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PROCEDURE

SCIENTIFIC ANALYSES

AP-SIII.9Q

Revision 1 ICN 1

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09/25/03
Date

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09/25/03
Date

CHANGE HISTORY

Revision Number	Interim Change No.	Effective Date	Description of Change
0	0	12/21/2001	Initial issue. Scientific analyses procedure prepared to separate scientific analyses from models and engineering analyses, and to address, in part, issues identified in BSC-01-C-001, LVMO-01-D-007, BSC-01-D-050, LVMO-00-D-118, BSC-01-D-078, and LVMO-00-D-119. Supersedes AP-3.10Q, *Analyses and Models*, for analyses performed to Supplement III, Scientific Investigation, of the *Quality Assurance Requirements and Description*, DOE/RW-0333P. Supersedes AP-3.12Q, *Calculations*, for calculations performed to Supplement III, Scientific Investigations, of the *Quality Assurance Requirements and Description*, DOE/RW-0333P. AP-3.12Q has been revised to address design/engineering calculations and analyses exclusively, and has been renamed *Design Calculations and Analyses*.
0	1	04/03/2002	ICN to clarify requirements of the Bechtel SAIC Company, LLC Quality Engineering Compliance Check; complete editorial changes; and clarify role of the originator.
1	0	07/08/2003	Complete revision to delete references to AP-2.21Q, *Quality Determinations and Planning for Scientific, Engineering, and Regulatory Compliance Activities*; incorporate changes to AP-SIII.2Q, *Qualification of Unqualified Data*; incorporate Document Action Request Numbers 3346, 3425, 6107, 6028, 6029, 6347, 6348, 7774, 8709, and 6734; identify steps that can be completed in any order; and state the requirements for incorporation of errata in accordance with AP-15.3Q, *Control of Technical Product Errors*.
1	1	09/30/2003	Interim Change Notice to clarify sequencing of action steps. Reference BSC(B)-03-D-220 and Document Action Request D10476. Incorporated Document Action Requests D7774, D10066, D10517, and D10728.

1.0 PURPOSE

This procedure establishes the responsibilities and the process for performing and documenting scientific and performance assessment analyses and calculations that are subject to the *Quality Assurance Requirements and Description* (QARD), DOE/RW-0333P. For the purposes of this procedure, scientific and performance assessment analyses and calculations are termed "scientific analyses." This procedure may be used for scientific analyses that are not subject to QARD requirements. Supplemental guidance for all scientific processes is contained in the *Scientific Processes Guidelines Manual*, MIS-WIS-MD-000001, located in the Office of Civilian Radioactive Waste Management Program Documents Database under the "Manual/Handbook" icon.

2.0 APPLICABILITY

This procedure applies to individuals within Bechtel SAIC Company, LLC (BSC), the National Laboratories, U.S. Geological Survey, BSC subcontractors, and other contractors who perform and document scientific analyses for the Office of Civilian Radioactive Waste Management. Design analyses are documented using AP-3.12Q, *Design Calculations and Analyses*.

3.0 DEFINITIONS

3.1 ***Abstraction***–The process of purposely simplifying a mathematical model (component, barrier, or subsystem process model) for incorporation into an overall system model of the geologic repository. The products of model abstractions may represent reduction in dimensionality, elimination of time dependence, tables obtained from more complex models, response surfaces derived from the use of more complex models, representations of a continuous process or entity with a few discrete elements, etc.

3.2 ***Assumption***–A statement or proposition that is taken to be true or representative in the absence of direct confirming data or evidence.

3.3 ***Checker***–A qualified individual other than the Originator, technically competent in the subject area of the document undergoing checking, responsible for confirming adequacy, accuracy, and completeness of the scientific analysis documentation.

3.4 ***Editorial Corrections***–Modifications made to a document, such as correcting grammar, spelling, or typographical errors; renumbering sections or attachments; and updating organizational titles. Editorial corrections do not affect the chronological sequence of work or the fundamental process, or alter assigned responsibilities.

3.5 ***Interim Change Notice (ICN)***–A method for updating limited portions of approved documentation (e.g., updating the To Be Verified [TBV] status).

3.6 ***Lead***–An individual assigned by the Responsible Manager to control a scientific analysis activity and having responsibility for assignment of personnel to the scientific analysis activity.

3.7 ***Model, Mathematical***–A mathematical representation of a conceptual model (system, process, or phenomenon) that is based on established scientific and engineering principles and from which the approximate behavior of a system, process, or phenomenon can be calculated within determinable limits of uncertainty (QARD).

3.8 ***Originator***–A technically competent individual assigned responsibility for performing a scientific analysis, for preparing scientific analysis documentation (e.g., analyst, investigator, preparer), and for ensuring the adequacy, accuracy, and completeness of the scientific analyses documentation.

3.9 ***Responsible Manager***–The individual having management responsibility for a scientific analysis activity, for assignment of a Lead to the scientific analysis activity, and for approving the scientific analysis documentation.

3.10 ***Scientific Analysis***–A documented study that 1) defines, calculates, or investigates scientific phenomena or parameters; 2) evaluates performance of components or aspects of the overall geologic repository; or 3) solves a mathematical problem by formula, algorithm, or other numerical method. A scientific analysis may involve numerical manipulations that are not part of a previously developed and validated mathematical model (per AP-SIII.10Q, *Models*) if the choice of method is evident from standard scientific practice, approach, or method. A scientific analysis may also use a previously developed and validated mathematical model (per AP-SIII.10Q) consistent with the mathematical model's intended use and stated limitations, but may not revise the mathematical model in order to complete the scientific analysis.

3.11 ***Sensitivity***–The degree to which the scientific analysis results are affected by changes in a selected input.

3.12 ***To Be Verified (TBV)***–Identification of information that is preliminary, needs to be reevaluated, and/or needs confirmation.

3.13 ***Traceability***–The ability to trace the history, application, or location of an item, data, or sample using recorded documentation (QARD).

3.14 ***Transparency***–The attribute of producing documents that are sufficiently detailed as to purpose, method, assumptions, inputs, conclusions, references, and units, such that a person technically qualified in the subject can understand the documents and ensure their adequacy without recourse to the Originator.

4.0 RESPONSIBILITIES

4.1 The Chief Science Officer is responsible for the preparation, change, and approval of this procedure.

4.2 The following positions or organizations are responsible for activities identified in Section 5.0 of this procedure:

a) Responsible Manager
b) Lead

c) Originator
d) Checker
e) Quality Engineering Representative (QER)
f) Reviewing Organization

5.0 PROCESS

Acronyms and abbreviations used in this procedure are defined in Attachment 1, Acronyms and Abbreviations.

PROCESS OUTLINE

Page
5.1 PLANNING 5
5.2 DEVELOPMENT AND DOCUMENTATION OF ANALYSES 6
5.3 CHECKING AND REVIEW 7
5.4 PRODUCT OUTPUT 11
5.5 APPROVALS 11
5.6 REVISIONS OR CHANGES 12
5.7 EDITORIAL CORRECTIONS 13

5.1 PLANNING

The Technical Work Plan (TWP) must be completed before beginning action steps in Paragraph 5.1.1.

5.1.1 Responsible Manager:

a) Control the development, documentation, checking, revision, change, and key technical activities of the scientific analysis activity in accordance with the requirements of this procedure. A Lead may be assigned to control these functions.

b) If a Lead has been assigned, provide the Lead with the applicable TWP prepared in accordance with AP-2.27Q, *Planning for Science Activities*.

5.1.2 Responsible Manager or Lead:

a) Review the TWP for the Work Package associated with the scientific analysis to be developed. If the TWP requires correction or revision, ensure that it is completed in accordance with AP-2.27Q.

b) If a previously developed and validated model is to be used to conduct the scientific analysis, provide justification in the TWP that the present scientific analysis activity is within the intended use, limitations, and validity of the model.

c) Assign an Originator to perform the scientific analysis activity. (The Lead may assume the Originator's responsibilities; however, the Lead may not assume the Checker's responsibilities when acting as an Originator.)

5.2 DEVELOPMENT AND DOCUMENTATION OF ANALYSES

It is not necessary for the action steps to be performed sequentially.

5.2.1 Originator:

a) Perform the scientific analysis and associated tasks in accordance with the applicable TWP and all applicable procedures. Scientific notebooks may be used in the scientific analysis in accordance with AP-SIII.1Q, *Scientific Notebooks*.

b) Obtain a document identifier (DI) for the scientific analysis from Document Control in accordance with AP-6.1Q, *Document Control*, and ensure that the DI, including revision number, appears on each page, except as noted in the attachments section of Attachment 2, Scientific Analysis Outline.

c) Use a sequential alphanumeric revision designator to denote the initial draft and each interim draft prior to approval (e.g., 00a, 00b, 01a).

d) Document the scientific analysis in accordance with Attachment 2. If a section is non-applicable, indicate that it is non-applicable after the section title and provide a rationale for non-applicability.

e) If using a previously validated mathematical model to complete the scientific analysis, obtain the appropriate model file/product output from the Technical Data Management System (TDMS).

f) Document technical product inputs used to develop the scientific analysis in the Document Input Reference System (DIRS) in accordance with AP-3.15Q, *Managing Technical Product Inputs*.

g) Ensure the scientific analysis report is legible and in a form suitable for reproduction, filing, and retrieval.

h) Complete the appropriate portions of Attachment 3, Scientific Analysis Cover Sheet.

i) Ensure that each scientific analysis page is sequentially numbered, beginning with Attachment 3 as page 1. (If revision history information exceeds the available space on the cover page, additional pages may be added.)

j) Ensure that attachments are identified by Roman numerals (e.g., Attachment I) and that attachment pages are numbered sequentially (e.g., Pages I-1 through I-6), except as noted in the attachments section of Attachment 2.

k) If any information with regard to naval fuel is included in the scientific analysis, have the Resident Manager for the Naval Nuclear Propulsion Program review the scientific analysis to ensure no unauthorized naval reactor information is included in the scientific analysis.

l) If software is used in the scientific analysis, ensure that it is controlled and documented in accordance with AP-SI.1Q, *Software Management*; AP-SI.2Q, *Qualification of Level A Software*; and/or AP-SI.3Q, *Software Independent Verification and Validation.*

m) Document software used in the scientific analysis in accordance with Section 3 of Attachment 2.

n) Document the qualification of unqualified data, developed in accordance with AP-SIII.2Q, *Qualification of Unqualified Data,* in Subsection 6.0 of the Scientific Analysis Documentation Outline.

5.2.2 Responsible Manager/Lead:

If the scientific analyses produces preliminary output that is needed as input, submit it in accordance with AP-SIII.3Q, *Submittal and Incorporation of Data/Technical Information to the Technical Data Management System.*

5.3 CHECKING AND REVIEW

It is not necessary for the action steps to be performed sequentially. However, all action steps through Paragraph 5.3.6 must be completed before beginning action steps in Paragraphs 5.3.7 through 5.3.12.

5.3.1 Responsible Manager or Lead:

Assign a Checker to check the scientific analysis documentation.

1) The Originator may not perform the checking function.

2) If no other technically competent individual is available, the Lead may perform checking.

5.3.2 Originator:

Provide to the Checker and QER (an optional Scientific Analysis Checklist [Form 1097 on the BSC Intranet Automated Forms System] may be completed by the Originator):

1) Check copies of the scientific analysis documentation. Clearly indicate, on Attachment 3, one copy as the Checker Check Copy, and one copy as the QER Check Copy, and initial and date.

2) The DIRS report.

3) Other supporting information and documentation that may be requested by the Checker or QER.

5.3.3 Checker:

a) Check the scientific analysis documentation for the following (an optional Scientific Analyses Checklist [Form 1097 on the BSC Intranet Automated Forms System] may be completed by the Checker):

1) The content of the scientific analysis is technically adequate, complete, and correct, and the documentation has been prepared in accordance with the requirements of this procedure and the applicable TWP.

2) Software, if used, is adequate for its intended use; is identified by software tracking number, title, and revision/version number; and has been controlled and documented in accordance with AP-SI.1Q and AP-SI.2Q.

3) Appropriate product inputs were selected, identified in the documentation and on the DIRS report, and cited and incorporated in the scientific analysis activity, in accordance with AP-3.15Q.

4) TBV/Unresolved Reference Number tracking numbers, if any, are included in DIRS in accordance with AP-3.15Q.

5) The implications of uncertainties and restrictions are discussed and evaluated.

6) The assumptions, constraints, bounds, or limits on the inputs are identified in the documentation, and their impact on the results is described and assessed in the documentation.

7) The discussion of scientific approach and/or technical methods is documented.

8) The referencing is thorough, accurate, and complete, including appropriate project tracking numbers (e.g., records accession numbers, Technical Information Center numbers, Data Tracking Numbers [DTNs]), and is consistent with the DIRS report.

9) The appropriateness for using a previously developed and validated model to complete the present scientific analysis is described.

10) Data used as direct inputs are verified to match information in the TDMS.

11) All errata, initiated in accordance with AP-16.1Q, *Condition Reporting and Resolution*, and documented against previous scientific analysis document revisions/changes, if any, are incorporated in the scientific analysis documentation.

12) The product output is accurate, correct, and technically adequate.

b) Clearly and legibly write, or mark electronically, all comments on the Checker Check Copy or indicate that there are no comments. (Comments may be documented separately if keyed to the Check Copy, and if comment documentation is signed, dated, and attached to the Check Copy.)

c) Initial and date the Checker Check Copy of Attachment 3.

d) Return documentation to the Originator.

5.3.4 QER:

a) For scientific analyses subject to QARD requirements, perform a quality assurance (QA) compliance check to ensure compliance with this procedure and the applicable TWP.

b) Clearly and legibly write, or mark electronically, all comments on the QER Check Copy or indicate that there are no comments (comments may be documented separately if keyed to the Check Copy and if comment documentation is signed, dated, and attached to the Check Copy).

c) Initial and date the QER Check Copy of Attachment 3.

d) Return documentation to the Originator.

5.3.5 Originator:

a) Resolve all comments with the Checker and QER and document resolution by mark up of the applicable Check Copy, including the rationale for any comments not incorporated or only partially incorporated. (Resolutions may be documented separately if keyed to the applicable Check Copy.)

b) Elevate unresolved comments to the next levels of management of the Originator and Checker/QER until resolution is achieved and document the resolution. (Resolutions may be documented separately if keyed to the applicable Check Copy.)

c) Modify the original scientific analysis documentation as required to incorporate comment resolution.

d) Denote the modified scientific analysis documentation by revising the alphanumeric revision designator.

e) Provide the modified copy, the DIRS report, and the applicable Check Copy to the Checker and QER.

5.3.6 Checker and QER:

a) Check the modified scientific analysis documentation by comparing it to the applicable Check Copy.

b) Indicate acceptance of the resolution of comments, including any comment that was not incorporated or was only partially incorporated by accepting the Originator's rationale or by providing separate justification. Initial and date the response, and sign and date the applicable Check Copy.

c) Return documentation to the Originator.

5.3.7 Originator:

Prepare a review copy of the scientific analysis documentation and forward to the Responsible Manager.

5.3.8 Responsible Manager and Lead:

a) Initiate a review in accordance with AP-2.14Q, *Document Review.* Reviews of ICNs are limited to the changes and the portions of the documentation affected by the changes.

b) Include the Chief Science Officer, organizations/disciplines providing input to the scientific analysis documentation, customer organizations/disciplines for the scientific analysis documentation, and organizations/disciplines affected by the scientific analysis documentation as mandatory reviewers on AP-2.14Q reviews of scientific analysis documentation.

5.3.9 Reviewing Organization:

a) Complete a review of the scientific analysis documentation in accordance with AP-2.14Q.

b) If the scientific analysis does not affect or impact the Reviewing Organization, indicate "not applicable" and return the review documentation.

5.3.10 Originator:

a) Resolve all comments with the reviewers in accordance with AP-2.14Q. Elevate unresolved comments to the next levels of management of the Originator and reviewers until resolution is achieved and document the resolution.

b) Develop a concurrence draft by modifying the AP-2.14Q review copy of the scientific analysis documentation, as required, to incorporate changes resulting from the comment resolution.

c) After the AP-2.14Q comments have been incorporated, provide the final concurrence copy of the scientific analysis documentation to the Responsible Manager/Lead, Checker, and QER.

5.3.11 Responsible Manager/Lead, Checker, and QER:

a) Ensure that the AP-2.14Q review comments, as resolved, have not adversely affected the scientific analysis documentation.

b) Resolve any adverse impacts with the Originator and the Reviewing Organization.

c) Indicate acceptance by signing and dating the documentation. Return the documentation to the Originator.

5.3.12 Originator:

Request lockout of changes to links in DIRS in accordance with AP-3.15Q.

5.4 PRODUCT OUTPUT

It is not necessary for the action steps to be performed sequentially.

Originator:

a) Submit the following items to the TDMS in accordance with AP-SIII.3Q:

1) Product output that replaces or supersedes product output or data that are currently in the TDMS.

2) Data that have undergone a status change, as a result of a qualification within the scientific analysis.

3) Other output may be submitted, as directed by the Responsible Manager.

b) Finalize or supersede preliminary product output, if any, in accordance with AP-SIII.3Q.

5.5 APPROVALS

5.5.1 Originator:

a) Prepare the scientific analysis documentation by changing the alphanumeric designator to a numeric designator (i.e., the initial technical product designator is "00," and subsequent revisions are "01," etc.) and update the revision history as needed.

b) Complete the Scientific Analysis Cover Sheet in accordance with the instructions in Attachment 3.

c) Process the approved scientific analysis in accordance with AP-6.1Q.

d) Submit supporting scientific analysis documentation to the Records Processing Center in accordance with Section 6.0 of this procedure.

5.5.2 Responsible Manager/Lead:

a) If modifications are required as a result of the U.S. Department of Energy's review (AP-7.5Q, *Submittal, Review, and Acceptance of Deliverables*), ensure the development and change process defined by this procedure is followed.

b) If the document resolves TBVs/Unresolved Reference Numbers, process in accordance with AP-3.15Q.

5.6 REVISIONS OR CHANGES

Responsible Manager:

a) Decide if an approved document needs to be modified as a revision or an ICN (no more than five ICNs may be made prior to a full revision). Reviews of ICNs are limited to the changes and the portions of the documentation affected by the changes.

b) When initiating a revision or change to an existing document, notify Document Control of the impending action to ensure version control.

c) Process a revision or change in accordance with requirements of Section 5.0 and indicate revisions or ICNs in the scientific analysis documentation using one of the following:

1) A black vertical line in the margin of the page clearly indicating which individual sections or subsections were revised and a brief description of the revision or change in Block 13 of Attachment 3.

2) A note in Block 13 of Attachment 3 indicating the entire scientific analysis documentation was revised because the changes were too extensive to use Step 5.6c)1).

d) For ICNs, if desired, use alphanumeric page designators (e.g., 10a) to avoid repaginating subsequent pages caused by the addition of text.

e) Maintain the history of all previous revisions and changes to the original on Attachment 3 by updating the Revision History blocks with each revision or ICN and by updating the Change History of the scientific analysis documentation.

f) Address any applicable errata, documented in accordance with AP-16.1Q, in the appropriate section of the scientific analysis document. List any errata addressed in the Remarks section of the Scientific Analysis Cover Sheet.

g) Cancel scientific analyses that are no longer relevant to the project in accordance with AP-6.1Q.

5.7 EDITORIAL CORRECTIONS

5.7.1 Originator:

a) If required to make editorial corrections to a document after approval, but prior to release for controlled distribution:

1) Make the correction(s) by drawing a single line through any incorrect text (i.e., pen/ink or electronic) and/or inserting any new or correct information.

2) Initial and date the correction(s).

3) Note the correction(s) in the Remarks section (Block 11) of Attachment 3.

b) Obtain the Responsible Manager/Lead's approval of the change(s) adjacent to the notation on Attachment 3.

5.7.2 Responsible Manager/Lead:

Initial and date Attachment 3 in the Remarks section, adjacent to the notation, to indicate approval of the correction(s).

6.0 RECORDS

The records listed in Subsections 6.1 and 6.2 shall be collected and submitted to the Records Processing Center in accordance with AP-17.1Q, *Records Management*, as individual records or included in a records package, as specified. The records listed in Subsection 6.3 shall be maintained and dispositioned by the Records Coordinator in accordance with AP-17.1Q.

6.1 QA RECORDS

Records Package for Scientific Analysis Subject to the QARD:

QER and Checker Check Copies of the scientific analysis documentation

Comments or comment sheets; review copy signed and dated by Responsible Manager/Lead, Checker, and QER; and all documents generated by AP-2.14Q reviews

Final copy of the DIRS report

Approved scientific analysis report

6.2 NON-QA LONG-TERM RECORDS

Records Package for Scientific Analysis Not Subject to the QARD:

Checker Check Copy of the scientific analysis documentation

Comments or comment sheets; review copy signed and dated by Responsible Manager/Lead and Checker; and all documents generated by AP-2.14Q reviews

Final copy of the DIRS report

Approved scientific analysis report

6.3 NON-QA SHORT-TERM RECORDS (THREE YEARS OR LESS RETENTION)

Scientific Analyses Checklist(s), if completed by Originator, Checker, and/or QER

7.0 REFERENCES

a) *Quality Assurance Requirements and Description*, DOE/RW-0333P

b) AP-2.14Q, *Document Review*

c) AP-2.22Q, *Classification Analyses and Maintenance of the Q-List*

d) AP-2.27Q, *Planning for Science Activities*

e) AP-3.12Q, *Design Calculations and Analyses*

f) AP-3.15Q, *Managing Technical Product Inputs*

g) AP-6.1Q, *Document Control*

h) AP-7.5Q, *Submittal, Review, and Acceptance of Deliverables*

i) AP-16.1Q, *Condition Reporting and Resolution*

j) AP-17.1Q, *Records Management*

k) AP-SI.1Q, *Software Management*

l) AP-SI.2Q, *Qualification of Level A Software*

m) AP-SI.3Q, *Software Independent Verification and Validation*

n) AP-SIII.1Q, *Scientific Notebooks*

o) AP-SIII.2Q, *Qualification of Unqualified Data*

p) AP-SIII.3Q, *Submittal and Incorporation of Data/Technical Information to the Technical Data Management System*

q) AP-SIII.10Q, *Models*

r) *Scientific Processes Guidelines Manual*, MIS-WIS-MD-000001

s) Office of Civilian Radioactive Waste Management Style Manual. Current version. http://connect.ymp.gov/artman/publish/stylemanual.shtml

8.0 ATTACHMENTS

Attachment 1 - Acronyms and Abbreviations
Attachment 2 - Scientific Analysis Outline
Attachment 3 - Scientific Analysis Cover Sheet

BSC	Bechtel SAIC Company, LLC
DI	document identifier
DIRS	Document Input Reference System
DTN	Data Tracking Number
ICN	Interim Change Notice
QA	quality assurance
QARD	Quality Assurance Requirements and Description
QER	Quality Engineering Representative
TBV	To Be Verified
TDMS	Technical Data Management System
TWP	Technical Work Plan

SCIENTIFIC ANALYSIS OUTLINE

If any of the following sections are not applicable to a particular scientific analysis, a brief statement of non-applicability is required for documentation purposes under each heading. Information presented in the scientific analysis documentation shall be transparent and traceable.

1. **Purpose**–This section shall provide a statement of the purpose of the scientific analysis, the scientific analysis limitations, and the scope of the scientific analysis documentation. It shall also refer to the TWP for the activity and discuss, as necessary, any deviations from that plan.

2. **QA**–This section shall include the applicability of the QA program, including evaluation of associated activities in accordance with appropriate implementing procedures. If scientific analyses or tasks included in the scientific analysis activity have been determined not to be subject to the QARD, provide justification. This section shall include the safety category of items and natural barriers if classified in accordance with the applicable implementing procedure (per AP-2.22Q, *Classification Analyses and Maintenance of the Q-List*). Reference the TWP for the determination of the applicability of the QARD. If the analysis investigates an item or barrier on the Q-List, identify the item or barrier and its safety category (Category 1, Category 2, beyond Category 2, or Non-Safety Category). This section shall identify the method(s) used to control the electronic management of data in accordance with the controls specified in the TWP and will describe any variance from the planned method(s).

3. **Use of Software**–This section shall include a list of all controlled and baselined software as described in AP-SI.1Q. Software shall be identified in the scientific analysis/model documentation by software title, software tracking number, and version number. Discuss why the software was selected and describe any limitations on outputs due to the selected software.

   If the solution to the calculation or analysis package used to support this technical product is obtained using the standard functions of a commercial off-the-shelf software program (e.g., EXCEL, MATHCAD, or EARTHVISION) and the results are not dependent on the software program used, this software does not need to follow AP-SI.1Q. If the results are not dependent on the software program, the actions performed (as indicated below) shall be documented in sufficient detail in this technical product to allow an independent reviewer to reproduce or verify the results by visual inspection or hand calculation without recourse to the Originator:

   - The formula or algorithm used
   - A listing of the inputs to the formula or algorithm
   - A listing of the outputs from the formula or algorithm
   - Other information (e.g., operating environment information) that would be required in order for any independent person to reproduce the work.

4. **Inputs**–Project data shall be referenced by DTN. Technical product inputs shall be correctly selected, identified in the scientific analysis documentation, correctly cited, and incorporated.

4.1 **Direct Inputs**–The appropriateness of technical product inputs directly used to develop the scientific analysis shall be documented and substantiated in this section.

- Provide lists or tables of technical product inputs.
- If the present study uses a previously developed and validated model to complete the present study, list associated DTNs, accession numbers, documentation titles, and document identifying numbers, as applicable.

4.2 **Criteria**–List criteria identified in Section 3 of the TWP, including requirements contained in applicable requirement documents (such as design interface documents) and any relevant acceptance or completion criteria.

4.3 **Codes and Standards**–Provide a list of the applicable codes and standards used in the scientific analysis by name, number, and date, including applicable revision status, using date or revision designator.

5. **Assumptions**–This section shall provide a list of the assumptions used to perform the scientific analysis. Discuss assumptions in upstream documentation or input documentation that may significantly impact the results of the present scientific analysis. The rationale for assumptions and the sections where the assumptions are used shall be identified. For frequently used assumptions, the comment "used throughout" may be substituted for a list of sections. Assumptions that require confirmation shall be designated in accordance with AP-3.15Q. If an assumption is determined not to require further confirmation, provide justification.

6. **Scientific Analysis Discussion**–Describe the technical bases, mathematical formulations, and numerical methods used.

Provide (separate) lists or tables of corroborating/supporting data, models, product output, or technical information used in the scientific analysis activity. Identify the sources of the corroborating/supporting information. Include additional discussions to substantiate input used in this section, if not included in Section 4. Address any differences in direct input values, between values brought forward in Section 4, and values used in this section.

The following topics shall be included in this section, as applicable, when documenting a scientific analysis:

- A detailed description of the scientific approach and/or technical methods
- Results of literature searches or other background data/information
- A discussion of uncertainties, sources of uncertainties, and impacts of uncertainties on scientific analysis output

- Units of measurement
- A discussion of assumptions, idealizations, and simplifications, including their bases or rationale
- A discussion of mathematical formulations, equations, algorithms, and numerical methods used
- Alternate scientific approaches and/or technical methods that were not used and the rationale for not selecting them
- Intended use of the output
- Appropriateness of the use of a previously developed and validated model to complete the present scientific analysis is described
- Other software/computational methods considered and the rationale for not selecting them.

7. **Conclusions**–This section shall provide a summary of the scientific analysis. The conclusions, including product output, as well as any decisions or recommendations, shall be presented in this section. Conclusions shall include any uncertainties and restrictions for subsequent use.

8. **Inputs and References**–Sources of inputs, software, DTNs, and cited references (including references used to justify assumptions) shall be listed in this section. Inputs and references include materials that support the conclusions of the scientific analysis. These may include published reports, technical papers, scientific notebooks, literature searches, or other background information. The Office of Civilian Radioactive Waste Management Style Manual (located on the BSC Intranet) may be used as guidance on formatting reference lists and citations.

Attachments–Supporting documentation, such as computer output, that are lengthy or cannot be conveniently included within the main text of the documentation may be included as attachments. Computer output may be attached as hard copy, read-only disk, or compact disk (read only memory), but must meet the requirements of AP-17.1Q for submittal to the TDMS. Computer output files included as attachments are exempt from page numbering, DI, and revision number requirements provided the total number of pages in each attachment (for hard copy) or complete file information including all file names, file dates and times, and file sizes are documented on the attachment. In case of printed attachments, the total page count for each attachment shall be documented on the Scientific Analysis Cover Sheet. Where the attachment is on computer media, the quantity and type of media shall be clearly identified.

OCRWM	SCIENTIFIC ANALYSIS COVER SHEET	1. QA: Page of

2. Scientific Analysis Title			
3. DI (including Revision Number)			
4. Total Attachments	5. Attachment Numbers - Number of pages in each		
	Printed Name	Signature	Date
6. Originator			
7. Checker			
8. QER			
9. Responsible Manager/Lead			
10. Responsible Manager			
11. Remarks EXAMPLE			

Revision History	
12. Revision/ICN No.	13. Description of Revision/Change

Attachment 3 - Scientific Analysis Cover Sheet

INSTRUCTIONS FOR COMPLETING THE SCIENTIFIC ANALYSIS COVER SHEET

Block Number

Originator

1. Enter the QA designator, page number, and total number of pages (excluding attachments).
2. Enter the title of the scientific analysis.
3. Enter the DI, including the revision number, assigned to the scientific analysis.
4. Indicate total number of attachments.
5. Indicate attachment number(s) and number of pages in each (e.g., I-11, II-5) or if list is long, identify where a listing is provided.
6. Print name, sign, and date.

Checker

7. Print name, sign, and date.

QER

8. Print name, sign, and date when all comments have been resolved and changes have been incorporated into the scientific analysis.

Responsible Manager/Lead

9. Print name, sign, and date to signify approval. (If a Lead was not assigned, the Responsible Manager should complete this block.)

Responsible Manager

10. Print name, sign, and date to signify approval.

Originator, Checker, QER, Lead

11. Enter any pertinent remarks.

Originator

12. Identify any revisions or changes to this scientific analysis, in order, starting with REV 00 and continuing to the latest revision.
13. For any revisions to this scientific analysis, enter a brief description of each revision, including the current revision and the reason for the change.