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QA: N/A

MAY 07 2002

OVERNIGHT MAIL

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U. S. Nuclear Regulatory Commission
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TRANSMITTAL OF REPORT ADDRESSING KEY TECHNICAL ISSUE (KTI)
TSPA I 4.05

Enclosed is procedure AP-SIII.10Q Revision 0, ICN 2, *Models*, which fulfills KTI Agreement, Total System Performance Assessment and Integration (TSPA I) 4.05 as described below.

TSPA I 4.05, TDR-WIS-PA-000005, Revision 0, "DOE will document the process used to develop confidence in the TSPA models (e.g., steps similar to those described in NUREG-1636). The detailed process is currently documented in the model development procedures that are being evaluated for process improvement in response to the model validation Corrective Action Report CAR-BSC-01-C-001. The upgraded model validation procedures will be available for NRC review in FY2002."

The model development procedure, AP-3.10Q, *Analyses and Models*, has been superseded by AP-SIII.10Q, *Models*, to separate models from scientific and engineering analyses. The new procedure includes improvements to address confidence building during the model development process. Model validation is no longer a post model development activity. Instead, model validation is an integral part of the model development process that begins at model conception/revision whereby the model validation approach and criteria are identified by the model owner, approved by Line Management, and reviewed and concurred with by the Chief Science Officer (CSO) prior to the commencement of the modeling activities.

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The CSO involvement provides an independent check that:

- the model validation planned approach and criteria are adequate and appropriate to build confidence in the model;
- timely self-identification of model validation issues and resolution are achieved; and
- model validation has been achieved once model development is complete.

This letter contains no additional regulatory commitments. Please direct any questions concerning this letter and its enclosure to Timothy C. Gunter at (702) 794-1343 or Mark C. Tynan at (702) 794-5457.

for J. Timothy Sullivan
Joseph D. Ziegler
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OL&RC:TCG-1047

Enclosure:

AP-SIII.10Q Revision 0, ICN 2, *Models*

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Office of Civilian Radioactive Waste Management

QA: QA

PROCEDURE

MODELS

AP-SIII.10Q

Revision 0 ICN 2

Effective Date: 05/03/2002

Preparer:

D. S. Bryan
D.S. Bryan

4/24/02
Date

Approval:

Jan L. Younker for
M.D. Voegle
Chief Science Officer

4-24-02
Date

ENCLOSURE

CHANGE HISTORY

<u>Revision Number</u>	<u>Interim Change No.</u>	<u>Effective Date</u>	<u>Description of Change</u>
0	0	12/21/2001	Initial issue. Models procedure prepared to separate models from scientific analyses 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, <i>Analyses and Models</i> , for models. AP-3.12Q, <i>Calculations</i> , has been revised to address design/engineering calculations and analyses exclusively, and has been renamed <i>Design Calculations and Analyses</i> . AP-SIII.9Q, <i>Scientific Analyses</i> , has been prepared to address analyses and calculations subject to <i>Quality Assurance Requirements and Description</i> , DOE/RW-0333P, Supplement III.
0	1	01/25/2002	ICN to modify applicability to those documents that did not complete the requirements of Section 5.0 through Subsection 5.6 of AP-3.10Q, <i>Analyses and Models</i> , on December 21, 2001; clarify requirements of the Bechtel SAIC Company, LLC Quality Engineering Compliance check; make editorial changes; clarify role of the originator; and clarify type of validation documentation to be reviewed and initiated by the Chief Science Officer.
0	2	05/03/2002	Interim Change Notice to bring model validation requirements in line with changes to the <i>Quality Assurance Requirements and Description</i> , DOE/RW-0333P, Revision 11; require incorporation of errata per AP-15.3, <i>Control of Technical Product Errors</i> ; and renumber the outline in Attachment 2.

1.0 PURPOSE

This procedure establishes the responsibilities and process for performing and documenting activities that constitute scientific and performance assessment modeling that is subject to the requirements of *Quality Assurance Requirements and Description (QARD)*, DOE/RW-0333P. This procedure may also be used for models that are not subject to QARD requirements. Scientific analyses and calculations should be documented using AP-SIII.9Q, *Scientific Analyses*. Design analyses should be documented using AP-3.12Q, *Design Calculations and Analyses*.

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 conduct, develop, modify, document, calibrate, or validate models in support of the Office of Civilian Radioactive Waste Management Program.

Model development, validation, and initial use, as well as any related work required to accomplish these tasks, shall be documented within the model(s) document. Work not directly required for model(s) development, validation, or initial use shall be documented separately, in accordance with applicable procedures.

Model documentation that completed the requirements of Section 5.0 through Subsection 5.6 of AP-3.10Q, *Analyses and Models*, on December 21, 2001, may be approved in accordance with AP-3.10Q. All other models in development or revision shall transition to meet the requirements of this procedure on the effective date of this procedure.

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 **Accepted Data**—Data considered as established fact (e.g., engineering handbooks, density tables, gravitational laws, or other physical constants) or data generally accepted by the scientific or engineering community and found to be technically defensible by those using it (QARD).
- 3.3 **Assumption**—A statement or proposition that is taken to be true or representative in the absence of direct confirming data or evidence.
- 3.4 **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 model documentation.

- 3.5 **Editorial Correction**—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 change responsibilities.
- 3.6 **Input**—Criteria, Reference Information Base (RIB) parameters, data or other technical information, bases, or requirements used to develop or support conclusions or results. This includes, but is not limited to, the following: requirements documents, technical reports, analyses, calculations, drawings, specifications, data, corroborating references, interface control documents, software baselined under configuration management per AP-SI.1Q, *Software Management*, etc. This does not include administrative procedures used to develop the technical product.
- 3.7 **Interim Change Notice (ICN)**—A method for updating (e.g., updating the To Be Verified [TBV] status) or revising limited portions of approved model documentation.
- 3.8 **Lead**—The individual assigned by the Responsible Manager to control a model activity and having responsibility for assignment of personnel performing activities associated with the model.
- 3.9 **Mandatory Comment**—A documented comment identifying that the model documentation does not satisfy assigned review or check criteria, does not meet applicable procedural requirements, or represents an interface issue.
- 3.10 **Model**—A representation of a system, process, or phenomenon, along with any hypotheses required to describe the process or system or explain the phenomenon, often mathematically (QARD). Model development typically progresses from conceptual to mathematical models. Mathematical model development typically progresses from process, to abstraction, and to system models.
- 3.11 **Model, Abstraction**—A product of the abstraction process that meets the definition of a mathematical model.
- 3.12 **Model, Conceptual**—A set of hypotheses consisting of assumptions, simplifications, and idealizations that describes the essential aspects of a system, process, or phenomenon. Such a model may consist of concepts related to geometrical elements of the object (size or shape); dimensionality (one-, two-, or three-dimensional); time dependence (steady-state or transient); applicable conservation principles (mass, momentum, energy); applicable constitutive relations, significant processes, natural laws, boundary conditions; and initial conditions.
- 3.13 **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. Mathematical models are distinct from scientific analyses in that the development of mathematical models involves incorporation of new or modified conceptual models, and scientific and engineering

principles, into software applications for the purposes of creating new or modified mathematical representations of systems, processes, and phenomena.

- 3.14 *Model, Process***—A mathematical model that represents an event, phenomenon, process, component, etc., or series of events, phenomena, processes, or components. A process model may undergo an abstraction for incorporation into a system model.
- 3.15 *Model, System***—A collection of interrelated mathematical models that represent the overall geologic repository or overall component subsystem of the geologic repository.
- 3.16 *Model Validation***—A process used to establish confidence that a mathematical model and its underlying conceptual model adequately represent with sufficient accuracy the system, process, or phenomenon in question.
- 3.17 *Originator***—A technically competent individual designated to perform a model activity and to prepare the model documentation and assigned the responsibility for ensuring the adequacy, accuracy, and completeness of the model documentation. For the purpose of this procedure, an all-inclusive term for a preparer, modeler, or investigator.
- 3.18 *Parameter***—Scientific data, performance assessment data, or engineering technical information that represents physical or chemical properties, consisting of an assigned variable name, and generally represented by a value or range of values. Select parameters that are potentially subject to varied interpretation and selection of multiple values, and subject to multiple use for various technical products within the Yucca Mountain Site Characterization Project reside in the RIB of the Technical Data Management System (TDMS).
- 3.19 *Responsible Manager***—The individual having management responsibility for a model activity, for assigning a Lead to the model activity, and for approving the model documentation. For the purpose of this procedure, Responsible Managers are Project and Functional Managers as identified in LP-1.0Q-M&O, *Organization*, or their direct reports.
- 3.20 *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 use a previously developed and validated mathematical model, within the mathematical model's intended use and stated limitations, but may not revise the mathematical model in order to complete the scientific analysis. A scientific analysis may involve numerical manipulations that are not part of a validated mathematical model, but only if: 1) the choice of method for such manipulations is evidence from standard practice and does not require justification and 2) the analysis results are not to be used to support licensing compliance arguments that require the additional confidence that would be attained by documenting the work as a model.
- 3.21 *Sensitivity***—The degree to which the model results are affected by changes in a selected model input.

3.22 *Software*—Computer programs, procedures, rules, associated documentation, and information pertaining to the operation of a computer system (QARD). Software may be used to formulate mathematical models.

3.23 *To Be Verified (TBV)*—Identification of information that is preliminary, needs to be re-evaluated, and/or needs confirmation.

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

3.25 *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 (CSO) is responsible for the preparation, change, and approval of this procedure.

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

- a) Responsible Manager
- b) Lead
- c) CSO
- d) Originator
- e) Checker
- f) Quality Engineering Representative (QER)
- g) Reviewing Organization

5.0 PROCESS

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

PROCESS OUTLINE

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5.1 PLANNING

5.1.1 Responsible Manager:

- a) Control the development, validation, checking, documentation, revision, change, and key technical activities of the model 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 Technical Work Plan (TWP) prepared in accordance with AP-2.21Q, *Quality Determinations and Planning for Scientific, Engineering, and Regulatory Compliance Activities*.
- c) Assign a Technical Contact and complete the appropriate section of Attachment 2, Model Cover Sheet.

5.1.2 Responsible Manager or Lead:

- a) Review the TWP for the Work Package associated with the model to be developed. If the TWP requires correction or revision, ensure that it is completed in accordance with AP-2.21Q.
- b) Ensure the applicable TWP includes adequate planning for model validation as per the requirements of Subsection 5.4 (the CSO will review TWPs that contain model validation plans).
- c) If a previously developed model is to be used outside of its intended use, limitation, or range of validity, provide justification and plans for validation in the applicable TWP.
- d) Assign an Originator to perform the modeling activity (the Lead may assume the Originator's responsibilities; however, the Lead may not assume the Checker's or Reviewer's responsibilities when acting as the Originator).

5.1.3 CSO:

Review the applicable TWP in accordance with AP-2.21Q to ensure that:

- 1) Plans for model development are appropriate and adequate for the model's stated purpose and meet the requirements of this procedure.
- 2) Plans for model validation are appropriate and adequate to obtain the level of confidence required for the model and meet the requirements of this procedure.

5.2 DEVELOPMENT AND DOCUMENTATION OF MODELS

Originator:

- a) Obtain a document identifier (DI) for the model documentation from Las Vegas Document Control in accordance with AP-6.1Q, *Controlled Distribution*.
- b) If revising a previously validated model, obtain the applicable model files (if those files are used in the current modeling activity) and the associated Data Tracking Numbers (DTN[s]) from the TDMS.
- c) Document the model using the annotated outline in Attachment 3, Model Documentation Outline. If a section in the annotated outline is not applicable, indicate that it is not applicable after the title and provide a rationale for non-applicability.
- d) If any information with regard to Naval fuel is shown on the model, have the Resident Manager for the Naval Nuclear Propulsion Program review the model to ensure no unauthorized Naval Reactors information is included in the model document.
- e) Document input sources, Unresolved Reference Numbers, and TBV information in accordance with AP-3.15Q, *Managing Technical Product Inputs*, using the Document Input Reference System (DIRS).
- f) Record the DI and revision/change number on each page of the model documentation unless the conditions for attachments, as specified in the Model Documentation Outline, apply.
- g) Use alphanumeric revision designators (e.g., Rev. 00a, Rev. 00b) to denote different drafts or versions in the development of the model documentation prior to the version submitted for final approval.
- h) Complete the appropriate sections of the Model Cover Sheet and Attachment 4, Model Revision Record, in accordance with the instructions for each attachment.
- i) Ensure documentation is legible and in a form suitable for reproduction, filing, and retrieval.
- j) Ensure each page is sequentially numbered, beginning with the cover page as page 1 and the revision page as page 2.
- k) Ensure attachments to documentation developed using the annotated outline in the Model Documentation Outline are identified by Roman numerals (e.g., Pages I-1 through I-7), except as noted in the instructions for Block 6 of the Model Cover Sheet.
- l) If software is to be used in the model activity, complete the requirements of Subsection 5.3 of this procedure.

5.3 USE OF SOFTWARE

Originator:

- a) If software is used, ensure that it is obtained, controlled, and documented in accordance with AP-SI.1Q.
- b) Document software used in the model in accordance with Section 3 of the Model Documentation Outline.

5.4 MODEL VALIDATION

5.4.1 Responsible Manager or Lead:

- a) Ensure mathematical models are validated for their intended purpose and stated limitations, and to the level of confidence required by the model's relative importance to the potential performance of the repository system. Validation is required for all mathematical models and their underlying conceptual models (validation is not required for conceptual models not implemented in mathematical models).
 - 1) Verify that the plans for model validation in the applicable TWP are adequate to ensure the appropriate level of validation required by the model's relative importance to the potential performance of the repository system. Incorporate any required changes to the TWP in accordance with AP-2.21Q.
 - 2) Identify and document the criteria used to determine the level of confidence in a model for the model's stated purpose in the TWP. Justify the rationale for selection of the confidence evaluation criteria in the TWP. The criteria may be qualitative or quantitative.
 - Criteria used to establish the adequacy of the scientific basis for the model are consistent with the intended use and justified in the documentation.
 - Criteria used to demonstrate that the model is sufficiently accurate for its intended use are consistent with parameter uncertainties and justified in the documentation.
 - 3) If validation activities are to extend beyond the documented completion of the current model, include a description of future activities that are to be completed and a justification for extending model validation in Subsection 6.1 of the Model Documentation Outline.
 - 4) Identify the supporting information needed to substantiate the model validation.

- 5) Submit any new or revised model TWP's to the CSO for review in accordance with Subsection 5.1 and AP-2.21Q.
- b) Ensure validation of the mathematical model and its underlying conceptual model includes documentation of decisions or activities that are implemented to generate confidence in the model during model development, including the following:
- 1) Selection of input parameters and/or input data, and a discussion of how the selection process builds confidence in the model.
 - 2) Description of calibration activities, and/or initial boundary condition runs, and/or run convergences, and a discussion of how the activity or activities build confidence in the model. Include a discussion of impacts of any run non-convergences.
 - 3) Discussion of the impacts of aggregate and input uncertainties to model results.
- c) Ensure documentation of post-development validation activities of mathematical models include one or more of the following, as required by the model's relative importance to the potential performance of the repository system and as approved in the applicable TWP:
- 1) Corroboration of model results with data acquired from the laboratory, field experiments, analog studies, or other relevant observations, not previously used to develop or calibrate the model
 - 2) Corroboration of results with alternative mathematical models
 - 3) Corroboration with data published in refereed journals or literature
 - 4) Peer Review per AP-2.12Q, *Peer Review*
 - 5) Technical review, planned in the applicable TWP, by reviewers independent of the development, checking, and interdisciplinary review of the model documentation (the Responsible Manager/Lead may not participate in this technical review of products for which they are directly responsible)
 - 6) Corroboration of abstraction model results to the results of the validated process model(s) from which the abstraction was derived
 - 7) Corroboration of pre-test model predictions to data collected during the associated testing
- d) Technical review through publication in a refereed professional journal or review by an external agency may be used to corroborate model validation

when used in conjunction with one or more of the post-development validation techniques described in Step 5.4.1c).

5.4.2 Originator:

- a) Validate the model to the level of confidence required in accordance with the TWP and the requirements of this procedure.
- b) Document model validation as described in Subsection 6.1 of the Model Documentation Outline.
- c) Submit draft documentation of the results of the validation activities to the CSO for review.

5.4.3 CSO:

- a) Review draft documentation of the validation activities to determine if the appropriate level of confidence, as identified in the applicable TWP, has been obtained.
- b) If the appropriate level of confidence has been obtained, initial or sign and date the draft model validation documentation.
- c) Return the documentation, with any recommendations, to the Originator.

5.5 TDMS SUBMITTALS

Originator:

- a) Evaluate the model documentation to determine if any data, including parameters, that are developed must be submitted to the TDMS based on the following criteria:
 - 1) The developed data do not currently reside in the TDMS.
 - 2) The developed data will be used to replace or supersede data that are currently in the TDMS.
 - 3) The data have undergone a status change as a result of the model documentation.
- b) Submit preliminary developed data to the TDMS in accordance with AP-SIII.3Q, *Submittal and Incorporation of Data to the Technical Data Management System*.
- c) If RIB parameters are developed, initiate the documentation of the parameters in accordance with AP-SIII.4Q, *Development, Review, Online Placement, and Maintenance of Individual Reference Information Base Data Items*.
- d) Notify the TDMS when preliminary data have completed the review, acceptance, or qualification process and should no longer be tagged as preliminary in the Automated Technical Data Tracking database.

- e) Submit the following information to the TDMS in accordance with AP-SIII.3Q:
- 1) Identification of software (e.g., name, version, revision, software tracking number, etc.)
 - 2) Identification of model documentation (e.g., title, DI number, etc.)
 - 3) Electronic files of input data or list of DTNs for data that already reside in the TDMS
 - 4) A comprehensive list of results in electronic form
 - 5) A list of constraints, assumptions, limitations, caveats, etc.
 - 6) Hardcopies of input and output files, or portions thereof, in order for TDMS personnel to verify uploads.

5.6 CHECK AND REVIEW

5.6.1 Responsible Manager or Lead:

Assign a Checker to check the model documentation.

- 1) The Originator may not perform the checking function.
- 2) If no other technically competent individual is available, the Lead may perform the check.

5.6.2 Originator:

Provide to the Checker and QER (an optional Models Checklist, Form 1098 on the BSC Intranet Automated Form System [AFS], may be completed by the Originator):

- 1) Check copies of the model documentation. Clearly indicate on the Model Cover Sheet one copy as the "Checker check copy" and one copy as the "QER check copy," initial, and date.
- 2) The DIRS report.
- 3) Other supporting information and documentation that would facilitate the checking process.
- 4) The draft model validation documentation initialed or signed by the CSO during the validation documentation review (Paragraph 5.4.3).

5.6.3 Checker:

- a) Check the model documentation ensuring that (an optional Models Checklist, Form 1098 on the BSC Intranet AFS, may be completed by the Checker):
 - 1) The technical content of the model is technically adequate, complete, and correct, and the documentation has been prepared in accordance with this procedure and the applicable TWP.
 - 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 AP-SI.1Q.
 - 3) Inputs were correctly selected, identified in the model documentation and on the DIRS report, cited and incorporated, and are appropriate for use in the modeling activity.
 - 4) Any assumed parameter or other input values are clearly identified and justified.
 - 5) TBV tracking numbers, if required, are included in DIRS in accordance with AP-3.15Q.
 - 6) The implications of uncertainties and restrictions are discussed and are evaluated within the model documentation.
 - 7) The assumptions, constraints, bounds, or limits on the inputs are identified in the model documentation, and their impact on the results are described and assessed in the documentation.
 - 8) The discussion of scientific approach and/or technical methods is documented in accordance with Section 6 of the Model Documentation Outline.
 - 9) The referencing is thorough, accurate, and complete, including appropriate project tracking numbers (e.g., records accession numbers, Technical Information Center numbers, and/or DTNs).
 - 10) Justification and model validation documentation are provided for using a previously developed model outside of its intended purpose, limitations, or range of validity.
 - 11) Data cited are verified to be the same as those in the TDMS.
 - 12) Validation has been completed in accordance with the applicable TWP and the requirements of this procedure.

- 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) Indicate mandatory comments with an asterisk.
- d) Initial and date the Checker check copy of the Model Cover Sheet and return the documentation to the Originator.

5.6.4 QER:

- a) For models subject to the QARD, perform a quality assurance (QA) check to ensure compliance with this procedure and the applicable TWP. An optional Models Checklist, Form 1098 on the BSC Intranet AFS, may be completed by the QER.
- 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) Indicate mandatory comments with an asterisk.
- d) Initial and date the check copy of the Model Cover Sheet and return to the Originator.
- e) Return documentation to the Originator.

5.6.5 Originator:

- a) Resolve all mandatory comments with the Checker and QER and document the resolution by mark up of the applicable check copy, including the rationale for mandatory comments not incorporated or only partially incorporated. Use insert pages as necessary. (Resolution may be documented separately if keyed to the applicable check copy.)
- b) Elevate unresolved mandatory comments to the next levels of management of the Originator and Checker/QER until resolution is achieved and document the resolution. (Resolution may be documented separately if keyed to the applicable check copy.)
- c) Modify the original model documentation, as required, to incorporate comment resolution.
- d) Denote the modified model documentation by revising the alphanumeric revision number.

- e) Provide the modified copy, DIRS report, and applicable check copy to the Checker and QER.

5.6.6 Checker and QER:

- a) Check the modified model documentation by comparing it to the applicable check copy.
- b) Indicate acceptance of the resolution of any mandatory 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 the documentation to the Originator.

5.6.7 Originator:

Prepare a review copy of the model documentation and forward it to the Responsible Manager.

5.6.8 Responsible Manager:

- a) Initiate an interdisciplinary review in accordance with AP-2.14Q, *Review of Technical Products and Data*. Reviews of ICNs are limited to the changes and the portions of the documentation affected by the changes.
- b) If the model documentation is a revision or supersedes any portion of another technical product as defined in AP-3.15Q (e.g., initial issuance, revision, change, supersession, or cancellation), initiate an impact review in accordance with AP-2.14Q.
- c) Include the CSO, organizations/disciplines providing input to the model documentation, customer organizations/disciplines for the model documentation, and organizations/disciplines impacted by the model documentation as mandatory reviewers on AP-2.14Q reviews of the model documentation.

5.6.9 Reviewing Organization:

- a) Complete a review of the model documentation in accordance with AP-2.14Q.
- b) If the model does not affect or impact the discipline or functional area of the reviewing organization, indicate "not applicable" and return the review documentation.

5.6.10 Originator:

- a) Resolve all mandatory comments with the reviewers in accordance with AP-2.14Q. Elevate unresolved mandatory comments to the next levels of

management of the Originator and reviewers until resolution is achieved and document the resolution.

- b) Modify the AP-2.14Q review copy of the model documentation, as required, to incorporate changes resulting from the comment resolution.
- c) Provide the modified AP-2.14Q review copy of the model documentation to the Lead, CSO, Checker, and QER.

5.6.11 Lead, CSO, Checker, and QER:

- a) Ensure that the AP-2.14Q review comments, as resolved, have not adversely affected the model documentation.
- b) Resolve any adverse impacts with the Originator and the Reviewing Organization.
- c) Indicate acceptance by signing and dating the review copy and return it to the Originator.

5.6.12 Originator:

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

5.7 APPROVALS

5.7.1 Originator:

- a) Prepare the model documentation by changing the alphanumeric designator to a numeric designator (i.e., the initial model documentation designator is "00," and subsequent revisions are "01," etc.) and updating the revision history, as necessary.
- b) Print or type name, sign, and date in Block 7 of the Model Cover Sheet.
- c) Obtain the CSO's printed or typed name, concurrence signature, and date in Block 8 of the Model Cover Sheet.
- d) Obtain the Checker's printed or typed name, concurrence signature, and date in Block 9 of the Model Cover Sheet.
- e) Obtain the QER's printed or typed name, concurrence signature, and date in Block 10 of the Model Cover Sheet.
- f) Obtain the Responsible Manager's/Lead's printed or typed name, approval signature, and date in Block 11 of the Model Cover Sheet.
- g) Obtain the Responsible Manager's printed or typed name, approval signature, and date in Block 12 of the Model Cover Sheet.

- h) Process final data submittal in accordance with Subsection 5.5.
- i) Process the model documentation in accordance with AP-6.1Q.
- j) Submit model documentation records to the Records Processing Center in accordance with Section 6.0.

5.7.2 Responsible Manager:

- 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*), including increasing the revision/change level indicator, ensure the development and change process defined by this procedure is followed.
- b) If the model documentation resolves TBVs/Unresolved Reference Numbers, process it in accordance with AP-3.15Q.

5.8 EDITORIAL CORRECTIONS

Originator:

- a) If the model documentation requires editorial corrections after approval but before distribution by Las Vegas Document Control, change the in-process master as follows:
 - 1) Mark the change(s) by drawing a single line through the change(s) (i.e., pen/ink or electronic changes) and/or inserting the new or correct information.
 - 2) Initial and date the change(s).
 - 3) Note the change(s) in the Remarks section (Block 13) of the Model Cover Sheet.
- b) Obtain the Responsible Manager's/Lead's approval of the change(s) adjacent to the notation on the Model Cover Sheet.

5.9 REVISIONS OR CHANGES

Responsible Manager:

- a) Determine whether the model documentation will be modified as a revision or as an ICN. 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 Las Vegas Document Control of the impending action to ensure version control.
- c) Issue no more than five ICNs against a documentation revision.

- d) Process a revision or change in accordance with requirements of Section 5.0 and indicate revisions or interim changes in the model documentation using one of the following:
- 1) A black vertical line in the margin of the page and notes on the Model Revision Record, clearly indicating which individual sections or subsections were revised, as applicable, and a brief description of the revision or change on the Model Revision Record
 - 2) A note on the Model Revision Record indicating the entire model documentation was revised because the changes were too extensive to use Step 5.9d)1).

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, *Record Source Responsibilities for Inclusionary Records*, as individual records or included in a records package, as specified. The records listed in Subsection 6.3 shall be dispositioned by the Record Source per the requirements of AP-32.4, *Records Retention and Disposition*.

6.1 QA RECORDS

Records Package for Models Subject to the QARD:

Draft model validation documentation, initialed or signed by the CSO during the validation documentation review

Checker and QER check copies of the model documentation

Comments or comment sheets; review copy signed and dated by Lead, CSO, Checker, and QER; and all documents generated by the AP-2.14Q interdisciplinary review

Final copy of the DIRS report

Evaluation of potential impact per AP-2.14Q and all documents generated by impact reviews

Records submitted in accordance with AP-6.1Q:

Approved model documentation

6.2 NON-QA INCLUSIONARY RECORDS

Records Package for Models Not Subject to the QARD:

Draft model validation documentation, initialed or signed by the CSO during the validation documentation review

Checker check copy of the model documentation

Comments or comment sheets; review copy signed and dated by Lead, CSO, Checker, and QER; and all documents generated by the AP-2.14Q interdisciplinary review

Final copy of the DIRS report

Evaluation of potential impact per AP-2.14Q and all documents generated by impact reviews

Records submitted in accordance with AP-6.1Q:

Approved model documentation

6.3 NON-QA EXCLUSIONARY RECORDS

Models Checklist(s), if completed by the Originator, Checker, or QER

7.0 REFERENCES

- a) *Quality Assurance Requirements and Description, DOE/RW-0333P*
- b) *AP-2.12Q, Peer Review*
- c) *AP-2.14Q, Review of Technical Products and Data*
- d) *AP-2.21Q, Quality Determinations and Planning for Scientific, Engineering, and Regulatory Compliance Activities*
- e) *AP-2.22Q, Classification Criteria and Maintenance of the Monitored Geologic Repository Q-List*
- f) *AP-3.12Q, Design Calculations and Analyses*
- g) *AP-3.15Q, Managing Technical Product Inputs*
- h) *AP-6.1Q, Controlled Distribution*
- i) *AP-7.5Q, Submittal, Review and Acceptance of Deliverables*
- j) *AP-17.1Q, Record Source Responsibilities for Inclusionary Records*
- k) *AP-32.4, Records Retention and Disposition*
- l) *AP-SI.1Q, Software Management*
- m) *AP-SIII.1Q, Scientific Notebooks*
- n) *AP-SIII.3Q, Submittal and Incorporation of Data to the Technical Data Management System*
- o) *AP-SIII.4Q, Development, Review, Online Placement, and Maintenance of Individual Reference Information Base Data Items*

- p) AP-SIII.9Q, *Scientific Analyses*
- q) LP-1.0Q-M&O, *Organization*
- r) *Style Manual for the Civilian Radioactive Waste Management System Management and Operating Contractor, B00000000-01717-3500-00004*

8.0 ATTACHMENTS

Forms attached to this procedure are controlled and distributed as full-size pages separate from this procedure and may be copied for use when implementing this procedure.

Attachment 1 - Acronyms and Abbreviations

Attachment 2 - Model Cover Sheet (Form AP-SIII.10Q.1)

Attachment 3 - Model Documentation Outline

Attachment 4 - Model Revision Record (Form AP-SIII.10Q.2)

AFS	Automated Forms System
BSC	Bechtel SAIC Company, LLC
CSO	Chief Science Officer
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
RIB	Reference Information Base
TBV	To Be Verified
TDMS	Technical Data Management System
TWP	Technical Work Plan

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT MODEL COVER SHEET <i>Complete Only Applicable Items</i>		1. QA: _____ Page: 1 of _____
2. Type of Mathematical Model		
<input type="checkbox"/> Process Model <input type="checkbox"/> Abstraction Model <input type="checkbox"/> System Model		
Describe Intended Use of Model:		
EXAMPLE		
Technical Contact/Department:		
3. Title:		
4. DI (including Rev. No. and Change No., if applicable):		
5. Total Attachments:		6. Attachment Numbers - No. of Pages in Each:
	Printed Name	Signature
7. Originator		
8. CSO		
9. Checker		
10. QER		
11. Responsible Manager/ Lead		
12. Responsible Manager		
13. Remarks:		

INSTRUCTIONS FOR MODEL COVER SHEET

Originator

1. Enter QA designator and total number of pages.
2. Check the model type and describe the intended use of the model. Enter the name of the Technical Contact/Department.
3. Enter the title of the model.
4. Enter the DI, including revision number (alphanumeric before approval, e.g., Rev. 00a, 01a) and change number, if applicable.
5. Indicate the total number of attachments.
6. Indicate the number of pages in each attachment (e.g., I-11, II-5, and III-20). Computer output may be included as hardcopy or as electronic data files contained on appropriate media. In the case of printed attachments, document the total page count for each attachment. If the attachment is on computer media, identify the quantity and type of media attached. If necessary, this information may be placed in Block 13, Remarks, with a reference to Block 6.
7. Print or type name; sign and date.

Steps 8 through 13 occur after checking is completed and the revision/change designator is changed to a numeric designator. Names may be preprinted.

CSO

8. Print or type name; sign and date, indicating acceptance of the model documentation.

Checker

9. Print or type name; sign and date when all comments have been resolved and changes have been incorporated into the model.

QER

10. Print or type name; sign and date when all comments have been resolved and changes have been incorporated into the model.

Responsible Manager/Lead

11. Print or type name; sign and date when all reviews have been completed and all issues have been resolved. (If a Lead was not assigned, the Responsible Manager should complete this box.)

Responsible Manager

12. Print or type name; sign and date to signify approval.

Originator, Checker, Lead, Responsible Manager, QER

13. Include remarks or supplemental information on attachments from Block 6, if required. Indicate any other limitations on the use of the model. The Remarks section of the review copy may also be used to document those draft documents that are in concurrent review and that were used as input (TBV).

MODEL DOCUMENTATION OUTLINE

If any of the following sections are not applicable to a particular model, a brief statement of non-applicability is required for documentation purposes under each heading. The document may include additional sections (e.g., an Executive Summary) to assist “users” of the model. Information presented in the model documentation shall be transparent and traceable.

1. **Purpose**—This section shall provide a statement of the purpose of the model, the model limitations (e.g., data available for model development, valid ranges of model application, spatial and temporal scaling), and scope of the model documentation. It shall also refer to the TWP for the activity and discuss, as necessary, any deviations from that plan.
2. **Quality Assurance**—This section shall include the applicability of the QA program, including evaluation of associated activities in accordance with appropriate implementing procedures (e.g., AP-2.21Q). This section shall include the quality level of items and natural barriers if classified in accordance with applicable implementing procedures (e.g., AP-2.22Q, *Classification Criteria and Maintenance of the Monitored Geologic Repository Q-List*). 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 (this includes non-exempt and exempt as defined in AP-SI.1Q). Software shall be identified in the model documentation by software title, software tracking number, and version number.

Computations using the standard functions of a commercial off-the-shelf software product are acceptable provided that the computation is documented in the model documentation and the results can be reproduced and/or hand calculated. The following shall be documented:

- 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 that would be required in order for a Checker or any other technically competent person to reproduce the computation(s).
4. **Inputs**—Project data shall be referenced by the DTN. The rationale for the use of established fact data, if applicable, shall be documented in this section. Justification shall be provided for unverified inputs that will not be carried to the output. Inputs shall be correctly selected, identified in the model documentation, correctly cited and incorporated. This section may contain applicable inputs as described in the following subsections.

- 4.1 **Data and Parameters**—Provide a list or tables of data and parameters and their sources. The values in the data cited shall be verified to be the same as those in the TDMS. The appropriateness of the data and parameters used as input to the model shall be described in this section. Document the use of established fact data in this section.
- 4.2 **Criteria**—Provide clearly identified criteria that are directly applicable and traceable to the subject of the model documentation. These criteria shall include the requirements contained in the applicable Requirement Documents that are identified as specific to the model subject. Applicable requirement(s) from Requirements Documents shall be cited after each criterion.
- 4.3 **Codes and Standards**—Provide a list of the applicable codes and standards used in the model 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 model activity. Discuss assumptions in immediately preceding upstream documentation or input documentation that may significantly impact the results of the present model. Document the assumptions made to develop the model and the rationale for the assumptions. If an assumption is determined not to require further confirmation, provide justification. Identify the subsections where assumptions are used. For frequently used assumptions, the comment “used throughout” may be substituted instead of individual references. Assumptions that require confirmation by testing, analysis, or design must also be designated in accordance with AP-3.15Q.
6. **Model Discussion**—Include a description of the system, process, or phenomenon conceptual model that is modeled and the scientific, engineering, and mathematical concepts/principles on which the mathematical model is based. Define the appropriateness of the model for the purposes and within the limitations stated in Section 1 of this attachment.

The use of a scientific notebook(s) in accordance with AP-SIII.1Q, *Scientific Notebooks*, as applicable, is allowed for documenting the model activities, but final model documentation shall be completed to the requirements of this procedure. The documentation can refer to the scientific notebook(s) by title, number, organization, records accession number, or similar information.

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

- A detailed description of the conceptual model and the conceptual model implementation (mathematical model)
- Results of literature searches or other background data

- A discussion of uncertainties, sources of uncertainties, and impacts of uncertainties on model output
- Sources of data
- Alternate models that were not used and the rationale for not selecting them
- Units of measurement
- Description of the input data used to generate input files for each model simulation
- A discussion of assumptions, idealizations, and simplifications, including their bases or rationale
- A discussion of initial and/or boundary conditions
- A discussion of mathematical formulations, equations, algorithms, and numerical methods used
- A discussion of the results of model testing, sensitivities, and calibration activities
- Intended use of the output data
- Other software/computational methods considered and the rationale for not selecting them.

7. Validation—The model validation documentation shall include:

- Documentation and discussion of activities performed in Subsection 5.4 of this procedure
- Criteria for ensuring the appropriate level of confidence has been obtained
- Results of the validation activities
- Rationale for determining that the validation criteria have been met
- Any future activities that need to be accomplished for model validation and a justification for extending model validation beyond the documented completion of the current model.

Because model validation may consist of a sequence of separate activities, each model validation activity should be documented in accordance with the requirements of this procedure upon its completion.

8. **Conclusions**—This section shall provide a summary of the modeling activity. The conclusions, including the DTNs of any associated developed data, as well as any decisions or recommendations based on the modeling activity, shall be presented in this section. Conclusions shall include any uncertainties and restrictions for subsequent use.
9. **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 model. These may include published reports, technical papers, scientific notebooks, literature searches, or other background information. The *Style Manual for the Civilian Radioactive Waste Management System Management and Operating Contractor*, B00000000-01717-3500-00004, may be used as guidance on formatting reference lists and citations.
10. **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 hardcopy, read-only disk, or compact disk (read only memory), but must meet the requirements of AP-17.1Q. 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 hardcopy) 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 Model Cover Sheet. Where the attachment is on computer media, the quantity and type of media shall be clearly identified on the Model Cover Sheet.

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT MODEL REVISION RECORD		1. Page: of:
2. Model Title:		
3. DI (including Rev. No. and Change No., if applicable):		
4. Revision/Change No.	5. Description of Revision/Change	
	EXAMPLE	

INSTRUCTIONS FOR MODEL REVISION RECORD

Originator

1. Enter the page number and total number of pages.
2. Enter the title of the model.
3. Enter the DI.
4. Enter the revision number(s) and change number, if applicable (date is optional).
5. Indicate the difference from the previous numeric revision by writing a brief description, including the reason for the change (e.g., "This revision incorporates changes to the model based on verification of the assumptions"), and include a brief description of the changes (e.g., "added Attachments I and II").