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TOKYO, JAPAN

December 6, 2013

Document Control Desk  
U.S. Nuclear Regulatory Commission  
Washington, DC 20555-0001

Attention: Mr. Perry Buckberg

Docket No. 52-021  
MHI Ref: UAP-HF-13283

**Subject: MHI's Supplemental Response to US-APWR DCD RAI No. 650-5093 (SRP 03.11)**

- References:** 1) "Request for Additional Information No. 650-5093 Revision 0, SRP Section: 03.11 – Environmental Qualification of Mechanical and Electrical Equipment, Application Section: 3.11," dated October 15, 2010, ML102930595.  
2) "MHI's Response to US-APWR DCD RAI No. 650-5093 Revision 0 (SRP 03.11)," UAP-HF-11035, dated February 17, 2011, ML110530414.

With this letter, Mitsubishi Heavy Industries, Ltd. (MHI) transmits to the U.S. Nuclear Regulatory Commission (NRC) a document entitled "MHI's Supplemental Response to US-APWR DCD RAI No. 650-5093 (SRP 03.11)."

Enclosed is the supplemental response to one RAI question, 03.11-39, contained within Reference 1. This question was responded to previously in Reference 2. The response to this RAI question is being supplemented to address comments from the NRC staff regarding Commercial Grade Dedication.

Please contact Mr. Joseph Tapia, General Manager of Licensing Department, Mitsubishi Nuclear Energy Systems, Inc. if the NRC has questions concerning any aspect of this submittal. His contact information is provided below.

Sincerely,



Yoshiaki Ogata,  
Executive Vice President  
Mitsubishi Nuclear Energy Systems, Inc.  
On behalf of Mitsubishi Heavy Industries, Ltd.

Enclosure:

1. Supplemental Response to US-APWR DCD RAI No. 650-5093 (SRP 03.11)

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CC: P. Buckberg  
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Docket No. 52-021  
MHI Ref: UAP-HF-13283

Enclosure 1

UAP-HF-13283  
Docket No. 52-021

Supplemental Response to US-APWR DCD RAI No. 650-5093  
(SRP 03.11)

December 2013

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**RESPONSE TO REQUEST FOR ADDITIONAL INFORMATION**

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12/6/2013

**US-APWR Design Certification**

**Mitsubishi Heavy Industries**

**Docket No. 52-021**

**RAI NO.:** NO. 650-5093 REVISION 0  
**SRP SECTION:** 03.11 – Environmental Qualification of Mechanical and Electrical Equipment  
**APPLICATION SECTION:** 3.11  
**DATE OF RAI ISSUE:** 10/15/2010

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**QUESTION NO. RAI 03.11-39**

In supplemental response to RAI Question 03.11-19, MHI proposed that Technical Report MUAP-08015, R1, Section 3.1.1, "10 CFR 50.49 Environmental Qualification of Electric Equipment Important to Safety for Nuclear Power Plants," be revised by adding, "An alternate methodology to qualifying equipment in harsh environments is to use commercial dedication methodologies to meet the 10 CFR 50.49 requirements for harsh electrical equipment environment qualification. This qualification method uses commercial grade dedication when the supplier lacks a 10 CFR 50, Appendix B QA program..." This is contrary to the staff position that qualifying equipment in harsh environments can't use commercial dedication methodologies to meet the 10 CFR 50.49 requirements. During the latest teleconference with MHI, the staff cited EPRI TR-102260, "Supplemental Guidance for the Application of EPRI report NP-5652 on the Utilization of Commercial Grade Items," which states that "Equipment Qualification is a part of the design process covered under 10 CFR Part 50, Appendix B, Criterion III which demonstrates either through the testing of a prototype, by engineering analysis of a prototype, or by historical performance demonstration of an item of the same design." On this basis, qualifying equipment in harsh environments is not allowed to use commercial dedication methods to meet the 10 CFR 50.49 requirements. However, EPRI commercial dedication method was conditionally approved by the NRC for satisfying 10 CFR Part 50, Appendix B. Revise Technical Report MUAP-08015, R1 where it is applicable (e.g., Sections 3.1.1, 3.7, Figure 7.1-EQ flow diagram).

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**ANSWER:**

This Request for Additional Information (RAI) appears to make the assertion that commercial grade dedication may not be used to qualify important to safety Structures, Systems and Components (SSCs) used in harsh environments. This application of commercial grade dedication for qualifying SSCs is supported by present statutory and regulatory positions. SSCs may be qualified using the conventional approaches used primarily up through the 1980's or by Commercial Grade Dedication (CGD). These two approaches are depicted in

the attached figure. In a recent NRC workshop *NRC Workshop on Vendor Oversight for New Reactor Construction*, Dec. 2008, R. McIntyre of the NRC made a presentation "Commercial Grade Dedication: Historical Perspective" (Adams accession number ML083400299), which provided an excellent summary of the history of the CGD approach for qualifying SSCs. The NRC presenter indicated that "Basic Components" as defined by 10 CFR Part 21 and the equipment qualification by commercial grade dedication of such components is allowed. Specifically, 10 CFR 21.3, applicable to new reactor vendors (**DCD, 10CFR52, Subpart E**, bold emphasis added) defines basic components and the commercial dedication process. Applicable portions are quoted below

*"Basic component.* (1)(i) When applied to nuclear power plants licensed under 10 CFR part 50 or **part 52** of this chapter, basic component means a structure, system, or component, or part thereof that affects its safety function necessary to assure:

(A) The integrity of the reactor coolant pressure boundary;"

The integrity of the reactor coolant pressure boundary would include SSCs located inside containment and by default therefore in a harsh environment. Furthermore, this section goes on to state:

"(ii) Basic components are items designed and manufactured under a quality assurance program complying with appendix B to part 50 of this chapter, or **commercial grade items which have successfully completed the dedication process.**"

Statutorily, the NRC has accepted commercial grade dedication as an acceptable method of verifying an SSC may be qualified for service in a harsh environment. In addition, this section further defines the commercial grade items and the dedication process:

*"Commercial grade item.* (1) When applied to nuclear power plants licensed pursuant to 10 CFR Part 30, 40, 50, 60, commercial grade item means a structure, system, or component, or part thereof that affects its safety function, that was not designed and manufactured as a basic component. Commercial grade items do not include items where the design and manufacturing process require in-process inspections and verifications to ensure that defects or failures to comply are identified and corrected (i.e., one or more critical characteristics of the item cannot be verified).

*Critical characteristics.* When applied to nuclear power plants licensed pursuant to 10 CFR Part 50, critical characteristics are those important design, material, and performance characteristics of a commercial grade item that, once verified, will provide reasonable assurance that the item will perform its intended safety function.

*Dedicating entity.* When applied to nuclear power plants licensed pursuant to 10 CFR Part 50, dedicating entity means the organization that performs the dedication process. Dedication may be performed by the manufacturer of the item, a third-party dedicating entity, or the licensee itself. The dedicating entity, pursuant to § 21.21(c) of this part, is responsible for identifying and evaluating deviations, reporting defects and failures to comply for the dedicated item, and maintaining auditable records of the dedication process.

*Dedication.* (1) When applied to nuclear power plants licensed pursuant to 10 CFR Part 30, 40, 50, 60, **dedication is an acceptance process undertaken to provide reasonable assurance that a commercial grade item to be used as a basic component will perform its intended safety function and, in this respect, is deemed equivalent to an item designed and manufactured under a 10 CFR Part**

**50, appendix B, quality assurance program.** This assurance is achieved by identifying the critical characteristics of the item and **verifying their acceptability by inspections, tests, or analyses performed by the purchaser** or third-party dedicating entity after delivery, supplemented as necessary by one or more of the following: commercial grade surveys; product inspections or witness at holdpoints at the manufacturer's facility, and analysis of historical records for acceptable performance. In all cases, the dedication process must be conducted in accordance with the applicable provisions of 10 CFR Part 50, appendix B. The process is considered complete when the item is designated for use as a basic component.

(2) When applied to facilities and activities licensed pursuant to 10 CFR Parts 30, 40, 50 (other than nuclear power plants), 60, 61, 63, 70, 71, or 72, dedication occurs after receipt when that item is designated for use as a basic component.”

The NRC has endorsed the commercial grade dedication process to be used during design and construction of a nuclear power plant in Regulatory Guide (RG) 1.28, Rev 4, *Quality Assurance Program Criteria (Design and Construction)*. RG 1.28 endorses ANSI/ASME NQA-1 (2008) and NQA-1a (2009). The Commercial Grade Dedication process is further defined in NQA-1a SUBPART 2.14, *Quality Assurance Requirements for Commercial Grade Items and Services*.

The following NRC references further expand on this process:

1. Generic Letter 91-05, Licensee Commercial-Grade Procurement and Dedication Programs, Washington, DC. April 9, 1991
2. NRC Inspection Procedure (IP) 38703, Commercial-Grade Dedication
3. NRC Inspection Procedure (IP) 43004, Inspection of Commercial-Grade Dedication Programs
4. NRC Inspection Procedure 88108, Quality Assurance: Control of Materials, Equipment, and Services (Pre-licensing and Construction).

In particular, IP 43004 specifically defines use of CGD applications for environmental and seismic qualification. IP 43004, step 7 states:

“7. Additional considerations for dedication of CGI for applications requiring environmental or seismic qualification:

(a) Utilization of non-destructive methods to verify the critical characteristics of the item to provide reasonable assurance that each individual commercial-grade item will perform in the design-basis accident/event **harsh environment** (e.g., loss of coolant accident, high energy line break, operating-basis earthquake, safe-shutdown earthquake). Like-for-like replacements should demonstrate performance equal to or better than the qualified prototype.

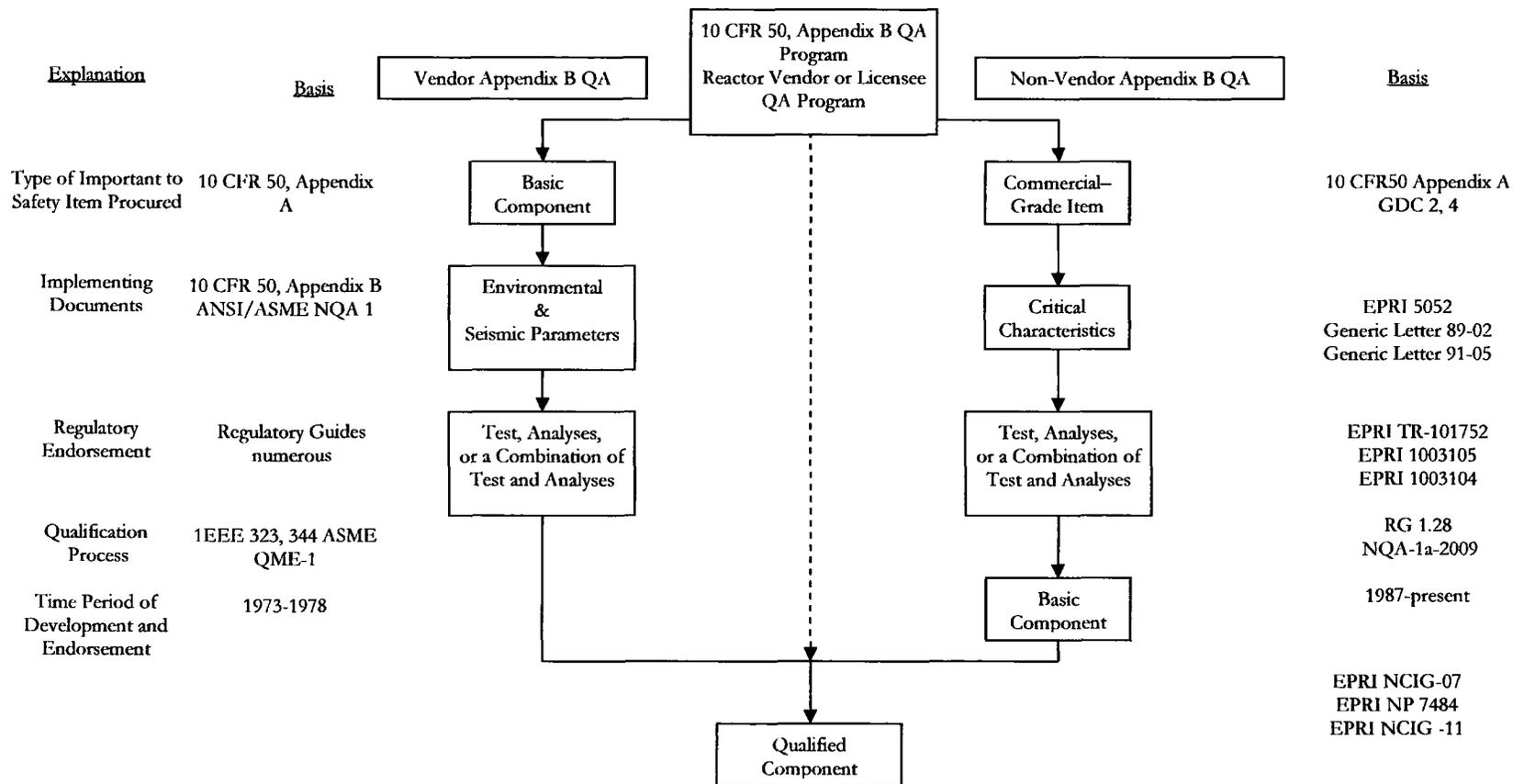
(b) The commercial-grade item's safety function(s), functional performance requirements, and success criteria determinations should include design service conditions (harsh environment, seismic).

(c) Seismic and environmental qualification should be treated as critical characteristics to be verified.”

These documents, taken in whole or in part, fully support the NRC's endorsement of the use of CGD as an appropriate methodology for qualifying important to safety and safety-related

SSCs for service in harsh environments. The wording in the MUAP-08015, R1 is consistent with the regulatory guidance cited above. As some references identified in this RAI response provide additional guidance and clarifications regarding CGD, these references and programmatic description enhancements will be added to the next revision of MUAP-08015 to more fully explain the use CGD in the US-APWR Equipment Qualification Program.

### EQUIPMENT ENVIRONMENTAL & SEISMIC QUALIFICATION PROCESS\*



\*Adopted from Figure 2.1 in EPRI TR 1003105, Dec, 2001 and revised to show additional references and enhanced framework.

**Impact on DCD**

There is no impact on the DCD.

**Impact on COLA**

There is no impact on the COLA.

**Impact on PRA**

There is no impact on the PRA.

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**SUPPLEMENTAL RESPONSE:**

This response supplements the response provided in MHI letter UAP-HF-11035, dated February 17, 2011 (ML110530414). As a result of recent discussions with the NRC staff regarding the use of Commercial Grade Dedication (CGD) methods as a part of the Environmental Qualification Program, additional changes will be made to MUAP-08015. These changes include revising Section 3.1.1 to indicate that CGD will be used in the procurement of qualified equipment. Additionally, Figure 7-1 is deleted from Section 7 and any reference to Commercial Grade Dedication is deleted from Section 7.7, "Equipment Qualification Process".

**Impact on DCD**

There is no impact on the DCD.

**Impact on R-COLA**

There is no impact on the R-COLA.

**Impact on PRA**

There is no impact on the R-COLA.

**Impact on Technical/Topical Report**

MUAP-08015 will be revised as shown in Attachment-1.

harsh environments are qualified pursuant to IEEE Std 323 (and other applicable IEEE standards) while mild environment SSCs can be considered qualified provided the environmental conditions are specified in a purchase specification and the vendor provides appropriate documentation for the equipment demonstrating that it complies with the purchase specification requirements. When appropriate, environmental qualification and procurement of mechanical and electrical equipment will be performed using a combination of qualification testing as described in Section 6.0 of this report, supplemented with an acceptable commercial grade dedication program and documentation as detailed in EPRI and NRC approved EPRI topical reports. This procurement method uses commercial grade dedication when the supplier lacks a 10 CFR 50, Appendix B QA program.

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Commercial grade dedication is based on nuclear industry documents (standards, codes, etc.) as outlined in NRC Inspection Procedures (IP) 38703, "Commercial-Grade Dedication" and IP 43004, "Inspection of Commercial Grade Dedication Programs", the EPRI reports referenced or endorsed therein and NQA-1a-2009, PART II, SUBPART 2.14. Of particular importance is the critical parameter characteristics definition for equipment requiring environmental qualification and the verification of these critical characteristics during the Environmental Qualification Program's harsh environment evaluation.

The purpose of commercial grade dedication acceptance is to provide reasonable assurance that an item meets specified requirements. Therefore, for applications which have environmental qualification requirements, these environmental qualification requirements will become an input to the commercial grade acceptance process when the selection of critical characteristics for acceptance is performed.

Non-destructive methods will be used to verify the critical characteristics of the item to provide reasonable assurance that each individual commercial-grade item will perform in the designbasis accident/event (e.g., loss of coolant accident, high-energy line break). The critical characteristics which relate to the environmental qualification requirements will be weighted heavily in selection of critical characteristics for acceptance and will become part of the Critical Characteristics. ~~An alternate methodology to qualifying equipment in harsh environments is to follow commercial dedication procedures, where acceptable, as outlined in EPRI and NRC approved EPRI topical reports.~~

### 3.1.2 10 CFR 50 Appendix A: General Design Criteria for Nuclear Power Plants

#### GDC 1: QUALITY STANDARDS AND RECORDS

This GDC requires ~~work that impacts important to safety SSCs be performed and documented using approved procedures and quality standards. This in essence requires a nuclear grade quality assurance program (QAP) that meets the requirements of 10 CFR 50, Appendix B. This in turn implies that all records associated with an EQP be maintained in accordance with the project QAP.~~

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~~The US-APWR DCD refers to the QAP for the US-APWR as required by GDC 1, quoting the regulation as follows:~~

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"Structures, systems, and components important to safety shall be designed, fabricated, erected, and tested to quality standards commensurate with the importance of the safety functions to be performed. Where generally recognized codes and standards are used, they shall be identified and evaluated to determine their applicability, adequacy, and sufficiency and shall be supplemented or modified as necessary to assure a

Displacements and support loads for the seismic II/I seismic loading are also considered as indicated in the DCD. Components or other equipment either included in seismic II/I piping such as valves and their operators are also evaluated for their structural integrity during an SSE. As needed, the results from this analysis may require seismic design for such non-safety components and EQ equipment qualification considerations for this seismic design in the procurement of these non-safety components. The implementation of the seismic II/I criteria is addressed in a project-specific EQ equipment qualification program.

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### 7.5 Critical Characteristics Applicable to the Design and Procurement Process

Critical SSC properties are those characteristics that are essential for the SSC's functional performance; the identifiable and/or measurable attributes of an SSC which provide assurance that the SSC will perform its design function (e.g., pump capacity, valve size, and material type).

Based on the design basis and performance of an SSC and its intended use, characteristics will be identified that are critical for acceptable performance. SSCs ~~important to safety~~ and their specification may inherently have one or more characteristics critical in assuring acceptability/equivalency of the SSC for an intended application. Purchase specifications provide (but are not limited to) guidance for this identification / selection process. Selection of EQ equipment qualification parameters and component requirements is based on complexity, safety function, and performance of the SSC. Typical EQ equipment qualification parameters to be considered are those listed in Section 4.0 of this Technical Report and include pressure, normal temperature, abnormal and/or peak temperature, humidity, radiation, submergence and qualified life (time). For seismic qualification, it should be determined if the SSC is seismically sensitive. If it is seismically sensitive, then the applicable documentation associated with the seismic qualification will be listed. This documentation may include additional equipment evaluation by screening and subsequent qualification testing, depending on screening results, which is required when ISRS used for equipment qualification EQ exhibit high-frequency exceedances due to site-specific exceedances of the ground motion response spectra. As per the guidance of Section B.1 of US NRC REG GUIDE 1.100 and US NRC interim staff guidance, such evaluations must be performed when exceedances occur in the 20 – 50 Hz range, and must demonstrate both structural integrity and functionality for seismic category I equipment.

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This information is captured during the design phase of a project and the critical characteristics are documented on the EQ Equipment Qualification Engineering Evaluation Form or other approved QA document to contain the needed Equipment Qualification Program EQP information.

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### 7.6 Equipment Qualification Process

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This section describes the combination of these guidance documents with the specific qualification of a given SSC. The nuclear safety determination for the individual component is determined by the system or structure in which it resides. Once that decision is made, the applicable environmental parameters are then established. ~~Once these equipment qualification EQ requirements are established, then the qualification process can begin by following the steps illustrated in Figure 7.1. Figure 7.1 is a logical decision tree for determining general Environmental Qualification requirements. This figure provides overall guidance and will be utilized during development of a PEQP.~~

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With any SSC, the engineering design for form, fit and function are the initial design steps. Components of a system will have design and operational requirements that are documented on the specifications and drawings for that component. Once the initial design is done for a specific project, then the equipment qualificationEQ process for the component can begin.

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~~In Figure 7.1, evaluation logic flows from top to bottom, starting with GDC for applicability for the individual SSC. Once the GDC and nuclear safety classification is done and answered positively, then a breakdown into type of SSC is required to find the applicable regulations as shown in the middle of Figure 7.1.~~

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The nuclear safety determination is the first step in the determination of the equipment qualificationEQ process for that component ~~with added steps illustrated in Figure 7.1~~. For example, a component inside containment may be subject to all of the environmental conditions discussed in the earlier parts of Section 4.0 of this Technical Report. However, it must first be categorized as to its type. The type classification is mechanical, electrical or other (structural or fire protection containment penetrations seals are examples of the other category). The next step is to determine if harsh or mild environmental conditions apply. A typical equipment qualificationEQ method is to identify the most severe equipment qualificationEQ parameter for a specific SSC and then apply those equipment qualificationEQ requirements to all the components of a similar design used throughout the plant. This approach is appropriate for smaller, less expensive components where there is little savings to be achieved for custom design. This approach addresses one of the operational requirements for spare parts by keeping them the same for all components of the same design.

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Section 4.0 of this Technical Report addresses the individual environmental parameters and their part in the qualification methodologies. Anticipated environmental conditions are the expected temperature, pressure, humidity (including submergence or impingement), chemical, radiation, seismic, aging and synergistic effects that an SSC may experience during normal, accident, testing and post accident conditions at the location within the facility at which the ~~important to safety~~ SSC requiring equipment qualification is installed. These environmental parameters must be considered when specifying the SSC. This is the engineering evaluation portion of the US-APWR Equipment Qualification ProgramEQP which is performed for each project. The US-APWR engineering EQequipment qualification evaluations for a specific project provide:

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- An auditable QA equipment qualificationEQ record
- SSC specifications with equipment qualificationEQ parameters as part of the procurement specifications
- Input to the Equipment Qualification ProgramEQP database including the SSC design and environmental parameters
- Acquisition of engineering design parameters
- Input for SSC Operation and Maintenance Technical Manuals
- A partial spare parts database
- Construction data to support preoperational tests
- Input for the ITAAC process where applicable

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~~The EQ equipment qualification description continues in Figure 7.1, where the regulations and design are combined for each SSC.~~ Once the requirements are set, then working with a vendor for the SSC will determine if the vendor's tests are adequate for the EQ equipment qualification or if separate performance tests are needed. These performance tests may be performed at a separate independent laboratory, or at the US-APWR nuclear plant site as part of startup qualification. Refer to Section 9.0 of this report for information regarding Laboratory Qualification and Vendor Testing. Refer to Section 10.0 of this report for additional information regarding the startup phase of a project.

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~~Qualification options are shown in the lower portion of Figure 7.1, including components that may undergo commercial grade dedication. The commercial grade dedication is the most involved of the paths leading to the component's EQ equipment qualification. In this case, all of the preceding engineering evaluation is required, plus matching the EQ equipment qualification requirements against the existing commercial component's qualifications. The use of commercial dedication is a project specific process.~~

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~~For a specific project, if commercial dedication is used to qualify a component then vendor tests or performance tests are completed and the remainder of the documentation and other database updates fall into the same procedure as other components for final equipment qualification EQ Qualification.~~

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#### 7.6.1 Site Specific Equipment Qualification Process

The US-APWR DCD describes the generic plant and is part of the basis for MHI obtaining a manufacturing license from the NRC. A project or site specific COL application is part of the basis for a utility (licensee) to obtain authorization to construct and operate a US-APWR. The DCD identifies the standard plant ~~important to safety and safety related~~ equipment that is to be qualified in support of a specific project. The COL identifies site-specific ~~important to safety and Safety Related~~ equipment that must also be qualified for use on a specific US-APWR. The qualification processes used on site specific ~~important to safety and Safety Related~~ equipment will use the same methods defined for the generic plant, however, they will be site or project specific. This process is described in Sections 8, 9, 10 and 11 of this [HW80] Technical Report [HW81].

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#### 7.7 Development of Aging Program, and Spare or Replacement Parts

Per 10 CFR 50.49(d)(5), "Equipment qualified by test must be preconditioned by natural or artificial (accelerated) aging to its end-of-installed life condition." The regulation describes the considerations for the aging testing including preconditioning a given SSC before any further aging tests. This testing is used to help determine the service life of an SSC [HW82] ~~important to safety~~. Aging requirements are SSC specific and are implemented on a project specific basis.

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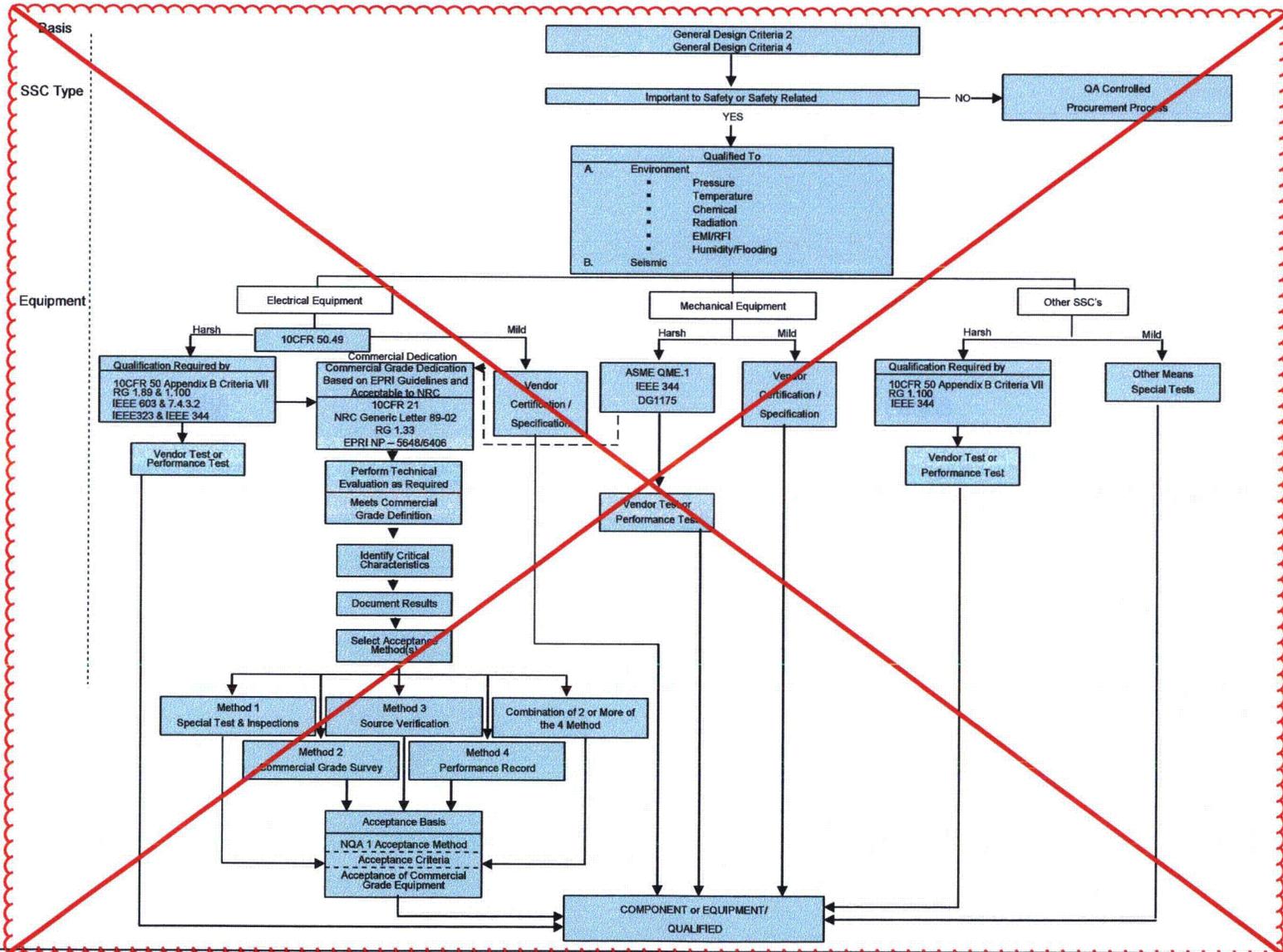
Spare parts lists are generated for each ~~safety related or important to safety~~ SSC requiring equipment qualification during the design and procurement phases of a project. On a specific US-APWR project, these spare parts are subject to the same equipment qualification EQ requirements as the original SSC. Where existing spares with the same specifications as originally purchased are not available, a commercial grade dedication program for the EQ equipment qualification process may be used subject to the limitations established for that project (see Section 8.0 of this Technical Report [HW83]). Within the commercial grade dedication program, each critical characteristic for an SSC is identified, evaluated by engineering, and documented in accordance with project specific procedures. During the

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Figure 7.1 ~~Equipment Qualification Flow Diagram Deleted~~



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