AREVA

E-27390
November 20, 2008

U. S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, DC 20555

Subject: Reply To A Notice Of Violation

To Whom It May Concern:

As required, this letter provides the Transnuclear, Inc. response to the Notice of Violation (NOV) included in NRC Inspection Report No. 72-1027/2008-201.The details of our response to this NOV are provided in the attachment to this letter.

With respect to the subject NOV, Transnuclear, Inc. would like to clarify an inaccuracy noted in Item A.5 of the NOV and the associated text contained in NRC Inspection Report No. 7201027/2008-201. Specifically, the NOV item and the inspection report text discuss two (2) NDE specifications that had not been approved by a qualified individual. Based on investigations performed, this condition is relevant to the "Bubble" Test Specification only. The other specification ("Leak" Test) discussed in the report, had been approved by an appropriately qualified individual.

Those documents referenced in this response are currently available or will be available for your review in our offices in Columbia, MD as the corrective and preventative actions necessary for full compliance are completed.

Please do not hesitate to contact me should you require any additional information or have any questions regarding this response.

Sincerely,

Christopher M. Lloyd
Director, Corporate Quality Assurance

Enclosure

TN Response to NRC NOV (9 pages)

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TN Project #10814 File

TRANSNUCLEAR RESPONSE TO USNRC NOTICE OF VIOLATION / 72-1027/2008-201
(Letter No. E-27390 - Enclosure)

NOV ITEM	REASON for VIOLATION	CORRECTIVE ACTIONS TAKEN / RESULTS ACHIEVED	PREVENTATIVE ACTIONS TO AVOID FURTHER VIOLATIONS	DATE OF FULL COMPLIANCE
A.1	Several Deviation Reports (DRs) were processed by ENSA that required TN (customer) approval; however, the customer approval process prescribed in ENSA General Procedure (GP) 15.1 does not apply to TN-related fabrication activities. This condition is contrary to the requirements of the ENSA Quality Manual regarding quality planning and therefore constitutes a violation of 10 CFR 72.150. ENSA has determined that following reason is the apparent cause of this condition: *GP 15.1 discusses the on-line approval process for use by a customer. The procedure also provides discussion to the effect that when the on-line system is down or in other situations, the Customer may send the temporary approval by means of a fax, letter, e-mail, etc. The intent of this paragraph is to make provisions for those customers without access to the on-line system to provide the required disposition.*	ENSA corrective action for this condition is stated below: *Revise Procedure GP 15.1 and provide clarity to the process for obtaining customer approvals when the on-line system is not being used.* TN concurs with the ENSA corrective action determination pending completion of a follow-up surveillance in the first quarter 2009.	ENSA preventative action to avoid further violation is stated below: 1. *Perform an evaluation of quality assurance program procedures to determine (and correct as necessary) if similar conditions exist.* 2. *Train affected personnel on the revised procedure(s).* TN concurs with the ENSA preventative action determination pending completion of a follow-up surveillance in the first quarter 2009.	ENSA procedure changes and review for similar conditions is scheduled for completion by 11/30/08. TN will review these documents for acceptability once submitted by ENSA. TN will perform follow-up surveillance to determine effectiveness of the corrective & preventative actions taken by ENSA. This surveillance will be performed during the first quarter of 2009 to coincide with completion of other corrective & preventative actions being taken by ENSA in response to this NOV and other corrective actions requested by TN. Full compliance is scheduled for 3/31/09 (including TN action) and is being tracked to completion by TN Supplier Finding Report (SFR) 2008-146.

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	These instructions should have been written such that the intent of the procedure was better stated. TN concurs with the ENSA apparent cause determination pending completion of a follow-up surveillance in the first quarter 2009.			
A.2	Two TN-related fabrication DRs (DR-CTN9-003 and 005) were processed that allowed work to continue at-risk pending final customer approval; however, the process prescribed in GP 15.1 to allow the release of work at-risk does not apply to TN-related fabrication activities. This condition is contrary to the requirements of the ENSA Quality Manual regarding quality planning and therefore constitutes a violation of 10 CFR 72.150. ENSA has determined that following reasons for the apparent cause of this condition: *The cross reference for use of GP 15.1 was not updated to reflect the requirement to use GP 7.10 (TN*	ENSA corrective action for this condition is stated below: 1. *Revise GP 15.1 to provide generic reference to risk release procedures.* 2. *Issue GP 7.10 for risk release of TN-related activities.* TN concurs with the ENSA corrective action determination pending completion of a follow-up surveillance in the first quarter 2009.	ENSA preventative action to avoid further violation is stated below: *Train affected personnel on revised / new procedures.* TN concurs with the ENSA preventative action determination pending acceptable clarification by ENSA of the apparent cause determination, identification of any additional preventative actions based on the apparent cause clarification and completion of a follow-up surveillance in the first quarter 2009.	ENSA procedure changes are scheduled for completion by 11/30/08. TN will review these documents for acceptability once submitted by ENSA. TN will perform follow-up surveillance to determine effectiveness of the corrective & preventative actions taken by ENSA. This surveillance will be performed during the first quarter of 2009 to coincide with completion of other corrective & preventative actions being taken by ENSA in response to this NOV and other corrective actions requested by TN. Full compliance is scheduled

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	specific) versus GP 7.8 (other customer) for risk release. GP 7.10 had been developed for the TN project. TN has not concurred with the apparent cause determination provided by ENSA. TN has requested further clarification from ENSA to identify why the cross reference was not updated.			for 3/31/09 (including TN action) and is being tracked to completion by TN Supplier Finding Report (SFR) 2008-146.
A.3	ENSA issued revisions to NC/DRs as well as corrective actions reports (CARs); however, GP 15.1 and 16.1 do not prescribe a process for making revisions to issued NC/DRs and CARs. This condition is contrary to the requirements of the ENSA Quality Manual regarding specifications, procedures and drawings and therefore constitutes a violation of 10 CFR 72.150. ENSA has determined the following reasons for the apparent cause of this condition: 1. *Requirements for revising NC/DRs had been placed in the*	ENSA corrective action for this condition is stated below: 1. *Revise GP 15.1 and include instructions for revising NC/DRs.* 2. *Revise GP 16.1 to include instructions for revising CARs.* TN concurs with the ENSA corrective action determination pending completion of a follow-up surveillance in the first quarter 2009.	ENSA preventative action to avoid further violation is stated below: 1. *Perform an evaluation of quality assurance program procedures to determine (and correct as necessary) if similar conditions exist.* 2. *Train affected personnel following completion of procedure revisions.* TN concurs with the ENSA preventative action determination pending completion of a follow-up surveillance in the first	ENSA procedure changes and review for similar conditions is scheduled for completion by 12/30/08. TN will review these documents for acceptability once submitted by ENSA. TN will perform follow-up surveillance to determine effectiveness of the corrective & preventative actions taken by ENSA. This surveillance will be performed during the first quarter of 2009 to coincide with completion of other corrective & preventative actions being taken by ENSA in response

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	NCR Computer System Users Manual. As this was a reference document for GP 15.1 it was not felt necessary to provide this instruction in the GP. 2. *Lack of revision control instruction for CARs in GP 16.1 was an oversight.* TN concurs with the ENSA apparent cause determination pending completion of a follow-up surveillance in the first quarter 2009.		quarter 2009.	to this NOV and other corrective actions requested by TN. Full compliance is scheduled for 3/31/09 (including TN action) and is being tracked to completion by TN Supplier Finding Report (SFR) 2008-193.
A.4	ENSA NC-0TN9-005, issued February 28, 2008, documented two non-conforming conditions related to purchased steel plate. The Non Conformity (NC) report was dispositioned as "use-as-is" and an ENSA Project Engineer had approved the disposition and the steel plate was released for use; however, the technical justification required for the "use-as-is" disposition only addressed one of the documented non-conformances. Therefore, the NC disposition was incomplete and the requirements of GP 15.1 were not met.	ENSA corrective action for this condition is stated below: *NC-0TN9-005 was revised to include a justification for the use-as-is disposition for plate flatness. This revision was completed and approved on 10/10/08 and the NC was closed on 11/11/08.* TN concurs with the ENSA corrective action determination pending completion of a follow-up surveillance in the first quarter 2009.	ENSA preventative action to avoid further violation is stated below: *Re-indoctrinated the Project Engineer on the requirements for nonconforming conditions. This was completed on 11/11/08.* TN concurs with the ENSA preventative action determination pending completion of a follow-up surveillance in the first quarter 2009.	TN will perform follow-up surveillance to determine effectiveness of the corrective & preventative actions taken by ENSA. This surveillance will be performed during the first quarter of 2009 to coincide with completion of other corrective & preventative actions being taken by ENSA in response to this NOV and other corrective actions requested by TN. Full compliance is scheduled for 3/31/09 (including TN action) and is being tracked

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	This condition is contrary to the requirements of ENSA Procedure GP 15.1 regarding the control of non-conforming items and therefore constitutes a violation of 10 CFR 72.150. ENSA has determined the following reason for the apparent cause of this condition: *The Project Engineer misunderstood Procedure 15.1 NC/DR requirements and believed that because this was an "internal" issue (did not effect TN requirements), the disposition could remain open until machining operations (plate ordered with extra stock) confirmed that the flatness values reported by the supplier were adequate and would support the "use-as-is" disposition.* TN concurs with the ENSA apparent cause determination pending completion of a follow-up surveillance in the first quarter 2009.			to completion by TN Supplier Finding Report (SFR) 2008-144.
A.5	ENSA procedure GP 5.3, Revision 17, "Preparation, Review, and Approval of Specifications," step 5.4, states, in part, that non-	ENSA corrective action for this condition is stated below: *Submit Specification*	ENSA preventative action to avoid further violation is stated below:	ENSA procedure changes and review for similar conditions is scheduled for completion by 11/30/08.

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	destructive examination (NDE) specifications will be approved by the appropriate Method Level III prior to use. Contrary to this requirement, ENSA did not follow GP 5.3 in that two NDE specifications had not been approved by an appropriate Method Level III individual. This condition is contrary to the requirements of ENSA Procedure GP 5.3 regarding the approval of specifications and therefore constitutes a violation of 10 CFR 72.150. ENSA has determined the following reason for the apparent cause of this condition: *The approver of the "Bubble Test Specification misunderstood GP 5.3 requirements.* TN has not concurred with the apparent cause determination provided by ENSA. TN has requested further clarification from ENSA to identify why the approver misunderstood GP requirements for specification update.	*0TN9CS007 for review by a qualified NDE Level III & reissue specification.* TN concurs with the ENSA corrective action determination pending completion of a follow-up surveillance in the first quarter 2009.	1. *Train / Indoctrinate appropriate personnel in the review and approval requirements of GP 5.3 (action complete 11/11/08)* 2. *Review other 0TN9 project documents and verify that the correct reviews and approvals were performed.* TN concurs with the ENSA preventative action determination pending acceptable clarification by ENSA of the apparent cause determination, identification of any additional preventative actions based on the apparent cause clarification and completion of a follow-up surveillance in the first quarter 2009.	TN will review these documents for acceptability once submitted by ENSA. TN will perform follow-up surveillance to determine effectiveness of the corrective & preventative actions taken by ENSA. This surveillance will be performed during the first quarter of 2009 to coincide with completion of other corrective & preventative actions being taken by ENSA in response to this NOV and other corrective actions requested by TN. Full compliance is scheduled for 3/31/09 (including TN action) and is being tracked to completion by TN Supplier Finding Report (SFR) 2008-147

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	See TN comment on this specific NOV item in cover letter.			
A.6	ENSA did not follow the requirements of TN Design Drawing 972-35-3 in that threaded inserts were procured commercial grade when they were required to be supplied as safety-related. This condition is contrary to the requirements of the ENSA Quality Manual for control of purchased materials, items and services and therefore constitutes a violation of 10 CFR 72.150. ENSA has determined the following reason for the apparent cause of this condition: *The Project Engineer did not understand all applicable procurement requirements from TN Specification E-18597 for the threaded inserts (required to procured as safety related or dedicated under a commercial grade dedication program for use in a safety related application).*	ENSA corrective action for this condition is stated below: 1. *ENSA will re-audit the supplier to determine if the supplier has acceptable controls for the supply of the threaded inserts as safety related components.* 2. *Once complete, the disposition of the threaded inserts will be provided to TN for review and approval.* TN concurs with the ENSA corrective action determination pending completion of a follow-up surveillance in the first quarter 2009.	ENSA preventative action to avoid further violation is stated below: 1. *Retrain / re-indoctrinate the Project Engineer on the requirements for safety related procurement activities. This action was completed 11/11/08.* 2. *Other actions as determined necessary by the Corrective Action Report.* TN concurs with the ENSA preventative action determination pending completion of a follow-up surveillance in the first quarter 2009.	ENSA re-audit of the supplier and completion of further evaluation of this condition under the ENSA corrective action program is scheduled for completion by 12/30/08. TN will review these documents for acceptability once submitted by ENSA. TN will perform follow-up surveillance to determine effectiveness of the corrective & preventative actions taken by ENSA. This surveillance will be performed during the first quarter of 2009 to coincide with completion of other corrective & preventative actions being taken by ENSA in response to this NOV and other corrective actions requested by TN. Full compliance is scheduled for 3/31/09 (including TN

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	As such, the Project Engineer believed that the inserts could be procured from a commercial supplier without a clear understanding of what constitutes appropriate controls for the dedication of a commercial grade item. ENSA does not have a commercial grade dedication program. *ENSA has also initiated a Corrective Action Report to further evaluate this condition.* TN will review the ENSA Corrective Action Report before making a final determination on the acceptability of the apparent cause.			action) and is being tracked to completion by TN Supplier Finding Report (SFR) 2008-143
A.7	ENSA, did not meet the requirements of TN Specification E-18597, Table 3-1, in that certified material test reports associated with purchase orders 0TN9/001, 0TN9/002, and 0TN9/902, had not been approved by TN prior to the release of the materials by ENSA for fabrication. This condition is contrary to the requirements of TN Specification E-18597 and therefore constitutes	ENSA corrective action for this condition is stated below: *Obtain the necessary CMTR approvals from TN.* TN concurs with the ENSA corrective action determination pending completion of a follow-up surveillance in the first quarter 2009.	ENSA preventative action to avoid further violation is stated below: 1. *Retrain / re-indoctrinate the Project Team on the requirements of contractual procedures. This action was completed 11/10/08.* 2. *Discuss with TN possible changes to Specification*	CMTR approvals will be completed by 11/30/08. TN will perform follow-up surveillance to determine effectiveness of the corrective & preventative actions taken by ENSA. This surveillance will be performed during the first quarter of 2009 to coincide with completion of other corrective & preventative actions being

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	a violation of 10 CFR 72.150. ENSA has determined the following reason for the apparent cause of this condition: *TN delays in providing approval of required documents (specifications, procedures, PQRs, etc.) resulted in staff efforts being focused on obtaining / resolving the required approvals in order to support manufacturing. However, during this period, CMTRs were not being effectively tracked such that the status of approval was not known resulting in this condition.* TN concurs with the ENSA apparent cause determination pending complete on follow-up surveillance in the first quarter 2009.		*E-18597 to improve methods for CMTR approvals.* TN concurs with the ENSA preventative action determination pending completion of a follow-up surveillance in the first quarter 2009.	taken by ENSA in response to this NOV and other corrective actions requested by TN. Full compliance is scheduled for 3/31/09 (including TN action) and is being tracked to completion by TN Supplier Finding Report (SFR) 2008-133