

# GEOSCIENCES AND ENGINEERING DIVISION

## CORRECTIVE ACTION REQUEST

CAR No: 2007-02

Associated AR, SR, NCR No: None

### PART A: DESCRIPTION OF CONDITION ADVERSE TO QUALITY

QAP-001, Scientific Notebook Control, Section 4.1, states that notebooks are considered to be "records-in-process" and requires that electronically maintained notebooks be protected from loss by continual maintenance on the GED computer network. QAP-012, Quality Assurance Records Control, Section 3.2, states in part, "Reasonable precautions shall be taken while gathering ...data...to preclude loss of electronic files."

There have been two recent occurrences of GED scientific notebooks being either completely or partially lost while being maintained as records-in-process on the GED computer network. SN 758E is completely missing from the network. SN 799E, Part 2, is missing data entered between June and September 2007. Network backup controls have, to date, failed to retrieve the missing data. It is currently unclear that the situation is confined to these two instances or whether they may be examples of a systemic problem(s).

Initiated by: M. Simpson  
Date: 10/22/07

Responsible Individual: P. Mackin/R. Brient  
Response Due: 1/19/07 (revised)

### PART B: PROPOSED ACTION

#### Clarification to condition adverse to quality:

The policy established in QAP-001, 4.1, to use the GED computer system back-up procedures for periodic capture of electronic scientific notebooks was based on AP-018, section 4.2, "Full backups will be accomplished automatically once a month after normal business hours. Incremental backups will occur each evening of the normal work week." Hardcopy notebook disaster recovery measures are applied every six months, so data loss could be as much as six months for this type notebook. AP-018 procedures should reduce the potential electronic notebook data loss to one month, however, in extraordinary situations AP-018 controls were ineffective. Full computer system back ups are written over after about three months, so file faults undetected during the three month period of back ups (i.e., notebooks with no entries for more than three months, which is fairly common) may result in complete loss of a notebook.

In both cases relevant to this CAR, the notebooks were maintained as Word Perfect files.

In the case of 458E, the entire notebook (one file) was not found on the investigator's computer D drive in September 2007, where the last entry had been made around August 2007. The loss (possible inadvertent deletion) of the file cannot be explained. Recovery of the August 2007 full back-up file was compromised by an inadvertent deletion while trying to recover the file and previous months' back up were no longer retained. However, the notebook owner had made a CD around April 2007, so the information in this notebook was recovered.

In the case of 799E, the notebook consisted of three files, one of which was corrupted as additions were being made to the file. The corruption was noticed when the file was being saved. Recovery was made from a monthly full back-up, however, several work days of documentation were lost because the daily backups were not recovered. Daily incremental back up was not effective in limiting data loss to one day. Fortunately, the notebook owner had made a CD back up copy and was able to recover the entire notebook.

1) **Extent of Condition:** The nonconforming condition applies to the current file back-up process. All electronic scientific notebooks that are maintained on GED shared drives are potentially affected.

2) **Root Cause:** QAP-001, when endorsing use of AP-018 back up procedures, assumed that electronic scientific notebook file faults would be detected during the period that full back ups are maintained. In the case of SN 799E, this assumption was true – the corrupted file was recognized as an entry was being attempted. However, the assumption is incorrect if file loss or corruption is not be detected fairly soon.

#### 3) Remedial Action:

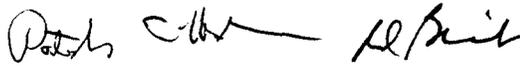
Proposed Completion Date: 1/19/2008

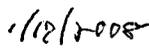
None required, all affected data were recovered from scheduled or personal back ups.

#### 4) Corrective Action to Preclude Recurrence:

Proposed Completion Date: 3/1/2008

QAP-001 shall be revised to require that computer systems are backed up to permanent files <sup>and 1/18/08</sup> ~~are performed~~ at least every six months. An acceptable system to provide permanent back ups will be developed by QA in coordination with IMS staff.

  
Manager/Director:

  
Date:

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**PART C: APPROVAL**  
Comments/Instructions

Director of QA: *M. Simpson (acting in this regard)* Date: *1/18/08*

**PART D: VERIFICATION OF CORRECTIVE ACTION IMPLEMENTATION**

*Revision 9, Change 1 to QAP-001 was effective 2/25/08 and includes revision as specified in corrective action. March 08 disaster recovery instructions include transfer of electronic notebooks to a DVD.*

Distribution:  
Original QA DIRECTOR/QA Records *BRIENT*  
ORIGINATOR *SIMPSON*  
PRINCIPAL INVESTIGATOR (DIRECTOR) *MACKIN*  
MANAGER *NA*  
ASSISTANT DIRECTOR *NA*  
DIVISION VICE PRESIDENT *PATRICK*

Verified by: *M. Simpson* Date: *3/4/08*