



ESH&Q DIVISION

Quality Assurance and Continuous Improvement

Bruce Lenzer

WHAT IS QUALITY?

- Two historic definitions:
 - 1) “fitness for use” - In order to exhibit “quality” a material, process, product or service must be fit for the use for which it is intended.
 - 2) “specification of what is wanted” - the production of things aimed at satisfying the specification, and the inspection of the things produced (W. A. Shewhart)
- In today’s regulatory environment, it is no longer sufficient to say that “we have a quality product”, it must be demonstrated through performance and documentation.

QUALITY DEFINITIONS

❖ **Quality:**

- ❖ The condition achieved when an item, service or process meets or exceeds the users' requirements or expectations.

❖ **Quality Assurance (QA):**

- ❖ All those actions that provide confidence that quality is achieved.

❖ **Quality Assurance Program (QAP):**

- ❖ A management system established to assign responsibilities and authorities, define policies and requirements, and provide for the performance and assessment of work.

QA/CI OVERVIEW

- **Quality Assurance Plan**
 - Incorporating DOE Contract expectations & industry standards
 - Policies and Procedures nearing completion
- **Quality Improvement Plan**
 - Based in findings from DOE-SURA Overlay Report
 - Few actions remaining
- **Contractor Assurance System Program Description**
 - Added to the contract in the Fall 2007
 - Oversight expectations for the overall contract
 - Includes ESH, Cyber Security, Integrated Safeguards and Security, and Emergency Management

WHY DO QUALITY?



WHY DO QUALITY?

- **QUALITY BENEFITS INCLUDE:**

- ✓ Minimize/eliminate rework
- ✓ Minimize/eliminate poor value processes
- ✓ Improve the effectiveness/efficiency of processes
- ✓ Reduce/avoid unnecessary costs
- ✓ Apply technology to optimize performance
- ✓ Meet customer requirements and expectations
- ✓ Do it right the first time
- ✓ Supports safety aspects of quality (e.g. counterfeit parts, material traceability)
- ✓ Collaborative team work (facilitated team etc.)
- ✓ Making better quality decision and creative solutions

Quality System Benefits

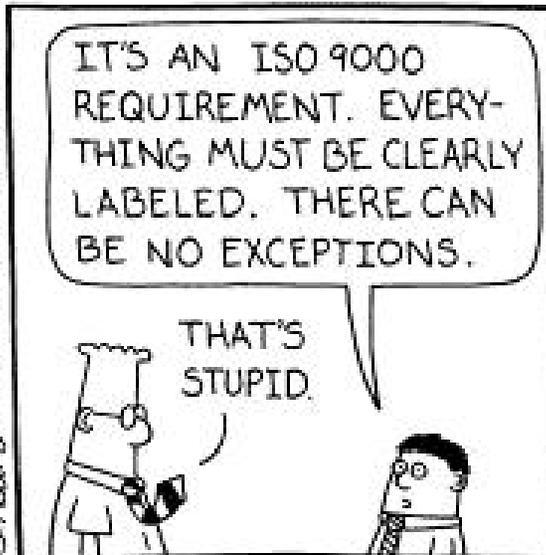
- ✓ Well defined and documented procedures improve the consistency of output
- ✓ Quality is constantly measured
- ✓ Procedures ensure corrective action is taken whenever defects occur
- ✓ Defect rates decrease
- ✓ Defects are caught earlier and are corrected at a lower cost
- ✓ Process Improvement leads to more cost effective performance
 - ✓ Value added vs. non Value added functions
 - ✓ Eliminate inefficiencies from temporary situations that have become permanent
 - ✓ Eliminate low value functions and develop corrective actions to improve poor value performance
- ✓ Defining procedures identifies current practices that are obsolete or inefficient
- ✓ Documented procedures are easier for new employees to follow
- ✓ Breaks down organizational barriers, fosters win-win solutions, and improves collaborative team performance through team building
- ✓ Improves cross organizational communications and performance

What is NOT Quality Assurance?

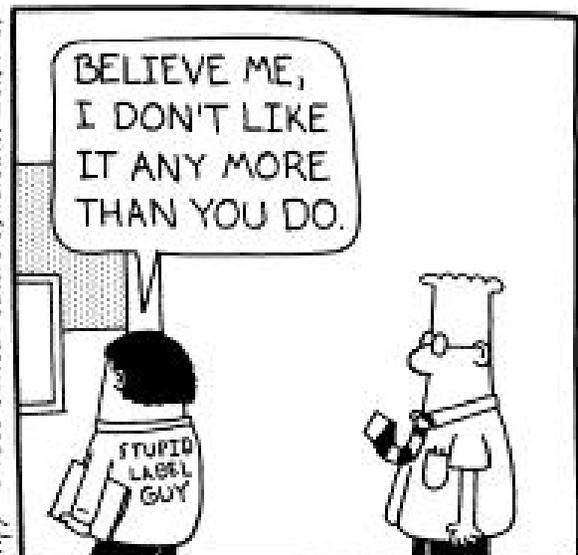




S. Adams E-mail: SCOTTADAMS@AOL.COM



11/7 © 1995 United Feature Syndicate, Inc.(MVC)



Copyright © 1995 United Feature Syndicate, Inc.
Redistribution in whole or in part prohibited

QUALITY & SAFETY INTERFACES

QA CRITERIA/ISM PRINCIPLES AND FUNCTION CROSSWALK TABLE

QA Criteria ISM Requirements	Program	Training & Qualification	Quality Improvement	Documents & Records	Work Processes	Design	Procurement	Inspection Accept. Test	Management Assessment	Independent Assessment
Line Management Responsibilities	X			X					X	
Clear Roles & Responsibilities	X			X					X	X
Competence Commensurate Responsibilities		X		X					X	X
Balanced Priorities	X			X					X	X
Define Work				X	X	X	X	X	X	X
Analyze Hazards				X	X	X	X	X	X	X
Identify Safety Standards, Requirements & Develop & Implement Controls				X	X	X	X	X	X	X
Operations Authorization/Controls				X	X		X	X	X	X
Feedback & Improvement			X	X	X			X	X	X

2 Faces of Quality

RUBBER

GLASS

Q/A- COST/EFFICIENCY

- Non-conforming Material
- Reduce Re-work/Rejects
- Supplier Performance
- Optimize Resources/Budget

Q/A- SAFETY

- ISM
- Suspect Counterfeit
- Non-Conforming Material

QUALITY ASSURANCE CRITERIA

BASIC REQUIREMENTS

MANAGEMENT

1. PROGRAM
2. PERSONNEL
TRAINING &
QUALIFICATION
3. QUALITY
IMPROVEMENT
4. DOCUMENTS &
RECORDS

PERFORMANCE

5. WORK
PROCESSES
6. DESIGN
7. PROCUREMENT
8. INSPECTION &
ACCEPTANCE
TESTING

ASSESSMENT

9. MANAGEMENT
ASSESSMENT
10. INDEPENDENT
ASSESSMENT

More detail on each of the 10 criteria to follow.

WHO IS RESPONSIBLE FOR QUALITY AT TJNAF?

- The achievement of quality requires that everyone be aware of the impact their function has on TJNAF's ability to "do science" and meet the lab's stated goals and objectives.
 - Quality Assurance involves establishing confidence that operations are performed as required.
 - We may know for a fact that we all do our jobs exactly right, however, without documentation, we cannot prove it.
 - Basically, "If you didn't document it, you didn't do it".

RESPONSIBILITIES FOR QUALITY ASSURANCE

MANAGERS

IMPLEMENT FEEDBACK

RESPONSIBLE AND ACCOUNTABLE FOR ALL ASPECTS OF QUALITY OF PERFORMANCE, INCLUDING PLANNING, ORGANIZATION, DIRECTION, CONTROL, AND SUPPORT

PERFORMERS

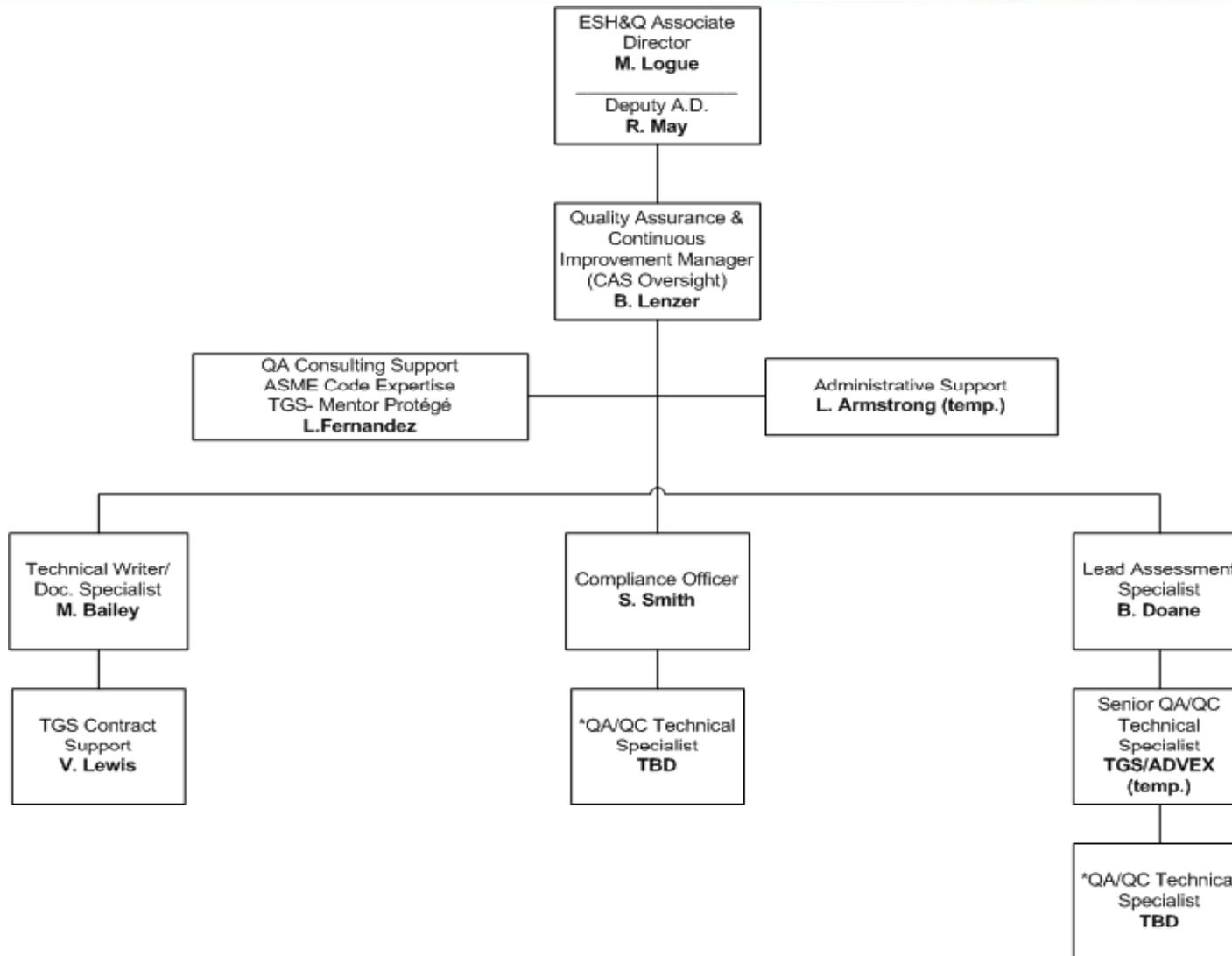
RESPONSIBLE FOR ACHIEVING QUALITY OF PERFORMANCE SO AS TO ENSURE SAFETY AND RELIABILITY

ASSESSORS

PROVIDE FEEDBACK

RESPONSIBLE FOR EVALUATING EFFECTIVENESS TO ACHIEVE QUALITY OF PERFORMANCE, IDENTIFY DEFICIENCIES, AND ENSURE CORRECTIONS

JLab QA/CI ORGANIZATION



Note: * To support Implementation Plans for DOE O226.1A- CAS DOE O414.1c, DOE O 210.2, 10 CFR 851

COMPLIANCE REPORTING

- Notable Event Reporting
- Occurrence Reporting
- Non-compliance Tracking System
- Quarterly Trend Analysis
- Performance Evaluation Measurement Plan Reporting for ESH&Q
- 10 CFR 851 CATS Screening
- Causal Analysis
- Corporate Operating Experience
 - Lessons Learned

DOCUMENT MANAGEMENT & TECHNICAL WRITING

- Manage & Coordinate ESH Manual Overhaul
 - Transferring documents from Framemaker to Word
 - Re-formatting documents to new standard
 - Streamline and simplify Documents
- ESH Manual revisions and updates
- Supports development and maintenance of QA/CI procedures
- Facilitate technical reviews of Policies and Procedures
- Performs technical writing and consulting to authors
- Controls documents and current versions using Docushare
- Update Web based links

ASSESSMENT & CORRECTIVE ACTION MANAGEMENT

- Manage Assessment Program
 - Independent and Management Self Assessments
 - Annual Assessment Schedule
 - Multi-Year Assessment Planning
- Corrective Action Management
 - Automated Quality Information Tracking System/Corrective Action Tracking System
 - Manage and trend Corrective Action Performance
- QA Inspection Program
 - Welding program management
 - Welding inspection
 - Supplier Evaluation
 - Materials Analysis
 - Receipt Inspection and Acceptance Testing Support

VALUE ENGINEERING & CONTINUOUS IMPROVEMENT

- Applied Quality & Value Management Techniques to Improve Products, Services, and Organizational Effectiveness
 - Facilitated High Performance Work Teams
 - Value Engineering/Value Analysis/Value Management
 - Six Sigma
 - Lean
 - Other Quality Improvement and Problem Solving Techniques
 - Assessments & Corrective/Preventive Actions

OTHER SUPPORT

- 12 GeV Quality Assurance
 - Review 12 GeV Specs.
 - Conduct Supplier Evaluations
 - Quality Assurance Consultation
- ASME Codes & Standards Consulting
- Weld Engineering Consulting

APPLYING QA TO YOUR WORK



QUALITY ASSURANCE (QA) UNDERLYING PRINCIPLES

1. Define policies and objectives.
 - Ensure understanding and acceptance
2. Specify roles, responsibilities, & authorities.
 - Ensure understanding and accepted.
3. Specify and communicate expectations.
 - Identify & allocate resources to achieve them.
4. Establish a culture that is conducive to quality achievement and continuous improvement.
5. Ensure people are competent at the work they do.
 - Training and qualification

QUALITY ASSURANCE UNDERLYING PRINCIPLES

(continued)

6. Ensure the right people have the right tools and information at the right time.
 - Work Control Doc's ATLIS
7. Seek and use relevant experience.
8. Plan and control the work.
9. Use the right materials, tools, and processes.
 - Control any changes to them
10. Assess work to ensure it meets expectations.
11. Identify and remedy errors and deficiencies.
12. Periodically review management processes to improve effectiveness and efficiency.

QA/CI CORE TEAM

- Bruce Lenzer, Manager, QA/CI
X7586 (blenzer@jlab.org)
- Mary Jo Bailey, Document Control/Technical Writer
X7277 (mbailey@jlab.org)
- Steve Smith, Compliance Reporting Officer
X7007 (sjsmith@jlab.org)
- Bob Doane, Lead Assessment Specialist
X6380 (bobdoane@jlab.org)
- Senior QA/QC Technical Specialist (TBD)

THE QA/CI WEB SITE

- Links available on the quality assurance/continuous improvement this site lead to information about quality functions and operations. Maint Site:
http://www.jlab.org/div_dept/dir_off/oa/
- Examples include:
 - [Assessment schedules and reports](#)
 - [Quality Assurance Plan](#)
 - [Quality Improvement Plan](#)
 - [JSA Requirements Management site](#)
 - Corrective Action Tracking System
 - Notable Events
 - Work Control Documents
 - Welding Procedures

QUESTIONS & ANSWERS

BACK-UP SLIDES



QUALITY ASSURANCE CRITERIA

QA CRITERIA

- CRITERIA 1 – PROGRAM MANAGEMENT
- CRITERIA 2 – PERSONNEL TRAINING & QUALIFICATION
- CRITERIA 3 – QUALITY IMPROVEMENT
- CRITERIA 4 – DOCUMENTS & RECORDS
- CRITERIA 5 – WORK PROCESSES
- CRITERIA 6 – DESIGN
- CRITERIA 7 – PROCUREMENT
- CRITERIA 8 – INSPECTION & ACCEPTANCE TESTING
- CRITERIA 9 – MANAGEMENT ASSESSMENT
- CRITERIA 10 – INDEPENDENT ASSESSMENT

QA CRITERIA

- **Management/Criterion 1—Program**
 - Establish an organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing work.
 - Establish management processes, including planning, scheduling, and providing resources for work.
- **Key Elements**
 - Senior management ownership
 - Performance objectives established
 - Responsibilities, authorities, and interfaces established
 - Individuals empowered
 - Application based on graded approach

QA CRITERIA (continued)

- **Management/Criterion 2—Personnel Training and Qualification**
 - Train and qualify personnel to be capable of performing assigned work.
 - Provide continuing training to personnel to maintain job proficiency.
- **Key Elements**
 - Affects all personnel
 - Stimulate professional development
 - Designed to address specific needs
 - Maintain proficiency and promote improvement
 - Conduct on-going review of training effectiveness

QA CRITERIA

- CRITERIA 1 – PROGRAM MANAGEMENT
- CRITERIA 2 – PERSONNEL TRAINING & QUALIFICATION
- CRITERIA 3 – QUALITY IMPROVEMENT
- CRITERIA 4 – DOCUMENTS & RECORDS
- CRITERIA 5 – WORK PROCESSES
- CRITERIA 6 – DESIGN
- CRITERIA 7 – PROCUREMENT
- CRITERIA 8 – INSPECTION & ACCEPTANCE TESTING
- CRITERIA 9 – MANAGEMENT ASSESSMENT
- CRITERIA 10 – INDEPENDENT ASSESSMENT

QA CRITERIA (continued)

- **Management/Criterion 3—Quality Improvement**
 - Establish & implement processes to detect and prevent quality problems.
 - Identify, control, and correct items, services, and processes that do not meet established requirements.
 - Identify the causes of problems, and include prevention of recurrence as a part of corrective action planning.
 - Review item characteristics, process implementation, & other quality-related information to identify items, services, & processes needing improvement.
- **Key Elements**
 - Standards and measures for performance
 - Problem identification, control, resolution, and follow-up
 - Cause analysis
 - Continuous improvement
 - Prevent problems

QA CRITERIA (continued)

- **Management/Criterion 4—Documents and Records**
 - Prepare, review, approve, issue, use, and revise documents to prescribe processes, specify requirements, or establish design.
 - Specify, prepare, review, approve, and maintain records.
- **Key Elements**
 - Scope of documents and records defined
 - Documents identified and controlled
 - Records identified and controlled

QA CRITERIA

- CRITERIA 1 – PROGRAM MANAGEMENT
- CRITERIA 2 – PERSONNEL TRAINING & QUALIFICATION
- CRITERIA 3 – QUALITY IMPROVEMENT
- CRITERIA 4 – DOCUMENTS & RECORDS
- **CRITERIA 5 – WORK PROCESSES**
- **CRITERIA 6 – DESIGN**
- CRITERIA 7 – PROCUREMENT
- CRITERIA 8 – INSPECTION & ACCEPTANCE TESTING
- CRITERIA 9 – MANAGEMENT ASSESSMENT
- CRITERIA 10 – INDEPENDENT ASSESSMENT

QA CRITERIA (continued)

- **Performance/Criterion 5—Work Processes**
 - Perform work consistent with technical standards, administrative controls, and hazard controls adopted to meet regulatory or contract requirements using approved instructions, procedures, etc.
 - Identify and control items to ensure their proper use.
 - Maintain items to prevent their damage, loss, or deterioration.
 - Calibrate and maintain equipment used for process monitoring or data collection.
- **Key Elements**
 - Management provides training, resources, and direction
 - Employees are responsible for their work
 - Review and improve processes

QA CRITERIA (continued)

- **Performance/Criterion 6—Design**
 - Design items and processes using sound engineering/scientific principles and appropriate standards.
 - Incorporate applicable requirements and design bases in design work and design changes.
 - Identify and control design interfaces.
 - Verify/validate the adequacy of design products using individuals or groups other than those who performed the work.
 - Verify/validate work before approval and implementation of the design.
- **Key Elements**
 - Design based on sound engineering/scientific principles
 - Changes must be justified
 - Interfaces must be identified and coordinated
 - Verification must be conducted

QA CRITERIA

- CRITERIA 1 – PROGRAM MANAGEMENT
- CRITERIA 2 – PERSONNEL TRAINING & QUALIFICATION
- CRITERIA 3 – QUALITY IMPROVEMENT
- CRITERIA 4 – DOCUMENTS & RECORDS
- CRITERIA 5 – WORK PROCESSES
- CRITERIA 6 – DESIGN
- CRITERIA 7 – PROCUREMENT
- CRITERIA 8 – INSPECTION & ACCEPTANCE TESTING
- CRITERIA 9 – MANAGEMENT ASSESSMENT
- CRITERIA 10 – INDEPENDENT ASSESSMENT

QA CRITERIA (continued)

- **Performance/Criterion 7—Procurement**

- Procure items and services that meet established requirements and perform as specified.
- Evaluate and select prospective suppliers on the basis of specified criteria.
- Establish and implement processes to ensure that approved suppliers continue to provide acceptable items and services.

- **Key Elements**

- Procured items and services must perform as specified and meet requirements
- Use qualified suppliers
- Acceptance of procured items and services in accordance with specified methodology

QA CRITERIA (continued)

- **Performance/Criterion 8—Inspection and Acceptance Testing**
 - Inspect and test specified items, services, and processes using established acceptance and performance criteria.
 - Calibrate and maintain equipment used for inspections & tests.
- **Key Elements**
 - Inspection
 - Conducted by, or for, the line organization
 - Inspection criteria specified
 - Acceptance Testing
 - Conducted by or for the line organization
 - Test and acceptance criteria specified

QA CRITERIA

- CRITERIA 1 – PROGRAM MANAGEMENT
- CRITERIA 2 – PERSONNEL TRAINING & QUALIFICATION
- CRITERIA 3 – QUALITY IMPROVEMENT
- CRITERIA 4 – DOCUMENTS & RECORDS
- CRITERIA 5 – WORK PROCESSES
- CRITERIA 6 – DESIGN
- CRITERIA 7 – PROCUREMENT
- CRITERIA 8 – INSPECTION & ACCEPTANCE TESTING
- CRITERIA 9 – MANAGEMENT ASSESSMENT
- CRITERIA 10 – INDEPENDENT ASSESSMENT

QA CRITERIA (continued)

- **Assessment/Criterion 9—Management Assessment**

Ensure that managers assess their management processes and identify and correct problems that hinder the organization from achieving its objectives.

- **Key Elements**

- Focuses on broad categories of management issues
- Addresses how well integrated management system is working
- Management responsibility and participation

QA CRITERIA (continued)

- **Assessment/Criterion 10—Independent Assessment**
 - Plan and conduct independent assessments to measure item and service quality and the adequacy of work performance & to promote improvement.
 - Establish sufficient authority and freedom from line management for independent assessment teams.
 - Ensure that persons conducting independent assessments are technically qualified and knowledgeable in the areas to be assessed.
- **Key Elements**
 - Implemented by independent organization representing senior management
 - Performance-based approach
 - Technically knowledgeable personnel
 - Focus on improving performance
 - Scheduling based on performance