

APPENDIX II

DATA QUALITY REQUIREMENTS FOR SUPPORTING DOCUMENTATION

This appendix addresses the data quality requirements for analytical data and other information that will be provided by the applicant to support the technology performance claim(s).

The supporting documentation must be of peer-review quality. The Verification Team will evaluate whether the data and other information are acceptable in terms of the following five (5) criteria:

1. Acceptability of independence in data generation
2. Acceptability/soundness/consistency of the methods used to generate the data
3. Accuracy, as determined by its calibration
4. Precision, as determined by replication
5. Statistical confidence, as measured by the number of independent samples or pieces of information

The evaluation of analytical data involves more than a review of summary results from analytical tests. As part of the evaluation, some of the criteria that the Verification Team will need to review include:

- The reasons for the sample collection
- When and where the samples were collected
- The procedure for the sample collection
- How the samples were prepared for analysis
- The appropriateness of the sampling and analytical procedures used
- What the analytical procedures can and cannot detect
- The Quality Assurance Program and Quality Control Procedures used
- The statistical methods used to analyze the data and to determine its statistical confidence

The technology evaluation may also include; a review of technical literature and patents, discussions with other experts in applicable areas of science and engineering, consultation with other independent evaluators of the technology, interviews with users of the technology, etc. The Verification Team will assess whether the documentation provided is acceptable in terms of its relevance, independence, credibility, consistency, abundance, and other related attributes.