

Ash Fall Project
AFP-AP-04, Attachment B
Considerations for Determining Qualification Methods

One or more combination of the 5 methods identified below can be used to qualify data. If methods 1, 2, and 3 are selected, an initial evaluation of the data quality and correctness shall be included. The team shall evaluate the data by comparing the methods used to plan, collect, and analyze the data against generally accepted scientific or engineering practices. If the evaluation determines the data to be adequate, proceed with implementation methods 1, 2, and/or 3. Or, either method 4 or 5 may be selected to qualify the data as determined by the Ash Fall Project.

1. Equivalent QA Program

The equivalent QA Program approach may be used for the qualification of unqualified data when the acquisition, development, or processing of data can be demonstrated to be functionally equivalent (i.e., similar in scope and implementation) to the general process requirements of the EM-QA-001 QA program. The employed practices or procedures must demonstrate industry acceptable scientific, engineering, or administrative practices or processes with appropriate documentation as defined in this procedure.

The following is a condition for an Equivalent QA Program approach:

Information or documentation is available for the qualification team to assess the functional equivalence of the data-gathering process to applicable EM-QA-001 concepts as identified by the attributes in Attachment C (e.g., 1, 2, 5, 6, 8, and/or 11).

Action to be Taken: Review available information and records with the evaluation criteria and document that they define a process that is functionally equivalent to applicable EM-QA-001 requirements.

2. Corroborating Data

The Corroborating Data approach may be used when data comparisons can be shown to substantiate or confirm parameter values. The corroborating data qualification process may include comparisons of unqualified to unqualified data, as well as unqualified to qualified data with appropriate compliance documentation as defined in this procedure.

The following are conditions for the use of corroborating data:

- a) Corroborating data are available for comparisons with the unqualified data set(s).
- b) Inferences drawn to corroborate the unqualified data can be clearly identified, justified, and documented.

Action to be Taken: Identify the data set(s) that will be used to corroborate the unqualified data set(s). Identify, justify, and document the rationale for using these data set(s) and the inferences drawn to corroborate the unqualified data.

3. Confirmatory Testing

The Confirmatory Testing approach may be used when previous test results are non-verifiable as a result of questionable testing methodology or a lack of applicable documentation. Consideration must be given to confirmatory testing resources and schedule requirements to ensure confirmatory testing is a viable qualification option within the project's funding and time constraints. Confirmatory test results must demonstrate direct correlation to previous test results; however, data extrapolation is acceptable within the limits defined in the compliance documentation defined in this procedure.

The following conditions for a Confirmatory Testing approach:

- a) Funding and schedule time are available.
- b) Similar test conditions are prescribed.
- c) Test result correlation or extrapolations are applicable.

Action to be Taken: Evaluate test funding and schedule requirements to determine the availability of resources and time to complete the testing. Ensure similar test and data reduction conditions can be established to replicate previous test results. If it is determined that resources and time permit confirmatory testing, and similar test and data reduction conditions can be replicated, implement the confirmatory testing process and document the applicability of the test result correlation or extrapolations with the documentation defined in this procedure.

4. Peer Review

Peer Review may be initiated per AFP-AP-10, *Peer Review*.

The following are examples of conditions for a Peer Review approach:

- a) The other four methods (1, 2, 3 and 5) cannot be applied or are inappropriate.
- b) The adequacy of information of the suitability of the implementing documents and methods essential to meet specified objectives cannot be established through testing, alternate calculations, or reference to previously established standards and practices.
- c) Critical interpretations have been made or conclusions have been drawn in the face of significant uncertainty.

- d) Novel, or beyond state-of-the-art, testing or analyses have been utilized.
- e) Detailed technical criteria or standard industry practices or procedures are not available.
- f) Test results are not reproducible.
- g) Data or interpretations are questionable or ambiguous.
- h) Data accuracy is questionable, such as data may not have been collected in conformance with an established NQA-1 QA program or equivalent QA program.

Action to be Taken: The Qualification Team will evaluate the data acquisition and development approach. The team will also summarize and evaluate the assumptions, calculations, extrapolations, alternate interpretations, methodology, acceptance criteria, and conclusions in data being qualified, as applicable. The team will compile supporting records and present the team's evaluation and supporting records package to a Peer Review Panel convened in accordance with AFP-AP-10, *Peer Review*. The Peer Review Panel will review the evaluation and supporting documentation, assess the adequacy of the data being qualified, and document their conclusions in a report in accordance with AFP-AP-10. In this method, the Qualification Team's evaluation and the Peer Review Panel Report will be the documentation of the qualification process.

5. Technical Assessment

The Technical Assessment approach may be used when it is determined that an independent evaluation of the data by a subject-matter expert is needed to raise the confidence of the data to a proper level for the intended use.

Either of the following conditions could require using the Technical Assessment approach:

- a) The confidence in the data is in question because data collection procedures are unavailable for review, or the procedures used are not adequate.
- b) Documentation or proof of proper data acquisition is unavailable for review.

Action to be Taken: Conduct an independent evaluation of the data and available documentation by a subject-matter expert who is independent from the data collection or data reduction process. It is required that documentation be traceable to the original source of the data (it is noted that the original source can be a scientific journal, publication, etc.) and that checking, review, and approval of the data (and data use) can be conducted without recourse to the subject-matter expert that is qualifying the data. The Technical Assessment should include one or a combination of the following:

- 1) Determination that the employed methodology is acceptable. A discussion and justification that the data collection methodology used was appropriate for the type of data under consideration (used appropriate equipment, typical of scientific and industry collection methods, etc.).
- 2) Determination that confidence in the data acquisition or developmental results is warranted. A discussion and justification that the data acquisition and/or subsequent data development (e.g., reduction or extrapolation) discussed in source documentation was appropriate for the type of data under consideration. This could include assurances that processes were conducted by qualified professionals; data were collected under proper environmental conditions; collected results and/or data development are appropriate, reasonable, and suitable for their intended use; etc.
- 3) Confirmation that the data have been used in similar applications. A discussion and documentation that the data have been used in applications that are similar to those for which the data will be used. Past applications could include data used by the U.S Regulatory Commission or Environmental Protection Agency (or their subcontractors) in technical evaluation reports, licensing proceedings, or safety evaluation reports; by nationally/internationally recognized scientific organizations (International Atomic Energy Agency, International Radioactive Waste consortiums, etc.); or by the scientific community, including publications, peer reviews, etc.