnel safety. As an example, more quality engineering design review, source inspection, and receiving inspection is appropriate for the vacuum chamber procurement than for the procurement of neutral beam injector power supplies since the latter are accessible for repair and maintenance.

1.2 MFTF Procedural Controls

An MFTF Project Procedures Manual should be prepared. The ideal procedures are those that clearly state how work is being performed by those project individuals that are observed to be cost effective and in control of their work. For controls not currently practiced, procedures should provide a cost effective common sense minimum of control that gives project management confidence that work will be performed to consistent standards of excellence. The MFTF manual should cover the subjects listed below:

1.2.1 Design Controls

- Specification Writing - The Mechanical Engineering (ME) Department Procedure is a good one for reference. The Project procedure should establish review and approval requirements.
- Drawing Preparation - The sequence of preparation, review, and approval events should be shown in flow chart format.
- Control and release of Design Documents.
- Design Change Control.
- Interface and Modification Control.

1.2.2 Procurement Controls

- Administrative Control - The Project Manager should control all internal and external procurements. The procedure should define procurement planning and scheduling requirements, status reporting, budget planning and reporting, and interfacing with purchasing functions.
- Procurement Document Review and Approval - Review and approval sequences to include those designated by the Project Manager, and should include the project quality engineer for originals and changes to in-house and external procurement documents.

- Changes should be documented by changed drawings or quick change notices so that any design change is captured by the design control system.

1.2.3 Fabrication and Assembly

- Methods of work planning, control and verification should be established. A traveler, fabrication procedure, or assembly specification should be required for all machine assembly and subassembly fabrication operations. The travelers or other work control documents should be prepared well in advance, reviewed by project management, technical personnel, and the quality engineer. The quality engineer should review the specification of inspection operations and assure the required inspection equipment and personnel are available when needed.

- Electronic and electrical workmanship standards should be specified to establish a uniform standard of excellence. Martin Marietta Corporation of Orlando, Florida, sells satisfactory visual standards of this sort.

- A procedure for control of machine materials, components, and hardware should be established. Through such controls as a bonded stockroom for release of material to the construction effort, inadvertent use of magnetic bolting or out-of-date age-sensitive materials can be avoided.

- A system for definition of acceptance status of MFTF components should be instituted. In simplest form, "accept" and "hold" tags would be used. Status information would be defined on the tag. A more complex system would reference the tag information to the system of nonconformance reporting.

1.2.4 Test and Operation Control

Test plans and operating plans should be prepared to define startup and experimental work involving production prototypes, tests of installed equipment, and integration testing. A procedure should specify the contents of the plans, require appropriate reviews (safety, physics, stress analysis, etc.), and establish approval requirements.

1.2.5 Quality Assurance Engineering

Procedures should define the specifics of Quality Assurance controls. These might include:

- QA review of Engineering documents.

- QA review of in-house fabrication and purchasing documents (job orders and purchase orders).

- Establishment of an inspection program for the MFTF facility for all machine assembly effort. The program should include inspection planning by quality engineers, an inspection office at MFTF, establishment of inspection status controls (an item, once inspected and accepted, should not be altered unless it is reinspected to a new acceptance criteria), and maintenance of retrievable inspection records to provide quick access to acceptance status of any component for MFTF.

- Establishment of a nonconforming material and corrective action system. LLL Form LL3810 could be used to report nonconformances, and a Material Review Board should be set up with a published list of acceptance authorities established by the project manager.

1.2.6 Measurement and Test Equipment Calibration Control

- Project procedures should establish which items are to be controlled.

- Lab resources should be used to maintain adequate calibration status.

- The program should include all gear, not just inspection equipment.

1.2.7 Safety

- MFTF Committee is needed to define safety hazards and review hazardous aspects of the work that are unique to MFTF. The committee should interact with the lab Health and Safety organizations--QA should be a part.

1.2.8 Records

- A system of records management is needed for MFTF design and quality records to include "as built" vendor submittals, inprocess assembly records, and records of inspection for LLL fabrications.

- Design records access should be provided at the MFTF facility in several places to provide the current configuration.

1.2.9 Audit Program

Procedural controls should be established that require audit by independent personnel to gauge compliance with project procedures on a regularly scheduled, comprehensive basis.

2.0 Other Programs

Several recommendations and conclusions are summarized in this section. Some statements that follow describe what LLL needs to do in order that future project quality engineer training have a base of specifics rather than frustrating generalities. Other statements are recommendations that resulted from interviews with LLL personnel.

2.1 Good Engineering Practice

A responsibility of the project Quality Engineer should be to monitor project work for compliance with standards for "good engineering practice," as practiced at LLL, and inform management when the standards are not met. Because we feel quality engineer training should include methods of engineering document review, we looked for, but could not find, up-to-date standards for good engineering practice. We recommend that LLL update and distribute the Mechanical Engineering Policies and Procedures Manual as soon as possible. The latest new procedure was distributed in 1973, the latest cover memo (which alludes to a new revision) was distributed in 1975. The manual is basically a good procedures document, has been in existence since 1966, and probably has wide acceptance at LLL.

2.2 QA Plan or No QA Plan Decision

We feel that the analysis to determine the need for a QA Plan should be independently verified by the LLL QA organization to prevent errors by someone of inadequate training or experience. Quality engineers should be trained to perform such an independent verification.

2.3 Project Quality Engineer Job Description

The project quality engineer's work scope needs to be well understood by the training agency if the PQE's are to be trained to be fully responsive to a project manager's needs. A statement of responsibility and authority for these individuals should be available prior to training program preparation. General Atomic could assist LLL in preparing the job description for the Project Quality Engineer.

2.4 Project Quality Engineer Candidates

General Atomic feels that candidates for Project Quality Engineer training should have certain minimum qualifications, otherwise training time will be wasted. Project Quality Engineers should be drawn from the ranks of those capable of being Project Engineers or Project Managers. The individuals should be intelligent, senior, independent, trained or successful in managing people, tactful, and have courage. They should have free access to high levels of management and the support of the Program Leader, Project Manager, and the Department Heads. LLL Quality Assurance should arrange to participate in the selection of Project Quality Engineers to help the Project Managers by bringing uniformity to the process.

2.5 Stopping Poor Quality or Out-of-Control Work

An essential ingredient in any quality assurance function is the responsibility for getting work stopped where serious consequences result from allowing work to proceed. The LLL QA Program does not address this point. Project Quality Engineers need to be trained to recognize when a stop work is needed (and when a stop work is not indicated), and to proceed through the proper chain of command to an individual with authority to accept responsibility for stopping work or not stopping work. The Project Quality Engineer must have access to such authority without fear of reprisal by someone in his management chain. The act of presenting management with such decisions must be viewed as a normal function of the Project Quality Engineer. Prior to training Project Quality Engineers in this subject, LLL should decide how the need to stop work will be handled internally.

2.6 Control of Procurement and Fabrication

Control of procurement and fabrication activity should be centralized to the project to allow the Project Quality Engineer access to all such documents. A standard, required sequence of review and tracking will bring great consistency to budget, schedule, and quality assurance controls, and to status reporting. Training Project Quality Engineers how to review procurement or fabrication documents will be futile if he doesn't see all such documents.

2.7 Uniformity of Control Systems - Documents

A uniform standard for the documents used to implement various types of work controls at LLL should be established. A number of such standard forms now exist in the form of specification formats, procurement documents, job orders - the system should be completed so that the entire QA system at LLL is operated by the same documents. Where possible, the same records management approach, the same quality forms (discrepancy reports, inspection planning, design and procurement document review check lists and sequence, status tags and records indices) should be used throughout LLL. This approach will prevent different quality engineers from developing a hodge-podge of control documents and systems everywhere. The system of forms should be documented in the procedure writing section of the LLL Quality Assurance Manual, and Project Quality Engineers should be trained in consistent application of the control documents.

2.8 Control of Work Sequencing

Work sequencing documents should be used for high dollar or highly complex fabrication or assembly operations at LLL. Project Quality Engineers should be trained in the advantages of such documents as they should be the project experts in the control of work to prevent errors. Documents such as travelers, specifications for assembly, process sheets, or manufacturing instruction sheets (showing the sequence of assembly) generally serve as the basis for development of detailed inprocess inspection planning. Training should be provided to the Project Quality Engineers in the mechanics of reviewing such documents and specifying cost effective quality assurance activity. If such documents are not available, the QE must be trained in a different manner to seek out the details of assembly or fabrication and establish effective inspection controls. The "Quality Project Engineers Training Course" outline (Appendix B) shows how

the QPE's should be educated to identify and weigh alternative methods of assurance. As an example of the need for work sequencing control documents, a manufacturing engineer should currently be working to determine the best sequence of operation and all additional tools and equipment required to prepare the winding equipment, establish adequately clean conditions, and wind the MFTF mirror coils. A Project Quality Engineer would work with the preliminary and final work sequencing documents to plan quality verification activities to support the manufacturing sequence.

2.9 Conflict of Interest

The Quality Assurance group personnel should stay out of the trap of technical specification writing to avoid conflicts of interest.

2.10 Facility Cleanliness

The MFTF facility needs great improvement in terms of cleanliness controls. Electronics technicians should not be eating at the areas where work is performed--small amounts of pickle juice and mayonnaise are ruinous to reliability. Project Quality Engineers should recognize such problems and seek improvement.

2.11 Program QA Needs

No matter how small the program is, it should not be ignored as far as quality assurance training is concerned. Today's small program may be tomorrow's large program if it is successful and efficient. Some programs were reviewed that could have benefited greatly from small amounts of receiving inspection activity.

2.12 Hazardous Facilities Quality Assurance

We feel that knowledgeable people from hazardous operations, such as the Plutonium and Tritium facilities, would benefit greatly from quality engineer training. They would be equipped to plan, conduct, and document inspections and audits to verify compliance with facility quality assurance plans and operating procedures.

2.13 Management Training

Department heads, division leaders, project managers, and group leaders need training to inform them of the benefits of a cost effective, common sense approach to quality assurance, and to develop their understanding of the responsibility of the Project Quality Engineers and the Quality Assurance resource group. They should know what to expect from the quality professional, and to take quick corrective action if proper support isn't realized for their QA dollars. The most efficient way to accomplish this training would be a management level workshop or concentrated management task force exercise patterned after the PQE course (Appendix B) and involving the PQE's who have completed the course.

3.0 Training

The intent of this contract was to establish a basic outline for the training that should be provided to the assigned QA project engineers and to stress the training approach to optimize attitude and motivation for a

cost effective QA Program. Both objectives have been accomplished in the appendix attachment, "Quality Project Engineers Course Outline."

The study has also illuminated training needs that would complement the efforts of the assigned Quality Project Engineers and help to achieve a total cost effective quality assurance program. Of immediate importance, LLL should initiate a new employees indoctrination program which includes a presentation of the LLL's WHAT/WHY/WHO/HOW of Quality. In addition, training needs for various personnel levels should be considered. A summary of these needs are recommended as follows.

Personnel Level	Topics
Upper Management	"QA Status Review for Each Project/Program"
Middle Management	"QA Program Development" "Managing for Quality" "Cost Effective QA Program"
QA Staff Personnel	See Appendix for Course Outline
Quality Project Engineers	See Appendix for Course Outline
Technical/Resource Staff	"Procedure Writing" "Assembly Planning" "Quality Engineering Concepts in R&D"
Procurement Personnel	"QA in the Procurement Cycle"
New Employees	"The WHAT/WHY/WHO/HOW of Quality"

APPENDIX

APPENDIX A

QUALITY ASSURANCE TRAINING COURSE OUTLINE

(Quality Assurance Staff Seminar)

COURSE OBJECTIVES

1. To provide a refresher review in the goals, elements, and optimum methodology of quality assurance in the research and development laboratory environment.

2. To accelerate the formulation of a consistent and cohesive quality assurance philosophy among the members of the Quality Assurance Staff, by stimulating the exploration of assurance concepts and the exchange of ideas and experience.

3. To produce a detailed instructional package for orientation of any future new members of the Quality Assurance Staff.

INSTRUCTIONAL METHODS

The instructor should lead a structured, full-participation discussion of the subject matter. The order of introduction of topics should be preplanned, and the instructor should have a schedule which gives approximate completion times for major segments of the planned subject matter, as well as anticipated completion times for the specific sub-topics. The instructor should recognize that developments during the discussion will cause variations in the lengths of some segments, and he must remain sufficiently flexible to allow for such variation without permitting any significant elements of the subject matter range to be omitted.

INSTRUCTIONAL MATERIALS

1. Bibliography of relevant publications, with specific references (where applicable) to the relevant material within those publications.

2. Basic list of types of forms that will probably be desirable for various controls within the LLL QA program, with a package of examples that show the essential information each form should provide for.

3. Situation summaries illustrating application of, or failure to apply, key quality assurance practices in programs of the type conducted at LLL.

OUTLINE

1.0 Quality Assurance Objectives

1.1 To minimize project costs due to mistakes, unclear specification of requirements, invalid results, etc.

1.2 To maximize the amount of data and/or functional system performance yield of each phase of a project.

1.3 To . . .

Approach: Develop the most appropriate list for the LLL application by suggesting one or two examples (as above) and eliciting others from the participants, then boiling down the list into a handful that are most clearly germaine to LLL, phrased to be most meaningful to LLL non-QA management and professional contributors.

2.0 Responsibility for Attaining Quality Goals

2.1 Developmental engineering

2.2 Test definition

2.3 Testing

2.4 Procurement

2.5 Fabrication/assembly

2.6 Installation

Approach: Discuss project-peculiar quality goals. Develop clear understanding of such specific goals and the overall objectives defined in 1.0. Develop five to ten such specific statements of objectives with participants. Record them. For each, determine who really would have the "make-or-break" responsibility for doing.

3.0 Assurance Functions

3.1 Direct controls

3.2 Surveillance

3.3 Verification

Approach: Guide participants in listing specific examples of each of the assurance functions, in terms of on-going or anticipated LLL projects.

4.0 Organization and Program Planning

4.1 QA Program Authority

4.2 Independence from Schedules/ Pressures

4.3 Access to Decision-Making Levels of Management

4.4 Freedom to Act on Problems Affecting Quality

4.5 Regular Reporting on QA Program Effectiveness

4.6 Documentation of QA Program Plan(s)

4.7 QA Training and Indoctrination Planning

Approach: The instructor should introduce each element of this section by brief summary of historical development and experience, then initiate open discussion of practical application in terms of LLL activities and management practices. The same approach should be used in each of the remaining sections.

5.0 Design Control

5.1 Identification/Definition of Design Requirements

5.2 Control of Design Interfaces

5.3 Design Verification

5.4 Design Change Control

5.5 Configuration Control

6.0 Control of Working Documents

6.1 Written Instructions, Procedures, and Drawings

6.2 Document Review/Approval

6.3 Controlled Distribution

6.4 Control of Obsolete Documents

7.0 Procurement Quality Assurance

7.1 Assurance of Full Communication of Technical and Quality Requirements in Procurement Documents

7.2 Control of Procurement Document Changes

7.3 Control of Supplier Document Submittals

7.4 Provision for Access to Supplier Facilities

7.5 Supplier Evaluation and Selection

7.6 Supplier QA Plans/Procedures

7.7 Source Surveillance, Inspection and Audit

7.8 Supplier Quality Trends

8.0 Inspection Controls

8.1 Determination and Specification of Appropriate Level of Inspection Control

8.2 Specification of Acceptance Criteria

8.3 Identification and Control of Materials

8.4 Control of Non-Conforming Materials

8.5 Non-Destructive Examination

8.6 Control of Functional Acceptance Testing

8.7 Inspector Qualification

9.0 Test Controls

9.1 Control of Measuring and Test Equipment

9.2 Test Planning Controls

9.3 Test Specification

9.4 Test Procedures

9 5 Test Evaluation

10.0 Corrective Action

10.1 Identification and Reporting of Problems

10.2 Investigation of Causes

10.3 Resolution of Immediate Problem

10.4 Investigation of Implications of Problem to Work and/or Project Results Already Obtained

10.5 Definition of Corrective Action for Previously Completed Work *and/or Results*

10.6 Definition of Measures to Preclude Recurrence

10.7 Corrective Action Reporting

10.8 Follow-Up

10.9 Feed-Through of Problem and Corrective Action Data to Concurrent Related Projects and to Future Activities

11.0 Quality Assurance Records

11.1 Identification of Project QA Records Requirements/Needs

11.2 Records Preparation and Accumulation Controls

11.3 Organization and Protection of Working Records

11.4 Long Term Retention and Preservation of Records

11.5 Records/Information Retrievability

12.0 Audit

12.1 Audit Activities Planning

12.2 Individual Audit Plan

12.3 Audit Performance

12.4 Resolution of Audit

12.5 Findings

12.6 Audit Reporting

12.7 Audit Follow-Up

APPENDIX B

COURSE OUTLINE

PROJECT QUALITY ENGINEERS TRAINING COURSE

PURPOSE

The Quality Project Engineers Training Course is intended to produce an in-depth understanding of quality assurance concepts, a working knowledge of practical, effective assurance methods, and a management-oriented approach to application of these concepts and methods. The course is specifically designed to enable qualified participants without prior quality assurance exposure to function immediately and effectively as independent managers of project quality assurance programs. It is also designed to provide a sound basis upon which the individual can build as he learns the mechanics of technical quality engineering tasks.

OVERALL APPROACH

The Quality Project Engineer Indoctrination Course should be structured as a guided workshop. The instructor must lead the participants as they develop a basic "applied quality assurance program" for the developmental environment. The participants' educational and experience backgrounds must be used as the sources from which effective assurance measures are shaped, and the participants should, as the workshop progresses, fit the measures they have developed into a comprehensive, integrated assurance program, expressed in development project language rather than the traditional Quality Assurance terms. Although the instructor must assure that measures already proven effective on successful development projects evolve during the workshop (by appropriate questioning of the participants or pursuit of chance remarks), he must be careful that such planted measures grow by the interchange of participant ideas and arguments, not by overt prompting on his part.

EXPECTED OUTCOME

The chief benefits of this workshop approach are: (a) No participant will feel that he is under pressure to abandon his accustomed professional role to become a neophyte in an alien discipline, (b) each participant will discover that all of his experience is directly applicable to the assurance process, (c) every participant will recognize that he has made a significant and irreplaceable contribution to both the form and the content of the basic program, (d) the program will sound and feel like the LLL projects and operations, rather than like a QA imposed overlay, (e) each participant will be sufficiently at home with the program and its basis to take the lead in developing (with the line management of his assigned project) the specific project assurance program, (f) each participant will acquire or reinforce his capacity to think with the management point of view--to place technical considerations as well as assurance principles in a context of cost, schedule and design performance results.

Introduction. Establish the desired pre-set in the students and outline the week's work.

1.0 The Assurance Product

1.1 Better schedule performance

1.2 More project for the money

1.3 Higher performance of end-item

1.4 Better end-item predictability

1.5 Higher reliability of results or end-item

Approach: Briefly describe each of the above "products" as it is exhibited in the conceptual phase of a project, preliminary design/design definition, testing (from exploratory through design verification), procurement, in-house fabrication/assembly, etc., and project test or demonstration. Provide one or two real life examples of each "product," "a" through "e" for each of these project phases, and develop additional down-to-earth LLL examples by student brainstorming. Keep heavy emphasis on the presumption that we are talking only about effective assurance measures.

2.0 Measures of Assurance Effectiveness

2.1 Degree of awareness of project objectives

2.2 Reliability of communication across project technical interfaces

2.3 Frequency of unpleasant surprise due to error or oversight

2.4 Rate of resolution of design uncertainties

2.5 Volume of internally caused design change activity

2.6 Volume of subcontract/procurement change activity

2.7 Frequency and severity of materials/hardware problems

2.8 Magnitude of schedule problems in test/operation/demonstration of end item.

Approach: Participants to develop listing of various measures of assurance effectiveness after introductory open discussion of what constitutes a usable, valid measurement. End result of effort should include most, if not all, of the above measurements and probably a few others. Participants to examine each such measurement in terms of how it might actually be quantified--how one might compare before-and-after performance when a control is introduced or tightened.

3.0 Controls for Assurance

3.1 The role of human error in project problems

3.2 Major types of human error

3.3 Sources or causes of each human error type

3.4 Commonsense ways of prevention, early detection, or minimizing impact of error due to each generic source or cause

3.5 Classification of these commonsense measures

Approach: The instructor must guide the participants through these five steps, but the development of each step must arise from participant experience and understanding. It is the instructor's function in this section to ensure that each of the five topics is converted into concrete terms that produce vivid mental images for the participants and that involve practical, significant items rather than hypothetical or vague generalities. He must establish a valid, definitive foundation upon which the participants will build the assurance program. (Note: Participants will learn that the term human error is broadly used to include erroneous decisions due to insufficient data.)

4.0 Assurance Program

4.1 Conceptual phase

4.1.1 Initial definition of objectives and constraints

4.1.2 Identification/evaluation of relevant theory, hypotheses, research

4.1.3 Identification/evaluation/selection of promising alternative approaches

4.1.4 Theoretical development and calculations

4.1.5 Identification/specification of experimental needs, exploratory test requirements

4.1.6 Experimental testing

4.1.7 Selection of optimum course(s) for follow-on development

4.1.8 *Definition of design criteria*

Approach: As the participants are expected to have little or no experience in theoretical development, controls analysis for activities 4.1.1 through 4.1.4, 4.1.7 and 4.1.8 above should be conducted in less depth than the rest of the program. However, the kind of intellectual effort and communication involved in those activities should be explained briefly, and the participants will be able to identify the most likely sources of error or invalid results. The appropriate assurance techniques can then readily be obtained from the output of 3.4 and 3.5.

4.2 Design Definition/Preliminary Design Phase

4.2.1 Evaluation of alternative hardware approaches

4.2.2 Evaluation of available hardware types and capabilities

4.2.3 Identification/definition of component development needs

4.2.4 Definition of test requirements to resolve design uncertainties

4.2.5 Test design/performance for obtaining design basis information

4.2.6 Definition of design interface parameters

4.2.7 The iterative process

4.2.8 Definition of final design requirements

Approach: The participants should accomplish in-depth analysis/definition of potential error sources in this program phase and identify the most effective control measures for prevention and/or early detection of errors. Such measures must include provisions for controlled, effective communication across every design interface, adequate test controls, early confirmation of preliminary design calculations by alternate simplified calculation or reference to appropriate existing work, etc. The instructor may need to provide subtle prompting.

4.3 Final Design

4.3.1 Project technical description

4.3.2 System specifications/system descriptions

4.3.3 System schematics/layouts

4.3.4 Component specifications

4.3.5 Final calculations

4.3.6 Test plans/test specifications for design verification

4.3.7 Test procedures

4.3.8 Procurement specifications

4.3.9 Design changes

Approach: Same approach as for 4.2.

4.4 Procurement Phase

4.4.1 Preparation/processing of procurement requisitions

4.4.2 Preparation of invitations to bid/bid package

4.4.3 Bid evaluation/supplier evaluation/supplier selection

4.4.4 Contract definition

4.4.5 Source inspection planning

4.4.6 Supplier data control

4.4.7 Source surveillance, liaison, inspection

4.4.8 Supplier performance evaluation/ trends analysis

Approach: Same as for 4.2.

4.5 In-house Fabrication/Assembly/Installation

4.5.1 Shop and inspection planning

4.5.2 Material control

4.5.3 Forming, machining, welding assembly

4.5.4 Construction/installation (as applicable)

Approach: Same as for 4.2.

4.6 Test/Demonstration Phase

4.6.1 Requirements specification

4.6.2 Test procedure preparation

4.6.3 Test equipment/set-up preparation

4.6.4 Test performance

4.6.5 Test results evaluation

4.6.6 Test reporting

Approach: Same as for 4.2.

NOTE: The instructor will assure that all appropriate elements of quality assurance are included in the program the participants develop: organization and planning, design controls, document control and working procedures, procurement quality assurance, test control and control of measuring and test equipment, special process controls, identification and control of materials and components, inspection, control of nonconforming materials and components, closed-loop corrective action, records management, and system audit. Although specific controls or practices will often be expressed in something other than the traditional QA terms, the instructor must assure that the participants know the QA equivalents so that they can work effectively with the QA staff.

APPENDIX C

QUESTIONNAIRE FOR QPE APPOINTEE NAME _____

1. Undergraduate Academic Major(s) (a) _____ Year Compl: _____
   (b) _____ _____
   (c) _____ _____
2. Graduate Academic Major(s) (a) _____ _____
   (b) _____ _____
   (c) _____ _____
3. Undergraduate Minor(s) (a) _____ _____
   (b) _____ _____
   (c) _____ _____
4. Graduate Minor(s) (a) _____ _____
   (b) _____ _____
   (c) _____ _____
5. Special Studies (Industry, Specialized Schools, etc.)
   Subj. (a) _____ Year Compl: _____
   (b) _____ _____
   (c) _____ _____
   (d) _____ _____
6. Which of these fields have been applied in specific job assignments?

	Field	Job Assignment	Approx. Time	Employer
(a)				
(b)				
(c)				
(d)				
(e)				
(f)				
(g)				

(h)_____ _____ _____ _____

(i)_____ _____ _____ _____

(j)_____ _____ _____ _____

7. Have you had to work with (or are you familiar with) any reliability, quality assurance, or quality control (inspection) codes, standards or regulations?

Yes ☐ No ☐

8. If Yes to (6), which ones? _____

_____

_____

_____

9. Have you been directly involved in:

(a) Design review? _____

(b) Review of purchase orders, RFQ's or RFP's? _____

(c) Review/evaluation of bids or proposals? _____

(d) Preparation of test plans or test specifications? _____

(e) Review of test plans or test specifications? _____

(f) Specification of quality provisions? _____

(g) Preparation or review of test procedures? _____

(h) Acceptance of purchased items, materials or services? _____

(i) Design and/or acceptance of test equipment? _____

(j) Design and/or acceptance of test set-ups? _____

(k) Trouble shooting for equipment malfunction? _____

(l) Failure analysis? _____

(m) Problem resolution or corrective action? _____

(n) Preparation of detailed work instructions/procedures? _____

(o) Review of detailed work instructions/procedures? _____

(p) Preparation or review of manufacturing or installation planning? _____

(q) Any other control-type activities? _____

(what kinds? _____

_____)

APPENDIX D

OUTLINE QUESTIONNAIRE FOR

REVIEW OF LLL'S TECHNICAL PROGRAM CONTROLS

PROGRAM:

A. DESIGN CONTROL

Drawing Preparation

- Drafting Standards - Format
- Drawing Review and Approval
- Release or Issue Process
- Change and Quick Change Process and Approval
- Standard Parts

System Design Basis or Criteria

- Title of Document
- Generation and Approval

Technical Specification

- Format, Style, and Contents
- Review, Release and Issue Process
- Change & Quick Change Process

Vendor Documents

- Approval and Submittal
- Control

Design Records Control

B. LABORATORY OPERATIONS

Experimental Planning

- Format & Record - Memo - Exp. Plan
- Approval

Experimental Results

- Report Format (Tech. Memo, Letter Report, Monthly Report)
- Formal Treatment as a Record
- Notebook Program

C. PROCUREMENT CONTROL

Request for Quotations

- QE Review
- Specification (Formal or Informal)
- Qualified Suppliers

Purchase Order Review & Control

- Quality Engineer Review/Approval
- Design Under Formal Change Control
- Inspection Rights

Post Award Conduct

- Inspection Visits Planned with Hold Points - Written Plan
- Who Inspects?
- Independent Assessment of Satisfaction of Quality Requirements
- Approval of Design Documents
- Provision of Acceptance Test Procedure

Receiving Inspection

D. IN HOUSE FABRICATION & ASSEMBLY

Manufacturing Planning

- Procedures or Travelers - Forms
- Inspection Acceptance Points
- Makeup of Planning and Scheduling Staff
- Is Inspection Required?

Inspection Planning

- Input to Travelers or Procedures
- Inspection Planning Requirement & Formating (Forms)
- Maintenance of Records of Inspection

Special Processes & Control

- Welding
- Brazing
- Ultrasonic Testing/X-Ray

E. QA RECORDS

- Control
- Storage
- Accessibility for Retrieval

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