Office of Civilian Radioactive Waste Management QA: QA

PROCEDURE

MODELS

AP-SIII.10Q

Revision 1 ICN 0

Effective Date: 03/14/2003

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3-12-03
Date

Approval:

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CHANGE HISTORY

Revision Number	Interim Change No.	Effective Date	Description of Change
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, *Analyses and Models*, for models. AP-3.12Q, *Calculations*, has been revised to address design/engineering calculations and analyses exclusively, and has been renamed *Design Calculations and Analyses*. AP-SIII.9Q, *Scientific Analyses*, has been prepared to address analyses and calculations subject to *Quality Assurance Requirements and Description*, 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, *Analyses and Models*, 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 *Quality Assurance Requirements and Description*, DOE/RW-0333P, Revision 11; require incorporation of errata per AP-15.3, *Control of Technical Product Errors*; and renumber the outline in Attachment 2.

CHANGE HISTORY (Continued)

Revision Number	Interim Change No.	Effective Date	Description of Change
1	0	03/14/2003	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, *Use of Accepted Data and Qualification of Unqualified Data*; incorporate Document Action Requests D3344, D6030, D6349, and D3424; incorporate resolution of Condition/Issue Identification and Reporting/Resolution System item 3162; and to state the requirements for incorporation of errata in accordance with AP-15.3Q *Control of Technical Product Errors*.

1.0 PURPOSE

This procedure establishes the responsibilities and process for 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. Supplemental guidance for all scientific processes is contained in the *Scientific Processes Guidelines Manual*, MIS-WIS-MD-00001, located on the OCRWM 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 conduct, develop, modify, document, calibrate, or validate models in support of the Office of Civilian Radioactive Waste Management Program.

Implementation of conceptual models into new mathematical models, or into mathematical models undergoing revision or change, must be documented in accordance with this procedure. Mathematical 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.

Scientific analyses and calculations are documented in accordance with AP-SIII.9Q, *Scientific Analyses*. Design analyses are documented in accordance with AP-3.12Q, *Design Calculations and Analyses*. Development, revision, configuration management, verification/validation, and/or qualification of software are documented separately in accordance with AP-SI.1Q, *Software Management*; AP-SI.2Q, *Qualification of Level A Developed or Modified Software*; and/or AP-SI.3Q, *Software Independent Verification and Validation*.

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 model documentation.

3.4 ***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.

3.5 ***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.

3.6 ***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.

3.7 ***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.

3.8 ***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.

3.9 ***Model, Abstraction***–A product of the abstraction process that meets the definition of a mathematical model (QARD).

3.10 ***Model, Conceptual***–A set of hypotheses consisting of assumptions, simplifications, and idealizations that describes the essential aspects of a system, process, or phenomenon (QARD). 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, and boundary conditions; and initial conditions. Conceptual models may be implemented into mathematical models.

3.11 ***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).

3.12 ***Model, Process***–A mathematical model that represents an event, phenomenon, process, component, etc., or series of events, phenomena, processes, or components, etc. A process model may undergo an abstraction for incorporation into a system model (QARD).

3.13 ***Model, System***–A collection of interrelated mathematical models that represent the overall geologic repository or overall component subsystem of the geologic repository (QARD).

3.14 ***Model Validation***–A process used to establish confidence that a mathematical model and its underlying conceptual model adequately represents with sufficient accuracy the phenomenon, process, or system in question (QARD).

3.15 ***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.

3.16 ***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-BSC, *Organization*, or their direct reports or organizational equivalents.

3.17 ***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) 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), within the mathematical model's intended use and stated limitations, but may not revise the mathematical model in order to complete the scientific analysis.

3.18 ***Sensitivity***–The degree to which the model results are affected by changes in a selected model input.

3.19 ***Software***–Computer programs, procedures, rules, and associated documentation pertaining to the operation of a computer system (QARD). Software may be used to formulate mathematical models. Mathematical models and software are not synonymous.

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

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

3.22 ***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) Originator
d) CSO
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

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-2.27Q, *Planning for Science Activities*.

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 revision, ensure that it is completed in accordance with AP-2.27Q.

1) Ensure the applicable TWP includes adequate planning for model validation, including the identification of the intended purpose of the model, the needed level of confidence for the model, the criteria to be used to determine that the appropriate level of confidence has been met, the plans for independent technical review per Subsection 5.4 (if any), and the plans for post-development model validation activities.

2) If a previously developed model is to be used outside of its intended use, limitation, or range of validity, justification and plans for validation shall be provided in the applicable TWP.

3) Ensure that the applicable TWP includes adequate planning (per AP-SIII.2Q, *Use of Accepted Data and Qualification of Unqualified Data*) for any required data qualification activities.

b) 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) and provide the originator the applicable TWP.

5.2 DOCUMENTATION

Originator:

a) The modeling activity and associated tasks shall be performed in accordance with the applicable TWP and all applicable procedures. Scientific notebooks may be used in the modeling activity in accordance with AP-SIII.1Q, *Scientific Notebooks*.

b) Obtain a document identifier (DI) for the model documentation from Las Vegas Document Control in accordance with AP-6.1Q, *Controlled Distribution*.

c) Record the DI and revision/change number on each page of the model documentation unless the conditions for attachments, as specified in Attachment 2, Model Documentation Outline, apply.

d) 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 Technical Data Management System (TDMS).

e) Document the model using the annotated outline in the 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.

f) If any information with regard to Naval fuel is included in the model document, 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.

g) Document technical product 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).

h) 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.

i) Complete the appropriate sections of Attachment 3, Model Cover Sheet, and Attachment 4, Model Revision Record, in accordance with the instructions for each attachment.

j) Ensure documentation is legible and in a form suitable for reproduction, filing, and retrieval.

k) Ensure each page is sequentially numbered, beginning with the cover page as page 1 and the revision page as page 2.

l) 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.

m) If software is to be used in the model activity, complete the requirements of Subsection 5.3 of this procedure.

n) If accepted data are to be used in the modeling activity, complete the requirements of Subsection 5.3 of this procedure.

o) If unqualified data are to be qualified and used in the modeling activity, complete the requirements of Subsection 5.3 of this procedure.

5.3 USE OF SOFTWARE, ACCEPTED DATA, AND DATA UNDERGOING QUALIFICATION

Originator:

a) If software is used, ensure that it is controlled and documented in accordance with AP-SI.1Q, AP-SI.2Q, and/or AP-SI.3Q.

b) Document software used in the model in accordance with Section 3 of the Model Documentation Outline.

c) Document the rationale for use of accepted data, developed in accordance with AP-SIII.2Q, in Subsection 4.1 of the Model Documentation Outline.

d) Document the rationale and provide justification for qualification of unqualified data, developed in accordance with AP-SIII.2Q, in Subsection 4.1 of the Model Documentation Outline.

e) Document the rationale and provide justification of the use of the data qualified in accordance with Paragraph 5.3d) in Subsection 4.1 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).

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 that mathematical models undergo one or more confidence building activities after the model has been developed (post-development model validation). The post-development model validation activity/activities shall be dependent upon and consistent with the model's intended use and required level of confidence, as follows:

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 Originator, Responsible Manager/Lead, Checker, QER, and interdisciplinary reviewers assigned to the model document/activity may not serve as an independent post-development model validation technical reviewer)

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 subsequent, associated testing.

d) Technical review through publication in a refereed professional journal or review by an external agency, documented by the external agency, may be used to demonstrate additional confidence in the model, if publication or review is used in conjunction with one or more of the post-development validation techniques described in Step 5.4.1c).

5.4.2 Originator:

a) Identify and document the intended purpose, and any limitations for the model in Section 1 of the model documentation outline.

b) Document the criteria used to determine that needed level of confidence for the model has been met in Section 7 of the Model Documentation Outline.

1) The criteria used to establish the adequacy of the scientific basis for the model must be consistent with the intended use of the model and must be justified in the documentation.

2) The criteria used to demonstrate that the model is sufficiently accurate for its intended use must be consistent with parameter uncertainties and must be justified in the documentation.

c) 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 Section 7 of the Model Documentation Outline.

d) Validate the model to the level of confidence required in accordance with the TWP and Paragraph 5.4.1c) of this procedure.

e) Document model validation as described in Section 7 of the Model Documentation Outline.

f) 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 on the first page of the draft model validation documentation, or indicate acceptance by electronic mail.

c) Return the documentation, with any recommendations, to the Originator.

5.5 CHECK AND REVIEW

5.5.1 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.

5.5.2 Originator:

Provide to the Checker and QER (an optional Models Checklist, Form 1098 on the BSC Intranet Automated Form System, 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. (Lengthy or large supporting documentation or files may be provided to the checker or QER in advance of the check package submittal.)

4) The draft model validation documentation initialed or signed by the CSO during the validation documentation review (Paragraph 5.4.3).

5.5.3 Checker:

a) Check the model documentation ensuring that (an optional Models Checklist, Form 1098 on the BSC Intranet Automated Form System, may be completed by the Checker):

1) The 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 controlled and documented in accordance with AP-SI.1Q, AP-SI.2Q, and/or AP-SI.3Q.

3) Technical product 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) Corroborating data, models, or information is clearly identified and is documented in accordance with AP-3.15Q.

5) Any assumption, accepted data, data undergoing qualification per AP-SIII.2Q, or other input values are clearly identified and justified.

6) TBV tracking numbers, if required, are included in DIRS in accordance with AP-3.15Q.

7) The implications of uncertainties and restrictions are discussed and are evaluated within the model documentation.

8) 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.

9) The discussion of scientific approach and/or technical methods is documented in accordance with Section 6 of the Model Documentation Outline.

10) The referencing is thorough, accurate, and complete, including appropriate project tracking numbers (e.g., records accession numbers, Technical Information Center numbers, and/or DTNs) and is consistent with the DIRS report.

11) Justification and model validation documentation are provided for using a previously developed model outside of its intended purpose, limitations, or range of validity.

12) Technical product inputs cited are verified to be the same as those in controlled sources.

13) Validation has been completed in accordance with the applicable TWP and the requirements of this procedure.

14) All errata, initiated in accordance with AP-15.3Q, *Control of Technical Product Errors*, and documented against previous model document revisions/changes, if any, are incorporated in the model documentation.

15) The DIRS report accurately reflects the usage of citations in the model documentation.

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.

5.5.4 QER:

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

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 the documentation to the Originator.

5.5.5 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.

5.5.6 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.

5.5.7 Originator:

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

5.5.8 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.

5.5.9 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.

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

c) After the AP-2.14Q comments have been closed, provide the final concurrence copy of the model documentation to the Lead, CSO, Checker, and QER.

5.5.11 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 documentation. Return the documentation to the Originator.

5.5.12 Originator:

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

5.6 OUTPUT SUBMITTALS

Originator:

a) Submit the following to the TDMS in accordance with AP-SIII.3Q, *Submittal and Incorporation of Data to the Technical Data Management System*::

1) Developed data and/or output that do not currently reside in the TDMS.

2) Developed data and/or output that will be used to replace or supersede data that are currently in the TDMS.

3) Data and/or output that have undergone a status change as a result of the model documentation.

b) Submit the following model 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.

c) If Reference Information Base 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.*

5.7 CONCURRENCE AND APPROVAL

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 the model documentation in accordance with AP-6.1Q.

i) 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 them 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).

e) Address any applicable technical errors, documented in accordance with AP-15.3Q in the appropriate section of the model document. List any TER log numbers addressed in the Remarks section of the Model Cover Sheet.

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.*

The approved model documentation is submitted in accordance with AP-6.1Q. The records package must cite, as a separate line item, the approved model documentation by date, accession number, and title.

6.1 QA RECORDS

Records Package for Models Subject to the QARD:

Draft model validation documentation, or electronic record of acceptance, initialed or signed and dated by the CSO

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, or electronic record of acceptance, initialed or signed and dated by the CSO

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, and/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-2.22Q, *Classification Criteria and Maintenance of the Monitored Geologic Repository Q-List*

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

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-15.3Q, *Control of Technical Product Errors*

k) AP-17.1Q, *Record Source Responsibilities for Inclusionary Records*

l) AP-32.4, *Records Retention and Disposition*

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

n) AP-SI.2Q, *Qualification of Level A Developed or Modified Software*

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

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

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

r) AP-SIII.4Q, *Development, Review, Online Placement, and Maintenance of Individual Reference Information Base Data Items*

s) AP-SIII.9Q, *Scientific Analyses*

t) LP-1.0Q-BSC, *Organization*

8.0 ATTACHMENTS

Forms and templates 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 Documentation Outline
Attachment 3 - Model Cover Sheet
Attachment 4 - Model Revision Record (Form AP-SIII.10Q.2)

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
TBV	To Be Verified
TDMS	Technical Data Management System
TWP	Technical Work Plan

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 the intended use 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.

2. **Quality Assurance**–This section shall include the applicability of the QA program, including evaluation of associated activities. If the modeling activity, or tasks included in the modeling activity, have been determined not to be subject to the QARD, provide justification. 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 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.

   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, EARTHVISION, etc.) 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 any independent person to reproduce the work.

4. **Inputs**–Project data shall be referenced by the DTN. Technical product 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**–The appropriateness of technical product inputs directly relied up to develop the model shall be described in this section. The rationale for use of any accepted data and the rationale and justification for the use and qualification of unqualified data shall be documented in this section.

- Provide lists or tables of technical product inputs that were used directly in the development of the model.

- If the present study uses, revises, or changes a previously developed and validated model to complete the present study, list associated DTNs, accession numbers, documentation titles, and document identifying numbers.

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. (Model Validation criteria should be documented in Section 7 of the model document.)

4.3 **Codes and Standards**–Provide a list of the applicable codes (if the model directly addresses federal or other code requirements) and standards (e.g., American Society for Testing and Materials or Occupational Safety and Health Administration 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. State whether the assumption requires confirmation. 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 to be 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, 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.

Provide lists or tables of corroborating/supporting data, models, or information used to develop the model. Identify the sources of the corroborating/supporting 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 information
- A discussion of uncertainties, sources of uncertainties, and impacts of uncertainties on model output
- Sources of inputs
- 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 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 model output
- Other software/computational methods considered and the rationale for not selecting them.

7. **Validation**–The model validation documentation shall include:

- Provide lists or tables of corroborating/supporting data, models, or information used to complete model validation activities. Identify the sources of the corroborating/supporting information.
- Documentation and discussion of activities performed in Subsection 5.4 of this procedure

- Results of the validation activities
- Model validation criteria for ensuring the appropriate level of confidence has been obtained, consistent with Subsection 5.4 and the applicable TWP
- 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 and/or output, 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 online Style Manual 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 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.

OCRWM	MODEL COVER SHEET	1. QA: Page of

2. Type of Mathematical Model

☐ Process Model ☐ Abstraction Model ☐ System Model

Describe Intended Use of Model

EXAMPLE

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	Date
7. Originator			
8. CSO			
9. Checker			
10. QER			
11. Responsible Manager/Lead			
12. Responsible Manager			

13. Remarks

Attachment 3 - Model Cover Sheet

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.

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.

Steps 7 through 13 occur after checking is completed and the revision/change designator is changed to a numeric designator. Names may be preprinted.

7. Print or type name; sign and date.

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 documentation.

QER

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

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).

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

AP-SIII.10Q.2 Rev. 11/21/2001

Attachment 4 - Model Revision Record

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. Identify any revisions or changes to this model documentation, in order, starting with Rev 00 and continuing through to the latest revision or change. 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").

QARD Software Requirements

General: Review of Existing or recent DRs and CARs and Software Audits and Surveillances

1 General Software Qualification & Administration **A**	2 Software V&V **B**	3 Software Algorithms **C**
4 Alternate Methods for Technical adequacy **C**	5A Software Procedures **E**	6 Classification **C**
7 Software Activity Plans **B**	8 Software Life-Cycle **B**	9 Requirements Phase **A**
10 Design Phase **B**	11 Implementation Phase **B**	12 Software Testing **B**
13 Operations and Maintenance Phase **A**	14 Installation and Checkout Phase **D**	15 Retirement Phase **D**
16 Software Controls • Baseline Change • Config Mgmt **D**	17 Software Use **C**	18 Error Reporting **C**
19 Traceability in Technical Products **C**	20 Acquired Software (Not under the QARD **D**	21 Participant Software **A**
22 Procurement **D**	23 Spreadsheets **B**	24 Routines & Macros Delete **B**
25 Software Used as Management Tools **B**	26 Documentation **A**	27 At the Labs **D** **A**

A **B** **C** **D** **E**

Sub-Teams

A = Christian and Norm M; B = Sam and Sid A C = Bruce and Harvey
D = John and Mario C E = Marlin

Randy Folk – software specialist
Rob Webber } QA specialists
Mark Ehrstrom }
Pat LaPlante

hearing Pat – not at all

1st week Nevada – preferable
2nd week – both teams
Berkeley 2 days M, T
Livermore W, Th
Friday – closeout
Ted's intent → 2 technical for 2 weeks

process –
28 areas

training – first afternoon
middle of next week

Grossman
Danna
Peckenpaugh
Chickbour
Povelike

• July ACNW —
PA + perf. confirmation

02/27/03
F.H. Dove

TABLE 3. COMPLETED (OR NEARLY COMPLETED) ANALYSES AND MODELS REPORTS (AMR) FOR DATA AUDIT

AMR Number	AMR Title	AMR ID	AMR to Checking	AMR Finish	Comments
Integrated Site Model/Natural Analog					
MDL-NBS-GS-000002	Geologic Framework Model 3.1	I0035	HAVE COPY		Completed FY'02.
MDL-NBS-GS-000005	Field Thermal Analysis	I0060	HAVE COPY		Completed FY'02. Previous data issues concerning site thermal conductivity. Assigned to Ron Linden.
Saturated Zone Flow and Transport					
					None completed by 03/10/03
Unsaturated Zone Flow and Transport					
ANL-NBS-HS-000015	3D UZ S/S Model Grid	U0000	NEED REPORT	02/21/03	Reviewed on Berkeley Audit
ANL-NBS-GS-000008	Future Climate Analysis	U0005	HAVE COPY		Completed FY'02
MDL-NBS-HS-000003	Calibrated properties Model	U0035	NEED REPORT	02/14/03	
Disruptive Events					
					None completed by 03/10/03
Biosphere					
ANL-MGR-MD-000005	Characteristics of Receptor for Biosphere Model	B0010	10/28/02 HAVE COPY	03/25/03	Essentially complete. Data obtained from reference sources outside YMP. Assigned to Harvey Dove.
ANL-MGR-MD-000006	Agricultural and Environmental Input Parameters for Biosphere Model	B0030	10/01/02 HAVE COPY	02/18/03	Essentially complete. Data obtained from reference sources outside YMP. Assigned to Harvey Dove.
Engineered Barrier System					
					None completed by 03/10/03
Waste Form Degradation					
TDR-EBS-MD-000022	EQ3/6 Data Quality Review	F0190	HAVE COPY	02/21/03	
Waste Package Degradation					
ANL-EBS-MD-000006	Hydrogen Induced Cracking of Drip Shield	W0105	NEED REPORT	03/07/03	

NOTE: AMR checking and finish dates based on BSC P3 Schedule of 02/12/2003

Department of Energy
Washington, DC 20585

QA: QA

MAY 09 2003

J. T. Mitchell, Jr.
President and General Manager
Bechtel SAIC Company, LLC
1180 Town Center Drive, M/S 423
Las Vegas, NV 89144

OFFICE OF QUALITY ASSURANCE (OQA) PERFORMANCE-BASED AUDIT OQAP-BSC-03-07 OF BECHTEL SAIC COMPANY, LLC (BSC) SOFTWARE PROCESSES AND LIFE-CYCLE ITEMS

A team of auditors and technical specialists representing the Office of Civilian Radioactive Waste Management will conduct a performance-based audit of BSC's implementation of the Quality Assurance Program, as described in the DOE/RW-0333P, Revision 13, *Quality Assurance Requirements and Description* document. The audit, originally scheduled for May 13 - 23, 2003, will be conducted during the period June 3 - 13, 2003.

The limited-scope audit will focus on software processes and related end-products to support the Yucca Mountain Project License Application and will take place at the BSC and U.S. Department of Energy (DOE) facilities in Las Vegas, Nevada. Audit activities will also be performed at two DOE laboratories, Lawrence Berkeley National Laboratory on June 9 - 10, 2003, and Lawrence Livermore National Laboratory on June 11 - 12, 2003.

Observers from the state of Nevada, the U.S. Nuclear Regulatory Commission, and other interested parties may accompany the audit team.

Please arrange for the appropriate space to conduct meetings, provide cognizant personnel to support the audit, and provide for audit team access to appropriate BSC and laboratory personnel, records, and documentation.

If you have any questions, please contact either Kerry M. Grooms at (702) 794-1367 or Marlin L. Horseman at (702) 794-5522.

for

R. Dennis Brown, Director
Office of Quality Assurance

OQA:KMG-1150

Enclosure:
Revised Audit Plan OQAP-BSC-03-07

cc w/encl:
Robert Latta, NRC, Las Vegas, NV
S. W. Lynch, State of Nevada, Carson City, NV
L. H. Carroll, GAO, Denver, CO
R. W. Andrews, BSC, Las Vegas, NV
J. E. Gebhart, BSC, Las Vegas, NV
J. L. Harding, BSC, Las Vegas, NV
M. A. Jaeger, BSC, Las Vegas, NV
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F. B. Platko, BSC, Las Vegas, NV
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F. N. Zinkevich, BSC, Las Vegas, NV
M. L. Horseman, NQS, Las Vegas, NV
M. A. Kavchak, NQS, Las Vegas, NV
File, NQS, Las Vegas, NV (original)
B. V. Hamilton-Ray, DOE/ORD (RW-31W), Las Vegas, NV
S. P. Mellington, DOE/ORD (RW-50W), Las Vegas, NV
V. W. Trebules, DOE/ORD (RW-20W), Las Vegas, NV
M. E. Van Der Puy, DOE/ORD (RW-30W), Las Vegas, NV
J. D. Ziegler, DOE/ORD (RW-40W), Las Vegas, NV

QA: QA

U.S. DEPARTMENT OF ENERGY
OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT

QUALITY ASSURANCE AUDIT PLAN

FOR

AUDIT OQAP-BSC-03-07

OF THE

BECHTEL SAIC COMPANY, LLC

AT

LAS VEGAS, NEVADA

JUNE 3 THROUGH 13, 2003

Prepared by: Marlin Horseman **Date:** May 5-2003
Marlin L. Horseman
Audit Team Leader
Navarro Quality Services

Approved by: for **Date:** 5/9/03
R. Dennis Brown
Director
Office of Quality Assurance

ENCLOSURE

1.0 SCOPE

The U.S. Department of Energy (DOE), Office of Civilian Radioactive Waste Management (OCRWM), representatives will conduct a performance-based audit during the period of June 3-13, 2003 of software activities performed by Bechtel SAIC Company, LLC (BSC), and two DOE labs. The audit team will review the effectiveness and implementation of applicable DOE software procedures, processes, and life-cycle items. In addition, the audit team will assure that the software requirements identified in the OCRWM DOE/RW-0333P, Revision 13, *Quality Assurance Requirements and Description* (QARD) document are being implemented effectively

2.0 AUDIT SCHEDULE

The following activities will be performed as indicated (all times are PDT):

Audit Team/Observer Meeting	1:00 p.m., June 2, 2003
Pre-Audit Conference	9:00 a.m., June 3, 2003
Audit Activities	9:30 a.m. to 4:00 p.m., June 3, 2003
	8:00 a.m. to 4:00 p.m., June 4-6, 2003
	8:00 a.m. to 4:00 p.m., June 9-12, 2003
	8:00 a.m. to 10:00 a.m., June 13, 2003
Post-Audit Conference	10:30 a.m., June 13, 2003 (tentative)

An audit team/observer meeting will be held each day at 4:00 p.m. to review audit progress, results, and activities to be completed. Beginning on Wednesday, June 4, 2003, there will be a daily Audit Team Leader/Observer/Auditee Management Meeting at 8:15 a.m. to communicate progress, concerns, potential deficiencies, and changes in schedule. The location of these meetings will be established prior to the audit.

3.0 REQUIREMENTS TO BE AUDITED AND APPLICABLE REFERENCES

The audit checklist will be developed from processes and life-cycle items described in the following documents:

- QARD, Revision 13
- AP-SI.1Q, applicable revision, *Software Management*
- AP-SI.2Q, applicable revision, *Qualification of Level A Developed or Modified Software*
- AP-SI.3Q, applicable revision, *Software Independent Verification and Validation*

The checklist will also contain effectiveness measurements based upon a performance-based review of various software processes and life-cycle items.

4.0 ACTIVITIES TO BE AUDITED

The audit team will evaluate the critical process steps involved with the development, control, use, and documentation of software that will be used in products that will support the license application. The processes and activities that are used to manage the acquisition, development, qualification, and use of software supporting the license application process will be evaluated to determine the implementation and effectiveness of these processes. The software process steps and representative, performance-based measurements and topics will be in those areas identified in the Attachment to this Audit Plan.

5.0 AUDIT TEAM MEMBERS AND OBSERVERS

Marlin Horseman, Navarro Quality Services (NQS)/Audit Team Leader
Sam Archuleta, NQS/Auditor
Harvey Dove, NQS/Technical Specialist
John Doyle, NQS/Auditor
Bruce Foster, NQS/Auditor
Christian Palay, NQS/Auditor
Sid Ailes, Duratec/Technical Specialist
Mario Chavez, John Hart Associates, Technical Specialist
Norm Moreau, Theseus Professional Services, Technical Specialist

Observers

Denny Brown, DOE/Office of Quality Assurance
U.S. Nuclear Regulatory Commission, and possibly Government Accounting Office and state of Nevada representatives

6.0 AUDIT CHECKLIST

OQAP-BSC-03-07, Performance-Based Software Checklist.

7.0 ATTACHMENT

Audit Team Assignment Table.

ATTACHMENT - AUDIT TEAM ASSIGNMENTS

Teams:
A = Christian Palay and Norm Moreau **B = Sam Archuleta and Sid Ailes** **C = Bruce Foster and Harvey Dove**
D = John Doyle and Mario Chavez **E = Marlin Horseman**

Area	Team	Subject	Comments
1	A	General Software Qualification and Administrative Activities	Prior to Use, Documentation, Training, Storage, Access
2	B	Software Verification and Validation	Independence, Responsibilities, Standards, Reviews, Error Reporting, Corrective Action, etc.
3	C	Software Algorithms	Correct Algorithms, No unintended Functions, Results, Test of Input Range, etc.
4	C	Alternative Methods for Technical Adequacy	Hand Calcs, other methods, etc
5	E	Software Procedures	Contain Upper-Tier Requirements, QA Controls, CAQ Documentation, etc.
6	C	Software Classification	The Type of Software is identified
7	B	Software Activity Plans	Description, Products, Responsible Orgs. Prior to start, Identify required Docs. Reviews, Error Reporting, etc.
8	B	General Software Life Cycle Activities	Applicability to Acquired, Procured, and Developed Software
9	A	Requirements Phase	RD, Functionality, Performance, Constraints, Interfaces, can be V&V'd, Traceable, Enough Detail, etc.
10	B	Design Phase	DD, Description of Major components of the Software, Test Plan Develop, Defined Ranges, Can be Coded, etc.
11	B	Implementation Phase	Design is Coded, meets design Specs, User Info, etc.
12	B	Software Testing Phase	Planned with Test Cases, Validation Testing, Mods, Regression Testing, No Unintended results
13	A	Operations and Maintenance Phase	Put under C.M., any Changes get V&V'd, and controlled, In-use Tests, Periodic Self-Checks
14	D	Installation and Checkout Phase	Installation Testing
15	D	Retirement Phase	Timely retirement and closure of activities of any software that has been retired, baseline changes

ATTACHMENT - AUDIT TEAM ASSIGNMENTS

Teams:
A = Christian Palay and Norm Moreau **B = Sam Archuleta and Sid Ailes** **C = Bruce Foster and Harvey Dove**
D = John Doyle and Mario Chavez **E = Marlin Horseman**

Area	Team	Subject	Comments
16	D	Software Controls	Change Control, Release and Control of Elements, Control & Documentation of Changes
17	C	Software Use	User responsibilities, training, and information
18	C	Error Reporting	User and developer organizations Reporting
19	C	Traceability in Technical Products	Traceability – Forward and Trace-back
20	D	Acquired Software (Software not developed under the QARD)	Qualification Process and Activities
21	A	Participant Software	Review of Participant Software and Documentation
22	D	Procurement of Software	Requirements in Procurement Documents
23	B	Spreadsheets	Qualification of spreadsheets used to support license application
24	B	Routines and Macros *DELETED*	Any controls and use of routines and macros
25	B	Software Used as Management Tools	Verification that the Designated Management Tools do not Implement QARD Requirements
26	A	Documentation and Records	Traceability through Records, Documentation
27	A& D	At the Labs	Sampling of Codes and Life-Cycle Activities for Software Used to Support the License Application
28	D	Review Software DRs, CARs, SDNs, etc	Identify Trends or Areas to Review and Areas for Improvement
29	All	Implementing Procedure Contains All Upper Tier Requirements	Adequacy and Logic