

May 9, 2016

Mr. James Powers
Vice President, Nuclear Island & Business Development
Toshiba America Energy Systems Corporation
3545 Whitehall Park Drive
Suite 500
Charlotte, NC 28273

SUBJECT: REGULATORY AUDIT PLAN FOR MAY 16-20, 2016, TOSHIBA "LICENSING TOPICAL REPORT FOR TOSHIBA NRW [NON RE-WRITABLE]-FPGA [FIELD PROGRAMMABLE GATE ARRAY]-BASED INSTRUMENTATION AND CONTROL SYSTEM FOR SAFETY-RELATED APPLICATION," UTLA 0020P, REVISION 2 (TAC NO. ME9861)

Dear Mr. Powers:

By letter dated February 23, 2015, Toshiba Corporation (Toshiba) submitted Revision 2 to "Licensing Topical Report For Toshiba NRW-FPGA-Based Instrumentation And Control System For Safety-Related Application" (Agencywide Documents Access and Management System Accession No. ML15062A183). The topical report (TR) is supported by documentation that includes plans, requirements, design specifications, programming and hardware testing, independent verification and validation, and equipment qualification testing.

The U.S. Nuclear Regulatory Commission (NRC) staff is currently reviewing the TR for use in safety system equipment at nuclear power plants. As part of its review, the NRC staff will be performing a regulatory audit of Toshiba. The dates for this audit will be May 16-20, 2016.

The audit will determine the degree that the processes and outputs used have resulted in satisfying regulatory requirements for safety system applications at nuclear power plants. This audit will provide information necessary to complete the NRC staff's evaluation of the Toshiba TR. Enclosed is a copy of the plan the NRC staff will follow on the audit.

J. Powers

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If you any questions or require any additional information, please feel free to contact me at 301-415-7297 or Joseph.Holonich@nrc.gov.

Sincerely,

/RA/

Joseph J. Holonich, Project Manager
Licensing Processes Branch
Division of Policy and Rulemaking
Office of Nuclear Reactor Regulation

Enclosure:
Audit Plan

Project No. 780

J. Powers

- 2 -

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DATE	05/02/2016	04/26/2016	0502/2016	05/06/2016	05/09/2016

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**U.S. NUCLEAR REGULATORY COMMISSION STAFF AUDIT PLAN FOR
TOSHIBA NONREWRITABLE FIELD-PROGRAMMABLE GATE ARRAY
BASED POWER RANGE MONITORING SYSTEM
AND OSCILLATION POWER RANGE MONITORING UNIT**

**MAY 16-20, 2016
TOKYO, JAPAN**

Background

The U.S. Nuclear Regulatory Commission (NRC) staff is currently engaged in a review of the Toshiba Non-Rewritable-Field-Programmable Gate Array (FPGA)-based Power Range Monitoring (PRM) and Oscillation Power Range Monitoring (OPRM) system licensing topical report (TR). The PRM system is a digital platform that Toshiba believes is appropriate for use in replacing existing PRM systems in boiling water reactors (BWRs) in U.S. nuclear plants. The OPRM unit is a digital unit that can be used in conjunction with PRM systems for advance BWRs to be constructed in the U.S.

Toshiba is seeking generic approval of the basic features and attributes of these two systems. This regulatory audit is intended to assist the NRC staff in confirming information submitted as part of the licensing TR.

Regulatory Audit Bases

The NRC staff is currently evaluating both Toshiba design and development processes for the PRM system and for the OPRM unit. To support this review, the staff will visit the Toshiba facility in Tokyo, Japan. The purpose of the audit is to review evidence that support compliance with NRC regulations concerning:

- Commercial Grade Dedication (Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21, as elaborated in Electric Power Research Institute TR-106439).
- Digital Safety System Software Quality and Processes (10 CFR Part 50, 10 CFR Part 50 Appendix A, and 10 CFR Part 50 Appendix B, as elaborated in BTP 7-14 and applicable regulatory guides (RGs)).
- Secure Development Environment (10 CFR Part 50 and 10 CFR Part 50 Appendix B, as elaborated in RG 1.152, Revision 3).

Regulatory Audit Scope

As part of the audit, the NRC staff will review non-docketed procedures and records related to Toshiba processes, as well as interview key Toshiba personnel. The staff will be evaluating whether the results of these actions substantiate that processes described in the licensing TR are being followed.

Enclosure

Information Necessary for the Regulatory Audit

Toshiba should be prepared to have the following documentation and information available.

- Requirements Threads – In order to gain an overview of the Toshiba PRM system and OPRM unit software and hardware development processes, the staff would like to see documentation from requirements phase through testing (i.e., records related to requirements, design, coding, testing, and verification).
- Commercial Grade Dedication – In order to help confirm the Toshiba commercial grade dedication activities for both the PRM system and OPRM unit, the staff would like to see:
 - In the dedication report for the critical physical characteristics, credit was taken for an internal quality assurance procedure, configuration management process, as well as an internal audit. The staff would like to review the records from the internal audit. If practical, the staff would also like to interview Toshiba personnel involved in the handling and acceptance of components that have undergone commercial grade dedication.
 - Procedures followed for processing of non-conformity reports. Those procedures, as well as a couple of the most recent examples of records related to non-conformity reports, would be valuable for the staff to review during the audit.
 - Processes used to develop and maintain the FPGAs used in the PRM system and OPRM unit.
- Digital Safety System Software Quality
 - Confirm the verification & validation processes are implemented, with a focus on record keeping, documentation, and management activities (including identification of documents associated with safety related components).
 - Confirm configuration management processes are implemented, with a focus on record keeping, documentation, and management activities (including identification of documents associated with safety related components).
- Secure Development Environment
 - This section of the audit will include interviews with Toshiba personnel and observations of the Toshiba development environment.

Team Assignments

The NRC staff performing the audit will be:

- Rossnyev Alvarado – audit team lead; commercial grade dedication of the PRM system; software processes (focus: independent verification & validation for both PRM system and OPRM unit; requirements threads for the PRM system).

- Samir Darbali – software processes (focus: configuration management for both PRM system and OPRM unit; secure development environment for both PRM system and OPRM unit).
- Daniel Warner – software processes (focus: requirements threads for the OPRM unit; software processes; commercial grade dedication of the PRM system).

Logistics

The audit will take place at the Toshiba facility in Tokyo, Japan. The audit will start on the morning of May 16, 2016 (Monday) and conclude at the close of business May 20, 2016 (Friday). The NRC audit team will be arriving in Tokyo on May 14, 2016, and departing May 21, 2016, so travel constraints should not impact our work week for the audit.

Our tentative schedule for the audit is as follows:

- Monday, May 16, 2016 (8:30 am – 5:00 pm)
 - Entrance meeting (NRC staff – purpose of audit; Toshiba staff – brief overview of platform and facility)
 - 10:00 a.m. – Factory/training facility tour
 - 1:00 p.m. – Tentative plan is for audit team to jointly work on a requirements thread to see an overview of the entire software development process.
- Tuesday, May 17, 2016, – Thursday, May 19, 2016 (8:30 a.m. – 5:00 p.m.)
 - 9:00 a.m. – Morning meeting between the NRC staff and Toshiba to discuss activities and logistics for the day
 - 9:30 a.m. – Review of Toshiba documentation/interviews with key Toshiba personnel – staff may work together or individually, as circumstances dictate
 - 4:30 p.m. – NRC staff internal meeting
 - 5:00 p.m. (as needed) - NRC staff and Toshiba discuss any observations from the day
- Friday, May 20, 2016 (8:30 a.m. – 5:00 p.m.)
 - 9:00 a.m. – NRC staff internal meeting - identification/resolution of any open items
 - 3:00 p.m. – Exit meeting (NRC staff – general overview of observations and identification of any open items)

As circumstances dictate, the above schedule can be modified.

Special Requests

The NRC audit team members have no Japanese language skills. Toshiba has already been contacted about making reasonable efforts to translate requested documents. In addition, Toshiba should provide Japanese-English translators to facilitate interviews with Toshiba employees, as well as help translate documents. The staff does not want to place an unreasonable burden on translation services and, thus, would appreciate feedback on any translation requests.

Also, the NRC staff may request (early in the week) certain records or documents (of reasonable length) be translated during the course of the audit (e.g., an additional requirements thread).

Deliverables

The NRC regulatory audit report should be issued by July 15, 2016.