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Enclosure 3

**Response to Portion of NRC Request for Additional
Information Letter No. 141 Related to ESBWR Design
Certification Application
RAI Number
7.1-76**

GEH Non-Proprietary Version



**GE-Hitachi Nuclear Energy
Nuclear**

3901 Castle Hayne Rd
Wilmington, NC 28401

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Revision 2 3
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**LICENSING TOPICAL REPORT
ESBWR I&C SOFTWARE MANAGEMENT ~~PLAN~~ PROGRAM MANUAL
(SMPM)**

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2.3 Supplemental Documents

The following supplemental documents are used in conjunction with the SMPM and enable the performance of the activities stated in Appendix A. These documents are subject to revision to remain current with GEH internal procedures, and do not require the SMPM to be updated when they are revised. Requirements, which are being met by these documents, will be maintained via RTM.

<u>Reference Number</u>	<u>Document Title</u>	<u>Document Number</u>
1.	ESBWR I&C Software Quality Assurance Plan (SQAPM)	NEDO-33245
<u>GE-Hitachi Nuclear Energy Procedures and Policies</u>		
	<u>Document Title</u>	<u>Abstract</u>
2.a	<u>Work Planning and Scheduling</u>	<u>Defines the process and responsibilities for developing and documenting work plans and schedules for customer-contracted design work and authorized projects.</u> <u>Four key purposes of a Project Work Plan are to define project scope, develop a schedule, monitor progress, and control resources.</u>
2.b	<u>Engineering Computer Programs</u>	<u>Defines requirements for the control of computer programs defined as Engineering Computer Programs.</u>
2.c	<u>Design Review</u>	<u>Defines responsibilities and procedural requirements for conducting formal, design adequacy evaluations.</u> <u>Design Reviews are used to verify that product designs meet customer, functional, contractual, safety, health, environmental, regulatory, industry codes and standards, and corporate requirements.</u>
2.d	<u>Design Record File</u>	<u>Defines the process for the generation of a Design Record File, which is a formal, controlled information record for in-progress and completed engineering work.</u>
2.e	<u>Material Request</u>	<u>Details responsibilities and procedural requirements for the release of technical, engineering, customer, and quality requirements that define material, equipment, labor, services and related data to meet GE-Hitachi Nuclear Energy (GEH) contract/purchase order, code, and regulatory requirements.</u>

2.f	<u>Independent Design Verification</u>	<u>Details roles and responsibilities for reviewing and substantiating a design to provide independent and documented confirmation that the design meets specified requirements.</u>
2.g	<u>Deferred Design Verification</u>	<u>Defines the process for deferring design verification and for clearing previous deferrals. The process applies to cases where a design, or portion of a design, must be released prior to completion of verification.</u>
2.h	<u>Document Initiation or Change by Engineering Review Memorandum/Engineering Change Notice</u>	<u>Establishes the requirements for the initiation of or change to engineering controlled documents by use of the Engineering Review Memorandum/Engineering Change Notice. The process ensures traceability, configuration, and quality assurance of engineering documents are maintained through the current document revision, status, and final disposition.</u>
2.i	<u>Procurement Initiation and Control</u>	<u>Specifies the requirements for procurement of material, equipment, and services, including the application of technical, engineering, customer, and quality requirements on purchase orders. Defines the requirements for establishing and maintaining the Approved Suppliers List.</u>
2.j	<u>Field Deviation Disposition Request</u>	<u>Establishes a process to document and disposition the technical position for field deviations to GEH supplied hardware, software, or services. Responsible individuals evaluate Field Deviation Disposition Request's to assure that the proposed field action meets safety, technical, quality, application and commercial requirements.</u>
2.k	<u>Safety-Related Classification</u>	<u>Defines the requirements used to identify structures, systems, components, parts, and technical services that are safety-related.</u> <u>Safety-related structures, systems, components, and parts provide safety-related functions necessary to assure:</u> <ol style="list-style-type: none"> <u>a. The integrity of the reactor coolant pressure boundary; or</u> <u>b. The capability to shut down the reactor and maintain it in a safe shutdown condition; or</u> <u>c. The capability to prevent or mitigate the consequences of accidents that could result in potential off site exposures comparable to 10CFR50.34(a)(1) or 10CFR100.11 guideline exposures, as applicable.</u>

2.1	<u>Operation and Maintenance Instruction Manuals</u>	<u>Defines requirements applicable to the preparation, review, and approval of Operation and Maintenance instruction manuals.</u>
2.m	<u>Self Assessment, Corrective Action and Audits</u>	<u>Specifies the responsibilities for actions to promptly identify, record and correct Conditions Adverse to Quality to assure that these conditions do not affect the quality of products or services. Defines the requirements and responsibilities for conducting ongoing self-assessments, focused self-assessments, and internal audits of organizations within GEH.</u>
2.n	<u>Quality and Technical Training</u>	<u>Defines the roles and responsibilities to assure personnel proficiency in quality and technical related activities. The Quality and Technical Training program:</u> <ul style="list-style-type: none"> <u>a. Ensures personnel are trained and proficient in assigned quality and technical tasks.</u> <u>b. Documents qualifications for technical positions, including minimum education, experience, and any special training requirements.</u> <u>c. Records training assignments in a centralized controlled training database.</u>
3.a	<u>Work Authorization</u>	<u>Establishes the requirements and responsibilities within GEH for the preparation and approval of Work Authorizations that communicate requirements to functional components of GEH or Global Nuclear Fuel.</u>
3.b	<u>Project Risk Management Procedure</u>	<u>Implements the project risk management requirements of GEH Policy. Provides a controlled process for risk management to maintain positive control of work situations, especially during critical tasks or activities.</u>
3.c	<u>Project Management Policy</u>	<u>Provides requirements for the single Project Management process across all GEH. The process components include project initiation, planning, scheduling, execution, controls, and post-delivery closeout.</u>
3.d	<u>Project Financial Management</u>	<u>Establishes specific requirements and describes typical methods that are used to assure project financial management activities are accomplished in compliance with GEH Policies.</u>

3.e	<u>Quality Policy and Quality System Requirements</u>	<u>Establishes the requirements of the GEH business quality system. Defines requirements necessary to implement the quality policy and to demonstrate, by performance both inside and outside GEH, total dedication to the attainment of quality leadership and customer satisfaction.</u>
3.f	<u>Nuclear Energy Quality Assurance Audit Requirements</u>	<u>Establishes the requirements and processes for a comprehensive audit program to verify the implementation and effectiveness of the GEH Quality System. The audit program requirements apply to hardware, software and service products and to all personnel who perform quality-related activities on them.</u>
3.g	<u>Reporting of Defects and Noncompliance Under 10CFR Part 21</u>	<u>Defines the requirements and responsibilities within GEH for ensuring compliance with the requirements of Part 21 of Title 10 of the Code of Federal Regulations, i.e., 10CFR21, "Reporting of Defects and Noncompliance".</u>
<u>Document Title</u>		<u>Document Number</u>
4.	<u>ESBWR Cyber Security Program Plan</u>	<u>NEDO-33295</u>
5.	<u>ESBWR HFE Training Development Implementation Plan</u>	<u>NEDO-33275</u>
6.	<u>IEEE Standard Glossary of Software Engineering Terminology</u>	<u>IEEE 610.12-1990</u>
7.	<u>Guidelines on Evaluation and Acceptance of Commercial Grade Digital Equipment in Nuclear Safety Applications</u>	<u>EPRI TR-106439</u>

3.0 SOFTWARE MANAGEMENT PLAN

3.1 Purpose and Scope

The purpose of the SMPM is to establish the managerial process and the technical direction for the design and development activities of the Digital Computer-Based I&C Software within the scope of the MMIS/HFE IP [2.1(1)].

3.2 Organization

The organization is established to address the control of software management and to ensure that independence is maintained between the design organization and the quality assurance, software safety, and Verification and Validation (V&V) organizations. The organization is shown in Figure 3-1.

This section describes the following ESBWR organization functions:

1. I&C and Electrical Systems Engineering.
2. Software Project Engineering (SPE).
3. Configuration Management. (HFE).
4. Project Management (i.e. Project Control).
5. Training.

3.2.1 I&C and Electrical Systems Engineering

The I&C software development organization is comprised of the GEENH I&C and Electrical Systems Engineering organization and the (GEENH and non- GEENH) software products vendor organization. The GEH I&C and Electrical System Engineering (I&C/ESE) Organization is comprised of the I&C and Electrical Systems Engineering Manager (I&C Manager), the platform Technical Project Engineers (TPEs), and the responsible I&C/ESE. This organization implements the activities defined in the SMPM.

The I&C Manager is responsible for overall performance and schedule of the software development effort, including work flow to the system TPEs, system engineers, and software products vendors. The platform TPEs are responsible for day to day management, coordination, and scheduling of the system design and software development effort and are responsible for interfacing with the system engineers and software product vendors. The TPEs are also responsible for providing status reports to the I&C Manager.

The I&C/ESE engineer is responsible for the design and development of the software products. The I&C/ESE is responsible for review, and for confirming that the design documentation and outputs produced by the software products vendors meets the technical requirements specified in the contract/purchase order.

The software product vendors shall produce the software described in this SMPM. The vendors

may be internal or external to GEENH. The vendors shall be organized such that a single Point of Contact (POC) is assigned the responsibility of interfacing with the TPE. Alternative POCs shall be assigned to take over the duties of the POC whenever the Primary POC is unavailable. The POC and alternative POCs shall be determined by the hardware/software vendor organization and may be any individual within the organization who is qualified to act as the organization's agent. Software developed by the vendors shall be in accordance with this SMPM and the SQAPM [2.3(1)].

3.2.2 Software Project Engineering

The SPE is independent of the I&C/ESE organization to ensure organizational freedom to perform the Quality tasks without undue pressure or conflict of interest related to budget or schedule.

The SPE organization, which is comprised of the following teams, is responsible for executing the quality tasks as described in the SQAPM [2.3(1)]:

- Independent Verification and Validation Team (IVVT)
- Software Safety Analysis Team (SST)
- Baseline Review Team (BRT)

The SPE organization is described in the SQAPM [2.3(1)] Subsection 3.3.5. The Simulation Assisted Engineering (SAE) and HFE teams do not perform the quality tasks and are not described in the SQAPM.

3.2.3 Training

Training requirements are addressed in Section 4.5 of this SMPM.

3.2.4 Configuration Management Manager

The Configuration Management Manager (CMM) has the overall responsibility and authority for the Configuration Management System (CMS), herein referred to as Product Data Management System (PDMS). The CMM responsibilities are addressed in the SCMP [2.3(1) Section 10.0].

3.2.5 Software Quality Assurance Manager

The SQA Manager interfaces with the SPE Manager and has the overall responsibility and authority for the SQA program. The SQA Manager responsibilities are addressed in the SQAPM [2.3(1)].

3.2.6 Project Management Team

The technical management of software products is the responsibility of the TPEs. The Project Management Team (PMT) is responsible for the commercial aspects of the project. A commercial Project Manager (PM) shall be assigned to oversee each of the projects, and shall be responsible for delivering the commitments of a Purchase Order and/or Sales Contract to the

Licensee.

The following activities are included:

1. Project work planning.
2. Development and maintenance of the integrated project schedule. The TPEs shall provide task inputs and support for this activity.
3. Update of the integrated schedule to show that project tasks are completely and accurately reflected.
4. Assignment of project resources and skill sets to support the project needs.
5. Preparation of project progress reports.
6. Project risk management assessment.
7. Project budgeting.
8. Engineering procurement and/or fabrication.
9. Communication with Licensee and vendors.

3.3 Organizational Boundaries and Interfaces

The SMPM and SQAPM [2.3(1)] specify the organizational structures for the I&C and Electrical Systems Engineering and SPE. This includes boundaries and relationships with the external and internal organizations. The PM provides the Licensee and vendor interface with the I&C/ESE and SPE organization. [[

]]

3.4 Organizational Responsibilities

Organizational responsibilities are defined in the following Sections:

3.4.1 New Units Engineering Manager

The New Unit Engineering Manager is responsible for the New Units Engineering organization. The ESBWR Engineering, Configuration Management, and SPE managers report to the New Units Engineering Manager.

3.4.2 ESBWR Engineering Manager

The ESBWR Engineering Manager is responsible for directing the engineering activities of the ESBWR Project. The ESBWR Engineering Manager reports to the New Units Engineering Manager.

3.4.3 I&C and Electrical Systems Engineering Manager

The I&C Manager is responsible for directing the engineering work of the I&C and Electrical Systems Engineering organization. The functional leads for various I&C/ESE functions report to the I&C and Electrical Systems Engineering Manager. The I&C/ESE Manager reports to the ESBWR Engineering Manager.

3.4.4 SPE Manager

The SPE Manager is responsible for the software quality tasks during the design and development of the software product. The SPE Manager reports to the I&C New Unit Engineering Manager.

3.4.5 SQA Manager

The SQA Manager, who interfaces with the SPE Manger, has the overall responsibility and authority of SQA Program. The SQA Manager reports to the Quality General Manager.

3.4.6 Training Services Lead (TSL)

The TSL is responsible for organizing the overall training process, including scheduling, budgeting, and resource allocation. The TSL reports to the Plant Performance and Optimization Manager.

3.4.7 Configuration Management Manager (CMM)

The CMM is responsible for the configuration management of the ESBWR project, including software products. The CMM reports to the New Units Engineering Manager.

3.4.8 Technical Project Engineer (TPE)

The TPEs have technical responsibility for the software tasks related to software or a group of software products. The TPE's report to the I&C/ Electrical Systems Engineering Manager.

3.5 Software Management Plan Change Control Process

The SMPM is applicable for the entire life cycle of the software product. It is anticipated that the software development cycle shall evolve with changes in software development technology. It is acceptable to revise the SMPM to improve quality. The change control process is described in the SQAPM [2.3(1)].

The SMPM is a controlled document under configuration control in accordance with the SCMP [2.3(1) Section 10.0]. [[

]]If a change to the SMPM is warranted, one of the SQA activities shall determine if NRC notification is required and shall track the notification process as defined by the MMIS HFE IP [2.1(1)].

Changes to the SMPM require approval of the I&C Manager and SPE Manager or designated appointees. [[

]] If changes to the SMPM are made, the SQA Manager must document an

evaluation showing that previously completed projects do not have to be reopened to implement the SMPM changes. When changes are made to the SMPM, requirements traceability will be maintained and verified.



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ESBWR - I&C Software Quality Assurance ~~Plan~~ Program Manual (SQAPM)

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2.3 SUPPLEMENTAL DOCUMENTS

The following supplemental documents are used in conjunction with the SQAPM and enable the performance of the activities stated in Appendix A. These documents are subject to revision to remain current with ~~GEEN~~ GEH internal procedures, and do not require the SQAPM to be updated when they are revised.

<u>Reference Number</u>	<u>Document Title</u>	<u>Document Number</u>
<u>1.</u>	<u>ESBWR I&C Software Management Program Manual (SMPM)</u>	<u>NEDO-33226</u>
<u>GE-Hitachi Nuclear Energy Procedures and Policies</u>		
<u>Reference Number</u>	<u>Document Title</u>	<u>Abstract</u>
<u>2.a</u>	<u>Work Planning and Scheduling</u>	<u>Defines the process and responsibilities for developing and documenting work plans and schedules for customer-contracted design work and authorized projects. Four key purposes of a Project Work Plan are to define project scope, develop a schedule, monitor progress, and control resources.</u>
<u>2.b</u>	<u>Product Data Management System</u>	<u>PDMS is the computer-based data system that stores, retrieves, and reports data relevant to the engineering definition of products and services offered and provided to customers. It provides current listings of the engineering documents under formal GE-Hitachi Nuclear Energy (GEH) change control (i.e., engineering controlled documents) that have been approved for issue or application to specific standard, requisition, fuel, and operating plant projects.</u>
<u>2.c</u>	<u>Supplier Design Services Document Review</u>	<u>Defines responsibilities and procedural requirements for review, approval, and control of documentation from suppliers for design services. Supplier submitted documents are entered as elements of the design basis in the Product Data Management System as engineering controlled documents or Design Record Files.</u>

NEDO-33245, Rev 2

2.d	<u>Engineering Test</u>	<u>Defines the process for specifying, performing, evaluating, and documenting engineering tests.</u>
2.e	<u>Design Review</u>	<u>Defines responsibilities and procedural requirements for conducting formal, design adequacy evaluations. Design Reviews are used to verify that product designs meet customer, functional, contractual, safety, health, environmental, regulatory, industry codes and standards, and corporate requirements.</u>
2.f	<u>Design Process</u>	<u>Defines the process for performing, documenting, and certifying design activities. Design activities include developing or modifying the design of systems, hardware and software, and the performance or modification of licensing studies, engineering evaluations, analyses, calculations and document preparation (e. g., specifications, drawings, reports).</u>
2.g	<u>Design Record File</u>	<u>Defines the process for the generation of a Design Record File, which is a formal, controlled information record for in-progress and completed engineering work.</u>
2.h	<u>Material Requests</u>	<u>Details responsibilities and procedural requirements for the release of technical, engineering, customer, and quality requirements that define material, equipment, labor, services and related data to meet GEH contract/purchase order, code, and regulatory requirements.</u>
2.i	<u>Independent Design Verification</u>	<u>Details roles and responsibilities for reviewing and substantiating a design to provide independent and documented confirmation that the design meets specified requirements.</u>
2.j	<u>Deferred Design Verification</u>	<u>Defines the process for deferring design verification and for clearing previous deferrals. The process applies to cases where a design, or portion of a design, must be released prior to completion of verification.</u>

NEDO-33245, Rev 2

<p>2.k</p>	<p><u>Document Initiation or Change by Engineering Review Memorandum/Engineering Change Notice</u></p>	<p><u>Establishes the requirements for the initiation of or change to engineering controlled documents by use of the Engineering Review Memorandum/Engineering Change Notice. The process ensures traceability, configuration, and quality assurance of engineering documents are maintained through the current document revision, status, and final disposition.</u></p>
<p>2.l</p>	<p><u>Procurement Initiation and Control</u></p>	<p><u>Specifies the requirements for procurement of material, equipment, and services, including the application of technical, engineering, customer, and quality requirements on purchase orders. Defines the requirements for establishing and maintaining the Approved Suppliers List.</u></p>
<p>2.m</p>	<p><u>Supplier Supporting Document Review</u></p>	<p><u>Defines responsibilities and procedural requirements for review and acceptance of supporting documents submitted by suppliers of material, equipment and services to satisfy GEH Purchase Order requirements.</u></p>
<p>2.n</p>	<p><u>Deviation Disposition Requests from Suppliers</u></p>	<p><u>Establishes the requirements and procedure for processing Deviation Disposition Requests submitted by suppliers to obtain a disposition of deviations from the technical requirements of GEH Purchase Order requirements.</u></p>
<p>2.o</p>	<p><u>Supplier Change Request</u></p>	<p><u>Defines supplier responsibility and procedural requirements for the submittal of a Supplier Change Request to obtain an exception or change to GEH Purchase Order requirements.</u></p>

NEDO-33245, Rev 2

<p>2.p</p>	<p><u>Engineering Change Control</u></p>	<p><u>Establishes the process used to control and authorize changes to engineering controlled documents to:</u></p> <ul style="list-style-type: none"> a. <u>Assure that total impact is considered before a change is approved and that the affected documents are identified and changed as approved;</u> b. <u>Provide authority for a change and identify all pertinent interfaces and organizations responsible for these interfaces; and,</u> c. <u>Provide accurate and traceable records of a change.</u>
<p>2.q</p>	<p><u>Field Deviation Disposition Request</u></p>	<p><u>Establishes a process to document and disposition the technical position for field deviations to GEH supplied hardware, software, or services. Responsible individuals evaluate Field Deviation Disposition Request's to assure that the proposed field action meets safety, technical, quality, application and commercial requirements.</u></p>
<p>2.r</p>	<p><u>Change Control Board</u></p>	<p><u>Defines the requirements and procedures applicable to the operation of a Change Control Board that is responsible for reviewing proposed changes to design or product configuration documents. Establishment of a Change Control Board and application of this procedure are at the discretion of project management for any particular project or group of projects.</u></p>
<p>2.s</p>	<p><u>Quality Record Computer Data</u></p>	<p><u>Prescribes the requirements, procedures, and responsibilities for the control, retention, and retrieval of quality record computer-based data maintained within the central computing facility of GEH. It includes, but is not restricted to, textual data, computer databases, computer program source data, and binary computer programs.</u></p>

NEDO-33245, Rev 2

<p><u>2.t</u></p>	<p><u>Safety-Related Classification</u></p>	<p><u>Defines the requirements used to identify structures, systems, components, parts, and technical services that are safety-related.</u></p> <p><u>Safety-related structures, systems, components, and parts provide safety-related functions necessary to assure:</u></p> <ul style="list-style-type: none"> a. <u>The integrity of the reactor coolant pressure boundary; or</u> b. <u>The capability to shut down the reactor and maintain it in a safe shutdown condition; or</u> c. <u>The capability to prevent or mitigate the consequences of accidents that could result in potential off site exposures comparable to 10CFR50.34(a)(1) or 10CFR100.11 guideline exposures, as applicable.</u>
<p><u>2.u</u></p>	<p><u>Dedication of Commercial Grade Items</u></p>	<p><u>Establishes the requirements and responsibilities for dedicating commercial grade items procured for use in safety-related applications.</u></p>
<p><u>2.v</u></p>	<p><u>Self Assessment, Corrective Action and Audits</u></p>	<p><u>Specifies the responsibilities for actions to promptly identify, record and correct Conditions Adverse to Quality to assure that these conditions do not affect the quality of products or services. Defines the requirements and responsibilities for conducting ongoing self-assessments, focused self-assessments, and internal audits of organizations within GEH.</u></p>
<p><u>2.w</u></p>	<p><u>Control of Nonconforming Material</u></p>	<p><u>Describes the methods by which nonconforming material is documented and controlled at GEH.</u></p>

NEDO-33245, Rev 2

<p>2.x</p>	<p><u>Quality and Technical Training</u></p>	<p><u>Defines the roles and responsibilities to assure personnel proficiency in quality and technical related activities. The Quality and Technical Training program:</u></p> <ul style="list-style-type: none"> a. <u>Ensures personnel are trained and proficient in assigned quality and technical tasks.</u> b. <u>Documents qualifications for technical positions, including minimum education, experience, and any special training requirements.</u> c. <u>Records training assignments in a centralized controlled training database.</u>
<p>3.a</p>	<p><u>Project Risk Management Procedure</u></p>	<p><u>Implements the project risk management requirements of GEH Policy. Provides a controlled process for risk management to maintain positive control of work situations, especially during critical tasks or activities.</u></p>
<p>3.b</p>	<p><u>Project Management Policy</u></p>	<p><u>Provides requirements for the single Project Management process across all GEH. The process components include project initiation, planning, scheduling, execution, controls, and post-delivery closeout.</u></p>
<p>3.c</p>	<p><u>Quality Policy and Quality System Requirements</u></p>	<p><u>Establishes the requirements of the GEH business quality system. Defines requirements necessary to implement the quality policy and to demonstrate, by performance both inside and outside GEH, total dedication to the attainment of quality leadership and customer satisfaction.</u></p>
<p>3.d</p>	<p><u>Nuclear Energy Quality Assurance Audit Requirements</u></p>	<p><u>Establishes the requirements and processes for a comprehensive audit program to verify the implementation and effectiveness of the GEH Quality System. The audit program requirements apply to hardware, software and service products and to all personnel who perform quality-related activities on them.</u></p>

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<p><u>3.e</u></p>	<p><u>Reporting of Defects and Noncompliance Under 10CFR Part 21</u></p>	<p><u>Defines the requirements and responsibilities within GEH for ensuring compliance with the requirements of Part 21 of Title 10 of the Code of Federal Regulations, i.e., 10CFR21, "Reporting of Defects and Noncompliance".</u></p>
<p><u>Reference Number</u></p>	<p><u>Document Title</u></p>	<p><u>Document Number</u></p>
<p><u>4.</u></p>	<p><u>IEEE Standard Glossary of Software Engineering Terminology</u></p>	<p><u>IEEE 610.12-1990</u></p>
<p><u>5.</u></p>	<p><u>Guidelines on Evaluation and Acceptance of Commercial Grade Digital Equipment in Nuclear Safety Applications</u></p>	<p><u>EPRI TR-106439</u></p>
<p><u>6.</u></p>	<p><u>ESBWR Cyber Security Program Plan</u></p>	<p><u>NEDO-33295</u></p>