BECHTEL SAIC COMPANY LLC

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Scientific Processes Guidelines Manual

By
Chief Science Office

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Enclosure 2

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CHANGE HISTORY

Revision Number	Interim Change No.	Effective Date	Description of Change
0	0	01/07/2002	Initial issue
1	0	09/20/2002	Revision to incorporate guidelines for: (1) integration of process models with the TSPA-LA; (2) determination of model importance and model validation; and (3) field and laboratory testing.

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PREFACE

This Scientific Processes Guidelines Manual was created to assist the Bechtel SAIC Company, LLC scientific organizations in the production of consistent technical products that comply in content, format, and process with the implementing procedures. Its goal is to provide clarification of the scientific procedures, guides, and standards, and to identify forms and checklists to be used by the originators and checkers of scientific documents during the processing of these documents.

This Scientific Processes Guidelines Manual is meant to be a working tool that works in conjunction with the applicable procedures. If you have any suggestions for improvement or recognize any conflicts with procedures, please contact the Bechtel SAIC Company, LLC Chief Science Officer. This manual is subject to change control and will be revised as needed as the underlying procedures change.

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ACRONYMS AND ABBREVIATIONS

ACM	Alternative Conceptual Model
AFS	Automated Forms System
ASTM	American Society for Testing and Materials
ATL	Abstraction Team Lead
BSC	Bechtel SAIC Company, LLC
CSO	Chief Science Office
DCAR	Document Control Action Request
DI	document identifier
DIRS	Document Input Reference System
DOE	U.S. Department of Energy
DTN	data tracking number
FEP	features, events, and processes
FTL	FEPs Team Lead
ICN	Interim Change Notice
ISMQAP	Integrated Safety Management Quality Assurance Procedure/Program/Plan
ITP	Installation Test Plan
ITR	Independent Technical Reviewer
LA	License Application
non-Q	non quality-affecting
OCRWM	Office of Civilian Radioactive Waste Management
PASS	Performance Assessment Strategy and Scope
PI	Principal Investigator
PTL	Parameter Team Lead
Q	quality-affecting
QA	quality assurance
QARD	Quality Assurance Requirements and Description
QE	Quality Engineering
QER	Quality Engineering Representative

ACRONYMS AND ABBREVIATIONS (Continued)

RIB	Reference Information Base
RPC	Records Processing Center
SME	Subject Matter Expert
SNR	Scientific Notebook Register
SPGM	Scientific Processes Guidelines Manual
SQ/C	Software Quality and Compliance
TBV	to be verified
TDMS	Technical Data Management System
TSPA	Total System Performance Assessment
TSPA-LA	Total System Performance Assessment-License Application
TSPA-SR	Total System Performance Assessment-Site Recommendation
TWP	Technical Work Plan
USGS	U.S. Geological Survey
UZ	Unsaturated Zone
VTP	Validation Test Plan
YMRP	Yucca Mountain Review Plan
YMP	Yucca Mountain Site Characterization Project

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1. INTRODUCTION

1.1 PURPOSE

The *Scientific Processes Guidelines Manual* (SPGM) explains the formal technical product preparation process established by Bechtel SAIC Company, LLC (BSC) for organizations that manage, oversee, control, or support interface with the scientific processes. This manual describes the processes, either required or recommended, for preparing technical products. Therefore, the SPGM serves as a ready reference for anyone performing scientific or performance assessment tasks or working in related functions.

Governing directives for technical product preparation include Administrative Procedures and other applicable instructions or orders. This SPGM is not intended to replace any of these procedures, instructions, or orders; rather, it is intended to complement them and to provide a consistent interpretation that can be used by all BSC personnel. One should always defer to the governing directives if discrepancies arise between this manual and the directives. The goal of BSC continues to be verbatim compliance with all quality assurance (QA) requirements.

The SPGM provides a foundation for an internal training program for new staff of the BSC scientific organizations. It can also serve as a refresher for current staff of the BSC scientific or performance assessment organizations and other personnel supporting these efforts. This manual also functions as a top-level description of the BSC scientific processes and products, including the following:

- Technical reports and products
- Scientific analyses and models
- Software management
- Scientific notebooks
- Testing.

1.2 SCOPE

The material contained in this SPGM applies, as a minimum, to BSC efforts that support scientific products governed by the U.S. Department of Energy (DOE) Document Development Policy (Dyer 1998). These guidelines are in addition to the requirements contained in applicable procedures.

This manual may also be used, as applicable, for BSC activities and products that are not covered by the DOE Document Development Policy (Dyer 1998).

1.3 KEY PROCESSES

Figure 1-1 presents a logic diagram showing the overall work control process for conducting scientific investigations in accordance with the *Quality Assurance Requirements and Description* (QARD) Supplement III (DOE 2002). These include the development of models, scientific analyses, and technical reports, as well as supporting field and laboratory investigations. All quality-affecting scientific investigations must be planned in the Technical Work Plan (TWP) in

accordance with AP-2.27Q, *Planning for Science Activities*. If the investigation involves field or laboratory testing activities, then a Scientific Investigation Test Plan(s) (SITP[s]) must be developed per AP-SIII.7Q, *Scientific Investigation Laboratory and Field Testing*. For laboratory and site-disturbing field activities, a FWP(s) (Field Work Package[s]) or a LWP(s) (Laboratory Work Package[s]) must be prepared in accordance with AP-5.2Q, *Testing Work Packages*. Data obtained from the testing activities are then used in developing of models, scientific analyses, and technical reports. A Scientific Analysis 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 Model is a set of hypotheses consisting of assumptions, simplifications, and idealizations that describes the essential aspects of a system, process, or phenomenon. When model(s) use is involved, a Scientific Analysis differs from a Model in that the former only uses a previously developed and validated model(s) as defined in AP-SIII.10Q, *Models* and AP-SIII.9Q, *Scientific Analyses*. When one only needs to summarize results of existing models or scientific analyses, one develops a technical report in accordance with AP-3.11Q, *Technical Reports*. Details of developing these technical products are provided in Sections 3 through 10.

1.4 ORGANIZATION OF DOCUMENT

This SPGM is organized for easy reference in producing scientific or performance assessment documents under BSC guidelines and procedures.

Section 2 describes the process for planning, including the preparation of Technical Work Plans (TWPs) for science and performance assessment activities in accordance with AP-2.27Q, Planning for Science Activities, and planning of field and laboratory test activities in accordance with AP-SIII.7Q, *Scientific Investigation Laboratory and Field Testing*, and AP-5.2Q, *Testing Work Packages*.

Section 3 describes the processes for implementing field and laboratory test activities in support of scientific investigations, including the development of test implementation documents in accordance with AP-5.2Q; work authorization/control in accordance with AP-2.23Q, *Work Request/Work Order Process*; and the implementation of test activities in accordance with AP-12.1Q, *Control of Measuring and Testing Equipment and Standards*; AP-7.7Q, *Acceptance of Items and Services*; and other procedures.

Section 4 describes the method for maintaining a record of al requirements, codes, standards, and other technical inputs in accordance with AP-3.15Q, *Managing Technical Product Inputs*, including an overview of the Document Input Reference System (DIRS) and basic instruction on submitting information to the DIRS as required by AP-3.15Q.

Section 5 describes the method for developing Analysis and Model Reports (AMRs) or other technical products. Included are information and detailed instructions for preparing technical documents (AP-3.11Q), models (AP-SIII.10Q), and scientific analyses and calculations (AP-SIII.9Q).

Section 6 describes the preparation, technical checking, review (AP-2.14Q, Impact Reviews), approval, document control, revisions, and other related parts of the progress for each of these

types of technical documents. Included is information on marking the check copy, selecting checkers, checker responsibilities, tracking, and information on using checklists. A table is presented that lists appropriate review organizations.

Section 7 describes the use and management of software products in support of quality affecting (Q) scientific and technical studies in accordance with AP-SI.1Q, *Software Management*.

Section 8 describes the use and management of scientific notebooks that are controlled by AP-SIII.1Q, *Scientific Notebook*.

Section 9 provides information on records, controlled documents, and deliverables. In includes responsibilities for document approval in accordance with the requirements of AP-6.1Q, *Controlled Distribution*; AP-IST-004, *Public Release Review, Approval, and Distribution of Technical and Non-Technical Products*; and AP-7.5Q, *Submittal, Review, and Acceptance of Deliverables*. It also includes an explanation of submittal of electronic copies of controlled documents to Document Control and a description of the requirements of AP-17.1Q, *Record Source Responsibilities for Inclusionary Records*.

Section 10 lists references identified in this manual.

Lastly, three appendices provide additional details on processes for model/analyses integration for the Total System Performance Assessment for License Application (TSPA-LA) (Appendix A), guidelines for determining levels of model importance and validation (Appendix B), and template outlines for Model Report Sections 4, 6, 7, and 8 (Appendix C).

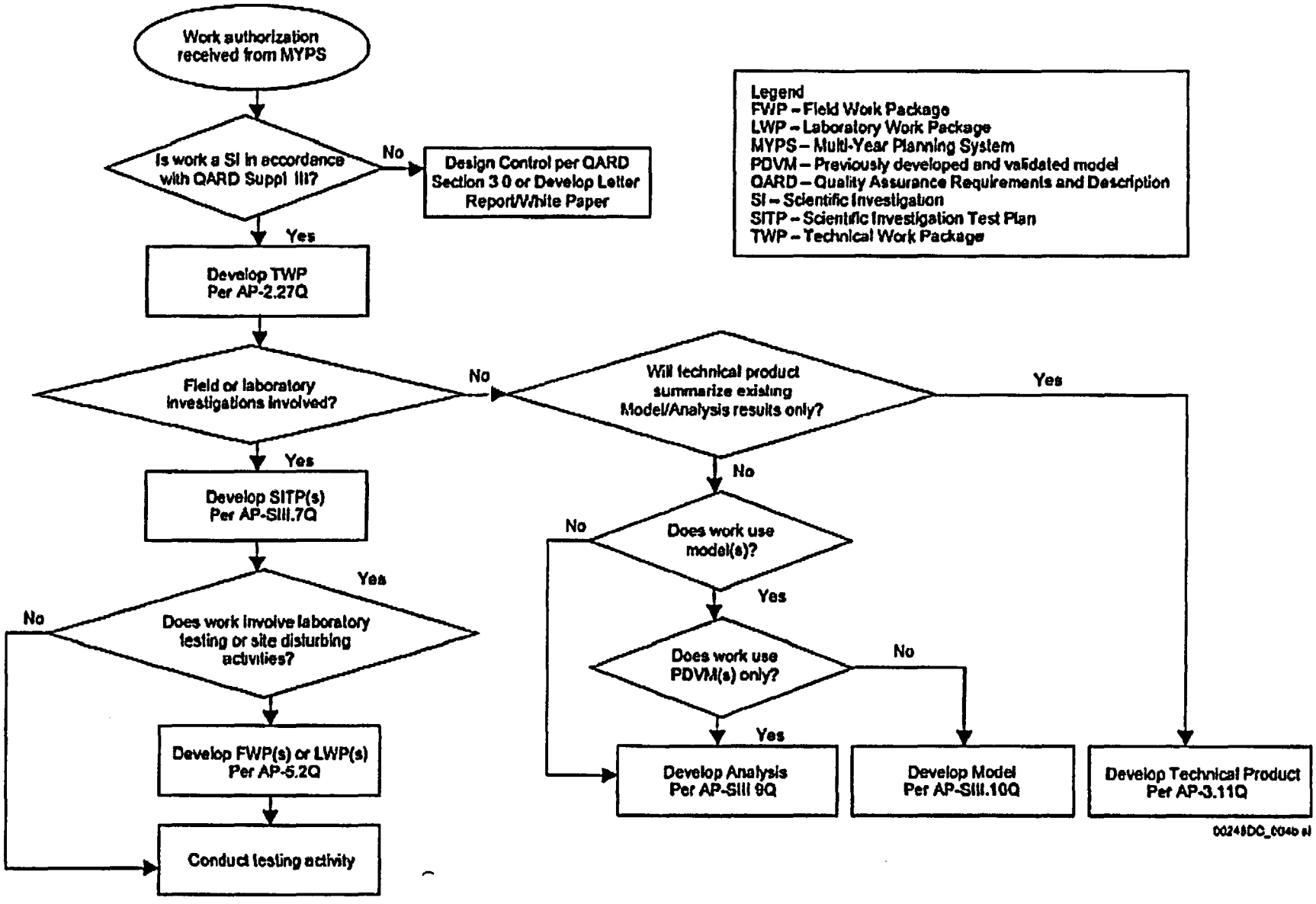

Figure 1-1. Overview of Work Control Process for Conducting Scientific Investigations

2. SCIENCE AND PERFORMANCE ASSESSMENT PRODUCT PLANNING

This section describes the method and process for planning science and performance assessment activities. Following an overview of the relevant procedures in Section2.1, Section2.2 describes the process for preparing planning documents, including outlines for TWPs and Scientific Investigations Test Plans (SITPs). Specific requirements in planning model validation activities are provided in Section 2.7 in accordance with AP-SIII.10Q. The key processes for planning formal technical products are illustrated in Figure 2-1, and discussed in the following sections.

2.1 OVERVIEW

Planning documents are developed to address *Quality Assurance Requirements and Description*, DOE/RW-0333P, and *Integrated Safety Management Quality Assurance Plan* (ISMQAP), DOE/RW-0333P, Addendum 1, requirements to identify any specific requirements the product or scientific investigation will meet. Since scientific planning documents are used to complement implementing procedures, it is particularly important to establish at the outset the goals/intended use, expected outcomes and criteria of scientific investigations, and products. Clear identification of each of these items will aid internal and external audiences in confirming that the outcomes are robust and appropriate for addressing their assigned regulatory and performance assessment needs. See Figure 2-1 for an overview of relationships among these procedures.

Three procedures govern planning of science and performance assessment (PA) activities: AP-2.27Q, AP-SIII.7Q, and AP-5.2Q.

AP-2.27Q addresses detailed planning for products to be prepared to AP-SIII.9Q or AP-SIII.10Q and science or PA products prepared to AP-3.11Q. It requires that TWPs be prepared for all BSC, national laboratories, or U.S. Geological Survey (USGS) Q and non quality-affecting (non-Q) activities, unless exempted as follows:

- Infrastructure and support activities that are governed by other implementing procedures (e.g., document control, records management, procedure development, and configuration management), except in circumstances wherein a support group is tasked to complete Q or non-Q activities directly tied to a technical product. In those cases, the controls of this procedure shall be applied.

- Program Management and Integration overhead accounts and/or management and oversight activities.

- Human resources activities, such as personnel performance appraisals, personnel placement, and employee assistance.

- Programmatic, cost estimating, and project control activities such as financial, resource, program, cost, and schedule planning and monitoring, not including procurement of Q items or services.

- Oral and written reports of work status (e.g., weekly and monthly reports, presentations, etc., not including reports required by the QARD).

- Administration activities such as facilities/space management, motor pool operations, reprographics services, mail services, telecommunications, supplies, and recycle management.

AP-SIII.7Q establishes the requirements for planning, executing, and reporting Q and non-Q field and laboratory investigations. This procedure also ensures that scientific investigations are planned, required pre-test predictions are completed and documented, and that Q activities are accomplished under controlled conditions in accordance with the QARD. All BSC, national laboratory, and USGS organizations conducting scientific investigations for the Office of Civilian Radioactive Waste Management (OCRWM) are required to complete SITPs. Additionally, BSC, national laboratories, and USGS personnel are required to prepare SITPs in accordance with AP-SIII.7Q and the applicable TWP.

AP-5.2Q establishes the responsibilities and process to initiate, develop, review, approve, issue, revise, and document Field Work Packages (FWPs) and Laboratory Work Packages (LWPs) for the OCRWM field and laboratory testing activities. That procedure also ensures that Q activities are planned and accomplished in accordance with the QARD and the ISMQAP.

TWPs, SITPs, and FWPs/LWPs address the planning requirements of Criterion 2.2.5 and Supplement III of the QARD, as well as the safety requirements of the ISMQAP. Although these procedures contain similar requirements, they address distinct planning needs. TWPs are prepared to document planning requirements needed to complete all scientific or PA milestones identified in the project baseline. TWPs may address requirements for a single activity (e.g., prepare AMR) or may address multiple related activities (e.g., complete scientific investigation, prepare AMR, prepare abstraction AMR). SITPs are prepared specifically to address the details and requirements necessary to execute the research aspects of a scientific investigation. Approved SITPs are often used to communicate to internal and external audiences the technical steps that will taken to ensure that testing goals are met in a safe and controlled manner. SITPs not only comply with the requirements of AP-SIII.7Q, but also meet any field/laboratory controls described in AP-5.2Q; FWPs/LWPs; and if the scientific investigation is to be completed by BSC, national laboratories, or USGS, any requirements specified in the controlling TWP. FWPs/LWPs are prepared to ensure that field test bed construction or excavation and laboratory apparatus construction or assembly is completed in accordance with specifications of the Principal Investigator (PI) and with any applicable Q requirements, DOE orders, American Society for Testing and Materials (ASTM) or industry standards, or safety regulations.

2.2 PREPARING PLANNING DOCUMENTS

2.2.1 Document Control

For TWPs, obtain a document identifier (DI) number from Document Control in accordance with AP-6.1, *Controlled Distribution*. DI numbers should be placed on the cover sheet and on each page of the TWP. Document Control has an information page on the BSC Intranet (http://m-o) to assist personnel in obtaining DI numbers.

For SITPs, create a unique identifier, #XX-YYYYY-ZZZ, to be used during AP-6.1Q controlled distribution, where XX denotes the fiscal year, YYYYY denotes the activity designation, and ZZZ is the sequential number of the SITP. Place this DI on the cover sheet and on each page of the SITP.

2.2.2 Version and Change Control

Use alphanumeric revision designators (e.g., Rev 00A, Rev 00B) to denote different drafts or versions during development or revision of planning documents, prior to preparing the final draft for approval. Place the alphanumeric designator on each page of the draft document.

When revising previously approved planning documents, indicate changed portions to the previously approved document with a black vertical line in the margin on the page(s) where changes were made and provide a brief description of the change within the body of the document or on the Revision History page.

2.2.3 Cover/Approval Sheets

Prepare a cover or approval sheet in accordance with the applicable procedure. Cover/approval sheets should include the document title, DI, QA designator, effective date of the document, the preparer's signature/date, and approval signatures/dates.

2.2.4 Quality, ISMQAP, and Supplement V Determinations

Complete quality, ISMQAP, and Supplement V evaluations or provide a reference to effective, previously completed determinations. Quality and ISMQAP determinations are completed while addressing the items contained in the Outline attachment of the TWP or SITP procedures. Any items subject to the QARD are considered Q and all procedure controls should be applied. If all controls cannot be applied, or all controls are not justified for an activity, identify which controls will be applied and provide a justification for those not applied in the appropriate portion of the Outline. The ISMQAP applies to any activities not subject to the QARD or any activities to which special controls will be applied, as follows:

- Non-Q activities associated with the Yucca Mountain Site Operations
- Non-Q activities associated with design, construction, operations, decommissioning, and closure of a monitored geologic repository
- Non-Q activities associated with acceptance, transport, and storage of spent nuclear fuel and high-level radioactive waste
- Non-Q activities associated with any of the three previous bullets.

If the ISMQAP applies to any activities in the planning document, then the preparer must address criterion 2.2.5 of the QARD, and therefore the Outline attachment to the implementing procedures, regardless of whether the activity is Q or not. By addressing all items in the TWP and/or SITP Outline attachments, the preparer ensures compliance with ISMQAP requirements for non-Q plans.

Complete an AP-SV.1Q, *Control of the Electronic Management of Information*, evaluation for all activities and scientific investigations or provide a reference to effective, previously completed evaluation. The evaluation may be completed for a single activity or for multiple, related activities. The purpose of the evaluation is to ensure that electronic information is controlled in accordance with Supplement V of the QARD. Document the outcome of the evaluation in the appropriate portion of the planning document and list any required mechanisms to be used to manage exchange, storage, or collection of electronic information.

2.3 TWP OUTLINE

Document the following information in the TWP (see the Technical Work Plan Outline in AP-2.27 for additional details and information requirements; see Appendix B of this manual for additional guidance). Address all numbered and bulleted items. If the information requested in the numbered/bulleted items has already been addressed in other controlled planning documents (e.g., SITPs, FWPs, or LWPs), cite the document and DI in the appropriate portion of the TWP. If any items are not applicable, state "N/A" and provide an explanation as to why they do not apply.

Section 1: Work Scope

This section should state the overall technical and/or performance objectives to be met by completing the activities controlled by the TWP. This section should also identify major tasks, performing organizations, an overall schedule, and any special task sequences.

Section 2: Scientific Approach or Technical Methods

This section should identify the intended use and/or purpose of each major activity and/or product. Also include:

- A listing of intended users/customers of the products developed under the TWP.
- A description of the scientific approach and technical methods for each activity. Lower level planning documentation may be referenced for field and laboratory testing and site disturbing activities (e.g., cite the applicable LWP, FWP, or SITP DI number).
- Plans to address uncertainties.
- A list of Features, Events, and Processes to be addressed or a reference to any effective Features, Events, and Processes documents that contain information relevant to the activities described in the TWP.
- A listing of alternative models/technical approaches that should be evaluated or documentation provided for why alternative models/approaches are not being considered.

If a pre-existing and previously validated model is to be used to complete the present activity, additional information is required:

- Justification for use of the pre-existing and validated model in the present study, including a statement determining the model will be used within the original range of validity and limitations.

- If the model will be taken outside of the range of validity and limitations, justification and validation plans must be provided if the present study is to produce quality-affecting outcomes.

TWPs for model development and validation should document:

- The needed level of confidence for each modeling activity, and the validation methods and the validation criteria to be met by completion of the validation activity. Refer to AP-SIII.10Q and Appendix B of the SPGM for information regarding selecting validation criteria.

- If model validation activities will be completed after initial documentation of the model, provide a description of these activities and justification for planning model validation forward.

- If an independent review (per AP-SIII.10Q) will be conducted to meet the requirements of post-development validation, state the required skills of the reviewers, the review criteria, the documentation to be provided to the reviewers, and any training to be completed by the reviewers prior to the review.

Section 3: Standards and Criteria

Identify all applicable standards and/or criteria in this section. Examples may include DOE Orders, safety regulations, ASTM standards, DOE acceptance and/or completion criteria, Yucca Mountain Review Plan acceptance criteria, performance requirements, and any requirements identified in source documents. Also, state the provisions for determining the level of accuracy, precision, and representativeness of results of each activity.

Section 4: Implementing Documents

For Q activities, identify the specific implementing procedures that will be required to directly conduct each activity (e.g., AP-SIII.10Q, AP-3.11Q, and AP-SIII.9Q). It is not necessary to list infrastructure and support procedures such as those addressing document control and records management (e.g., AP-6.1Q and AP-17.1Q). For non-Q activities (as determined in Section 8 of the TWP), state the specific procedural requirements that will be required to directly conduct each activity (e.g., requirements from AP-SI.1Q, Software Management; AP-SIII.10Q).

Section 5: Equipment

Identify the major field or laboratory systems or equipment necessary to conduct the work, or reference the applicable FWP(s) or SITP(s) that contains equipment information. The TWP or

the referenced lower level planning documentation should provide any known calibration requirements.

Section 6: Records

Provide instructions to users of the TWP to collect and submit all records generated as a result of implementing procedures in accordance with AP-17.1Q.

Section 7: Quality Verifications

Identify any quality verifications, other than surveillances or audits, that are required during the execution of the TWP. Address any requirements for technical verification in accordance with AP-3.20Q, *Technical/Design Verification.*

Section 8: Prerequisites, Special Controls, Environmental Conditions, Processes, or Skills

This section should describe the applicability of the QARD and ISMQAP. Refer to the Technical Work Plan Outline in AP-2.27Q, item 8 to determine applicability. Also, describe any prerequisites that must be satisfied before work begins, including receipt of data/input(s) under development and identify the organizations responsible for developing the input(s). State the results of the evaluation required by AP-SV.1Q and the method(s) or the implementing documents to be used for control of electronic management of electronic information. If the quality of the results cannot be readily determined by inspection or testing, identify applicable controls, processes, or skills necessary to ensure defendable results (e.g., surveillance, peer reviews, special qualifications, expert elicitations). Any required special environmental controls (e.g., non-ambient conditions) needed to conduct the work should be described in this section as well.

Section 9: Software

In this section, list software and associated software tracking numbers to be used to conduct the work, if known, and indicate whether the listed software is qualified or unqualified.

Section 10: Organizational Interfaces

Identify any organizational interfaces, other than input and customer organizations, and state their roles/responsibilities in relation to completing the work described in the TWP.

2.4 SITP OUTLINE

Document the following information in the SITP (see Attachment 2 of AP-SIII.7Q for additional details and information requirements). Address all numbered and bulleted items. If the information requested in the numbered/bulleted items has already been addressed in other controlled planning documents (e.g., TWPs, FWPs, or LWPs), cite the document and DI in the appropriate portion of the SITP. If any items are not applicable, state "N/A" and provide an explanation as to why they do not apply.

Section 1: Work Scope

This section should state the overall technical and/or performance objectives to be met by completing the activities controlled by the SITP. For plans to be completed by BSC, national laboratories, or the USGS, cite the controlling TWP. This section should also identify major tasks, performing organizations, an overall schedule, and any special task sequences.

Section 2: Applicability of the QARD and ISMQAP

State the applicability of the QARD and the ISMQAP (see Item 8 in Section 2.3 of this manual).

Section 3:Controlling Documents

State whether implementing procedures, scientific notebooks, or a combination of both will be used to complete the scientific investigation. For Q SITPs, provide a list of implementing procedures to be used to complete the work. For non-Q scientific investigations, state the specific requirements within implementing procedures that will be used to control the work (e.g., software or data submittal requirements of AP-SIII.9Q or AP-SIII.10Q). It is not necessary to list infrastructure and support procedures such as those addressing document control and records management (e.g., AP-6.1Q and AP-17.1Q).

Section 4:Scientific Approach/Technical Methods

The following information should be included in this section:

- Identify whether Pre-Test Predictions will be completed and the implementing procedure to be used to develop the predictions (e.g. AP-SIII.10Q or AP-SIII.9Q), or provide a justification for not completing pre-test predictions.

- Provide a description of conceptual bases of the scientific investigation and scientific approach/technical methodology for completing the scientific investigation.

- List software to be used. List software and associated software tracking numbers to be used to conduct the work, if known. Indicate whether the listed software is qualified or unqualified. For Q scientific investigations, ensure that software is obtained, controlled, and documented in accordance with AP-SI.1Q.

- For Q activities, include the results of an evaluation in accordance with AP-SV.1Q, *Control of the Electronic Management of Information*. For all scientific investigations, describe methods for recording and reducing data and results.

- Identify the results/data expected to be obtained during and at the conclusion of the scientific investigation

- Provide a description of the mechanisms to be used to control accuracy, precision, and representativeness of results, addressing the following specific items:

  - Experimental/Sampling Artifacts

- Control/Determination of Independent Conditional Variables
- Control/Determination of the Boundary Conditions
- Instrument Calibration and Instrument Error
- Instrument Calibration
- Instrument Error
- Handling Unexpected Results/Conditions
- Unexpected Results
- Unexpected Conditions.

Section 5:Equipment and Calibration Requirements

List major equipment to be used and identify the calibration requirements for each in accordance with the applicable measuring and test equipment (M&TE) procedures. It is not necessary to list office equipment.

Section 6:Criteria, Standards, Orders, and Regulations

State the criteria (e.g., DOE or Yucca Mountain Review Plan criteria), applicable standards (e.g., Occupational Safety and Health Administration [OSHA] or ASTM standards), orders, regulations, performance requirements, or source document requirements.

Section 7:Hold Points, Quality Verifications, Checklists, and Readiness Reviews

State whether there is a need for a QAP-2-6 Readiness Review, mandatory hold points, quality verifications (other than surveillances or audits), or creation and completion of any pre-/post-test checklists. If any of these are required, briefly describe the plans/schedule to complete them.

Section 8:Prerequisites

Describe any prerequisites that must be satisfied before work begins, including receipt of data/input(s) under development. Identify the organizations responsible for developing the data/input(s).

Section 9:Special Quality and Environmental Controls

If the quality of the results to be derived from Q scientific investigations cannot be readily determined by inspection or testing, identify applicable controls, processes, or skills necessary to ensure defendable results (e.g., surveillance, peer reviews, special qualifications, expert elicitations). For all scientific investigations, state whether any special environmental controls (e.g., non-ambient conditions) are required to conduct the work.

Section 10:Records

Provide instructions to organizations performing work to collect and submit records, generated as a result of implementing procedures, in accordance with AP-17.1Q.

Section 11:References

Provide citations to any referenced material.

2.5 FWP/LWP OUTLINE

See Section 3 of this manual for further information, and refer to AP-5.2Q for instructions for completing these planning documents.

2.6 CONDUCTING REVIEWS OF PLANNING DOCUMENTS

Reviews of TWPs and SITPs may be completed by electronic mail or by using a review record and comment sheets (Forms AP-5.1Q.4 and AP-5.1Q.5, respectively, from AP-5.1Q, *Plan and Procedure Preparation, Review, and Approval*). Records of reviews conducted by electronic mail must be printed, marked with the appropriate QA designator, numbered "page X of Y," dated, and signed.

Refer to Section 5 of AP-5.2Q if conducting a review of FWPs/LWPs.

2.6.1 Identifying Reviewers and Criteria

BSC Quality Engineering, implementing organizations, and customer organizations are required to participate in reviews of TWPs and SITPs. The Chief Science Officer (CSO) is required to participate in reviews of all science and PA TWPs. The USGS Technical Project Officer (TPO) participates in reviews of SITPs and TWPs that involve USGS resources. Licensing; Environmental, Safety and Health (ES&H); and other organizations should also be included in reviews of TWPs of products that affect these organizations.

Review criteria should include, at a minimum, whether the planning document is technically adequate, whether the products described are appropriate for their intended use, and whether the planning document meets the requirements of the controlling procedure. Additional technical, management, programmatic, and licensing review criteria can be assigned as needed. Reviewers should document their comments in writing and should indicate which comments are mandatory. Mandatory comments are those comments that document that the draft text does not meet a review criterion or a procedural requirement, or represents an interface issue. If no mandatory comments are generated, reviewers should respond by stating that there are no comments.

2.6.2 Comment Responses

The preparer of the planning document should develop and document responses to mandatory comments. The rationale for not including or partially including mandatory comments should also be documented. The preparer should modify the review draft of the SITP to incorporate resolution of mandatory comments. The preparer should forward the comment responses to reviewers, and if the responses are acceptable, obtain reviewers' written acceptance of mandatory comment responses. Unresolved mandatory comments should be elevated to the next levels of management until resolution is achieved, and the final resolution should also be documented.

2.6.3 Review Records

All review documentation (i.e., list of reviewers, review criteria, comments and responses, review draft and concurrence draft, and acceptance of comment responses) should be collected and submitted with the planning document records package in accordance with Section 6.0 of the implementing procedures and AP-17.1Q, *Record Source Responsibilities for Inclusionary Records.*

2.6.4 Approvals, Controlled Distribution, and Cancellations

Scientific planning documents should be signed by the preparer, approved by the appropriate sub-project manager (or equivalent), and submitted for controlled distribution in accordance with AP-6.1Q. If the work controlled by the planning document is completed or removed from the baseline, follow the instructions for cancellation within the applicable planning procedure and AP-6.1Q.

2.7 MODEL VALIDATION PLANNING

For scientific activities involving model development, a plan must be developed for model validation in accordance with AP-SIII.10Q. Responsible Managers are assigned the task of completing model validation plans. The CSO is a mandatory reviewer of all TWPs containing model validation plans. If needed, the TWP can be revised to address any items not included in the initial plan. If the plans for the modeling activity change during the model development, it is the responsibility of the TWP Manager to revise the TWP to reflect the changes prior to completion of the impacted tasks.

Plans for the validation of each model should establish the set of activities to be used to demonstrate confidence. The following items should be addressed in model validation plans:

1) Identify the licensing position, technical issue, or TSPA component the model directly supports (e.g., intended use of the model).

2) Identify any limitations on the use of the model (e.g., model is for static conditions only and cannot be used for dynamic processes).

3) Determine the level of confidence required for the model. Three levels of model importance have been identified and corresponding model validation guidelines are provided in Appendix B for development of models supporting the TSPA-LA. In addition, the following questions may be helpful while developing the validation strategy:

    - Is the model extrapolated over large distances, spaces, or time frames?
    - Does the model have large uncertainties?
    - Will the model be used to demonstrate compliance or licensing positions?

- Will the output of the model have impacts (positive or negative) to TSPA dose calculation results?

4) Prepare a validation plan in accordance with the requirements of AP-SIII.10Q and AP-2.27Q. All models must meet the requirements of Paragraph 5.4.1b) of AP-SIII.10Q. This paragraph requires a description of all activities completed to increase confidence in the model output while the model was under development.

5) Define the supporting information needed to build confidence in the model. Validation plans must include one or more of the post-development activities listed in Paragraph 5.4.1c) of AP-SIII.10Q. Appendix B provides useful guidance for establishing the appropriate level of confidence for a given model area. Post-development model validation plans may extend into the future with appropriate justification. For example, test scale models developed to predict the behavior of field and laboratory testing are expected to undergo post-development validation with data collected during testing. Validation plans developed for these models will be planned for completion into the future, when testing has been initiated and data has been acquired. Post-development model validation plans should not cite budget or schedule constraints as justification for extending post-development validation into the future.

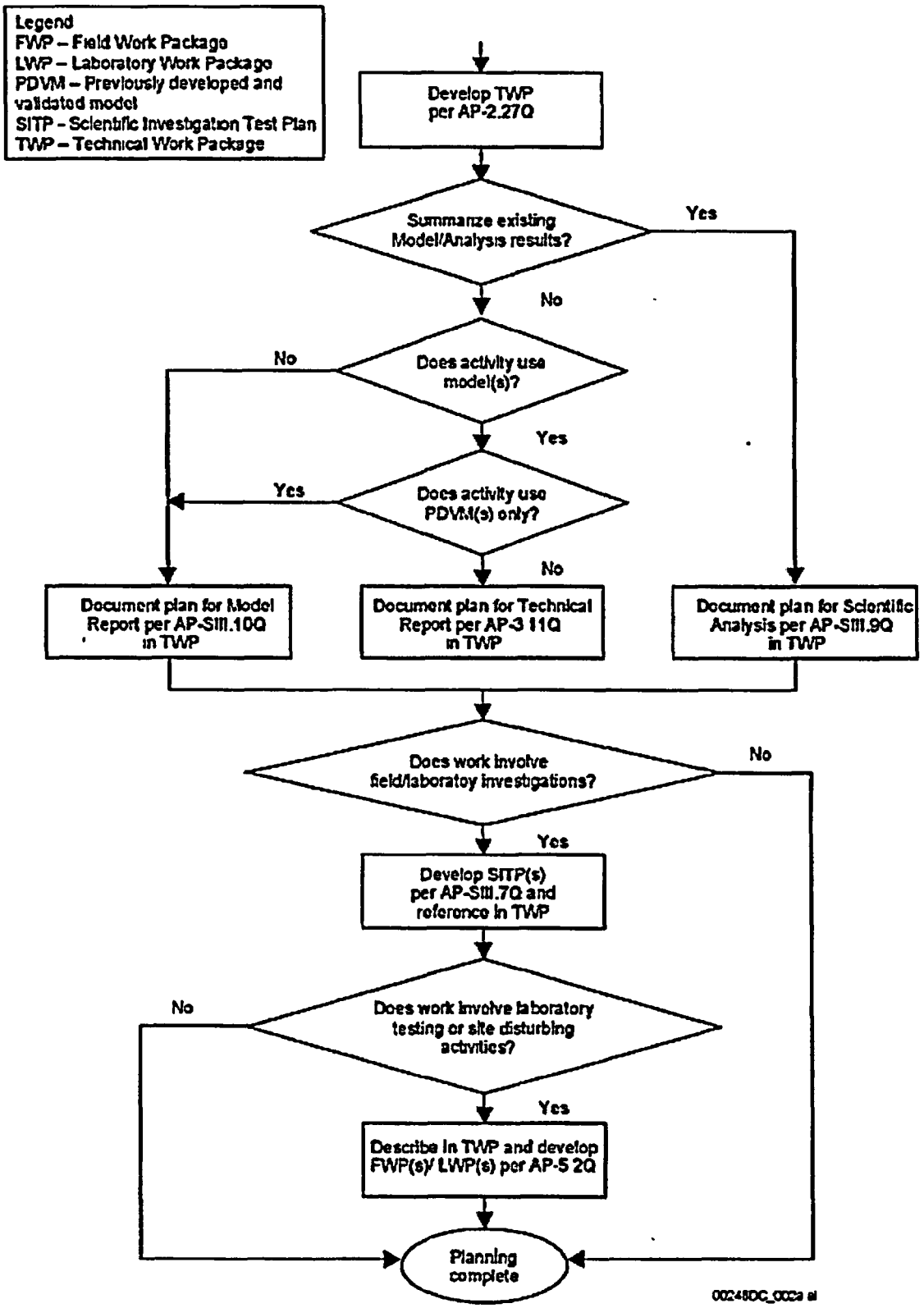

Figure 2-1. Typical Process for Preparing Planning Documents

3. FIELD AND LABORATORY TESTING

This section describes the processes underlying an approved TWP to successfully implement a proposed test in compliance with QARD and Integrated Safety Management (ISM) requirements. These separate, but related, processes are 1) development of a controlled, implementing document; 2) work authorization/control; and 3) field implementation. Information on test planning is provided in Section 2. Key processes for conducting field and laboratory test activities are shown in Figure 3-1.

3.1 IMPLEMENTING DOCUMENTS FOR TESTING

QARD criterion 5 requires work to be performed in accordance with controlled implementing documents. Scientific investigations at the Yucca Mountain Site Characterization Project (YMP) use FWPs and/or LWPs developed and controlled in accordance with AP-5.2Q as the implementing document. Development of a FWP/LWP for a particular testing activity is the responsibility of a Project Engineer (PE) assigned by the BSC Test Coordination Office. An FWP/LWP establishes roles/responsibilities, workscope description, applicable procedures, and implementing controls/requirements integrated between the various disciplines/departments and other Project Participants on the YMP program. These implementing controls/requirements can be generally categorized as follows:

- Project requirements:
  - AP-2.27Q Technical Work Plan (see Section 3.3)
  - AP-SIII.7Q Scientific Investigation Test Plan (see Section 3.4)
  - AP-5.2Q Testing Work Packages
  - AP-2.23Q Work Request/Work Order Process.
- PI requirements:
  - Test bed construction concept and methodology
  - Access requirements
  - Data collection needs/requirements
  - Planned Tracer, Fluid, and Material (TFM) use
  - Other PI test-related needs/requirements.
- QARD requirements:
  - Technical procedure and/or scientific notebook use
  - Software management
  - Control and management of electronic data
  - Sample collection and control
  - M&TE calibration requirements
  - Record responsibility
  - Submittal of data to the Technical Data Management System (TDMS).

- Determination of Importance Evaluation controls – Q controls resulting from evaluations related to:
  - Test interference issues
  - Potential waste isolation concerns
  - Approval of TFM use for a planned testing, construction, design or Operations and Maintenance (O&M) activities and TFM reporting responsibility.
- Land Access and Environmental Compliance requirements:
  - DOE land access authorization based on existing Right-of-Way-Reservation (ROWR) agreements and Real Estate Operations Permits (REOPs)
  - Archeological and biological pre-activity survey requirements for planned site-disturbing activities
  - Environmental stipulations for protection of the environment and endangered species
  - State of Nevada permit requirements related to existing Air Quality, Underground Injection Control (UIC), and water use and discharge permits.
- Safety and Health requirements:
  - Safety and Health review with hazard analysis and mitigation for the scope of work planned
  - Job Safety Analyses
  - Medical Needs Analyses
  - Site access and safety-related training requirements
  - Hazardous material use, transportation, and control.
- Construction and Site Operation requirements:
  - Engineering or design requirements
  - System, Structure, and Component (SSC) facility requirements
  - Constructability and craft support requirements
  - Other site support requirements/interfaces (e.g., Ranch Control, medical support, logistic support).

Careful integration and coordination of these aspects of the Program along with clear definition of workscope, roles, and responsibilities is a key to the ultimate success of a proposed testing program in a nuclear culture.

3.2 WORK AUTHORIZATION/CONTROL

Operations authorization is a key principle of the Integrated Safety Management System used on the YMP to accomplish physical work activities. AP-2.23Q, *Work Request/Work Order Process*, is the procedure used on the YMP to authorize this work. Approved work authorization documents produced via the AP-2.23Q process include Work Instructions/Work Orders specific to the individual or group of individuals performing key tasks under the umbrella of the overall scientific investigation. Construction and craft support work activities supporting a testing activity are authorized via AP-2.23Q Work Orders developed under the responsibility of Site Operations planners. Scientific work activities supporting a test are authorized via AP-2.23Q Work Instructions developed under the responsibility of the Test Coordination Office. Worker involvement in the development of these written instructions is necessary to identify efficient and safe methods to accomplish a given workscope based on the worker's areas of individual expertise.

Key attributes of all AP-2.23Q Work Instructions/Work Orders authorizing work include the following:

- Workscope
  - Identification of workscope to be performed by the individual or group of individuals
  - Identification of a Person-In-Charge for the work activities
  - References to be used in accomplishing the work activities, including procedures, FWPs, standards, and criteria
  - Equipment or special tool requirements
  - Materials/quantities required
  - Work location
  - Attachments such as Job Safety Analyses, drawings, vendor manuals, etc.
  - Applicable permits required to perform the job activities.
- Special information such as sequence of work activities, notifications, or other relevant information

- Task Steps
  - Identification of task steps required to perform the work activity
  - Acceptance criteria, as applicable.
- Hazard identification and mitigation(s) specific to the work activities being performed
- Special qualifications or training requirements
  - Standard training requirements for performing physical work activities at YMP surface-based sites include Site Access Training (SAT) and American Red Cross First Aid/CPR training. Additional training required for underground access to the Exploratory Studies Facility (ESF) includes General Underground Training (GUT), Respiratory Protection training, and Hearing Conservation training. A summary of the standard training requirements and the associated safety equipment required can be found in Section 11.2 of the "ES&H Electronic Manual" located on the BSC Intranet on the "Working Safely/ISM" web page
  - Special training requirements for specific work activities (e.g., laser safety, scaffolds/ladders, electrical safety, lockout/tagout, confined space entry, radiological worker)
  - Special qualifications required (e.g., certified welder, licensed water-well driller).
- Employee feedback and/or comments.

3.3 FIELD IMPLEMENTATION

Upon completion of test planning and implementation documentation, and work authorization requirements, testing activities are ready for implementation in the field. Key components of all successful YMP field testing programs include, but are not limited to, the following items. In addition, implementation of the test activities often involves scientific software (AP-SI.1Q), scientific notebooks (AP-SIII.1Q, *Scientific Notebooks*), records maintenance (AP-17.1Q, *Record Source Responsibilities for Inclusionary Records*), and data submittal (AP-SIII.3Q, *Submittal and Incorporation of Data to the Technical Data Management System*), which are described in detail in Sections 6, 7, and 10, respectively.

Calibration of M&TE–A prerequisite to the use of M&TE for Q measurements and data collection activities is calibration of the instrument(s) prior to data collection activities, and at regular intervals, to ensure the instrument(s) are capable of the accuracy required by the test. AP-12.1Q, *Control of Measuring and Testing Equipment and Standards*, is the Project standard procedure used for M&TE calibration control. Vendors used for M&TE calibrations must be qualified under an approved QA program and listed on the Project's "Qualified Supplier List." Several vendors are currently qualified for M&TE calibration for the YMP. Regardless of the vendor used, an approved Statement of Work (SOW) (i.e., Statement of Quality and Technical Requirements) must accompany the procurement documents and specific instrument(s) to the calibration laboratory. Development of the SOW and procurement documents for calibration services should be coordinated through the Engineered Barrier Systems (EBS) or Natural Barrier

Systems (NBS) procurement coordinators and BSC Procurement. Upon receipt of M&TE back from the calibration laboratory, an Acceptance Report for Calibration Services must be completed prior to use in accordance with AP-7.7Q, *Acceptance of Items and Services.*

Records Responsibility–Inclusionary records generated as a result of the implementation of SITPs FWPs/LWPs, technical procedures, Scientific Notebooks, and other planning or implementing documents must be handled, stored, and submitted to the Records Processing Center (RPC) in accordance with AP-17.1Q.

Submittal of Data to the TDMS–Acquired or developed data resulting from testing activities must be submitted to the TDMS prior to use in Q Analyses, Models, or Calculations. Submittal of data is accomplished using AP-SIII.3Q, *Submittal and Incorporation of Data to the Technical Data Management System.*

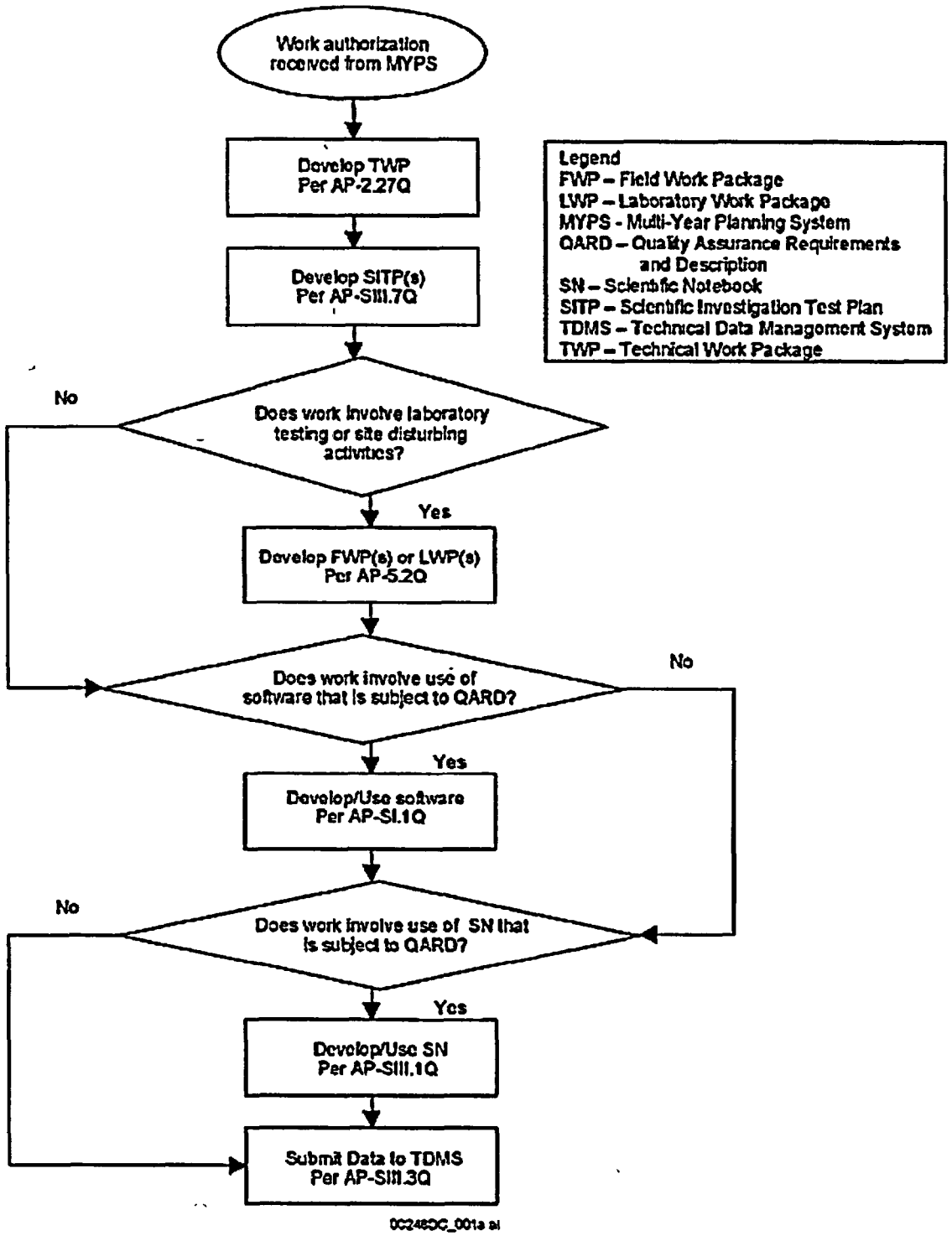

Figure 3-1. Typical Process for Field and Laboratory Testing

4. CONTROL OF INPUTS

This section describes the method for maintaining a record of all requirements, codes, standards, and other technical product inputs to the License Application (LA), Final Environmental Impact Statement (FEIS), and Total System Performance Assessment (TSPA) products. AP-3.15Q, *Managing Technical Product Inputs*, defines the procedural requirements for technical product inputs, including data and other technical information (such as design information) that can be used as inputs. The procedure applies to both Q and non-Q technical products. Additional guidance is described in the following sections.

4.1 INFORMATION FLOW

The selection and use of proper technical product inputs requires careful coordination and record keeping to maintain traceability of the source and quality of the information. A number of procedures are used in conjunction to ensure that technical product inputs are properly used and tracked and to ensure that impacts due to changes in these inputs are assessed and documented. The following paragraphs describe these processes and provide an overview of their relationship in accomplishing this task.

The development of technical products is controlled in accordance with:

- AP-SIII.10Q for establishing the responsibilities and process for preparing models
- AP-3.11Q for establishing the responsibilities and processes for preparing technical reports
- AP-SIII.9Q for establishing the responsibilities and process for preparing scientific analyses
- AP-3.12Q for establishing the responsibilities and processes for preparing design calculations and analyses.

Each of these procedures invokes AP-3.15Q to track the status of technical product inputs. AP-3.15Q establishes responsibilities and processes required to capture, track, and status technical product inputs, to be verifieds (TBVs), Unresolved Reference Numbers, and Library Tracking Numbers. The processes defined in AP-3.15Q require 1) evaluation that the input is correct, and 2) tracking of values that need to be evaluated further before being used in LA. (See Figure 1-1 for an overview of these processes).

In addition, a process for documenting the impact of changed inputs on technical products is provided. If the input is technical information (from an uncontrolled source), it can only be used as an assumption until the information is incorporated into a controlled source in accordance with project procedures. If input is data, then it is retrieved from the TDMS. Data that are directly relied upon to address safety and waste isolation issues must be qualified from origin, accepted, or undergo qualification using the process established in AP-SIII.2Q.

AP-SIII.2Q establishes the responsibilities and processes for qualifying data. AP-SIII.2Q provides the requirements for use of information from sources external to the project (i.e.,

journal articles, books, accepted data [fact]). Information from outside the Project (i.e., book, journal article) must be placed in the Technical Information Center, whether it is used as reference or input.

4.2 INPUT LISTS

Input represents information that, if changed, may alter the results or conclusions of the technical product. Appropriate inputs include, but are not limited to:

- Requirements documents
- Technical reports
- Analyses
- Calculations
- Data (from the TDMS)
- External references
- Testing work packages
- Interface control documents
- Information Exchange Drawings (IED)
- Software.

The originator should obtain all data from the TDMS database, accessible on the BSC Intranet. The data tracking number (DTN) provided by the TDMS with the data will be listed in the reference section of the document and in Block 2 of the DIRS, which is an electronic database accessible on the BSC Intranet used to track the inputs. Technical information refers to the information that is not subject to entry and control by the TDMS database. Technical information may consist of conclusions, methods, design-related parameters, and other similar types of information. Technical information that is used as a direct input should be obtained from a controlled source as defined in AP-3.15Q. Technical information can also be used as 1) justification for an assumption that is fully justified within the technical product; 2) support for an assumption that requires further confirmation (i.e., tracked as TBV); 3) corroborating information; or 4) a reference only (e.g., when identifying previous work on a topic). If the technical information (e.g., design information) is not available from a controlled source (e.g., a system description document), the originator should initiate a request for technical information as described in AP-3.15Q.

4.2.1 Use of Qualified and Unqualified Data

All data that are directly used in a Q analysis or model must be qualified. Data collected using project procedures approved prior to June 30, 1999 are considered unverified (although they may be qualified). If qualified data are used to support a Principal Factor (defined in AP-3.15Q, Attachment 1) and were collected prior to June 30, 1999, the DTN must be confirmed using the checklist in AP-3.15Q. The "Verification" section of the Automated Data Tracking entry will indicate whether this has already been done.

Unqualified data may only be used in the following manner:

- To Corroborate Qualified Data–Unqualified data can be used to increase confidence in a qualified data set. This can be useful when the qualified data are based on a small number of measurements and there are a large number of unqualified measurements. When used in this manner, the unqualified and qualified data sets cannot be merged and must be kept separate. The values directly used in the analysis must come from the qualified data. The unqualified data are only used to provide additional confidence about the representativeness of the qualified data.

- To Validate Models–Unqualified data can be used to validate models and their output. The unqualified data are considered corroborative information in this use.

- To Corroborate Assumptions–Unqualified data can be used to justify or corroborate an assumption on the parameter value. The assumed value can be based on unqualified data from the site, analog information from other locations, literature sources, or other similar information. The assumption would state that the assumed value(s) is believed to be representative of site conditions based on the sources cited. The unqualified data or information are cited in the assumptions section of the document. However, the assumption (not the unqualified data) is cited at the point where the assumed value is used in the document.

- When the Analysis is Insensitive to the Data Used–If it can be demonstrated that the results of the analysis are insensitive to the input value used, then unqualified data may be used as source for that input value.

- If the investigator determines that unqualified data must be used as a direct source for the analysis, then the data must be qualified in accordance with AP-SIII.2Q, *Qualification of Unqualified Data and the Documentation of Rationale for Accepted Data.* Qualification using this method qualifies the data for appropriate use by any investigator on the Project.

4.2.2 Use of TBVs

If unqualified, uncontrolled, or unconfirmed preliminary information is used, a TBV will be assigned to indicate the input status in the DIRS during technical product development until the input information is qualified, controlled, or confirmed. Investigators requesting a TBV will be expected to supply detailed planning and schedule information for resolving the TBV. The Responsible Manager for the technical product is committed to resolving all TBVs before the time that fully qualified technical products are required (e.g., LA).

Once the input source is approved and in a controlled source, the temporary TBV designator is removed and replaced with the approved input information in the DIRS. At that time, an impact review of affected technical products is performed, as described in Section 7 of this manual. If the TBV resolution results in a change in a technical product, the document should be revised or reissued as an Interim Change Notice (ICN).

Before the document is submitted for checking, the originator must input required information not already in the DIRS database into DIRS and inform Reference Control that the references require verification. This will ensure that the references are properly identified and retrievable during checking and will allow Reference Control to verify the references in parallel with document production.

4.2.3 Use of Assumptions

AP-SIII.9Q and AP-SIII.10Q allow the use of assumptions provided rationale is given for their use. In cases where an assumption is supported by a reference, the reference is considered corroborating information. The input status of the referenced material in the DIRS is considered "N/A - Corroborative Information." Assumptions should be fully justified by arguments in the technical product and not require further confirmation. Consequently, where assumptions are not adequately justified by the rationale presented in the analysis/model, the assumption should be tracked as a TBV in accordance with AP-3.15Q. An assumption that is justified for its intended purpose and supports the current revision/ICN of the document does not require a TBV number even though additional work is planned to support future revisions/ICNs of the document.

4.2.4 Use of the Reference Information Base and Other Reference Databases

Data from the Reference Information Base (RIB) should only be used if the entry indicates that the RIB data are qualified. If the data in the RIB entry are not qualified, then the RIB item should be used to identify those sources to the RIB entry that are qualified and may be used as sources. AP-SIII.2Q requires any RIB DTN used as a source and not qualified to be qualified before the LA.

For specific data sets and/or data files where recurrent uses exist from multiple organizations, the identification of a qualified reference database submitted to the TDMS may be made by the responsible project manager and should be utilized for all technical products. In cases where reference databases have been identified, technical products using data that are not included in the identified reference database, justification for its use should be made within the technical product consistent with the applicable procedures. This typically can apply to specific groups of data, data sets and data files within the TDMS as appropriate (e.g. the EQ3/6 thermodynamic data file for geochemical calculations, data0.ymp, would be an appropriate reference database).

4.2.5 Technical Product Output

DTNs may be identified as being technical product output. These DTNs may be used without restriction (TBVs are not carried forward into the user's document). Technical product output is assigned to DTNs that are the output from technical products that were prepared and approved under procedures in effect after June 30, 1999.

4.2.6 Accepted Data

All accepted data sources must be listed in the Accepted Data database in TDMS. Data (usually from sources external to the Project) may be considered to be accepted for use through the process outlined in AP-SIII.2Q on the Accepted Data Identification Request form. Accepted data may be used without restriction in scientific analyses and models.

4.2.7 Using the DIRS

All DTNs will be listed in Block 2 of the DIRS. DIRS sheets must be printed and submitted to the checker, and must be included as a separate record in the records package. The document originator is responsible for having the inputs entered into the DIRS database as early as possible so that Reference Control can verify the references.

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5. TECHNICAL PRODUCTS

This section describes the method of development and modification of models, scientific analyses, and technical reports. The processes of developing technical products are described with additional information on developing software and scientific notebooks provided in Sections 7 and 8 of this manual.

Development of the technical reports is described in Section 6, including model reports (Section 6.1.5) and scientific analysis reports (Section 6.1.6). It is especially important to integrate models and analyses with the Total System Performance Assessment (TSPA) model. This integration is critical to improve transparency, traceability, and consistency in the treatment of FEPs, model abstractions, alternative conceptual models, parameters, and uncertainty in the TSPA model. Appendix A summarizes the processes that will be used by TSPA to support this integration. Appendix B provides guidance related to validation of the subsystem and abstraction models that support the TSPA-LA model; and similar guidance will be developed in a separate document for the validation of the TSPA-LA model. Appendix C provides model/analyses report templates for Sections 4 (Inputs), 6 (Model Discussion) and 8 (Conclusions), and guidance related to Section 7 (Validation) of a Model Report. It is intended that these templates and guidance provide the originator resources to improve transparency, traceability, and consistency in the model/analyses documentation.

The key processes for developing and documenting formal technical products are illustrated in Figure 5-1.

5.1 MODELS

This section describes the method of development of models in accordance with AP-SIII.10Q. Models are distinct from scientific analyses (conducted in accordance with AP-SIII.9Q) in that the development of 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. Scientific analyses are documented studies that involve the application of previously developed and validated models to investigate or evaluate systems, processes, and phenomena.

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

A model is 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 (DOE 2002). Model development typically progresses from conceptual to mathematical models. Mathematical model development typically progresses from process, to abstraction, and to system models. In the context of the TSPA-LA model development and documentation, a computational model is a tool developed to provide a solution to the mathematical model using analytical or numerical techniques. An abstraction model is the simplification of a mathematical model (component, barrier, or subsystem process model) for incorporation into the system

model. Model abstractions typically involve reduction in dimensionality, elimination of time dependence, grouping and tabulation of results from more complex models to create look-up tables, representations of a continuous process/entity with fewer discrete elements, etc.

Typically, process models are used to identify and understand important processes and relationships among them. Abstraction models ideally capture the essence of the process model important to the TSPA system model. Not all abstraction models implemented in the TSPA system model are based on underlying process models; some are directly based on data gathered through testing or scientific analyses.

The process of developing models involves nine steps. These steps are interrelated and in some cases are carried out simultaneously. There is, however, a sequential nature to the model development process.

Step 1. Define the Purpose of the Model

This important step defines the output variables or performance parameters that will be provided by the subsystem model and how these performance parameters will be used. Performance parameters correspond to output quantities that are used as input by other models or analyses. Details are provided in Section 3.3 for planning model development activities.

Step 2. Identify and Screen Potentially Relevant Features, Events, and Processes (FEPs)

This step decides what FEPs are sufficiently important to include in the model being developed. The model developer identifies the FEPs that are screened in during model development and provides a summary in the model report of how these FEPs are included. Total System Performance Assessment-Site Recommendation (TSPA-SR) screening of the FEPs will be the basis for the LA, unless modifications are justified by results of post-Site Recommendation investigations. See Appendix A, Section A.2 for further guidance on how this process will be completed for the LA. Reference to the appropriate features, events, and processes (FEP) AMR is made for those FEPs that are screened out of the model.

Step 3. Develop the Base-Case Conceptual Model

This step develops the description of the physical subsystem being modeled and its environment. The description includes a summary of included FEPs from Step 2, specification of boundary and initial conditions, geometry of the subsystem, components or features of the subsystem, physical and chemical processes occurring within the subsystem, and a description of how these processes occur and are coupled. Independent and dependent variables and parameters selected to represent these processes are specified. During the conceptual model development step, no mathematical equations are written; only conceptual issues are considered. The fundamental assumptions and simplifications employed when developing the conceptual model are stated and justified. Assumptions that are deemed conservative are explained and choices among competing assumptions are justified. In addition, if the model being developed is an abstraction model that further simplifies the representation of important processes relevant to subsystem behavior, the developer describes why the abstraction process retains a representation of the important physical and chemical processes and the relationships among them. Finally, important uncertainties related to parameters and processes are noted and discussed.

Step 4. Identify and Screen Alternative Conceptual Models

The goal of this step is to identify alternative conceptual models (ACMs) and to document the process of screening out those ACMs that are not plausible (see Appendix A, Section A.3.2). Documentation of this step provides traceable consideration of all ACMs to determine ACMs that are not consistent with the state of knowledge. This step typically overlaps with Step 3 and is used to help ensure that the base-case model is formulated such that it adequately captures the range of plausible and reasonable conceptual model uncertainty.

In this step the model developer identifies and documents potential ACMs. This activity is generally accomplished by changing assumptions or simplifications involving key parameters or processes employed in the base-case conceptual model. The identification of viable ACMs may also be accomplished by reviewing the international literature for related studies.

The second activity in this step is the screening of identified ACMs. ACMs are screened out by arguing that their representation of processes are inconsistent with the state of knowledge or using heuristic arguments to refute their plausibility (see also Appendix A, Section A.3.2). It should be emphasized when ACMs have been considered and screened out in previous model development iterations. ACMs that are not screened out in this step are further evaluated in Step 6.

Step 5. Formulate the Mathematical and Computational Model for the Base-Case Conceptual Model

This step involves two related activities, the formulation of the mathematical model and the formulation of the computational model. The first activity is to develop a mathematical model from the base-case conceptual model. The mathematical model includes complete specification of all governing equations (e.g., partial differential equations, ordinary differential equations, algebraic equations, or empirical relationships), auxiliary relations, boundary conditions, and initial conditions of the system. In addition, all parameters and independent and dependent variables in the equations are defined and identified as deterministic or non-deterministic.

The second activity converts the mathematical model into a computational model that can be implemented on the computer using analytical or numerical techniques.

Step 6. Formulate Mathematical and Computational Models for Alternative Conceptual Models not Screened Out in Step 4.

In Step 4, ACMs are considered and screened for quantitative evaluation. If an ACM could not be screened from quantitative evaluation, then it is necessary to develop the mathematical and computational models for the ACM. In this step, Step 5 is repeated for each ACM. Note that in many cases an ACM will be a variation of the base-case model and therefore similar to the base-case model in many respects. This step emphasizes the key differences between the ACM and base-case model, uses notation consistent with the base-case model, and defines those variables and parameters not previously defined. See Appendix A, Section A.3.3 for further discussion of the approach for the LA.

Step 7. Develop Inputs for Base-Case and Alternative Models

This step develops the inputs necessary to implement the computational models for their intended purpose. Input values are specified for all boundary conditions, initial conditions, and parameters in the mathematical model. Typically, input values fall into two categories, fixed parameters (i.e., constant or known spatially and temporally) and uncertain parameters. Uncertain parameters are assigned multiple values because of imprecise knowledge about the parameter. Quantification of parameter uncertainty is handled by developing quantitative parameter distributions that act as a representation of the distribution of possible values that could be realized for a given parameter. Parameter uncertainty includes both reducible (epistemic) uncertainty and irreducible (aleatoric) uncertainty. The reducible uncertainty is formerly called varaibility in process models of geologic systems.

Step 8. Comparison of Base-Case and Alternative Conceptual Models

The objective of this step is to determine if an ACM gives significantly different behavior or performance as compared to the base-case model. This quantitative comparison is relevant to the model purpose and therefore focuses on comparing output or performance parameters that are specified in the first step of the model development process. This comparison is made for a sufficient time period and number of locations in the subsystem.

Step 9. Validate Base-Case Model and Alternative Models that are Implemented in TSPA-LA

Demonstrating regulatory compliance will involve the use of complex predictive models that are supported by data from field and laboratory tests, natural analog studies, and by expert judgement. It is essential that model documentation supporting compliance arguments 1) address applicable regulatory requirements; 2) be scientifically defensible; and 3) be traceable and transparent.

Validation, or confidence building, is a means to ensure that the simulated system behavior is sufficiently consistent with observed behavior to give confidence in model outcomes. The degree of confidence required for each model depends on the model's specified use and relative importance to performance. The minimum threshold to be achieved in validating each model is to establish an adequate scientific basis for regulatory credibility. Guidance for determining the level of model importance is provided in Appendix B.

In this important step, the model developer must validate the model for its intended purpose as defined in Step 1. AP-SIII.10Q describes the options available for validating a model. In general, the model developer uses technical bases established in each step of the model development process previously described to build confidence in the model. Emphasizing the following factors in each step of the model development process reinforces confidence:

- A credible scientific and engineering approach was taken to a) capture future state (aleatoric, see definition in Section A.1.1 of Appendix A), parameter, and model uncertainties; b) evaluate and interpret the data; and c) formulate defensible assumptions and simplifications.

- When additional information is collected, the uncertainties in the model are expected to reduce and the range of model output is expected to narrow.

The PA project has identified three levels of model importance and corresponding validation guidelines commensurate with each level of model importance (see Appendix B). The levels of model significance are defined based on TSPA sensitivity analyses and conclusions presented in prioritization report *Risk Information to Support Prioritization of Performance Assessment Models*, TDR-WIS-PA-000009. The three levels of model significance and corresponding validation guidelines are described in Appendix B. In addition, Table B.1-1, summarizing model significance by model component, is presented along with model significance summaries. This information is provided to help Responsible Managers and Model Developers ensure that the degree of confidence required for each model is consistent with our current understanding of the model's relative importance to performance. It is important to note that models summarized in Table B.1-1 are TSPA component models that provide input directly to the TSPA system model. Many project models do not provide input to the TSPA system model directly, but provide input or scientific bases to the component model. These underlying models should meet validation guidelines consistent with the TSPA component models that they support.

The responsibility for adequate model planning, documentation, and validation lies with the Responsible Manager. Authority to complete activities may be delegated, but the responsibility for the quality and completeness of the final product(s) may not.

The CSO oversees the development and execution of model validation activities. The responsibilities of the CSO are:

1) Provide mentoring and assistance during planning, development and validation of modeling activities.

2) Review all TWPs containing model validation plans to ensure that the model's relative importance to safety is identified and is appropriate for the model's intended use, and to ensure that the proposed validation plans and criteria are adequate to obtain the level of confidence required for the model

3) Review Subsection 6.1 of model documentation to ensure that the needed level of confidence has been obtained and that evidence is provided showing validation criteria are met.

5.2 SCIENTIFIC ANALYSES

This section describes the method of development of scientific analyses in accordance with AP-SIII.9Q. A scientific analysis 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 present scientific analysis. A scientific analysis may also involve numerical manipulations if 1) the choice of method for such manipulations is

evident from standard practice and does not require justification and 2) use of the analysis results in licensing does not require the additional confidence that would be attained by documenting the work as a model. Furthermore, AP-SIII.9Q also controls performance assessment calculations and analyses (e.g., abstractions of scientific analyses) that meet the definition of a scientific analysis and do not meet the definition of a mathematical model.

Other than the lack of requirement for model validation, scientific analyses are subject to similar requirements to models in their planning and documentation processes. Guidelines are provided in Section 2.2 for the planning and in Section 6.1.6 for the documentation of scientific analyses.

5.3 TECHNICAL REPORTS

Technical reports are fact-based documents used to present results or conclusions of scientific investigations or to summarize the more formal models prepared in accordance with AP-SIII.10Q. Technical reports are prepared in accordance with AP-3.11Q. Technical reports include requirements documents, design reports, and reports of major studies not otherwise covered by other procedures. AP-3.11Q does not permit the use of software or the development/documentation of new calculations, analyses or models within the AP-3.11Q technical report.

Technical reports are used to document, in a narrative format, compliance with regulatory requirements; specify overarching, top level design and licensing requirements, assumptions, and criteria; express preliminary technical concepts or ideas; assemble related ideas into a single document; or summarize the current state of knowledge on a scientific topic or suite of topics (e.g., total system evaluation). A technical report can consist of everything from a simple technical white paper to a multi-volume project deliverable.

Technical reports are not intended for use as a direct feed for detailed design development, construction, fabrication, or procurement, although they can be referenced. Because technical reports are less structured than analyses and models, the procedure allows for certain flexibility of format and content that is not provided for in analyses, calculations, and models, although the requirements for technical accuracy, traceability, and defensibility are the same.

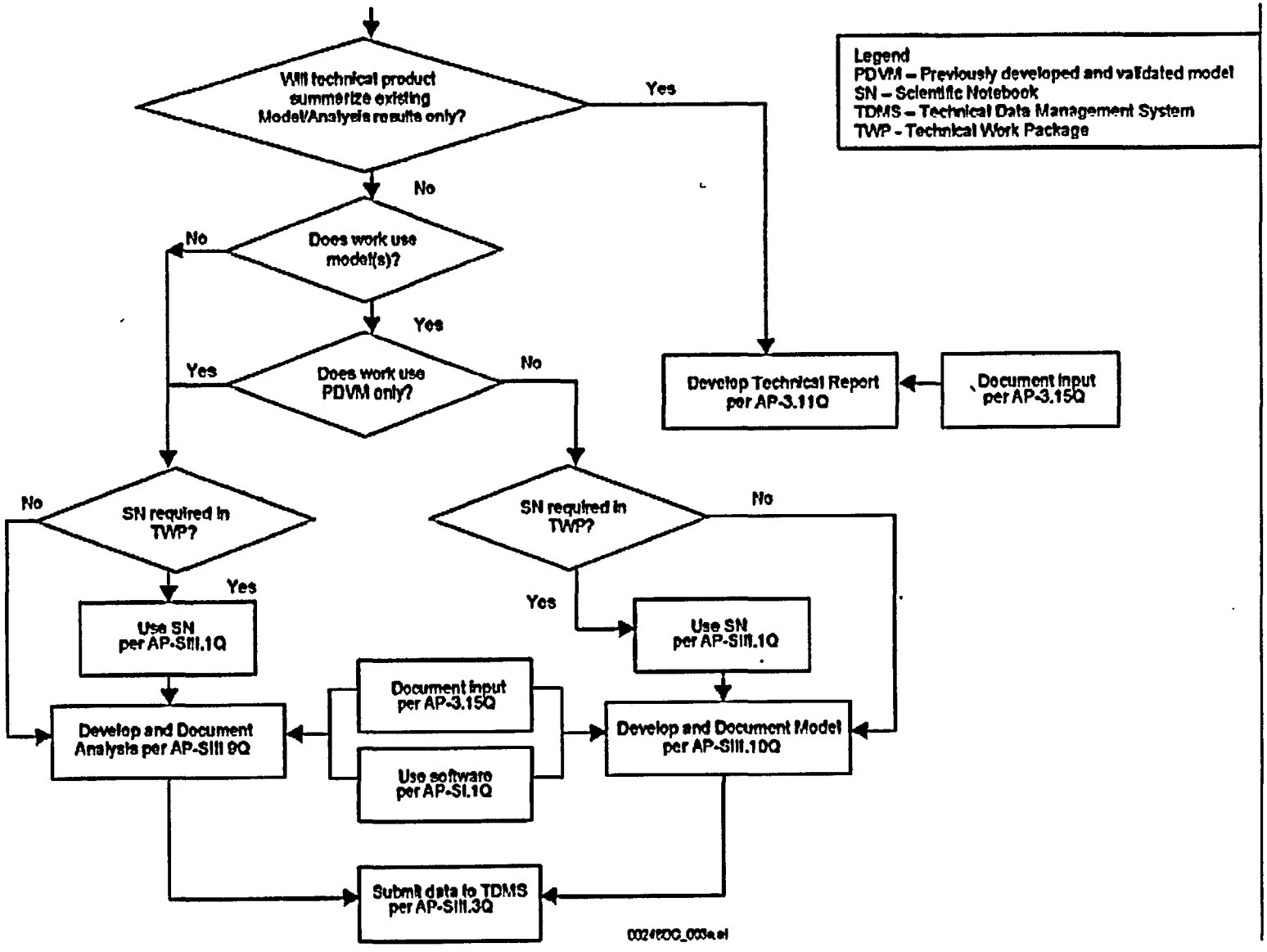

Figure 5-1. Process for Developing and Documenting Formal Technical Products.

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6. DEVELOPMENT OF TECHNICAL PRODUCTS

6.1 PRODUCT PREPARATION

Development of models, scientific analyses, or technical report involves the preparation, checking, review, approval, and if applicable, revision of the report. Figures 6-1 and 6-2 illustrate the checking and review processes. The following sections describe the processes that are common to the preparation of all technical products. The aspects that are unique to the documentation of model reports (AP-SIII.10Q) and analysis reports (AP-SIII.9Q) are further described in Sections 6.1.5 and 6.1.6, respectively.

As a first step in developing the report, the originator will obtain a DI from Document Control in accordance with AP-6.1Q. DIs should be requested from Las Vegas Document Control by e-mail. The information that must be provided with all DI requests to Document Control is detailed in the online DI instructions, available through the BSC home page. Additionally, if the work will modify an existing AMR or technical report, the originator should obtain an electronic copy of the controlled document from Las Vegas Document Development and Production.

6.1.1 Version Control

The originator will establish version control in the following manner:

- When initiating a new document, indicate the revision designator with an alphanumeric draft indicator as REV 00A. Starting with REV 00A for the first check or review copy, the alphanumeric draft indicator advances at every draft that will produce a distinct record copy (one that will be submitted with the records package). The REV 00B draft could be a back-check copy or a review copy, the REV 00C draft could indicate another review copy, and so on. Preliminary working drafts and comment resolution drafts may be used, but they should include appropriate notation to distinguish them from procedurally required records. The final, approved version will omit any alphanumeric draft indicator and will appear as REV 00.

- Subsequent revisions advance the revision number and begin alphanumeric drafts over at "A."

Therefore, in-progress versions of documents, including check copies and review drafts are always designated with an alphanumeric draft indicator (e.g., REV 00A, REV 01A, REV 03D), and approved documents only show the final revision designator without any draft indicator (e.g., REV 00, REV 04).

6.1.2 Document Preparation

The originator for a technical document is the person who ensures that the technical report is complete and accurate, meets the objective, and is written in accordance with the development plan. The originator's approval signature denotes that the following technical report attributes are adequately satisfied:

- The technical document is in compliance with applicable requirements, including technical, regulatory, and format requirements.
- Positions and statements concerning issues addressed by the technical report are supported by the required quality of information and documentation.
- Positions and statements are clear and unambiguous.
- Positions and statements have adequate basis and the underlying rationale is clearly described.
- Potential safety and environmental concerns are fully addressed.
- Data is accurate and traceable to the source.
- Unknown, unverified, or conditional information is clearly identified.
- The technical report is as complete and self-contained as possible and contains complete and validated references.

6.1.3 Writing Quality and Consistency

The originator should state positions and conclusions clearly and transparently and ensure that positions and conclusions are adequately supported. The technical report should be as complete and self-contained as possible. Each potential safety and environmental concern raised by the technical report should be fully addressed. The originator must be aware of alternative or contradictory views and fully address these in the technical report if not adequately addressed in the cited references. In a similar vein, the originator must be aware of contradictions in referenced models, analyses, or data and fully address these in the technical report if not adequately addressed in the cited references. The originator must state underlying assumptions and the justification for their use clearly and unambiguously. The originator must ensure that the editorial quality (e.g., structure, format, tone, consistent use of measurement units, and presentation of graphics) conforms with the standards of the Style Manual (CRWMS M&O 1999) to allow for publication or release to the public, as appropriate.

While preparing the preliminary draft, the originator should interface with other disciplines, subject matter experts, and functional groups to coordinate interfaces and resolve technical positions and conclusions.

6.1.4 Attachments and Electronic Media

Lengthy attachments and computer output should be stored as electronic media and included as an attachment. Electronic media attachments should include a list of files, file name, date, and time, and file size. The preferred method, however, is to obtain a DTN for the data contained in the electronic media attachments. The originator shall prepare any other electronic media in accordance with AP-17.1Q for submittal to the RPC. This requires submission of a printout or data stored on a compact disk.

6.1.5 Model Reports

This section describes aspects of documentation that are unique to the activities performed in accordance with AP-SIII.10Q. Products of FEP activities and abstraction processes that meet the definition of mathematical models should be documented in accordance with AP-SIII.10Q. AP-SIII.10Q does not permit internal qualification of data. Data requiring qualification should be processed via AP-SIII.2Q.

Modeling results that meet the following criteria should be submitted to the TDMS in accordance with AP-SIII.3Q, *Submittal and Incorporation of Data to the Technical Data Management System*:

- The results are developed data not currently residing in the TDMS.
- The results are developed data that will be used to replace or supersede data that are in the TDMS.
- The results cause the status of the data to change (e.g., used to remove a TBV).

Use of software during model development and validation should be documented in accordance with AP-SI.1Q and Section 3 of the Model Documentation Outline in AP-SIII.10Q.

Models and model documentation shall be developed in accordance with the Model Documentation Outline in AP-SIII.10Q. All sections of the Model Documentation Outline are to be addressed. If any sections are not applicable, justification must be provided in the model documentation. Additional information is provided for Sections 4, 5, and 6 of the Model Documentation Outline:

- Inputs with references to source documents must be identified in Section 4 of the model documentation. Citations shall be as specific as possible, including page numbers or table numbers. The input sources must be identified on the DIRS, as described in Section 4 of this manual. Inputs that have bounds, conditions, or values that must be verified are identified as TBV. The method for identifying, maintaining, and releasing these items is defined in AP-3.15Q. Items based on unqualified data or unconfirmed input carried into the output documents will be identified and maintained in accordance with AP-3.15Q. Ensure that the disposition in the documentation matches the TBV description form at the time of document approval. In models that contain TBVs, the TBV identification numbers should be cited in the Remarks section of the cover sheet for easy reference.

- Adequate explanations must be provided in Section 5 of the model documentation for the selection of all assumptions, including justification for use in the model document. State whether confirmation is required for any assumption. Justification must be provided for stating that an assumption does not require future confirmation. A statement such as "confirmation of this value is not required" is not an adequate explanation. Additionally, any assumption contained in upstream documentation that impacts the present model must be documented and discussed in the present model documentation.

- The model discussion, Section 6 of the model documentation, should include a description of both the conceptual model and the mathematical model. The discussion should also include uncertainties, alternate models, model testing, and boundary/initial conditions. Refer to the Model Documentation Outline, Section 6, in AP-SIII.10Q for additional requirements.

6.1.6 Scientific Analysis Reports

This section describes aspects of documentation that are unique to the activities performed in accordance with AP-SIII.9Q. Products of FEP activities and abstraction processes that meet the definition of scientific analyses (i.e., do not meet the definition of mathematical models) should be documented in accordance with AP-SIII.9Q.

The Scientific Analysis Outline in AP-SIII.9Q requires references to be documented in the Section 8 of the scientific analysis documentation.

Scientific analyses documentation shall be developed in accordance with the Scientific Analysis Outline in AP-SIII.9Q. All sections of the Scientific Analysis Outline are to be addressed. If any sections are not applicable, justification must be provided in the scientific analyses documentation. Additional information is provided for Sections 4, 5, and 6 of the Scientific Analysis Outline:

- Inputs with references to source documents must be identified in Section 4 of the scientific analysis documentation. Citations shall be as specific as possible, including page numbers or table numbers. The input sources must be identified on the DIRS, as described in Section 4 of this manual. Inputs that have bounds, conditions, or values that must be verified are identified as TBV. The method for identifying, maintaining, and releasing these items is defined in AP-3.15Q. Items based on unqualified data or unconfirmed input carried into the output documents will be identified and maintained in accordance with AP-3.15Q. The disposition in the documentation must match the TBV description form at the time of document approval. In scientific analyses that contain TBVs, the TBV identification numbers should be cited in the Remarks section of the cover sheet for easy reference.

- Adequate explanations must be provided in Section 5 of the scientific analyses documentation for the selection of all assumptions, including justification for use in the scientific analysis. State whether future confirmation is required for assumptions. Justification must be provided for stating that an assumption does not require future

confirmation. A statement such as "confirmation of this value is not required" is not an adequate explanation. Additionally, any assumption contained in upstream documentation that impacts the present study must be documented and discussed in the present scientific analyses documentation.

- The scientific analysis discussion, Section 6 of the scientific analyses documentation, should include a description of the conceptual bases for the study. The discussion should also include uncertainties and the appropriateness of the use of previously developed and validated models to complete the present scientific analyses. Refer to the Scientific Analysis Outline in AP-SIII.9Q for additional discussion requirements.

Scientific analysis results that meet the following criteria should be submitted to the TDMS, in accordance with AP-SIII.3Q:

- The results are developed data that do not currently reside in the TDMS.
- The results are developed data that will be used to replace or supersede data that are in the TDMS.
- The results cause the status of the data to change (e.g., used to remove a TBV).

Use of software should be documented in accordance with AP-SI.1Q and Section 3 of the Scientific Analyses Outline in AP-SIII.9Q.

6.2 CHECKING OF TECHNICAL PRODUCTS

The technical and compliance check of a document will be coordinated by the Responsible Manager or document Lead. The compliance check is completed by the Quality Engineering Representative (QER), who will be assigned to the product by BSC Quality Engineering (QE). The check package must be assembled as described in Section 7.2.1 of this manual. Originators are encouraged to use the optional checklists appropriate for their products when preparing product documentation and assembling the check package. These checklists are found on the Automated Forms System (AFS) on the BSC Intranet. The QER and checker are encouraged to use the appropriate optional checklist to facilitate the checking process. Checking must be complete prior to initiating interdisciplinary review.

To provide evidence that the computer data have been checked, the checker will note on the cover sheet of the check copy that the computer data referenced in the document were checked and that input data are accurate and traceable to the source, then sign and date the cover sheet.

If a hardcopy of the electronic media or a lengthy attachment is included in the check package, the checker shall note on the cover sheet of the check copy suggesting that the material be submitted as a separate record and included as a reference.

The QER and the checker will review the modified technical product documentation after the interdisciplinary review has been completed to ensure that no adverse impacts have resulted from comment resolution.

Additional information on product checking is provided in the following sections.

6.2.1 Assembly of Technical Products for Discipline Check

Originator:

- An optional BSC checklist, located in the AFSweb of the BSC Intranet, may be completed to ensure that the document is ready for checking.

- For documents subject to the requirements of the QARD, prepare two copies for checking. (For technical products not subject to the requirements of the QARD, a compliance check is not required.) Mark the cover sheet of one copy of the technical product (if applicable) as "CHECKER CHECK COPY" and the other copy as "QER CHECK COPY."

- Ensure that the revision designator shown on the CHECKER CHECK COPY or the QER CHECK COPY DI and revision history is alphanumeric (e.g., REV 00A).

- Assemble Checker and QER check packages and submit the packages to the assigned technical and compliance checkers. (For technical products not subject to the requirements of the QARD, a compliance check by a BSC QER is not required.) The check packages should include:

  - A copy of the document and DIRS report marked "CHECKER CHECK COPY" or "QER CHECK COPY"

  - A copy of the TWP

  - For Level 3 deliverables, a copy of the Multi-Year Planning System deliverable description, including completion and evaluation criteria for the document

  - For AP-3.11Q documents, a copy of the AP-3.11Q Checking and Approval Record, completed to appropriate level

  - Any other supporting documentation that is not readily available to the Checker.

6.2.2 Selection of A Checker

Document Lead/Responsible Manager:

Select qualified personnel to complete the technical check for technical documents in accordance with the appropriate procedures. Contact BSC QE to coordinate the completion of the compliance check.

Technical checkers must have technical qualifications similar to the originator of the product they are checking. Checkers must have satisfactorily completed Checker Training. In addition, they must be independent of the work (checkers may not be assigned to check work they

performed). However, there is no restriction preventing a checker from checking a technical product that uses inputs the checker previously helped develop.

Multiple checkers may be assigned to a technical product. This may be needed due to the nature of the technical information, size and complexity of the document, or the need for separate technical and compliance checkers. BSC QERs focus on compliance with procedural requirements; technical checkers focus on technical adequacy, accuracy, and completeness. For documents requiring multiple technical checkers, one technical checker will be designated as primary technical checker and will have responsibility for overall coordination of the team effort.

6.2.3 Technical Check of Technical Products

Technical Checker:

- Confirm the contents of the check package to ensure that all supporting information required for checking has been provided.
- Immediately notify the document Lead/Responsible Manager if:
  - You cannot complete all or part of an assigned checking task (e.g., no access to the DIRS database from a remote location).
  - You are not fully qualified to check a particular section or subject.
  - The documentation is incomplete or not ready for checking.
- Ensure the defensibility of the product.
- Check the document for completeness, technical adequacy and accuracy, and compliance with all applicable governing procedures and processes. An optional BSC Checklist, found on the AFSweb of the BSC Intranet, may be completed to facilitate the check process.
- If multiple checkers are assigned, use separate check copies for each checker or initial and date each comment on a single master check copy. Each checker should identify which sections they have checked in a note on the cover sheet or title page. In addition, each checker will complete and sign an appropriate checklist.
- Indicate all comments clearly and legibly, in red ink or in red font electronically, on the CHECKER CHECK COPY. Indicating correct items with a yellow highlighting marker (a single yellow line through an item will indicate that a sentence, paragraph, page, or detail is correct) is recommended but not mandatory. A comment continuation sheet may be used, if necessary, but there must be traceability between the CHECKER CHECK COPY and the comment continuation sheet. Mandatory comments shall be denoted by asterisk (*).
- Print "checked by" and initial and date the document adjacent to the "CHECKER CHECK COPY" label on the cover sheet. If multiple checkers are used, each checker

should initial and date and make a notation on the CHECKER CHECK COPY indicating which sections they checked.

- Return the Checker check package to the originator for comment resolution and incorporation. The technical checker should ensure that the originator has a clear understanding of all mandatory comments.

- Checker and the originator should confer regularly. Communication is key to the expeditious completion of checking.

QER:

- For technical products subject to QARD requirements, perform a compliance check of the document for compliance with procedural and quality requirements.

- Clearly and legibly write or mark electronically comments on the check copy of the document. Comments may be documented separately if keyed to the review copy and if comment documentation is signed, dated, and attached to the review copy. Indicate mandatory comments by asterisk (*).

- Return the QE compliance check documentation to the originator for comment resolution and incorporation.

Originator:

- Confer with the checker(s), and QER as appropriate, to resolve all comments. Propose resolutions for comments that are accepted and justification statements for those comments that are rejected, or request modified acceptance.

- If necessary, elevate unresolved mandatory comments to the next level of management of both the originator and the checker for resolution. If mandatory comments are elevated for resolution, complete documentation of the resolution must be provided on the CHECKER CHECK COPY or QER CHECK COPY.

- Modify the original document, in accordance with agreements made in comment resolution, and place a green check mark adjacent to each comment on the CHEKCER CHECK COPY or QER CHECK COPY as incorporation of resolution is completed. Justification statements, for comment resolutions that deviate from the wording of mandatory comments, should be noted on the CHECKER CHECK COPY in dark ink.

- Forward the check package with the modified document and the CHECK COPY to the checker(s), and to the QER as appropriate.

Checker and QER:

- Check the modified document by comparing to the original CHECKER CHECK COPY or QER CHECK COPY.

- Checkers will indicate acceptance of comment incorporation by signing and dating the CHECKER CHECK COPY or QER CHECK COPY. The Originator's justification statements for those mandatory comments that have been rejected or that document a modified resolution must be initialed and dated by the Checker to indicate acceptance. If more than one person checked the document, the primary checker has the discretion of checking all comment resolutions or may have the supporting checkers check their respective sections.

- If one master CHECKER CHECK COPY was used for multiple checkers, each will need to place an orange check mark adjacent to each of their comments on the initial CHECKER CHECK COPY to indicate acceptance of comment incorporation.

- Return the modified document, the entire check package or QE review package, and all other documentation to the originator.

Originator:

- Following completion of interdiscipline or impact review(s) in accordance with AP-2.14Q, determine the appropriate version designator, print or type name, and sign and date the Review Coordination record and cover sheet.

Checker and QER:

- Review the document to ensure that comment resolution and incorporation resulting from reviews has not adversely affected the document.

Checker:

- Confirm that DIRS accurately reflects the technical product input and its status.

- Confirm that tracking numbers (i.e., TBV or Unresolved Reference Number) have been assigned for non-verified inputs in accordance with AP-3.15Q.

- Confirm that all open comments from the original check have been resolved and incorporated.

- Print or type name, and sign and date the review copy.

6.3 REVIEWING TECHNICAL PRODUCTS

AP-SIII.10Q and AP-SIII.9Q provide criteria for identifying mandatory reviewers and require that all models and scientific analyses undergo AP-2.14Q review. The reviewing organization may respond to a review of models or scientific analyses with "not applicable" indicating that the reviewing organization will not be impacted by the issuance of the technical product. AP-3.11Q requires an interdisciplinary review only if other disciplines or functional areas are potentially impacted by the issuance of technical product.

Responsible Managers are encouraged to use Las Vegas Review Coordination to coordinate the review. Review criteria are based on standard review criteria and any specific criteria established during the document planning phase. Reviewers should be given a copy of the development plan or the criteria to which they are to review the document. The reviewers should also be given a copy of the review forms. The review copy should include a unique alphanumeric revision number and the cover sheet should be marked "Review Copy." Sufficient time must be allowed for a complete and adequate review, normally not less than 5 working days.

An AP-2.14Q interdisciplinary review by the following organizations must be initiated by the document Lead/Responsible Manager for models and scientific analyses documentation:

- **CSO**

- **Organizations or BSC Departments Providing Input:** Organizations (e.g., USGS or national laboratories) or departments that supplied technical input to the technical document review to ensure that the data used in the input document is the latest version, the actual data as used is accurate, the dataset is complete, and the data was used in the document appropriately and within its bounding conditions.

- **Customer Organizations for BSC Departments:** Organizations (e.g., USGS or national laboratories) or departments that use output from the technical document review to ensure that the information or conclusions developed are complete and adequate for their stated purpose.

- **Other affected or impacted organizations:** Additional reviewing organizations may be identified by the document Lead. The review documentation may be marked as "not applicable" and returned to the initiating organization if the document under review does not affect or impact the reviewing organization.

- **DOE:** Technical leads from the Office of Project Execution will review models/scientific analyses documents where appropriate.

Reviews of AP-3.11Q documentation may include any or all of the reviewing organizations identified for AP-SIII.10Q and AP-SIII.9Q reviews, as determined by the document Lead/Responsible Manager.

6.3.1 Selection of Additional Reviewer

Document Leads are strongly encouraged to use Las Vegas Review Coordination when conducting reviews. The chart provided in Table 6-1 may be used to help determine whether AP-2.14Q reviews are required by additional organizations.

Table 6-1. Identification of Additional Reviewers

Questions	If Yes, Then
Is the document a Level 3 deliverable or being developed as inputs to Level 3 deliverables, as inputs to the Final Environmental Impact Statement, or for publication?	DOE should be included as a reviewing organization
Does the document have personnel health and safety implications?	Send the document to the BSC Health and Safety organization for review.
Does the document have potential environmental impacts or affect current or future federal or state environmental permits?	Send the document to the BSC Environmental organization for review.
Does the document deal with systems, equipment or processes that will eventually be built?	Send the document to the BSC Site Construction organization for a constructability review
Does the document address open Key Technical Issue, document existing Key Technical Issue agreements/status, or agreements or potentially impact Key Technical Issue agreements?	Send the document to Licensing for review.
Does the document have any radiological components or implications?	Send the document to the Radiological and Regional Programs Department for review

The manager of the department or organization should be identified as the formal reviewer on the Review Record (available on the BSC Intranet AFS). The manager may delegate the review.

6.3.2 Instructions to Reviewers

AP-2.14Q provides a set of standard review criteria. These criteria should be carefully selected for each reviewing organization. The procedure also provides for the creation of individualized review criteria. It is suggested that Las Vegas Review Coordination be contacted to coordinate the review. Las Vegas Review Coordination will complete and send the review draft, review record, review criteria, and comment sheets to the identified reviewers. The document Lead will be asked to provide the information required to complete the forms.

6.3.3 Performance of the Review

The review draft will be identified with an alphanumeric revision designator (e.g., 00A, 00B, etc.). The concurrence draft will have the next alphanumeric revision. For example, if the review draft was 00B, the concurrence draft will be 00C, and if further changes resulted in the need for a second concurrence draft, that draft would be 00D.

Different methods for comment documentation may be chosen for the same review. For instance, if most of the reviewers are in Las Vegas, but one is in Albuquerque, the review copy markup method might be chosen for Las Vegas personnel, but an electronic method may be chosen for the one reviewer in Albuquerque. In such a case, the review record sent to the Albuquerque reviewer would have just the electronic method box checked, but all other review records for the other reviewers would have the review copy markup box checked.

This review process is designed to allow for the electronic transmittal of reviews. Only when the concurrence and acceptance signatures are required do hard copies of review records and comment sheets need to be printed.

6.4 APPROVAL

The originator will:

- Annotate the documentation as final by replacing the alphanumeric revision designator with a numeric revision designator (e.g., replacing "00B" with "00").
- Ensure the revision/ICN designator of the initial issue of the documentation is "00/00" and subsequent revisions are "01," "02," etc.; subsequent ICNs to a revision are "01," "02," etc. (e.g., Rev. 02/ICN 04).
- If applicable, ensure the revision history for the current revision of the documentation is entered on the final cover sheet. Alphanumeric revision designators are not required.
- Obtain the required signatures on the final cover sheet, as applicable.

The Responsible Manager for the technical product is the person who assigns the work, ensures that it is completed in accordance with the plan and the procedure, and approves the final technical document prior to its release to Document Control. The Responsible Manager's approval signature denotes that the following technical product attributes are adequately satisfied:

- The objective is clearly met.
- The procedure and review processes were rigorously followed.
- The technical product is complete and accurate in all respects (i.e., technical adequacy, clarity, and scope).
- The document appropriately addresses contradictory literature and conclusions.
- The check and the review have been completed, and the checking and review comments have been adequately resolved.
- The technical product complies with all quality requirements and acceptance criteria.

It is critical that the individual approving the technical product has read and understands the documentation and its implications and has had an adequate time to review it. The approval signature releases the technical product for use. Once approved and accepted by Document Control, any modifications will cause a revision or change to the product and will require appropriate reviews.

6.5 REVISION OR INTERIM CHANGE

The Responsible Manager/Lead shall process revisions or changes to technical products in accordance with the applicable procedure. The originator should obtain an electronic version of the document to be revised or changed from Las Vegas Document Control. A statement should

be included in the introduction of the new version identifying the superseded document. The DIRS must be updated in parallel with document development per AP-3.15Q.

The Responsible Manager/Lead should determine if modifications to a technical product will be completed as a revision or ICN. An ICN may be used for editorial, organizational, input status, status of assumptions, or other minor changes. Changes to methods, conclusions, the technical content of underlying assumptions, recommendations, issue resolutions status, technical discussions, etc., should be included in a revision of the technical product. The Responsible Manager should inform the Originator of any Deficiency Report, Corrective Action Report, or Condition/Issue Identification Reporting/Resolution System item to include. The originator may use alphanumeric page designators (e.g., page 11a) as part of the ICN if necessary to avoid repagination of subsequent pages caused by additional text. However, to eliminate problems with page numbering, the originator may choose to identify the ICN as part of the footer on each page of the document. No more than five ICNs may be in effect on one technical product. Note that although an ICN modifies only selected pages, the record copy of the technical product will be a completely assembled copy. In other words, the record copy of *XYZ Analysis*, REV 00, ICN 4 will contain the Revision 00 document updated with the modified pages from four ICNs.

The originator may indicate revision or interim changes in the technical product using one of the following:

1) A black vertical line in the margin of the changed pages
2) A note in the revision record clearly indicating the specific location of the changes
3) A note on the revision record indicating that the entire report was revised.

A combination of 1) and 2) can be used when software limitations (e.g., figures and tables) do not allow automatic placement of changes.

Reviews of ICNs are limited to the changed portions of the technical product and the portions of the technical product impacted by the changes.

Approved technical products are submitted to document control and records in accordance with AP-6.1Q.

6.6 DOCUMENT CONTROL AND RECORDS

Technical products are controlled documents and must be submitted to Document Control in accordance with AP-6.1Q. Document Control will maintain the official list of current documents and their latest revisions. The originator should not transmit a second copy. This is to prevent having two different versions of the document in the records system.

Document Control will maintain the accession number of all controlled documents so that they can be quickly retrieved. Document Control will provide the accession number for the current controlled version, if requested. Las Vegas Document Development and Production maintains the electronic version of the controlled document for use in later revisions.

Technical products often combine many electronic files in several media to accomplish a coherent print document. The files, their location, the order in which they are combined to create

the document, the software media, and who is maintaining the files must be listed when the approved technical product is submitted to Document Control.

6.6.1 Pen and Ink Changes

Originators and approvers may not make pen and ink changes to documents subject to AP-6.1Q and distributed by Document Control. Modifications to technical products subject to AP-6.1Q, even editorial corrections, must be made as a revision or ICN to the technical product and be subject to the requirements of the applicable procedure. This ensures that only one version of the final approved technical product is catalogued in the records system under a document revision number and that the electronic version contains the same information as the copy available in the records system.

Originators and approvers may make pen and ink changes to approved documents not subject to AP-6.1Q provided that they have not been distributed by Document Control. Pen and ink modifications must be initialed, dated, and noted in the remarks section of the applicable Cover Sheet.

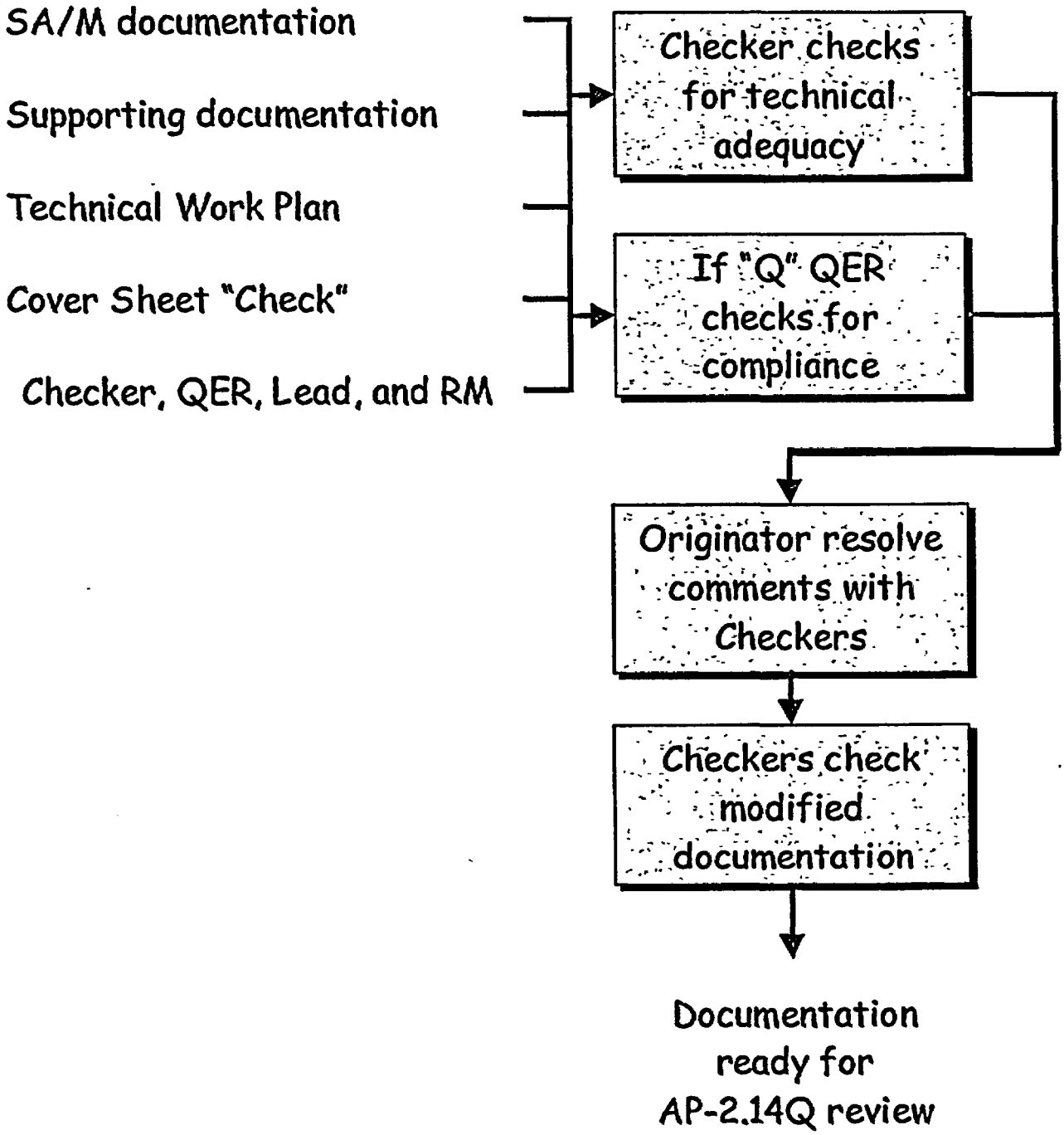

Figure 6-1. Typical Process for Checking Formal Technical Products

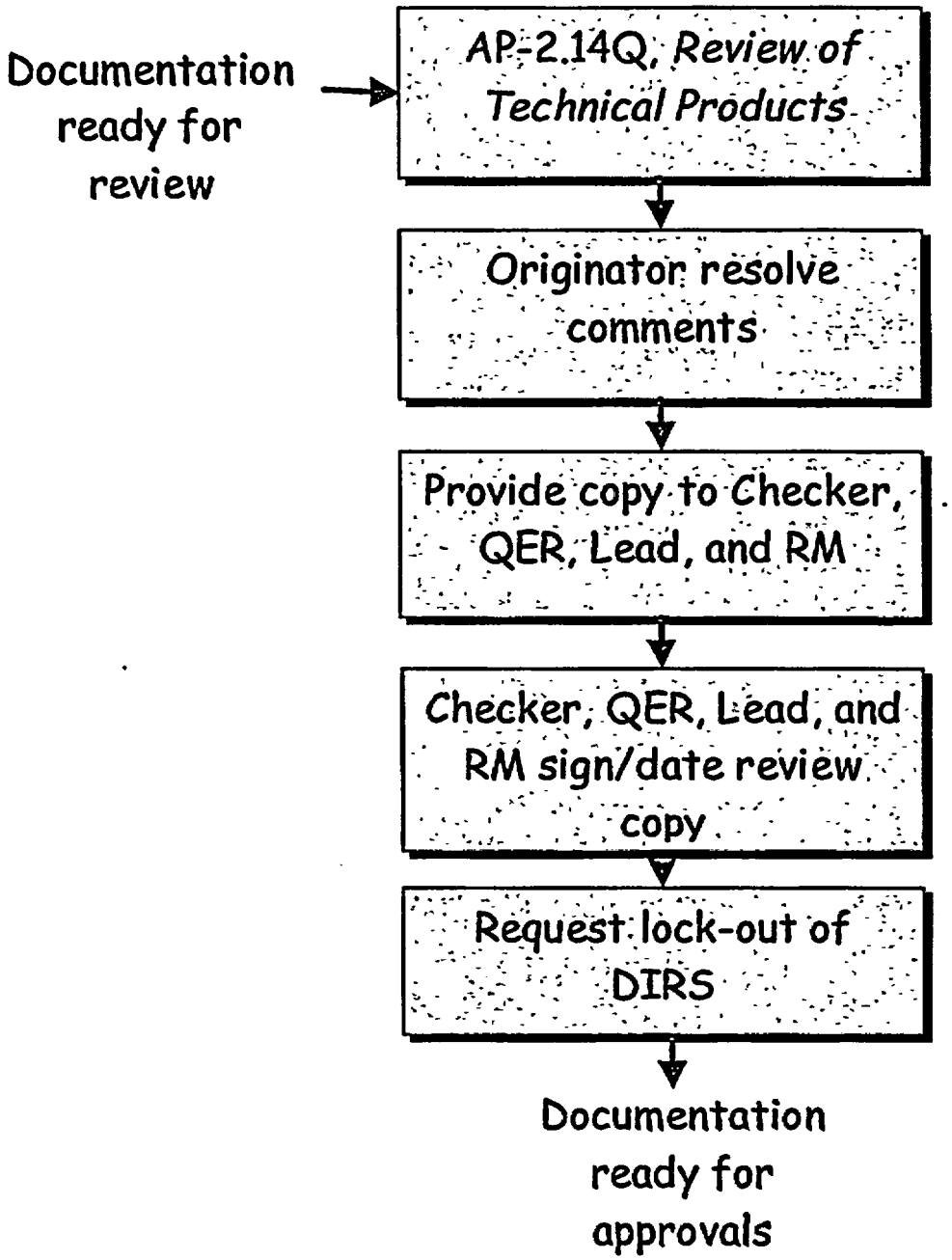

Figure 6-2. Typical Process for Reviewing Formal Technical Products

7. SOFTWARE MANAGEMENT

The primary role of software management is to ensure that software products used in support of Q scientific and technical studies have been appropriately qualified and baselined within the appropriate range of validation. The software product use for scientific processes that create Q products will be controlled in accordance with AP-SI.1Q.

AP-SI.1Q processes apply to all OCRWM Affected Organizations subject to the QARD (DOE 2002) including BSC direct-support contractor and USGS personnel who acquire, modify, develop, control, or submit software products for use by the OCRWM program. Software products subject to AP-SI.1Q requirements cannot be used in Q activities prior to the software being qualified and baselined except as provided in AP-SI.1Q.

Each software product used by OCRWM personnel is processed through a software life cycle. This software life cycle is defined by phases of planning, requirements definition, design, implementation, validation, operations, and maintenance.

The software requirements must be traceable throughout the software life cycle. Independent technical verification of the software products must be performed at the completion of each phase of the life cycle to ensure that requirements are traceable throughout the process. This is accomplished through independent verification performed at the end of each phase of life cycle. This verification must be performed by technical staff not associated with the software product development efforts. The purpose of this verification activity is to verify that the products generated by the specific life cycle phases meet the conditions or requirements imposed at the start of the phase. Documentation of review comments and their resolution will be retained until comments are resolved and submitted as controlled records.

7.1 SOFTWARE CATEGORIZATION

Prior to software life cycle document development and preferably before code development, the software product must be categorized to determine what documentation will be required. The categorization (grading) of software is determined based on the critical nature of the software and the level of effort involved in the planning, requirements definition, design, implementation, validation, operations, and maintenance phases of the software product.

The categorization (grading) process of all software products is conducted in accordance with AP-SI.1Q.

7.2 EXEMPTED SOFTWARE

Software products used for Q work may be exempted from qualification processes. The exempted software products are determined by processes outlined in AP-SI.1Q.

7.3 COMMERCIAL OFF-THE-SHELF SOFTWARE

Commercial Off-The-Shelf software products are software products that are purchased through the authorized and approved OCRWM procurement process. These software products are required to be processed through the OCRWM Software Configuration Management

organization upon arrival from the supplier. The OCRWM Software Configuration Management organization verifies that the Commercial Off-The-Shelf software has a current license and meets federal license and copyright limitations.

7.4 ACQUIRED SOFTWARE

Acquired software includes software products that were developed external to the YMP (i.e., internal U.S. National Laboratory software, internet freeware, or shareware, etc.). These software products are controlled by AP-SI.1Q; however, since these software products have already been coded, the software design document element of the software life cycle is not required.

7.5 SOFTWARE DOCUMENTATION

All software product processes and required documentation to qualify and baseline the software products for use on the YMP are outlined in AP-SI.1Q.

7.6 SOFTWARE VALIDATION

The Software Validation Process level of detail is dependent upon the categorization level of the software product which is outlined in AP-SI.1Q.

The Software Validation Process starts with the software product requirements definition phase documented in the Requirements Document or documentation element depending upon the categorization level of the software product. The defined requirements must be testable, and the results must be provided as objective evidence. The requirements definition(s) phase should be identified and documented in a requirements matrix, or equivalent, so that subsequent steps identified in the design, installation, and validation testing can refer back to the defined requirements for the software product.

Once all of the requirements have been identified, the design and development of test cases should start in order to demonstrate the requirements' validity. Each test case should have a unique alpha and/or numeric identifier. A single test may test several requirements. Some requirements may be tested more than once. The acceptance criteria should be added to the matrix. The testing process and test cases are documented in the Validation Test Plan (VTP) or documentation element depending upon the level of categorization for the software product.

The complete and accurate installation of the software product is documented in the Installation Test Plan (ITP). The ITP should document the pre-installation tasks, actions necessary to complete the installation procedure, and the installation test case(s) to accurately confirm a correct installation and ready-for-use condition. The completion of the ITP or documentation element depending upon the categorization level of the software product is outlined in AP-SI.1Q.

Upon completion of the software product code development, unit testing, and system testing, the Responsible Manager is notified that the software product is ready for an independent validation testing process. Before independent testing can begin, the Responsible Manager must select an Independent Validation Tester to perform the software product testing. The Independent Validation Tester operates independent of the software product development environment and

should be technically knowledgeable of the software management processes in order to perform the validation testing process.

The Independent Validation Tester performs installation and testing in accordance with the ITP. Following satisfactory installation, the test cases documented in the VTP are conducted. Like the ITP, the VTP results must provide objective evidence of the successful demonstration (i.e., the results should meet acceptance criteria specified in the VTP).

With successful demonstration of the ITP and the VTP, the objective evidence must be assembled in the Validation Test Report or documentation element depending upon the categorization level of the software product. The prepared Validation Test Report should discuss the results of each test case and whether the acceptance criteria were met.

7.7 SOFTWARE QUALIFICATION

Software products are qualified through a defined software life cycle development phase(s) to ensure the quality of the software product required by the QARD (DOE 2002). The phases provide a systematic approach to software development, management, and maintenance, allowing the software product to proceed in a traceable, planned, and orderly manner.

The qualification process level of detail for an individual software product is dependent upon the categorization level of the software product. The level of categorization is determined based on the critical nature of the software and the level of effort involved in the completion of the planning, requirements, design, implementation and validation phases of the software life cycle.

The categorization level of the software product determines the level of detail of the qualification process. The qualification process implements an Independent Technical Reviewer (ITR) selected and approved by the Responsible Manager. The ITR is independent of the planning, development, and testing phases of the software product. The ITR should be technically knowledgeable of the software management processes and the ITR responsibilities outlined in AP-SI.1Q.

A formal compliance review process takes place after completion of specified Control Points during the software life cycle development process. The formal compliance review is performed by an Information Technology Software Management Analyst and consists of a compliance review of the entire software qualification package at each Control Point in accordance with AP-SI.1Q. The Information Technology Software Management Analyst compliance review comments must be resolved before qualification and baselining of the software package. This compliance review is a significant phase of the qualification and baselining of a software product.

7.8 SOFTWARE QUALITY AND COMPLIANCE

The Software Quality and Compliance (SQ/C) Program is implemented early in the software life cycle and recognized as an integral part of the software product development process. The SQ/C Program will ensure the establishment of required software development, design, testing, and validation processes. The SQ/C Program will assess, review, and audit the compliance of the

software product life cycle processes to ensure each software project is in accordance with AP-SI.1Q.

7.9 SOFTWARE MANAGEMENT INFORMATION

Any questions and/or issues regarding the software management of existing or pending software product development should be directed to the SQ/C organization.

8. SCIENTIFIC NOTEBOOKS

AP-SIII.1Q provides requirements for initiating, maintaining, and closing scientific notebooks.

A scientific notebook must be a defensible document detailing the acquisition of data, interpretation of results, etc., which may be used in support of LA. To that end, the contents of a scientific notebook must be a record of events, actions, decisions, and results.

The chronologically detailed process documented in a scientific notebook must be clear and thorough enough to allow a comparably experienced investigator to replicate the experiment, study, or modeling without recourse to the original investigator. The benefit to the PI of being clear and thorough enough is that the process encourages the PI (writing for the unknown third party) to carefully think through the work process. The scientific notebook must be linked to an approved planning document (by including it in the scientific notebook or referring to it).

8.1 FORMAT AND MAINTENANCE OF THE SCIENTIFIC NOTEBOOK

Scientific notebook entries must be legible. Entries may be typed or printed on separate paper and attached in the notebook. Attachments are commonly made by signing and dating across the scientific notebook and the added entry.

The bound scientific notebook, with consecutively numbered pages, is required. However, supplemental material is not conveniently recorded in such a book (e.g., long computer printouts, extensive calibration certificates, plastic pages of floppy disks, or compact disks in pockets). In such cases, a three-ring binder is better for compiling and maintaining the supplemental information. It is important that the PI properly paginate the supplemental material and maintain a table of contents. Additionally, the PI must insert a cross-linking statement in the scientific notebook referencing each item of supplemental material. The supplemental binder must be labeled as an attachment to the given notebook by its notebook identifier.

8.2 IDENTIFICATION AND CONTROL OF THE SCIENTIFIC NOTEBOOK

The Scientific Notebook Register (SNR) is the authorized source for obtaining an alphanumeric identifier for YMP scientific notebooks. The SNR is located on the YMP Lotus Notes Database Catalog. Upon entering the requested input, a unique scientific notebook alphanumeric identifier is assigned by the SNR. The title should be sufficiently descriptive to enable a search for, and retrieval of, the notebook from the Records Information System (RISweb) (the "Title" field will accept up to 150 characters).

The identifier is generated from a series of inputs as prompted, including the organization using the notebook. For example, a USGS scientific notebook No. 2, Volume 1, would have the format SN-USGS-SCI-002-V1. Instruction to use the SNR is available by clicking on the "help" button; it also indicates whom to contact as the database administrator for help if corrections are needed after the initial input entries are saved.

8.3 SCIENTIFIC NOTEBOOK INITIAL ENTRY

The initial entry, as outlined in AP-SIII.1Q, serves to define basic requirements and goals of the investigation. For example, standards and/or criteria are to be noted. An example of standards are the numerous ASTM Standards accepted throughout the industry and used to control some YMP investigations.

Identification of M&TE and any calibration specifications are required. Copies of calibration records should be included in the scientific notebook or its attachment, or the calibration records should be referenced within the scientific notebook by accession number. Any requirements, including calibration requirements and calibration records of M&TE that are known during the development of the scientific notebook initial entry, should be included in the initial entry. However, notation of such information can be added or changed at any point in the notebook.

Signatures and initials of investigators serve to provide credibility and traceability of notebook entries and are not to be lined-out if any personnel leave the Project. Those entries supported by lined-out signatures or initials would be rendered invalid. Examples of signatures and initials are in effect for the duration of the work.

Citation of previous work upon which the investigation will build, or that will provide a process or technique to follow, is an area of past notebook problems. Pasting copyrighted material into the notebook is not allowed unless the Technical Information Center has requested and received permission to copy and use that material. The notebook will be scanned and posted on the Internet via the RISweb and thus will represent public dissemination of that copyrighted material. If the citation is to a published professional journal or text cited, it is better to cite the reference including pages. If copyrighted material needs to be included, copyright permission must be requested early and is not always granted. A late stage correction can seriously impact acceptance in the RPC, which in turn can delay the notebook becoming a referenced record.

An amendment to the initial entry (examples may include changes in process, scope, or personnel not covered in initial entry) can be made at any time during an investigation and inserted sequentially in the scientific notebook. Cross-referencing of the initial entry and any amended initial entry is then required to indicate to the reader that the initial entry has been revised or altered.

Ensure that the study/investigation commences only after the successful completion of the Initial Entry Compliance Review.

8.4 SCIENTIFIC NOTEBOOK IN-PROCESS ENTRIES

In-process entries document the execution of the plan. All scientific notebook entries shall be made prior to beginning the next workday's activities. Each entry that is not entered into the scientific notebook on the date the work is performed shall display the date on which the work was done and the date of its entry in the notebook.

In-process entries document the steps of the investigation. These entries should also describe any changes or problems encountered along with the identified solutions, decisions to change the process along with the reasons, and any interim results. Requirements identified or calibration

work performed following the initial entry should be documented within the in-process entries wherever chronologically appropriate.

If there is a need to amend a page or section, such as the list of persons authorized to make entries in the scientific notebook, the PI is encouraged to create an amended entry and insert it on the next available page. For overall clarity, it is essential to make cross-linking statements on the amendment and the original page so that the reader can readily be directed to both statements.

8.5 SCIENTIFIC NOTEBOOK REVIEWS

AP-SIII.1Q requires the Responsible Manager (or PI) and the Compliance Reviewer to sign the Compliance Review Worksheet to document appropriate completion of reviews. All Compliance Reviews, except the final Compliance Review, may be performed before or concurrently with the Technical Review.

To coordinate reviews, the Responsible Manager will assume the Lead function if the PI and investigator are the same person. If the review is only for a segment of the notebook, ensure that the closing statement indicates the date(s)/page(s) that the Technical Review covers and note the ongoing status of the investigation.

Note that review documentation is to be attached in the scientific notebook rather than being put with supplementary records. This has the advantage of maintaining the thoroughness and contemporaneous nature of the scientific notebook record and serves to make future reviews and audits more efficient.

8.6 SUBMITTAL AND TRACEABILITY OF DATA

The submittal of data produced by scientific investigations requires that a Record Road Map be completed (Form AP-3.15Q.2). Be advised that there is a delay between submission of scientific information to the TDMS and the time those data are entered into the database and available for use. Prior to submittal to the TDMS, data must go through an independent technical review in accordance with AP-2.14Q. The PI must be cognizant of the user's schedule and allow adequate time for the technical review and submittal of data to the TDMS.

It is not always known in advance which data will be used in a technical product. It is therefore recommended that a list of DTNs and a one-line statement of the data topic of each DTN be entered as a list on a dedicated page (or pages). This is preferable to having the DTNs disbursed throughout the scientific notebook. With that page (or pages) noted in the table of contents, any user or reviewer will be readily directed to the list of DTNs.

8.7 CLOSURE OF SCIENTIFIC NOTEBOOKS

Although it is not stated in the procedure, each separate supplemental record referenced in the scientific notebook and submitted to the RPC with the notebook must be adequately labeled to link that record with the scientific notebook by its scientific notebook identifier.

Reference the subsequent notebook, if applicable, in the closing statement at the end of the notebook where the work will continue from one notebook to another. Generally, if a notebook

has one or more closely related studies documented in other scientific notebooks, a reference should be made in each to properly cross-link the relevant notebooks.

8.8 RECORDS

A scientific notebook is a federal record and will be used, after being scanned to electronic format, for many years via the records system. As such, scientific notebooks are controlled by AP-17.Q, *Record Source Responsibilities for Inclusionary Records*, which is described in Section 10 for general purposes. Additional specific guidelines for the implementation of AP-17Q for scientific notebooks are provided as follows.

In order to meet the legibility requirements of AP-17.1Q, materials attached to a page shall not overlap other material. This refers to incorporating such things as photomicrographs or instrument printouts in a notebook in such a way as to overlap underlying entry material. The essential guidance is that each page must be available intact to be copied or scanned. Black ink is preferable, as blue and some other colors often do not scan or copy well. To avoid delays in having the notebook accepted by the RPC, use care to ensure that information is not cut off page edges.

AP-17.1Q (Paragraph 5.2f)2)) requires that records be submitted to the RPC within one year of completion of the first record of that package. The dated signature of the initial entry determines the beginning of that one-year deadline. Therefore, a copy of a complete notebook, or segment (for multi-year studies) notebook, must be submitted no later than one year from the first entry in the notebook. Records must be submitted on an annual basis thereafter. For each submittal of a scientific notebook, the record must contain a copy of the first page where the scientific notebook identification number and QA designator are displayed. Each corrected entry (by a single line through the incorrect information and the new information added) must be initialed and dated.

AP-SIII.1Q specifically assigns record responsibility to the PI. Since originals of a scientific notebook are one-of-a-kind records, special care must be taken to ensure their security. In addition to careful compliance with the required methods for protecting records described in Subsection 5.3 of AP-17.1Q, copying scientific notebooks for dual storage is highly recommended. Scientific notebooks should be periodically copied (monthly, quarterly, or as the planning document dictates) and duplicates should be kept in a location separate from the original scientific notebook.

Although a scientific notebook is controlled by AP-SIII.1Q, the PI is advised to be aware of AP-17.1Q requirements as violation of those requirements will result in significant delays in notebook acceptance by the YMP records system.

9. RECORDS, CONTROLLED DOCUMENTS, AND DELIVERABLES

The following procedures are the implementing procedures for document control and records/record packages activities:

- AP-6.1Q
- AP-17.1Q
- AP-IST-004
- AP-7.5Q.

Due to the many administrative tasks required in the submittal of a document, the Las Vegas Document Management Services group is available to assist the technical staff in submitting documents to Document Control for controlled distribution and to the RPC for processing into the record system. The Document Management Services group provides consistency in the document and records process, which enhances the quality of the final product.

9.1 APPROVED DOCUMENTS

Per governing procedures, Document Control receives the approved document for controlled distribution per AP-6.1Q and is responsible for submitting the approved document to the RPC for processing into the record system. An accession number for the approved document is assigned by the RPC and the number is provided to Document Control. Document Control will note the accession number on the Document Control Action Request (DCAR) and return a copy of the DCAR to the document owner. When submitting the records package for the development of the approved document, the document owner should list the approved document title and the accession number on the records package table of contents, indicating a zero page count. The accession number and zero page count indicate that the document has been previously processed and is not included in the records package but must be linked to the package when processed by the RPC.

9.1.1 AP-6.1Q, Controlled Distribution

The document owner submits the approved document with a DCAR to Document Control for controlled distribution.

9.1.2 AP-IST-004, Public Release Review, Approval, and Distribution of Technical and Non-Technical Products

This process is required for documents that will be subject to external review and placed on the Internet or that are identified as publications for release to the public. The document originator must submit a Request for Publication Review (Form YMP-269) and the BSC Nevada Site Local Technical Review Request (Form 0711) to Review Coordination with the approved document.

9.1.3 AP-7.5Q, Submittal, Review, and Acceptance of Deliverables

This process is required when a Level 3 deliverable is identified in the approved Control Account Plans in the YMP *Project Cost and Schedule Baseline* (YMP 1999) as requiring submittal to Review Coordination for the Yucca Mountain Site Characterization Office

acceptance review. The approved form (Form AP-7.5Q.1), transmittal letter to DOE, document, and copies of the applicable Control Account Plan sheets are required at the time of submittal to Review Coordination. If the original approved document was submitted to Document Control in accordance with AP-6.1Q at the same time or prior to the acceptance review, then another copy of the document will not be accepted. Document Control will copy the original document submitted in accordance with AP-6.1Q for this review.

9.2 ELECTRONIC COPIES OF CONTROLLED DOCUMENTS

Electronic copies of all documents are sent to Document Control as a management requirement for use in later revisions of the document. This requirement only applies to program generated documents, not externally generated documents. All program-generated files used to create a document must be submitted in their original source format with instructions for recreating the document. If a document was created with Word, Excel, and MicroStation, .doc, .xls, and .dgn files would be submitted with the Electronic Source File Verification form in accordance with AP-6.1Q. Do not translate these files into another format.

The document owner, as identified on the Electronic Source File Verification form, is the level of responsible individual identified in the governing procedure of the document required to submit the approved document to Document Control. For example, if a particular procedure calls out the Operations Manager, then the manager will sign as the document owner on the Electronic Source File Verification form.

9.3 AP-17.1Q, RECORD SOURCE RESPONSIBILITIES FOR INCLUSIONARY RECORDS

Technical staff should use AP-17.1Q when developing records. AP-17.1Q clearly instructs the record source on how to create records in a manner that meets the requirements of the QARD (DOE 2002) and will be acceptable by the RPC when submitting records for processing into the record system.

Section 6.0 of all governing procedures identifies the appropriate records generated as a result of the implementing procedure.

All records, Q and non-Q, will meet the following requirements:

- **Blank Spaces**–Account for all blank lines and spaces in a record by entering "N/A" unless directed otherwise by procedures or form instructions.

- **Appropriate Corrections**–To correct a record that has not been submitted to the RPC, the record source will draw a single line through the incorrect or unintentionally obliterated information. Place the correct information in close proximity, date and initial, stamp, or sign the correction. Note that the use of felt pens to cross out or line through incorrect information can in itself cause obliterated information. Likewise, whiteout and post-it notes may not be used on records.

- **Legibility**–The record source must ensure that all records are legible. Records that are not legible must either be enhanced or recreated. Enhancing constitutes a correction and must be dated and initialed, stamped, or signed.

- **Obliteration**–The record source will provide a statement that indicates that obliterated information is intentional and does not impact the technical meaning or content of the record. The record source will initial or sign, and date by the statement. If the obliteration does impact the technical content or meaning, and the record cannot be regenerated, a Performance/Deficiency Report must be initiated for Q records. Documentation (e.g., a memo or a statement on the record) must be provided for non-Q records.

- **QA Designators**–The Record Source must place a QA designator on the first page of each record. The QA designators are:

  - QA: QA Lifetime records

  - QA: N/A Non-Q records

  - QA: L Lifetime (no longer used in AP-17.1Q, but may be used if the process of a document is allowed to continue under a previous procedure)

  - QA: N Nonpermanent (no longer used in AP-17.1Q, but may be used if the process of a document is allowed to continue under a previous procedure).

- **Titles**–Create a title (subject) that identifies the contents of the record and the item or activity to which the record applies in order to facilitate indexing of the record for future identification and retrievability (e.g., "Muck Storage Design," "Steel Set Design"). Incomplete titles (e.g., "Design Verification Package for...") are not acceptable.

- **Lotus Notes**–If an e-mail is a QA record, it must be dated, signed, marked with the appropriate QA designator, and marked with page 1 of X. (This does not have to be the preparer of the document, but must be somebody who has the authority and the qualification to do so.)

9.4 DATABASES USED BY DOCUMENT CONTROL, CONFIGURATION MANAGEMENT, AND THE RECORDS PROCESSING CENTER

Document Control–Document Control database used to track Controlled Documents and other processes (see below databases), in accordance with AP-6.1Q.

- Public Release documents
- Review and Acceptance of deliverables
- Document Processing
- Document Development and Production.

RISWeb–Located on the Intranet. RISweb can be accessed by all project staff for locating records/record packages submitted to and processed by the RPC.

10. REFERENCES

10.1 DOCUMENTS CITED

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APPENDIX A

PROCESSES FOR MODEL/ANALYSES INTEGRATION IN TSPA-LA

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The EPA and NRC in their regulations (40 CFR 197 and 10 CFR 63, respectively) specifically acknowledge that uncertainty in the dose is a key issue and specifically call for including uncertainty in order to develop a "reasonable expectation" of compliance. Hence, identifying, categorizing, quantifying, evaluating, and documenting uncertainties are important tasks of a performance assessment (hereafter referred to as a total system performance assessment [TSPA] to emphasize the inclusion of all subsystems of the Yucca Mountain disposal system). The objectives and strategy for inclusion of the uncertainty in the postclosure safety case are presented in *Uncertainty and Analyses and Strategy* [157389].

Much progress in accomplishing these tasks was made in performing the *FY01 Supplemental Science and Performance Analyses (SSPA)* [155950] Volume 1, [154659] Volume 2. Doing these tasks in a consistent manner for the numerous supporting models and parameters is also important. Processes for building upon the progress in the Supplemental Science and Performance Analyses (SSPA) and providing more consistency for TSPA-LA have been developed in *Guidelines for Developing and Documenting Alternative Conceptual Models, Model Abstractions, and Parameter Uncertainty in the Total System Performance Assessment for the License Application* [158794]) (referred to *as Guideline Document* herein) and are summarized herein.

Section A.1 introduces key terms and the team concept that will be used to treat uncertainty consistently in TSPA-SR. The three major sources of uncertainty for geologic disposal system are uncertainty in (a) *completeness* (i.e., uncertainty in capturing all applicable features, events, and processes [FEPs] of item 1 above); (2) *model form* (i.e., uncertainty about the hypotheses and appropriate model implementation in evaluating the dose and calculating the probability of FEP occurrence); and (3) *parameters* (i.e., uncertainty in the best parameter to use in the selected model form for both the consequence and probability models). The term "parameter" is used here to include designators for alternative models or model structures. Figure A-1 shows the relationships among data/parameters, models, analyses, and TSPA-LA.

Section A.2 describes the current status of FEPs and enhancements planned for the TSPA-LA TDR-WIS-PA-000005 REV 00, *The Enhanced Plan for Features, Events, and Processes (FEPs) at Yucca Mountain* [158966]. Sections A.3 and A.4 discuss the basic processes established in the treatment of model form uncertainty (divided further into alternative conceptual models and model abstractions). Section A.5 discusses parameter uncertainty.

A.1 UNCERTAINTY

This section distinguishes between two types of uncertainty and introduces the team approach to treating uncertainty.

A.1.1 Aleatoric and Epistemic Uncertainty

Aleatory uncertainty refers to uncertainty for which sufficient knowledge is unobtainable such that the corresponding parameters are treated as chance occurrences of features, events, and processes. These parameters may be conveniently used to form scenarios related to chance

either in designing the TSPA simulation or within a component of the TSPA model. For example, this inexactness can arise because both volcanic disruption and no volcanic disruption are possible states of the disposal system that need to be considered, because the microstructure of the material and the microenvironment vary across a waste package surface, or because different individuals vary in their tolerance to contaminants. This type of parameter inexactness is also called Type A, stochastic, irreducible, or variable uncertainty. Both aleatory and stochastic formally refer to randomness in processes (e.g., radioisotope decay), but the general lack of knowledge about the state of the system (e.g., volcanic disruption or no volcanic disruption) is now also associated with these words. The term "variable uncertainty" emphasizes the variability among individual characteristics of a population. This type of inexactness cannot be reduced through further testing and data collection (e.g., variability of a population to the tolerance of contaminants cannot be reduced through further testing); it can only be better characterized, and, thus, this first type of parameter uncertainty is also referred to as irreducible uncertainty.

Epistemic uncertainty arises from a lack of knowledge about a parameter because the data are limited or there are alternative interpretations of the available data. The parameter is not variable because of an intrinsic characteristic of the entity but because an analyst does not know what the precise value of the parameter should be. For example, there is substantial epistemic uncertainty in many quantities used in PA for the Yucca Mountain site (e.g., solubilities, distribution coefficients, permeabilities). Further, there can also be epistemic uncertainty in quantities used to characterize aleatory uncertainty (e.g., rates at which igneous and seismic events occur). This type of inexactness is also called Type B, state of knowledge, or reducible uncertainty. Epistemic refers to the "state of knowledge" about a parameter. The state of knowledge about the exact value of the parameter can increase through testing and data collection such that the uncertainty is "reducible." Developing a probabilistic distribution for a parameter is the usual way to explicitly describe epistemic uncertainty.

Distinguishing between these two types of uncertainty is not important to estimates of mean risk, but is important in many instances to understand the results and how the uncertainties might be better characterized (or possibly reduced) by the collection of more data. The desire to maintain a separation between aleatory and epistemic uncertainty affects the design of the analysis (e.g., separate analysis of volcanic disruption and no volcanic disruption). It may also affect the design of individual components (e.g., the component modeling corrosion of the waste package).

A.1.2 Team Approach for Treating Uncertainty in Model Form and Parameters

The TSPA-LA must integrate information from many sources and document the uncertainty from these numerous sources. An external review of TSPA-SR found numerous examples of parameters where the documentation adequately explained the various sources of uncertainty (e.g., measurement error or experiment representativeness); however, in other situations this documentation was lacking, *Evaluation of Uncertainty Treatment in the Technical Documents Supporting TSPA-SR* [157389]. To maintain consistency in the interface with other organizations and consistency in the integration, the Performance Assessment Strategy and Scope (PASS) Sub-project has established a team leader in parameter uncertainty, Parameter Team Lead (PTL), and a team leader for model form uncertainty, Abstraction Team Lead (ATL). The other two members of the team are the Subject Matter Expert (SME) from the appropriate

department, who are most knowledgeable about individual underlying process models and their uncertain parameters, and a TSPA analyst from the TSPA Department.

A.2. FEATURES, EVENTS, AND PROCESSES

The development of a comprehensive list of features, events, and processes (FEPs) potentially relevant to the post-closure performance of the potential Yucca Mountain repository is an ongoing, iterative process based on site-specific information, design, and regulations.

An Enhanced FEP Plan (TDR-WIS-PA-000005 REV 00 [158966], *The Enhanced Plan for Features, Events, and Processes (FEPs) at Yucca Mountain*) will be developed to address those FEP reviews, and to identify specific enhancements to the FEP analysis approach to support LA.

These enhancements include a team approach for consistency (Section A.2.1) and specific aspects of the FEP analysis (Section A.2.2).

A.2.1 Interface Team for FEPs

A team approach will be used to provide for consistency in the identification and screening of FEPs (see Section 3.2, TDR-WIS-PA-000005 REV 00 [158966], *The Enhanced Plan for Features, Events, and Processes (FEPs) at Yucca Mountain*). FEP Team members will include a FEP Team Lead (FTL), FEP AMR Leads, and SMEs.

The FTL will manage the process of implementing the Enhanced FEP Plan (TDR-WIS-PA-000005 REV 00 [158966], *The Enhanced Plan for Features, Events, and Processes (FEPs) at Yucca Mountain*). A FEP AMR Lead and one or more SMEs will be identified for each of the subject areas. The FEP AMR Leads are responsible for ensuring that relevant FEPs are treated appropriately within their FEP AMRs. The SMEs are the personnel most knowledgeable about individual FEPs and are responsible for developing explicit screening discussions for documentation in the FEP AMRs. The FTL and supporting individuals from within the PASS Sub-project (the FEP Team) will work closely with the FEP AMR Leads and SMEs.

These functional roles may or may not correspond directly with the existing or future PA Project organizational structure. However, it is expected that individuals selected for the FTL role and FEP Team will be designated by, and report to, the PASS Sub-project managers. The FEP AMR Leads and SMEs will be designated by, and report to, the various departments and the respective subproject managers. This allows for the input and documentation to the TSPA–LA to be controlled within the PA Project.

A.2.2 FEP Analysis for TSPA-LA

For TSPA-LA, the FEP analysis approach is the same as for TSPA-SR, and it corresponds with the review methods and acceptance criterion in the Yucca Mountain Review Plan (YMRP) (NRC 2002, Section 4.2.1.2.1). The current status of FEP analysis is summarized below. Specific enhancements under consideration for TSPA-LA (CRWMS 2002 [MOL.20020417.0385], Section 3.2) are also noted.

Identification and Classification of FEPs–An initial list of FEPs relevant to Yucca Mountain was developed from a comprehensive list of FEPs from radioactive waste disposal programs in other countries [154365], Section 2.1, *The Development of Information Catalogued in REV00 of the YMP FEP Database*) and was supplemented with additional YMP-specific FEPs from project literature, technical workshops, and reviews [154365], Sections 2.2 through 2.4.

The current version of the YMP FEP Database (REV 00 ICN 02) (CRWMS M&O 2001. *Software Management Report: FEPs Database Software Program Version 0.2.* STN: 10418-.2-00 [Danen and Ehrhorn 2001]) contains the same 328 primary FEPS.

Enhancements to the identification and classification of FEPs for TSPA-LA include:

- Develop a hierarchical classification scheme that facilitates navigation within the database for reviewers and, where possible, parallels the structure used to describe TSPA-LA. This will improve transparency and traceability, but will not change the number or screening of FEPs.

- Refine the existing FEP list for consistency with the new classification scheme and for a more consistent level of detail between FEPs. This will not change the technical content of the overall FEP list, but may result in a minor change in the number of FEPs due to re-organization of certain FEPs.

- Provide an ongoing systematic process for configuration management, evaluation and tracking of potential new FEP and changes to existing FEPs.

Screening of FEPs–Each of the 328 primary FEPs is screened for inclusion or exclusion in the TSPA on the basis of probability or consequence criteria, developed from 10 CFR 63 (66 FR 55732, p. 55807).

FEPs that are inconsistent with specific requirements in 10 CFR 63 may be excluded (screened out) from the TSPA. The most notable examples are FEPs that are inconsistent with regulatory specification of the human intrusion analysis and/or the critical group characteristics.

Enhancements to the screening of FEPs for TSPA-LA include:

- Update screening discussions for consistency with final 10 CFR 63, where necessary.

- Enhance screening arguments to ensure adequate basis for excluded FEPs, where necessary (i.e., specific reference to criteria in 10 CFR 63.114(d) through (f)).

- Enhance documentation for included FEPs, where necessary. This includes explicit references to included in FEPs in technical AMRs and documentation of the mapping of included FEPs to TSPA model components.

A.3 MODEL FORM UNCERTAINTY: ALTERNATIVE CONCEPTUAL MODELS (ACMs)

Development of alternative conceptual models (ACMs) is a technique to specifically acknowledge model form uncertainty. The NRC in 10 CFR 63.114(c) specifically requires the DOE to "Consider alternative conceptual models of features and processes that are consistent with available data and current scientific understanding and evaluate the effects that alternative conceptual models have on the performance of the geologic repository." The *Guidelines Document* [158794] outlines a process for evaluating ACMs that is overseen by the ATL and discussed in Section A.3.1. The *Guidelines Document* introduces a process to consistently document the creation and screening of ACMs by various SMEs. This portion of the process is reviewed in Section A.3.2. Those ACMs thought reasonable (based on, for example, precedent established by other analysts) and significantly different (based on, for example, differences in results) are passed on to TSPA analysts for their evaluation. This process is reviewed in Section A.3.3. The impact of ACMs on TSPA-LA is reviewed in Section A.3.4. The need to reevaluate FEP screening is mentioned in Section A.3.5, and general aspects of the documentation are reviewed in Section A.3.6.

A.3.1 Interface Team for ACMs

To provide consistency in addressing ACMs, the *Guidelines Document* identifies two essential participants: the Abstraction Team Lead (ATL) and the SME. Various TSPA analysts and Process Modelers will provide technical support at the request of the ATL and SME. The term, "Abstraction Team Lead," is intentional because the person directing the consideration of alternative conceptual models can be the same individual that is used to address model abstraction issues. One ATL has been designated to address all ACMs from across the various subject areas to provide for consistency in the guidance given to the multiple SME's on the appropriateness of proposed ACMs. The goal of establishing an ATL is to provide even-handedness in introducing ACMs. The ATL will be vigilant in selecting ACMs such that their use neither introduces specious ACMs nor neglect to introduce important ACMs that need to be addressed in the TSPA-LA. The process provides for review and concurrence by the ATL and the SME prior to implementation of the alternative conceptual models in the TSPA–LA. It also specifies that the implementation of ACMs in the TSPA–LA be checked and reviewed by both the ATL and SME.

A.3.2 Identification and Screening of ACMs

The first activity is to determine whether any ACMs are consistent with available data and scientific understanding. The consistency with available data and scientific understanding, and the reasonableness of ACMs, was previously considered and documented by the SMEs as part of the TSPA-SR process, although in varying degrees of detail. (For example, the various Process Model Report (PMRs) list several ACMs that were not incorporated.) This first activity requires the SMEs, in consultation with the ATL and TSPA analysts, to carefully examine the existing models; to identify previously considered ACMs; and to reevaluate their consistency with data in light of current project knowledge and supporting documentation used for the TSPA-SR, SSPA, and the TSPA-FEIS. For example, the consideration of stress corrosion cracking may be

represented by one or more ACMs that were not previously considered, since only the conservative model was chosen for use in TSPA–SR.

The SME will also review the list of model sensitivities/key parameters from the TSPA-SR, SSPA or other project documents (to be provided by the ATL) to identify where the use of ACMs would be most appropriate and suitable for implementation into TSPA-LA. That is, the SMEs should allocate their time to those ACMs that past experience has shown are an important influence on the results (according to a risk-informed approach). However, the intent is not to exclude ACMs that might show an impact simply because the original ACM did not show an impact. The SME will also reexamine FEPs to determine the appropriateness of modifying an existing screening decision (i.e., change from exclude to include) or identifying areas where an alternative treatment is appropriate.

The SME will determine if one or more conceptual models differ significantly from the existing conceptual model, are consistent with available data and current scientific understanding, and are reasonable. The definition of ACM in 10 CFR 63.114(c) includes "consistent with available data and current scientific understanding." Thus, a proposed model should be disqualified if it is verifiably inconsistent with any of the information. (Of course, any model of a real system could eventually be shown not to agree with all the data in every instance since it is not the real system, but rather a model. Hence, each alternative conceptual model must be consistent with the available data in those areas that are important to the analysis.) The screening would first be done qualitatively, based on the SME's technical judgement. If ACMs could not be screened from a qualitative evaluation, then it would be necessary to develop the appropriate mathematical and computational models. However, since the ACM would often be a variation of some base-case, usually existing qualified or readily qualifiable computational software could be used.

The initial examination of ACMs will be documented in the corresponding model report. This documentation will include a list of the ACMs reviewed by the SME, the decision made regarding consistency with available data and scientific understanding and reasonableness, and the basis for the decisions made. If, in the SME's judgment, only one conceptual model is consistent with all information, then uncertainty from associated ACMs is not significant.

A.3.3 ACM Evaluation for Use in TSPA-LA

The responsible SME will evaluate whether any retained ACMs for the subsystem process should be developed further. For example, the SME may present results from process models to demonstrate that the ACMs do or do not produce significantly different results for the subsystem component model. The ATL will review the SME recommendations. The ATL is responsible for determining which, if any, ACMs to implement in the TSPA–LA and for recommending the approach for implementation. If all ACMs predict behavior similar to the existing subsystem component used in the TSPA–SR, then ACM uncertainty is insignificant. In this case, the ATL will determine which one of the ACMs and existing subsystem components to carry forward to the TSPA–LA. The ATL will advise the SME of the determination, the determination will be documented in the model report by the SME, and a brief summary of this determination will be included in the TSPA–LA documentation by the ATL.

If differences in results from ACMs appear to be significant at the subsystem level, the next usual activity is for the SME (and process modelers) to develop appropriate model abstractions, based on the ACMs, for inclusion in the TSPA-LA. However, it is possible that building abstractions would not be necessary; conceivably, an underlying process model might not exist for the phenomena under consideration (e.g., curve fits to experimental data) and, consequently, abstractions would have been used directly in the evaluation at the subsystem level. The abstraction of phenomena into TSPA-LA is the same for each ACM and is discussed more completely in Section A.3.4. Also, the YMP QA procedures require using validated models in the TSPA-LA and so eventually each abstraction of an ACM that is used in TSPA-LA would have to be validated (the definition of validation does not preclude having multiple valid ACMs). It is important to recognize that confidence can be enhanced, i.e., model validation improved, when model uncertainty in general and ACMs in particular are addressed and included in the postclosure performance assessment. The major difference when multiple models are used to abstract phenomena is that differences between ACMs need to be addressed at either the subsystem or the total system level as discussed in the next section.

In some cases, the mathematical expressions or model abstractions of ACMs are not straightforward or the number of ACMs can be large. Although the Project intends to reduce the number of conservative assumptions for parameter values, for ACMs the ATL and SME may have to select what are thought to be the most conservative ACMs rather than propagate a range of ACMs. Conservatism at the subsystem level (e.g., in the choice of a conservative ACM) will be made based on the judgment of the ATL and SME that the model identified as conservative is the one that produces the subsystem result more likely to have a negative impact on system performance. The ATL and SME will provide a basis for that judgment, which will be documented in the relevant AMR.

A.3.4 ACM Impact Analysis in TSPA-LA

Should the system level impact of any ACMs appear important enough to quantify for the TSPA–LA, one of two approaches will be used. For those ACMs for which little controversy exists (i.e., it is the SME's judgement that either representation would be generally considered reasonable or acceptable), TSPA analysts will incorporate the ACMs directly into the TSPA–LA as a meta-model. A parameter will be used to select between the two or more alternatives. This selection parameter will have a distribution assigned based on confidence as to the applicability of the various ACMs based on the SME's judgement. The judgment of these weights is not arbitrary but it is unavoidably subjective and documentation of the technical basis for selection and weighting of ACMs will be included.

The Project plans to use weights to include multiple ACMs in most cases; however for model alternatives with significantly different system result implications, the TSPA Analyst may choose to run the full TSPA simulation for each alternative and report the results. With this approach, it may be necessary to consider combinations of the ACMs. The Project would first attempt to consider interactions (e.g., nonlinear coupling) of ACMs qualitatively but if qualitative arguments are insufficient, the TSPA will also run various combinations of the ACMs, with the final compliance case utilizing the more conservative results.

A.3.5 FEPs

Guidance for the treatment of FEPs during consideration of ACMs is not different from guidance for FEPs in general. However, the SME must keep in mind that decisions concerning ACMs are not independent of decisions concerning FEPs. For example, if an ACM is already screened out by the FEP process, the SME should not include it. However, if there is uncertainty in the screening argument, or if the ACM results in a different mechanism for including the FEP, the FEP should be further evaluated as a potential new FEP or a potential change to an existing FEP.

A.3.6 Documentation

A primary goal of the *Guideline Document* [158794] was to ensure that sufficient documentation was generated such that the NRC will understand all the uncertainty that contributes to how the mean system performance is calculated, whether the uncertainty comes from parameters or ACMs. The NRC also should be able to assess whether the DOE has appropriately included ACMs.

For TSPA–SR, the description of the consideration and treatment of ACMs was placed in the corresponding AMRs. Similarly for TSPA-LA, all ACMs will be documented in the respective model reports in accordance with administrative procedure AP-SIII.10Q, *Models*. This documentation will be in the form of an attachment or distinct section to the model report, such that the updated documentation clearly distinguishes between different models. The documentation for any ACM implemented into the TSPA–LA will include a qualitative description, unambiguous mathematical description of the model, and some form of validation. More detailed guidance on documentation is provided in Appendix C.

The TSPA–LA model report, prepared in accordance with administrative procedure AP-SIII.10Q, *Models*, will document the basis for deciding that an ACM brought forward by the SME was appropriate for implementation in the TSPA–LA. Additionally, an Appendix to the TSPA–LA report will list each of the ACMs evaluated in the TSPA-LA and provide a brief description.

A.4 ABSTRACTIONS FOR USE IN TSPA-LA

As stated by the EPA (66 FR 32102, [155216], p. 32102): "Simplifications and assumptions are involved in these modeling efforts out of necessity because of the complexity and time frames involved, and the choices made will determine the extent to which the modeling simulations realistically simulate the disposal system's performance. If choices are made that make the simulations very unrealistic, the confidence that can be placed on modeling results is very limited."

Often the term *abstraction* is applied to any simplification done to move from the real world, to a conceptual model, to a mathematical model, to a computational model, and then to the applied model. However, on the YMP, the term is used to distinguish between models that include details of the physical and chemical phenomena of a process under consideration (i.e., process models), and total system submodels (i.e., abstraction models) that are generally less complex than the process model but ideally capture the essence of the process model that is important to the total system model. The use of model abstractions can be a method to gain computational

speed at the system level. Several possible techniques or combination of techniques can be used to simplify the process mode for use in the total system model as described in the TSPA–SR documentation ([153246], Appendix A, Section A.2). These include: (1) discretization of results from process models into look-up tables, (2) development of response surfaces (i.e., polynomial fits to results), (3) description of results as probability distributions, (4) development of linear transfer functions and (5) reducing dimensionality.

A.4.1 Interface Team for Abstraction

To provide consistency in implementation, documentation, propagation of uncertainty and variability from the process mode to the abstraction model, and in validation of the methods used in abstraction, the *Guidelines Document* [158794] identifies two essential participants. As with the guidance on ACMs, these participants are the ATL and the SME. The intent of the guidelines is that one ATL will be designated to address all model abstraction issues across the various subject areas. . The ATL will also serve as the team lead for addressing alternative conceptual models, because of the interrelationship of these two subject areas.

A.4.2 Identify New and Revised Abstractions

The TSPA–LA is an iteration of previous TSPA analyses, incorporating improved models based on enhanced model validations and results from ongoing testing. The ATL and TSPA analysts will meet to review the abstractions used in the TSPA–SR and TSPA–FEIS to identify any new or additional abstractions needed for the TSPA–LA. This identification will consider the findings of the TSPA–SR, SSPA, and previous sensitivity studies to identify the importance of various model components and consider the level of resolution needed from the model abstraction by considering the level of resolution of the other TSPA model components that the model abstraction feeds. Model abstractions that address key model components and/or key parameters will likely need a greater degree of resolution than those that do not.

The ATL will initiate an interface meeting with the appropriate SMEs to discuss TSPA needs (e.g., list of model components where additional model abstraction may be warranted) and learn of changes in model components proposed by the SMEs. The SME may identify technical issues in proceeding with a recommended model abstraction or may propose alternatives that would be more suitable for model abstraction. The SME will provide such information to the ATL for further consideration. For example, in some cases, it may be advised that addressing parameter uncertainty and variability may be difficult if the current abstraction is used in which case, new abstractions or a more detailed representational model may be required.

A.4.3 Develop Model Abstraction

In constructing the model abstraction, the SME (and Process Modelers) must consider the level of resolution of the process model and the level of resolution in the TSPA–LA model components. Consequently, the SME (and Process Modeler) will work in consultation with the ATL (and TSPA analysts) during the model abstraction development. This includes discussion regarding selection of any conservative components, parameter uncertainties, and evaluation of linear and non-linear models when conservatism is used. The EPA notes in the preamble to 40 CFR 197 ([155216], p. 32102), "Inappropriate simplifications can mask the effects of processes

that will in reality determine disposal system performance, if the uncertainties involved with these simplifications are not recognized." Consequently, the model abstractions used in the TSPA–LA must capture the important uncertainty and variability of the underlying process model. A description of how this uncertainty and variability was captured must be described in the corresponding model report. Often this uncertainty and variability will be captured through parameter distributions; hence, the SME should also solicit input from the PTL to consider the feasibility of developing defensible parameter distributions.

The SME (and Process Modeler) are responsible for developing, validating, and documenting the model abstraction in the respective model report per the requirements of AP-SIII.10Q. The basis of the abstraction and the techniques used will be documented in such a way that they are clearly identifiable and readily explained to an external reviewer.

A.4.4 Incorporate Abstraction into TSPA-LA

To incorporate an abstraction into TSPA-LA, the TSPA analyst will obtain a controlled copy of any software and parameters needed to implement the model abstraction. Then, the TSPA analyst will integrate the model abstraction into the TSPA–LA. The TSPA analyst also documents the integration of the abstraction in the TSPA–LA model report. The ATL iterates with the TSPA analyst until the model abstraction is properly implemented and documented. If any changes were made for the purpose of integration, the TSPA analyst will ensure compliance with any applicable software control procedures. When the TSPA analyst has completed his tasks, the ATL and the SME perform a joint review of the integration activities, model report documentation, and abstraction results. The ATL also ensures that the development, description of the propagation of uncertainty and variability, and validation of the model abstraction are documented in the supporting model report.

A.4.5 Documentation

For TSPA-LA, the technical basis for an abstraction and the development and validation of the model abstraction will be documented in the corresponding model reports in accordance with administrative procedure AP-SIII.10Q, *Models*. As previously described for ACMs, this documentation will be provided as an attachment or distinct section to the model report such that the description is more transparent. The documentation will include both a qualitative description, an unambiguous mathematical description of the model abstraction, and validation of the model. More detailed guidance on the documentation is provided in the Appendix C.

As noted above, the TSPA–LA model report will document how the model abstraction was used in the TSPA–LA. The TSPA–LA model report will note any changes from the model abstraction as documented in the respective model report that were needed to integrate the model abstractions within the TSPA–LA.

A.5 TSPA MODEL PARAMETERS AND DEVELOPMENT OF PARAMETER DISTRIBUTIONS

Internal and external reviews of YMP documents developed for the Site Recommendation, including the TSPA-SR (CRWMS 2000 [DIRS 153246]), found inconsistencies in the processes and methods used to develop and document uncertainties. These reviews are summarized and

evaluated in *Uncertainty Analyses and Strategy* [157389]). In addition, this document identifies strategies to meet the 10 CFR 63.114(b) requirement in the TSPA-LA. A key component of these strategies was to develop detailed guidance on the treatment of parameters and parameter uncertainty. This guidance is documented in Section 4 of the *Guideline Document* [158794]. The methods and approach detailed in that document will be implemented in the TSPA-LA to provide for a consistent treatment in categorizing, quantifying, evaluating, and documenting parameters and parameter uncertainties.

A.5.1 Parameter Development Team

The process of characterizing the parameter uncertainty must be tailored to the type of pertinent data and information available and the use of the parameter in the TSPA models. Hence, a team approach will be used to provide for consistency in the identification and development of TSPA Model parameters and parameter uncertainty (see the *Guideline Document*, Sections 1.3.1 and 4.2, [158794]). Key Parameter Development Team members will include the PTL and Subject Matter Experts (SMEs). The PTL will manage the process of implementing the guidelines (the *Guideline Document* [158794]), and work closely with the SMEs to identify parameters and develop parameter distributions. The PTL will be assisted in this process by one or more experts in statistical analysis and uncertainty analysis.

The SMEs are generally the principal investigators that are most knowledgeable about individual process models and their uncertain parameters. The SMEs will provide the technical expertise to identify, implement, and document the treatment of parameter uncertainty using the processes identified in the *Guideline Document* [158794]. The PTL, and SMEs will be supported by Process Modeler(s), TSPA Analyst(s), and the TSPA Data Base Administrator. The Process Modeler will assist the SME in the development, documentation, and validation of appropriate parameters. The TSPA Analyst will integrate the parameters in the TSPA-LA. The TSPA Data Base Administrator will work with the PTL to document the parameters in a controlled database that is directly linked to the TSPA GoldSim model. The functional roles for the different team members are as follows:

Parameter Team Lead (PTL)–Individual assigned responsibility to lead the process for ensuring the consistent treatment and documentation of parameter values, parameter distributions, and parameter uncertainty used in the TSPA-LA. The PTL will have access to experts in statistical analysis and uncertainty analysis to add their expertise to the process.

Subject Matter Expert (SME)–Personnel who are most knowledgeable about individual process models and uncertain parameters associated with the process models. The SME is responsible for identifying and developing parameters (including values, distributions, and uncertainty) consistent with these guidelines for use in the TSPA-LA.

Process Modeler–Personnel assigned to assist the SME in developing and implementing process models for use in the TSPA-LA.

TSPA Analyst–Personnel assigned to integrate parameters, alternative conceptual models, and model abstractions in the TSPA-LA model.

TSPA Data Base Administrator–Personnel assigned to set up and administer the parameter database; operate the software used to maintain the parameter database; enter data, and verify data entry (approved by the PTL) into the parameter database.

A.5.2 Identify TSPA Model Parameters

To initiate this process of identifying TSPA model parameters and for any newly developed component models for TSPA–LA, the PTL and TSPA Analysts will describe the computational model (implemented mathematical model) in the TSPA and identify the set of TSPA model simulation settings and component model input parameters that are necessary to perform the calculations for the TSPA. The PTL will categorize the parameters as either model-control parameters or model configuration parameters. TSPA model simulation settings will be officially tracked when a simulation is warehoused in YMP's TDMS. Component model input parameters will be further categorized by the PTL as fixed or uncertain parameters. Uncertain parameters, for which. there are few data and are important to the TSPA model and its performance, may be assigned through expert opinion/professional judgment of the SMEs or evaluated through a formal expert elicitation using appropriate procedure. The PASS Sub-project Manager, in consultation with the PTL and other Department Managers, will select those parameters, if any, requiring assignment through expert elicitation. These few parameters will be categorized as uncertain but specified through expert elicitation. Note, however, that the DOE does not intend to require expert elicitation in lieu of professional judgment in the vast majority of situations.

The TSPA for Yucca Mountain has historically included a large number of uncertain parameters (~300) to cover the variety of uncertainty in the modeled processes. Though many are not important to the overall dose calculated, the approach will be continued for TSPA-LA to ensure that TSPA-LA is able to identify parameters that become more important because of improvements in the system models or because the analysis is no longer using conservative values for many parameters.

A.5.3 Develop Fixed Parameter Values

In those few instances when a parameter is fixed at a single value in TSPA-LA, either the mean of the distribution (as developed below) or a recognized "best estimate" as defined by the parameter development team will be used.

A.5.4 Develop Distributions for Parameter Uncertainty

The TSPA Analyst will describe the pertinent TSPA model component and pertinent parameters to the SME and PTL. In turn, the SME describes the pertinent data for developing model parameters to the TSPA Analyst and PTL. An SME may supplement the site-specific data with (a) other qualified data approved for use according to appropriate QA procedures, and (b) other information necessary to fully characterize the uncertainty. The source of underlying information will be documented on a Parameter Entry Form or equivalent memorandum.

The Parameter Development Team (PTL, SME, and TSPA Analyst) will develop a parameter distribution for uncertain parameters as follows.

Step 1. SME determines whether relevant site-specific observational data exist for the parameter in question. If observational data exist, go to Step 2; if no or limited observational data are found, go to Step 3.

Step 2. Determine the size of the combined observational data. If the number of values in the data set is sufficient, as defined by the PTL, and representative, as defined by the SME, and at the appropriate model scale, as defined by the TSPA Analyst, use the data directly to evaluate the parameter range and distribution If the data are sufficient and representative but not at the appropriate scale, use the data indirectly to evaluate the parameter distribution If a distribution is developed with available data, proceed to Step 5. Otherwise, go to Step 3.

Step 3. Often the SME will have some observational data related to a model parameter, but the primary question will be whether the environment of the measurements adequately represents the future environment of the disposal system. In this situation, and others where no observational data are available, the PTL request that the SME provide subjective estimates of:

a) The range of the parameter (i.e., the minimum and maximum values taken by the parameter), and

b) One of the following (in decreasing order of preference):

   i) Percentile points for the distribution of the parameter (e.g., the 25th, 50th [median], and 75th percentiles),

   ii) Mean value and standard deviation of the distribution, or

   iii) Mean value.

The range and distribution for the parameter must take into account the model form and the treatment of aleatoric and epistemic uncertainty in the TSPA analysis (CRWMS 2002 [158592] see Section 4.1.2). For example, if the abstracted component of the TSPA model does not discretize spatially or temporally, then the parameter distribution must account for this temporal or spatial variability (aleatory uncertainty) in a suitably averaged manner. Occasionally, an SME may be overconfident in a model and specify too narrow a range; at other times, an SME may be overly cautious and specify too wide a range. The PTL will provide the oversight to consistently develop appropriate ranges for distributions. To skew a range too narrowly or broadly, would bias the mean and violate the intent of 10 CFR 63.304(4).

Step 4. The PTL, in consultation with the SME and TSPA Analyst, will construct a distribution depending upon the kind of subjective estimate that has been provided. The construction will be in accordance with informational entropy theory to the extent practicable (see Section 4.1.2 of the *Guideline Document* [158794]). These may include the following distributions, or other distributions as justified by the available data:

a) Uniform PDF over the range of the parameter,
b) Piecewise-linear CDF based on the subjective percentiles,
c) Beta PDF based on the subjective range, mean value, and standard deviation,
d) Normal PDF (truncated) based on the subjective mean value and standard deviation,

e) Exponential PDF (truncated) based on the subjective range and mean value.

Step 5. The three members of the parameter development team will review the distribution created. The process of producing a distribution is repeated, possibly after supplying more information and data, and further explanation of the TSPA model and parameter until a meaningful distribution is produced. The PA Project will rely upon the expertise residing in the parameter development team to apply any specific methods appropriate to incorporate "soft" information. Concurrence by all three members of the team is signified by signatures on the Parameter Entry Form (see Figure A-2) or equivalent memorandum.

After completing the parameter development as documented on the Parameter Entry Form (Figure A-2) or equivalent memorandum, the SME will include this form or memorandum as part of the DTN submittal to the TDMS in conformance with AP-SIII.3Q, *Submittal and Incorporation of Data to the Technical Data Management System*. An attachment to this form will include a road map of the DTN so that another user (e.g., member of the TSPA inputs data base team) can easily access that individual parameter.

A.5.5 Documentation of TSPA Parameters

All TSPA-LA model input parameters (both uncertain and certain) will be developed using the process described in Section A.5.3 and will be documented in the appropriate individual process model report (AMR) by the SME according to administrative procedure AP-SIII.10Q, *Models*. The individual AMR will include an identification of process model input data and parameters (Section 4 of the AMR), a detailed discussion of the uncertainties associated with the AMR inputs (Section 6 of the AMR), and a detailed discussion of all outputs developed in the AMR (Section 8 of the AMR). The discussion of AMR inputs and outputs will address the YMRP (NRC 2002) review criteria that requires providing the technical bases for parameter values, assumed ranges, probability distributions, and bounding assumptions used in conceptual models, process models, and alternative conceptual models, considered in the TSPA-LA. More detailed guidance on documentation is provided in Appendix C.

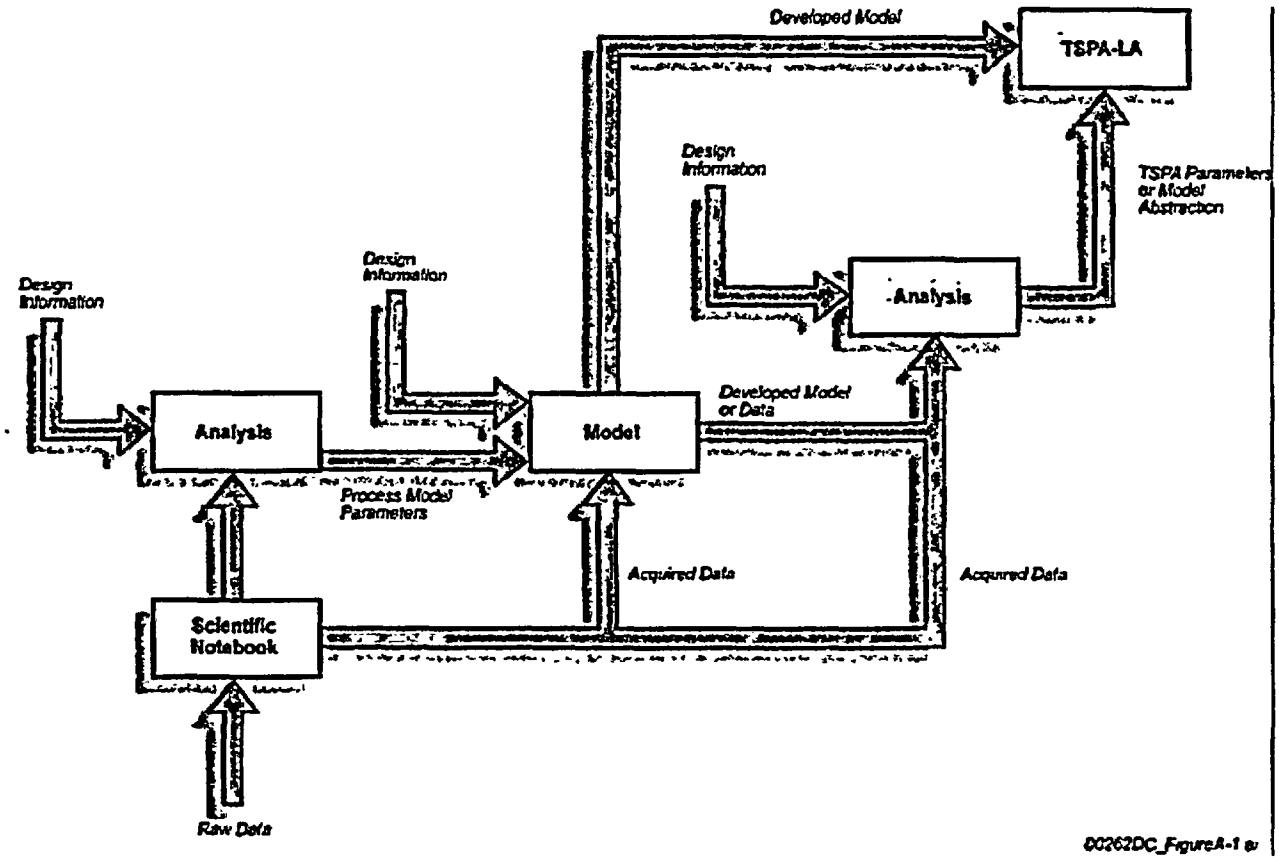

Figure A-1. TSPA Model/Analysis/Data Hierarchy

BSC	**Disturbance Documentation Survey** *Complete only applicable items*	QA: Page of

☐ Modification ☐ Error Correction ☐ New ☐ Deactivation

Parameter	Id
Material	Idmtrl
Model	Idpram
Category	Units

Distribution	
Type	Mean
	Median
	Std Dev
Values	Attachment ☐ Yes ☐ No

Source	
Interpretation	
Qualified Data? ☐ Yes ☐ No	Attachment ☐ Yes ☐ No

Parameter Entry Approved By:

Parameter Team Leader (Print)	(Signature)	Date

Concurrence::

Subject Matter Expert (Print)	(Signature)	Date
Performance Assessment Analyst (Print)	(Signature)	Date

Entered By:

(Print)	(Signature)	Date

Entry Checked By:

(Print)	(Signature)	Date

MIS-WIS-MD-000001 Rev. 00 1118 (Rev 08/21/2002)

Figure A-2. Disturbance Document Summary

APPENDIX B

LEVELS OF MODEL IMPORTANCE AND VALIDATION

APPENDIX B
LEVELS OF MODEL IMPORTANCE AND VALIDATION

This appendix describes three levels of model importance and corresponding validation guidelines commensurate with each level of model importance. The levels of model importance are based on Total System Performance Assessment (TSPA) System Sensitivity analyses and conclusions presented in *Risk Information to Support Prioritization of Performance Assessment Models*, TDR-WIS-PA-000009 REV 00 (Rickertsen 2002; herein referred to as the *Prioritization Report*). A table summarizing model significance by model component along with model importance summaries are also presented. It is important to note that models summarized in Table B.1-1 are TSPA component models that provide input directly to the TSPA system model. Many project models do not provide input to the TSPA system model directly, but provide input or scientific bases to the component model. The level of confidence for these supporting models should be consistent with the confidence level of the TSPA component model.

AP-SIII.10Q, *Models*, requires that TSPA model components be validated for their intended purpose and stated limitations, and to the level of confidence required by the component's relative importance to the potential performance of the repository system. Three levels of model validation are defined as follows, with the level of validation increasing with an increasing level of model importance ranging from low to moderate to high. Models whose variation could lead to a potentially significant effect on the estimate of mean annual dose (e.g., a change greater than 1 mrem/year) should receive a high or Level III model validation. Models whose variation could lead to moderate effect on estimate of mean annual dose (less than 1 mrem/year, but greater than 0.1 mrem/year) should receive Level II model validation. Level I validation is sufficient for models of less importance to the estimate of mean annual dose.

Level I Validation

Level I validation should include, at a minimum, discussion of documented decisions and activities that are implemented during the model development process that build confidence and verify that a reasonable, credible, technical approach using scientific and engineering principles was taken to:

a) Evaluate and select input parameters and/or data

b) Formulate defensible assumptions and simplifications

c) Ensure consistency with physical principles, such as conservation of mass, energy, and momentum

d) Represent important future state (aleatoric), parameter, and alternative model uncertainties

e) Ensure simulation conditions have been set up to span the range of intended use and avoid inconsistent outputs

f) Ensure that model predictions (performance parameters) adequately represent the range of possible outcomes, consistent with important uncertainties.

For post-model development validation per AP-SIII.10Q, chose a single method described in Section 5.4.1 c of AP-SIII.10Q, consistent with a model of limited importance to the mean annual dose.

Level II Validation

Level II validation should include Level I criteria (a) through (f) and a single post-development model validation method described in Section 5.4.1 c of AP-SIII.10Q, consistent with a model of moderate importance to mean annual dose.

Level III Validation

Level III validation should include Level II criteria and documentation that demonstrates model predictions are reasonably corroborated by at least two post-development model validation methods described in Section 5.4.1 c of AP-SIII.10Q.

Levels of model importance for each TSPA component model are summarized in Table B.1-1.

Table B.1-1. Guidelines of Minimum Levels of Model Validation

Climate and Infiltration		I
Unsaturated-Zone Flow		I
Seepage into Emplacement Drifts		I
In-Drift Moisture and Chemistry		
	Invert Moisture and Chemistry	I
	Waste Package/Drip Shield Moisture and Chemistry	II
Waste Package/Drip Shield Degradation		III/I
Radionuclide Release Rates and Concentrations		
	Radionuclide Inventory	II
	Radionuclide Screening	I
	Temperature, Amount of Water, and Chemistry in Waste Package	I
	Degradation of Waste Forms including Cladding	I
	Concentrations of Dissolved Radionuclides and Colloid-Associated Radionuclides	II(Pu) I(other)
	Radionuclide Transport from Waste Package to Drift Wall through Invert	I
	Drift Shadow	I
Unsaturated-Zone Radionuclide Transport		II
Saturated-Zone Flow and Radionuclide Transport		II
Probability of Igneous Activity		
	Eruptive Release Probability	III
	Ground-Water Release Probability	II

Table B.1-1. Guidelines of Minimum Levels of Model Validation (Continued)

Damage to Engineered Barriers by Igneous Activity	Number of WPs intersected by Conduit	III
	Number of WPs disrupted by magma	II
Transport of Radionuclides following Igneous Activity		
	Transport by Ground Water	I
	Wind Speed and Direction	II
Biosphere		
	Soil thickness, removal, and redistribution	III
	Soil, plant, and ingestion submodels	I

The following model discussions are slightly revised versions of discussions provided in Section 4 of the Prioritization Report.

CLIMATE AND NET INFILTRATION

The climate and net infiltration component defines the representation of the water percolating into the mountain in the TSPA model. This component plays a role in determining the amount of water that might contact waste, mobilize radionuclides, and transport radionuclides from the repository to the water table. TSPA sensitivity studies show only a limited sensitivity to the amount of water contacting the waste or the flow transporting radionuclides. In particular, studies discussed in Section 3.3.1 of the *Prioritization Report* do not show a strong sensitivity of the estimate of mean annual dose to this model component. Therefore, although the TSPA model requires that net infiltration input be identified to define the unsaturated zone flow system, the details of the models for climate and net infiltration (i.e., future state, parameter, and alternative model uncertainties in the models) do not significantly affect the estimated performance of the repository system. Considering the low level of importance of the model to the estimate of mean annual dose, confidence gained through Level I model validation should provide an adequate basis for TSPA-LA.

UNSATURATED ZONE FLOW

This component describes the representation of flow in the unsaturated zone above and below the repository in the TSPA model. This component defines the percolation flux at the repository horizon and also indirectly encompasses any effects of heat on the unsaturated zone flow. As indicated in Section 4.1 of the *Prioritization Report*, TSPA sensitivity studies do not show a strong sensitivity of the estimate of mean annual dose to this model component. Accordingly, uncertainties in this component, including those associated with the effects of heat, do not significantly affect the estimated performance of the repository. Considering the low level of importance of the model to the estimate of mean annual dose, confidence gained through Level I model validation should provide an adequate basis for TSPA-LA.

SEEPAGE INTO EMPLACEMENT DRIFTS

This component provides the representation of water movement into the emplacement drifts from the host rock in the TSPA model. As indicated in Section 3.3.2 of the *Prioritization Report*, the TSPA sensitivity studies conducted here do not show a significant sensitivity of the estimate of mean annual dose in the first 10,000 years on the amount of seepage. Accordingly, future state, parameter, and alternative model uncertainties in the seepage model, including those associated with effects of heat and drift degradation, are not important to potential performance of the repository system. Considering the low level of importance of the model to the estimate of mean annual dose, confidence gained through Level I model validation should provide an adequate basis for TSPA-LA.

IN-DRIFT MOISTURE AND CHEMISTRY

This component provides the representation of the moisture and water chemistry conditions in the drift invert in the TSPA model. These conditions determine the radionuclide transport properties of the invert in this model. The discussion in Section 3.3.3 of the *Prioritization Report* indicates that the estimate of mean annual dose in the first 10,000 years is not sensitive to these conditions. That is, although they are represented in the TSPA model, the details of the models used to represent them are not important to potential performance. Considering the low level of importance of the model to the estimate of mean annual dose, confidence gained through Level I model validation should provide an adequate basis for TSPA-LA.

This component is also used in applications external to TSPA to provide the possible range of moisture and chemical conditions on the waste package and drip shield. These conditions are implicitly taken into account in terms of the uncertainties in the waste package and drip shield degradation rates in the current model. These degradation rates are important to the estimate of mean annual dose. Accordingly, the validation efforts should focus on confirming that the ranges accounted for in the degradation models adequately represent the conditions expected over the next 10,000 years. Considering the wide margin provided in the current degradation models, confidence gained through Level II model validation should provide an adequate basis for TSPA-LA.

WASTE PACKAGE AND DRIP SHIELD DEGRADATION

The models in this area include corrosion of the waste package and drip shield. This area also describes early failure of these barriers, e.g., early failure of the waste package due to improper heat treatment. The TSPA sensitivity studies in Section 3.3.4 of the *Prioritization Report* show that the performance of these barriers plays an important role in the estimate of mean annual dose in the first 10,000 years. In particular, this estimate is strongly affected if there is a significant probability of waste package breaching before 10,000 years. It is further affected if, in addition to the waste package, the probability of drip shield breaching before 10,000 years is significant.

The base-case model does not show significant breaching of waste packages before 10,000 years, either as a result of normal degradation or as a result of early failures associated with improper heat treatment. In particular, the following features are evidenced in the current model:

- The fraction of waste packages expected to fail early due to improper heat treatment or other fabrication defects
- The general corrosion rates of the waste package outer barrier material, including enhancements of the general corrosion rate by microbial effects and aging
- Factors affecting stress corrosion cracking degradation (stress thresholds for crack growth, number and character of defects in the weld region, etc.)
- Localized corrosion (crevice corrosion or pitting) of the waste package outer barrier.

Model validation should focus on establishing confidence in these features. Considering the importance of the waste package degradation model to the estimate of mean annual dose, confidence gained through Level III model validation should provide an adequate basis for TSPA-LA. For the drip shield degradation model, confidence gained through Level I model validation should provide an adequate basis for TSPA-LA.

RADIONUCLIDE RELEASE RATES AND CONCENTRATIONS

The components in this category define the rate of release of radionuclides from the engineered barrier system. These TSPA model components include the following:

- Radionuclide inventory in each waste package
- Temperature and water in the waste package and chemistry of that water (and the evolution of those factors with time)
- Degradation of the waste form, including breaching of CSNF cladding and dissolution of the waste form matrix
- Concentrations of dissolved radionuclides and colloid-associated radionuclides
- Radionuclide transport from the waste package and through the drift invert.

The TSPA sensitivity studies in Sections 3.3.6 through 3.3.11 of the *Prioritization Report* indicate that the estimate of mean annual dose in the first 10,000 years has only a minor dependence on in-package temperature, moisture, chemistry, CSNF cladding degradation, waste-form dissolution, colloid-associated radionuclide concentrations, and transport characteristics of the drift invert. That is, although the TSPA model requires that model components for these quantities be specified, the uncertainties in these components are not important to the quantitative estimate of post-closure system performance. Considering the low level of importance of these components to the estimate of mean annual dose, confidence gained through Level I model validation should provide an adequate basis for TSPA-LA.

The mean annual dose estimate is directly proportional to the inventories of the radionuclides that dominate that estimate. The radionuclides that dominate the estimate of mean annual dose include americium-241, plutonium-238, plutonium-239, and plutonium-240. Validation of the inventories of these four radionuclides should consider their range of uncertainty and variability. Considering the level of mean annual dose associated with these radionuclides in this scenario, confidence gained through Level II model validation should provide an adequate basis for TSPA-LA.

The estimate of the 10,000-year mean annual dose for the groundwater release scenario is dominated by plutonium-239, carbon-14, technetium-99, iodine-129, and neptunium-237. The total contribution of these radionuclides to the mean annual dose estimate is insignificant. Therefore, an adequate level of confidence in the inventories of these radionuclides would be obtained if the range of uncertainty and variability in their values were evaluated. Considering the mean annual dose associated with the groundwater release scenarios, confidence gained through Level I model validation should provide an adequate basis for TSPA-LA.

The screening of radionuclides from the TSPA studies should be validated. Validation activities in this case should consider the range of characteristics (half-life, solubility, and retardation characteristics) of these radionuclides. Considering the low level of importance of these radionuclides, confidence gained through Level I model validation should provide an adequate basis for TSPA-LA.

Sensitivity studies show some dependence of the estimate of mean annual dose and groundwater concentrations on the solubility limit of plutonium. The current model considers very wide ranges for each of these, but an expected value in each case that is less than 10 mg/L under expected conditions. The estimate of mean annual dose for the groundwater release scenarios is not significant. An adequate degree of confidence in the solubility limits would be obtained if the range of uncertainties in the models and the abstractions implementing them were evaluated. Considering the level of importance of the plutonium solubility limit to the estimate of mean annual dose, confidence gained through Level II model validation should provide an adequate basis for TSPA-LA. For the solubility of other elements, confidence gained through Level I model validation should provide an adequate basis for TSPA-LA.

The ratio of diffusive and advective transport through the drift invert plays a role in determining the transport of radionuclides in the unsaturated zone. Diffusive release from the drift invert is transferred to the rock matrix and advective release is transferred into the fracture system of the host rock. Validation of this ratio should consider the assumptions and parameter ranges taken into account in determining its value. In view of the low importance of the transport characteristics of the drift invert and the role of transport in the unsaturated zone, confidence gained through Level I model validation should provide an adequate basis for TSPA-LA.

UNSATURATED ZONE RADIONUCLIDE TRANSPORT

This component provides the representation of unsaturated zone radionuclide transport in the TSPA model. Pathways for transport as well as transport characteristics along those pathways are represented. It also describes drift-scale and mountain-scale processes that disperse and delay migration of radionuclides from the engineered barrier system to the water table.

The TSPA sensitivity studies in Section 3.3.10 of the *Prioritization Report* show a significant effect of the unsaturated zone radionuclide transport barrier on the estimate of mean annual dose for the groundwater release scenarios. The most significant effect of this barrier is the delay to the transport of radionuclides of relatively short half-life but high potential dose, including strontium-90 and cesium-137. The current model results in travel time through the unsaturated zone of several thousand years, enough time to reduce the mean annual dose for these radionuclides to negligible levels. Therefore, considering the level of importance of the model to the estimate of mean annual dose, confidence gained through Level II model validation should provide an adequate basis for TSPA-LA.

The model validation efforts should consider the different scales to which the model is applied. That is, an appropriate degree of confidence in the model would be obtained if the uncertainties at the mountain scale and at the drift scale were each explicitly evaluated. Of particular importance in this regard is the validation of the drift-scale model. The TSPA model assumes that advective release from the engineered barrier system enters only the host rock fracture system while diffusive release enters only the matrix. The validation efforts should include a focus providing confidence in this representation.

Transport characteristics of other, more-mobile radionuclides such as carbon-14, technetium-99, and iodine-129 play no significant role in the estimate of mean annual dose. TSPA sensitivity studies show that, in addition, the estimate of mean annual dose is not sensitive to the specific transport characteristics of radionuclides, such as neptunium-237 and the plutonium isotopes. Accordingly, an appropriate level of confidence would be obtained for the models of transport of these radionuclides by showing they are consistent with measured values of the transport characteristics, such as sorption and matrix diffusion. Considering the low level of importance of the model to the estimate of mean annual dose, Level I validation is appropriate for these radionuclides.

SATURATED ZONE FLOW AND RADIONUCLIDE TRANSPORT

This component provides the TSPA representation of water flow and radionuclide transport below the water table from the repository location to the accessible environment in Amargosa Valley. The saturated zone model therefore describes the pathways for transport of the radionuclides in the volcanic aquifers and the valley fill alluvium and the fluxes of water along these pathways. The model also describes the transport characteristics of the radionuclides as they move in these pathways.

The TSPA sensitivity studies in Section 3.3.12 of the *Prioritization Report* show a significant effect of the combined unsaturated zone and saturated zone radionuclide transport barriers on the estimate of mean annual dose for the groundwater release scenarios. The most significant effect of these barriers is the delay to the transport of radionuclides of relatively short half-life but high potential dose, including strontium-90 and cesium-137. The current model results in travel time through the volcanic aquifers and the valley-fill alluvium of thousands of years, enough time to reduce the mean annual dose for these radionuclides to negligible levels. Considering the level of importance of the model to the estimate of mean annual dose, confidence gained through Level II model validation should provide an adequate basis for TSPA-LA.

PROBABILITY OF IGNEOUS ACTIVITY

The probability of igneous activity is represented in the TSPA model in terms of two factors:

- Igneous activity eruptive release probability (probability of igneous eruption through the repository)
- Igneous activity groundwater release probability (probability of igneous intrusion into emplacement drifts).

TSPA studies in Section 3.3.13 of the *Prioritization Report* indicate that the igneous activity eruptive release scenario dominates the estimates of mean annual dose. The estimated peak mean-annual dose is proportional to the mean probability of the eruption. Considering the potential importance of this estimate to mean annual dose, confidence gained through Level III model validation should provide an adequate basis for TSPA-LA.

The estimate of mean annual dose for the igneous activity groundwater release scenario is less than that for the eruptive release scenario and this estimate is proportional to the mean event probability of the current model. While a lower level of validation is needed for this probability, the validation activities for the probability of igneous intrusion would be related to those for igneous eruption. Accordingly, confidence gained through Level II model validation should provide an adequate basis for TSPA-LA.

DAMAGE TO ENGINEERED BARRIERS BY IGNEOUS ACTIVITY

The TSPA model includes components to take into account the following:

- Damage to waste packages, drip shields, and cladding as a result of igneous intrusion
- Damage to waste packages, drip shields, and cladding as a result of igneous eruption.

TSPA studies in Section 3.3.14 of the *Prioritization Report* indicate that the igneous activity eruptive release scenario dominates the estimates of mean annual dose. The peak mean annual dose is proportional to the mean amount of radionuclides erupted. In the TSPA model this latter quantity is determined from the mean number of waste packages intersected by conduits during the event. Adequate confidence in this number would therefore be obtained by considering parameters, assumed ranges, and bounding assumptions in the context of this quantity. Considering the importance of the mean number of waste packages disrupted to the estimate of mean annual dose, confidence gained through Level III model validation should provide an adequate basis for TSPA-LA.

The estimate of mean-annual dose for the igneous activity groundwater release scenario is proportional to the mean number of waste packages and drip shields disrupted by magma intruding into the emplacement drifts. The TSPA model also considers damage to waste packages not contacted by magma, but the limited extent of this damage in the model (on the order of 10 cm^2 breach area) leads to an insignificant contribution to the mean annual dose. Therefore, validation efforts focus on the estimate of the number of waste packages contacted by magma and the degree of damage to other waste packages. Considering the level of importance

of these factors to the estimate of mean annual dose, confidence gained through Level II model validation should provide an adequate basis for TSPA-LA.

ATOMOSPHERIC TRANSPORT OF ERUPTED RADIONUCLIDES

The TSPA model includes a component to represent transport of radionuclides in the atmosphere following eruption from the repository. This component is determined by factors including the volume of erupted material, the particle size of the radionuclide-bearing tephra, the wind speed and direction, and the deposition of tephra in Amargosa Valley. The TSPA sensitivity studies in Sections 3.3.15 of the *Prioritization Report* indicate that, of these factors, the only ones that bear significantly on the estimate of mean annual dose are the mean wind speed and direction. Accordingly, adequate confidence in this TSPA model area would be obtained by considering the uncertainties and assumptions in the representation of these factors. Considering the effect of these factors on the estimate of mean annual dose, confidence gained through Level II model validation should provide an adequate basis for TSPA-LA.

BIOSPHERE CHARACTERISTICS

This component provides the representation of processes leading to uptake of radionuclides by individuals and the effects of that uptake in the TSPA model. The outputs of this model are groundwater release and eruptive release biosphere dose conversion factors (BDCFs) that translate radionuclide concentrations in groundwater, air, and soil into annual dose. The mean annual dose is therefore directly proportional to these BDCFs.

The submodels associated with the igneous activity eruptive release scenario have a stronger influence on the estimate of total mean annual dose than those associated with the groundwater release scenarios. The mean annual dose for this scenario is currently estimated to be moderately significant and the contribution of the biosphere submodels to uncertainty in this estimate is less than a factor of two. The soil, air, and inhalation submodels dominate the BDCFs for the eruptive release scenario. The validation activities should therefore focus on considerations of the conceptual models, process-level models, and abstractions for the TSPA model as they apply to these submodels. In addition, the validation activities should consider the representation of soil thickness, removal, and aeolian and fluvial redistribution. Considering the importance of the biosphere models and the models for the soil thickness, removal, and redistribution to mean annual dose, confidence gained through Level III model validation should provide an adequate basis for TSPA-LA.

The mean annual dose for the groundwater release scenarios is currently estimated to be insignificant in the first 10,000 years. The contribution of the biosphere submodels for this scenario to uncertainty in this estimate is less than a factor of two. The soil submodel, the plant submodel, and the ingestion submodel dominate the estimate of the BDCF for these scenarios. Confidence gained through Level I model validation should provide an adequate basis for TSPA-LA.

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APPENDIX C

TEMPLATE OUTLINES FOR MODEL REPORT SECTIONS 4, 6, 7, AND 8

APPENDIX C
TEMPLATE OUTLINES FOR MODEL REPORT SECTIONS 4, 6, 7, AND 8

The templates in this appendix outline information that supplements model documentation requirements specified in Attachment 3 of AP-SIII.10Q. These templates do not address every requirement in procedure AP-SIII.10Q, rather they focus on providing a framework for a consistent approach to documenting inputs, model uncertainties, model validation, and model outputs. Users of the SPGM should review all AP-SIII.10Q requirements and defer to the procedure if discrepancies arise between this manual and the procedure.

C.1 Generic Template for Section 4.1 of an AMR

This template provides guidance on the desired content for this subsection of Section 4 - Inputs. Because the types of inputs from different AMR are not the same, this template does not prescribe a specific table format. It is up to each SME to develop a table for inputs that fit the format for their output. However, all AMR input should be presented in a tabular format to the extent practical. For AMRs with large input files, these files can be included by reference (DTN) in the table.

This template is not intended to replace any other AP-SIII.10Q requirements. Users of this manual should defer to the procedure if discrepancies arise between this manual and the procedure.

4. Inputs

4.1 Data, Parameters, and Other Model/Analyses Inputs

This subsection identifies all input data, parameters, and other forms of model/analyses inputs [e.g., response surfaces, look-up tables, empirical equations developed to fit data] that are used in models/analyses that are detailed in this AMR.

4.1.1 Data

The data providing input for the development of parameters used in the models/analyses documented in this AMR are identified in Table 4.1-1.

Table 4.1-1. Input Data

Data Name	Data Source	DTN

Data definition – As it pertains to QARD Supplement III, information developed as a result of scientific investigation activities, including information extracted from reference sources, and

performance assessment analysis. This includes data generated as a result of characterizing waste forms.

The AMR author should address the following discussion points in this subsection:

- Provide a brief description of the data set(s) used and the appropriateness for using these data as input to the model/analyses documented in this AMR.
- Provide a brief roadmap to what data are in the DTN. This discussion is not applicable to DTNs that include only the data used. It is applicable if the DTN includes other data that are not used.
- Provide a description on how the data are used to develop input parameters for the model/analyses.
- Identify that the discussion of uncertainty in the input data are addressed in Section 6.4.1.

4.1.2 Parameters and Parameter Uncertainty

The input parameters used in the model/analyses documented in this AMR are identified in Table 4.1-2.

Table 4.1-2. Input Parameters

Parameter Name	Parameter Source	DTN	Parameter Value(s)	Units	Distribution (or single value if fixed)

The AMR author should address the following discussion points in this subsection:

- Provide a brief description of each input parameter, how it is used in the model/analyses, and the appropriateness for using the parameters as input to the model/analyses documented in this AMR.
- Provide a brief roadmap to what parameters are in the DTN. This discussion is not applicable to DTNs that include only the parameters used in this AMR. It is applicable if the DTN includes other parameters that are not used.
- Identify that the discussion of uncertainty in the input parameters is addressed in Section 6.4.1.

4.1.3 Other Model/Analyses Inputs (if applicable)

Other input information used in the model/analyses documented in this AMR is identified in Table 4.1-3. This other input information could be response surfaces, look-up tables, empirical equations used to describe a data set, design information, etc. It is important to note that all data input to LA AMRs shall be qualified per AP-SIII.2Q prior to use. Other information used to develop parameter distributions shall be presented in Section 5, Assumptions or Section 6, Model Discussion.

Table 4.1-3. Other Model/Analyses Input Information

Input Name	Input Description		Input Uncertainty

The AMR author should address the following discussion points in this subsection:

- Provide a brief description of the other model/analyses inputs, how they are used in the model/analyses, and the appropriateness for using these inputs for the model/analyses documented in this AMR.
- Provide a brief roadmap of the source for these.
- Identify that the discussion of uncertainty in the input information is addressed in Section 6.4.1.

C.2 Generic Template for Section 6 of an AMR

This template provides guidance on the desired content for Section 6 Model Discussion of an AMR. Because the types of outputs from different AMR are not the same, this template does not prescribe a specific table format. It is up to each SME to develop a table for FEPs dispositioned in the TSPA-LA, ACMs considered, and inputs used in his/her model(s) that fit the format for their intended use. However, all this information should be presented in a tabular format to the extent practical. For AMRs with large input or FEP listings, these files can be included by reference (DTN) in the table.

This template is not intended to replace any other AP-SIII.10Q requirements. Users of this manual should defer to the procedure if discrepancies arise between this manual and the procedure.

6. Model Discussion

6.1 Modeling Objectives

The purpose of this section is to summarize the problem to be modeled, the modeling objectives, and to describe the interrelationships between the model being developed and the LA model hierarchy (i.e., inputs provided from upstream models, analyses, data and output feeds to downstream models or TSPA). *(See example Schematic at the end of this outline, provide similar schematic for each model and summarize information specific to that model on the schematic)*

- Describe problem to be modeled
- Specify output quantities or performance measures that will be used as inputs to downstream models and/or analyses
- Specify model inputs from upstream data sources, design information, or analyses output
- Describe how model output quantities are to be used.
- If the model is used directly in the TSPA system model describe its role.

6.2 Features, Events, and Processes Included in Model

- Provide a complete listing of FEPs described in this model report. The following paragraph and table are provided for documentation consistency.

The development of a comprehensive list of features, events, and processes (FEPs) potentially relevant to post-closure performance of the potential Yucca Mountain repository is an ongoing, iterative process based on site-specific information, design, and regulations. The approach for developing an initial list of FEPs, in support of TSPA-SR (CRWMS M&O 2000), was documented in Freeze et al. (2001). The initial FEP list contained 328 FEPs, of which 176 were included in TSPA-SR models (CRWMS M&O 2000, Tables B-9 through B-17). To support TSPA-LA, the FEP list was re-evaluated in accordance with the Enhanced FEP Plan (BSC 2002; Section 3.2). Table 6.2.1 provides a list of FEPs that are included in TSPA-LA models described in this model document. Details of the implementation of these FEPs in TSPA-LA are summarized in Section 6.9.

For each of the included FEPs listed in Table 6.2.1, the implementation in TSPA-LA is described in this model document. Details of the implementations are summarized here in the table, including specific references to Sections within this document.

Table 6.2.1. Included FEPs for This Model Report and Their Disposition in TSPA-LA

FEP No.	FEP Name	Section Where Disposition is Described	Summary of Disposition in TSPA-LA

- The AMR author should populate the first two columns of this Table with all included FEPs, using the Table from the TWP as a basis. Check with FEPs team lead to ensure that all included FEPs are listed. Any changes from the TWP Table should be noted (to avoid the need to revise the TWP). The third column should provide a reference to a previous section (and paragraph if possible) where the implementation of the FEP is described. The fourth column should provide a summary of the implementation. It should include model and/or parameter names used to implement the FEP. In some cases it may be necessary to elaborate on the previous text to better describe the implementation of the FEP. In the case of shared FEPs it is only necessary to address implementation relevant to this model document. This column will provide the basis (or perhaps be used verbatim) for the TSPA Disposition field in the FEP AMR and FEP Database.

- Guidance for TSPA Disposition in the Enhanced FEP Plan is as follows: "For included FEPs this is the main screening discussion. A summary discussion of the treatment of the FEP in the TSPA must be presented. A reference to an AMR describing a model and/or model abstraction is desirable. In some cases, a FEP may affect multiple facets of the project, may be relevant to more than one FEP AMR subject area, or may not fit neatly within the FEP AMR structure. In these cases, rather than create multiple separate FEPs, these shared FEPs will be assigned to more than one FEP AMR."

6.3 Base-Case Conceptual Model

The purpose of this section is to provide a detailed description of the physical subsystem being modeled and its environment. Include a summary of included FEPs, specification of boundary and initial conditions, geometry of the subsystem, components or features of the subsystem, physical and chemical processes occurring within the subsystem, and a description of how these processes occur.

- Provide a physical description of the subsystem, including important features or components

- Provide a summary of included FEPs and how they are captured by the conceptual model

- Describe physical and chemical processes, and couplings, important to subsystem performance

- Describe conditions and environment in which subsystem is expected to operate including boundary and initial conditions
- Discuss how laboratory or field data support understanding of processes and environmental conditions
- Identify and discuss important and relevant future state, parameter, and process uncertainties associated with

- Structural features

- Physical and chemical processes

- Subsystem environment

- Discuss assumptions and simplifications employed when formulating the base-case conceptual model
- Justify conservative assumptions and choices among competing assumptions
- Discuss the dependent and independent variables and parameters that will be chosen to represent the important processes and features of the subsystem
- Identify elements of the subsystem and environment that will be treated as uncertain

6.4 Consideration of Alternative Conceptual Models

Alternative conceptual models are based on assumptions and simplifications that are different from those employed in the base-case model. An important reason for considering ACMs is to help build confidence that changes in modeling assumptions or simplifications will not change conclusions regarding subsystem and total system performance. Conceptual model uncertainty results from sparse observational data and a lack of available information to corroborate or refute plausible alternative interpretations of the subsystem and the processes occurring within the subsystem.

- Summarize alternative conceptual models
- Identify and discuss additional alternative conceptual models to be considered
- For each alternative conceptual model discuss each of the elements in Section 6.2 and contrast them with the base-case model
- Provide rationale for excluding ACM from further evaluation if appropriate.
- If ACM cannot be screened from further evaluation describe why
- Provide a table summarizing ACMs considered, key assumptions distinguishing ACMs, and ACM screening status and basis

Table 6.4.1. Alternative Conceptual Models Considered

Alternative Conceptual Model	Key Assumptions	Screening Assessment and Basis

6.5 Model Formulation for Base-Case Model

6.5.1 Mathematical Description of Base-Case Conceptual Model

The mathematical description is a translation of the conceptual model into a mathematical form that is consistent with the modeling objectives, available data, and knowledge of important parts of the system. When describing the mathematical model discuss any relevant assumptions, simplifications, and justifications necessary to make the model tractable and practical. Note: If the mathematical description resides in the system, describe the model and reference the applicable mathematical AP-SI.1Q software documentation. If the mathematical description is general and not specific to the base-case model, include specific description in this section.

- Overview

- Outline how mathematical model is formulated and presented

- Describe how modeling objectives will be satisfied

- If subsystem model is comprised of submodels give a description of how submodels are combined and present mathematical models for each in a logical sequence (following format below)

- Discuss any additional assumptions and simplifications employed when formulating the mathematical model

- Discuss any additional uncertainties that are introduced

- Mathematical Model Description

- Governing partial differential equations, algebraic equations, or empirical equations

- Boundary conditions

- Initial conditions

- Mathematical expressions relating subsystem performance measures to dependent variables and environmental or system parameters

- Define nomenclature for dependent and independent variables and coefficients in equations

- Roman Letters

- Greek Letters

- Dimensionless Numbers

- Special Symbols

6.5.2 Base-Case Model Inputs

This subsection summarizes all input data, parameters, and/or other input information [response surfaces, look-up tables, empirical equations, numerical solution parameters] for the models/analyses that are detailed in this AMR. This subsection should be coordinated with, and cross-referenced to, Section 4. In addition, the uncertainties associated with these input are identified and discussed.

- Because the types of inputs are not the same for each AMR, this template does not prescribe a specific table format. It is up to each SME to develop a table for inputs that fit the format for their output. However, all AMR input should be presented in a tabular format to the extent practical. For AMRs with large input files, these files can be included by reference (DTN) in the table.

- In addition to identifying inputs, the uncertainty associated with these inputs should be explicitly identified and discussed. These discussions should address the YMRP review criteria that requires providing the technical bases for parameter values, assumed ranges, probability distributions, and bounding assumptions used in conceptual models, process models, and alternative conceptual models, considered in the TSPA.

- Tabulate input values for all coefficients in the governing equations.

Table 6.5.1. Model/Analyses Inputs Used in X Model

Input Name	Input Description	Input Source (DTN if applicable)	Value or Distribution (Units)	Type of Uncertainty (Aleatoric or Epistemic)

- Provide a brief qualitative description of each input and the intended use of the input.

- Identify the intended use of the output data, parameters, or information.

- Provide a discussion of parameter uncertainty and variability for each model input. Identify if the uncertainty is aleatoric or epistemic (see Section 4.1.1 of the Guidelines document [TDR-WIS-PA-000008 Rev00 ICN01A]). This discussion should address the YMRP review criteria that requires providing the technical bases supporting the use of

selected of parameter values, assumed ranges, probability distributions, and bounding assumptions in conceptual models, process models, and alternative conceptual models, considered in the TSPA.

6.5.3 Summary of Computational Model

Summarize how the mathematical model is implemented and solved. If model is implemented in GOLDSIM directly provide a description of how this implementation is to be done. If model is implemented in another computer code that is external to GOLDSIM or is linked to GOLDSIM provide a brief summary of the numerical algorithm used for solving the model equations.

6.6 Model Formulation for Alternative Conceptual Models (this section only applies if an ACM must be evaluated quantitatively)

For each alternative conceptual model present a mathematical model description and summary of computational model for each ACM in a separate subsection. If an ACM's mathematical model is similar to the base-case mathematical model it is not necessary to present a complete formulation if model differences can be clearly explained and presented. An example of such a case is when an ACM's mathematical model is obtained by simply setting a term to zero in the base-case mathematical model.

6.6.1 Mathematical Description of Alternative Conceptual Model (this section only applies if an ACM must be discretely evaluated)

- Overview

  - Outline how mathematical model is formulated and presented

  - Describe how modeling objectives will be satisfied

  - Discuss any additional assumptions and simplifications employed when formulating the mathematical model

  - Discuss any additional uncertainties that are introduced

- Mathematical Model Description

  - Governing partial differential equations, algebraic equations, or empirical equations

  - Boundary conditions

  - Initial conditions

- Mathematical expressions relating subsystem performance measures to dependent variables and environmental or system parameters

- Define nomenclature for dependent and independent variables and coefficients in equations

- Roman Letters

- Greek Letters

- Dimensionless Numbers

- Special Symbols

6.6.2 Summary of Alternative Computational Models

Summarize how the alternative mathematical models are implemented and solved. If model is implemented in GOLDSIM directly provide a description of this implementation is to be done. If model is implemented in another computer code that is external to GOLDSIM or is linked to GOLDSIM provide a brief summary of the numerical algorithm used for solving the model equations and provide reference to computer code.

6.7 Base-Case Model Results

This section describes the approach taken to complete the base-case model analyses and presents the results that will support the model objectives outlined in Section 6.1. If the model is an abstraction, abstraction results that will be used in the TSPA-LA shall be summarized. [Note: If no analyses are performed using the model, with the exception of analyses conducted to support the validation of the model, this section may be eliminated.]

6.7.1 Overview

- Summarize modeling approach

- Software used

- Sources of data

- Calibration activities

- Summarize the base-case model runs that will be performed to meet modeling objectives outlined in Section 6.1

- Summarize sensitivity analyses to be performed

- Summarize how results will be post processed and analyzed

6.7.2 Base-Case Model Results

This section presents analyses that will support the model objectives outlined in Section 6.1

- Discuss behavior of performance measures

- Describe range of results

- Evolution of results in time

- Discuss important couplings among processes and their impact on performance measures

- Discuss impact of uncertainties on performance measures

- Describe how data uncertainty is propagated

- Discuss and rank importance of uncertainties

- Summarize why uncertainty is adequately represented

- Discuss why results are consistent with output from detailed process models (if an abstraction) and/or empirical observations

6.8 Evaluation of Alternative Models and Model Uncertainty (this section only applies if an ACM must be evaluated quantitatively)

The objective of this section is to assess model uncertainty by making quantitative comparisons between the base-case model and those alternative models that could not be excluded in Section 6.3.

6.8.1 Overview

- Describe approach that will be used for comparison of alternative models to the base-case model

- Describe performance measures and calculations that will be used to evaluate alternative models

- Discuss comparison criteria

6.8.2 Alternative Model Problem Setup

For each ACM, describe problem setup, identify key differences in inputs between models relative to the base-case model setup (see Section 6.6.2), and provide results. Problem setup and results should be described in a separate subsection for each alternative model.

6.8.3 Alternative Model 1 Results

This section presents the results of an alternative model

- Discuss behavior of performance measures

- Describe range of results

- Evolution of results in time

- Discuss impact of uncertainties on performance measures

- Describe how data uncertainty is propagated

- Discuss and rank importance of uncertainties

- Summarize why uncertainty is adequately represented

6.8.4 Assessment of Alternative Models

Summarize base-case and alternative model results in a comparative uncertainty analysis. The goal here is to assess if ACMs lead to significant differences in simulated performance measures that would in turn potentially affect total system performance.

- Comparison of Results

- Present graphs or plots comparing ACM and base-case model results

- Comparisons should be made between the distributions of base-case model output values and alternative model output values for each performance measure defined in Section 6.1

- Significant differences would be those differences where a) the range of output values for the alternative model is much broader or narrower that the base-case model, and b) the extreme values of the distribution are much greater or smaller

- Summary

- Discuss significant model uncertainties and their cause

- Provide a table summarizing ACMs evaluated, key assumptions distinguishing ACMs, and results of evaluation

Table 6.8.1. Alternative Conceptual Models Considered

Alternative Conceptual Model	Key Assumptions	Summary of Subsystem Evaluation	Recommend TSPA Evaluation

6.9 Description of Barrier Capability *(this section is applicable to model reports that document models for – Infiltration, Unsaturated Zone [UZ] Flow, UZ Transport, Waste*

Package/Drip-shield Degradation, Cladding Failure, Waste-form Degradation, EBS Transport, Saturated Zone Flow, and Saturated Zone Transport)

This section should present analyses of barrier capability and describe the capability of the barrier to prevent or delay the movement of water or radioactive materials. The extent of analyses and discussion presented will be commensurate with barrier importance.

6.9.1 Analyses of barrier capability

- Discuss analyses that quantify the ability of a barrier to prevent or delay the movement of water or radioactive materials

- Focus on subsystem capability measures, e.g.,

- Assess effectiveness of surface soils and topography to limit infiltration

- Assess the amount of water diverted around the emplacement drifts

- Assess material lifetimes and types of waste package and drip shield failure modes that will affect the rate of water contacting waste

- Assess the amount of radionuclide retardation provided by corrosion materials from waste package internals (measured in mass or concentration over time)

- Assess material lifetimes and failure modes of cladding and waste forms, and possible rates of radionuclide release from the waste form

- Assess the amount of radionuclide retardation provided in the UZ and Saturated Zone (measured in mass or concentration over time)

- Quantify uncertainty in barrier performance and rank important uncertainties and their contribution to uncertainty in barrier performance

6.9.2 Summary of Barrier Capability

- Describe the capability of the barrier to prevent or substantially delay the movement of water or radioactive materials, including the uncertainty associated with this capability and the consistency with approaches used in the total system performance assessment

- See table of example summaries. These summaries should be expanded by discussing all features of a barrier that contribute to its capacity for preventing or delaying the movement of water or radioactive materials. Discuss uncertainties associated with each feature and how those uncertainties impact barrier capability.

Table 6.10.1. Example Summaries of Barrier and Performance Functions for a Yucca Mountain Repository

Surficial soils and topography	Limit rainfall at site due to and climate, limit infiltration into the unsaturated zone due to evaporation, transpiration, and runoff
Unsaturated rock layers overlying the repository and host unit	Reduce the amount of water entering emplacement drifts by subsurface processes (e g., lateral diversion, capillary barrier, thermal processes, thickness of unsaturated zone)
Unsaturated rock layers below the repository	Delay radionuclide transport to the water table due to drift shadow zone, sorption, and matrix diffusion, reduce radionuclide concentrations by dilution in perched water
Saturated Zone volcanic tuff and alluvial deposits below the water table from below the repository to point of compliance	Delay radionuclide transport to the receptor location because of water residence time, matrix diffusion, and sorption; reduce radionuclide concentrations by dilution and natural attenuation
Drip shield around the waste packages	Prevent/reduce water contacting the waste package and waste form by diverting water flow around the waste package, and limiting advective transport through the invert
Waste package	Prevent water from contacting the waste form for the effective life of the package; limit structural damage to waste form from rockfall; limit water contacting waste form; limit radionuclide transport out of waste package; prevent in-package criticality
Cladding	Delay and/or limit liquid water contacting spent nuclear fuel after waste packages have degraded, limit radionuclide mobilization/transport (Note no cladding is present for High Level Radioactive Waste)
Waste form (Commercial Spent Nuclear Fuel, DOE Spent Nuclear Fuel, DOE High-Level Radioactive Waste)	Limit radionuclide releases as a result of slow waste form degradation, low radionuclide solubilities, and in-package sorption
Invert	Limit diffusive transport of radionuclides out of the engineered barrier system

7.0 Validation

- See Models Procedure AP-SIII.10Q, REV 0, ICN2
- For abstraction models, validation documentation should also include:

- Comparison between model abstraction results and process model results

- Comparison of propagated uncertainty and variability between the process model and model abstraction.

C.3 Generic template for Section 8 of an AMR

This template provides guidance on the desired content for the output subsection of Section 8 - Conclusions. Because the types of outputs from different AMR are not the same, this template does not prescribe a specific table format. It is up to each SME to develop a table for outputs that fit the format for their output. However, all AMR output should be presented in a tabular

format to the extent practical. For AMRs with large output files, these files can be included by reference (DTN) in the table.

In addition to identifying outputs, the uncertainty associated with these outputs should be explicitly identified and discussed.

This template is not intended to replace any other AP-SIII.10Q requirements. Users of this manual should defer to the procedure if discrepancies arise between this manual and the procedure.

8.2 Model Outputs

This subsection identifies and summarizes all outputs, including models, developed from the models/analyses that are detailed in this analysis/model report. Summarize how the outputs and/or models are to be used. In addition, identify and discuss uncertainties associated with the outputs. This discussion should address the YMRP review criteria that requires providing the technical bases for parameter values, assumed ranges, probability distributions, and bounding assumptions used in conceptual models, process models, and alternative conceptual models, considered in the TSPA.

8.2.1 Developed Output

The outputs developed from the model/analyses documented in this analysis/model report are identified in Table 8.2-1(example only – different types of outputs [e.g., data, parameters, response surfaces, formulas describing empirical relationships, output tables] may require different table formats).

Table 8.2-1. Output Developed in this AMR

Output Name	Output Description	DTN	Output Uncertainty		
			Sources of Uncertainty	Uncertainty Distribution (if applicable)	Characteristic Values (if applicable)

The AMR author should address the following discussion points in this subsection:

- Provide a brief qualitative description of each developed output, a quantitative description of any output probability distributions, the intended use of the developed output, and what downstream models/analyses will use these developed output.

8.2.1 Output Uncertainty

The AMR author should address the following discussion points in this subsection:

- Provide a discussion that identifies uncertainties associated with input data/parameters and the uncertainties associated with the model/analyses (conceptual and numerical model uncertainties).

- Provide a discussion on the impact of propagating these input uncertainties on the output resulting from implementing the model/analyses described in this AMR.

- Provide a discussion on the process used to establish developed output uncertainty distributions (see Section 4.2.1 of the Guidelines document [TDR-WIS-PA-000008 Rev00, ICN01A]).

- The above discussions should address the YMRP review criteria that requires providing the technical bases supporting the use of selected parameter values, assumed ranges, probability distributions, and bounding assumptions in conceptual models, process models, and alternative conceptual models considered in the TSPA.