ornl

ORNL/M-2359



OAK RIDGE
NATIONAL
LABORATORY

MARTIN MARIETTA

# Quality Assurance Grading Guidelines for Research and Development at DOE Facilities (DOE Order 5700.6C)

MANAGED BY
MARTIN MARIETTA ENERGY SYSTEMS, INC.
FOR THE UNITED STATES
DEPARTMENT OF ENERGY

ORNL/M-2359

# Quality Assurance Grading Guidelines for Research and Development at DOE Facilities (DOE Order 5700.6C)

Thomas B. Powell
ORNL Office of Quality Programs and Inspection

Robert N. Morris
ORNL Metals and Ceramics Division

, Published-October 1992

Prepared by
Oak Ridge National Laboratory
Oak Ridge, Tennessee 37831-6285
managed by
Martin Marietta Energy Systems, Inc.
for the
U.S. Department of Energy
under contract DE-AC05-84OR21400

CONTENTS

## ACRONYMS AND INITIALISMS

| | |
|---|---|
| CCCTF | Gore Conduction Cooldown Test Facility |
| CFRs | Code of Federal Regulations |
| DEARs | Department of Energy Acquisition Regulations |
| DOE | U.S. Department of Energy |
| DOE-ER | DOE Office of Energy Research |
| ES&H | environmental, safety, and health |
| FARs | Federal Acquisition Regulations |
| GRS | General Records Schedule |
| IAEA | International Atomic Energy Agency |
| MHTGR | modular high-temperature gas-cooled reactor |
| NARA | National Archives and Records Administration |
| NPR | New Production Reactors |
| QA | quality assurance |
| QAP | Quality Assurance Program |
| QAS | quality assurance specialist |
| R&D | research and development |
| SPC | statistical process control |

# 1. INTRODUCTION

The quality assurance (QA) requirements for the U.S. Department of Energy (DOE) are established in DOE Order 5700.6C.[1] This order is applicable for all DOE departmental elements, management, and maintenance and operating contractors and requires that documented Quality Assurance Programs (QAPs) are prepared at all levels; it has one attachment.[2] The DOE Office of Energy Research (DOE-ER) has issued a standard to ensure implementation of the full intent of this order in the ER community.[3]

DOE Order 5700.6C does not address the phases of a DOE project; however, DOE Order 4700.1[4] defines the seven phases (Fig. 1) of a DOE project as follows:

| Phase | Description |
|---|---|
| 1. Basic research | Systematic, fundamental study directed toward fuller scientific knowledge or understanding of subjects bearing on national energy needs. |
| 2. Applied research | Systematic study directed toward fuller scientific knowledge for direct use in fulfilling specific energy requirements. |
| 3. Technology or exploration development | Systematic application of knowledge from research toward proof of technology, including development of nonspecific application prototypes and processes. |
| 4. Advanced development | Effort that leads ultimately to a particular application or product. Advance development can cut across several scientific disciplines and explore innovations in a particular area of one or more energy technologies. |
| 5. Engineering development | Systematic use of the knowledge and understanding gained from research and technology development to achieve the detailed design, construction, and test for performance, producibility, and reliability of energy system prototypes, pilot plants, and research facilities. This also includes the preparation of appropriate National Environmental Policy Act documentation. |

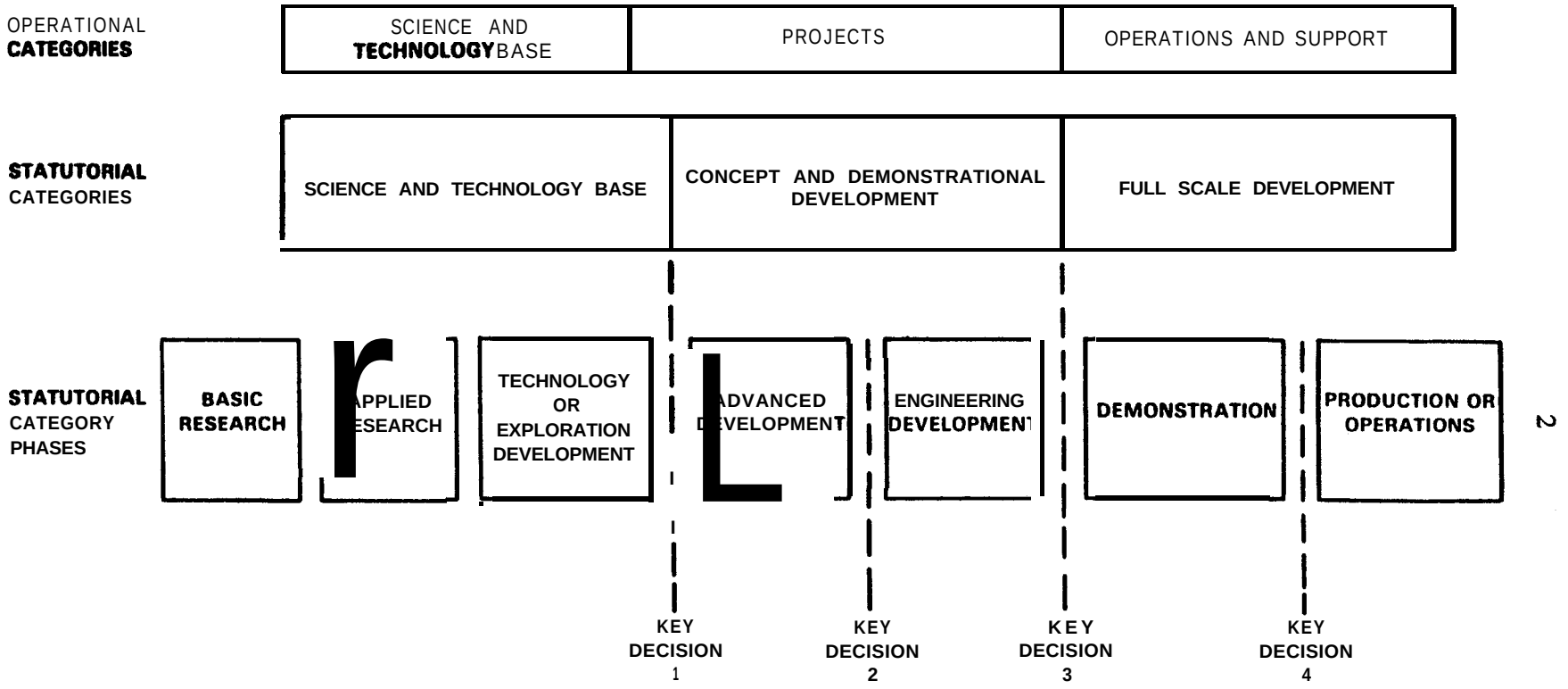


**Fig. 1. Categories of work effort and research and development or acquisition phases.**
**("Project Management System," DOE *Order* 4700.1** in DOE ***Manual,*** Vol. 10, U.S. DOE, March 6, 1987)

| | |
|---|---|
| 6. Demonstration | Verification of economic and environmental viability through design, construction, and test and evaluation of large energy systems in operational circumstances. |
| 7. Production or operations | (a) Production-Producing the item in quantity, bulk, or other parameters that meet specifically stated requirements.<br><br>(b) Operations-Bringing the system or project from prototype or pilot plan operational testing status to full-scale operational condition to meet stated objectives. |

The following questions arise:

1. For which phases is DOE Order 5700.6C[2] applicable?
2. For which phases is DOE-ER-STD-6001-92[3] applicable?
3. Are some other standards applicable for some of the phases?

A solution to these questions may be found in the method published by the International Atomic Energy Agency (IAEA)? In this paper the IAEA approach is used to address QA grading for research and development (R&D) phases 1, '2, 3, and 4.

DOE Order 5700.6C[6] states that "Risk is the fundamental consideration in determining to what extent the QAP should be applied to 'items and processes. Risk is a quantitative and/or qualitative expression of possible loss wliich considers both probability of event occurrence causing harm or loss and the consequences of that event."

The risk involved in R&D work (phases 1, 2, 3, and 4) can be associated and evaluated with the following:

- the direct environmental, safety, and health (ES&H) impact on employees and the public that is caused by the conduct of R&D;
- the indirect ES&H impact on the public that is caused by the application of results from R&D, which can be approximated by the maturity of the project (as discussed below);
- the complexity of the project; and
- the importance of the data.

The effects of these four types of risk can be evaluated by assigning a qualitative risk score for each of the four areas.

## 2 ENVIRONMENTAL, SAFETY, AND HEALTH RISK

R&D efforts have potential for contaminating the environment, affecting the health of employees and the general public, and causing safety hazards for employees and the public. Table 1 can be used to determine the risk score an R&D project would have from ES&H concerns.

**Table 1. Environmental, safety, and health risk[a]**

| Risk score (choose one) | Description |
|---|---|
| 1 | No risk to health and safety and/or negligible inconvenience and cost |
| 2 | Limited risk to health and safety |
| 3 | Moderate risk to health and safety |
| 4 | Significant risk to health or safety of laboratory personnel or limited risk to the public |
| 5 | Significant risk to health and safety of both laboratory personnel and the public |

[a]Risk is a function of probability of an undesirable event and consequences of an undesirable event (i.e., probability times consequences). Early in the project the probabilities of undesirable events may be unknown. A qualitative risk score may be obtained by analysis of hazards that could lead to undesirable events. Complex projects may need an analysis similar to the methods described in ***Hazard Screening Application Guide, Safety Analysis Report Update Program,*** CSET-2 Martin Marietta Energy Systems, Oak Ridge, Tenn., December 1990. CSET-2 presents a method for identifying hazards and consequences for the Safety Analysis Report process.

## 3. PROJECT MATURITY RISK

A fault occurring during basic research has a much lower probability of negative influence on the design input (assembled during the early part of the engineering development **phase)** than would a fault occurring during advanced development. This is because each phase would **have its** unique self-assessment activities, corrective action procedures, peer reviews, etc., that would correct problems and procedures and ensure that necessary actions were taken to prevent recurrence. Table 2 provides a risk score associated with each R&D phase.

**Table 2 Research and development phase"**

| Risk score (choose one) | Phase | Description |
|---|---|---|
| 1 | Basic research | Systematic, fundamental study directed toward fuller scientific knowledge or understanding of subjects bearing on national energy needs. |
| 2 | Applied research | Systematic study directed toward fuller **scientific** knowledge for direct use in fulfilling specific energy requirements. |
| 3 | Technology or exploratory development | Systematic application of knowledge from research toward proof of technology, including development of nonspecific application prototypes and processes. |
| 4 | Advanced development | Effort that leads ultimately to a particular application or product. Advance development can cut across several scientific disciplines and explore innovations in a particular area of one or more energy technologies. |
| NA | Engineering development! | Systematic use of the knowledge and understanding gained from research and technology development to achieve the detailed design, construction, and test for performance, producibility, and reliability of energy system prototypes, pilot plants, and research facilities. |

"Research and development phases are defined in "Project Management System," DOE Order 4700.1 in ***DOE Manual,*** Vol. 10, U.S. DOE, Mar. 6, 1987.

[b]**This** QA grading method for research and development is not applicable for engineering development. The method described in International Atomic Energy Agency, ***Grading of Quality Assurance Requirements,*** Technical Report No. 328, Vienna, Austria, should be considered for **DOE project** phases **5, 6,** and 7.

## 4. COMPLEXITY RISK

The risk associated with a fault that occurs during an R&D effort will be proportional to the complexity of the activity. Table 3 provides a risk score for the complexity of the project.

**Table 3. Complexity**

| Risk score (choose **one)** | Description |
|---|---|
| 1 | Effort is minimal and simple. |
| 2 | Effort is significant but simple. |
| 3 | Effort presents some complexity. May include some minor design and construction of experiments and/or test apparatus. |
| 4 | Effort is extensive or complex. May include major design and construction of experimental equipment and test apparatus. |
| 5 | Effort is extensive and complex. May include extensive design and construction of experimental equipment or test apparatus. |

## 5. IMPORTANCE OF DATA

The risk associated with fundamental project flaws or failure to meet customer QA expectations during an R&D effort can often be reflected in the importance of the data. Incorrect or corrupt data can doom an otherwise well functioning project. In addition, several projects may make use of the data generated by one, often unrelated, project. Table 4 provides a risk score for the importance of the data generated for a given project.

Table 4. Importance of data

| Risk score (choose one) | Description |
|---|---|
| 1 | Data/process is of a scoping nature only. |
| 2 | Data/process is to be used in conceptual designs only and will be verified before the project moves forward. |
| 3 | Erroneous data/process will not have any serious environmental, safety, health, cost, or schedule impacts on the project. |
| 4 | Erroneous data/process will have serious cost and/or schedule impacts on the project, but environmental, safety, and health (ES&H) impacts will be small. |
| 5 | Erroneous data/process will have serious cost and/or schedule impacts on the project along with serious ES&H impacts. |

## 6. TOTAL RISK

The total risk can be approximated by the sum of risk scores given for ES&H, phase, complexity, and importance of data. This combined risk score can be used with a table similar to Table 5 to select the appropriate quality standards to use in the QAP. Table 5 is an example of a QA grading scheme and may not be appropriate for some organizations. Each organization may need to develop their own QA grading scheme.

**Table 5. Selection** of QA level

| Combined risk score | QA level | Standards |
|---|---|---|
| >14 | I | The QAP must address all elements of DOE Order 5700.6C.[a] |
| 9 to 14 | II | The QAP must address all elements of DOE-ER-STD-6001-92.6 |
| 4 to 8 | III | The QAP should address the elements of appropriate standards.[a,b,c] |

[a] "Quality Assurance, "DOE Order 5700.6C in ***DOE Manual,*** Vol. 15, U.S. DOE, Aug. 21, 1991, Attachment 1.

[b] ***Implementation Guide for Quality Assurance Programs for Basic and Applied Research,*** DOE-ER-STD-6001-92, June 1992.

[c] ***'Quality Management and Quality System Elements for Laboratories-Guidelines,*** ANSI/ASQC Q2-1991, Milwaukee, Wis., 1991.

Projects that consistently score a 1 or a 2 on individual risk areas would total 4 to 8 and would clearly define the lower limit of the risk scale; therefore, their QA level would be III. More complex, but not excessively large or hazardous, projects would score in the 2 to 4 range per risk area, with an average score per area near 3. This range would give the projects a total score in the 9 to 14 range. Note that an average score of 3 on each risk area (a modest level) would give a total of 12. This total is clearly within the moderate risk region; therefore, the 9 to 14 range earns the QA ranking of II. Finally, the highest risk projects would have scores per risk area in the 3 to 5 range, with an average score near 4 or more. Their totals would be in the 15 to 19 range and would therefore earn the QA ranking of I. Note that because the project maturity risk area is limited at 4 (for R&D), the total cannot exceed 19.

Because all assessments of this nature have a certain subjectivity, serious under- or over-rating of the QA level of a project can be avoided by the use of a team approach so that investigator bias can be eliminated. (See Sect. 7, "Team Approach.")

## 7. TEAM APPROACH

The risk scoring described should be accomplished by a multidiscipline team and may need to include representation from the appropriate DOE field office or DOE headquarters sponsoring organization. This approach minimizes the bias any group may bring to the process. It also provides a forum among the working groups, management, and the customer so that the risks, costs, and schedules of a project may be understood by all. The risk scoring can be done for the site, for divisions within the site, or for projects and activities within the site. The QA levels assigned for a research site can be presented in a table similar to Table 6.

Table 6. Example classification for a research site

| Activity | Environmental safety and health | Phase | Complexity | Importance of data | Total | QA level |
|---|---|---|---|---|---|---|
| National Laboratory | 3 | 4 | 4 | 4 | 15 | I |
| Division A | 2 | 2 | 2 | 1 | 7 | III |
| Division B | 2 | 2 | 4 | 3 | 11 | II |
| Project C | 1 | 1 | 1 | 1 | 4 | III |
| Project D | 3 | 4 | 5 | 5 | 17 | I |

## 8. GRADING WITHIN A QA LEVEL

Additional QA grading for an organization or project can be accomplished once the general QA grade levels have been established in a format that is similar to Table 6. For example, in Table 6 Project D was evaluated as QA level I. It was the consensus of the organization that not all ten criteria (see below) warranted the level of rigor required by DOE Order 5700.6C.[2] Project D evaluated each DOE Order 5700.6C criterion individually, using the risk-scoring method from Tables 1, 2, 3, and 4. Results such as those shown in Table 7 will allow line management to better allocate personnel and resources so that R&D efforts can be completed in a timely manner, at a reasonable cost, and in compliance with customer needs.

Table 7. Project D example

| Criteria | Environmental safety and health | Phase | Complexity | Importance of data | Total | QA level |
|---|---|---|---|---|---|---|
| 1. Program | 1 | 4 | 5 | 4 | 14 | II |
| 2. Personnel training and qualification | 2 | 4 | 5 | 4 | 15 | I |
| 3. Quality improvement | 3 | 4 | 5 | 4 | 16 | I |
| 4. Documents and records | 1 | 4 | 5 | 4 | 14 | II |
| 5. Work process | 3 | 4 | 5 | 4 | 16 | I |
| 6. Design | 3 | 4 | 5 | 4 | 16 | I |
| 7. Procurement | 1 | 4 | 5 | 4 | 14 | II |
| 8. Inspection and acceptance testing | 3 | 4 | 5 | 4 | 16 | I |
| 9. Management assessment | 1 | 4 | 5 | 4 | 14 | II |
| 10. Independent assessment | 1 | 4 | 5 | 4 | 14 | II |

## 9. EXAMPLE QA LEVEL DETERMINATION

Activity Title: New Production Reactors (NPR) Testing of HRB 17/18 in the ORNL Core Conduction Cooldown Test Facility (CCCTF)

Plan Number: NP-FFP-TP2

**References:** a. "Quality Assurance," DOE Order 5700.6C in ***DOE Manual,*** Vol. 15, U.S. DOE, Aug. 21, 1991.
b. ***Implementation Guide for Quality Assurance Programs for Basic and Applied Research,*** DOE-ER-STD-6001-92, June 1992.

Justifications are included.

Results of risk-based analysis:

| Environmental safety and health | Phase | Complexity | Importance of data | Total | **QA** level |
|---|---|---|---|---|---|
| 2 | 4 | 3 | 4 | 13 | II |

Prepared by _____
Principal Investigator/Date

**Approved by** _____
Task Manager/Date

**Concurrences**

_____ _____
Assistant Project Director/Date Project Director/Date

_____ _____
Division QAS/Date NPR QA/Date

cc: NPR-RMS-DCC-RC

## 10. CCCTF QA GRADING JUSTIFICATIONS

Item: Environmental, Safety, and Health Risk

Risk Score: 2-Limited risk to health and safety

The CCCTF furnace will be operated within a hot cell environment and will contain only a limited amount of fuel at a time. Should problems occur and massive fuel failure result, the furnace will provide the first level of containment. Should the furnace fail, the hot cell will provide containment and shielding. Massive explosions or violent pressure increases that would cause breach of the hot cell are not credible with the small amount of materials and stored energy available.

Primary concerns are personnel exposure and contamination. These will be controlled by the design of the experiment, the limited amount of fuel used, and administrative controls.

Item: Complexity Risk

Risk Score: 3-Effort presents some complexity

To a large extent, the CCCTF makes use of commercially available components and well established techniques. These commercial components are modified for our use, but these modifications do not require extensive engineering calculations or modeling. Operation of the CCCTF is based on simple control theory and makes use of “off-the-shelf’ software for system operation and data collection. The basic needs of gamma counting, radiochemistry, metallography, and process control are all well established disciplines. The complexity arises from the operation of many different subsystems at the same time, for long periods of time in a hot cell environment, and the coordination of several groups from different divisions of the Laboratory.

‘The primary concern is that a system malfunction will occur that will result in an incorrect test environment, that data collection or analysis may be compromised in some way, or that the project may incur long delays.

Item: Project Maturity Risk

Risk Score: 4-Advanced development

The purpose of the CCCTP is to test vendor fuel and to provide a data base for fuel evaluation and selection. The fuel concept has existed for many years, and the current goal is to produce (vendor) and test (us) high-quality fuel for the NP and NE project.

Primary concerns are that the CCCTP will not provide the test environment that the fuel designer needs. This could result in poor quality fuel being accepted or in high quality fuel being rejected. Both unfavorable outcomes could seriously impact the cost and safety of the final reactor design because of the need for fission product containment.

Item: Importance of Data

Risk Score: 4

NPR modular high-temperature gas-cooled reactor (MHTGR) design depends heavily on the use of fuel having a very high degree of fission product retention under normal and accident conditions.

Incorrect or corrupt data could result in the use of poor quality fuel in the reactor or, conversely, the termination of the project because the fuel quality was underestimated.

## 11. CONCLUSIONS

A risk-based approach to QA has been outlined along with a grading system. This approach is implemented within the framework of a multidiscipline team. The team ensures a nonbiased approach to QA standards and provides a forum for discussion among the working groups, management, and the customer.

The purpose of this approach is to comply with DOE QA needs in a timely and cost-efficient manner.

## 12 GRADED QA REQUIREMENTS

Graded QA requirements were taken from DOE Order 5700.6C[2] for level I and from DOE-ER-STD-6001-92[3] for level II. These requirements are included in this guideline for convenience.

### A Management

#### 1. Criterion l-Program

Organizations shall develop, implement, and maintain a written QAP. The QAP shall describe the organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing adequacy of work. The QAP shall describe the management system, including planning, scheduling, and cost control considerations.

QALEVELI

a. Senior management should develop and issue a written quality assurance policy statement which commits the organization to implement a formal QAP.

b. Senior management should retain and exercise the responsibility for the scope and implementation of an effective QAP. Line management is responsible for the achievement of quality. Each individual is responsible for the quality of his/her work.

c. The QAP should promote effective and efficient achievement of performance objectives.

d. The QAP should be binding on all personnel, including those having responsibility for planning and scheduling. Management should take the necessary actions to ensure that the QAP is understood and implemented.

e. The quality of items and processes should be ensured to an extent consistent with their risk.

f. The QAP should describe or provide reference to organizational structure, functional responsibilities, levels of authority, and interfaces. The description should include the onsite and offsite organizational elements that function within the scope of the QAP. The organization should establish criteria for developing individual QAPs or combining similar work under a single QAP when appropriate. Functional responsibilities include work such as planning; training and personnel development; preparing, reviewing, approving, and verifying designs; qualifying suppliers; preparing, reviewing, approving, and 'issuing instructions, procedures, schedules, and procurement documents; purchasing; verifying supplier work; identifying and controlling hardware and software; manufacturing; managing and operating facilities; calibrating and controlling measurmg and test equipment; conducting investigations and

acquiring data; performing maintenance, repair, and improvements; performing assessments; and controlling records.

g. A common vocabulary that is consistent and representative of the work being performed should be adopted. Key terminology should be defined. Personnel indoctrination should include appropriate definitions to ensure consistent understanding and communication.

h. Work assigned to parties outside the organization should be identified. For assigned work, management controls should be established, responsibilities assigned, and lines of communication identified.

i. Initial estimates, used in planning, should be based on sound data and assumptions relating to personnel, material/service costs, availabilities, and productivity.

j. Readiness reviews should be performed prior to major scheduled or planned work and should be performed to verify at least the following characteristics:

(1) work prerequisites have been satisfied;

(2) detailed technical and QA procedures have been reviewed for adequacy and appropriateness;

(3) personnel have been suitably trained and qualified; and

(4) the proper equipment, material, and resources are available.

k. Responsibility and authority to stop unsatisfactory work should be assigned such that planning and schedule considerations do not override safety considerations. A readiness review in accordance with paragraph A.1.j, above, should be performed prior to restarting work.

QA LEVEL II

The QAP should be a total management system that is management's strategy for successfully carrying out the mission defined in the facility's contract. The goal should be to effectively utilize the facility's organizational infrastructure to provide the resources and support necessary to carry out research programs. The basic precepts are:

a. DOE Orders prescribe a wide variety of management systems to help contractors achieve their mission goals. There is no single DOE Order that has been written specifically to integrate these requirements and other laboratory policies into a total management system. The 10 criteria of DOE 5700.6C can be used as functional categories that interrelate DOE Orders and laboratory policies into a total management system. When management at DOE-ER facilities believes the management systems required in other DOE Orders are

adequate to fulfil the intent of one or more of the 10 criteria, they should not interpret DOE Order 5700.6C as requiring the development of duplicate or redundant management systems.

b. Management is responsible for developing and implementing a written QAP which is binding on all personnel and describes organizational structure, functional responsibilities, levels of authority, and organizational interfaces.

c. Achieving quality should be a line responsibility, with personnel being responsible for achieving their assigned performance objectives. Line management should clearly define how the requirements described in the applicable QAP translate into the day-to-day work performed by the personnel they supervise.

d. Management should define and adopt a site-specific QA terminology that is representative of the disciplines in their organization. Management should be trained in this terminology to ensure consistent understanding and communication.

e. Management should delegate authority to stop unsafe work or work of inadequate quality.

2. Criterion 2-Personnel Training and Qualification

Personnel shall be trained and qualified to ensure they are capable of performing their assigned work Personnel shall be provided continuing training to ensure that job proficiency is maintained.

**QA LEVEL I**

a. Personnel performing work should be capable of performing their assigned tasks. Qualification requirements should be established for specific job categories such as operators, designers, managers, supervisors, inspectors, welders, engineers, scientists, and independent assessment personnel. Training includes both education in principles and enhancement of skills and practices. Training should ensure that the worker understands the processes and tools he/she is using, the extent and sources of variability in those processes and tools, and the degree to which he/she does and does not have control over that variability.

b. Training should emphasize correct performance of work and provide understanding of why quality requirements exist. In addition, training should provide an understanding of the fundamentals of the work and its context. Training instruction should address potential consequences of improper work and focus attention on “doing it right the first time.”

c. Training plans should address and stimulate professional development. Training plans should provide for maintenance of proficiency and progressive

improvement, and should not be limited to attainment of initial qualification. Training plans for management personnel should include professional, managerial, communication, and interpersonal skills.

d. Personnel performing work that requires special skills or abilities should be qualified prior to performing work. Qualification should include demonstrated proficiency of each candidate and periodically thereafter to maintain skills to meet current practices.

e. Training should provide curricula that address specific needs, and it should be presented by qualified instructors.

f. Training should be subject to on-going review to determine program and instruction effectiveness. Training and qualification should be upgraded whenever needed improvements or other enhancements are identified.

## QA LEVEL II

Management should help to develop the expertise needed for personnel to achieve the mission of DOE-ER sponsored facilities. The type of training should reflect the fact that basic and applied research involves the collaborative effort of personnel who have widely divergent levels of education, skills, and experience (for example, operators, designers, engineers, welders, scientists, technicians, and craftspersons).

a. The education that is required for obtaining a university/college degree (or other professional certification) should constitute qualification for working within the discipline in which the degree was granted.* Equivalent work experience and technical activity in a related discipline may also constitute acceptable qualification. Because training by mentoring is crucial to the continued intellectual development of personnel, management should utilize technically competent mentors to model the problem-solving strategies needed both to achieve the laboratory's mission and enhance the intellectual development of personnel.

b. For work that does not require an accredited university/college degree or other professional certification, management should develop training that is appropriate to the complexity and hazards involved in the work and utilize technically competent mentors when appropriate. If the complexity of the work or the hazards involved make more formal training programs appropriate, they should be developed to achieve and maintain proficiency.

---

*A large fraction of the personnel in DOE research environments have earned graduate level degrees in science and engineering. A graduate level education develops the intellectual skills needed to pursue careers of independent research in a specific discipline by assigning complex scientific and engineering problems to students with sophisticated problem-solving strategies being modeled by mentors and academic advisors. This type of training is not recipe-like or procedural.

c. All personnel with management responsibilities should receive training in managerial, communication, and interpersonal skills that is appropriately tailored to the organization that they supervise. In disciplines where this training is not included in the manager's university or college curricula (such as the scientific and engineering disciplines), senior management should require such training as part of the functional responsibilities of those managers.

d. Laboratory management should provide training in the areas of ES&H for facility personnel and outside users who perform research at the facility. The detail and extent of the training should be commensurate with the hazards associated with the work being performed.

3. Criterion 3-Quality Improvement

The organization shall establish and implement processes to detect and prevent quality problems and to ensure quality improvement. Items and processes that do not meet established requirements shall be identified, controlled, and corrected. Correction shall include identifying the causes of problems and preventing recurrence. Item reliability, process implementation, and other quality-related information shall be reviewed and the data analyzed to identify items and processes needing improvement.

**QALEVELI**

a. Processes should be established and implemented with the objective of preventing problems and improving quality. Examples of planning and problem prevention include but are not limited to peer reviews, design reviews, probabilistic risk assessments, safety analysis reports, and reliability/availability/maintainability analyses. The focus of quality improvement should be to reduce the variability of every process which influences the quality of the product.

b. Performance data, internal and external failure costs, prevention costs, and other quality-related information should be analyzed to identify trends that adversely impact quality and to identify opportunities to improve items and processes. Examples of such information include increasing process capability studies which define assignable and inherent causes of process variability, failure rates, increasing corrective maintenance, and decreasing preventive maintenance resources. To identify commonalities, this analysis should consider information from external sources and not be limited to one type of work, one facility, or one contractor.

c. Processes should be established and implemented to promote continuous improvement. This includes the identification and improvement of expected performance standards and associated performance measures.

d. All personnel should identify nonconforming items and processes. All personnel should be encouraged by management to identify and suggest

improvements. All personnel should be granted the freedom and authority to stop work until effective corrective action is taken.

e. Items and processes that do not meet established requirements, goals, or do not result in the anticipated quality should be promptly identified, documented, analyzed, resolved, and followed up. The extent of cause analyses for nonconforming items and processes should be commensurate with the importance or significance of the problem.

f. Management, at all levels, should foster a "no-fault" attitude to encourage the identification of nonconforming items and processes. Management should be involved in the quality improvement process to ensure that proper focus is given, adequate resources are allocated and difficult issues are resolved. A process for resolving professional differences of views and opinions should be established and implemented.

g. Nonconforming items and processes should be properly controlled to prevent their inadvertent test, installation, or use. They should be reviewed by the organization that originally reviewed and approved the items or processes or a designated organization that is qualified and knowledgeable. The justification for disposition should be appropriately documented.

h. Reworked, repaired, and replacement items and processes should be inspected and tested in accordance with original requirements or specified alternatives.

i. Personnel responsible for analyzing and dispositioning nonconformances should have an adequate technical understanding of the area in which they are working and have access to pertinent background information relative to the nonconformance.

## QA LEVEL II

a. Quality problems are often inherent in existing management systems and workers have little or no control over eliminating these problems or improving performance. Management should empower personnel to eliminate these ineffective management systems and improve performance by driving decision making authority to the lowest effective organizational level where the maximum expertise is localized.

b. When appropriate, management should be encouraged to use statistical methods (or other management tools) to help make the organizational decisions necessary to improve quality.*

c. Management should foster a "no-fault" attitude where all personnel are encouraged to identify and report performance problems to the appropriate

---

'For example, statistical process control (SPC), pareto analysis, or other appropriate methods.

level of management, and management should take appropriate corrective action.

d. Management should implement systems for documenting failures and nonconformances and for identifying, analyzing, resolving, and following up on recurring programmatic and technical problems. The extent of cause analysis and corrective action should be commensurate with the significance of the problem. Management should utilize a "lessons learned" system to improve performance when appropriate.

e. Laboratory management should implement strategies for improving the quality of DOE-ER sponsored research programs.*

4. Criterion 4-Documents and Records

Documents shall be prepared, reviewed, approved, issued, used, and revised to prescribe processes, specify requirements, or establish design. Records shall be specified, prepared, reviewed, approved, and maintained.

QALEVELI

a. Documents

(1) A process should be established and implemented to control preparation, review, approval, issuance, use, and revision of documents that establish policies, prescribe work, specify requirements, or establish design.

(2) The scope of the document control system should be defined. Examples of documents to be controlled include drawings, data files (including various media), calculations, specifications, computer codes, purchase orders and related documents, vendor-supplied documents, procedures, work instructions, operator aids, and data sheets.

(3) Revisions to controlled documents should be reviewed and approved by the organization that originally reviewed and approved the documents. An alternative organization may be designated based on technical competence and capability. Timeliness guidelines should be implemented for distribution of new or revised controlled documents.

(4) Controlled documents should be distributed to and used by personnel performing work.

*This is commonly done through the mechanism of scientific and technical advisory committees that provide technical guidance to laboratory management. Other peer review mechanisms can be used by management to improve the performance of research in progress when appropriate.

(5) Control of superseded and canceled documents should include measures to ensure that only correct documents are in use. Record copies should be marked "superseded" or "canceled" and kept for a specified retention period.

b. Records

(1) A process should be established and implemented to ensure that sufficient records (for example, records of design, environmental conditions, applied research and development, procurement, construction, data acquisition, assessments, inspection, testing, maintenance, and modification) are specified, prepared, reviewed, approved, and maintained to accurately reflect completed work. The maintenance of records should include provisions for retention, protection, preservation, traceability, accountability, and retrievability.

(2) For records that require special processing and control, such as computer codes or information on high density media or optical disks, hardware and software required to maintain and access records should be controlled to ensure records are usable.

(3) Records holding facilities are reserved for storage of inactive records and may not meet the physical requirements or have appropriate staff to maintain active records. Active records requiring special handling, storage, and processing should not be sent to records holding facilities. Users should refer to the General Records Schedule (GRS) or DOE 1324.2A[7] for retention and disposition of records.

(4) The National Archives and Records Administration (NARA) exercises final authority for approving the disposition of government records. Use of the GRS, which is published by the NARA, and the DOE unique schedules approved by the NARA are mandatory.

(5) Some standards that provide interpretive quality assurance guidance may differ in records management terminology from the NARA requirements. In those instances, care should be taken to ensure that the requirements of both the NARA and standards are followed.

## QA LEVEL II

a. Management should develop requirements for documenting the organization, functions, policies, decisions, procedures, and essential transactions of organizations at an appropriate level of detail. The objective should be to maximize the usefulness of DOE and contractor records, and minimize the cost of document and records management and the paperwork and record keeping burden within DOE and its contractors.

b. Management should determine which work is of sufficient complexity or hazard to require the preparation of controlled documents. When a document is defined as a "controlled document," procedures that describe the preparation, review, approval, issuance, and revision of the document should be developed.

c. Management should implement a records management system to ensure that appropriate records are retained and retrievable.

## B. Performance

1. Criterion S-Work Processes

Work shall be performed to established technical standards and administrative controls. Work shall be performed under controlled conditions using approved instructions, procedures, or other appropriate means. Items shall be identified and controlled to ensure their proper use. Items shall be maintained to prevent their damage, loss, or deterioration. Equipment used for process monitoring or data collection shall be calibrated and maintained.

QALEVELI

a. Work

(1) Personnel performing work are responsible for the quality of their work. Because the individual worker is the first line in ensuring quality, personnel should be knowledgeable of requirements for work they perform and the capability of the tools and processes they use.

(2) Line managers should ensure that personnel working under their supervision are provided the necessary training, resources, and administrative controls to accomplish assigned tasks. Criteria describing acceptable work performance should be defined for the worker.

(3) Line managers should review work and related information to ensure that the desired quality is being achieved and to identify areas needing improvement.

(4) Work should be planned, authorized, and accomplished under controlled conditions using technical standards, instructions, procedures, or other appropriate means of a detail commensurate with the complexity and risk of the work.

(5) Work-related instructions, procedures, and other forms of direction should be developed, verified, validated, and approved by technically competent personnel.

b. Identification and Control of Items

(1) Processes should be established and implemented to identify, control, and maintain items.

(2) Identification of items should be maintained to ensure appropriate traceability.

(3) Processes should be established and implemented to control consumables and items with limited shelf life, prevent the use of incorrect or defective items, and control samples.

c. Handling, Storing, and Shipping

(1) A process should be established and implemented to control the handling, storage, shipping, cleaning, and preservation of items to prevent damage, loss, or deterioration.

(2) Marking and labeling of items should be maintained throughout packaging, shipping, handling, and storage. Marking and labeling should provide information to identify items and provide instructions or special controls to preserve items' integrity. Requirements for off-site transportation should be established and implemented.

(3) Special protective measures (such as containers, shock absorbers, accelerometers, inert gas atmospheres, and specific temperature and moisture levels) should be specified and provided when required to maintain acceptable quality.

d. Calibration and Maintenance of Monitoring and Data Collection Equipment

(1) A process should be established and implemented to control the calibration, maintenance, and use of measuring and test equipment used for monitoring and data collection.

(2) Monitoring and data collection equipment should be of the accuracy and type suitable for the intended use. The types of equipment included should be specified. Equipment should have calibration certifications traceable to national standards, where possible.

## QALEVELII

a. Human Resource Management

(1) Management should strive for effective human resource management with the goals of hiring and maintaining an efficient and effective work force and appropriately utilizing personnel skills in the assignment of work responsibilities.

(2) The individual worker is the first line in ensuring quality, but management is primarily responsible for ensuring that people who are assigned to tasks have the appropriate academic qualification, professional certification, or skills and experience to carry out the work successfully.

(3) Management is responsible for planning, authorizing, and specifying (to an appropriate level of detail) the conditions under which work is to be performed. This should include the calibration of measuring and test equipment. Management should specify which work is sufficiently complex or involves sufficient hazard to be performed to written procedures. When written procedures are deemed appropriate by management, they should be prepared, revised, approved, and distributed by appropriately knowledgeable managers.

(4) Management should define the performance objectives for which personnel will be held accountable. Criteria which define acceptable work performance and achievement of performance objectives should be defined for personnel with the goal of acknowledging when work has been performed acceptably and identifying areas for improvement.

b. Material Resource Management

The laboratory contract defines a variety of management systems to be applied to material resources through the applicable DOE Orders and Code of Federal Regulations (CFRs). Management should not interpret this portion of Criterion 5 as requiring the development of redundant management systems that are already imposed by these requirements.

(1) Management should implement an effective item resource management system that identifies and controls items in common use stores and warehouse storage to prevent damage, loss, or deterioration.

(2) Management should implement an effective management system that ensures that items are properly handled, shipped, and received.

2 Criterion 6-Design

Items and processes shall be designed using sound engineering/scientific principles and appropriate standards. Design work, including changes, shall incorporate applicable requirements and design bases. Design interfaces shall be identified and controlled. The adequacy of design products shall be verified or validated by individuals or groups other than those who performed the work. Verification and validation work shall be completed before approval and implementation of the design.

QA LEVEL I

a. A process should be established and implemented for design using sound engineering/scientific principles and appropriate standards such as those in DOE Order 6430.1A.[8] Provisions should include control of design requirements, inputs, processes, outputs, changes, records, and organizational interfaces.

b. Design input, such as the design bases, reliability requirements, and fire protection requirements, should be correctly translated into design output, such as specifications, drawings, procedures, and instructions.

c. Changes to final designs, field changes, modifications, and nonconforming items dispositioned "use as is" or "repair" should be justified and subject to design control measures commensurate with the original design. This work should include assurance that the design analyses for the items are still valid. Changes should be approved by the original design organization or a technically qualified designate.

d. Design interfaces should be identified and controlled, and design efforts should be coordinated among and within participating organizations. Interface controls should include the assignment of responsibility and the establishment of procedures among participating design organizations.

e. Design records, maintained to provide evidence that the design was properly accomplished, should include not only the final design output and its revision but also important design steps (calculations, analyses, and computer programs, for example) and sources of input that support final output.

f. The acceptability of design work and documents, including design inputs, processes, outputs, and changes, should be verified. Computer programs should be proven through previous use, or validated through testing or simulation prior to use.

g. Design verification should be performed by a qualified individual(s) or group(s) other than those who performed the original design-but who may be from the same organization. The extent of verification should be based on the complexity, risk, and uniqueness of the design.

h. Verification methods include, but are not limited to, design reviews, alternate calculations, and qualification testing. Separate verification may not be needed for multiple uses of identical or previously proven designs, unless they are intended for different applications or different performance criteria.

i. Testing to verify or validate acceptability of a specific design feature should demonstrate acceptable performance under conditions that simulate the most adverse design conditions. Operating or test modes and environmental

conditions in which items must perform satisfactorily should be considered in determining the most adverse conditions.

j. Design verification should be completed before design output is used by other organizations or to support other work, such as procurement, manufacture, construction, or experiment. When this timing cannot be achieved, the unverified portion of the design should be identified and controlled. In all cases, design verifications should be completed before relying on the item to perform its function and before installation becomes irreversible (requiring extensive demolition or rework).

**QALEVELII**

a. Sound engineering/scientific principles and appropriate technical standards should be incorporated into designs to ensure that they will perform as intended.

b. Management should define ES&H related design input and design review requirements for apparatus including those designed by "outside users" to ensure compliance with facility ES&H requirements.

c. Management should selectively apply the guidance below to a level of detail that is commensurate with the scale, cost, complexity, and hazards and phase of a design (conceptual to final). Design controls should be defined to ensure that:

(1) Design input is correctly translated into specifications and drawings. This should include items such as fire protection requirements, design bases, and reliability requirements.

(2) Final designs, field changes, and modifications should be approved by the original design organization or a technically competent designee.

(3) Design interfaces and corresponding responsibilities are defined so that design efforts are effectively coordinated among the participating organizations.

(4) Design records are incorporated into the records management system.

(5) Design inputs, processes, outputs, and changes are validated by qualified individuals or groups other than those who performed the original design but who may be from the same organization. The level of detail of validation and the methods used should be appropriate to the design.

(6) Designs are validated prior to procurement, manufacture, or construction. When this is not possible, designs should be validated prior to the installation and use of the item.

d. Management should define and implement procedures for the design and development of computer software to a level of detail that is appropriate to the complexity, cost, and hazards associated with the software.

3. Criterion 7-Procurement

The organization shall ensure that procured items and services meet established requirements and perform as specified. Prospective suppliers shall be evaluated and selected on the basis of specified criteria. The organization shall ensure that approved suppliers can continue to provide acceptable items and services.

**QA LEVEL I**

a. A process should be established and implemented to ensure that purchased items and services meet established requirements and perform as expected.

b. Applicable technical and administrative requirements such as specifications, codes, standards, tests, and inspections should be invoked for procurement of items and services. Procurement documents should include acceptance criteria.

c. Appropriate controls for the selection, determination of suitability, evaluation, and receipt of all purchased items, including commercial-grade items, should be imposed to ensure that they perform as expected.

d. Prospective suppliers should be evaluated to ensure that only qualified suppliers are selected.

e. Qualified suppliers and, as necessary, sub-tier suppliers should be monitored periodically to ensure that acceptable items and services continue to be supplied.

f. Purchased items and services should be accepted using specified methods (such as review of manufacturing process control data, source verification, receipt inspection, pre-installation and post-installation tests, certificates of conformance, or a combination of these methods).

g. Before a procured item is used or placed in service, procurement specification, inspection, and test requirements are to be satisfied and nonconformances properly dispositioned.

h. The actual performance of items should be compared with original performance criteria. User group surveys, supplier evaluations, inspection and test results, and performance data should be reviewed to determine procurement effectiveness.

i. The quality of purchased items and services should be verified at intervals to a degree consistent with the item's or service's complexity, risk, quantity, and frequency of procurement.

j. In cases where there are indications that suppliers knowingly supplied items and services of substandard quality, this information should be forwarded to the DOE Office of Inspector General.

## QA LEVEL II

The facility contract specifies a variety of management controls to be applied to procurements and sub-contracts through the applicable DOE Orders, Department of Energy Acquisition Regulations (DEARS) and Federal Acquisition Regulations (FARs). Management should not interpret Criterion 7 (Procurement) as requiring the development of redundant management systems that are already imposed by these requirements.

a. Management should irnplement a procurement and subcontracts management system that complies with the appropriate procurement and subcontract procedures as required by the facility contract.

b. Management should require that personnel include the applicable specifications (ES&H and technical) in procurement and subcontract documents.

c. Management should develop qualified suppliers early in design or procurement processes when possible. Management should ensure that specifications and expectations are properly communicated to prospective suppliers and that qualification is based on the appropriate demonstration that they can supply acceptable items and services on schedule.

d. Management should evaluate prospective suppliers to ensure that qualified and responsible suppliers are selected. Suppliers should be appropriately monitored to ensure that acceptable items and services continue to be supplied.

e. Management should develop requirements for inspection of incoming items.

4. Criterion &Inspection and Acceptance Testing

Inspection and acceptance testing of specified items and processes shall be conducted using established acceptance and performance criteria. Equipment used for inspections and tests shall be calibrated and maintained.

## QALEVELI

a. Inspection

(1) A process should be established and implemented to specify when and what type of inspections (source, in-process, final, receipt, maintenance, and in-service, for example) are required. Administrative controls and

status indicators should be used to preclude inadvertent bypassing of required inspections and to prevent inadvertent operation of the item or process.

(2) Inspections may be implemented by or for the organization performing the work to be inspected. Personnel may not inspect their own work for acceptance. The level of inspection and the degree of independence of inspection personnel should be based on risk and complexity.

(3) Provisions to ensure inspection planning is properly accomplished should be established. Planning should identify item characteristics and processes to be inspected, inspection techniques, acceptance criteria, hold points, and the organization responsible for performing inspection.

(4) When acceptance criteria are not met, deficiencies should be resolved and reinspection should occur as required.

b. Acceptance Testing

(1) Testing processes should be established and implemented to demonstrate that items and processes will perform as intended. Testing should include, as appropriate, bench tests and proof tests before installation, pre-operational tests, post-maintenance tests, post-modification tests, and operational tests. Testing should be structured so that proving designs should not be confused with proofing the adequacy of work.

(2) Testing may be implemented by or for the organization performing the work to be tested. When an organization performs its own testing, personnel with the organization should not test their own work for acceptance.

(3) Item and process test requirements and acceptance criteria should be provided by or approved by the organization responsible for design. Administrative controls and status indicators should be used to preclude inadvertent bypassing of required tests or operation of the item or process.

(4) Test procedures should be developed and should include:

(a) instructions and prerequisites to perform the test;

(b) completeness and accuracy of data;

(c) use of test equipment;

(d) acceptance criteria;

(e) inspection hold points as required; and

(f) test article configuration.

(5) Retesting of items or processes to determine that they meet acceptance criteria is required after deficiencies are corrected.

c. Measuring and Test Equipment

(1) A process should be established and implemented to control calibration, maintenance, accountability, and use of equipment to control any process parameter which influences the quality of an item's characteristics, or which is used for in-process or final inspection of an item.

(2) The types of equipment to be used, such as instruments, tools, gages, reference and transfer standards, and nondestructive examination equipment, should be defined.

(3) Measuring and test equipment should be calibrated at specified intervals, or immediately before and after use, on the basis of the item's required accuracy, intended use, frequency of use, stability characteristics, and other conditions affecting its performance.

(4) Measuring and test equipment should be labeled, tagged, or otherwise controlled to indicate its calibration status and ensure traceability to calibration test data.

(5) Measuring and test equipment should be calibrated against standards having an accuracy that will ensure that equipment being calibrated will be within required tolerances. If nationally recognized standards exist, calibration standards should be traceable to such standards.

(6) Measuring and test equipment found out-of-calibration or out-of-tolerance should be tagged or segregated and not used until it is successfully recalibrated. The acceptability of items or processes measured, inspected, or tested with an out-of-tolerance device should be determined.

## QA LEVEL II

a. Management should define the types of work that require formal inspections and acceptance testing (for example, fabrication, assembly, installation, construction, ES&H, or procurement). When an inspection or acceptance test is performed, the characteristics and processes to be inspected or tested, the inspection techniques to be used, the hold points, and the acceptance criteria should be defined as appropriate. Properly calibrated and maintained measuring and test equipment should be used for acceptance testing.

b. Laboratory management should develop requirements for readiness reviews of facility and experimental systems prior to beginning work.' The extent and detail of the review should be commensurate with the scale, cost, complexity, and hazards involved in these systems.

C. Assessment

1. Criterion 9—Management Assessment

Management at all levels shall periodically assess the integrated quality assurance program and its performance. Problems that hinder the organization from achieving its objectives shall be identified and corrected.

## QA LEVEL I

a. Planned and periodic management assessments should be established and implemented as a way to improve quality. Management assessments should focus on how well the integrated quality assurance program is working and should identify management problems that hinder the organization from achieving its objectives in accordance with quality, safety, and environmental requirements.

b. Senior management should retain overall responsibility for management assessments. Direct participation by senior management during management assessments is essential. This process should involve all levels of management, as appropriate.

c. Management assessment results should be documented. Senior management should take prompt action and document resulting decisions in response to recommendations resulting from the management assessment process. Follow-up should include an evaluation of the effectiveness of management's actions.

## QALEVELII

a. Management at all levels should periodically evaluate the effectiveness of the QAP and other management systems. A management assessment should be an introspective analysis that evaluates whether or not the management infrastructure of the laboratory, institution, or organizational unit is properly focused on achieving its mission objectives, with appropriate goals (including cost-effectiveness and ES&H) being defined for improving performance.

b. Management at all levels should periodically evaluate the performance of their organizations, focusing on how effectively human and material resources are being utilized with respect to the mission goals. An effective management

---

'In larger projects where some subsystems are operational while others are being phased in, management should perform readiness reviews prior to operation of the subsystems that are being completed.

assessment should evaluate 1) the state of worker knowledge, motivation, and morale; 2) the atmosphere of creativity and improvement; 3) the level of mutual confidence and collaboration among workers; 4) the adequacy of human and material resources, and 5) the management of ES&H in the performance of work processes. The results of the evaluations should be reported to senior management.

c. Laboratory management should periodically evaluate the on-going work performed as part of a Field Work Proposal or-experiment. They should also evaluate the scientific and technical progress at the conclusion of a research program or experiment.

2. Criterion **10—Independent** Assessment

Planned and periodic independent assessments shall be conducted to measure item quality and process effectiveness and to promote improvement. The organization performing independent assessments shall have sufficient authority and freedom from the line organization to carry out its responsibilities. Persons conducting independent assessments shall be technically qualified and knowledgeable in the areas assessed.

QALEVELI

a. A process of planned and periodic independent assessments should be established and implemented by an independent assessment organization. Independent assessments should focus on improving items and processes by emphasizing line organization's achievement of quality.

b. Personnel performing independent assessments should act in a management advisory function. Their responsibilities are to monitor work performance, identify abnormal performance and precursors of potential problems, identify opportunities for improvement, report results to a level of management having the authority to effect corrective action, and verify satisfactory resolution of problems.

c. Personnel performing independent assessments should be technically knowledgeable and focus on improving the quality of the processes that lead to the end product.

d. Personnel performing independent assessments should not have direct responsibilities in the area they are assessing.

e. Independent assessments should be conducted using criteria that describe acceptable work performance and promote improvement.

f. Scheduling of assessments and allocation of resources should be based on the status, risk, and complexity of the item or process being assessed. Scheduling

should be flexible and additional attention should be given to areas of questionable performance.

g. Assessment results should be tracked and resolved by management having responsibility in the area assessed. Follow-up review of deficient areas should be initiated as necessary.

h. Responses to assessments should include the following, as applicable: action to correct the deficiency; cause identification; actions to prevent recurrence; lessons learned; and actions to be taken for improvement.

## QA LEVEL II

a. Independent assessment personnel should act as a management advisory function. They should assess how effectively the QAP and other management systems are being implemented in the day-to-day work of personnel. An effective independent assessment should not be limited to the study of documents but should evaluate the performance of work and actions that cannot be reflected solely by documents.

b. All assessments of the implementation of the QAP should be based on the QAP that has been approved by the Director, Office of Energy Research. Independent assessment personnel that are external to laboratory management should not reinterpret the requirements agreed to in the approved QAP. If laboratory management believes that the implementation of the assessment results will require changes to the approved QAP (other than corrections to punctuation, spelling, or other editorial items), these changes should be approved in writing by the Director, Office of Energy Research prior to implementation by the contractor as required by DOE Order 5700.6C [9.a.(4)].[9]

c. Assessment teams should view the organization being assessed as the "customer" of the assessment results and strive to produce high-quality, organizationally meaningful feedback about the achievement of the laboratory mission.

d. Assessment teams should include peers who are technically competent to review the work being assessed but who have not participated in that work.*

e. The results of independent assessments should be resolved by the management who have line responsibility for the assessed area in a timely fashion. The actions involved in the resolution of assessment results should be documented and tracked.

---

*The use of Visiting Committees, Program Advisory Committees, High Energy Physics Advisory Panel, Nuclear Science Advisory Committee, and reviews by the cognizant DOE Program Managers are examples of independent assessments.

## 13. REFERENCES


1. "Quality Assurance," DOE Order 5700.6C in ***DOE Manual,*** Vol. 15, U.S. DOE, Aug. 21, 1991.
2. Ref. 1, Attachment 1, "Guidance for Developing and Implementing Quality Assurance Programs," Aug. 21, 1991.
3. ***Implementation Guide for Quality Assurance Programs for Basic and Applied Research,*** DOE-ER-STD-6001-92, June 1992.
4. "Project Management System," DOE Order 4700.1 in ***DOE Manual,*** Vol. 10, U.S. DOE, Mar. 6, 1987.
5. International Atomic Energy Agency, ***Grading of Quality Assurance Requirements,*** Technical Report No. 328, Vienna, Austria.
6. Ref. 1, Attachment 1, Sect. II, "Guidance," Aug. 21, 1991.
7. "Records Disposition," DOE Order 1324.2A in ***DOE Manual,*** Vol. 2, U.S. DOE, Sept. 13, 1988.
8. "General Design Criteria," DOE Order 6430.1A in ***DOE Manual,*** Vol. 15, U.S. DOE, Apr. 6, 1989.
9. Ref. 1, 9.a.(4).

INTERNAL DISTRIBUTION

1. B. R. Appleton
2. W. D. Arnold, Jr.
3. W. G. Askew
4. C. 0. Beasley
5. D. E. Beck
6. S. B. Benson
7. H. D. Bewley
8. L. F. Blankner
9. R. W. Bonnett
10. W. A Brooke
11. C. A Burtis
12. A. M. Byrd
13. W. A Camp
14. W. L. Capshaw
15. M. H. Carpenter
16. G. E. Chitwood
17. J. A Clinard
18. H. T. Conner
19. J. E. Cormier
20. J. M. Corum
21. G. L. Cottrell
22. C. G. Cowart
23. D. F. Craig
24. S. Das
25. F. E. Denny
26. W. I. Dothard
27. J. N. Dumont
28. M. W. England
29. R. E. Fenstermaker
30. D. W. Frazier
31. M. L. Gildner
32. D. D. Greene
33. R. M. Harrington
34. K. A Hendrix
35. D. 0. Hobson
36. P. B. Hoke
37. F. J. Homan
38. D. J. Horen
39. T. E. Home
40. D. T. Ingersoll
41. K. W. Isham
42. J. S. Ivey
43. W. G. Jackson
44. R. A Jacobus
45. T. M. Jennings
46. N. D. Johnson
47. H. Jones
48. T. R. Jones
49. J. E. Jones, Jr.
50. L. M. Jordan
51. K. S. Joy
52. M. J. Kania
53. A F. Kiriluk
54. G. Q. Kirk
55. R. R. Knott
56. S. E. Lewis-Lambert
57. J. A Long
58. B. L. Maupin
59. P. E. Melroy
60. W. A Miller
61. W. H. Miller, Jr.
62. T. A Morris
63-67. R. N. Morris
68. D. L. Moses
69. T. F. Orlin
70. R. C. Orrin
71. W. E. A Palmer
72. G. D. Parker
73. G. A Potter
74-78. T. B. Powell
79. D. G. Prater
80. L. 0. Ramsett
81. D. G. Reagan
82. P. L. Rittenhouse
83. L. E. Roberson
84. D. B. Rosine
85. D. L. Shuter
86. L. C. Smith
87. 0. M. Stansfield
88. J. 0. Stiegler
89. J. H. Swanks
90. J. Z. Tischler
91. D. L. Van Dusen
92. M. C. Vance
93. A L. Wachs
94. J. L. Wagner
95. C. D. West
96. D. L. Williams
97. B. K. Williams
98. M. A Woody

99. B. A Worley
100-101. Laboratory Records Department
102. Laboratory Records, ORNL-RC
103. Document Reference Section
104. Central Research Library
105. ORNL Patent Section

## EXTERNAL DISTRIBUTION

106. J. Bartel, Sandia National Laboratory, Organization 8441, P.O. Box 969, Livermore, CA 94551-0969
107. W. E. Best, Department of Energy, Office of New Production Reactors, NP-33, Room 6H024, Washington, DC 20585
108. M. Bodnarczuk, Fermi National Accelerator Laboratory, P.O. Box 500, Batavia, IL 60510
109. D. Bushmire, Sandia National Laboratory, Organization 7252, P.O. Box 5800, Albuquerque, NM 87185
110. P. Bussolini, Los Alamos National Laboratory, P.O. Box 1663, MS F736, Los Alamos, NM 87545
111. J. Cerino, Stanford Synchrotron Radiation Laboratory, P.O. Box 4349, Bin #69, Stanford, CA 94309
112. J. DeLooper, Princeton Plasma Physics Laboratory, P.O. Box 451, Princeton, NJ 08544
113. R. Duncan, Department of Energy, Office of New Production Reactors, NP-44, Room 1H088, 1000 Independence Avenue, SW, Washington, DC 20585
114. J. H. Eckert, Ames Laboratory, 109 O&L Bldg., Iowa State University, Ames, IA 50011
115. S. M. Franks, Department of Energy, Office of New Production Reactors, NP-61, Room 1E278, 1000 Independence Avenue, SW, Washington, DC 20585
116. R. R. Geoffrion, Los Alamos National Laboratory, P.O. Box 1663, MS G736, Los Alamos, NM 87545
117. P. Guthals, Los Alamos National Laboratory, P.O. Box 1663, MS A120, Los Alamos, NM 87545
118. J. Hahn, Stanford Linear Accelerator Center, P.O. Box 4349, Stanford, CA 94309
119. T. Hassler, Continuous Electron Beam Accelerator Facility, 12000 Jefferson Ave., Newport News, VA 23606
120. F. Hawkins, Department of Energy, NE-72, Washington, DC 20585
121. J. J. Jicha, Jr., Department of Energy, Office of New Production Reactors, NP-40, Room 1H023, 1000 Independence Avenue, SW, Washington, DC 20585
122. H. C. Johnson, Department of Energy, Office of New Production Reactors, NP-33, Room GE216, 1000 Independence Avenue, SW, Washington, DC 20585
123. G. L. Johnson, U.S. Environmental Protection Agency, 401 M Street SW, Washington, DC 20460
124. C. M. Johnson, Department of Energy, Office of New Production Reactors, NP-60, Room IE278, 1000 Independence Avenue, SW, Washington, DC 20585
125. M. Rim, Stanford Synchrotron Radiation Laboratory, P.O. Box 4349, Bin #69, Stanford, CA 94309
126. L D. Kimrod, New Production Reactor Department, EG&G Idaho, Inc., P.O. Box 1625, Idaho Falls, ID 83415

127. J. F. Koonce, Jr., Head Office of Assessment & Assurance, Lawrence Berkeley National Laboratory, Bldg. 50A, Rm. 5117, Berkeley, CA 94720
128. G. D. Merkel, Salt River Project, Materials & Quality Services, P.O. Box 52025, Phoenix, AZ 85072-2025
129. J. D. Nulton, Department of Energy, Office of New Production Reactors, NP-60, Room 1H087, 1000 Independence Avenue, SW, Washington, DC 20585
130. G. Nuss, National Renewable Energy Laboratory, 1617 N. Cole Blvd., Golden, CO 80401
131. Office of Assistant Manager, Energy Research and Development, DOE-OR, P.O. Box 2001, Oak Ridge, TN 37831
132-142. Office of Scientific and Technical Information, Department of Energy, Oak Ridge, TN 37831
143. J. R. Palmer, Lawrence Livermore National Laboratory, P.O. Box 808, L430, Livermore, CA 94550
144. J. P. Paradise, Department of Energy, Office of New Production Reactors, NP-33, Room 6H024, 1000 Independence Avenue, SW, Washington, DC 20585
145. R. D. Patterson, Los Alamos National Laboratory, P.O. Box 1663, MS K307, Los Alamos, NM 87545
146. R. K. Patterson, U.S. Environmental Protection Agency, Atmospheric Research Laboratory, Research Triangle Park, NC 27711
147. G. Schreiber, Argonne National Laboratory, 9700 S. Cass Avenue, Argonne, IL 60139
148. M. Shear, Brookhaven National Laboratory, Upton, NY 11973
149. R. Sood, Fermi National Accelerator Laboratory, P.O. Box 500, Batavia, IL 60510
150. W. K. Sowder, New Production Reactor Department, EG&G Idaho, Inc., P.O. Box 1625, Idaho Falls, ID 83415
151. E. P. Stroupe, New Production Reactor Department, EG&G Idaho, Inc. P.O. Box 1625, Idaho Falls, ID 83415
152. D. Summers, Los Alamos National Laboratory, P.O. Box 1663, MS K307, Los Alamos, NM 87545
153. International Atomic Energy Agency, Wagramerstrasse 5, P.O. Box 100, A-1400 Vienna, Austria