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QUALITY ASSURANCE PROGRAM RECOMMENDATIONS REPORT

Prepared for

**Nuclear Regulatory Commission
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1 INTRODUCTION

In anticipation of an appropriation for and authorization of the Nuclear Regulatory Commission (NRC) as the federal regulator for the Hanford, Washington Tank Waste Remediation System (TWRS) at the Hanford Site in Washington State, the NRC has initiated a program to ensure a seamless transition of the oversight responsibilities from the U.S. Department of Energy (DOE) to the NRC. An important aspect of this program is the development of quality assurance (QA)-related regulatory requirements and guidance for the TWRS. The CNWRA has been tasked to prepare a QA requirements report that recommends QA regulatory requirements and guidance for the NRC application to TWRS.

The approach taken to develop the recommendations was to review the current NRC QA regulations and guidance, DOE QA regulations and guidance, lessons learned from nuclear QA program implementation, and QA practices of industries with comparable (i.e., high) risk. An analysis of the survey results illustrated the differences as well as the areas in common among the various QA program regulations. From the analysis, QA program characteristics most appropriate to regulation of the TWRS were identified, and an approach to QA regulation and guidance recommended that captures those appropriate characteristics.

This report was prepared in two segments. First, a survey of pertinent QA regulations, guidance, and practices was conducted. This first segment of work produced the Quality Assurance Program Survey Report, which was transmitted to the NRC on February 26, 1997. Second, an analysis of the survey results and recommendations was prepared. This report documents both segments of the task and incorporates NRC staff comments on the draft report.

2 QUALITY ASSURANCE PROGRAM SURVEY

2.1 SURVEY OF NUCLEAR REGULATORY COMMISSION REGULATIONS AND GUIDANCE

Table 2-1 provides a summary comparison of quality assurance requirements established in 10 CFR Part 50, Appendix B; 10 CFR 830.120; and ISO-9001 (International Organization for Standardization, 1994). Its contents are used throughout this chapter to (i) identify the QA program elements and their scope within the various QA program regulations and standards, and (ii) facilitate comparisons of these three approaches to establishing QA programs.

Table 2-1. Comparison of quality assurance program elements

10 CFR 50, Appendix B (NRC)	10 CFR 830.120 (DOE)	ISO-9001 (International Standard)
I. Organization authority and duties <ul style="list-style-type: none"> • QA functions • QA authority and organizational freedom • QA reporting to management • QA access to management 	1. Management <ul style="list-style-type: none"> (i) Program <ul style="list-style-type: none"> • written QA program • organizational structure • functional responsibilities • levels of authority • organizational interfaces • describe management processes 	4.1 Management Responsibility <ul style="list-style-type: none"> • quality policy • organization • responsibility and authority • verification resources and personnel • management representative (for QA) • management review
II. Quality Assurance Program <ul style="list-style-type: none"> • scope of QA program • control consistent with importance • conditions suitably controlled • indoctrination and training • QA program review by management 	1. Management <ul style="list-style-type: none"> (i) Program (ii) Personnel Training and Qualification <ul style="list-style-type: none"> • proficiency maintenance 3. Assessment <ul style="list-style-type: none"> (i) Management Assessment 	4.2 Quality System <ul style="list-style-type: none"> • instructions documented • instructions effectively implemented 4.3 Contract Review 4.18 Training <ul style="list-style-type: none"> • training needs identified • personnel qualified • records of training
III. Design Control <ul style="list-style-type: none"> • design basis • interface control • design verification • design testing • design changes 	2. Performance <ul style="list-style-type: none"> (ii) Design <ul style="list-style-type: none"> • design basis • design verification or validation prior to approval and implementation of the design 	4.4 Design Control <ul style="list-style-type: none"> • design output documentation • design verification • design changes
IV. Procurement Document Control <ul style="list-style-type: none"> • procurement data • contractor QA requirements 	2. Performance <ul style="list-style-type: none"> (iii) Procurement <ul style="list-style-type: none"> • established requirements 	4.6 Purchasing <ul style="list-style-type: none"> • purchasing data • supplier quality system requirements

Table 2-1. Comparison of quality assurance program elements (cont'd)

10 CFR 50, Appendix B (NRC)	10 CFR 830.120 (DOE)	ISO-9001 (International Standard)
<p>V. Instructions, Procedures, and Drawings</p> <ul style="list-style-type: none"> • instructions documented • acceptance criteria included 	<p>1. Management</p> <p>(iv) Documents and Records</p> <ul style="list-style-type: none"> • documents prepared, reviewed, approved, issued, used, and revised to prescribe processes • records specified, prepared, reviewed, approved, and maintained <p>2. Performance</p> <p>(i) Work Processes</p> <ul style="list-style-type: none"> • performed using approved instructions 	<p>4.5 Document and Data Control</p> <ul style="list-style-type: none"> • document review and approval prior to issue
<p>VI. Document Control</p> <ul style="list-style-type: none"> • issuance control • review and approval • distribution to point of use • document changes 	<p>1. Management</p> <p>(iv) Documents and Records</p> <ul style="list-style-type: none"> • documents prepared, reviewed, issued, approved, used, and revised to prescribe processes <p>2. Performance</p> <p>(i) Work Processes</p> <ul style="list-style-type: none"> • performed using approved instruction 	<p>4.5 Document and Data Control</p> <ul style="list-style-type: none"> • documents available at point of use • obsolete documents removed from point use
<p>VII. Control of Purchased Material, Equipment, and Services</p> <ul style="list-style-type: none"> • source evaluation • source selection • source and receipt inspection • contractor assessment 	<p>2. Performance</p> <p>(iii) Procurement</p> <ul style="list-style-type: none"> • supplier evaluation and selection • supplier assessment 	<p>4.6 Purchasing</p> <ul style="list-style-type: none"> • assessment of sub-contractors • subcontractor selection • verification of purchased product • control of purchaser supplied product
<p>VIII. Identification and Control of Materials, Parts, and Components</p> <ul style="list-style-type: none"> • prevent use of incorrect or defective items 	<p>2. Performance</p> <p>(i) Work Processes</p> <ul style="list-style-type: none"> • identification and control to ensure proper use 	<p>4.8 Product Identification and Traceability</p>
<p>IX. Control of Special Processes</p> <ul style="list-style-type: none"> • qualified personnel • qualified procedures 	<p>2. Performance</p> <p>(i) Work Processes</p> <ul style="list-style-type: none"> • performance to established standards and controls 	<p>4.9 Process Control</p> <ul style="list-style-type: none"> • work instructions documented • characteristics controlled and monitored • special processes qualified

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Table 2-1. Comparison of quality assurance program elements (cont'd)

10 CFR 50, Appendix B (NRC)	10 CFR 830.120 (DOE)	ISO-9001 (International Standard)
<p>X. Inspection</p> <ul style="list-style-type: none"> • inspector independence • process monitoring • hold point planning 	<p>2. Performance</p> <p>(iv) Inspection and Acceptance Testing</p> <ul style="list-style-type: none"> • acceptance and performance criteria applied • equipment calibrated and maintained 	<p>4.10 Inspection and Testing</p> <ul style="list-style-type: none"> • receiving inspection • in-process inspection and testing • final inspection and testing • inspection and test records
<p>XI. Test Control</p> <ul style="list-style-type: none"> • test procedures and acceptance criteria documented • test results documented • results evaluated 	<p>2. Performance</p> <p>(iv) Inspection and Acceptance Testing</p> <ul style="list-style-type: none"> • acceptance and performance criteria applied • equipment calibrated and maintained 	<p>4.10 Inspection and Testing</p> <ul style="list-style-type: none"> • in-process inspection and testing • final inspection and testing • inspection and test records
<p>XII. Control of Measuring and Test Equipment</p> <ul style="list-style-type: none"> • calibration and control to maintain accuracy 	<p>2. Performance</p> <p>(i) Work Processes</p> <p>(iv) Inspection and Acceptance Testing</p> <ul style="list-style-type: none"> • equipment calibrated and maintained 	<p>4.11 Control of Inspection, Measurement, and Test Equipment</p> <ul style="list-style-type: none"> • controlled, calibrated and maintained • known measurement uncertainty • use within required capability
<p>XIII. Handling, Storage, and Shipping</p>	<p>2. Performance</p> <p>(i) Work Processes</p>	<p>4.15 Handling, Storage, Packaging, Preservation, and Delivery</p>
<p>XIV. Inspection, Test, and Operating Status</p>	<p>2. Performance</p> <p>(iv) Inspection and Acceptance Testing</p>	<p>4.12 Inspection and Test Status</p>
<p>XV. Nonconforming Materials, Parts, or Components</p> <ul style="list-style-type: none"> • identified and segregated • disposed • documented 	<p>1. Management</p> <p>(iii) Quality Improvement</p> <ul style="list-style-type: none"> • nonconformances identified, controlled and corrected 	<p>4.13 Control of Nonconforming Product</p> <ul style="list-style-type: none"> • identified, documented • evaluated, segregated, disposed
<p>XVI. Corrective Action</p> <ul style="list-style-type: none"> • identified and corrected • cause determined • action to preclude recurrence identified • documented and reported to management 	<p>1. Management</p> <p>(iii) Quality Improvement</p> <ul style="list-style-type: none"> • causes identified • recurrence prevented • processes needing improvement identified 	<p>4.14 Corrective and Preventive Action</p> <ul style="list-style-type: none"> • cause investigated • potential causes detected and eliminated • preventive actions taken • effectiveness of corrective actions determined

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Table 2-1. Comparison of quality assurance program elements (cont'd)

10 CFR 50, Appendix B (NRC)	10 CFR 830.120 (DOE)	ISO-9001 (International Standard)
XVII. Quality Assurance Records <ul style="list-style-type: none"> • records scope • identifiable and retrievable • records retained 	1. Management <ul style="list-style-type: none"> (iv) Documents and Records <ul style="list-style-type: none"> • records specified, prepared, reviewed, approved, and maintained 	4.16 Control of Quality Records <ul style="list-style-type: none"> • identified, collected, indexed, filed, stored, maintained, and disposed
XVIII. Audits <ul style="list-style-type: none"> • written procedures or checklists • results documented • results reported to management • follow-up action 	3. Assessment <ul style="list-style-type: none"> (ii) Independent Assessment <ul style="list-style-type: none"> • assessments planned and conducted • work performance measured and improvement promoted • assessor authority and freedom • assessors technically qualified 	4.17 Internal Quality Audits <ul style="list-style-type: none"> • scheduled based on status and importance • documented procedures • results documented and reported to management • timely corrective action
		Uncorrelated elements: <ul style="list-style-type: none"> 4.7 Control of Customer-Supplied Product 4.19 Servicing <ul style="list-style-type: none"> • when specified by contract 4.20 Statistical Techniques <ul style="list-style-type: none"> • where appropriate to determine process capability and product characteristics

2.1.1 Nuclear Regulatory Commission Regulations

QA provisions of the NRC regulations applicable to licensing various types of nuclear facilities were reviewed to compare their approaches. Summaries of the regulations reviewed are provided in appendix 1 of this report.

In each case, the QA program criteria identified in the regulations were those of 10 CFR Part 50, Appendix B (hereafter called Appendix B) (Nuclear Regulatory Commission, 1975) or slight variations of Appendix B. The various approaches taken by the regulations may be summarized as follows:

- Appendix B is incorporated by reference [10 CFR Part 60, Subpart G and 10 CFR 70.22(f) footnote].
- QA criteria similar to Appendix B are presented, with minor variations from Appendix B to tailor the regulation to the specific application (10 CFR Part 71, Subpart H and 10 CFR Part 72, Subpart G).

- No QA criteria are specified, but guidance identifies Appendix B as an acceptable approach (10 CFR Part 61, guidance in NUREG-1293).
- ASME NQA-1 (American Society of Mechanical Engineers, 1989a), the consensus standard for implementing Appendix B, is identified as the QA program basis (10 CFR 76.93).

While the QA program basis for the NRC regulations is consistent, the method of identifying those criteria and guidance varies, as illustrated in the previous paragraph. In most cases, Appendix B has been determined to be flexible enough that it can be applied to a wide variety of activities other than nuclear power plants and fuel reprocessing facilities, its original target. In a few other cases, such as 10 CFR Parts 71 and 72, the NRC determined that QA criteria tailored to a specific application were beneficial.

Appendix B consists of eighteen criteria that provide control of activities consistent with their importance to safety (table 2-1 identifies the criteria and the major topics within the criteria). The criteria address design, construction, and operation of facilities, as well as programmatic concerns that affect quality and safety such as organization, training, documents, records, quality verification, nonconformance, and corrective action. The criteria are very general, so additional direction or guidance has been necessary to ensure effective implementation of appropriate controls.

2.1.2 Nuclear Regulatory Commission Guidance and Consensus Standards

NRC guidance related to QA is provided in Regulatory Guides and NUREGs. The current population of Regulatory Guides and NUREGs was searched to identify those that provide QA-related guidance, directly or indirectly, to licensees or potential licensees. The pertinent NRC QA-related guidance exists in the following forms.

- Endorsement of consensus standards, with or without additional NRC guidance, as "Regulatory Positions" describing acceptable methods of addressing QA regulatory requirements
- Identification of QA program criteria and/or guidance
- License application format and content guidance
- Licensing document review plans (primarily for the NRC use)
- Results of studies and workshops concerning lessons learned from QA program implementation
- Specific guidance for the high-level waste (HLW) program concerning peer review, existing data, computer code documentation, and items and activities subject to QA requirements

The Regulatory Guides and NUREGs reviewed are listed in appendices 2 and 3 of this report, respectively, along with a brief analysis of each.

The most significant sources of guidance for nuclear power plant QA programs are Regulatory Guides 1.28 and 1.33. Regulatory Guide 1.28 identifies ASME NQA-1 (American Society of Mechanical Engineers, 1989a) as an acceptable method for addressing Appendix B during design and construction. Regulatory Guide 1.33 endorses ANSI/ANS 3.2 (American Nuclear Society, 1994) for application during operations.

ASME NQA-1 is a consensus industry standard consisting of (i) Basic Requirements, essentially equivalent to the individual criteria of Appendix B, (ii) Mandatory Supplements, and (iii) nonmandatory guidance in Appendixes. Each succeeding tier of ASME NQA-1 (i.e., Basic Requirements, Mandatory Supplements, and nonmandatory guidance) provides increasingly more specific methods for addressing the Appendix B criteria. The following example uses design verification criteria to illustrate the levels of guidance provided in ASME NQA-1 for implementation of Appendix B.

Appendix B Criterion III, Design Control:

“...The design control measures shall provide for verifying or checking the adequacy of design, such as by the performance of design reviews, by the use of alternate or simplified calculational methods, or the performance of a suitable testing program. The verifying or checking process shall be performed by individuals or groups other than those that those that who performed the original design, but who may be from the same organization...”

ASME NQA-1, 3. Design Control Basic Requirement:

“...Design adequacy shall be verified by persons other than those who designed the item...”

ASME NQA-1, Supplement 3S-1, Mandatory Supplement on Design: Design Verification

“Design control measures shall be applied to verify the adequacy of the design, such as by one or more of the following: the performance of design reviews, the use of alternate calculations, or the performance of qualification tests. Verification of computer programs shall include appropriate testing. The responsible design organization shall identify and document the particular design verification method(s) used. The results of the design verification shall be clearly documented with the identification of the verifier clearly indicated. Design verification shall be performed by any competent individual(s) or group(s) other than those who performed the original design but who may be from the same organization. The verification may be performed by the originator’s supervisor, provided the supervisor did not specify a singular design approach or rule out certain considerations and did not establish the design inputs used in the design, or provided the supervisor is the only individual in the organization competent to perform the verification. cursory supervisor reviews do not satisfy the intent of this Standard.

Verification shall be performed in a timely manner. Design verification, for the level of design activity accomplished, shall be performed prior to release for procurement, manufacture, construction, or release to another organization for use in other design activities except in those cases where this timing cannot be met, such as when

insufficient data exist. In those cases, the unverified portion of the design shall be identified and controlled. In all cases, the design verification shall be completed prior to relying upon the component, system, structure, or computer program to perform its function.

4.1 Extent of Design Verification

The extent of the design verification required is a function of the importance to safety, the complexity of the design, the degree of standardization, the state of the art, and similarity with previously proven designs. Where the design has been subjected to a verification process in accordance with this Standard, the verification process need not be duplicated for identical designs. However, the applicability of standardized or previously proven designs, with respect to meeting pertinent design inputs, shall be verified for each application. Known problems affecting the standard or previously proven designs and their effects on other features shall be considered. The original design and associated verification measures shall be adequately documented and referenced in the files of subsequent application of the design.

Where changes to previously verified designs have been made, design verification shall be required for the changes, including evaluation of the effects of those changes on the overall design and on any design analyses upon which the design is based that are affected by the change to previously verified design.

4.2 Methods

Acceptable verification methods include, but are not limited to, any one or a combination of the following: design reviews, alternate calculations, and qualification testing.

4.2.1 Design Reviews. These are critical reviews to provide assurance that the final design is correct and satisfactory. Where applicable, (a) through (f) below shall be addressed.

- (a) Were the design inputs correctly selected?
- (b) Are assumptions necessary to perform the design activity adequately described and reasonable? Where necessary, are the assumptions identified for subsequent reverifications when the detailed design activities are completed?
- (c) Was an appropriate design method used?
- (d) Were the design inputs correctly incorporated into the design?
- (e) Is the design output reasonable compared to design inputs?
- (f) Are the necessary design input and verification requirements for interfacing organizations specified in the design documents or in supporting procedures or instructions?

4.2.2 Alternate Calculations. These are calculations or analyses that are made with alternate methods to verify correctness of the original calculations or analyses. The appropriateness of assumptions, input data used, and the computer program or other calculation method used shall also be reviewed.

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4.2.3 Qualification Tests. Where design adequacy is to be verified by qualification tests, the tests shall be identified. The test configuration shall be clearly defined and documented. Testing shall demonstrate adequacy of performance under conditions that simulate the most adverse design conditions. Operating modes and environmental conditions in which the item must perform satisfactorily shall be considered in determining the most adverse conditions. Where the test is intended to verify only specific design features, the other features shall be documented and evaluated by the responsible design organization to assure that test requirements have been met.

If qualification testing indicates that modifications to the item are necessary to obtain acceptable performance, the modification shall be documented and the item modified and retested or otherwise verified to assure satisfactory performance. When tests are being performed on models or mock-ups, scaling laws shall be established and verified. The results of model test work shall be subject to error analysis, where applicable, prior to use in final design work."

ASME NQA-1, Appendix 3A-1, Nonmandatory Guidance on Design Control: Design Verification

"Design verification for some designs or specific design features may be achieved by suitable qualification testing of a prototype or initial production unit. Qualification testing may be used in combination with other verification methods. For example, it may be most effective to verify that an instrument cabinet is designed to withstand the maximum earthquake-caused vibratory motions by actually subjecting the cabinet and its associated components to shaker tests which correspond to these vibratory motions. The shaker tests will not, however, verify that the circuitry is designed correctly or that the component in the cabinet will perform its intended function. Other tests or verification means are required to confirm that remaining design functions are adequately performed by the instrumentation and that those components perform the intended functions for the varying conditions in which they are subjected."

For nuclear power plant operations, ANSI/ANS-3.2 provides guidance for implementing Appendix B emphasizing maintenance, surveillance testing, calibration and inspections, configuration management of design modifications, fire protection, chemistry and radiochemistry, radioactive waste control, and housekeeping and cleanliness. Again, using design control as an example, ANSI/ANS-3.2 refers to ASME NQA-1 for basic design controls, but addresses a uniquely operational concern as follows:

"5.2.10 Configuration Management. A configuration management program shall be implemented to ensure that plant facilities, equipment, drawings, and procedures continue to reflect plant design accurately throughout the life of the plant. As a minimum, the program shall clearly identify responsibilities and provide controls for:

- (1) Documenting, reviewing, approving, and revising design inputs and assumptions.
- (2) Translating design inputs and assumptions into design requirements
- (3) Ensuring that design requirements are accurately reflected by plant facilities and physical features.

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- (4) Ensuring that plant procedures and training materials are consistent with design inputs and assumptions, design output documents, accident analysis assumptions and results, and plant licensing documents.
- (5) Ensuring that affected documents are changed when related documents in the program are changed.
- (6) Providing access to design input, design output, and accident analysis documents for personnel who develop or revise plant procedures."

For NRC regulations other than 10 CFR Part 50, the QA guidance for operations has not been separate from the guidance applied to design and construction. Several NUREGs have identified ASME NQA-1 as a source of implementation guidance for all phases of activities.

2.2 SURVEY OF U.S. DEPARTMENT OF ENERGY REGULATIONS AND GUIDANCE

The DOE has applied two QA regulations to its nuclear-related activities. 10 CFR Part 50, Appendix B is being applied to DOE nuclear activities that are regulated by the NRC, in particular those under 10 CFR Part 60 (Nuclear Regulatory Commission, 1991). 10 CFR 830.120 (U.S. Department of Energy, 1994a), which is also known as DOE Order 5700.6C, is applied to DOE activities other than those regulated by the NRC. 10 CFR 830.120 has 10 program elements organized broadly under management, performance, and assessment topics.

The DOE has implemented a QA program for their HLW program addressing Appendix B. This program, which is regulated by the NRC through 10 CFR Part 60, uses ASME NQA-1 as the requirements basis. Additional requirements for this program are provided through the QA Requirements and Description (QARD) document (U.S. Department of Energy, 1995). NRC guidance for 10 CFR Part 60 QA programs is provided in NUREGs -0856, -1297, -1298, -1318, and -1323 (see appendix 3 for summaries of these NUREGs). These NUREGs are addressed in the main text of the QARD and in its supplements, establishing requirements in addition to the 18 Appendix B criteria. QARD appendices covering the range of DOE HLW-related functions—High Level Waste Form Production, Transportation, and Mined Geologic Disposal System—identify additional requirements tailored to the specific type of activity.

The design verification example was used again to compare the QARD with other guidance. A detailed analysis of the QARD showed it to be essentially identical to ASME NQA-1; Design Control Basic Requirement and Mandatory Supplement 3S-1.

DOE nuclear facilities not regulated by the NRC are required to develop and implement QA programs in compliance with 10 CFR 830.120; its program elements and major topics are shown in table 2-1. In addition to containing program elements common to most other quality programs, 10 CFR 830.120 has a clear emphasis on quality improvement. Section 1 (iii) requires "processes to detect and prevent quality problems" and analysis to "identify items, services, and processes needing improvement." In addition, 10 CFR 830.120 has been characterized as having a performance-based approach (Hawkins, 1991) to QA. The performance-based approach is most evident in section 3 (ii), which requires that independent assessment be "planned and conducted to measure item and service quality, to measure the adequacy of work performance, and to promote improvement"

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(emphasis added). This contrasts with the more commonly applied programmatic approach, which indirectly measures quality program effectiveness by assessing program controls.

The DOE has developed an implementation guide for 10 CFR 830.120 (U.S. Department of Energy, 1994b). Using the design vitrification process as an example, it appears that this DOE guidance addresses the same topics as ASME NQA-1, but in less detail:

“6.5 Design Verification. Design verification is a formal documented process to establish that the resulting system, structure, or component will be fit for the intended use. Design verification methods include, but are not limited to, technical reviews, peer reviews, alternate calculations, and qualification testing. When appropriate, the verification process may take previous validations of similar designs or on similar features of other designs into account. The design verification process may be used to identify opportunities for improvements in the efficiency, productivity, safety, reliability, or cost of the designed system, structure, or component.

Design verification should be performed by technically knowledgeable persons separate from those who performed the design. Interim verifications may be made at predetermined stages of design development. The extent and number of design verifications should be based on a graded approach and should depend on the designed product's complexity and importance to project success.”

The DOE implementation guide also identifies consensus standards and other documents that may be used for additional guidance. These standards include ISO-9001 (International Organization for Standardization, 1994a) which is discussed in section 2.3 of this report, ASME NQA-1, and the QARD.

DOE contracts for the privatization of TWRS activities related to waste processing require the contractors to develop and implement QA programs addressing 10 CFR 830.120. In addition to the 10 CFR 830.120 implementation guide (U.S. Department of Energy, 1994b), the privatization contractors were provided with the DOE guide for reviewing the privatization contractor QA programs (U.S. Department of Energy, 1996), which focuses on how 10 CFR 830.120 applies in the early stages of TWRS activities, primarily planning and design. For the design verification example, the review guide quoted directly from the 10 CFR 830.120 implementation guide, but in other QA program elements, guidance pertinent to the specific scope of work was provided.

For the privatization contracts, QA is presented as part of a larger, more general area that includes radiological, nuclear, and process safety. This health and safety orientation emphasizes process risk analysis is addressed in the Occupational Safety and Health Administration (OSHA) regulation in 29 CFR 1910.119, (Occupational Safety and Health Administration, 1996). Section 2.3 of this report discusses 29 CFR 1910.119 as it is applied in the chemical process industry, an industry comparable to the TWRS in terms of nonradiological hazards.

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2.3 SURVEY OF HAZARDOUS CHEMICALS PROCESSING INDUSTRY QUALITY ASSURANCE PRACTICES

Literature surveys of QA programs used in the chemical processing industry revealed two distinct areas of program focus; on product quality and on process safety management. In regard to product quality, the ISO-9001 consensus standard has been applied. As illustrated in table 2-1, ISO-9001 consists of 20 program elements, 18 of which closely mirror Appendix B criteria. ISO-9001 adds servicing and statistical techniques as two additional elements. ISO-9001 provides an emphasis on quality improvement in the corrective action element by adding preventive action for potentially adverse conditions in addition to requiring action for existent adverse conditions.

Following the previous design verification examples, ISO-9001 is comparable to Appendix B in level of detail and topics covered, but is not as detailed as NQA-1 Mandatory Supplement 3S-1. ISO-9001 addresses design verification as follows:

“The supplier shall plan, establish, document, and assign to competent personnel functions for verifying the design.

Design verification shall establish that the design output meets the design input requirements by means of design control measures such as:

- (a) holding and recording design reviews;
- (b) undertaking qualification tests and demonstrations;
- (c) carrying out alternative calculations;
- (d) comparing the new design with a similar proven design, if available.”

The survey did not reveal any specific application of ISO-9001 to items and activities important to safety, which has been the most common application for the nuclear QA regulations and standards. However, further investigation into the areas of process safety, hazards, and accidents identified 29 CFR 1910.119 (Occupational Safety and Health Administration, 1996) as the regulation applicable to process safety management of highly hazardous chemicals. The OSHA regulation provides an analog to the regulation of nuclear-related items and activities important to safety, although 29 CFR 1910.119 is slightly more focused on worker safety.

An analysis of 29 CFR 1910.119 shows close parallels to typical QA program criteria, addressing requirements for (i) a formally documented program and procedures, (ii) training, and (iii) audits. The primary focus of 29 CFR 1910.119 is on hazards analysis, which has elements in common with the design control element of QA programs. This type of analysis is also required by draft NUREG-1520 (Nuclear Regulatory Commission, 1995), for integrated safety analysis. In further comparison to QA program requirements, the OSHA regulation provides greater industry specific detail, and some typical QA criteria (e.g., identification and control of items, special process controls, and records) are absent.

Guidance for implementing 29 CFR 1910.119 has been developed by industry groups such as the American Institute for Chemical Engineers (AIChE), which established the Center for Chemical Process Safety in March 1985 (Carmody, 1990; Schreiber, 1990, 1991, 1994; Stricoff, 1990; Sweeney, 1992; Connelly, 1993; Gallup, 1993). The guidance describes specific methods, including process hazard

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analysis, that may be employed in process safety management. Both the OSHA and AICHE actions were precipitated by accidents at Bhopal, India and other locations.

2.4 SURVEY OF NUCLEAR QUALITY ASSURANCE PROGRAM IMPLEMENTATION LESSONS LEARNED

The survey identified two reports of significant activities that have been initiated to evaluate nuclear power plant QA program implementation. Investigations published in NUREG-1055, Improving Quality and the Assurance of Quality in the Design and Construction of Nuclear Power Plants (Altman et al., 1984) were initiated by the "Ford Amendment" to the NRC Authorization Act for fiscal years 1982-1983. Its purpose was to determine the causes and possible solutions to quality problems in the construction of several nuclear power plants. NUREG/CP-0129, Workshop on Program for Elimination of Requirements Marginal to Safety (Dey et al., 1993) compiled the results of an NRC sponsored workshop documenting the experiences of utilities and their support contractors during the nuclear power plant operations phase.

NUREG-1055 identified root causes of construction QA program failures as

- General management breakdowns, which led to failure of the quality system
- Lack of nuclear experience, from the perspectives of the regulatory environment and technical complexity
- Construction project participants assuming roles beyond their experience and capabilities
- NRC activities focusing primarily on operating plants, less on construction, and even less on design (because the risk to the public was construed as less in the earlier phases of activities)
- NRC deemphasizing the utility's capability to manage when the construction permit was authorized
- NRC placing more importance on descriptions of QA programs than on implementation

The recommendations of the study included (i) minimizing the number of design changes (through more complete design prior to initiation of construction), (ii) conditioning construction permits (CPs) on post-CP demonstration by the applicant of its management capability and effectiveness, (iii) utilizing audits by industry groups as well as NRC assessments, (iv) expanding the resident inspector program to plants under construction, focusing on performance rather than on form and documentation, with routine assessments of management capability rather than only when remedial action is necessary, and (v) using comprehensive third party audits of plants under construction and of future CP applicants, along with NRC Construction Appraisal Team inspections.

NUREG/CP-0129 concluded that Appendix B is basically sound and allows some flexibility but is focused on design (as opposed to operation), and its language encourages an emphasis on form rather than performance. Implementation guidance and nuclear power plant QA organizations have emphasized compliance and documentation rather than performance.

Recommendations and observations of workshop participants were

- QA needs to become a function of the entire organization.
- Many other countries have used Appendix B for guidance, but generally apply a less strict interpretation of the requirements.
- The needed changes in QA program implementation do not require, but may be facilitated by, revision of Appendix B.
- QA should be focused on the areas that have risk significance, using the insights provided by risk assessments.
- QA audits could be replaced by performance monitoring activities. Some participants stated that cultural changes (to performance monitoring) are needed, in the industry approach and in NRC implementation, inspection, and enforcement.

The NRC has also had experience with the implementation of the DOE HLW QA program, which addresses Appendix B. While this experience has not been formally summarized and analyzed, many of the same types of problems were encountered, as reported in NUREG-1055 and NUREG/CP-0129, in some cases causing stop-work orders. Some program participants were not accustomed to operating in a highly regulated environment and were not experienced in applying QA to research and development activities. Many questioned the appropriateness and applicability of Appendix B to research and development because of its orientation toward design, construction, and operation in an engineered (as opposed to a natural, more variable) environment.

The NRC has an ongoing initiative regarding graded QA (Nuclear Regulatory Commission, 1996). A program incorporating graded QA varies the level of control based on the importance of an item or activity to safety (or to other objectives of the QA program). Appendix B, consensus standards and other lessons learned encourage application of a graded approach, but graded QA programs have been utilized in relatively few situations.

The NRC initiative on graded QA is intended to provide a safety benefit by allowing licensees and the NRC to preferentially allocate resources to items of higher safety significance, and to provide cost savings by reducing the resources spent on items of less safety significance. Four essential elements of a graded QA program have been identified by the NRC:

- A process that determines the safety significance of structures, systems, and components (SSCs) in a reasonable and consistent manner
- The implementation of appropriate QA controls for SSCs, or groups of SSCs, according to safety function and safety significance
- An effective root-cause analysis and corrective action program
- A means of reassessing SSC safety significance and QA controls when new information becomes available

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Utilizing this NRC approach to graded QA, the safety significance determination should integrate deterministic and probabilistic risk assessments and should utilize an expert panel to determine safety significance levels. The highest safety significance items would normally retain existing controls. For lower safety classifications, reduced controls, such as reduced sampling, documentation, or verification may be appropriate, but a reasonable level of confidence should be preserved that each SSC will perform required safety functions. Corrective actions and root-cause analysis should consider whether the specific graded QA controls for SSCs are sufficient. Failures of lower safety significance items should be evaluated to determine if reduced controls cause unacceptable decreases in performance. Likewise, operational feedback should be used to assess both the safety significance determination and the QA controls.

Gaseous diffusion plants operating under 10 CFR Part 76 (ASME NQA-1 QA program requirements) have implemented graded QA programs that have been accepted by the NRC (United States Enrichment Corporation, 1996). The QA grading defines categories Q (all QA program sections apply), AQ (Augmented Quality—all, part, or alternatives to the Q requirements are imposed), and NS (Non-Safety, to which the QA program does not apply). The quality categorization was determined considering (i) the applicable regulations, codes, and standards; (ii) the complexity or uniqueness of an item (or activity) and the environment in which it has to function; (iii) the quality history of the item in service; (iv) the degree to which functional compliance may be demonstrated or assessed by testing, inspection, or preventive maintenance; (v) the anticipated life of the item; (vi) the degree of standardization of the item; (vii) the importance of data generated; (viii) the reproducibility of results; and (ix) the consequence of failure.

In summary, the lessons learned from nuclear QA program implementation are that (i) the basic criteria of Appendix B are valid, (ii) licensee success is dependent upon the experience of their team in regulated nuclear activities, (iii) early involvement and identification of problem areas by the regulator are essential, and (iv) a graded approach can be utilized to provide an effective and economical QA program.

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3 ANALYSIS OF THE QUALITY ASSURANCE PROGRAM SURVEY

3.1 Analysis of Quality Assurance Program Regulations and Standards

Summaries of the 10 CFR Part 50, Appendix B; 10 CFR 830.120; and ISO-9001 QA program requirements are presented in table 2-1. The table and the discussions in the text indicate that the various QA program regulations and standards address similar program elements in similar fashions. The differences between the QA programs appear in terms of the areas of emphasis. For example, continuous improvement is identified in 10 CFR 830.120 and ISO-9001, a graded application of QA criteria is identified in Appendix B and 10 CFR 830.120, and performance-based assessments are identified 10 CFR 830.120 and are suggested in Appendix B guidance. Of particular significance is that the differences in the QA program approaches do not constitute conflicts among the QA programs. The areas of emphasis, along with the lessons learned from QA program implementation, comprise QA program attributes that should be embodied in the QA program for the TWRS. Specifically, the TWRS QA program should

- Address the 18 criteria of Appendix B
- Promote continuous improvement
- Provide a graded approach based on safety significance
- Provide a performance-based approach

The three QA programs that may be considered for the TWRS, Appendix B, 10 CFR 830.120, and ISO-9001, were evaluated with regard to these attributes, and the evaluation is illustrated in table 3-1.

While none of the three QA programs is ideal relative to these attributes, Appendix B and 10 CFR 830.120 capture most of the attributes. Except for continuous improvement, which is not specifically addressed in Appendix B, the NRC and DOE regulations appear to be equivalent at the topical level.

In order to determine the degree to which Appendix B and 10 CFR 830.120 are similar at a more detailed level, an additional analysis was performed. Several areas of potentially significant differences were identified. The following paragraphs discuss those areas and identify sources of information that may resolve the differences.

QA Organizational Independence: Criterion I of Appendix B is explicit with respect to (i) identifying QA functions, including verification (checking, auditing, inspecting), (ii) requiring authority and organizational freedom of the QA organization (i.e., those performing QA functions), and (iii) specifying QA organizational reporting and access to management. Furthermore, most NRC standard review plans (e.g., NUREGs 0800 and 1520) require that conformance to specified requirements be verified by individuals or groups within an independent QA organization. In contrast, 10 CFR 830.120 requires only that the QA program describe the organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work. However, under the

Table 3-1. Comparison of quality assurance program attributes

Attributes	10 CFR 50, Appendix B (NRC)	10 CFR 830.120 (DOE)	ISO-9001 (International Standard)
Addresses the 18 criteria of Appendix B	Yes	Yes ¹	Yes
Promotes continuous improvement	No	Yes	Yes
Provides for a graded approach based on safety significance	Yes	Yes	No
Provides for a performance-based approach	Yes ²	Yes	No
¹ Table 2-1 demonstrates how the 10 criteria of 10 CFR 830-120 address the 18 criteria of Appendix B. ² Appendix B addresses the performance-based approach through regulatory guides.			

section entitled "Independent Assessment," the DOE regulation requires that the group performing independent assessments have sufficient authority and freedom to carry out its responsibilities. The independence criteria of 10 CFR 830.120 are consistent with most of the Appendix B criteria.

Organizational independence is addressed by the DOE implementation guide (U.S. Department of Energy, 1994b) which includes within its discussion of independent assessments such methods as inspections, peer and technical reviews, audits, and surveillances. This list of methods is essentially the same as the Appendix B, criterion I list of QA functions. The DOE implementation guide also places conditions on the organization performing independent assessments similar to the conditions placed upon the QA organization by Appendix B, that is, reporting to a sufficiently high level of management to ensure organizational independence and access to appropriate levels of authority.

Audits versus Assessments: Criterion 18 of Appendix B requires audits to verify compliance with the QA program and to determine its effectiveness. In contrast, 10 CFR 830.120 requires independent assessment to measure item and service quality, to measure the adequacy of work performance, and to promote improvement. Aside from the emphasis on performance (results) and on improvement, the difference in terminology causes concern as to whether Appendix B audits would be satisfied by 10 CFR 830.120 independent assessments.

The implementation guide resolves this concern by defining the range of independent assessments to include methods such as inspections, peer and technical reviews, audits, surveillances, or combinations thereof.

Level of Detail: Many of the requirements of 10 CFR 830.120 are less explicit than the corresponding requirements of Appendix B. However, the analysis found no areas of contradiction between the two regulations and no omissions of program requirements.

This general concern may be resolved by the DOE 10 CFR 830.120 implementation guide (U.S. Department of Energy, 1994b), which includes references to applicable standards. The standards "provide acceptable methods for implementing many of the requirements.... The principles, recommended approaches, and applications contained in these standards may be used in conjunction with 10 CFR 830.120 in the development and implementation of an effective...system."

Using the design control element as an example, the 10 CFR 830.120 implementation guide identifies consensus standards as additional sources of guidance, including:

- ISO-9001, Section 4.4, Design Control (International Organization for Standardization, 1994a)
- ISO-9004, Section 8, Quality in Specification and Design (International Organization for Standardization, 1994b)
- DOE/RW/0333P Section 3.0, Design Control and Supplement I, Software (U.S. Department of Energy, 1995)
- ASME NQA-1 Basic Requirement 3, Design Control, Supplement 3S-1, Supplementary Requirements for Design Control, and Nonmandatory Appendix 3A-1, Nonmandatory Guidance on Design Control (American Society of Mechanical Engineers, 1989a)
- ASME NQA-2, Part 2.7, Quality Assurance Requirements for Computer Software for Nuclear Facility Applications (American Society of Mechanical Engineers, 1989b).

Therefore, the consensus standards developed to aid implementation of Appendix B (i.e., NQA-1 and NQA-2) are also being identified as guidance for implementing 10 CFR 830.120. As a consequence, QA programs developed to address the DOE regulation are likely to address Appendix B criteria.

This analysis of Appendix B and 10 CFR 830.120 indicates that the 10 CFR 830.120 approach, controls, and extent of control are similar to those of Appendix B. Consequently, 10 CFR 830.120 may be considered to be equivalent to Appendix B so long as the implementation guidance is appropriately used.

3.2 Analysis of Approaches to Regulations and Guidance

Based on the survey described in chapter 2 of this report, three options of presenting QA program criteria in NRC regulations are used. Each of these is briefly discussed in the following paragraphs with a discussion of potential application to the TWRS.

Direct Reference to Appendix B: 10 CFR Part 60, Subpart G and other NRC regulations identify QA criteria by direct reference to Appendix B, with brief clarification of the scope and

application of the QA criteria to the specific regulatory program. While this approach is consistent with NRC practice, it does not capture the attribute of continuous improvement. As was necessary for nuclear power plants, NRC guidance may be necessary to emphasize the QA program characteristics not specifically mentioned in Appendix B, and to provide any necessary tailoring of Appendix B for the application to the TWRS.

Unique QA Criteria: 10 CFR Part 71, for packaging and transportation of radioactive material, lists unique QA criteria organized into 18 elements that are minor variations of the corresponding Appendix B criteria. This approach has merit in that the QA program attributes lacking in Appendix B could be provided, as well as any tailoring necessary to suit the TWRS. Presentation of the QA program requirements in 18 criteria would be consistent with NRC practice, so long as major departures from the basic requirements of Appendix B were not taken.

Reference to a Consensus Standard: 10 CFR Part 76, for gaseous diffusion plants, identifies NQA-1 as its QA program requirements. While requiring an NQA-1 program is roughly the same as requiring an Appendix B program, identifying a consensus standard may open up the option of citing other standards, such as ISO-9001, or perhaps another regulation, such as 10 CFR 830.120. As is evident from table 3-1, ISO-9001 would require considerable guidance to address graded and performance-based QA, but guidance could not overcome its inconsistency with both NRC and DOE practices. As discussed in section 3.1, 10 CFR 830.120, with its implementation guide and referenced consensus standards, is equivalent to Appendix B. The most significant obstacle to the use of 10 CFR 830.120 may be NRC staff acceptance of an approach that does not explicitly follow the 18 criteria of Appendix B.

4 RECOMMENDED APPROACH TO NUCLEAR REGULATORY COMMISSION QUALITY ASSURANCE REGULATION OF THE TANK WASTE REMEDIATION SYSTEM

As indicated in the analysis presented in chapter 3 of this report, ideal QA program regulation and guidance would have all of the attributes listed in table 3-1. Therefore, for the TWRS QA regulation/guidance, the CNWRA recommends that the NRC develop an approach that encompasses all of the attributes through unique QA criteria using the models of 10 CFR Parts 71 and 72, to provide

- Format following the organization of the 18 criteria of Appendix B
- Basic requirements inclusive of Appendix B and 10 CFR 830.120 criteria
- Continuous improvement
- A graded approach based on safety significance
- A performance-based approach

DOE QA programs developed to meet 10 CFR 830.120 and using the appropriate guidance should satisfy this regulation/guidance. In other words, if TWRS QA programs are developed prior to NRC regulation or guidance and use appropriate DOE guidance, these programs are likely to satisfy NRC requirements.

The TWRS QA program requirements can be developed by enhancements to several of the elements of Appendix B, as follows:

- To promote **continuous improvement**, Criterion XVI—Corrective Action should address failure prevention and continuous improvement by requiring that “Measures shall be established to assure that conditions adverse to quality and potentially adverse to quality...are promptly identified and corrected...”. Criterion XVIII—Audits should expand the objectives “...to verify compliance with all aspects of the quality assurance program, to determine the effectiveness of the program, and to promote improvement.”
- The **graded approach**, already suggested in Criterion II—Quality Assurance Program, could be enhanced to “...provide control...to an extent consistent with their importance to safety using a graded approach.” The scope of control could also be expanded beyond safety to reliability, product performance, and environmental considerations.
- The **performance-based approach** could be addressed in Criterion I—Organization, which should expand the definition of QA functions, to include “...verifying, such as by inspections, peer and technical reviews, audits, surveillances, or combinations thereof that activities most directly related to final objectives and safety, reliability, and product performance have been properly performed.” Criterion XVIII—Audits, should include “...to verify compliance with all aspects of the quality assurance program, to determine the effectiveness of the program, to measure the adequacy of work performance,... .”

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In addition to QA program criteria, NRC should provide guidance for implementation of the TWRS QA regulation which includes

- Identification of the consensus standards and other sources of guidance, such as NQA-1 (American Society of Mechanical Engineers, 1989a), NQA-2 (American Society of Mechanical Engineers, 1989b), ISO-9001 and ISO-9004 (International Organization for Standardization, 1994b), and 10 CFR 830.120 and its implementation guide (U.S. Department of Energy, 1994b). An endorsement of consensus standards may include requirements to comply with certain nonmandatory guidance, as was done in Regulatory Guide 1.28 (see appendix 2). However, an endorsement of consensus standards should not contradict the TWRS QA enhancements to Appendix B discussed above.
- Acceptance of QA programs developed to meet 10 CFR 830.120 provided that the QA programs adequately incorporate the 10 CFR 830.120 implementation plan and its referenced consensus standards.

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5 CONCLUSIONS

The objective of this task was to recommend to the NRC an approach to QA regulation and guidance for the TWRS. The survey of regulations, guidance, QA practices, and lessons learned from nuclear QA program implementation was undertaken to identify the various approaches taken by the NRC, the DOE, and in the chemical processing industry with similarly hazardous processes.

The survey revealed (i) a common basis in all of the QA programs, (ii) differences in programs in terms of areas of emphasis, but no conflict, and (iii) a number of somewhat different approaches that had been taken in the NRC QA regulations.

The subsequent analysis compared the existing QA program regulations and standards and developed a compilation of attributes from these QA programs. While none of the three QA regulations/standards—10 CFR Part 50, Appendix B; 10 CFR 830.120; or ISO-9001—appeared to address all attributes, Appendix B and 10 CFR 830.120 include most of them. More detailed analysis, when taking implementation guidance into account, revealed equivalent criteria and controls in Appendix B and 10 CFR 830.120.

For the TWRS, CNWRA recommends that the NRC provide a QA regulation and guidance unique to the TWRS, structured around the 18 criteria of Appendix B, and capturing the emphasis of 10 CFR 830.120 on continuous improvement and an explicit performance-based approach. This approach would also provide a seamless transition from DOE to NRC QA regulation of the TWRS.

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6 REFERENCES

- Altman, W., T. Ankrum, and W. Brach. 1984. *Improving Quality and the Assurance of Quality in the Design and Construction of Nuclear Power Plants*. NUREG-1055. Washington, DC: Nuclear Regulatory Commission.
- American Nuclear Society. 1994. *Quality Assurance for the Operational Phase of Nuclear Power Plants*. ANSI/ANS-3.2-1994. La Grange Park, IL: American Nuclear Society.
- American Society of Mechanical Engineers. 1989a. *Quality Assurance Program Requirements for Nuclear Facilities*. NQA-1-1989. New York, NY: American Society of Mechanical Engineers.
- American Society of Mechanical Engineers. 1989b. *Quality Assurance Requirements for Nuclear Power Plants*. NQA-2-1989. New York, NY: American Society of Mechanical Engineers.
- Carmody, T.W. 1990. Update on AIChE's center for chemical process safety. *Plant/Operations Progress* 9(3): 141-142.
- Connelly, E. 1993. Process safety management system performance measures for the chemical industry. *Proceedings of the Human Factors and Ergonomics Society 37th Annual Meeting—1993*. Santa Monica, CA: Human Factors Society 2: 896-900.
- Dey, M., F. Arsenault, M. Patterson, and M. Gaal. 1993. *Workshop on Program for Elimination of Requirements Marginal to Safety*. NUREG/CP-0129. Washington, DC: Nuclear Regulatory Commission: 119-145.
- Gallup, J.G. 1993. Process safety management of highly hazardous chemicals. *AIPE Facilities: The Journal of Plant and Facilities Management and Engineering* 20(6): 40-42.
- Hawkins, F.C. 1991. Quality assurance: a performance-based approach. *Proceedings of the Eighteenth Annual National Energy Division Conference*. Danvers, MA: American Society for Quality Control: 6B 1.1-1.7.
- International Organization for Standardization. 1994a. *Quality Systems—Model for Quality Assurance in Design/Development, Production, Installation, and Servicing*. ISO-9001. Geneva, Switzerland: International Organization for Standardization.
- International Organization for Standardization. 1994b. *Quality Management and Quality System Elements—Guidance*. ISO-9004. Geneva, Switzerland: International Organization for Standardization.
- Nuclear Regulatory Commission. 1975. *Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants*. Title 10, Energy, Part 50, Appendix B. Washington, DC: U.S. Government Printing Office.
- Nuclear Regulatory Commission. 1991. *Disposal of High-Level Radioactive Wastes in Geologic Repositories*. Title 10, Energy, Part 60. Washington, DC: U.S. Government Printing Office.

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- Nuclear Regulatory Commission. 1995. *Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility*. Draft NUREG-1520. Washington, DC: Nuclear Regulatory Commission, Office of Nuclear Material Safety and Safeguards: 4.0-1 through 4.0-14.
- Nuclear Regulatory Commission. 1996. *NRR Draft Evaluation Guide—Development of Graded Quality Assurance Programs*. Draft—Revision 5. January 1996.
- Occupational Safety and Health Administration. 1996. *Process Safety Management for Highly Hazardous Chemicals*. Title 29, Labor, Part 1910 (29 CFR 1910.119). Washington, DC: U.S. Government Printing Office.
- Schreiber, S. 1990. The center for chemical process safety. *Plant/Operations Progress* 9(3): 143-144.
- Schreiber, S. 1991. Guidelines for technical management of chemical process safety. *Plant/Operations Progress* 10(2): 65-68.
- Schreiber, S. 1994. Measuring performance and effectiveness of process safety management. *Process Safety Progress* 13(2): 64-68.
- Stricoff, R.C. 1990. Implementing process safety management systems. *Plant/Operations Progress* 9(4): 236-237.
- Sweeney, J.C. 1992. Measuring process safety management. *Plant/Operations Progress* 11(2): 89-98.
- U.S. Department of Energy. 1994a. *Quality Assurance*. Title 10, Energy, Part 830 (10 CFR 830.120). Washington, DC: U.S. Government Printing Office.
- U.S. Department of Energy. 1994b. *Implementation Guide for Use with 10 CFR Part 830.120 Quality Assurance Final Guide*. DOE G-830.120-Rev. 0. Washington, DC: U.S. Department of Energy.
- U.S. Department of Energy. 1995. *Office of Civilian Radioactive Waste Management Quality Assurance Requirements and Description*. DOE/RW-0333P, Revision 5. Washington, DC: U.S. Department of Energy.
- U.S. Department of Energy. 1996. *Guidance for Review of TWRS Privatization Contractor Initial Quality Assurance Program*. DOE/RL/REG-96-1. Richland, WA: U.S. Department of Energy, Richland Operations Office, Office of Radiological, Nuclear, and Process Safety Regulation for TWRS Privatization Contractors.
- United States Enrichment Corporation. 1996. *Quality Assurance Program—Gaseous Diffusion Plants*. Revision 3, May 31, 1996. Paducah, KY: United States Enrichment Corporation.

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APPENDIX 1

**NUCLEAR REGULATORY COMMISSION REGULATIONS FOR
QUALITY ASSURANCE**

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NUCLEAR REGULATORY COMMISSION REGULATIONS FOR QUALITY ASSURANCE

10 CFR Part 50, Appendix B Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants

Eighteen quality program elements are identified which apply to site characterization, design, construction, operation, and decommissioning/closure. A graded approach, applying controls consistent with the importance to safety of an item or activity, is identified.

10 CFR Part 60 Disposal of High-Level Radioactive Wastes in Geologic Repositories

Subpart G (60.150-60.152), The regulation is applied to structures, systems, and components important to safety, design and characterization of barriers important to waste isolation, and related activities. The QA program is to be based on the criteria of Appendix B, as applicable to the scope of high-level waste disposal activities.

10 CFR Part 61 Licensing Requirements for Land Disposal of Radioactive Wastes

The license application must describe the quality assurance program developed and applied by the applicant for the determination of natural disposal site characteristics and for quality assurance during design, construction, operation, and closure of the land disposal facility and the receipt, handling, and emplacement of waste. Specific quality assurance criteria are not provided in the regulation; however, NUREG-1293, Quality Assurance Guidance for Low-Level Radioactive Waste Disposal Facility (Pittiglio, 1989) endorses Appendix B.

10 CFR Part 70 Domestic Licensing of Special Nuclear Material

The license application must contain a description of the quality assurance program to be applied to the design, fabrication, construction, testing and operation of the structures, systems, and components of the plant, including a discussion of how the criteria in Appendix B of 10 CFR Part 50 will be met.

10 CFR Part 71 Packaging and Transportation of Radioactive Material

Quality assurance criteria similar to the eighteen criteria of Appendix B are identified, but with additional requirements specific to transportation package design, construction, and use. The regulation indicates that existing Appendix B programs are acceptable for meeting these criteria.

10 CFR Part 72 Licensing Requirements for the Independent Storage of Spent Nuclear Fuel and High-Level Radioactive Waste

Quality assurance criteria similar to the eighteen criteria of Appendix B are identified, but with supplementary requirements specific to independent storage. The regulation indicates that existing Appendix B programs are acceptable for meeting these criteria.

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10 CFR Part 76 Certification of Gaseous Diffusion Plants

The operator of the gaseous diffusion plants is required to establish, maintain and execute a QA program satisfying the applicable requirements of ASME NQA-1-1989 or acceptable alternatives to the applicable requirements.

APPENDIX 2
QUALITY ASSURANCE RELATED REGULATORY GUIDES

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QUALITY ASSURANCE RELATED REGULATORY GUIDES

Regulatory Guide 1.8, Rev 2 4/87 Qualification and Training of Personnel for Nuclear Power Plants

Endorses ANSI/ANS-3.1-1981, "Selection, Qualification, and Training of Personnel for Nuclear Power Plants" with some modifications.

Regulatory Guide 1.26, Rev 3 2/76 Quality Group Classifications and Standards for Water-, Steam-, and Radioactive-Waste-Containing Components of Nuclear Power Plants

Identifies a quality classification system related to specific national standards that may be used to determine quality classes acceptable to the NRC staff for satisfying General Design Criterion 1 for safety related components, other than those within the reactor coolant pressure boundary. Guidance is provided by defining 4 quality classes of nuclear plant components (based on the importance to safety) and the code class associated with the quality classification.

Regulatory Guide 1.28, Rev 3 8/85 Quality Assurance Program Requirements (Design and Construction)

Endorses ASME NQA-1-1983 "Quality Assurance Program Requirements for Nuclear Power Plants" and ASME NQA-1a Addenda. In some cases, the NRC recommends using the non-mandatory guidance of ASME NQA-1 in addition to the addenda.

Regulatory Guide 1.33, Rev 2, 2/78 Quality Assurance Program Requirements (Operations)

Endorses ANSI N18.7-1976/ANS-3.2, "Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants."

Regulatory Guide 1.37, 3/73 Quality Assurance Requirements for Cleaning of Fluid Systems and Associated Components of Water-Cooled Nuclear Power Plants

Endorses ANSI N45.2.1 "Cleaning of Fluid Systems and Associated Components during Construction Phase of Nuclear Power Plants."

Regulatory Guide 1.38, Rev 2 5/77 Quality Assurance Requirements for Packaging, Shipping, Receiving, Storage, and Handling of Items for Water-Cooled Nuclear Power Plants

Endorses ANSI N45.2.2-1972, "Packaging, Shipping, Receiving, Storage, and Handling of Items for Water-Cooled Nuclear Power Plants During the Construction Phase."

Regulatory Guide 1.54, 6/73

Quality Assurance Requirements for Protective Coatings Applied to Water-Cooled Nuclear Power Plants

Endorses ANSI N101.4-1972, "Quality Assurance for Protective Coatings Applied to Nuclear Facilities."

Regulatory Guide 1.64, Rev 2 6/76

Quality Assurance Requirements for the Design of Nuclear Power Plants

Endorses ANSI N45.2.11-1976, "Quality Assurance Requirements for the Design of Nuclear Power Plants."

Regulatory Guide 1.74, 2/74

Quality Assurance Terms and Definitions

Endorses ANSI N45.2.10-1973, "Quality Assurance Terms and Definitions."

Regulatory Guide 1.88, Rev 2, 10/76

Collection, Storage, and Maintenance of Nuclear Power Plant Quality Assurance Records

Endorses ANSI N45.2.9-1974, "Requirements for Collection, Storage, and Maintenance of Quality Assurance Records for Nuclear Power Plants" and, for protection from fire, an alternative to ANSI N45.2.9-1974 (Subdivision 5.6); NFPA No. 232-1975 "Standard for the Protection of Records."

Regulatory Guide 1.94, Rev 1, 4/76

Quality Assurance Requirements for Installation, Inspection, and Testing of Structural Concrete and Structural Steel During the Construction Phase of Nuclear Power Plants

Endorses ANSI N45.2.5-1974, "Supplementary Quality Assurance Requirements for Installation, Inspection, and Testing of Structural Concrete and Structural Steel During the Construction Phase of Nuclear Power Plants."

Regulatory Guide 1.116, 5/77

Quality Assurance Requirements for Installation, Inspection, and Testing of Mechanical Equipment and Systems

Endorses ANSI N45.2.8-1975, "Supplementary Quality Assurance Requirements for Installation, Inspection, and Testing of Mechanical Equipment and Systems for the Construction Phase of Nuclear Power Plants."

Regulatory Guide 1.123, Rev 1, 7/77

Quality Assurance Requirements for Control of Procurement of Items and Services for Nuclear Power Plants

Endorses ANSI N45.2.13-1976, "Quality Assurance Requirements for Control of Procurement of Items and Services for Nuclear Power Plants."

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Regulatory Guide 1.144, Rev 1, 9/80
Auditing of Quality Assurance Programs for Nuclear Power Plants

Endorses ANSI N45.2.12-1977, "Requirements for Auditing of Quality Assurance Programs for Nuclear Power Plants."

Regulatory Guide 1.146, 8/80
Qualification of Quality Assurance Program Audit Personnel for Nuclear Power Plants

Endorses ANSI N45.2.23-1978, "Qualification of Quality Assurance Program Audit Personnel for Nuclear Power Plants."

Regulatory Guide 2.5, 5/77
Quality Assurance Program Requirements for Research Reactors

Endorses ANSI N402-1976, "Quality Assurance Program Requirements for Research Reactors."

Regulatory Guide 3.3, Rev 1, 3/74
Quality Assurance Program Requirements for Fuel Reprocessing Plants and for Plutonium Processing and Fuel Fabrication Plants

Endorses ANSI N45.2-1971, "Quality Assurance Program Requirements for Nuclear Power Plants."

Regulatory Guide 3.21, 3/74
Quality Assurance Requirements for Protective Coatings Applied to Fuel Reprocessing and to Plutonium Processing and Fuel Fabrication Plants

Endorses ANSI N101.4-1972, "Quality Assurance Protective Coatings Applied to Nuclear Facilities."

Regulatory Guide 3.28, 5/75
Welder Qualification for Welding in Areas of Limited Accessibility in Fuel Reprocessing Plants and in Plutonium Processing and Fuel Fabrication Plants

Endorses the ASME Boiler and Pressure Vessel Code, Section IX, "Welding and Brazing Qualification," with modifications to perform qualification welds under simulated access conditions.

Regulatory Guide 3.53, 7/82
Applicability of Existing Regulatory Guides to the Design and Operation of an Independent Spent Fuel Storage Installation

Identifies existing guidance in tables (i) applicable to design, (ii) applicable to operations, and (iii) specific to an ISFSI. Each table is divided into subjects as well. Quality Assurance for design and construction refers to Reg Guide 1.28 (endorsing ANSI N45.2-1977) and for QA terms, 1.74. For operations, Quality Assurance—Environmental Monitoring is noted.

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Regulatory Guide 4.15, Rev 1, 2/79

Quality Assurance for Radiological Monitoring Programs (Normal Operations)—Effluent Streams and the Environment

Describes an acceptable method for designing a program to assure the quality of measurement results of radioactive materials in the effluent and environment outside nuclear facilities during normal operations, to comply with 10 CFR 20.106 and Appendix B. This guide sets forth QA program criteria covering organization, personnel qualification, procedures and instructions, records, sampling, radioanalytical laboratory operations (calibration, performance checks, control samples, intra-laboratory analysis, computations) continuous monitoring systems, review and analysis of data, and audits.

Regulatory Guide 6.9, 2/95

Establishing Quality Assurance Programs for the Manufacture and Distribution of Sealed Sources and Devices Containing Byproduct Material

Describes an acceptable method for complying with 10 CFR 32.210. This guide provides 13 criteria for a QA program, but has the provision to accept an ISO or ANSI based program (implying ISO 9001). The guide also has three appendices for auditing the QA program, examples of records and documentation, and quality control specifications for certain exempt products (smoke detectors).

Regulatory Guide 7.10, Rev 1, 6/86

Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material

Describes an acceptable method for complying with 10 CFR Part 71, Subpart H. Endorses a graded approach to QA program implementation, split into three specific applications: (i) design and fabrication of the packaging, (ii) procurement and use of the completed packaging, and (iii) use of radiographic exposure devices. This follows the 18 criteria of 10 CFR Part 71, Subpart H, and provides clarification similar to that of ASME NQA-1.

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APPENDIX 3
QUALITY ASSURANCE RELATED NUREGS

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QUALITY ASSURANCE RELATED NUREGS

NUREG/CP-0129 4/93

Workshop on Program for Elimination of Requirements Marginal to Safety

The comments of industry experts in several areas, including quality assurance are compiled. Areas in which changes might be made to improve quality and to remove burdensome requirements having marginal impacts on quality are identified.

NUREG-0800, Section 17.1, Rev 2, 7/81

Quality Assurance During the Design and Construction Phases (Standard Review Plan-SRP)

NUREG-0800, Section 17.3, Rev 0, 8/90

Quality Assurance Program Description

This SRP provides the method for NRC reviews of QA program descriptions that may be topical reports or parts of a safety analysis report. It addresses the 18 criteria of Appendix B, but follows a slightly reorganized format. The major sections of the SRP are Management, Performance/Verification, and Self Assessment.

NUREG-0856, 6/83

Final Technical Position on Documentation of Computer Codes for High-Level Waste Management

This NUREG was prepared to provide guidance to the DOE on what is necessary for computer codes that the NRC will need to evaluate. It is not a comprehensive software QA guide.

NUREG-1055, 5/84

Improving Quality and the Assurance of Quality in the Design and Construction of Nuclear Power Plants (W. Altman, T. Ankrum, W. Brach)

This NUREG reports on a study of several nuclear power plant constructions that encountered significant quality and management problems, and compares them to plants having relatively few problems. Identifies root causes and recommends changes for the licensee and the NRC.

NUREG-1199, Rev 1, 1/88

Standard Format and Content of a License Application for a Low-Level Radioactive Waste Disposal Facility—Chapter 9.0, Quality Assurance

Basic requirements plus additional guidance following the 18 criteria of Appendix B are provided consistent with NUREG-1293.

NUREG-1200, Rev.1, 1/88

Standard Review Plan for the Review of a License Application for a Low-Level Radioactive Waste Disposal Facility—Chapter 9.0, Quality Assurance During the Design, Construction, and Operation

NRC review methods and acceptance criteria are identified.

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NUREG-1293, Rev. 1, 4/91
Quality Assurance Guidance for Low-Level Radioactive Waste Disposal Facility
(C.L. Pittiglio, Jr., D. Hedges)

Guidance to an applicant for a low-level waste disposal facility license in meeting requirements of 10 CFR 61.12(j), which requires a description of the QA program is provided. Note that Part 61 has no specific QA criteria, but this guidance endorses Appendix B.

NUREG-1297, 2/88
Peer Review for High-Level Nuclear Waste Repositories Generic Technical Position (GTP)
(W.D. Altman, J.P. Donnelly, J.E. Kennedy)

This generic technical position describes how peer reviews can be utilized to provide adequate confidence in work performed.

NUREG-1298, 2/88
Qualification of Existing Data for High-Level Nuclear Waste Repositories Generic Technical Position
(W.D. Altman, J.P. Donnelly, J.E. Kennedy)

This generic technical position identifies several methods for qualifying data not collected under an acceptable QA program.

NUREG-1318, 4/88
Technical Position on Items and Activities in the High-Level Waste Geologic Repository Program Subject to Quality Assurance Requirements (A.B. Duncan, S.G. Bilhorn, J.E. Kennedy)

Provides guidance on how to identify items and activities subject to QA requirements; important to safety and important to waste isolation.

NUREG-1323, Rev 1, 12/95
License Application Review Plan for a Geologic Repository for Spent Nuclear Fuel and High-Level Radioactive Waste—Chapter 10 Quality Assurance, Review Plan 10.0, Quality Assurance

This provides the NRC review methods and acceptance criteria.

NUREG-1324 2/92
Proposed Method for Regulating Major Materials Licensees

Defines an ideal regulatory evaluation system based on a review of NRC current licensing and oversight programs for fuel cycle and large materials plants. For QA programs, Appendix B is recommended.

NUREG-1383 10/90
Guidance on the Application of Quality Assurance for Characterizing a Low-Level Radioactive Waste Disposal Site (C.L. Pittiglio, R.J. Starmer, D. Hedges)

This provides guidance on a quality control program for determining the natural characteristics of the site as required in 10 CFR Part 61. It covers (i) the regulatory basis for a QA program, (ii) parameters and tests for evaluating a disposal site, (iii) documentation of laboratory and field test procedures,

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(iv) qualifications and training for personnel conducting site characterization activities, (v) storage of site characterization data, and (vi) records of site characterization activities.

NUREG-1520 Draft 3/95

Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility

Identifies NQA-1 or equivalent as the QA program criteria. Emphasizes the option to apply graded QA to activities and structures, systems, and components important to safety. Relies on integrated safety analyses to identify the SSCs.

NUREG/CR-4271 5/85

Recommended Safety, Reliability, Quality Assurance and Management Aerospace Techniques With Possible Application by the DOE to the High-Level Radioactive Waste Repository Program (W.M. Bland)

This NUREG identifies the techniques applied in the NASA programs that may be acceptable for the HLW program. Techniques recommended include System Safety, Failure Modes and Effects Analysis/Critical Items List, Problem Reporting and Corrective Action, Electrical, Electronic, and Electromechanical Parts Control, Equipment Certification, Data Verification, Milestone Reviews, and Configuration Management.

NUREG/CR-4369, 1/86

Quality Assurance Plan for Computer Software Supporting the U.S. Nuclear Regulatory Commission's High-Level Waste Management Program (G.F. Wilkinson, G.E. Runkle — SNL)

Describes the QA controls to be applied to software that Sandia develops for the NRC in the HLW program.

NUREG/CR-4640, 8/87

Handbook of Software Quality Assurance Techniques Applicable to the Nuclear Industry (J.L. Bryant, N.P. Wilburn — PNL)

This report provides detailed guidance for controlling software. It takes a software life cycle approach, identifying various controls throughout the design, development, implementation, and maintenance phases.

NUREG/CR-4678, 9/86

A Method for Using PRA to Establish Quality Assurance Program Applicability (D.R. Gallup, D.W. Whitehead, M.G. Vannoni)

This report identifies a method for ranking systems and activities according to their importance to safety, to determine the level of QA program applicability to that item or activity.

NUREG/CR-5152, 7/89

Comparison and Regulatory Impact of NQA-1 and NQA-2 with N45.2 QA Standards (B. Scanga and J. Stokely — SAIC)

Compared to N45.2, ASME NQA-1 is usually less prescriptive. When more prescriptive, it is to emphasize the performance-based QA approach. ASME NQA-2 deals with technical guidance; generally

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it is more prescriptive because it is comprehensive in comparison to ASME N45.2. ASME NQA-1 and ASME NQA-2.

NUREG/CR-6314, 4/96

Quality Assurance Inspections for Shipping and Storage Containers (H.M. Stromberg, G.D. Roberts, J.H. Bryce — INEL)

For 10 CFR Part 71 and Part 72 shipping containers, this provides the NRC staff with specific inspection criteria for the overall QA program and an inspection checklist.

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NRC COMMENTS/CNWRA RESPONSES

1. On page 2-3, the first column of Table 2-1 should include Criteria XIII and XIV with the other columns filled in as appropriate.

These criteria were inadvertently omitted during preparation of the report. Added to the table

XIII. Handling, Storage, and Shipping	2. Performance (i) Work Processes	4.15 Handling, Storage, Packaging, Preservation, and Delivery
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XIV. Inspection, Test, and Operating Status	2. Performance (iv) Inspection and Acceptance Testing	4.12 Inspection and Test Status
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2. The reference to 10 CFR 70.22(f) at the first bullet on page 2-4 (and perhaps the reference to 10 CFR Part 70 in Appendix A) should make it clear that the QA requirements are specified only for each applicant for a license and each licensee "to possess and use special nuclear material in a plutonium processing and fuel fabrication plant" and that 10 CFR Part 70 does not specify any QA requirements for other fuel cycle applicants/licensees.

The primary point being made in this section is that NRC has taken a number of different approaches, and to identify those approaches. The application of 70.22(f) to only a portion of Part 70 applicants does not affect the point that is being made. While this could easily be changed, it may confuse the primary point. No changes.

3. Reference to Table 1-1 in the last paragraph of Section 2.2.2 should be changed to reference Table 2-1.

Agree. The text was changed as follows:

Appendix B consists of eighteen criteria that provide control of activities consistent with their importance to safety (table 2-1 identifies its criteria and the major topics of the criteria). The criteria address design, construction, and operation of facilities, as well as programmatic concerns that affect quality and safety such as organization, training, documents, records, quality verification, nonconformance, and corrective action. The criteria are very general, so additional direction or guidance has been necessary to ensure effective implementation of appropriate controls.

4. The first bullet in Section 2.1.2 should note that NRC endorsement of consensus standards may be with or without additional NRC guidance as "Regulatory Positions."

Agree. This clarifies the form of the guidance.

- Endorsement of certain consensus standards (with or without additional NRC guidance as "Regulatory Positions") as acceptable methods of addressing QA regulatory requirements

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5. The third paragraph of Section 2.1.2 should make it clear that Regulatory Guides 1.28 and 1.33 apply to the design, construction, and operation of nuclear power plants. Also consider whether the fact that the Regulatory Position in these Regulatory Guides provides additional guidance (beyond a simple endorsement of the referenced standards) should be noted in the paragraph.

Agree. This identifies the target of the guidance. It was not mentioned before because it was felt that the existence of guidance, regardless of the target, was the primary point.

The most significant guidance for nuclear power plant QA programs is that of Regulatory Guide 1.28, which identifies ASME NQA-1 (American Society of Mechanical Engineers, 1989a) as an acceptable method for addressing Appendix B during design and construction, and Regulatory Guide 1.33 which endorses ANSI/ANS 3.2 (American Nuclear Society, 1994) for application during operations.

6. The first sentence of Section 2.2 should be limited to DOE's application of two QA regulations to its nuclear or nuclear safety management activities.

Agree.

The DOE has applied two QA regulations to its nuclear-related activities. 10 CFR Part 50, Appendix B is being applied to DOE activities that are regulated by the NRC, in particular those under 10 CFR Part 60, (Nuclear Regulatory Commission, 1991). 10 CFR 830.120 (U.S. Department of Energy, 1994), which is also known as DOE Order 5700.6C, is applied to DOE activities other than those regulated by the NRC. 10 CFR 830.120 has 10 program elements organized broadly under management, performance, and assessment.

7. The relationship between the NUREGs listed in the second paragraph of Section 2.2 and the supplements in the QARD is not clear. (Also, this appears to be the first time "HLW" is used in the report. If so, it should be defined. Should CFR be defined similarly?)

The NUREGs are identified in the QARD as guidance sources, and the QARD addresses these sources in the Supplements. The paragraph was revised to clarify.

The DOE has implemented for a QA program for high-level radioactive waste (HLW) related activities addressing Appendix B. ASME NQA-1 is identified as the primary source of implementation guidance. Additional requirements for this program are provided through the QA Requirements and Description (QARD) document (U.S. Department of Energy, 1995). NRC guidance unique to HLW are provided in NUREGs -0856, -1297, -1298, -1318, and -1323 (see appendix 3 for summaries of these NUREGs). This guidance is addressed in supplements to the QARD covering Software, Sample Control, Scientific Investigation, and Field Surveying. QARD Appendices covering the range of DOE HLW-related functions—High Level Waste Form Production, Transportation, and Mined Geologic Disposal System—identify additional requirements tailored to the specific type of activity.

8. We suggest a rewrite of the fourth paragraph of Section 2.2 because:

- a) The first words of the paragraph should be "DOE nuclear facilities are required to have developed and implemented QA programs..." or words to that effect (because that's the law).

- b) The second sentence refers to "the differences" between 830.120 and Appendix B. The sentence goes on to list but a single difference, and the plurality of the differences in the "Furthermore" sentence is somewhat awkward. Suggest an adjective such as key, important, significant, principle, or primary before "differences" (or difference) and a rewrite of the sentence.
- c) The third sentence indicates that quality improvement "encompasses nonconformance control and corrective action." While this is true, it is also true that quality improvement should also encompass other aspects of TQM. If the point is that Appendix B addresses quality improvement only through nonconformance control and corrective action, this should be clarified. So should any other point(s) that are being made.
- d) The fifth sentence equates "assessments" to "audits and surveillances." Everyone may not understand/agree that assessment = audits + surveillances. For example, the Federal Register Notice that introduced Section 17.3 of NUREG-0800 (SRP for nuclear power plants) indicates that the self-assessment function includes "safety committee activities, audits, and other independent assessments" (Federal Register / Vol. 55, No. 164 / Thursday, August 23, 1990 / Notices - 34635). We suggest the equation be deleted or expanded upon.
- e) The discussion of "performance-based" approach to QA versus a "programmatic" approach should recognize that an Appendix B QA program can be applied in a performance-based manner (as is being done on the HLW program). At least that is the intent. Also, the Federal Register Notice referenced above states that Section 17.3 of the SRP for nuclear power plants "puts in place a performance-oriented quality assurance program review plan...." This indicates (to some, at least) that an Appendix B QA program can be as "performance-based" as an 830.120 QA program.

Therefore, we suggest you consider whether or not the "key" differences are: 1) the 830.120 requirement for "quality improvement" versus the Appendix B requirement for only nonconformance control and corrective action and 2) the 830.120 emphasis on "assessments" versus Appendix B emphasis on "audits." Whatever the "key" differences are, they should be clearly described and their effect(s) should be discussed in the report.

This paragraph was rewritten to concentrate on describing 830.120 instead of comparing it to Appendix B. Chapter 3 will be the place where the regulations are compared. Also, the controversial topics identified in the comments are now avoided.

Most DOE nuclear facilities are required to develop and implement QA programs addressing 10 CFR 830.120; its program elements and major topics shown in table 2-1. In addition to the program elements in common with most other quality programs, 10 CFR 830.120 has a deliberate emphasis on quality improvement, Section 1 (iii) requiring "processes to detect and prevent quality problems" and analysis to "identify items, services, and processes needing improvement." In addition, 10 CFR 830.120 has been characterized as a performance-based approach (Hawkins, 1991) to quality assurance. The performance-based approach is most evident in Section 3 (ii), which requires that independent assessment be "planned and conducted to measure item and service quality, to measure the adequacy of work performance, and to promote improvement." This contrasts with a the more commonly applied programmatic approach, which indirectly measures quality program effectiveness by assessing program controls (instead of directly measuring quality and performance).

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9. Paragraph 5 of Section 2.2 indicates the DOE guidance for implementing 830.120 was issued in 1996. We suggest you check that date since our copy is dated April 15, 1994. Also, to indicate that the DOE guidance for design verification (the quoted two paragraphs - 13 lines) "closely follows" that of ASME NQA-1 (the quoted two+ pages) appears to us to be an overstatement without some words addressing the difference in detail (verbosity?).

Right, the date was incorrect. The overstatement was replaced with a more accurate statement.

Guidance for implementation of 10 CFR 830.120 is provided in an implementation guide (U.S. Department of Energy, 1994b6a). Calling on the design verification example once again, this DOE guidance addresses the same topics as ~~closely follows that of~~ ASME NQA-1, ~~but in less detail~~:

10. The last paragraph in Section 2.2 addresses the fact that "QA is presented as part of a larger, more general area considering radiological, nuclear, and process safety." We suggest you consider whether or not the report should address how the privatization contracts address (or do not address) product quality. There has been some discussion within FCSS whether there should be separate QAPDs and separate personnel to implement/monitor the QA for process safety and the QA for product quality. Would having the responsibilities for both create a conflict of interest? Section 3.3.3 of the current Draft SRP for a fuel cycle facility states:

"The reviewer should recognize that facility safety is not the only criterion for QA programs at a fuel cycle facility. The applicant's clients will impose product-related QA criteria. NRC concern is limited to ensuring that nuclear safety and related chemical and fire safety criteria are met." (Underline added.)

While the quality of the electricity from a nuclear power plant has never been an NRC concern, the quality of products (such as reactor pressure vessels, fuel elements, storage and transport casks, and radioactive glass to go into a geologic repository) as it relates to public health and safety has long been a concern of the NRC. CNWRA recommendations in this regard would be welcomed.

While not applied to the power itself, various other nuclear QA programs have been applied to end products to the extent that those end products affect worker and public safety and health. At Savannah River and West Valley, the QARD is applied to the waste form to assure that waste acceptance criteria are met. The TWRS is roughly equivalent to the HLW vitrification, so the safety QA program should also be applied to the waste form (but not necessarily a separate QA program). No changes.

11. The first paragraph in Section 2.3 states: "As illustrated in Table 2-1, ISO-9001 consists of 20 program elements...." It appears in Table 2-1 that Section 4 of ISO-9001 consists of 20 program elements except that 4.7, 4.12, and 4.15 are not in the table. Response to suggestion 1 above may correct this; otherwise, we suggest the wording in this paragraph be revised. The last sentence of the paragraph points out that ISO-9001 slightly emphasizes quality improvement by adding preventive action for potentially adverse conditions to the corrective action element. Is this the same as or different from the Appendix B requirement that "The identification of the significant condition adverse to quality, the cause of the condition, and the corrective actions taken shall be documented and reported...."?

The missing criteria (XIII and XIV) take care of 4.15 and 4.12. 4.7 was added to the uncorrelated elements.

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Uncorrelated elements:

4.7 Control of Customer-Supplied Product

4.19 Servicing

- when specified by contract

4.20 Statistical Techniques

- where appropriate to determine process capability and product characteristics

12. For consistency, a comparison of the ISO guidance for design verification to that in NQA-1 should be included in Section 2.3 (paragraph 2) like the comparison of the DOE guidance to that in NQA-1 is included in Section 2.2 (paragraph 5 - but see suggestion 9 above), or the comparison in Section 2.2 should be deleted.

Agree.

Following the previous design verification examples, ISO-9001 is comparable to Appendix B in its level of detail and topics covered, but is not as detailed as NQA-1 Mandatory Supplement 3S-1. ISO-9001 addresses design verification as follows:

13. The differentiation between "safety-related" and "important to safety" is mentioned for the first time in the fifth paragraph of Section 2.3 of the report. This differentiation is worthy of a report in itself. Since it has not been necessary to broach the subject in the first 10 pages of the report, we suggest you consider whether it is necessary to bring it up on page 11.

There was no intent to distinguish between safety-related and important-to-safety. One term will be used.

The survey did not reveal any specific application of ISO-9001 to ~~safety-related~~ items and activities important to safety, which has been the most common application of the nuclear QA regulations and standards. However, further investigation in the areas of process safety, hazards, and accidents identified 29 CFR 1910.119 (Occupational Safety and Health Administration, 1996) as the OSHA regulation applicable to process safety management of highly hazardous chemicals. The OSHA regulation provides an analog to the nuclear regulation of items and activities important to safety, albeit slightly more narrowly focused on worker safety.

14. Are there significant similarities/differences between OSHA's process hazards analysis (last paragraph of Section 2.3) and NRC's integrated safety analysis that should be pointed out in the report?

A comparison of the ISA and OSHA is not within the scope of this QA report. Under CNWRA's TWRS task 5, NRC's ISA guidance is compared to DOE's guidance (DOE guidance includes the OSHA reg), so probably doesn't need to be brought up in this report.

15. The first paragraph in Section 3.1 states that an 830.120 QA program is based on its impact on product quality. Our understanding is that 830.120 is used at West Valley and Savannah River as the QA program for process safety and DOE's QARD is used for product quality. We've been told a) that West Valley uses one QA program, based on 830.120, for process safety and a different QA program, based on the QARD, for product quality, and b) that Savannah River has only one QA program, which meets both 830.120 and the QARD, that it uses for both process safety and product quality. We suggest that the paragraph be revised.

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The phrase "impact on product quality" was intended to recognize the performance-based slant to independent assessments in 830.120. It was not intended to reflect on the application of the QA program to certain processes or products.

For another reason, this section will be changed (in regard to performance-based) because the NRC position (guidance) and 830.120 (text) are actually quite similar.

The detailed illustrations of the 10 CFR Part 50, Appendix B; 10 CFR 830.120; and ISO-9001 QA program requirements are presented in table 2-1. The table, along with the discussions in the text, show that the various QA program regulations and standards (i) address similar program elements, and (ii) address the program elements in similar fashions. The differences between the QA programs appear more in terms of particular areas of emphasis, for example, continuous improvement is identified in 10 CFR 830.120 and ISO-9001, a graded application of QA criteria is identified in Appendix B and 10 CFR 830.120, and performance-based assessments are identified 10 CFR 830.120 and suggested in Appendix B guidance. Similarly, but much more specifically, 29 CFR 1910.119 identifies the specific methods of risk analysis that will be applied to determine the necessary safety measures. Of particular significance is that the differences in the QA program approaches do not constitute conflicts between the QA programs, but rather particular areas of emphasis, each with its own attributes. These areas of emphasis, along with the lessons learned from QA program implementation, comprise QA program attributes that should be embodied in the program for the TWRS. These include the following:

16. Contrary to a previous suggestion, "smooth" transition in the third paragraph of Section 3.1 (and elsewhere - such as at the bottom of page 3-4) should be changed to "seamless" transition.

Seamless will be substituted for smooth throughout.

17. The fourth paragraph of Section 3.1 refers to the TWRS QA regulation. We suggest that it would be more appropriate to refer to the TWRS QA regulation/guidance since it is questionable whether the NRC will issue appropriate regulation or guidance first.

Will use regulation/guidance.

While we agree that the regulation/guidance should address each of the noted attributes, the primary objective of the regulation/guidance should be the health and safety of the public, not "this collection of attributes."

Agree - will reword to indicate that these attributes are "ideals" rather than objectives.

The ideal TWRS QA regulation/guidance should have, ~~as its primary objective~~, this collection of attributes. The three likely candidate QA program regulations/standards for the TWRS, that is, Appendix B, 10 CFR 830.120, and ISO-9001, were evaluated with regard to these attributes, as illustrated in table 3-1.

Further, we question whether NRC would seriously consider using either 830.120 or ISO-9001 as a regulatory or guidance document for TWRS. We suggest that the paragraph be revised.

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An important consideration in the analysis and recommendation phases (Chapter 4 and 5) is consistency with the NRC approach, which might eliminate from consideration anything but Appendix B. However, in the literature search phase, our tasking specifically requires the CNWRA to investigate the DOE and chemical processing QA regulations and standards.

18. In light of the information gained at the observed April 1997, DOE audit at the Savannah River Defense Waste Processing Facility, we suggest you consider revising or eliminating the paragraph at the bottom of page 3-1 - top of page 3-2.

The practices of West Valley and Savannah River do not change the fact that 830.120 may have some very desirable (or undesirable) characteristics that should be considered, or that 830.120 is THE regulation applied to the TWRS privatization contractors.

On another point, since NRC has endorsed the performance based approach, 830.120 does not stand out as clearly superior. The argument will now be to show that 830.120 and Appendix B are equivalent to a very high degree. However, each could benefit from incorporating some of the other's attributes. This can also support the argument that a program developed to meet 830.120 is likely to satisfy Appendix B.

While none of the three QA programs is ideal relative to these attributes, Appendix B and 10 CFR 830.120 each capture most of the attributes. Except for quality improvement, which is not specifically addressed in Appendix B, the NRC and DOE appear to be equivalent at the topical level.

Table 3-1. Comparison of quality assurance program attributes

Attributes	10 CFR 50, Appendix B (NRC)	10 CFR 830.120 (DOE)	ISO-9001 (International Standard)
Addresses the 18 criteria of Appendix B	Yes	Yes	Yes
Promotes continuous improvement	No	Yes	Yes
Provides for a graded approach based on safety significance	Yes	Yes	No
Provides for a performance-based approach	Yes (see note)	Yes	No
Consistent with the NRC approach	Yes	No	No
Consistent with the DOE TWRS approach	No	Yes	No
Note: Appendix B does not specifically call for a performance-based approach, but NRC guidance recommends it.			

In order to determine the degree to which Appendix B and 10 CFR 830.120 are similar at a more detailed level, an addition analysis was undertaken. Several topics of potentially significant differences were identified. The following paragraphs discuss those topics and identify sources of information to resolve the differences.

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19. The reaction to suggestion 8 can affect Table 3-1 as regards whether Appendix B provides a performance-based approach.

Agree - Appendix B can be considered performance-based from the guidance - accept.

Also, the "No" regarding Appendix B providing for a graded approach based on safety significance does not appear appropriate based on the statement in Criterion II of Appendix B: "The quality assurance program shall provide control over activities affecting the quality of the identified structures, systems, and components, to an extent consistent with their importance to safety."

Graded should have been a yes for Appendix B.

Finally, as regards the table, it isn't clear why or how the NRC *approach* to QA is not consistent with the DOE *approach*. We suggest that, if the last two lines of the table (and the two added attributes listed in the text) are not deleted, clarification should be provided.

Appendix B is not consistent with the TWRS approach because the 830.120 QA program would not have the same form as an Appendix B program.

20. The discussion on "QA Organizational Independence" on pages 3-2 and 3-3 should be reconsidered. For example, except by its lists of applicable standards and references in its Implementation Guide, DOE does not require a "QA organization." While the same could be said of SRP 17.3, it was not the intent of the writer of SRP 17.3 to eliminate the SRP 17.1 and 17.2 guidance for a QA organization, and we question whether the Lockhart quotation reflects an actual NRC position. The concept of holding line management responsible for the quality/safety of the processes and the product has not changed, nor has the NRC requirement for appropriate independent checks and balances.

Upon reevaluation, the second paragraph discussing QA organization independence and the changing philosophies is somewhat speculative, and, while references are cited, the statements made are somewhat subjective. This paragraph and the Lockhart reference in the third paragraph were deleted.

The guidance for 830.120, along with common practices (i.e., likely use of QA practitioners familiar with the Appendix B approach), will adequately direct the contractors to establish independent QA organizations even though 830.120 does not specify such. 830.120 does require that certain functions (that are the same as those associated with the QA organization in Appendix B) be performed by an independent group.

QA Organizational Independence: Criterion I of Appendix B goes into great detail with respect to (i) identifying QA functions, including verification (checking, auditing, inspecting), (ii) requiring authority and organizational freedom of the QA organization (i.e., those performing QA functions), and (iii) QA organization reporting and access to management. Furthermore, most NRC standard review plans (e.g., NUREGs-0800 and -1520) have required that conformance to specified requirements be verified by individuals or groups within an independent QA organization. In contrast, 10 CFR 830.120 requires only that the QA program describe the organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work. However, under the section entitled "Independent Assessment," the DOE regulation requires that the group performing independent assessments

have sufficient authority and freedom from the line functions to carry out its responsibilities. ~~These independence criteria mirror some of the Appendix B criteria stated above.~~

~~This difference may reflect a primary shift in QA philosophy since Appendix B was established around 30 years ago. At that time, production (line) and QA organizations were seen as having mutually exclusive and, at times, opposing objectives. Independence of the verifiers from the line organization was considered to be essential to avoid a conflict of interest. Contemporary QA philosophy emphasizes that the responsibility for attaining quality resides with the worker performing the activity, and that peer inspection reinforces ownership of the activity and its quality (Lancaster, 1993). 10 CFR 830.120 reflects this contemporary approach, and places no constraints on the individuals or organizations performing most of the verifications (except independent assessments), so long as the responsibility and authority for verifications are declared.~~

The organizational independence concern is addressed by the DOE implementation guide (U.S. Department of Energy, 1996a) which includes within its discussion of independent assessments such methods as inspections, peer and technical reviews, audits, and surveillances. This list of methods is essentially the same as the Appendix B, criterion I list of QA functions. The DOE implementation guide also places conditions on the organization performing independent assessments similar to the conditions placed upon the QA organization by Appendix B, that is, reporting to a sufficiently high level of management to ensure organizational independence and access to appropriate levels of authority. ~~In addition, the latest issue of the NRC standard review plan for nuclear power plants, SRP 17.3 (see NUREG 0800), the NRC position regarding verification by the QA organization has shifted, "it now...permits the licensee (applicant) the latitude to totally (or proportionately) integrate the quality program into the line organizations" (Loekhart, 1993).~~

21. The section headed "Levels of QA and Graded QA" raises several questions. The NRC standard review plan for a fuel cycle facility (draft NUREG 1520), even when issued, will not be a "regulation" as it is indicated to be in the parenthetical expression ("which is the NRC regulation intended to apply to the TWRS"). Whether or not NUREG 1520 "interpreted Appendix B" is questionable. The 10 CFR Part 70 that the SRP is based on is not the current version but is also a draft document. Finally, it is not clear how a concern about 830.120 can be resolved by an NRC initiative. The section should be clarified.

This topic is not considered to be an area of difference after all. 830.120 calls for a graded approach, which implies various levels of control. The wording of Appendix B and 830.120 are now being interpreted as equivalent, so the topic of concern will be deleted.

~~**Levels of QA and Graded QA:** Criterion II of Appendix B states "The quality assurance program shall provide control over activities affecting the quality of the identified structures, systems and components, to an extent consistent with their importance to safety." The corresponding section 10 CFR 830.120 (b)(1) states "The criteria of paragraph (e) of this section (Quality assurance criteria) shall be applied using a graded approach." (Title of section (e) added). The NRC standard review plan (draft NUREG 1520) for a draft 10 CFR Part 70 (intended to apply to the TWRS) expects the licensee to establish various levels of control, primarily based on the integrated safety analysis called for in the draft 10 CFR Part 70. A concern may be expressed that 10 CFR 830.120 does not specifically require levels of control.~~

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~~This concern should be resolved through an NRC initiative on graded QA programs (Nuclear Regulatory Commission, 1996), which would specify grading of quality elements into two or more categories of safety significance, with appropriate QA requirements associated with the safety significance categories. While 10 CFR 830.120 does not use the terms "levels of control" or "quality levels" are not explicitly stated, the concept is clearly presented. The examples of graded QA program implementation presented in section 2.4 of this report suggest that varying levels of control are implicit in graded QA program implementation.~~

22. The paragraph starting at the bottom of page 3-3 and concluding at the top of page 3-4 discusses a fourth concern - a "general" concern. The difference between this "general concern" and the "three primary areas of concern" should be clarified if it remains in the report. For clarity and consistency, we suggest that this paragraph have the same format as the other three.

This will be changed from a general concern to the same approach as the others, and titled "Level of Detail."

Level of Detail: Many of the elements of 10 CFR 830.120 are less explicit than the corresponding criteria of Appendix B; however, the analysis found no areas of contradiction between the two regulations nor of omissions of program requirements.

This general concern may be resolved by the DOE 10 CFR 830.120 implementation guide (U.S. Department of Energy, 1994b) which includes in the discussion of each of its elements, reference to specific sections of applicable standards. The standards "provide acceptable methods for implementing many of the requirements... The principles, recommended approaches, and applications contained in these standards may be used in conjunction with 10 CFR 830.120 in the development and implementation of an effective...system."

Using the design control element as an example, the 10 CFR 830.120 implementation guide identifies consensus standards as additional sources of guidance, including

- ISO-9001, Section 4.4 Design Control (International Organization for Standardization, 1994a)
- ISO-9004, Section 8, Quality in Specification and Design (International Organization for Standardization, 1994b)
- DOE/RW/0333P Section 3.0, Design Control and Supplement I, Software (U.S. Department of Energy, 1995)
- ASME NQA-1 Basic Requirement 3, Design Control, Supplement 3S-1, Supplementary Requirements for Design Control, and Nonmandatory Appendix 3A-1, Nonmandatory Guidance on Design Control (American Society of Mechanical Engineers, 1989a)
- ASME NQA-2, Part 2.7, Quality Assurance Requirements for Computer Software for Nuclear Facility Applications (American Society of Mechanical Engineers, 1989b).

Therefore, the primary consensus standards developed to aid implementation of Appendix B (i.e., NQA-1 and NQA-2) are also being identified as guidance for implementing 10 CFR 830.120, so QA programs developed to address the DOE regulation are likely to address Appendix B criteria.

This detailed analysis of 10 CFR 830.120 indicates that its approach, controls, and extent of control are much closer to that of Appendix B than was initially apparent. Consequently, 10 CFR 830.120 may be considered to be equivalent to Appendix B.

23. We suggest you consider whether the readers of page 3-4 will know whether the “consensus standards developed to aid implementation of Appendix B” includes each of the five bullet items above the statement or only the last two.

Corrected in #22.

24. It is not clear that identifying standards as additional sources of guidance in the 830.120 implementation guide is equivalent to providing the guidance in the 830.120 implementation guide itself. This equivalency appears to be assumed in the discussion in Section 3.1 on page 3-4 of the report. Justification for the assumption should be provided (or the discussion be changed) since it seems probable that QA program developers, implementers, and reviewers may not make the effort to review the additional sources of guidance or know what portions of the additional sources of guidance need to be followed.

NRC and DOE are endorsing the consensus standards in the same fashion; NRC identifying guidance in Reg Guide 1.28 by reference, and the 830.120 implementation guide by reference. While Appendix B starts off with more information in some areas, both end up at NQA-1. No change.

25. The first sentence in Section 3.2 of the report states that “three options of presenting QA program criteria can be proposed.” It would be more correct to say that “three options (or methods) of presenting QA program requirements have been used by the NRC in the past.”

Agree.

Based on the survey described in chapter 2 of this report, three options of presenting QA program criteria in **NRC regulations have been used in the past:**

26. The last sentence at the bottom of page 3-4 of the report indicates that direct reference to Appendix B plus new NRC guidance “cannot entirely satisfy the objective of being consistent with current DOE practices....” For clarity, “because...” be added to the sentence to explain why this is true or some other change be made to the paragraph.

Based on the previous changes, the suitability of this approach for meeting consistency with the DOE approach are no longer valid, so the text was changed as follows:

Direct Reference to Appendix B: 10 CFR Part 60, Subpart G and other NRC regulations identify QA criteria by direct reference to Appendix B, with brief clarification of the scope and application of the QA criteria. While this approach is obviously consistent with NRC practice, it does not capture some of the important characteristics of a contemporary QA program, namely continuous improvement. NRC guidance may be necessary to endorse consensus standards

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(NQA-1 and NQA-2), to emphasize the QA program characteristics not specifically mentioned in Appendix B, and to provide any necessary tailoring of Appendix B for the application to the TWRS.

27. The first sentence of page 3-5 should be revised to read: "10 CFR Part 71 for packaging and transportation of radioactive material lists...." and, similarly, the first sentence of the next paragraph should be revised to read: "10 CFR Part 76 for gaseous diffusion plants identifies...."

Citing the application of the regulation is not really important for this report, other than the fact that the regulation describes QA requirements. The appendix describing Part 76 does mention gaseous diffusion plants, but it will be changed anyway.

Unique QA Criteria: 10 CFR Part 71 for packaging and transportation of radioactive material lists unique QA criteria that are organized into 18 criteria that are but minor variations on Appendix B. This approach has merit in that the QA program characteristics lacking in Appendix B could be provided, as well as any tailoring to the TWRS. Presentation of the QA program requirements in 18 criteria would be consistent with NRC practice, so long as major departures from the fundamental aspects of Appendix B were not taken. If 10 CFR 830.120 were merged with Appendix B, consistency with DOE practices should also be realized. The DOE implementation guide (U.S. Department of Energy, 1994b) appears to be an important bridge to the consensus standards, so equivalent NRC guidance may be necessary.

28. Under "Reference to a Consensus Standard" on page 3-5 of the report, it is not clear why 830.120 is referred to as a "standard." It is not a "consensus standard." If you are suggesting the NRC reference 830.120 in a controlling regulation, the sub-heading be changed. Another approach would be to show referencing 830.120 as a fourth option under a different sub-heading.

Accept

Reference to a Consensus Standard: 10 CFR Part 76 for gaseous diffusion plants identifies NQA-1 as its QA program criteria. ~~This approach may open up the option of citing other standards, such as ISO 9001 or 10 CFR 830.120. As evident from table 3-1, ISO 9001 would require considerable guidance to address graded and performance based QA, but guidance could not overcome its inconsistency with both NRC and DOE practices. 10 CFR 830.120 provides an excellent match with the QA program characteristics, but may require NRC guidance to assure that NQA-1 was followed, so that QA program implementation would be consistent with implementation of Appendix B programs. While this would match DOE practices, the most significant obstacle may be NRC staff acceptance of an approach not following the 18 criteria of Appendix B. Identifying NQA-1 as the QA criteria is equivalent to requiring compliance with Appendix B, so would offer the same benefits and obligations as a direct reference to Appendix B previously discussed.~~

29. Recognizing that the NRC has referenced NQA-1 in 10 CFR 76, it is not clear why the report suggests referencing a different consensus standard such as ISO-9001. Advantages and disadvantages of such a departure from past practice should be addressed in the report if the report recommends that option be considered.

This section should only be looking at what NRC has done in the past. Accept, see item 28.

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30. We are not certain that changing the term "quality assurance function" to "independent assessment" is an enhancement to Appendix B as indicated under Criterion I on page 4-1 of the report. (Could eliminating the term, "quality assurance functions" lead to the elimination of the quality assurance organization?)

Agree. It was not an important point, and will be dropped. See #32 for a complete rewrite.

31. Under Criterion II on page 4-1 of the report, "to safety" should be inserted between "importance" and "should" in the first sentence and "be" should be inserted between "may" and "introduced" in the third sentence. Also, we suggest the concept of expanding the Appendix B discussion of providing control over activities consistent with their importance to safety to reliability and product performance should make it clear that NRC's interest in reliability and product performance relates to how these factors affect (or can affect) public health and safety.

Accept - The desire was (only) to make the application of the QA programs appear more generic (as opposed to strictly important to safety.) See #32 for a complete rewrite.

32. We suggest that the report include specific justification for each recommendation given in Section 4 of the report. Additional detail regarding the recommendations would also prove helpful. For example, how would the CENTER recommend the NRC include "identification of consensus standards and other sources of guidance" in the NRC guidance?

Individual justification added for each change. Will also rearrange the presentation of the changes in terms of the attributes.

4. RECOMMENDED APPROACH TO NUCLEAR REGULATORY COMMISSION QUALITY ASSURANCE REGULATION OF THE TANK WASTE REMEDIATION SYSTEM

As indicated in the analysis presented in chapter 3 of this report, an ideal QA regulation would have all of the attributes listed in table 3-1. However, the programmatic attributes, i.e., consistency with the NRC approach and consistency with the DOE approach, appear to be mutually exclusive. The detailed analysis presented in chapter 3 addresses this apparent conflict by demonstrating that, although Appendix B and 10 CFR 830.120 differ in format, their content, when supplementary guidance is considered, is essentially the same. Therefore, for the TWRS QA regulation/guidance, the CNWRA recommends that the NRC develop an approach that can encompass all of the attributes. This should be accomplished through specification of unique QA criteria following the models of 10 CFR Parts 71 and 72, as follows:

- Format following the 18 criteria of Appendix B
- Content consistent with 10 CFR 830.120
- Promoting continuous improvement
- Providing a graded approach based on safety significance
- Providing a performance-based approach

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35. The conclusions in Section 5 of the report should be reexamined in light of any significant response to the suggestions given above, and the section should be revised accordingly as appropriate.

Agree - not much impact, except to emphasize the equivalency of 830.120 and Appendix B.

The objective of this task was to recommend to the NRC an approach to regulation and guidance for the TWRS in regard to QA. The survey of regulations, guidance, QA practices, and lessons learned from nuclear QA program implementation was undertaken to identify the various approaches that had been taken by the NRC, the DOE, and in the chemical processing industry, with similarly hazardous processes. The survey revealed (i) a common basis in all of the QA programs, (ii) differences in programs in terms of emphasis, but none in conflict with the others, and (iii) a number of somewhat different approaches that had been taken in the NRC QA regulations.

The subsequent analysis compared the existing QA program regulations and standards and developed a compilation of attributes from these QA programs. While none of the three QA regulations/standards—10 CFR Part 50, Appendix B, 10 CFR 830.120, or ISO-9001—appeared to address all attributes, Appendix B and 10 CFR 830.120 captures most of the attributes. Upon deeper analysis, much closer correlation between the NRC and DOE approaches was realized.

The NRC has taken a variety of approaches to their QA regulations. From the start with Appendix B, subsequent regulations adopted Appendix B verbatim, provided modified Appendix B criteria, or endorsed a consensus standard. From these options, a recommended approach to QA regulation/guidance of the TWRS was formulated that captures the combined attributes of the various QA programs and follows NRC precedent in its presentation. The recommendation to the NRC is to provide a QA regulation unique to the TWRS, structured around the 18 criteria of Appendix B, and capturing the contemporary emphasis of 10 CFR 830.120 in its emphasis on continuous improvement and explicit statement of its performance-based approach. With such an approach to the NRC QA regulation of the TWRS, the overall objective of providing a smooth transition from DOE to NRC QA regulation of the TWRS should be met.