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Discussion material for Nov. 9th 2017 call
with the NRC
-Document Quality Issues-

Remarks:

1	Dec. 5, 2017	- Corrected typos after the discussion with NRC. - Added the document number on all pages.	<i>A. Hinokuma</i> Dec. 5, 2017	<i>A. Hinokuma</i> Dec. 5, 2017	<i>D. Oshima</i> Dec. 5, 2017
0	Nov. 7, 2017	Initial Issue	A. Hinokuma Nov. 7, 2017	A. Hinokuma Nov. 7, 2017	D. Oshima Nov. 7, 2017
Rev	Date	Description	Approved	Reviewed	Prepared

1. Purpose

This document was prepared for the discussions with the NRC in the call scheduled for Nov. 9th 2017.

This document summarizes document quality issues revealed in the process of NRC review of “Toshiba NRW-FPGA-Based Instrumentation and Control System for Safety-Related Application.”

2. Scope

The quality issues are summarized in the following three (3) tables.

- Table 1 Conditions revealed after NRC Audit May 2016
- Table 2 Conditions revealed by NRC Audit May 2016
- Table 3 QA program elements analysis

Table 1 summarizes conditions found after the NRC Audit held in May 2016. Toshiba understands those conditions cause NRC concerns and Toshiba expects that these conditions are the main discussion points for the Nov. 9th call.

For information, Table 2 summarizes conditions found before and during the NRC Audit held in May 2016. CARs and SCARs were issued and closed, except for a CAR shown in Table 2.

Table 3 summarizes the results of Toshiba analysis and maps the conditions in Table 1 and Table 2 in accordance with the 18 elements of quality defined in 10 CFR 50 Appendix B and explained in NQA-1.

Note 1) Most of the conditions which the NRC referred in the e-mail dated Oct. 17th, 2017 are included in Table 1. CAR-16-074(Item 2-1), SCAR-16-010(Item 2-2), and SCAR-16-011(Item 2-3) are included in Table 2 because they were issued during the NRC Audit in May 2016.

Note 2) Items 1-1 through 1-8, 1-10 and 1-11 in Table 1 and Items 2-1 through 2-3 in Table 2 are the issues addressed in the e-mail from the NRC dated Oct. 17th, 2017.

Table 1 Conditions revealed after NRC Audit May 2016

Item No.	Condition	CAR	Disposition	Status	Completion date	Category (NQA-1 criteria)	Impact to test specimens and test results
1-1	Many revisions to Table IV-4-1 due to inconsistencies identified during review. (Open Item 98)	CAR-17-050	<p>Table IV-4-1 was revised to correct all the errors and inconsistencies found so far.</p> <p>Toshiba understands that the cause of inconsistencies in Table IV-4-1 includes:</p> <ul style="list-style-type: none"> - poor initial understanding of EPRI TR-107330, - providing a high level compliance statements (reflecting compliance with the same idea, technically modified for the PRM or OPRM) rather than detailed descriptions with insufficient focus on literal compliance, - insufficient descriptions for application specific criteria due to the difficulties Toshiba had in interpreting and mapping the PLC centered requirements to FPGA-Based requirements. <p>These lessons learned shall be documented as a document and Toshiba's staff will be trained on the process.</p> <p>No change is required for test specimens and test results.</p>	On going	Dec. 28, 2017	Other than NQA-1 Quality elements	No impact
1-2	In Table IV-4-1 of the LTR, Toshiba shows compliance with EPRI requirements. However, in many cases (e.g., Item D in Section 7.2.2 of the ERS) we found that the acceptance criteria used for these tests are different than those in EPRI TR-107330. Toshiba specifies acceptance criteria in the ERS. (Open Item 100)	CAR-17-050	Same as Item 1-1 above.	On going	Dec. 28, 2017	Other than NQA-1 Quality elements	No impact

Item No.	Condition	CAR	Disposition	Status	Completion date	Category (NQA-1 criteria)	Impact to test specimens and test results
1-3	For Tests IEC 61000-4-4, 4-5, and 4-12, Toshiba specifies requirements in Sections 5.5.4 and 5.5.5 of the ERS for testing to low and medium exposure levels. However, Table III-2-3 of the LTR shows testing only to low exposure levels. (Open Item 117-1)	CAR-17-051	<p>The ERS will be revised.</p> <p>After document quality issues were identified before and during the Audit in May 2016, Toshiba expected more issues would be found. The errors and inconsistencies were found in the course of the NRC review. Toshiba has been archiving these errors, and will correct the associated documents after completing the extent of condition review, searching for further errors and inconsistencies.</p> <p>Toshiba understands that the causes for the errors and inconsistencies include:</p> <ul style="list-style-type: none"> - understanding in the early stage of the project, preparing the documents for the first time, - lack of appropriate and sufficient level of focus for change impact analysis, when a next tier design or test document is revised and the upper tier document is not revised, - lack of easily understandable mapping of the relationship among the documents that helps to track inter-dependency among the documents. <p>Based on the understandings above, Toshiba will prepare a document that defines the inter-dependency review among the documents. Toshiba is performing an extent of condition review to find further errors and inconsistencies before revising the documents at the appropriate time in the future.</p> <p>No change is required for test specimens and test results.</p>	<p>On going</p> <p>Toshiba has already started extent condition review.</p>	Feb. 28, 2018	3 (Design Control)	No impact

Item No.	Condition	CAR	Disposition	Status	Completion date	Category (NQA-1 criteria)	Impact to test specimens and test results
1-4	<p>Toshiba has been checking the documents in preparation to docket the documents the NRC requested in the RAI. Toshiba found the following issues.</p> <p>The NRC asked: "Table B10.2 of the Qualification Test Summary Report for IEC 61000-4-5 shows testing of [Line and Neutral] and Ground; whereas, Section 6.4.2.3 of the Qualification Test Summary Report shows this test point only for the Ring Wave (IEC 61000-4-12). Please clarify if this is a typographical error."</p> <p>Toshiba responded to the question by stating that Toshiba would correct Section 6.4.2.3 by stating that table B10.2 is correct. The applicable part of Section 6.4.2.3 of the Qualification Test Summary Report is copied below.</p> <p>6.4.2.3 Surge Withstand Capability Test In this test, surges were applied to the Test Specimen Units in accordance with IEC 61000-4-12 (for Ring Wave) and IEC 61000-4-5 (for Combination Wave). Surges were applied to the leads of power cable No. 10. The combinations of the power leads to which the surges were applied were as follows: Line and Neutral Line and Ground Neutral and Ground [Line and Neutral] and Ground, only for Ring Wave.</p> <p>However, when Toshiba checked the Toshiba test record for this test, Toshiba found only test records for a Ring Wave test of "[Line and Neutral] and Ground." With this finding, Toshiba would like to correct Toshiba's earlier response in such way that the surge withstand test for "[Line and Neutral] and Ground" was performed only for the Ring Wave test, and to correct Table B10.2 and keep the description of Section 6.4.2.3 consistent with the position above. (Open Item 117-3)</p> <p>This issue is a follow-up issue of item 1-10.</p>	<p>CAR-17-047 (This CAR is a follow-up CAR to CAR-16-130)</p>	<p>The Qualification Test Summary Report has been revised to correct the errors and inconsistencies found so far.</p> <p>Toshiba understands the issue of this CAR-17-047 is that Toshiba corrected the answer provided to the NRC to an earlier NRC question.</p> <p>Toshiba provided the wrong answers since relied on internal documents without a deep dive confirmation to the level of QA records (data).</p> <p>For this specific question, Toshiba checked the QA records (data) and determined that the previous answer should be corrected to be consistent with QA records (data).</p> <p>To make sure to provide correct answers in the discussion and communication with NRC Toshiba will develop a procedure which incorporates the consistency review with the QA records.</p> <p>No change is required for test specimens and test results.</p>	On going	Feb. 28, 2018	<p>6 (Document Control)</p> <p>6-1 Conditions in descriptions</p>	No impact

Item No.	Condition	CAR	Disposition	Status	Completion date	Category (NQA-1 criteria)	Impact to test specimens and test results
1-5	Tables B13.1 and B13.2 of the Qualification Test Summary Report are not consistent with the description of AO modules tested in Section III-2.2.3.6 of the LTR. For example, AO modules for the FLOW Unit are not included in the tables. (Open Item 119-2)	CAR-17-051	The Qualification Test Summary Report has been revised to correct this error. This issue will be addressed in CAR-17-051 for further corrective action. See also Item 1-3. No change requires for test specimens and test results.	On going	Feb. 28, 2018	6 (Document Control) 6-1 Conditions in descriptions	No impact
1-6	Toshiba submitted some documents (including both Proprietary and non-Proprietary) to NRC with a submittal letter (TOS-CR-FPG-20107-0002) on Sep. 29, 2017; however, the following conditions were found by NRC. 1) FC51-3702-1000, Rev. 4 (non-Proprietary version), on the left-hand side at the top, the page still has a box stating it contains confidential and proprietary information. 2) FPG-PLN-C51-0006, Rev. 4. The file is Rev 4 but the letter enclosure says Rev 5. (Documents docket on Oct. 4, 2017)	CAR-17-049	Toshiba has submitted the correct documents. The rules for submitting the documents to be docketed have been implicit. This error was caused by the omission of required step(s), with the individual under tight time pressure. Toshiba will prepare the procedure which defines check items for submitting documents to the NRC. No change is required for test specimens and test results.	On going	Jan. 31, 2018	6 (Document Control) 6-2 Document Handling Control	No impact
1-7	"Staff would like to ask that Toshiba be more proactive in formally providing the type of information you sent in your email. If we had not done the supplemental audit, we might not have known about your design changes. The staff cannot reach a rigorous conclusion on whether the Toshiba design is acceptable for use if changes are made to the design and staff does not have all the necessary design information available to it." (E-mail received on Jul. 17, 2017 regarding LVPS and PFC modules LVPS and PCF modules.	N/A	Toshiba did not expect that the e-mail from Toshiba could be interpreted by the NRC as a design change. Toshiba understands Toshiba should have been more careful not to invite miscommunications. Toshiba expects the e-mail communications and a telephone conference, which followed after Toshiba original e-mail dated Jul. 17, 2017, clarified Toshiba's intention and resolved NRC concerns. Toshiba will document this lesson learned and perform the training. No change is required for test specimens and test results.	On going	Dec. 28, 2017	N/A	No impact

Item No.	Condition	CAR	Disposition	Status	Completion date	Category (NQA-1 criteria)	Impact to test specimens and test results
1-8	Corrections to information provided in Open item 117-3 and FPG-DRT-C51-0005, "NICSD [Nuclear Instrumentation and Control Systems Department] Critical Digital Report." (E-mail received on Sep. 25, 2017)	CAR-17-048	Regarding corrections to information provided in Open item 117-3, see Item 1-4. The NICSD Critical Digital Review Report has been revised to correct this error. This issue will be addressed in the CAR-17-051 for further corrective action, see Item 1-3. No change is required for test specimens and test results.	On going	Feb. 28, 2018	6 (Document Control) 6-2 Document Handling Control	No Impact
1-9	During NRC review of the SER for FPGA PRM, it was found following condition on Qualification Test Summary Report (FPG-TRT-C51-0101 Rev.1); The Frequency range for compliance as shown in the tables and figures in Appendix B.3 of the Qualification Test Summary Report. The following is unclear: a. Section 5.4.3.1 of the Qualification Test Summary Report (FPG-TRT-C51-0101 Rev.1) states the frequency range was from 120 Hz to 10 kHz; however, Figure 5-7of the Equipment Requirement Specification (ERS) for the less than 1 kVA AC limit extends to 60 Hz. In addition, Table III-2-3 of the LTR shows the frequency range from 60 Hz to 10 kHz.	CAR-16-129	The Qualification Test Summary Report (FPG-TRT-C51-0101) has been revised to correct this issue. This issue will be addressed in the CAR-17-051 for further corrective action. See Item 1-3. No change is required for test specimens and test results.	On going	Feb. 28, 2018	6 (Document Control) 6-1 Conditions in descriptions	No impact
1-10	During NRC review of the SER for FPGA PRM, it was found following condition on the Qualification Test Summary Report (FPG-TRT-C51-0101 Rev.1); Table B10.2 of the Qualification Test Summary Report for IEC 61000-4-5 shows testing of [Line and Neutral] and Ground; whereas, Section 6.4.2.3 of the Qualification Test Summary Report shows this test point only for the Ring Wave (IEC 61000-4-12). This item is associated with 1-4.	CAR-16-130 (This CAR is associated with CAR-17-047)	The Qualification Test Summary Report (FPG-TRT-C51-0101 Rev.1) has been revised to correct this error and other errors. CAR-17-047 for item 1-4 addresses further discussion. See Item 1-4. No change is required for test specimens and test results.	On going	Feb. 28, 2018	6 (Document Control) 6-1 Conditions in descriptions	No impact

Item No.	Condition	CAR	Disposition	Status	Completion date	Category (NQA-1 criteria)	Impact to test specimens and test results
1-11	During NRC review of the SER for FPGA PRM, it was found following condition on the Qualification Test Summary Report (FPG-TRT-C51-0101 Rev.1); Tables B13.1 and B13.2 of the Qualification Test Summary Report are not consistent with the description of AO modules tested in Section III-2.2.3.6 of the LTR. For example, AO modules for the FLOW Unit are not included in the tables.	CAR-16-131	<p>The Qualification Test Summary Report (FPG-TRT-C51-0101) has been revised to correct for this issue.</p> <p>This issue will be addressed in CAR-17-051 for further corrective action. See Item 1-3 and Item 1-5.</p> <p>No change is required for test specimens and test results.</p>	On going	Feb. 28, 2018	<p>6 (Document Control)</p> <p>6-1 Conditions in descriptions</p>	No impact
1-12	<p>Toshiba found the following condition during the SER Project.</p> <p>NRC asked Toshiba by No.19 of RAI Letter Date March 9, 2016 that "(Open Item 64) The OPRM Unit Detailed Specification (FC51-3702-1000) identifies a power factor correction module (PFC). This module is not included in the TR, Tables II-2-6 and II-B-1. However, Section II-A-3-1 of the TR lists two PFCs modules as part of the test specimen for the OPRM unit. Please clarify if the PFC module was part of the EQ testing. Additionally, confirm if the PFC module is part of the OPRM unit, and thus part of the system under review."</p> <p>Toshiba responded to NRC by ML1699A166 that "The PFC module is not part of the test specimen, and is out of the scope of review for the OPRM unit." However, that Toshiba response was inadequate to the actual test condition in which the PFCs were part of the test specimen.</p>	CAR-17-026	<p>Toshiba has corrected the inadequate response (ML1699A166) to the RAI dated March 9, 2016 (RAI 2) in the response to RAI 3.</p> <p>CAR-17-047 addresses a similar issue (Item 1-4) in which Toshiba later corrected a previous answer.</p> <p>The same corrective action CAR-17-047 shall be applied to this Item 1-12.</p> <p>No change is required for test specimens and test results.</p>	Complete	Sep. 27, 2017	Other than NQA-1 Quality elements	No impact

Table 2 Conditions revealed by NRC Audit May 2016

Item No.	Condition	CAR	Disposition	Status	Completion date	Category (NQA-1 criteria)	Impact to test specimens and test results
2-1	During the NRC Audit for Toshiba for FPGA Qualification Project, it was found that Appendix A (Comparison Table of ERS/PQAP Requirements and Qualification Activities for Ensured Satisfaction) of Final Technical Evaluation Report (FPG-DRT-C51-0102 Rev.0) has typo. This table describes "Qualification Test Summary Report (FPG-TRT-C51-1001, Rev.0)" but correct description is "Qualification Test Summary Report (FPG-TRT-C51-0101, Rev.0).	CAR-16-074	Final Technical Evaluation Report (FPG-DRT-C51-0102 Rev.0) was revised to correct the typo. No change is required for test specimens and test results.	Complete	Jul. 4, 2016	6 (Document Control) 6-1 Conditions in descriptions	No impact
2-2	Para6.2.2 of NICSD Software V&V Plan (5B8K0038 Rev.7) describes that for an anomaly found during the design verification, reviews of SSAR, NICSD IV&V team has a responsibility for issuance of SCAR in accordance with AS-300A009. Even AS-300A009 was replaced by NQ-3009 issued on Aug. 31, 2012, the V&V Plan did not change the applicable procedure.	SCAR-16-010	The IV&V team revised the NICSD software V&V Plan to refer to NQ-3009 in place of AS-300A009 as the corrective action procedure. No change is required for test specimens and test results.	Complete	Jul. 8, 2016	2 (QA program / procedure)	No impact

Item No.	Condition	CAR	Disposition	Status	Completion date	Category (NQA-1 criteria)	Impact to test specimens and test results
2-3	<p>“Procedure for Control of Nonconformance and Corrective Action NQ-3019” applies to non-conformances that occur on Safety related products and services at NICSD. NQ-3019 refers to AS-300A009 as shown below.</p> <p>(1) Paragraph 6.1.2 When the condition is classified as significant, Significant Level (High Significant (HS) or Significant (S)) shall be assigned in accordance with the Appendix A of the AS Standard “Corrective Action Request Application Procedure” (AS-300A009).</p> <p>(2) Paragraph 6.2.4 After the verification of the completion of corrective action, through audit to make a judgment if the corrective action taken continues to be effective. NICS-QA describes points to be verified in Audit Planning and instructs to audit team leader before audit. If the corrective action has not functioned effectively, issue CAR in accordance with AS-300A009.</p> <p>(3) Paragraph 6.4 New Corrective Action Request Initiation: When a further condition adverse to quality is detected during the investigation, disposition and corrective action process, the further condition shall be documented and separately controlled by using Corrective Action Request in accordance with AS-300A009 “Corrective Action Request Application Procedure”.</p>	SCAR-16-011	<p>In NQ-3019, NICS-QC revised the following Paragraphs referring to “AS-300A009” to “NQ-3009”</p> <p>(1) Para 6.1.2 (2) Para 6.2.4 (3) Para 6.4</p> <p>No change is required for test specimens and test results.</p>	Complete	Jun. 17, 2016	2 (QA program / procedure)	No impact

Item No.	Condition	CAR	Disposition	Status	Completion date	Category (NQA-1 criteria)	Impact to test specimens and test results
2-4	<p>During the NRC Audit for Toshiba for FPGA Qualification Project, it was found following condition in NICSD V&V Plan (5B8K0038 rev.7). It should be evaluated and a disposition should be taken if NED V&V Plan has same conditions. This CAR is issued for extent of condition of SCAR-16-018.</p> <p>NICSD Software V&V Plan (5B8K0038 rev.7) describes measures for source code review and control of problems, nonconformances and conditions, as below. But these descriptions do not present the actual implementation during FPGA project V&V activities.</p> <p>5.5.1 VHDL Source Code Reviews The NICSD IV&V Team shall review the source code to verify correctness, consistency, completeness, accuracy, and traceability to the design specifications...</p> <p>7.1 Anomaly Reporting and Resolution 7.1.1 Problems Found in NICSD Activities If a problem is found in NICSD activities including V&V, the problem shall be reported using SNNR and SCAR...</p> <p>7.1.2 Problems Found in PPDD Activities If PPDD finds any problem in the configuration items during FPGA Testing and Module Validation Testing, problems shall be reported using a Vendor Nonconformance Report (VNNR).</p> <p>The PPDD engineers who perform FPGA or module testing shall document any test failures, any product or configuration nonconformance, or any errors in the test procedure using Problem Reporting Sheets (PRSS).</p>	CAR-16-075	<p>The current NED V&V Plans are appropriate for the past V&V activities.</p> <p>However, the IV&V Team revised the NED PRM V&V Plan (FPG-PLN-C51-0006 Rev.4) and OPRM V&V Plan (FA32-3709-0001 Rev.3) according to the recommendation. In the case of NED, Section 7.1.1 corresponds to "problems found in NED activities." The revised V&V Plans clarifies that Section 7 applies to base-lined documents, and adds a notice to Section 7 that non-base-lined documents anomalies are controlled in accordance with Section 4.6.1 "Verification" using Design Verification Report and in accordance with Section 5.1.3 "Interface with NICSD," using Vendor generated Document Check list.</p> <p>The revision of V&V Plans does not affect the past V&V activities because the revision only clarifies the actual V&V activities not requiring further V& V activities.</p> <p>The NED V&V Team does not have the responsibility of any code review and testing which are described in Sections 5.1.1 and 7.1.2 of NICSD V&V Plan, therefore it is not necessary to revise the document to include those activities.</p> <p>No change is required for test specimens and test results.</p>	Complete	Jun. 28, 2017	2 (QA program / procedure)	No impact
2-5	<p>During the NRC Audit for Toshiba NICSD (OPRM FPGA Qualification Project), it was found that V&V Plan refers the quality procedures and specific Toshiba report name such as "Design Verification Procedure (AS-200A002)" and Design Verification Report (DVR) to describe the control. More reader friendly description would be preferred.</p>	CAR-16-073	<p>The IV&V Team revised the OPRM V&V Plan so that the V&V Plan provides a brief description of the activities prescribed in the AS-standard when the V&V Plan references an AS-standard.</p> <p>No change is required for test specimens and test results.</p>	Complete	Jun. 28, 2016	6 (Document Control) 6-3 Recommendation for easy understanding	No impact

Item No.	Condition	CAR	Disposition	Status	Completion date	Category (NQA-1 criteria)	Impact to test specimens and test results
2-6	During the NRC Audit for Toshiba NICSD (OPRM FPGA Qualification Project), it was found that the unintended sheets were included in the hard copy of submittal document (FC51-1505-1001 Rev.0, Final Technical Evaluation Report for FPGA-based Safety-Related Systems (Proprietary version)) related letter TOS-CR-FPG-2015-0008 on Aug. 26. 2015 by TANE.	CAR-16-071	Rework – the affected document FC51-1505-1001 Rev.0, Final Technical Evaluation Report for FPGA-based Safety-Related System (Proprietary Version), was reissued to the NRC with the correct content. No change is required for test specimens and test results.	Complete	Jun. 17, 2016	6 (Document Control) 6-2 Document Handling Control	No impact
2-7	During the NRC Audit for Toshiba NICSD (OPRM FPGA Qualification Project), it was found that the software problem control process which was actually implemented in the project was not prescribed in NQ standards.	SCAR-16-019	NISC revised related NQ-2013 standard. No change is required for test specimens and test results.	Complete	Jun. 22, 2016	2 (QA program / procedure)	No impact
2-8	NICSD Software V&V Plan (5B8K0038 rev.7) describes measures for source code review and control of problems, nonconformances and conditions, as below. But these descriptions do not present the actual implementation during FPGA project V&V activities. 5.5.1 VHDL Source Code Reviews The NICSD IV&V Team shall review the source code to verify correctness, consistency, completeness, accuracy, and traceability to the design specifications... 7.1 Anomaly Reporting and Resolution 7.1.1 Problems Found in NICSD Activities If a problem found in NICSD activities including V&V, the problem shall be reported using SNNR and SCAR... 7.1.2 Problems Found in PPDD Activities If PPDD finds any problem in the configuration items during FPGA Testing and Module Validation Testing, problems shall be reported using a Vendor Nonconformance Report (VNNR). The PPDD engineers who perform FPGA or module testing shall document any test failures, any product or configuration nonconformance, or any errors in the test procedure using Problem Reporting Sheets (PRSs).	SCAR-16-018	The IV&V team revised the V&V Plan (5B8K0038) in order to reflect correctly the process used during source code review. No change is required for test specimens and test results.	Complete	Jun. 6, 2016	2 (QA program / procedure)	No impact

Item No.	Condition	CAR	Disposition	Status	Completion date	Category (NQA-1 criteria)	Impact to test specimens and test results
2-9	<p>During the NRC Audit for Toshiba NICSD (OPRM FPGA Qualification Project), it was found the following condition.</p> <p>Security Assessment Meeting Minutes (Design Phase MOM-JHS-000046) recorded two open items. One is access right to file server, and another one is security control at TDMS.</p> <p>Security Assessment Meeting Minutes (Implementation and Integration Phase MOM-JHS-000052) recorded the access right was still open and the security control was closed.</p> <p>Security Assessment Meeting Minutes (System Validation Testing Phase MOM-JHS-000059) did not describe the situation of the access right.</p>	SCAR-16-017	<p>The IV&V team revised the meeting minutes (MOM-JHS-000059) in order to show that open item of the access right was closed.</p> <p>No change is required for test specimens and test results.</p>	Complete	Jun. 13, 2016	Other than NQA-1 quality elements (MOM description)	No impact
2-10	During the NRC Audit for Toshiba NICSD (OPRM FPGA Qualification Project), it was found that V&V Plan refers the quality procedures and specific Toshiba report name such as "Design Verification Procedure (AS-200A002)" and Design Verification Report (DVR) to describe the control. More reader friendly description would be preferred.	SCAR-16-016	<p>The IV&V team revised the V&V plan, in order to add a summary description of the purpose of procedure.</p> <p>No change is required for test specimens and test results.</p>	Complete	Jul. 7, 2016	6 (Document Control) 6-3 Recommendation for easy understanding	No impact
2-11	<p>Paragraph 5.2. Audits, Surveillances and Commercial Grade Surveys of "Software Quality Assurance Plan FA32-3701-1001/5B8K0037" described the followings.</p> <p>The NICS-QA conducts <u>an annual audit or evaluation of the performance and capability of the PPDD every year.</u> The NICS-QA <u>also</u> conducts the Commercial Grade Survey (CGS) at least every 3 years for the PPDD.</p> <p>The underlined description is not consistent with implementation.</p>	SCAR-16-015	<p>The description in Paragraph 5.2 "Audits, Surveillances and Commercial Grade Surveys" of Software Quality Assurance Plan FA32-3701-1001/5B8K0037 was corrected so that the CG Survey is performed every three year and annual evaluation is performed in years other than the year of CG Survey.</p> <p>No change is required for test specimens and test results.</p>	Complete	May 25, 2016	6 (Document Control) 6-3 Recommendation for easy understanding	No impact

Item No.	Condition	CAR	Disposition	Status	Completion date	Category (NQA-1 criteria)	Impact to test specimens and test results
2-12	<p>“Procedure for Evaluation of Suppliers NQ-3005” prescribes evaluation and qualification methods of suppliers for procured items and services. NQ-3005 refers to AS-300A009 as shown below.</p> <p>9.6.2 When corrective actions are to be required, the Survey/Audit team shall prepare the “Corrective Action Request (EXHIBIT-6)” in accordance with “Corrective Action Application Measure (AS-300A009)”, and the Lead Auditor and the Manager of NICS-QA shall approve it. In judging significance level of the findings, the Survey/Audit team shall refer Appendix-A "Significance Level Criteria Guidelines" in "Corrective Action Request Application Procedure (AS-300A009)."</p> <p>9.7 Follow-ups Action Follow-up Action to the Corrective Actions Requests shall be Complete in accordance with "Corrective Action Request Application Procedure (AS-300A009)."</p>	SCAR-16-013	<p>(1) NICS-QA evaluated and resolved the gap between NQ-3009 that provides the “Significance level criteria guideline” and Appendix-A of AS-300A009. (2) NQCS-QA revised NQ-3005.</p> <p>No change is required for test specimens and test results.</p>	Complete	Jun. 21, 2016	2 (QA program / procedure)	No impact

Item No.	Condition	CAR	Disposition	Status	Completion date	Category (NQA-1 criteria)	Impact to test specimens and test results
2-13	<p>“Procedure for Control of Nonconformance and Corrective Action NQ-3019” applies to non-conformances that occur on Safety related products and services at NICS. Chapter 3 of this procedure describes responsibilities of QA and QC managers, but this description seems duplicated and not clear, as below.</p> <p>(1) The Manager of Quality Assurance Group for Nuclear Instrumentation & Control Systems (hereinafter referred to as NICS-QA) has overall responsibility for the detection, control, disposition and correction of all nonconforming conditions. He also has overall responsibility to assure that corrective action is taken to rectify significant conditions adverse to quality and to preclude repetition.</p> <p>(2) The Manager of Quality Control Section for Nuclear Instrumentation & Control Systems (hereinafter referred to as NICS-QC) has responsibility to control of nonconformances, and to verify dispositioned results for all safety-related items which NICS is responsible, and has authority for the following:</p> <ol style="list-style-type: none"> a. Issuance/review of SNNR-I for nonconformance relating to the item b. Assignment of a responsible organization for disposition and corrective action c. Control of further process for the nonconforming items d. Verification of dispositioned results e. Instruction to stop work related to the nonconformance, and resuming the work. 	SCAR-16-012	<p>NICS-QC reviewed the description of the responsibility of the NQ-3019 and NICS-QC revised it.</p> <p>No change is required for test specimens and test results.</p>	Complete	Jun. 17, 2016	2 (QA program / procedure)	No impact
2-14	<p>During the self-assessment, ESDD found that NICS did not submit FE library files used in the FPG/SER project by storing them in an appropriate media, such as CD-R to NED inconsistent with reference documents requirements.</p>	CAR-16-069	<p>NICS copied and submitted the DVD-R of the FE Library File to NED from the stored DVD-R. It satisfies the requirement of SQAP (FPG-PLN-C51-0002/RS-5073917 Rev.11).</p> <p>No change is required for test specimens and test results.</p>	Complete	Jun. 9, 2017	17 (QA record)	No impact

Item No.	Condition	CAR	Disposition	Status	Completion date	Category (NQA-1 criteria)	Impact to test specimens and test results
2-15	During the self-assessment, NED QA found the following defects and errors in FPGA test records.	CAR-16-066	<p>Quality records were corrected because of clarified errors and omissions.</p> <p>VNNR-16-103 was issued for one of the errors and actions were taken in accordance with the response of "Defect on Test Record for LPRM/APRM Unit Spare Chassis."</p> <p>In addition, to check if there are similar cases, the test records of equipment delivered through CGI performed by NICS-QC, which were issued for the NRW-FPGA-Based PRM System, were reviewed again.</p> <p>No change is required for test specimens and test results.</p>	Complete	Jun. 1, 2017	11 (Test control)	No impact
2-16	During the self-assessment, NED QA found the following defects and errors in FPGA test records.	CAR-16-065	<p>The typos and omissions which were found in the quality records were corrected.</p> <p>The test records which were issued by NQAD for PRM Qualification Project were investigated to make sure that the same kind of defects and errors are not included in other records.</p> <p>No change is required for test specimens and test results.</p>	Complete	Jun. 2, 2017	11 (Test control)	No impact
2-17	ESDD performed the self-assessment of their project documents for the PRM/OPRM Qualification Project. This assessment is performing as extend condition of CAR-16-037. During the self-assessment, discrepancies in the attached list are found.	CAR-16-040	<p>ESDD prepared a plan (schedule) for correction of the identified errors.</p> <p>CAR-17-051 in Table 1 refers to this CAR-16-040.</p> <p>No change is required for test specimens and test results.</p>	On going	Feb. 28, 2018	6 (Document Control) 6-1 Conditions in descriptions	No impact
2-18	NICSD and PPDD are performing a self-assessment of their design documents for the PRM/OPRM Qualification Project. This assessment is performing as extent of condition of CAR-16-037. During the self-assessment, discrepancies were found.	CAR-16-039	<p>NICSD and PPDD completed the self-assessment and identified discrepancies in other documents. NICSD and PPDD revised the documents to resolve the discrepancies.</p> <p>No change is required for test specimens and test results.</p>	Complete	Feb. 15, 2017	3 (Design control)	No impact

Item No.	Condition	CAR	Disposition	Status	Completion date	Category (NQA-1 criteria)	Impact to test specimens and test results
2-19	Toshiba has found the following condition during the self-assessment; Changes to the AO module described in Section 2.4 of the Qualification Test Summary Report (FPG-TRT-C51-0101 Rev.0) do not cover all actual design changes.	CAR-16-038	ESDD revised the Qualification Test Summary Report to consistent with the actual design changes. The revised documents are consistent with the response to the NRC RAI dated March 9 th , 2016. No change is required for test specimens and test results.	Complete	Mar. 31, 2016	6 (Document Control) 6-1 Conditions in descriptions	No impact
2-20	NRC has identified that Toshiba has inconsistencies: a. The PRM System Qualification Test Summary (FPG-DRT-C51-0101, Rev. 0), Figure 5-1, "Actual Test Flow Diagram," does not match Figure 4-1, "Master Test Plan Flow Diagram," in the Master Test Plan (FPG-PLN-C51-0005, Rev. 3). b. The cover page of the Qualification Test Summary Report identifies as document number "FPG-TRT-C51-0101." However, the pages inside (at the top of the page), identify this document as "FPG-DRT-C51-0101." c. The Master Test Plan (FPG-PLN-C51-0005, Rev. 3) does not identify the achievable amplitudes for both Operation Basis Earthquake (OBE) and Safe Shutdown Earthquake (SSE) seismic events. d. The PRM System Qualification Test Summary (FPG-DRT-C51-0101, Rev. 0), page 25, references Table 4-1 and Figure 4-5, but these references were not included in the document.	CAR-16-037	ESDD revised the documents to resolve the inconsistencies identified by NRC. The documents revisions are consistent with the response to the NRC RAI dated March 9th, 2016. No change is required for test specimens and test results.	Complete	Apr. 28, 2016	6 (Document Control) 6-2 Document Handling Control 6-1 Conditions in descriptions	No impact

Table 3 QA program element analysis

QA Program elements of NQA-1	Conditions identified after NRC audit in Table 1	Conditions identified before and during NRC audit in Table 2	Total number
2.QA program / procedure	0	7	7
3.Design Control	1	1	2
6.Document Control			
6-1 Conditions in descriptions*	5	4	9
6-2 Document handling Control	2	2	4
6-3 Recommendation for easy understanding	0	3	3
11. Test Control	0	2	2
17. QA Record	0	1	1
19. Other than NQA-1 quality elements	3	1	4
Total number	11	21	32

* Conditions found in documents other than design documents such as summary reports.

Toshiba notes:

- (1) Sub-categories 6-1 through 6-3 and Category 19 are added by Toshiba.
- (2) 16 (50%) conditions are mapped into "6 Document Control," 9 of which are mapped into "6-1 Conditions in descriptions." Five (5) conditions mapped into "6-1 Conditions in descriptions" in Table 1 originate in the documents prepared before the NRC audit in May 2016.
- (3) The number of Conditions mapped into "2. QA program / procedure" after the audit is reduced to 0 so far, and conditions mapped into "6-1 Conditions in descriptions" are dominant after the audit while the identified Conditions are archived for future revisions of the documents. Toshiba will take further actions as described in Table.1.
- (4) Item 1-7 is not mapped into any element. Item 2-20 is mapped into two elements.
- (5) Reviews completed to date have only identified documentation related issues; no issues identified have had a technical impact on test specimens, test results, or test conclusions. Extent of condition reviews are ongoing in several areas as identified in Tables 1 and 2 as part of Toshiba's Quality Assurance process. Based on previous reviews, Toshiba does not expect any impact on the test results or conclusions. Toshiba will notify the NRC if any additional items which impact the test results and conclusion are identified.