

GEOSCIENCES AND ENGINEERING DIVISION

QUALITY ASSURANCE PROCEDURE

Proc. QAP-013

Revision 8 Chg 2

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Title: **QAP-013 QUALITY PLANNING**

EFFECTIVITY AND APPROVAL

Revision 8 of this procedure became effective on 8/22/2005. This procedure consists of the pages and changes listed below.

<u>Page No.</u>	<u>Change</u>	<u>Date Effective</u>
ALL	2	8/24/2006

Change 1: Clarifies that QRAMs are to be prepared during the proposal process.

Change 2: Removes software schedules from the QRAM and in section 3.2.4.

Supersedes Procedure No. QAP-013, Rev.8, Chg 1, dated 7/7/2006

Prepared by

Date

Approved by

Date

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8/10/2006

/s/Wes Patrick

8/10/2006

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QAP-013 QUALITY PLANNING

1. PURPOSE

The purpose of this procedure is to identify methods for applying the Geosciences and Engineering Division (Division) quality assurance (QA) program to specific activities.

2. RESPONSIBILITY

2.1 The Director of QA, project manager, and Director or Assistant Director are responsible for review and approval of quality planning documents.

2.2 Project managers and principal investigators (PIs) are responsible for identifying QA requirements applicable to Division tasks and projects.

2.3 Individuals performing activities affecting quality are responsible for using quality planning documents to guide implementation of the QA program for those activities.

3. PROCEDURE

3.1 Initial quality planning for Division tasks and projects shall be performed when work is proposed. Planning shall be documented on a Quality Requirements Application Matrix (QRAM), form QAP-17, and shall be evaluated and approved (see 3.2.6) as part of the QA review of the proposal required by QAP-002, Review of Documents, Reports, and Papers.

3.2 The QRAM shall identify how the quality program will be applied to a specific activity. Additional quality measures required by clients or regulations shall also be identified in the QRAM.

3.2.1 A QRAM shall be prepared by the cognizant manager and PI for each project, activity or task for proposed work. QRAMs will generally correspond to task-level elements of the work breakdown structure, when applicable. The QRAM shall reference the corresponding project or proposal number (and revision) for which the QRAM is written.

3.2.2 The QRAM shall include a brief description of the scope of work. Quality Assurance Procedures (QAPs), Technical Operating Procedures (TOPs), and Administrative Procedures (APs) applicable to the activity shall be identified based on the type of work to be performed and the ultimate use of the products. The QRAM is organized according to various types of activities (e.g., laboratory and field, software use and development, data and data analysis) that guide identification of applicable procedures.

3.2.3 Consultants and subcontractors expected to be used to support the task or project shall be identified on the QRAM. This information should be used by the project manager and PI to effectively guide and manage consultant and subcontractor activities.

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3.2.4 The QRAM shall identify scientific and engineering software to be used in analysis and software to be developed. Whenever possible, the software version shall be identified. The software status in regard to TOP-018 control (e.g., release) and validation shall be identified. Project management shall ensure software is under TOP-018 control before it is used in calculations. Likewise, project management shall ensure software is validated according to TOP-018 before it is used in regulatory reviews or other sensitive applications. The schedule for implementing these controls shall be documented in software development plans, software requirements description, software development plan, software validation plan, scientific notebook, or other record, as appropriate.

3.2.5 As necessary, the QRAM shall identify any additional implementing procedures that may need to be developed to provide adequate controls.

3.2.6 The QRAM and QRAM revisions shall be reviewed and approved by the project manager, Director of QA, and responsible Director or Assistant Director in Block 3 of the QRAM form. These reviews shall confirm that the QRAM accurately reflects the activity and correctly identifies the applicable procedures. The reviews will also confirm that software expected to be used has the appropriate control and validation status, or that plans are made to bring software into appropriate control, when necessary.

3.2.7 When contracts are awarded, the applicable QRAM shall be reviewed by the manager to confirm that the information is still correct and to revise the QRAM as necessary. Whenever the scope of work covered by a QRAM is significantly changed, the QRAM shall be reevaluated and if needed, revised.

4. RECORDS

4.1 QRAMs and revisions shall be controlled as QA records in accordance with QAP-012, Quality Assurance Records Control.

4.2 Active QRAMs shall be available for electronic viewing by Division staff on the QA website.