January 4, 2008

MEMORANDUM TO: Stacey L. Rosenberg, Branch Chief
Special Projects Branch
Division of Policy and Rulemaking
Office of Nuclear Reactor Regulation

FROM: Vanice A. Perin, Project Manager **/RA/**
Special Projects Branch
Division of Policy and Rulemaking
Office of Nuclear Reactor Regulation

SUBJECT: SUMMARY OF OCTOBER 15, 2007, CATEGORY 2 MEETING WITH TOSHIBA CORPORATION (TAC NO. MD6688)

On October 15, 2007, the U.S. Nuclear Regulatory Commission (NRC) held a meeting with representatives of Toshiba International Corporation (hereafter referred to as Toshiba) at NRC Headquarters, One White Flint North, 11555 Rockville Pike, Rockville, Maryland. The meeting announcement is in the Agencywide Documents Access and Management System as Accession No. ML072740017. The purpose of the meeting was to discuss the contents of Toshiba's Generic Topical Report (TR) on "Non-Rewritable Field Programmable Gate Array-Based Instrumentation and Control System Design Process (FPGA)" and the necessary support documentation that must accompany a TR to be reviewed by the NRC staff. This was a Category 2 meeting and in addition to Toshiba representatives attending the meeting, Toshiba staff in Japan participated via telephone. Members of the public were also present and a list of attendees is provided as Enclosure 1.

The meeting started with introductory remarks by both NRC staff and Toshiba representatives. Enclosure 2, "Consolidated List of Documents Requested to be Docketed for Acceptance Review," was provided by the NRC staff to the meeting attendees.

The Toshiba representatives stated that Toshiba plans to submit two TRs to the NRC as a two phased approach. The first of the TRs will be related to Toshiba's plans, methods, and procedures; and the second will be more specific to the FPGA system. The NRC staff expressed surprise over the statement on the two phased approach. The NRC staff pointed out that if the first TR is on concepts, procedures, and process on how to develop a system, then a number of the items in the provided list would not be required with the first TR, specifically those items dealing with results. Documents from the list related to instructions and plans on how to accomplish, control, verify, and test the development process should be provided to support the first TR. The NRC staff also pointed out that during the acceptance review most of the emphasis will be placed on verifying what is needed to perform the review of a TR (i.e., if the TR information is enough, complete, and technically sufficient).

The meeting continued with the discussion of each of the items in the list of documents with emphasis on the ones related to planning, software life cycle, verification and validation, quality assurance plan, and system requirements. The NRC staff stated that the provided list should not be used simply as a check-off list, and that it should be examined regarding items that are

appropriate and required for specific types of TRs. Also, the NRC staff clarified that a safety evaluation (SE) can be performed only on materials that have been properly submitted to the NRC and docketed.

The NRC staff explained that some documents in the list may be integrated as chapters or sections of major documents, as appropriate. However, the tables of contents and indexes should clearly indicate the location of the required documentation, for the benefit of the NRC staff reviewer.

The NRC staff instructed the Toshiba representatives on how to submit proprietary and non-proprietary versions of the TRs. In addition, the procedures for handling, justifying, and marking proprietary information were discussed. The NRC staff clarified that after the proprietary version of the TR is submitted, the non-proprietary version can follow slightly later, maybe by a few weeks, without delaying the review schedule.

The Toshiba representatives stated that many of the documents shown in the NRC list were already developed and would be submitted to the NRC with the TRs.

The NRC staff estimated that the TR review may take about one year considering the current and expected work load. The NRC staff indicated that the first TR on concepts, plans, and processes needs to be approved before the second TR is approved; however the second TR that is more specific to the FPGA system can be submitted before the first TR is approved.

The following schedule was discussed as an estimated time table; however, the NRC staff did not commit to the schedule:

- Toshiba submits the first TR around November 1, 2007.
- NRC staff completes the acceptance review around December 1, 2007.
- NRC staff sends the first set of requests for additional information (RAIs) to Toshiba by April 2008. This may be the only set of RAIs submitted to Toshiba by the NRC staff.
- Toshiba submits the second TR on system development in the spring of 2008.
- SE on first TR to be completed in November 2008.

The Toshiba representatives indicated the desire for another public meeting at the time of the submittal and/or at the time of the acceptance review, and also in the early spring in conjunction with the second TR submittal. The NRC staff stated that the acceptance review would determine if another public meeting was needed sooner.

Both the Toshiba representative and the NRC staff agreed to the use of e-mails and conference calls to handle minor items and provide clarifications whenever possible. In addition, it was agreed upon that meetings would be conducted as necessary to keep the schedule.

The Toshiba representatives indicated a desire for the NRC staff responsible for writing the SE to travel to Japan to visit their site and view their equipment. The NRC staff stated that the current “continuing resolution” may affect travel plans.

At the end of the meeting, the members of the public were given an opportunity to comment and they declined. The meeting was adjourned on time.

Project No. 729

Enclosures: 1. List of Attendees
2. Consolidated List of Documents

cc w/encl: See next page

CONTACT: Vanice A. Perin, NRR/DPR
301-415-8143

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List of Attendees for October 15, 2007	
Name	**Organization**
Rossnyev Alvarado	MPR Associates
Steven Arndt Eugene Eagle, Jr.	NRC/NRR/DE NRC/NRO/DE
Toshifumi Hayashi (via phone from Japan)	Toshiba
David Herrell	MPR Associates
Ryuji Iwasaki	Toshiba
Ian Jung Paul Loeser	NRC/NRO/DE NRC/NRR/DE
Jerry Mauck	STP 3 & 4
Tadashi Miyazaki (via phone from Japan) Hideki Nishiyama (via phone from Japan)	Toshiba Toshiba
Naotaka Oda (via phone from Japan)	Toshiba
Vanice Perin	NRC/NRR/DPR
David Rahn	NRC/RES/DE
Toshifumi Sato Hirofumi Takeda (via phone from Japan)	Toshiba Toshiba
Michael Waterman	NRC/RES/DE

ENCLOSURE 1

Consolidated List of Documents Required to Be Docketed Prior to Acceptance Review

1. Commercial Grade Dedication Plans
2. D3 Analysis
3. Description of system in sufficient detail to determine compliance with the ISG on Communications
4. Design Analysis Report
5. Design Report on computer integrity, test and calibration; and Fault detection and self-diagnostics
6. Detailed theory of operation description.
7. Draft Set point methodology
8. EMI, Temperature, Humidity, and Seismic testing plans
9. Software QA Plan / Procedures
10. System description to block diagram level
11. Hardware & Software Architecture Descriptions
12. Preliminary FMEA (non-docketed)
13. Quality Assurance Plan for digital hardware and software
14. Reliability Analysis
15. Safety Analysis
16. System Requirements Specification
17. System Test Plan
18. Software Life Cycle Documentation
    a. Software CM Plan
    b. Software Design Specification
    c. Software Development Plan;
    d. Software Installation Plan
    e. Software Integration Plan
    f. Software Maintenance Plan
    g. Software Management Plan
    h. Software Operations Plan
    I. Software Project Risk Management Program
    j. Software Requirements Specification
    k. Software Safety Plan
    l. Software Test Plan
    m. Software Tool Verification Program
    n. Software Training Plan
    o. Software V&V Plan and procedures

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