C.1 GENERAL

This appendix contains modifications of requirements and descriptions unique to work conducted for the MGDS. Modifications provided relate to specific sections or supplements. In those cases when a section or supplement requires no modification, reference to the section or supplement is omitted.

C.2 REQUIREMENTS

C.2.1 Modification of QARD Section 2.0, Quality Assurance Program

A. The use of expert elicitation may be considered when one or more of the following conditions exist:

1. Empirical data are not reasonably obtainable, or the analyses are not practical to perform;
2. Uncertainties are large and significant to a demonstration of regulatory compliance;
3. More than one conceptual model is permitted by the available data; or
4. Technical interpretations are required to properly assess the knowledge and uncertainty in data, processes, and models.

B. In conducting an expert elicitation, a systematic process for its conduct shall be implemented, including appropriate issue-focused workshops, so that the results of the elicitation accurately reflect data, process, and model uncertainty.

The systematic elicitation process shall consist of the following steps:

1. The objectives are explicitly defined to reflect a clear understanding of how the judgments will be used.
2. Potential conflicts of interest and criteria used to select subject-matter experts are documented.
3. The generalist and normative experts work with the subject-matter experts or expert teams to decompose the objectives of the assessment into focused subissues.
4. Background information, including qualified, accepted, and existing data, is assembled and provided to the subject-matter experts without bias before the elicitation.
5. Pre-elicitation training is provided to the subject-matter experts.

6. The elicitation interviews are structured in a consistent manner, considering the specific issues for which assessments are required.

7. Post-elicitation feedback is provided before the subject-matter experts complete the final documentation of their assessments.

8. The process of aggregating expert assessments is clearly described, including the individual expert's uncertainties and the aggregate uncertainty of multiple experts.

9. Documentation of the elicitation process is assembled.

C. New data shall be reviewed to determine relevance with respect to the experts' assessments, including the need for reassessment.

D. Software which has not been qualified in accordance with Supplement I and existing data may be used in the expert elicitation process. The results of the expert elicitation are considered qualified; however, the expert elicitation process is not considered a method for the qualification of software or existing data used as input.

C.2.2 Modification of QARD Section 4.0, Procurement Document Control

As an alternative to requiring a documented QA program (see Subsection 4.2.1C) for suppliers of analytical services (measurement of properties or other characterization of samples) supporting scientific investigations, these procurements may be controlled in accordance with Appendix C.2.3

C.2.3 Modification of QARD Section 7.0, Control of Purchased Items and Services

Where analytical services in support of scientific investigation are obtained, the following requirements are an acceptable alternative to the requirements of Section 7.0. The purchaser shall:

A. Prior to issuing the procurement document, develop a documented quality control sample plan that describes:

1. The number of quality control samples and approach to be used for submitting these (blind, duplicate, spike, etc.).

2. The preparation and analysis of quality control samples, or identification of the source, e.g., nationally recognized standards.

3. Acceptance criteria.

4. How the number of quality control samples, the approach, and acceptance criteria provide confidence in the accuracy/precision of the data.

B. Ensure that quality control analytical results are received and evaluated against acceptance criteria, prior to use of data.

C. Ensure that data, quality control analytical results, the quality control sample plan, and evaluation documentation are submitted as QA records.

C.2.4 Modification of QARD Section 9.0, Control of Special Processes

Special processes associated with work products specified in work controlling documents (such as job packages or work requests) shall comply with the requirements specified in Section 9.0, Control of Special Processes.

C.2.5 Modification of QARD Section 10.0, Inspections

If required by work controlling documents (such as job packages or work requests) work products shall be subject to inspection in accordance with Section 10.0 of the QARD.

C.2.6 Modification of QARD Section 15.0, Nonconformances

Nonconforming products resulting from activities specified in work controlling documents (such as job packages or work requests) shall be documented, evaluated, identified, segregated, and dispositioned in accordance with Section 15.0, Nonconformances, of this QARD.