



Southwest Research Institute® Nonconformance Report



IDENTIFICATION		
Submitted By: Brient, Robert D.	Date: 15-JUL-10	Report Number: 2010-NCR-0171
Division: 20 – GEOSCIENCES & ENGINEERING 01.03: QA		Project Number: 14002.01.021
Quality Program: GED (20) QAM		
Associated Report: N/A		
Responsible Organization: SwRI Responsible		
Defect Code: Procedure Deficiency		
10 CFR Part 21 Reportable: No		
Description of the Nonconformance: Control of Software Three (3) of six (6) software packages missing information Software Release Notice (SRN) for Abaqus 6.9-EF1 did not contain installation/acceptance results or Software Validation Plan SRN for Ansys / Fluent v12.1 and Shaw v2.3.6 did not contain evidence of installation/acceptance testing Requirement: TOP-018, Development and Control of Scientific and Engineering Software, Sections 4.3.3, 4.3.4, 6.1		
Issued To: Robert Brient	Response Due Date: 22-JUL-10	
SwRI cc: Axler, Keith M (20), Chowdhury, Asadul H. (20), Ferrill, David A. (20), Mackin, Patrick C. (20), Mohanty, Sitakanta (20), Patrick, Wesley C. (20), Pearcy, English C. (20), Sagar, Budhi (20), Stamatakis, John A. (20), Walter, Gary R (20), Winterle, James R. (20), Wittmeyer, Gordon W. (20)		
RESPONSE(S)		
Disposition: Accept as is		
Customer Approval of Disposition Required? NO		
Proposed Action to Address Nonconformance: For the three software items identified, installation test results were obtained from the software users and inserted into the software files in QA records. This action was completed by 7/15/2010. In addition, TOP-018 will be revised to (1) clarify the extent of documentation for installation test results and (2) to exempt software obtained from suppliers qualified on the SwRI Approved Supplier List from validation documentation requirements because the suppliers approved QA program will have been verified to provide adequate software validation meeting GED requirements.		
Response By: Brient, Robert D.	Date: 30-JUL-10	Target Date for Action: 20-AUG-10
APPROVALS		
Management Approval: Hawkins, Frederick W	Date: 30-JUL-10	
QA Approval: Hawkins, Frederick W	Date: 30-JUL-10	
Comments: The proposed corrective actions have adequately addressed this issue.		
VERIFICATION		
Verification of Action Taken: As noted in the Proposed Actions, the installation test results for the three software items were inserted into the software files in QA records by 7/15/2010. In addition, the proposed procedure changes were made to TOP-018 Rev. 10, Change 4, approved on 8/18/2010.		

Verified By: Hawkins, Frederick W	Date: 18-AUG-10

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