Department of Energy
Office of Civilian Radioactive Waste Management
Office of Repository Development
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QA: N/A
Project No. WM-00011

DEC 15 2004

OVERNIGHT MAIL

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TRANSMITTAL OF NUREG-1804, SECTION 2.5.1 LINKAGE WITH QUALITY ASSURANCE REQUIREMENTS AND DESCRIPTION (QARD), REVISION 17, DOE/RW-0333P

This letter transmits the Yucca Mountain Project (YMP) Positions and Justifications taken in QARD, Revision 17, regarding NUREG-1804 Section 2.5.1. The enclosed table shows the affected NUREG-1804, Section 2.5.1 Acceptance Criteria, the YMP position and, where necessary, the Justification for YMP Position.

The U.S. Department of Energy's Office of Civilian Radioactive Waste Management is requesting U.S. Nuclear Regulatory Commission (NRC) review and acceptance of the QARD, Revision 17 transmitted to the NRC on September 17, 2004 by February 28, 2005.

Any commitments associated with the QA program are contained within the QARD. If you have any questions or require additional information, please contact David C. Haught at (702) 794-5474 or e-mail david_haught@ymp.gov, or Michael L. Ulshafer at (702) 821-8412 or e-mail michael_ulshafer@ymp.gov.

Joseph D. Ziegler, Director
Office of License Application & Strategy

OLA&S:DCH-0240

Enclosure:
NUREG-1804 Section 2.5.1 linkage with
DOE/RW-0333P, QARD R17

NMSS07

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NUREG-1804 Section 2.5.1 linkage with DOE/RW-0333P, QARD R17

NRC NUREG-1804 Section	NRC NUREG-1804 requirements	Notes, YMP Position, etc.	Justification for YMP Position
2.5.1 Req:4	This review plan is written to accommodate the use of graded quality assurance controls for structures, systems, and components and barriers, important to safety or waste isolation that have been categorized as low-safety-risk-significant. If a graded quality assurance process is selected by the U.S. Department of Energy, the review provisions contained in this Yucca Mountain Review Plan section must be applied to structures, systems, and components and barriers categorized as high-safety-risk-significant. As provided for in Acceptance Criterion 2 of this Section (2.5.1.2), the U.S. Department of Energy may propose reduced quality assurance controls for selected elements of the quality assurance program, for structures, systems, and components and barriers categorized as low-safety-risk-significant. This categorization process must be risk-informed. If graded quality assurance is not used, the review provisions contained in this Section (2.5.1) of the Yucca Mountain Review Plan would apply to all structures, systems, and components and barriers subject to the quality assurance requirements contained in 10 CFR Part 63. As provided for in this Section (2.5.1) of the Yucca Mountain Review Plan, the U.S. Department of Energy may propose alternatives to these review provisions.	The YMP will not implement a "Graded Quality Assurance Process."	
2.5.1.3 AC-1(3)(a) Req:1	The U.S. Department of Energy describes how responsibility is exercised for the overall program. The extent of management oversight is addressed, including the location, qualifications, and number of personnel performing these functions, and the bases for them;	The YMRP requires YMP to describe how the responsibility for the management oversight of the overall QA program is implemented by providing information regarding the location and number of persons performing this function. • Currently the QA staff that is responsible for the required management oversight is located in the YMP offices in Las Vegas, NV where the majority of activities are being performed by YMP and its principal contractors, therefore the location is considered appropriate. As the performance of activities at the geologic repository increases, YMP will relocate QA personnel as necessary. • The staff size has been evaluated and based on the level of quality related activities, performance trends, and future projections. The number of the YMP and its support contractors, has been determined to be appropriate.	YMP has determined it is not appropriate to place the specific number and location of personnel in the QARD in order to minimize the potential for numerous QARD revisions.
2.5.1.3 AC-1(5) Req:1	Organization charts clearly identify all on-site and off-site organizational elements that function under the cognizance of the quality assurance program (e.g., design, engineering, procurement, shipping, receiving,	Organization Charts are not included in the QARD, a textual description of the	10CFR63.144 provides for the use of descriptive text in lieu of

NRC NUREG-1804 Section	NRC NUREG-1804 requirements	Notes, YMP Position, etc.	Justification for YMP Position
	storage, manufacturing, construction, inspection, auditing, testing, instrumentation and control), engineering, maintenance and preclosure (operations), modifications, dismantling, etc.; the lines of responsibility; and a description of the bases for determining the size of the quality assurance organization, including the inspection staff;	organization is presented in the QARD.	organizational charts. The QARD provides a discussion of QA functions of key positions and reporting relationships.
2.5.1.3 AC-1(6) Req:1	The U.S. Department of Energy (and principal contractors) describes the quality assurance responsibilities of each of the organizational elements noted on the organization charts. The authorities and duties of individual positions and organizations performing activities important to safety or waste isolation are clearly established and delineated in writing;	Organization Charts are not included in the QARD, a textual description of the organization is presented in the QARD.	10CFR63.144 provides for the use of descriptive text in lieu of organizational charts. The QARD provides a discussion of QA functions of key positions and reporting relationships.
2.5.1.3 AC-1(14) Req:1	Designated quality assurance individuals are involved in day-to-day facility activities important to safety or important to waste isolation. For example, the quality assurance organization routinely attends and participates in daily work schedule and status meetings to assure that it is kept abreast of day-to-day work assignments. There is adequate quality assurance coverage relative to procedural and inspection controls, acceptance criteria, and quality assurance staffing and qualification of personnel to carry out quality assurance assignments;	See position presented in 2.5.1.3 AC-1(3)(a) Req:1.	Same as justification presented in 2.5.1.3 AC-1(3)(a) Req:1.
2.5.1.3 AC-1(16) Req:1	If the quality assurance organizational structure of the U.S. Department of Energy or its principal contractors identifies a position for an individual, at the construction site, or the geologic repository operations area, that is responsible for directing and managing the site quality assurance program, there must be controls identified for this position in the quality assurance program.	YMP does not have this organization.	
2.5.1.3 AC-1(16) Req:2	These controls must assure that the individual assigned to this position has: (i) an appropriate level within the organizational structure,	YMP does not have this organization.	
2.5.1.3 AC-1(16) Req:3	[These controls must assure that the individual assigned to this position has:] (ii) identified responsibilities, and	YMP does not have this organization.	
2.5.1.3 AC-1(16) Req:4	[These controls must assure that the individual assigned to this position has:] (iii) authority to exercise proper control over the quality assurance program.	YMP does not have this organization.	
2.5.1.3 AC-1(16) Req:5	These controls must also assure that this individual is free from nonquality assurance duties and can thus give full attention to ensuring that the quality assurance program at the repository site is being effectively implemented	YMP does not have this organization.	
2.5.1.3 AC-2(4) Req:1	The quality assurance organization reviews and documents concurrence with these quality-related procedures;	"Quality Assurance Organization," defined in glossary. Review may be performed by qualified personnel other than those from the QA organization.	The YMP Position is consistent with the NRC policy of "line ownership" of the QA program. Personnel will be trained and qualified as necessary to perform this function. This justification is also consistent with 2.5.1.3 AC-

* Reference letter Ziegler to U.S. NRC, Director, Division of High-Level Waste Repository Safety, dtd 9/17/04, enclosure 2 for Table1A.

NRC NUREG-1804 Section	NRC NUREG-1804 requirements	Notes, YMP Position, etc.	Justification for YMP Position
			6(3).
2.5.1.3 AC-2(5) Req:1	The quality-affecting procedural controls and changes to procedural controls, of the principal contractors should be provided for the applicant's review with documented agreement of acceptance before initiation of activities affected by the quality assurance program;	In lieu of a review of only the principal contractor's quality-affecting procedural controls, and changes to these procedural controls, YMP will additionally review certain other selected procedures.	Instead of only stipulating that YMP will review the principal contractor's procedural controls and changes thereto, YMP is specifying that it will review additional procedures that it deems appropriate.
2.5.1.3 AC-2(6) Req:1	Provisions are included for notifying the U.S. Nuclear Regulatory Commission of changes for review and acceptance of the accepted description of the quality assurance program, in accordance with 10 CFR 63.144. Changes to the U.S. Nuclear Regulatory Commission-approved quality assurance program must be processed in accordance with the applicable requirements of 10 CFR 63.144, and revisions to the U.S. Department of Energy quality assurance program documentation should be forwarded to the U.S. Nuclear Regulatory Commission;	The YMP will comply with the requirements of 10 CFR 63.144.	Those regulations which are applicable to the design, construction, and operation of the Geologic Repository Operations Area (GROA) are considered to be "Regulatory Obligations" whether they are included in the QARD or not. YMP will implement all applicable and current Rules and Regulations required by the NRC.
2.5.1.3 AC-2(6) Req:2	The U.S. Department of Energy should inform the High-Level Waste Branch of changes in the quality assurance program organizational elements, when possible, within 30 days after announcement.	The YMP will comply with the requirements of 10 CFR 63.144.	Those regulations which are applicable to the design, construction, and operation of the Geologic Repository Operations Area (GROA) are considered to be "Regulatory Obligations" whether they are included in the QARD or not. YMP will implement all applicable and current Rules and Regulations required by the NRC.
2.5.1.3 AC-2(7) Req:1	The U.S. Department of Energy (and its principal contractors) commit to comply with: (i) the requirements in 10 CFR 63.44, 63.73, and 63.141-144; and (ii) the documents and regulatory positions and documents contained in Section 2.5.1.5 of the Yucca Mountain Review Plan and any exceptions contained in the acceptance criteria. Further, the U.S. Department of Energy (and its principal contractors) commit to conduct activities under 10 CFR 63.73 and 10 CFR Part 21 commercial-grade-item dedication activities, in accordance with the quality assurance program;	The YMP will comply with the requirements of 10 CFR 63.32 or 63.44; 10 CFR 63.73; 10 CFR 63.141; 10 CFR 63.142; 10 CFR 63.143; 10 CFR 63.144; and 10 CFR 21. In addition, see the QARD, Table 1.	Those regulations which are applicable to the design, construction, and operation of the Geologic Repository Operations Area (GROA) are considered to be "Regulatory Obligations"

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NRC NUREG-1804 Section	NRC NUREG-1804 requirements	Notes, YMP Position, etc.	Justification for YMP Position
			whether they are included in the QARD or not. YMP will implement all applicable and current Rules and Regulations required by the NRC.
2.5.1.3 AC-2(7) Req:2	The quality assurance organization and the necessary technical organizations should participate early in the quality assurance program definition stage to assess and identify the extent that quality assurance controls are to be applied to specific structures, systems, and components and barriers important to waste isolation. This effort may involve applying a defined graded approach to certain structures, systems, and components in accordance with their safety/risk significance and affects such disciplines as design, procurement, document control, inspection tests, special processes, records, and audits.	The YMP will not implement a "Graded Quality Assurance Process."	
2.5.1.3 AC-2(8) Req:1	The Graded Quality Assurance Process: A graded application of quality assurance, if used, requires U.S. Department of Energy justification and U.S. Nuclear Regulatory Commission reviewer acceptance. A graded quality assurance program is structured to apply quality assurance measures and controls to all items and activities in proportion to their importance to safety or importance to waste isolation. The graded approach for the application of quality assurance controls must be adequately described. The quality assurance program should identify items and activities that are important to safety or important to waste isolation and their degree of importance based on the safety/risk significance of the items and activities. High-safety-risk-significant items and activities should have a high level of control (e.g., the full application of the quality assurance controls), and less-safety-risk-significant items and activities may have reduced quality assurance controls applied. However, the U.S. Department of Energy may chose to apply the highest level of quality assurance controls to all items and activities.	The YMP will not implement a "Graded Quality Assurance Process."	
2.5.1.3 AC-2(8) Req:2	If the U.S. Department of Energy decides to apply quality assurance controls in a graded manner, its quality assurance program must address the various elements of the graded quality assurance process. The activities related to the graded quality assurance process include:	The YMP will not implement a "Graded Quality Assurance Process."	
2.5.1.3 AC-2(8)(a) Req:1	The safety-risk-significance categorization process is adequately described and is subject to review in accordance with Section 2.1.1.6 (for preclosure) and Section 2.2.1 (for postclosure) of the Yucca Mountain Review Plan (U.S. Nuclear Regulatory Commission, 2001). Although this review is performed using other sections of the Yucca Mountain Review Plan, the quality assurance program should describe, at a high level, the safety- risk-significance categorization process;	The YMP will not implement a "Graded Quality Assurance Process."	
2.5.1.3 AC-2(8)(a) Req:2	Provisions for reassessing the safety-risk-significance categorization when new information becomes available should be appropriately described.	The YMP will not implement a "Graded Quality Assurance Process."	
2.5.1.3 AC-2(8)(b) Req:1	The U.S. Department of Energy may select two or more safety-risk-significance categories (e.g., high, low, or medium). The quality assurance program describes each safety-risk-significance category selected;	The YMP will not implement a "Graded Quality Assurance Process."	
2.5.1.3 AC-2(8)(c) Req:1	The selection of graded quality assurance controls to be applied to each safety-risk-significant category must be	The YMP will not implement a "Graded	

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NRC NUREG-1804 Section	NRC NUREG-1804 requirements	Notes, YMP Position, etc.	Justification for YMP Position
	described in adequate detail. Section 3.2, "Potential Areas for Implementing Graded Quality Assurance Program Controls," of Regulatory Guide 1.176, "An Approach for Plant-Specific, Risk-informed Decision-Making: Graded Quality Assurance" (U.S. Nuclear Regulatory Commission, 1998), provides guidance on acceptable application of graded quality assurance controls. In proposing reduced quality assurance controls, the following two basic objectives should be kept in mind: (i) the graded quality assurance program should be sufficient to reasonably ensure the design integrity and ability of the structures, systems, and components or barrier to successfully perform its intended important to safety or waste-isolation function, and (ii) the graded quality assurance program should include processes and documentation that support an effective corrective action program. The selection of graded quality assurance controls may be applied to any element of the quality assurance program;	Quality Assurance Process."	
2.5.1.3 AC-2(8)(d) Req:1	Provisions for a feedback process to adjust graded quality assurance controls should be described. Provisions for reassessing the quality assurance controls when new information becomes available through adverse trends or nonconformance reporting should be described;	The YMP will not implement a "Graded Quality Assurance Process."	
2.5.1.3 AC-2(8)(d) Req:2	The U.S. Department of Energy quality assurance program description should discuss elements specifically related to effective corrective actions and causal analysis. Because it is not completely understood at the onset of the graded quality assurance program how changes will ultimately affect structures, systems, and components fabrication, construction, installation, testing, and performance, and given that the categorization process cannot address these changes in a quantitative manner, it is important that the U.S. Department of Energy have an effective process in place so that adjustments can be made in the graded quality assurance program on the basis of repository and industry experiences. Within this area, the U.S. Department of Energy process controls should have the capability to determine whether structures, systems, and components have been treated properly in the graded quality assurance program. Failures, or adverse performance degradations, of low-safety-risk-significant structures, systems, and components should be identified in accordance with the U.S. Department of Energy corrective action programs, so that the U.S. Department of Energy can ascertain whether the reduction of the quality assurance controls has resulted in excessive nonconformances and an unacceptable decrease in performance of structures, systems, and components and barriers.	The YMP will not implement a "Graded Quality Assurance Process."	
2.5.1.3 AC-2(8)(d) Req:3	The U.S. Department of Energy should employ techniques such as monitoring, surveillance, and trend analysis to identify when a structure, system, and component is found to be unacceptable or the reliability and availability of low-safety-risk-significant structures, systems, and components are trending toward unacceptable levels. Structure, system, and component monitoring approaches should be used to accomplish this goal.	The YMP will not implement a "Graded Quality Assurance Process."	
2.5.1.3 AC-2(8)(e) Req:1	Provisions for an effective root-cause analysis and corrective action as a result of the feedback process should be described. Provisions should also be described for evaluating common cause/mode failures. The U.S. Department of Energy corrective action efforts should determine, as a minimum, the apparent cause of repetitive failures of structures, systems, and components under the graded quality assurance controls so that it can be decided whether graded quality assurance controls should be adjusted. In some instances, a failure may result in an unanticipated event and may cause the categorization of the structures, systems, and components to	The YMP will not implement a "Graded Quality Assurance Process."	

NRC NUREG-1804 Section	NRC NUREG-1804 requirements	Notes, YMP Position, etc.	Justification for YMP Position
	be changed;		
2.5.1.3 AC-2(8)(f) Req:1	Provisions should also be in place for the U.S. Department of Energy to obtain documented U.S. Nuclear Regulatory Commission approval before implementing any quality assurance program changes that reduce previous commitments; and	The YMP will not implement a "Graded Quality Assurance Process."	
2.5.1.3 AC-2(8)(g) Req:1	The use of reduced sampling plans for low-safety-risk-significant structures, systems, and components and related activities is required to be documented in accordance with Acceptance Criterion 3 of this section.	The YMP will not implement a "Graded Quality Assurance Process."	
2.5.1.3 AC-2(9) Req:1	Existing or proposed quality assurance procedures are identified that reflect the documents and regulatory positions contained in Section 2.5.1.5 of the Yucca Mountain Review Plan. The requirements in 10 CFR Parts 21 and 63.73, and each criterion of 10 CFR 63.142 will be met by documented procedures. In addition, activities conducted under 10 CFR 63.73 and commercial-grade-item-dedication activities conducted under 10 CFR Part 21 must conform to the applicable provisions of the quality assurance program;	The YMP will comply with the requirements of 10 CFR 63.32 or 63.44; 10 CFR 63.73; 10 CFR 63.141; 10 CFR 63.142; 10 CFR 63.143; 10 CFR 63.144; and 10 CFR 21. In addition, see the QARD, Table 1.	Those regulations which are applicable to the design, construction, and operation of the Geologic Repository Operations Area (GROA) are considered to be "Regulatory Obligations" whether they are included in the QARD or not. YMP will implement all applicable and current Rules and Regulations required by the NRC.
2.5.1.3 AC-2(10) Req:1	A description is provided that emphasizes how the docketed quality assurance program description controls, particularly the requirements in 10 CFR 63.21 (c)(20), 63.44, 63.73, and 63.141-144 and the regulatory positions and documents contained in Section 2.5.1.5 of the Yucca Mountain Review Plan, will be implemented properly;	The YMP will comply with the requirements of 10 CFR 63.21(c)(20); 10 CFR 63.32 or 63.44; 10 CFR 63.73; 10 CFR 63.141; 10 CFR 63.142; 10 CFR 63.143; 10 CFR 63.144; and 10 CFR 21. In addition, see the QARD, Table 1.	Those regulations which are applicable to the design, construction, and operation of the Geologic Repository Operations Area (GROA) are considered to be "Regulatory Obligations" whether they are included in the QARD or not. YMP will implement all applicable and current Rules and Regulations required by the NRC.
2.5.1.3 AC-2(12) Req:1	Quality-related activities (such as design and procurement) initiated before the U.S. Nuclear Regulatory Commission issuance of the license are controlled under a U.S. Nuclear Regulatory Commission-approved quality assurance program in accordance with the requirements of 10 CFR Part 63, Subpart G. Approved procedures and a sufficient number of trained personnel should be available to implement the applicable portion of the quality assurance program before the initiation of the activity;	Quality affecting work is and will continue to be performed in accordance with the QARD, which through Revision 15, the NRC has accepted for controlling DOE's present work activities. The NRC review was in accordance with 10CFR 63.	Included in YMP Position.
2.5.1.3 AC-2(13) Req:1	A summary description is provided on how responsibilities and control of quality-related activities are	Quality related activities will not be	

NRC NUREG-1804 Section	NRC NUREG-1804 requirements	Notes, YMP Position, etc.	Justification for YMP Position
	transferred from principal contractors to the U.S. Department of Energy during any phase out of principal contractor activities;	transferred from the principal contractors to the U.S. Department of Energy during any phase out of principal contractor activities during the design and construction phase.	
2.5.1.3 AC-2(16)(d) Req:1	Proficiency tests are given to personnel performing and verifying activities affecting quality, and acceptance criteria are developed to determine if individuals are properly trained and qualified;	The requirement for proficiency testing is to be applied to personnel performing the quality assurance functions of: 1) assuring that an appropriate quality assurance program is established effectively executed; and 2) those verifying that activities important to waste isolation and important to safety functions have been correctly performed. The personnel performing these quality assurance functions are delineated in Section 2.2.11B – E.	10 CFR 63.142(b)(1) i-ii provides the criteria for what is determined to be quality assurance program functions. Personnel performing these functions are required to be trained, qualified, and certified as stated in QARD Section 2.2.11B – E. The initial certification requires testing, as appropriate, to determine the individual's proficiency in performing the quality assurance function. Inherent within the training, qualification, and certification program is a determination, on a recurring basis, of the proficiency of the personnel. Other personnel performing activities affecting quality will be indoctrinated, trained, and retrained to assure their proficiency is achieved and maintained as outlined in QARD Section 2.2.11A.
2.5.1.3 AC-3(11) Req:1	Procedures are established and described, requiring that design drawings and specifications be reviewed by the quality assurance organization to assure that the documents: (i) are prepared, reviewed, and approved in accordance with the U.S. Department of Energy procedures; and	In lieu of requiring the Quality Assurance organization to perform in-line reviews, YMP will require "qualified personnel" to perform these reviews in addition to QA personnel.	The YMP position is consistent with the NRC policy of "line ownership" of the QA program. Personnel will be trained and qualified as necessary to perform this function. This is also consistent with 2.5.1.3 AC-6(3).
2.5.1.3 AC-3(11) Req:2	[Procedures are established and described, requiring that design drawings and specifications be reviewed by the	In lieu of requiring the Quality Assurance	The YMP position is consistent

NRC NUREG-1804 Section	NRC NUREG-1804 requirements	Notes, YMP Position, etc.	Justification for YMP Position
	quality assurance organization to assure that the documents:] (ii) contain the necessary quality assurance requirements such as inspection and test requirements, acceptance requirements, and the extent to which inspection and test results are required to be documented;	organization to perform in-line reviews, YMP will require "qualified personnel" to perform these reviews in addition to QA personnel.	with the NRC policy of "line ownership" of the QA program. Personnel will be trained and qualified as necessary to perform this function. This is also consistent with 2.5.3.1 AC-6(3).
2.5.1.3 AC-3(17)(m) Req:1	As applicable, other requirements of the U.S. Department of Energy quality assurance program apply to the control of software supporting a safety or waste isolation function.	The QARD is the DOE QA program that is applicable to Important To Safety and Important To Waste Isolation Structures Systems, and Components and related activities and specifies software requirements based on NQA-1, 2000, Subpart 2.7. There are no requirements applicable to the 10 CFR 63.142 DOE QA program other than those delineated in the QARD.	
2.5.1.3 AC-3(21) Req:1	The applicable change control requirements of 10 CFR 63.44 are described; and	The YMP will comply with the requirements of 10 CFR 63.32 or 63.44; 10 CFR 63.73; 10 CFR 63.141; 10 CFR 63.142; 10 CFR 63.143; 10 CFR 63.144; and 10 CFR 21.	Those regulations which are applicable to the design, construction, and operation of the Geologic Repository Operations Area (GROA) are considered to be "Regulatory Obligations" whether they are included in the QARD or not. YMP will implement all applicable and current Rules and Regulations required by the NRC.
2.5.1.3 AC-3(22) Req:1	Procedures are established describing methods of reviewing and qualifying data used in design that were collected without a fully implemented 10 CFR Part 63 quality assurance program [NUREG-1298 (U.S. Nuclear Regulatory Commission, 1988)].	See YMP Position presented in the QARD, Table 1, item E.	See Table 1A* for justification description.
2.5.1.3 AC-3(23) Req:1	Procedures are established describing the use of expert elicitation. The procedure complies with NUREG-1563, Branch Technical Position on the Use of Expert Elicitation in the High-Level Radioactive Waste Program (U.S. Nuclear Regulatory Commission, 1996) as addressed in Section 2.5.4 of this review plan; and	See YMP Position presented in the QARD, Table 1, item F.	See Table 1A* for justification description.
2.5.1.3 AC-3(24) Req:1	Procedures are established describing the use of peer review [NUREG-1297 (U.S. Nuclear Regulatory Commission, 1988)].	See YMP Position presented in the QARD, Table 1, item D.	See Table 1A* for justification description.
2.5.1.3 AC-6(3) Req:1	Procedures are established to assure that changes to documents are reviewed and approved by the same	See YMP Position presented in the QARD,	See Table 1A* for justification

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NRC NUREG-1804 Section	NRC NUREG-1804 requirements	Notes, YMP Position, etc.	Justification for YMP Position
	organizations that performed the initial review and approval or by other qualified responsible organizations delegated by the U.S. Department of Energy;	Table 1, item A8.	description.
2.5.1.3 AC-7(8) Req:2	For procurement of commercial-grade items, Section 10, "Commercial Grade Items," of Supplement 7S-1 of NQA-1 -1983, "Supplementary Requirements for Control of Purchased Items and Services" (American Society of Mechanical Engineers, 1983), does not adequately address commercial-grade item dedication. The guidance provided in this acceptance criteria should be used for commercial-grade item dedication.	The QARD will implement the definitions and requirements provided in the YMRP and 10CFR 21 for a commercial grade program. See also the QARD, Table 1, item J.	See Table 1A* for justification description.
2.5.1.3 AC-7(8) Req:3	Where the U.S. Department of Energy elects to purchase commercial-grade items and dedicate the items for use as basic components, as permitted by the requirements contained in 10 CFR Part 21, the quality assurance program must provide for the following to assure that the dedicated item will perform its intended safety or waste-isolation function	YMP Position, the QARD will implement the definitions and requirements provided in the YMRP and 10CFR 21 for a commercial grade program. See also the QARD, Table 1, item J.	See Table 1A* for justification description.
2.5.1.3 AC-7(8)(c) Req:1	If these definitions are used, the U.S. Department of Energy commits to comply with all the provisions associated with the definitions;	By inclusion in the QARD, DOE commits to the use of these defined terms.	
2.5.1.3 AC-7(8)(e) Req:1	It is preferred that the above definitions be used. However, additional definitions and guidance for commercial-grade item dedication are provided in Electric Power Research Institute (1988), NP-5652, as endorsed by U.S. Nuclear Regulatory Commission Generic Letter 89-02 (U.S. Nuclear Regulatory Commission, 1989) and Generic Letter 91-05 (U.S. Nuclear Regulatory Commission, 1991). Although these documents are applicable for 10 CFR Part 50 licensees, certain elements of these documents may be appropriate for 10 CFR Part 63 commercial-grade-item-dedication activities.	See the QARD, Table 1, item J for commitment to EPRI NP-5652.	See Table 1A* for justification description.
2.5.1.3 AC-7(12) Req:1	For the purchase of American Society of Mechanical Engineers Section III Code items, the U.S. Nuclear Regulatory Commission considers the referenced edition of NQA-1 in the endorsed versions of the Code to be acceptable only for the construction of American Society of Mechanical Engineers Section III items when the referenced edition of NQA-1 is used in conjunction with the other quality assurance, administrative, and reporting requirements contained in the American Society of Mechanical Engineers Section III Code. Further, applicable provisions contained in the U.S. Department of Energy quality assurance program and requirements contained in the regulations also need to be met and must be used in conjunction with the American Society of Mechanical Engineers Section III Code; and	In lieu of utilizing an NRC "endorsed" version of the ASME Section III Code, the YMP may also use ASME Section III Code versions that are "otherwise approved by the NRC."	The addition of the words - - - - "or otherwise approved by the NRC" - - - - will allow more flexibility in selection of Code versions. This flexibility may be needed for the design and fabrication of certain ASME Section III structures, systems, or components. This addition will also allow the project to seek NRC approval for the use of non-endorsed versions of the Code. This is consistent with the NRC guidance provided in Section 2.1.1 of YMRP, in which the NRC states, "Thus, the U. S. Department of Energy has

* Reference letter Ziegler to U.S. NRC, Director, Division of High-Level Waste Repository Safety, dtd 9/17/04, enclosure 2 for Table1A.

NRC NUREG-1804 Section	NRC NUREG-1804 requirements	Notes, YMP Position, etc.	Justification for YMP Position
			flexibility to use any codes, standards, and methodologies to be applicable and appropriate."
2.5.1.3 AC-8(13) Req:1	As applicable, other requirements of the U.S. Department of Energy quality assurance program apply to the identification and control of materials, parts, and components (including samples).	The QARD is the DOE QA program that is applicable to Important To Safety and Important To Waste Isolation Structures, Systems, and Components and related activities.	As stated in the YMP Position.
2.5.1.3 AC-9(1) Req:1	The criteria for determining those processes that are controlled as special processes are described. As complete a listing as possible of special processes, which are generally those processes where direct inspection is impossible or disadvantageous, should be provided. Examples of special processes include welding, heat treating, nondestructive examination, and chemical cleaning;	The inclusion of a "complete list as possible of special processes" in the QARD will not provide added benefit to QA program users, therefore, an exception will be taken to maintaining a current listing of special processes in the QARD.	In addition to the typical special processes, i.e., welding, heat treating, chemical cleaning, and nondestructive testing, YMP will develop additional processes in accordance with controlling procedures. Special processes will be controlled by procedures. Additionally, the inclusion of a comprehensive list would necessitate additional revisions to the QARD as additional ones are added to the "list." Although such revisions would undoubtedly be classified as "non-reductions," it would still require processing of a revision, including the 24 month update. The non-inclusion of such a list is consistent with the Quality Assurance Program Descriptions which have been approved by the NRC for 10 CFR Part 50 and Part 72 licensees.
2.5.1.3 AC-10(2) Req:1	Organizational responsibilities for inspection are adequately described. Individuals performing inspections are other than those who performed or directly supervised the activity being inspected and do not report directly to the immediate supervisors who are responsible for the activity being inspected. If the individuals performing inspections are not part of the quality assurance organization, the inspection procedures, personnel qualification criteria, and independence from undue pressure such as cost and schedule should be reviewed and found	Individuals not within the QA organization will not perform inspections for acceptance.	

NRC NUREG-1804 Section	NRC NUREG-1804 requirements	Notes, YMP Position, etc.	Justification for YMP Position
	acceptable by the quality assurance organization before the initiation of the activity;		
2.5.1.3 AC-10(4) Req:1	Inspection procedures, instructions, or checklists provide for the following: identification of characteristics and activities to be inspected; description of the method of inspection; identification of the individuals or groups responsible for performing the inspection operation in accordance with the provisions of the second bullet under this acceptance criteria; acceptance and rejection criteria; identification of required procedures, drawings, specifications, and revisions thereof; records of the identity of the inspector or data recorder and the results of the inspection operation; and specification of necessary measuring and test equipment, including accuracy requirements;	Rejection criteria will not be identified as an inspection characteristic; YMP will only document acceptance criteria. Items or services not meeting acceptance criteria will be rejected.	This position is consistent with NQA-1, 10S-1, Para. 4.1, which requires "acceptance criteria."
2.5.1.3 AC-10(7) Req:1	When inspections associated with normal operations of the site (e.g., routine maintenance, surveillance, tests) are performed by individuals other than those who performed or directly supervised the work, but are within the same group, the following controls are required: (i) the qualification criteria for the inspection personnel are reviewed and found acceptable by the quality assurance organization before initiating the inspection; and	The QARD Rev 17 covers the period up to the receipt of the license to receive and possess; therefore, it is silent on the "inspections associated with normal operations." The QARD will be revised as necessary to address preclosure activities at the appropriate time.	The QARD will be revised prior to the license amendment to receive and possess HLW and SNF and to address start-up, operations, and as necessary to address preclosure activities at the appropriate time
2.5.1.3 AC-10(7) Req:2	[When inspections associated with normal operations of the site (e.g., routine maintenance, surveillance, tests) are performed by individuals other than those who performed or directly supervised the work, but are within the same group, the following controls are required:] (ii) the quality of the work can be objectively demonstrated through a functional test when the activity involves breaching a pressure-retaining item; and	The QARD Rev 17 covers the period up to the receipt of the license to receive and possess; therefore, it is silent on the "inspections associated with normal operations." The QARD will be revised as necessary to address preclosure activities at the appropriate time.	The QARD will be revised prior to the license amendment to receive and possess HLW and SNF and to address start-up, operations, and as necessary to address preclosure activities at the appropriate time
2.5.1.3 AC-10(10) Req:1	Procedures are established describing methods of reviewing and qualifying data that were collected without a fully implemented 10 CFR Part 63 quality assurance program [NUREG-1298 (U.S. Nuclear Regulatory Commission, 1988)].	See YMP Position presented in the QARD, Table 1, item E.	See Table 1A* for justification description.
2.5.1.3 AC-16(1) Req:1	Procedures are established and described indicating an effective corrective action program has been established. The quality assurance organization reviews and documents concurrence with the procedures;	Same as presented in 2.5.1.3 AC-3(11) Req:1.	Same as presented in 2.5.1.3 AC-3(11) Req:1.
2.5.1.3 AC-16(2) Req:1	Corrective action is documented and initiated after the determination of a condition adverse to quality, such as a nonconformance, failure, malfunction, deficiency, deviation, or defect in material, equipment, or samples. Conditions adverse to quality should be identified promptly and corrected as soon as practical. The quality assurance organization is involved in the documented concurrence of the adequacy of the corrective action. Followup action is taken by the quality assurance organization to verify proper implementation of corrective action and to close out the corrective action in a timely manner;	In lieu of the Quality Assurance organization being responsible for concurrence and follow-up, it is the YMP position that line management is responsible for both of these activities.	The NRC accepted this position in Revision 15 of the QARD, reference NRC letter dated July 22, 2004.
2.5.1.3 AC-17(2) Req:1	The scope of the quality assurance records program is described. Quality assurance records include scientific, engineering, and operational data and logs; results of reviews, inspections, tests, audits, and material analyses;	See YMP Positions presented identified below in Section 2.5.1.3 AC-17(7), (8), (9),	See Table 1A* for justification description.

* Reference letter Ziegler to U.S. NRC, Director, Division of High-Level Waste Repository Safety, dtd 9/17/04, enclosure 2 for Table1A.

NRC NUREG-1804 Section	NRC NUREG-1804 requirements	Notes, YMP Position, etc.	Justification for YMP Position
	monitoring of work performance; maintenance and modification procedures and related inspection results; reportable occurrences; computer software supporting a safety or waste isolation function; qualification of personnel, procedures, and equipment; and other documentation such as design records, drawings, specifications, procurement documents, calibration procedures and reports, design review reports, peer review reports, nonconformance reports, corrective action reports, as-built drawings, and other records required by preclosure and postclosure operating conditions;	(10), & (12).	
2.5.1.3 AC-17(7) Req:1	Provisions are made for the disposition of quality assurance records, including: ensuring that disposition of records is governed by the most stringent regulatory requirements that apply to records (this may be an agency other than the U.S. Nuclear Regulatory Commission); ensuring that suppliers' nonpermanent records are properly controlled and retained for required periods; and ensuring that quality assurance records are protected against damage, deterioration, or loss;	See the QARD, Table 1, item A14.	See Table 1A* for justification description.
2.5.1.3 AC-17(8) Req:1	Suitable controls are established and described for controlling, protecting, and maintaining quality assurance records before they are entered and stored in a quality assurance record storage area;	See the QARD, Table 1, item A11.	See Table 1A* for justification description.
2.5.1.3 AC-17(9) Req:1	Suitable facilities for the storage, preservation, and safekeeping of quality assurance records are described and satisfy the provisions contained in Section 4, "Storage, Preservation, and Safekeeping," of Supplement 17S-1 of NQA-1-1983 (American Society of Mechanical Engineers, 1983), "Supplementary Requirements for Quality Assurance Records";	See the QARD Table 1, items A10, A11, and A12.	See Table 1A* for justification description.
2.5.1.3 AC-17(10) Req:1	Guidance for storing quality assurance records, using electronic media, is provided in Regulatory Issue Summary 2000-18 (U.S. Nuclear Regulatory Commission, 2000);	See the QARD, Table 1, item I.	See Table 1A* for justification description.
2.5.1.3 AC-17(12) Req:1	For quality assurance records, Section 2.8, Retention of Records, of Supplement 17S-1 of NQA-1 -1983 (American Society of Mechanical Engineers, 1983), Supplementary Requirements for Quality Assurance Records, states that the retention period for nonpermanent records is required to be established in writing. Programmatic nonpermanent records should be retained for at least 10 years or the life of the item if less than 10 years. For programmatic nonpermanent records, the retention period should be considered to begin on completion of the activity. For product nonpermanent records generated before facility licensing, the retention period should be considered to begin on completion of delivery. In addition, product and programmatic nonpermanent records should be retained at least until the date of the start of preclosure site operational activities. Table 1 of Regulatory Guide 1.28, Revision 3 (U.S. Nuclear Regulatory Commission, 1985), provides a list of nonpermanent and lifetime records and their respective retention times. Records similar to those identified in Table 1 of Regulatory Guide 1.28 are required to be maintained for the repository for the durations identified. Although Table 1 is intended to be a comprehensive list, it is the U.S. Department of Energy responsibility to assure itself, in accordance with the Records Section of 10 CFR 63.142, that sufficient records are maintained to furnish evidence of activities affecting quality. Table 1 is not applicable for preoperational test or operational phase records at this time because the final design and operating practices have not been developed. Further, Table 1 does not address site characterization records. It should be recognized that the nomenclature of these records may vary. For records not listed in Table 1, the type of record most nearly	See the QARD, Table 1, item A1 and A10.	See Table 1A* for justification description.

* Reference letter Ziegler to U.S. NRC, Director, Division of High-Level Waste Repository Safety, dtd 9/17/04, enclosure 2 for Table1A.

NRC NUREG-1804 Section	NRC NUREG-1804 requirements	Notes, YMP Position, etc.	Justification for YMP Position
	describing the record in question should be followed with respect to its retention period. The following definitions apply to the records:		
2.5.1.3 AC-17(12)(a) Req:1	Programmatic nonpermanent records are those documents that were used to prescribe activities affecting quality, but that are not considered permanent records. Such records include documents prescribing the planning, execution, and auditing of activities affecting quality. Records such as audit checklists, audit results, and actual examinations used to qualify inspection and test personnel are included in this category; and	See the QARD, Table 1, items A1, A10, and A11.	See Table 1A* for justification description.
2.5.1.3 AC-17(12)(b) Req:1	Product nonpermanent records document that specific structures, systems, and components of the repository site have been designed and constructed in accordance with applicable requirements, but are such that is it not necessary to retain them as lifetime records. These records include design, verification data, receiving records, calibration records, maintenance records, inspection records, radiographs not associated with in-service inspection, and test records that are not otherwise designated as lifetime records.	See the QARD, Table 1, items A.1, A10, and A11.	See Table 1A* for justification description.
2.5.1.3 AC-18(6)(h) Req:1	The purchase of American Society of Mechanical Engineers Section III Code items. [Note: For the purchase of such items, the U.S. Nuclear Regulatory Commission has only endorsed certain editions and addenda of the American Society of Mechanical Engineers Section III Code (American Society of Mechanical Engineers, 1998) and in doing so has indirectly endorsed quality assurance standards referenced in the Code. The U.S. Nuclear Regulatory Commission considers the referenced edition of NQA-1 (American Society of Mechanical Engineers, 1983) in the endorsed versions of the Code to be acceptable only for the construction of American Society of Mechanical Engineers Section III items when the referenced edition of NQA-1 is used in conjunction with the other quality assurance, administrative, and reporting requirements contained in the American Society of Mechanical Engineers Section III Code. Applicable provisions contained in the U.S. Department of Energy quality assurance program and requirements contained in the regulations also need to be met]; and	In lieu of utilizing an NRC "endorsed" version of the ASME Section III Code, the YMP may also use ASME Section III Code versions that are "otherwise approved by the NRC."	The addition of the words - - - - "or otherwise approved by the NRC" - - - - will allow more flexibility in selection of Code versions. This flexibility may be needed for the design and fabrication of certain ASME Section III structures, systems, or components. This addition will also allow the project to seek NRC approval for the use of non-endorsed versions of the Code. This is consistent with the NRC guidance provided in Section 2.1.1 of YMRP, in which the NRC states, "Thus, the U. S. Department of Energy has flexibility to use any codes, standards, and methodologies it demonstrates to be applicable and appropriate."
2.5.1.3 AC-18(9) Req:1	Where the on-site quality assurance organization does not report to the off-site organization:	YMP does not have an off-site QA organization.	
2.5.1.3 AC-18(9)(a) Req:1	The off-site quality assurance organization conducts audits sufficient to verify adequacy of activities conducted by the on-site quality assurance organization;	YMP does not have an off-site QA organization.	

* Reference letter Ziegler to U.S. NRC, Director, Division of High-Level Waste Repository Safety, dtd 9/17/04, enclosure 2 for Table1A.

NRC NUREG-1804 Section	NRC NUREG-1804 requirements	Notes, YMP Position, etc.	Justification for YMP Position
2.5.1.3 AC-18(9)(b) Req:1	The off-site quality assurance organization reviews and concurs in the schedule and scope of audits performed by the on-site quality assurance organization; and	YMP does not have an off-site QA organization.	
2.5.1.3 AC-18(9)(c) Req:1	Results of audits performed by the on-site quality assurance organization are provided to the off-site quality assurance organization for review and assessment.	YMP does not have an off-site QA organization.	
2.5.1.3 AC-18(11) Req:1	The audited organization describes in a formal report the corrective action to be taken to address findings. This report is submitted to the auditing organization and responsible management of the audited organization; and	A similar requirement exists in NQA-1-1983. An exception has been provided to this aspect of the audit program as it applies to internal audits; see the QARD, Table 1, items A15 and A16.	See Table 1A* for justification description.
2.5.1.3 AC-18(12) Req:1	Provisions are established and described to assure that the cause of each finding is identified, resulting corrective action is described, and followup action is accomplished to assure proper closeout of deficiencies.	In order to be consistent with 10 CFR 63.142(q) "Corrective Action," a cause determination is only required if the audit finding is classified as a significant condition adverse to quality.	Included within YMP Position.

* Reference letter Ziegler to U.S. NRC, Director, Division of High-Level Waste Repository Safety, dtd 9/17/04, enclosure 2 for Table1A.