



**GEOSCIENCES AND ENGINEERING DIVISION  
QUALITY ASSURANCE  
SURVEILLANCE REPORT**

PROJECT NO.: N/A

REPORT No.: 2006-16

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SURVEILLANCE SCOPE: Validation Testing of TPA, Version 5.1

REFERENCE DOCUMENTS: TOP-018, Development and Control of Scientific and Engineering Software

START DATE:  
July 11, 2006

END DATE:  
July 26, 2006

QA REPRESENTATIVE:  
Randolph Folck

PERSONS CONDUCTING ACTIVITY: R. Janetzke, J. Winterle, R. Rice, F. Osidele, R. Benke, A. Simpkins, N. Epps, G. Adams

**SATISFACTORY FINDINGS:**

Assessed validation activities related to TPA modules: numrecip, mechfail, uzft, ashremob, and dcags. Verified through interview and review of objective evidence that (a) validation tests are being designed to demonstrate correct and successful implementation of the underlying theory and algorithms of the software, (b) validation test results are being reviewed to ensure they are understandable, explainable and reasonable and (c) test failures are being documented on software change reports to ensure correction and re-testing.

**UNSATISFACTORY FINDINGS:**

The TOP-018 required software validation plan was not finalized and reviewed in accordance with QAP-002 prior to the commencement of software validation testing. No CAR or NCR was issued since (a) TOP-018 does not specify "when" the validation plan is to be issued, (b) guidance, in the form of notes to validation test teams, had been issued outlining the approach to the validation of the TPA software, and (c) issues with the TPA validation test plan are being resolved via the technical review process.

NCR NO.: None

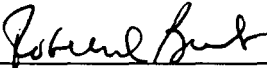
CAR NO.: None

ATTACHMENTS: None

**RECOMMENDATIONS/ACTIONS:**

See page 2.

**APPROVED:**



DATE: 7/31/2006

**DISTRIBUTION:**

ORIGINAL—QA RECORDS  
DIRECTOR, QA  
ASSISTANT DIRECTOR S. Mohanty  
MANAGER J. Winterle  
PRINCIPAL INVESTIGATOR R. Janetzke

Recommendations:

- The TPA validation effort consists of eighteen validation tasks. A software validation test report (SVTR) will be prepared for each validation task and, compiled with other SVTRs, will form the basis for the TPA software validation report. A note to the validation test teams states that it is permissible to identify, in advance, who will be the technical reviewer and that the test team should obtain feedback on the preliminary test plans to ensure the final plan/report will be satisfactory. It is recommended that (a) the test teams take credit for these preliminary reviews by documenting review comments per QAP-002 and (b) upon completion of each validation task, the corresponding SVTR be submitted for technical review in accordance with QAP-002. This early "documented review" will ensure timely identification and correction of problems, reduce review time of the final TPA validation report, and support the on-time delivery of the validated TPA software.
- Consider incorporating a time line for development and approval of required documentation into TOP-018 .
- Consider incorporating a process in QAP-002 to facilitate staged or incremental development and review of large GED documents.