Enclosure 1

Assessment Document;

Comparison of 10CFR50 Appendix B, ASME NQA-1-1994, and NUREG-0800 Chapter 17.5 Requirement versus JEAG4101-1993, 2000

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Mitsubishi Heavy Industries, Ltd. 16-5, Konan 2-chome, Minato-ku Tokyo 108-8215 Japan

Mitsubishi Heavy Industries, LTD.

Assessment Document

Comparison of 10CFR50 Appendix B, ASME NQA-1-1994, and NUREG-0800 Chapter 17.5 Requirements versus JEAG4101-1993, 2000

US-APWR

PQD-HD-19004 Rev.0

MITSUBISHI HEAVY INDUSTRIES, LTD.

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Con	nparison of 1	0CFR50 App	endix B, ASN	ME NQA-1-19	94, and	NUREG-0800 Chapter 17.5
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1. STATEMENT OF PURPOSE

The purpose of this document is to provide a comparison of the JEAG4101-1993, 2000 versus US NRC 10CFR50 Appendix B, ASME NQA-1-1994 standard, NUREG-0800 Section 17.5, and an assessment of the impact of differences, if any, on the MHI QA Manual or Procedure and their proposed disposition.

Section 2 of this document provides method of comparison. Section 3 provides a summary of major differences with respect to standards and assessment of differences for MHI QA manual or Procedure. Section 4 provides a detailed Comparison Table.

2. METHOD OF COMPARISON

The Comparison Table (Section 4) provides a comparison of the requirements of the 10CFR50 Appendix B, ASME NQA-1-1994, and NUREG-0800 Section 17.5 versus the requirements of JEAG4101-1993, 2000.

The scope of the comparison in the Comparison Table is limited to the elements of the QA program requirements as defined in 10CFR50, Appendix B and as applicable to US-APWR Design Certification. The following parts of ASME NQA-1-1994 with corresponding requirements in the JEAG4101-1993, 2000 are not included:

- Part I: Quality Assurance Requirements for Nuclear Facility Applications;

- Part II: Non-mandatory Appendices.

For this comparison, ASME NQA-1-1994 is used as the reference document. Therefore, the clauses and paragraphs of other documents are aligned with the requirements stated in ASME NQA-1-1994, For example, the text of NUREG-0800 Section 17.5 in the Comparison Table is not in the same order as it appears in the original document.

3. SUMMARY OF MAJOR DIFFERENCES

3.1 Difference in structure

The ASME NQA - I - 1994 standard contains 18 main clauses that are modeled after the 18 criteria of 10CFR50, Appendix B. Each of these main clauses contains Basic

Requirements. Additional detailed requirements are included as mandatory Supplements for each of these clauses.

JEAG4101-1993 consists of two chapters and Chapter 2 is divided into four categories as follows.

1) Basic Matters (BASIC)

2) Supplementary and Recommended Matters (SUPPLE)

3) Reference Maters (REF)

4) Explanations (EX)

The boldface indicates the abbreviations used in the Comparison Table.

JEAG4101-2000 has two categories as follows;

1) BASIC REQIREMENTS (BAISIC)

2) REFERENCE MATTERS (Qn) n: 1 through 14

BASIC REQUIREMENTS consists of four chapters and two annexes. Two annexes are;

a. Supplementary Information on the Basic Requirements (SI)

 b. Necessary Considerations at the Time of Procurement from ISO Certificate Holders (EX)

c. REFERENCE MATTERS have fourteen items and each item is divided into several chapters and sections.

The boldface indicates the abbreviations using in the Comparison Table. REFERENCE MATTERS No. 10 Section 3.3 (Chapter 3), for example, is shown in the Comparison Table as **Q10 3.3**. Where the explanation in each REFERENCE MATTERS item is used in Comparison Table, it is shown as **Q10 EX** (explanation in Q10).

3.2 Difference in Requirements

The Comparison Table (Section4) provides:

- (a) A description of the requirements as identified in 10CFR50 Appendix B, Standard Review Plan Section 17.5, ASME NQA-1-1994, and JEAG4101-1993, 2000.
- (b) Identification of differences with respect to the Japanese Guidelines and the
- (c) An assessment of differences

Overall, both ASME NQA - 1 and JEAG4101-1993, 2000 require that quality assurance programs applicable to nuclear facilities address the same quality assurance program criteria as 10CFR 50 Appendix B. This comparison shows that there are no fundamental differences between ASME NQA-1-1994 and JEAG4101-1993, 2000 requirements

regarding 10CFR50 Appendix B criteria, however, there are differences in descriptions of implementation details described below;

a. Electronic record storage

The requirements regarding electronic storage of records and control of measuring and test equipment have evolved with the technology were the same in the earlier versions of the guidelines as they are today and as they are in current U.S. Standards.

b. Organization

The control of organization, personnel qualification, for example, is considered a part of Management control, not of the QA control in Japan. Therefore some requirements are not as detailed in Japanese standards.

c. Others.

A few requirements such as QA role and personnel qualification in design control are not addressed in Japanese Guidelines.

d. Preoccupied Requirement.

MHI QA manual took (or just have taken) some requirements in advance, whereas JEAG4101 had not reflected that requirements, for example, qualification examination of lead auditors.

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4. COMPARISON TABLE

I Organization II Quality Assurance Program IH **Design Control** IV Procurement Document Control V Instructions, Procedures, and Drawings VI **Document Control** VII Control of Purchased Items and Services Х Inspection XI **Test Control** XII Control of Measuring and Test Equipment XV Control of Nonconforming Items XVI **Corrective Action** XVII Quality Assurance Records XVIII Audits



COMPARISON TABLE I Organization (1/8)

	Standard Review Plan	1)	2)	2)	·····	Assessment of Difference
10 CFR 50 Appendix B	NUREG -0800	ASME NQA-1-1994Edtion	JEAG4101-1993	JEAG4101-2000	Differences	for MHI Manual or
	Section 17.5					Procedure
I. Organization	2. Individual managers are	Basic Requirement 1	Chapter 1	BASIC	Three standards have a	No significant Difference;
The applicant shall be	to ensure that personnel	Organization	3. QUALITY ASSURANCE	2,1,2 Implementation of	same concept and similar	No impact on the MHI QA
responsible for the	working under their	_	RESPONSIBILITY	Quality Assurance	requirements.	Manual or Procedure.
establishment and	management are qualified	The organizational	(1) The plant owner is	Programme		
execution of the quality	in accordance with written	structure, functional	responsible for	(1) Management	The description of	
assurance program.	procedures and that only	responsibilities, levels of	establishment and	responsible for quality	organizational freedom and	
	qualified personnel are	authority, and lines of	implementation of a quality	assurance activity shall	independency of QA	
The authority and duties of	permitted to perform those	communication for	assurance programme for	establish, implement and	Personnel in NQA-1 and	
persons and organizations	activities for which they are	activities affecting quality	nuclear power plants. In	maintain a quality	JEAG4101-1993 are	
performing activities	qualified. (NQA-1)	shall be documented.	addition, the plant owner	assurance programme.	similar, though	
affecting the safety-related	3. The QAPD is to contain	Persons or organizations	performs investigations,	(2) The quality assurance	organizational freedom and	
functions of structures,	an organizational	responsible for assuring	examinations, and	programme shall include	independency of QA	
systems, and components	description that addresses	that an appropriate quality	evaluations by using	details of how work is to be	Personnel are required, not	
shall be clearly established	the organizational	assurance program has	personnel who operate	managed, performed and	conceptually, but	
and delineated in writing.	structure, functional	been established and	independently from other	assessed.	specifically as	
These activities include	responsibilities, levels of	verifying that activities	organizations responsible	(3) The quality assurance	Supplemental Information	
both the performing	authority, and interfaces.	affecting quality have been	for these tasks.	programme shall include	in JEAG4101-2000.	
functions of attaining	The organizational	correctly performed shall	(Explanation-4)	the organizational		
quality objectives and the	description is to include the	have sufficient authority,		structure, functional	Based on the concept that	
quality assurance	onsite and offsite	access to work areas, and	(Explanation-4):	responsibilities, levels of	planning appropriate	
functions. The quality	organizational elements	organizational freedom to:	'investigations,	authority and interfaces for	quality assurance program	
assurance functions are	that function under the	(a) identify quality	examinations, and	those managing,	and establishing necessary	
those of (a) assuring that	cognizance of the QA	problems;	eva1uations by using	performing and assessing	organization to realize the	
an appropriate quality	program. Functional	(b) initiate, recommend, or	personnel who operate	the adequacy of work.	quality assurance program,	
assurance program is	responsibilities include	provide solutions to quality	independently from other	(4) The quality assurance	JEAG4101-2000 does not	
established and effectively	activities such as	problems through	organizations responsible	programme shall address	specify the item	
executed and (b) verifying,	preparing, reviewing,	designated channels;	for these tasks' has the	management measures,	"Organization".	
such as by checking,	approving, and verifying	(c) verify implementation of	following meanings.	including planning,		
auditing, and inspection,	designs; qualifying	solutions; and	'Personnel' refers to those	scheduling and resource		
that activities affecting the	suppliers; preparing,	(d) assure that further	under the direct control of	considerations.		
safety-related functions	reviewing, approving, and	processing, delivery,	plant management and			
have been correctly	issuing instructions,	installation, or use is	independent from	SUPPLE		
performed. The persons	procedures, schedules,	controlled until proper	individuals and	1. Supplemental		
and organizations	and procurement	disposition of a	organizations that are	Information about		
performing quality	documents; purchasing;	nonconformance,	responsible for	"QUALITY ASSURANCE		
assurance functions shall	verifying supplier activities;	deficiency, or	implementing quality	PROGRAMME"		
have sufficient authority	identifying and controlling	unsatisfactory condition	assurance tasks. These			
and organizational freedom	acceptable and	has occurred.	personnel objectively	Responsibility and authority		
to identify quality problems;	nonconforming hardware	Such persons or	investigate, examine, and	to stop unsatisfactory work		
to initiate, recommend, or	and software;	organizations shall have	evaluate the effectiveness	is assigned in such a		
provide solutions; and to	manufacturing; calibrating	direct access to	and appropriateness of	manner that planning,		
verify implementation of	and controlling measuring	responsible management	quality assurance activities	scheduling and other		
solutions. Such persons	and test equipment;	at a level where	at nuclear power plants,	considerations do not		
and organizations	qualitying and controlling	appropriate action can be		overlide safety		
performing quality	special processes;	enected. Such persons of	After evolucting their	programma alea requires		
assurance functions shall	constructing; inspecting;	to a management loval		that reviews be considered		
report to a management	nesting; startup; operating;	to a management level	proposo suggestions and	prior to restart of work in		
authority and	performing maintenance;	and croppizational freedom	give eninions to	etopping the work was		
autionly and	function: and controlling	and organizational needom:	give opinions to	soppring the work was		
including sufficient	records For multiple	are provided, including	make recommendations	quality under control		
independence from cost	organizations the interfere	from post and schodule	and give advice to the	quanty under control.		
independence from cost	organizations, the interface	nom cost and schedule	Land give advice to the			

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COMPARISON TABLE I Organization (2/8)

and schedule when opposed to safety considerations, are provided. Section 17.5 (Considerations, are provided. Considerations considerations are clearly defined. (Considerations, considerations, are provided. Individuals and organizations mentioned above endexving to follow up any connective actions. 3. Supplemental information about Procedure 0 Considerations, are provided. Considerations are clearly organizations steps applicants, (NQA-1 and ANSI N18.7). Considerationed ANSI N18.7). Supplemental information about 3. Supplemental information about 1 Considerationed applicants, (NQA-1 and ANSI N18.7). Considerationed ANSI N18.7). Considerationed applicants, (NQA-1) Personnel responsibilies organizations supplemental information analyzing non-conformances have an adequate understanding of the area in which they are working and access to persitter tacks; dofined. Personnel responsibilies organizations supplemental information analyzing non-conformances have an adequate understanding of the area in which they are working and access to periment background information concerning the non-conformance. They dofined. The organization its responsibility for esponsibility assurance entrusted with the ersponsibility or implementing the QA program and referring appropriate matters to the top management to a time aschedue considerations do nedetariation with persons in other senior management positions do inderation with personsin other senior management positions do inderation with personsible	10 CFR 50 Appendix B	Standard Review Plan NUREG -0800	1) ASME NQA-1-1994Edtion	JEAG4101-1993	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or
and schedule when opposed to safety considerations, are provided. responsibilities are clearly operational, and organizational elements are not applicable to DC applications 1 (NDA-1 and A S. Supplemental information about NON-CONTROLAND CORRECTVE ACTIONS* (2) The plant owner may which the responsibility for carrying out the audit functions are established. The individuals and filling these positions are to: (NGA-1) a. Inve sufficient authority and organizational feetoments to implement authority and organizational feetoment to implement authority and organizational feetoment to implement authority and organizational feetoment to implement authority appropriate matters to the top management elevel autifications of the appropriate matters to the top clear authority and communication with persons in other senior management positions of communication with persons in other senior management positions of clear authority and organizations and the extent in a timely manner considerations. 3. Supplemental Information about automation about automation about appropriate matters to the top management elevel autifications do not unduly influence decision making d. have effective lines of communication with persons in other senior management positions of communication with persons in other senior management positions d. May delegation of work to participants outside of the applicant or holder's organizations is the senior management positions d. have effective lines of communication with persons in other senior management positions d. have effective lines of communication with persons to ther senior management positions d. May delegation of work to particaparts ouside of the applicant or holder's organizatio	·	Section 17.5					Procedure
opposed to safety considerations, are provided. defined. (Considerations, are not applicants). (NOA-1 and ANSI NTs.7) organizations mentioned applicants.) (NOA-1 and ANSI NTs.7) 3. Supplemental information about "NOA-CONFORMANCE CONTROL AND CONTROL AND C	and schedule when	responsibilities are clearly	considerations.	individuals and			
Considerations, are provided. Operational, and maintenance organizational elements are not applicable to DC applicants), INDA-1 and AS. Managay above endeavoing to values Information about actions. (2) The plant owner may delegate to computation functions are established. (2) The plant owner may delegate to computations such as plant which the responsibility for suppliers, a part of this functions are established. Personnel responsibile for delegate to computations such as plant one-conformances have an adequate understanding of the area in which they are working and access to positions are to: (NOA-1) a. have sufficient authority and organizational freedom to implement assigned Personnel responsibility defined. The organization suppliers, a part of the responsibility for Personnel responsibility defined. The organization information other and organizational freedom to implement assigned Personnel responsibility defined. The organization information other are also independent from cost and schedule considerations. 0. be responsibility evel sufficiently high to ensure that cost and decision making d. have effective lines of communication with persons in other senior management positions decision making d. have effective lines of communication with persons in other senior management positions decision making d. have effective lines of communication with persons in other senior management positions decision making d. have effective lines of communication with persons in other senior management positions decision making d. have effective lines of communication with persons in other senior management positions decision making d. have effective lines of communication with persons in other senior management positions d. have effective lines of communication with persons in other senior manag	opposed to safety	defined. (Onsite/offsite,		organizations mentioned	3. Supplemental		
provided. provided.	considerations, are	operational, and		above endeavoring to	Information about		
organizational elements are not applicable to DC applicants.) (NQA-1 and ANSI N18.77) actions. CONTROL AND CONTROL And applicant or not undy and analyzing organizations such as plant organizations such as plant functions are established. Personnel responsibile for classifying and analyzing organizations such as plant organizations such as plant organizational firedom and organizational firedom to implement assigned to pragnational freedom program and referming appropriate matters to the top management [n 4 Amagement [n 4 A	provided.	maintenance		follow up any corrective	"NON-CONFORMANCE		
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b. Management positions in which the responsibility for carrying out the audit functions are established.Organizations spint suppliers or equipment suppliers or equipment and organizational freedom to implement assigned responsibility effect responsibility in the same responsibility in the same responsibility in the organizations that have been entrusted with e responsibility of the responsibility of responsibility for equipment and implement and and access supplement and implementance and implement and <br< td=""><td></td><td>ANSI N18.7)</td><td></td><td>delegate to other</td><td>Personnel responsible for</td><td></td><td></td></br<>		ANSI N18.7)		delegate to other	Personnel responsible for		
which the responsibility for carrying out the audit functions are established.suppliers of equipment suppliers, a part of its suppliers, a part of its suppliers, a part of its suppliers, a part of its responsibility for implement and information concerning the non-conformances to be working and access to pertinent background information concerning the non-conformances. They are also independent from cost and schedule cost and schedule cost and schedule cost and schedule cost and schedule to management in a timely management e. report at a management level sufficiently high to ensure that cost and schedule considerations do not unduly influence decision making decision making persons in other senior management positionssuppliers of equipment suppliers of equipment and cost and schedule cost and schedule co		5. Management positions in		organizations such as plant	classifying and analyzing		
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and described as follows: Chapter 2 nave achieved the desired		and described as follows:		Chapter 2	nave achieved the desired		
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a. The organizational 2.1 General personnel performing the		a. The organizational		2.1 General	personnel performing the		
elements responsible for An organizational structure work do not inspect their		elements responsible for	:	An organizational structure	work do not inspect their		
delegated work are snall be established to own work for acceptance.		delegated work are		shall be established to	own work for acceptance.		
b Management expertise		h Managament controls	·	ensure the implementation	performing acceptonce		
or quality assurance performing acceptance	1	and lines of communication		programmes	inspections are technically		
and mes of communication programmes. Inspections are technically	1.	and lines or communication		programmes.	inspections are technically		
designated person or bis		designated parson or bin	1	2.2 Responsibility and	winpetent.		
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delegated Automy Automy Automy		delegated	1	An organizational structure	10 Supplemental		
organization) are identified with clearly defined Information about		organization) are identified		with clearly defined	Information about		
and documented.		and documented.		functional responsibilities	"INDEPENDENT		

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COMPARISON TABLE I Organization (3/8)

, 10 CFR 50 Appendix B	Standard Review Plan NUREG -0800	1) ASME NOA-1-1994Edtion	2) JEAG4101-1993	2) JEAG4101-2000	Differences	Assessment of Difference for MHI Manual or
	Section 17.5			1		Procedure
10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5 C. Responsibility for the QA program and the extent of management oversight is established. d. The performance of delegated work is formally evaluated by the applicant or holder. 8. Responsibility and authority to stop unsatisfactory work and control further processing, delivery, installation, or use of nonconforming items (e.g., SSCs, parts, materials, equipment, consumable materials, and software) is assigned by the applicant or holder such that cost and schedule considerations. (NQA-1) 9. Individuals assigned the responsibility for ensuring effective execution of any portion of the QA program at any location have direct access to such levels of management as may be	ASME NQA-1-1994Edtion	JEAG4101-1993 ²¹ and levels of authority, or assignment of scope of work shall be established to implement quality assurance programmes. The following shall be taken into consideration at the establishment of the organization: a. The fundamental responsibility to attain the required quality resides with the individual or responsible organization who implements the works. b. When verification of conformance to established requirements is necessary, it is implemented by those who do not have direct responsibility for implementing the work. c. The individuals and organizations who verify conformance to the quality of work, and who guide and advise the establishment of adequate quality assurance programmes for efficient implementation of cettivition have the	JEAG4101-2000 ASSESSMENT A system of planned and documented internal and external audits is carried out to assess the adequacy and effectiveness of the QA programme. Assessment personnel operate as an arm of, and as an advisor to, senior management. The assessments focus on evaluating the performance of work and actions, and include the review and evaluation of QA documents.	Differences	Assessment of Difference for MHI Manual or Procedure
	management as may be necessary to perform this function. (NQA-1)	Supplement 1S-1 Supplementary Requirements for	implementation of activities, have the authority necessary to implement these steps. 2.3 Communication and coordination among organizations When quality assurance programmes are implemented by plural organizations, internal and external communication systems among organizations shall be clearly defined. The methods of communication and adjustment among organizations shall		This NQA-1-1994 clause is a paragraph introducing the additional requirements in	See below

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COMPARISON TABLE

I Organization (4/8)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17 5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
		Organization 1. General This Supplement provides amplified requirements for organization. It supplements the requirement of Basic Requirement 1 of this Standard and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Standard.			the Supplementary Requirements. It specifies that the Supplementary Requirements apply when and to the extent specified by the organization invoking Part I of NQA-1-1994.	Procedure
Because of the many variables involved, such as the number of personnel, the type of activity being performed, and the location or locations where activities are performed, the organizational structure for executing the quality assurance program may take various forms provided that the persons and organizations assigned the quality assurance functions have this required authority and organizational freedom.	10. Personnel performing work activities such as, but not limited to, design, engineering, procurement, manufacturing, construction, installation, startup, maintenance, and modification are responsible for achieving acceptable quality. (NQA-1)	 2.1 The organizational structure and the responsibility assignments shall be such that: (a) quality is achieved and maintained by those who have been assigned responsibility for performing work; and (b) quality achievement is verified by persons or organizations not directly responsible for performing the work. 	Chapter 2 BASIC 2.2 Responsibility and authority a. The fundamental responsibility to attain the required quality resides with the individual or responsible organization who implements the works. b. When verification of conformance to established requirements is necessary, it is implemented by those who do not have direct responsibility for implementing the work.	BASIC 2.1.2 Implementation of Quality Assurance Programme (See above) 2.1.3 Constitution of Quality Assurance Programme The quality Assurance programme shall provide an interdisciplinary approach involving many organizational components. (1) Quality assurance programme shall include the consideration about the items below. a . Managers provide planning, direction, resources and support to achieve the organization's objectives b . Staff performing assessments evaluate the effectiveness of management processes and work performance (2) The quality assurance programme shall be binding on everybody.	Three standards have a same concept and similar requirements.	No significant Difference; No impact on the MHI QA Manual or Procedure.
The applicant may delegate to others, such as	11. The applicant or holder	2.2 Delegation of Work The individual(s) or	Chapter 1 3 QUALITY ASSURANCE	BASIC 2.1.1Responsibility for	Three standards have a same concept and similar	No significant Difference; No impact on the MHLQA

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COMPARISON TABLE I Organization (5/8)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
contractors, agents, or consultants, the work of establishing and executing the quality assurance program, or any part thereof, but shall retain responsibility therefore,	the activities of planning, establishing, and implementing the overall QA program to others but is to retain the responsibility for the program. (NQA-1) 12. When the applicant or holder delegates responsibility for planning, establishing, or implementing any part of the overall QA program, sufficient authority to accomplish the assigned responsibility also is delegated. (NQA-1)	organization(s) responsible for establishing and executing a quality assurance program under this Standard may delegate any or all of the work to others but shall retain responsibility therefore.	RESPONSIBILITY (3) The organizations that have been entrusted with a part of the responsibility for establishment and implementation of the quality assurance plan are responsible for establishing and implementing the quality assurance programme within the entrusted extent. (Explanation-5)	Quality Assurance Programme (2) If the responsible organization delegates to other organizations the work of establishing and implementing all or a part of the overall quality assurance programme, it shall retain responsibility for the effectiveness of the programme in all circumstances. SUPPLE 1. Supplemental Information about "QUALITY ASSURANCE PROGRAMME" The QA programme assigns responsibility to the line organization to carry out the work to achieve the organization to perform the tasks they have been assigned. Line management is responsible for achieving quality in the items and services provided by the organization. Individual workers are responsible for the quality of their own work.	requirements.	Manual or Procedure.
		2.3 Nonconforming items Responsibility for the control of further processing, delivery, installation, or operation of nonconforming items shall be designated in writing.	Unapter 2 SUPPLE 10.3.1 Control method for review and disposition The following should be taken into consideration to establish control methods for review and disposition of non-conforming items and services: a. Assignment of review responsibility and the	3. Supplemental Information about "NON-CONFORMANCE CONTROL AND CORRECTIVE ACTIONS" Line managers establish and implement measures promptly to identify, document, classify, analyze, correct, eliminate	same concept and similar requirements.	No significant Difference; No impact on the MHI QA Manual or Procedure.

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COMPARISON TABLE

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I Organization (6/8)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
			authority to make disposition decisions b. Disposition procedures (a) Preparation of report (b) Reporting format decisions (c) Reporting route and others c. Disposition of items (a) Do not use or receive (b) Use or receive after repair (c) Use or receive as is d. Evaluation of item or service influence on other areas e. Verification after completion of disposition (a) Reinspection or retesting (b) Review of revised documents, etc.	and follow up activities, items, services or processes that do not meet established requirements and goals or do not result in the anticipated quality.		
Irrespective of the organizational structure, the individual(s) assigned the responsibility for assuring effective execution of any portion of the quality assurance program at any location where activities subject to this appendix are being performed shall have direct access to such levels of management as may be necessary to perform this function.		3 Multiple Organizations 3.1 Responsibility Where more than one organization is involved in the execution of activities covered by this Part (Part I), the responsibility and authority of each organization shall be clearly established and documented.	Chapter 2 BASIC 2.3 Communication and coordination among organizations When quality assurance programmes are implemented by plural organizations, internal and external communication systems among organizations shall be clearly defined. The methods of communication and adjustment among organizations shall	BASIC 2.1.2 Implementation of Quality Assurance Programme (3) The quality assurance programme shall include the organizational structure, functional responsibilities, levels of authority and interfaces for those managing, performing and assessing the adequacy of work. SUPPLE 1. Supplemental Information about "QUALITY ASSURANCE PROGRAMME" The QA programme is binding on all personnel, including those with responsibility for planning, scheduling and resource considerations. The QA programme describes or provides reference to the	Three standards have a same concept and similar requirements.	No significant Difference; No impact on the MHI QA Manual or Procedure.

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10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	1) ASME NQA-1-1994Edtion	2) JEAG4101-1993	2) JEAG4101-2000	Differences	Assessment of Difference for MHI Manual or Procedure
				organizational structure, functional responsibilities, levels of authority and interfaces for all segments of the organization. It is the intent of this basic requirement to ensure that the appropriate authorities are established and to enable the organization to carry out its functional responsibilities in management, performance of work, and in the assessment of the adequacy of work.		
		3.2 Interface Control 3.2.1 The external interfaces between organizations and the internal interfaces between organizational units, and changes thereto, shall be documented. 3.2.2 Interface responsibilities shall be defined and documented.	Chapter 2 SUPPLE 2.3 Communication and coordination among organizations (1) The function of each organization and the relations among the organizations should be defined clearly when methods for communication and adjustment among the organizations are established. (2) At the procurement stage, communication and adjustment should be implemented among not only purchaser organizations but also organization groups between the purchaser and the supplier.	SUPPLE 1. Supplemental Information about "QUALITY ASSURANCE PROGRAMME" The QA programme identifies all work delegated to outside organizations, and lines of communication and interfaces between internal and external organizations. The responsibility of each organization, as it relates to the assigned work, is described.	Three standards have a same concept and similar requirements.	No significant Difference; No impact on the MHI QA Manual or Procedure.
	1. At the most senior management level, the applicant or holder (i.e., the organization applying to have its QAPD reviewed and accepted by the NRC) is to issue a written QAPD that establishes the quality policy and commits the		-	SUPPLE 1. Supplemental Information about "QUALITY ASSURANCE PROGRAMME" As part of the QA programme, senior management is to develop	There is a similar description in JEAG4101-2000, though the description is not found in JEAG4101-1993.	Significant Deference in JEAG4101-1993; No impact on the MHI QA Program, because MHI has the same manner and has already applied.

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COMPARISON TABLE I Organization (8/8)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	2) JEAG4101-2000	Differences	Assessment of Difference for MHI Manual or Procedure
	organization to implement it. (ANSI N18.7)			and issue a written QA policy statement that establishes the management's concept and objectives regarding quality. This policy statement must clearly reflect the commitment of senior management to the attainment and continuous improvement of quality.	·	
	4. The QA program requires independence between the organization performing checking functions from the organization responsible for performing the functions. (This provision applies to DC applicant, ESP, and construction QA programs. This provision is not applicable to design reviews/verifications. The provision for design review/verification is addressed in C.2.f.) (10 CFR 50.34(f)(3)(iii)(A))		General: See above About Design Review/Verification; See Section III. Design Control 4.Design Verification	General: See above About Design Review/Verification; See Section III. Design Control 4.Design Verification	General: See above About Design Review/Verification; See Section III. Design Control 4.Design Verification	General: See above About Design Review/Verification; See Section III. Design Control 4.Design Verification
	7. Management ensures that the size of the QA organization is commensurate with its duties and responsibilities. (This applies to DC applicants, ESP, and construction QA programs.) (10 CFR 50.34(f)(3)(iii)(F))		- -	BASIC 2.1.1 Responsibility for Quality Assurance Programme (3) Management responsible for quality assurance activity shall provide resources including personnel, methods, materials, equipment and circumstances, and support for the effective implementation of the quality assurance programme consistent with specified time schedules for accomplishing project activities.	There is a same meaning clause in JEAG4101-2000, though the description is not found in JEAG4101-1993.	Significant Deference in JEAG4101-1993; No impact on the MHI QA Program, because this issue has already been conducted as management level action item in MHI. Also, MHI has established the QA Program for management to realize this requirement by reporting the result of assessment(self-assessme nt, non-conformance and audit, etc.) directly to top management.

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II Quality Assurance Program (1/32)

	Standard Review Plan	· • •	2)	21		Assessment of Difference
10 CFR 50 Appendix B	NUREG -0800	ASME NQA-1-1994Edtion	JEAG4101-1993	JEAG4101-2000	Differences	for MHI Manual or
	Section 17.5					Procedure
II. Quality Assurance	3. The QA program	Basic Requirement 2	BASIC	BASIC	Three standards have	No Significant Difference;
Program	ensures that activities	Quality Assurance Program	1.2 Establishment of quality	2.1 Quality Assurance	similar requirements.	No Impact on the MHI QA
The applicant shall	affecting quality are		assurance programmes	Programme	NQA-1 Basic Requirement	Manual or Procedure.
establish at the earliest	accomplished under	A documented quality	(Explanation 1-1)	2.1.1 Responsibility for	2 is essentially a summary	
practicable time consistent	suitably controlled	assurance programishall	(1) Prior to quality	Quality Assurance	of the main elements of an	1
with the schedule for	conditions Controlled	be planned implemented	assurance activities quality	Programme	effective OA program It	
accomplishing the	conditions include the use	and maintained in	assurance programmes	(1) The responsible	identifies high level	
	of appropriate equipment:	accordance with this Part	shall be developed and	organization shall also be	requirements for	
activities, a quality	auitable anvironmental	(Part I) or partians thereof	documented	responsible for the	verification program	
assurance program which	suitable environmental	The program shall identify	documented.	ostablishment and	accessment training and	
complies with the	conditions for	the program shall dentily		implementation of the	qualification the control of	
requirements of this	accomplishing the activity,	which it applies. The	1.2.1 Development and	averal quality assurance	itome processes and	
appendix. This program		which it applies. The	1.2.1 Development and		processes and	
shall be documented by	the fall mess; and assurance	establishment of the	documentation of quality	(2) If the reenensible	practices, etc.	
written policies,	that all prerequisites for the	program shall include	The developed and	(2) If the responsible		
procedures, or instructions	given activity have been	consideration of the	The developed and	organization delegates to		
and shall be carried out	satistied. (NQA-1)	technical aspects of the	documented quality	other organizations the		
throughout plant life in		activities affecting quality.	assurance programmes	work of establishing and		
accordance with those	4. The OA program is	The program shall provide	should be approved by the	Implementing all or a part		
policies, procedures, or	required to be documented	control over activities	person who has been	of the overall quality		
instructions. The applicant	by written policies,	affecting quality to an	assigned responsibility for	assurance programme, it		
shall identify the structures,	procedures, or instructions.	extent consistent with their	the establishment and	shall retain responsibility		
systems, and components	(NQA-1)	importance. The program	implementation of the	for the effectiveness of the		
to be covered by the quality		shall be established at the	programmes. (Explanation	programme in all		
assurance program and the	5. The QA program is	earliest time consistent with	1-4)	circumstances.		
major organizations	binding on all participating	the schedule for		(3) Management		
participating in the	organizations from the top	accomplishing the	1.2.2 Contents of quality	responsible for quality		
program, together with the	executive to all workers	activities.	assurance programmes	assurance activity shall		
designated functions of	whose activities may	The program shall provide	(1) The requirements for	provide resources including		
these organizations. The	influence quality. (NQA-1)	for the planning and	quality assurance	personnel, methods,		
quality assurance program		accomplishment of	programmes should be	materials, equipment and		
shall provide control over	6. The applicant or holder	activities affecting quality	identified according to the	circumstances, and support		
activities affecting the	retains and exercises the	under suitably controlled	contents described in	for the effective		
quality of the identified	responsibility for the scope	conditions. Controlled	section 2 through 13 in this	implementation of the		
structures, systems, and	and implementation of an	conditions include the use	guide.	quality assurance		
components, to an extent	effective overall QA	of appropriate equipment,	(2) The degree of quality	programme consistent with		
consistent with their	program. (NQA-1)	suitable environmental	assurance activity	specified time schedules		
importance to safety.		, conditions for	implementation should be	for accomplishing project		
Activities affecting quality	7. The applicant or holder	accomplishing the activity,	clarified according to the	activities.		
shall be accomplished	is responsible for ensuring	and assurance that	characteristics of items or			
under suitably controlled	that the applicable portion	prerequisites for the given	services.	2.1.2 Implementation of		
conditions. Controlled	of the QA program is	activity have been satisfied.		Quality Assurance		
conditions include the use	properly documented,	The program shall provide	1.3 Review of quality	Programme		
of appropriate equipment;	approved, and	for any special controls,	assurance programmes	(1) Management		
suitable environmental	implemented (people are	processes, test equipment,	(1) The adequacy of quality	responsible for quality		
conditions for	trained and resources are	tools, and skills to attain the	assurance programmes	assurance activity shall		1
accomplishing the activity,	available) before an activity	required quality and for	and the implementation of	establish, implement and		1
such as adequate	within the scope of the QA	verification of quality.	quality assurance activities	maintain a quality		
cleanness; and assurance	program is undertaken by	The program shall provide	based on these	assurance programme.		
that all prerequisites for the	the applicant/holder or by	for indoctrination and	programmes shall be	(2) The quality assurance		
given activity have been	others. (NQA-1)	training, as necessary, of	reviewed by the person	programme shall include	1	
satisfied. The program		personnel performing	who has been assigned the	details of how work is to be		1
shall take into account the		activities affecting quality to	responsibility for their	managed, performed and		1
need for special controls,		assure that suitable	establishment and	assessed.	<u> </u>	

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II Quality Assurance Program (2/32)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17 5	1) ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ^{2}}	Differences	Assessment of Difference for MHI Manual or Procedure
processes, test equipment,	00000000000	proficiency is achieved and	implementation.	(3) The quality assurance		
tools, and skills to attain the		maintained.	(Explanation 1-3)	programme shall include		
required quality, and the		Management of those		the organizational		
need for verification of		organizations implementing	(2) Corrective action shall	structure, functional		
quality by inspection and		the quality assurance	be taken if deficiencies in	responsibilities, levels of		
test. The program shall		program, or portions	quality assurance	authority and interfaces for		
provide for indoctrination		thereof, shall regularly	programmes are	those managing,		
and training of personnel		assess the adequacy of	discovered by review.	performing and assessing		
performing activities		that part of the program for		the adequacy of work.		
affecting quality as		which they are responsible	2.4 Indoctrination and	(4) The quality assurance		
necessary to assure that		and shall assure its	training	programme shall address		
suitable proficiency is		effective implementation.	All personnel responsible	management measures,		
achieved and maintained.			for implementing activities	including planning,		
The applicant shall		야 한 것 같아.	affecting quality shall be	scheduling and resource		
regularly review the status		· · · · · · · · · · · · · · · · · · ·	indoctrinated and trained	considerations.		
and adequacy of the quality			as necessary according to			
assurance program.			their educational	2.1.3 Constitution of		
Management of other			background, experience,	Quality Assurance		
organizations participating			(Evaluation 2.4)	The multiple commence		
In the quality assurance			(Explanation 2-1)	The quality assurance		
program snall regularly			DEE	programme snall provide		
review the status and			121 Development and	an interdisciplinary		
adequacy of that part of the		200 S.	1.2.1 Development and	approach involving many		
which they are executing "			(1) The understanding of	components		
which they are executing.		10 align and 10 al	the concents 'quality' and	(1) Quality assurance		
			'quality assurance' is	programme shall include		
		N N	important	the consideration about the		
			(2) Quality assurance	items below		
			programmes consist of an	a Managers provide		
			adequate combination of	planning, direction.		
		l.	two fundamental activities.	resources and support to		
			namely control-oriented	achieve the organization's		
		1	and work-oriented	objectives		
			activities.	b. Staff performing the work		
			(Explanation 1-5)	achieve quality		
			(3) These are two kinds of	c. Staff performing		
		•	documents for	assessments evaluate the		
			control-oriented activities	effectiveness of		
		~	(administration	management processes		
		,	documents). These are	and work performance		
		1	quality assurance	(2) The quality assurance		
		5 1	programme documents,	programme snall be		
			and control procedures for	binding on everybody.		
			quality assurance. when	2.1.4 Application of Graded		
			documents the matters to	Approach to Quality		
			be considered are as			
			follows:	(1) Nuclear safety shall be		
			(Explanation 1-6, 1-7)	the fundamental		
		1	a All requirements in this	consideration in the		
I I			quide necessary for the	identification of the items		
			items or services	services and processes to		

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10:CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993	JEAG4101-2000	Differences	Assessment of Difference for MHI Manual or Procedure
10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	1) ASME NQA-1-1994Edtion	2) JEAG4101-1993 concerned are described in the quality assurance programme documents. And description of these documents is detailed enough to convince the management responsible for the establishment and implementation of the plan of the adequency at the time of review. Furthermore, the matters to be included in the quality assurance programme documents are below, but the documentation is not necessary for non-applicable items and services. (a) Purpose of the quality assurance programme (b) Scope of the items and services covered by the quality assurance programme (c) Review of the quality assurance programme (d) Organizations for the quality assurance programme (e) Document control (f) Design control	JEAG4101-2000 which the quality assurance programme applies. (2) A graded approach based on the relative importance to nuclear safety of each item, service or process shall be used in the applications of the quality assurance programme. (3) The graded approach shall reflect a planned and recognized difference in the applications of specific quality assurance requirements. 2.2 Training and Qualification Personnel shall be trained and qualified in accordance with a grade of his knowledge, experience and skill so that they are competent to perform their asafety and the safety consequences of their activities. SUPPLE	Differences	Assessment of Difference for MHI Manual or Procedure
			(f) Design control (g) Procurement control (h) Material and component control (i) Fabrication and installation control (j) Inspection and test	SUPPLE 2. Supplemental Information about "TRAINING AND QUALIFICATION"		
			(k) Operation and maintenance control (l) Non-conformance control (m) Actions for prevention of recurrence	address and stimulate professional development and include professional, managerial, communication and interpersonal skills.		
			 (n) Control of quality records (o) Audits b. Control procedures for quality assurance indicate the detailed processes and methods for all activities to accomplish the quality 	Individual personnel training plans are not limited to initial qualification but provide maintenance of proficiency and progressive improvement. This ensures that all employees are continually aware of		

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II Quality Assurance Program (4/32)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17,5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
			assurance requirements. These procedures are to be described to simplify	state of the art technology and processes relative to the work they perform.		
			encourage appropriate execution of control	Q1 2.1 Conorol		
			The following are also to be included as appropriate in	(1) The plant owner and the other participating		
			(a) Purpose of the procedures	establish a Quality Assurance Programme		
		i .	(c) Definition of specific	each organization is responsible in the nuclear		
			(d) A series of processes to	(2) Followings are the examples of the matters		
			the purpose of the procedure, method, and	implement in order to establish a Quality		
			(e) Document format for	a) Activities to be implemented shall be		
			instruction (f) Type of quality record to be described and format of	b) Along with confirmation of applicable regulations,		
			(4) The documents for	rules provided by plant owner in the management		
			(documents for works) include the work plan	be confirmed and determined whether or not		
			procedures, work instructions, and drawings.	reflected in the routine activities.		
			documents, the matters to be considered are as	insufficiency in the current Quality Assurance Programme regarding the		
			(Explanation 1-8, 1-9) a. The work plan documents are to be	requirements based on the basic matters and the		
			described in such a way to plan the work carried out by each organization	guidelines, improvement and new development of the Quality Assurance		
			beforehand and execute it systematically and orderly. And if necessary, the	Programme shall be conducted according to the determined priority.		
			working matters, working processes, working standards to be applied.	d) In the case of any change in the Quality Assurance Programme. the		
1			and working schedule, etc.	timing of implementing the		

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II Quality Assurance Program (5/32)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17,5	ASME NQA-1-1994Edtion	JEAG4101-1993	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
			are to be included in the work plan documents;	change shall be clearly identified.		
			work procedures, work	2.5 Grading		
			instructions, and drawings	(1) The application extent of		
			provide concrete	requirements may be		
			information. This will make	determined according to the		
			appropriate executions of activities possible	relative importance of the		
•			according to the control	safety of the nuclear power		
			procedures for quality	plant. Graded approach		
			assurance and the work	could be applicable so that the essential requirements		
			documents are to be	may be satisfied and the		
			concise and clear.	required quality and safety		
			(5) The existing quality	may be ensured.		
			applicable if the necessary	stringent quality assurance		
		2	requirements in this guide	requirements shall be		
		}	are reflected in these	applicable to the matters in the bighest grade and the		
			their review.	most tempered quality		
				assurance requirements		
			1.2.2 Contents of quality	shall be applicable to the		
			The most important way to	Grading approach shall be		
		r.	clarify the degree that	applicable to the following		
			quality assurance activities	matters:		
			consider the influence that	educations and trainings		
			the functional	b) Level of specified		
			non-conformity of items	instructions and extent of		
			the safety of nuclear power	c) Necessity and level of		
			plants.	specified inspection plan		
			Additional matters to be	d) Level of confirmation and		
		•	a The complexity	e) Requirements for material		
			uniqueness, or novelty of	traceability		
			the item or service	f) Type of assessment		
			controls and inspection for	(stored		
			processes, methods, and	(3) In applying grading		
			equipment	approach to the matters		
			c. The degree to which compliance for functional	matters shall be taken into		
			requirements can be	consideration.		
			demonstrated by inspection	a) Complexity, uniqueness		
		,	or testing	and innovation of the item		
			degree of standardization	b) Necessity of special		
			of the item or service	control and inspection for		

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COMPARISON TABLE II Quality Assurance Program (6/32)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17 5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
	Section 17.5		e. The accessibility to the item installed for maintenance, in-service inspection, and replacement	the process, method and equipment c) Degree of feasibility for suitability of functional requirements by inspection / test. d) Level of quality history and standardization of item and service e) Accessibility of post-installation items for maintenance, in-service inspection and replacement (4) In the case of any change in item, service or process, the grade for which quality assurance requirements are applicable may be more stringent or more tempered depending on the change of importance related to the safety of nuclear power plant. 3.1.6Timing to Establish the Pragramme The requirements and critical matters for a specific stage of the Quality Assurance Programme shall be considered at an early phase so that they should be established before starting the stage. For instance, following matters shall be included in establishing the operation-related Quality Assurance Programme: a) Establishment of task-related documents that are documented with sufficient specificity b) Ensuring educated / trained, competent personnel c) Improvement of working place, equipments, tools and suitable working environment 4.4.1 Evaluation of Quality		Procedure
				Assurance Programme		

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II Quality Assurance Program (7/32)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
				The individual responsible for establishment and performance of Quality Assurance Programme shall evaluate validity of the Quality Assurance Programme and its performance for which is requested. [Explanation Q1-9]		
		Supplement 2S-1 Supplementary Requirements for the Qualification of Inspection and Test Personnel 1 GENERAL This Supplement provides amplified requirements for the qualification of personnel who perform inspection and testing to verify conformance to specified requirements for the purpose of acceptability. It supplements the requirements of Basic Requirement 2 of this Standard and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Standard. The requirements of this Supplement do not apply to the qualification of personnel for performance of nondestructive examination.	-	-	This NQA-1-1994 clause is a paragraph introducing the additional requirements in the Supplementary Requirements. It specifies that the Supplementary Requirements apply when and to the extent specified by the organization invoking Part I of NQA-1-1994. It excludes NDE personnel from the requirements of this Supplement.	See below
	T. TRAINING AND QUALIFICATION - INSPECTION AND TEST (10 CFR Part 50, Appendix B, Criterion II) 2. Written procedures for the qualification of inspection and test	2 CERTIFICATION 2.1 Qualification Requirements The responsible organization shall designate those activities that require qualified inspection and test personnel and the	BASIC 8.2 Inspection control (3) Inspections shall be carried out by people other than those who carried out the work subject to inspection. The qualification of the inspectors shall also be	Q4 2.3 Education/Training and Qualification (1) The qualification shall be performed correspond to knowledge, experience, and skill so that the personnel understand the importance of activity on	SRP and Three standards have similar requirements, though JEAGs do not have explicit requirements for qualification of inspection and test personnel. Unique NQA-1 requirements are:	No Significant Difference; No impact on the MHI QA Manual or Procedure, because MHI does not inspect or test. MHI requires this NQA-1 provision to vendor at the procurement of inspection and/or test such as design

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COMPARISON TABLE II Quality Assurance Program (8/32)

	Standard Poview Plan					Assessment of Difference
10 CFR 50 Appendix B	NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	for MHI Manual or Procedure
	personnel, and for the assurance that only those personnel who perform inspection and test activities are required to be established. (NQA-1) T. TRAINING AND QUALIFICATION - INSPECTION AND TEST (10 CFR Part 50, Appendix B, Criterion II) 6. Inspections by persons during on-the-job training for qualification is performed under the direct observation and supervision of a qualified person and verification of the conformance is by the qualification is achieved. (Approved via SE (Accession No. ML050700416).)	minimum requirements for such personnel. Further, the responsible organization shall establish written procedures for the qualification of inspection and test personnel, and for the assurance that only those personnel who meet the requirements of this Supplement are permitted to perform inspection and test activities When a single inspection or test requires implementation by a team or a group, personnel not meeting the requirements of this Part (Part I) may be used in data-taking assignments or in plant or equipment operation, provided they are supervised or overseen by a qualified individual.	established when necessary. REF. 8.2.3 Inspector (1) Because inspection testing (such as non destructive testing) requires inspector-level skills, inspector qualification is necessary.	safety and achieve their assigned role, as necessary. 3.2 Inspector (1) When the qualification of inspector skill such as non-destructive test (examination) is required, the qualification of inspector shall be specified.	 Establish written procedures for: The qualification of inspection and test personnel; The assurance that only those personnel who meet the requirements of this Supplement are permitted to perform inspection and test activities. Use personnel not meeting the qualification requirements of ASME NQA-1-1994 only in data-taking assignments or in plant or equipment operation, provided they are supervised or overseen by a qualified individual. 	qualification tests.
		2.2 Personnel Selection Personnel selected for performing inspection and test activities shall have the experience or training commensurate with the scope, complexity, or special nature of the activities.	BASIC 2.4 Indoctrination and training All personnel responsible for implementing activities affecting quality shall be indoctrinated and trained as necessary according to their educational background, experience, and proficiency. (Explanation 2-1) SUPPLE 2.4 Indoctrination and training Indoctrination and training programmes, in such areas as engineering and skills, should be established and	Q1 4.2.2 Personnel Plan Appropriate number of personnel shall be selected according to implementation schedule of the Quality Assurance Programme and workload of tasks, then educations / trainings of the staff as well as task assignment of the staff shall be determined. Considerations shall be given to necessity of special skills and educations / trainings.	Three standards have similar requirements.	No Significant Difference; No impact on the MHI QA Manual or Procedure.

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COMPARISON TABLE II Quality Assurance Program (9/32)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	1) ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
			implemented for all personnel responsible for implementing quality assurance activities affecting quality at each stage such as design, procurement, fabrication, installation, and operation and maintenance.			
			REF. 2.4 Indoctrination and training (1) Upon the establishment of indoctrination and training programmes for fabrication, installation, and operation and maintenance stages, a consideration regarding those who require qualifications according to laws and regulation is to be taken account of. (Explanation 2-2) (2) In regard to indoctrination and training for the acquisition of personnel qualifications, it is important to establish programmes and implement them from a long-term point of view.			
		2.3 Indoctrination Provisions shall be made for the indoctrination of personnel as to the technical objectives and requirements of the applicable codes and standards, and the quality assurance program elements that are to be employed.	See above	Q1 4.3.4 Educations and Trainings Using Instructions When work instructions are used or when significant level of revision is made on the work instructions, the division responsible for the task shall perform personnel educations and trainings necessary for the task. This is also an opportunity for the manager to explain the importance of thorough conformance to the instructions. Further, the results of the educations	Three standards have similar requirements. JEAG4101-2000 also requires the management role to personnel indoctrination and training.	No Significant Difference; No impact on the MHI QA Manual or Procedure.

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COMPARISON TABLE II Quality Assurance Program (10/32)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
				and trainings performed shall be reflected in the instructions and the instructions shall be revised appropriately to rectify problems identified in the results.		
				Q4 2.3 Education/Training and Qualification (1) The qualification shall be performed correspond to knowledge, experience, and skill so that the personnel understand the importance of activity on safety and achieve their assigned role, as necessary.		
		2.4 Training The need for a formal training program shall be determined, and such training activities shall be conducted as required to qualify personnel who perform inspections and tests. On-the-job training shall also be included in the program, with emphasis on firsthand experience gained through actual performance of inspections and tests.	See above	Q1 4.3.1 Performance of Educations and Trainings (1) All the personnel who perform management tasks, works and evaluation activities shall understand organizational objectives related to safety of product quality, personnel and general public as well as their direct involvements with quality policies and the Quality policies and the Quality Assurance Programme in the introductory and continued trainings and educations depending on the level of knowledge, experience and skill. If necessary, records of education and training plan for fabrication, erection, operation and maintenance stages, considerations shall be given to the necessity of qualifications concerning the tasks for	Three standards have similar requirement. JEAG4101-2000 also requires management responsibility to understand the importance of not only the quality of the items and services, but related to nuclear safety of product quality.	No Significant Difference; No impact on the MHI QA Manual or Procedure.

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COMPARISON TABLE II Quality Assurance Program (11/32)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ^{2}}	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
				mandatory based on laws and standards. (3) Plans shall be developed and implemented based on a long-term viewpoint concerning the educations and trainings related to acquisition of qualifications.		
				4.3.5 Educations and Trainings on Professional Matters It is important to promote improvement of professional techniques and skills. Because the skills of personnel can be gradually improved by educations and trainings, educations and trainings shall be conducted on continuous basis so that initially qualified level of works and skills can be further improved.		
				Q4 2.3 Education/Training and Qualification (1) The qualification shall be performed correspond to knowledge, experience, and skill so that the personnel understand the importance of activity on safety and achieve their assigned role, as necessary. (2) In training and fostering of technical personnel, past education, training and experience of assigned personnel shall be referred. (3) In personnel training for inspection and test, inspection/testing experience including OJT shall be regarded as important.		
	T. TRAINING AND QUALIFICATION - INSPECTION AND TEST	2.5 Determination of Initial Capability The capabilities of a	See above	Q1 4.3.5 Educations and Trainings on Professional	SRP and three standards have similar requirements.	No Significant Difference; No impact on the MHI QA Manual or Procedure.

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COMPARISON TABLE II Quality Assurance Program (12/32)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
	(10 CFR Part 50, Appendix B, Criterion II) 5. Inspection and test personnel initial qualification requirements are based on education, training, and experience and demonstration of capability in performing the type of inspection or test commensurate with the job. (Approved via SE (Accession No. ML050700416).)	candidate for certification shall be initially determined by a suitable evaluation of the candidate's education, experience, training, and either test results or capability demonstration.		Matters It is important to promote improvement of professional techniques and skills. Because the skills of personnel can be gradually improved by educations and trainings, educations and trainings shall be conducted on continuous basis so that initially qualified level of works and skills can be further improved. Q4 2.3 Education/Training and Qualification (1) The qualification shall be performed correspond to knowledge, experience, and skill so that the personnel understand the importance of activity on safety and achieve their assigned role, as necessary. (2) In training and fostering of technical personnel, past education, training and experience of assigned personnel shall be referred.		
	T. TRAINING AND QUALIFICATION - INSPECTION AND TEST (10 CFR Part 50, Appendix B, Criterion II) 1. The job performance of inspection and test personnel are reevaluated at periodic intervals not to exceed 3 years. (NQA-1)	2.6 Evaluation of Performance The job performance of inspection and test personnel shall be reevaluated at periodic intervals not to exceed 3 years. Reevaluation shall be by evidence of continued satisfactory performance or redetermination of capability in accordance with the requirements of para. 2.5 above. If during this evaluation or at any other time, it is determined by the responsible organization that the capabilities of a individual	See above	4.3.5 Educations and Trainings on Professional Matters It is important to promote improvement of professional techniques and skills. Because the skills of personnel can be gradually improved by educations and trainings, educations and trainings shall be conducted on continuous basis so that initially qualified level of works and skills can be further improved.	SRP and three standards have similar requirements. But JEAGs do not have explicit requirements for the periodic reassessment of the qualifications of inspection and test personnel.	No Significant Difference; No impact on the MHI QA Manual or Procedure, because MHI does not inspect or test by itself at DC stage. MHI requires this NQA-1 provision to vendor at the procurement of the inspection and test such as design qualification tests.

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COMPARISON TABLE II Quality Assurance Program (13/32)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
	3. Any person who has not performed inspection or testing activities in his/her qualified area for a period of 1 year is reevaluated prior to performing inspection and test activities. (NQA-1)	are not in accordance with the qualification requirements specified for the job, that person shall be removed from that activity until such time as the required capability has been demonstrated. Any person who has not performed inspection or testing activities in his qualified area for a period of 1 year shall be reevaluated by a redetermination of required capability in accordance with the requirements of para. 2.5 above.				
	T. TRAINING AND QUALIFICATION - INSPECTION AND TEST (10 CFR Part 50, Appendix B, Criterion II) 4. Training and certification records for inspection and test personnel are maintained as follows: (NQA-1) a. employer's name b. identification of person being certified c. activities certified to perform d. basis used for certification which includes such factors as education, experience, indoctrination, and training test results, where applicable e. results of periodic evaluation f. results of periodic exaluations, when required g. signature of employer's designated representative who is responsible for such certification n h. examination results i. date of certification or	 2.7 Certificate of Qualification The qualification of personnel shall be certified in writing in an appropriate form, including the following information: (a) employer's name; (b) identification of person being certified; (c) activities certified to perform; (d) basis used for certification, which includes such factors as: (1) education, experience, indoctrination, and training (2) test results, where applicable (3) results of capability demonstration (e) results of periodic evaluation; (f) results of physical examinations, when required; (g) signature of employer's designated representative who is responsible for such certification; (h) date of certification expiration. 	See above	Q4 2.3 Education/Training and Qualification (4) When certificate for qualification and re- qualification is required, it shall be documented with appropriate form. Guidance for education/training graded approach is provided in "this guideline (reference matters) Q1 (Quality Assurance Programme)"	SRP and three standards have similar requirements. But JEAGs do not have explicit requirements for the certificate of qualification of inspection and test personnel.	See above

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10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
	certification expiration j. results of capability demonstration					
		2.8 Physical The responsible organization shall identify any special physical characteristics needed in the performance of each activity, including the need for initial and subsequent physical examination.	-	_	JEAGs do not have a specific requirement for identifying any special physical characteristics of inspection and tests personnel.	See above
		3 RECORDS 3.1 Record Files Records of personnel qualification shall be estab- lished and maintained by the employer. These rec- ords shall include the information required by para. 2.7 above.	BASIC 2.4 Indoctrination and training All personnel responsible for implementing activities affecting quality shall be indoctrinated and trained as necessary according to their educational background, experience, and proficiency. (Explanation 2-1) SUPPLE 2.4 Indoctrination and training Indoctrination and training programmes, in such areas as engineering and skills, should be established and implemented for all personnel responsible for implementing quality assurance activities affecting quality at each stage such as design, procurement, fabrication, installation, and operation and maintenance. REF. 2.4 Indoctrination and training (1) Upon the establishment of indoctrination and training programmes for fabrication, installation, and operation and maintenance stages a consideration	Q1 4.3.1 Performance of Educations and Trainings (1) All the personnel who perform management tasks, works and evaluation activities shall understand organizational objectives related to safety of product quality, personnel and general public as well as their direct involvements with quality policies and the Quality Assurance Programme in the introductory and continued trainings and educations depending on the level of knowledge, experience and skill. If necessary, records of educations and trainings shall be maintained. (4) Records of the qualified personnel shall be maintained appropriately.	Three standards have similar requirements.	No Significant Difference; No impact on the MHI QA Manual or Procedure.

COMPARISON TABLE II Quality Assurance Program (14/32)

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II Quality Assurance Program (15/32)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
			regarding those who require qualifications according to laws and regulation is to be taken account of. (Explanation 2-2) (2) In regard to indoctrination and training for the acquisition of personnel qualifications, it is important to establish programmes and implement them from a long-term point of view.			
		Supplement 2S-2 Supplementary Requirements for the Qualification of Nondestructive Examination Personnel	N/A This NDE personnel qualification requirement is not applied on this DC application.	N/A This NDE personnel qualification requirement is not applied on this DC application.	_	-
		1 GENERAL This Supplement provides amplified requirements for the qualification of personnel who perform radiographic (RT), magnetic particle (MT), ultrasonic (UT), liquid penetrant (PT), electromagnetic (ET), neutron radiographic (NRT), leak testing (LT), acoustic emission (AE), and visual testing (VT) [hereinafter referred to as nondestructive examination (NDE)] to verify conformance to specified requirements. It supplements the requirements of Basic Requirement sof Basic Requirement sof Basic Requirement vhen and to the extent specified by the organization invoking this Part (Part I). 2 CERTIFICATION 2.1 Applicable Documents The American Society of				

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COMPARISON TABLE II Quality Assurance Program (16/32)

	Ol I D D					Accomment of Difference
10 CFR 50 Appendix B	NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	for MHI Manual or Procedure
		Nondestructive Testing Recommended Practice No. SNT-TC-1A, June 1980 Edition, and its applicable supplements shall apply as requirements to NDE personnel covered by this Supplement. 2.2 Program The responsible organization shall establish written procedures for the control and administration of NDE personnel training, examination, and certification. 2.3 Records Records of personnel qualification shall be established and maintained by the employer.				
		Supplement 2S-3 Supplementary Requirements for the Qualification of Quality Assurance Program Audit Personnel 1 GENERAL This Supplement provides amplified requirements for the qualification of an audit team leader, henceforth identified as a Lead Auditor, who organizes and directs audits, reports audit findings, and evaluates corrective action. This Supplement also provides amplified requirements for the qualifications of individuals, henceforth referred to as Auditors, who participate in an audit, such as technical specialists, management representatives, and auditors-in-training. It supplements the requirements of Basic Requirement 2 of this Part	-		This NQA-1-1994 clause is a paragraph introducing the additional requirements in the Supplementary Requirements. It specifies that the Supplementary Requirements apply when and to the extent specified by the organization invoking Part I of NQA-1-1994.	See below

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COMPARISON TABLE II Quality Assurance Program (17/32)

Conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Part (Part I).BASIC 2.4 Indoctrination and trainingQ5 2.4.1 Planning Managers should make arrangements for be used the audit personnel qualifications and the requirements for the used is pecialists to accomplish the audiling of quality assurance auditing regurames shall baveBASIC 2.4 Indoctrination and trainingQ5 2.4.1 Planning Managers should make arrangements to ensure that all personnel performing assessment attining and experience, accomplish the auditing of quality assurance auditing organizes thall baveNo Significant Differer No impact on the MH Managers should make arrangements for the use of the requirements for the use of technical specialists to accomplish the auditing of quality assurance auditing assurance au	10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	1) ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
S. TRAINING AND QUALIFICATION CRITERIA - QUALITY ASURANCE (10 CFR Part 50, Appendix B, Criterion II)			conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Part (Part I).			-	
 A Training programs to ensure that QA auditors shall have, or be given, appropriate training or orientation to develop their competence for activities to be audited. Aduditors shall have, or be given, appropriate training or orientation to develop their competence for management that QA auditors management taking the following methods: a. Orientation that provides a diviting functions shall be developed by one or more of the methods given in (a) through (C) below. Shall be developed by one or more of the methods: a. Orientation that provides a diviting functions shall be developed by one or more of the methods given in (a) through (C) below. Shall be developed and understanding of this Part implementing audits and the auditing or registration are developed at the auditing of the part implementing audits. b. A training program that provides general and the auditing or granization sproedures for implementing audits. b. A training program that provides general and specialized training in audit performance. General implementing audits, and reporting results. b. A training program that provides general and specialized training in audit performance. General and results for guality contacted training in audit performance. General and specialized training in audit performance. General and and results for guality contacted the auditing or ganization. b. A training program that provides general and and percenting results. b. A training from produces general and and percenting results. characteristics, or guality for guality and results for guality contacted throng in audity and results for guality and tasses and experise or the and results for guality and tasses and and experise or the origistration. the following traing shall be developed by concords and the based on experise and and experise to the auditing or ganization. the following traing shall be developed by concords and t		S. TRAINING AND QUALIFICATION CRITERIA - QUALITY ASSURANCE (10 CFR Part 50, Appendix B, Criterion II)	2 QUALIFICATION OF AUDITORS 2.1 Responsibility of Auditing Organization The responsible auditing organization shall establish the audit personnel qualifications and the requirements for the use of technical specialists to accomplish the auditing of quality assurance programs. Personnel selected for quality assurance auditing assignments shall have experience or training commensurate with the scope, complexity, or special nature of the activities to be audited. Auditors shall have, or be given, appropriate training or orientation to develop their competence for performing required audits. Competence of the various auditing functions shall be developed by one or more of the methods given in (a) through (c) below: (a) orientation to provide a working knowledge and understanding of this Part (Part I) and the auditing organization's procedures for implementing audits and reporting results; (b) training programs to provide general and specialized training in audit performances, objectives, characteristics,	BASIC 2.4 Indoctrination and training All personnel responsible for implementing activities affecting quality shall be indoctrinated and trained as necessary according to their educational background, experience, and proficiency. (Explanation 2-1) 13.2 Management of audit An audit organization shall establish the methods for managing audits. SUPPLE 13.2 Management of audit The audit organization should establish the methods for audit management, taking the following into consideration. REF. 13.2 Audit management 13.2.1 Auditor qualification or registration (1) The following knowledge, experience, and capability shall be considered when an auditor is qualified or registered: a. Special knowledge and experience of the area to be audited b. Knowledge and	Q5 2.4.1 Planning Managers should make arrangements to ensure that all personnel performing assessment activities, including themselves, have appropriate qualification, training and experience. 2.4.2 Qualification and Education (1) For personnel performing assessment, for example, following educations should be performed. A. QA principle B. Methodology of assessment (2) The assessors should have technical knowledge, experites ability, and experience. The assessors are desirable to have effective observation skill and better mutual understanding, and ability to maintain confidentiality and objectivity. (3) In selecting team leaders of independent assessment organization should nominate them based on experience, expertise ability, and assessment organization should nominate them based on experience, expertise ability, and assessment participating experience etc. (4) The assessors are desirable to be qualified or registered through necessary internal procedures.	Three standards have similar requirements. JEAGs do not have explicit requirements for qualification of auditors. The requirements of JEAG4101-2000 are summaries of "Qualification and Education of assessors (not only auditors)", though those of NQA-1 and JEAG4101-1993 are specific requirements of auditors.	No Significant Difference; No impact on the MHI QA Manual or Procedure, because MHI has established and applied the auditor and lead auditor qualification procedure in accordance with the NQA-1.

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COMPARISON TABLE

11	Quality Assurance	Program	(18/32)
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10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	1) ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ^{2}}	Differences	Assessment of Difference for MHI Manual or Procedure
	training includes methods of examining, questioning, evaluating, and documenting specific audit items and methods of closing out audit findings. c. Training that includes planning, performing, reporting, and follow-up action involved in conducting audits	and results of quality auditing. Specialized training shall include methods of examining, questioning, evaluating, and documenting specific audit items and methods of closing out audit findings. (c) on-the-job training, guidance, and counseling under the direct supervision of a Lead Auditor. Such training shall include planning, performing, reporting, and follow-up action involved in conducting audits.	methodology and techniques c. Knowledge of standards, procedures, and production processes d. Skill in communication, suitability, faithfulness, etc.			
	S. TRAINING AND QUALIFICATION CRITERIA - QUALITY ASSURANCE (10 CFR Part 50, Appendix B, Criterion II) 4. Lead auditors are qualified as follows: a. demonstrated capability to communicate effectively, both in writing and orally (NQA-1)	3 QUALIFICATION OF LEAD AUDITORS An individual shall meet the requirements of paras. 3.1 through 3.4 below prior to being designated a Lead Auditor. 3.1 Communication Skills The prospective Lead Auditor shall have the capability to communicate effectively, both in writing and orally. These skills shall be attested to in writing by the Lead Auditor's employer.	REF. 13.2.1 Auditor qualification or registration (1) The following knowledge, experience, and capability shall be considered when an auditor is qualified or registered: a. Special knowledge and experience of the area to be audited b. Knowledge and experience of audit methodology and techniques c. Knowledge of standards, procedures, and production processes d. Skill in communication, suitability, faithfulness, etc. (2) The following knowledge, experience, and capability shall be considered when a lead auditor of the audit team is qualified or registered: a. Education,	Q5 2.4.2 Qualification and Education (3) In selecting team leaders of independent assessment, assessment organization should nominate them based on experience, expertise ability, and assessment participating experience etc.	Three standards have similar requirements. The requirement of JEAG4101-2000 is a summery of selection of lead auditor, though NQA-1 and JEAG4101-1993 describe more detailed provisions.	No Significant Difference; No impact on the MHI QA Manual or Procedure, because MHI has established and applied the auditor and lead auditor qualification procedure in accordance with the NQA-1.

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COMPARISON TABLE II Quality Assurance Program (19/32)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	() ASME NQA-1-1994Edtion	JEAG4101-1993	2) JEAG4101-2000	Differences	Assessment of Difference for MHI Manual or Procedure
			experience, professional ability, etc. b. Experience with audits c. Experience in document reviewing concerning quality assurance d. Experience in participating in general education, seminars, etc. on quality assurance			
	S. TRAINING AND QUALIFICATION CRITERIA - QUALITY ASSURANCE (10 CFR Part 50, Appendix B, Criterion II) 4. Lead auditors are qualified as follows:	3.2 Training Prospective Lead Auditors shall have training to the extent necessary to assure their competence in auditing skills. Training in the following areas shall be given based upon management evaluation of the particular needs of each prospective Lead Auditor.	BASIC 2.4 Indoctrination and training All personnel responsible for implementing activities affecting quality shall be indoctrinated and trained as necessary according to their educational background, experience, and proficiency. (Explanation 2-1) EXP.2-1 "Activities affecting quality" in this sentence includes not only work-oriented activities but also specific control-oriented activities (audits, etc.). REF 13.2.1 Auditor qualification or registration (See above in detail)	Q5 2.4.2 Qualification and Education (2) The assessors should have technical knowledge, expertise ability, and experience. The assesors are desirable to have effective observation skill and better mutual understanding, and ability to maintain confidentiality and objectivity.	See above	No Significant Difference; No impact on the MHI QA Manual or Procedure, because MHI has established and applied the auditor and lead auditor qualification procedure in accordance with the NQA-1.
	b. demonstrated knowledge and understanding of the following: (NQA-1) (1) QA program and other nuclear-related codes, standards, regulations, and regulatory guides, as applicable (2) general structure of QA programs as a whole and applicable elements	 3.2.1 Knowledge and understanding of this Part (Part I) and other nuclear-related codes, standards, regulations, and regulatory guides, as applicable. 3.2.2 General structure of quality assurance programs as a whole and applicable elements as defined in this Part (Part I). 	REF 13.2.1 Auditor qualification or registration (1) The following knowledge, experience, and capability shall be considered when an auditor is qualified or registered: a. Special knowledge and experience of the area to be audited b. Knowledge and	Q5 2.4.2 Qualification and Education (2) The assessors should have technical knowledge, expertise ability, and experience. The assessors are desirable to have effective observation skill and better mutual understanding, and ability to maintain confidentiality and objectivity.	Three standards have similar requirements. The requirements of JEAGs are summaries of "Qualification of Lead Auditor" and are not directly specified, though NQA-1 describes directly more detailed provisions.	No Significant Difference; No impact on the MHI QA Manual or Procedure, because MHI has established and applied the auditor and lead auditor qualification procedure in accordance with the NQA-1.

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COMPARISON TABLE II Quality Assurance Program (20/32)

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10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	1) ASME NQA-1-1994Edtion	2) JEAG4101-1993	2) JEAG4101-2000	Differences	Assessment of Difference for MHI Manual or Procedure
	 (3) auditing techniques of examining, questioning, evaluating, and reporting; methods of identifying and <i>following up on corrective</i> action items; and closing out audit findings (4) audit planning in the quality-related functions for designing, purchasing, fabricating, handling, shipping, receiving, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, modifying, and safety of the nuclear facility 	3.2.3 Auditing techniques of examining, questioning, evaluating, and reporting; methods of identifying and following up on corrective action items; and closing out audit findings. 3.2.4 Audit planning in the quality-related functions for the following activities: siting, designing, purchasing, fabricating, handling, shipping, receiving, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, modifying, and decommissioning of nuclear facilities or associated components, and safety aspects of the nuclear facility. 3.2.5 On-the-job training to include applicable elements of the audit program.	experience of audit methodology and techniques c. Knowledge of standards, procedures, and production processes d. Skill in communication, suitability, faithfulness, etc. (2) The following knowledge, experience, and capability shall be considered when a lead auditor of the audit team is qualified or registered: a. Education, experience, professional ability, etc. b. Experience with audits c. Experience in document reviewing concerning quality assurance d. Experience in participating in general education, seminars, etc. on quality assurance			
	S. TRAINING AND QUALIFICATION CRITERIA - QUALITY ASSURANCE (10 CFR Part 50, Appendix B, Criterion II) 4. Lead auditors are qualified as follows: c. participated in a minimum of five QA audits within a period of time not to exceed 3 years prior to the date of qualification, one audit of which is a nuclear QA audit within the year prior to qualification or for individuals with related industry experience, demonstrated ability to properly implement the audit process, to effectively organize and report results	3.3 Audit Participation The prospective Lead Auditor shall have participated in a minimum of five (5) quality assurance audits within a period of time not to exceed 3 years prior to the date of qualification, one audit of which shall be a nuclear qualification prior to his qualification	REF 13.2.1 Auditor qualification or registration (2) The following knowledge, experience, and capability shall be considered when a lead auditor of the audit team is qualified or registered: a. Education, experience, professional ability, etc. b. Experience with audits c. Experience in document reviewing concerning quality assurance d. Experience in participating in general education, seminars, etc. on quality assurance	Q5 2.4.2 Qualification and Education (3) In selecting team leaders of independent assessment, assessment organization should nominate them based on experience, expertise ability, and assessment participating experience etc.	See above	No Significant Difference; No impact on the MHI QA Manual or Procedure, because MHI has established and applied the auditor and lead auditor qualification procedure in accordance with the NQA-1.

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COMPARISON TABLE II Quality Assurance Program (21/32)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
	including participation in at least one nuclear audit within the year preceding the date of qualification (Approved via SE (Accession No. ML050700416).)					
	S. TRAINING AND QUALIFICATION CRITERIA - QUALITY ASSURANCE (10 CFR Part 50, Appendix B, Criterion II) 4. Lead auditors are qualified as follows: d. successfully completed an examination, which may be oral, written, practical, or any combination of the three types (NQA-1)	3.4 Examination The prospective Lead Auditor shall pass an examination which shall evaluate his comprehension of and ability to apply the body of knowledge identified in para. 3.2 above. The examination may be oral, written, practical, or any combination of the three types. The development and administration of the examination shall be in accordance with Section 5 of this Supplement.	SUPPLE 13.2.1 Auditor qualification or registration It is desirable that auditors be qualified or registered according to internal company procedures. (Explanation 13-1) Exp 13-1: Instead of qualifying or registering auditors in advance, there is another inside procedure method. Select or designate auditors when organizing the audit team, taking their knowledge, experience, and proficiency into consideration.	Q5 2.4.2 Qualification and Education (4) The assessors are desirable to be qualified or registered through necessary internal procedures.	JEAGs do not specify clearly the examination of lead auditor, though NQA-1 specifies it.	Significant Difference; No impact on the MHI QA Manual or Procedure, because MHI has established and applied the auditor and lead auditor qualification procedure in accordance with the NQA-1.
		4 MAINTENANCE OF QUALIFICATION 4.1 Maintenance of Proficiency Lead Auditors shall maintain their proficiency through one or more of the following: regular and active participation in the audit process; review and study of codes, standards, procedures, instructions, and other documents related to quality assurance program and program auditing or participation in training program(s). Based. on annual assessment, management may extend the qualification, require retraining, or require retraining, or require retraining, or require retraining shall be documented,		Q5 2.4.3 Retention Management The assessors should maintain their proficiency and technical knowledge by, for example: A. regular participation in assessments B. study of codes, standards, procedures, practices and other related documents; C. participation in training course and seminars; D. spending an appropriate amount of time in the field Guidance for training are shown in "this guide (reference matters) Q1 (Quality Assurance Programme)"	NQA-1 and JEAG4101-2000 have similar requirements, though JEAG4101-1993 do not have explicit requirements for maintenance of qualification.	No Significant Difference; No impact on the MHI QA Manual or Procedure, because MHI has established and applied the auditor and lead auditor qualification procedure in accordance with the NQA-1.

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COMPARISON TABLE II Quality Assurance Program (22/32)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	2) JEAG4101-2000	Differences	Assessment of Difference for MHI Manual or Procedure
		4.2 Requalification Lead Auditors who fail to maintain their proficiency for a period of 2 years or more shall require requalification. Requalification shall include retraining in accordance with the requirements of para: 3.2 above, reexamination in accordance with para. 3.4 above, and participation as an Auditor in at least one nuclear quality assurance audit.	_		JEAGs do not specify any detailed requirements for the requalification of lead auditors.	Significant Difference; No impact on the MHI QA Manual or Procedure, because MHI has established and applied the auditor and lead auditor qualification procedure in accordance with the NQA-1.
		5 ADMINISTRATION 5.1 Organizational Responsibility Training of auditors shall be the responsibility of the employer. The responsible auditing organization shall select and assign personnel who are independent of any direct responsibility for performance of the activities which they will- audit. The Lead Auditor shall, prior to commencing the audit, concur that assigned personnel collectively have experience or training commensurate with the scope, complexity, or special nature of the activities to be audited.	BASIC 13.3 Execution of audit Audit organizations shall carry out audits according to the established methods. SUPPLE 13.3.1 Audit team organizations Audit organizations should perform the following when organizing the audit team: a. Selecting auditors from organizations other than that which is audited b. Deciding lead auditor and auditors REF. 13.3.1 Audit team organization (1) The roles of the lead auditor are as follows: a. Preparation of audit, investigation, and pre-audit conference b. Command of the audit, team c. Reporting of the audit, etc. by putting together findings and corrective actions (2) Members of the team might be selected from among experienced	Q5 2.1.4 Independent Assessment Independent assessment should be conducted on behalf of senior management by an organizational unit or assigned outside agency which is independent of the work to be assessed. Managers should not regard the independent assessment as an opportunity to avoid carrying out their self-assessment. The assessment unit should devote itself to assisting management to improve effectiveness and work performance.	Three standards have similar requirements, though JEAGs do not specify the responsibility of lead auditor to confirm that audit team members are appropriately qualified.	No Significant Difference; No impact on the MHI QA Manual or Procedure, because MHI has established and applied the auditor and lead auditor qualification procedure in accordance with the NQA-1.

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COMPARISON TABLE II Quality Assurance Program (23/32)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	() ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	2) JEAG4101-2000	Differences	Assessment of Difference for MHI Manual or Procedure
		• • • •	technical specialists in addition to the qualified or registered auditors. (3) Audit teams are not to force auditees to show information which the auditee judges to be confidential business or technology.			
		5.2 Qualification Examination The development and administration of the examination for a Lead Auditor required by para. 3.4 above is the responsibility of the employer. The employer may delegate this activity to an independent certifying agency, but shall retain responsibility for conformance of the examination and its administration to this Part (Part I). Integrity of the examination shall be maintained by the employer or certifying agency through appropriate confidentiality of files and; where applicable, proctoring of examinations. Copies of the objective evidence regarding the type(s) and content of the examinations) shall be retained by the employer in accordance with the requirements of Section 6 below.			JEAGs do not clearly specify any detailed requirements for examination of lead auditor.	Significant Difference; No impact on the MHI QA Manual or Procedure, because MHI has established and applied the auditor and lead auditor qualification procedure in accordance with the NQA-1.
	S. TRAINING AND QUALIFICATION CRITERIA - QUALITY ASSURANCE (10 CFR Part 50, Appendix B, Criterion II) 5. Records of personnel qualifications for Auditors performing audits are	6.RECORDS 6.1 General Records of personnel qualifications for Auditors and Lead Auditors performing audits shall be established and maintained by the employer	-	Q1 4.3.1 Performance of Educations and Trainings (1) All the personnel who perform management tasks, works and evaluation activities shall understand organizational objectives related to safety of product quality,	JEAG4101-1993 does not specify any detailed requirements for maintaining qualification records of auditors and lead auditors. And JEAGs do not specify any detailed requirements for lead auditor certification.	See above

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COMPARISON TABLE II Quality Assurance Program (24/32)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17 5	ASME NQA-1-1994Edtion	2) JEAG4101-1993	2) JEAG4101-2000	Differences	Assessment of Difference for MHI Manual or Procedure
	required to be established and maintained. Records for each Lead Auditor are updated annually and each Lead Auditor is certified as being qualified to lead audits. (NQA-1) S. TRAINING AND QUALIFICATION CRITERIA - QUALITY ASSURANCE (10 CFR Part 50, Appendix B, Criterion II) 6. Lead Auditor certification, at a minimum, documents the following: (NQA-1) a. employer's name b. auditor's name c. date of certification or recertification d. basis of qualification (i.e., education, experience, communication skills, training, examination) e. signature of designated representative who is responsible for such certification	 6.2 Certification of Qualification Each Lead Auditor shall be certified by his employer as being qualified to lead audits. This certification shall, as a minimum, document the following: (a) employer's name: (b) Lead Auditor's name; (c) date of certification or recertification; (d) basis of qualification (i.e., education, experience, communication skills, training, examination, etc.); (e) signature of employer's designated representative who is responsible for such certification. 6.3 Updating of Lead Auditors' Records Records for each Lead Auditor shall be maintained and updated annually 		personnel and general public as well as their direct involvements with quality Assurance Programme in the introductory and continued trainings and educations depending on the level of knowledge, experience and skill. If necessary, records of educations and trainings shall be maintained. (4) Records of the qualified personnel shall be maintained appropriately.		
		Supplement 2S-4 Supplementary Requirements for Personnel Indoctrination and Training 1 GENERAL This Supplement provides amplified requirements for the indoctrination and training of personnel performing or managing activities affecting quality. It supplements the requirements of Basic Requirement 2 of this Part (Part I) and shall be used in conjunction with that Basic	-	-	This NQA-1-1994 clause is a paragraph introducing the additional requirements in the Supplementary Requirements. It specifies that the Supplementary Requirements apply when and to the extent specified by the organization invoking Part I of NQA-1-1994.	See below

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COMPARISON TABLE II Quality Assurance Program (25/32)

10 CFR 50 Appendix B	Standard Review Plan, NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993	2) JEAG4101-2000	Differences	Assessment of Difference for MHI Manual or Procedure
		Requirement when and to the extent specified by the organization invoking this Part (Part I).				
		2 APPLICABILITY This Supplement applies to personnel performing or managing activities affecting quality. Personnel to be indoctrinated or trained shall be identified. The extent of indoctrination and training shall be commensurate with the following: (a) the scope, complexity, and nature of the activity; and (b) the education, experience, and proficiency of the person. Activities affecting quality include siting, designing, purchasing, fabricating, handling, shipping, receiving, storing, cleaning, erecting, installing, inspecting, refueling, modifying, and decommissioning.	BASIC 2.4 Indoctrination and training All personnel responsible for implementing activities affecting quality shall be indoctrinated and trained as necessary according to their educational background, experience, and proficiency. (Explanation 2-1) SUPPLE 2.4 Indoctrination and training Indoctrination and training programmes, in such areas as engineering and skills, should be established and implemented for all personnel responsible for implementing quality assurance activities affecting quality at each stage such as design, procurement, fabrication, installation, and operation and maintenance. REF. 2.4 Indoctrination and training (1) Upon the establishment of indoctrination and training trogrammes for fabrication, installation, and operation and maintenance stages, a consideration require qualifications according to laws and regulation is to be taken account of. (Explanation 2-2) (2) In regard to indoctrination and training	Q1 4.3.1 Performance of Educations and Trainings (1) All the personnel who perform management tasks, works and evaluation activities shall understand organizational objectives related to safety of product quality, personnel and general public as well as their direct involvements with quality policies and the Quality Assurance Programme in the introductory and continued trainings and educations depending on the level of knowledge, experience and skill. If necessary, records of educations and trainings shall be maintained. (2) In establishing education and training plan for fabrication, erection, operation and maintenance stages, considerations shall be given to the necessity of qualifications concerning the tasks for which qualification is mandatory based on laws and standards.	Three standards have similar requirements.	No Significant Difference; No impact on the MHI QA Manual or Procedure.
	1	1	for the acquisition of			

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COMPARISON TABLE II Quality Assurance Program (26/32)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
			personnel qualifications, it is important to establish programmes and implement them from a long-term point of view.			
		3 INDOCTRINATION Personnel shall be indoctrinated in the following subjects as they relate to a particular function: (a) general criteria, including applicable codes, standards, and company procedures; (b) applicable quality assurance program elements; and (c) job responsibilities and authority.	See above	Q4 3.2 Inspector (1) When the qualification of inspector skill such as non-destructive test (examination) is required, the qualification of inspector shall be specified. (2) Check for work control, for example, intermediate check in-process may be conducted by worker oneself. (3) In final inspection/test, degree of independence of inspector shall be specified.	Three standards have similar requirements.	No Significant Difference; No impact on the MHI QA Manual or Procedure.
		4 TRAINING Training shall be provided, if needed, to: (a) achieve initial proficiency; (b) maintain proficiency; and (c) adapt to changes in technology, methods, or job responsibilities.	See above	Q1 4.3.1 Performance of Educations and Trainings (1) All the personnel who perform management tasks, works and evaluation activities shall understand organizational objectives related to safety of product quality, personnel and general public as well as their direct involvements with quality policies and the Quality policies and the Quality Assurance Programme in the introductory and continued trainings and educations depending on the level of knowledge, experience and skill. If necessary, records of educations and trainings shall be maintained. 4.3.4 Educations and Trainings Using Instructions	Three standards have similar requirements. JEAG4101-2000's description of requirements for training is classified as work.	No Significant Difference; No impact on the MHI QA Manual or Procedure.

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II Quality Assurance Program (27/32)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	1) ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
				used or when significant level of revision is made on the work instructions, the division responsible for the task shall perform personnel educations and trainings necessary for the task. This is also an opportunity for the manager to explain the importance of thorough conformance to the instructions. Further, the results of the educations and trainings performed shall be reflected in the instructions shall be revised appropriately to rectify problems identified in the results. 4.3.5 Educations and Trainings on Professional Matters It is important to promote improvement of professional techniques and skills. Because the skills of personnel can be gradually improved by educations and trainings shall be conducted on continuous basis so that initially qualified level of works and skills can be further improved.		
		5 RECORDS Records of the implementation of indoctrination and training may take the form of: (a) attendance sheets; (b) training logs; or (c) personnel training records.	See above	Q1 4.3.1 Performance of Educations and Trainings (1) All the personnel who perform management tasks, works and evaluation activities shall understand organizational objectives related to safety of product quality, personnel and general public as well as their direct involvements with quality policies and the Quality	Three standards have similar requirements.	No Significant Difference; No impact on the MHI QA Manual or Procedure.

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COMPARISON TABLE II Quality Assurance Program (28/32)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
				Assurance Programme in the introductory and continued trainings and educations depending on the level of knowledge, experience and skill. If necessary, records of educations and trainings shall be maintained. (4) Records of the qualified personnel shall be maintained appropriately.		
				4.3.4 Educations and Trainings Using Instructions When work instructions are used or when significant level of revision is made on the work instructions, the division responsible for the tack shall porform		
				personnel educations and trainings necessary for the task. This is also an opportunity for the manager to explain the importance of thorough conformance to the instructions. Further, the		
				results of the educations and trainings performed shall be reflected in the instructions and the instructions shall be revised appropriately to rectify problems identified in the results.		
				4.3.5 Educations and Trainings on Professional Matters It is important to promote improvement of professional techniques and skills. Because the skills of personnel can be		
				gradually improved by educations and trainings, educations and trainings shall be conducted on continuous basis so that initially qualified level of		

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II Quality Assurance Program (29/32)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	2) JEAG4101-1993	2) JEAG4101-2000	Differences	Assessment of Difference for MHI Manual or Procedure
				works and skills can be further improved.		
	1. Management of those organizations implementing the QA program, or portions thereof, assess the adequacy of that part of the program for which they are responsible and assure its effective implementation at least once each year or at least once during the life of the activity, which is ever shorter. However, the period for assessing operational QA programs may be extended to once every two years. (Approved via a safety evaluation (SE) (Accession No. 9903310187).)		BASIC 1.3 Review of quality assurance programmes (1) The adequacy of quality assurance programmes and the implementation of quality assurance activities based on these programmes shall be reviewed by the person who has been assigned the responsibility for their establishment and implementation. (Explanation 1-3)	Q1 4.4 Evaluation, Analysis and Improvement 4.4.1 Evaluation of Quality Assurance Programme The individual responsible for establishment and performance of Quality Assurance Programme shall evaluate validity of the Quality Assurance Programme and its performance for which is requested. [Explanation Q1-9] 4.4.2 Evaluation, Analysis and Improvement of Performance (1) Manager shall evaluate and analyze performance of the Programme. Giving considerations to failure, damage, repair and their frequency, delay, error, loss time, uncompleted workload, level of conformance to the requirements and improvement, he / she shall establish or other appropriate evaluation / analysis method to achieve the Programme. Guidance on the for the achievement is shown in Q5 (Assessment) and Q13 (Operation) in the Reference Matters section. [Explanation Q1-10] (2) If any necessity to change management process occurs as a result of evaluation, specified procedure for change shall be taken. If necessary, opinions about the change	SRP and two JEAG standards have similar requirements, though JEAGs do not have explicit provision for the frequency of QA program assessment.	No Significant Difference; No impact on the MHI QA Manual or Procedure, because MHI has established and applied the management review procedure for the assessment of QA program.
				mangers of the upper level. (3) The targeted date of		

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COMPARISON TABLE II Quality Assurance Program (30/32)

		·····				Assessment of Difference
10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	for MHI Manual or Procedure
				implementing and completing the improvement based on the evaluation results shall be clearly identified and the progress shall be followed on continuous basis.		
	2. The QAPD includes the criteria used to identify the items and activities to which the QA program applies. A list of the SSCs and/or activities under the control of the QA program is required to be established and maintained at the applicant's or holder's facility. (10 CFR 50.34(f)(3)(ii))			Q1 2.5 Grading (1) The application extent of the quality assurance requirements may be determined according to the relative importance of the item, service and process to safety of the nuclear power plant. Graded approach could be applicable so that the essential requirements may be satisfied and the required quality and safety may be ensured.	JEAG4101-1993 does not have a specific requirement for identification of items and activities to which QA program applies. Also JEAG4101-2000 does not specify it directly.	Significant Difference; No impact on the MHI QA Manual, because MHI prepares a list of SSCs under control of the QA program.
•	8. A general grace period of 90 days may be applied to provisions that are required to be performed on a periodic basis unless otherwise noted. Annual evaluations and audits that must be performed on a triennial basis are examples where the 90 day general grace period could be applied. The grace period does not allow the "clock" for a particular activity to be reset forward. The "clock" for an activity is reset backwards by performing the activity early. (Approved via SE (Accession No. 9807270331).)		-	-	JEAGs do not have a specific provision for a grace period.	Significant Difference; No impact on the MHI QA Manual, because MHI describes the provision of a grace period in QAP for US-APWR project.
	S. TRAINING AND QUALIFICATION CRITERIA - QUALITY ASSURANCE (10 CFR Part 50, Appendix B, Criterion II) 2. The individual		_	-	JEAGs do not have a specific provision for qualification about the responsible personnel of implementing QAP.	Significant Difference; No impact on the MHI QA Manual, because MHI establishes and applies the qualification procedure for management of QAP implementation.

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COMPARISON TABLE II Quality Assurance Program (31/32)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17,5	ASME NQA-1-1994Edtion	JEAG4101-1993 ^{2}}	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
	responsible for management of the implementation of the QA plan is qualified as follows: (Regulatory Guide 1.8)					
	 a. Education: baccalaureate in engineering or related science b. Minimum experience for the position: 4 years of 					
	related experience (3 of the 4 years must include 2 years of nuclear power plant experience and 1 year of supervisory or					
	c. Special Requirements: management and supervisory skills and evorement or training	1 				
	including leadership, interpersonal communication, management responsibilities motivation					
	of personnel, problem analysis and decision making, and administrative policies and procedures					
	 d. 1 year of experience performing quality verification activities e. Individuals who do not possess these formal 	,				
	education and minimum experience requirements should not be eliminated automatically when other factors provide sufficient					
	demonstration of their abilities. These other factors are evaluated on a case-by-case basis and approved and documented by senior management.					
	S. TRAINING AND QUALIFICATION CRITERIA - QUALITY ASSURANCE (10 CFR Part 50, Appendix B, Criterion II) 3. Individuals responsible				JEAGs do not have a specific provision for the qualification about the personnel of planning, implementing and maintaining of the QAP.	Significant Difference; No impact on the MHI QA Manual, because MHI establishes and applies the qualification procedure for personnel of planning, implementing and

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10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
	for planning, implementing, and maintaining the QA plan are qualified as follows: (Regulatory Guide 1.8) a. Education: high school diploma b. Minimum experience: 1 year related experience c. Individuals who do not possess these formal education and minimum experience requirements should not be eliminated automatically when other factors provide sufficient demonstration of their abilities. These other factors are evaluated on a case-by-case basis and approved and documented by senior management.					maintaining the QAP.

COMPARISON TABLE

II Quality Assurance Program (32/32)

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COMPARISON TABLE III Design Control (1/28)

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10'CFR 50'Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ^{2),}	Differences	Assessment of Difference for MHI Manual or Procedure
III. Design Control Measures shall be established to assure that applicable regulatory requirements and the design basis, as defined in § 50.2 and as specified in the license application, for those structures, systems, and components to which this appendix applies are correctly translated into specifications, drawings, procedures, and instructions.	1. Design Control a. A program is required to be established for the design of items. The program includes provisions to control design inputs, processes, outputs, changes, interfaces, records, and organizational interfaces. (NQA-1) b. Design inputs (e.g., the design bases, performance and regulatory requirements, and codes and standards) are correctly translated into design outputs (e.g., specifications, drawings, procedures, and instructions). (NQA-1)	Basic Requirement 3 Design Control The design shall be defined; controlled, and verified. Applicable design inputs shall be appropriately specified on a timely basis and correctly translated into design documents. Design interfaces shall be identified and controlled. Design adequacy shall be verified by persons other than those who designed the item. Design changes, including field changes, shall be governed by control measures commensurate with those applied to the original design.	Chapter 2 BASIC 4.1 General (1) Control measures shall be established for activities at the design stage to ensure that the design requirements such as regulations, codes, standards, and basic design conditions are satisfied. (Explanation 4-3) (2) The control measures shall include the following: a. Design process (Explanation 4-4) b. Design interface c. Design verification d. Design verification d. Design verification (2) Design verification (2) Design verification (2) Design verification (2) Design verification shall be implemented by individuals or groups other than those who performed the original design. 4.5 Design changes (Explanation 4-13) (2) Design changes shall be subject to the same design control measures as those applied to the original design.	BASIC 3.2.1 General Design, including subsequent changes, shall be carried out in accordance with established engineering codes and standar ds, and shall incorporate applicable requirements and design bases. 3.2.2 Design Procedures and Interfaces Design procedures shall be established to incorporate design requirements into design nequirements into design documents properly and design interfaces shall be identified and controlled. 3.2.3 Design Verification and Design Verification and Design voldidion The adequacy of design, including design tools and design inputs and outputs shall be verified or validated by individuals or groups other than those who originally performed the work. Verification and approval shall be completed before issuing the design changes Design changes shall be subject to the same design control measures as those applied to the original design.	Three standards have similar requirements.	No significant Difference; No impact on the MHI QA Manual or Procedure.
		Supplement 3S-1 Supplementary Requirements for Design Control 1 GENERAL This Supplement provides amplified requirements for design control. It supplements the requirements of Basic			a paragraph introducing the additional requirements in the Supplementary Requirements. It specifies that the Supplementary Requirements apply when and to the extent specified by the organization invoking Part I of NQA-1-1994.	See delow

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COMPARISON TABLE

	Des	ign (Con	trol	(2/28)	
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10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	1) ASME NQA-1-1994Edtion	JEAG4101-1993	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
	1. Design Control	Requirement 3 of this Part (Part 1) and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Part (Part I). 2 DESIGN INPUT Applicable design inputs	Chapter 2 BASIC	SI 6. Supplemental	Three standards have	Except as noted below,
	I. Applicable design inputs, such as design bases, performance requirements, regulatory requirements, codes, and standards, are identified and documented, and their selection reviewed and approved by the responsible design organization. Changes from approved design inputs, including the reason for the changes, are identified, approved, documented, and controlled. (NQA-1)	Applicable design inputs, such as design bases, performance requirements, regulatory requirements, codes, and standards, shall be identified and documented, and their selection reviewed and approved by the responsible design organization. The design input shall be specified and approved on a timely basis and to the level of detail necessary to permit the design activity to be carried out in a correct manner and to provide a consistent basis for making design decisions, accomplishing design changes, changes from approved design inputs, including the reason for the changes, shall be identified, approved, documented, and controlled.	BASIC 4.2 Design process (Explanation 4-5) (1) Control measures shall be established to ensure that design requirements are correctly incorporated in the design documents. They shall include provisions for controlling the changes and deviations from the design requirements. (Explanation 4-6, 4-7) SUPPLE 4.2.1 Design process planning and design implementing Taking the following into consideration, a design process should be planned and a design activity should be implemented. a. Establishment of design process as follows: (a) Design requirements (b) Design documentation b. On structure, system, or component, selection, and reviewing the adequacy of the applications: (a) of materials and parts which are essential to functioning thereof (b) of fabrication/installation methods applied thereon 4.2.2 Design requirements In determining the control measures for design	6. Supplemental Information about "DESIGN" Design inputs are correctly translated to design outputs. Design inputs include all requirements for the design, such as the technical bases for the design (design basis), performance requirements, and safety and security requirements. The design outputs include specifications, drawings, procedures and instructions. Design inputs, processes, outputs and changes are verified. Computer programs used in design are validated through testing or simulation prior to use if not proven through previous use. Individuals or groups performing design verification are qualified to perform the original design. Verification is performed by individuals other than those who performed the design (but who may be from the same organization). The extent of verification is based on the complexity, associated hazards and uniqueness of the design.	similar requirements. The requirements of NQA-1 are a summary requirements of *Design Input*, while JEAGs describe more detailed provisions including samples. JEAG4101-1993 REF 4.2.1 d addresses use of research and development, and verification requirements concerning its use in design. Such details are not in U.S. standards.	there are no significant Difference; No impact on the MHI QA Manual or Procedure. Qualification test completed under MHI QA Program are re-evaluated to ensure consistency with U.S. standards.
L			should be included:			

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COMPARISON TABLE III Design Control (3/28)

10'CFR 50'Appendix B	Standard Review Plan NUREG -0800 Section 17.5	1) ASME NQA-1-1994Edtion	JEAG4101-1993 ^{2}}	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
	Section 17.5		a. Specify the design requirements b. Designate the division or department responsible for the design requirements and changes thereto c. Review and approve the design requirements in accordance with established procedures to preclude the use of incorrect data REF 4.2.1 Design process. planning and design implementation For design process planning and design implementation, the following are to be taken into account, as additional matters: a. Suitable selection of parts and their assemblies which are essential to the function of structures, systems, and components, and the review and approval for their adequate application. b. Specifying suitable quality standards as necessary for structures, systems, components, and their parts, and the review andapproval for their adequate selection(Explanation 4-16, 4-17) c. Similar control measures to those mentioned in be when changing specified quality standards or deciding of items andservices deviate from the standards d. Arrangement of design information, accumulated from research and	Q10 3.2 Design Input 3.2.1 Management of Design Input (1) Design inputs (See Appendix II) shall be clarified, documented, approved and controlled including the changes made in later phase. (2) When unclear design input information is found, the information shall be clarified before starting design activities.		Procedure
			experience, taking their implementation for design			

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COMPARISON TABLE III Design Control (4/28)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	1) ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
			work and verification into consideration.			
These measures shall include provisions to assure that appropriate quality standards are specified and included in design documents and that deviations from such standards are controlled. Measures shall also be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the safety-related functions of the structures, systems and components.	 Design Control The design process	3 DESIGN PROCESS The responsible design organization shall prescribe and document the design activities on a timely basis and to the level of detail necessary to permit the design process to be carried out in a correct manner, and to permit verification that the design meets requirements. Design documents shall be adequate to support facility design, construction, and operation. Appropriate quality standards shall be identified and documented, and their selection reviewed and approved. Changes from specified quality standards, including the reasons for the changes, shall be identified, approved, documented; and controlled. Design methods, materials, parts, equipment, and processes that are essential to the function of the structure, system, or component shall be selected and reviewed for suitability of application. Applicable information derived from experience, as set forth in reports or other documentation, shall be made available to cognizant design personnel.	Chapter 2 BASIC 4.1 General (1) Control measures shall be established for activities at the design stage to ensure that the design requirements such as regulations, codes, standards, and basic design conditions are satisfied. (Explanation 4-3) (2) The control measures shall include the following: a. Design process (Explanation 4-4) b. Design interface c. Design verification d. Design changes REF. 4.1 General In establishing design control measures, the following are to be considered: a. Identifying the starting point for design-related quality assurance activities and the application scope of design activities. In this case, different degrees of controls may be assigned taking, as appropriate, the degree of importance to safety, nature of the design activities, advancement of various components, systems and structures, and nature of the design phase, etc. into consideration. (Explanation 4-15) b. Preparation of design control procedure document to implement	Q10 Q10 2.6 Design Plan (1) Design plan shall be prepared at an early stage before starting design activities. Based on the design plan, activities to be implemented in each organization shall be Clarified (Itemization of tasks and mutual relationship). (2) In establishing design plan, scope of tasks and activity schedule shall be clarified including the tasks to be conducted by the other organizations, and following issues are stated as appropriate: a) Design method b) Software requirements (Codes of software to be developed or software requiring validation) c) Test requirements including the areas of certification, prototype and seismic characteristics; Requirements on design review, design verification and validation. d) Requirements on management resources e) Check ponts in design process f) Input from other specialty fields such as safety, reliability, maintenance ability, human factor, standardization, etc. 3.2 Design Input (1) Design Inputs (See Angendri II) shall be	Three standards have similar requirements. The requirements of NQA-1 are a summary of "Design Process", while JEAGs describe more detailed provisions including samples. JEAG4101-1993 REF 4.1 b 4.(3) includes use of historical reports and verification requirements regarding their use. U.S. standards do not include such details.	Except as noted below, there are no significant Difference; No impact on the MHI QA Manual or Procedure. Qualification test completed under MHI QA Program are re-evaluated to ensure consistency with U.S. standards.
			design activities Typical items to be covered by design control procedure	clarified, documented, approved and controlled including the changes		

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COMPARISON TABLE III Design Control (5/28)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
			document are as follows:	made in later phase.		
			[Typical items to be	(2) when unclear design		
			covered by procedures for	the information is found,		
			design control	che information shall be		
		·	1. Organization and its	design estivities		
			scope of work and	design activities.		
			2 Indestrination and	2.2.2 Confirmation of		
			z. muocumation and	Design Requirements		
			2 Design desumant central	Evolution O10 4		
			(proparation, raviow	(1) Design requirements		
			approval issuance	chall be confirmed with the		1
			revision storage)	purpose to confirm the		
			A Decign process	purpose to commune		
			(1) Identification of	basis of the design given		
			appropriate design	by order issuer or to ensure		
			criteria and other design	clarification This		
			requirements	confirmation shall be		
			(2) Designation of quality	conducted based on the		
1			standards acceptance	general design standards		1
			criteria, and requirements	specified in the Safety		
			for recording	Design Review Plan for		
		:	(3) Use of historical reports	Nuclear Power		
			in practice	Facilities(NISA Guideline).		
			5. Design interfaces	(2) So that assessment can		
			6. Design verification	be conducted by engineers		
			7. Design changes	other than those who		
		×	8. Execution of activities to	conducted the		
1		(prevent recurrence	confirmation, confirmation		(
			9. Audit of design activities	of the design requirements		
				shall be conducted in		
			4.2.1 Design process.	details and recorded.		
			planning and design			
		5	implementation	EX.10-4		
			(See above in detail)	(1) Quality standards refers		
		i		to the general names of		
				standards and criteria		
				issued by various		
			SUPPLE	organization, including		
			4.2.1 Design process	"Technical Standards for		
			planning and design	Nuclear Power Generation		
			implementing	Equipment", "Standard for		
			laking the following into	Boller and Pressure Vessel		
			consideration, a design	Structures", "Japanese		
			process should be planned	industrial Standards (JIS)",		
ļ			and a design activity should	Japan Electric Association		
l			pe implemented.	Electric Acception Outda		
			a. Establishment of design			
			(a) Design requirements	(JEAG) . Designer shall ensure to		
		ľ	(a) Design requirements	coolify appropriate quality		
			(b) Design analyses	specify appropriate quality		
1			(d) Design documentation	stanualus in the design		
1						

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COMPARISON TABLE III Design Control (6/28)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17 5	ASME NQA-1-1994Edition	JEAG4101-1993 ²⁾	2) JEAG4101-2000	Differences	Assessment of Difference for MHI Manual or Procedure
			 b. On structure, system, or component, selection, and reviewing the adequacy of the applications: (a) of materials and parts which are essential to functioning thereof (b) of fabrication/installation methods applied thereon 4.2.2 Design requirements in determining the control measures for design requirements, the following should be included: a. Specify the design requirements b. Designate the division or department responsible for the design requirements in accordance with established procedures to preclude the use of incorrect data 	responsible for specifying appropriate quality standards as well as its application scope and grade in the documents one's issues. Especially, if partial modification is made on the widely-used universal criteria / standard in design, or, when selecting items suitable for specific specifications through testing and inspection from the products manufactured based on universal criteria / standards, clear statement shall be made in the design documents about the fact that the concerned item is different from universal products, while appropriate consideration should be given also so that the item can be discerned from the universal products. (2) Specification of guality standards: a) Regulatory classification b) Specification of grade and rating based on standards c) Selection and designation of specifications corresponding to types and models d) Action requirements in the cases where standard design product / specifications is selected / designated; items suitable for specifications is selected; or partial processing is performed.		
(See above)	1. Design Control c. The final design (approved design output documents and approved	The final design (approved design output documents and approved changes (thereto) shall: (a) be relatable to the	Chapter 2 REF. 4.2.1 Design process. planning and design implementation	SI 6. Supplemental Information about "DESIGN"	I hree standards have similar requirements.	No significant Difference; No impact on the MHI QA Manual or Procedure.

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III Design Control (7/28)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993	2). JEAG4101-2000	Differences	Assessment of Difference for MHI Manual or Procedure
	changes) identifies assemblies and/or components that are part of the item being designed. (NQA-1)	design input by documentation in sufficient detail to permit design verification; and (b) identify assemblies and/or components that are part of the item being designed. When such an assembly or component part is a commercial grade item that, prior to its installation, is modified or selected by special inspection and/or testing to requirements that are more restrictive than the Supplier's published product description, the component part shall be represented as different from the commercial grade item in a manner traceable to a documented definition of the difference.	For design process planning and design implementation, the following are to be taken into account, as additional matters: d. Arrangement of design information, accumulated from research and development and experience, taking their implementation for design work and verification into consideration. 4.2.2 Design requirements (2) Design requirements are to confirm that the activity concerned has been carried out correctly, and that it provides a consistent basis for evaluating each design analysis, verification, and change. 4.4.1 Method of design verification (1) Design verification is implemented to review, confirm, or substantiate that all design requirements are correctly incorporated in the design documents and that the design is adequate. EX.4-16	Design inputs are correctly translated to design outputs. Design inputs include all requirements for the design, such as the technical bases for the design (design basis), performance requirements, and safety and security requirements. The design outputs include specifications, drawings, procedures and instructions. Q10 EX 10-4 (See above)		
			"Quality standard" refers collectively to "The technical standards for construction of nuclear power plant components," "The standard for construction of boilors and			
			variance of boliers and pressure vessels," "Japanese Industrial Standards (JISL" "Japan Electric Association Code (JEAC)," "Japan Electric Association Guide (JEAG)" and standards and norms			
		·	issued by other societies or			

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COMPARISON TABLE III Design Control (8/28)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	(ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
	Section 17.5		associations. Designers and design organizations are responsible for confirming that appropriate quality standardsf are specified in the design requirements, designating the appropriate standards, the scope to apply them, and the grade in the documents which they, issue. Especially, when designs are performed to standards or norms with partial modifications made to the generally used commercial ones, or when items complying with the designated specifications are selected from the products manufactured to commercial grade standards or norms by inspection/testing, it is necessary to make sure that the products are represented in the design			Procedure
			document as different from commercial grade items.			
	1. Design Control h. Design analysis documents are legible and in a form suitable for record keeping. They are sufficiently detailed as to purpose, method, assumptions, design input, references, and units such that a person technically qualified in the subject can review and understand the analyses and verify the adequacy of the results without recourse to the originator. (NQA-1) 1. Design Control k. Calculations are	3.1 Design Analyses Design analyses shall be performed in a planned; controlled, and. documented manner. Design analysis documents shall be legible and in a form-suitable for reproduction, filing, and retrieval. They shall be sufficiently detailed as to purpose, method, assumptions; design input, references, and units such that a person technically qualified in the subject can review and understand the analyses and verify the adequacy of the results without recourse to the originator. Calculations shall be identifiable by subject	Chapter 2 BASIC 1.2 Establishment of quality assurance programmes (Explanation 1-1) (3) Quality assurance programmes shall be implemented in accordance with appropriate documents. (Explanation 1-2) REF. 12.2.1 Generation of records (1) Information to be described in the records includes the following: a. Necessary information b. All information described in the records is legible c. All information described in the records is factual	Q10 3.3 Design Work 3.3.1 Design Analysis Design analysis shall be conducted and design analysis documents shall be formulated based on the design procedure. [Explanation Q10-4] 3.4 Design Review 3.4.1 Purpose of Design Review (1) Purpose of the review is to ensure that output documents should properly and sufficiently satisfy requirements on design specifications (e.g. functional requirements, safety requirements, laws and regulations, industry standards, etc.).	Three standards have similar requirements except for the following matter. The specified description of a person technically qualified in the design activity is not found in both JEAGs.	Significant Differences; No impact on MHI procedure, because MHI has established " Qualification Procedure for Personnel for Design Activity" and applied, though there had been the personnel system in MHI used for a long time. MHI personnel system; In MHI personnel system; In MHI personnel system; specified work content is limited to appropriate responsible person depending on the duty position and type of job respectively. "Personnel Qualification" is carried out from a standpoint of above-mentioned explanation.

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	Standard Review Plan	1)	2)	2)	.	Assessment of Difference
10 CFR 50 Appendix B	NUREG -0800	ASME NQA-1-1994Edtion	JEAG4101-1993	JEAG4101-2000	Differences	for MHI Manual or
	Section 17.5					Procedure
	identifiable by subject	(including structure,	(2) In addition to the above,	(2) In reviewed design, if it		For person in charge of
	(including the SSC to which	system, or component to	the following information is	is found that the design has		design activity, the duty
	the calculation applies),	which the calculation	to be described in records:	potential problem or is		position is determined in
	originator, reviewer, and	applies), originator,	a. Identification number of	insufficient to satisfy		accordance with the actual
	date, or by other data such	reviewer, and date; or by	records	requirements, the		job experience,
	that the calculations are	other data such that the	b. Names of plants and	corrective action shall be		acknowledgement of
	retrievable. (NQA-1)	calculations are retrievable.	units, and names of items	made so that the final		professional degree and
			or services	design should conform to		systematized actual job
			c. Names of organizations	the design intention.		acknowledgement.
			that generated the record	Ũ		The type of job (job
			d. Date, sign, or seal for	3.4.2 Method of Design		classification) is
			generation, review, and	Review		segmentalized such as
			approval of the record	(1) At an appropriate stage		investigative research,
			e. Applied codes	of design specified review		R&D. technology, design
			standards, or procedures	on the design process shall		control, technical
				be planned performed and		computing and radiation
			SUPPLE	documented.		control.
			4 2 3 Design analyses	Representatives from the		
		· ·	Design analyses should be	design organizations		
			implemented according to	involved in the design		
			the design process plan	stages within the scope of		
			and design analysis reports	design review shall be		
			should be documented	included in the participants		
			(Explanation 4-14)	of the review Range of the		
			a Purnose of analysis	review may include the		
			h Analysis method	design review by a single		
			c Assumption and	participant to the design		
			conditions set for the	review with the involvement		
			analysis	of multiple organizations		
		1	d Design requirements	(2) Following items shall be		
			a Referenced data books	confirmed as appropriate in		
			and documents	the design review		
			f Computer programmes	a) Appropriateness of		
			input data and output data	selection of design		
			a Unit evetem	requirements		
			g. onic system	b) Appropriateness and		
			REF	rationality of design-related		
		i .	4 2 3 Design analyses	assumptions		
			In design analysis	c) Appropriateness of		
			documents the following	design method and		
			are to be included as	conformance to specified		
			and to be included, as	quality standards		
			appropriate.	d) Proper reflection of		
			4.2.4 Design documents	design requirements in		
]	×	The design documents are	design documents and		
		1	to include the following on	appropriateness of the		
1			appropriate:	appropriateriess of the		
			appropriate.	a) Conformance to design		
			a. Use of ionnat, drafting	e) contormance to design		
•			abbroviations, etc.	0 Specification of		
	1		appreviations, etc.	n openication of		
			b. Idenuication method for	necessary design		
			design documents by plant	requirements and		
	1	1	i name, document number.	verification requirements		1

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COMPARISON TABLE III Design Control (10/28)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	1) ASME NQA-1-1994Edtion	JEAG4101-1993	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
			revision number, applying objects, etc. c. Indication method for design document status, such as review, approval, and revision d. Proceeding of processes	for the design interface organizations		
			for review, approval, etc. e. Method of storage for originals and distribution of copies f. Method of revision, partial changes, and control of obsolete design documents			
			g. Method of issuance for completed documents h. Control measures for non-conformance in regard to design documents			
	 Design Control Control of computer programs used for design analysis includes the following: (NQA-1) (1) Computer program acceptability is preverified or the results verified with the design analysis for each application. (2) Computer programs are controlled to ensure that changes are documented	(a) Computer programs may be utilized for design analysis without individual verification of the program for each application provided: (1) the computer program has been verified to show that it produces correct solutions for the encoded mathematical model within defined limits for each parameter, employed; and (2) the encoded mathematical model has been shown to produce a valid solution to the physical problem associated with the particular application. Computer programs shall be controlled to assure that changes are documented and approved by authorized personnel. Where changes to previously verified computer programs are made, verification shall be required for the change, including evaluation of the effects of these changes on	1.QUALITY ASSURANCE PROGRAMMES 1.1 General (Not described) 1.2 Establishment of quality assurance programmes 1.2.2 Contents of quality assurance programmes The most important way to clarify the degree that quality assurance activities are performed is to consider the influence that the functional non-conformity of items and service errors have on the safety of nuclear power plants. Additional matters to be considered are as follows: D. The need for special controls and inspection for processes, methods, and equipment	Q10 3.1.3 Software Management In the case of using computer software for analysis purpose, their verification and validation shall be conducted. Guidance on the software is provided in Q1 (Quality Assurance Programs) of this guide (Reference Matters). Q1 2.6 Configuration Control of Software (1) Configuration Control of Software (1) Configuration Control Programme shall be established and implemented to assure mutual identification of software and the related documents and their maintenance in the clearly defined status. (2) In the Configuration Control Programme, software items within the scope of management and the activities to be implemented shall be	JEAG4101-1993 Special control of process, methods and equipment is specified as the requirements of QA Program, though JEAG4101-1993 doesn't have explicit provisions for computer program verification. JEAG4101-2000 requires the verification and configuration control of computer program.	No Significant Differences; No impact on MHI procedure, because MHI had recognized the requirement of special control specified in JEAG4101-1993 as the control of computer program and established " The Control Procedure of Computer Software" and applied it since 1995.

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COMPARISON TABLE III Design Control (11/28)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	2) JEAG4101-1993	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
	construction QA programs.) (10 CFR 50.34(f)(3)(iii)(H)) q. QA personnel are included in the documented review and concurrence in quality-related procedures associated with design, construction, and installation. (This applies to DC applicants, ESP, and construction QA programs.) (10 CFR 50.34(f)(3)(iii)(C))			concerning the software and the related documents. [Explanation Q1-6] (3) Control method shall be determined on components basis to identify all versions of software items and the related documents within the scope of configuration control. Following items shall be identified for each software: a) Documents related to component specifications and design specifications and design specifications b) Utility software of each device, etc. c) Interface with other software and hardware d) Related document and it's storage place (4) Method to identify, document and approve any change in software shall be determined.		
	 Design Controt Documentation of design analyses includes the following, as applicable: (NQA-1) definition of the objective of the analyses definition of design inputs and their sources results of literature searches or other applicable background data didentification of assumptions and indication of those that must be verified as the design proceeds didentification of any computer calculation, including computer type, computer program (e.g., name), revision identification, inputs, outputs, evidence of or reference to computer program verification, and the bases (or reference 	 (b) Documentation of design analyses shall include (1) through (6) below: (1) definition of the objective of the analyses; (2) definition of design inputs and their sources; (3) results of literature searches or other applicable background data; (4) identification of assumptions and indication of those that must be verified as the design proceeds; (5) identification of any computer calculation; including computer type, computer program (e.g., name), revision identification, inputs, outputs, evidence of or reference to computer program verification, and the bases (or reference 	Chapter 2 REF 4.2.3 Design analyses In design analysis documents the following are to be included, as appropriate: a. Purpose of analysis b. Analysis method c. Assumption and conditions set for the analysis d. Design requirements e. Referenced data books and documents f. Computer programmes, input data, and output data g. Unit system	BASIC 3.2.3 Design Verification and Design Validation The adequacy of design, including design tools and design inputs and outputs shall be verified or validated by individuals or groups other than those who originally performed the work. Verification and approval shall be completed before issuing the design document. Q10 EX. 10-5 (1) Design analysis includes following items: a) Transient analysis b) Radiation protection and dose equivalent evaluation c) Reactor physics analysis d) Thermal hydraulic analysis e) Stress analysis	Three standards have similar requirements.	No significant Difference; No impact on the MHI QA Manual or Procedure.

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COMPARISON TABLE III Design Control (12/28)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800	ASME NQA-1-1994Edtion	JEAG4101-1993 ²¹	JEAG4101-2000 ^{2\}	Differences	Assessment of Difference for MHI Manual or Procedure
	thereto) supporting application of the computer program to the specific physical problem (6) review and approval	thereto) supporting application of the computer program to the specific physical problem; (6) review and approval.		(including seismic analysis) f) Event analysis (2) Design analysis documents shall include following items as follows. a) Analysis purpose b) Analysis methodology c) Assumption and conditions served as basis of analysis d) Design requirements e) Referenced material and data f) Computer program, input / output data g) Unit system Q1 2.6 (See above)		
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 by the performance of a suitable testing program. The verifying or checking process shall be performed by individuals or groups other than those who performed the original design, but who may be from the same organization. Design control measures shall be applied to items such as the following: reactor physics, stress, thermal, hydraulic, and accident analyses;	 Design Verification Verification methods include, but are not limited to, design reviews, alternative calculations, and qualification testing. The responsible design organization is required to identify and document the particular design verification method(s) used. (NQA-1) Design Verification 	4 DESIGN VERIFICATION Design control measures shall be applied to verify the adequacy of 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 design verification shall be clearly documented with the identification of the verifier clearly indicated. Design verification shall be	Chapter 2 BASIC 4.4 Design verification (1) Control measures shall be established to verify the adequacy of design, as appropriate, through design reviews, alternative calculations, verification tests (such as prototype or qualification test, engineering, proof or acceptance test, or other applicable test) or other applicable test) or other suitable methods according to the degree of importance of the structure, system, or component concerned. (Explanation 4-9, 4-10, 4-11, 4-12) (2) Design verification shall be implemented by individuals or groups other than those who performed the original design.	BASIC 3.2.3 Design Verification and Design Validation The adequacy of design, including design tools and design inputs and outputs shall be verified or validated by individuals or groups other than those who originally performed the work. Verification and approval shall be completed before issuing the design document. BASIC Exp. 3-2 Design verification may be carried out by a person of the section to which the original designer is belonging.	Three standards have similar requirements, though JEAGs don't have explicit provisions for the originator's supervisor performing verification. JEAG4101-1993 BASIC 4.4 (1) allows other suitable methods for design verification. Explanation 4-12 lists specific methods and alternative controls. U.S. standards do not include these details. JEAG4101-2000 allows "at risk" use of unverified design	Except as noted below, there are no significant Difference; No impact on the MHI QA Manual or Procedure. MHI QA Manual also requires additional verification by person who is not the originator's supervisor. Qualification test completed under MHI QA Program are re-evaluated to ensure consistency with U.S. standards. No impact; "at risk" use of unverified design will not result in any deviations
compatibility of materials; accessibility for inservice inspection, maintenance, and repair; and delineation of acceptance criteria for inspections and tests.	 Ine ventying or checking process is performed by individuals or groups other than those who performed the original design, but who may be from the same 	performed by any competent individual(s) or group(s) other than those who performed the original design but who may be from the same	(c) Design vernication results shall be documented. (Explanation 4-12)	Design inputs, processes, outputs and changes are		Final design will satisfy applicable requirements.

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10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	() ASME NQA-1-1994Edtion	JEAG4101-1993	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
	Section 17.5 organization. The designer's immediate supervisor can perform the design verification provided the supervisor did not specify a singular design approach, or rule out certain design considerations; the supervisor did not establish the design; and the supervisor of the only individual in the organization competent to perform the verification. (NQA-1) 2. Design Verification e. Design verification is completed before design outputs are used by other organizations for design work and before they are used to support other activities such as procurement, manufacture, or construction. When this timing cannot be achieved, the unverified portion of the design is identified and controlled. In all cases, the design verification is completed before relying on the item to perform its intended function. (NQA-1)	organization. This verification may be performed by the originator's supervisor, pro- vided the supervisor did not specify a singular design approach or rule out certain- design considerations and did not establish the design or, provided the supervisor is the only individual in the organization competent to perform the verification. Cursory supervisory 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 upon the component, system, structure, or computer program to perform its function.	Other design verification methods include the following: These methods are to be controlled and performed, in principle, in the same way as verification testing described in this guide: a. Verification in commissioning, etc. of the plant b. Verification by model engineering, etc. c. Verification by actual results obtained from earlier constructed plants REF. 4.4.5 Performing verification Design verification may be performed by individuals who belong to the same division to which the original designer belongs, including the originator's supervisor. (Explanation 4-4): In general, "design process" covers serial activities that begin with identification of design requirements, followed by work based on those requirements, and verification is so important it is referred to as the conclusive activity that assures design quality. It furthermore includes methods such as venification testing	verified. Computer programs used in design are validated through testing or simulation prior to use if not proven through previous use. Individuals or groups performing design verification are qualified to perform the original design. Verification is performed by individuals other than those who performed the design (but who may be from the same organization). The extent of verification is based on the complexity, associated hazards and uniqueness of the design. Some typical design verification methods include design review, alternate calculation and qualification testing. Previously proven designs do not require verification unless they are intended for different. Tests used to verify or validate design features are conducted under conditions simulating the most adverse operating conditions. Design verification is usually completed before design output is used by other organizations, or to support other work such as procurement, manufacturing, construction, or research and development. In specially controlled circumstances, installation of unverified portions of design may proceed only to a point where extensive demolition or rework would not be required to replace or modify the design		Procedure
L			the series of processes. It	[L

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COMPARISON TABLE III Design Control (14/28)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ^{2),}	Differences	Assessment of Difference for MHI Manual or Procedure
			is therefore treated here independently as "c. Design verification."	Q10 3.5.2 Verification Method (2) Design verification shall be implemented and documented by individuals or groups with sufficient ability, including the superior of the designer, who are not involved in the designing while these can belong to the same organization as that of the designer. In conducting the verification, access to all the related information shall be ensured. Each individual responsible for checking, verification and approval shall be clearly identified.		
	2. Design Verification h. The verification process need not be duplicated for identical designs. However, the applicability of standardized or previously proven design, with respect to meeting pertinent design inputs, is verified for each application. The original design and associated verification measures are documented in records for subsequent application of the design. (NQA-1)	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 the similarity, with previously proven designs. Where the design has been subjected to a verification process in accordance with this Part (Part I), 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	Chapter 2 SUPPLE 4.4.1 Method of design verification (2) It is not necessary to implement design verification repeatedly for identical structures, systems, or components, but even in such cases, a verification should be made that design requirements applying to the design are the same for each application.	SI 6. Supplemental Information about "DESIGN" Some typical design verification methods include design review, alternate calculation and qualification testing. Previously proven designs do not require verification unless they are intended for different applications or the performance criteria are different. Tests used to verify or validate design features are conducted under conditions simulating the most adverse operating conditions. Q10 3.5.2 Verification Method (3) Various methods may be employed for design verification including design review, use of alternative	Three standards have similar requirements.	No significant Difference; No impact on the MHI QA Manual or Procedure.

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COMPARISON TABLE III Design Control (15/28)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
		original design and associated verification measures shall be adequately documented and referenced in the files of subsequent application of the design.		calculation and appropriate test plan. When determining extent of the design verification based on the graded approach, considerations shall be given to the safety-related importance and complexity of the design as well as the similarity with the previously approved design. (4) While it is not required that design verification is redundantly performed for the identical structure, system or component, it shall be verified in each time case that the applicable design requirements are equivalent even in such cases		
Y	2. Design Verification g. Whenever changes to previously verified designs are made, design verification is 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 a previously verified design. (NQA-1)	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.	Chapter 2 SUPPLE 4.4.1 Method of design verification (3) Where changes (including new design) to previously verified designs have been made, design verification should be implemented for those changes, including evaluation of their effects on the overall design.	Q10 3.7.2 Method of Design Change (2) Considerations shall be given to the impact accompanying the design change and the impact on the other designs. (4) Information for the change shall be communicated to the organizations considered susceptible to the impact to be caused by the change. (5) In the case where some change is made on the previously verified design (including new design), design verification shall be conducted for the concerned change, including the evaluation of the impact on the design as whole. SI 6. Supplemental Information about "DESIGN"	Three standards have similar requirements.	No significant Difference; No impact on the MHI QA Manual or Procedure.

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COMPARISON TABLE III Design Control (16/28)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
		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:	Chapter 2 SUPPLE 4.4.1 Method of design verification (1) Of design reviews, altemative calculations, verification testing, and other suitable methods, one or more should be implemented as appropriate according to the degree of importance of the structure, system, or component concerned, to verify the adequacy of design.	Evidence that the design was properly accomplished is supported by design records that include the final design, important design steps such as calculations, analyses and computer programs, and sources of design input that support design output. The design organization also provides records of design changes. Q10 3.5.2 Verification Method. (3) Various methods may be employed for design verification including design review, use of alternative calculation and appropriate test plan. When determining extent of the design verification based on the graded approach, considerations shall be given to the safety-related importance and complexity of the design as well as the similarity with the previously approved design.	Three standards have similar requirements.	No significant Difference; No impact on the MHI QA Manual or Procedure.
	2. Design Verification b. Design inputs, processes, outputs, and changes are verified. The final design (approved design output documents and approved changes thereto) is relatable to the design input by documentation in sufficient detail to permit design verification and the identification of the verifier clearly indicated. When applicable, design reviews answer the following questions: (NQA-1) (1) Were the design inputs correctly selected? (2) Are assumptions	 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 	Chapter 2 SUPPLE 4.4.2 Design review (Explanation 4-9) The type and method of design review should be specified in design control procedures, etc. 4.4.6 Documentation of venification results To permit confirmation that the design verification has been properly implemented, design verification results should be documented with the individuals who have verified and approved, and the date of verification.	SI 6. Supplemental Information about "DESIGN" Design inputs, processes, outputs and changes are verified. Q10 3.4.2 Method of Design Review (2) Following items shall be confirmed as appropriate in the design review: a) Appropriateness of selection of design requirements b) Appropriateness and rationality of design-related	Three standards have similar requirements.	No significant Difference; No impact on the MHI QA Manual or Procedure.

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COMPARISON TABLE III Design Control (17/28)

10/CFR 50 Appendix B	Standard Review Plan NUREG -0800	1) ASME NQA-1-1994Edtion	2) JEAG4101-1993	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or
	Section 17.5 design activity adequately described and reasonable? Are the assumptions adequately identified to enable subsequent reverifications after detailed design activities are completed? (3) Was an appropriate design method used? (4) Were the design inputs correctly incorporated into the design? (5) Are the necessary design inputs and verification requirements for interfacing organizations specified in the design documents or in supporting procedures or instructions? (6) Is the design output' reasonable compared to the 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?	REF. 4.4.2 Design review The following are to be confirmed, as necessary, in the design review: a. Adequacy of selection of design requirements b. Propriety and reasonability of assumptions adopted in the design c. Propriety of design method and compliance with specified quality standards d. Correct incorporation of design requirements into the design documents and propriety of the contents e. Compliance with design process f. Designation of necessary design and verification requirements for related organizations with design interface EX.4.9 "Design reviews" are activities that confirm that the design documents are correct and satisfactory through a versatile review of such documents. These range from review by a single person to review by the group or organization charged with the design work. The depth of design reviews ranges from a limited check of specific design documents and of the design approach and its results to a detailed check or review performed systematically.	assumptions c) Appropriateness of design method and conformance to specified quality standards d) Proper reflection of design requirements and appropriateness of the contents e) Conformance to design procedures f) Specification of necessary design requirements and verification requirements for the design interface organizations	Three standards have	No significant Difference:
	c. Alternate calculations are calculations or	Calculations. These are calculations or analyses	SUPPLE 4.4.3 Alternative	3.5.3 Alternative Calculation	similar requirements.	No impact on the MHI QA Manual or Procedure.
	analyses that are made	that are made with	calculations (Explanation	(1) Verification of	<u>l</u>	l

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COMPARISON TABLE

111	Design	Control ((18/28)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
	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 are reviewed. (NQA-1)	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.	 4-10) (1) Alternative calculation methods should be those that are capable of confirming the adequacy of the original design. (2) Where alternative calculations are implemented, the adequacy of calculation assumptions, design requirements, and computer codes should also be confirmed as in the case of the original design calculation. EX.4-10 *Alternative calculations" are methods to verify calculations or analyses by comparing the results with those obtained by other calculations or analyses. 	correctness of calculation or analysis shall be performed based on the comparison with the results of alternative calculation or analysis. (2) In conducting alternative calculation, review shall be performed to confirm appropriateness of the employed assumptions, design input data, computer codes and the other calculation methods. (3) While precisely identical results are not required in the alternative methods, no significant difference that has serious impact on the safety is allowed.		
Where a test program is used to verify the adequacy of a specific design feature in lieu of other verifying or checking processes, it shall include suitable qualifications testing of a prototype unit under the most adverse design conditions.	2. Design Verification d. Where design adequacy is verified by qualification tests, the tests are identified. The test configuration is clearly defined and documented. Testing demonstrates the adequacy of performance under conditions that simulate the most adverse design conditions. Operating modes and environmental conditions in which the item must perform satisfactorily are considered in determining the most adverse conditions. Where the test is intended to verify only specific design features, the other features of the design are verified by other means. Test results are documented and evaluated by the responsible design organization to ensure that	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 of the design shall be verified by other means. Test results shall be documented and evaluated by the responsible design	Chapter 2 8.3 Test control (2) The tests shall be performed in accordance with procedures etc. by suitable persons under suitable environmental conditions. (4) The test results and the judgement of acceptance or rejection shall be formulated in a document. SUPPLE 4.4.4 Verification testing (Explanation 4-11) (1) Verification tests should be implemented in accordance with test procedures. (2) When tests are being implemented on scale models, scaling laws should be verified. (3) In principle, qualification tests should be performed, if possible, under the most	Q10 3.5.4 3.5.4 Qualification Test (1) Appropriate qualification test for model or prototype may be performed as design verification. (2) When qualification test is performed with the purpose to verify that the concerned design is appropriate for all the design requirements, the test shall be conducted under the test conditions that satisfy all the design requirements. (3) When test to verify the appropriateness of design contents is planned, appropriate test under the most adverse design conditions shall be performed concerning the specific design conditions	Three standards have similar requirements. JEAGs don't describe explicit provisions for the modification to the item, because the activity of the modification is considered to be included in the design verification. JEAGs allow extrapolation of test conditions provided design adequacy can be assured.	Except as noted below, there are no significant Difference; No impact on the MHI QA Manual or Procedure. Qualification test completed under MHI QA Program are re-evaluated to ensure consistency with U.S. standards.

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COMPARISON TABLE

10'CFR' 50'Appendix B'	Standard Review Plan NUREG -0800 Section 17:5	() ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
	test requirements have been met. If qualification testing indicates that modifications to the item are necessary to obtain acceptable performance, the modification is documented and the item modified and retested or otherwise verified to ensure satisfactory performance. When tests are being performed on models or mockups, scaling laws are required to be established and verified. The results of model test work are subject to error analysis, where applicable, prior to use in final design work. (NQA-1)	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 venified to assure satisfactory performance. When tests are being performed on models or mockups, 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.	adverse conditions for the specific design requirements. Where this is not possible, these may be performed under other conditions provided that the test results can be extrapolated to the most adverse design conditions and the adequacy of the design can be verified for specific requirements. (4) When qualification testing is intended to confirm the adequacy of the design for all design requirements, tests should be carried out under conditions which satisfy all these requirements. Where the testing is intended only to verify specific items, the adequacy of the design for other design requirements should be verified by other means. (5) Verification test results should be evaluated to assure that design requirements have been satisfied. EX.4-11 "Verification testing" is a method to verify some designs or specific design requirements using a prototype unit, etc. under adequate conditions.	can not executed, the test may be acceptable as far as the results can be extrapolated with the most adverse conditions. However, if it isn't the case, alternative method for design verification shall be applied. (5) If the verification for the other design requirement, verification for the other design requirements shall be conducted by other methods. (6) Qualification test shall be conducted in a test facility based on procedures. The procedures shall be specified for the related requirements and acceptance criteria, and be clearly identified the test configuration of models or prototypes concerned. (7) Test results shall be documented and appropriate staff shall review that all test requirements were satisfied.		
Design changes, including field changes, shall be subject to design control measures commensurate with those applied to the original design and be approved by the organization that performed the original design unless the applicant designates another responsible organization.	 Design Control Design Control Changes to final designs (including field changes and modifications) and dispositions of nonconforming items to use-as-is or repair are subject to design control measures commensurate with those applied to the original design and approved by the organization that performed 	5 CHANGE CONTROL Changes to final designs, field changes, modifications to operating facilities, and nonconforming items dispositioned use-as-is or repair shall be justified and subject to design control- measures commensurate with those applied to the original design. These measures shall include	Chapter 2 BASIC 4.5 Design changes (Explanation 4-13) (1) Control measures shall be provided for effecting design changes (including on-site changes). (2) Design changes shall be subject to the same design control measures as those applied to the original design.	BASIC 3.2.4 Design Changes Design changes shall be subject to the same design control measures as those applied to the original design. SI 6. Supplemental Information about "DESIGN"	inree standards nave similar requirements.	No significant Difference; No impact on the MHI QA Manual or Procedure.

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COMPARISON TABLE III Design Control (20/28)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17 5	1) ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
10 CFR 50 Appendix B	NUREG-0800 Section 17.5 the original design or a qualified designate. The designate has demonstrated competence in the specific design area of interest and has an adequate understanding of the requirements and intent of the original design. (NQA-1)	ASME NQA-1-1994Edlion assurance that the design analyses for the structure, system, or component are. still valid. Changes shall be approved by the same affected groups or organizations which reviewed and approved the original design documents; except where an organization which originally was responsible for approving a particular design document is no longer responsible, then the Owner or his designee shall designate a new responsible organization. The designated organization, Shall-have demonstrated competence in the specific design area of interest and have an adequate understanding of the requirements and intent of the original design.	JEAG4101-1993 Review and approval of design change documents, in principle, shall be implemented by the same individuals or organizations who reviewed and approved the original design documents. (3) Methods shall be established for transmitting information concerning the design changes. The information, in principle, shall be transmitted by document to affected organizations. SUPPLE 4.5.1 Control measures for design changes When design changes are effected, the reasons, changed portions, circumstances of the changes, and others should, in principle, be documented. REF. 4.5.1 Control measures for design changes For design changes the following are to be considered: a. Evaluation of the influences brought about by the design changes and their adequacy b. Documentation of the required disposition c. Transmission of information concerning design changes of the review and approval of design change for the review and approval of design change	JEAG4101-2000 Design changes are justified and subject to design control measures commensurate with the original design. Design changes include field changes, modifications and non-conforming items designated for use-as-is or repair. Changes are subject to configuration and design control measures and approved by the original design organization or a technically qualified alternate. Q10 3.7.2 3.7.2 Method of Design Change (1) In the case of design change, the reason of change shall be documented. (3) Design change shall be reviewed and approved by the following organizations: a) Groups and organizations responsible for the original design documents b) Other design area as well as other organizations using the original design documents	Differences	for MHI Manual or Procedure
			reviewed and approved the	1]

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COMPARISON TABLE III Design Control (21/28)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
			originals, others may be designated. This designation assumes that they have access as necessary to concerned background information, they have demonstrated competence in their specific design area, and they have an adequate understanding of the requirements and intent concerning the original design.			
		When a design change is approved other than by revision to the affected design documents, measures shall be established to incorporate the change into these documents, where such incorporation is appropriate.	Chapter 2 BASIC 4.5 Design changes (Explanation 4-13) (3) Methods shall be established for transmitting information concerning the design changes. The information, in principle, shall be transmitted by document to affected organizations.	Q10 3.7.2 Method of Design Change (2) Considerations shall be given to the impact accompanying the design change and the impact on the other designs. (4) Information for the change shall be communicated to the organizations considered susceptible to the impact to be caused by the change. (5) In the case where some change is made on the previously verified design (including new design), design verification shall be conducted for the concerned change, including the evaluation of the impact on the design as whole.		
	1. Design Control p. Where a significant design change is necessary because of an incorrect design, the design process and verification procedure is reviewed and modified as necessary. (NQA-1)	Where a significant design change is necessary because of an incorrect design, the design process and verification procedure shall be reviewed and modified as necessary.	Chapter 2 REF. 4.1 General b. Preparation of design control procedure document to implement design activities Typical items to be covered by design control procedure document are as follows: SUPPLE 11. ACTIONS TO PREVENT RECURRENCE	Q2 4.2.1 Planning, Decision, and Performance of Corrective Action Based on the cause of occurrence, necessity of the corrective action should be determined, and when decided to be necessary, then required corrective action should be planned, decided, and performed. In general, the corrective action is determined by the	Three standards have similar requirements. The requirements of the significant non-conforming matters including design and design process are clearly described in "Action to Prevent Recurrence" in JEAGs.	No significant Difference; No impact on the MHI QA Manual or Procedure.

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COMPARISON TABLE III Design Control (22/28)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
			11.3 Planning, decision, and execution of corrective action (1) For the planning, decision, and implementation of corrective action, at least the following should be considered: a. Reflection corrective action on the same type of products (including future and operating plants) b. Reflection on the same type of services (2) The following should also be considered, as necessary: a. Reflection on quality assurance programmes b. Reflection on design, procurement, fabrication/installation, inspection/ test, and operation/maintenance procedures, etc. c. Reflection on facilities and equipment d. Reflection on indoctrination and training (3) Follow-up activities should be performed to ensure that the corrective actions have been implemented.	organization which performed the decision of the measures for the non-conformity. (1) At least the followings should be taken into consideration: A. Reflection to the same products (succeeding products, existing products) B. Reflection to the same services (2) In addition, the followings should be taken into consideration, as appropriate A. Reflection to the quality assurance program B. Reflection to the procedures on design, procurement, manufacturing, installation, inspection, testing, operation and maintenance C. Reflection to facilities and components (including the withdrawal of defected products) D. Reflection to education and training		
Measures shall be established for the identification and control of design interfaces and for coordination among participating design organizations. These measures shall include the establishment of procedures among participating design organizations for the review, approval, release, distribution, and revision of documents involving design interfaces.	1. Design Control f. Interface controls (internal and external between participating design organizations and across technical disciplines) for the purpose of developing, reviewing, approving, releasing, distributing, and revising design inputs and outputs are defined. Design information transmitted across interfaces is documented and controlled. Transmittals identify the status of the	6 INTERFACE CONTROL Design interfaces shall be identified and controlled and the design efforts shall be coordinated among the participating organizations. Interface controls shall include the assignment of responsibility and the establishment of procedures among participating design organizations for the review, approval, release, distribution, and revision of documents involving design interfaces.	Chapter 2 BASIC 4.3 Design interface (1) Design interfaces between organizations performing the designs shall be identified in the document. (Explanation 4-8) (2) The information related to the design interfaces shall be controlled by establishing methods for communicating them. SUPPLE 4.3 Design interface	SI 6. Supplemental Information about "DESIGN" The design process requires the use of sound engineering/scientific principles and appropriate design standards. Design requirements, inputs, processes, outputs, changes, records and organizational interfaces are controlled. Interfaces among all organizations involved in	Three standards have similar requirements.	No significant Difference; No impact on the MHI QA Manual or Procedure.

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COMPARISON TABLE III Design Control (23/28)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	1) ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	2) JEAG4101-2000	Differences	Assessment of Difference for MHI Manual or Procedure
10°CFR 50'Appendix B	NURE G-0800. Section 17.5 design information or document provided and, where necessary, identify incomplete items which require further evaluation, review, or approval. Where it is necessary to initially transmit design information orally or by other informal means, the transmittal is controlled document. (NQA-1)	ASME NGA-1-1994Edtion Design information transmitted across interfaces shall be documented and controlled: Transmittals shall identify the status of the design information or document provided and, where necessary, identify incomplete items which require further evaluation, review, or approval. Where it is necessary to initially transmit design information orally or by other informal means; the transmittal shall be confirmed promptly by a controlled document.	JEAG4101-1993 4.3.1 Interface between organizations (1) Prior to implementing design activities, measures should be established to control external design interfaces (those between organizations) and internal design interfaces (those between the departments inside the organization). (2) Responsibilities concerning design interfaces between design organizations should be clearly defined. (3) The organization responsible for preparation, review, approval, issuance, distribution, and revision of design documents related to design interfaces should be identified. 4.3.2 Communication between organizations (1) Control measures should be established for transmitting information necessary to design (including changes as work progresses) to organizations concerned. (2) When design information is transmitted from one design organization to another, it should be transmitted by means of specifications, drawings, or other documents equivalent to them. When design information is initially transmitted orally or by other informal means in an urgent case or others, the transmittal should later be confirmed by controlled documents. REF. A.3 Design interface	JEAG4101-2000 the design are identified, coordinated and controlled. Control of interfaces includes assignment of responsibilities and establishment of procedures among participating internal and external organizations. Q10 2.4 2.4 Interface (1) The adjustment of interfaces shall be agreed among participant organizations of design activities. The examples of interfaces are as follows. a) Interface between technical specialties in design organization b) Interface between technical specialties in design organization b) Interface between technical specialties in design organization b) Construction organization c. Commissioning organization d. Operation organization e. Decommissioning organization (2) Each organization participating in design tasks shall clarify its interface organization and integrate the issue into documents with the purpose to manage the information flow. Responsibilities to formulate, review, approve, issue, distribute and revise the information to be shared by the interface organizations shall be clearly identified and	Linerences	Procedure
			4.3.1 Interface between organizations	documented. [Explanation Q10-2]	_	

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COMPARISON TABLE III Design Control (24/28)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
			Many organizations are often responsible for design interface documents. When there are two or more organizations responsible for a document, one responsible organization is to be identified for each item. 4.3.2 Communication between organizations (1) Of the information transmitted concerning design interfaces, the status of the information provided and required items such as coordination, evaluation, review, or approval are to be identified, as necessary, (2) Control measures are to be established according to this guide, as necessary, for interfaces between the design organization and organizations involved in other stages such as procurement, fabrication, installation, operation, and maintenance.	Q10 EX. 10-2 If information is communicated verbally in emergency, the contents of communication shall be confirmed later by using appropriate documents under control.		
	1. Design Control g. Design records, maintained to provide evidence that the design was properly accomplished, include not only the final design output and revisions to the final output, but also the important design steps (e.g., calculations, analyses, and computer programs) and the sources of input that support the final output. (NQA-1)	7 DOCUMENTATION AND RECORDS Design documentation and records, which provide evidence that the design and design verification processes were performed in accordance with the requirements of this Part (Part I), shall be collected, stored, and maintained in accordance with documented procedures. The documentation shall include not only final design documents, such as drawings and specifications, and revisions thereto but also documentation which identifies the important	Chapter 2 REF 4.1 General In establishing design control measures, the following are to be considered: b. Preparation of design control procedure document to implement design activities Typical items to be covered by design control procedure document are as follows: 4.2.4 Design documents b. Identification method for design documents by plant name, document number, revision number, applying objects, etc.	SI 6. Supplemental Information about "DESIGN" Evidence that the design was properly accomplished is supported by design records that include the final design, important design steps such as calculations, analyses and computer programs, and sources of design input that support design organization also provides records of design changes. Q10 2.8 Document Control and	Three standards have similar requirements. The requirements of NQA-1 are a summary of "Documentation and Records", while JEAGs describe more detailed provisions including samples.	No significant Difference; No impact on the MHI QA Manual or Procedure.

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COMPARISON TABLE III Design Control (25/28)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	2) JEAG4101-1993	2) JEAG4101-2000	Differences	Assessment of Difference for MHI Manual or Procedure
		steps, including sources of design inputs that support the final design. Subpart 2.7 [See Commitments section Below]	a. Use of format, drafting method, symbols, abbreviations, etc. b. Identification method for design documents by plant name, document number, revision number, applying objects, etc. c. Indication method for design document status, such as review, approval, and revision d. Proceeding of processes for review, approval, etc. e. Method of forage for originals and distribution of copies f. Method of revision, partial changes, and control of obsolete design documents g. Method of issuance for completed documents h. Control measures for non-conformance in regard to design documents	Quality Records (1) Procedure for preparation, review, approval, issue, revision and control of documents shall be established. (2) Followings are the processes for preparation, correction and control of design-related information. a) Drawing control standards b) Standardization symbols c) Identification system d) Display of the current status e) Check method f) Requirements on review and approval g) Issue, distribution and storage (3) So that the latest and pertinent information can be used for formulating and making revision on design input documents, management shall be conducted as follows. a) Organizations responsible for prepareing, reviewing, approving, issuing and revising documents shall be clearly identified. b) Documents to be used for design activities shall be clearly identified with description of document name, revision status, issue date or other related information for proper identification of the document concerned. c) Design documents related to interfaces (intre-organization and intra-organization shall be adjusted and controlfed. d) Abolished documents shall be removed from the place of use or stored in a way prevent inadvertent		

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COMPARISON TABLE III Design Control (26/28)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
				use. (4) Specifications and other design outputs such as installation documents, instructions, commissioning documents and test procedures shall be controlled. (5) Records control methods shall be established including the statements about agreements and responsibilities for categorization, receipt, indexes, storage, search and handling of design documents. (6) Requirements on records shall be specified so that design activities should be controled and the evidence for secure achievement of requested safety should be available. Guidance on the document control and records is provided in Q3 (Document Control and Records) of this guide		
	n, The QA role in design and analysis activities is defined. Design documents are reviewed by individuals knowledgeable and qualified in QA to ensure the documents contain the necessary QA requirements. (This applies to DC applicants, ESP, and construction QA programs.) (10 CFR 50.34(f)(3)(iii)(H))		BASIC 2.4 Indoctrination and training All personnel responsible for implementing activities affecting quality shall be indoctrinated and trained as necessary according to their educational background, experience, and proficiency. (Explanation 2-1) REF 1.2.1 (3) These are two kinds of documents for control-oriented activities (administration documents). These are quality assurance programme documents, and control procedures for	(Reference Matters). SI 2. Supplemental Information about "TRAINING AND QUALIFICATION" To achieve quality and maintain safety, personnel have to the capable of performing their assigned tasks. Training emphasizes correct performance of work and, where appropriate, provides an understanding of QA principles and the relevant management procedures; it emphasizes personal accountability and responsibility, describes the main systems and components of the unclear power plant, and provides	JEAGs describe role of QA in performing safety-related design activities and indoctrination and training of personnel.	No Significant Difference; No impact on the MHI QA Manual or Procedure.

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COMPARISON TABLE III Design Control (27/28)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	2) JEAG4101-2000	Differences	Assessment of Difference for MHI Manual or Procedure
10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 quality assurance. When preparing these documents, the matters to be considered are as follows: b. Control procedures for quality assurance indicate the detailed processes and methods for all activities to accomplish the quality assurance requirements. These procedures are to be described to simplify understanding and encourage appropriate execution of control processes and methods. The following are also to be included as appropriate in the procedures: (a) Purpose of the procedures (b) Scope of the procedures (c) Definition of specific terms used in the procedures (d) A series of processes to be executed to accomplish the purpose of the procedures (e) Document format for communication and instruction (f) Type of quality record to be described and format of the record (4) The documents for work-oriented activities (documents for works) include the work plan documents, work procedures, work instructions, and drawings.	JEAG4101-2000 an understanding of nuclear power plant operation. This training includes both education in principles and enhancement of skills and practices by on-the-job training and the use of simulators and mock-ups where possible. Training ensures that everyone understands the processes and tools they are using and provides an understanding of what constitutes acceptable quality for items and services they produce as well as the processes they control. The training programme focuses attention on 'doing it right the first time'.	Differences	Assessment of Difference for MHI Manual or Procedure
			documents, the matters to be considered are as follows: (Explanation 1-8, 1-9) a. The work plan documents are to be			

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COMPARISON TABLE III Design Control (28/28)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ^{2}}	2) JEAG4101-2000	Differences	Assessment of Difference for MHI Manual or Procedure
	Section 17.5		described in such a way to plan the work carried out by each organization beforehand and execute it systematically and orderly. And if necessary, the working matters, working processes, working standards to be applied, and working schedule, etc. are to be included in the work plan documents; b. The documents, such as work procedures, work instructions, and drawings are to be described to provide concrete information. This will make appropriate executions of activities possible according to the control procedures for quality assurance and the work plan document. The documents are to be concise and clear. (5) The existing quality assurance programmes are			Procedure
			applicable if the necessary requirements in this guide are reflected in these programmes as a result of their review.		IEACs do pot require OA	
	q. uA personnel are included in the documented review and concurrence in quality-related procedures associated with design, construction, and installation. (This applies to DC applicants, ESP, and construction QA programs.) (10 CFR 50.34(f)(3)(iii)(C))		-	-	approval of quality-related design procedures.	US-APWR quality-related procedures.

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COMPARISON TABLE IV Procurement Document Control (1/18)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
IV. Procurement Document Control Measures shall be established to assure that applicable regulatory requirements, design bases, and other requirements, design bases, and other requirements which are necessary to assure adequate quality are suitably included or referenced in the documents for procurement of material, equipment, and services, whether purchased by the applicant or by its contractors or subcontractors. To the extent necessary, procurement documents shall require contractors or subcontractors to provide a quality assurance program consistent with the pertinent provisions of this appendix.		Basic Requirement 4 Procurement Document Control Applicable design bases and other requirements necessary to assure adequate quality shall be included or referenced in documents for procurement of items and services. To the extent necessary, procurement documents shall require Suppliers to have a quality assurance program consistent with the applicable requirements of this Part (Part I).	BASIC 5.2 Clarifying quality requirements (1) Quality requirements shall be specified in the procurement documents. (Explanation 5-3) (2) The following shall be included in the quality requirements to ensure adequate quality: (Explanation 5-11) a. Scope of work implemented by bidders b. Technical requirements such as design, fabrication, installation, inspection, testing, applicable regulations, etc. c. Provision for the submission of quality assurance programmes d. Provision for access to the supplier's place of business for the purpose of inspection, testing, audit, etc. e. Provision for the submission and storage of records f. Provision for extending the application of requirements in the procurement documents to the contractor's suppliers	Q6 3.2 Contents of Procurement Documents The procurement documents shall include description on the following matters as appropriate and the responsibility related to each matter. [Explanation Q6-4] a) Scope of work b) Technical requirements c) Requirements on testing and inspection d) Access to supplier's facility e) Quality assurance standards and additional requirements f) Requirements on documents g) Requirements on documents and quality records h) Submission timing of documents and quality records h) Non-conformance report j) Control of Subcontractor by Supplier k) Items and Services Supplied by Purchaser 3.2.5 Quality Assurance Standards and Additional Requirements (1) Applicable quality assurance standards shall be clearly stipulated. (2) When purchaser refers to domestic or international quality assurance standards such as ISO, ASME and others, the purchaser shall perform evaluation to review whether or not additional requirements shall be stipulated to conform to this Guide. (3) In the cases where performance of internal quality audit is required and / or international standards	Three standards have similar requirements. The requirements of NQA-1 are summaries of "Procurement Document Control", while JEAGs describe more detailed provisions including samples. There is not the section named "Procurement Document Control" in JEAGs, so the matter is included in the section "Procurement Control" (JEAG4101-1993) or "Procurement of Items and Services"(JEAG4101-2000).	No significant Difference; No impact on the MHI QA Manual or Procedure.

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COMPARISON TABLE IV Procurement Document Control (2/18)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
				are refered, optional articles shall be stated as appropriate in the procurement documents.		
		Supplement 4S-1- Supplementary Requirements for Procurement Document Control 1 GENERAL This Supplement provides amplified requirements for procurement document control. It supplements the requirements of Basic Requirement 4 of this Part (Part.I) and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Part (Part 1).	-	-	This NQA-1-1994 clause is a paragraph introducing the additional requirements in the Supplementary Requirements. It specifies that the Supplementary Requirements apply when and to the extent specified by the organization invoking Part I of NQA-1-1994.	See below
	2. Procurement documents include provisions for the following: (NQA-1)	2 CONTENT OF THE PROCUREMENT DOCUMENTS Procurement documents issued at all tiers of procurement shall include provisions for the following, as deemed necessary by the Purchaser.	BASIC 5.2 Clarifying quality requirements (1) Quality requirements shall be specified in the procurement documents. (Explanation 5-3) (2) The following shall be included in the quality requirements to ensure adequate quality: (Explanation 5-11)	Q6 3.2 Contents of Procurement Documents The procurement documents shall include description on the following matters as appropriate and the responsibility related to each matter. [Explanation Q6-4]	Three standards have similar requirements.	No significant Difference; No impact on the MHI QA Manual or Procedure.
	a. a statement of the scope of the work performed by the supplier	2.1 Scope of Work A statement of the scope of the work to be performed by the Supplier shall be in the procurement documents.	BASIC 5.2 Clarifying quality requirements (2) The following shall be included in the quality requirements to ensure adequate quality: (Explanation 5-11) a. Scope of work implemented by bidders REF. 5.2.2 Quality requirements (1) Concrete contents of quality requirements	Q6 3.2 Contents of Procurement Documents a) Scope of work	Three standards have similar requirements.	No significant Difference; No impact on the MHI QA Manual or Procedure.

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COMPARISON TABLE IV Procurement Document Control (3/18)

1	0 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993	2) JEAG4101-2000	Differences	Assessment of Difference for MHI Manual or Procedure
				include the following: a. Scope of work implemented by bidder The scope of work implemented by the bidder (in case of plural bidders, mutual interfacing), etc. is included.			
		b. a specification of technical requirements, and where necessary, references to specific drawings, specifications, codes, standards, regulations, procedures, or instructions, including revisions thereto that describe the items or services furnished c. identification of test, inspection, and acceptance requirements of the purchaser for monitoring and evaluating the supplier's performance	2.2 Technical Requirements Technical requirements shall be specified in the procurement documents. Where necessary, these requirements shall be specified by reference to specific drawings, specifications, codes, standards, regulations, procedures, or instructions, including revisions thereto that describe the items or services to be furnished. The procurement documents shall provide for identification of test, inspection, and acceptance requirements of the Purchaser for monitoring and evaluating the Supplier's performance.	BASIC 5.2 Clarifying quality requirements (2) The following shall be included in the quality requirements to ensure adequate quality: (Explanation 5-11) b. Technical requirements such as design, fabrication, installation, inspection, testing, applicable regulations, etc REF. 5.2.2 Quality requirements (1) Concrete contents of quality requirements include the following: b. Technical requirements such as design, fabrication and installation, inspection and testing, etc. Performance and function requirements, criteria for the design interface, requirements for the materials and parts, and requirements for the fabrication, inspection and testing, cleaning, packing, and installation, etc. are included.	Q6 3.2 Contents of Procurement Documents b) Technical requirements c) Requirements on testing and inspection 3.2.2 Technical Requirements (1) Technical requirements shall be stipulated by reference of the technical documents. Among the technical documents, rules and regulations, standards, criteria, specifications, drawings, requirements on process as well as requirements concerning approval and qualification of items, procedures, processes and components are available. (2) The purchaser may request personnel qualification in order to be conform to specific technical requirements (e.g. welding, testing, inspection, heat treatment, etc.). (3) Among the technical requirements, requirements on performance and functions as well as the requirements on design interface, material and parts, manufacturing, installation, testing and inspections, cleaning, storage, handling, packing and operations may be included. (4) Each item of the	Three standards have similar requirements. The requirements of NQA-1 and JEAG4101-1993 are summaries of "Technical Requirements", while JEAG4101-2000 describes more detailed provisions including samples.	No significant Difference; No impact on the MHI QA Manual or Procedure.

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COMPARISON TABLE IV Procurement Document Control (4/18)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ^{2}}	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
				requirements shall be determined as feasible, available for verification and enable the item and service concerned to achieve the intended purpose by their conformance to the		
				requirements. 3.2.3 Requirements about Testing and Inspection (1) When requesting inspection or testing of items, requirements shall		
				be clearly stipulated in the procurement documents. For instance, authorization testing such as verification test on seismic reliability or environment test may be		
				the case. (2) Even if any requirements based on testing are determined, suppliers shall not be exempted from the		
				responsibility of determining the test requirements for assuring quality of items. Purchaser may request the suppliers to perform additional		
				testing with the purpose to verify conformance of the item to the cited laws and regulations, standards, criteria and specifications based on the standpoint to confirm whether or not the		
				 (3) Judgment criteria of the applicable standards shall be stipulated in the specifications. 		
				 (4) Purchaser may request hold point or status indicator in a specific stage of manufacturing. (5) Details of the testing and inspection activities 		

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IV Procurement Document Control (5/18)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section: 17.5	ASME NQA-1-1994Edtion	2) JEAG4101-1993	2) JEAG4101-2000	Differences	Assessment of Difference for MHI Manual or Procedure
				shall be planned by suppliers. (6) When supplier verifies any item or process at the subcontractor's facility, the supplier shall describe the procedure of verification and the method of issuing shipment permission in the procurement documents. Guidance on the testing and inspection is shown in Q4 (Inspection and Testing) of the Reference Matters section of this Guide.		
	d. the supplier's documented QA program that is determined to meet the applicable requirements of Appendix B to 10 CFR 50 as appropriate to the circumstances of procurement (or the supplier may work under the applicant's approved QA program) 6. The program is applied to all phases of procurement. As necessary, this may require verification of activities of suppliers below the first tier. (NQA-1)	2.3 Quality Assurance Program Requirements Procurement documents shall require that the Supplier have a documented quality assurance program that implements portions or all of the requirements of this Part (Part I).	BASIC 5.2 Clarifying quality requirements (2) The following shall be included in the quality requirements to ensure adequate quality: (Explanation 5-11) c. Provision for the submission of quality assurance programmes REF. 5.2.2 Quality requirements (1) Concrete contents of quality requirements include the following: c. Provisions for submitting quality assurance programmes Quality assurance programmes issued by bidders are deemed satisfactory if they include the purchaser's requirements.	Q6 3.2.5 Quality Assurance Standards and Additional Requirements (1) Applicable quality assurance standards shall be clearly stipulated. (2) When purchaser refers to domestic or international quality assurance standards such as ISO, ASME and others, the purchaser shall perform evaluation to review whether or not additional requirements shall be stipulated to conform to this Guide. (3) In the cases where performance of internal quality audit is required and / or international standards are refered, optional articles shall be stated as appropriate in the procurement documents. 3.2.6 Documentation Requirements (1) The documents that purchaser request supplier to submit for review or approval purpose shall be clearly identified in the procurement documents. As the documents requiring approval, there are	Three standards have similar requirements. The requirements of NQA-1 and JEAG4101-1993 are summaries of "QA Program Requirements", while JEAG4101-2000 describes more detailed provisions including samples.	No significant Difference; No impact on the MHI QA Manual or Procedure.

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COMPARISON TABLE IV Procurement Document Control (6/18)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
				specifications, design literature, testing and inspection reports, procedures and manuals related to manufacturing, testing and maintenance, drawings and supplier's quality assurance plan among others. (2) When deciding personnel to approve documents, following matters shall be considered: a) Who (purchaser, supplier or its subcontractor) shall be responsible for the design? b) Capability and responsibility of supplier and its subcontractor under the multi-contractor supply system.		
		The extent of the program required shall depend upon the type and use of the item or service being procured. The procurement documents shall require the Supplier to incorporate appropriate quality assurance program requirements in subtler procurement documents.	REF. 5.2.2 Quality requirements (1) Concrete contents of quality requirements include the following: g. Provision for extending the application of procurement documents requirements to the contractor's suppliers. This clarifies extending the application of purchaser quality requirements to the subcontractors and the bounds of purchaser approval for subcontractors.	Q6 3.2 Contents of Procurement Documents The procurement documents shall include description on the following matters as appropriate and the responsibility related to each matter. [Explanation Q6-4] a) Scope of work b) Technical requirements c) Requirements on testing and inspection d) Access to supplier's facility e) Quality assurance standards and additional requirements f) Requirements on documents g) Requirements on quality records h) Submission timing of documents and quality records i) Non-conformance report j) Control of Subcontractor by Supolier	Three standards have similar requirements. The requirements of NQA-1 and JEAG4101-1993 are summaries of "QA Program Requirements", while JEAG4101-2000 describes more detailed provisions including samples.	No significant Difference; No impact on the MHI QA Manual or Procedure.

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COMPARISON TABLE IV Procurement Document Control (7/18)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
· · · · · · · · · · · · · · · · · · ·	Section 17.5	<u></u>		k) Items and Services	•	Tibleduie
				Supplied by Purchaser		
	ļ	J]]
				3.2.10 Control of		
				Subcontractor by Supplier		
				(1) Suppliers shall be		
		-		responsible for controlling		
				their subcontractors unless		
				otherwise determined by		
				purchaser. The clarification		
		,		of the evaluation items as		
				well as the verification and		
				evaluation of the		
		· · ·		performance of the		
				subcontractors shall belong		
				to a part of these suppliers'		
				responsibilities. (See		
				Chapter 6 for suppliers		
				vernication and evaluation		
				(2) Suppliers shall clearly		
				(2) Suppliers shall clearly		1
				subcontractors the method		
				of suppliers' control and the		
				scope of mutual		
				responsibilities. These shall		
			•	be determined based on		
				the product types, the		
				effect of the subcontracted		
				items to final product		
				quality, and, if applicable,		
		1 mm		the quality audit reports		
		-		and / or quality records for		
				the proved performance		
		1		and achievement of the		
				subcontractors.		
				(3) The supplier shall not		
				use the purchaser's)
				ovidence of subcentractors'		
				effective performance of		
				the quality control		
				(4) In closing contract with		
				subcontractors, supplier		
	1			shall obtain consent that		
	1			subcontractors accept the		
				access to their facility of		
				purchaser or supplier as a		1
				duty based on the contract.		
				Further, based on the		
				importance of the items		
		1		and services within the	· ·	
				scope of subcontractor		

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COMPARISON TABLE IV Procurement Document Control (8/18)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	1) ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
				contract, supplier shall request subcontractors to satisfy the purchaser's quality assurance requirements. (5) If supplier subcontract critical items and services to subcontractors, the purchaser shall clarify the purchaser's scope of approve concerning the supplier's subcontractors.		
	e. access to the supplier's plant facilities and records for inspection or audit by the purchaser, his/her designated representative, and/or other parties authorized by the purchaser	2.4 Right of Access At each tier of a procurement, the procurement documents shall provide for access to the Supplier's plant facilities and records for inspection or audit by the Purchaser, his designated representative, and/or other parties authorized by the Purchaser.	BASIC 5.2 Clarifying quality requirements (2) The following shall be included in the quality requirements to ensure adequate quality: (Explanation 5-11) d. Provision for access to the supplier's place of business for the purpose of inspection, testing, audit, etc. REF. 5.2.2 Quality requirements include the following: d. Provision for access to the bidder's place of business to inspect and test, and audit, etc. The necessity for access to the supplier's place of business is to be clarified according to the scope of products or services to which inspection and testing, and audit, etc. are applied and the importance and content complexity, etc. of the items or services.	Q6 3.2 Contents of Procurement Documents d) Access to supplier's facility 3.2.4 Access to Supplier's Facility or its subcontractor's facility to perform inspection, testing, audit and surveillance shall be clearly described in the procurement documents, where details of the access shall be stipulated depending on the scope, important and complexity of the contents. These activities may be either performed by purchaser or commissioned to another organization that works as agent. Supplier's application of this requirement to the subcontractor shall be detailed in 3.2.10.	Three standards have similar requirements.	No significant Difference; No impact on the MHI QA Manual or Procedure.
	f. identification of the documentation and date of submission required to be	2.5 Documentation Requirements The procurement	BASIC 5.2 Clarifying quality requirements	Q6 3.2 Contents of Procurement Documents	Three standards have similar requirements.	No significant Difference; No impact on the MHI QA Manual or Procedure.
	submitted for information, review, or approval by the	documents at all tiers shall identify the documentation	(2) The following shall be included in the quality	t) Requirements on documents	and JEAG4101-1993 are	

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COMPARISON TABLE IV Procurement Document Control (9/18)

	Standard Review Plan	1)	2)	2)	2	Assessment of Difference
10 CFR 50 Appendix B	NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993	JEAG4101-2000	Differences	for MHI Manual or Procedure
	purchaser	required to be submitted for information, review, or approval by the Purchaser. The time of submittal shall also be established: When the Purchaser requires the Supplier to maintain specific quality assurance records, the retention times and disposition requirements shall be prescribed.	requirements to ensure adequate quality: (Explanation 5-11) e. Provision for the submission of documents and submission and storage of records REF. 5.2.2 Quality requirements of quality requirements include the following: e. Provision for the submission of documents and storage of records, such as specifications, procedures, drawings, and quality records These are submitted for study or purchaser approval, and they detail submission steps, schedule of documents, and the way that storage and disposal of quality records, etc. is done.	 g) Requirements on quality records 3.2.6 Documentation Requirements (1) The documents that purchaser request supplier to submit for review or approval purpose shall be clearly identified in the procurement documents. As the documents requiring approval, there are specifications, design literature, testing and inspection reports, procedures and manuals related to manufacturing, testing and maintenance, drawings and supplier's quality assurance plan among others. (2) When deciding personnel to approve documents, following matters shall be considered: a) Who (purchaser, supplier or its subcontractor) shall be responsibility of supplier and its subcontractor under the multi-contractor supply system. 3.2.7 Quality Records Requirements (1) Requirements for quality records (including material samples) to suppliers shall be clearly identified. In this case a list of quality records including all the requirements for quality records submitted by suppliers. (2) Suppliers shall clearly identified in the submitted by suppliers. (2) Suppliers shall clearly identified in the submitted by suppliers. 	summaries of "Documentation Requirements", while JEAG4101-2000 describes more detailed provisions including samples.	
				by their subcontractors		

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10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
				including the methods of confirmation, storage, submission and disposition. The quality records that purchaser requests them to submit with the purpose to assure the conformance of their items and services to the requirements are also included in this scope. (3) Concerning the quality records, retention times and responsibility of maintenance by suppliers shall be determined. Detailed guidance for the requirements on quality records is shown in Q3 (Document control and records) of the Reference Matters section of this Guide.		
				 3.2.8 Submission Timing of Document and Quality Records (1) Method and timing of submitting necessary documents and quality records shall be clearly indicted to suppliers. (2) In determining the timing of submission, hold points, key processes as well as period necessary for document submission and return shall be taken into consideration. 		
	g. purchaser's requirements for reporting and approving disposition of nonconformances	2.6 Nonconformances The procurement documents shall include Purchaser's requirements for reporting and approving disposition of nonconformances.	BASIC 5.2 Clarifying quality requirements (2) The following shall be included in the quality requirements to ensure adequate quality: (Explanation 5-11) f. Provision for the treatment of non-conforming items REF. 5.2.2 Quality requirements	Q6 3.2 Contents of Procurement Documents i) Non-conformance report 3.2.9 Non-conformance Report (1) Purchaser shall state the request for reporting deviation from procurement requirements (scope of report and disposition, etc). (2) Supplier shall clearly identify the	Three standards have similar requirements.	No significant Difference; No impact on the MHI QA Manual or Procedure.

COMPARISON TABLE

IV Procurement Document Control (10/18)

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COMPARISON TABLE IV Procurement Document Control (11/18)

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10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993	JEAG4101-2000	Differences	Assessment of Difference for MHI Manual or Procedure
			(1) Concrete contents of quality requirements include the following: f. Provision for the treatment of non-conforming items This establishes the bounds of reports to purchaser and the way that nonconforming items or services are treated.	non-conformance control process. (3) The division responsible for addressing non-conformance to the specified procurement requirements shall be clearly identified.		
		2.7 Spare and Replacement Parts The procurement documents shall require the identification of appropriate spare and replacement parts or assemblies and the appropriate delineation of the technical and quality assurance related data required for ordering these parts or assemblies.	-	Q6 9.1 Procurement of Spare Parts (1) Spare parts for plant may be obtained at the initial product procurement stage. (2) While the spare parts shall be conformant to the same quality assurance requirements as those for the original product, they need to satisfy additional requirements to ensure protection during the long storage period. (3) Following are the elements to be considered when deciding the number of spare parts: a) Number of products susceptible to failure and safety-related importance b) Special characteristics in manufacturing process that would make future manufacturing difficult c) Concerns about current spare parts supply d) Expected delivery time and storage life e) Delay in delivery caused by import of spare parts from overseas f) Suspension of distribution from approved manufactures	JEAG4101-1993 doesn't explicitly address the requirements about procurement of spare and replacement parts. JEAG4101-2000 pays attention to procure spare and replacement parts appropriately, but the approach is different from the one of NQA-1.	Significant Difference; Some impact on the MHI QA Manual or Procedure. This requirement is not applicable to US-APWR Design Certification stage. MHI will add this requirement on the Procurement Control Procedure for applicable stage with the progress of the project, if necessary.
	5. A review of the	3 PROCUREMENT	BASIC	Q6	Three standards have	No significant Difference;
	procurement documents and changes thereto are	DOCUMENT REVIEW A review of the	3 Document Control 3.1 General	3.3.1 Review and Approval of Procurement Documents	similar requirements.	No impact on the MHI QA Manual or Procedure.

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COMPARISON TABLE IV Procurement Document Control (12/18)

····	Standard Poview Plan				·····	Assessment of Difference
10 CFR 50 Appendix B	NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	for MHI Manual or Procedure
	documents transmitted to the prospective supplier(s) include appropriate provisions to ensure that items or services will meet the specified requirements. (NQA-1)	and changes thereto shall be made to assure that documents transmitted to the prospective Supplier(s) include appropriate provisions to assure that items or services will meet the specified requirements. Reviews shall be performed and documented to provide objective evidence of satisfactory accomplishment of such review prior to contract award:	control measures for preparation, review and approval, issuance and distribution, and change of documents essential to quality assurance activities shall be established to ensure that the appropriate and correct documents are employed for quality assurance activities. 3.2 Document preparation, review, and approval Control measures for preparation, review, and approval of documents shall be established. In determining the control measures, the individuals or organizations responsible for preparation, review, and approval of each document concerned shall be identified. 3.3 Document issuance and distribution Control measures for the issuance and distribution of documents shall be established. (Explanation 3-1)	(2) Procurement documents shall receive review and approval before issuing so that all the requirements should be included and those requirements should securely conform to specific requirement, purchaser's procedures and regulatory requirements.	Procurent Document Review are described in the section "Document Control" in JEAG4101-1993.	
			 3.4 Document change control Document change control Document change control measures shall be established. In determining these measures, the following shall be considered: a. In principle, changed documents are to be reviewed and approved by the same individuals or organizations who performed the original review and approval. b. The review and approval. c. The review and approval of changed documents are to be implemented by the use of necessary 			

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COMPARISON TABLE IV Procurement Document Control (13/18)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993	2) JEAG4101-2000	Differences	Assessment of Difference for MHI Manual or Procedure
			information and an understanding of original requirements and their background. c. Changed or revised documents are to be			
			identified. d. Enough attention is to be paid to prevent the use of obsolete documents, and information concerning the			
			changed document is to be promptly relayed to affected individuals and organizations. EX.3-1			
		· · · · · · · · · · · · · · · · · · ·	Documents related to each stage, from design to operation and maintenance, are divided into those issued by the organization that performs			
			(e.g. procedures and instructions for fabrication/installation),, and those issued by others			
			which do not perform the activities directly (e.g. design documents and procurement documents for fabrication/installation).			
		· · · · · ·	Basic Matters 3.3 describes those documents issued and distributed the by the organization which performs activities, and			
			Supplementary and Recommended Matters 3.3 describes both those documents issued and distributed by the			
-		1	performs activities and those issued by other organizations and received by the former.			
			SUPPLE 5.2.1 Specifying in procurement documents (1) It is desirable to specify the quality requirements of			

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COMPARISON TABLE IV Procurement Document Control (14/18)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	1) ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
			items and services in the procurement documents, and the purchaser and supplier should agree on them beforehand. (2) As for changes in quality requirements, it is desirable to evaluate and examine the adequacy of the supplementary or corrective requirements prior to contract changes and incorporate the results discussed between purchaser and supplier in the procurement documents,			
	3. Changes made as a result of the bid evaluations or pre-contract negotiations are incorporated into the procurement documents. The review of such changes and their effects are completed prior to contract award.	Changes made as a result of the bid evaluations or precontract negotiations shall be incorporated into the procurement documents	SUPPLE 5.2.1 (2) (See above)	Q6 3.3.2 Change of Procurement Documents (4) It is desired that the items that undergo any change should be included in the procurement documents based on the consultation between purchaser and supplier. Guidance on the control of document change is shown in Q3 (Document control and records) of the Reference Matters section of this Guide.	Three standards have similar requirements.	No significant Difference; No impact on the MHI QA Manual or Procedure.
		The review of such changes and their effects shall be completed prior to contract award. This review shall include the following considerations: (a) appropriate requirements specified in Section 2 of this Supplement; (b) determination of any additional or modified design criteria; (c) analysis of exceptions or changes requested or specified by the Supplier and determination of the	SUPPLE 5.2.1(1) 5.2.1 (2) (See above)	Q6 6.1 Coordination between Purchaser and Supplier Purchaser and Supplier shall confirm, evaluate and verify how the supplier fulfills the procurement requirements. The task may be conducted by either the purchaser, an agent specified by the other issuer or the other agency authorized by the purchaser. Following activities are the examples of the above-mentioned activities:	Three standards have similar requirements. The requirements of NQA-1 and JEAG4101-1993 are summaries of "the review of the change of requirements and their effect", while JEAG4101-2000 describes more detailed provisions including samples.	No significant Difference; No impact on the MHI QA Manual or Procedure.

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COMPARISON TABLE IV Procurement Document Control (15/18)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	2) JEAG4101-1993	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion effects such changes may have on the intent of the procurement documents or quality of the item or service to be furnished.	2) JEAG4101-1993	 JEAG4101-2000 a) Purchaser and suppler shall mutually confirm the intention of specifications and procurement documents, and, if there is any difference or incompleteness between contract / order requirements and estimated specifications, or, there if there is any unclear or contradictory requirement, all doubts and queries shall be settled with the responsible party who requests the concerned requirement. b) The purchaser shall request supplier to clearly indicate the plan concerning the methods, processes and procedures to be used to satisfy the procurement requirement shall be made between the purchaser and the supplier regarding the reflection of the experiences. d) Documents prepared and processed within the framework of activities to satisfy the procurement requirement shall be reviewed. e) Change of contents shall be clarified and processed and processed and processed. f) Method of forwarding and accepting documents ball be reviewed. g) The records of confirmation of contract contents shall be maintained. 	Differences	Assessment of Difference' for MHI Manual or Procedure
				I he above activities can be utilized also in future as standards for selecting suppliers.		

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10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	1) ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	1) ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	2) JEAG4101-2000 6.2 Communication before and after Contract (1) Purchaser shall make adjustment before and after the complexity and scope of items and services. To establish mutual understanding between purchaser and supplier concerning the following matters within the framework of these activities, meeting or other communication forms may be used. It is recommended to make documents for the adjustment results under the mutual agreement of the purchaser and the supplier. a) Procurement requirements b) Purchaser's intention to monitor and evaluate supplier's performance. c) Plan, manufacturing technique, testing and inspections that supplier employs to conform to the requirements of procurement documents. (2) Purchaser shall clarify the notification timing of the necessary information as early as possible the procurement process. (3) The level and necessity of communication before and after the contract shall be determined depending on the special characteristics and complexity of items, procurement frequency with the same supplier as well as the supply	Differences	Assessment of Difference for MHI Manual or Procedure
	(2.000)		PASIC	the past.	Three standards have	Significant Difference:
	((3.continue)	Reviews required by this	BASIC		Three standards have	Significant Difference;

IV Procurement Document Control (16/18)

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IV Procurement Document Control (17/18)

, 10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
	Reviews are performed by personnel who have access to pertinent information and who have an adequate understanding of the requirements and intent of the procurement documents. (NQA-1)	Section shall be performed by personnel who have access to pertinent information and who have an adequate understanding of the requirements and intent of the procurement documents.	3.2 Document preparation, review, and approval Control measures for preparation, review, and approval of documents shall be established. In determining the control measures, the individuals or organizations responsible for preparation, review, and approval of each document concerned shall be identified.	3.3.1 Review and Approval of Procurement Documents (1) Responsibility of reviewing and approving procurement documents in the purchaser's organization shall be clearly identified.	similar requirements, though JEAGs don't have concrete provisions for reviewer. The responsibility of reviewer are the same.	No impact on the MHI QA Manual or Procedure, because it has been specified that cognizant personnel shall review the procurement document in the MHI QA Manual.
	4. Procurement document changes are subject to the same degree of control as utilized in the preparation of the original documents. (NCA-1)	4 PROCUREMENT DOCUMENT CHANGES Procurement document changes shall be subject to the same degree of control as utilized in the preparation of the original documents.	BASIC 3.4 Document change control Document change control measures shall be established. In determining these measures, the following shall be considered: a. In principle, changed documents are to be reviewed and approved by the same individuals or organizations who performed the original review and approval. b. The review and approval. b. The review and approval. changed documents are to be implemented by the use of necessary information and an understanding of original requirements and their background. c. Changed or revised documents are to be identified. d. Enough attention is to be paid to prevent the use of obsolete documents, and information concerning the changed document is to be promptly relayed to affected individuals and organizations. EX.3-1 Documents related to each	Q6 3.3.2 Change of Procurement Documents (1) Concerning the change of procurement document, review and approval shall be conducted before issuing any document effecting the change so as to ensure that the change has no negative impact on the other structures, systems and components of the plant. (2) The supplier shall notify the approved change to the purchaser. (3) The change of procurement document shall be subject to the same degree of control as utilized in the preparation of the original documents. (4) It is desired that the items that undergo any change should be included in the procurement documents based on the consultation between purchaser and supplier. Guidance on the control of document change is shown in Q3 (Document control and records) of the Reference Matters section of this Guide.	Three standards have similar requirements. The requirements of NQA-1 are summaries of "Procurement Document Change", while JEAG4101-2000 describes more detailed provisions including samples. The requirements of Document Control are described in JEAG4101-1993 column, in which the procurement document is referred.	No significant Difference; No impact on the MHI QA Manual or Procedure.
			stage, from design to operation and			

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COMPARISON TABLE IV Procurement Document Control (18/18)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion,	JEAG4101-1993 ²⁾	JEAG4101-2000	Differences	Assessment of Difference for MHI Manual or Procedure
			maintenance, are divided into those issued by the organization that performs activities at each stage (e.g. procedures and instructions for fabrication/installation),, and those issued by others which do not perform the activities directly (e.g. design documents and procurement documents for fabrication/installation). Basic Matters 3.3 describes those documents issued and distributed the by the organization which performs activities, and Supplementary and Recommended Matters 3.3 describes both those documents issued and distributed by the organization which performs activities and those issued by other organizations and received by the former.			
	1. Applicable technical, regulatory, administrative, and reporting requirements (such as specifications, codes, standards, tests, inspections, special processes, and 10 CFR Part 21, "Reporting of Defects and Noncompliance," are invoked for procurement of items and services. (Approved via SE (Accession No. ML050700416).)		BASIC 5.2 Clarifying quality requirements (2) The following shall be included in the quality requirements to ensure adequate quality: (Explanation 5-11) b. Technical requirements such as design, fabrication, installation, inspection, testing, applicable regulations, etc	Q6 3.2 Contents of Procurement Documents b) Technical requirements c) Requirements on testing and inspection 3.2.2 Technical Requirements (1) Technical requirements shall be stipulated by reference of the technical documents. Among the technical documents, rules and regulations, standards, criteria, specifications, drawings, requirements on process as well as requirements concerning approval and qualification of items, procedures, processes and components are available.	Though 10CFR Part21 is not specified in JEAGs, other requirements in three standards are same.	Significant Difference; No impact on the MHI QA Manual or Procedure, because 10CFR Part21 has been invokes in MHI "Procurement Control Procedure".

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COMPARISON TABLE V Instructions, Procedures, and Drawings (1/1)

' 10'CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
V. Instructions, Procedures and Drawings Activities affecting quality shall be prescribed by		Basic Requirement 5 Instructions, Procedures and Drawings				
documented instructions, procedures, or drawings, of a type appropriate to the circumstances and shall be accomplished in accordance with these instructions, procedures, or drawings. Instructions, procedures, or drawings shall include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished.	 Activities affecting quality are prescribed by documented instructions, procedures, or drawings and are accomplished in accordance with these instructions, procedures, or drawings. (NQA-1) Instructions, procedures, or drawings include appropriate quantitative or qualitative acceptance criteria for determining that activities have been satisfactorily accomplished. (NQA-1) 	Activities affecting quality shall be prescribed by and performed in accordance with documented instructions, procedures, or drawings of a type appropriate to the circumstances. These documents shall include or reference appropriate quantitative or qualitative acceptance criteria for determining that prescribed activities have been satisfactorily accomplished.	REF 1.2.1 1.2.1 Development and documentation (2) Quality assurance programs consist of an adequate combination of two fundamental activities, namely control-oriented and work-oriented activities (4) The documents for work-oriented activities (documents for works) include the work plan documents, work procedures, work instructions, and drawings. When preparing these documents, the matters to be considered are as follows: b. The documents, such as work procedures, work instructions, and drawings are to be described to provide concrete information. This will make appropriate executions of activities possible according to the control procedures for quality assurance and the work plan document. The documents are to be concise and clear.	Q1 4.2.3 Preparation of Work Plan and Instructions, etc Work plans, process sheets, instructions, technical instructions and drawings are established to determine specific activities necessary for task performance. These shall be established to be consistent to the management process described in the Quality Assurance Plan. For establishing work plan, instructions, sufficient considerations shall be given to make plans and schedules that instruct task performers clearly about how they can perform the task appropriately and how they can streamline their tasks.	Three standards have similar requirements.	No significant Difference; No impact on the MHI QA Manual or Procedure.

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COMPARISON TABLE VI Document Control (1/6)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	1) ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
VI. Document Control Measures shall be established to control the issuance of documents, such as instructions, procedures, and drawings, including changes thereto, which prescribe all activities affecting quality. These measures shall assure that documents, including changes, are reviewed for adequacy and approved for release by authorized personnel and are distributed to and used at the location where the prescribed activity is performed. Changes to documents shall be reviewed and approved by the same organizations that performed the original review and approval unless the applicant designates another responsible organization.		Basic Requirement 6 Document Control The preparation, issue, and, change of documents that specify quality requirements or prescribe activities affecting quality shall be controlled to assure that correct documents are being employed. Such documents, including changes thereto, shall be reviewed for adequacy and approved for release by authorized personnel.	 BASIC 3.1 General Control measures for preparation, review and approval, issuance and distribution, and change of documents essential to quality assurance activities shall be established to ensure that the appropriate and correct documents are employed for quality assurance activities. 3.2 Document preparation, review, and approval Control measures for preparation, review, and approval of documents shall be established. In determining the control measures, the individuals or organizations responsible for preparation, review, and approval of each document concerned shall be identified. 	Q3 2.1 General (1) In the nulegible power plant, document control system should be established to perform the document preparation, review, approval, issuance, distribution (including access), revision and retention that are necessary and indispensable to control, implementation and verification of works and, if necessary, adequacy confirmation should be performed. [Explanation Q3-1] Further, in case of document control using computer system, the same manner should be applied. (2) In document control system, organization or personal responsibilities regarding each stage of site investigation, design, construction, commissioning, operation, and decommissioning should be provided and documented.	Three standards have similar requirements.	No significant Difference; No impact on the MHI QA Manual or Procedure.

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COMPARISON TABLE VI Document Control (2/6)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
		Supplement 6S-1 Supplementary Requirements for Document Control 1 GENERAL This Supplement provides amplified requirements for a document control system. It supplements the requirements of Basic Requirement 6 of this Part (Part I) and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Part (Part I). The documents which shall be controlled in accordance with this Supplement are only those documents which specify quality requirements or prescribe activities affecting quality such as instructions, procedures, and drawings. The term document control used throughout this Supplement is defined as the act of assuring that documents are reviewed for adequacy, approved for release by authorized personnel, and distributed to and used at the location where the prescribed activity is performed.			This NQA-1-1994 clause is a paragraph introducing the additional requirements in the Supplementary Requirements. It specifies that the Supplementary Requirements apply when and to the extent specified by the organization invoking Part 1 of NQA-1-1994.	See below
	 A program is required to be established to control the development, review, approval, issue, use, and revision of documents. (NQA-1) Controlled copies of instructions and procedural documents are distributed to and used by the person 	2 DOCUMENT PREPARATION, REVIEW, APPROVAL, AND ISSUANCE The control system shall be documented and shall provide for (a) through (c) below: (a) identification of documents to be controlled and their specified distribution;	BASIC 3.2 Document preparation, review, and approval Control measures for preparation, review, and approval of documents shall be established. In determining the control measures, the individuals or organizations responsible for preparation, review, and approval of each document concerned	Q3 3.1 Preparation of Documents (1) Management shall make legible the responsible organization or person for document preparation/control. (2) Documents, at preparation stage, should be controlled with the indication in order to legiblely discriminate from previously	Three standards have similar requirements. The requirements of NQA-1 are summaries of "DOCUMENT PREPARATION, REVIEW, APPROVAL, AND ISSUANCE", while. JEAG4101-2000 describes more detailed provisions including samples.	No significant Difference; No impact on the MHI QA Manual or Procedure.

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COMPARISON TABLE VI Document Control (3/6)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800	ASME NQA-1-1994Edtion	JEAG4101-1993 ^{2}}	2) JEAG4101-2000	Differences	Assessment of Difference for MHI Manual or
	Section 17.5				-	Procedure
	performing the activity.	(b) identification of	shall be identified.	issued documents.		
	(NQA-1)	assignment of		(3) Appropriate identification		
		responsibility	3.3 Document issuance	system should be		
	6. The control system is	for preparing, reviewing,	and distribution	established to discriminate		
	documented as follows:	approving, and issuing	Control measures for the	each document individually		
	(NQA-1)	documents;	issuance and distribution of	(4) For documents relating		
	a. the identification of	(c) review of documents for	documents shall be	nardware and software, the		
	controlled documents	adequacy completeness,	established. (Explanation	correspondence with		
	b. the specified distribution	and correctness prior to	3-1)	applicable items should be		
	of controlled documents for	approval and issuance.	0.4 Deserves at all and	established, if necessary.		
	use at the appropriate		3.4 Document change	(5) At preparation of		
			Desument shanne control	appropriate		
	c. the individuals		monouron shall be	control method should be		
	responsible for preparation,		astablished in determining	applied evaluating the		
	distribution of controlled	· · · · ·	these measures the	araded approach system #		
	documento are identified		following shall be	pecessan		
	d controlled documents	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	considered:	necessaiy.		
	a. controlled documents		d Enough attention is to be	2.2 Peview of Document		
	are reviewed for adequacy,		noid to provent the use of	and Confirmation of		
	completeness, and	the second state of the second second	obsolete documente and	Appropriateness		
	distribution		information concerning the	(1) When the document is		
	a a method to ensure the	1	changed document is to be	issued review should be		
	correct documents are		promptly relayed to	performed before issuance		
	being used		affected individuals and	In review the document		
	being used	state of the second	organizations	should be examined		
	9 Procedures for control of		orgenniser on or	contents closely to be		· ·
	the documents and			necessary and sufficient.		
	changes thereto are			referring requirements and		
	required to be established			recommendations		
	to preclude the possibility	15 A		considering safety		
	or use of outdated or			importance.		
	inappropriate documents.			(3) The organization or		
	Document control		1	person who perform the		
	measures provide for the	· · · ·		review shall be available the		
	following: (ANSI N18.7)	l		basic information for the		
	a. identifying the proper			effective review.		
	document to be used in			In addition, the sufficient		
	performing the activity			consideration for safety		
	b. coordinating and	· · ·		should be confirmed.		
	controlling interface					[[
	documents	· · · · ·		3.3 Approval of Documents		
	c. ascertaining that proper			Management shall make		
	documents are being used	·	1	legible responsible person		
			1	for approval of documents.		
	5. The distribution of new		1	Documents should be		
	and revised controlled	ľ		approved and issued, after		
	documents is in	:		review of the documents		
	accordance with			based on described above		
	established source			methou.		
	documents. Superseded			2.4 leavenee and		
	Luocuments are controlled.	1	1	J.H ISSUALICE ALL		

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COMPARISON TABLE VI Document Control (4/6)

10'CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	1) ASME NQA-1-1994Edtion	JEAG4101-1993	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
	(ANSI N18.7)			Distribution of Documents (1) The document issuance and distribution system should be established, in which the latest distribution list should be used. At the use of documents, personnel shall confirm if it is approved and use. And, in this system, change of documents should be certainly transferred to all relating personnel and organizations.		
	3. Revisions of controlled documents are reviewed for adequacy and approved for release by the same organization that originally reviewed and approved the documents or by a designated organization that is qualified and knowledgeable. The reviewing organization has access to pertinent background data or information necessary to base their approval. (NQA-1)	3 DOCUMENT CHANGES 3.1 Major Changes Changes to documents, other than those defined as minor changes in para. 3.2 below, are considered as major changes and shall be reviewed and approved by the same organizations that performed the original review and approval unless other organizations are specifically designated. The reviewing organization shall have access to pertinent background data or information upon which to base their approval.	BASIC 3.4 Document change control Document change control measures shall be established. In determining these measures, the following shall be considered: a. In principle, changed documents are to be reviewed and approved by the same individuals or organizations who performed the original review and approval. b. The review and approval. b. The review and approval. of changed documents are to be implemented by the use of necessary information and an understanding of original requirements and their background. c. Changed or revised documents are to be identified. d. Enough attention is to be paid to prevent the use of obsolete documents, and information concerning the changed document is to be promptly relayed to affected individuals and organizations.	Q3 3.6 Modification Control of Documents (1) When changes are needed in documents, review and approval same level as the original document should be performed. (2) When some document changes would affect several other documents, affected documents also should be revised correspondingly. (3) In case of change, appropriate measures should be used to clarify the changes in the document such as sidelining on revised portion or numbering for revised number, as well as reason for change and background information should be described.	Three standards have similar requirements.	No significant Difference; No impact on the MHI QA Manual or Procedure.

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COMPARISON TABLE VI Document Control (5/6)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
	7. Minor changes to documents, such as inconsequential editorial corrections, are not required to receive the same review and approval as the original documents. To avoid a possible omission of a required review, the type of minor changes that do not require such a review and approval and the persons who can authorize such a decision are clearly delineated. (NQA-1)	3.2 Minor Changes Minor changes to documents, such as inconsequential editorial corrections, shall not require that the revised documents receive the same review and approval as the original documents. To avoid a possible omission of a required review, the type of minor changes that do not require such a review and approval and the persons who can authorize such a decision shall be clearly delineated.			JEAG4101 has no requirements for control of minor changes. All changes are subject to the same control.	Significant Difference; No impact on the MHI QA Manual or Procedure, because MHI has established and applied Minor Changes procedure.
	2. The scope of the document control program is defined. Examples of controlled documents include design drawings, as-built drawings, engineering calculations, design specifications, purchase orders and related documents, vendor-supplied documents, audit and surveillance procedures, operating procedures, emergency operating procedures, technical specifications, nonconformance reports, corrective action reports, work instructions and procedures, calibration procedures, quality verification procedures, inspection and test reports, and all such documents made electronically available. (ANSI N18.7 and Appendix B/RIS 2000-18)	2 DOCUMENT PREPARATION, REVIEW, APPROVAL, AND ISSUANCE The control system shall be documented and shall provide for (a) through (c) below: (a) Identification of documents to be controlled and their specified distribution;	BASIC 3.2 Document preparation, review, and approval Control measures for preparation, review, and approval of documents shall be established. In determining the control measures, the individuals or organizations responsible for preparation, review, and approval of each document concerned shall be identified.	Q3 3.1 Preparation of Documents (2) Documents, at preparation stage, should be controlled with the indication in order to legiblely discriminate from previously issued documents. (3) Appropriate identification system should be established to discriminate each document individually.	Three standards have similar requirements.	No significant Difference; No impact on the MHI QA Manual or Procedure.

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COMPARISON TABLE VI Document Control (6/6)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
	8. Procedures used during					N/A
	reviewed by an individual					
	knowledgeable in the area					
	affected by the procedure					
	every 2 years to determine					
	if changes are necessary or					
	desirable. (ANSI N18.7)					
	be reviewed every 2 years					
	provided that all of the					
	following are met:					
	Approved via SE					
	ML003675798).)	the state of the				
	a. Applicable procedures					
	modification to a system					
	b. Applicable procedures					
	are reviewed following an					
	an accident, such as	and the second				
	operator error, or					
	equipment malfunction.					
	c. Procedures are updated					
	discrepancies are found.					
	d. Procedures are reviewed					
	prior to use if not used in the previous 2 years					
	e. A QA program audit of					
	procedures is conducted					
L	every 2 years.					

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COMPARISON TABLE VII Control of Purchased Items and Services (1/27)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993	JEAG4101-2000	Differences	Assessment of Difference for MHI Manual or Procedure
VII. Control of Purchased Material, Equipment, and Services Measures shall be established to assure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents. These measures shall include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products upon delivery. Documentary evidence that material and equipment conform to the procurement requirements shall be available at the nuclear powerplant or fuel reprocessing plant site prior to installation or use of such material and equipment. This documentary evidence shall be sufficient to identify the specific requirements, such as codes, standards, or specifications, met by the purchased material and edipment. The effectiveness of the control of quality by contractors and subcontractors shall be assessed by the applicant or designee at intervals consistent with the	1. A program is required to be established that ensures that purchased items and services conform to specified requirements. (NQA-1) 4. The program includes provisions (e.g., source verification, receipt inspection, preinstallation and postinstallation tests, and certificates of conformance) for accepting purchased items and services. (NQA-1)	Basic Requirement 7 Control of Purchased Items and Services The procurement of items and services shall be controlled to assure conformance with specified requirements. Such control shall provide for the following as appropriate: source evaluation and selection, evaluation of objective evidence of quality furnished by the Supplier, source inspection, audit, and examination of items or services upon delivery or completion.	BASIC 5.1 General To procure items and services of adequate quality, methods for specifying quality requirements, evaluation of bidders, and control measures of procured items and services shall be established.	BASIC 3.3 Procurement of Items and Services 3.3.1 Procurement Control Procured items and services shall meet established requirements and perform as specified. 3.3.2 Identification of Quality Requirements Requirements necessary to ensure the quality of items and services shall be developed and specified in the procurement documents. 3.3.3 Evaluation of Suppliers Suppliers shall be evaluated and selected on the basis of specified criteria. 3.3.4 Control of Purchased Items and Services (1) Evidence that purchased items and services meet procurement requirements shall be available before they are used. (2) Requirements for reporting deviations from procurement documents.	Three standards have similar requirements.	No significant difference; No impact on the MHI QA manual or procedure.
or designee at intervals consistent with the importance, complexity,			:			

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COMPARISON TABLE VII Control of Purchased Items and Services (2/27)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800	1) ASME NQA-1-1994Edtion	2) JEAG4101-1993	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or
and quantity of the product	Section 17.5				·······	Trocedure
		Supplement 7S-1 Supplementary Requirements for Control of Purchased Items and Services				
		1 GENERAL This Supplement provides amplified requirements for control of purchased items and services. It supplements the requirements of Basic Requirement 7 of this Part (Part I) and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Part (Part I). This Supplement includes requirements for source selection, bid evaluation. Supplier performance evaluation, and verification of conformance.	_	_	This NQA-1-1994 clause is a paragraph introducing the additional requirements in the Supplementary Requirements. It specifies that the Supplementary Requirements apply when and to the extent specified by the organization invoking Part I of NQA-1-1994.	See below
	8. Procurement activities are documented to ensure a systematic approach to the procurement process, identification of procurement methods, and organizational responsibilities.	2 PROCUREMENT PLANNING Procurement activities shall be planned and documented to assure a systematic approach to the procurement planning shall result in the documented identification of procurement methods and organizational responsibilities Planning shall determine the following: (a) what is to be accomplished; (b) who is to accomplish it; (c) how it is to be accomplished, (d) when it is to be accomplished. Planning shall be	BASIC 5.2 Clarifying quality requirements (1) Quality requirements shall be specified in the procurement documents. (Explanation 5-3) (2) The following shall be included in the quality requirements to ensure adequate quality: (Explanation 5-4) a. Scope of work implemented by bidders b. Technical requirements such as design, fabrication, installation, inspection, testing, applicable regulations, etc. c. Provision for the submission of quality assurance programmes	Q6 2.2 Establishment of Procurement System The plant owner shall establish a procurement system that conform to the requirements of this Guide within the framework of Quality Assurance Programme. In the procurement system, following matters shall be implemented by staffs who perform procurement activities: (1) The information forwarded to suppliers shall be clear, concise and not ambiguous, including technical and quality assurance-related requirements with appropriate description of	Three standards have similar requirements. The specific clause, "Procurement Planning" described in NQA-1, is not found in both JEAG4101-1993 and JEAG4101-2000, but "Procurement Planning" is included in section "Quality Assurance Program" and managed as planning of work.	No significant difference; No impact on the MHI QA manual or procedure.

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COMPARISON TABLE VII Control of Purchased Items and Services (3/27)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
		accomplished as early as practicable, and no later than at the start of those procurement activities which are required to be controlled, to assure interface compatibility and a uniform approach to the procurement process.	d. Provision for access to the supplier's place of business for the purpose of inspection, testing, audit, etc. e. Provision for the submission of documents and submission and storage of records f. Provision for the treatment of non—conforming items g. Provision for extending the application of requirements in the procurement documents to the operatoric augultant	matters requested for items and services. (2) Supplier shall be selected on the basis of the ability to supply items continuously and services in a specified manner, including the continuous supply of spare parts. (3) The staffs shall confirm that suppliers continuously perform activities that satisfy requirements of purchaser. (4) The staffs shall confirm that items and services		
			the contractor's suppliers 5.3 Evaluation of bidders In selecting suppliers, the purchaser shall evaluate whether or not the bidders are able to supply items or services conforming to the procurements of the procurement documents. The following shall be included as appropriate in bidder evaluations: a. Technical ability and quality assurance system	conform to the requirements of procurement documents and perform securely perform expected performance. (5) The documents and quality records that indicate conformance of items and processes to requested specifications shall be available at the nuclear facility before they are erected or used. The purchaser shall make this		
			 b. Past supply records of items or services c. Past use records of items or services d. Samples of items 5.4 Control of procured items and services (1) Control measures which confirm that purchased items and services conform 	point clear in the procurement documents. [Explanation Q6-2] (6) Responsible organization to facilitate communication with suppliers shall be established concerning the contract-related matters. (7) To ensure the key date such as the date of		
			to the requirements of the procurement documents shall be established. (2) Quality records which certify that the purchased items conform to the requirements of the procurement documents shall be made available at factory or at site prior to	delivery, interfaces between plant owner and supplier or suppliers and subcontractor as well as the interface among suppliers shall be clearly identified depending on the necessity. The examples of		

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10 CFR 50 Appendix B	ndard Review Plan NUREG -0800 ASME NQA-1-1 Section 17.5	994Edtion JEAG41	01-1993 ⁻²⁾ JEAG4101-20	2) 000 Differences	Assessment of Difference for MHI Manual or Procedure
		their use. (Ex SUPPLE 5.2.1 Specify procurement (1) It is desira the quality red items and ser procurement 4 and the purch supplier shou them beforeh (2) As for cha quality require desirable to e examine the a the supplement corrective red prior to contra and incorpora discussed bei purchaser am- the procurem documents,	planation 5-5) procurement proce purchasing items a services is shown i Appendix. documents BASIC ble to specify luirements of occuments, aser and d agree on and. BASIC 2.1.2 Implementatii Quality Assurance 2.1.2 Implementatii Quality Assurance Programme (2) The quality assurance programme shall ir details of how work managed, perform assessed. valuate and dequacy of nitary or uirements ict changes te the results ween d supplier in ent and.	ess for and in on of urance iclude k is to be ed and	
		REF. 5.2.2 Quality (1) Concrete quality requiring include the for d. Provision for the bidder's p business to in test, and aud The necessity the supplier's business is to according to f products or su which inspect testing, and a applied and the and content of etc. of the iter services.	requirements contents of ements llowing: or access to lace of spect and t, etc. of or access to place of be clarified he scope of ervices to ion and udit, etc. are he importance omplexity, ns or s of quality ogrammes ortant way to pree that		

COMPARISON TABLE

VII Control of Purchased Items and Services (4/27)

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COMPARISON TABLE

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VII Control of Purchased Items and Services (5/27)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	2) JEAG4101-2000 ⁷	Differences	Assessment of Difference for MHI Manual or Procedure
			consider the influence that the functional non-conformity of items and service errors have on the safety of nuclear power plants. Additional matters to be considered are as follows: b. The need for special controls and inspection for processes, methods, and equipment.			
	Procurement activities involve the following: (NQA-1) a. procurement document preparation, review, and change control b. selection of procurement sources c. bid evaluation and award d. purchaser control of supplier performance e. verification (surveillance, inspection, or audit) activities by purchaser, including notification for hold and witness points f. control of nonconformances g. corrective action h. acceptance of item or service i. QA records	Planning shall result in the documented identification of methods to be used in procurement activities, sequence of actions and milestones indicating the completion of these activities, and the preparation of applicable procedures prior to the initiation of each individual activity listed below. Planning shall provide for the integration of (a) through (i) below: (a) procurement document preparation, review, and change control; (b) selection of procurement sources; (c) bid evaluation and award; (d) Purchaser control of Supplier performance; (e) verification (surveillance, inspection, or audit) activities by Purchaser, including notification for hold and witness points; (f) cornective action; (h) acceptance of item or service; (i) quality assurance records.	See above	Q6 3.2 Contents of Procurement Documents a) Scope of work b) Technical requirements c) Requirements on testing and inspection d) Access to supplier's facility e) Quality assurance standards and additional requirements f) Requirements on documents g) Requirements on quality records h) Submission timing of documents and quality records i) Non-conformance report j) Control of Subcontractor by Supplier k) Items and Services Supplied by Purchaser BASIC 2.1.2 Implementation of Quality Assurance Programme (2) The quality assurance programme shall include details of how work is to be managed, performed and assessed.	Three standards have similar requirements. The specific clause, "Procurement Planning" described in NQA-1, in not found in both JEAG4101-1993 and JEAG4101-2000, but "Procurement Planning" is included in section "Quality Assurance Program" and managed as planning of work.	No significant difference; No impact on the MHI QA manual or procedure.

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COMPARISON TABLE VII Control of Purchased Items and Services (6/27)

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10 CFR 50 Appendix B	Standard Review Plan NUREG -0800	1) ASME NQA-1-1994Edtion	2) JEAG4101-1993	2) JEAG4101-2000	Differences	Assessment of Difference for MHI Manual or
	Section 17.5					Procedure
	2. The program includes	3 SUPPLIER SELECTION	BASIC	Q6		· · · · · · · · · · · · · · · · · · ·
	provisions for evaluating	3.1 Source Evaluation and	5.3 Evaluation of bidders	4.3 Evaluation Method	Three standards have	No significant difference:
	prospective suppliers and	Selection	In selecting suppliers, the	The evaluation method and	similar requirements.	No impact on the MHI QA
	selecting only qualified	The selection of Suppliers	purchaser shall evaluate	the results of evaluation in	JEAG 4101-1993 describes	manual or procedure.
	suppliers, (ANSI N18.7)	shall be based on	whether or not the bidders	evaluating supplier shall be	only fundamental	· · · · · · · · · · · · · · · · · · ·
		evaluation of their	are able to supply items or	documented and	requirement, on the other	
1	6. The procurement of	capability to provide items	services conforming to the	maintained. Example of	hand, JEAG 4101-2000	
	components, including	or services in accordance	requirements of the	evaluation method is as	describes more detailed	
	spare and replacement	with the requirements of	procurement documents.	follows:	provisions.	
	parts, is subject to guality	the procurement	The following shall be	(1) The past achievement		
1	and technical requirements	documents prior to award	included as appropriate in	of the supplier shall be		
	suitable for their intended	of contract.	bidder evaluations:	evaluated concerning the		
	service and to the	Procurement source	a. Technical ability and	proper functioning of the		
	purchaser's QA program	evaluation and selection	quality assurance system	supplied items. Following		
	requirements. (ANSI	measures shall be	b. Past supply records of	matters are the examples:		
	N18.7)	implemented by the	items or services	a) Experience of users of		
	-	Purchaser and shall	c. Past use records of	the identical or similar		
		provide for identification of	items or services	items or services supplied		
		the Purchaser's	 d. Samples of items 	by the prospect supplier.		
		organizational		b) Review of the records		
		responsibilities for	REF.	accumulated through past		
		determining Supplier	5.3 Evaluation of bidders	procurement activities and	Three standards have	No significant difference;
		capability.	(1) Concrete items for	operation experiences	similar requirements.	No impact on the MHI QA
	9. Measures for evaluation	Measures for evaluation	evaluation are as follows:	regarding the items	JEAG 4101-1993 describes	manual or procedure.
	and selection of	and selection of	a. Technical ability and	concerned.	only fundamental	
	procurement sources, and	procurement sources, and	quality assurance system	c) Review of the past data	requirement, on the other	
	the results therefrom, are	the results therefrom shall	a) Technical ability or	regarding the items or	hand, JEAG 4101-2000	
ļ	documented and include	be documented and shall	capacity of the bidders	services to be procured	describes more detailed	
	any or all of the following:	include one or more of (a)	manufacturing equipment	that can indicate the	provisions.	
	(NQA-1)	through (c) below:	concerning the items or	current performance of the		
	a. evaluation of the	(a) evaluation of the	services to be purchased	prospect supplier.		
	suppliers history of	Supplier's nistory of	b) Policy of bidders	If there is no recent record		
	providing an identical or	providing an identical or	regarding quality, quality	available, purchaser shall		
	similar product which	similar product which	assurance programme, and	request the prospect		
	periornis satisfactorily in	performs satisfactorily in	b Supply records	supplier to submit		
	actual use	The Supplier's history shall	b. Supply records	aquivalant itoms or apprice		
		reflect current canability	or services	as an ovidence of the		
	b supplier's current quality	(b) Supplier's current	These are hidder supply	current performance		
	records supported by	quality records supported	records of the items or	(2) Quality Assurance Plan		
	documented qualitative and	by documented qualitative	services that are the same	of the prospect supplier		
	quantitative information	and quantitative	or similar to those to be	shall be evaluated		
	which can be objectively	information which can be	purchased	In this evaluation		
	evaluated	objectively evaluated	c Records of item or	considerations may be		
	c. supplier's technical and	(c) Supplier's technical and	service use	given to the third party		
	quality capability as	quality canability as	Records of use and the	qualification (e.g. ISO		
	determined by a direct	determined by a direct	quality level of the items or	ASME, etc.) concerning the		
	evaluation of its facilities	evaluation of his facilities	services to be purchased	scope related to the		
	and personnel and the	and personnel-and the	that are the same as or	concerned services.		
	implementation of its QA	implementation of his	similar to the one	(3) Evaluation of prospect		
	program	quality assurance program.	possessed by the	suppliers shall be		
			purchaser.	performed based on their		

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COMPARISON TABLE VII Control of Purchased Items and Services (7/27)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17,5	ASME NQA-1-1994Edtion	JEAG4101-1993	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
			d. Samples of items Conformity to quality requirements for the samples of the items to be procured.	technical performance, manufacturing equipment, personnel and quality assurance programme. Guidance on the evaluation is shown in Q5 (Assessment) of the Reference Matters section of this Guide. (4) Current quality assurance records of the prospect suppliers evidenced by qualitative or quantitative document information such as statistic records or equivalent showing the ability of the prospect suppliers shall be evaluated in an objective manner. (5) Ability of the prospect suppliers shall be evaluated by investigating their current products or samples similar to the current products.		
		 4 BID EVALUATION Bid evaluation shall determine the extent of conformance to the procurement documents. This evaluation shall be performed by individuals or organizations designated to evaluate the following subjects, as applicable to the type of procurement: (a) technical considerations (b) quality assurance requirements (c) Supplier's personnel (d) Supplier's production capability (e) Supplier's past performance (f) alternates (g) exceptions Prior to the award of the contract, the Purchaser shall resolve or obtain commitments to resolve 	SUPPLE 5.3 Evaluation of bidders (1) The purchaser should identify the responsible individuals or organizations for the evaluation of bidders, and should document the results. REF. 5.3 Evaluation of bidders (1) Concrete items for evaluation are as follows: a. Technical ability and quality assurance system a) Technical ability or capacity of the bidders manufacturing equipment concerning the items or services to be purchased b) Policy of bidders regarding quality, quality assurance programme, and their implementation b. Supply records	Q6 5.1 Estimation Evaluation (1) The estimation submitted by suppliers shall be checked for its conformance to the requirements of procurement documents. (2) Evaluation and decision making by purchaser concerning the estimation shall be conducted with the cooperation of the divisions responsible for technical activities and procurement activities. The division responsible for the evaluation shall be determined according to the scale and complexity of the items or services to be procured. 3.2 Contents of Procurement Documents	Three standards have similar requirements. JEAG 4101-1993 and JEAG 4101-2000 describe more detailed provisions.	No significant difference; No impact on the MHI QA manual or procedure.

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COMPARISON TABLE VII Control of Purchased Items and Services (8/27)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
		unacceptable quality conditions resulting from the bid evaluation	regarding the use of items or services These are bidder supply records of the items or services that are the same or similar to those to be	 a) Scope of work b) Technical requirements c) Requirements on testing and inspection d) Access to supplier's facility 		
			c. Records of item or service use Records of use and the quality level of the items or convices to be nurchased	e) Quality assurance standards and additional requirements f) Requirements on documents c) Requirements on quality		
			that are the same as or similar to the one possessed by the purchaser. d. Samples of items	y records h) Submission timing of documents and quality records i) Non-conformance report		
		5 SMDDI IEP	Conformity to quality requirements for the samples of the items to be procured.	j) Control of Subcontractor by Supplier k) Items and Services Supplied by Purchaser		
	10. The purchaser of items and services is required to establish measures to	PERFORMANCE EVALUATION The Purchaser of items and services shall establish measures to interface with	5.4 Control of procured items and services (1) Control measures which confirm that purchased items and services conform	4.3 Evaluation Method (1) The past achievement of the supplier shall be evaluated concerning the proper functioning of the	The difference in the style of description is found among these three standards, but they have similar requirements.	No significant difference; No impact on the MHI QA manual or procedure.
	interface with the supplier and to verify the supplier's performance as deemed necessary by the purchaser. The measures	the Supplier and to verify Supplier's performance as deemed necessary by the Purchaser. The measures shall include (a) through (f)	to the requirements of the procurement documents shall be established. (2) Quality records which certify that the purchased	supplied items. Following matters are the examples: a) Experience of users of the identical or similar items or services supplied		
	include the following: (NQA-1) a. establishing an understanding between purchaser and supplier of	below: (a) establishing an understanding between Purchaser and Supplier of the provisions and	items conform to the requirements of the procurement documents shall be made available at factory or at site prior to	by the prospect supplier. b) Review of the records accumulated through past procurement activities and operation experiences		
	the provisions and specifications of the procurement documents b. requiring the supplier to identify planning	specifications of the procurement documents; (b) requiring the Supplier to identify planning techniques and processes	their use. (Explanation 5-5) REF. 5.2.2 Quality requirements (1) Concrete contents of	regarding the items concerned. c) Review of the past data regarding the items or services to be procured		
	techniques and processes utilized in fulfilling procurement document requirements c. reviewing supplier	to be utilized in fulfilling procurement document requirements; (c) reviewing Supplier documents which are	quality requirements include the following: a. Scope of work implemented by bidder The scope of work	that can indicate the current performance of the prospect supplier. If there is no recent record available, purchaser shall		
	documents which are generated or processed during activities fulfilling procurement requirements	generated or processed during activities fulfilling procurement requirements; (d) identifying and	implemented by the bidder (in case of plural bidders, mutual interfacing), etc. is included.	request the prospect supplier to submit information concerning the equivalent items or service		

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COMPARISON TABLE VII Control of Purchased Items and Services (9/27)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17,5	1) ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
	d. identifying and processing necessary change information	processing necessary change information; (e) establishing method of	b. Technical requirements such as design, fabrication and installation, inspection	as an evidence of the current performance.		
	e. establishing a method of	document information	and testing, etc.	6.1 Coordination between		
	document information	exchange between	Performance and function	Purchaser and Supplier		
	exchange between	Purchaser and Supplier;	requirements, criteria for	Purchaser and supplier		
	f establishing the extent of	(i) establishing the extent of	requirements for the	verify how the supplier		
	source surveillance and	inspection activities	materials and parts and	fulfills the procurement		
	inspection activities	These verification activities	requirements for the	requirements. The task		
	·····	shall be conducted as early	fabrication, inspection and	may be conducted by either		
		as practicable.	testing, cleaning, packing,	the purchaser, an agent		
	i. ensuring that the	The Purchaser's	and installation, etc. are	specified by the other		
	purchaser's verification	verification activities,	included.	issuer or the other agency		
	activities do not relieve the	however, shall not relieve	c. Provisions for submitting	authorized by the		
	supplier of its	responsibilities for	quality assurance	Following activities are the		
	verification of quality	verification of quality	Quality assurance	examples of the		
	achievement	achievement.	programmes issued by	above-mentioned activities:		
			bidders are deemed	a) Purchaser and suppler		
		۰.	satisfactory if they include	shall mutually confirm the		
			the purchaser's	intention of specifications		
			requirements.	and procurement		
			d. Provision for access to	any difference or		
1			business to inspect and	incompleteness between		
			test, and audit, etc.	contract / order		
			The necessity for access to	requirements and		
		·	the supplier's place of	estimated specifications,		
		and the second sec	business is to be clarified	or, there if there is any		
			according to the scope of	unclear or contradictory		
			which inspection and	queries shall be settled with		
			testing, and audit, etc. are	the responsible party who		
			applied and the importance	requests the concerned		
			and content complexity,	requirement.		
			etc. of the items or	b) The purchaser shall		
			services.	request supplier to clearly		
			e. Provision for the	concerning the methods		
			and storage of records	processes and procedures		
·			such as specifications.	to be used to satisfy the		
			procedures, drawings, and	procurement requirements		
			quality records	and confirm the feasibility		
			These are submitted for	of the plan.		
		,	study or purchaser	c) Adjustment shall be		
			approval, and they detail	nurchaser and the supplier		
			of documents and the way	regarding the reflection of		
			that storage and disposal of	the experiences.		
			quality records, etc. is	d) Documents prepared		
			done.	and processed within the		

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10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17,5	ASME NQA-1-1994Edtion	JEAG4101-1993	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
			f. Provision for the treatment of non-conforming items This establishes the bounds of reports to purchaser and the way that nonconforming items or services are treated. g. Provision for extending the application of procurement documents requirements to the contractor's suppliers. This clarifies extending the application of purchaser quality requirements to the subcontractors and the bounds of purchaser	framework of activities to satisfy the procurement requirements shall be reviewed. e) Change of contents shall be clarified and processed. f) Method of forwarding and accepting documents between purchaser and supplier shall be established. g) The records of confirmation of contract contents shall be maintained. The above activities can be utilized also in future as standards for selecting		
			approval for subcontractors.	suppliers. 6.2 Communication before and after Contract (1) Purchaser shall make adjustment before and after the contract depending on the complexity and scope of items and services. To establish mutual understanding between purchaser and supplier concerning the following matters within the framework of these		
				activities, meeting or other communication forms may be used. It is recommended to make documents for the adjustment results under the mutual agreement of the purchaser and the supplier. a) Procurement requirements b) Purchaser's intention to monitor and evaluate supplier's performance. c) Plan, manufacturing technique, testing and inspections that supplier employs to conform to the requirements of		

COMPARISON TABLE VII Control of Purchased Items and Services (10/27)

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COMPARISON TABLE VII Control of Purchased Items and Services (11/27)

10 CFR' 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	2) JEAG4101-2000	Differences	Assessment of Difference for MHI Manual or Procedure
				procurement documents. (2) Purchaser shall clarify the notification timing of the necessary information as early as possible the procurement process. (3) The level and necessity of communication before and after the contract shall be determined depending on the special characteristics and complexity of items, procurement frequency with the same supplier as well as the supply performance regarding the similar items or services in the past.		
		5.1 Extent of Activities The extent of verification activities; including planning, shall be a function of the relative importance, complexity, and quantity of the item or services procured and the Supplier's quality performance. Verification activities shall be accomplished by qualified personnel assigned to check, inspect, audit, or witness the activities of. Suppliers.	SUPPLE 5.4.1 Control measures for procured items and services (1) Inspection and testing; a. To confirm that procured items and services conform to the requirements of the procurement documents, the purchaser should plan and perform inspection and testing. b. Inspection and testing should be performed by using the procedures, instructions, check sheets, etc., in which requirements and acceptance criteria are provided.	Q6 6.1 Coordination between Purchaser and Supplier Purchaser and supplier shall confirm, evaluate and verify how the supplier fulfills the procurement requirements. The task may be conducted by either the purchaser, an agent specified by the other issuer or the other agency authorized by the purchaser.	Three standards have similar requirements.	No significant difference; No impact on the MHI QA manual or procedure.
		5.2 Records Activities performed to verify conformance to requirements of procurement documents shall be recorded; Source surveillances and inspections, audits, receiving inspections, nonconformances, dispositions, waivers, and corrective actions shall be	BASIC 5.4 Control of procured items and services (1) Control measures which confirm that purchased items and services conform to the requirements of the procurement documents shall be established. (2) Quality records which certify that the purchased items conform to the	Q6 3.2 Contents of Procurement Documents a) Scope of work b) Technical requirements c) Requirements on testing and inspection d) Access to supplier's facility e) Quality assurance standards and additional requirements	Three standards have similar requirements.	No significant difference; No impact on the MHI QA manual or procedure.

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COMPARISON TABLE VII Control of Purchased Items and Services (12/27)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17,5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
		documented. The Purchaser shall assure that his documentation is evaluated to determine, the Supplier's quality assurance program effectiveness.	requirements of the procurement documents shall be made available at factory or at site prior to their use. (Explanation 5-5)	 f) Requirements on documents g) Requirements on quality records h) Submission timing of documents and quality records i) Non-conformance report j) Control of Subcontractor by Supplier k) Items and Services Supplied by Purchaser 3.2.7 Quality Records Requirements for quality records (including material samples) to suppliers shall be clearly identified. In this case a list of quality records including all the requirements for quality records including all the requirements for quality records including all the requirements for quality record may be used. This list may be submitted by suppliers. 		
		6 CONTROL OF, SUPPLIER GENERATED DOCUMENTS Supplier generated documents shall be controlled, handled, and approved in accordance with established methods. Means shall be implemented to as sure that the submittal of these documents is accomplished in accordance with the procurement document requirements. These measures shall provide for the acquisition, processing, and recorded evaluation of technical, inspection, and test data against acceptance criteria.	SUPPLE 5.4.1 Control measures for procured items and services (3) Control of documents submitted by supplier; Purchaser should provide control measures for submission and return of documents submitted by supplier.	Q6 6.3 Submission, Review and Approval of Documents (1) Purchaser shall stipulate the methods of submission and return of the documents submitted by supplier including the submission / return route and due date, etc. Guidance for the document control is shown in Q3 (Document control and records) of the Reference Matters section of this Guide. (2) The documents requiring approval of purchaser shall be reviewed by appropriate staff of the purchaser after submission to determine the conformance of the documents to requirements of procurement documents.	Three standards have similar requirements though JEAG 4101-1993 describes only fundamental requirement, on the other hand, JEAG 4101-2000 describes more detailed provisions.	No significant difference; No impact on the MHI QA manual or procedure.

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COMPARISON TABLE VII Control of Purchased Items and Services (13/27)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 ⁰ Section 17.5 ⁰	ASME NQA-1-1994Edtion	2) JEAG4101-1993	JEAG4101-2000 ^{2}}	Differences	Assessment of Difference for MHI Manual or Procedure
				(3) After the review, if the documents conform to the requirements, the individual assigned by purchaser for the review task shall issue an approval. If non-conformance is found, the documents shall be return to the supplier for necessary action or activities.		
		7 CONTROL OF CHANGES IN ITEMS OR SERVICES The Purchaser and Supplier shall assure that measures to control changes in procurement documented, and documented, and documented and are in accordance with this Part (Part I).	SUPPLE 5.2.1 Specifying in procurement documents (2) As for changes in quality requirements, it is desirable to evaluate and examine the adequacy of the supplementary or corrective requirements prior to contract changes and incorporate the results discussed between purchaser and supplier in the procurement documents,	Q6 3.3.2 Change of Procurement Documents (1) Concerning the change of procurement document, review and approval shall be conducted before issuing any document effecting the change so as to ensure that the change has no negative impact on the other structures, systems and components of the plant. (2) The supplier shall notify the approved change to the purchaser. (3) The change of procurement document shall be subject to the same degree of control as utilized in the preparation of the original documents. (4) It is desired that the items that undergo any change should be included in the procurement documents based on the consultation between purchaser and supplier. Guidance on the control of document change is shown in Q3 (Document control and records) of the Reference Matters section of this Guide.	Three standards have similar requirements.	No significant difference; No impact on the MHI QA manual or procedure.

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10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
				be clarified and processed. f) Method of forwarding and accepting documents between purchaser and supplier shall be established.		
	 5. The program is to include provisions for ensuring that procurement, inspection, and test requirements have been satisfied before an item is placed in service or used. (Approved via SE (Accession No. ML050700416).) 17. Measures to verify the quality of purchased items and services are described. (ANSI N18.7) 	8 ACCEPTANCE OF ITEM OR SERVICE 8.1 General Methods shall be established for the acceptance of an item or service being furnished by the Supplier. Prior to offering the item or service for acceptance, the Supplier shall verify that the item or service being furnished complies with the procurement requirements. Where required by code, regulation, or contract requirement, documentary evidence that items conform to procurement documents shall be available at the nuclear facility site prior to installation or use.	SUPPLE 5.4.1 Control measures for procured items and services (1) Inspection and testing; a. To confirm that procured items and services conform to the requirements of the procurement documents, the purchaser should plan and perform inspection and testing. b. Inspection and testing should be performed by using the procedures, instructions, check sheets, etc., in which requirements and acceptance criteria are provided. REF. 5.4.1 Control measures for procured items and services (1) Inspection and testing planning are as follows: a. Implemented items : dimension inspection, appearance inspection, appearance inspection, aptex services, and confirmation, etc. c. Implementation method : all items, sampling, witness, records, and confirmation, etc. d. Implementation place : supplier, purchaser, etc.	Q6 6.1 Coordination between Purchaser and Supplier b) The purchaser shall request supplier to clearly indicate the plan concerning the methods, processes and procedures to be used to satisfy the procurement requirements and confirm the feasibility of the plan 7.1 Receiving Inspection of Items (1) Purchaser shall perform inspection at receiving to verify that items and the related documents such as material certificate conform to requirements. 7.2 Receiving of Items [Explanation Q6-5] (1) Items shall not be received for use, manufacture or installation before all the inspections are completed without problem and all the specified documents such as material certificate are received and reviewed.	The difference in the style of description is found among these three standards, but the gist of description is same.	No significant difference; No impact on the MHI QA manual or procedure.
	15. Purchaser methods used to accept an item or related service from a supplier are supplier	8.2 Methods of Acceptance Purchaser methods used to accept an item or related service from a Supplier shall be Supplier Certificate	REF. 5.4.1 Control measures for procured items and services (1) Inspection and testing	Q6 6.5 Inspection and Testing in Supplier's Facility (3) Following are the examples of inspections	The difference in the style of description is found among these three standards, but the gist of	No significant difference; No impact on the MHI QA manual or procedure.

COMPARISON TABLE VII Control of Purchased Items and Services (14/27)

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COMPARISON TABLE VII Control of Purchased Items and Services (15/27)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	() ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
	certificate of conformance, source verification, receiving inspection, postinstallation test, or a combination thereof. (NQA-1)	of Conformance, source verification, receiving inspection, or post-installation test at the nuclear facility site, or a combination thereof.	planning are as follows: a. Implemented items : dimension inspection, appearance inspection, pressure testing, etc. b. Implementation method : all items, sampling, witness, records, and confirmation, etc. c. Implementation time : haftway, upon completion, after installation, etc. d. Implementation place : supplier, purchaser, etc.	and testing: a) Implementation item: dimensional inspection, visual inspection, appearance, pressure tests, etc. b) Implementation method: 100% vs. sampling, on-site inspection vs. record review, etc. c) Implementation timing: In process; upon completion, after installation, etc. d) Implementation site: supplier's facility, purchaser's facility, etc. 7.1 Receiving Inspection of Items (1) Purchaser shall perform inspection at receiving to verify that items and the related documents such as material certificate conform to requirements.	description is same.	
	 16. A certificate of conformance shall contain, as a minimum, the following criteria: (NQA-1) a. The purchased material or equipment is identified, such as by the purchase order number. b. The specific procurement requirements met by the purchased material or equipment, such as codes, standards, pre-installation tests, and other specifications, are identified. This may be accomplished by including a list of the specific requirements or by providing, onsite, a copy of the purchase order and the procurement specifications or drawings, together with a suitable certificate. The 	 8.2.1 Certificate of Conformance. When a Certificate of Conformance is used, the minimum criteria of (a) through (f) below shall be met. (a) The certificate shall identify the purchased material or equipment, such as by the purchase order number. (b) The certificate shall identify the specific procurement requirements met by the purchased material or equipment, such as codes, standards, and other specifications. This may be accomplished by including a list of the specific requirements or by providing, on-site, a copy of the purchase order and the procurement specifications 			Both JEAG4101-1993 and JEAG4101-2000 does not have detailed requirements regarding C.O.C.	Significant difference; No impact on the MHI QA manual or procedure. C.O.C. is supposed to be not applicable in DC stage activity. MHI's material control manual in fabrication stage, has description of "Certificate of Conformance."

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COMPARISON TABLE VII Control of Purchased Items and Services (16/27)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17 5	1) ASME NQA-1-1994Edtion	2) JEAG4101-1993	JEAG4101-2000 ^{2).}	Differences	Assessment of Difference for MHI Manual or Procedure
	procurement requirements	suitable certificate. The	· · · · · · · · · · · · · · · · · · ·			
	identified include any	procurement requirements				
	approved changes.	identified shall include any				
	waivers, or deviations	approved changes				
	applicable to the subject	waivers, or deviations			1	
	material or equipment.	applicable to the subject				
	c. Any procurement	material or equipment.				
	requirements that have not	(c) The certificate shall				
	been met, together with an	identify any procurement				
	explanation and the means	requirements that have not				
	for resolving the	been met, together with an				
	nonconformances, are	explanation and the means				
	identified.	for resolving the				
	d. The certificate is signed	non-conformances.				
	or otherwise authenticated	(d) The certificate shall be				
	by a person who is	signed or otherwise				
	responsible for this QA	autnenticated by a person				
	function and whose	who is responsible for this				
	function and position are	quality assurance function				
	described in the	and whose function and				
		the Purchaser's or				
	A program.	Supplier's qualify		÷		
	including the procedures	assurance program				
	followed in filling out a	(e) The certification				
	certificate and the	system including the				
	administrative procedures	procedures to be followed				
	for review and approval of	in filling out a certificate				
	the certificates, is	and the administrative				
	described in the	procedures for review and				
	purchaser's or supplier's	approval of the certificates,				
	QA program.	shall be described in the				
	f. Means are provided to	Purchaser's or Supplier's				
	verify the validity of supplier	qualify assurance program.				
	certificates and the	(f) Means shall be provided				
	effectiveness of the	to verify the validity of				
	certification system, such	Supplier certificates and				
	as during the performance	the effectiveness of the				
	of audits of the supplier or	certification system, such				
	independent inspection or	as during the performance				
	test of the items. Such	of audits of the Supplier or				
	verification is conducted by	independent inspection or				
	the purchaser at intervals	test of the items. Such				
	commensurate with the	vernication shall be				
	suppliers past quality	Durchaser at intervals				
	penormance.	commensurate with the				
		Supplier's past qualify				
		performance.				
		8.2.2 Source Verification	SUPPLE	Q6	101	
	1	When source verification is	5.4.1 Control measures for	6.5 Inspection and Testing	Three standards have	No significant difference;

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COMPARISON TABLE VII Control of Purchased Items and Services (17/27)

<u> </u>	Standard Review Plan	1)	2)	2)		Assessment of Difference
10 CFR 50 Appendix B	NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993	JEAG4101-2000 ²	Differences	for MHI Manual or. Procedure
	18. Source verification is required to be implemented in accordance with plans to perform inspections, examinations, or tests at predetermined points. Upon purchaser acceptance of source verification, documented evidence of acceptance is furnished to the receiving destination of the item, to the purchaser, and to the supplier. (NQA-1)	used, it shall be performed at intervals consistent with the importance and complexity of the item or service, and it shall be implemented to monitor, witness, or observe activities. Source verification shall be implemented in accordance with plans to perform inspections, examinations, or tests at predetermined points. Upon Purchaser acceptance of source verification, documented evidence of acceptance shall be furnished to the receiving destination of the item, to the Purchaser, and to the Supplier.	procured items and services The following should be included in control measures as appropriate: (1) Inspection and testing; a. To confirm that procured items and services conform to the requirements of the procurement documents, the purchaser should plan and perform inspection and testing. b. Inspection and testing should be performed by using the procedures, instructions, check sheets, etc., in which requirements and acceptance criteria are provided. (2) Treatment after reception; (Explanation 5-6) When procured items and services could not be confirmed to have satisfied procurement requirements at the time of reception, the control measures thereafter should be established and implemented. (3) Control of documents submitted by supplier; Purchaser should provide control measures for submission and return of documents submitted by supplier; It is desirable for the purchaser to instruct and advise the supplier to smoothly execute design, fabrication, installation, inspection, testing, etc. according to the purchaser's requirements. REF. 5.4.1 Control measures for	in Supplier's Facility (1) Testing and inspection activities at suppliers' facility shall be conducted based on the requirements of procurement documents. (2) Inspection and testing shall be performed according to the requirements on inspection and testing, procedures for prescribing criteria, instructions and check sheets, etc. (3) Following are the examples of inspections and testing: a) Implementation item: dimensional inspection, appearance, pressure tests, etc. b) Implementation method: 100% vs. sampling, on-site inspection vs. record review, etc. c) Implementation timing: In process; upon completion, after installation, etc. d) Implementation site: supplier's facility, purchaser's facility, etc. (4) The performance of these testing and inspections shall not constitute the exemption of the order supplier's responsibility to supply items or services that are acceptable. If inspection at the supplier's facility, is conducted at the subcontractor's facility, the responsibility to manage activities of the purchaser remains with the supplier (See Item 3.2.10).	similar requirements. The difference in the style of description is found among these three standards, but the gist of description is same. For example, the requirement of "Source Verification" in NQA-1 corresponds to the requirement of Ref. 5.4.1(3) "Guide and advice to supplier" in JEAG4101-1993 and 6.5" Inspection and Testing in Supplier's Facility" in JEAG4101-2000.	No impact on the MHI QA manual or procedure.
			procured items and	<u> </u>		

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10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17,5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
			services			
			(1) Inspection and testing			
J			planning are as follows:			
			a. Implemented items :			
			dimension inspection,			
			appearance inspection,			
			pressure testing, etc.			
			b. Implementation method :			
		-	all items, sampling,			
			confirmation ato			
			c Implementation time :			
			halfway upon completion			
			after installation, etc.			
		· .	d. Implementation place :			
			supplier, purchaser, etc.			
			(2) Control items for			
			treatment after reception			
			are as follows:			
			a. Preparation of receiving			
			conditions etc.			
			b. Decision of confirmation			
			for unconfirmed			
			procurement requirements			
			c. Treatment of items when			
			non-conformance occurs			
			(3) Control measures for			
			documents submitted by			
			supplier are as follows:			
			a. Route of document	[
		. · · · · · · · · · · · · · · · · · · ·	submission and return			
			b. Term of document			
			(4) Indestrination advice to			
}		· · ·	supplier are as follows:			
		and the second	a Provisions for quality	ſ		
		19 J.	assurance organizations.			
			quality consciousness, etc.			
			b. Matters taken into			
			consideration during			
	[designing (Function, use	1		1
		· · · · · · · · · · · · · · · · · · ·	conditions, interface, etc.			
			Including their backgrounds			
		:	as necessary)			
			and installation techniques			
[[(equipment etc.	1		1
			d. Provisions for the			
			inspection and testing			
			methods, records, etc.			

COMPARISON TABLE VII Control of Purchased Items and Services (18/27)

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COMPARISON TABLE VII Control of Purchased Items and Services (19/27)

	Standard Review Plan	1)	2)	2)		Assessment of Difference
10 CFR 50 Appendix B	NUREG -0800	ASME NQA-1-1994Edtion	JEAG4101-1993	JEAG4101-2000	Differences	for MHI Manual or
	Section 17.5			,		Procedure
		8.2.3 Receiving Inspection	See above	04		
	19 When receiving	When receiving inspection		4.4 Accentance hy	Three standards have	No significant difference
	inspection is used	is used, purchased items		Receiving Inspection	similar requirements	No impact on the MHI OA
1	purchased items are	chall be increated as	1	(1) Acceptance by	IEAG 4101-2000 describes	manual or procedure
	inspected as passage to	shall be inspected as			more detailed provisions in	manual of procedure.
	inspected as necessary to	necessary to verify		receiving inspection alone	O decalled provisions in	
	verify conformance to	conformance to specified		shall be considered when :	Q4 inspection and lest	
	specified requirements,	requirements, taking into		a. Item are relatively simple	Control" 4.4 Acceptance by	
	taking into account source	account source verification		and standard in term of	Receiving Inspection".	
	verification and audit	and audit activities and the		design, manufacture and		
	activities and the	demonstrated qualify		testing		
	demonstrated quality	performance of the		b. The item is adaptable to		
1	performance of the	Supplier, Receiving	1	standard or automated		
	supplier, Receiving	inspection shall be		inspection and/or testing		
	inspection is performed in	performed in accordance		after delivery to verify		
	accordance with	with established		quality characteristics		
1	procedures and inspection	procedures and inspection		c Receiving inspection		
1	instructions to verify by	instructions to varify by		does not require operations		
1	objective evidence auch	abientive evidence such		that could advarcally affect		
	footure evidence such	footure evidence such		the integrity function or		
	reatures as proper	features as proper		the integrity, function or		
	configuration; identification;	configuration; identification;		cleanliness or item		
	dimensional, physical, and	dimensional, physical, and		d. Item are susceptible to		
	other characteristics;	other characteristics;		damage during transit		
	freedom from shipping	freedom from shipping		(2) Incoming items shall not		
1	damage; and cleanliness.	damage; and cleanness.		be used or processed until		
	Receiving inspection is	Receiving inspection shall		conformance to specified		
	coordinated with review of	be coordinated with review		requirements has been		
	supplier documentation	of Supplier documentation		verified. The verification		
	when procurement	when procurement		shall be in accordance with		
	documents require such	documents require such		the quality plan or		
1	documentation furnished	documentation to be		procedures		
	prior to receiving	furnished prior to receiving		(3) Receiving inspection		
	inspection (NOA-1)	inspection		shall be co-ordinated with a		
	inspection. (Non-1)	inspection.		review of the supplied		
				documents when		
			2	accuments with		
				to accompany the item of to		
1	1			he furnished before		
1	1	1		be rurnished before		
J	J	J	J	receiving inspection take		
				place. Such supplied	[
				documents may include.		
		,		a. material analysis		•
				certificates		
		:		b. type test certificates		
		a de la companya de l		c. specific test results		
				d. specified inspection data		
				e. calibration certificates		
1		ľ		f. supplier declaration of		
1	1	1	1	compliance with specified		
1		t .		requirements		
		, , , , , , , , , , , , , , , , , , ,		g release certification		
1				h non-conformance		
1				roporte		
1		1		I TEDURS.		

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10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	1) ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
				Q6 7.1 Receiving Inspection of Items (1) Purchaser shall perform inspection at receiving to verify that items and the related documents such as material certificate conform		
				to requirements. (2) To perform secure receiving, procurement documents shall be distributed to the product receiving division and inform the division of the receiving date.		
				(3) Purchaser shall determine the extent of necessary receiving inspection. The extent may vary depending on the complexity and safety-related importance of the items, extent of the		
				verification conducted at supplier's facility and the past performance of the supplier. (4) All the non-conformance found in the receiving inspection		
				shall be addressed based on Q2 (Non-conformance control and corrective actions) of this Guide (Reference Matters). Guidance on the testing, inspection and receiving of items and services is		
	· · ·	8.2.4 Post-Installation	See above	shown in Q4 (inspection and Testing) of the Reference Matters section of this Guide.		
	20. When post-installation testing is used for acceptance of purchased items, postinstallation test and acceptance	Testing. When post-installation testing is used, post-installation test requirements and acceptance documentation		 7.3 Testing after Installation of Items (1) If conformance of an item cannot be sufficiently verified until the completion of testing in installation 	Three standards have similar requirements. The difference in the style of description is found in JEAG4101-1993, but the gist of description is same.	No significant difference; No impact on the MHI QA manual or procedure.

COMPARISON TABLE VII Control of Purchased Items and Services (20/27)

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COMPARISON TABLE VII Control of Purchased Items and Services (21/27)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
	documentation recommended by the supplier are required to be considered. (NQA-1)	shall be mutually established by the Purchaser and Supplier.		status, appropriate directions shall be given to installation staff to perform testing after installation. These directions shall be reflected in the requirements to be stated in the procurement documents. (2) Supplier shall perform testing in installation status before delivering the item to the purchaser.		
	11. In certain cases involving procurement of services only, such as third party inspection; engineering and consulting services; auditing; and installation, repair, overhaul, or maintenance work, the purchaser accepts the service by any or all of the following methods: (NQA-1) a. technical verification of data produced b. surveillance and/or audit of the activity c. review of objective evidence for conformance to the procurement document requirements (e.g., certifications, stress reports)	8:3 Acceptance of Services Only In certain cases involving procurement of services only, such as third party inspection; engineering and consulting services; and installation, repair, overhaul, or maintenance work, the Purchaser shall accept the service by any or all of the following methods: (a) technical verification of data produced; (b) surveillance and/or audit of the activity; (c) review of objective evidence for conformance to the procurement document requirements such as certifications, stress reports, etc.	REF. 5.4.1 Control measures for procured items and services (1) Inspection and testing planning are as follows: a. Implemented items : dimension inspection, appearance inspection, pressure testing, etc. b. Implementation method : all items, sampling, witness, records, and confirmation, etc. c. Implementation time : halfway, upon completion, after installation, etc. d. Implementation place : supplier, purchaser, etc. (2) Control items for treatment after reception are as follows: a. Preparation of receiving conditions etc. b. Decision of confirmation method, time, and person for unconfirmed procurement requirements c. Treatment of items when non-conformance occurs (3) Control measures for documents submitted by supplier are as follows: a. Route of document submission and return b. Term of document submission and return	Q6 7.4 Receiving of Services (1) Purchaser shall stipulate the Receiving criteria of services and confirm the activities. (2) Conformance of services shall be confirmed by requesting submission of performance records such as monitoring activity records and testing / inspection records. (3) The records of receiving test or inspection shall be used to evaluate and confirm ability of suppliers.	Three standards have similar requirements. JEAG4101-1993 don't describe the requirement for "Acceptance of Services Only" distinctly.	No significant difference; No impact on the MHI QA manual or procedure.

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10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17 5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
			supplier are as follows: a. Provisions for quality assurance organizations, quality consciousness, etc. b. Matters taken into consideration during designing (Function, use conditions, interface, etc. including their backgrounds as necessary) c. Provisions for fabrication and installation techniques, equipment, etc. d. Provisions for the inspection and testing methods, records, etc.			
	 The purchaser and supplier are required to establish a documented method for the disposition of nonconforming items. (NQA-1) The supplier is required to send the purchaser all nonconforming reports from procurement documentation requirements generated during the manufacturing process. As a minimum, nonconforming reports contain the following information: (NQA-1) a. description of nonconforming item b. evaluation of nonconforming item c. recommended corrective action (i.e, use-as-is or repair) d. technical justification for corrective action The purchaser is 	9 CONTROL OF SUPPLIER NONCONFORMANCES The Purchaser and Supplier shall establish and document methods for disposition of items and services that do not meet procurement documentation requirements. These methods shall contain provision for (a) through (e) below: (a) evaluation of nonconforming; items; (b) submittal of nonconformance notice to Purchaser by Supplier as directed by the Purchaser. These submittals shall include Supplier- recommended disposition (e.g., use-as-is or repair) and technical justification. Nonconformances to the procurement requirements or Purchaser-approved documents, which consist of one or more of the following, shall be submitted to the Purchaser for approval of the recommended disposition: (1) technical or material	BASIC 10.3 Review and disposition for non-conforming items and services (3) In cases where non-conforming items and services which do not satisfy requirements for procurement are used or received as is or after significant repair work, their technical adequacy shall be documented and approved by the purchaser. REF. 5.2.2 Quality requirements (1) Concrete contents of quality requirements include the following: f. Provision for the treatment of non-conforming items This establishes the bounds of reports to purchaser and the way that nonconforming items or services are treated.	Q6 6.7 Control of Non-Conformance (1) The non-conformance found in the procurement process shall be addressed based on Q2 (Non-conformance control and corrective actions) of this Guide (Reference Matters). (2) The non-conformance found by purchaser shall be reported to supplier immediately so that the supplier can address the case based on the non-conformance control system. 3.2.9 Non-conformance Report (1) Purchaser shall state the request for reporting deviation from procurement requirements (scope of report and action method, etc). Q2 3.1(2) Conditions and events to be handled by the non-conformance control process could include: a. Physical characteristics	Three standards have similar requirements. Basic requirement, 10.3 "Review and disposition for non-conforming items and services" in JEAG4101-1993 is applied to "Control of Supplier Nonconformance". Basic requirement, Chapter 3"Control of Nonconformance" in JEAG4101-2000 1993 is applied to "Control of Supplier Nonconformance".	No significant difference; No impact on the MHI QA manual or procedure.

COMPARISON TABLE

VII Control of Purchased Items and Services (22/27)

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10 CFR 50 Appendix B	Standard Review Plan: NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	2) JEAG4101-1993	2) JEAG4101-2000	Differences	Assessment of Difference for MHI Manualior Procedure
	required to approve the supplier's recommended disposition and technical justification for nonconformances that involve any of the following: (NQA-1) a. technical or material requirement is violated b. a requirement in purchaser-approved supplier document was violated c. nonconformance cannot be corrected by continuation of the original manufacturing process or by rework d. the item does not conform to the original requirement even though the item can be restored to a condition such that the capability of the item to function is unimpaired	requirement is violated; (2) requirement in Supplier documents, which has been approved by the Purchaser, is violated; (3) nonconformance cannot be corrected by continuation of the original manufacturing process or by rework; (4) the item does not conform to the original requirement even though the item can be restored to a condition such that the capability of the item to function is unimpaired; (c) Purchaser disposition of Supplier recommendation; (d) verification of the implementation of the disposition; (e) maintenance of records of Supplier-submitted nonconformances.		outside specified limits, such as dimensional and/or material parameters, installation errors and item/system performance deficiencies. b. Deviations from approved process parameters or procedures. c. Failure of personnel to implement work, inspection or test instructions. d. Inadequate documentation, containing incorrect or incomplete information. e. Inadequate training of personnel to perform safety related tasks for which they have been given responsibility. f. Incidents, malfunctions and failures. 3.5.1 Review (1) Non-conformances should be reviewed as soon as practicable by appropriate personnel who should be selected by taking the following into account: A. QA grade or classification of the affected products, services or processes B. Necessity for the safety implications of the non-conformance to be independently reviewed C. Necessity to involve the design organization or other persons who have access to the original design information, including any subsequent modifications D. Necessity to involve the operation organization E. Necessity to involve the operation organization E. Necessity to involve the original supplier (provider)		

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	Standard Review Plan	1)	2)	2)		Assessment of Difference
10 CFR 50 Appendix B	NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993	JEAG4101-2000 ²¹	Differences	for MHI Manual or Procedure
		1		3.5.2 Disposition		1
				(1) Non-conformity		
		1		(including procurement		
				items) could be designated		
				In one following ways:		
				(a) "Reject" (also		
				sometimes referred to as		
				The per conforming		
				product convice or process		
				is not fit for the intended		
				non-conformance should		
		× I		be marked and segregated		
		1		as soon as the action is		
				agreed and approved.		
				(b) "Repair"		
				The non-conforming item,		
				when repaired (or in the		
		1		case of documents revised)		
				is capable of functioning in		
				accordance with the design		
		1		requirements, although it		
				does not fully conform to		
		and the second second		the original design	· · ·	
		and the second s		specification. Temporary		
		200 N		repair should have a		
				prescribed period of		
				validity.		
				The product is capable of		
		and the second sec		being fully restored to the		
				original specification		
				requirements i e some		
				additional rework carried		
		· ·		out under suitable		1
			•	conditions will correct the		
				non-conformance.		
		· · · · ·		(d) "Accept with conditions"		
				It is likely that the		
				non-conformance products,		
1	1	1 1		services and process will		1
				be fit for use under special,		
				specified conditions.		
				(e) "Accept without		
	1			sometimes referred to as		
1	1	· I		It is likely that the		
				non-conforming products		
				services or process		
[deviates marginally from		

COMPARISON TABLE VII Control of Purchased Items and Services (24/27)

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COMPARISON TABLE VII Control of Purchased Items and Services (25/27)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	2} JEAG4101-1993	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
				specified requirements but is still declared fit use. (2) For the significant modifications which require the approval by the purchaser, the scope of modification should be previously defined between the purchaser and contractor. (3) After completion of the disposition, following verifications should be implemented with the way decided at the review stage: (a) Reinspection, Retesting (b) Revision of the prepared documents		
		10 COMMERCIAL GRADE ITEMS Where the design utilizes commercial grade items, the following requirements are an acceptable alternate to other requirements of this Supplement, except as noted in (b) below and the requirements of. Supplement 4S-1. (a) The commercial grade item is identified in an approved design output document. An alternate commercial grade item may be applied, provided the cognizant design organization provides verification that the alternate commercial grade item will perform the intended function and will meet design requirements applicable to both the replaced item and its application. (b) Source evaluation and selection, where determined necessary by the Purchaser based on complexity and importance	_	Q6 8.1 Research of Commercial Grade Items (1) Commercial grade items may be adopted if any record to evidence conformance to the requirements is available. (2) To secure deliver of proper products, sufficient information obtained from the brochures and supplier's specifications shall be stated in the procurement documents. If necessary, information of related technical data and commercial grade items concerned shall be obtained. (3) When adopting a marketed product, analysis or testing for confirmation may be necessary depending on the cases so as to verify that the product should perform the ability as intended.	JEAG4101-1993 doesn't have relevant description. In JEAG4101-2000, the description of commercial grade items is indicated under the limited condition.	Significant difference; No impact on the MHI QA manual or procedure. Commercial Grade Items are supposed to be not applicable in DC stage activity.

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10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
		to safety, shall be in accordance with para, 3.1. of this Supplement. (c) Commercial grade items shall be identified in the purchase order by the manufacturer's published product description (for example, cataloo number).				
		 (d) After receipt of a commercial grade item, the Purchaser shall determine that: (1) damage was not sustained during shipment; (2) the item received was the item ordered; (3) inspection and/or testing is accomplished, as required by the Purchaser, to assure conformance with the manufacturer's published requirements; (4) documentation, as applicable to the item, was received and is acceptable. 	-	Q6 8.2 Evaluation of Commercial Grade Items If marketed product is used in the area related to safety functions, sufficient technical evaluations shall be performed regarding the product complexity and safety-related importance. The characteristics considered necessary to the functions shall be incorporated in the procurement documents as an Receiving criteria.	See above	See above
	3. The program includes provisions for ensuring that qualified suppliers continue to provide acceptable products and services. (ANSI N18.7)		SUPPLE 5.4.1 Control measures for procured items and services (4) Guide and advice to supplier; It is desirable for the purchaser to instruct and advise the supplier to smoothly execute design, fabrication, installation, inspection, installation, inspection, installation, inspection, itesting, etc. according to the purchaser's requirements. REF. 5.4.1 Control measures for procured items and services (4) Indoctrination, advice to supplier are as follows: a. Provisions for quality assurance organizations, quality consciousness, etc. b. Matters taken into	Q6 6.4 Guidance and Advice to Supplier (1) So that suppliers can implement design, manufacturing, installation, inspection and testing smoothing corresponding to the procurement requirements of purchaser, it is recommended that the order issue give guidance and advice to the suppliers depending on the necessity. (2) Following are the examples of guidance and advice to suppliers: a) Matters related to quality assurance system, quality awareness, etc. b) Considerations on designing (function, use conditions, interfaces and their background	JEAGs describe the requirement that qualified suppliers continue to provide acceptable products and services by instruction.	No significant difference; No impact on the MHI QA manual or procedure, because JEAGs describe details.

COMPARISON TABLE VII Control of Purchased Items and Services (26/27)

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COMPARISON TABLE

VII Control of Purchased Items and Services (27/27)

10 CFR 50 Appendix B	Standard Review Plan N⊍REG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	2) JEAG4101-2000	Differences	Assessment of Difference for MHI Manual or Procedure
			consideration during designing (Function, use conditions, interface, etc. including their backgrounds as necessary) c. Provisions for fabrication and installation techniques, equipment, etc. d. Provisions for the inspection and testing methods, records, etc.	depending on the necessity). c) Matters related to manufacturing / installation technology, equipment, etc. d) Matters related to inspection and testing methods, records, etc.		

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COMPARISON TABLE X Inspection (1/15)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or
	Section 17.5					Procedure
X. Inspection		Basic Requirement 10	BASIC 8.1 General	BASIC 3.4 Inspection and Testing	Three standards have similar requirements.	No significant Difference; No impact on the MHI QA
A program for inspection of			Control measures	for Acceptance		Manual or Procedure.
activities affecting quality		Inspections required to	concerning inspection and	3.4.1 General		
shall be established and		verify conformance of an	testing shall be established	(1) Inspection and testing		
executed by or for the		item or activity to specified	to verify the conformity to	of specified items, services		
organization performing the		requirements shall be	established requirements	and processes shall be		
activity to verify		planned and executed	for items and services.	conducted using		
conformance with the		Characteristics to be		established acceptance		
documented instructions,		inspected and inspection	8.2 Inspection control	and performance criteria.		-
procedures, and drawings		methods to be employed	A program for	(2) The level of inspection		
for accomplishing the		shall be specified.	inspections shall be	and testing and the degree		
activity. Such inspection		Inspection results shall be	established and	of independence of		
shall be performed by		documented. Inspection for	implemented to verify that	personnel shall be		
individuals other than those		acceptance shall be	the items and services	established.		
who performed the activity		performed by persons	conform to the			
being inspected.		other than those who	specifications, procedures,	3.4.2 Hold Points and		
Examinations,		performed or directly	instructions, and drawings.	Status Indicators		
measurements, or tests of		supervised the work being	(2) Inspections shall be	(1) Administrative controls,		
material or products		inspected.	performed in accordance	such as hold points and		
processed shall be			with inspection procedures,	status indicators, shall be		
performed for each work			etc.	used to preclude the		
operation where necessary			(3) Inspections shall be	bypassing of required		
to assure quality. If		· ·	carried out by people other	inspections and tests.		
inspection of processed			than those who carried out	(2) Any inadvertent use,		
material or products is			ine work subject to	installation or operation of		
impossible or		the state of the s	mspection. The	nems, services and		
disadvantageous, indirect			qualification of the	processes which have not		
control by monitoring		, · ·	actablished when	increations and tests shall		
processing methods,			established when	be provented		
shall be provided Both			(6) The results of the	be prevented.		
inspection and process			inspections and the			
monitoring shall be			indoment of accentance or			
provided when control is			rejection shall be			
inadequate without both If		1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 -	formulated in a document			
mandatory inspection hold		, Ar 1				
noints which require		Supplement 10S-1				
witnessing or inspecting by		Supplementary				
the applicant's designated		Requirements for				
representative and beyond		Inspection				
which work shall not		1 GENERAL			This NOA-1-1994 clause is	See below.
proceed without the		This Supplement provides			a paragraph introducing the	
consent of its designated		amplified requirements for	-	_	additional requirements in	
representative are		inspection of items and		[the Supplementary	
required, the specific hold		activities. It supplements			Requirements. It specifies	
points shall be indicated in		the requirements of Basic			that the Supplementary	
appropriate documents.		Requirement 10 of this Part			Requirements apply when	
		(Part I) and shall be used in			and to the extent specified	
		conjunction with that Basic			by the organization	

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COMPARISON TABLE X Inspection (2/15)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800	ASME NQA-1-1994Edtion	JEAG4101-1993	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or
	Section 17.5	Requirement when and to the extent specified by the organization invoking this Part (Part I).		<u>,</u>	invoking Part 1 of NQA-1-1994.	Procedure
	6. Inspection requirements and acceptance criteria include specified requirements contained in the applicable design documents or other pertinent technical documents approved by the responsible design organization. (NQA-1)	2 INSPECTION REQUIREMENTS Inspection requirements and acceptance criteria shall include specified requirements contained in the applicable design documents or other pertinent technical. documents approved by the responsible design organization. Inspection activities shall be documented and controlled by instructions, procedures, drawings, checklists, travelers, or other appropriate means.	BASIC 8.2 Inspection control (1) A program for inspections shall be established and implemented to verify that the items and services conform to the specifications, procedures, instructions, and drawings. SUPPLE 8.2.2 Inspection procedure, etc. Inspections shall be performed in accordance with procedures, etc. (including instructions and check sheets), which clarify the requirements and acceptance criteria. REF. 8.2.2 Inspection procedures, etc. Items included in the inspection procedures are as follows: a. Items to be inspected, purpose of inspection, and inspection item b. Applicable regulations, codes, and standards c. Inspection method/procedures and recorded items d. Acceptance criteria e. Format of inspection record f. Other necessary provisions	Q4 2.1 Procedures and Instructions (1) Inspection and test procedures/instructions shall be prepared with special attention on criterion for judging, usage, equipment requirements, record requirements, and individual verification requirements. Guidance for procedures and instructions are provided in "this guide (reference matters) Q1(Quality Assurance Program)" 2.2 Grading (1) Safety of the nuclear power plant shall be considered basically when the quality assurance program is applied for items, services, and processes. (2) In application of the quality assurance program, grading may be applied according to the relative importance of items, services or processes for the nuclear power plant. (3) In application of graded approach, differences applied individual components and items shall be clarified at planning stage, and be reflected to quality asurance requirements. (4) In inspection and test activities, examples of applicable graded approach items are provided as follows: a. Necessity of verification of	Three standards have similar requirements. The requirements of NQA-1 are a summary of "Inspection control". JEAG4101-1993 specifies requirements for inspection including detailed procedure items. JEAG4101-2000 has comparable requirements to JEAG4101-1993.	See above.

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COMPARISON TABLE X Inspection (3/15)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	2) JEAG4101-2000	Differences	Assessment of Difference for MHI Manual or Procedure
				b. Training of inspection/ test personnel and qualification c. Necessity of inspection/ test program d. Contents and degree of inspection/ test procedures e. Responsibility for review and approval of inspection/ test documents f. Review of conformity g. Requirements for preparation of records and retention Guidance for graded approach is provided in "this guideline (reference matters) Q1 (Quality Assurance Program) "		
		3 PERSONNEL 3.1 Reporting Independence Inspection personnel shall not report directly to the immediate supervisors who are responsible for performing the work being inspected.	BASIC 2.2 Responsibility and authority An organizational structure with clearly defined functional responsibilities and levels of authority, or assignment of scope of work shall be established to implement quality assurance programmes. The following shall be taken into consideration at the establishment of the organization: a. The fundamental responsibility to attain the required quality resides with the individual or responsible organization who implements the works. b. When verification of conformance to established requirements is necessary, it is implemented by those who do not have direct responsibility for implementing the work. c. The individuals and organizations who verify conformance to the quality of work, and who guide and	BASIC 3.4.1 General (2) The level of inspection and testing and the degree of independence of personnel shall be established. Q4 3.2 Inspector (1) When the qualification of inspector skill such as non-destructive test (examination) is required, the qualification of inspector shall be specified. (2) Check for work control, for example, intermediate check in-process may be conducted by worker oneself. (3) In final inspection/test, degree of independence of inspector shall be specified. BASIC EXP.3-3 Inspection and testing may be implemented by the worker himself, an inspector belonging to the manufacturing section, an	Three standards have similar requirements. JEAG4101-1993 specifies comparable requirements in "Responsibility and authority" to NQA-1. JEAG4101-2000 specifies comparable requirements in qualification of inspector to NQA-1.	No significant Difference; No impact on the MHI QA Manual or Procedure.

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COMPARISON TABLE X Inspection (4/15)

10'CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
			adequate quality assurance programmes for efficient implementation of activities, have the authority necessary to implement these steps.	belonging to quality assurance section, or an inspector belonging to the third party inspection organization. The degree of independence of personnel shall be established considering the proper combination with inspection method such as sampling, witness and confirmation of records.		
	 9. Those activities that require qualified inspection personnel are defined. (NQA-1) 5. Inspections are performed by individuals other than those who performed the activity being inspected. Inspection personnel do not report directly to the immediate supervisors who are responsible for performing the work being inspected. (Only applicable to operational QA programs.) (Approved via SE (Accession No. ML050700416).) 	3.2 Qualification Each person who verifies conformance of work activities for purposes of acceptance shall be qualified to perform the assigned inspection task. Inspections by persons during on-the-job training for qualification shall be performed under the direct observation and supervision of a qualified person and verification of conformance shall be by the qualified person until certification is achieved.	REF. 8.2.3 Inspector (1) Because inspection testing (such as non destructive testing) requires inspector-level skills, inspector qualification is necessary. (2) Work control checks e.g. intermediate checking of the process, can be performed by the worker.	Q4 3.2 Inspector (1) When the qualification of inspector skill such as non-destructive test (examination) is required, the qualification of inspector shall be specified. (2) Check for work control, for example, intermediate check in-process may be conducted by worker oneself. (3) In final inspection/test, degree of independence of inspector shall be specified.	Three standards have similar requirements. In JEAG4101-2000, it is specified that responsibility and authority for inspection personnel shall be assured in the independence.	No significant Difference; No impact on the MHI QA Manual or Procedure.
	3. Provisions to identify inspection hold points, beyond which work is not to proceed without the consent of the inspection organization, are defined. (NQA-1)	4 INSPECTION HOLD POINTS If mandatory inspection hold points are required beyond which work shall not proceed without the specific consent of the designated representative, the specific hold points shall be indicated in appropriate documents. Consent to waive specified hold points shall be recorded prior to continuation of work beyond the designated hold point.	BASIC 8.3 Test control (3) In cases where tests are required at a hold point, the hold point shall be indicated in advance in a suitable document. SUPPLE 8.3.3 Hold point The Hold point should be indicated in proper documents such as procedures, instructions, etc. EX.8-1 "Hold point" is the point beyond which work may	BASIC 3.4.2 Hold Points and Status Indicators (1) Administrative controls, such as hold points and status indicators, shall be used to preclude the bypassing of required inspections and tests. Q4 3.3 Acceptance Inspection, Test (1) Until comparison check with provided requirements will be complete, items (including fabricating materials) and services shall not be proceeded to	Three standards have similar requirements. The requirements of NQA-1 are a summary of test control with hold points, while JEAGS specifies more detailed provisions including the definition of hold points.	No significant Difference; No impact on the MHI QA Manual or Procedure.

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COMPARISON TABLE X Inspection (5/15)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
			not proceed without the approval of specified organizations. "Specified organizations" according to circumstances refers to various organizations, which include the quality assurance division of the plant owner and supplier and official inspection organizations. "The proper document indicating the hold point" means various forms of documents such as specifications, procedures and working control documents.	the next process or be used. [Explanation Q4 - 1] (2) Check shall be conducted according to the appropriate inspection and test programs or procedures. The acceptance inspection and test shall be conducted including the review in agreement with the applied documents.		
	 A program establishes the inspections to be performed (source, in-process, final, receipt, maintenance, modification, in-service, and operations). The inspection program may be implemented by or for the organization performing the activity inspected. (Approved via SE (Accession No. ML050700416).) Provisions to ensure inspection planning is properly accomplished are required to be established. Planning activities are to identify the characteristics and activities inspected, the inspection methods, the acceptance criteria, and the organization responsible for performing the inspection. (NQA-1) 	5 INSPECTION PLANNING 5.1 Planning for inspection activities shall be accomplished and documented. The documentation shall identify characteristics, methods, and acceptance criteria, and shall provide for recording objective evidence of inspection results.	BASIC 8.2 Inspection control (1) A program for inspections shall be established and implemented to verify that the items and services conform to the specifications, procedures, instructions, and drawings. SUPPLE 8.2.1 Inspection program When establishing a programme for inspected, types of inspections, the items to be inspected, types of inspections, method and schedule thereof, etc. should be included as appropriate. REF. 8.2.1 Inspection program The inspection program The inspection program is as follows: a. Items to be : Vessels, piping, pumps and valves, etc. inspected b. Inspection item : Dimensional/visual inspection, pressure test, etc.	Q4 Q4-3.1 3.1 Inspection and testing stage Inspection and testing whether performed by the responsible organization or by supplier, take place at place at three identifiable stage. These are : (1) Receiving inspection and testing, prior to commencement of work (2) In-process inspection/monitoring, during performance of the work Final inspection and acceptance testing, upon completion of the work 3.6 Inspection and test programs shall be prepared and used to control inspection and test items, verification methods and criterion for judging shall be specified in inspection	Three standards have similar requirements. The requirements of NQA-1 are a summary of inspection control or program, while JEAGs describe more detailed requirements including inspection and test items. In JEAG4101-1993, it is specified that adequate inspections shall be executed according to kind or method. JEAG4101-2000 specifies requirements for inspections at identifiable stages.	No significant Difference; No impact on the MHI QA Manual or Procedure.

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COMPARISON TABLE X Inspection (6/15)

1	Standard Review Plan	1)	2)	2)		Assessment of Difference
10 CFR 50 Appendix B	NUREG -0800	ASME NQA-1-1994Edtion	JEAG4101-1993	JEAG4101-2000	Differences	for MHI Manual or
	Section 17.5	l	· · · · · · · · · · · · · · · · · · ·		·	Procedure
			c. Inspection method :	and test programs to confirm		
			100% or sampling	the agreement with		
			inspection, witnessed or	requirements. [Explanation]		ļ j
		*	recorded inspection, etc.	Q4-2]		
			d. Timing of inspection :In	(3) Examples of information		
			process, after fabrication or	to be included in inspection		
			after installation, etc.	and test programs are as		
		į	e. Organization : Pre-use	follows:		
			inspection, etc.	a. Equipment name, item or		
			f. Place of inspection :	system name, reference		
			Supplier, purchaser, etc.	items on contract, document		
		1	g. Kind of inspection :	number, status and general		
			Commercial, model, and	information such as relating		
			annual inspection, etc.	procedures and drawings.		
				b. List of all inspection and		
				test items: all items and		
				services subjected to		
				inspection and test shall be		
				clarified in these programs		
				and referred.		
				c. Procedures, work		
				instructions, specifications or		
				standards (specific part, if		
				applicable) to be related to		
				each operation, inspection		
				or test.		
		n. N		a. Clarification of each		
				e. Clamication of each		
				norronnol and proparation		
				of record to demonstrate		
				that adequately		
				implemented		
				f Identification of hold points		
				that prevent to proceed to		
				next process without		
		r.		approval from the nominated		
		r		organization or person		
) · · ·		g. Requirements for each		
				witnessing of each		
' f				inspection and test or hold		1
				point.		
				h. Record format prepared		
		· ·		for each inspection and test.		
				i. Organization or person		
				authorized to have final		
	ľ			judgment.		
				(4) When it is impossible to		
				inspect after manufacturing,		
				assembling or installation. or		
				requiring another		
				management during		

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COMPARISON TABLE

X Inspection (7/15)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
				process, indirect management such as manufacturing method, equipment or worker skill control shall be provided.		
		5.2. Sampling. Where a sample is used to verify acceptability of a group of items, the sampling procedure shall be based on recognized standard practices.	REF. 8.2.1 Inspection program c. Inspection method : 100% or sampling inspection, witnessed or recorded inspection, etc.	Q4 3.4 Intermediate Inspection, Monitoring (1) In accordance with the inspection and test programs or procedures, items and services shall be identified according to work progrees, and inspection and test shall be performed. (2) Conformity of items and services shall be checked by appropriate process monitoring and control method. (3) Control method shall be established to reserve the items or interrupt the next work process, until required inspection/ test are completed, be reported and verified by the specified person. (4) In order to confirm the adequacy of capability of the work process, as necessary, each stage of process shall be monitored and evaluated. (5) In order to sample, or to evaluate the capability of work process, adequate statistical method may be used. These measures shall be used with fully established principle.	Three standards have similar requirements. JEAG4101-1993 does not have explicit requirements (provisions) for "Sampling procedure". However, it is specified that sampling shall be applied. In JEAG4101-2000, it is specified that adequate statistical method shall be used in order to sample. JEAG4101-2000 specifies a comparable requirement including the usage of method to NQA-1.	No significant Difference; No impact on the MHI QA Manual or Procedure.
		6 IN-PROCESS INSPECTION 6.1 Inspection Inspection of items In-process or under construction shall be performed for work activities where necessary to verify quality. If	SUPPLE 8.2.1 Inspection program When establishing a program for inspections, the items to be inspected, types of inspections, method and schedule thereof, etc. should be included as appropriate.	Q4 3.4 Intermediate Inspection, Monitoring (1) In accordance with the inspection and test programs or procedures, items and services shall be identified according to work progress, and inspection	Three standards have similar requirements, JEAG4101-1993 specifies comparable requirements to NQA-1, while JEAG4101-2000 specifies detailed requirements including work activities such as monitoring or	No significant Difference; No impact on the MHI QA Manual or Procedure.

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COMPARISON TABLE X Inspection (8/15)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
		items is impossible or disadvantageous, indirect control by monitoring of processing methods, equipment, and personnel shall be provided. Both inspection and process monitoring shall be provided when control is inadequate without both.	REF. 8.2.1 Inspection program d. Timing of inspection :In process, after fabrication or after installation, etc.	 (2) Conformity of items and services shall be checked by appropriate process monitoring and control method. (3) Control method shall be established to reserve the items or interrupt the next work process, until required inspection/ test are completed, be reported and verified by the specified person. (4) In order to confirm the adequacy of capability of the work process, as necessary, each stage of process shall be monitored and evaluated. (5) In order to sample, or to evaluate the capability of work process, adequate statistical method may be used. These measures shall be used with fully established principle. 		
				 3.6 Inspection, Test Program (4) When it is impossible to inspect after manufacturing, assembling or installation, or requiring another management during process, indirect management such as manufacturing method, equipment or worker skill control shall be provided. 		
		6.2 Combined Inspection and Monitoring 6.2.1 A combination of inspection and process monitoring methods, when used, shall be performed in a systematic manner to assure that the specified requirements for control of the process and quality of the item are being achieved throughout the duration of		See Q4-3.4 (4), (5)	There are difference between JEAG4101-1993 and NQA-1. JEAG4101-1993 does not have explicit description. In JEAG4101-2000, it is specified that monitoring and sampling shall be applied in parallel as method to verify process or items.	With regard to the "inspection and Monitoring ", inspection activities are clarified and specified in the program including kind of inspections in JEAG4101-1993. No impact on MHI QA Manual or Procedure.

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COMPARISON TABLE X Inspection (9/15)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17 5	ASME NQA-1-1994Edtion	2) JEAG4101-1993	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
		the process: 6.2.2 Controls, where required, shall be established and documented for the coordination and sequencing of these activities at established inspection points during successive stages of the conducted process or construction.				
		7 FINAL INSPECTIONS 7.1 Resolution of Non-conformances Final inspections shall include a records review of the results and resolution of non-conformances identified by prior inspections. The final' inspection shall be planned to arrive at a conclusion regarding conformance of the item to specified requirements.	BASIC 8.2 Inspection control (1) program for inspections shall be established and implemented to verify that the items and services conform to the specifications, procedures, instructions, and drawings. REF. 8.2.1 Inspection program The inspection program as follows: a. Items to be : Vessels, piping, pumps and valves, etc. inspected b. Inspection item : Dimensional/visual inspection, pressure test, etc. c. Inspection method : 100% or sampling inspection, witnessed or recorded inspection, etc. d. Timing of inspection recorded inspection, etc. e. Organization : Pre-use inspection, etc. f. Place of inspection : Supplier, purchaser, etc. g. Kind of inspection : Commercial, model, and annual inspection, etc.	Q4 2.4 Non-conformity Management and Measures to Prevent Recurrence It shall be regarded as non-conformity when inspection/test are not conducted based on requirements, or feature/characteristic are not correspond to the prescribed requirements. Guidance for non-conformity management and the corrective actions is provided in "this guide (reference matters) Q1 (Quality Assurance Program)"	With regard to the requirement, JEAGs do not have explicit description. However, it is specified that inspection results shall be verified as basic requirement.	No significant Difference; No impact on the MHI QA Manual or Procedure.
		7.2 Inspection Requirements Completed items shall be	See above	Q4 3.5 Final Inspection, Test (1) Based on the	Three standards have similar requirements. JEAG4101-1993 specifies	No significant Difference; No impact on the MHI QA Manual or Procedure.

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COMPARISON TABLE X Inspection (10/15)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	2) JEAG4101-1993	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
10 CFR 50 Appendix B	NUREG-0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²¹	JEAG4101-2000 ²¹ procedures, final inspection and test shall be conducted to confirm that all preceding stage inspection/test are completed and prescribed requirements are satisfied. (2) Based on inspection/test programs or procedures, the completed item shall be confirmed to be correspond to prescribed requirements. (3) Items and services shall not be served, until all activities provided in the inspection and test programs are completed. Relating records and documents shall be prepared based on specifications and obtained approval. EX.Q4-2 (1) The examples of items for planning of inspection and test are provided as follows. a. Subjective items : vessel, piping, pump, valves and electric motor, etc. b. Performance items : dimension, visual, pressure test, electric characteristics, operation, performance test, etc. c. Procedure : sampling, inspection with witness, confirmation of record, etc. d. Time schedule : in-service, completion, after installation, test for signle component and	Differences inspection requirements in the program. With regard to JEAG4101-2000, detailed requirements are specified including items and procedures, though the requirements of NQA-1 are a summary of "Final Inspection, Test".	for MHI Manual or Procedure
				system, start-up test, etc. e. Implementation system : inspection, commissioning, etc. f. Location : vendor, plant owner, factory, field, etc.		

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COMPARISON TABLE X Inspection (11/15)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
	Section 17.5.			commercial inspection, type test, periodic inspection, commissioning, periodic test, etc. (2) The examples of requirements which are included in inspection and test are provided as		Pioceable
				a. Items tested, purposes, items for inspection and test b. Regulation, standards, codes c. Method, procedure, record items d. Acceptance criteria e. Results formatting f. Required condition for		
	4. Inspection results are documented by the inspector, reviewed by authorized personnel qualified to evaluate the technical adequacy of the inspection results, and controlled by instructions, procedures, and drawings. (NQA-1)	7.3 Acceptance The acceptance of the item shall be documented and approved by authorized personnel.	BASIC 8.2 Inspection control (3) Inspections shall be carried out by people other than those who carried out the work subject to inspection. The qualification of the inspectors shall also be established when necessary. (6) The results of the inspections and the judgement of acceptance or rejection shall be formulated in a document. REF. 8.2.2 Inspection procedures, etc. d. Acceptance criteria	Q4 3.6 Inspection, Test Program (1) Inspection and test programs shall be prepared and used to control inspection activities, and to record the results of the activities. (3) Examples of information to be included in inspection and test programs are as follows: d. Criterion for judging g. Requirements for each witnessing of each inspection and test or hold point. h. Record format prepared for each inspection and test. i. Organization or person authorized to have final judgment. 3.9 Test Requirements for items and services, as necessary, including test frequency and criterion for judging shall be verified by testing. (1) Test requirements shall	Three standards have similar requirements. In JEAGs, it is specified that the judgment of acceptance shall be documented and approved based on the responsibility and authority.	No significant Difference; No impact on the MHI QA Manual or Procedure.

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COMPARISON TABLE X Inspection (12/15)

10°CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section: 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993	2) JEAG4101-2000	Differences	Assessment of Difference for MHI Manual or Procedure
				be specified including frequency and criterion for judging. Unless otherwise specified, these requirements shall be approved by organization which has responsibility for specification of the tested item or system. (3) The purpose of test shall be defined and specified in the procedure to ensure that premise condition of test is satisfied, adequate equipment is available and properly used, necessary monitoring conducted, and appropriate environmental condition maintained. Test procedures shall, as appropriate, include the following provisions: b. Presence of trained personnel n. Criterion for judging o. Format of report, record, and approval p. Measures when result is (4) Test result shall be documented and evaluated to ensure that the test requirements are satisfied i. Person who evaluated the		
	7. Modifications, repairs, or replacements of items	7.4 Modifications, Repairs, or Replacements	SUPPLE. 9.6.3 Repair work control	Q13 Operation 3.28.9 Review and	Three standards have similar requirements.	No significant Difference; No impact on the MHI QA
	performed subsequent to final inspection require reinspection or retest, as appropriate, to verify acceptability. (NQA-1)	Modifications, repairs, or replacements of items performed subsequent to final inspection shall require re-inspection or retest, as appropriate, to verify acceptability.	 When repair work is to be done to maintain the quality of structures, systems, and components, repair programs should be established and control measures should be specified taking the following into consideration: Review and approval of work which is determined important for safety by relevant organizations (Explanation 9-5) 	verification for inspection results Completed installations and acceptance test results shall be reviewed and verified against the approved design, by the designer, prior to plant acceptance of modified system/component. Acceptance tests shall include specific acceptance criteria based on performance criteria and testing requirements	Three standards have similar requirements. In JEAG4101-1993, it is specified that repair work shall be reviewed and approved based on requirements in inspection program, while In JEAG4101-2000, it is specified that review and verification shall be based on acceptance tests for modified system or component.	Manual or Procedure.

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COMPARISON TABLE X Inspection (13/15)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17,5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
			 b. Procurement control of Items and services c. Identification, handling, and storage to use proper materials and components (including parts) 	specified as part of the modification process.		
		8 INSERVICE INSPECTION 8.1 Planning and Performance Required in-service inspection or surveillance of structures, systems, or components shall be planned and executed by or for the organization responsible for operation.	BASIC 9.6 Maintenance control Maintenance activities such as patrols and checks, periodic inspections, repairs, etc. shall be carried out in accordance with established procedures, etc. (Explanation 9-3) Also, when modification work is to be carried out, it shall be controlled in accordance with the applicable provisions of this guide. SUPPLE 9.6.2 Periodic inspection (1) Periodic inspection programs should be established to verify that the quality of structures, systems, and components is maintained, and control measures should be defined. (2) After completing inspection, the results should be reported to relevant organizations, as necessary. EX.9-3 Periodic inspection plans, inspection procedures, inspection 8 (INSPECTION AND TEST CONTROL).	Q4 5.2 In-Service Inspection, Test (1) Inspection and test during In-service are indispensable to preventive maintenance intending to early detection of potential failure of the items, and provide the judgment data regarding continual operation and lifetime extension for plant. (2) In-service inspection and test shall be performed giving priority to safety related items, in order to ensure that performance is not notably degraded or deviated from design intended condition due to operation. (3) In-service inspection and test shall include routine check and periodic test that plant outage can be required. These inspection and test shall be evalided. (4) In periodical in-service inspection and test activities, operability and reliability of the system shall be evaluated. (5) For the purpose of evaluation, inspection and test results during plant outage shall be recorded using appropriate media such as photograph, video, printout of measuring results by instruments, computer recording etc.	Three standards have similar requirements. The requirements of NQA-1 are a summary of "Maintenance control (93)", or "In-Service Inspection (00)", while JEAGS specify more detailed requirements including samples.	No significant Difference; No impact on the MHI QA Manual or Procedure.
	1	1	•	(6) Results of the in-service		1

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COMPARISON TABLE X Inspection (14/15)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
				inspection shall be promptly reviewed and evaluated. For non-conformity, their root cause shall be investigated. Their causing data shall be trend analyzed using statistical method, as necessary. (7) All in-service inspection and test implemented for operating plant shall be evaluated periodically by plant manager. And, plant manager also shall conduct periodic review of the results. Problems which can have an effect on plant safety operation and necessary to call attention shall be		
		8.2 Methods Inspection methods shall be established and executed to verify that the characteristics of an item continue to remain within specified limits. Inspection methods shall include evaluations of performance capability of essential emergency and safety systems and equipment, verification of calibration and integrity of instruments and verification of maintenance, as appropriate.	See above.	See above	See above.	See above.
	8. Inspection records identify item inspected, date of inspection, the inspector's identity, type of observation, results, or acceptability, and reference to information on action taken in connection with nonconformances. (NQA-1)	9 RECORDS Records shall; as a minimum, identify (a) through (f) below: (a) item inspected (b) date of inspection (c) inspector (d) type of observation (e) results or acceptability (f) reference to information on action taken in	BASIC 8.2 Inspection control (6) The results of the inspections and the judgement of acceptance or rejection shall be formulated in a document. SUPPLE 8.2.6 Inspection results It is desirable to prepare	Q4 3.9 Test (5) Examples of items described in the test records are provided as follows: a. Test procedures and test program to be referred b. Tested items and test stage c. Test date and time d. Equipment and its	Three standards have similar requirements.	No significant Difference; No impact on the MHI QA Manual or Procedure.

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COMPARISON TABLE X Inspection (15/15)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	1) ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
		connection with non-conformances.	formats of records, 8.3.4 Test results It is desirable to prepare formats of records.	calibration condition (as appropriate) e. Test performer and data collector f. Inspection method g. Results and their conformity h. Measures taken for non-conformity i. Person who evaluated the test results		

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COMPARISON TABLE XI Test Control (1/31)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
XI. Test Control A test program shall be established to assure that all testing required to demonstrate that structures, systems, and components will perform satisfactorily in service is identified and performed in accordance with written test procedures which incorporate the requirements and acceptance limits contained in applicable design documents. The test program shall include, as appropriate, proof tests prior to installation, preoperational tests during nuclear power plant or fuel reprocessing plant operation, of structures, systems, and components. Test procedures shall include provisions for assuring that all prerequisites for the given test have been met, that adequate test	1. A test control program is required to be established to demonstrate that items will perform satisfactorily in service. (NOA-1)	Basic Requirement 11 Test Control Tests required to verify conformance of an item or computer program to specified requirements and to demonstrate satisfactory performance for service shall be planned and executed. Characteristics to be tested and test methods to be employed shall be specified. Test results shall be documented and their conformance with acceptance criteria shall be evaluated. Tests required to collect data, such as for sitting or design input, shall be planned, executed, documented, and evaluated.	BASIC 8.3 Test control (1) A program for testing shall be established and executed to verify that the items conform to established requirements. (2) The tests shall be performed in accordance with procedures etc. by suitable persons under suitable persons under suitable persons under suitable persons under suitable persons under suitable denvert (3) In cases where tests are required at a hold point, the hold point shall be indicated in advance in a suitable document. (4) The test results and the judgment of acceptance or rejection shall be formulated in a document,	SI S. Supplemental Information about "INSPECTION AND TESTING FOR ACCEPTANCE" ————————————————————————————————————	Three standards have similar requirements. JEAG4101-1993 8.3 (2) refers to "suitable persons". SRP17.5, 2 refers to "activities that require qualified personnel". SRP17.5, 4 and NQA-1 refer to "trained personnel" as applicable.	Except as noted below, there are no significant Difference; No impact on the MHI QA Manual or Procedure. Qualification test completed under MHI QA Program are re-evaluated to ensure consistency with U.S. standards.

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COMPARISON_TABLE XI Test Control (2/31)

	Standard Review Plan	1)	2)	2)		Assessment of Difference
10 CFR 50 Appendix B	NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²¹	JEAG4101-2000 ²¹	Differences	for MHI Manual or Procedure
				a. Prototype qualification test b. Performance test c. Protest prior to installation d. Installation test e. Commissioning by system f. Operation test Test requirements and criterion for judging shall be specified based on applicable design documents or other relating documents.		
instrumentation is available and used, and that the test is performed under suitable environmental conditions. Test results shall be documented and evaluated to assure that test requirements have been satisfied.		Supplement 11S-1 Supplementary Requirements for Test Control 1 GENERAL This Supplement provides amplified requirements for test control. If supplements the requirements of Basic Requirement 11 of this Part (Part I) and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Part (Part I).			This NQA-1-1994 clause is a paragraph introducing the additional requirements in the Supplementary Requirements. It specifies that the Supplementary Requirements apply when and to the extent specified by the organization invoking Part 1 of NQA-1-1994.	See below.
	 Criteria are defined that specify when testing is required and activities that require qualified test personnel. (NQA-1) The test control program includes, as appropriate, proof tests before installation, preoperational tests, postmaintenance tests, and operational tests. (NQA-1) 	2 TEST REQUIREMENTS Test requirements and acceptance criteria shall be provided or approved by the organization responsible for the design of the item to be tested unless otherwise designated. Required tests, including, as appropriate, prototype qualification tests, production tests, proof tests prior to installation, construction tests, pre-operational tests, and operational tests shall be controlled. Test	REF. 4.4.4 Verification testing In test procedures for verification testing the following are to be described: Design conditions, test conditions, acceptance limits and other conditions such as environmental conditions, test devices, and requirements for data acquisition, etc. SUPPLE 4.4.4 Verification testing (Explanation 4-11) (1) Verification tests should	Q4 3.9 Test (1) Test requirements shall be specified including frequency and criterion for judging. Unless otherwise specified, these requirements shall be approved by organization which has responsibility for specification of the tested item or system. Test includes the followings: a. Prototype qualification test b. production test	Three standards have similar requirements.	No significant Difference; No impact on the MHI QA Manual or Procedure.

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COMPARISON TABLE XI Test Control (3/31)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	1) ASME NQA-1-1994Edtion	2) JEAG4101-1993	2) JEAG4101-2000	Differences	Assessment of Difference for MHI Manual or Procedure
	Section 17.5	acceptance criteria shall be based upon specified requirements contained in applicable design or other. pertinent technical documents.	be implemented in accordance with test procedures. (2) When tests are being implemented on scale models, scaling laws should be verified. (3) In principle, qualification tests should be performed, if possible, under the most adverse conditions for the specific design requirements. Where this is not possible, these may be performed under other conditions provided that the test results can be extrapolated to the most adverse design conditions and the adequacy of the design can be verified for specific requirements. (4) When qualification testing is intended to confirm the adequacy of the design for all design requirements, tests should be carried out under conditions which satisfy all these requirements. Where the testing is intended only to verify specific items, the adequacy of the design for other design requirements should be verified by other means. (5) Verification test results	 c. Protest prior to installation d. Installation test e. Commissioning by system f. Operation test Test requirements and criterion for judging shall be specified based on applicable design documents or other relating documents. (2) Prior to service, adequate computer software test shall be performed. 		Procedure
		; ;	should be evaluated to assure that design requirements have been satisfied.			
			REF. 8.3.1 Test program The test program is as follows: a. Items to be tested : Motors, pumps, valves, etc. b. Test item : elecitric characteristics, performance, characteristic test, etc.			

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COMPARISON TABLE XI Test Control (4/31)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
			c. Test method : 100% or sampling test, witnessed or recorded confirmation, etc. d. Timing of test : Component test, pre-operational testing, start-up testing, etc. e. Organization : Pre-operational testing and start-up testing, etc. f. Place of testing : Factory or site, etc. g. Kind of testing : Pre-operational, start-up, and periodic testing, etc.			
	4. Test procedures are developed that specify the necessary calibrated instrumentation, instructions and prerequisites to perform the test, appropriate equipment, trained personnel, condition of test equipment and the item tested, suitable environmental conditions, acceptance criteria, mandatory test hold points as required, and provisions for data acquisition. (NQA-1)	3 TEST PROCEDURES Test procedures shall include or reference test objectives and provisions for assuring that prerequisites for the given test have been met, that adequate instrumentation is available and used, that necessary monitoring is performed, and that suitable environmental conditions are maintained. Prerequisites shall include the following, as applicable: calibrated instrumentation, appropriate equipment, trained personnel; condition of test equipment and the item to be tested, suitable environmental conditions, and provisions for data acquisition. In lieu of specially prepared written test procedures, appropriate sections of related documents, such as ASTM methods. Supplier manuals, equipment maintenance instructions, or travelers with acceptance criteria, can be used. Such documents shall include adequate instructions to assure the required quality	BASIC 8.4 Calibration and control of measuring instruments and test equipment (1) Methods shall be established for assuring that the measuring instruments and test equipment, etc. used for judging the result of inspections and tests are of the proper ranges, type, accuracy, and precision. (2) The measuring instruments and test equipment shall be calibrated and ad just-ed at specified intervals or before use to maintain necessary accuracy. (3) When the accuracy of the measuring instruments and test equipment is found to be beyond permissible limits, an evaluation shall be made of the validity of inspections or tests after the last calibration, and the acceptance of inspected or tested items shall be reassessed. (4) Control measures shall be established for proper handling, storage, and use of the measuring and test equipment.	Q4 3.9 Test (3) The purpose of test shall be defined and specified in the procedure to ensure that premise condition of test is satisfied, adequate equipment is available and properly used, necessary monitoring conducted, and appropriate environmental condition maintained. Test procedures shall, as appropriate, include the following provisions: a. Properly calibrated measuring and test equipment b. Presence of trained personnel c. Condition of test equipment and tested items d. Appropriate environment e. Data collection system f. Requirements for test and test sequence g. Requirement scope of input parameter h. Identification of required test stage j. Criteria to decide test case j. Requirements for hardware and software combination (integration)	Three standards have similar requirements. SRP17.5, 4 and NQA-1 11S-1, 3 refer to "condition of test equipment". JEAG4101-1993 do not specifically address this.	Except as noted below, there are no significant Difference; No impact on the MHI QA Manual or Procedure. Qualification test completed under MHI QA Program are re-evaluated to ensure consistency with U.S. standards.

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COMPARISON TABLE XI Test Control (5/31)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	1) ASME NQA-1-1994Edtion	JEAG4101-1993	2) JEAG4101-2000	Differences	Assessment of Difference for MHI Manual or Procedure
		of work.	REF. 8.3.2 Test procedures, etc. Items to be included in test procedures are as follows: a. Items to be tested, test item b. Applicable regulations, codes, and standards c. Test methods/ procedures and recorded items d. Acceptance criteria e. Format of test record f. Other necessary provisions	test I. Software validation and performance criteria m. Predicted power n. Criterion for judging o. Format of report, record, and approval p. Measures when result is not acceptable q. Process condition when necessary (including initial condition) r. Cautions and restrictions during test s. Reference documents		
	5. Test results are documented and evaluated by a responsible authority to ensure the test requirements have been satisfied. (NQA-1)	4 TEST RESULTS Test results shall be documented and evaluated by a responsible authority to assure that test requirements have been satisfied	BASIC 8.3 Test control (4) The test results and the judgment of acceptance or rejection shall be formulated in a document. SUPPLE 4.4.6 Documentation of verification results To permit confirmation that the design verification has been properly implemented, design verification results should be documented with the identification of the individuals who have verified and approved, and the date of verification. SUPPLE 8.3.4 Test results It is desirable to prepare formats of records.	Q4 3.9 Test (4) Test result shall be documented and evaluated to ensure that the test requirements are satisfied.	Three standards have similar requirements.	No significant Difference; No impact on the MHI QA Manual or Procedure.
	6. Test records, at a minimum, identify the item tested, date of test, tester or data recorder, type of observation, results and acceptability, action taken in connection with any deviations noted, and person evaluating test	5 TEST RECORDS Test records shall, as a minimum, identify (a) through (g) below: (a) item tested (b) date of test (c) tester or data recorder (d) type of observation (e) results and acceptability	See above	Q4 3.9 Test (5) Examples of items described in the test records are provided as follows: a. Test procedures and test program to be referred b. Tested items and test stage	With regard to JEAG4101-1993, test records are specified in "8.3.2 Test procedures, etc", while JEAG4101-2000 specifies comparable requirements in examples of test records to NQA-1.	No significant Difference; No impact on the MHI QA Manual or Procedure.

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COMPARISON TABLE XI Test Control (6/31)

	Stondard Dovious Dian				<u> </u>	Assessment of Difference
10 CFR 50 Appendix B	NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993	JEAG4101-2000 ²⁾	Differences	for MHI Manual or Procedure
	results. (NQA-1)	(f) action taken in connection with any deviations noted (g) person evaluating test results		c. Test date and time d. Equipment and its calibration condition (as appropriate) e. Test performer and data collector f. Inspection method g. Results and their conformity h. Measures taken for non-conformity i. Person who evaluated the test results		
		Supplement 11S-2 Supplementary Requirements for Computer Program Testing 1 GENERAL This Supplement provides amplified requirements for testing of computer programs and associated computer systems. It supplements the requirements of Basic Requirement 11 of this Part (Part I) and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Part (Part I).		_	This NQA-1-1994 clause is a paragraph introducing the additional requirements in the Supplementary Requirements. It specifies only that the Supplementary Requirements apply when and to the extent specified by the organization invoking Part 1 of NQA-1-1994.	See below.
		2 TEST REQUIREMENTS Test requirements and acceptance criteria shall be provided or approved by the organization responsible for the design or use of the program to be tested unless otherwise designated. Required tests including (as appropriate) verification tests, hardware integration tests, hardware integration tests and in-use tests shall be controlled. Test requirements and acceptance criteria shall be based upon applicable		See Q10 3.1.3 3.1.3 Software Management Q10 3.5.2 3.5.2 Verification Method (1) Verification activities shall be conducted according to the plan. (2) Design verification shall be implemented and documented by individuals or groups with sufficient ability, including the superior of the designer, who are not involved in the designing while these can belong to the same organization as that of the	In JEAG4101-1993, it is recognized that computer program testing can be included in design control because computer software has been used as a design evaluation tool. Therefore, it is recognized that the concept of design verification can be applied for the computer programs such as design analysis code. The requirements of JEAG4101-2000 are generally same as JEAG1993, though software manacements are	Significant Difference; No impact on the MHI QA Manual or Procedure. Because, the requirements for software performance verification in MHI Software Control Procedure are equivalent to NQA-1. The requirement items which shall be verified for design requirements such as computer program flow, variables of calculation models, parameters, and constant value,etc. are specified.

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COMPARISON TABLE XI Test Control (7/31)

10 CER 50 Appendix B	Standard Review Plan	ASME NOA-1-1994Edition	2)	2)	Differences	Assessment of Difference
	Section 17.5			00101-2000	Dincrentes	Procedure
		technical documents.		designer. In conducting the	specified unlike	maintainability of computer
				verification, access to all	JEAG4101-1993.	software with computer
		1		the related information		performance, it is specified
		(shall be ensured. Each		that the division in charge
]			individual responsible for		shall establish software
				checking, verification and		maintenance procedures
	}			approval shall be clearly		such as maintaining
				identified.		software function, security
				(3) various methods may		control to store the
				be employed for design		software and maintain them
				roview use of alternative		manual
		•		calculation and appropriate		manuar.
				test plan. When		
				determining extent of the		
				design verification based		
		2 1		on the graded approach.		
				considerations shall be		
				given to the safety-related		
				importance and complexity]
				of the design as well as the		
				similarity with the		
				previously approved		
		i i i i i i i i i i i i i i i i i i i		design.		
				(4) While it is not required		
				that design verification is		
				the identical structure		
				system or component it		
				shall be verified in each		
				time case that the		
				applicable design		
				requirements are		
		- -		equivalent even in such		
				cases.		
		2.1 Verification Tests		Q10 3.5.3	See above.	Significant Difference; No
		Venfication tests shall		3.5.3 Alternative		impact on the MHI QA
		demonstrate the capability		Calculation		Manual or Procedure.
		or the computer program to		(1) verification of		In MHI Software Control
		test problems		or applysis shall be		itoms are specified as
		encompassing the range of		performed based on the		follows
		permitted usage defined by		comparison with the results		(1) comparison with
		the program		of alternative calculation or		manual calculations
		documentation. Acceptable		analysis.		(2) comparison with the
		test problem solutions are		(2) In conducting		result of other software
		as follows:		alternative calculation.		verified for application
		(a) hand calculations:		review shall be performed		to the similar analysis
		(b) calculations using		to confirm appropriateness		or design.
		comparable proven		of the employed		(3) verification by official
		programs; or		assumptions, design input		organizations
	L	 (c) empirical data and 		data, computer codes and		The requirement items

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COMPARISON TABLE XI Test Control (8/31)

· · · · · · · · · · · · · · · · · · ·	Standard Peview Plan					Assessment of Difference
10 CFR 50 Appendix B	NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	for MHI Manual or Procedure
10 CFR 50 Appendix B	NUREG-0800. Section 17.5	ASME NQA-1-1994Edtion information from technical literature. For programs used for operational control, testing shall demonstrate required performance over the range of operation of the controlled function or process. Depending on the complexity of the computer program being tested, testing may range from a single test of the completed computer program to a series of tests performed at various stages of computer program development to verify correct translation between stages and proper working of individual modules, followed by an overall computer program test. Regardless of the number of stages of testing performed, verification testing shall be sufficient to establish that test requirements are satisfied and that the computer program produces a valid result for its intended function.	JEAG4101-1993	JEAG4101-2000 the other calculation methods. (3) While precisely identical results are not required in the alternative methods, no significant difference that has serious impact on the safety is allowed. Q10 3.5.4 Qualification Test (1) Appropriate qualification test for model or prototype may be performed as design verification. (2) When qualification test is performed with the purpose to verify that the concerned design is appropriate for all the design requirements, the test shall be conducted under the test conditions that satisfy all the design requirements. (3) When test to verify the appropriate ness of design contents is planned, appropriate test under the most adverse design conditions shall be performed concerning the specific design contents to be verified. (4) If a test under the most adverse design conditions. However, if it isn't the case, alternative method for design verification shall be applied. (5) If the verification purpose is executed for the specific design	Lifferences	for MHI Manual or <u>Procedure</u> which shall be verified for design requirements such as computer program flow, variables of calculation models, parameters, and constant value are specified. The design practice in MHI is executed based on the control procedure which is equivalent to NQA-1.
				conducted by other		
				the other design requirements shall be conducted by other methods		

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COMPARISON TABLE XI Test Control (9/31)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section: 17:5	1) ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
				 (6) Qualification test shall be conducted in a test facility based on procedures. The procedures shall be specified for the related requirements and acceptance criteria, and be clearly identified the test configuration of models or prototypes concerned. (7) Test results shall be documented and appropriate staff shall review that all test requirements were satisfied. 		
		2.2 In-Use Tests Test problems shall be developed and documented to permit confirmation of acceptable performance of the computer program in the operating system. Test problems shall be run whenever the computer program is installed on a different computer, or when significant hardware or operating system configuration changes are made. Periodic in-use manual or automatic self-check routines shall be prescribed and performed for those applications where computer failures or drift can affect required performance.		See above	See above.	Significant Difference; No impact on the MHI QA Manual or Procedure. Because, in MHI Software Control Procedure, it is required that the inspections for feasibility, stability, reliability, operability, and maintainability in computer operating system shall be executed. The design practice in MHI is executed based on the control procedure which is equivalent to NQA-1.
		3 TEST PROCEDURES Test procedures or plans shall specify the following, as applicable: (a) required tests and test sequence (b) required ranges of input parameters (c) identification of the stages at which testing is required	· _	See above	See above.	Significant Difference; No impact on the MHI QA Manual or Procedure. Because, in MHI Software Control Procedure, it is specified that inspection method, procedure, and acceptance criteria for computer software verification shall be defined.

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COMPARISON TABLE XI Test Control (10/31)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or
		 (d) criteria for establishing test cases (e) requirements for testing logic branches (f) requirements for hardware integration (g) anticipated output values (h) acceptance criteria (i) reports, records, standard formatting, and conventions 				The design practice in MHI is executed based on the control procedure which is equivalent to NQA-1.
		4 TEST RESULTS Test results shall be documented. Verification test results shall be evaluated by a responsible authority to assure that test requirements have been satisfied.		See above	See above	Significant Difference; No impact on the MHI QA Manual or Procedure. Because, in MHI Software Control Procedure, the documents such as development plan, design specifications and verification report, etc. shall be described. The design practice in MHI is executed based on the control procedure which is equivalent to NQA-1.
		5 TEST RECORDS (a) Verification test records shall identify (1) through (10) below. (1) computer program tested (2) computer hardware used (3) test equipment and calibrations, where applicable (4) date of test (5) tester or data recorder (6) simulation models used, where applicable (7) test problems (8) results and acceptability (9) action taken in connection with any deviations noted (10) person evaluating test results	_	See above	See above	Significant Difference; No impact on the MHI QA Manual or Procedure. Because, in MHI Software Control Procedure, the test records such as inspection method, procedure, acceptance criteria and results etc. in verification test shall be described. The design practice in MHI is executed based on the control procedure which is equivalent to NQA-1.

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COMPARISON TABLE XI Test Control (11/31)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000	Differences	Assessment of Difference for MHI Manual or Procedure
		 (b) In-use test results shall identify (1) through (6) below. (1) computer program tested (2) computer hardware used (3) test equipment and calibrations, where applicable (4) date of test (5) tester or data recorder (6) acceptability Subpart 2.7 Quality Assurance Requirements of Computer Software for Nuclear Facility Applications [See Commitments section below for details.] 				
- -		SUBPART 2.7 Quality Assurance Requirements of Computer Software for Nuclear Facility Applications 1. GENERAL Subpart 2.7 provides requirements for the development, procurement, maintenance, and use of computer software, as applied to the design, construction, operation, modification, repair, and maintenance of nuclear facilities. It supplements the requirements of Part I and shall be used in conjunction with applicable Basic and Supplementary	_	-	In JEAGs, it is recognized that computer program testing can be included in design control because computer software has been used as a design evaluation tool. Therefore, it is recognized that the concept of design verification can be applied for the computer programs such as design analysis code. Judging from the details of JEAGs, it is considered that	In MHI QA manuals (Nuclear Energy Systems Engineering Center QA Manual), the requirements for computer software and computer operating system are specified in "Computer Software Control Procedure (CSCP)" and "Computer Processed Engineering Data Control Procedure (CPEDCP)". With regard to the detailed computer software control

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COMPARISON TABLE X1 Test Control (12/31)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17 5	ASME NQA-1-1994Edtion	JEAG4101-1993	2) JEAG4101-2000	Differences	Assessment of Difference for MHI Manual or Procedure
		Sections of Part I when and to the extent specified by the organization invoking Subpart 2.7.			the comparison between JEAGs and Subpart 2.7 should not be executed.	procedure, the assessment of difference between Subpart 2.7 and MHI QA manual is described as below.
		Subpart 2.7. 1.1 Definitions The following definitions are provided to assure a uniform understanding of terms as they are used in Subpart 2.7 (see Section 13), baseline — software that has been formally reviewed and agreed upon, and that can only be changed through formal change control procedures code ¹ — one or more computer program, or part of a computer program — refer to Part I, Supplement S-1 configuration control — the process of identifying and defining the configuration items in a system, controlling the release and change of these items throughout the system life cycle, recording and reporting the status of configuration item ¹ — a collection of hardware or software elements treated as a unit for the purpose of configuration control error ¹ — a discrepancy between a computed, observed or measured value or condition and the true, specified, or theoretically correct value or condition Portability ¹ — the ease with which software can be				manual is described as below. Explanatory notes such as methods, scope, etc. are described in both control procedures.
		transferred from one computer system or environment to another software ¹ — computer				

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COMPARISON TABLE XI Test Control (13/31)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
	1	programs procedures				
		rules and associated		1	9	
{ 	1	documentation and data			·	1
		pertaining to the operation	}			
		of a computer system				
	1	software life cycle ¹ - the	1			
		period of time that starts				
1		when a software product is)			
		conceived and ends when			{	
(1	the software product is no				
		longer available for routine				
1		use The software life cycle				
		typically includes a				
{	}	requirements phase a				1
i i i i i i i i i i i i i i i i i i i		design phase an				
1	ļ	implementation phase a				
		test phase an installation				
}	1	and checkout phase an				
	1	operation and maintenance				
		phase, and sometimes a				
1	1	retirement phase				1 1
		software quality assurance				1 1
		plan — a plan for the				
		development of software				{ }
1		products necessary to				
ł		provide adequate	1			ł ł
1	4	confidence that the software				
		conforms to established				}
1	1	requirements				
		software validation the				}
1		test and evaluation of the				
(1	completed software to				1
		ensure compliance with				
		software requirements	-			}
		software verification - the				
		process of determining]
1	1	whether or not the product				1
		of a given phase of the				
		software development				1
		cycle fulfills the				
		requirements imposed by				1 (
		the previous phase				
1]	systems software' —) (
	l	software designed for a				I I
	1	specific computer system or				1
	l	tamily of computer systems				
}	1	to facilitate the operation				1 1
1	1	and maintenance of the				1
	1	computer system and		ĺ		1 1
	[associated programs, for				
	1	example, operating		ĺ		1 1
L	L	systems, compilers, utilities				

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10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
	Section 17.5	testing ¹ — the process of exercising or evaluating a system or system component by manual or automated means, to verify that it satisfies specified requirements or to identify differences between expected and actual results test case ¹ — a specific set of test data and associated procedures developed for a particular objective, such as to exercise a particular program path or to verify compliance with a specific requirement test plan ¹ — a document describing the approach to be taken for intended testing activities. The plan typically identifies the items to be tested, the testing to be performed, test sequences, personnel requirements, and evaluation criteria ¹ These definitions have been copied from ANSI/IEEE 729-1983, Glossary of Software Engineering Terminology,				Procedure
		with the permission of IEEE.				
		2 GENERAL REQUIREMENTS 2.1 Applicability The requirements set forth in Subpart 2.7 apply to computer software used to produce or manipulate data which is used directly in the design, analysis, and operation of structures, systems, and components. The application of specific requirements shall be prescribed in plan(s) for software quality assurance and in written policies and	_		_	In CSCP, it is specified that the procedure shall be applied to all software products used for a nuclear plant, as follows. (1) The calculation programs for accident analysis, transient analysis, etc. (2) The programs to generate drawings, data base, etc. The software products widely available and proven in the market are

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XI lest Control (15/31)	
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10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
		procedures.				excluded in "Explanatory Notes". The management for computer software in MHI is executed based on the control procedure which is equivalent to Subpart 2.7.
		3 SOFTWARE LIFE CYCLE This Part (Part II) is based on a software life cycle model similar to IEEE 1012 which illustrates a systematic approach to software development and maintenance. It is not the intent of Subpart 2.7 to endorse, or restrict any particular model, provided it encompasses the activities associated with the representative software life cycle (Figure 3). Software development shall proceed in a traceable, planned, and orderly manner. The number of phases and relative emphasis placed on each phase of software development will depend on the nature and complexity of the software. Software development may be performed in an iterative or sequential manner.			_	In CSCP, it is specified that the procedure shall be established for development, revision, verification, shipping, registration, notice, usage, keeping, disposition and non-conformance control in each stages for the development in "3. Basic Requirements". The management for computer software in MHI is executed based on the control procedure which is equivalent to Subpart 2.7.
		3.1 Requirements Phase During this phase the requirements that the software must satisfy that performance, design constraints, attributes, and external interfaces as outlined in Section 6.2, shall be specified, documented, and reviewed. These	_	_	-	In CSCP, it is specified that development plan such as basic specifications, development system and development process shall be prepared and reviewed by associated division in "5.1 Planning stage". The management for computer software in MHI is executed based on the

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COMPARISON TABLE XI Test Control (16/31)

10 CER 50 Appendix B	Standard Review Plan	ASME NOA-1-1994Edition	2)	(EAC4101-2000)	Differences	Assessment of Difference
	Section 17.5		36764101-1995	JEAG4101-2000		Procedure
		requirements shall define the response of the software to anticipated classes of input data, and shall provide the detail and information necessary to design the software. Requirements phase activities include the preparation of plans for software verification and validation typically called the software verification and validation and				control procedure which is equivalent to Subpart 2.7.
		and validation plan.	[
		3.2 Design Phase During this phase a software design based on the requirements shall be developed, documented, and reviewed. The design shall specify the overall structure (control and data flow), and the reduction of the overall structure into physical solutions (algorithms, equations, control logic, and data structures). The design may necessitate the modification of the requirements documentation. Design phase software verification and validation activities shall consist of: (a) the generation of design-based test cases; and (c) the review of the software design to ensure that the requirements are addressed.		-		In CSCP, it is specified that the design specification for computer software shall be clarified and reviewed, the reason and details for the change shall be documented when the design specifications have been revised in "5.2 Design stage". The management for computer software in MHI is executed based on the control procedure which is equivalent to Subpart 2.7.
1		3.3 Implementation Phase During this phase the design shall be translated into a programming language, and the				In CSCP, it is specified that software shall be developed and revised based on development blan and design

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COMPARISON TABLE XI Test Control (17/31)

10'CFR' 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	1) ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	2) JEAG4101-2000	Differences	Assessment of Difference for MHI Manual or Procedure
		implemented software shall be analyzed to identify and correct errors. Implementation phase software verification activities shall consist of the examination of computer program listings to assure adherence to coding standards and conventions. ² This Figure has been copied from ANSI/IEEE 729-1983, Glossary of Software Engineering Terminology, with the permission of IEEE.	_	_	-	specification in "5.3 Production stage". The management for computer software in MHI is executed based on the control procedure which is equivalent to Subpart 2.7.
		 3.4 Testing Phase During this phase the design as implemented in code shall be exercised by executing the test cases. Failure to successfully execute the test cases shall be reviewed to determine if modifications of the requirements, the design, the implementation, or the test plans and test cases are required. Testing phase activities shall consist of the validation of the code to assure adherence to the requirements, and to assure that the software produces correct results for the test cases. To evaluate technical adequacy, the software test case results can be compared to results from alternative methods, such as: (a) analysis without computer program; (c) experiments and tests; (d) strandard methods. 	-	_	_	In CSCP, it is specified that software shall be verified by reviewers who are not involved in applicable software division in "5.4 Design Verification Stage". The verification methods are concretely specified as follows. (1) Comparison with manual calculation (2) Comparison with the test or the conformable correlation equation (3) Verification by official organizations, etc. The management for computer software in MHI is executed based on the control procedure which is equivalent to Subpart 2.7.

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COMPARISON TABLE XI Test Control (18/31)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17 5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
		with known solutions; or (e) confirmed published data and correlations.				
		See Part 1, Supplement 11S-2 "Supplementary Requirements for Computer Program Testing," for amplified test requirements.				
		3.5 Installation and Checkout Phase During this phase the software becomes part of a system incorporating applicable software components, hardware, and data: The process of integrating the software with applicable components may consist of installing hardware, installing hardware, installing the program, reformatting or creating databases, and verifying that all components have been included. Installation and checkout phase software verification and validation activities shall consist of: (a) the execution of tests for installation and integration; and (b) the documentation of the approval of the software for operational use.		_	_	In CSCP, it is specified that inspection shall be executed for methods, procedure, acceptance criteria, stability/reliability, etc in "5.5 Shipping". The management for computer software in MHI is executed based on the control procedure which is equivalent to Subpart 2.7.
		3.6 Operations and Maintenance Phase Prior to this phase the software has been approved for operational use. Further activity shall consist of maintenance of the software to remove latent errors (corrective maintenance), to respond to new or revised	_			In CSCP, it is specified that inspection shall be executed for operability, maintainability and actual function, etc. in "5.5 Shipping". The management for computer software in MHI is executed based on the control procedure which is equivalent to Subpart 2.7

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COMPARISON TABLE XI Test Control (19/31)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section: 17.5	1) ASME NQA-1-1994Edtion	JEAG4101-1993 ^{2}}	2) JEAG4101-2000	Differences	Assessment of Difference for MHI Manual or Procedure
		maintenance), or to adapt the software to changes in the operating environment (adaptive maintenance). Software modifications shall be approved, documented, verified and validated, and controlled. In-use tests shall be performed in accordance with Supplement 11S-2 of Part I.				
		3.7 Retirement Phase During the retirement phase the support for a software product is terminated, and the routine use of the software shall be prevented.	_	_	—	In CSCP, it is specified that the division in charge shall control for the date, person in charge and reason when the software is removed from service in "5.12 Removal from Service". The management for computer software in MHI is executed based on the control procedure which is equivalent to Subpart 2.7.
		4 SOFTWARE VERIFICATION AND VALIDATION Software verification and validation activities shall: (a) ensure that the software adequately and correctly performs all intended functions; and (b) ensure that the software does not perform any unintended function that either by itself or in combination with other functions can degrade the entire system. Software verification and validation activities shall be planned and performed for each system configuration which may impact the software. The results of software verification and validation activities shall be documented. Software verification and validation.	_	-		In CSCP, it is specified that the review shall be executed for program flow chart and source list, the verification shall be executed based on methods in 3.4 Testing Phase. The management for computer software in MHI is executed based on the control procedure which is equivalent to Subpart 2.7.

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COMPARISON TABLE

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
		shall be performed by individuals other than those who designed the software. ³ , ³ Verification and validation is equivalent to Supplement 3S-1, para. 4				
		4.1 Software Verification Software verification shall be performed during the software development to ensure that the products of a given cycle phase fulfill the requirements of the previous phase or phases.				See above.
		4.2 Software Validation Software validation is performed at the end of the implementation phase to ensure that the code satisfies the requirements. Software validation activities, such as the development of test plans and test cases shall be integrated into each phase of the software life cycle. Testing shall be the primary method of software validation. The validation of modifications shall be subject to selective regression testing to detect errors introduced during the modification of systems or system components, to verify that the modifications have not caused unintended adverse effects, or to verify that a modified system(s) or system component(s) still meets specified requirements.	- , .	_	_	In CSCP, it is specified that the software shall be run across the appropriate range for the variables, parameters and calculation model to validate using "Attached sheet-3". The management for computer software in MHI is executed based on the control procedure which is equivalent to Subpart 2.7.
	- 100-1-110 ⁰ -	5 SOFTWARE CONFIGURATION CONTROL				In CSCP, it is specified that the software version number shall be recorded

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COMPARISON TABLE XI Test Control (21/31)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	1) ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	2) JEAG4101-2000	Differences	Assessment of Difference for MHI Manual or Procedure
		5.1 Configuration Identification A configuration baseline shall be defined at the completion of each major phase of the software development. Approved changes created subsequent to a baseline shall be added to the baseline. A baseline shall define the most recent approved software configuration. A labeling system for configuration. A labeling system for configuration items shall be implemented that: (a) uniquely identifies each configuration item; (b) identifies changes to configuration items by revision; and (c) provides the ability to uniquely identify each configuration of the revised software available for use.	-	_		and software revision shall adequately controlled to prevent the incorrect use, etc. in "5.7 Configuration Control and Revision Control and Revision Control". The management for computer software in MHI is executed based on the control procedure which is equivalent to Subpart 2.7.
		5.2 Configuration Change Control Changes to software shall be formally documented. This documentation shall contain a description of the change, the rationale for the change, and the identification of affected baselines. The change shall be formally evaluated and approved by the organization responsible for the original design, unless an alternate organization has been given the authority to approve the changes. Only authorized changes shall be made to software baselines. Software verification activities shall be performed for the change as necessary to			_	See above.

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COMPARISON TABLE XI Test Control (22/31)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
		ensure the change is appropriately reflected in software documentation, and to ensure that document traceability is maintained. Software validation shall be performed as necessary for the change.				
		5.3 Configuration Status Accounting The information that is needed to manage a configuration shall be documented. This information shall identify the approved configuration, the status of proposed changes to the configuration, the status of approved changes, and information to support the functions of configuration identification, and configuration control.	_	_	_	In CSCP, it is specified that control record shall be prepared for status of every developed or devised software in "5.8 Registration and Notice". The management for computer software in MHI is executed based on the control procedure which is equivalent to Subpart 2.7.
		6 DOCUMENTATION The following sections identify the required documentation for software. 6.1 Plan(s) for Software Quality Assurance A plan(s) for assuring software quality assurance shall be in existence for each new software project at the start of the software life cycle, or for procured software when it enters the purchaser's organization. This plan(s) may be prepared individually for each software project, or may exist as a generic document to be applied to software prepared within or procured by an organization, or may be		_	-	See 3.1.

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COMPARISON TABLE XI Test Control (23/31)

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10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	2) JEAG4101-2000	Differences	Assessment of Difference for MHI Manual or Procedure
		overall quality assurance program. The plan for software quality assurance shall identify: (a) the software products to which it applies; (b) the organizations responsible for performing the work and achieving software quality and their tasks and responsibilities; (c) required documentation; (d) standards, conventions, techniques, or methodologies which shall guide the software development, as well as methods to assure compliance to the same; (e) the required software reviews; and (f) the methods for error reporting and corrective action.				
		 6.2 Software Requirements Documentation Software requirements documentation shall outline the requirements that the proposed software must satisfy. The requirements shall, as applicable, address the following: (a) functionality — the functions the software is to perform; (b) performance — the time-related issues of software operation such as speed, recovery time, response time, etc.; (c) design constraints imposed on implementation phase activities — any elements that will restrict design options; (d) attributes — non-time-related issues of 		-	-	In CSCP, it is specified that the requirements such as performance, stability/reliability and operability shall be included as a inspection report in "5.5 Shipping". The management for computer software in MHI is executed based on the control procedure which is equivalent to Subpart 2.7.

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COMPARISON TABLE XI Test Control (24/31)

	Standard Review Plan			2)	L	Assessment of Difference
10 CFR 50 Appendix B	NUREG -0800	ASME NQA-1-1994Edtion	JEAG4101-1993	JEAG4101-2000 ²¹	Differences	for MHI Manual or
		software operation such as portability, acceptance criteria, access control, maintainability, etc.; and (e) external interfaces — interactions with people, hardware, and other software. An item can be called a software requirement only if its achievement can be verified and validated. Software requirements shall be traceable throughout the remaining stages of the software development cycle.				
		 6.3 Software Design and Implementation Documentation Software design and implementation documentation includes a document or series of documents that shall contain: (a) a description of the major components of the software design as they relate to the software requirements; (b) a technical description of the software with respect to the theoretical basis, mathematical model, control logic, and data structure; (c) a description of the allowable or prescribed ranges for inputs and outputs; (d) the design described in a manner that can be translated into code; and (e) computer program listing(s). 	_	-	_	In CSCP, it is specified that Software Design and Implementation shall be documented as reports for development plan, design specifications, verification and inspection, etc in "5.5 Shipping". The management for computer software in MHI is executed based on the control procedure which is equivalent to Subpart 2.7.
	-	6.4 Software Verification and Validation				See above.
1	1	Documentation		1		

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COMPARISON TABLE XI Test Control (25/31)

10 CFR 50'Appendix B'	Standard Review Plan NUREG -0800 Section 17.5	() ASME NQA-1-1994Edtion	JEAG4101-1993	2) JEAG4101-2000	Differences	Assessment of Difference for MHI Manual or Procedure
		Software verification and validation documentation shall describe the tasks, and criteria for accomplishing the verification of the software in each phase, and the validation of the software at the end of the development cycle. The documentation shall also specify the hardware and software configurations pertinent to the software verification and validation. The documentation shall be organized in a manner that allows traceability to both the software requirements and the software design. This documentation shall also contain the results of the execution of the software verification and validation activities, and shall include the results of reviews and tests, and a summary of the status of the software, e.g., incomplete design performance and application requirements.	_	_		
		 6.5 User Documentation User documentation, as a minimum, shall include: (a) user instructions that contain an introduction, a description of the user's interaction with the software, and a description of any required training necessary to use the software; (b) input and output specifications; (c) input and output formats; (d) a description of system limitations; (e) a description of user messages initiated as a 	-	_	-	In CSCP, it is specified that operating Instruction shall be prepared and revised when the software has been developed or revised in "5.3 Production Stage". The items in operating instruction are as follows. (1) Objective (2) Features and major togic (3) Program structure (4) Customer requirements The management for computer software in MHI is executed based on the control procedure which is equivalent to Subpart 2.7.

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COMPARISON TABLE XI Test Control (26/31)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
		result of improper input and how the user can respond; (f) information for obtaining user and maintenance support.				
		7 VERIFICATION REVIEWS Verification reviews shall identify the participants and their specific responsibilities during the review and in the preparation and distribution of the review documentation. The reviewed documents shall be updated and placed under configuration control. Documentation of review comments and their disposition shall be retained until they are incorporated into the updated software. Comments and their disposition not incorporated shall be retained in accordance with established procedures,		_	_	In CSCP, it is specified that software shall be verified by reviewer who are not involved in applicable software division in "5.4 Design verification stage". The management for computer software in MHI is executed based on the control procedure which is equivalent to Subpart 2.7.
		7.1 Software Requirements Review The review of software requirements shall be performed at the completion of the software requirements documentation. This review shall assure that the requirements are complete, verifiable, consistent, and technically feasible. The review shall also assure that the requirements will result in feasible and usable code.	-	-	_	In CSCP, it is specified that development plan such as basic specifications, development system and development process shall be prepared and reviewed by associated division in "5.1 Planning stage". The management for computer software in MHI is executed based on the control procedure which is equivalent to Subpart 2.7.
		7.2 Software Design Review The software design				In CSCP, it is specified that the design specification for

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COMPARISON TABLE XI Test Control (27/31)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ^{2}}	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
		review shall be held at the completion of the software design documentation. This review shall meet the design verification requirements of Supplement 3S-1 of Part I. This review shall evaluate the technical adequacy of the design approach, and assure internal completeness, consistency, clarity, and correctness of the software design, and shall verify that the software design is traceable to the requirements.	_	_	_	computer software shall be clarified and reviewed, the reason and details for the change shall be documented when the design specifications have been revised in "5.2 Design stage". The management for computer software in MHI is executed based on the control procedure which is equivalent to Subpart 2.7.
		7.3 Development Documentation Review Upon completion of the testing phase (and the installation phase if necessary) the development cycle documentation shall be reviewed and approved to assure completion and acceptability.	_	-	_	In CSCP, it is specified that reports for development plan, design specifications, verification and inspection shall be reviewed and approved in "5.5 Shipping". The management for computer software in MHI is executed based on the control procedure which is equivalent to Subpart 2.7.
		8 PROBLEM REPORTING AND CORRECTIVE ACTION A formal procedure of software problem and corrective action shall be established for software errors, and failures. This problem reporting system shall assure that problems are promptly reported to affected organizations to assure formal processing of problem resolutions. Problems in software may be classified by the organization responsible for the evaluation. Any classification system shall have defined criteria	-	-		In CSCP, it is specified that the control procedures including the corrective actions and recurrence protection shall be established for the developed or updated software in "5.6 Non-conformance Control". The management for computer software in MHI is executed based on the control procedure which is equivalent to Subpart 2.7.

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COMPARISON TABLE

- XI	Test Control	(28/31)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	1) ASME NQA-1-1994Edtion	JEAG4101-1993	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
		based on the impact of the software output. Corrective action by the responsible organization shall assure that. (a) problems are identified, evaluated, documented, and, if required corrected; (b) problems are assessed for impact on past and present applications of the software by the responsible organization; (c) corrections or changes shall be controlled in accordance with Section 5.2; and (d) preventive actions and corrective actions results are provided to affected organizations.				
		9 ACCESS CONTROL To the extent appropriate, controls shall be established to permit authorized and prevent unauthorized access to a computer system.		_	_	In CPEDCP, it is specified that the control procedures including the restrictive use of the system and the reference data shall be established in the computer operating system in "5.7 Security Control System". The management for computer software in MHI is executed based on the control procedure which is equivalent to Subpart 2.7.
		10 PROCUREMENT 10.1 Software Individuals or organizations developing and supplying software shall be required to have policies and procedures that meet the applicable requirements of this Subpart as specified in procurement documents. The documentation that is required by this Subpart shall be delivered or made			_	In CSCP, it is specified that procurement services shall be executed based on "procurement Control Procedure" when the development or modification of software are subcontracted to a vendor in "5.11Procurement Control". The management for computer software in MHI

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COMPARISON TABLE XI Test Control (29/31)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993	JEAG4101-2000, ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
		available by the Supplier to the Purchaser. The applicable requirements of this Subpart shall become the responsibility of the Purchaser upon receipt of software. Typically this software enters the Purchaser's organization at the start of the installation and checkout phase. The Supplier shall report software errors, or failures, to the Purchaser, and the Purchaser shall report software errors to the Supplier.				is executed based on the control procedure which is equivalent to Subpart 2.7.
		10.2 Software Services The organization providing software services, such as verification and validation, shall have a plan(s) for software quality assurance that meets the requirements of this Subpart as specified in procurement documents. The user organization shall determine the adequacy of this plan.		_	-	In Procurement Control Procedure, it is specified that verification procedure shall be defined and the verification shall be executed for the software developed by supplier in "5.5 Inspections and Tests". The management for computer software in MHI is executed based on the control procedure which is equivalent to Subpart 2.7.
		11 SOFTWARE DEVELOPED NOT USING THIS SUBPART Existing software and procured or otherwise acquired software that has not been previously approved under a program consistent with NQA-1 for use in its intended application shall be evaluated in accordance with the requirements of this Subpart. This software shall be uniquely identified and controlled prior to evaluation; and placed under configuration control	~		_	In Subpart 2.7, it is specified that the software which has not been previously approved under NQA-1 shall be evaluated based on Subpart 2.7. The software which is used in MHI has been verified using a comparable CSCP to Subpart 2.7. The management for computer software in MHI is executed based on the control procedure which is equivalent to Subpart 2.7.

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COMPARISON TABLE XI Test Control (30/31)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993	2) JEAG4101-2000	Differences	Assessment of Difference for MHI Manual or Procedure
	· · · · · · · · · · · · · · · · · · ·	prior to use as software				
	}	approved in accordance				
		with this Subpart. The user		· · ·		1 1
		organization shall perform				
	[and document the above				
		evaluation of the software				
	}	to:				
		(a) determine the				1 1
		adequacy to support				
		operation and				}
		maintenance, and				
	1	(b) identify the activities				
		to be performed and the				
		documentation that is				
	1	needed. This				
		determination shall be				
	1	documented and shall				
	1	identify as a minimum:				1 1
]	(1) capabilities and				
		limitations for intended				
		Use; (2) test place and test				
	1	(2) test plans and test				1
		the capabilities within the				
		limitatione and				
		(3) instructions for use				1 1
		within the limits of the				
		canabilities				
		Exceptions from the				
	}	documentation				
		requirements of this				1 1
	ļ	Subpart and the				
		justification for acceptance				
		shall be documented.				
		The results of the above				
	1	evaluation and the				
]	performance of the				
		activities identified by this				
		evaluation shall be				1 1
	1	reviewed and approved.				J
	1	I ne resulting				
		occumentation and				
		associated computer				1 1
	J	the current baseline				1
		Revisions to previously				
		baselined software				1
	1	received from				j l
	1	organizations not required				
	J	to follow this Subpart shall				· · · · · · · · · · · · · · · · · · ·
		be evaluated with this				
	1	Section				1

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COMPARISON TABLE XI Test Control (31/31)

10°CFR' 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
		12 RECORDS Record copies of required documentation shall be retained with other project records as required by codes, standards, specifications, plans or procedures.		_	_	 In CSCP, it is specified that the software control record shall be contain as follows. (1) Software title (2) Brief description of software (3) Design specifications, verification report and operating instructions (4) Follow up history of the software version (5) Applicable machine type, etc. The management for computer software in MHI is executed based on the control procedure which is equivalent to Subpart 2.7

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COMPARISON TABLE XII Control of Measuring and Test Equipment (1/7)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	1) ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
XII. Control of Measuring and Test Equipment Measures shall be established to assure that tools, gages, instruments, and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated, and adjusted at specified periods to maintain accuracy within necessary limits.	1. A program is required to be established to control the calibration, maintenance, and use of measuring and test equipment. (NQA-1)	Basic Requirement 12 Control of Measuring and Test Equipment Tools, gages, instruments, and other measuring and test equipment used for activities affecting quality shall be controlled and at specified periods calibrated and adjusted to maintain accuracy within necessary limits.	BASIC 8.4 Calibration and control of measuring instruments and test equipment (1) Methods shall be established for assuring that the measuring instruments and test equipment, etc. used for judging the result of inspections and tests are of the proper ranges, type, accuracy, and precision. (2) The measuring instruments and test equipment shall be calibrated and ad just-ed at specified intervals or before use to maintain necessary accuracy.	BASIC 3.1.2 Control of Facilities, Equipment and Jigs Facilities, equipment and jigs used for process monitoring, data collection, and inspections and tests shall be of the proper range, type, accuracy and precision. Q4 3.7 Measurement, Test Equipment (1) Tools, gauges, measuring instruments and other measurement test equipment (including test software and tool) which is used to determine item conformity of items and services shall be used with adequate range, type, correctness and accuracy.	Three standards have similar requirements.	No significant Difference; No impact on the MHI QA Manual or Procedure.
		Supplement 12S-1 Supplementary Requirements for Control of Measuring and Test Eauloment				
		1: GENERAL This Supplement provides amplified requirements for control of measuring and test equipment. It supplements the requirements the Basic Requirement 12 of this Part (Part I) and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Part (Part I)	-	-	This NQA-1-1994 clause is a paragraph introducing the additional requirements in the Supplementary Requirements. It specifies that the Supplementary Requirements apply when and to the extent specified by the organization invoking Part 1 of NQA-1-1994.	See below
	2. The types of equipment covered by the program (e.g., instruments, tools,	2 SELECTION Selection of measuring and test equipment shall be controlled to assure that	BASIC 8.4 Calibration and control of measuring instruments and test equipment	Q4 3.7 Measurement, Test Equipment (1) Tools, gauges,	Three standards have similar requirements.	No significant Difference; No impact on the MHI QA Manual or Procedure.

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COMPARISON TABLE

XII Control of Measuring and Test Equipment (2/7)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	() ASME NQA-1-1994Edtion	JEAG4101-1993	2) JEAG4101-2000	Differences	Assessment of Difference for MH/ Manual or Procedure
	gages, reference and transfer standards, and nondestructive examination equipment) are defined. (NQA-1)	such items are of proper type, range, accuracy, and tolerance to accomplish the function of determining conformance to specified requirements.	(1) Methods shall be established for assuring that the measuring instruments and test equipment, etc. used for judging the result of inspections and tests are of the proper ranges, type, accuracy, and precision.	measuring instruments and other measurement test equipment (including test software and tool) which is used to determine item condition and verify the conformity of items and services shall be used with adequate range, type, correctness and accuracy.		
	4. Measuring and test equipment are calibrated, adjusted, and maintained at prescribed intervals or, prior to use, against certified equipment having known valid relationships to nationally recognized standards. If no nationally recognized standards exist, the bases for calibration are documented. (NQA-1)	3 CALIBRATION AND CONTROL 3.1 Calibration Measuring and test equipment shall be calibrated, adjusted, and maintained at prescribed intervals or, prior to use, against certified equipment having known valid retationships to nationally recognized standards. If no nationally recognized standards exist, the bases for calibration shall be documented:	BASIC 8.4 Calibration and control of measuring instruments and test equipment (1) Methods shall be established for assuring that the measuring instruments and test equipment, etc. used for judging the result of inspections and tests are of the proper ranges, type, accuracy, and precision. (2) The measuring instruments and test equipment shall be calibrated and ad just-ed at specified intervals or before use to maintain necessary accuracy. (3) When the accuracy of the measuring instruments and test equipment is found, to be beyond permissible limits, an evaluation shall be made of the validity of inspections or tests after the last calibration, and the acceptance of inspected or tested items shall be reassessed. (4) Control measures shall be established for proper handling, storage, and use of the measuring and test equipment.	Q4 3.7 Measurement, Test Equipment (2) Selection, identification, usage, calibration requirements, and calibration frequency of all measuring and test devices used to determine item qualify and operation condition shall be specified. Management responsibility of measuring and test equipments shall be clarified. Examples of items to be provided are provided as follows: a. Measuring item, required accuracy, and clarification of selection of adequate measuring and test equipments b. Identification, calibration and adjustment of all measuring and test equipment and devices which have an effect on item quality shall be conducted at prescribed interval or before usage, by comparison with the equipment ensured adequacy by nationally or internationally qualified standard are not exist, the standard in written document.	Three standards have similar requirements.	No significant Difference; No impact on the MHI QA Manual or Procedure.

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10 CFR 50 Appendix B	NUREG -0800 Section 17.5	1) ASME NQA-1-1994Edtion	2) JEAG4101-1993	, JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
	When measuring and test equipment is found out of calibration, an evaluation is made and documented of the validity of previous inspection or test results and of the acceptability of items previously inspected or tested. 5. Measuring and test equipment found out of calibration is tagged or segregated and not used until it is recalibrated. If any measuring or test equipment is consistently found out of calibration, it is repaired or replaced. A calibration is performed when the accuracy of the equipment is suspect. (NQA-1)	3.2 Control The method and interval of calibration for each item shall be defined, based on the type of equipment stability characteristics, required accuracy, intended use, and other conditions affecting measurement control. When measuring and test equipment is found to be ² out of calibration, an evaluation shall be made and documented of the validity of previous inspection or test results and of the acceptability of items previously inspected or tested. Out-of-calibration devices shall be tagged or segregated and not used until they have been recalibrated. If any measuring or test equipment is consistently found to be out of calibration, it shall be repaired or replaced: A calibration shall be performed when the accuracy of the equipment is suspect.	BASIC 8.4 Calibration and control of measuring instruments and test equipment (1) Methods shall be established for assuring that the measuring instruments and test equipment, etc. used for judging the result of inspections and tests are of the proper ranges, type, accuracy, and precision. (2) The measuring instruments and test equipment shall be calibrated and ad just-ed at specified intervals or before use to maintain necessary accuracy. (3) When the accuracy of the measuring instruments and test equipment is found to be beyond permissible limits, an evaluation shall be made of the validity of inspections or tests after the last calibration, and the acceptance of inspected or tested items shall be reassessed. (4) Control measures shall be established for proper handling, storage, and use of the measuring and test equipment. SUPPLE 8.4.2 Performance of calibration/adjustment It is desirable to record the results of calibration and adjustment as necessary and indicate the identification of the instruments, and test equipment. REF. 8.4.3 Confirmation of validity In cases where	Q4 3.7 Measurement, Test Equipment (2) Selection, identification, usage, calibration requirements, and calibration frequency of all measuring and test devices used to determine item quality and operation condition shall be specified. Management responsibility of measuring and test equipments shall be clarified. Examples of items to be provided are provided as follows: c. Preparation, documentation and revision/disposal of the calibration procedures, when equipment type, ID number, location, check frequency, check method, criterion for judging, measures and results are not sufficient for the requirement. e. Appropriate indication showing calibration condition or identification of measuring and test equipment by the approved identification record. g. When identified that measuring and test equipment is out of calibration range, review shall be conducted for validity of measurement performed previously and documented. For this purpose, usage history of the measuring equipment and test device shall be recorded, or name and number of measuring equipment which used for recording of inspection and test etc. shall be recorded.	Three standards have similar requirements. The requirements of NQA-1 are summaries of "Control", while JEAGs describe more detailed provisions including samples.	No significant Difference; No impact on the MHI QA Manual or Procedure.

COMPARISON TABLE XII Control of Measuring and Test Equipment (3/7)

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COMPARISON TABLE XII Control of Measuring and Test Equipment (4/7)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
			reinvestigation of acceptance or rejection of items etc. by evaluation of inspection/test validity is required, it is necessary to identify the inspection/test in which the measuring instruments, etc. were used. Methods to control the above include recording the application history of measuring instruments and test equipment, or describing the name and number of measuring instruments, etc. on the inspection/test record.			
	6. Calibration and control measures are not required for rulers, tape measures, levels, and other such devices, if normal commercial equipment provides adequate accuracy. (NQA-1)	3.3 Commercial Devices Calibration and control measures may not be required for rulers, tape measures, levels, and other such devices, if normal commercial equipment provides adequate accuracy.	_	_	JEAG4101 is silent with respect to "commercial devices" as defined in ASME NQA-1-1994.	No significant Difference; No impact on the MHI QA Manual or Procedure.
	and test equipment to perform its intended function are maintained. (NQA-1)	4 HANDLING AND STORAGE Measuring and test equipment shall be properly handled and stored to maintain accuracy.	BASIC 8.4 Calibration and control of measuring instruments and test equipment (4) Control measures shall be established for proper handling, storage, and use of the measuring and test equipment.	Q4 3.7 Measurement, Test Equipment (2) Selection, identification, usage, calibration requirements, and calibration frequency of all measuring and test devices used to determine item quality and operation condition shall be specified. Management responsibility of measuring and test equipments shall be clarified. Examples of items to be provided are provided as follows: i. In usage of calibrated equipment, handling and storage, control to ensure that correctness and adequacy is maintained.	Three standards have similar requirements.	No significant Difference; No impact on the MHI QA Manual or Procedure.

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COMPARISON TABLE

XII Control of Measuring and Test Equipment (5/7)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or
	7. Records of catibration status and the capability of measuring	5 RECORDS Records shall be maintained and equipment shall be suitably marked to indicate calibration status.	SUPPL. 8.4.2 Performance of calibration/adjustment It is desirable to record the results of calibration and adjustment as necessary and indicate the identification of the instruments, and test equipment. REF 8.5.1 Indication of inspection and test status Methods to indicate inspection/test status include marking, tagging, and labeling.	Q4 3.7 Measurement, Test Equipment (2) Selection, identification, usage, calibration requirements, and calibration frequency of all measuring and test devices used to determine item quality and operation condition shall be specified. Management responsibility of measuring and test equipments shall be clarified. Examples of items to be provided are provided as follows: e. Appropriate indication showing calibration condition or identification of measuring and test equipment by the approved identification record. f. Retention of the calibration record of measuring and test equipment.	Three standards have similar requirements. The requirements of NQA-1 are summaries of "RECORDS", while JEAG4101-2000 describes more detailed provisions including samples.	Procedure No significant Difference; No impact on the MHI QA Manual or Procedure.
	3. Measuring and test equipment is labeled, tagged, or otherwise controlled to indicate its calibration status and to ensure its traceability to calibration test data. (Approved via SE (Accession No. ML050700416).)	3.2 Control 5 RECORDS	See above	See above	See above	See above
	8. For procurement of commercial-grade calibration services for safety-related applications, laboratory accreditation programs administered by the National Institute of Standards and Technology and by the American Association for Laboratory Accreditation, as recognized through the mutual recognition arrangement of the				JEAG4101 is silent with respect to "commercial-grade calibration services" as defined in NUREG-0800 Section 17.5.	Significant Difference; No impact on the MHI QA Manual or Procedure. MHI usually perform suppliers audit even if the mentioned conditions are met. To apply this provision or not will be considered later.

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COMPARISON TABLE XII Control of Measuring and Test Equipment (6/7)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	2) JEAG4101-1993	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
	Section 17.5 International Laboratory Accreditation Program (ILAC), are acceptable in lieu of a supplier audit, commercial-grade survey, or in-process surveillance provided that all of the following conditions are met: (Approved via SE (Accession No. ML052710224).) a. The alternative method is documented in the QA program description. b. Accreditation is to ANSI/ISO/IEC 17025, "General Requirements for the Competence of Testing and Calibration Laboratories." c. Use of the alternative method is limited to the National Voluntary Accreditation Program and the American Association for Laboratory Accreditation, as recognized by ILAC signatories.					Procedure
	accreditation covers the contracted services. e. Purchase documents impose additional technical and administrative requirements to satisfy necessary QA program and					
	technical requirements. f. Purchase documents require reporting as-found calibration data when calibrated items are found to be out-of-tolerance. g. Purchase documents require identification of the laboratory equipment/standards used. h. The alternative method is limited to the domention					
	calibration service suppliers. i. The alternative method is					

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| 10 CFR 50 Appendix B | Standard Review Plan
NUREG -0800
Section 17.5 | ASME NQA-1-1994Edtion | 2)
JEAG4101-1993 | JEAG4101-2000 ²⁾ | Differences | Assessment of Difference
for MHI Manual or
Procedure |
|----------------------|--|-----------------------|---------------------|-----------------------------|-------------|--|
| | applicable to subsuppliers
of calibration service
suppliers, provided the
above conditions are met. | | | | | |

COMPARISON TABLE XII Control of Measuring and Test Equipment (7/7)

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XV COMPARISON TABLE Control of Nonconforming Items (1/7)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
XV. Nonconforming Materials, Parts, or Components Measures shall be established to control materials, parts, or components which do not conform to requirements in order to prevent their inadvertent use or installation. These measures shall include, as appropriate, procedures for identification, documentation, segregation, disposition, and notification to affected organizations. Nonconforming items shall be reviewed and accepted, rejected, repaired or reworked in accordance with documented procedures.	1. A nonconforming item (a deficiency in characteristic, documentation, or procedure that renders the quality of an item or activity unacceptable or indeterminate) is properly controlled to prevent its inadvertent test, installation, or use. As appropriate, procedures are used for the identification, documentation, segregation, disposition and notification of the nonconforming items to the affected organizations. (NQA-1)	Basic Requirement 15 CONTROL OF NONCONFORMING ITEMS Items that do not conform to specified requirements shall be controlled to prevent inadvertent installation or use. Controls shall provide for identification, evaluation, segregation when practical, and disposition of nonconforming items, and for notification to affected organizations. Supplement 15S-1 Supplementary Requirements for the Control of Nonconforming Items	BASIC 10.1 General Control measures concerning review and disposition for the identification and disposition thereafter of the non-conforming items or services shall be established to prevent their inadvertent use or receipt in cases where non-conforming items or services such as through the design to operation and maintenance stages. (Explanation 10-1) SUPPLE. 10.2 Identification of non-conformances The following should be taken into consideration to establish control methods for identification of non-conformances: a. Identification methods (a) Marking (b) Tagging (c) Segregation (d) Recording on document sheet (e) Other appropriate methods b. Organization to implement identification markings (including releasing from the non-conforming status after disposition).	Q2 2.1 (1) Management shall establish and maintain a process or processes that provide for identifying, reporting, reviewing and physically controlling items, services or processes that do not conform to specified requirements. (2) It is possible to develop several different processes to control non-conforming items, services or processes such as work defects, event reporting, operating rule breaches, technical specification violations, assessment findings, etc. Each process should make provisions to prevent the inadvertent use or installation of items, services or processes that do not conform and ensure that effective corrective action is taken. Non-conformances should be regarded as opportunities for improvement and as such should be used as an input to the quality improvement process. Management should assign sufficient resources for this purpose. (3) Management should ensure that those performing work are aware of and use the process for prompt notification and reporting of non-conformances. (4) Management at all levels should encourage personnel to discover and report not-conformances. (5) Management should allocate responsibilities so	Three standards have similar requirements.	No significant Difference; No impact on the MHI QA Manual or Procedure.

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COMPARISON TABLE

XV Control of Nonconforming Items (2/7)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
				that the handling of non-conformances is monitored from the time they are identified to verified completion of the agreed corrective action, including providing feedback to those personnel who discovered the non-conformance.		
		1. GENERAL This Supplement provides amplified requirements for the control of nonconforming items. It supplements the requirements of Basic Requirement 15 of this Standard and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking-this Standard.	_	_	This NQA-1-1994 clause is a paragraph introducing the additional requirements in the Supplementary Requirements. It specifies that the Supplementary Requirements apply when and to the extent specified by the organization invoking Part 1 of NQA-1-1994.	See below.
		 2. IDENTIFICATION (a) identification of nonconforming items shall be by marking, tagging, or other. methods which shall, not adversely affect the end use of the item. The identification shall be legible and easily recognizable. (b) If identification of each nonconforming item is not practical, the container, package, or segregated storage area, as appropriate, shall be identified. 	BASIC 10.2 Identification of non-conformances Non-conforming items and services shall be identified by appropriate methods to prevent their inadvertent use or receipt. SUPPLE. 10.2 Identification of non-conformances The following should be taken into consideration to establish control methods for identification of non-conformances: a. Identification methods (a) Marking (b) Tagging (c) Segregation (d) Recording on document sheet (e) Other appropriate methods b. Organization to	Q2 3.4 Identification, Indication As soon as products, services or processes are recognized as being non-conforming, they should be controlled appropriately. The following should be taken into consideration to establish control methods for identification of non-conformances. (1) Identification Methods a. Marking b. Tagging c. Segregation d. Recording on document sheet e. Other appropriate methods (2) Organization to perform the Identification indication (including the release from the non-conformity status after disposition)	Three standards have similar requirements. Three standards specifies requirements for representative identification such as marking, tagging and segregation, etc	No significant Difference; No impact on the MHI QA Manual or Procedure.

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XV Control of Nonconforming Items (3/7)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edition	JEAG4101-1993	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
			implement identification markings (including releasing from the non-conforming status after disposition). REF.10.2 10.2 Identification of non-conformance of services that are difficult to correlate with products shall be identified by recording into reference documents (procedures, etc.) or other documents (reports, eto).	 3.4.1 Marking, Tagging Marking and Tagging are to ensure the followings: (1) Marking, tagging or other information is consistent with the content of the non-conformance report (Refer to Sub-Section 3.2) (2) The inspection, test or operational status of product, services or processes should be clarified (3) The non-conforming status should be clarified both on the products and at any remote operation or indication equipments connected to it. (4) It should be clarified who is authorized to change the status of products, services or processes. (5) Any restrictions on the use of products or services should be identified. 		
		 SEGREGATION (a) Nonconforming items shall be segregated, when practical, by placing them in a clearly identified and designated hold area until properly dispositioned. (b) When segregation is impractical or impossible due to physical conditions such as size, weight, or access limitations, other precautions shall be employed to preclude inadvertent use of a nonconforming item. 	SUPPLE. 10.2 Identification of non-conformances The following should be taken into consideration to establish control methods for identification of non-conformances: a. Identification methods (a) Marking (b) Tagging (c) Segregation (d) Recording on document sheet (e) Other appropriate methods	Q2 3.4.2 Segregation (1) Physical segregation of non-conforming products, services or processes should be considered to ensure that it is not used before any agreed and approved corrective action has been taken. (2) Segregation may be achieved by removal to a secure area, placing, behind barriers, isolating the non-conforming item, or stopping the service or process, or by administrative control. 3.4.3 Others Regarding non-conformance on service, identification should be performed by describing in related	JEAG4101-1993 does not have detailed requirements for segregation, while JEAG4101-2000 species requirements for segregation including applicable condition and activities.	No significant Difference; No impact on the MHI QA Manual or Procedure. With regard to MHI procedure in basic design, it is specified that the information for the non-conformance shall be communicated to the related divisions in order to prevent the impact. It is evaluated that the requirement has comparable effect to segregation.

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XV COMPARISON TABLE Control of Nonconforming Items (4/7)

,	Standard Review Plan	1)	2)	2)		Assessment of Difference
10 CFR 50 Appendix B	NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²¹	JEAG4101-2000 ²	Differences	for MHI Manual or Procedure
				documents (procedures), or recording in the other document (report).		
	2. A nonconforming item is reviewed and accepted, rejected, repaired or reworked in accordance with documented procedures. Further processing, delivery, installation, or use of a nonconforming item is controlled pending an evaluation and an approved disposition by authorized personnel. (NQA-1)	 4. DISPOSITION 4.1 Control Nonconforming characteristics shall be reviewed and recommended dispositions of nonconforming items shall be proposed and approved in accordance with documented procedures. Further processing, delivery, installation, or use of, a nonconforming item shall be controlled pending an evaluation and an approved disposition by authorized personnel 	SUPPLE 10.3.1 Control method for review and disposition The following should be taken into consideration to establish control methods for review and disposition of non-conforming items and services: a. Assignment of review responsibility and the authority to make disposition decisions b. Disposition procedures (a) Preparation of report (b) Reporting format decisions (c) Reporting route and others c. Disposition of items (a) Do not use or receive (b) Use or receive after repair (c) Use or receive as is d. Evaluation of item or service influence on other areas e. Verification after completion of disposition (a) Re-inspection or retesting (b) Review of revised documents, etc.	BASIC 2.3.2 Review and Disposition for Non-conforming Items and Services The disposition for non-conforming items and services shall be decided according to established procedures after evaluating their influence to nuclear safety. The responsibility for review of non-conformances and the authority to dispose of them shall be defined. Q2 3.5.1 Review (1) Non-conformances should be reviewed as soon as practicable by appropriate personnel who should be selected by taking the following into account: a. QA grade or classification of the affected products, services or processes b. Necessity for the safety implications of the non-conformance to be independently reviewed c. Necessity to involve the design information, including any subsequent modifications d. Necessity to involve the operation organization e. Necessity to involve the operation organization	Three standards have similar requirements. JEAG's specify detailed requirements including applicable condition and activities.	No significant Difference; No impact on the MHI QA Manual or Procedure.
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XV Control of Nonconforming Items (5/7)

ι. · ·	Standard Review Plan	P 40			I!	Assessment of Difference
10°CFR 50 Appendix B	NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²¹	Differences	for MHI Manual or Procedure
	3. The responsibility and authority for the evaluation and disposition of nonconforming items are defined. (NQA-1)	4.2 Responsibility and Authority The responsibility and authority for the evaluation and disposition of nonconforming items shall be defined.	BASIC 10.3 Review and disposition for non-conforming items and services (2) The responsibility for review of non-conformances and the authority to dispose of them shall be defined.	BASIC 2.3.2 Review and Disposition for Non-conforming Items and Services The disposition for non-conforming items and services shall be decided according to established procedures after evaluating their influence to nuclear safety. The responsibility for review of non-conformances and the authority to dispose of them shall be defined. Q2 3.5.1 Review (1) Non-conformances should be reviewed as soon as practicable by appropriate personnel who should be selected by taking the following into account: a. QA grade or classification of the affected products, services or processes b. Necessity for the safety implications of the non-conformance to be independently reviewed c. Necessity to involve the design organization or other persons who have access to the original design information, including any subsequent modifications d. Necessity to involve the operation organization e. Necessity to involve the onginal supplier (provider)	Three standards have similar requirements. JEAG4101-1993 has comparable the requirement to NQA-1, while JEAG4101-2000 specifies more detailed requirements including review items.	No significant Difference; No impact on the MHI QA Manual or Procedure.
	evaluations to determine a disposition have	Personnel performing evaluations to determine		(1) Non-conformances should be reviewed as	have explicit requirements	impact on the MHI QA Manual or Procedure
	demonstrated competence	a disposition shall have		soon as practicable by	evaluation, while	With regard to the

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XV Control of Nonconforming Items (6/7)

	Standard Review Plan	1)	2)	2)		Assessment of Difference
10 CFR 50 Appendix B	NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²	JEAG4101-2000 ²¹	Differences	for MHI Manual or Procedure
	in the specific area they are evaluating, have an adequate understanding of the requirements, and have access to pertinent background information. (NQA-1)	demonstrated competence in the specific area they are evaluating, have an adequate understanding of the requirements, and have access to pertinent background information.		appropriate personnel who shall be selected by taking the following into account: a. QA grade or classification of the affected products, services or processes b. Necessity for the safety implications of the non-conformance to be independently reviewed c. Necessity to involve the design organization or other persons who have access to the original design information, including any subsequent modifications d. Necessity to involve the operation organization e. Necessity to involve the original supplier (provider)	JEAG4101-2000 specifies comparable requirements for the personnel evaluation to NQA-1.	qualification of design personnel in MHI, it is specified that he shall be qualified based on experience, skill level and evaluation by the manager.
	 5. The disposition, such as use as-is, reject, repair, or rework, of nonconforming items is identified and documented. Technical justification for the acceptability of a nonconforming item, dispositioned repair, or use as-is is documented. (NQA-1) 7. A nonconformance to design requirements dispositioned as use as-is or repair is subject to design control measures commensurate with those applied to the original design. The as-built records are required, reflect the accepted deviation. (NQA-1) 	4.4 Disposition The disposition, such as use-as-is, reject, repair, or rework, of nonconforming items shall be identified and documented. Technical justification for the acceptability of a nonconforming item, dispositioned repair, or use as is shall be documented. Non-conformances to design requirements dispositioned use as is or repair shall be subject to design control measures commensurate with those applied to the original design. The as-built records, if such records are required, shall reflect the accepted deviation.	SUPPLE 10.3.1 Control method for review and disposition The following should be taken into consideration to establish control methods for review and disposition of non-conforming items and services: a. Assignment of review responsibility and the authority to make disposition decisions b. Disposition procedures (a) Preparation of report (b) Reporting format decisions (c) Reporting route and others c. Disposition of items (a) Do not use or receive (b) Use or receive a fis d. Evaluation of item or service influence on other areas e. Verification after completion of disposition	Q2 3.5.2 Disposition (1) Non-conformity (including procurement items) could be designated in one following ways: (a) "Reject" (also sometimes referred to as Scrap) The non-conforming product, service or process is not fit for the intended use. Such non-conformance should be marked and segregated as soon as the action is agreed and approved. (b) "Repair" The non-conforming item, when repaired (or in the case of documents revised) is capable of functioning in accordance with the design requirements, although it does not fully conform to the original design specification. Temporary repair should have a prescribed period of validity. (c) "Rework"	Three standards have similar requirements.	No significant Difference; No impact on the MHI QA Manual or Procedure.

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XV Control of Nonconforming Items (7/7)

10 CEP 50 Appondix P	Standard Review Plan		2)	2)	Differences	Assessment of Difference
	Section: 17.5	ASIVE NUA-1-1994Edilon	JEAG4101-1993	JEAG4101-2000	Differences	Procedure
			 (a) Re-inspection or retesting (b) Review of revised documents, etc. BASIC 10.3 Review and disposition for non-conforming items and services (3) In cases where non-conforming items and services which do not satisfy requirements for procurement are used or received as is or after significant repair work, their technical adequacy shall be documented and approved by the purchaser. 	The product is capable of being fully restored to the original specification requirements, i.e. some additional rework carried out under suitable conditions will correct the non-conformance. (d) "Accept with conditions" It is likely that the non-conformance products, services and process will be fit for use under special, specified conditions. (e) "Accept without modification" (also sometimes referred to as Use-as-is) It is likely that the non-conforming products, services or process deviates marginally from specified requirements but is still declared fit use. (2) For the significant modifications which require the approval by the purchaser, the scope of modifications should be previously defined between the purchaser and contractor. (3) After completion of the disposition, following verifications should be implemented with the way decided at the review stage: (a) Re-inspection, Retesting (b) Revision of the prepared		
<u> </u>	6. Reworked, repaired, and	4.5 Repaired or Reworked	SUPPLE	See above	Three standards have	No significant Difference;
	replacement items are inspected and tested in accordance with the original inspection and test requirements or specified alternatives. (NQA-1)	Items Repaired or reworked items shall be reexamined in accordance with applicable procedures and with the original acceptance criteria unless the nonconforming item disposition has established alternate acceptance criteria.	 10.3.1 Control method for review and disposition e. Verification after completion of disposition (a) Re-inspection or retesting (b) Review of revised documents, etc. 		similar requirements.	No impact on the MHI QA Manual or Procedure.

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COMPARISON TABLE XVI Corrective Action (1/3)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17 5	ASME NQA-1-1994Edtion	2) JEAG4101-1993	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
XVI. Corrective Action Measures shall be established to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances are promptly identified and corrected. In the case of significant conditions adverse to quality, the measures shall assure that the cause of the condition is determined and corrective action taken to preclude repetition. The identification of the significant condition adverse to quality, the cause of the condition, and the corrective action taken shall be documented and reported to appropriate levels of management.	 A corrective action program is required to be established that includes prompt identification, documentation, classification, and correction of the conditions. The program is to include provisions that ensure that corrective actions are not inadvertently nullified by subsequent actions. (NQA-1) For significant conditions adverse to quality, the cause of the condition shall be determined and corrective actions take to prevent recurrence. These shall be reported to appropriate levels of management and follow-up action taken to verify implementation of corrective actions. (NQA-1) 	Basic Requirement 16 CORRECTIVE ACTION Conditions adverse to quality shall be identified promptly and corrected as soon as practical. In the case of a significant condition adverse to quality, the cause of the condition shall be determined and corrective action taken to preclude recurrence. The identification, cause, and corrective action for significant conditions adverse to quality shall be documented and reported to appropriate levels of management; follow-up action shall be taken to verify implementation of this corrective action.	 BASIC 11.1 General Control measures shall be established to clarify the causes of nonconforming items, and corrective action shall be taken to prevent recurrence and executed. 11.2 Clarification of causes Causes of non-conformances shall be clarified prior to establishing corrective action to prevent recurrence. 11.3 Planning, decision, and execution of corrective action to be taken to prevent recurrence shall be planned, decided, and executed based on the clarified causes. 11.4 Cause and corrective action information Causes of non-conformances and corrective action to prevent recurrence shall be reported to concerned organizations. 	Q2 4.2.1 Planning, Decision, and Performance of Corrective Action Based on the cause of occurrence, necessity of the corrective action should be determined, and when decided to be necessary, then required corrective action should be planned, decided, and executed. In general, the corrective action is determined by the organization which made the decision of the measures for the non-conformance. (1) For the planning, decision, and implementation of corrective action, at least the following should be considered: A. Reflection corrective action on the same type of products (including future and operating plants) B. Reflection on the same type of services (2) In addition, the followings should also be considered, as necessary: A. Reflection on design, procurement, fabrication/installation, inspection/ test, and operation/maintenance procedures, etc. C. Reflection on facilities and equipments (including the withdrawal of defected products) D. Reflection on indoctrination and training (3) Follow-up activities should be performed to ensure that the corrective actions have been implemented	Three standards have similar requirements. The requirements of NQA-1 are summaries of "CORRECTIVE ACTION", while JEAGs describe more detailed provisions.	No significant Difference; No impact on the MHI QA Manual or Procedure.

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COMPARISON TABLE XVI Corrective Action (2/3)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993	JEAG4101-2000, ^{2),}	Differences	Assessment of Difference for MHI Manual or Procedure
		•		(4) Corrective action may not be considered to be completed until all affected documents are reviewed and revised, and the evidence of verification is documented.		
	3. Specific responsibilities within the corrective action program may be delegated, but the applicant or holder maintains responsibility for the program's effectiveness. (ANSI N18.7)				JEAG4101 is silent with respect to "Specific responsibilities within the corrective action program" as described in NUREG-0800.	Significant Difference; No impact on the MHI QA Manual or Procedure, because MHI has established and applied Specific responsibilities within the corrective action program procedure.
	4. The program requires all personnel to identify conditions that are adverse to quality. (ANSI N18.7)			Q2 2.1.1 Management Responsibilities (4) Management should ensure that those performing work are aware of and use the process for prompt notification and reporting of non-conformances. (5) Management at all levels should encourage personnel to discover and report non-conformances.	JEAG4101-1993 is silent with respect to "Management Responsibilities" as described in NUREG-0800.	Significant Difference; No impact on the MHI QA Manual or Procedure, because MHI has established and applied Management Responsibilities procedure.
	5. Reports of conditions that are adverse to quality are analyzed to identify trends in quality performance. Significant conditions and trends adverse to quality are reported to the appropriate level of management. (ANSI N18.7)		REF 11. Actions to Prevent Recurrence 11.1 General It is important to establish and perform corrective action by identifying the causes through examining changes in actual quality results or trends in past non-conformances.	Q2 2.1.1 Management Responsibilities (3) Non-conformances should be regarded as opportunities for improvement and as such should be used an input to the quality improvement process. 4.3 Preventive Action (2) Management should periodically analyze available information, such as non-conformance reports, audit reports, maintenance reports, operating logs, significant event registers, plant safety reviews, etc. This analysis	Three standards have similar requirements. Though there is not clearly described that "Significant conditions and trends adverse to quality are reported to the appropriate level of management" in JEAGS.	No significant Difference; No impact on the MHI QA Manual or Procedure.

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COMPARISON TABLE XVI Corrective Action (3/3)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	1) ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
				should seek out trends in order to identify problem areas requiring root cause analysis, to confirm that appropriate actions have been taken to prevent repetition of the non-conformances and to enhance plant safety and performance. Information on incidents, events or quality related problems available from other nuclear power plants/organizations (operational experience feedback) should be assessed in order that suitable preventive measures can be developed and implemented.		

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COMPARISON TABLE XVII Quality Assurance Records (1/25)

	Standard Review Plan	1)	2)	2)	D'#	Assessment of Difference
10 CFR 50 Appendix B	NUREG -0800 Section 17.5	ASME NQA-1-1994Eduon	JEAG4101-1993	JEAG4101-2000	Differences	Procedure
XVII. Quality Assurance Records Sufficient records shall be maintained to furnish evidence of activities affecting quality. The records shall include at least the following: Operating logs and the results of reviews, inspections, tests, audits, monitoring of work performance, and materials analyses. The records shall also include closely-related data such as qualifications of personnel, procedures, and equipment. Inspection and test records shall, as a minimum, identify the inspector or data recorder, the type of observation, the results, the acceptability, and the action taken in connection with any deficiencies noted. Records shall be identifiable and retrievable. Consistent with applicable regulatory requirements, the applicant shall establish requirements concerning record retention, such as duration, location, and assigned responsibility.	 Measures are required to be established that ensure that sufficient records of completed items and activities affecting quality are appropriately stored. (ANSI N18.7) The program is to provide provisions for the administration, receipt, storage, preservation, safekeeping, retrieval, and disposition of all records. All records must be retrievable, maintained in a readable format, and safeguarded against equipment malfunction or human error. Document access controls, user privileges, and other appropriate security controls must be established. (ANSI N18.7) 	Basic Requirement 17 QUALITY ASSURANCE RECORDS Records that furnish documentary evidence of quality shall be specified, prepared, and maintained. Records shall be legible, identifiable, and retrievable. Records shall be protected against damage, deterioration, or loss. Requirements and responsibilities for record transmittal, distribution, retention, maintenance, and disposition shall be established and documented.	BASIC 12.1 General Control measures for generation, handling, and retention of quality records shall be established to ensure the control of quality records.	BASIC 2.4.3 Preparation of Records relating to personnel and records that describe the status, configuration and characteristics of items and services, describe the performance of processes and represent objective evidence of quality shall be specified, prepared, reviewed, approved and maintained. 2.4.4 Identification, Handling and Storing of Records A records system shall be established to provide for the identification, collection, indexing, filing, storing, maintenance, retrieval and disposal of records. SI 4. Supplemental Information about "DOCUMENT CONTROL AND RECORDS" A records system is established and implemented to ensure that sufficient records are specified, prepared, reviewed, approved and maintained to reflect completed work accurately. For example, records of design, procurement, construction, inspection, testing, operation, maintenance, modification, training, and research and development are typically required. Records that require special processing and	Three standards have similar requirements. The requirements of NQA-1 and JEAG4101-1993 are fundamental description. On the other hand, the description of JEAG4101-2000 describes exemplified requirements of QA records.	No significant difference; No impact on the MHI QA manual or procedure.

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COMPARISON TABLE XVII Quality Assurance Records (2/25)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Editon	2} JEAG4101-1993	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
				control, such as computer codes and software, and information stored on high density media or optical disks, are maintained and controlled to ensure they are readily retrievable and usable. The QA programme addresses both permanent and non-permanent records and defines their respective retention times. Storage facilities for records are maintained.		No significant difference; No impact on the MHI QA manual or procedure.
		Supplement 17S-1 Supplementary Requirements for Quality Assurance Records 1. GENERAL This Supplement provides amplified requirements for quality assurance records. It supplements the requirements of Basic Requirement 17 of this Standard and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Standard. The requirements of this Supplement apply to quality assurance records which have been completed. The term records, used throughout this Supplement, is to be interpreted as Quality Assurance Records.	_	-	This NQA-1-1994 clause is a paragraph introducing the additional requirements in the Supplementary Requirements. It specifies that the Supplementary Requirements apply when and to the extent specified by the organization invoking Part I of NQA-1-1994.	See below
		2. RECORDS ADMINISTRATION 2.1 Records System A records system(s) shall be established by the	BASIC 12.1 General Control measures for generation, handling, and retention of quality records	Q3 4.1 General (1) The plant owner(responsible organization), in accordance	Three standards have similar requirements though JEAG 4101-1993 describes only fundamental	No significant difference; No impact on the MHI QA manual or procedure.

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COMPARISON TABLE XVII Quality Assurance Records (3/25)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edlion	JEAG4101-1993	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
	2. The records system(s) is (are) defined, implemented, and enforced in accordance with written procedures, instructions, or other documentation.	organization responsible at the earliest practicable time consistent with the schedule for accomplishing work activities and in compliance with the general requirements of this Supplement. The records system(s) shall be defined; implemented, and enforced in accordance with written procedures, instructions, or other documentation.	shall be established to ensure the control of quality records.	with the applicable laws, codes, standards, and specifications, shall establish a quality record system to legiblely provide for, prepare, approve, and maintain the quality records, and implement. (2) Responsibility of maintain and managing of the quality record system should be legiblely prescribed and documented. (3) As examples of quality records, there are site investigation, design, construction, commissioning, operation, and decommissioning, and those records include, for example, the followings: A. Results of inspection, tests, review, assessment, monitoring of work performance and material analysis B. Test materials, test piece C. Operation log, training, qualification, and other relating data (4) The quality records should be handled by quality record system as follows: A. categorize B. record of receipt C. makes retrievable condition D. clarifies the retention period by indexing and retains at appropriate location in the quality record facility files E. retains under the controlled environment F. reflecting the actual plant condition, makes correction and supplement	requirement, on the other hand, JEAG 4101-2000 describes more detailed provisions.	
	8. The applicable design specifications, procurement documents, test	The applicable design specifications, procurement documents,	12.2 Generation of quality records (1) When carrying out the	4.3 Evaluation Method(2) Quality Assurance Plan of the prospect supplier	Three standards have similar requirements though JEAG 4101-1993	No significant difference; No impact on the MHI QA manual or procedure.

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COMPARISON TABLE

XVII Quality Assurance Records (4/25)

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10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	2) JEAG4101-2000	Differences	Assessment of Difference for MHI Manual or Procedure
	procedures, operational procedures, or other documents specify the records generated, supplied, or maintained. (NQA-1) 6. The program requires that records be examined for adequacy, legibility and completeness. (NQA-1)	test procedures, operational procedures, or other documents shall specify the records to be generated, supplied, or maintained by or for the Owner. Documents that are designated to become records shall be legible, accurate, and completed appropriate to the work accomplished.	quality assurance programmes, adequate quality records shall be generated. (2) Each quality record shall be such that it can be correlated according to the corresponding item or service.	shall be evaluated. In this evaluation, considerations may be given to the third party qualification (e.g. ISO, ASME, etc.) concerning the scope related to the concerned services.	and JEAG4101-2000 describes only fundamental requirement.	
		2.3 Record Validation Documents shall be considered valid records only if stamped, initialed, or signed and dated by authorized personnel or otherwise authenticated. This authentication may take the form of a statement by the responsible individual or organization. Handwritten signatures are not required if the document is clearly identified as a statement by the reporting individual or organization. These records may be origina1s or reproduced copies.	REF. 12.2.1 Generation of records (1) Information to be described in the records includes the following: a. Necessary information b. All information described in the records is legible c. All information described (2) In addition to the above, the following information is to be described in records: a. Identification number of records b. Names of plants and units, and names of items or services c. Names of organizations that generated the record d. Date, sign, or seal for generation, review, and approval of the record e. Applied codes, standards, or procedures	Q3 4.3.1 Control (1) Quality records (e.g. design specifications, investigation documents, construction procedures, test procedures, operation procedures) should be categorized as one of three categorized submitted to plant owner, or quality records retained for plant owner, and controlled. (2) Quality records should be approved by authorized person. A. approved date by authorized person B. Sealing (stamp) or signature of authorized person or other certification (3) When quality records copied from one media to another different media, some cases become legally ineffective, Quality records should be retained with appropriate media. (4) During retention, for example, copying to maintain image quality etc. adequate control should be controlled. (5) Quality records should be legible, complete, identifiable to the relating	Three standards have similar requirements. JEAG4101-2000 describes specified provision.	No significant difference; No impact on the MHI QA manual or procedure.

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COMPARISON TABLE XVII Quality Assurance Records (5/25)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
				equipment (parts), service or process, and made of appropriate materials to resist deterioration for the required retention period. (6) Selection guidance of retention media for various quality record retention periods is shown in Appendix I.	Three standards have similar requirements. JEAG4101-2000 describes specified provision.	No significant difference; No impact on the MHI QA manual or procedure.
		2.4 Index The records shall be indexed. The indexing: system(s) shall include, as a minimum, record retention times and the location of the record with in the record system.	SUPPLE 12.3.3 Retrieval and access (1) Quality records should be made readily retrievable at storage areas by suitable methods such as indexing, as necessary. (2) It is desirable to ease access to necessary records under access control at the storage area for quality records.	Q3 4.1 General (4) The quality records should be handled by quality record system as follows: A. categorize B. record of receipt C. makes retrievable condition D. clarifies the retention period by indexing and retains at appropriate location in the quality record facility files E. retains under the controlled environment F. reflecting the actual plant condition, makes correction and supplement 4.3.1 Control (7) Quality records should be listed as following index examples: A. Subject, identification name or relating equipment (parts), service or process B. Quality record number C. Plant name and unit name D. Organization or person prepared quality records E. Date, signature or sealing of quality records preparation, review, and approval F. Applicable criteria, standards or procedures	Three standards have similar requirements. JEAG4101-2000 describes fundamental requirement in 4.1(4) and 4.3.1(7).	No significant difference; No impact on the MHI QA manual or procedure.
				G. Retention period H. Retention location in retention place		

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10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	1) ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
				Indexing method should be specified before quality records receipt. Equipment (parts) and relating quality record should be retrievable by indexing.		
		2.5 Distribution The records shall be distributed, handled, and controlled in accordance with written procedures.	BASIC 12.3 Handling of quality records Control measures for the handling of quality records, such as submittal/ receipt, correction/addition, and retrieval/access shall be defined. REF. 12.3.1 Submittal and receipt Upon defining the procedure for submitting or receiving records, the following are to be taken into consideration: a. List of records designated to be submitted b. List of records for submittal or receipt c. Confirmation of submitted or received records	Q3 4.3.3 Submission and Receipt (1) Quality records should be planned (kind, date etc.) submission or receipt and it should be managed to ensure that records are available at the require time. (2) Quality records should be controlled so that complete, legible, and make suitable quality record (form) for retention at receipt. (3) In deciding the procedures of submission or receipt of quality records, the followings should be considered: A. Quality records list designated to be submission B. Quality records list submitted or receipted C. Confirmation of quality records submitted or receipted	Three standards have similar requirements.	No significant difference; No impact on the MHI QA manual or procedure.
		2.6 Identification Records and/or indexing system(s) shall provide sufficient information to permit identification between the record and the item(s) or activity(ies) to which it applies.	REF. 12.2.1 Generation of records (1) Information to be described in the records includes the following: a. Necessary information b. All information described in the records is legible c. All information described in the records is factual (2) In addition to the above, the following information is to be described in records: a. Identification number of records b. Names of plants and units and names of items	Q3 Appendix I . (7) Quality records should be listed as following index examples: A. Subject, identification name or relating equipment (parts), service or process B. Quality record number C. Plant name and unit name D. Organization or person prepared quality records E. Date, signature or sealing of quality records preparation, review, and approval F. Applicable criteria	Three standards have similar requirements though both JEAG4101-1993 and JEAG 4101-2000 specify the requirement of NQA-1. Description of NQA-1 is Conceptual, but JEAG4101-1993 and JEAG4101-2000 specify requirements.	No significant difference; No impact on the MHI QA manual or procedure.

COMPARISON TABLE XVII Quality Assurance Records (6/25)

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COMPARISON TABLE XVII Quality Assurance Records (7/25)

	10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	1) ASME NQA-1-1994Edtion	2) JEAG4101-1993	JEAG4101-2000 ^{2),}	Differences	Assessment of Difference for MHI Manual or Procedure
, .				or services c. Names of organizations that generated the record d. Date, sign, or seal for generation, review, and approval of the record e. Applied codes, standards, or procedures	standards or procedures G. Retention period H. Retention location in retention place Indexing method should be specified before quality records receipt. Equipment (parts) and relating quality record should be retrievable by indexing.		
					 4.3.2 Preparation (4) Quality records should posses the followings: [Explanation Q3 - 4] A. Include necessary information B. Readable all information included C. All information included demonstrate the actual fact (5) Quality records should describe, at the same time, items such as 4.3.1(7). 		
		11. Records are classified as Lifetime or Nonpermanent. Lifetime records are those that meet one or more of the following criteria: (NQA-1) a. significant value in demonstrating capability for safe operation b. significant value in maintaining, reworking, repairing, replacing, or modifying an item c. significant value in determining the cause of an accident or malfunction of an item d. provision of required baseline data for inservice inspections and inservice tests	2.7 Classification Records shall be classified as Lifetime or Nonpermanent by the Owner, or his agent when authorized, in accordance with the criteria given in paras. 2.7.1 and 2.7.2 below.	SUPPLE 12.4 Retention of quality records 12.4.1 Retention period and categories of quality records (1) Quality records should be categorized as 'permanent records' and 'non-permanent records' with their retention periods specified.	Q3 4.2 Categorization of Quality Records (1) Quality records should be categorized as permanent or non-permanent by retention period. Example of retention categorization of quality records is shown in Appendix III, and setting process of retention period is shown in Appendix IV.	Three standards have similar requirements.	No significant difference; No impact on the MHI QA manual or procedure.
			2.7.1 Lifetime Records. Lifetime records are those that meet one or more of the following criteria:	SUPPLE 12.4 Retention of quality records 12.4.1 Retention period and categories of quality	Q3 4.2 Categorization of Quality Records (2) In decision of the retention period, the	Three standards have similar requirements.	No significant difference; No impact on the MHI QA manual or procedure.

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10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
	12. Lifetime records are required to be maintained for the life of the particular item while it is installed in the plant or stored for future use. (NQA-1)	 (a) those which would be of significant value in demonstrating capability for safe operation; (b) those which would be of significant value in maintaining; reworking, repairing, replacing, or modifying an item; (c) those which would be of significant value in determining the cause of an accident or. malfunction of an item; (d) those which provide required baseline data for in-service inspections. Lifetime records are required to be maintained by or for the plant owner for the life of the particular item while it is installed in the plant or stored for future use. 	records (3) Among records with the following retention purposes, those technical records directly necessary in terms of activity or work at stages of operation/ maintenance should be retained as permanent records: a. To demonstrate the capability for safe operation of a nuclear power plant b. To enable routine patrol/checks, periodic inspections or repair of the item c. To enable modification of the item d. To determine the cause of an item's malfunction e. To provide required baseline data for in-service inspection of the item	followings should be considered: A. Purpose of retention B. System/Constitution elements C. Necessity degree D. Verification of final required time E. Retention period F. Requirements on quality records retention by laws and regulations (3) Within the following records, technical records directly required for service and work at the operation/maintenance stage should be considered permanent retention. [Explanation Q3-2] A. Records of equipment at factory shipping B. Records of facility at completion C. Test and commissioning records of facility D. Basic data necessary at in-service inspection E. Records indicating safety operation capability F. Records indicating personnel performance capability G. Records indicating that plant is operated, tested, and inspected according to design requirements and instructions H. Records indicating that plant is maintained its function according to design requirements, maintenance program, and instructions I. Plant performance history to evaluate the design reliability J. Records indicating the perione with statutory and regulatory requirements K. Records for		

COMPARISON TABLE XVII Quality Assurance Records (8/25)

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COMPARISON TABLE XVII Quality Assurance Records (9/25)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ^{2),}	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
				maintenance, re-manufacturing, repair, replace or modification of equipment (parts) L. Records indicating that qualities of initially installed equipment (parts) or replaced equipment (parts) meet the specified requirements M. Records providing information for decommissioning N. Records of inspection results of accidents, failures, non-conformities		
	13. Nonpermanent records are those required to show evidence that an activity was performed in accordance with the applicable requirements but need not be retained for the life of the item because they do not meet the criteria for lifetime records.	2.7.2 Nonpermanent Records. Nonpermanent records are those required to show evidence that an activity was performed in accordance with the applicable requirements but need not be retained for the life of the item because they do not meet the criteria for lifetime records.	REF. 12.4.1 Retention period and categories of quality records (2) When determining the specific retention periods for records classified as non-permanent, the final verification timing for demonstrating the accomplishment of quality assurance activities is to be clarified, and the appropriate retention period is to be determined accordingly.	Q3 4.2 Categorization of Quality Records (5) In order to establish the specific retention period for records categorized as non-permanent quality records, should be clarified the final verification time when the quality records is used to testify the achievement of quality assurance activities, and should be established the retention period correspondingly.	Three standards have similar requirements.	No significant difference; No impact on the MHI QA manual or procedure.
	The retention period for nonpermanent records is established in writing. (NQA-1)	2.8 Retention of Records Records shall be retained in accordance with the above classifications. The retention period for nonpermanent records shall be established in writing.	BASIC 12.4 Retention of quality records The types of quality records and retention periods shall be clarified, and control methods for retention shall be defined. (Explanation 12-1) SUPPLE 12.4.1 Retention period and categories of quality records (1) Quality records should be categorized as 'permanent records' and 'non-permanent records'	Q3 4.2 Categorization of Quality Records (1) Quality records should be categorized as permanent or non-permanent by retention period. Example of retention categorization of quality records is shown in Appendix III, and setting process of retention period is shown in Appendix IV.	Three standards have similar requirements.	No significant difference; No impact on the MHI QA manual or procedure.

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COMPARISON TABLE XVII Quality Assurance Records (10/25)

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10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	2} JEAG4101-2000	Differences	Assessment of Difference for MHI Manual or Procedure
			with their retention periods specified.			
	17. Records are corrected in accordance with procedures which provide for appropriate review or approval by the originating organization. The correction includes the date and the identification of the person authorized to issue such correction.	2.9 Corrected Information in Records Records may be corrected in accordance with procedures which provide for appropriate review or approval by the originating organization. The correction shall include the date and the identification of the person authorized to issue such correction.	SUPPLE 12.3.2 Correction and addition of quality records When records are to be corrected or added, this should be done in accordance with appropriate procedures by the organization which originated the records. REF. 12.3.2 Correction and addition of quality records (1) Upon defining the procedure for correcting or adding records, the following are to be taken into consideration: a. Retaining the original information which caused the corrections or additions b. Handling of the original records which have been subjected to correction or addition c. Indication of the date and name of organization that performed the correction or addition (2) When the correction or addition the organization the impossible, another appropriate organization may correct or add the records.	Q3 4.3.4 Amendment/Addition (1) Approval for amendment/addition of quality records should be provided by original organization or by designated authorized organization or person. (2) In deciding the procedures of amendment/addition, the followings should be considered: A. Retention of information caused of amendment/addition of quality records B. Dealing of initial quality records subjected of amendment/addition of quality records C. Description of organization name and name of person to be carried out amendment/addition of quality records and date.	Three standards have similar requirements.	No significant difference; No impact on the MHI QA manual or procedure.
		3. RECEIPT 3.1 Responsibility The individual or organization responsible for receiving records shall provide protection from damage or loss during the time that the records are in their possession.	SUPPLE 12.3.1 Submittal and receipt It is desirable to clarify the types of subject records when submitting or receiving quality records. REF. 12.3.1 Submittal and receipt	Q3 4.3.3 Submission and Receipt (1) Quality records should be planned (kind, date etc.) submission or receipt and it should be managed to ensure that records are available at the require time. (2) Quality records should	Three standards have similar requirements. The gist of each description is equal.	No significant difference; No impact on the MHI QA manual or procedure.

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COMPARISON TABLE XVII Quality Assurance Records (11/25)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	1) ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
			Upon defining the procedure for submitting or receiving records, the following are to be taken into consideration: a. List of records designated to be submitted b. List of records for submittal or receipt c. Confirmation of submitted or received records	be controlled so that complete, legible, and make suitable quality record (form) for retention at receipt.		
	 18. The person or organization responsible for receiving the records is designated. This designee is responsible for organizing and implementing a system of receipt control of records for permanent and temporary storage 19. At a minimum, a receipt control system includes the following: (NQA-1) a. a method for designating the required records b. a method for identifying records received c. procedures for receipt and inspection of incoming records d. a method for submittal of completed records to the storage facility without unnecessary delay 	 3.2 Receipt Control Each organization responsible for the receipt of records shall designate a person or organization responsible for receiving the records. The designee shall be responsible for organizing and implementing a system of receipt control of records for permanent and temporary storage. As a minimum, a receipt control system shall include the following: (a) a method for designating the required records; (b) a method far identifying records received; (c) procedures for receipt and inspection of incoming records; (d) a method for submittal of completed records to the storage facility without unnecessary delay. 	REF. 12.3.1 Submittal and receipt Upon defining the procedure for submitting or receiving records, the following are to be taken into consideration: a. List of records designated to be submitted b. List of records for submittal or receipt c. Confirmation of submitted or received records	Q3 4.1 General (2) Responsibility of maintain and managing of the quality record system should be legiblely prescribed and documented. 4.2 Categorization of Quality Records (4) Within permanent quality records, the quality records of special items should be retained and maintained by plant owner or contractor, at least until the items are removed/disposed. (5) In order to establish the specific retention period for records categorized as non-permanent quality records, should be clarified the final verification time when the quality records is used to testify the achievement of quality assurance activities, and should be established the retention period correspondingly. 4.3.3 Submission and Receipt (3) In deciding the procedures of submission or receipt of quality records, the followings should be considered:	Three standards have similar requirements. JEAG4101-1993 describes the fundamental requirement of NAQ-1.	No significant difference; No impact on the MHI QA manual or procedure.

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COMPARISON TABLE XVII Quality Assurance Records (12/25)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
				A. Quality records list designated to be submission B. Quality records list submitted or receipted C. Confirmation of quality records submitted or receipted		
	20. Each receipt control system is structured to permit a current and accurate assessment of the status of records during the receiving process. (NQA-1)	3.3 Status Each receipt control system shall be structured to permit a current and accurate assessment of the status of records during the receiving process.	REF. 12.3.1 Submittal and receipt Upon defining the procedure for submitting or receiving records, the following are to be taken into consideration: a. List of records designated to be submitted b. List of records for submittal or receipt c. Confirmation of submitted or received records	Q3 4.3.3 Submission and Receipt (3) In deciding the procedures of submission or receipt of quality records, the followings should be considered: A. Quality records list designated to be submission B. Quality records list submitted or receipted C. Confirmation of quality records submitted or receipted	NQA-1 description is conceptual while JEAGs indicate specified control requirements.	No significant difference; No impact on the MHI QA manual or procedure.
		 4. STORAGE, PRESERVATION, AND SAFEKEEPING 4.1 Storage The records shall be stored in predetermined location(s) that meet the requirements of applicable standards, codes, and regulatory agencies. Prior to storage of records, a written storage. procedure shall be prepared and responsibility assigned for enforcing the requirements of that procedure. This procedure shall include, as a minimum, (a) through (g) below: (a) description of the storage facility; (b) the filing system to be 	REF. 12.4.2 Storage The following are to be taken into account for storage facility features: a. Location of facilities, type, structure, etc. b. Prevention of flooding c. Ventilation and temperature/humidity d. Fire protection BASIC 12.4 Retention of quality records The types of quality records and retention periods shall be defined, (Explanation 12-1) SUPPLE 12.4.2 Storage (1) Quality records should	Q3 4.4 Requirements for Retention (1) Plant owner should establish the requirements for retention methods and retention locations in order to maintain, retain, and protect the quality records and relating test materials/test piece over period from receipt to disposition. (2) Quality record retention system should be included, for example, the followings: [Explanation Q3 - 5] A. Description of retention facility records; Example of retention facility is shown in Appendix II. B. Filling method to be used C. Method to confirm that receipted quality records	Three standards have similar requirements. The gist of each description is nearly equal.	No significant difference; No impact on the MHI QA manual or procedure.

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COMPARISON TABLE XVII Quality Assurance Records (13/25)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	2) JEAG4101-2000	Differences	Assessment of Difference for MHI Manual or Procedure
		 (c) a method for verifying that the records received are in agreement with the transmittal document and that the records are legible; (d) a method of verifying that the records are those designated (see para. 3.2 above) (e) the rules governing access to and control of the files; (f) a method for maintaining control of and accountability for records removed from the storage facility; (g) a method of riling supplemental information (see para. 2.9 above) and disposing of superseded records. 	as to prevent deterioration or loss. (2) It is desirable to difine procedures including the following, prior to storing records in a storage area: a. Records configuration for storage and their retention periods (Explanation 12-3) b. Collating of records and list of retained records c. Personnel access control to storage area d. Filing of corrected or added records and disposition methods for obsolete records e. Control of removed records from storage area 12.4.3 Transfer of quality records When transferring records, transfer methods should be clarified. 12.4.4 Disposition of quality records The organization responsible for records retention should define the procedures for disposition. To encourage smooth operation, it is desirable to dispose of non-permanent records after specified retention periods.	(delivery) and the quality records are in good conditions. D. Method to compare that quality records consist with retrieval E. Rule of access to file and file control F. Method to control of quality records retrieved from retention facility and responsibility G. Method to file information of amendment/addition and to repeal or dispose of replaced quality records H. Periodic checking to confirm that quality records H. Periodic checking to confirm that quality records are not damaged, degraded, or missed At the checking of quality records, the followings should be taken into consideration: A. Retention condition of quality records is appropriate B. Retained in appropriate place C. Quality records retention area is in good condition (3) Capability to read data shall be maintained to prevent that old data		
		 4.2 Preservation. Records shall be stored in a manner approved by the organization or organizations responsible for storage. In order to preclude deterioration of the records, the requirements of (a) through (c) below shall apply. (a) Provisions shall be 	REF. 12.4.2 Storage The following are to be taken into account for storage facility features: a. Location of facilities, type, structure, etc. b. Prevention of flooding c. Ventilation and temperature/humidity d. Fire protection 12.4.3 Transfer of quality	Q3 4.4 Requirements for Retention (4) Quality records should be retained the method which allow prevent the damage, deterioration or missing. Examples of retention methods for various retention media are shown in Appendix II . (5) Paper made quality records should be kept in	Three standards have similar requirements. The gist of each description is nearly equal.	No significant difference; No impact on the MHI QA manual or procedure.

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COMPARISON TABLE XVII Quality Assurance Records (14/25)

	Oten dend Device Dien	1				Assessment of Difference
10 CFR 50 Appendix B	NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ^{2),}	Differences	for MHI Manual or Procedure
		 made in the storage arrangement to prevent damage from moisture, temperature, and pressure. (b) Records shall be firmly attached in binders or placed in folders or envelopes for storage in steel file cabinets or on shelving in containers. (c) Provisions shall be made for special processed records (such as radiographs, photographs, negatives, microform, and magnetic media) to prevent damage from excessive light, stacking, electromagnetic fields, temperature, and humidity. 	records Upon transferring records, the following are to be taken into account: a. Name of organization or place to receive transferred records b. List of records to be transferred c. Identifying the configuration of the records to be transferred (original, reproduced copy, microfilms, etc.) d. Collating transferred records EX.12.3 (1) When selecting a configuration to retain quality records, the following are to be taken into consideration: a) Retained of originals a. Recording methods are to be legible, not deteriorated, nor discolored b. Each record is to have identification such as record number and page number c. Records are to carry the name of the issuing organization, personal seal, or signature of the generator, reviewer, and approver d. Control to prevent inadvertent correction b) Retained as reproduceable copies (copy, microfilm, electronic/optical media) a. Duplicating no more or no less information than that included in the original, and reproducing similar information b. Control to prevent inadvertent correction or deletion	shelf or packaging box by binder, or retention holder or envelope. Steel cabinet or strong safety box is desirable. (6) Quality records prepared with specific method should be retained in accordance with recommended method described in manufacturer's instructions, as well as meet the applicable criteria. Examples of quality records prepared with specific method are as follows: Radiation film, Photograph, Micro-film, Magnetic-tape, Micro-diskette, Laser-disk, and quality records sensitive to light, pressure, humidity, magnetic field, dust, temperature etc.		

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COMPARISON TABLE XVII Quality Assurance Records (15/25)

	Standard Review Plan	1)-	2)	2)		Assessment of Difference
10 CFR 50 Appendix B	NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993	JEAG4101-2000	Differences	for MHI Manual or Procedure
			c. Periodic renewal taking the media's validity period into consideration (2) The attached Table 7 shows considerations for use of duplicates.			
		4.3 Safekeeping : Measures shall be established to preclude the entry of unauthorized personnel into the storage area. These measures shall guard against larceny and vandalism. Measures shall be taken to provide for replacement, restoration, or substitution of lost or damaged records.	SUPPLE 12.3.3 Retrieval and access (2) It is desirable to ease access to necessary records under access control at the storage area for quality records.	Q3 4.3.5 Retrieval and access (2) Although, during retention period, quality records are accessible at any time, however, access to retention area should be controlled.	NQA-1 describes requirement as "Safekeeping", while JEAGs describe it among other requirements or indicate it by specifying requirements.	No significant difference; No impact on the MHI QA manual or procedure.
		 4.4 Storage Facilities Records shall be stored in facilities constructed and maintained in a manner which minimizes the risk of damage or destruction from the following: (a) natural disasters-such as winds, floods, or fires; (b) environmental conditions such as high and low temperatures and humidity; (c) infestation of insects, mold, or rodents. There are two satisfactory methods of providing storage facilities, single or dual. 	REF. 12.4.2 Storage The following are to be taken into account for storage facility features: a. Location of facilities, type, structure, etc. b. Prevention of flooding c. Ventilation and temperature/humidity d. Fire protection	Q3 4.4 Requirements for Retention (7) Quality record retention facility should be the facility which protect from failure and damage by fire, flood, insect, rodent animal (rat etc.) and prevent deterioration from bad environment by light, temperature, humidity. (8) In installation of retention facility, the following features should be taken into consideration as additional factors: A. Location and security B. Structural feature and building structure including interior finish C. Piping layout and drain D. Ventilation, temperature, and humidity control E. Fire protection, fire detection, and fire fighting F. Electromagnetic protection (9) When it is impossible to attable the expression	The requirements of NQA-1 and JEAG4101-2000 are similar. JEAG4101-1993 describes the basic requirements only and does not refer to dual storage facility.	MHI adopts dual storage facility in Yokohama and Kobe. Significant Differences; No impact on MHI procedure, because MHI has manuals, such as "Control Manual of Security for Electronic Information", "Control Manual of Access to Information Resource", "Emergency Response Manual of Information System", specifies basic requirements.

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COMPARISON TABLE XVII Quality Assurance Records (16/25)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
				retention conditions, retention of one set copy of quality records in the separate facility should be taken into consideration. In this case, locations and building structures of both facilities should be taken into attention so that the possibility of occurrence of quality records damage, missing, and degradation at a same time would be sufficiently low enough. (See above)		
		 4.4.1 Single Storage Facility. Design and construction of a single record storage facility shall meet the criteria of (a) through (i) below: (a) reinforced concrete, concrete block, masonry, or equal construction; (b) floor and roof with drainage control. if a floor drain is provided, a check valve.(or equal) shall be included. (c) doors, structure and frames, and hardware 	REF. 12.4.2 Storage The following are to be taken into account for storage facility features: a. Location of facilities, type, structure, etc. b. Prevention of flooding c. Ventilation and temperature/humidity d. Fire protection EX.12-3 (1) When selecting a configuration to retain quality records, the following are to be taken into consideration: a) Retained of originals	Q3 Annex-II (See attached papers)	NAQ-1 and JEAG4101-2000 describe detailed requirements, but JEAG4101-1993 describes the basic requirements only.	MHI adopts dual storage facility in Yokohama and Kobe. Significant Differences; No impact on MHI procedure. MHI's manuals, such as "Control Manual of Security for Electronic Information", "Control Manual of Access to Information Resource", "Emergency Response Manual of Information System", specifies basic requirements.
		 snair be designed to comply with the requirements of a minimum 2 hr fire rating; (d) sealant applied over walls as a moisture or condensation barrier; (e) surface sealant on floor providing a hard wear surface to minimize concrete dusting; (f) foundation sealant and provisions for drainage; (g) forced air circulation with filter system; (h) fire protection system; 	a. recording methods are to be legible, not deteriorated, nor discolored b. Each record is to have identification such as record number and page number c. Records are to carry the name of the issuing organization, personal seal, or signature of the generator, reviewer, and approver d. Control to prevent inadvertent correction b) Retained as reproduceable copies (copy, microfilm, electronic/optical		Both JEAG4101-1993 and JEAG4101-2000 describe the basic requirement only and does not have specified provisions for storage facility.	MHI adopts dual storage facility in Yokohama and Kobe. No Significant Differences; No impact on MHI procedure. MHI's manuals, such as "Control Manual of Security for Electronic Information", "Control Manual of Access to Information Resource", "Emergency Response Manual of Information System", specifies basic requirements.

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COMPARISON TABLE XVII Quality Assurance Records (17/25)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	1) ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000	Differences	Assessment of Difference for MHI Manual or Procedure
		 (i) only those penetrations used exclusively for fire protection, communication, lighting, or temperature/ humidity control are allowed; all such penetrations shall be sealed or dampened to comply with the minimum 2 hr fire protection rating. The construction details shall be reviewed for adequacy of protection of contents by a person who is competent in the technical field of fire protection and fire extinguishing. If the storage facility is located within a building or structure, the environment and construction of that building can provide a portion or all of these criteria. 	media) a. Duplicating no more or no less information than that included in the original, and reproducing similar information b. Control to prevent inadvertent correction or deletion c. Periodic renewal taking the media's validity period into consideration (2) The attached Table 7 shows considerations for use of duplicates. (Explanation 12-4): "Particular item describe" in this sentence means any item which is important to safety and that which has been pre-determined between the plant owner and the supplier. This item also includes their spare parts.			
		 4.4.2 Alternate Single Storage Facility. The following are acceptable alternatives to the criteria of para.4.4.1 above for a single storage facility. (a) 2 hr fire rated vault meeting NFPA 232-1986 or NFPA 232AM-1986 or both;¹ (b) 2 hr fire rated Class B file containers meeting the requirements of NFPA 232-1986 or NFPA 232AM-1986 or both;¹ or (c) 2 hr fire rated file room meeting the requirements of NFPA 232-1986 or NFPA 232AM-1986 or both¹ with the following 	-	~	JEAGs does not describe regarding "Alternate Single Storage Facility"	MHI adopts dual storage facility in Yokohama and Kobe. Significant Differences; No impact on MHI procedure, because MHI has manuals, such as "Control Manual of Security for Electronic Information", "Control Manual of Access to Information Resource", "Emergency Response Manual of Information System", specifies basic requirements.

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COMPARISON TABLE XVII Quality Assurance Records (18/25)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	2) JEAG4101-2000	Differences	Assessment of Difference for MHI Manual or Procedure
		 additional provisions: (1) early warning fire detection and automatic fire suppression capability with electronic supervision at a constantly attended central station; (2) records storage in fully enclosed metal cabinets; (3) adequate access and aisle ways; (4) prohibition in the room of work not directly associated with record storage or retrieval; (5) prohibition in the room of smoking, eating, or drinking; (6) 2hr fire rated dampers or doors in all boundary penetrations. 				
		4.4.3 Temporary Storage. When temporary storage of records (such as for processing, review, or use) is required by an organization's procedures, the records shall be stored in a 1 hr fire rated container. The procedures shall specify the maximum allowable time limit for temporary storage. The container shall bear a UL label (or equivalent) certifying 1 hr fire protection or be certified by a person competent in the technical field of fire protection.		_	JEAGs does not describe regarding "Temporary Storage."	When temporary storage of records is required, QA records are stored in dual storage facilities. Significant Differences; No impact on MHI procedure.
		4.4.4 Dual Storage Facilities. If dual storage facilities for each record	_	Q3 4.4 Requirements for Retention	JEAG4101-1993 does not have specified provisions	No Significant Differences; No impact on MHI

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COMPARISON TABLE XVII Quality Assurance Records (19/25)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17,5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
		are provided, the storage facilities shall be at locations sufficiently remote from each other to eliminate the chance of exposure to a simultaneous hazard. Each storage facility is not required to satisfy the requirements of para. 4.4.1, para. 4.4.2, or para. 4.4.3 above, but shall meet the other requirements of this Standard. ¹ NFPA 232-I986 and NFPA 232AM-1986 are published by the National Fire Protection Association, Batterymarch Park, Quincy, MA 02269.		(9) When it is impossible to establish the appropriate retention conditions, retention of one set copy of quality records in the separate facility should be taken into consideration. In this case, locations and building structures of both facilities should be taken into attention so that the possibility of occurrence of quality records damage, missing, and degradation at a same time would be sufficiently low enough.	regarding "dual storage".	procedure, because MHI has manuals, such as "Control Manual of Security for Electronic Information", "Control Manual of Access to Information Resource", "Emergency Response Manual of Information System", specifies basic requirements.
-		5. RETRIEVAL Storage systems shall provide for retrieval of information in accordance with planned retrieval times based upon the record type. A list shall be maintained designating those personnel who shall have access to the files. Records maintained by a. Supplier at his facility or other location shall be accessible to the Purchaser or his designated alternate, e.g., the Owner,	SUPPLE 12.3.3 Retrieval and access (1) Quality records should be made readily retrievable at storage areas by suitable methods such as indexing, as necessary. (2) It is desirable to ease access to necessary records under access control at the storage area for quality records. REF. 12.3.3 Retrieval and access Some indexing contents are as follows: a. Name of plant and unit b. Name of item or service c. Name of organization which originated the record d. Retention period of the records	Q3 4.3.5 Retrieval and access (1) Quality records, filing with index, should be controlled retaining in the facility that retrievable when necessary. (2) Although, during retention period, quality records are accessible at any time, however, access to retention area should be controlled. (3) Retention outside of site and access to the required documents at emergency should be considered. 4.4 Requirements for Retention (2) Quality record retention system should be included, for example, the followings: [Explanation Q3-5] E. Rule of access to file and file control	JEAGs don't describe requirements the followings. • A list designates personnel who can access to the files. • Records access by purchaser.	 A list designates personnel who can access to the files, is displayed in MHI. Purchaser or regulatory authority is excluded on the above list, only if the supervisor accompanies with them. Significant difference; No impact on the MHI QA manual or procedure.
		Records accumulated at various locations, prior to	12.4.3 Transfer of quality records	4.3.6 Transfer and disposition	JEAG4101-1993 does not	Significant difference; No impact on the MHI QA

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COMPARISON TABLE

XVII Quality Assurance Records (20/25)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17,5	1) ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	2) JEAG4101-2000	Differences	Assessment of Difference for MHI Manual or Procedure
	3 For QA records in	transfer, shall be made accessible to the Owner directly or through the procuring organization. The custodian shall inventory the submittals, acknowledge receipt, and process these records in accordance with this Standard. Various regulatory agencies have requirements concerning records that are within the scope of this Standard. The most stringent requirements shall be used in determining the final disposition. The Supplier's nonpermanent records shall not be disposed of until the applicable conditions listed in (a) through (e) below are satisfied: (a) items are released for shipment, a Code Data Report is signed, or a Code Symbol Stamp is affixed; (b) regulatory requirements are satisfied; (c) operational status permits; (d) warranty consideration is satisfied; (e) Purchaser's requirements are satisfied.	Upon transferring records, the following are to be taken into account: a. Name of organization or place to receive transferred records b. List of records to be transferred c. Identifying the configuration of the records to be transferred (original, reproduced copy, microfilms, etc.) d. Collating transferred records with the list of records 12.4.4 Disposition of quality records Even if the records are categorized as permanent, those for particular items may be disposed once they are removed.	 Plant owner should make legible the responsible person for transfer and disposition of quality records. Plant owner or person who designated by the organization, in case of transfer of quality records, should obtain the information regarding receipt and disposition of quality records. And, quality records should not be transferred to place where plant owner does not manage. In performing transfer, the followings should be taken into consideration: A. Organization and location transferred B. Comparison of quality record list and transferred quality records Plant owner should retain quality records which is categorized according to "4.2 Categorization of Quality Records " for prescribed retention period. Quality records may be disposed by plant owner or with plant owner's consent. 	JEAGs do not describe	manual or procedure, because MHI's related manual indicate that the final disposition is to determined by consent of plant owener.
	electronic media, the program includes provisions for the generation, distribution, use, maintenance, storage, and disposition of electronic records. The plan provides for all acceptable media on				requirements clearly regarding electronic records.	No impact on MHI procedure, because MHI has MHI's manuals, such as "Control Manual of Security for Electronic Information", "Control Manual of Access to Information Resource",

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COMPARISON TABLE XVII Quality Assurance Records (21/25)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
	which electronic records are created and stored. Also, the program should include provisions to verify that the media is appropriate, suitable for the capture or storage of records, and error/defect free. The applicant's program must implement Generic Letter 88-18, "Plant Record Storage on Optical Disks." (Appendix B/RIS 2000-18)					"Emergency Response Manual of Information System", specifies basic requirements.
	5. Design documentation and records, which provide evidence that the design and design verification processes were properly performed are collected, stored, and maintained in accordance with documented procedures. The documentation includes not only final design documents, such as drawings and specifications, and revisions thereto but also documentation which identifies the important steps, including sources of design inputs that support the final design. (ANSI N18.7)	III. Design Control 7 DOCUMENTATION AND RECORDS Design documentation and records, which provide evidence that the design and design verification processes were performed in accordance with the requirements of this Part (Part I), shall be collected, stored, and maintained in accordance with documented procedures. The documentation shall include not only final design documents, such as drawings and specifications, and revisions thereto but also documentation which identifies the important steps, including sources of design inputs that support the final design. Subpart 2.7 [See Commitments section Below]	Chapter 2 REF 4.1 General In establishing design control measures, the following are to be considered: b. Preparation of design control procedure document to implement design activities Typical items to be covered by design control procedure document are as follows: 4.2.4 Design documents b. Identification method for design documents by plant name, document number, revision number, applying objects, etc. a. Use of format, drafting method, symbols, abbreviations, etc. b. Identification method for design document s by plant name, document number, revision number, applying objects, etc. c. Indication method for design document status, such as review, approval, and revision d. Proceeding of processes for review, approval, etc. e. Method of storage for originals and distribution of	SI 6. Supplemental Information about "DESIGN" Evidence that the design was properly accomplished is supported by design records that include the final design, important design steps such as calculations, analyses and computer programs, and sources of design input that support design output. The design organization also provides records of design changes. Q10 2.8 Document Control and Quality Records (1) Procedure for preparation, review, approval, issue, revision and control of documents shall be established. (2) Followings are the processes for preparation, correction and control of design-related information. a) Drawing control standards b) Standardization symbols c) Identification system d) Display of the current status	JEAGs have similar requirements. The requirements of SRP are design documentation and records, while JEAG's describe more detailed provisions.	No significant Difference; No impact on the MHI QA Manual or Procedure.

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COMPARISON TABLE XVII Quality Assurance Records (22/25)

copies e) Check method f. Method of revision, praid f) Requirements on review changes, and control of dbacket design focusion g) Issue, distribution and completed documents completed documents g) Issue, distribution and non-conformance in regard to design documents g) Control measures non-conformance in regard to design documents g) Control measures non-conformance in regard to design documents g) Control measures non-conformance in regard to design documents g) Control measures non-conformance in regard to design documents g) Control measures non-conformance in regard to design documents g) Control measures non-conformance in regard to design documents g) Control measures non-conformance in regard to design documents g) Control measures non-conformance in regard to design documents g) Control measures non-conformance in regard to design documents g) Control measures non-conformance measures to design documents g) Control measures non-conformance measures to design documents g) Contrements n	10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17,5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
		Section 17.5		copies f. Method of revision, partial changes, and control of obsolete design documents g. Method of issuance for completed documents h. Control measures for non-conformance in regard to design documents	 e) Check method f) Requirements on review and approval g) Issue, distribution and storage (3) So that the latest and pertinent information can be used for formulating and making revision on design input documents, management shall be conducted as follows. a) Organizations responsible for prepareing, reviewing, approving, issuing and revising documents shall be clearly identified. b) Documents to be used for design activities shall be clearly identified with description of document name, revision status, issue date or other related information for proper identification of the document concerned. c) Design documents shall be removed from the place of use or stored in a way prevent inadvertent use. (4) Specifications and other design outputs such as installation documents, instructions, commissioning documents and test procedures shall be controlled. (5) Records control methods shall be established including the statements and responsibilities for 		Procedure

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COMPARISON TABLE XVII Quality Assurance Records (23/25)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
				indexes, storage, search and handling of design documents. (6) Requirements on records shall be specified so that design activities should be controled and the evidence for secure achievement of requested safety should be available. Guidance on the document control and records is provided in Q3 (Document Control and Records) of this guide (Reference Matters).		
	7. Requirements and responsibilities for record transmittal, location, distribution, retention, maintenance, and disposition are described. Training is provided for individuals or organizations in charge of electronic records generation, data/media storage, implementation of security measures, migration/ regeneration, and recovery. (RIS 2000-18)		_		JEAGs do not describe requirements clearly regarding electronic records.	Significant Differences; No impact on MHI procedure, because MHI has manuals, such as "Control Manual of Security for Electronic Information", "Control Manual of Access to Information Resource", "Emergency Response Manual of Information System", specifies basic requirements.
	9. Documents are considered valid records only if stamped, initialed, authenticated, or signed and dated by authorized personnel. This authentication may take the form of a statement by the responsible individual or organization. Handwritten signatures are not required if the document is clearly identified as a statement by the reporting individual or organization. These records may be originals or reproduced copies. For electronic records, authentication is accomplished by manually				JEAGs do not describe requirements clearly regarding electronic records.	Significant Differences; No impact on MHI procedure, because MHI has manuals, such as "Control Manual of Security for Electronic Information", "Control Manual of Access to Information Resource", "Emergency Response Manual of Information System", specifies basic requirements

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COMPARISON TABLE XVII Quality Assurance Records (24/25)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17 5	ASME NQA-1-1994Edtion	JEAG4101-1993	JEAG4101-2000	Differences	Assessment of Difference for MHI Manual or Procedure
	affixing seal, signature, an electronic representation (user ID/password combination, digital signature) or other acceptable process control that ensures genuineness, validity, or reliability. Authorized personnel with access to electronic records and information systems should have a unique user ID/password for access. The system should provide controls for users who enter or alter information in electronic records to ensure its data integrity and prevent unauthorized alteration or erasure. Transfer of authentication authority is documented and controlled in accordance with written procedures. (RIS 2000-18)					
	10. Records and/or indexing system(s) provide sufficient information to permit identification between the record and the item(s) or activity(ies) to which they apply. For electronic records, in addition to the minimum indexing information requirements, the software name, version, and equipment (hardware) used to produce and maintain the electronic media must be provided. (Appendix B/RIS 2000-18)				JEAGs do not describe requirements clearly regarding electronic records.	Significant Differences; No impact on MHI procedure, because MHI has manuals, such as "Control Manual of Security for Electronic Information", "Control Manual of Access to Information Resource", "Emergency Response Manual of Information System", specifies basic requirements
	14. Electronic records classified as lifetime or nonpermanent are subject to the same retention requirements prescribed for paper records/hardcopies. Retention requirements for electronic records also				JEAGs do not describe requirements clearly regarding electronic records.	Significant Differences; No impact on MHI procedure because MHI has manuals, such as "Control Manual of Security for Electronic Information", "Control Manual of Access

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COMPARISON TABLE XVII Quality Assurance Records (25/25)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	1) ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
	identify and maintain the information system (software/hardware), the documentation that describes the information system operation and use, and the record standard it produces. (RIS 2000-18)					to Information Resource", "Emergency Response Manual of Information System", specifies basic requirements
	15. An electronic record migration/ regeneration program is implemented for electronic records stored in media with a standard life expectancy that fails to meet the specific retention period. This program is implemented in accordance with documented procedures that provide for appropriate record authentication, quality verification of the completion, and accuracy of the data transferred. (RIS 2000-18)				JEAGs do not describe requirements clearly regarding electronic records.	Significant Differences; No impact on MHI procedure because MHI has manuals, such as "Control Manual of Security for Electronic Information", "Control Manual of Access to Information Resource", "Emergency Response Manual of Information System", specifies basic requirements
	16. Electronic media should be stored in a dust-free environment, away from electronic devices and demagnetizing equipment. Media should be maintained at the constant temperature of 40 to 80 degrees Fahrenheit, with a constant relative humidity of 30 to 50 percent. Magnetic and optical media should be tested periodically to identify any loss of data, to ensure that they are free of permanent errors, and that the record system hardware/software still supports the retrieval of the records. (RIS 2000-18)	·			JEAGs do not describe requirements clearly regarding electronic records.	Significant Differences; No impact on MHI procedure because MHI has manuals, such as "Control Manual of Security for Electronic Information", "Control Manual of Access to Information Resource", "Emergency Response Manual of Information System", specifies basic requirements

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COMPARISON TABLE XVIII Audits (1/17)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
XVIII. Audits A comprehensive system of planned and periodic audits shall be carried out to verify compliance with all aspects of the quality assurance		Basic Requirement 18 AUDITS Planned and scheduled audits shall be performed to verify compliance with all aspects of the quality	BASIC 13.1 General Measures for audits shall be established to verify, as necessary, the implementation and effectiveness of the guality	BASIC 4.1 Management Self-assessment (1) Management at all levels shall regularly assess the processes for which it is responsible. In	Three standards have similar requirements. In JEAG4101-2000, the requirements for audits are specified as part of assessments.	No significant Difference; No impact on the MHI QA Manual or Procedure.
program and to determine the effectiveness of the program. The audits shall be performed in accordance with the written procedures or check lists by appropriately trained		assurance program and to determine its effectiveness. These audits shall be performed in accordance with written procedures or checklists by personnel who do not have direct	assurance program. 13.2 Management of audit An audit organization shall establish the methods for managing audits.	this case, the assessment may be performed in respective organization unit in lieu of respective manager. (2) Management shall determine its effectiveness		
personnel not having direct responsibilities in the areas being audited. Audit results shall be documented and reviewed by management having responsibility in the		performing the activities being audited. Audit results shall be documented and reported to and reviewed by responsible	13.3 Execution of audit Audit organizations shall carry out audits according to the established methods. 13.4 Corrective action	in establishing, promoting and achieving nuclear safety objectives. (3) Management process weaknesses and barriers that hinder the		
area audited. Followup action, including reaudit of deficient areas, shall be taken where indicated. [35 FR 10499, June 27, 1970, as amended at 36 FR 18301 Sant 11 1971		management: Follow-up action shall be taken where indicated:	If findings necessitate corrective action, implementation of the corrective action shall be verified.	achievement of the nuclear safety objectives for nuclear power plant shall be identified and corrected. 4.2 Independent Assessments		
40 FR 3210D, Jan. 20, 1975] ¹ While the term "applicant" is used in these criteria, the requirements are, of course, applicable after			 assurance programs (1) The adequacy of quality assurance programs and the implementation of quality assurance activities based on these programs 	4.2.1 Conduct of independent assessment Independent assessments shall be conducted on behalf of management to		
such a person has received a license to construct and operate a nuclear powerplant or a fuel reprocessing plant			shall be reviewed by the person who has been assigned the responsibility for their establishment and implementation. (Explanation 1-3)	measure the effectiveness of management processes and the adequacy of work performance, to monitor item and service quality and to promote		
			EX.1-3 "Reviews" include reviews for quality information based on the verification results of the items or	Improvement. Independent assessments consist of audits, reviews, checks and other methods. 4.2.2 Management of		
			services and for audit reports in regard to the implementation status of quality assurance programs.	independent assessment (1) An organizational unit shall be established, or outside agency assigned, with the responsibility to		

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COMPARISON TABLE XVIII Audits (2/17)

10'CFR' 50 Appendix B'	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
				conduct independent assessments. (2) It shall have sufficient authority and organizational freedom to carry out its responsibilities. (3) Persons conducting independent assessment shall not participate directly in the work being assessed.		
				4.2.3 Consideration on the results of the independent assessments The results of the independent assessments shall be considered by management and, where necessary, actions shall be taken to implement improvements.		
		Supplement 18S-1 Supplementary Requirements for Audits 1. GENERAL This Supplement provides amplified requirements for quality assurance audits. It supplements the audit requirements of Basic Requirement 18 of this Standard and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Standard.	See above	See above	This NQA-1-1994 clause is a paragraph introducing the additional requirements in the Supplementary Requirements. It specifies that the Supplementary Requirements apply when and to the extent specified by the organization invoking Part 1 of NQA-1-1994.	See blow.
	6. A program of planned and periodic audits is required to be established to confirm that activities affecting quality comply with the QA program and that the QA program has been implemented effectively. The audit schedule is reviewed	 SCHEDULING Internal or external quality assurance audits, or both, shall be scheduled in a manner to provide coverage and. coordination with ongoing quality assurance program activities. Audits shall be 	SUPPLE 13.2.2 Timing of audit execution It is desirable to perform an audit for the following cases according to the status and degree of importance of objective activities to be audited: a. When it is necessary to	Q5 4.2 Program of Assessment (1) An assessment plan should be established, taking into account the organization's activities affecting safety and the frequency and results of previous assessments.	Three standards have similar requirements. The requirements of NQA-1 are a summary of "Timing of audit execution". JEAGs specify more detailed requirements including timing or criteria for judging based on activities.	Significant Difference; No impact on the MHI QA Manual or Procedure, because it is specified that internal audits shall be executed annually and QA programs and activities shall be continually evaluated in MHI QA audit procedure.

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COMPARISON TABLE

XVIII	Audits	(3/17)
VAU	Audits	(3/17)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17 5	1) ASME NQA-1-1994Edtion	JEAG4101-1993	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
	periodically and revised as	scheduled at a frequency	evaluate the quality	Assessments may be		10000010
	necessary to ensure that	commensurate with the	assurance program of the	conducted on a limited	In SRP, the frequency of	
	coverage is maintained	status and importance of	supplier and its capability of	scope of activity across a	audit is specified based on	
	current. (NQA-1)	the activity. The audit	executing the program prior	number of organizational	the condition whether	
		schedule shall be	to orders	units, or on all activities in a	facilities in operation has	
	3. Internal Audits (NQA-1)	reviewed periodically and	b. When it is necessary to	single organizational unit,	placed or not. Further, the	
	a. Internal audits of	revised as necessary to	verify the supplier's	or a combination of these.	extension of audit interval	
	organization and facility	as sure that coverage is	compliance with the quality	(4) The assessment	is based on the QA	
	activities, conducted prior	maintained current.	assurance program after	schedule should allow	activities. On the other	
1	10	Regularly scheduled	orders	adequate time for	nanu, JEAGS uo not	
	placing the facility in	audits shall be	c. when significant	preparation, conduct of the	of audito	
	performed in such a	additional audits of	assurance program such	identified concerns and	of addits.	
	manner as to ensure that	specific subjects when	as significant changes in	reporting of results		
	an audit of all applicable	necessary to provide	organization or procedures	reporting of resolts.		
	OA program elements is	adequate coverage	have taken place			
	completed for each	adequate obverage.	d. When a significant			
	functional area at least	· .	non-conformance has			
	once each year or at least		occurred or might occur			
	once during the life of the		due to deficiency of the			
	activity, whichever is		quality assurance program			
	shorter. Internal audits of	·	or deficiency in			
	activities, conducted after	1. 1. N	implementing the quality			
	placing the facility in		assurance activity			
	operation, should be		e. When it is necessary to			
	performed in such a		verify implementation of the			
	manner as to ensure that	-	corrective action			
]	an audit of all applicable		t. When it is necessary to			
	QA program elements is		verify periodically the state			
	functional area within a		of implementation and the			
	noriod of two yoors		assurance program			
	b Internal audit		assurance program			
	frequencies of well	1				
	established activities.					
	conducted after placing the					
	facility in operation, may be				1	
1	extended one year at a					
	time beyond the two-year					
	interval based on the					
	results of an annual					
	evaluation of the applicable					
	tunctional area and					
	functional area activities				1	
	are being satisfactorily					1
1	accomplished The			1		
	evaluation should include a			1	1	
	detailed performance					
	analysis of the functional					
	area based upon					
	applicable internal and	ļ.			1	

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COMPARISON TABLE XVIII Audits (4/17)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	1) ASME NQA-1-1994Edtion	2) JEAG4101-1993	2) JEAG4101-2000	Differences	Assessment of Difference for MHI Manual or Procedure
	external source data and due consideration of the impact of any function area changes in responsibility, resources or management. However, the internal audit frequency interval should not exceed a maximum of four years. If an adverse trend is identified in the applicable functional area, the extension of the internal audit frequency interval should be rescinded and an audit scheduled as soon as practicable.					
	8. The auditing organization develops and documents an audit plan for each audit. This plan identifies the audit scope, requirements, audit personnel, activities to be audited, organizations to be notified, applicable documents, schedule, and written procedures or checklists. (NQA-1)	3. PREPARATION 3. 1 Audit Plan The auditing organization shall develop and document an audit plan for each audit. This plan shall identify the audit scope, requirements, audit personnel, activities to be audited, organizations to be notified, applicable. documents, schedule, and written procedures or checklists.	SUPPLE 13.3.2 Pre-audit activities Audit organizations should establish appropriate audit execution plans prior to the audit, and perform the audit according to these plans. REF. 13.2.4 Audit procedures The following are to be included in audit procedures: a. Audit team b. Execution sequence, frequency, timing, etc. c. Objective scope of audit d. Audit plan documentation e. Notification to the auditee f. Audit report g. Findings, recommended matters, and their corrective actions h. Confirmation of corrective actions 13.3.2 Pre-audit activities Audit execution plan is to include the following: a. Audit objective scope and business contents	Q5 4.2 Program of Assessment (2) At the plan of assessment, the areas to be aimed at assessment, activities, and requirements of assessment should be selected. Assessment activities should be performed not to impact to the safety of the power plant. Assessment activities should be planned to impact minimum to the routine power plant activities. (5) Items to be included in the programs are as follows: a. Subject division of assessment b. Scope to be covered and work activities c. Member of assessment team d. Performance schedule e. Check list, Procedures f. Notification of assessment	Three standards have similar requirements. The requirements of NQA-1 are a summary of audits planning. JEAG4101-1993 specifies more detailed requirements including pre-audit activities. In JEAG4101-2000, it is specified that information or resource shall be utilized to achieve practical effect. JEAG4101-2000 specifies comparable requirements to NQA-1.	No significant Difference; No impact on the MHI QA Manual or Procedure.

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COMPARISON TABLE XVIII Audits (5/17)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17,5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ^{2}}	Differences	Assessment of Difference for MHI Manual or Procedure
			c. Audit team members d. Audit scheduling table e. Audit check list and procedures f. Audit notification			
	1. Personnel performing audit activities are not to have direct responsibilities in the activity they are auditing. (NQA-1)	3.2 Personnel The auditing organization shall select and assign auditors who are independent of any direct responsibility for performance of the activities which they will audit. in the case of internal audits, personnel having direct responsibility for performing the activities being audited shall not be involved in the selection of the audit team. Audit personnel shall have sufficient authority and organizational freedom to make the audit process meaningful and effective.	SUPPLE 13.2.1 Auditor qualification or registration It is desirable that auditors be qualified or registered according to internal company procedures. (Explanation 13-1) 13.3.1 Audit team organizations Audit organizations should perform the following when organizing the audit team: a. Selecting auditors from organizations other than that which is audited b. Deciding lead auditor and auditors REF. 13.2.1 Auditor qualification or registration (1) The following knowledge, experience, and capability shall be considered when an auditor is qualified or registered: a. Special knowledge and experience of the area to be audited b. Knowledge and experience of audit methodology and techniques c. Knowledge of standards, procedures, and production processes d. Skill in communication, suitability, faithfulness, etc. (2) The following knowledge, experience, and capability shall be considered when a lead auditor of the audit team is	Q5 3.3.4 Structure and Method of Assessment Organization (1)The assessment Unit could be supplemented by persons from other departments on short-term support, either for the duration of the assessment or for career development purposes. Such persons should have an understanding of the work area being assessed and be conversant with the type of assessment. (2) Personnel conducting independent assessment should not have responsibility for the work performance being assessed. Assessment personnel should exercise objectivity in examining evidence and in forming conclusions. (3) A team leader should be appointed to manage all phases of an individual assessment. The team leader should be responsible for: a. Selection of team members b. Planning c. Representing the team d. Managing the team during the assessment e. Preparing and submitting the report f. Chacking the effectiveness of corrective actions. (4) Team members should obey team leader's instruction and guidance (5) Inexperienced neonle on	Three standards have similar requirements. The requirements of NQA-1 are a summary of auditor qualification, while JEAGs describe more detailed provisions including responsibilities and authorities. Especially, JEAG 4101-2000 specifies the roles, activities, obligation and training for team member so that the audit can be effectively executed.	No significant Difference; No impact on the MHI QA Manual or Procedure.
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10,CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	1) ASME NQA-1-1994Edtion	JEAG4101-1993	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
			qualified or registered: a. Education, experience, professional ability, etc. b. Experience with audits c. Experience in document reviewing concerning quality assurance d. Experience in participating in general education, seminars, etc. on quality assurance	the team should be adequately monitored and supervised until they are considered proficient in the type of assessment being carried out. (6)The attitude of assessors can also have an impact on the value of assessment. Assessors should be capable of looking for improvement opportunities and providing recommendations to management. Problems should be reported in a way that will help management understand what actions are needed. (7) An independent assessment is not necessarily conducted by the assessment organization. It may be conducted as the independent assessment by the staff organized for specific assessment or the joint team including assessment organization members.		
		3.3 Selection of Audit Team An audit team shall be identified prior to the beginning of each audit. This team shall contain one or more auditors and shall have an individual appointed to lead the team who organizes and directs the audit, coordinates the preparation and issuance of the audit report, and evaluates responses. The audit team leader shall ensure that the audit team is prepared prior to initiation of the audit.	SUPPLE 13.3.1 Audit team organizations Audit organizations should perform the following when organizing the audit team: a. Selecting auditors from organizations other than that which is audited b. Deciding lead auditor and auditors REF. 13.3.1 Audit team organization (1) The roles of the lead auditor are as follows: a. Preparation of audit, investigation, and pre-audit conference	See above	See above.	See above.

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COMPARISON TABLE XVIII Audits (7/17)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	1) ASME NQA-1-1994Edtion	JEAG4101-1993	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
			 b. Command of the audit team c. Reporting of the audit, etc. by putting together findings and corrective actions (2) Members of the team might be selected from among experienced technical specialists in addition to the qualified or registered auditors. (3) Audit teams are not to force auditees to show information which the auditee judges to be confidential business or technology. 			
	 2. Audits are accomplished using instructions, procedures or checklists by qualified personnel. (NQA-1) 9. Audit results are documented and reported to and reviewed by responsible management. (NQA-1) 	4. PERFORMANCE Audits shall be performed in accordance with written procedures or checklists. Auditing shall begin as early in the life of the activity as practical and shall be continued at intervals consistent with the schedule for accomplishing the activity. Elements that have been selected for audit shall be evaluated against specified requirements. Objective evidence shall be examined to the depth necessary to determine if these elements are being implemented effectively. Audit results shall be reviewed by management having responsibility for the area audited. Conditions	SUPPLE 13.3.4 Execution of audit Audits should be executed according to checklists or procedures to verify that the quality assurance requirements are satisfied. 13.3.5 Explanation and confirmation of audit results To conclude the audit, a post audit meeting should be organized between the audit team and the audited organization so the audit team can explain the audit team can explain the audit findings, if any, and thus ensure that the audit findings are reasonable and agreeable. REF. 13.3.4 Execution of audit (1) Auditee is to make preparations for investigation facilities, documents, and records. (2) The following are to be	Q5 4.3 Performance of Assessment (1) Assessment should concentrate on observation actually being performed. Many activities can only be properly evaluated after a thorough in-process observation has taken place. Assessors should also interview personnel and examine completed work activities. Where activities are not being performed at the time of assessment, a decision should be made on whether they should be observed at a later date. (2) When assessing an activity, the assessor should observe the sequence of operationa and investigation in more detail if a problem is suspected. (3) If, during the course of the assessment, a deficiency is found, the assessor should observe	Three standards have similar requirements. The requirements of NQA-1 are a summary of "Performance of Assessments", while JEAGs specify more detailed requirements including audit activities.	No significant Difference; • No impact on the MHI QA Manual or Procedure.
		requiring prompt corrective action shall be reported immediately to management of the	assurance program b Review of specifications	other similar activities to determine the nature and extent of the problem (for example whether it exists		

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COMPARISON TABLE XVIII Audits (8/17)

10 CFR 50'Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
		audited organization.	procedures, and instructions c. Confirmation of the execution status of the quality assurance activities d. Investigation of personnel training and qualification statuses e. Investigation of approved or accepted products, design calculations, drawing, etc. f. Investigation of process control and its records g. Follow-up for the findings and corrective actions of the previous audit	throughout the organization). (4) In an assessment, information on equipment, personnel qualification and training should be examined. The assessor may need to ask personnel specific questions to determine, for example, their experience or knowledge of procedures. The assessor may also check the conformance with, and the adequacy of, the procedures. (5) Although assessment should be conducted according to the approved program, flexible correspondence should be required depend on the situations. The assessor should pursue any questionable area after consultation with the team leader. (6) When potential non-conformances are encountered, the assessor should check to determine if these have already been identified by management and if actions are being implemented to correct them. Conditions found during the assessment which require prompt attention should be immediately brought to the attention of management. (7) When potential non-conformances are detected, they should be discussed with the responsible persons to avoid misunderstandings.		
	signed by the audit team leader and issued, and it includes the following	The audit report shall be signed by the audit team leader and issued, and it	13.3.6 Audit reports The audit team should prepare audit reports	4.5 Report (1) Assessment results should be reported clearly	similar requirements.	No impact on the MHI QA Manual or Procedure.

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COMPARISON TABLE XVIII Audits (9/17)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ^{2}}	Differences	Assessment of Difference for MHI Manual or Procedure
	information, as appropriate: (NQA-1) a. description of the audit scope b. identification of the auditors c. identification of persons contacted during audit activities d. summary of audit results, including a statement on the effectiveness of the QA program elements which were audited e. description of each reported adverse audit finding in sufficient detail to enable corrective action to be taken by the audited organization	 shall include the following information, as appropriate: (a) description of the audit scope; (b) identification of the auditors; (c) identification of persons contacted during audit activities; (d) summary of audit results, including a statement on the effectiveness of the quality assurance Program elements, which were audited; (e) description of each reported adverse audit finding in sufficient detail to enable corrective action to be taken by the audited organization. 	without delay. REF. 13.3.6 Audit Reports (1) The following are to be included in the audit report. In case there are findings, their basis for inclusion is to be clearly stated: a. Brief discription for the objectives and scope of the audit b. Main documents list used for evaluation c. Names of the audit team members d. Auditee's main representatives e. Brief discription of the pre-audit conference f. Brief discription of the findings and evaluation of quality assurance activities g. Recommendations for improving quality assurance programmes (2) The audit report is to be distributed to the audited organization after receiving the approval of the responsible person at the audit organization.	and promptly. The assessment report should communicate findings in a way that makes their significance readily apparent. For reports to be effective, they must be submitted in their final form as quickly as possible, emphasizing particular items if necessary. The report should include: a. A List of findings [Explanation Q5 - 5] b. A List of personnel contacted and procedures reviewed, c. A description of assessment methods adopted by the assessors, d. References to the assessed and why they are important, e. A summary statement on whether the activities assessed were satisfactory or not, f. Opportunities for Improvement. (2) Final report should be distributed to the assessed organization, after approval by the responsible person of the assessment organization.		
		6. RESPONSE Management of the audited organization or activity shall investigate adverse audit findings, schedule corrective action, including measures to prevent recurrence, and notify the appropriate organization in writing of action taken or planned. The adequacy of audit	SUPPLE 13.4.1 Preparation of corrective action report After the audited organization examines the findings to which it agreed, it should prepare and submit a report of its corrective actions to the audit team within a specified period. 13.4.2 Evaluation of the	Q5 4.5 Report (3) The assessed organization should receive the final report and confirm the contents of it. When the matter not agreed exists, prompt notification should be sent to the assessment organization. Q5 4.6 Follow-up Activity (1) The assessed	Three standards have similar requirements. The requirements of NQA-1 are a summary of "corrective action program", while JEAGs specify more detailed requirements for documents including activities.	No significant Difference; No impact on the MHI QA Manual or Procedure.

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10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
			corrective action report The audit team should evaluate the report received from the audited organization. If there are points which cannot be agreed upon, the audit team should inform the audited organization of those points. REF. 13.4.1 Preparation of the corrective action report The following are to be included in the audit report on corrective action: a. Contents of the findings b. Contents of the findings b. Contents of the findings corrective actions c. Name of the responsible person for corrective actions d. Completed date or planned date for the corrective actions e. Name of the person who confirms the completion of corrective actions	organization should review and investigate assessment findings to determine corrective action, and prepare an implementation schedule and a written response to the report within a given time. The corrective actions and implementation schedule should be discussed between management and the team leader to help ensure that the corrective actions are adequate. (2) The assessed organization should review and report on the progress achieved in completing corrective actions, so that senior management are aware of the status of corrective actions in their organization. (3) The assessment unit should evaluate the contents of the corrective action report submitted from assessed organization, and when the matter not agreed exist, notification should be sent to the assessed organization.		
	Follow-up action of deficient areas is initiated as necessary. (NQA-1)	7. FOLLOW-UP ACTION' Follow-up action shall be taken to verify that corrective action is accomplished as scheduled.	SUPPLE 13.4.3 Follow-up for corrective action The audit team and the audited organization should follow-up corrective action. REF. 13.4.3 Follow-up for corrective action Follow-up for corrective actions is to be performed according to the following procedures, as necessary: a. The audited organization is to report the results of evaluations it has done on its corrective actions to the auditing organization	Q5-4.6 4.6 Follow-up Activities (4) The assessment unit and the assessed organization should follow-up the corrective actions.	Three standards have similar requirements.	No significant Difference; No impact on the MHI QA Manual or Procedure.

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COMPARISON TABLE XVIII Audits (11/17)

, 10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²¹	Differences	Assessment of Difference for MHI Manual or Procedure
			b. Follow-up activities may include re-audits by the auditing organization or confirmation by documents			
		8. RECORDS Audit records shall include audit plans, audit reports, written replies, and the record of completion of corrective action.	REF. 13.3.6 Audit Reports (1) The following are to be included in the audit report. In case there are findings, their basis for inclusion is to be clearly stated: a. Brief discription for the objectives and scope of the audit b. Main documents list used for evaluation c. Names of the audit team members d. Auditee's main representatives e. Brief discription of the pre-audit conference f. Brief discription of the pre-audit conference f. Brief discription.of the findings and evaluation of quality assurance activities g. Recommendations for improving quality assurance programs (2) The audit report is to be distributed to the audited organization after receiving the approval of the responsible person at the audit organization. 13.4.1 Preparation of the corrective action report The following are to be included in the audit report on corrective actions c. Name of the responsible person for corrective actions d. Completed date or planned date for the corrective actions	Q5-4.2 4.2 Program of Assessment (5) Items to be included in the programs are as follows: a. Subject division of assessment b. Scope to be covered and work activities c. Member of assessment team d. Performance schedule e. Check list, Procedures f. Notification of assessment 4.5 Report (1) Assessment results should be reported clearly and promptly. The assessment report should communicate findings in a way that makes their significance readily apparent. For reports to be effective, they must be submitted in their final form as quickly as possible, emphasizing particular items if necessary. The report should include: a. A List of personnel contacted and procedures reviewed, c. A description of assessment methods adopted by the assessors, d. References to the assessment plan which indicate what area were assessed and why they are important, e. A summary statement on whether the activities assessed were satisfactory or not	Three standards have similar requirements. Especially, in JEAG4101-2000, it is specified that the requirements for significant items shall be included so that assessment results should be clearly and promptly reported.	No significant Difference; No impact on the MHI QA Manual or Procedure.
			e. Name of the person who confirms the completion of	f. Opportunities for		

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COMPARISON TABLE XVIII Audits (12/17)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edition	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or Procedure
			corrective actions	Improvement. 4.6 Follow-up Activity (5) On completion of all corrective action, the assessment should be closed.		
	5. An audit process is developed and implemented. Periodic inspections of systems, software applications, and media are performed to ensure electronic records retrievability, integrity, and retention period. (RIS 2000-18)		CUDDUE	05214	There are no significant	With regard to "Audit process", JEAGs do not have explicit requirements. No impact on the MHI QA Manual or Procedure. It is specified that electric records such as engineering data shall be strictly controlled based on periodic backup and preventive measures for degradation, etc. in "Computer Processed Engineering Data Control Procedure". Further these processes are included in audit items.
	independent evaluation of activities and procedures. (ANSI N18.7)		13.3.1 Audit team organizations Audit organizations should perform the following when organizing the audit team: a. Selecting auditors from organizations other than that which is audited b. Deciding lead auditor and auditors	2.1.4 Independent Assessment Independent assessment should be conducted on behalf of senior management by an organizational unit or assigned outside agency which is independent of the work to be assessed. Managers should not regard the independent assessment as an opportunity to avoid carrying out their self-assessment. The assessment unit should devote itself to assisting management to improve effectiveness and work performance.	differences between JEAGs and SRP.	No impact on the MHI QA Manual or Procedure.

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COMPARISON TABLE XVIII Audits (13/17)

	Standard Review Plan	1)	2)	2)		Assessment of Difference
10 CFR 50 Appendix B	NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²¹	JEAG4101-2000 ²¹	Differences	for MHI Manual or Procedure
	out under the requirements of the QA program is delegated to others, the work is audited by the QA audit program. (ANSI N18.7)		SUPPLE 13.2.2 Timing of audit execution It is desirable to perform an audit for the following cases according to the status and degree of importance of objective activities to be audited: a. When it is necessary to evaluate the quality assurance program of the supplier and its capability of executing the program prior to orders b. When it is necessary to verify the supplier's compliance with the quality assurance program after orders EXP13-2 Audits consist of the external audit which the purchaser conducts for the supplier and the internal audit which they conduct for their internal organization.	 4.3Evaluation Method 4.3Evaluation method and the results of evaluation in evaluating supplier shall be documented and maintained. Example of evaluation method is as follows: (1) The past achievement of the supplier shall be evaluated concerning the proper functioning of the supplied items. Following matters are the examples: a) Experience of users of the identical or similar items or services supplied by the prospect supplier. b) Review of the records accumulated through past procurement activities and operation experiences regarding the items concerned. c) Review of the past data regarding the items or services to be procured that can indicate the current performance of the prospect supplier. if there is no recent record available, purchaser shall request the prospect supplier to submit information concerning the equivalent items or service as an evidence of the current performance. (2) Quality Assurance Plan of the prospect supplier shall be evaluated. In this evaluation, considerations may be given to the third party qualification (e.g. ISO, ASME, etc.) concerning the scope related to the concerned services. (3) Evaluation of prospect suppliers shall be performed based on their 	I here are no significant differences between JEAGs and SRP. SRP specifies requirements for procurements audits. Especially, in JEAG4101-2000, it is specified in detail that the capability, performance and QA programs, etc. for the supplier shall be documented and evaluated.	No significant Difference; No impact on the MHI QA Manual or Procedure.

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COMPARISON TABLE XVIII Audits (14/17)

10/CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	2) JEAG4101-1993	2), JEAG4101-2000	Differences	Assessment of Difference for MHI Manual or Procedure
				technical performance, manufacturing equipment, personnel and quality assurance program. Guidance on the evaluation is shown in Q5 of the Reference Matters section of this Guide. (4) Current quality assurance records of the prospect suppliers evidenced by qualitative or quantitative document information such as statistic records or equivalent showing the ability of the prospect suppliers shall be evaluated in an objective manner. (5) Ability of the prospect suppliers shall be evaluated by investigating their current products or samples similar to the current products.		

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COMPARISON TABLE XVIII Audits (15/17)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17 5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	JEAG4101-2000 ²⁾	Differences	Assessment of Difference for MHI Manual or
	Section 17.5. 11. Procurement audits of suppliers are accomplished as follows: (Regulatory Guide 1.28) a. Audits are not necessary for procuring the following items: (1) those that are relatively simple and standard in design, manufacturing, and testing (2) those that are adaptable to standard or automated inspections or tests of the end product to verify quality characteristics after delivery b. Audits are conducted as follows for procurement of items not covered by the exceptions in 11(a) above: (1) The supplier's QA program is audited on a triennial basis. (2) The triennial period begins when the first audit is performed. (3) An audit is initially performed after the supflier has completed sufficient work to demonstrate that its organization is implementing a QA program. (4) If a subsequent contract or a contract modification significantly enlarges the scope of or changes the methods or controls for activities performed by the same supplier, an audit of the modified requirements is conducted, thus starting a new triennial period. (5) If the supplier is implementing the same QA program for other customers that is proposed for use on the auditing party's contract, the		5.3 Evaluation of bidders In selecting suppliers, the purchaser shall evaluate whether or not the bidders are able to supply items or services conforming to the requirements of the procurement documents. The following shall be included as appropriate in bidder evaluations: a. Technical ability and quality assurance system b. Past supply records of items or services c. Past use records of items or services d. Samples of items	Q6-4.3 4.3 Evaluation Method The evaluation method and the results of evaluation in evaluating supplier shall be documented and maintained. Examples of evaluation method are as follows: (1) The past achievement of the supplier shall be evaluated concerning the proper functioning of the supplied items. Following matters are the examples: a)Experience of users of the identical or similar items or services supplier. b)Review of the records accumulated through past procurement activities and operation experiences regarding the items concerned. c)Review of the past data regarding the items or services to be procured that can indicate the current performance of the prospect supplier. If there is no recent record available, purchaser shall request the prospect supplier to submit information concerning the equivalent items or service as an evidence of the current performance. (2) Quality Assurance Plan of the prospect supplier shall be evaluated. In this evaluation, considerations may be given to the third party qualification (e.g. ISO, ASME, etc.) concerning the scope related to the concerned services. (3) Evaluation of prospect suppliers shall be performed based on their	Three standards have similar requirements. JEAG4101-1993 specifies requirements for evaluation of supplier including checking items, while JEAG4101-2000 specifies requirements for confirmation, evaluation and review in procurement including activities. However JEAGs do not specify audit interval. In SRP, it is specified that the judgment whether audits are necessary or not shall be executed based on importance or complexity.	Procedure: No significant Difference; No impact on the MHI QA Manual or Procedure. In MHI Procurements Control Procedure, it is specified that procurement audit shall be executed every three years including evaluation for a short-term procurement activities.

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COMPARISON TABLE XVIII Audits (16/17)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5	ASME NQA-1-1994Edtion	JEAG4101-1993 ²⁾	2) JEAG4101-2000	Differences	Assessment of Difference for MHI Manual or Procedure
	preaward survey may serve as the first triennial audit. Therefore, when such preaward surveys are employed as the first triennial audits, they must satisfy the same audit elements and criteria as those used on other triennial audits. (6) If more than one purchaser buys from a single supplier, a purchaser may either perform or arrange for an audit of the supplier on behalf of itself and other purchasers to reduce the number of external audits of the supplier. The scope of this audit should satisfy the needs of all of the purchasers, and the audit report should be distributed to all the purchasers for whom the audit was conducted. Nevertheless, each of the purchasers relying on the results of an audit performed on behalf of several purchasers remains individually responsible for the adequacy of the audit.			technical performance, manufacturing equipment, personnel and quality assurance program. Guidance on the evaluation is shown in Q5 (Assessment) of the Reference Matters section of this Guide. (4) Current quality assurance records of the prospect suppliers evidenced by qualitative or quantitative document information such as statistic records or equivalent showing the ability of the prospect suppliers shall be evaluated in an objective manner. (5) Ability of the prospect suppliers shall be evaluated by investigating their current products or samples similar to the current products.		
	 12. Evaluations of suppliers are documented and take into account the following, where applicable: (Approved via SE (Accession No. ML050700416).) (a) Receipt inspection, operating experience, and supplier evaluation programs are reviewed on an ongoing basis as the information becomes available. The results of the review are promptly 		See BASIC 5.3 SUPPLE 5.3 5.3 Evaluation of bidders (1) The purchaser should identify the responsible individuals or organizations for the evaluation of bidders, and should document the results. (2) During the evaluation of the quality assurance system it is desirable to refer to section 13 'AUDIT' in this guide. REF 5.3 5.3 Evaluation of bidders	See above.	SRP specifies requirements based on the identification whether receipt inspection has been executed or not, while JEAGs specify detailed requirements for evaluation items without the identification.	No significant Difference; No impact on the MHI QA Manual or Procedure.

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COMPARISON TABLE XVIII Audits (17/17)

10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17 5	ASME NQA-1-1994Edtion	JEAG4101-1993	2) JEAG4101-2000	Differences	Assessment of Difference for MHI Manual or Procedure
10 CFR 50 Appendix B	Standard Review Plan NUREG -0800 Section 17.5 considered for effect on a supplier's continued qualification and adjustments made as necessary (including corrective actions, adjustments of supplier audit plans, and input to third party auditing entities, as warnated). Additionally, results are reviewed periodically to determine if, as a whole, they constitute a significant condition adverse to quality requiring additional action. (b) If there is no ongoing receipt inspection or operating experience with which to analyze the supplier for a period of twelve months, an annual evaluation shall be performed as follows: (1) review of supplier-furnished documents and records such as certificates of conformance, nonconformance notices, and corrective actions (2) results of previous source verifications, audits, and receiving inspections (3) operating experience of identical or similar products furnished by the same supplier (4) results of audits from	1) ASME NQA-1-1994Edtion	JEAG4101-1993 ²¹ (1) Concrete items for evaluation are as follows: a. Technical ability and quality assurance system a) Technical ability or capacity of the bidders manufacturing equipment concerning the items or services to be purchased b) Policy of bidders regarding quality, quality assurance program, and their implementation b. Supply records regarding the use of items or services These are bidder supply records of the items or services that are the same or similar to those to be purchased. c. Records of item or services to be purchased that are the same as or similar to those to be purchased that are the same as or similar to the one possessed by the purchaser. d. Samples of items Conformity to quality requirements for the samples of the items to be procured. (2) There are various restrictions on the evaluation of bidders of imported items. Countermeasures are as follows:	JEAG4101-2000 ²¹	Differences	Assessment of Difference for MHI Manual or Procedure
	 (3) operating experience of identical or similar products furnished by the same supplier (4) results of audits from other sources (e.g., customer, ASME, or NRC 		restrictions on the evaluation of bidders of imported items. Countermeasures are as follows: a. Selection of suppliers qualified by an official			
	audits)	· · · · ·	organization such as the ASME, etc. b. Selection of suppliers with good results These results refer to important matters other than purchase specifications.			

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MUAP-07003 Rev.0

Enclosure 2

Re-evaluation Procedure of Past Acquired Design Results

January 2007

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Re-evaluation Procedure of Past Acquired Design Results

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Mitsubishi Heavy Industries, Ltd. 16-5, Konan 2-chome, Minato-ku Tokyo 108-8215 Japan

Mitsubishi Heavy Industries, LTD.

US-APWR Quality Assurance Manual

Re-evaluation Procedure of Past Acquired Design Results

PQF-HD-18041-026 Rev.1

Mitsubishi Heavy Industries, LTD. Nuclear Energy Systems Headquarters

	Revise	Approve	Boylow	Propara	Paga	Revision
No.	Date		neview	Flepare	Fage	
Re	e-evaluation	Procedure of	Past Acquire	ed Design Ro	esults	PQF-HD-18041-026
0	12.26.'06	12/26/'06 N.Miyakoshi	12/26/'06 K.Imamura	12/26/'06 S.Yamada		New Issuance
1	1.24.'07	01/54/107.	1/107	1/24/107	All Pages	Editorial Corrections
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Revision History

(i)

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6. Attachment ······

(ii) PQF-HD-18041-026 Rev.I Purpose

This procedure describes the process for evaluating the acceptability of previous design verification data or results, when applied to US-APWR project.

- 2. Responsibility
 - (1) General Managers of Engineering Departments in Nuclear Energy Systems Engineering Center (N-Center Manager) are responsible for:
 - a) the evaluation results of previous design verification data or results when they are applied to US-APWR project.

b) retaining the evaluation records with the original records.

- (2) General Manager of Nuclear Energy Systems Quality & Safety Management Department (NESQD Manager) is responsible for reviewing that the evaluation of the previous design verification data or results is performed in accordance with this procedure.
- Scope

This procedure governs the evaluation of previous design verification data or results for US-APWR project.

4. Procedure

When the previous design verification data or results produced in accordance with a prior version of MHI's QA plan are proposed for use in the US-APWR project, the responsible N-Center Manager shall evaluate them for use in the US-APWR design. The evaluation shall be performed in accordance with this procedure, and the results recorded on the Attached SHEET-1 "Evaluation Sheet of Past Design Qualification Data".

4.1 Identification of design data or results

The responsible N-Center Manager shall identify the design verification data or results to be evaluated for US-APWR project.

4.2 Evaluation

The responsible N-Center Manager shall perform the evaluation of design verification data or results in accordance with the following procedure.

(1) Procedure

a) Confirmation of Test Procedure

Qualified personnel of the design organization responsible for re-evaluation shall confirm that the past design data were obtained using a test procedure that is consistent with the currently relevant design prerequisites.

- b) Evaluation of test personnel
 - Qualified personnel of the design organization responsible for re-evaluation shall confirm that the past test was performed by those who meet the present requirement of competence.
- c) Evaluation of test equipment

Qualified personnel of the design organization responsible for re-evaluation shall confirm the accuracy of test equipments and measurements by taking consideration of test objectives and acquired results and evaluate.

d) Evaluation of test procedure (execution)

Qualified personnel of the design organization responsible for re-evaluation shall

confirm that the test was executed as specified in the test procedure.

e) Evaluation of test results

The test results at that time shall be evaluated by comparing them with other test result and/or expected result.

f) Evaluation of design personnel concerning to the test

Qualified personnel of the design organization responsible for re-evaluation shall confirm that the design personnel responsible for the test at that time participated in the test process from preparation to witness, and with respect to prove objectivity of test, he also confirms whether witness inspection by third party was performed or not.

(2) The responsible N-Center Manager shall send the evaluation results sheet to NESQD Manager.

- (3) The NESQD Manager shall evaluate it from the results of the re-evaluation and fill in the decision to the SHEET-1 "Evaluation Sheet of Past Design Qualification Data". When re-evaluation results are not acceptable, NESQD Manager shall apprise the responsible N-Center Manager to take corrective action. Corrective Action shall be performed in accordance with 'Corrective Action Procedure (PQF-HD-18041-061)'.
 (4) Responsible N-Center Manager shall take the necessary action, and he shall report to NESQD Manager.
- (5) NESQD Manager shall follow and confirm the results.

5. Records

The responsible N-Center Manager shall retain the completed evaluation sheet with evidence as to the record for plant lifetime.

6. Attachment

(1) SHEET-1 : Evaluation Sheet of Past Design Qualification Data

PQF-HD-18041-026 Rev. 1



Attachment (4/4)

SHEET-1

Evaluation Sheet of Past Design Qualification Data

Design Document / Data Name		Engineering Se	ction		
Approve	Re	view	Prepare		
: :					
Evaluation	ltem		Evaluation F	Results	
 a) Confirmation of test procedure Qualified personnel of the design organ shall confirm that the past design data we that is consistent with the currently relevant 	ization responsible for re-evaluation ere obtained using a test procedure ant design prerequisites.	-			
b) Evaluation of test personnel Qualified personnel of the design organ shall confirm that the past test was perfor present requirement of competence.					
c) Evaluation of test equipment			•		
Qualified personnel of the design organ shall confirm the accuracy of test equipm consideration of test objects and acquire	S A	MP			
Qualified personnel of the design organ shall confirm that the test was executed	ization responsible for re-evaluation as specified in the test procedure.				
 e) Evaluation of test results The test results at that time shall be eva other test result and/or expected result. 	aluated by comparing them with		· · · · · · · · · · · · · · · · · · ·		
f) Evaluation of design personnel concern Confirm that the design personnel response participated in the test process from prep to prove objectivity of test; he also confirm third party was performed or not	ting to the test onsible for the test at that time paration to witness, and with respect ms whether witness inspection by				
	Overall Evaluation		Approve	Review	
NESQD	· · ·				

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