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International Thermonuclear Experimental Reactor U.S. Home Team

Quality Assurance Plan

William K. Sowder

LOCKHEED MARTIN

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Experimental Reactor
U.S. Home Team**

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Published October 1998

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ITER U.S. HOME TEAM
QUALITY ASSURANCE PLAN

Record of Revision

Revision 0

Initial issue of ITER U.S. Home Team *Quality Assurance Plan*

Approved

**U.S. ITER HOME TEAM
QUALITY ASSURANCE PLAN**

APPROVALS

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Feb. 29, 1996
Date

PREFACE

The International Thermonuclear Experimental Reactor (ITER) project is unique in that the work is divided among an international Joint Central Team and four Home Teams, with the overall responsibility for the quality of activities performed during the project residing with the ITER Director. The ultimate responsibility for the adequacy of work performed on tasks assigned to the U.S. Home Team resides with the U.S. Home Team Leader and the U.S. Department of Energy Office of Fusion Energy (DOE-OFE).

This document constitutes the quality assurance plan for the ITER U.S. Home Team. This plan describes the controls exercised by U. S. Home Team management and the Performing Institutions to ensure the quality of tasks performed and the data developed for the Engineering Design Activities assigned to the U.S. Home Team and, in particular, the Research and Development Large Projects (7).

This plan addresses the DOE quality assurance requirements of 10 CFR 830.120, "Quality Assurance." The plan also describes U.S. Home Team quality commitments to the ITER Quality Assurance Program. The ITER Quality Assurance Program is based on the principles described in the International Atomic Energy Agency Standard No. 50-C-QA, "Quality Assurance for Safety in Nuclear Power Plants and Other Nuclear Facilities." Each commitment is supported with preferred implementation methodology that will be used in evaluating the task quality plans to be submitted by the Performing Institutions. The implementing provisions of the program are based on guidance provided in American National Standards Institute/American Society of Mechanical Engineers NQA-1 1994, "Quality Assurance." The individual Performing Institutions will implement the appropriate quality program provisions through their own established quality plans that have been reviewed and found to comply with U.S. Home Team quality assurance plan commitments to the ITER Quality Assurance Program.

The extent of quality program provisions applied to any specific task is proportional to, and appropriate for, the safety and/or project success significance of the task, as determined by the cognizant Technical Manager and the U.S. Home Team Quality Coordinator. In general, the research and development activities will have only those controls appropriate to ensure the quality of the manufacturing activity and validate the resultant data.

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International Thermonuclear Experimental Reactor U.S. Home Team

Quality Assurance Plan

1. INTRODUCTION

It is the policy of the International Thermonuclear Experimental Reactor (ITER) U.S. Home Team that activities performed by the team members will be of the highest quality possible that is appropriate to the specific activity being performed and the significance of that activity to the success of the overall ITER project. The U.S. Home Team management and the line management of the Performing Institutions are directly responsible for the quality of the tasks performed for ITER.

It is the goal of U.S. Home Team management to provide assurances that the Engineering Design Activities associated with the Research and Development (R&D) Large Projects conducted by the Performing Institutions yield designs, data, and other results for facilities, systems, components, equipment, and materials that (1) conform to established requirements, (2) are fully traceable to valid data, and (3) are capable of withstanding detailed technical reviews.

1.1 Common Terminology

The international nature of the ITER project introduces difficulties dealing with terminology. The technical nature of the project mandates the use of common terminology whenever possible. A glossary of terms is contained in the *ITER Management Plan for Engineering Design Activities*, "Quality Management and Quality Assurance - Vocabulary," Appendix G, ISO-8402:1994. That glossary provides a consistent basis of quality terminology.

Where other special terms are used in U.S. Home Team documents, they should be defined within the document. Training of project personnel in the procedures should cover significant terms and definitions.

1.2 Assigned and Delegated Work

All design or R&D activities of the U.S. Home Team are conducted by Performing Institutions. These institutions may be national laboratories, universities, or industrial firms. Each Performing Institution is held responsible for the quality of the work assigned to them by the U.S. Home Team management.

Work assignments to Performing Institution subcontractors or suppliers will be by contract documents and defined scopes of work. Applicable quality requirements should be passed to the subcontracted or supplier organization, but the responsibility for meeting the necessary quality requirements remains with the Performing Institution.

1.3 Planning and Scheduling

The planning and scheduling process for U.S. Home Team activities is discussed in detail in the *ITER Management Plan for Engineering Design Activities*, ITER/US/9-PC-02-08. The planning effort is an integrated effort involving the ITER Joint Central Team, the U.S. Department of Energy Office of Fusion Energy (DOE-OFE), the U.S. Home Team, and the Performing Institutions. The ITER project has an overall project plan and projected schedule. Necessary R&D and engineering tasks have been identified and addressed in an integrated schedule.

1.3.1 Implementation Plan

The U.S. Home Team and the Performing Institutions shall develop an implementation plan for each Large R&D Project for which they are the lead, to be agreed with the ITER Joint Central Team and the Home Teams involved prior to implementation.

The implementation plan shall:

- Complement the Home Team's quality assurance plans
- Describe how the requirements of the technical specification will be met
- Address the interfaces between the different Home Teams involved.

It shall define, as appropriate:

- The specific allocation of resources, duties, responsibilities, and authorities
- The specific procedures, methods, and work instructions to be applied
- The records to maintain and demonstrate achievement of the required quality
- The methods of communication to be established between the organizations involved.

2. QUALITY MANAGEMENT PROGRAM

The U.S. Home Team Leader is responsible for the ITER U.S. Home Team quality assurance plan and for ensuring the implementation of its provisions. The provisions of the plan are implemented by each member of the U.S. Home Team through established quality plans. The U.S. Home Team Leader, or Quality Coordinator, will review and endorse the quality plans of the team members for applicability to U.S. Home Team activities.

Achieving the objectives of this plan requires the support of all participating personnel. Adherence to the U.S. Home Team quality plan provisions and to applicable Performing Institution quality plans, implementation procedures, and instructions is mandatory for all U.S. Home Team personnel who are performing activities that come under the auspices of the U.S. Home Team.

The quality assurance program will use a graded approach, and the extent of application of individual quality requirements is determined for each task based on the work involved and importance to project objectives.

Each person performing U.S. Home Team work is responsible for the quality of the work they perform, meeting their customers' requirements, and consistently striving for improvement.

2.1 Quality Program Objectives

2.1.1 Performance Objectives

The objectives of this plan are to ensure:

- The attainment of the level of quality necessary to accomplish the ITER project objectives commensurate with the project's responsibility for protection of the public health and safety, protection of the environment, and reliable facility operation
- That structures, systems, and components designed, procured, fabricated, installed, constructed, and tested for the ITER project conform to established and documented requirements.

2.1.2 Achievement of Objectives

To achieve the objectives of the quality program, the U.S. Home Team management will:

- Develop a U.S. Home Team quality assurance plan to establish a consistent approach to quality by U.S. Home Team members
- Develop a systematic methodology for application of U.S. Home Team quality program provisions to individual tasks assigned to Performing Institutions for the Large R&D Projects

- Assign applicable quality plan implementation responsibilities to Performing Institutions, including subsequent pass-down responsibility to subcontractors, as appropriate
- Approve the quality plans of each Performing Institution for assigned U.S. Home Team tasks.

2.1.3 Performance Monitoring

To monitor achievement of these objectives, the U.S. Home Team management and the Performing Institutions will establish processes for identifying, tracking, and reporting indicators of project performance. These indicators will be tracked on an ongoing basis and reported to responsible management. The performance indicators should include items such as:

- Assessment, audit, and surveillance findings
- Commitment action and corrective action status
- Project cost and schedule
- Project milestone status
- Occurrence reporting status
- Corrective action verifications.

2.2 Roles and Responsibilities

Within the United States, the DOE-OFE is responsible for the ITER Engineering Design Activities, and the DOE-OFE is the organization identified to carry out the DOE responsibilities. The DOE-OFE provides funding, contract administration, and programmatic direction to the Performing Institutions and monitors progress against baselines. To assist with carrying out these responsibilities, the DOE-OFE established the U.S. Home Team management, which is headed by the U.S. Home Team Leader.

The organization of the Performing Institution, or portion thereof performing U.S. Home Team activities, will be established and documented. The documentation will depict lines of authority and communications. Applicable interfaces between performing organizations will be defined. Personnel performing quality assuring activities will be independent of those performing the assigned tasks and have access to a level of management sufficient to resolve conflicts.

The U.S. Home Team Leader is responsible for executing the ITER tasks assigned to the United States and, as such, reports to the ITER Director. Working with the DOE-OFE, the U.S. Home Team Leader is also responsible for the technical integration and coordination of assigned tasks; technical and program planning for assigned tasks; Home Team administration; ITER Joint Central Team and U.S. Joint Work Site liaison; and direction of all Home Team assigned development, design, procurement, component fabrication, and testing activities. He is responsible for the quality of tasks performed by the U.S. Home Team

management and by the Performing Institutions. He has established this quality assurance plan to ensure the quality of activities performed by the U.S. Home Team.

The U.S. Home Team Leader has delegated his technical responsibility and authority to Technical Managers for Physics, In-Vessel Systems, Ex-Vessel Systems, and Engineering. They are responsible for the quality of the tasks and activities assigned to them and performed by Performing Institutions under their purview. A detailed discussion of the organization of the U.S. Home Team and its individual role and responsibilities is contained in the *ITER Management Plan for Engineering Design Activities*, ITER/US/9-PC-02-08.

Task agreements from the ITER Director and performance memoranda are key elements in defining the technical work for the project. The performance memoranda address technical and resource requirements, assign milestones, identify deliverables, and identify funding by task and category. These are developed for assigned tasks with input from the Performing Institutions.

The U.S. Home Team Quality Coordinator reports administratively to the U.S. Home Team Leader, with programmatic line of communications to the ITER Quality Assurance Group. The U.S. Home Team Quality Coordinator assists the U.S. Home Team Leader in carrying out his responsibility for establishing and maintaining an effective quality assurance plan for the U.S. Home Team activities (see Figure 1). In carrying out these responsibilities, the U.S. Home Team Quality Coordinator is authorized by the U.S. Home Team Leader to:

- Develop and document a U.S. Home Team quality program philosophy that complies with ITER Quality Assurance Program and DOE requirements
- Review and approve the quality plans of Performing Institutions for applicability to assigned U.S. Home Team activities
- Assist Performing Institutions in the development and implementation of their quality plans for assigned activities
- Establish and implement a monitoring program of audits, surveillance inspections, and assessments of the U.S. Home Team management and Performing Institutions to verify that work is performed in accordance with the established quality assurance requirements and that the work meets applicable codes and standards
- Establish and maintain interfaces with member organizations on quality-related matters, as necessary, to implement the U.S. Home Team quality assurance plan.

2.3 Stop-work Authority

Everyone on the U.S. Home Team has the right and responsibility to notify responsible management of unsatisfactory work or unapproved practices and, if necessary, stop unsatisfactory or unsafe work or control further processing, delivery, or installation of nonconforming materials.

Figure 1. U.S. Home Team quality interfaces.

Restarting stopped work should be by an established process that is commensurate with the complexity and significance of the stopped work and the reason it was stopped. As part of their training/indoctrination, personnel performing U.S. Home Team activities should receive instruction on the authority and the process to stop work.

2.4 Continuous Quality Improvement

The ITER facility is to be a world-class fusion research facility. Every aspect of its development is directed toward being the best of its kind. This attitude is prevalent and is fostered throughout the project. The principal practice for quality improvement on U.S. Home Team assigned activities is extensive up-front task planning and timely monitoring of the task performance.

The U. S. Home Team management is convinced that those closest to the working level of an activity are the most knowledgeable of the activity and its problems or shortfalls. The U.S. Home Team management strongly encourages all personnel to offer their recommendations for improvements of its processes and programs. These recommendations should be considered at the lowest appropriate organizational level in order to expedite improvement implementation.

U.S. Home Team management recognizes that there will be problems during the course of the project. Project personnel are required and encouraged to report problems to appropriate management for correction. Identifying problems is the necessary first step in getting them fixed and preventing their

recurrence. Corrective actions for identified problems are focused on improvement of management or safety systems, not on punitive actions for project personnel.

Applicable quality performance indicators will be examined by the individual Performing Institutions for positive or adverse trends, and the results will be reported to U.S. Home Team Quality Coordinator. If warranted, corrective actions will be initiated by the Performing Institution to effect quality improvement.

2.4.1 Nonconformance Reporting

An item of hardware or data that does not meet its specified performance or documentation requirements is identified as being nonconforming. A nonconformance report will be used to document deviation from the specified attribute. Each nonconforming item will be prominently identified, tagged, or uniquely identified and, when practical, segregated to prevent its use. The nonconformance report will be evaluated and resolved by the appropriate organization specifying the attribute and quality assurance personnel.

Following the review and dispositioning of the nonconformance report, the item will be either placed back in service, repaired, reworked, or rejected. If the item is repaired or reworked to return it to a satisfactory condition, it must be inspected or reviewed to confirm its fitness for use. When the item has been determined to be acceptable, it may be released for normal processing or use. Under appropriate conditions and controls, an item of hardware or data may be released for restricted use pending nonconformance report resolution and return of the item to unrestricted use.

The Performing Institution personnel who are involved with the dispositioning of nonconformances shall be competent in the technical areas in question and knowledgeable of the intended application of the item being dispositioned. When this is not achievable within the Performing Institution, the nonconformance report may be referred to the U.S. Home Team.

2.5 Personnel Training and Qualification

2.5.1 Training Requirements

U.S. Home Team and Performing Institution personnel will be trained, as appropriate, on their organization's specific policies, plans, and procedures for performing assigned U.S. Home Team tasks. Documentation of personnel training will be established and include such items as attendance lists, training outlines, and read-and-acknowledgment sheets, as appropriate, for the training given.

2.5.2 Task Oriented Training

Training of project personnel will focus on the information and understanding necessary to perform project functions. Training needs to ensure that project personnel:

- Possess knowledge of applicable procedures to be used to conduct assigned tasks
- Have a working knowledge of project requirements

- Understand project terminology and organizational arrangements
- Understand the safety conditions of the work tasks, ranging from office environments to experimental test facilities
- Know the consequences of project delays, increased cost, and inadequate quality attainment
- Continue to maintain technical proficiency through attendance at organizational staff meetings, attendance at professional seminars, and reading literature pertaining to task functions
- Review management control systems for process improvement considerations
- Understand self-assessments and the importance of continuous improvement.

2.5.3 Training Plans

Training of Performing Institution personnel in requirements for the project will be in accordance with plans identifying the appropriate topics for project personnel according to their functions within the project.

2.5.4 Qualification in Special Skills

The qualifications of personnel who perform special processes such as welding, heat treating, and nondestructive examination are the responsibility of the Performing Institution. The qualifications of these personnel will be in accordance with nationally recognized codes and standards, such as those developed by the American Society of Mechanical Engineers (ASME) and the American Welding Society (AWS) for welding and the American Society for Nondestructive Testing (ASNT) for nondestructive examination.

If appropriate for the tasks assigned, the Performing Institution will establish and maintain special process procedures and the documentation of personnel qualifications. Depending on the criticality of these processes, these control measures may be reviewed by the U.S. Home Team management.

2.5.5 Instructor Qualifications

Instructors for special or technical skills that directly affect the quality of project activities will be qualified in the skills being taught and should be qualified in basic instructional skills. Current active participation in the subject activity being presented may constitute sufficient qualifications for conducting U.S. Home Team project training.

2.6 Documents and Records

2.6.1 Documents

A system for control of documents and data ensures appropriate review and approval for use. Approved procedures will be used to implement quality program requirements to ensure that all activities affecting quality are planned, controlled, and documented.

Controlled documents are those documents from the ITER Joint Central Team, DOE-OFE, or U.S. Home Team Project Office that provide direction to the Performing Institutions. Documents subject to controls include, but are not limited to:

- Task agreements and performance memoranda
- Management plans
- Quality assurance plans
- Design documents (i.e., design drawings, safety documentation, technical specifications, etc.).

The Performing Institution will implement a system of control for documents and data that ensures the proper documents are used and maintained for U.S. Home Team activities.

Documents prepared, used, and maintained by the Performing Institution typically involve process procedures; design drawings, and equipment specifications. These documents will be controlled from preparation through distribution. Documents subject to control include, but are not limited to:

- Technical activity reports and data
- Analysis reports (e.g., safety analysis)
- Procedures
- Drawings
- Procurement documents.

The document control system will be reviewed and approved by the U.S. Home Team management and will be subject to verification by assessment.

The Performing Institution will implement an appropriate system of document review and approval for use. Procedures from each Performing Institution applicable to the U.S. Home Team activities will be reviewed by the U.S. Home Team management for acceptability.

The U.S. Home Team quality program requires that work activities be accomplished using current approved drawings, procedures, and reference project data. Performing institution document control procedures shall require the recipient to acknowledge receipt of the new or revised material and to properly mark superseded or canceled documents to ensure that correct information is used in the performance of U.S. Home Team activities.

Revisions to Performing Institution documents subject to document controls will be reviewed and approved by the organization(s) that originally approved the document. Methods should be implemented that ensure the timely issuance of the revisions to personnel using the controlled document.

2.6.2 Records

The activities assigned to the U.S. Home Team and the Performing Institutions result in data, technical reports, drawings, specifications, and analyses that contribute to the final design of the ITER. Records that provide a traceable trail to the published results shall exist in support of each of these deliverables. Original items, or documents, should be provided where possible, but a high-quality reproducible copy is acceptable.

It is the responsibility of the Performing Institution to identify, collect, classify, index, file, and maintain the records of work performed for U.S. Home Team tasks. The indexing system and the filing system should provide ready identification and retrievability of requested records.

Records will be filed in a storage system that provides a suitable environment to minimize deterioration or damage and prevent loss.

Special processed records such as radiographic film, magnetic media, optical media, archival samples, and photographs will be handled and stored to preclude damage from excessive light, improper storage, electromagnetic fields, temperature, and humidity. At a minimum, manufacturer information for proper handling and storage should be used in preparing proper controls for these types of records.

2.6.3 Record Retention and Disposition

The U.S. Home Team will provide the Performing Institutions with criteria for the retention and disposition of records. In all cases, the U.S. Home Team records will be retained until completion of Engineering Data Activities and will be dispositioned, as directed by the U.S. Home Team, the DOE-OFE, or the ITER Joint Central Team.

3. WORK PROCESSES

3.1 Procedures

Processes that affect the quality of items or services will be controlled by the development and use of specific procedures and by training personnel in these procedures. Process procedures will address the following elements, as applicable:

- References to applicable codes, such as those developed by the ASME or the Institute of Electrical and Electronic Engineers (IEEE)
- References to applicable standards for welding and nondestructive examination
- Establishment of suitable environmental conditions, including periodic monitoring
- Specific roles and responsibilities in accomplishing the activities
- Qualification and certification of personnel
- Specification of acceptance criteria (specifically called out, not just a reference to applicable codes or standards)
- Specification of equipment to be used, calibration requirements, and controlled parameters
- Description of the records that are to be generated and maintained
- Provisions for recording data or denoting acceptance or rejection, as appropriate.

Procedures for performing processes must be followed to ensure the consistency of the process. When process improvements are identified, they should be incorporated into procedures using an established formal document change control process. Procedures will be reviewed on a periodic cycle by appropriate management for continued applicability and validity. Necessary changes will be formally processed.

The U.S. Home Team Management may review applicable procedures from each Performing Institution for processes critical to the performance of assigned tasks.

3.2 Identification and Control of Items

The identification of materials used by the Performing Institutions is essential to providing traceable activity results. Identification and control of hardware and software items will be accomplished by the Performing Institutions in accordance with established internal procedures that provide traceability to the items' condition and acceptability for the intended service.

Hardware and software items will be identified and controlled consistent with their intended use. The identification of each item should be established as early as practical in its creation or collection. The

appropriate requirements for identification will be contained in the engineering documents, such as drawings and equipment specifications, or included in the procurement documents. These requirements will include proper location of identification markings, use of approved marking materials, measures for verifying identity before release for shipment, and traceability of the materials, parts, and component identification to ensure only acceptable materials (i.e., no counterfeit/suspect parts and/or substandard parts) are used in U.S. Home Team activities. Material and equipment test samples that have lost their identity or traceability will not be used for any quality-affecting activity.

Material and equipment test samples generated from U.S. Home Team activities shall be properly identified in an appropriate manner that clearly signifies its "tested" status so that it cannot be mistaken as new or unused.

3.3 Handling, Storage, and Shipping

3.3.1 Handling and Shipping of Items and Materials

Special requirements for the handling and shipping of items to prevent damage or deterioration will be contained in specifications, drawings, or supplier documents that become part of the documentation package for the item.

Handling and shipping processes should allow for different methods to provide appropriate care in handling and shipping in accordance with the manufacturer's recommendations. Handling and shipping provisions should consider types of containers, preventive maintenance, and other environmental or safety considerations applicable to the items. Where multiple organizations are involved, procedures should describe interface and any chain-of-custody requirements.

3.3.2 Storage of Items and Materials

Suppliers of items will be directed, in procurement documents, to identify any special protective measures that should be observed during storage. If any such measures are required, the recommendations of the supplier will be factored into the storage of the subject item(s). Provisions will be established for the control of consumable materials and materials with limited shelf life. These provisions will include the following:

- Controls will be consistent with the planned duration and conditions of storage and describe actions to be taken when items have a maximum life expectancy while in storage. These controls are to include marking the shelf life expiration on the item(s), periodic surveillances for outdated items, and administratively controlling the purchase, segregation, identification, and disposition of consumable materials.
- Storage areas will be designed and constructed to ensure that items are maintained in environmental conditions commensurate with their intended purpose and storage requirements.

3.4 Calibration and Maintenance of Monitoring and Data Collection Equipment

3.4.1 Calibration Control of Process

The Performing Institutions will identify the measuring and data collection equipment that will be used in performing U.S. Home Team tasks. The required accuracy and reliability of each item will be determined, and appropriate maintenance/calibration specifications will be developed. Specifications shall be equal to or better than manufacturers' published data.

Equipment will be calibrated at appropriate determined intervals to controlled procedures for that equipment by qualified technicians. Some equipment, due to its nature, is best calibrated or verified immediately prior to being used. Equipment calibration may be performed by a dedicated group or by the user, whichever is most appropriate. The calibration of measuring or data-collection equipment must be traceable—typically to nationally or internationally recognized standards, such as those developed by the National Institute of Standards and Technology. When the standard used is not traceable to a nationally or internationally recognized standard, the basis of its use must be justified and the calibration results documented. The standard used to calibrate an instrument shall be least as good as the instrument being calibrated.

When instrumentation used on U.S. Home Team activities is found to be out of calibration tolerance, the appropriate Performing Institution manager will be notified. A determination will be made of the effects of the error on all test, analysis, or item certification data since the last calibration, and these determinations will be documented. Suppliers discovering out-of-tolerance instruments shall evaluate the effect on the deliverables and notify the appropriate Task Area Leader.

3.4.2 Calibration Labeling and Documentation

All measuring and data collection equipment will be labeled to identify its calibration status. The label should include the instrument identification number, the name of the person performing the calibration, the date of last calibration, and the date the next calibration is due. When any instrument is not so labeled (for example, due to size restrictions or surface characteristics), the instrument will be identified, and the user will maintain documentation equivalent to the label.

For instruments that obviously do not require calibration, a tag stating that calibration is not required should be attached to ensure the instrument is not used where a calibrated instrument is required.

Instruments used for U.S. Home Team activities will have records of calibration retained in project files. Those records should provide the following information to establish the traceability of the instrument's calibration:

- Instrument identification—type, make, model, and serial or control number

- Date of calibration, performer, procedure used, and standard used
- As-found instrument performance and as-left instrument performance.

3.5 Design Control

Design controls will be implemented by both the U.S. Home Team management and by the Performing Institutions for applicable design activities assigned to the U.S. Home Team. The preparation, review, and approval of design documents for the U.S. Home Team assigned tasks are accomplished through controlled procedures that establish the approval authorities and responsibilities between the U.S. Home Team management and the Performing Institutions. The U.S. Home Team Engineering Manager has oversight for all engineering tasks assigned to the U.S. Home Team.

The decentralized structure of the U.S. Home Team, with Performing Institutions geographically distributed across the country, presents difficulties in implementing this element of the quality program. Frequent technical review meetings, regular weekly discussion and status reports, management review meetings, quarterly review meetings, and periodic design reviews are the techniques used in the review and approval of U.S. Home Team work.

Performing Institution design control measures for test facilities focus on the design documentation for the test section. These are usually composed of fabrication drawings and attendant calculations. Design of test facilities will be subject to technical reviews, as required by the ITER design activity. Formal design verification may be required based on the risk associated with the test and the intended use of its results.

3.5.1 Design Input

All U.S. Home Team design tasks will be performed using the technical specifications, requirements, and criteria established by the ITER Joint Central Team. Exceptions to the use of the established technical criteria in the design or analysis of reference ITER systems or components assigned via task agreements require approval by the ITER Joint Central Team.

Input requirements are incorporated into design documents, descriptions, specifications, or drawings by specific statement or by reference. The level of authority for review and approval of design input will be established in design control procedures based on the importance of the structure, system, or component to overall facility safety and reliable operation.

Following initial preparation, a design document or a change thereto is reviewed by the appropriate technical support organizations, as needed, to verify that the document contains the applicable requirements. Review criteria include regulatory requirements; applicable codes and standards; quality requirements; suitability of materials and parts, nuclear physics, seismic stress, radiation, and accident analyses; access for inspection, maintenance, and repair; and testability. Also included is the establishment of acceptance criteria.

The Performing Institution is responsible for providing assurance that design controls do not allow nonconforming, substandard, or incorrect products to be introduced into the facility. The Performing

Institution is to develop programs to ensure the adequacy of critical parameters of items used in safety-related applications.

3.5.2 Design Interfaces

Each Performing Institution will implement design review and approval procedures that provide for both internal and external design interface controls. Each system will include the identification of all physical and functional interface requirements imposed by that system upon other systems. These interfaces will change as the details of the design evolve and will be updated by the ITER Joint Central Team through formal design change methods. Changes to ITER Joint Central Team and U.S. Home Team design documents will be reviewed by the same organizations, including the support organizations, that approved the original documents.

3.5.3 Design Records

Design documents, such as "as installed drawings," design review records, and associated changes will be collected, stored, and maintained in a systematic and controlled manner. The quality records system procedures will specify the specific controls and identify the design records to be maintained. Typically, design records include design input basis documents, calculations, design development computer models, approved drawings, specifications, and computer programs used in design calculations.

Design records for test facilities should be kept current to aid in system or test problem solving. Red-line markups of system drawings are an acceptable method for keeping documents current as long as the markups are legible and reproducible and the control of these types of changes (i.e., who makes changes, who approves changes, etc.) are clearly defined in implementation procedures.

3.5.4 Design Verification

During the design process, design verification activities will be performed by the Performing Institutions, as required, to ensure the adequacy of their designs. Design adequacy may be verified through one, or a combination of, the following approaches:

- Conducting design reviews
- Performing independent confirmatory calculations
- Use of qualification tests
- Benchmarking against a similar successful design.

Design verification reviews should be conducted by qualified individuals or groups, other than those who performed the original design. Personnel who participate in verification activities should be technically qualified at a level at least equivalent to that of the original designer or design team. Independent reviewers should be included in the design reviews. Where independent reviewers are not desired or are unavailable, this will be documented as part of the review.

Computer programs used to provide data that serve as the design basis of a structure, system, or component will be formally verified and validated to the extent appropriate to the classification of the structure, system, or component for which they were used.

Design verification will be performed before release for procurement, manufacture, construction, or unconditional release to other organizations for use in associated designs. In all cases, the final design verification will be completed before the design is relied upon to perform its function.

3.5.5 Qualification Testing

Qualification testing to verify the acceptability of a specific design will be conducted in accordance with approved procedures that address, at a minimum:

- Use of adequate instrumentation
- Provisions for test monitoring
- Specification of suitable environmental conditions
- Delineation of test prerequisites, such as calibrated instrumentation, appropriate equipment, trained personnel, and data acquisition equipment
- Demonstration of acceptable performance under conditions that simulate the appropriate adverse design conditions
- Delineation of performance specifications, including acceptable deviations from baseline (or mean) benchmarks.

3.6 Research and Development

A need for data may originate from any group or discipline within the project. It may come from the ITER Joint Central Team, another Home Team, or a Performing Institution. The data needed must be as clearly defined as possible in order to develop the most efficient method of obtaining the data. The appropriate Technical Manager works with Performing Institutions to draft a plan for obtaining the needed data.

All U.S. Home Team R&D tasks will be performed using the technical specifications, requirements, and criteria established by the ITER Joint Central Team. Exception to the use of the established technical criteria in the performance of R&D tasks assigned via task agreements requires approval by the ITER Joint Central Team.

R&D activities must be fully documented in order to support a critical peer review and provide traceability of the derived data throughout the development process. Any assumptions used in developing the needed data must be identified and their use justified. The principal concerns for these R&D activities are the

validity and traceability of the resultant data. U.S. Home Team R&D activities carried out by Performing Institutions will be defined, controlled, verified, and documented.

The quality program controls that the Performing Institution should apply to R&D activities are those good scientific practices that provide traceability and validity of the data. Any data to be used as inputs that were not obtained under a formalized quality program will be reviewed and evaluated for acceptability by the responsible U.S. Home Team Technical Manager. Performing Institution procedures will address such activities as peer review and technical review for the qualification of the data. Where appropriate, all such data should also have the concurrence of the cognizant ITER Joint Central Team member.

3.6.1 Experiment Systems

The designs of experimental systems used in the development of data need to be formally design reviewed to verify their adequacy for developing the desired data. Critical aspects of the experiment system that affect experimental results will be fully documented with appropriate records retained. Examples of such aspects could be calibration of the data acquisition systems, confirmation of the system materials, and system operating parameters in accordance with the data development plan.

3.6.2 Data Reduction and Analysis

Derived data are seldom obtained in the exact form needed. Raw data are usually reduced either by manual analysis or through available computer analysis programs. This is a critical step in data development. Reasonable measures should be taken to provide confidence in the reduced data results. Comparisons should be made with alternate calculations where validated alternate techniques are available and accepted. Alternate computer data reduction codes should be used for comparison where practically available. Benchmarks of the data reduction process for areas where the end data are known assist in developing confidence in the data reduction process.

3.7 Computer Code and Model Development

3.7.1 Computer Model Development

The development of a computer model is every bit as complex and rigorous as the design and fabrication of the hardware the model represents. The model design must be formally reviewed and validated as would its hardware counterpart. Complete model validation may not be possible until the final hardware product is created and operated. When this is the situation, operational testing plans must provide the necessary data points to fully validate the model or performance code for later uses. Interim benchmarks can and must be established that provide reasonable interim confidence in the model's validity as part of the formal process planned to fully verify the model.

3.7.2 Computer Software Management

Computer software management shall be established to maintain control of software used in the R&D and design activities of the U.S. Home Team. The procedures and work processes used to establish and maintain control of software formulate a structured software methodology for software acquisition,

development, change, maintenance, and disposition. The software management methodology consists of the following:

- Software planning and software requirements analysis
- Analysis of benefits and costs
- Resource estimating
- Life-cycle management
- Acquisition and development
- Configuration management
- Operational system reviews.

3.8 Procurement

The U.S. Home Team and Performing Institutions will implement procurements in accordance with their internal procurement process. Since the funding for U.S. Home Team procurements is from the DOE, all U.S. Home Team procurements must comply with the requirements of Federal regulations, such as the Federal acquisition regulations and the DOE acquisition regulations. U.S. Home Team procurements are subject to U.S. Home Team, DOE, and General Services Administration review and audit.

In general, the procurement process consists of the following steps: (1) identification of a needed item or service, (2) establishment of technical and quality requirements, (3) evaluation and selection of a supplier, (4) monitoring of supplier performance, (5) handling of deviations from requirements, (6) acceptance of items and services, and (7) handling of substandard items and services.

3.8.1 Identification of Needed Items or Services

The need for an item is usually identified from a parts list, bill of materials, or assembly drawing for a larger component or system. If the item is commercially available, then it should be fully specifiable by the vendor's catalog number or by the published performance data. If the item must be fabricated specifically for an intended application, the item should be described in an equipment specification or on drawings of the item. If the services of a contractor or supplier are being obtained, then a performance memorandum or a statement of work should be prepared that specifies the services to be performed and the expected deliverables.

3.8.2 Establishment of Technical and Quality Requirements

The procurement process should provide for the necessary technical and quality review of the procurement documentation to ensure that appropriate technical and quality requirements are adequately and

clearly stated. Technical and quality requirements for U.S. Home Team equipment and systems should be prepared in the form of technical or equipment specifications.

Procured services will be in accordance with the governing statements of work. These documents should specify the work to be done, the required documentation of the work, the qualifications of those performing the work, and the required schedule for performing the activities. These documents should also include all appropriate technical and quality requirements. The reviews and approvals of these procurements will be in accordance with the approved Performing Institution procedures.

3.8.3 Evaluation and Selection of Suppliers

In selecting contractors and suppliers, the Performing Institutions will review the potential contractor's or supplier's capability to provide the needed items or services. This evaluation should include an assessment of the candidate's quality capabilities (programmatic and quality of items provided). These evaluations should be documented to provide evidence of review and evaluation of suppliers before contract award. Contractors should be required to establish supplier evaluation mechanisms for qualifying and selecting their suppliers.

Qualified suppliers are sources that have demonstrated, through a special audit or through a history of performance, that they can supply items or services of high quality, as required, with appropriate documentation. The selection of the Performing Institution contractors or suppliers should be made from qualified suppliers in accordance with applicable Federal acquisition regulations.

3.8.4 Monitoring of Supplier Performance

The extent of supplier monitoring will be a function of the criticality of the item being supplied and the performance history of the supplier for similar items or services. As necessary, the Performing Institution should perform in-process surveillance, inspections, or reviews at the supplier's facility when a specific attribute of an item or process cannot be verified upon delivery of the completed item or service. Contractor suppliers of critical items should also be monitored to ensure that items and services conform to requirements.

3.8.5 Item Deviation from Requirements

Suppliers may request to depart from the technical specifications or quality requirements contained in the contract or purchase order. The Performing Institution's procurement process will have provisions for handling deviation requests from suppliers. The supplier should describe the proposed deviation; identify the changes, additions, or deletions to the technical requirements, specifically identifying what portions of the technical requirements are affected; justify the adequacy of the proposed deviation to satisfy the application technically; state the extent to which the original document remains in effect; identify the number of items that will be affected by the proposed deviation; and provide a schedule of actions necessary to complete the proposed changes. Deviation requests will be reviewed/approved in accordance with established procedures.

Suppliers may discover that the product does not meet the specified requirements. In such cases, a nonconformance report should be submitted to the purchaser identifying the nature and extent of the nonconformance and requesting disposition.

3.8.6 Item or Service Acceptance

Item or service acceptance occurs after objective evidence that acceptance criteria have been met. Acceptance involves receiving inspection reports, contract deliverables and attendant evaluations, contractor oversight reports (e.g., audit, surveillance, performance), and contractor/supplier performance documentation.

Contractors and suppliers of services will be required to provide deliverables in the form of reports, studies, progress reports, etc. These should be evaluated by project personnel and handled accordingly.

Performing Institution procedures should require that procured items not be released for unconditional use until all procurement requirements have been satisfied, including the resolution of nonconformances.

3.8.7 Substandard Items and Services

Items and services that are found to be substandard and that suppliers have knowingly provided will be reported to the U.S. Home Team Leader and DOE-OFE Manager for review and subsequent reporting to the DOE Office of the Inspector General.

3.9 Inspection and Testing Activities

3.9.1 Inspection

Inspection activities will be conducted by Performing Institutions and contractors in accordance with approved procedures. Inspection activities should be those required to ensure that work activity items and/or materials are in accordance with their design.

Inspections should be conducted in accordance with inspection planning tailored to the items being inspected and their importance to ITER project success. Inspection planning should be developed based on specification requirements, drawing requirements, and degree of complexity. Inspection planning should appropriately address:

- Inspection methods, including specific reference to inspection procedures
- Tests required to be monitored or witnessed
- Characteristics to be inspected
- Identification of mandatory hold points, as required, and acceptance criteria.

The inspection status of the item will be documented by labeling, tagging, inspection reports, or signatures on manufacturing or inspection plans or receipt inspection documents. Status documentation ensures that inspections will not be bypassed and that equipment, material, or fabricated assemblies will not be released for further work activities until the inspections are complete and the results accepted.

When inspection activities identify a nonconformance with a requirement, a nonconformance report will be initiated by the person performing the inspection. The nonconformance report will be processed in accordance with the process described in Performing Institution procedures.

3.9.2 Testing

Testing is accomplished where critical performance characteristics of an item cannot be verified by static inspection methods. Test planning should determine the type of tests required (e.g., prototype qualification testing, production testing, proof testing before installation, construction testing, and pre-operations testing). Test planning should document the test parameters, methods, test article configuration, and acceptance limits. Test requirements and acceptance criteria should be established by the user organization. Test requirements and acceptance criteria should be based on item performance requirements. Testing to verify or validate the acceptability of design features will be conducted in accordance with approved procedures that address, as applicable:

- Instructions on test performance, including hold points, as required
- Provisions for test monitoring, calibrated instrumentation, and data acquisition
- Suitable environmental conditions
- Qualification of testing personnel
- Established acceptance criteria.

Standard test methods should be used when practical. Use of equipment supplier manuals is also encouraged when testing equipment at a shop or during installation.

Test records will be maintained and will identify:

- Item or system tested, including test boundaries
- Date(s) of test
- Test personnel or data recording personnel
- Type of observation (e.g., pressure over time) and results observed
- Notation of deviations and subsequent evaluations
- Signature of person accepting results.

4. PROGRAM ASSESSMENTS

4.1 Readiness Reviews

The Performing Institutions are responsible for conducting appropriate and timely reviews for assigned tasks. The readiness of an activity, or one phase of an activity, to proceed to the next phase or to the next follow-on activity needs to be assessed and agreed upon prior to proceeding. Activity readiness reviews will be scheduled prior to startup of major activities. The objectives of the readiness review are to ensure that unnecessary or unexpected delays will not occur before going ahead on an activity until necessary prerequisites have been fully accomplished, documented, and ensured correct. Examples are pre-startup reviews of an experimental test facility, use of new computer programs, or the design review of a planned test facility.

This review will be of varying degrees of formality, as appropriate to the activity being evaluated. The Performing Institution line management will determine the timing and extent of the readiness reviews with the concurrence of the U.S. Home Team Technical Manager. The U.S. Home Team Technical Manager may elect to participate in the review, as deemed necessary. DOE Order 5480.31, "Operational Readiness Reviews," may be used as a guide in the performance of these reviews.

4.2 Management Self-assessment

The U.S. Home Team management obtains information on the effectiveness of the U.S. Home Team management and its quality assurance plan from the following project activities:

- Project coordination efforts
- Project reporting about the status of project tasks in relation to established goals and milestones
- Project performance indicators
- Project-level quality assessments that provide the U.S. Home Team management with information about the overall progress of the project organization in identifying and implementing administrative control systems, the quality of work performed, and areas in which improvement is necessary
- Technical and peer reviews for U.S. Home Team assigned activities.

The Performing Institutions are the implementing point of almost all of the U.S. Home Team quality program provisions. As such, the Performing Institutions are in the best position to assess their effectiveness and take appropriate corrective actions to improve their performance based on the nature of the activities being performed for the U.S. Home Team.

The most effective assessment comes from the individual performing assigned tasks. The assessments at this level are usually not formally documented but are usually the most detailed in nature. The

direct involvement of the performing individual in status reporting and problem solving is often the best opportunity for effective corrective action and quality improvement. Procedures with clear acceptance criteria for judging performance provide direct feedback to the performer.

Performance information is provided to the Performing Institution's management from the following sources, as applicable to the institution and the U.S. Home Team activities being performed:

- Task readiness reviews conducted to determine the ability of the task participants to start a particular operation. These reviews should be conducted in accordance with established procedures. Readiness reviews are not an audit, but rather a peer check of having performed all necessary prerequisites before starting an activity or continuing from one phase to another.
- Quality audits performed by Performing Institution quality assurance personnel. These audits assess the Performing Institution's implementation of, and conformance to, the quality program for U.S. Home Team activities.
- Quality surveillances of ongoing work activities (such as design review meetings or research testing) to verify work performance in accordance with established procedures applicable to the work activity. Surveillance is the act of process monitoring to evaluate in-process work, review corrective action completion status and effectiveness, and review documents and records pertinent to items or activities.
- Task Area Leader meetings that provide regular progress reporting, problem reporting, and adequacy assessments of tests (either ongoing or proposed).
- Procedure deviation reporting by line personnel to identify problems to line management for correction.

4.3 Independent Assessments

Independent assessments of the U.S. Home Team activities consist of two distinct types: assessments under the control of the project but performed by organizations and personnel that are independent of the activities being assessed, and assessments not controlled by the project and performed by outside organizations.

The following activities are self-initiated independent assessments of project performance and quality program effectiveness:

- Peer reviews or workshops conducted by technically qualified personnel who are independent of the U.S. Home Team activities to assess the adequacy of project decisions, design bases, and progress in meeting stated performance objectives

- Assessments of Performing Institutions to determine conformance to U. S. Home Team quality assurance plan requirements, DOE orders, and other regulatory policies affecting the performance of U.S. Home Team activities
- Readiness reviews conducted by independent reviewers to determine readiness to proceed with selected activities.

The following activities are independent assessments of project performance and quality program effectiveness initiated by organizations that exercise overview of the U.S. Home Team activities:

- ITER Joint Central Team and U.S. Home Team organized peer reviews or workshops conducted by technically qualified personnel who are independent of the project to assess the adequacy of project decisions, design bases, and progress in meeting stated performance objectives
- DOE-OFE assessments of U.S. Home Team activities that provide the project with higher-level oversight information for use in correcting project deficiencies
- ITER Quality Assurance Group assessments of U.S. Home Team activities for compliance with ITER quality program requirements.

Self-initiated independent assessments are viewed as constructive and are conducted with the prime goal of improving the work process. Assessment results are reviewed for opportunities for improvements, for needed corrective actions, and to identify observed exemplary performance. Assessment responses will include, as appropriate, remedial actions to correct the cited deficiency, root cause determination, actions taken to prevent recurrence, lessons learned, and changes in work practices to result in improvements.

4.4 Assessment Responses

Responses to self-initiated independent assessments should include, as appropriate, remedial actions to correct the cited deficiency, root cause determination, actions taken to prevent recurrence, lessons learned, and improvement initiatives. Periodic status reports on the progress of corrective actions should be made to assessing organizations until the action is completed, accepted, and closed.

Responses to external assessments will comply with the instructions provided by the external organization but should, as a minimum, provide the same information as for self-initiated assessments.

4.5 Documentation of Results

Each of the self-assessment processes discussed above should result in some documentation. Specific overview activities such as audits, surveillances, reviews, and assessments result in formal documentation of results and corrective actions. Reporting activities such as status reports, award fee reports, and planning efforts usually result in less detailed documentation (e.g., meeting minutes and milestone objectives). Individual performer assessment results usually take the form of nonconformance reports or procedure deviation or revision requests.