



Environmental Management Consolidated Business Center Ash Fall Project

Qualification of Unqualified Data

Procedure: AFP-AP-04
Revision 0, 01/24/16

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Revision: 0

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1.0 PURPOSE

The purpose of this procedure is to establish the responsibilities and process for the qualification of unqualified data for the Ash Fall Project.

2.0 SCOPE

The scope of this procedure is to describe the process for identifying data sets and for the qualification of unqualified data implemented by the Department of Energy Environmental Management Consolidated Business Center (EMCBC) Ash Fall Project supporting the Office of River Protection (ORP) Program.

3.0 APPLICABILITY

This procedure applies to EMCBC Ash Fall Project personnel who are responsible for qualification of unqualified numerical/graphical data that are used to develop, calibrate, or directly input process algorithms, formulas, or models that are important to Ash Fall Distribution and Resuspension research and development activities.

This procedure does not apply to Established Fact data or numerical data obtained from an established/authoritative data source (American Society of Mechanical Engineers, American Society for Testing and Materials, etc.)

4.0 REQUIREMENTS and REFERENCES

4.1 Requirements

4.1.1 EM-QA-001, *EM Quality Assurance Program (QAP)*

4.1.2 ASME NQA-1-2008/2009a, *Quality Assurance Requirements for Nuclear Facility Applications*

4.2 References

4.2.1 AFP-QAPP-01, *Quality Assurance Project Plan (QAPP)*

4.2.2 AFP-AP-03, *Data Control*

4.2.3 AFP-AP-05, *Control of the Electronic Management of Information*

4.2.4 AFP-AP-06, *Software Management Control*

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4.2.5 AFP-AP-07, *Model Validation*

4.2.6 AFP-AP-10, *Peer Review*

4.2.7 AFP-AP-12, *Procedure Development*

4.2.8 AFP-AP-13, *Document Review*

4.2.9 AFP-AP-14, *Document Control*

4.2.10 AFP-AP-20, *Quality Assurance Records*

5.0 DEFINITIONS and ACRONYMS

- 5.1 Data (Collected) – Factual information obtained from investigation activities such as sample collection, physical measurements, testing, and analyses, both in the field and in a laboratory.
- 5.2 Established Fact – Information accepted by the scientific and engineering community (e.g., sources that scientists would use in their standard work practices such as density tables; gravitational laws; equations of state established in engineering and scientific notebooks; professional society/industry codes and standards; numerical data from federal, state, or local government organizations such as the National Weather Service, Census Bureau, or Department of Agriculture; or other recognized authoritative sources).
- 5.3 Qualification of Data – A formal process intended to provide a desired level of confidence that data are suitable for their intended use.
- 5.4 Qualified Data – Data collected under an approved Quality Assurance (QA) program that meets the requirements of EM-QA-001, or an equivalent implemented QA program (i.e., qualified from origin) or unqualified data that have undergone the qualification process or data that is considered Established Fact.
- 5.5 Subject-Matter Expert – An individual recognized by his or her peers as an authority on a specific topic.
- 5.6 Technical Assessment – Used for data qualification purposes, a technical assessment is an evaluation of the technical merit of unqualified data against established criteria.

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- 5.7 Unqualified Data – Data not collected under an approved QA program that meets the requirements of EM-QA-001 or an equivalent implemented QA program.

6.0 RESPONSIBILITIES

6.1 ORP Project Engineer

- 6.1.1 Responsible for the establishment of the scope, schedule, resources, interfaces necessary for the qualification of unqualified data.

6.2 Ash Fall Staff

- 6.2.1 The Ash Project staff (Research Scientists) are responsible for initiating Attachment A – Data Qualification Plan and the selection of one of the 5 qualification methods established in Attachment B – Considerations for Determining Qualification Methods.

6.3 Qualification Chairperson (Analysis/Model Originator)

- 6.3.1 The Analysis/Model Originator (when documenting the qualification in an analysis or model report) is, by definition, the Qualification Chairperson when the qualification is performed within the Analysis or Model Report.
- 6.3.2 The Chairperson is responsible for coordinating the Data Qualification and is technically competent in the discipline pertaining to the data under consideration to conduct the qualification of data.

6.4 Data Qualification Team Members

- 6.4.1 Responsible for participating on the Data Qualification team under the direction of the Chairperson and is technically competent in the discipline pertaining to the data under consideration to conduct the qualification of data (other than the initiators – Ash Fall Staff – of Attachment A – Data Qualification Plan).

6.5 Data Checker

- 6.5.1 Responsible for checking the qualification of the data documented in a data qualification report in accordance with this procedure.

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7.0 GENERAL INFORMATION

None.

8.0 PROCEDURE

8.1 Planning the Qualification of Unqualified Data.

8.1.1 The ORP Project Engineer shall designate a Qualification Chairperson who is technically competent in the discipline pertaining to the data under consideration to conduct the qualification of data.

8.1.2 The Qualification Chairperson shall:

8.1.2.1 Collect background information on the data set(s) to be qualified (e.g., pertinent records associated with the data set(s) to be considered, any available procedures or documentation of data development methodology, data acquisition or development, prior reviews of data).

8.1.2.2 Prepare or revise, as appropriate, the Data Qualification Plan per Attachment A. The planning documents shall include the following elements:

8.1.2.2.1 A listing of the unqualified data set(s).

8.1.2.2.2 The method(s) of qualification and rationale for selecting the method(s) in accordance with Attachment B – Considerations for Determining Qualification Methods, and Attachment C – Qualification Process Attributes

8.1.2.2.3 The Data Qualification Team:

- At a minimum, the team shall consist of at least two members: the Qualification Chairperson and another technically competent individual. The technical competence of the team members should include technical areas of the data under consideration.
- Team Members selected should be independent of the data sets to be qualified (i.e., team members did not participate in the acquisition or

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development of the data sets to be qualified). If independence cannot be achieved, provide the rationale for choosing the teammates and provide the method(s) for mitigating any conflict of interest.

8.1.2.2.4 Data evaluation criteria are based on the process attributes in Attachment C. The evaluation criteria provide the topics or considerations on which the Data Qualification Team will be expected to provide judgments.

8.1.2.2.5 Identification of procedures to be used to control the evaluation process, as applicable (AFP-AP-10, *Peer Review*, AFP-AP-07, *Model Validation*, AFP-AP-06, *Software Management Control*, etc.)

8.1.2.3 Obtain approval for the Attachment A – Data Qualification Plan.

8.1.2.4 Obtain a Document Identifier for the Qualification Report in accordance with AFP-AP-14, *Document Control*.

8.2 Conducting a Data Qualification Task

8.2.1 The Qualification Chairperson (Analysis/Model Originator) or Data Qualification Team Members shall perform the following:

8.2.1.1 Complete the data qualification task in accordance with Attachment A – Data Qualification Plan, and applicable procedures.

8.2.1.2 Provide documentation that recommends superseding data sets and/or adding new data sets that result from the qualification task in accordance with AFP-AP-03, *Data Control*.

8.3 Check, Review, and Documentation of Results

8.3.1 The Qualification Chairperson (Analysis/Model Originator) or Data Qualification Team Members shall perform the following:

8.3.1.1 Document the results of the data qualification task. Data qualification tasks may be documented in a Data Qualification

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Report or as a part of an analysis or model report prepared in accordance with AFP-AP-07, *Model Validation*. The Data Qualification Report, analysis, or model report shall include, as applicable, a discussion of the following items:

- 8.3.1.1.1 The data set(s) for qualification.
 - 8.3.1.1.2 The method(s) of qualification selected and rationale.
 - 8.3.1.1.3 Evaluation Criteria.
 - 8.3.1.1.4 An evaluation of the technical correctness of the data, as applicable.
 - 8.3.1.1.5 Data generated by the evaluation, as applicable.
 - 8.3.1.1.6 The evaluation results.
 - 8.3.1.1.7 A conclusion for/against changing the qualification status of the data based on the team's judgments in response to the evaluation criteria and the evaluation results. Refer to the Attachment A – Data Qualification Plan, as appropriate.
 - 8.3.1.1.8 The appropriate rationale for abandoning any of the qualification methods, if appropriate.
 - 8.3.1.1.9 A discussion of any limits or caveats that should be considered by potential users of the data.
 - 8.3.1.1.10 Identification of any supporting information used in the qualification effort by the appropriate reference identifier (Data Tracking Number [DTN] or other tracking catalog number, etc.)
 - 8.3.1.1.11 Reference to the Attachment A – Data Qualification Plan. Deviations to the plan should be documented and justified in the report.
- 8.3.1.2 Assign a Checker when the qualification is documented in a data qualification report in accordance with this procedure. When

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prepared in accordance with AFP-AP-07, *Model Validation*, the check function of that procedure is applicable.

- 8.3.2 If the qualification is documented in a data qualification report in accordance with this procedure, the Checker shall ensure the following:
 - 8.3.2.1 The content of the report is technically adequate, complete, and correct, and the documentation has been prepared in accordance with this procedure and the Attachment A – Data Qualification Plan.
 - 8.3.2.2 Software, if used, is adequate for its intended use; is identified by the software tracking number, title, and revision/version number; and has been obtained, controlled, and documented in accordance with AFP-AP-06, *Software Management Control*.
 - 8.3.2.3 Data were correctly selected, identified in the report documentation, cited and incorporated, and are appropriate for use.
 - 8.3.2.4 Uncertainties and restrictions are discussed within the report documentation.
 - 8.3.2.5 The assumptions, constraints, bounds, or limits on the data are identified in the documentation.
 - 8.3.2.6 The referencing is thorough, accurate, and complete, including appropriate project tracking numbers (e.g., Data Tracking Numbers, etc.).
 - 8.3.2.7 Document comments and comment resolution utilizing the AFP-AP-13 *Document Review*, Form 13-1 – Document Review and Comment Record.
- 8.3.3 The ORP Project Engineer shall:
 - 8.3.3.1 Approve or reject the Data Qualification Report or the data qualification performed within the technical product (by approval of the technical product).
 - 8.3.3.2 If the qualification is being conducted within a work product (Model Report, Engineering Report, etc.) and 1) the qualification is “providing a desired level of confidence that the data are suitable

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for their intended use,” and 2) the intended use is only for that work product, then no action is required under AFP-AP-03, *Data Control*.

8.3.3.3 Provide the EMCBC Coordinator with the list of qualified data sets for submittal of data in accordance with AFP-AP-03, *Data Control*.

8.3.3.4 Prepare and submit the records identified in Section 9.0.

8.3.3.5 Submit the approved Data Qualification Report to Document Control in accordance with AFP-AP-14, *Document Control*.

9.0 RECORDS

9.1 The approved document in its entirety shall be submitted by the EMCBC Coordinator to records in accordance with AFP-AP-20, *Quality Assurance Records*.

9.2 The following are considered Lifetime QA Records:

- Data Qualification Plan,
- Data Qualification Report,
- Checker Review Documentation,
- AFP-AP-13, Form 13-1 – Document Review and Comment Record.

10.0 FORMS USED

None.

11.0 ATTACHMENTS

Attachment A – Data Qualification Plan

Attachment B – Considerations for Determining Qualification Methods

Attachment C – Qualification Process Attributes

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Attachment A – Data Qualification Plan

Ash Fall Project AFP-AP-04, Attachment A	Data Qualification Plan	Form Version: 0 Total Pages:
Section I - Organizational Information		
Qualification Title:		
Requesting Organization/Initiator:		
Section II - Process Planning Requirements		
1. List of Unqualified Data to be Evaluated		
2. Type of Data Qualification Method(s) including rationale for selection of method(s) (Attachment B) and qualification attributes (Attachment C)		
3. Data Qualification Team and Additional Support Staff Required		
4. Data Evaluation Criteria		
5. Identification of Procedures Used		
Section III – Approval		
Qualification Chairperson Printed Name	Qualification Chairperson Signature	Date
Responsible Manager Printed Name	Responsible Manager Signature	Date

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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.

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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.

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- 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.

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- 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.

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Attachment C Qualification Process Attributes

The process of qualifying unqualified data may consist of any of the five methods or a combination of methods identified in Attachment B. It is not expected that all of these attributes will need to be examined for each data set under review. In certain cases, replication of test results, for example, could provide confidence in data in lieu of specific QA measures such as independent audits. Attributes that may need to be considered in the qualification process are:

- 1) Qualifications of personnel or organizations generating the data are comparable to qualification requirements of personnel generating similar data under an approved NQA-1 type QA program.
- 2) The technical adequacy of equipment and procedures used to collect and analyze the data.
- 3) The extent to which the data demonstrate the properties of interest (e.g., physical, chemical, geologic, mechanical).
- 4) The environmental conditions under which the data were obtained if germane to the quality of data.
- 5) The quality and reliability of the measurement control program under which the data were generated.
- 6) The extent to which the conditions under which the data were generated may partially meet an NQA-1 type QA Program.
- 7) Prior uses of the data and associated verification processes.
- 8) Prior peer or other professional reviews of the data and their results.
- 9) Extent and reliability of the documentation associated with the data.
- 10) Extent and quality of corroborating data or confirmatory testing results.
- 11) The degree to which independent audits of the process that generated the data were conducted.

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Form 12-1 – Record of Revision

DOCUMENT: AFP-AP-04, *Qualification of Unqualified Data*

Revision Number	Description of Changes	Revision on Pages	Effective Date
0	Initial Issue	All	01/24/2016