



Environmental Management Consolidated Business Center Ash Fall Project

Peer Review

Procedure: AFP-AP-10
Revision 0, 02/28/16

Peer Review

Revision: 0
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1.0 PURPOSE

The purpose of this procedure establishes the responsibilities, requirements and methodologies to be used for the peer reviews conducted for the Ash Fall Project. This procedure was developed utilizing the guidance of NUREG-1297, *Peer Review for High-Level Nuclear Waste Repositories*.

2.0 SCOPE

The scope of this procedure is to describe the process for conducting a peer review of model validation activities 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 supporting the ORP Program who are responsible for performing a peer review of the model validation activities that are important to the Ash Fall Project.

Note: The USGS and NOAA can use this procedure as a guide to conduct an internal peer review prior to any formal Ash Fall Project peer reviews performed in accordance with this procedure.

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-13, *Document Review*

4.2.3 AFP-AP-14, *Document Control*

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

5.0 DEFINITIONS and ACRONYMS

- 5.1 Independence – The peer was not involved as a participant, supervisor, technical reviewer, or advisor in the work being reviewed and, to the extent practical, has sufficient freedom from funding considerations to ensure that the work is impartially reviewed.
- 5.2 Peer – A person having technical expertise in the subject matter to be reviewed to a degree at least equivalent to that needed for the original work.
- 5.3 Peer review – A documented, critical review performed by peers who are independent of the work being reviewed. A peer review is an in-depth critique of assumptions, calculations, extrapolations, alternate interpretations, methodology, and acceptance criteria employed, and of conclusions drawn in the original work. It will assess the adequacy of the original work and determine its acceptability for use.
- 5.4 Peer review panel – An assembly of peers representing an appropriate spectrum of knowledge and experience in the subject matter to be reviewed.
- 5.5 Peer review manager – The administrative manager of the peer review process.
- 5.6 Peer Review Panel Selection Committee – A committee, led by the peer review manager that selects the peer review panel members.
- 5.7 Peer review chairperson – A peer review panel member designated by the peer review manager to provide technical leadership to the peer review panel and to determine the manner in which the required peer review evaluations and reporting are conducted.
- 5.8 Peer review observer protocol – Documented instructions for observer interaction with the peer review panel.
- 5.9 Peer review observers – Representatives of regulatory entities, stakeholders, Ash Fall Project staff, and ORP participant organizations with the express need to observe the peer review process.
- 5.10 Peer review plan – Documents the approach, purpose, and scope of a peer review.

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- 5.11 Peer review procedure – Documents responsibilities and methods for conducting a peer review. Meets the criteria established in NUREG-1297 and in Attachment A of this procedure.
- 5.12 Peer review report – In-depth documentation of the proceedings and findings of a peer review.

6.0 RESPONSIBILITIES

6.1 ORP Lead Engineer

- 6.1.1 Responsible for acquiring the services for the conduct of a peer review consistent with this procedure.
- 6.1.2 Assigned as the peer review manager prior to initiation of the peer review process.
- 6.1.3 Ensures that information and data required to support the peer review are assembled and complete.
- 6.1.4 Ensures that the peer review procedure and peer review plan are reviewed by the appropriate Ash Fall Project staff in accordance with AFP-AP-13, *Document Review* as needed.
- 6.1.5 Provides the required interfaces to ensure effective flow of information and logistic support for the peer review process.
- 6.1.6 Ensures necessary communications with the Defense Nuclear Facility Safety Board (DNFSB), ORP Senior Management, and other interested stakeholders.

6.2 Quality Assurance Lead (Ash Fall Project)

- 6.2.1 Responsible for the overall assessment of the peer review process.

7.0 GENERAL INFORMATION

None.

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8.0 PROCEDURE

8.1 Peer Review Process

8.1.1 The peer review shall be used as a management tool to achieve confidence in the validity of certain technical judgments. The intent of a peer review is to pass judgment on the technical adequacy of the work or data submitted for review, to identify aspects of the work on which technical consensus exists, to identify aspects on which technical consensus does not exist, and to identify aspects of the work believed to be incorrect or requiring amplification. A peer review process provides assurance in cases where scientific uncertainties and ambiguities exist but in which technical judgments and decisions still must be made. In general, peer reviews should be used in a confirmatory sense. Peer reviews shall not be used as a substitute for readily collectable data. Conclusions based on inadequate or limited data cannot be improved by subjecting those conclusions to the peer review process.

8.2 Peer Review Process Initiation

8.2.1 The ORP Engineering Lead, or designee shall initiate a peer review that includes:

- A. Development of a peer review plan, in accordance with Attachment A.
- B. The specific scope of the peer review to be conducted, including a schedule for review activities and delivery of the final report.
- C. The requirement that the peer review process be conducted in accordance with this procedure.
- D. The requirement for the peer review manager to transfer any necessary QA records to the responsible USGS/NOAA technical representatives.

8.3 Peer Review Panel and Selection Committee

8.3.1 The ORP Engineering Lead shall lead the peer panel and selection committee and shall document the selection of two individuals to serve on the selection committee using the following criteria:

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- A. Knowledge of the peer review process
- B. Knowledge of the potentially qualified peer review candidates
- C. Impartiality and no organizational conflict of interest

8.3.2 The selection committee, with the aid of a technical advisor if necessary, shall select panel members using the following criteria:

- A. An alternate panel member may be selected in the event that a selected panel member is unable to participate in the peer review.
- B. The number of panel members varies with the complexity of the work to be reviewed, the number of technical disciplines involved, the degree to which uncertainties in the data or technical approach exist, and the extent to which differing viewpoints are strongly held within the applicable technical and scientific community concerning the issues under review.
- C. The collective technical expertise and qualifications of panel members shall span the issues and areas involved in the work to be reviewed, including any differing bodies of scientific thought. Technical areas more central to the work to be reviewed shall receive proportionally more representation on the peer review panel. The panel should represent the major schools of scientific thought and the potential for technical or organizational partiality should be minimized by the formation of a balanced peer review panel.
- D. The panel members shall have recognized and verifiable technical qualifications at least equivalent to those needed for the original work under review (the primary consideration in the selection process) in the technical area the panel member has been selected to cover. The qualifications of each panel member, and of the peer review panel as a whole, shall relate to the importance of the subject matter to be reviewed.
- E. The panel members shall be independent of the original work to be reviewed.

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- 8.3.3 Because of the Department of Energy's (DOE's) extensive effort in the waste management area, the unavailability of other technical expertise in certain areas, and the possibility of reducing the technical qualifications of the reviewers in order to maintain total independence, it may not be possible to exclude all DOE or DOE contractor personnel from participating in a peer review. In cases where total independence requirements cannot be met, the Peer Review Manager shall document in a memo to file, the rationale as to why someone of equivalent technical qualifications and greater independence, if applicable, was not selected. The memo shall be included in the QA record package.
- 8.3.4 The Peer Review Manager shall ensure the education and pertinent experience of each panel member is verified and documented on the Peer Review Plan Member Verification of Education/Employment Form 10-1.
- 8.3.5 Each panel member shall document the rationale for independence on Determination of Peer Review Panel Member Independence Form 10-2.
- 8.3.6 The Peer Review Manager shall review, verify and approve the Peer Review Panel Member Independence Form 10-2.
- 8.3.7 The Peer Review Panel Selection Committee shall eliminate potential peer review panel members from consideration based on information provided on the list and the following criteria:
- A. Equally or more qualified individuals are available
 - B. The candidate is not available
 - C. The candidate has a potential or perceived organizational conflict of interest
- 8.3.8 The Peer Review Panel Selection Committee shall document the rationale for selection and non-selection of peer review panel members on Peer Review Panel Selection Justification/Decision Form 10-3.
- 8.3.9 The Peer Review Manager shall ensure the services of the selected panel members are retained.
- 8.3.10 If an appointed peer review panel member is unable to continue as a standing member, the Peer Review Manager will reconvene the selection committee to select an alternate member in accordance with the applicable sections of this procedure or opt to continue with the remaining panel

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members. The Peer Review Manager will document in a memo the basis for the decision.

8.3.11 The Peer Review Manager shall select and appoint a chairperson from the panel members.

8.4 Peer Review Panel Member Orientation

8.4.1 The Peer Review Manager shall ensure that all panel members have received adequate orientation prior to performing their assigned work.

A. Orientation may take the form of reading assignments, briefings, or classroom training.

B. Orientation shall be facilitated by the Peer Review Manager and shall include the applicable sections of the following:

- AFP-QAPP-001, *Quality Assurance Program Plan (QAPP)*
- AFP-AP-10, *Peer Review*
- Peer Review Plan
- The peer review process, including the administrative requirements
- A brief summary of the peer review technical subject matter, which may include a briefing by the scientist or engineer responsible for the study being reviewed.

C. If an orientation meeting is held, attendance at orientation shall be documented on Peer Review Panel Member Orientation Form 10-4.

8.5 Peer Review Plan

8.5.1 The Peer Review Manager shall prepare a Peer Review Plan in accordance with Attachment A, Peer Review Plan.

8.5.2 The Peer Review Plan shall be reviewed and approved by the ORP Engineering Lead, Peer Review Manager and the Chairperson.

8.5.3 Changes to the Peer Review Plan shall be reviewed and approved in the same manner as the original. The Peer Review Manager may approve minor changes (e.g., editorial, renumbering sections, reformatting forms, updating

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organization titles, and clarifications that do not change intent) to the peer review plan.

8.6 Interfaces

8.6.1 The Peer Review Manager or Chairperson will ensure that all observers are introduced in the pre-review meeting and initial review sessions.

8.6.2 Prior to starting the panel session, the Peer Review Manager or Chairperson will provide a brief introduction, summary of review objectives, and expectations for observer conduct as follows:

- A. Observers are not active participants in the peer review process.
- B. Observer communication with panel members during formal panel sessions is disallowed unless requested by a panel member or when prior approval is obtained from the Chairperson.
- C. Observers may submit questions in writing to the Peer Review Manager or Chairperson during breaks or other designated times unless otherwise requested by panel members or approved by the Peer Review Manager. Observers should limit questions to issues directly related to the information/data being reviewed. Observer questions and panel responses will be addressed only if prior approval is obtained from the Peer Review Manager and the approved questions are documented on Observer Inquiry Form 10-5.
- D. Observers shall be permitted copies of information distributed to panel members during the peer review process upon request to the Peer Review Manager. Such requests for information shall be documented.
- E. Observers are permitted to submit to the panel relevant information that is within the scope of the peer review. The information must first be given to the Peer Review Manager for documentation.
- F. Observers must obtain authorization for the Peer Review Manager to attend the daily caucus meetings.

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8.7 Peer Review Process

- 8.7.1 The panel members shall conduct the peer review in accordance with the requirements of this procedure and the Peer Review Plan.
- 8.7.2 The panel members shall ensure the review consists of an in-depth analysis and evaluation of:
 - A. Validity of assumptions
 - B. Alternate interpretations
 - C. Uncertainty of results and consequences if wrong
 - D. Appropriateness and limitations of methodology and procedures
 - E. Adequacy of application
 - F. Accuracy of calculations
 - G. Validity of conclusions
 - H. Adequacy of requirements and criteria.
- 8.7.3 The panel members shall interact to ensure that sufficient consideration is given to interdisciplinary and coupled data and information.
- 8.7.4 The Peer Review Manager or Chairperson shall:
 - A. Provide technical leadership of the panel and determine the manner in which the required peer review evaluations are conducted.
 - B. Delegate the assignments of specific review tasks and activities among peer review panel members.
 - C. Provide the required coordination between the panel and the ORP Engineering Lead to ensure that an effective and responsible flow of information and logistic/ technical support is provided.
 - D. Provide the ORP Engineering Lead with periodic progress reports on the status of the peer review.
- 8.7.5 The Peer Review Manager or Chairperson shall conduct daily caucuses, as needed, of the peer review panel to address issues, concerns, questions, conflicts, etc.

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8.7.6 The Peer Review Manager or Chairperson shall develop caucus minutes, and initial the minutes to signify they have been reviewed and they represent the work of the panel.

8.8 Schedule/Status

8.8.1 The Peer Review Manager or Chairperson shall provide the Ash Fall Project staff with a detailed schedule and updates, as required. This information will be provided to observers as requested.

8.9 Peer Review Report

8.9.1 The peer review chairperson, with assistance from the peer review manager as needed, shall ensure that the peer review panel findings are documented and that the peer review report is prepared.

8.9.2 The peer review report shall:

- A. Be signed by each peer review panel member
- B. Describe the work or issue that was reviewed
- C. Describe the conclusions reached by the peer review panel and the conclusions reached by the peer review process
- D. Provide individual statements by the peer review panel members, reflecting dissenting views or additional comments, as appropriate
- E. List the peer review panel members and provide acceptability information (i.e., technical qualifications and independence) for each member, including any potential technical and or organizational conflict of interest

8.9.3 In the event that issues affecting the defined purpose of the peer review are identified in the peer review report, the panel may be reconvened to review supplementary information provided to resolve such issues. If the panel is reconvened, the Peer Review Manager or Chairperson shall ensure the review of the supplementary data and information are conducted in accordance with this procedure, and the results of the supplementary peer review are documented in a supplementary peer review report.

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8.10 Peer Review Process Support

8.10.1 The ORP Engineering Lead, or designee shall:

- A. Verify that information and data required to support the peer review are assembled, complete, and provided to the peer review panel.
- B. Process requests for information, including any additional information required by the peer review panel, in a timely manner.
- C. Provide required interfaces to ensure effective flow of information and logistic support for the peer review process.
- D. Initiate the AFP-AP-13, *Document Review* process if changes are made to the peer review plan that will affect the implementation of this procedure.
- E. Ensure that any changes to this peer review procedure are reviewed in accordance with AFP-AP-13, *Document Review*.

8.11 Peer Review Process Conclusion

8.11.1 The ORP Engineering Lead, or designee shall review the final peer review report and any supplemental information for impacts and further actions required.

8.11.2 The ORP Engineering Lead, or designee shall notify the affected organizations and stakeholders of the conclusions of the peer review.

8.12 Quality Assurance Assessments

8.12.1 The QA Lead will assess the peer review process to ensure that it conforms to this procedure.

8.12.2 The QA Lead shall present any assessment findings to the responsible ORP Engineering Lead, or designee, who in turn submits them to the Organizations conducting the peer review.

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8.12.3 The QA Lead shall review the resolution of any findings to ensure that they include an assessment of the impact of the findings on completed and ongoing peer reviews, as applicable.

9.0 RECORDS

9.1 The documents supporting the peer review 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:

- Peer review panel manager qualification documentation (Resume)
- Peer review plan
- Documentation for appointment of the peer review panel member selection committee
- Memo providing rationale for selection of panel members without total independence
- Peer review panel member qualification and selection documentation including:
 - ✓ Verification of education/employment documentation (Form 10-1)
 - ✓ Determination of peer review panel member independence documentation (Form 10-2)
 - ✓ Justification/decision related to peer review panel selection (Form 10-3)
- Determination of peer review panel member independence documentation
- Peer review panel selection documentation
- Service acquisition documents (beginning with request for peer review from ORP through peer review panel member service provider contracting documentation)
- Peer review panel orientation documentation and attendance form(s) (Form 10-4)
- Written minutes of meetings, deliberations and activities
- Observer inquiry forms and/or relevant information that is within the scope of the peer review submitted by an observer to the panel (Form 10-5)
- Peer review report.

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10.0 FORMS USED

- Form 10-1 – Peer Review Panel Member Verification of Education/Employment
- Form 10-2 – Determination of Peer Review Panel Member Independence
- Form 10-3 – Peer Review Panel Selection Justification/Decision
- Form 10-4 – Peer Review Panel Orientation
- Form 10-5 – Observer Inquiry

11.0 ATTACHMENTS

- Attachment A – Peer Review Plan

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Attachment A – Peer Review Plan

The Peer Review Plan shall contain, as a minimum:

- A. The scope of the peer review and description of the work to be reviewed
- B. The intended use of the work
- C. The composition of the peer review panel
- D. Suggested methods (e.g., the method used to document observations, comments, and conclusions)
- E. The schedule to complete the peer review report
- F. The frequency of status reports

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Form 10-2
Determination of Peer Review Panel Member Independence

Are you currently employed by DOE or a DOE contractor? Yes/No

Were you employed by DOE or a DOE contractor previously? Yes/No
(If yes, give dates, location, organization, position, and type of work performed.)

Do you have or have you had any direct involvement or financial interest Yes/No
in the work under review?
(If yes, describe.)

Is there any reason why you cannot perform an impartial peer review? Yes/No
(If yes, describe.)

Is there any aspect of your past that may lead to a perception of bias in the Yes/No
results of your peer review?
(If yes, describe.)

I pledge that my review of this work will be completely impartial and based solely on the information available during the review.

Panel Member Signature	Panel Member Printed Name	Date
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Peer Review Manager Signature	Peer Review Manager Printed Name	Date
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Form 10-3
Peer Review Panel Selection Justification/Decision

Selection committee members:

Peer review entitled:

Peer review panel composition:

1. _____

2. _____

3. _____

4. _____

5. _____

Justification:

Date: _____

Selection committee signatures:

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Form 10-5
Observer Inquiry

Observer: _____

Date: _____

Organization: _____

Peer review subject or title: _____

COMMENTS:

RESPONSE: _____

Peer Review Manager/Peer Review Chairperson:

Printed Name

Signature

Date

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Form 12-1 – Record of Revision

DOCUMENT: AFP-AP-10, *Peer Review*

Revision Number	Description of Changes	Revision on Pages	Effective Date
0	Initial Issue	All	02/28/2016