

Safety-Related
 Non-Safety-Related
 ASME CODE
 Others()

是正処置依頼票

CORRECTIVE ACTION REQUEST

ISSUED DATE May 16 2016

CAR 処置部門/供給者 NICSD V&V Team		関連図書 REFERENCE DOCUMENT Software V&V Plan 5B8K0038 rev.7	
要求回答期限 REQUIRED REPLY DATE	May. 17, 2016	品質を損なう状態 CONDITION ADVERSE TO QUALITY (CATQ) <input type="checkbox"/> 極重大 Highly significant CATQ <input type="checkbox"/> 重大 Significant CATQ <input checked="" type="checkbox"/> 軽微 Not significant CATQ	CATQ 以外 NOT (CATQ) <input type="checkbox"/> 推奨 Recommendation <input type="checkbox"/> その他 Other condition
不適合内容 DESCRIPTION OF CONDITION ADVERSE TO QUALITY Para6.2.2 of NICSD Software V&V Plan (5B8K0038 rev.7) describes that for an anomaly found during the design verification, reviews of SSARs..., 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.		<input checked="" type="checkbox"/> 初回 FIRST OCCURRENCE <input type="checkbox"/> 再発生 REPETITIVE	
処置勧告 RECOMMENDED CORRECTIVE ACTION Revise the NICSD Software V&V Plan (5B8K0038 rev.7) Evaluate any influence that might be caused by the gap between NQ-3009 and AS-300A009 that is used with the modifications by NQ-1003. Re-training of NQ-1003 and 3009 to the engineers in IV&V team.		Manager of NICS-QA 堀口 May 16, '16	Initiated by 河野 May 16, '16
是正処置者の記載欄 TO BE COMPLETED BY RECIPIENT			
原因 CAUSE IV&V チームは、V&V 計画書 Rev.0 を 2011 年 11 月 10 日発行した際に、AS-300A009 を参照した。その後、NQ-3009 が発行されたときに、NQ-1003 が改訂された。その際、AS-300A009 と NQ-3009 の記載は同等であったものの、IV&V チームは V&V 計画書への反映を行わなかった。 The IV&V team referenced AS-300A009 when issuing the V&V Plan Rev. 0 on November 10, 2011. Later NQ-1003 was revised when NQ-3009 was issued in August, 2012. Then the IV&V team did not revise the V&V Plan to incorporate, even though descriptions of NQ-3009 and AS-300A009 were equivalent.			
提案処置内容 PROPOSED DISPOSITION IV&V チームは、是正処置要領として AS-300A009 の代わりに NQ-3009 を参照するために、NICSD V&V 計画書を改訂する。 The IV&V team revises the NICSD Software V&V Plan to refer to NQ-3009 in place of AS-300A009 as the corrective action procedure.			
提案是正処置 (影響範囲を含む) PROPOSED CORRECTIVE ACTION (INCLUDING EXTENT OF CONDITION) NQ-3009 の発行時に AS-300A009 と NQ-3009 の差分評価が実施され、発行後も AS-300A009 の改訂の NQ-3009 への反映が実施されている。そのため、AS-300A009 と NQ-3009 の記載は同等であり、V&V 計画書の参照図書を AS-300A009 から NQ-3009 に変更しても、影響ないことを確認した。よって、是正処置としては、V&V 計画書の参照図書に於ける AS-300A009 から NQ-3009 への変更について教育だけ実施する。 When NQ-3009 was issued, the differential evaluation between AS-300A009 and NQ-3009 was implemented (see attachment-1). After the issuance of NQ-3009, revisions of AS-300A009 have been reflected to NQ-3009 (see attachment-2). Because descriptions of AS-300A009 and NQ-3009 are equivalent, there is no influence by the change of the reference document from AS-300A009 to NQ-3009. Therefore the IV&V Lead provides indoctrination to the V&V team with regard to NQ-1003 and NQ-3009 as a corrective action.			
10CFR21 に基づく評価 Evaluation for 10CFR21 is	<input type="checkbox"/> 必要 Necessary <input checked="" type="checkbox"/> 不要 Not Necessary <input type="checkbox"/> 判定不能 No capability of evaluation	Group NICSD IV&V Team Approved by: 丹葉 May. 19, '16 Prepared by: 北園 May. 18, '16	
是正日限 DUE DATE	(2016-7-18) Changed by S.Kono Jun. 20, '16		
提案調査 Proposal Review	<input checked="" type="checkbox"/> 合格 Acceptable <input type="checkbox"/> 不合格 Unacceptable	CAR オナー Reviewed by CAR Owner	河野 May 20, '16 サイン Sign/日付 Date
		[] 長承認 Approved by Manager of NICS-QA	堀口 May 23, '16 サイン Sign/日付 Date
CAR 処置部門管理者の検証 Verification of Corrective Action Result by the Responsible Organization Line Manager	<input checked="" type="checkbox"/> 合格 Acceptable <input type="checkbox"/> 不合格 Unacceptable (SCAR No.)	CAR 処置部門管理者 Verified by Responsible Organization Line Manager	佐藤 Jul. 8, '16 サイン Sign/日付 Date
是正処置結果の確認 Verification of Corrective Action Result	<input checked="" type="checkbox"/> 合格 Acceptable <input type="checkbox"/> 不合格 Unacceptable (SCAR No.)	CAR オナー Reviewed by CAR Owner	河野 Jul. 8, '16 サイン Sign/日付 Date
確認エビデンス Verified Evidences	- NICSD SVVP (FA32-3709-1000, Rev.8) - Indoctrination Record by Circulation [] 長承認 NICS-QA/6040		堀口 July 8, '16 サイン Sign/日付 Date

Safety-Related
 Non-Safety-Related
 ASME CODE
 Others ()

是正処置依頼票
 CORRECTIVE ACTION REQUEST

ISSUED DATE May 16 2016

CAR 処置部門/供給者 NICS-QC	関連図書 REFERENCE DOCUMENT Procedure for Control of Nonconformance and Corrective Action NQ-3019
-------------------------	--

要求回答期限 REQUIRED REPLY DATE	May. 17, 2016	品質を損なう状態 CONDITION ADVERSE TO QUALITY (CATQ)	CATQ 以外 NOT (CATQ)
		<input type="checkbox"/> 極重大 Highly significant CATQ	<input type="checkbox"/> 重大 Significant CATQ
		<input checked="" type="checkbox"/> 軽微 Not significant CATQ	<input type="checkbox"/> 推奨 Recommendation
			<input type="checkbox"/> その他 Other condition

不適合内容 DESCRIPTION OF CONDITION ADVERSE TO QUALITY
 "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.

初回
FIRST OCCURRENCE
 再発生
REPETITIVE

処置勧告 RECOMMENDED CORRECTIVE ACTION (1) Evaluate the gap between NQ-3009 that specify "Significance level criteria guideline" and Appendix-A of AS-300A009. (2) Revise NQ-3019	Manager of NICS-QA 堀口 May 16, '16	Initiated by 河野 May 16, '16
---	---	-----------------------------------

是正処置者の記載欄 TO BE COMPLETED BY RECIPIENT

原因 CAUSE
 是正処置依頼要領(NQ-3009)が 2012 年 8 月に発行された際、NQ-3009 の参照規程を AS-300A009 から NQ-3009 に変更しなかった。"Significance level criteria guideline"と AS-300A009 の Appendix-A は同等の内容ではあった。
 添付参照
 When the "Corrective Action Request Application Procedure" (NQ-3009) was issued in August, 2012, the reference Standard in NQ-3019 was not changed from AS-300A009 to NQ-3009, even though "Significance level criteria guideline" of NQ-3009 and Appendix-A of AS-300A009 were equivalent description. (Refer to Attachment-1)

提案処置内容 PROPOSED DISPOSITION
 NQ-3019の AS-300A009 を参照している以下の項を NQ-3009 に改訂する。
 In the NQ-3019, NISC-QC Revise the following Paragraphs referring to "AS-300A009" to "NQ-3009".
 (1) Para 6.1.2
 (2) Para 6.2.4
 (3) Para 6.4

提案是正処置 (影響範囲を含む) PROPOSED CORRECTIVE ACTION (INCLUDING EXTENT OF CONDITION)
 NISC-QC already performed differential evaluation between AS-300A009 and NQ-3009 as mentioned above. Therefore, any corrective action is not necessary other than Case-study indoctrination.
 The Case-study to member of the NISC-QC is performed using this SCAR to make corrected NQ-3019 well-known.

10CFR21 に基づく評価 Evaluation for 10CFR21 is	<input type="checkbox"/> 必要 Necessary (Evaluation Report ID:) <input checked="" type="checkbox"/> 不要 Not Necessary <input type="checkbox"/> 判定不能 No capability of evaluation	Group NISC-QC Approved by 堀口 May 18, 2016	Prepared by 河野 May 17, '16
是正日限 DUE DATE	2016-6-17 堀口 June 17, 2016 (2016-5-27 for disposition, 2016-6-2 for corrective action)		

提案調査 Proposal Review	<input checked="" type="checkbox"/> 合格 Acceptable <input type="checkbox"/> 不合格 Unacceptable	CARオーナー Reviewed by CAR Owner [] 長承認 Approved by Manager of NICS-QA	<u> </u> May 19, '16 サイン Sign / 日付 Date <u> </u> May 23, '16 サイン Sign / 日付 Date
CAR 処置部門管理者の検証 Verification of Corrective Action Result by the Responsible Organization Line Manager	<input checked="" type="checkbox"/> 合格 Acceptable <input type="checkbox"/> 不合格 Unacceptable (SCAR No. _____)	CAR 処置部門管理者 Verified by Responsible Organization Line Manager	<u> </u> June 17, 2016 サイン Sign / 日付 Date
是正処置結果の確認 Verification of Corrective Action Result	<input checked="" type="checkbox"/> 合格 Acceptable <input type="checkbox"/> 不合格 Unacceptable (SCAR No. _____)	CARオーナー Reviewed by CAR Owner	<u> </u> June 17, '16 サイン Sign / 日付 Date
確認エビデンス Verified Evidences	- NA-3019 Rev 8 - Indoctrination/Training Record (Lecture Type) NICS - QC16002	[] 長承認 Approved by Manager of NICS-QA	<u> </u> June 17, '16 サイン Sign / 日付 Date

Safety-Related
 Non-Safety-Related
 ASME CODE
 Others ()

是正処置依頼票
 CORRECTIVE ACTION REQUEST

ISSUED DATE May 17 2016

CAR 処置部門/供給者 NICS-QC		関連図書 REFERENCE DOCUMENT Procedure for Control of Nonconformance and Corrective Action NQ-3019	
要求回答期限 REQUIRED REPLY DATE	May. 17, 2016	品質を損なう状態 CONDITION ADVERSE TO QUALITY (CATQ)	CATQ 以外 NOT (CATQ)
		<input type="checkbox"/> 極重大 Highly significant CATQ	<input type="checkbox"/> 重大 Significant CATQ
		<input checked="" type="checkbox"/> 軽微 Not significant CATQ	<input type="checkbox"/> 推奨 Recommendation
			<input type="checkbox"/> その他 Other condition
不適合内容 DESCRIPTION OF CONDITION ADVERSE TO QUALITY		<input checked="" type="checkbox"/> 初回 FIRST OCCURRENCE <input type="checkbox"/> 再発生 REPETITIVE	
"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 descriptions seems duplicated and not clear, as below.			

処置勧告 RECOMMENDED CORRECTIVE ACTION	Manager of NICS-QA	Initiated by
(1) Review Chapter 5 & 6 to check the QA and QC managers' responsibilities in detail. (2) Revise the description of the responsibility based on the review.	堀口 May 17, '16	河野 May 17, '16

是正処置者の記載欄 TO BE COMPLETED BY RECIPIENT

原因 CAUSE
N/A

提案処置内容 PROPOSED DISPOSITION
 []は NQ-3019 の責任の記述をレビューし改訂します。
 NISC-QC review the description of the responsibility of the NQ-3019, and NISC-QC revise it.

提案是正処置 (影響範囲を含む) PROPOSED CORRECTIVE ACTION (INCLUDING EXTENT OF CONDITION)
 N/A

10CFR21 に基づく評価 Evaluation for 10CFR21 is	<input type="checkbox"/> 必要 Necessary (Evaluation Report ID:) <input checked="" type="checkbox"/> 不要 Not Necessary <input type="checkbox"/> 判定不能 No capability of evaluation	Group NISC-QC
		Approved by
		Prepared by
是正日限 DUE DATE	2016-6-17 堀口 May 31, '16 (2016-5-31)	堀口 May 18, 2016

提案調査 Proposal Review	<input checked="" type="checkbox"/> 合格 Acceptable <input type="checkbox"/> 不合格 Unacceptable	CARオーナー Reviewed by CAR Owner	[]長承認 Approved by Manager of NICS-QA
		[] Sign./Date	[] Sign./Date

CAR 処置部門管理者の検証 Verification of Corrective Action Result by the Responsible Organization Line Manager	<input checked="" type="checkbox"/> 合格 Acceptable <input type="checkbox"/> 不合格 Unacceptable (SCAR No. _____)	CAR 処置部門管理者 Verified by Responsible Organization Line Manager	長谷 June 17, 2016 サイン Sign / 日付 Date
是正処置結果の確認 Verification of Corrective Action Result	<input checked="" type="checkbox"/> 合格 Acceptable <input type="checkbox"/> 不合格 Unacceptable (SCAR No. _____)	CARオーナー Reviewed by CAR Owner	河野 June 17, '16 サイン Sign / 日付 Date
確認エビデンス Verified Evidences NR-3019 Rev. 8		[] 長承認 Approved by Manager of NICS-QA	堀 June 17, '16 サイン Sign / 日付 Date

Safety-Related
 Non-Safety-Related
 ASME CODE
 Others ()

Added by
 S. Kono
 Jul. 8, '16
 是正処置依頼票

SCAR No. SCAR-16-013

CORRECTIVE ACTION REQUEST

ISSUED DATE May 17, 2016

CAR 処置部門/供給者 TO RESPONSIBLE ORG. / SUPPLIER		関連図書 REFERENCE DOCUMENT	
NICS-QA		Procedure for Evaluation of Suppliers NQ-3005 Rev.13	
要求回答期限 REQUIRED REPLY DATE	May 18, 2016	品質を損なう状態 CONDITION ADVERSE TO QUALITY (CATQ)	CATQ 以外 NOT (CATQ)
		<input type="checkbox"/> 軽微 <input type="checkbox"/> 重大 <input type="checkbox"/> 極めて重大 High significant CATQ Significant CATQ Not significant CATQ	<input type="checkbox"/> 推奨 <input type="checkbox"/> その他 Recommendation Other condition
不適合内容 DESCRIPTION OF CONDITION ADVERSE TO QUALITY		<input checked="" type="checkbox"/> 初回 FIRST OCCURRENCE <input type="checkbox"/> 再発生 REPETITIVE	
"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.		C	
処置勧告 RECOMMENDED CORRECTIVE ACTION		Lead Auditor to NICS-QA Initiated by	
(1) Evaluate the gap between NQ-3009 that specify "Significance level criteria guideline" and Appendix-A of AS-300A009. (2) Revise NQ-3005		堀 May 17, '16	河野 May 17, '16
是正処置者の記載欄 TO BE COMPLETED RECIPIENT			
原因 CAUSE N/A			
提案処置内容 PROPOSED DISPOSITION (1) NICS-QA evaluates the gap between NQ-3009 that specify "Significance level criteria guideline" and Appendix-A of AS-300A009. (2) NICS-QA revises NQ-3005.			
提案是正処置 (影響範囲を含む) PROPOSED CORRECTIVE ACTION (INCLUDING EXTENT OF CONDITION) N/A			
10CFR21 に基づく評価 Evaluation for 10CFR21 is	<input type="checkbox"/> 必要 Necessary (Evaluation Report ID:) <input checked="" type="checkbox"/> 不要 Not Necessary <input type="checkbox"/> 判定不能 No capability of evaluation	Group NICS-QA () Approved by Prepared by	
是正日限 DUE DATE (2016-05-18)		堀口 May 23, '16	河野 May 20, '16
提案調査 Proposal Review	<input checked="" type="checkbox"/> 合格 Acceptable <input type="checkbox"/> 不合格 Unacceptable	CARオーナー Reviewed by CAR Owner 河野 May 23, '16 サイン Sign / 日付 Date 堀 May 24, '16 監査長承認 Approved by Lead Auditor to NICS-QA サイン Sign / 日付 Date	

CAR 処置部門管理者の検証 Verification of Corrective Action Result by the Responsible Organization Line Manager	<input checked="" type="checkbox"/> 合格 Acceptable <input type="checkbox"/> 不合格 Unacceptable (SCAR No. _____)	CAR処置部門管理者 Verified by Responsible Organization Line Manager	堀 June 21, '16 サイン Sign / 日付 Date
是正処置結果の確認 Verification of Corrective Action Result	<input checked="" type="checkbox"/> 合格 Acceptable <input type="checkbox"/> 不合格 Unacceptable (SCAR No. _____)	CARオーナー Reviewed by CAR Owner	堀 June 21, '16 サイン Sign / 日付 Date
確認エビデンス Verified Evidences (1) Attachment -2 for SCAR-16-013 Attachment -3 for SCAR-16-013 (2) NB-3005 Rev.14	監査長承認 Approved by Lead Auditor to NICS-QA	堀 June 21, '16 サイン Sign / 日付 Date	

Safety-Related
 Non-Safety-Related
 ASME CODE
 Others ()

Added by
 S. Kono
 Jul. 8, '16

是正処置依頼票

CORRECTIVE ACTION REQUEST

ISSUED DATE May.19.2016

CAR 処置部門/供給者 TO RESPONSIBLE ORG. / SUPPLIER NICS-QA		関連図書 REFERENCE DOCUMENT Software Quality Assurance Plan FA32-3701-1001/5B8K0037 Rev.1	
要求回答期限 REQUIRED REPLY DATE	May 19, 2016.	品質を損なう状態 CONDITION ADVERSE TO QUALITY (CATQ)	CATQ 以外 NOT (CATQ)
		<input type="checkbox"/> 極重大 High significant CATQ <input type="checkbox"/> 重大 Significant CATQ <input checked="" type="checkbox"/> 軽微 Not significant CATQ	<input type="checkbox"/> 推奨 Recommendation <input type="checkbox"/> その他 Other occasion
不適合内容 DESCRIPTION OF CONDITION ADVERSE TO QUALITY		<input checked="" type="checkbox"/> 初回 FIRST OCCURRENCE <input type="checkbox"/> 再発生 REPETITIVE	
Para 5.2. Audits, Surveillances and Commercial Grade Surveys of "Software Quality Assurance Plan FA32-3701-1001/5B8K0037" described the followings. The NICS-QA conducts an annual audit or evaluation of the performance and capability of the PPDD every year. The NICS-QA also conducts the Commercial Grade Survey (CGS) at least every 3 years for the PPDD. The underlined description is not consistent with Implementation.			
処置勧告 RECOMMENDED CORRECTIVE ACTION		Lead Auditor to NICS-QA	Initiated by
The underlined description should be corrected to be consistent with the implementation.		堀 May 19, 2016	堀口 May 19, 2016
是正処置者の記載欄 TO BE COMPLETED RECIPIENT			
原因 CAUSE NA.			
提案処置内容 PROPOSED DISPOSITION The description in Para 5.2. "Audits, Surveillances and Commercial Grade Surveys" of "Software Quality Assurance Plan FA32-3701-1001/5B8K0037" is corrected so that CG Survey is performed every three year and annual evaluation is performed in year other than the year of CG Survey.			
提案是正処置 (影響範囲を含む) PROPOSED CORRECTIVE ACTION (INCLUDING EXTENT OF CONDITION) NA			
10CFR21 に基づく評価 Evaluation for 10CFR21 is	<input type="checkbox"/> 必要 Necessary (Evaluation Report ID:) <input checked="" type="checkbox"/> 不要 Not Necessary <input type="checkbox"/> 判定不能 No capability of evaluation	Group NICS-QA	
		Approved by	Prepared by
		堀口 May 23, '16	堀 May 19, '16
是正日限 DUE DATE (2016-5-25)			
提案調査 Proposal Review	<input checked="" type="checkbox"/> 合格 Acceptable <input type="checkbox"/> 不合格 Unacceptable	CARオーナー Reviewed by CAR Owner	サイン Sign/日付 Date May 24, '16
CAR 処置部門管理者の検証 Verification of Corrective Action Result by the Responsible Organization Line Manager	<input checked="" type="checkbox"/> 合格 Acceptable <input type="checkbox"/> 不合格 Unacceptable (SCAR No.)	CAR 処置部門管理者 Verified by Responsible Organization Line Manager	サイン Sign/日付 Date 堀口 May 25, '16
是正処置結果の確認 Verification of Corrective Action Result	<input checked="" type="checkbox"/> 合格 Acceptable <input type="checkbox"/> 不合格 Unacceptable (SCAR No.)	CARオーナー Reviewed by CAR Owner	サイン Sign/日付 Date
確認エビデンス Verified Evidences	5B8K0037 Rev. 2 5B8K0037 Rev. 3 Added 堀 July 7, 2016	監査長承認 Approved by Lead Auditor to NICS-QA	サイン Sign/日付 Date 堀 May 25, '16

Safety-Related
 Non-Safety-Related
 ASME CODE
 Others()

Added by
S. Kono
Jul. 8, '16

是正処置依頼票

CORRECTIVE ACTION REQUEST

ISSUED DATE May 18 2016

CAR 処置部門 / 供給者 TO RESPONSIBLE ORG. / SUPPLIER NICSD V&V team		関連図書 REFERENCE DOCUMENT Verification and Validation Plan (FA32-3709-1000 Rev.7)					
要求回答期限 REQUIRED REPLY DATE	May 19, '16	品質を損なう状態 CONDITION ADVERSE TO QUALITY (CATQ) <input type="checkbox"/> 極重大 High significant CATQ <input type="checkbox"/> 重大 Significant CATQ <input type="checkbox"/> 軽微 Not significant CATQ	CATQ 以外 NOT (CATQ) <input checked="" type="checkbox"/> 推奨 Recommendation <input type="checkbox"/> その他 Other condition				
不適合内容 DESCRIPTION OF CONDITION ADVERSE TO QUALITY 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.		<input checked="" type="checkbox"/> 初回 FIRST OCCURRENCE <input type="checkbox"/> 再発生 REPETITIVE					
処置勧告 RECOMMENDED CORRECTIVE ACTION In addition to referencing the procedures, summary description of purpose of procedure should be added to V&V Plan.		<table border="1"> <tr> <td>NICS-QA</td> <td>Initiated by</td> </tr> <tr> <td>堀口 May 18, '16</td> <td>河野 May 18, '16</td> </tr> </table>		NICS-QA	Initiated by	堀口 May 18, '16	河野 May 18, '16
NICS-QA	Initiated by						
堀口 May 18, '16	河野 May 18, '16						

是正処置者の記載欄 TO BE COMPLETED RECIPIENT

原因 CAUSE
N/A

提案処置内容 PROPOSED DISPOSITION
IV&V チームは規程の目的の簡略な記述を加えるために V&V 計画を改訂します。
The IV&V team revises the V&V plan, in order to add a summary description of the purpose of procedure.

提案是正処置 (影響範囲を含む) PROPOSED CORRECTIVE ACTION (INCLUDING EXTENT OF CONDITION)
N/A

10CFR21 に基づく評価 Evaluation for 10CFR21 is
 必要 Necessary (Evaluation Report ID:)
 不要 Not Necessary
 判定不能 No capability of evaluation

是正日限 DUE DATE (2016-~~6-15~~⁷⁻⁸) *changed by S. Kono June 20, '16*

Group NICSD V&V Team	
Approved by	Prepared by
<i>堀口</i> May 19, '16	<i>北園</i> May 19, '16

提案調査 Proposal Review
 合格 Acceptable
 不合格 Unacceptable

CARオーナー Reviewed by CAR Owner *河野 May 19, '16*
 サイン Sign / 日付 Date

{ *堀口* } 監査長承認 Manager of Approved by Lead Auditor to NICS-QA *堀口 May 19, '16*
 サイン Sign / 日付 Date

The title was corrected by S. Kono

CAR 処置部門管理者の検証 Verification of Corrective Action Result by the Responsible Organization Line Manager
 合格 Acceptable
 不合格 Unacceptable (SCAR No.)

CAR 処置部門管理者 Verified by Responsible Organization Line Manager
佐藤 Jul 4, '16
 サイン Sign / 日付 Date

Nov. 11, '16

是正処置結果の確認 Verification of Corrective Action Result
 合格 Acceptable
 不合格 Unacceptable (SCAR No.)

CARオーナー Reviewed by CAR Owner
河野 Jul 6, '16
 サイン Sign / 日付 Date

確認エビデンス Verified Evidences
 NICSD VVP (FA32-3709-1000 Rev.8)
 (See Boxed articles in attachment -2)

監査長承認 Manager of Approved by Lead Auditor to NICS-QA *堀口 July 7, '16*
 サイン Sign / 日付 Date


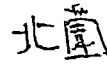

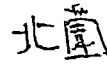

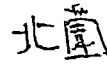





The title was corrected by S. Kono Nov. 11, '16

Safety-Related
 Non-Safety-Related
 ASME CODE
 Others()

是正処置依頼票
 CORRECTIVE ACTION REQUEST

ISSUED DATE May 19 2016

CAR 処置部門/供給者 NICSD V&V Team		関連図書 REFERENCE DOCUMENT Software V&V Plan 5B8K0038 rev.7	
要求回答期限 REQUIRED REPLY DATE	May. 20, 2016	品質を損なう状態 <input type="checkbox"/> 極重大 Highly significant CATQ	CONDITION ADVERSE TO QUALITY (CATQ) <input type="checkbox"/> 重大 Significant CATQ
		<input checked="" type="checkbox"/> 軽微 Not significant CATQ	CATQ 以外 NOT (CATQ) <input type="checkbox"/> 推奨 Recommendation
			<input type="checkbox"/> その他 Other condition
不適合内容 DESCRIPTION OF CONDITN ADVERSE TO QUALITY		<input checked="" type="checkbox"/> 初回 FIRST OCCURRENCE <input type="checkbox"/> 再発生 REPETITIVE	
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)			
処置勧告 RECOMMENDED CORRECTIVE ACTION		Manager of NICS-QA	Initiated by
Revise the NICSD Software V&V Plan (5B8K0038 rev.7) to describe the source code review considering independence of V&V team, and processes for controlling problems, nonconformances and conditions. Evaluate any influence that might be caused by the different control.		堀口 May 19, '16	河野 May 19, '16

是正処置者の記載欄		TO BE COMPLETED BY RECIPIENT							
<p>原因 CAUSE N/A</p>									
<p>提案処置内容 PROPOSED DISPOSITION IV & Vチームはソース・コード・レビューの問題のコントロールのプロセスについて記述するためにV & V計画(5B8K0038)を改訂します。 The IV&V team revises the V&V Plan (5B8K0038), in order to describe the process of control of the problem of source code review.</p>									
<p>提案是正処置 (影響範囲を含む) PROPOSED CORRECTIVE ACTION (INCLUDING EXTENT OF CONDITION) N/A</p>									
<p>10CFR21に基づく評価 Evaluation for 10CFR21 is</p>	<p><input type="checkbox"/> 必要 Necessary (Evaluation Report ID:) <input checked="" type="checkbox"/> 不要 Not Necessary <input type="checkbox"/> 判定不能 No capability of evaluation</p>	<table border="1" style="width:100%; border-collapse: collapse;"> <tr> <th colspan="2" style="text-align: left;">Group NICS-D IV&V Team</th> </tr> <tr> <th style="width:50%;">Approved by</th> <th style="width:50%;">Prepared by</th> </tr> <tr> <td style="text-align: center;">  May 20, '16 </td> <td style="text-align: center;">  May 20, '16 </td> </tr> </table>		Group NICS-D IV&V Team		Approved by	Prepared by	 May 20, '16	 May 20, '16
Group NICS-D IV&V Team									
Approved by	Prepared by								
 May 20, '16	 May 20, '16								
<p>是正日限 DUE DATE (2016-6-15⁷⁻⁸)</p>	<p><i>Changed by S. Kono June 20, '16</i></p>								
<p>提案調査 Proposal Review</p>	<p><input checked="" type="checkbox"/> 合格 Acceptable <input type="checkbox"/> 不合格 Unacceptable</p>	<p>CARオーナー Reviewed by CAR Owner</p>	<p> May 20, '16 サイン Sign./日付 Date</p>						
		<p>[] 長承認 Approved by Manager of NICS-QA</p>	<p> May 10, '16 サイン Sign./日付 Date</p>						
<p>CAR 処置部門管理者の検証 Verification of Corrective Action Result by the Responsible Organization Line Manager</p>	<p><input checked="" type="checkbox"/> 合格 Acceptable <input type="checkbox"/> 不合格 Unacceptable (SCAR No.)</p>	<p>CAR 処置部門管理者 Verified by Responsible Organization Line Manager</p>	<p> Jul. 4, '16 サイン Sign./日付 Date</p>						
<p>是正処置結果の確認 Verification of Corrective Action Result</p>	<p><input checked="" type="checkbox"/> 合格 Acceptable <input type="checkbox"/> 不合格 Unacceptable (SCAR No.)</p>	<p>CARオーナー Reviewed by CAR Owner</p>	<p> Jul. 6, '16 サイン Sign./日付 Date</p>						
<p>確認エビデンス Verified Evidences</p>	<p>NICS-D VVP (FA32-3709-1000 Rev.8) (See boxed articles in attachment-2)</p>		<p>[] 長承認 Approved by Manager of NICS-QA</p> <p> July 7, '16 サイン Sign./日付 Date</p>						

Safety-Related
 Non-Safety-Related
 ASME CODE
 Others ()

是正処置依頼票

CORRECTIVE ACTION REQUEST

ISSUED DATE May 19, 2016

CAR 処置部門/供給者 TO RESPONSIBLE ORG. / SUPPLIER NISD		関連図書 REFERENCE DOCUMENT Preparation Guide for Verification and Validation Plan NQ-2013	
要求回答期限 REQUIRED REPLY DATE	May 20, 2016	品質を損なう状態 CONDITION ADVERSE TO QUALITY (CATQ) <input type="checkbox"/> 極重大 High significant CATQ <input type="checkbox"/> 重大 Significant CATQ <input checked="" type="checkbox"/> 軽微 Not significant CATQ	CATQ 以外 NOT (CATQ) <input type="checkbox"/> 推奨 Recommendation <input type="checkbox"/> その他 Other condition
不適合内容 DESCRIPTION OF CONDITION ADVERSE TO QUALITY During the NRC Audit for Toshiba NISD (OPRM FPGA Qualification Project), it was found that the software problem contro process which was actually implemented in the project was not prescribed in NQ standards.		<input checked="" type="checkbox"/> 初回 FIRST OCCURRENCE <input type="checkbox"/> 再発生 REPETITIVE	
処置勧告 RECOMMENDED CORRECTIVE ACTION Prescribe the software problem control process in NQ standards.		Manager of NICS-QA 堀口 May 19, '16	Initiated by 河野 May 19, '16
是正処置者の記載欄 TO BE COMPLETED RECIPIENT			
原因 CAUSE N/A			
提案処置内容 PROPOSED DISPOSITION NISD revised related NO standards.			
提案是正処置 (影響範囲を含む) PROPOSED CORRECTIVE ACTION (INCLUDING EXTENT OF CONDITION) N/A			
10CFR21 に基づく評価 Evaluation for 10CFR21 is	<input type="checkbox"/> 必要 Necessary (Evaluation Report ID:) <input checked="" type="checkbox"/> 不要 Not Necessary <input type="checkbox"/> 判定不能 No capability of evaluation	Group	NISD
是正日限 DUE DATE (2016-6-30)		Approved by 脇田 May 20, 2016	Prepared by 河野 May 20, '16
提案調査 Proposal Review	<input checked="" type="checkbox"/> 合格 Acceptable <input type="checkbox"/> 不合格 Unacceptable	CARオーナー Reviewed by CAR Owner [] 長承認 Approved by NICS-QA Manager	河野 May 20, '16 サイン Sign / 日付 Date 堀口 May 23, '16 サイン Sign / 日付 Date
CAR 処置部門管理者の検証 Verification of Corrective Action Result by the Responsible Organization Line Manager	<input checked="" type="checkbox"/> 合格 Acceptable <input type="checkbox"/> 不合格 Unacceptable (SCAR No.)	CAR 処置部門管理者 Verified by Responsible Organization Line Manager	脇田 June 22, 2016 サイン Sign / 日付 Date
是正処置結果の確認 Verification of Corrective Action Result	<input checked="" type="checkbox"/> 合格 Acceptable <input type="checkbox"/> 不合格 Unacceptable (SCAR No.)	CARオーナー Reviewed by CAR Owner	河野 Jun. 22, 2016 サイン Sign / 日付 Date
確認エビデンス Verified Evidences	NA-2013 Rev. 5		[] 長承認 Approved by NICS-QA Manager 堀口 June 22, '16 サイン Sign / 日付 Date

<input checked="" type="checkbox"/> Safety-related
<input type="checkbox"/> Non-Safety-related
<input type="checkbox"/> ASME CODE
<input type="checkbox"/> Others ()

是正処置依頼票
CORRECTIVE ACTION REQUEST

ISSUED DATE: 5/18/2016

責任部門/外注業者 TO RESPONSIBLE ORG./VENDOR ESDD []		関連図書 REFERENCE DOCUMENT: Verification and Validation Plan (FA32-3709-0001 Rev.3)	
状態の発見元 INFORMATION SOURCE <input type="checkbox"/> 内部監査 Internal Audit <input checked="" type="checkbox"/> 外部組織による監査 External Organization's Audit <input type="checkbox"/> ベンダー監査 Vendor Survey <input type="checkbox"/> 不適合点検査/サーベイランス Nonconformance / Witness Inspection / Surveillance <input type="checkbox"/> 客先クレーム Customer Complaint <input type="checkbox"/> その他の活動 Other activities			
要求回答期限 REQUIRED REPLY DATE May 20 2016	品質を損う状態 CONDITION ADVERSE TO QUALITY (CATQ) <input type="checkbox"/> 極重大 High significant CATQ <input type="checkbox"/> 重大 Significant CATQ <input type="checkbox"/> 軽微 Not significant CATQ		CATQ 以外 Not CATQ <input checked="" type="checkbox"/> 推奨 Recommendation <input type="checkbox"/> その他 Other conditions
件名 Title V&V Plan description Improvement			
不適合内容 DESCRIPTION OF CONDITION ADVERSE TO QUALITY During the NRC Audit for Toshiba for 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.			<input checked="" type="checkbox"/> 初回 FIRST OCCURRENCE <input type="checkbox"/> 再発生 REPETITIVE
処置勧告 RECOMMENDED CORRECTIVE ACTION In addition to referencing the procedures, summary description of purpose of procedure should be added to V&V Plan.			
		Approved by NQAD 74. Penfina 5/19/2016	Prepared by D. Collins May 18, 2016

是正処置部門の記載欄 TO BE COMPLETED RECIPIENT											
原因 CAUSE Since this CAR is classified as recommendation, this is N/A.											
提案処置内容 PROPOSED DISPOSITION The IV&V Team will revise the OPRM V&V Plan so that the V&V Plan provides brief descriptions of the activities prescribed in the AS-standard when the V&V Plan references an AS-standard.											
提案是正処置 (影響範囲を含む.) PROPOSED CORRECTIVE ACTION (INCLUDING EXTENT OF CONDITION) Since this CAR is classified as recommendation, this is N/A.											
10CFR21に基づく評価 Evaluation for 10CFR21 is	<table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td colspan="2"> <input type="checkbox"/> 必要 Necessary (Evaluation Report ID:) </td> </tr> <tr> <td colspan="2"> <input checked="" type="checkbox"/> 不要 Not Necessary </td> </tr> <tr> <td colspan="2"> <input type="checkbox"/> 評価不能 No capability of evaluation </td> </tr> <tr> <td style="width: 50%;"> Group: ESDD. </td> <td style="width: 50%;"></td> </tr> <tr> <td style="width: 50%;"> Approved by <i>M. Oron</i> May 20, 2016 </td> <td style="width: 50%;"> Prepared by <i>T. Hayashi</i> May 20, 2016 </td> </tr> </table>	<input type="checkbox"/> 必要 Necessary (Evaluation Report ID:)		<input checked="" type="checkbox"/> 不要 Not Necessary		<input type="checkbox"/> 評価不能 No capability of evaluation		Group: ESDD.		Approved by <i>M. Oron</i> May 20, 2016	Prepared by <i>T. Hayashi</i> May 20, 2016
<input type="checkbox"/> 必要 Necessary (Evaluation Report ID:)											
<input checked="" type="checkbox"/> 不要 Not Necessary											
<input type="checkbox"/> 評価不能 No capability of evaluation											
Group: ESDD.											
Approved by <i>M. Oron</i> May 20, 2016	Prepared by <i>T. Hayashi</i> May 20, 2016										
是正日限 * DUE DATE Jun. 20, 2016 Jun. 30, 2016 * See the Attachment A for detail. 2016 Jun 21, 2016											
提案調査 Proposal Review											
<input checked="" type="checkbox"/> 合格 Acceptable <input type="checkbox"/> 不合格 Unacceptable											
CAR 責任部門 Reviewed by CAR Owner <i>D. Bedina</i> May 20 2016 サイン Sign/日付 Date	承認 Approved by NQAD <i>T. Fujino</i> 5/20/2016 サイン Sign/日付 Date										
是正処置部門管理者の確認 Verification of Corrective Action Result by the Responsible Organization Line Manager <input checked="" type="checkbox"/> 合格 Acceptable <input type="checkbox"/> 不合格 Unacceptable (CAR No. _____)	是正処置結果の確認 Verification of Corrective Action Result 検証エビデンス Verification Evidence [FA 32-3709-001 Rev. 4 FPA-PLNCS1-006 Rev. 5]										
責任部門管理者の検証 Verified by Responsible Organization Line Manager <i>M. Oron</i> Jun. 28, '16 サイン Sign/日付 Date	<input checked="" type="checkbox"/> 合格 Acceptable <input type="checkbox"/> 不合格 Unacceptable (CAR No. _____)										
	CAR 責任部門 Reviewed by CAR Owner <i>D. Bedina</i> June 28 2016 サイン Sign/日付 Date										
	承認 Approved by NQAD <i>T. Fujino</i> 6/29/2016 サイン Sign/日付 Date										

CAR No. CAR-16-075 (1/2)

<input checked="" type="checkbox"/> Safety-related
<input type="checkbox"/> Non-Safety-related
<input type="checkbox"/> ASME CODE
<input type="checkbox"/> Others ()

是正処置依頼票
CORRECTIVE ACTION REQUEST

ISSUED DATE: 5/19/2016

責任部門/外注業者 TO RESPONSIBLE ORG./VENDOR ESDD []		関連図書 REFERENCE DOCUMENT: Verification and Validation Plan (FPG-PLN-C51-0006 Rev.4) Verification and Validation Plan (FA32-3709-0001 Rev.3) SCAR-16-018	
状態の発見元 INFORMATION SOURCE <input type="checkbox"/> 内部監査 Internal Audit <input type="checkbox"/> 不適合応会検査/サーベランス Nonconformance / Witness Inspection / Surveillance <input type="checkbox"/> その他の活動 Other activities			
		<input checked="" type="checkbox"/> 外部組織による監査 External Organization's Audit <input type="checkbox"/> ベンダー監査 Vendor Survey <input type="checkbox"/> 客先クレーム Customer Complaint	
要求回答期限 REQUIRED REPLY DATE May 20 2016	品質を測る状態 CONDITION ADVERSE TO QUALITY (CATQ) <input type="checkbox"/> 重大 I/High significant CATQ <input type="checkbox"/> 重大 Significant CATQ <input type="checkbox"/> 軽微 Not significant CATQ		CATQ 以外 Not CATQ <input checked="" type="checkbox"/> 推奨 Recommendation <input type="checkbox"/> その他 Other condition
件名 Title Evaluation of V&V Plans description			
不適合内容 DESCRIPTION OF CONDITION ADVERSE TO QUALITY			<input checked="" type="checkbox"/> 初回 FIRST OCCURRENCE <input type="checkbox"/> 再発生 REPETITIVE
<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 evaluate and take a disposition if NED V&V Plan has same conditions. This CAR is issued for extend 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 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) 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> <p>処置勧告 RECOMMENDED CORRECTIVE ACTION</p> <p>Revise the NED PRM V&V Plan (FPG-PLN-C51-0006 Rev.4) and OPRM V&V Plan (FA32-3709-0001 Rev.3) to describe the source code review considering independence of V&V team, and processes for controlling problems, nonconformances and conditions if necessary. Evaluate any influence that might be caused by the different control if necessary.</p>			
		Approved by NQAD H. Hoffman 5/19/2016	Prepared by S. Collins May 19, 2016

是正処置部門の記載欄 TO BE COMPLETED RECIPIENT	
原因 CAUSE Since this CAR is classified as recommendation, this is N/A.	
提案処置内容 PROPOSED DISPOSITION The current NED V&V Plans are appropriate for the past V&V activities. However, the IV&V Team will revise 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 will clarify that Section 7 applies to base-lined documents, and add 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. The revision of V&V Plans will not affect the past V&V activities because the revision will only clarify the actual V&V activities not requiring further V&V activities. NED V&V Team has not 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 for those activities.	
提案是正処置 (影響範囲を含む。) PROPOSED CORRECTIVE ACTION (INCLUDING EXTENT OF CONDITION) Since this CAR is classified as recommendation, this is N/A.	
10CFR21 に基づく評価 Evaluation for 10CFR21 is	Group: ESDD
<input type="checkbox"/> 必要 Necessary (Evaluation Report ID:) <input checked="" type="checkbox"/> 不要 Not Necessary <input type="checkbox"/> 評価不能 No capability of evaluation	Approved by Prepared by
是正日限 * DUE DATE Jun. 20 2016 Jun. 30, 2016 * See the Attachment A for detail. 2016.16.28.	M. Uemura May 20, 2016 T. Murayama May 20, 2016
提案調査 Proposal Review	<input checked="" type="checkbox"/> 合格 Acceptable <input type="checkbox"/> 不合格 Unacceptable
CAR 責任部門 Reviewed by CAR Owner	[承認] Approved by NQAD
M. Uemura May 20 2016 サイン Sign / 日付 Date	H. Hoshino 5/20/2016 サイン Sign / 日付 Date
是正処置部門管理者の確認 Verification of Corrective Action Result by the Responsible Organization Line Manager <input checked="" type="checkbox"/> 合格 Acceptable <input type="checkbox"/> 不合格 Unacceptable (CAR No. _____) 責任部門管理者の検証 Verified by Responsible Organization Line Manager M. Uemura / Jun. 28, '16 サイン Sign / 日付 Date	是正処置結果の確認 Verification of Corrective Action Result 検証エビデンス Verification Evidence [FA32-3709-0001 Rev.4 FPG-PLN-C51-0006 Rev.5] <input checked="" type="checkbox"/> 合格 Acceptable <input type="checkbox"/> 不合格 Unacceptable (CAR No. _____) June 28 CAR 責任部門 Reviewed by CAR Owner M. Uemura 2016 サイン Sign / 日付 Date [承認] Approved by NQAD H. Hoshino 2016 サイン Sign / 日付 Date