

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

TECHNICAL OPERATING PROCEDURE

Proc. TOP-001

Revision 0

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Title

TOP-001 PROGRAM ARCHITECTURE DEVELOPMENT AND MAINTENANCE

EFFECTIVITY AND APPROVAL

Revision 0 of this procedure became effective on June 13, 1988. This procedure consists of the pages and changes listed below.

<u>Page No.</u>	<u>Change</u>	<u>Date Effective</u>
1 - 7	-	6/13/88

SUPERSEDED

Supersedes Procedure No. None

Approvals

Written By <i>Bruce Mahato</i>	Date <i>6/10/88</i>	Technical Review <i>Wesley Patrick</i>	Date <i>6/10/88</i>
Quality Assurance <i>Thomas C. Schovik</i>	Date <i>6/11/88</i>	Cognizant Director <i>Allen R. Whiting</i>	Date <i>6/3/88</i>

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TOP-001 PROGRAM ARCHITECTURE DEVELOPMENT AND MAINTENANCE

1. PURPOSE AND SCOPE

The purpose of this procedure is to provide the broad guidelines for developing (Part A) and maintaining (Part B) the PA at the Center. Additional specific guidelines are provided by work instructions that will be subsequently developed, as needed. The development and maintenance activities are addressed in separate sections of this Technical Operating Procedure (TOP).

2. DEFINITION

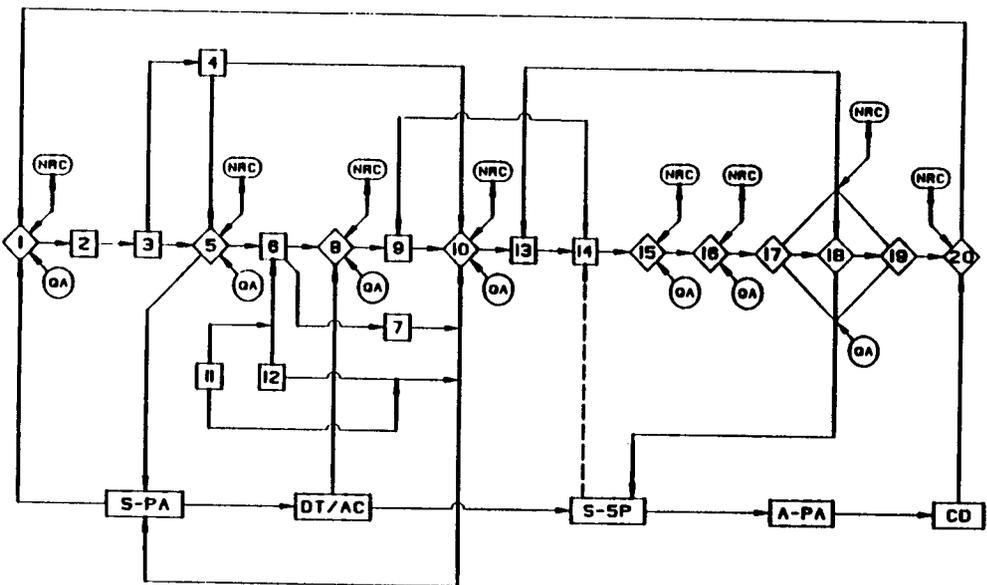
Program Architecture (PA) is the overall system description for the Nuclear Regulatory Commission High-Level Waste (NRC-HLW) repository licensing system. It is mission-oriented, requirements based, proactive, and provides a basis for integration of all activities related to the NRC-HLW mission.

As noted on the process diagram for developing and maintaining a PA (Fig. 1), the indicated 20-step approach leads to issue resolution. The development and maintenance of the PA is an ongoing process containing subprocesses reflecting refinement loops back through earlier steps to produce and maintain the PA as a current product. The complete PA may require modification to certain of these steps or additional steps not currently identified in the process diagram but which may become necessary as the PA matures and develops. As indicated in Figure 1, the Elements/Subelements develop and submit their input according to prior instructions produced by WSE&I. These process activities are indicated by the squares in Figure 1. The PA development process involves initial and supplementary inputs from the Elements/Subelements along with information from other related and off-line parallel activities that provide the information to be integrated by the WSE&I Subelement at the process steps indicated in Figure 1 by the diamonds. This allows integrated products to be produced by the WSE&I Subelement that ultimately lead to the complete development of the PA. At the completion of the diamond integration points, the products reflect a QA certification and NRC approval consistent with the requirements of the Center contractual and QA responsibilities.

3. RESPONSIBILITY

3.1 The Director of SE&I is responsible for the implementation of this procedure.

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- X** PHASE OF THE PROCESS REQUIRING WORK AT AND INPUT FROM THE PROGRAM ELEMENTS
- X** PHASE OF THE PROCESS REQUIRING INTEGRATION
- NRC** REVIEW AND APPROVAL BY NUCLEAR REGULATORY COMMISSION
- QA** REVIEW AND APPROVAL BY QUALITY ASSURANCE

- LEGEND**
1. IDENTIFY APPLICABLE STATUTES AND REGULATIONS
 2. ANALYZE REGULATORY REQUIREMENTS
 3. IDENTIFY AND CATEGORIZE ALL REQUIRED FINDINGS
 4. DESCRIBE AND QUANTIFY REGULATORY UNCERTAINTIES
 5. IDENTIFY INTERRELATIONSHIPS AMONG WASTE SYSTEM COMPONENTS AND FINDINGS
 6. IDENTIFY INFORMATION REQUIRED FOR FINDING
 7. DESCRIBE AND QUANTIFY TECHNICAL UNCERTAINTIES
 8. IDENTIFY CAPABILITIES FOR PROCESSING INFORMATION
 9. DEVELOP AND PRIORITIZE COSTS, SCHEDULES AND LEAD TIMES TO OBTAIN REQUIRED INFORMATION AND CAPABILITIES
 10. CONSOLIDATE AND RANK ALL UNCERTAINTIES AFFECTING FINDING
 11. OBTAIN DOE INFORMATION REQUIREMENTS AND UNCERTAINTIES
 12. OBTAIN INFORMATION REQUIREMENTS AND UNCERTAINTIES OF STATES, INDIAN TRIBES AND OTHERS
 13. SPECIFY ALTERNATE PROGRAMS AND CHANGES TO REDUCE CRITICAL UNCERTAINTIES
 14. DEVELOP COSTS, SCHEDULES, LEAD TIMES, BENEFITS AND RISKS FOR EACH ALTERNATE PROGRAM
 15. ANALYZE PROGRAM TRADE-OFFS
 16. RECOMMEND UNCERTAINTY REDUCTION PROGRAMS AND CHANGES INCLUDING A RECOMMENDED RESEARCH PLAN
 17. DISPLAY NETWORK AND CRITICAL PATH FOR EACH FINDING
 18. DISPLAY TOTAL PROGRAM FOR EACH FINDING
 19. DOCUMENT PROGRAM STRUCTURE AND CHANGES
 20. ISSUE RESOLUTION
- S-PA SUPPORT PROGRAM ARCHITECTURE
 DT/AC DEVELOP TECHNICAL AND ANALYTICAL CAPABILITY
 S-5P SUPPORT FIVE YEAR PLAN
 A-PA ALTERNATE PROGRAM ARCHITECTURE
 CO COMPLIANCE DETERMINATION

Fig. 1 - Process Diagram for Developing and Maintaining a Program Architecture

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3.2 The cognizant Element/Subelement Managers are responsible for following this procedure and applying the work instructions and criteria provided by the WSE&I Subelement Manager.

3.3 The Center Director of Quality Assurance is responsible for providing independent surveillance, review, or audits to verify implementation of this procedure and for certifying the associated products.

3.4 The Center Director of Information Management Systems is responsible for providing computer programming expertise, hardware, and software required to develop and maintain the PA. The Director of IMS appoints or acts as the Database Administrator who provides primary control over the integrity of the PA.

4. PROCEDURE

A. Program Architecture Development

4.1 The first step in the procedure is for WSE&I to issue work instructions to all or certain Element/Subelement Managers of the Center, as appropriate. The work instructions, which are controlled documents and include associated criteria, form the basis for Element/Subelement Managers to begin work. The work instructions shall be clearly stated, terms defined, examples provided and time constraints stated as applicable.

The following format outline provides general guidance for the WSE&I Subelement to use in preparing work instructions to the Elements/Subelements. As a minimum, the noted sections should be used. Work instructions will be prepared in the form of TOP's with a designation denoting their subordinate relationship (e.g. TOP-001-01). These instructions should be provided before commencement of work on each of the various process blocks or set of such blocks shown in the Process Diagram (Fig. 1) for Developing and Maintaining a Program Architecture.

Format Outline for Work Instructions/Guidelines

Purpose and Scope
Definitions
Responsibility
Criteria
Procedure
Format and Content Guide for Inputs
Records
Quality Assurance

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4.2 Any questions by the Element/Subelement Managers will be addressed by the WSE&I Subelement Manager. If needed, the written work instructions will be modified and reissued to ensure that all Element/Subelement Managers questions are adequately addressed and that the work instructions provide clear and unambiguous direction.

4.3 The Element/Subelement Managers are required to address the WSE&I work instructions and apply appropriate resources to the work. If the Element/Subelement Manager must recruit additional personnel to perform the work, the Manager shall maintain a professional data sheet or resume for the individual(s).

4.4 Worksheets associated with any manually-generated, non-electronic input to the WSE&I Subelement shall be identified by name of Element/Subelement, person performing the work, by the regulation or statute, or other identification as necessary. When working in the electronic media, particular fields within the database will contain the basic documents and identifications associated with inputs to the WSE&I Subelement.

4.5 The Element/Subelement input shall be received by the WSE&I Subelement and put into the PA database as required. Controls will include designation of a single database administrator, administrative procedures, and "write protection" to strictly protect the database.

4.6 When the Element/Subelement input is at the phase of the process requiring relational database integration, the WSE&I Subelement shall utilize various resources to review and evaluate the specific applicability and correctness of the input in the context of established criteria. This shall include initiation of a Program Architecture Review Committee (PARC), a group of individuals selected to provide a check on the initial Element/Subelement work. The PARC membership will be selected by the WSE&I Subelement Manager and concurred in by the Center Technical Director and Director of SE&I. Based upon the subject matter being reviewed and the need for specific disciplines required to address those subjects. Oversight of the activities of the PARC will be provided by the WSE&I Subelement Manager. The NRC CNWRA Program Manager may assign one or more members of his staff to observe the proceedings of the PARC from time-to-time and will be advised of the PARC schedule by the WSE&I Subelement Manager.

The Committee shall utilize the section 4.1 criteria, augmented as necessary by new developments in the licensing arena and/or further maturation in the Center's systems engineering approach. The work of the PARC shall be documented in a written format, with the Committee members identified as voting or only participating. Initial entries that are rejected from the PA database shall be maintained in a

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separate electronic file, from where they can be recalled and reviewed as needed in the future. In addition to submittals of such documentation to the NRC as part of scheduled deliverables, the Center will maintain at least one paper copy and one electronic media copy of all records generated for the duration of the Contract. Records of the above proceedings will be maintained in the Center controlled files.

In each case where there is process integration for the PA relational database, the PARC shall be invoked to provide a documented review and decision-making point in the development of the PA. The PARC shall be the Center focal point and final determining authority regarding inputs to the PA.

Subsequent to certification at each integration step, changes to the relational database will be controlled by means of "write protections" and by PARC guidelines promulgated to review and revise subsequent integrated products.

4.7 Quality Assurance shall verify, through independent surveillance, reviews or audits, that this procedure is implemented and followed by Center personnel during those phases of the process requiring development and integration of the PA.

4.8 Integrated output from the WSE&I Subelement, in the form of Major Milestones, shall be certified by a Quality Assurance review and sent to the appropriate NRC office in the form requested by the NRC for their review and comment. Center Intermediate Milestones shall be provided to the appropriate NRC office and each NRC Program Element/Subelement Manager in the form of courtesy copies appropriately identified. These will be provided at the time the certified integrated products are transmitted to the NRC.

B. Program Architecture Maintenance

This Section is reserved to expedite promulgation of Part A of this procedure, which is time-critical at this stage in implementing the systems engineering approach at the Center.

4.1 Maintenance of and changes to the Center PA shall be addressed in a revision to this procedure after initial establishment, submittal, and approval of specified parts of the PA. Configuration control and change control procedures will be developed and implemented, as necessary, in accordance with the provisions of the Center Quality Assurance Manual and Center Systems Engineering Management Plan (both drafts in preparation at this time). Configuration control and change control will be applied to certified contents of the PA.

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5. RECORDS

Records will be developed and maintained in accordance with Sections 4.3-4.6 and 4.8 of this procedure. These work instructions provided for in Section 4.1 may cause other records to be generated. These will be developed and maintained in accordance with supplemental guidance provided in the work instructions.

6. QUALITY ASSURANCE

Quality Assurance provisions of this TOP are as specified in Sections 4.6 and 4.7. Either electronic or hardcopy objective evidence is acceptable for independent verification of actions taken in executing this TOP. Records will be maintained of audits performed on the activities related to this TOP.

Center for Nuclear Waste Regulatory Analyses

FOR ADDRESSEE ONLY

FACSIMILE TRANSMITTAL SHEET

DATE: 6-13-88
TO: Phil Attomare / B. Stiftenpole
TELEPHONE NO: 301/492-3400
TELEPHONE NO. OF FACSIMILE MACHINE: 301/492-0259
FROM: Bro Allen Whiting
TELEPHONE NO: 512/522-5156
NUMBER OF PAGES (INCLUDING THIS COVER SHEET): 105

FOR ADDRESSEE ONLY

SOUTHWEST RESEARCH INSTITUTE TELEPHONE NO. IS 512/684-5111.
PLEASE SEND RETURN TRANSMISSIONS TO 512/522- 5155

THE MACHINE IS A XEROX-7010 AND WILL AUTOMATICALLY ANSWER AND RECEIVE.
IF YOU NEED MANUAL ASSISTANCE, PLEASE CALL 512/684-5111 ext. 5160

FOR OPERATOR USE:

Date/Time Received or Sent: _____
Person Receiving or Sending: _____
Comments: _____



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TOP-001 PROGRAM ARCHITECTURE DEVELOPMENT AND MAINTENANCE

EFFECTIVITY AND APPROVAL

Revision 1 of this procedure became effective on June 27, 1988. This procedure consists of the pages and changes listed below.

<u>Page No.</u>	<u>Change</u>	<u>Date Effective</u>
1 - 7	p.2, section 2, para. 2, revised wording to fit new definition and process.	6/27/88
	p.3, Fig. 1 replaced.	6/27/88
	p.6, 4.6, para. 2, wording revised.	6/27/88

SUPERSEDED

*By Revision 2, Change 0,
10/17/91*

Supersedes Procedure No. TOP-001 Revision 0

Approvals

Written By <i>Samuel Kalant</i>	Date <i>6/26/88</i>	Technical Review <i>Wesley A. Strub</i>	Date <i>6/27/88</i>
Quality Assurance <i>J.C. Schovich</i>	Date <i>6/27/88</i>	Cognizant Director <i>Allen R. Whiting</i>	Date <i>6/27/88</i>

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TOP-001 PROGRAM ARCHITECTURE DEVELOPMENT AND MAINTENANCE

1. PURPOSE AND SCOPE

The purpose of this procedure is to provide the broad guidelines for developing (Part A) and maintaining (Part B) the Program Architecture at the Center. Additional specific guidelines are provided by work instructions that will be subsequently developed, as needed. The development and maintenance activities are addressed in separate sections of this Technical Operating Procedure (TOP).

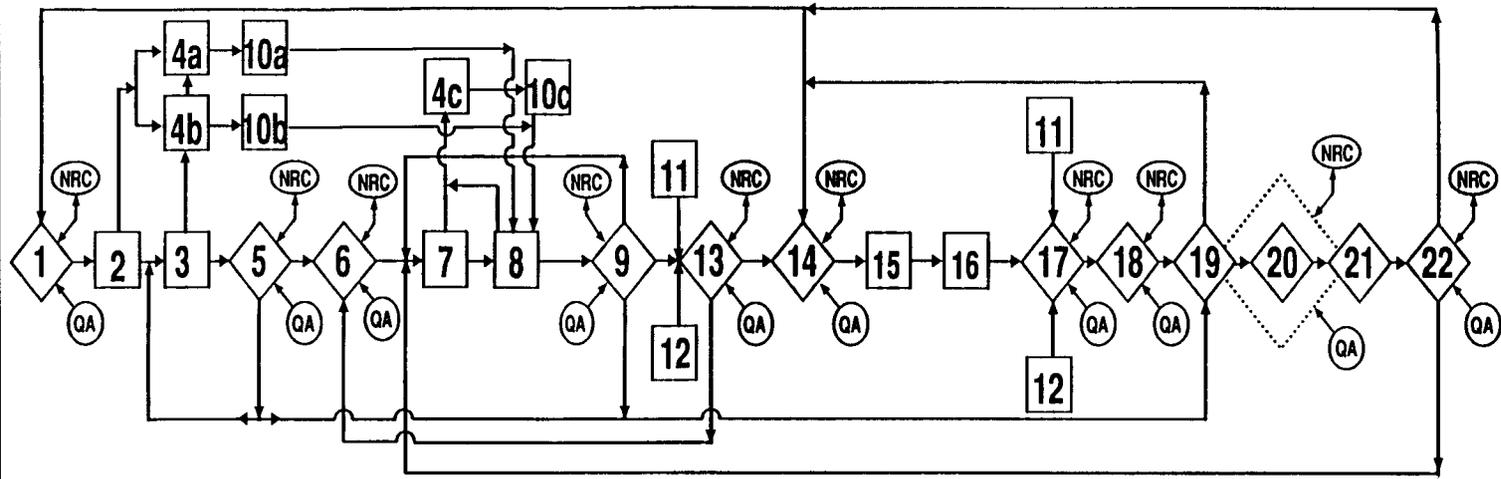
2. DEFINITION

Program Architecture (PA) is the overall system description for the Nuclear Regulatory Commission High-Level Waste (NRC-HLW) repository licensing system. It is mission-oriented, requirements based, proactive, and provides a basis for integration of all activities related to the NRC-HLW mission.

As noted on the process diagram for developing and maintaining a PA (Fig. 1), the indicated 22-step approach leads to uncertainty reduction and evaluation of DOE compliance with the applicable statutes and regulations. The development and maintenance of the PA is an ongoing process containing subprocesses reflecting refinement loops back through earlier steps to produce and maintain the PA as a current product. The complete PA may require modification to certain of these steps or additional steps not currently identified in the process diagram but which may become necessary as the PA matures and develops. As indicated in Figure 1, the Elements/Subelements develop and submit their input according to prior instructions produced by WSE&I. These process activities are indicated by the squares in Figure 1. The PA development process involves initial and supplementary inputs from the Elements/Subelements along with information from other related and off-line parallel activities that provide the information to be integrated by the WSE&I Subelement at the process steps indicated in Figure 1 by the diamonds. This allows integrated products to be produced by the WSE&I Subelement that ultimately lead to the complete development of the PA. At the completion of the diamond integration points, the products reflect a QA certification and NRC approval consistent with the requirements of the Center contractual and QA responsibilities.

3. RESPONSIBILITY

3.1 The Director of SE&I is responsible for the implementation of this procedure.



X PHASE OF THE PROCESS REQUIRING WORK AT AND INPUT FROM THE PROGRAM ELEMENTS **X** PHASE OF THE PROCESS REQUIRING INTEGRATION **NRC** REVIEW AND APPROVAL BY NUCLEAR REGULATORY COMMISSION **QA** REVIEW AND APPROVAL BY QUALITY ASSURANCE

- 1. IDENTIFY POTENTIALLY APPLICABLE REGULATIONS
- 2. ANALYZE REGULATORY REQUIREMENTS
- 3. IDENTIFY AND LIST ELEMENTS OF PROOF
- 4a. IDENTIFY AND DESCRIBE INSTITUTIONAL UNCERTAINTIES
- 4b. IDENTIFY AND DESCRIBE REGULATORY UNCERTAINTIES
- 4c. IDENTIFY AND DESCRIBE TECHNICAL UNCERTAINTIES
- 5. INTEGRATE AND REVIEW REGULATORY REQUIREMENTS; AND INTEGRATE, REVIEW, AND REVISE ELEMENTS OF PROOF
- 6. SELECT SUBSET OF REGULATIONS FOR FURTHER ANALYSIS BASED ON TIME-CRITICAL NATURE
- 7. IDENTIFY BASIC APPROACH FOR COMPLIANCE DETERMINATION METHODS (REVISE AT SUBSEQUENT ITERATIONS)
- 8. IDENTIFY INFORMATION REQUIREMENTS
- 9. INTEGRATE, REVIEW, AND REVISE COMPLIANCE DETERMINATION METHODS, ELEMENTS OF PROOF, AND INFORMATION REQUIREMENTS

- 10a. IDENTIFY INSTITUTIONAL UNCERTAINTY QUESTIONS
- 10b. IDENTIFY REGULATORY UNCERTAINTY QUESTIONS
- 10c. IDENTIFY TECHNICAL UNCERTAINTY QUESTIONS
- 11. OBTAIN DOE "ISSUES", INFORMATION NEEDS AND UNCERTAINTIES
- 12. OBTAIN STATE, TRIBE, AND OTHER AFFECTED PARTIES "ISSUES", INFORMATION NEEDS AND UNCERTAINTIES
- 13. INTEGRATE, CONSOLIDATE, AND RANK UNCERTAINTIES AND UNCERTAINTY QUESTIONS (INCLUDING DOE AND STATE ITEMS)
- 14. IF UNCERTAINTY, UNCERTAINTY QUESTION, OR INFORMATION REQUIREMENT IS UNRESOLVED, FLAG AS OPEN ITEM; SELECT ITEMS FOR NRC ACTION; IDENTIFY OTHER ACTION PARTIES

- 15. IDENTIFY UNCERTAINTY REDUCTION METHODS AND RELATED INFORMATION REQUIREMENTS; SPECIFY ALTERNATE NRC PROGRAMS FOR UNCERTAINTY REDUCTION
- 16. DEVELOP COSTS, SCHEDULES, AND LEAD TIMES FOR NRC PROGRAMS
- 17. ANALYZE ALTERNATIVES AND NRC PROGRAM TRADEOFFS
- 18. RECOMMEND NRC PROGRAM INCLUDING OVERALL RESEARCH PROGRAM PLAN
- 19. DEVELOP AND DISPLAY NETWORK AND CRITICAL PATH FOR EACH REGULATORY REQUIREMENT
- 20. DEVELOP AND DISPLAY NETWORK FOR TOTAL PROGRAM
- 21. CONTROL AND DOCUMENT PROGRAM STRUCTURE AND CHANGES
- 22. CONDUCT NRC PROGRAM

Fig. 1 - Process Diagram for Developing and Maintaining the Program Architecture

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3.2 The cognizant Element/Subelement Managers are responsible for following this procedure and applying the work instructions and criteria provided by the WSE&I Subelement Manager.

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3.4 The Center Director of Information Management Systems is responsible for providing computer programming expertise, hardware, and software required to develop and maintain the PA. The Director of IMS appoints or acts as the Database Administrator who provides primary control over the integrity of the PA.

4. PROCEDURE

A. Program Architecture Development

4.1 The first step in the procedure is for WSE&I to issue work instructions to all or certain Element/Subelement Managers of the Center, as appropriate. The work instructions, which are controlled documents and include associated criteria, form the basis for Element/Subelement Managers to begin work. The work instructions shall be clearly stated, terms defined, examples provided and time constraints stated as applicable.

The following format outline provides general guidance for the WSE&I Subelement to use in preparing work instructions to the Elements/Subelements. As a minimum, the noted sections should be used. Work instructions will be prepared in the form of TOP's with a designation denoting their subordinate relationship (e.g. TOP-001-01). These instructions should be provided before commencement of work on each of the various process blocks or set of such blocks shown in the Process Diagram (Fig. 1) for Developing and Maintaining the Program Architecture.

Format Outline for Work Instructions/Guidelines

Purpose and Scope
Definitions
Responsibility
Criteria
Procedure
Format and Content Guide for Inputs
Records
Quality Assurance

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4.2 Any questions by the Element/Subelement Managers will be addressed by the WSE&I Subelement Manager. If needed, the written work instructions will be modified and reissued to ensure that all Element/Subelement Managers questions are adequately addressed and that the work instructions provide clear and unambiguous direction.

4.3 The Element/Subelement Managers are required to address the WSE&I work instructions and apply appropriate resources to the work. If the Element/Subelement Manager must recruit additional personnel to perform the work, the Manager shall maintain a professional data sheet or resume for the individual(s).

4.4 Worksheets associated with any manually-generated, non-electronic input to the WSE&I Subelement shall be identified by name of Element/Subelement, person performing the work, by the regulation or statute, or other identification as necessary. When working in the electronic media, particular fields within the database will contain the basic documents and identifications associated with inputs to the WSE&I Subelement.

4.5 The Element/Subelement input shall be received by the WSE&I Subelement and put into the PA database as required. Controls will include designation of a single database administrator, administrative procedures, and "write protection" to strictly protect the database.

4.6 When the Element/Subelement input is at the phase of the process requiring relational database integration, the WSE&I Subelement shall utilize various resources to review and evaluate the specific applicability and correctness of the input in the context of established criteria. This shall include initiation of a Program Architecture Review Committee (PARC), a group of individuals selected to provide a check on the initial Element/Subelement work. The PARC membership will be selected by the WSE&I Subelement Manager and concurred in by the Center Technical Director and Director of SE&I. Based upon the subject matter being reviewed and the need for specific disciplines required to address those subjects. Oversight of the activities of the PARC will be provided by the WSE&I Subelement Manager. The NRC CNWRA Program Manager may assign one or more members of his staff to observe the proceedings of the PARC from time-to-time and will be advised of the PARC schedule by the WSE&I Subelement Manager.

The Committee shall utilize the section 4.1 criteria, augmented as necessary by new developments in the licensing arena and/or further maturation in the Center's systems engineering approach. The work of the PARC shall be documented in a written format, with the Committee members identified as voting or only participating. Initial entries that are rejected from the PA database shall be maintained in a

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separate electronic file, from where they can be recalled and reviewed as needed in the future. The Center will maintain at least one paper copy and one electronic media copy of all submittals to the NRC, for the duration of the contract. Records of the PARC proceedings will be maintained in the Center controlled files.

In each case where there is process integration for the PA relational database, the PARC shall be invoked to provide a documented review and decision-making point in the development of the PA. The PARC shall be the Center focal point and final determining authority regarding inputs to the PA.

Subsequent to certification at each integration step, changes to the relational database will be controlled by means of "write protections" and by PARC guidelines promulgated to review and revise subsequent integrated products.

4.7 Quality Assurance shall verify, through independent surveillance, reviews or audits, that this procedure is implemented and followed by Center personnel during those phases of the process requiring development and integration of the PA.

4.8 Integrated output from the WSE&I Subelement, in the form of Major Milestones, shall be certified by a Quality Assurance review and sent to the appropriate NRC office in the form requested by the NRC for their review and comment. Center Intermediate Milestones shall be provided to the appropriate NRC office and each NRC Program Element/Subelement Manager in the form of courtesy copies appropriately identified. These will be provided at the time the certified integrated products are transmitted to the NRC.

B. Program Architecture Maintenance

This Section is reserved to expedite promulgation of Part A of this procedure, which is time-critical at this stage in implementing the systems engineering approach at the Center.

4.1 Maintenance of and changes to the Center PA shall be addressed in a revision to this procedure after initial establishment, submittal, and approval of specified parts of the PA. Configuration control and change control procedures will be developed and implemented, as necessary, in accordance with the provisions of the Center Quality Assurance Manual and Center Systems Engineering Management Plan (both drafts in preparation at this time). Configuration control and change control will be applied to certified contents of the PA.

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5. RECORDS

Records will be developed and maintained in accordance with Sections 4.3-4.6 and 4.8 of this procedure. These work instructions provided for in Section 4.1 may cause other records to be generated. These will be developed and maintained in accordance with supplemental guidance provided in the work instructions.

6. QUALITY ASSURANCE

Quality Assurance provisions of this TOP are as specified in Sections 4.6 and 4.7. Either electronic or hardcopy objective evidence is acceptable for independent verification of actions taken in executing this TOP. Records will be maintained of audits performed on the activities related to this TOP.

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

M E M O R A N D U M

TO: Phillip M. Altomare June 27, 1988
FROM: Allen R. Whiting *ARW*
SUBJECT: Revised Technical Operating Procedure-001 Revision 1

Attached is the subject item which has been revised to include latest approved Figure 1 in accordance with your review comments.

The subject item is transmitted herewith for your information and for implementation by the Center staff.

/yl
Attachment

cc: J. Bunting

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

M E M O R A N D U M

TO: R. Adler P. Nair June 27, 1988
H. Garcia W. Patrick
J. Hageman R. Pierce
R. Johnson J. Russell
J. Latz A. Whiting

FROM: Bruce Mabrito *Bruce Mabrito*

SUBJECT: Technical Operating Procedure-001 Revision 1

Attached is Center TOP-001 Revision 1, effective 6/27/88. Destroy your copy of Center TOP-001 Revision 0 and insert this latest revision in your Center Operating Procedures notebook.

If you have questions on this process, contact Henry Garcia or myself.

BEM/y
Attachment

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Title
TOP-001 PROGRAM ARCHITECTURE DEVELOPMENT AND MAINTENANCE

EFFECTIVITY AND APPROVAL

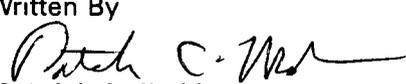
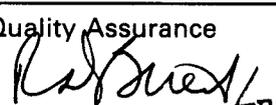
Revision 2 of this procedure became effective on 10/14/91. This procedure consists of the pages and changes listed below.

<u>Page No.</u>	<u>Change</u>	<u>Date Effective</u>
ALL	0	

SUPERSEDED

Supersedes Procedure No. TOP-001, Revision 1, TOP-001-03, TOP-001-04, TOP-001-05

Approvals

Written By  Patrick C. Mackin	Date 10/9/91	Technical Review  Ted Romine	Date 10/10/91
Quality Assurance  Bruce Mabrito	Date 10/14/91	Cognizant Director  Wesley C. Patrick	Date 10/11/91

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TOP-001 PROGRAM ARCHITECTURE DEVELOPMENT AND MAINTENANCE

1. PURPOSE

The purpose of this procedure is to prescribe the methods for developing the Systematic Regulatory Analysis (SRA) segment of the Program Architecture (PA) and maintaining PA products in the associated Program Architecture Database (PADB). Additional specific direction shall be provided in the form of Technical Operating Procedures (TOP) as required. This procedure implements the requirements of CQAM Section 3.

2. BACKGROUND

Experience gained in the development and maintenance of the PA has necessitated the revision of TOP-001 and its subordinate procedures. Accordingly, this revision modifies and streamlines the PA process and incorporates the provisions of TOP-001-03 (Submission and Verification of Program Architecture Database Entries), TOP-001-04 (Selection of Regulatory Topics for Program Architecture Analysis), and TOP-001-05 (Implementing the Systematic Regulatory Analysis Process); allowing those three subordinate TOPs to be superseded. Most significantly, the functions of the Program Architecture Review Committee (PARC), as prescribed in TOP-001-03, have been replaced by standard Center document review procedures under this TOP and QAP-002 (Review of CNWRA Documents, Reports, Papers and Presentation Materials).

The Program Architecture Process Diagram (Figure 1) has been revised to clarify the interface of Compliance Determination Strategies and Compliance Determination Methods with the PA process and to remove "QA" and "NRC" review and approval indicators, which misleadingly implied restricted Nuclear Regulatory Commission (NRC) involvement in the PA process.

3. DEFINITIONS

- Analyst - an individual assigned by an Element Manager to conduct SRA or to develop documents for the PADB. Analysts must be professionally qualified for the specific assignment (as determined by the Element Manager), must have been trained for the assignment (training to be provided by WSE&I Element Manager), and must utilize approved procedures in the conduct of SRA or PADB work.
- Program Architecture - the overall system description for the NRC High-Level Waste (HLW) repository licensing system. It is mission-oriented, requirements-based, proactive and provides a basis for integration of all activities related to the NRC HLW mission.

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Figure 1 (Program Architecture Process Diagram) displays the PA 22-step process. This process is iterative and contains many subprocesses which provide feedback paths for refinement and update. Any particular step in the process may be executed by staff of the NRC, Center or a combination thereof as appropriate to the task, resource availability and other related factors. As Figure 1 shows, the efforts of the NRC, the Center and other affected parties shall be integrated to ensure the effectiveness and efficiency of the overall licensing process.

- **Program Architecture Database** - the repository for the principal information necessary to (1) provide guidance and consultation for Department of Energy (DOE) prelicensing plans and activities and (2) develop and execute the overall NRC regulatory program for Nuclear Waste Policy Act waste management activities. It is made up of several data and text records whose number and, in some cases, content may change as amendments of the law, rulemaking, program changes or improved technical information dictate. Among the records are the complete texts of the applicable statutes and regulations; individual Regulatory Requirements; Regulatory Elements of Proof and Technical Review Components for such requirements; NRC Compliance Determination Strategies and Methods; Uncertainty Reduction Methods; Information Requirements; and summaries of Compliance Demonstration Methods planned by the DOE.
- **Program Architecture Support System** - a computer-based system comprised of (1) the PADB, (2) the computer hardware and software necessary to construct, protect, interrogate and manage that database, and (3) the network hardware and software that allows controlled remote interrogation of the PADB and provides the interfaces with NUDOC, the Licensing Support System and other remote databases.
- **Systematic Regulatory Analysis** - that portion of the PA which assesses the statutory and regulatory responsibilities of the NRC in a comprehensive, structured manner. This assessment is controlled by appropriate Technical Operating Procedures. SRA begins with the identification of statutory and regulatory requirements relevant to the High Level Nuclear Waste Management System. This system includes one or more mined geologic repositories, interim storage facilities, and nuclear waste transportation casks.
- **Synopsis** - a PADB-generated report which presents all the database information associated with a PA structural element in a format suitable for development, review and approval.

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4. RESPONSIBILITIES

4.1 Deputy Technical Director for Systems Engineering and Integration (SE&I)

The Deputy Technical Director for Systems Engineering and Integration (SE&I) shall be responsible for the implementation of this procedure. He shall define the requirements for the Program Architecture Support System (PASS) and provide procedures, training and integration for the execution of this procedure.

4.2 WSE&I Element Manager

The WSE&I Element Manager shall assist the Deputy Technical Director for SE&I in defining the requirements for PASS and providing procedures, training and integration for the execution of this procedure.

4.3 Center Element Managers

Cognizant Center Element Managers shall be responsible for developing and maintaining elements of the PA through the application of SRA to their respective work and for entering the results in the PADB as appropriate. This responsibility includes ensuring that products of this effort receive the appropriate review in accordance with this procedure, with QAP-002 for the Center, and with appropriate NRC staff procedures.

4.4 Analysts and Reviewers

Analysts and reviewers shall be responsible for performing their work in accordance with this procedure and QAP-002.

5. PROCEDURE

5.1 Figure 2 (Program Architecture Development and Maintenance) depicts the procedure delineated herein. This procedure, QAP-002, and NRC staff procedures, as appropriate, shall be used for preparation, review and approval of documents supporting PA development and maintenance.

5.2 Element Managers shall ensure that analysts and reviewers have the required professional qualifications to perform their assignments, have been trained specifically for those assignments, and are using approved procedures. Training shall be conducted and documented as required by CQAM Section 2.

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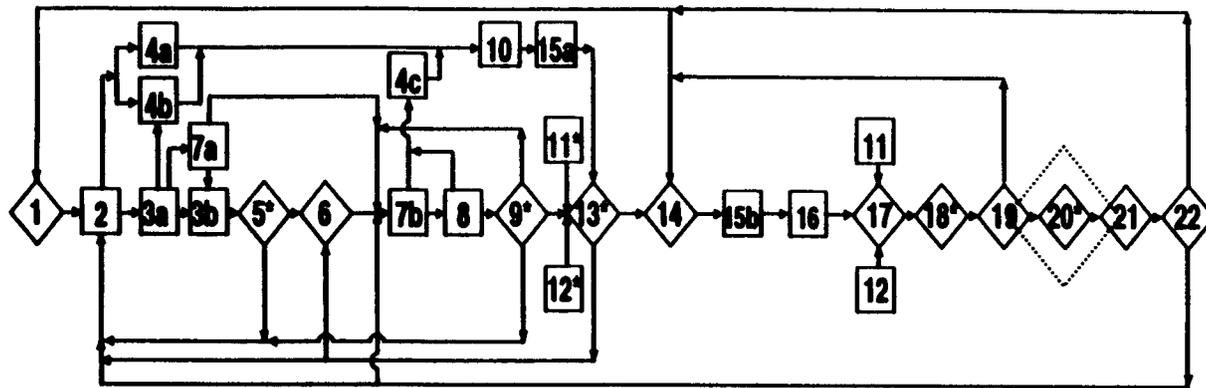
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- 5.3 Items shall be selected for SRA or PA development and maintenance consistent with contractual direction from the NRC.
- 5.4 For PADB documents, detailed instructions in the form of TOPs subordinate to this procedure shall be provided which specify content and format. The Deputy Technical Director for SE&I shall develop these procedures in coordination with the NRC staff using QAP-008 (Document Control). These procedures shall be reviewed in accordance with QAP-002.
- 5.5 Element Managers shall assign analysts to tasks, as required. Where appropriate, NRC and Center analysts may work as groups.
- 5.6 Analysts shall produce PADB documents in a Synopsis Report format which will be specified within the appropriate TOP.
- 5.7 After the analysts have completed the development of a PA document, the cognizant Element Manager shall be responsible for obtaining the appropriate review. Within the Center, a review shall be conducted in accordance with QAP-002. Within the NRC, equivalent review procedures shall be utilized. Any lack of concurrence between NRC and Center reviewers shall be resolved by the appropriate NRC management and the Center President or Technical Director. The results of these resolutions will be documented and included in the records of the review process required by QAP-002. For PADB documents, in order to ensure the quality of the PADB, the reviews discussed above shall be conducted on hard copy output from the PADB. As specified in QAP-002, QA verification shall be the last review step and shall be conducted following Center and NRC concurrence in the document.

6. RECORDS

- 6.1 QA records generated as a direct result of this procedure are (1) a hard copy Synopsis Report from the PADB for each approved document and (2) documentation of resolution of lack of concurrence between NRC and Center reviewers.
- 6.2 Training records for analysts shall be maintained as required by CQAM Section 2.
- 6.3 Document review records shall be maintained as required by QAP-002.



- X** DIAMOND WITH 'X' PHASE OF THE PROCESS REQUIRING REVIEW AND APPROVAL
X SQUARE WITH 'X' PHASE OF THE PROCESS REQUIRING WORK AND INPUT FROM THE PROGRAM ELEMENTS
X DIAMOND WITH 'X' PHASE OF THE PROCESS REQUIRING INTEGRATION
1. Identify Potentially Applicable Statutes and Regulations
 2. Analyze and Identify Regulatory Requirements
 - 3a. Identify Regulatory Elements of Proof and Define Logic Structure
 - 3b. Identify Technical Review Components and Define Logic Structures
 - 4a. Identify and Correlate Institutional Uncertainties
 - 4b. Identify and Correlate Regulatory Uncertainties
 - 4c. Identify and Correlate Technical Uncertainties
 5. Review, Revise and Integrate Regulatory Requirements, Regulatory Elements of Proof, and Technical Review Components
 6. Select Subset of Regulatory Requirements for Further Analysis Based on Time-Critical Nature
 - 7a. Develop Compliance Determination Strategies
 - 7b. Identify Compliance Determination Methods
 8. Identify and Correlate Information Requirements for Compliance Determination
 9. Review, Review and Integrate Compliance Determination Methods and Associated Information Requirements
 10. Define NRC Composite Uncertainties
 11. Obtain DOE "Issues", Compliance Demonstration Methods, Information Needs, Uncertainties and Uncertainty Reduction Methods
 - 11a. Obtain State, Tribe, and Other Affected Parties "Issues", Compliance Evaluation Methods, Information Needs, and Uncertainties
 - 11b. Obtain State, Tribe, and Other Affected Parties "Issues", Compliance Evaluation Methods, Information Needs, and Uncertainties
 12. Obtain State, Tribe, and Other Affected Parties "Issues", Compliance Evaluation Methods, Information Needs, and Uncertainties
 - 12a. Obtain State, Tribe, and Other Affected Parties "Issues", Compliance Evaluation Methods, Information Needs, and Uncertainties
 - 12b. Obtain State, Tribe, and Other Affected Parties "Issues", Compliance Evaluation Methods, Information Needs, and Uncertainties
 13. Identify and Correlate Information Requirements for Uncertainty Reduction; Rank NRC Composite Uncertainties
 - 13a. Identify and Correlate Information Requirements for Uncertainty Reduction; Rank NRC Composite Uncertainties
 - 13b. Identify and Correlate Information Requirements for Uncertainty Reduction; Rank NRC Composite Uncertainties
 14. Define Composite Information Requirements; Make Initial Selection of Composite Information Requirements for NRC Action; Identify Other Action Agencies
 15. Analyze Alternative Uncertainty Reduction Methods, Draft the Postulated Uncertainty Reduction Language (PURL) for Recommended Rulemakings, and Submit to NRC for Review.
 - 15a. Analyze Alternative Uncertainty Reduction Methods, Draft the Postulated Uncertainty Reduction Language (PURL) for Recommended Rulemakings, and Submit to NRC for Review.
 - 15b. Analyze Alternative Uncertainty Reduction Methods, Draft the Postulated Uncertainty Reduction Language (PURL) for Recommended Rulemakings, and Submit to NRC for Review.
 - 15c. Analyze Alternative Uncertainty Reduction Methods, Draft the Postulated Uncertainty Reduction Language (PURL) for Recommended Rulemakings, and Submit to NRC for Review.
 - 15d. Analyze Alternative Uncertainty Reduction Methods, Draft the Postulated Uncertainty Reduction Language (PURL) for Recommended Rulemakings, and Submit to NRC for Review.
 - 15e. Define Alternative NRC Programs for Each Composite Information Requirement, Uncertainty Reduction, and Compliance Determination
 16. Develop Costs, Schedules, and Lead Times for Alternative NRC Programs
 17. Analyze and Perform Tradeoffs of Alternative NRC Programs
 18. Recommend Overall NRC Programs Including Overall Research Program Plan
 19. Develop and Display the Network and Critical Path for Each Regulatory Requirement
 20. Develop and Display Network for Total Program
 21. Control and Document Program Structure and Changes
 22. Conduct the NRC program
- It is assumed that at least one affected party will request information to perform an independent "compliance evaluation".*

FIGURE 1. PROCESS DIAGRAM FOR DEVELOPING AND MAINTAINING THE PROGRAM ARCHITECTURE

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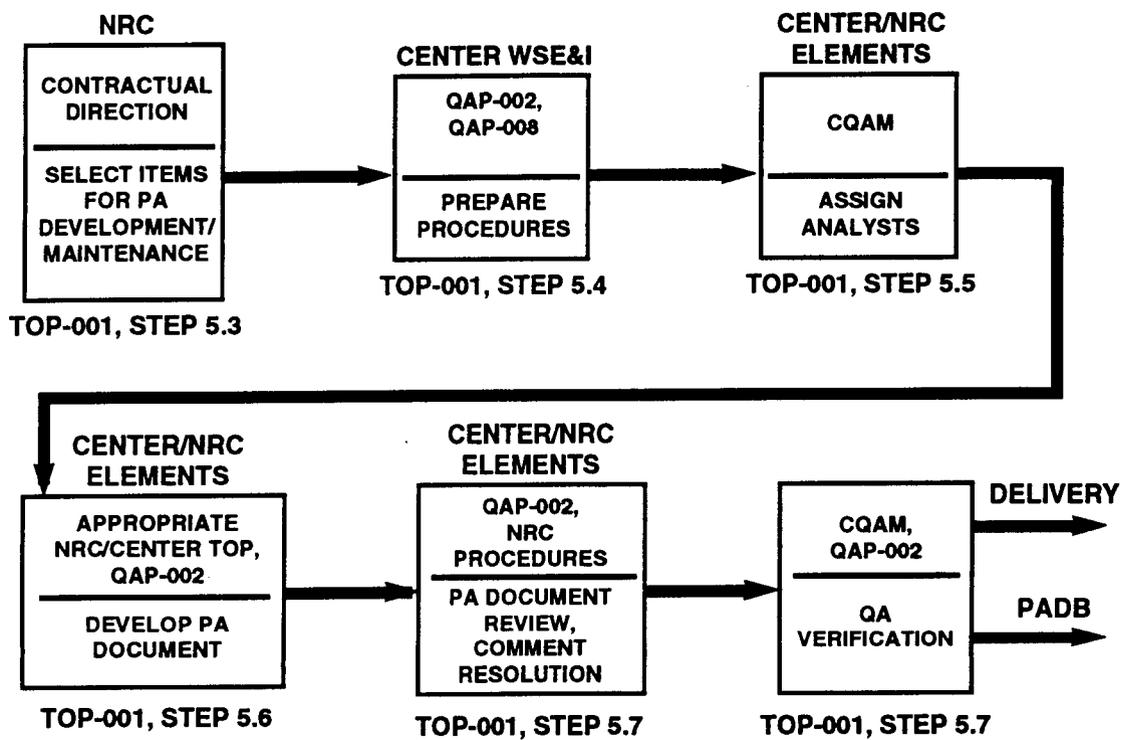


FIGURE 2 - PROGRAM ARCHITECTURE DEVELOPMENT AND MAINTENANCE

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EFFECTIVITY AND APPROVAL

Revision 2 of this procedure became effective on 10/14/91. This procedure consists of the pages and changes listed below.

<u>Page No.</u>	<u>Change</u>	<u>Date Effective</u>
All	0	10/14/91

This procedure is obsolete and is thereby deleted. Material addressed by this procedure is now being addressed in NRC Systematic Regulatory Analysis Planning documents.

SUPERSEDED

Supersedes Procedure No. N/A

Approvals

Written By <i>R.D. Bueh</i>	Date <i>9/8/93</i>	Technical Review <i>[Signature]</i>	Date <i>9/9/93</i>
Quality Assurance <i>[Signature]</i>	Date <i>9/9/93</i>	Cognizant Director <i>[Signature]</i>	Date <i>9/15/93</i>