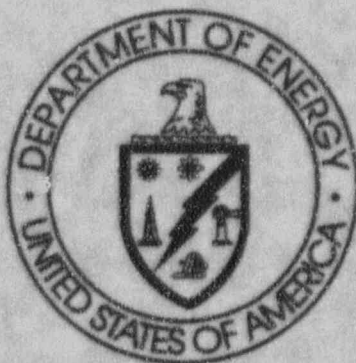


# **Guidance for Review of TWRS Privatization Contractor Initial Quality Assurance Program**



October 1996

Office of Radiological, Nuclear, and Process  
Safety Regulation for TWRS Privatization Contractors

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## PREFACE

The Department of Energy's (DOE) Richland Operations Office (RL) issued the *TWRS Privatization Request for Proposal (RFP)* for Hanford Tank Waste Remediation System (TWRS) Privatization in February 1996. Offerors were requested to submit proposals for the initial processing of the tank waste at Hanford. Some of this radioactive waste has been stored in large underground storage tanks at the Hanford Site since 1944. Currently, approximately 56 million gallons of waste containing approximately 240,000 metric tons of processed chemicals and 250 mega-curies of radionuclides are being stored in 177 tanks. These caustic wastes are in the form of liquids, slurries, saltcakes, and sludges. The wastes stored in the tanks are defined as high-level radioactive waste (10 CFR Part 50, Appendix F) and hazardous waste (Resource Conservation and Recovery Act).

Under the privatization concept, DOE will purchase waste treatment services from a contractor-owned, contractor-operated facility under a fixed-price contract. DOE will provide the waste feedstock to be processed but maintain ownership of the waste. The contractor must: a) provide private financing; b) design the equipment and facility; c) apply for and receive required permits and licenses; d) construct the facility and bring it on-line; e) operate the facility to treat the waste according to DOE specifications; and f) deactivate the facility.

The TWRS Privatization Program is divided into two phases, Phase I and Phase II. Phase I is a proof-of-concept/commercial demonstration-scale effort the objectives of which are to a) demonstrate the technical and business viability of using privatized contractors to treat Hanford tank waste; b) define and maintain adequate levels of radiological, nuclear, process, and occupational safety; c) maintain environmental protection and compliance; and d) substantially reduce life-cycle costs and time required to treat the tank waste. The Phase I effort consists of two parts: Part A and Part B.

Part A consists of a twenty-month development period to establish appropriate and necessary technical, operational, regulatory, business, and financial elements. This will include identification by the TWRS Privatization Contractors and approval by DOE of appropriate safety standards, formulation by the Contractors and approval by DOE of integrated safety management plans, and preparation by the Contractors and evaluation by DOE of initial safety assessments. Of the twenty-month period, sixteen months will be used by the Contractors to develop the Part-A products and four months will be used by DOE to evaluate the products.

Part B consists of a demonstration period to provide tank waste treatment services by one or more of the TWRS Privatization Contractors who successfully complete Part A. Demonstration will address a range of wastes representative of those in the Hanford tanks. Part B will be 10 to 14 years in duration. Within Part B, wastes will be processed during a 5- to 9-year period and will result in treatment of 6 to 13 percent of the Hanford tank waste.

Phase II will be a full-scale production phase in which the remaining tank waste will be processed on a schedule that will accomplish removal from all single-shelled tanks by the year 2018. The objectives of Phase II are to a) implement the lessons learned from Phase I; and b) process all tank waste into forms suitable for final disposal.

A key element of the TWRS Privatization Contracts is DOE regulation of radiological, nuclear, and process safety through the establishment of a specifically chartered, dedicated Regulatory Unit (RU) at RL. This regulation by the RU is authorized by the document entitled *Policy for Radiological, Nuclear, and Process Safety Regulation of TWRS Privatization Contractors* (referred to

as the Policy) and implemented through the document entitled *Memorandum of Agreement for the Execution of Radiological, Nuclear, and Process Safety Regulation of the TWRS Privatization Contractors* (referred to as the MOA). The Policy is signed by the Under Secretary of Energy; the Manager, RL; the Assistant Secretary for Environment, Safety and Health (ASEH); and the Assistant Secretary for Environmental Management (ASEM). The MOA is signed by the Manager, RL; the ASEH; and the ASEM. The nature and characteristics of this regulation are also specified in these documents. The MOA details certain interactions among RL, the ASEH, and the ASEM as well as their respective roles and responsibilities for implementation of this regulation.

The authority of the RU to regulate the TWRS Privatization Contractors is derived solely from the terms of the TWRS Privatization Contracts. Its authority to regulate the Contractors on behalf of DOE is derived from the Policy. The nature and scope of this special regulation (in the sense that it is based on terms of a contract rather than formal regulations) is delineated in the MOA, the TWRS Privatization Contracts, and the four documents (listed below), which are incorporated into the Contracts. This special regulation by the RU in no way replaces any legally established external regulatory authority to regulate in accordance with their duly promulgated regulations nor relieves the Contractors from any obligations to comply with such regulations or to be subject to the enforcement practices contained therein.

The Policy, the MOA, the TWRS Privatization Contracts, and the four documents incorporated in the Contracts define the essential elements of the regulatory program, which will be executed by the RU and to which the TWRS Privatization Contractors must conform. The four documents incorporated in the Contracts (and also incorporated in the MOA) are

*Concept of the DOE Regulatory Process for Radiological, Nuclear, and Process Safety for TWRS Privatization Contractors, DOE/RL-96-0005,*

*DOE Regulatory Process for Radiological, Nuclear, and Process Safety for TWRS Privatization Contractors, DOE/RL-96-0003,*

*Top-Level Radiological, Nuclear, and Process Safety Standards and Principles for TWRS Privatization Contractors, DOE/RL-96-0006, and*

*Process for Establishing a Set of Radiological, Nuclear, and Process Safety Standards and Requirements for TWRS Privatization, DOE/RL-96-0004.*

In the execution of the regulatory program, the RU will consider not only the relevant approaches and practices of DOE but also those of the Nuclear Regulatory Commission (NRC). The Policy states that

"It is DOE's policy that TWRS privatized contractor activities be regulated in a manner that assures adequate radiological, nuclear, and process safety by application of regulatory concepts and principles consistent with those of the Nuclear Regulatory Commission."

To this end, the RU will interact with the NRC (under the provisions of a memorandum of understanding with the NRC) during development of regulatory guidance and during execution of the regulatory program to ensure implementation of this policy.

All documents issued by the Office of Radiological, Nuclear, and Process Safety Regulation for TWRS Privatization Contractors are available to the public through the DOE/RL Public Reading Room at the Washington State University, Tri-Cities Campus, 100 Sprout Road, Room 130 West, Richland, Washington.

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## 1. INTRODUCTION

Under its Contract, each TWRS Privatization Contractor is required to submit an initial Quality Assurance Program (QAP) that supports performance of Part-A activities 45 days after Contract award. The Contract further stipulates that the QAP be based on existing Contractor systems wherever possible. The Department of Energy (DOE) Regulatory Unit (RU), Office of Radiological, Nuclear, and Process Safety Regulation for TWRS Privatization Contractors at the Richland Operations Office (RL), will provide comments within 15 days of the Contractor's submission. This Guide provides the basis which the RU will use to review the Contractor's initial QAP and develop comments.

The Reviewer should be aware that new rules and regulations establish requirements that go beyond a prescriptive approach to product quality, to a tailored approach to the quality of all Contractor activities consistent with their importance. Particularly, the DOE/RL Regulatory Unit views the Contractor's QAP as a primary tool of Contractor management to guarantee that quality achievement is integrated into the Contractor's total activities through integrated planning, implementation, assessment, and corrective actions. It also means that the quality assurance approaches should be tailored to the activity, for example, the quality assurance for design (application of defined techniques) and for analyses (intellectual inquiry activities) may differ in approach and application. Since the DOE/RL Regulatory interest in quality assurance is dominated by interest in the Contractor management's achievement of meaningful quality for all activities that influence safety, the Reviewer should expect the QAP to be an essential integrated feature of the Contractor's Integrated Safety Management Plan (ISMP).

## 2. PURPOSE

The DOE has issued, 10 CFR Part 830.120, Quality Assurance Requirements (the Rule), and a related implementation guide which apply to the TWRS Privatization Contractors. When the Rule was issued, DOE practices and requirements focused mainly on management and operating contractors. While these practices are still generally applicable, some differing perspectives also exist that reflect the present relationship between the TWRS Privatization Contractors and the DOE. These differing perspectives are expressed here.

This Guide accommodates the new relationship between the DOE and its Privatized Contractors; incor-

porates the effects of the requirements in the document *Top-Level Radiological, Nuclear, and Process Safety Standards and Principles for TWRS Privatization Contractors*, DOE/RL-96-0006; Revision 0; and addresses the requirements in the Contract for Contractor submittal of an initial QAP. An effort has been made to focus on known Part A activities. The Reviewer should note that the initial QAP is an interim measure to establish a basis for Contractor work until the standards are established. The QAP, based on the results of the standards identification process should be submitted for approval as part of the ISMP. Finally, this Guide also addresses Reviewer actions to support the potential future transition to Nuclear Regulatory Commission (NRC) regulation. (See Section 8.0.)

## 3. STRUCTURE

Section 4 identifies the requirements and provides additional considerations important to the review of the QAP. Section 5 lists Part-A activities that should be included by the Contractor in the initial QAP and provides the guiding principle for judging the Contractor's selection of other Part-A activities that should also be included in the QAP. Section 6 provides the Quality Assurance Criteria considered to be most important to Part-A activities. Section 7 provides specific guidance for the review of the initial QAP and identifies attributes the RU considers important and which constitutes its expectations for the Contractor's QAP. Section 8 notes the possible transition of the regulatory program to the NRC in the future and provides additional instructions to the Reviewer related to that transition. This Guide reserves the use of italicized text to set apart text quoted from authoritative sources.

## 4. QUALITY ASSURANCE REQUIREMENTS

In the four documents describing DOE's regulatory approach, DOE/RL-96-0002 through 0006, there are three tenets that are basic to the TWRS Privatization Contractors for radiological, nuclear, and process safety. The Contractor is responsible for:

- *Achieving adequate safety;*
- *Complying to applicable laws, and legal requirements, and*
- *Conforming to top-level safety standards and principles stipulated by the DOE.*

The QA principles stipulated by DOE, which are contained in the document *Top-Level Radiological, Nuclear, and Process Safety Standards and Principles for*

TWRS Privatization Contractors, DOE/RL-96-0006; Revision 0, are as follows:

#### 4.1.4.1 Safety/Quality Culture

*A safety/quality program should be established that governs the Contractor's actions and interactions of all personnel and organizations engaged in activities related to the facility and emphasizes excellence in all activities. The Contractor should have safety and quality responsibilities specifically identified in its operations.*

#### 4.1.6.1 Quality Assurance Application

*Quality assurance and quality control should be applied throughout all phases and to all activities associated with the facility as part of a comprehensive system to ensure with high confidence that all items delivered and services and tasks performed meet required standards.*

This same source also stipulates other principles related to activities subject to quality control including Configuration Management, Section 4.1.5; Design, Section 4.2.1; and Proven Engineering Practices/Margins, Section 4.2.2.

The Reviewer guidance provided herein is based on the principles found in the document containing the top-level safety standards and principle stipulated by DOE, the QA Rule, that is, 10 CFR Part 830.120, and the companion guidance document to the Rule, *Implementation Guide for use with 10 CFR Part 830.120 Quality Assurance*, G-830.120-Rev. 0, April 15, 1994.

### 5. PART-A QA RELATED ACTIVITIES

Under the phased structure of the TWRS Privatization Program, work related to the design spans Part A and Part B of Phase I (see Preface on inside of the cover). The Contractor is responsible for identifying all Part-A activities which will be subject to QA. This selection will be subject to review.

Part-A activities are limited by the Contract to design and design-related activities. While the safety significance of Part-A activities to the Part-A period of work is limited, the influence of Part-A activities on Part-B activities is of interest in the initial QAP review. Some of the Part-A activities that must be emphasized in the initial QAP are safety deliverables of the Contract.

Based on the Contract, the Reviewer should expect the Contractor's activities that support the develop-

ment of Part-A deliverables for radiological, nuclear, and process safety (Table S4-1)<sup>1</sup>, and the design activities to be emphasized in the initial QAP. In addition to design, the deliverables of key interest to the RU include:

- Safety Requirements Document
- Integrated Safety Management Plan
- Hazards Analysis Report
- Employee Concerns Management System
- Radiation Exposure Standard for Workers Under Accident Conditions
- Quality Assurance Program
- Initial Safety Assessment

As mentioned earlier, the Contractor's selection of other Part-A activities to be included in the initial QAP should be considered and reviewed. The guiding principle governing the Contractor's selection of other Part-A activities is to choose those activities which will have a lasting influence on the safety to be achieved in Part B. The Reviewer should expect the Contractor to declare which of the Part-A results they will use in Part B should their participation continue, and should expect those activities to be emphasized in its QAP.

### 6. KEY 10 CFR PART 830.120 QA CRITERIA FOR PART-A

The Rule has three general requirements and ten specific Criteria. Section 5 addresses Part-A activities that should be emphasized in the initial QAP. As noted in the next section, the Reviewer should expect the initial QAP to include a discussion of how the general requirements and each QA Criterion will be satisfied. Because the profile of activities in Part A is limited to design and design-related activities and not to construction, operations, or deactivation, and because the Contractor is required to apply the Criteria using a graded approach, the Reviewer should expect the Contractor to provide a greater level of detail for certain Criterion than for others.

The Reviewer should balance the review with the individual importance of the Criterion. Procurement, for example, is not a large part of Part-A activities. However, if Part-A activities involve procurement implementation standards and practices for Part B, procurement of design or design development studies, this Criterion should be considered. The following table lists the Rule's Criteria, a judgment as to their

<sup>1</sup> Part A deliverables for Radiological, Nuclear, and Process Safety contained in Table S4-1, Section C, p. 22, of *TWRS Privatization Request for Proposals*, DE-RP06-96RL13308, February 1996.



expected use in Part A, and the reasoning for that judgment. Table 1 is to be used by the Reviewer in preparing for the review. It should not be construed

as providing special relief to the Contractor from any obligations under the Rule.

**Table 1. Relative Measure of Criteria Applicability to Part-A Work**

<b>CONSIDERATION OF THE RULE'S 10 CRITERIA IN THE REVIEW OF CONTRACTOR'S PART-A QA PROGRAM</b>			
<b>CRITERION</b>	<b>TITLE</b>	<b>EXPECTED USE IN PART A</b>	<b>JUSTIFICATION</b>
1	Program	Greater	To achieve Part-A deliverables the organization must be well defined and functional.
2	Qualification & Training of Personnel	Greater	Qualified personnel strongly impact the quality of the design.
3	Quality Improvement	Lesser	Design controls probably suffice.
4	Documents & Records	Greater	Consideration should be given to D&R storing media, retention & retrieval.
5	Work Processes	Greater	Engages management and worker in quality design processes.
6	Design	Greater	This is the main emphasis of Part A.
7	Procurement	Lesser	Limited to procurement of design and design development studies in Part A.
8	Inspection and Acceptance Testing	Lesser	May have some implications in defining item or process prototypes.
9	Management Assessments	Greater	Management needs organizational control.
10	Independent Assessments	Lesser	In Part A, assessments are part of design control.

## **7. QA ATTRIBUTES AND REVIEW**

### **7.1 Introduction**

The intent of this Guide is to encourage the Reviewer to judge the adequacy of the Contractor's measures to accomplish quality, rather than its compliance with established prescriptions. Ultimately, the Contractor should be judged on the effectiveness of its measures to achieve excellence. This will require the Contractor to adopt a coherent and rational approach that addresses the QA needs and is effective for achieving quality in Part-A activities. The Reviewer should be receptive to any competent and rational approach developed within the framework of the Rule and the top-level safety standards and principles stipulated by

DOE. A common sense approach to the requirements as they apply to Part-A activities is expected. Requirements having major influence on the quality of Part-A, safety-significant results should receive more detailed and extensive treatment. Those requirements justifiably meriting reduced attention, may receive less.

The guidance below is organized to follow the structure of the Rule. There are general requirements (called General Quality Assurance Program Requirements) for the QAP, as well as specific Criteria that should be satisfied by the QAP. The General Quality Assurance Program Requirements noted below address: 1) demonstrating how the ten Criteria are satisfied, 2) using the graded approach, and 3) using the appropriate standards. These general requirements in-

fluence the Contractor's use of the ten Criteria. The Reviewer is to judge the adequacy of the Contractor's approach to these general requirements.

In the Rule, and in this Guide, the ten Criteria are grouped into three sections: Management, Performance, and Assessment. Each of the ten Criteria has a number of specific requirements. Reviewers should judge the adequacy of the Contractor's response to satisfying each Criterion.

For each requirement listed below, this section quotes related requirements contained in the top-level safety standards and principles stipulated by DOE, and provides reviewer guidance on what the Reviewer ought to expect in the QAP and important considerations for judging the adequacy of the Contractor's approach. Contractor use of related sections in the companion document to the Rule, *Implementation Guide for 10 CFR Part 830.120*, G-830.120-REV. 0, April 15, 1994, is acceptable, insofar as, all of the QA requirements for TWRS Privatization Contractors are addressed. Contractor use of NQA-1<sup>2</sup> style information is also acceptable provided the information is organized and presented in a manner which demonstrates that the requirements of the Rule are effectively satisfied.

During the review process, the Reviewer should: 1) become familiar with the Implementation Guide for the Rule, 2) read the review statements in this section for each requirement, 3) become familiar with the Contractor's QAP and implementation plan, if provided, 4) evaluate the Contractor's QAP against the review statements in this Guide and relative to the scope of work for Part A, and 5) judge if the QAP, if implemented, would satisfy the requirements of the Rule and the related top-level safety standards and principles stipulated by DOE. The Reviewer, therefore, needs to have a working knowledge of quality requirements, methods for implementing quality programs, and of the TWRS Privatization Program.

## 7.2 General Quality Assurance Program Requirements

There are three general requirements of 10 CFR Part 830.120, Quality Assurance Requirements, part (b) Quality Assurance Program:

**Requirement 1** *A QAP shall include a discussion of how the criteria of paragraph (c) of this section will be satisfied.*

<sup>2</sup> ASME NQA-1-1994 Edition, *Quality Assurance Requirements for Nuclear Facility Applications*.

**Review** Under the Rule there is flexibility for the Contractor to devise its own approach for achieving quality. The Contractor may choose those measures upon which it intends to rely. However, with the uncertainty introduced by this flexibility, a Contractor's stated commitment in the QAP to comply with the ten Criteria does not provide sufficient information to judge the adequacy of its approach. The Reviewer should expect a discussion of what activities will be placed under the QAP and how QA measures will be used to achieve quality. This discussion will include methods and systems to be used and specifically identify how the Criteria are to be satisfied. The use of existing systems is acceptable, provided they meet adequate standards for the functions they are intended to perform. For either existing or proposed systems, the Reviewer should expect a description of the functions to be performed and the standards to which they conform.

**Requirement 2** *The criteria of paragraph (c) of this section shall be applied using a graded approach.*

**Review** All Contractor activities are subject to QA but not all processes, items, activities, or services have the same effect on quality or safety. A graded approach is to be used in the application of the Criteria. According to the Rule:

*"Graded Approach means a process by which the level of analysis, documentation, and actions necessary to comply with a requirement in this Part are commensurate with:*

- (1) The relative importance to safety, safeguards, and security;*
- (2) The magnitude of any hazard involved;*
- (3) The life cycle stage of a facility;*
- (4) The programmatic mission of a facility;*
- (5) The particular characteristics of a facility; and*
- (6) Any other relevant factor."*

The Reviewer should expect a presentation of the rationale and method used by the Contractor to discriminate between levels of analysis, documentation, and actions, as well as a description of the method's application and its results. The rationale should take into consideration the above six factors as they apply to the Contractor. The objective of the graded approach is to establish the level of effort necessary to achieve quality; therefore, the Reviewer should judge the adequacy of the process applied to activities in the context of their importance to safety and quality and their continued influence in Part B.

**Requirement 3** *The contractor shall use appropriate standards, whenever applicable, to develop and implement its QAP.*



### Review For the Privatization Contractors,

*"The DOE regulatory approach requires that the Contractor take an active and significant role in identifying and recommending the standards and requirements it will use to achieve adequate safety for its specific activities".<sup>3</sup>*

The Reviewer should expect a presentation of the standards used by the Contractor to develop the initial QAP and a justification for their use. Because the results of the standards and requirements identification process will not be available for the initial QAP, the Reviewer should consider the acceptability of the standards in the context of commercial and DOE practice such as ASQC E4<sup>4</sup>, ASME NQA-1<sup>5</sup>, and ASQC Q 9001<sup>6</sup>. As a minimum, the Reviewer should confirm the Contractor's use of the Rule and QA-related top-level safety standards and principles stipulated by DOE in the QAP.

### **7.3 Quality Assurance Criteria That Apply To Work Management**

#### *Criterion 1: Program*

Introduction The general requirements just discussed in Section 7.2 are concerned with measures to achieve safety, the necessary level of effort, and the use of acceptable standards. This Criterion addresses the management systems for implementing the QAP.

Requirement 4 *A written QAP shall be developed, implemented, and maintained.*

Review The Reviewer should expect a presentation of the Contractor's management system. The management system should include the Contractor's methods for managing, performing, and assessing the adequacy of work, including work assigned to partners or parties outside the organization.

The Reviewer should evaluate the Contractor's management system's capability to achieve quality, with emphasis on the contractor's requirements for management qualification and participation. The Reviewer should be satisfied that the method and resources for developing, implementing, and maintain-

ing the QAP are adequate. The Reviewer should confirm that the Contractor's policies and requirements establishing the management system include provisions for management's development of measures to ensure that all personnel, including management, implement the management system. The Reviewer should identify a commitment to develop an implementation plan and evaluate the methods of management implementation and maintenance. Maintenance considerations may include: 1) periodic program reviews, 2) demonstration of adequacy, 3) provisions for changes, and 4) method of approval. The Reviewer should identify the Contractor's policies and requirements for assessing the adequacy of work.

Requirement 5 *The QAP shall describe the organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work.*

Review The Reviewer should evaluate the adequacy of the Contractor's organizational structure and the provisions enabling those personnel responsible for developing and implementing the QAP to have adequate lines of communication and sufficient influence to be effective. The Reviewer should see a presentation of the function of the various parts of the organization, their responsibilities, and how each supports the mission, i.e., organizational unit responsibilities, the level of authority for each tier of the organization, the interfaces among personnel managing, performing, and assessing the work, and authorities, responsibilities, and interfaces among multiple contractors or subcontractors. The communication among different organizations and between the organization and parties outside the organization should be described. The Reviewer should identify and evaluate a method for resolving inconsistencies among organizations and between organizations and parties.

Requirement 6 *The QAP shall describe the management processes, including planning, scheduling, and resource considerations.*

Review The Reviewer should identify and evaluate the adequacy of the Contractor's policies and requirements that establish the management processes. The Reviewer should identify and evaluate the Contractor's cost schedule control system (CSCS) and the Management Information System (MIS). The Reviewer should assess how the CSCS will be used, including the ability to track program progress and handle resource loading. The Reviewer should determine if the MIS is in place, and assess how it will be used and its adequacy to accommodate interfaces with all organizations and parties.

<sup>3</sup> DOE/RL-96-0005; Revision 0, February 1996, p. 1.

<sup>4</sup> ANSI/ASQC Standard E4, *Quality Systems Requirements for Environmental Programs*, 1994.

<sup>5</sup> ASME NQA-1-1994 Edition, *Quality Assurance Requirements for Nuclear Facility Applications*.

<sup>6</sup> ANSI/ASQC-Q9001, *Quality Systems -Model for Quality Assurance in Design/Development, Production, Installation, and Servicing*, 1993.

### *Criterion 2: Personnel Training and Qualification*

**Introduction** This Criterion addresses the ability of personnel to perform their work. It applies to all Contractor activities, including design, and should be used consistent with the results of the graded approach. In evaluating the Contractor's approach, the Reviewer should consider the constraints imposed by the dynamic nature of Part-A activities and the limited period of work on the Contractor's selection of methods to satisfy this Criterion.

**Requirement 7** *Personnel shall be trained and qualified to ensure they are capable of performing their assigned work.*

Related top-level safety standards and principles stipulated by DOE

#### *4.3.4.1 Personnel Training*

*Personnel engaged in activities bearing on facility safety should be trained and qualified to perform their duties.*

**Review** The Reviewer should identify and evaluate the Contractor's policies, requirements, and methods to ensure that personnel are trained and qualified to perform their work. Consider the following questions. Are the personnel required to have an adequate understanding of the work they are to perform? Does the Contractor certify the qualifications of its personnel and is the process adequate? Has the Contractor identified the skills required to perform the work of Part A, such as knowledge of systems engineering methods, special computer codes, etc.?

The Reviewer should identify and evaluate the Contractor's provisions for training. The evaluation may consider 1) formal and informal training, such as on-the-job training, 2) training formats including seminars and classroom instruction, 3) establishing minimum requirements for each job task, 4) instructor qualification and experience, 5) appropriate training materials and facilities, and 6) assessing personnel proficiency.

**Requirement 8** *Personnel shall be provided continuing training to ensure that job proficiency is maintained.*

Related top-level safety standards and principles stipulated by DOE

#### *4.3.4.2 Training Programs*

*Programs should be established for continual training of operations and maintenance personnel*

*to enable them to perform their duties safely and efficiently.*

#### *4.3.4.3 Conditions Beyond Design Basis*

*Operating staff should be trained and retrained in the procedures to follow if conditions exceed the design basis of the facility.*

**Review** The Reviewer should identify and evaluate the Contractor's policies and requirements to establish continuing training. The constraints imposed by the dynamic nature of Part-A activities and the limited period of work should be considered while gauging the importance and judging the adequacy of the Contractor's approach. The Reviewer should consider the approach of using refresher courses to ensure personnel are trained in current procedures and on organizational processes, particularly if a condition adverse to quality may involve processes being performed incorrectly. The evaluation may consider 1) a periodic assessment of training needs, 2) an assessment of process problems that may be solved by training, 3) instructor qualification and experience, 4) appropriate instruction materials and facilities, and 5) assessment of personnel proficiency.

### *Criterion 3: Quality Improvement*

**Introduction** This Criterion addresses the processes to continually improve quality. It applies to all Contractor activities, including design, and should be used consistent with the results of the graded approach. In the evaluation, the Reviewer should consider the constraints imposed by the dynamic nature of Part-A activities and the limited period of work on the Contractor's selection of methods to satisfy this Criterion.

**Requirement 9** *Processes to detect and prevent quality problems shall be established and implemented.*

#### **Review**

*"Quality Improvement is a dual fold process of addressing and remedying sporadic problems, sudden adverse changes in the status quo of a work process, and solving chronic problems, long-standing adverse conditions in a work process, i.e. continual scrap of several percent, to improve a work process by changing the status quo to a new improved level."<sup>7</sup>*

<sup>7</sup> Derived from *Quality Planning and Analysis*, by J. M. Juran and Frank M. Gryna, Jr., McGraw-Hill, 1980, p. 99.

The Reviewer should identify and evaluate the Contractor's policies, requirements, and methods to detect and prevent quality problems, take prompt, effective, and complete corrective actions, and improve performance. The Reviewer should consider Contractor's management measures to document and communicate the policies to all levels of the organization and among organizations, to implement related practices, including those to improve worker awareness of the importance of quality, to encourage participation of all workers in quality improvement, and to vest authority in workers to identify quality problems and initiate corrective actions. The Reviewer should consider the use of methods like the Shewhart Cycle (also known as the Plan, Do, Check, Act or PDCA cycle) by the Contractor to formalize the process of improving planning activities, procedures, processes, and designs.

**Requirement 10** *Items, services, and processes that do not meet established requirements shall be identified, controlled, and corrected according to the importance of the problem and the work affected. Correction shall include identifying the causes of problems and working to prevent recurrence. Item characteristics, process implementation, and other quality-related information shall be reviewed and the data analyzed to identify items and processes needing improvement.*

**Review** The Reviewer should identify and evaluate the Contractor's policies for implementing procedures that identify, control, and correct quality deficiencies. The Reviewer should consider the Contractor's use of methods for controlling items, services, or processes that do not meet requirements or specifications such as a classification system using the structure: accept, reject, repair, rework, use-as-is, or re-evaluate; and the methods for identification and correction including the tools of tracking, trending, and root cause analysis to ensure that the underlying causes of quality problems are averted.

#### *Criterion 4: Documents and Records*

**Introduction** This Criterion addresses the control of documents and record functions related to processes, requirements, and design. It provides requirements affecting matters such as configuration control, related to work performance, such as design.

**Requirement 11** *Documents shall be prepared, reviewed, approved, issued, used, and revised to prescribe processes, specify requirements, or establish design.*

**Review** A document is recorded information that describes, specifies, reports, certifies, requires, or pro-

vides data or results<sup>8</sup>. It controls policies, administrative and technical information regarding processes, requirements, and design. The Reviewer should identify and evaluate the Contractor's policies and requirements for document control and the implementation of a documents control process. The Reviewer should consider measures that ensure all elements of the organization establish document control procedures. The Reviewer should identify and evaluate the Contractor's requirements and standards for document preparation, review, approval, use, access, and revision. The Reviewer should consider approaches for controlling distribution, identifying recipients, and establishing required actions when documents are revised or canceled consistent with the results of the graded approach. The Reviewer should consider measures that ensure qualified reviewers based on subject matter expertise. The Reviewer should also evaluate the Contractor's QAP document control provisions against the requirements for configuration management in the top-level safety standards and principles stipulated by DOE. (See Criterion 5, *Work Processes*, and Criterion 6, *Design*.)

**Requirement 12** *Records shall be specified, prepared, reviewed, approved, and maintained.*

**Review** A record is recorded information that is retained for its expected future value.<sup>9</sup> The Reviewer should identify and evaluate the Contractor's policies and requirements for the specification, preparation, review, approval, and maintenance of records. The Reviewer should consider how records are determined, the process of preparation, the method of review, the process of approval, and the system for maintenance in light of a graded approach. The Reviewer should evaluate the Contractor's record control system considering the requirements for retention, protection, preservation, changes, and traceability. He or she should assess the adequacy of requirements to preserve the integrity of the storage system and the media. The Reviewer should use the records control system requirements of NARA (National Archives and Records Administration) to assess control of the TWRS Privatized Program Government records.

<sup>8</sup> From 10 CFR Part 830.3, Definitions: *Document* means recorded information that describes, specifies, reports, certifies, requires, or provides data or results. A document is not considered a record until it meets the definition of a record.

<sup>9</sup> From 10 CFR Part 830.3, Definitions: *Record* means a completed document or other media that provides objective evidence of an item, service, or process.



## 7.4 Quality Assurance Criteria That Apply To Work Performance

### *Criterion 5: Work Processes*

**Introduction** This Criterion addresses measures to achieve process goals. It applies to all Contractor activities such as planning, scheduling, accounting, project management, design, analysis, fabrication, procurement, construction, installation, testing, operation, modification, maintenance, and deactivation consistent with the results of the graded approach. The Reviewer should consider the scope of Part-A activities in the evaluation of the Contractor's approach. In particular, Requirements 14, 15, and 16 should require less detailed information from The Contractor.

**Requirement 13** *Work shall be performed to established technical standards and administrative controls using approved instructions, procedures, or other appropriate means.*

**Review** The Reviewer should identify and evaluate the Contractor's policies and requirements for such management controls as providing criteria for acceptable work performance, planning and designing work processes; ensuring qualified personnel to accomplish the work; ensuring personnel take responsibility for the quality of their own work and that they follow prescribed standards, procedures, or instructions. Documents expressing management controls should 1) clearly identify authorities, responsibilities, and interfaces, 2) be readily accessible to and usable by the workers, and 3) address work process elements such as methods to prevent use of incorrect or defective items. The Reviewer should also evaluate the Contractor's work process measures intended for use in Part B. The Reviewer should evaluate the attention given to each important element of each work process: people, equipment, environmental conditions, supply, management, support, resources, and requirements, based on the results of the graded approach.

**Requirement 14** *Items shall be identified and controlled to ensure their proper use.*

**Review** "Item is an all-inclusive term used in place of any of the following: appurtenance, assembly, component, equipment, material, module, part, structure, subassembly, subsystem, system, unit, or support system".<sup>10</sup>

The Reviewer should identify Contractor's policies and requirements for identifying and controlling items. The Reviewer should expect the Contractor to use a system to inventory items and a method to track and control items and accompanying documentation, depending on importance. The Reviewer should confirm Contractor's management's commitment to a system that is readily usable by workers. The Reviewer should identify Contractor's policies and requirements ensuring that personnel take responsibility for proper use of the items. The Reviewer should see that the following are addressed: one of a kind items, items specific to a particular craft, and common items that may be misused.

**Requirement 15** *Items shall be maintained to prevent their damage, loss, or deterioration.*

**Review** The Reviewer should identify and evaluate the Contractor's policies and requirements for a process or procedure that ensures item maintenance or special care according to their importance (graded approach). The Reviewer should consider measures in the maintenance management program to promote worker safety and environmental protection, and to monitor item condition. The Reviewer should consider the following attributes: maintenance requirements, an item control process, maintenance schedules, personnel or organization identified for maintenance, assignment of authority and resources to meet requirements, handling and storage requirements to prevent damage, a method of measuring deterioration, and establishing metrics for determining deterioration. A provision should be included for identifying items with unique requirements such as in-storage maintenance, limited shelf life, or ones that pose a particular hazard to the environment, facilities, or personnel.

**Requirement 16** *Equipment used for process monitoring or data collection shall be calibrated and maintained.*

**Review** The Reviewer should identify and evaluate the Contractor's policies and requirements for identifying, controlling, and maintaining equipment used for monitoring processes or collecting process or other data. The Reviewer should identify and evaluate the Contractor's requirements for a formal, documented, calibration program. The Reviewer should consider requirements for 1) calibration standards traceable to the National Institute of Standards and Technology (NIST), or some other nationally recognized standard, or a method that gives the basis for the calibration; and 2) procedures and training for those workers who perform calibrations. The training pro-

<sup>10</sup> From 10 CFR Part 830.3, Definitions: *Item is an all-inclusive term used in place of any of the following: appurtenance, assembly, component, equip-*

*ment, material, module, part, structure, subassembly, subsystem, system, unit, or support system.*

gram should include training for personnel that maintain such equipment.

#### *Criterion 6: Design*

**Introduction** This Criterion addresses the definition, control, and verification of design and is more specific than those measures stipulated for Criterion 5, *Work Processes*. It applies to the design and supporting activities such as analysis. This Criterion recognizes the need for additional measures, including the control of design inputs, outputs, verification, configuration and design changes, documentation, records, and technical interfaces consistent with the results of the graded approach. This Criterion ensures that adequate measures exist for systems, structures, and components important to safety. The Reviewer should recognize the potential importance of this Criterion to Part-A activities.

Principles stipulated by DOE that are related to the activities subject to this Criterion include "Configuration Management," Section 4.1.5, "Design," Section 4.2.1, and "Proven Engineering Practices/Margins," Section 4.2.2 of the Top-Level Radiological, Nuclear, and Process Safety Standards and Principles for TWRS Privatization Contractors, DOE/RL-96-0006; Revision 0. Sections 4.1 and 4.2 are included in Appendix A for the Reviewer's convenience.

**Requirement 17** *Items and processes shall be designed using sound engineering/scientific principles and appropriate standards.*

Related top-level safety standards and principles stipulated by DOE.

##### *4.2.2.1 Proven Engineering Practices*

*Safety technologies incorporated into the facility design should have been proven by experience or testing and should be reflected in approved codes and standards. Significant new design features should be introduced only after thorough research and model or prototype testing at the component, system, or facility level, as appropriate.*

**Review** The Reviewer should identify and evaluate the Contractor's policies and requirements for using sound engineering/scientific principles. The Reviewer should consider the use of accepted design practices; valid analytical methods, tools, and data; proven technology or measures to demonstrate adequacy of new technology; and formal design processes that ensure quality. The Reviewer should confirm the Contractor's measures that address the QA methods

unique to analysis. The Reviewer should also verify measures to preclude the use of unverified design data and ensure that appropriate verification or qualification testing is completed before design data are used in subsequent activities, consistent with the results of the graded approach. The Reviewer should identify and evaluate the Contractor's requirements for identifying and using suitable standards appropriate to the design product.

**Requirement 18** *Design work, including changes, shall incorporate applicable requirements and design bases.*

Related top-level safety standards and principles stipulated by DOE

#### *4.1.5 Configuration Management*

##### *4.1.5.1 Formal Configuration Management*

*Formal configuration management should be applied to all facility activities during the program's lifetime to ensure that programmatic objectives, including safety, are fully achieved. Work should be performed and controlled according to pre-approved plans and procedures that clearly delineate responsibilities. Documented records should be retained.*

##### *4.1.5.2 Contractor Design Knowledge*

*The Contractor operating organizations should become and remain familiar with the features and limitations of components included in the design of the facility. They should obtain appropriate input from the design organization on pre-operational testing, operating procedures, and the planning and conduct of training.*

##### *4.1.5.3 Design Documentation*

*A system should be used to control and maintain accurate as-built drawings during the life of the facility.*

**Review** The Reviewer should identify and evaluate the Contractor's policies and requirements for a formal process, including systems engineering, to properly establish and accurately incorporate requirements and design bases into the design and design changes. The Reviewer should verify that design changes, including those made during fabrication or construction, subsequent modifications, and any nonconforming items will be subject to design standards and controls consistent with those applied to the original design. The Reviewer should identify requirements for configuration management and control to ensure that de-

sign documents and records are appropriately generated, controlled, and retained. The following is an accepted consensus standard definition for *Configuration Management (CM)*<sup>11</sup>.

*"An integrated management program that establishes consistency among design requirements, physical configuration, and facility documentation, and maintains this consistency throughout the life of the facility as changes occur. The CM program consists of CM functions associated with the following program elements: program management, design requirements, document control, change control, and assessments. The CM program also includes design reconstitution and material condition and aging management as adjunct programs."*

The Reviewer should identify and evaluate the Contractor's requirements for a process to identify structures, systems, and components (SSCs) important to safety based on the results of the graded approach and should be able to establish the life expectancy of the SSC<sup>12</sup>. The Reviewer should also identify requirements for design documents to be usable by all end users.

**Requirement 19** *Design interfaces shall be identified and controlled.*

**Review** The Reviewer should identify and evaluate the Contractor's policies and requirements for determining design interfaces among interacting disciplines or multiple contractors, both technical and administrative. These interacting disciplines and organizations should have well-defined roles with respect to responsibilities, design reviews, design-basis exchange among disciplines and organizations, deliverables among disciplines and organizations, and associated approvals. The Reviewer should identify and evaluate the Contractor's requirements for an interface control system that avoids, or identifies and corrects conflicts.

**Requirement 20** *The adequacy of design products shall be verified or validated by individuals or groups other than those who performed the work.*

**Review** Design verification is a formal documented process to establish that the resulting system, struc-

ture, or component will be fit for its intended use. The Reviewer should identify and evaluate the Contractor's policy and requirements to verify or validate design products consistent with the results of the graded approach. Measures may include technical reviews, peer reviews, alternate calculations, qualification testing or limited use of reviews of comparable systems. Interim reviews may be made at predetermined stages of development. The extent and number of reviews should be based on the importance and complexity of the design product. The Reviewer should confirm that technically qualified personnel, separate from those performing the design, will verify the design. The Reviewer may consider measures to promote quality improvement as part of the design verification.

**Requirement 21** *Verification and validation work shall be completed before approval and implementation of the design.*

**Review** The Reviewer should identify and evaluate the Contractor's policies and requirements to verify and validate the design before its use by other organizations. If verification cannot be completed before use by other organizations, unverified portions of the design should be identified and controlled. In all cases the design should be verified before it is approved and implemented.

#### Criterion 7: Procurement

**Introduction** This Criterion addresses the Contractor's establishing of measures to ensure that items and services provided by suppliers meet end-user requirements consistent with the results of the graded approach. The Reviewer should acknowledge the limited procurement during Part-A activities in the evaluation of the Contractor's approach to this Criterion. Should procurement become a significant consideration, the Reviewer is referred to the Implementation Guide for 10 CFR Part 830.120 for a fuller description of the measures to be considered in the evaluation.

**Requirement 22** *Procured items and services shall meet established requirements and perform as specified.*

**Review** The Reviewer should identify and evaluate the Contractor's policies and requirements for the planning and control of the procurement process consistent with the results of the graded approach. The Reviewer should focus on measures to ensure the procurement process meets end-user requirements. Measures should provide for the clear, complete, and accurate communication of end-user requirements to

<sup>11</sup> DOE-STD-1073-93-Pt. 1, "Guide for Operational Configuration Management Programs," Glossary, page x.

<sup>12</sup> Top-level Radiological, Nuclear, and Process Standards and Principles for TWRS Privatization Contractors, DOE/RL-96-0006; Revision 0, Sections; 4.2.2.2, 4.2.2.3, 4.2.7.1, and 4.2.7.2.



the supplier; meeting suppliers', designers', and end-users' requirements during production of the item or services; and delivering the product on time and maintaining it until use.

End-user requirements should include supplier documentation, handling, packaging, shipping, or storage requirements. The Reviewer should identify and evaluate the Contractor's policies and requirements for documenting and controlling nonconforming items or services until compliance with the technical requirements is demonstrated; and for acceptable deviations from requirements to be documented, controlled, reviewed, and approved.

**Requirement 23** *Prospective suppliers shall be evaluated and selected on the basis of specified criteria.*

**Review** The Reviewer should identify Contractor's policies and requirements to ensure suppliers are qualified to provide required items or services. The Reviewer may consider use of metrics such as performance history and results of supplier evaluation based on facility visits or documented evidence.

**Requirement 24** *Processes to ensure that approved suppliers continue to provide acceptable items and services shall be established and implemented.*

**Review** The Reviewer should identify and evaluate the Contractor's policies and requirements to establish a process to continually evaluate a supplier's continued capability to provide acceptable items and services. The extent and number of reviews should be based on the results of the graded approach. Enhanced reviews may be stimulated by receipt of nonconforming items from the supplier. The Reviewer may consider performance criteria such as: work activities, facility inspection, process evaluation, progress reports, change information, and nonconformance reviews.

#### *Criterion 8: Inspection and Acceptance Testing*

**Introduction** This Criterion addresses Contractor inspection and testing provisions to verify that systems, structures, and components (SSCs) are acceptable to specified requirements, consistent with the results of the graded approach. The Reviewer should consider the limited use of SSCs during Part-A activities in the evaluation of the Contractor's approach. Should use of SSCs become a significant consideration, the Reviewer is referred to the Implementation Guide for 10 CFR Part 830.120 for a fuller description of measures to be considered in the evaluation.

**Requirement 25.** *Inspection and testing of specified items, services, and processes shall be conducted using established acceptance and performance criteria.*

Related top-level safety standards and principles stipulated by DOE

#### *4.3.5.1 Operational Testing, Inspection, and Maintenance*

*Structures, systems, and components important to safety should be the subject of appropriate, regular preventive maintenance, inspection, and testing and servicing when needed, to ensure that they remain capable of meeting their design requirements throughout the life of the facility. Such activities should be carried out in accordance with written procedures supported by quality assurance measures.*

**Review** The Reviewer should identify and evaluate the Contractor's policies and requirements to establish inspection and testing of SSCs consistent with Part-A activities and the results of the graded approach. The Reviewer should consider measures to ensure that inspection and testing acceptance and performance criteria are developed based on requirements, and inspection and testing activities are adequately planned, controlled, and documented. The Reviewer should consider provisions to control disposition of SSCs that do not conform, including tracking, repair, replacement, re-testing, and revaluation to specified criteria and disposal. The Reviewer should identify measures to ensure that equipment used for inspections is appropriate, and that personnel performing inspections and tests are trained and qualified in the test procedures and the equipment to be used and are certified in the appropriate discipline as necessary, e.g., Non-Destructive Examination qualifications.

**Requirement 26** *Equipment used for inspections and tests shall be calibrated and maintained.*

**Review** The Reviewer should identify Contractor's policies and requirements, to establish a formal, documented, calibration program consistent with Part-A activities and the results of the graded approach. Calibration standards should be traceable to a recognized authority, such as the National Institute of Standards and Technology that gives the basis for the calibration. The Reviewer should evaluate the Contractor's provisions for the calibration of equipment and instruments used to establish the acceptance of items, processes, procedures or services; corrective actions where out-of-calibration conditions occur; and the use of qualified personnel performing calibrations.

## 7.5 Quality Assurance Criteria That Apply To Work Assessment

### *Criterion 9: Management Assessment*

**Introduction** This Criterion addresses Contractor management awareness of its organizational performance related to achieving its goals and objectives and to the provisions management uses to encourage a continuous quality improvement process and to ensure corrective actions are promptly, effectively and completely addressed. This Criterion applies to all Contractor activities and should be used consistent with the results of the graded approach. The Reviewer should consider the constraints imposed by the dynamic nature of Part-A activities and the limited period of work on the Contractor's selection of methods to satisfy this Criterion.

**Requirement 27** *Management shall assess their management processes.*

**Review** This Reviewer should identify and evaluate the Contractor's policies and requirements for assessing management processes. The Reviewer should consider measures to establish organizational goals and objectives, and the conduct of periodic assessments that evaluate the effectiveness of the entire integrated management system to focus on achieving organizational goals. These measures should be consistent with the period of work for Part-A activities. The Reviewer should consider management identification of 1) processes for assessment such as strategic planning, organizational interfaces, cost control, use of performance indicators, staff training and qualifications, and supervisory oversight and support; 2) conditions such as employee knowledge, motivation, and morale; worker trust and communication; worker dedication to creativity and improvement; and adequacy of human resources; and 3) work observations such as upward evaluations, worker interviews, review of documentation, and conduct of drills or exercises.

**Requirement 28** *Problems that hinder the organization from achieving its objectives shall be identified and corrected.*

**Review** The Reviewer should identify Contractor's policies and requirements for identification and correction of problems that hinder the organization from achieving its objectives, including corrective actions. The Reviewer should consider measures to use the information acquired during assessments combined with other internal and external information to identify problems and to develop input to a continuous improvement process. The Reviewer should evaluate

the attention given by the Contractor to methods of improving processes and eliminating the barriers to achieving strategic goals and objectives.

### *Criterion 10: Independent Assessment*

**Introduction** This Criterion addresses management awareness of performance of work processes related to the requirements and expectations of customers and toward achieving the organization's goals and objectives. The Reviewer should evaluate the Contractor's measures to assess its establishment of the QAP and implementation. The provisions for input to a continuous quality improvement process should also be considered. The Reviewer should consider the constraints imposed by the dynamic nature of Part-A activities and the limited period of work on the Contractor's selection of methods to satisfy this Criterion.

**Requirement 29** *Independent assessments shall be planned and conducted to measure item and service quality, to measure the adequacy of work performance, and to promote improvement.*

**Related top-level safety standards and principles stipulated by DOE**

#### *4.3.1.5 Internal Surveillance and Audits*

*Internal safety review procedures should be used by the Contractor to provide a continuing surveillance and audit of facility operational safety and to support the facility manager in overall safety responsibilities.*

and

#### *4.4.1 Safety Review Organization*

*The Contractor should establish a framework for its safety review organizations that are responsible for assuring the safety of the facility. The separation between the responsibilities of the safety review organizations and those of the other organizations should remain clear so that the safety review organizations retain their independence as safety authorities.*

**Review** The Reviewer should identify and evaluate the Contractor's policies and requirements for management to develop and implement an independent assessment program. The program should assess organizations, programs, and projects with the objective of evaluating the performance of work processes, and promoting improvement with regard to requirements and expectations of DOE. The Reviewer should consider the establishment of specified criteria grounded

in a performance-based approach. The Reviewer should consider the planning of assessments, and selection of activities for assessment, such as design, that are most directly related to final objectives, and its emphasis on safety and product quality. The Reviewer should consider the selection of types of independent assessments such as inspections, peer and technical reviews, audits, surveillances, or combinations thereof; and the frequency of independent assessments in light of activities being assessed and their importance. The Reviewer should evaluate the effectiveness of the Contractor's approach to measure item and service quality, to measure adequacy of work performance, and to promote improvement.

**Requirement 30** *The group performing independent assessments shall have sufficient authority and freedom from the line to carry out its responsibilities.*

**Review** The Reviewer should evaluate the independence and authority afforded the Contractor's group performing the assessment. The Reviewer should consider the advisory function of the group, the level to which the group reports in the overall organization, and its independence and access to appropriate authority. The Reviewer should also confirm that the group would have no direct responsibilities or dependencies in the areas they are assessing. The Reviewer should also confirm that the group's role includes assisting those who are being assessed to improve quality.

**Requirement 31** *Persons conducting independent assessments shall be technically qualified and knowledgeable in the areas assessed.*

Related top-level safety standards and principles stipulated by DOE

#### 4.4.2 Qualified Personnel

*Internal safety oversight should be conducted by qualified personnel to ensure that the safety standards are consistently met.*

**Review** The Reviewer should identify Contractor's policies and requirements for ensuring personnel conducting independent assessments are technically qualified and knowledgeable. The Reviewer should consider measures to establish appropriate qualifications for the assessments and to select appropriate personnel for conduct of the assessment. For assessments performed by personnel who are internal to the organization, the Reviewer should identify a policy that requires the use of certified personnel, as established by Criterion 2 for assessing work. For assessments performed by personnel who are external to the organization, the Reviewer should identify a policy that requires a certification program be established to en-

sure the assessor's credentials, qualifying them to perform the particular assessment.

## 8. OTHER CONSIDERATIONS

As an additional consideration, it should be noted that the DOE intends to transition regulation of the TWRS Privatization Contractors to the NRC in the future. It will be extremely useful to document the level of consistency that exists between the Contractor's initial QAP as reviewed against 10 CFR Part 830.120 and NRC requirements. Within the bounds of 10 CFR Part 830.120, the Reviewer should evaluate the Contractor's initial QAP for consistency with NRC QA practices related to 10 CFR 70. Inconsistencies with NRC requirements should be noted for use by the RU to assist the future transition. This part of the review will not reflect on the acceptability of the Contractor's initial QAP, but is only for the benefit of the RU.

## 9. SOURCES

1. TWRS Privatization Request for Proposals, DE-RP06-96RL13308, February 1996.
2. 10 CFR Part 820 - Procedural Rules for DOE Nuclear Activities, September 1993.
3. G 414.1-1, *Implementation Guide for the use with the Independent and Management Assessment Requirements of 10 CFR Part 830.120 and the Order 5700.6C Quality Assurance*, REV. 0, August 1996.
4. DOE P 450.4, *Safety Management System Policy*, August 28, 1996.
5. ANSI/ASQC Standard E4, *Quality Systems Requirements for Environmental Programs*, 1994.
6. 10 CFR Part 830.3, *Definitions*, April 5, 1996.
7. 10 CFR Part 830.120, *Quality Assurance Requirements*, April 5, 1996.
8. 10 CFR Part 70, *Domestic Licensing of Special Nuclear Material*, as amended through September 1996.
9. *Concept of the DOE Regulatory Process for Radiological, Nuclear, and Process Safety for TWRS Privatization Contractors*, DOE/RL-96-0005.
10. *DOE Regulatory Process for Radiological, Nuclear, and Process Safety for TWRS Privatization Contractors*, DOE/RL-96-0003.



11. *Top-Level Radiological, Nuclear, and Process Safety Standards and Principles for TWRS Privatization Contractors*, DOE/RL-96-0006.
12. *Process for Establishing a Set of Radiological, Nuclear, and Process Safety Standards and Requirements for TWRS Privatization*, DOE/RL-96-0004.
13. *Implementation Guide for 10 CFR 830.120*, G-830.120-REV. 0, April 15, 1994.
14. ANSI/ASQC-Q9001, *Quality Systems - Model for Quality Assurance in Design/Development, Production, Installation, and Servicing*, 1993.
15. ASME NQA-1, *Quality Assurance Requirements for Nuclear Facilities Applications*, 1994 Edition.
16. DOE 5700.6C, *Quality Assurance*, August 21, 1991.
17. IAEA Code on the Safety of Nuclear Power Plants: Quality Assurance, Safety Series No. 50-C-QA (Rev.1), 1988.
18. DOE Order 5000.3B, *Occurrence Reporting and Processing of Operations Information*, February 22, 1993.
19. *Quality Planning and Analysis*, J. M. Juran and Frank M. Gryna, Jr., McGraw-Hill, 1980.
20. *Statistical Method from the Viewpoint of Quality Control*, Walter A. Shewhart, Graduate School, Department of Agriculture, Washington, D. C., 1939, and Dover in 1986.

## 10. ABBREVIATIONS

CFR	Code of Federal Regulation
CM	Configuration Management
DOE	Department of Energy
NRC	Nuclear Regulatory Commission
QA	Quality Assurance
QAP	Quality Assurance Program
RL	Richland Operations Office
RFP	TWRS Privatization Request for Proposal
RU	Office of Radiological, Nuclear, and Process Safety Regulation (Regulatory Unit)
SSC	Structures, Systems, and Components
TWRS	Hanford Tank Waste Remediation System

## 11. GLOSSARY

Administrative Controls. Provisions relating to organization and management, procedures, record keeping, assessment, and reporting necessary to ensure safe operation of a facility.

Common-Cause Failures. Dependent failures that are caused by a condition external to a system or set of components that make system or multiple component failures more probable than multiple independent failures.

Common-Mode Failures. Dependent failures caused by susceptibilities inherent in certain systems or components that make their failures more probable than multiple independent failures due to those components having the same design or design conditions that would result in the same level of degradation.

Contractor(s). The private company(ies) selected to contract with DOE for construction and operation of the technologies and facilities necessary to retrieve, process tank waste, and deliver treated waste products to DOE for storage or disposal.

Controlled Area. The physical area enclosing the facility by a common perimeter (security fence). Access to this area can be controlled by the Contractor. The controlled area may include identified restricted areas.

Design.<sup>13</sup> The process and the result of developing the concept, detailed plans, supporting calculations and specifications for a nuclear facility and its parts.

Design Basis. The information that identifies the specific functions to be performed by structures, systems, or components of the facility and the specific values or ranges of values chosen for controlling parameters as reference bounds for design.

Director of the Regulatory Unit. An individual who has been delegated the authority to execute the radiological, nuclear, and process safety regulation of TWRS Privatization Contractors.

Document. Document means recorded information that describes, specifies, reports, certifies, requires, or provides data or results. A document is not considered a record until it meets the definition of record.

Facility. Those buildings and equipment directed to a common purpose and those activities and supporting elements occurring at a single location.

<sup>13</sup> Derived from the definition of design used in IAEA Code on the Safety of Nuclear Power Plants: Quality Assurance, 50-C-QA (Rev.1)

**Graded Approach.** A process by which the level of analysis, documentation, and actions necessary to comply with a requirement in this part are commensurate with:

- 1) The relative importance to safety, safeguards, and security;
- 2) The magnitude of any hazard involved;
- 3) The life cycle stage of a facility;
- 4) The programmatic mission of a facility;
- 5) The particular characteristics of a facility; and
- 6) Any other relevant factor.

**Integrated Safety Management Plan (ISMP) Evaluation Report.** The document, approved and issued by the Director of the Regulatory Unit, that addresses the adequacy of the Contractor's Integrated Safety Management Program as reflected in its Integrated Safety Management Plan.

**Integrated Safety Management Program.** A set of integrated activities that is directed toward the management or control of radiological, nuclear, and process hazards such that adequate protection is provided to workers, the public, and the environment.

**Item.** Item is an all-inclusive term used in place of any of the following: appurtenance, assembly, component, equipment, material, module, part, structure, subassembly, subsystem, system, unit, or support systems.

**Nonreactor Nuclear Facility.** Those activities or operations that involve radioactive and/or fissionable materials in such form and quantity that a nuclear hazard potentially exists to the employees or the general public. Incidental use and generating of radioactive materials in a facility operation (e.g., check and calibration sources, use of radioactive sources in research and experimental and analytical laboratory activities, electron microscopes, and X-ray machines) would not ordinarily require the facility to be included in this definition. Transportation of radioactive materials, accelerators and reactors and their operations are not included. The application of any rule to a nonreactor nuclear facility shall be applied using a graded approach. Included are activities or operations that:

- 1) Produce, process, or store radioactive liquid or solid waste, fissionable materials, or tritium;
- 2) Conduct separations operations;
- 3) Conduct irradiated materials inspection, fuel fabrication, decontamination, or recovery operations;
- 4) Conduct fuel enrichment operations;
- 5) Perform environmental remediation or waste management activities involving radioactive materials; or
- 6) Design, manufacture, or assemble items for use with radioactive materials and/or fissionable materials in such form or quantity that a nuclear hazard potentially exists.

materials in such form or quantity that a nuclear hazard potentially exists.

**Normal Operation.** Steady-state operation and those departures from steady-state operation that are expected frequently or regularly in the course of facility operation, system testing, and maintenance. It includes conditions such as startup, shutdown, standby, anticipated operational occurrences, operation with specific equipment out of service as permitted by the approved operational constraints, and routine inspection, testing, and maintenance of components and systems during any of these conditions if it is consistent with the approved operational constraints.

**Nuclear Facility.** Reactor and nonreactor nuclear facilities.

**Process.** (Related to Safety) Any activity involving a highly hazardous chemical including use, storage, manufacturing, handling, or the on-site movement of such chemicals, or a combination of these activities.

**Process.** (Related to Quality Assurance) A series of actions that achieves an end or result.

**Process Safety.** The operation of facilities that handle, use, process, or store hazardous materials in a manner free of episodic or catastrophic incidents. However, the handling, use, processing, and storage of materials with inherent hazardous properties can never be done in the total absence of risk. Process safety is an ideal condition towards which one strives.

**Public.** Individuals who are not occupationally engaged at the Hanford Site.

**Quality.** The condition achieved when an item, service, or process meets or exceeds the user's requirements and expectations.

**Quality Assurance.** All those actions that provide confidence that quality is achieved.

**Quality Assurance Program or QAP.** The overall program established to assign responsibilities and authorities, define policies and requirements, and provide for the performance and assessment of work.

**Record.** A completed document or other media that provides objective evidence of an item, service, or process.

**Regulatory Unit.** The organization reporting to the Director of the Regulatory Unit dedicated to supporting the Director in executing regulatory authority.

**Reliability Targets.** Quantified probabilistic expectations that a component, equipment, or system will perform its intended function satisfactorily under given circumstances, such as environmental conditions, limitations as to operation time, and frequency and thoroughness of maintenance for a specified period.

riod of time. Identified important to safety items are expected to perform their function satisfactorily through all design basis accident conditions.

**Requirements.** Standards that are mandated by an authority through statute, regulation, or contract.

**Safe State.** A situation in which the facility process has been rendered safe and no pressurized material flow occurs in the process lines. Any active, energy generating, process reactions are in controlled or passive equipment. The structures, systems, and components necessary to reach and maintain this condition are functioning in a stable manner, with all process parameters within normal safe state ranges.

**Service.** The performance of work, such as design, construction, fabrication, inspection, nondestructive examination/testing, environmental qualification, equipment qualification, repair, installation, or the like.

**Standards.** The expressed expectation for the performance of work.

**Worker.** Worker means an individual within the controlled area of the facility performing work for or in conjunction with the Contractor or utilizing Contractor facilities.

## APPENDIX A. ADDENDUM TO CRITERION 6, DESIGN

The following is an addendum to Criterion 6, *Design*. This appendix is a duplication of Section 4.2, "Design, Construction, and Pre-Operational Testing" of the DOE document titled, *Top-Level Radiological, Nuclear, and Process Safety Standards and Principles for TWRS Privatization Contractors*, DOE/RL-96-0006; Revision 0. Because conformance to DOE/RL-96-0006 is required, this Section will be used by the Reviewers to evaluate the Contractor's Quality Assurance Program plan of the TWRS Privatization Program.

### 4.2 Design, Construction, and Pre-Operational Testing

#### 4.2.1 Design

##### 4.2.1.1 Safety Design

The facility should be designed for a set of events such as: normal operation, including anticipated operational occurrences, maintenance, and testing; external events; and postulated accidents.

##### 4.2.1.2 Risk Assessment

Acceptable risk analyses should be applied during the design to delineate provisions for the prevention and mitigation, including emergency preparedness and response, of otherwise risk-dominant events.

##### 4.2.1.3 Safety Analysis

A safety analysis should be carried out as required to evaluate the safety performance of the design and identify requirements for operations.

#### 4.2.2 Proven Engineering Practices/Margins

##### 4.2.2.1 Proven Engineering Practices

Safety technologies incorporated into the facility design should have been proven by experience or testing and should be reflected in approved codes and standards. Significant new design features should be introduced only after thorough research and model or prototype testing at the component, system, or facility level, as appropriate.

##### 4.2.2.2 Common-Mode/Common-Cause Failure

Design provisions should be included to limit the loss of safety functions due to damage to several structures, systems, or components important to safety resulting from a common-cause or common-mode failure.

##### 4.2.2.3 Safety System Design and Qualification

Structures, systems, and components important to safety should be designed and qualified to function as intended in the environments associated with the events for which they are intended to respond. The effects of aging on normal and abnormal functioning should be considered in design and qualification.

##### 4.2.2.4 Codes and Standards

Codes and standards for vessels and piping should be supplemented by additional measures (such as erosion/corrosion programs and piping in-service inspections) to mitigate conditions arising that could lead to an unacceptable release of radioactivity during the operational life of the facility.

##### 4.2.2.5 Criticality

The facility should be designed and operated in a manner that prevents nuclear criticality.

#### 4.2.3 Radiation Protection

##### 4.2.3.1 Radiation Protection Practices



An acceptable system of radiation protection practices should be followed in the design, construction, and pre-operational testing phases of the facility for the protection of workers and the public.

#### 4.2.3.2 Radiation Protection Features

At the design stage, radiation protection features should be incorporated to protect workers from radiation exposure and to keep emissions of radioactive effluents ALARA and within prescribed limits.

#### 4.2.3.3 Deactivation, Decontamination, and Decommissioning Design

The design of the facility should incorporate provisions to facilitate deactivation and the final decommissioning. The objective of these provisions should be to reduce radiation exposures to Hanford Site personnel and the public both during and following deactivation and decommissioning activities and to minimize the quantity of radioactive waste generated during deactivation, decontamination and decommissioning.

#### 4.2.3.4 Deactivation Plan

There should be an approved plan for deactivation of the facility before it is constructed.

#### 4.2.4 Emergency Preparedness

##### 4.2.4.1 Support Facilities

The facility design should provide additional capability to place and maintain the facility in a safe state following an accident if the normal control areas are expected to become uninhabitable.

#### 4.2.5 Inherent/Passive Safety Characteristics

##### 4.2.5.1 Safety Margin Enhancement

Design features that enhance the margins of safety through simplified, inherent, passive, or other highly reliable means to accomplish safety functions should be employed to the maximum extent practical.

#### 4.2.6 Human Factors

##### 4.2.6.1 Human Error

The possibility of human error in facility operations should be taken into account in the design by facilitating correct decisions by operators and inhibiting wrong decisions and by providing means for detecting and correcting or compensating for error.

#### 4.2.6.2 Instrumentation and Control Design

Sufficient instrumentation and control capability should be provided so that under normal operating and postulated accident conditions the operators can diagnose facility conditions, place and maintain the facility in a safe state, and mitigate accidents. If necessary, measures should be provided to protect the operator in the performance of these functions.

#### 4.2.6.3 Safety Status

Parameters to be monitored in the control room should be selected and their displays should be arranged to ensure that operators have clear and unambiguous indications of the status of facility conditions important to safety, especially for the purpose of identifying and diagnosing the actuation and operation of a system or components important to safety.

#### 4.2.7 Reliability, Availability, Maintainability, and Inspectability (RAMI)

##### 4.2.7.1 Reliability

Reliability targets should be assigned to structures, systems, and components or functions important to safety. The targets should be consistent with the roles of the structures, systems, and components or functions in different accident conditions. Provision should be made for appropriate testing and inspection of structures, systems, and components for which reliability targets have been set.

##### 4.2.7.2 Availability, Maintainability, and Inspectability

Structures, systems and components important to safety should be designated, designed and constructed for appropriate inspection, testing, and maintenance throughout their operating lives to verify their continued acceptability for service with an adequate safety margin.

#### 4.2.8 Pre-Operational Testing

##### 4.2.8.1 Testing Program

A pre-operational testing program should be established and followed to demonstrate that the entire facility, especially items important to safety, have been constructed and function according to the design intent, and to ensure that weaknesses are detected and corrected.

##### 4.2.8.2 Operational Systems and Functional Testing Procedures Validation

Procedures for normal facility and systems operation and for functional tests to be performed during the operating phase should be validated as part of the pre-operational testing program.

#### 4.2.8.3 Safety Systems Data

During pre-operational testing, detailed diagnostic data should be collected on systems and components important to safety and the initial operating parameters of the systems and components should be recorded.

#### 4.2.8.4 Design Operating Characteristics

During the pre-operational testing program, the as-built operating characteristics of process systems, and systems and components important to safety should be determined and documented. Operating points should be adjusted to conform to values in the design basis. Training procedures and limiting conditions for operation should be modified to accurately reflect the operating characteristics of the systems and components as built.