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Title TOP-001-05 IMPLEMENTING THE SYSTEMATIC REGULATORY ANALYSIS PROCESS

EFFECTIVITY AND APPROVAL

Revision 0 of this procedure became effective on 3 December 1990. This procedure consists of the pages and changes listed below.

Page No.	Change	Date Effective
1-39	-	3 December 1990

SUPERSEDED

Supersedes Procedure No. None

Approvals

Written By	Date	Technical Review	Date
P. Mackin	11/30/90	W. Patrick	12/3/90
Quality Assurance	**Date**	**Cognizant Director**	**Date**
Bruce Mabrito	12/3/90	A. Whiting	12/3/90

CNWRA Form TOP-1

TOP-001-05

IMPLEMENTING THE SYSTEMATIC REGULATORY ANALYSIS PROCESS

1. PURPOSE

The purpose of this procedure is to provide integrating instructions for implementing the Systematic Regulatory Analysis (SRA) process. Other Technical Operating Procedures (TOP), as referenced herein, provide direction for conducting specific portions of that process. This TOP prescribes the manner in which those various procedures are to be linked.

2. DEFINITIONS

2.1 LOGIC STRUCTURE INPUT FORMS
Logic structure input forms consist of the Data Element Linkage Input Form, and the Cross Linkage Input Form. These forms are used by the analyst in preparing information to be entered into the Program Architecture Data Base (PADB). They specify the logical relationships between information elements in the Program Architecture. They are contained within Attachment A to this TOP.

2.2 LOAD SHEETS
Load sheets are prepared by the WSE&I Element and provide formatted SRA data for pre-Program Architecture Review Committee (pre-PARC) entry into the PADB. Load sheets are addressed in TOP-001-02.

2.3 SRA SYNOPSES
SRA Synopses are designed to maximize analyst productivity and promote rapid entry of SRA information into the PADB by providing a report-like format in which the Elements submit SRA products to the WSE&I Element for transfer onto Load Sheets. Synopsis Addenda include inputs to facilitate database query and SRA information retrieval. Selected addenda items may be deferred to allow the PADB to be developed without waiting for all the SRA data associated with a Regulatory Requirement to be complete. SRA Synopses and Addenda are described in Attachment A to this TOP. Addenda items which may be deferred are identified in the Attachment.

Additional applicable definitions may be found in the following procedures:

TOP-001	Program Architecture Development and Maintenance
TOP-001-02	Program Architecture Relational Database Work Instruction
TOP-001-03	Submission and Verification of Program Architecture Database Entries
TOP-001-04	Selection of Regulatory Topics for Program Architecture Analysis
QAP-002	Review and Approval of Technical Reports

3. RESPONSIBILITIES

3.1 The WSE&I Element Manager is delegated responsibility for implementation of this procedure.

3.2 Analysts are responsible for conducting their responsibilities in accordance with this and other related procedures.

4. PROCEDURE

4.1 The detailed activities conducted during SRA and PADB development are covered in other procedures. This procedure provides the direction for the integration of those procedures in the implementation of SRA. Figure 1 (Implementing the SRA Process) depicts the integrated process.

4.2 The WSE&I Element Manager shall direct the selection of regulatory requirement topics for SRA and assign them to the appropriate Element Manager utilizing the procedures in TOP-001-04.

4.3 The Element Manager shall conduct SRA on assigned topics in accordance with TOP-001-02.

4.3.1 As SRA information is developed for a specific topic, SRA Synopses and Addenda are prepared in accordance with Attachment A to this TOP to support the eventual loading of SRA information into the PADB.

4.3.2 A Regulatory Element of Proof Logic Structure Diagram shall be prepared for the Regulatory Element of Proof Set (PS), and a Technical Review Component Logic Structure Diagram shall be prepared for each Technical Review Component Set (TS) which contains an "OR" logic relationship. Each logic structure shall be prepared in two formats; Boolean and binary.

4.3.3 Logic Structure Input Forms shall be prepared in order to document the logical relationships between elements of SRA data identified in section 4.3.2 in a format that can be used in the database program. These Logic Structure Input Forms allow the proper binary logic relationships to be entered into the PADB and also serve as a means of verifying the logic structure as it is ultimately produced in the PADB.

4.3.4 These products shall then be subjected to a pre-PARC review by the Element Manager in accordance with QAP-002 and TOP-001-03. This review is conducted to verify the technical accuracy, adequacy and completeness of the SRA data. It is vital in that it is the most thorough technical review this data will receive.

4.4 Upon completion of the pre-PARC technical review, the WSE&I Element Manager shall receive the SRA products, prepare the necessary load sheets in accordance with TOP-001-02 and direct the pre-PARC loading of data into the PADB. It is important to note that at this point in the procedure, the data cannot be accessed as a part of the PADB by unauthorized users.

4.5 The PARC shall be convened under the provisions of TOP-001-03 for the purpose of verifying that the information which has been submitted for entry into the PADB satisfies the requirements of TOP-001-02 as completely as possible and that it is correct and clearly written.

4.5.1 The PARC may concur in the entry of the SRA products into the PADB, or it may refer those products back to the Element Manager for further technical or administrative processing.

4.5.2 The PARC shall compare the computer generated logic structure for the SRA products with the logic

structure diagrams and the Logic Structure Input Forms generated by the analysts within the Element to ensure that the original relationships are correct and that the proper relationships have been maintained.

4.6 Following concurrence by the PARC that SRA information is ready for entry into the PADB, Quality Assurance verification shall be completed in accordance with the Center Quality Assurance Manual (CQAM). If necessitated by the results of the Quality Assurance verification, the SRA information shall be returned to the PARC for remedial action.

4.7 Certified SRA products shall be released to the PADB by the WSE&I Element, and change control shall be initiated.

5. RECORDS

5.1 SRA Synopses and their Addenda shall be processed and retained as Quality Assurance records in accordance with CQAM Section 17.

SUPERSEDED

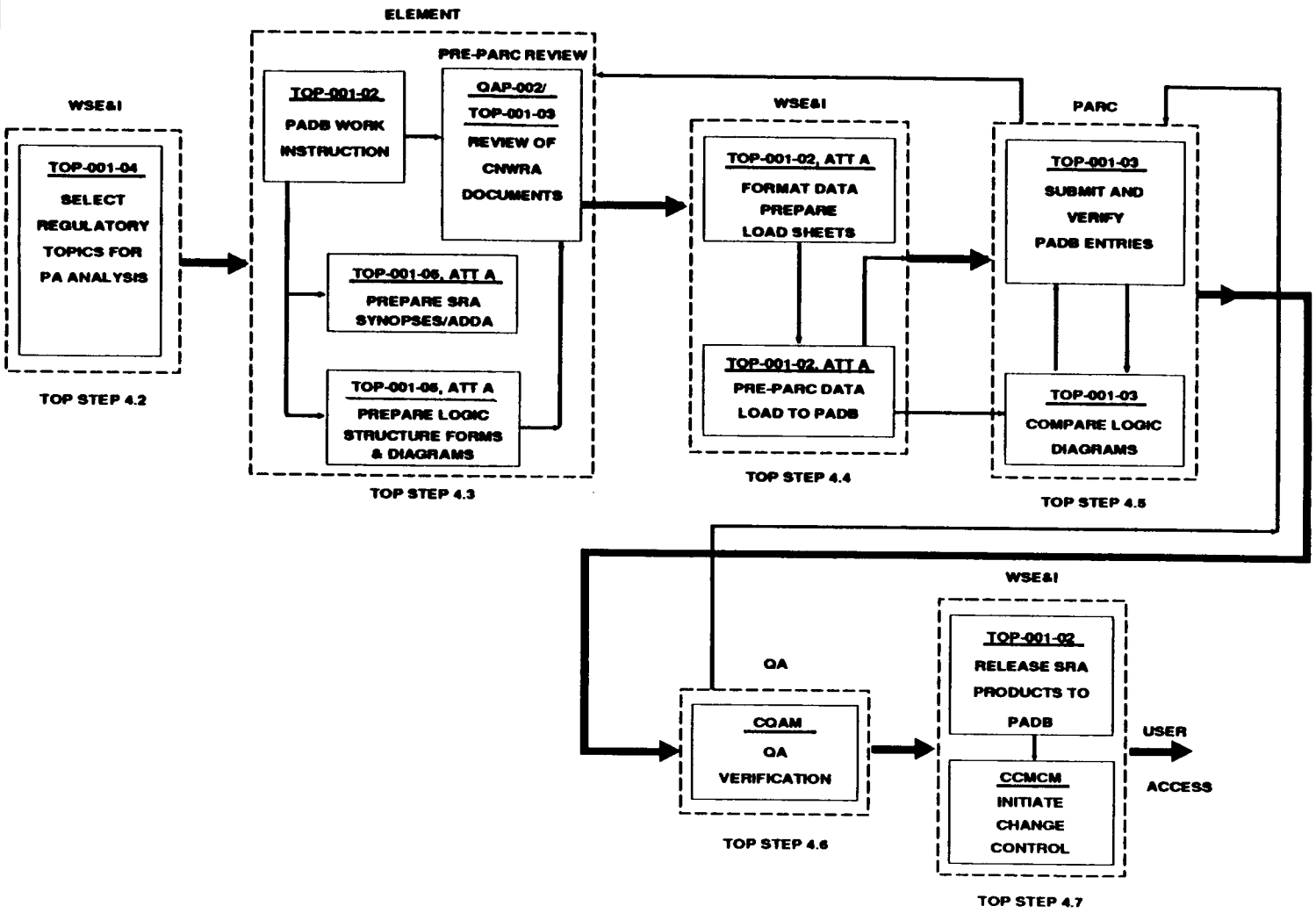

Figure 1 - Implementing the SRA Process

ATTACHMENT A

PROCEDURE FOR USE OF THE SRA SYNOPSIS, SRA SYNOPSIS ADDENDA, AND LOGIC STRUCTURE INPUT FORMS

1. INSTRUCTIONS FOR PREPARATION OF SRA SYNOPSIS

The following outline and checklist of principal content is applicable to all Regulatory Requirements "synopses" developed in the Systematic Regulatory Analysis (SRA) process.

The organization of synopses is based on the logic structures ("hierarchies") developed first for the Regulatory Elements of Proof (REOP), then expanded by the logic of the associated Technical Review Components, and duplicated by the logic structure of the Compliance Determination Methods.

The synopsis will begin with the citations of the Regulatory Texts that make up the subject Regulatory Requirement. The list of citations will be followed by the Regulatory Elements of Proof textual hierarchy (the Boolean logic diagram will be included at the front of the synopsis report) and the hierarchies of the Technical Review Components sets. The full texts of the Regulatory Texts included in the Regulatory Requirement together with their Statutory Bases, rationales and references will be grouped in a separate section. That section will include the citations, rationales and references for Excluded Regulatory Texts.

As may be seen in the outline below (see Contents), the balance of the Program Architecture (PA) elements are to be similarly grouped consistent with their basic relationships. That is, elements with a direct relationship to the Compliance Determination Strategy/Methods (which have an "associative" relationship to the elements in the Regulatory Requirements group) are grouped under "Compliance Determination". The presence of a potential Uncertainty in any of the preceding elements will be indicated by inserting "POTENTIAL UNCERTAINTY", followed by the PASS ID and Uncertainty Topic.

Similarly, uncertainties and the elements derived from them will be grouped under the heading "Potential Uncertainties". Other elements derived from or supporting individual elements will be collected into individual sections for ready reference. This includes Composite Information Requirements, rationales and associated references, and Open Items.

FORMAT

All Synopses are to be prepared in a common report format as follows: [This format may be stored as a User Profile. See DW4 manual, pg 233.]

Typestyle -- standard elite (12 pitch) [DW4 F7, 3, Typestyle 86]
Margins -- Left 10, right 90 [DW4 F7, 1]
Spacing -- Single space [DW4 F7, 2, Line Spacing = 1]
Justification -- Left and right [DW4 F7, 2, Line Justification = J]
DW4 default on other settings.

- All titles, text paragraphs, bullets and lists are to be blocked [CTRL T in DW4].
- All abbreviations and acronyms are to be spelled-out the first time they are used.
- DO NOT USE UNDERLINES OR BRACKETS []; they are not available from the mainframe, which will be the eventual source of Synopsis-style reports.
- Individual Regulatory Elements of Proof are to be numbered in accordance with draft TOP-001-02 Rev. 1, Attachment A, Section 5.8 (page A31).
- Individual Technical Review Components are to be numbered in accordance with the above TOP, Section 5.8 and Section 6.12a (page A46).
- Individual Compliance Determination Methods are to be numbered in accordance with the above TOP, Section 5.8 and Section 12a, Content (page A86).
- Individual Information Requirements are to be numbered in accordance with the above TOP, Section 5.8 and Section 20a (page A153).
- Individual Potential Uncertainties are to be numbered in accordance with the above TOP, Section 5.8 and Section 14a (page A105).

For the general layout of Synopsis entries, see the attached example.

HEADER

Create a header for the Synopsis (in DW4, CTRL-F7, 1, to set up header) that includes the RR number at the extreme left and the page number at the extreme right. As appropriate "DRAFT" may be centered in the header. To install the automatic page numbering, while in the header, press F8, then select "Page Number" from the DW4 Instructions menu.

The header should appear as follows:

RRxxxx Page #

TITLES

The first title is to always be "SYSTEMATIC REGULATORY ANALYSIS SYNOPSIS" in all caps, centered. The second title, double-spaced and centered under the first, again in all caps, is to be the Topic of the Regulatory Requirement. The second title is separated from Section 1 by a triple-space.

CONTENTS

The following is the general outline for a Regulatory Requirement Synopsis that is to be delivered to the NRC. Exceptions may be made for a specific tailored deliverable as directed by the WSE&I Element Manager.

[NOTE: For the Uncertainty Analysis, major sections will be numbered in order. Because of potential differences (caused by Technical Uncertainties), section numbers are shown in this instruction as "#.".]

TEMPLATE FOR
SYSTEMATIC REGULATORY ANALYSIS SYNOPSIS

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PREFACE

The Regulatory Requirement Synopsis is intended to serve two principal purposes: (1) to provide the most efficient tool for use by the regulatory analysts in recording the results of the Systematic Regulatory Analysis of statutes and regulations applicable to the NRC High-Level Waste Management Program, and (2) to document the key products of that analysis in a standard, reader-friendly format. In addition, this format (1) conserves Center professional staff time since it is more easily reviewed by Center review groups and management, and (2) is readily translatable to computer input forms by a trained clerk-typist.

The content of the SRA Synopsis will be expanded as additional parts of the process are undertaken (e.g., Uncertainty Reduction Methods Analysis, the consolidation of Uncertainties).

NOTE: In the instructions which follow, the bullet entries are intended to serve as a checklist for each section of the Synopsis. THE BULLET ENTRIES ARE INTENDED TO BE COMPLETE. Consult the referenced sections of TOP 001-02, Rev 1, ATT A for additional information.

NOTE: In the instructions which follow, information placed within brackets, [ ], is intended to identify sources of additional information or to provide guidance on the type of entry which is to appear in the completed Synopsis. The words in the brackets are not themselves part of the Synopsis as submitted.

NOTE: Underlining is not to be used in Synopses. Underlining in the examples which follow is intended to provide emphasis to assist analysts.

REGULATORY REQUIREMENT SYNOPSIS

[TOPIC OF THE REGULATORY REQUIREMENT]

REQUIREMENT

Regulatory Requirement Citation(s)
[Included Regulatory Text only - see TOP-001-02, pg A5, fourth paragraph]

Primary Regulatory Text Citation [see TOP-001-02, Sec 3.5a, pg A14]

[Citation in non-std format] [Revision date]

Potential Uncertainty [see TOP-001-02, Sec 14a and 14c, pg A106]

PASS Identification Number: RRxxxx/UN0001
Topic: [see TOP-001-02, Sec 14c, pg A106]

Associated Regulatory Text Citation(s) [see TOP-001-02, pg. A5, fourth paragraph, and Sec 3.5a, pg. A14]

- o listed in alphanumeric order of citations
- o proper use of *
- o revision date included for statutes and regulations

[First citation in non-std format] [Revision date]

[Second citation in non-std format] [Revision date]

Potential Uncertainty [see TOP-001-02, Sec 14a and 14c, pg A106]

PASS Identification Number: RRxxxx/UN0002
Topic: [see TOP-001-02, Sec 14c, pg A106]

[Third citation in non-std format] [Revision date]

Referenced Regulatory Text Citation(s) [see TOP-001-02, pg. A5, fourth paragraph, and Sec 3.5a, pg A14]

- o listed in alphanumeric order of citations
- o citations in nonstandard format
- o proper use of *
- o revision date included for statutes and regulations

[First citation] [Revision date]

Potential Uncertainty [see TOP-001-02, Sec 14a and 14c, pg A106]

PASS Identification Number: RRxxxx/UN003
Topic: [see TOP-001-02, Sec 14c, pg A106]

The full text(s) of the above listed Regulatory Text(s) is(are) included in the Appendix, "Regulatory Requirement Text(s) and Rationale(s)".

The full text(s) and rationale(s) for the Potential Uncertainty(ies) is(are) included in the section entitled "Potential Uncertainty(ies)".

Regulatory Element(s) of Proof and Technical Review Components

PS0001 -- [Topic of the RR]

[NOTES: (1) If the RR contains just one citation, omit the PASS ID line above since the PS number and topic would be redundant. (2) Insert the REOP Boolean logic diagram (Figure 1) as the first page following the start of this subsection. The figure is to include the logic operators and, for each individual REOP, (a) the unique part of the PASS ID number (EPxxxx), (b) topic of the individual REOP, and (c) citation of the parent Regulatory Text in standard format. See TOP-001-02, Sec 5.8, pg A31]

DOE SHALL DEMONSTRATE THAT:

EP0100 -- [Topic in lower case - see TOP-001-02, Sec 5.14c, pg A35]

[Text of first REOP - see Sec 5.14f, pg A36]

- reads as if prefaced by "DOE shall demonstrate that: "
- REOP is entered in all caps
- the EP, RC and NC numbering convention is defined i n TOP-001-02, Table A1, pg A32
- each individual REOP is a complete Regulatory Text
- language change is minimum necessary to change tense
- identify in parenthesis () the citation of the Reg. Text on which the REOP is based (i.e., the parent) -- use standard format

EP0200 -- [Topic in lower case - see TOP-001-02, Sec 5.14c, pg A35]

[Text of second REOP -- see instruction checklist above]

[Continue as above for all individual Regulatory Elements of Proof. Follow each end-point EP with its Technical Review Components set (TS) in the following format. If and only if, the logic of the TS includes one or more "OR" relationships, provide the Boolean logic diagram for the set. If a higher-level EP requires a Technical Review Component (RC) not identified for one of its daughter EPs, follow that higher-level EP with a description of the individual RC in the same format.]

Technical Review Components for [end-point EP PASS ID]

TSxxxx -- [Topic of TS in lower case - see TOP-001-02, Sec 6.3, pg A42. The Technical Review Components set (TS) numbering convention is defined in TOP-001-02, Sec. 6.1, pg A42]. Use the topic of the parent end point EP.

DOE SHALL PROVIDE:

RCxxxx -- [Topic of first individual Technical Review Component (RC) in lower case - see TOP-001-02, Sec 6.12c, pg. A47. The RC numbering convention is defined in TOP-001-02, Table A1, pg. A32]

[Text of first RC - see TOP-001-02, Sec 6.12e, pg. A47] reads as if prefaced by "DOE shall provide: "

- o complete statement of individual RC entered in lower-case
- o where appropriate, provide probability and/or confidence requirements
- o follow statement of alternative RC with "This is an acceptable alternative for [enter the PASS ID Number(s) of the alternative(s)]"
- o end with "(TECHNICAL REVIEW COMPONENT)" based on [see TOP-001-02, Sec 6.12e]

[logic operator]

RCxxxx -- [Topic of second RC in lower case - see TOP-001-02, Sec 6.12c, pg A47]

[Text of second RC - see instruction checklist above]

[Continue as above for each individual RC in the set associated with the subject end-point EP]

Rationale for Logical Relationships of Regulatory Elements of Proof Set [see TOP-001-02, Sec 5.9, pg A32]

- o rationale, criteria, assumptions and other bases for decisions made in identifying PS relationships
- o assumptions used to develop logic in the presence of uncertainty(ies)
- o germane and positive comments/observations with contributor name and date
- o denote references used by inserting "(Reference n0)" immediately after material obtained from another document
- o end Rationale with name of analyst and date of analysis

Reference(s) for PS Logical Relationships Rationale [see TOP-001-02, Sec 5.10, pg A33]

- o list and number references in order cited above
- o include for each reference, as applicable:
  - document title
  - publication (e.g., Federal Register, NUREG-0804)
  - author
  - originating agency (e.g., NRC)
  - beginning and ending page numbers of the specifically relevant material

Potential Regulatory Uncertainty [see TOP-001-02, Sec 14a and 14c, pg A106 -- only uncertainties related to REOP logic]

PASS Identification Number: RRxxxx/UN0004
Topic: [see TOP-001-02, Sec 14a, pg A106]

Rationale for Logical Relationships of Technical Review Components Set TSxxxx [see TOP-001-02, Sec. 6.8, pg A44]

[If the TS includes any "OR" relationships, include the set Hierarchy (the Boolean diagram of the set logic). The format is to be the same as that for the REOP logic diagram. See TOP-001-02, Sec. 6.7, pg A44]

Topic of TSxxxx

- o rationale for the inclusion of each branch in the hierarchy (i.e., for each "OR").
- o germane and positive comments/observations with contributor name and date
- o denote references used by inserting "(Reference n0)" immediately after material obtained from another document
- o end Rationale with name of analyst and date of analysis

<u>Rationales for Individual Technical Review Components of TSxxxx</u> [see TOP-001-02, Sec. 6.12f, pg A48]

RCxxxx -- [Topic of first individual Technical Review Component (RC) in lower case - see TOP-001-02, Sec 6.12c, pg A47]

- o describe the need for the subject RC
- o rationale, criteria, assumptions and other bases for decisions made in developing the individual RC, an assigned tolerance or confidence requirement, or the rationale
- o assumptions used to develop RC in the presence of previously identified uncertainty(ies) in the parent EP
- o germane and positive comments/observations with contributor name and date
- o denote references used by inserting "(Reference n0)" immediately after material obtained from another document
- o end Rationale with name of analyst and date of analysis

[Continue as above for each individual RC in the set]

<u>Reference(s) for TS Logical Relationships Rationale and Individual RC Rationales for TSxxxx</u> [see TOP-001-02, Sec 5.10, pg A33]

- o list and number references in order cited above
- o include for each reference, as applicable:
  - document title
  - publication (e.g., Federal Register, NUREG-0804)
  - author

- originating agency (e.g., NRC)
- beginning and ending page numbers of the specifically relevant material

[Continue as above for the Technical Review Components set for each end-point EP]

COMPLIANCE DETERMINATION

Compliance Determination Strategy

NS0001 -- [Topic of NRC Compliance Determination Strategy - see TOP-001-02, Sec 11.3, pg A79]

- o general approach or overall plan for NRC determination of compliance with the subject Regulatory Elements of Proof set [see TOP-001-02, Sec 11.5, pg A80]

Rationale for Strategy [see TOP-001-02, Sec 11.6, pg A80]

- o rationale, criteria, assumptions and other bases for decisions made in developing or selecting the strategy
- o germane and positive comments/observations with contributor name and date
- o denote references used by inserting "(Reference n0)" immediately after material obtained from another document
- o end Rationale with name of analyst and date of analysis

Reference(s) for Strategy and Rationale [see TOP-001-02, Sec 11.7, pg A81]

- o list and number references in order cited above
- o include for each reference, as applicable:
  - document title
  - publication (e.g., Federal Register, NUREG-0804)
  - author
  - originating agency (e.g., NRC)
  - beginning and ending page numbers of the specifically relevant material

Compliance Determination Methods and Information Requirements

THE NRC WILL:

NC0100 -- [Topic of first individual Compliance Determination Method in lower case - see TOP-001-02, Sec 12d, pg A87. The NC numbering convention is defined in TOP-001-02, Table A1, pg A32]

Associated Regulatory Element of Proof: EP0100
OR
Associated Technical Review Component: RCxxxx
[This is the PASS ID of the EP or RC to which the NC applies]

Preliminary Compliance Determination Method Description [see TOP-001-02, Sec 12h, pg A88]

- o reads as if prefaced by "The NRC will: "
- o one or more of the following:
  - major steps and method(s) for reviewing/evaluating applicable part(s) of license application
  - independent analysis method
  - confirmatory research/investigation method
  - performance confirmation review/analysis method
- o sufficiently specific to provide basis for identification of Information Requirements (IR)
- o if method is documented, reference the source document
- o denote references used by inserting "(Reference n0)" immediately after material obtained from another document

Potential Technical Uncertainty

PASS Identification Number: RRxxxx/UN0007
Topic: [see TOP-001-02, Sec 14c, pg A106]

Information Requirement(s) for NC0100
[AS APPLICABLE, consistent with the Compliance Determination Strategy]

IRxxxx [Topic of first IR in lower case - see TOP-001-02, Sec 20c, pg A153]

Potential Technical Uncertainty

PASS Identification Number: RRxxxx/UN0011
Topic: [see TOP-001-02, Sec 14c, pg A106]

[Text of first IR - see TOP-001-02, Sec 20g, pg A154]

- o parameter, property or condition of interest at or above the level that would be
  - measured in the lab or field

- obtained from records or the literature
- required for design analysis/review

o needed accuracy or precision (tolerance) or statistical confidence

o significant requirements or constraints on information [see TOP-001-02, Sec 20g, pg A154]

[Continue as above for each individual IR for the subject NC]

Rationale for Compliance Determination Method NC0100 [see TOP-001-02, Sec 12i, pg A89]

o rationale, criteria, assumptions and other bases for decisions made in developing or selecting the NC

o germane and positive comments/observations

o denote references used by inserting "(Reference n0)" immediately after material obtained from another document

o end Rationale with name of analyst and date of analysis

Reference(s) for Compliance Determination Method Description and Rationale for NC0100 [see TOP 001-02, Sec 12j, pg A89]

o list and number references in order cited above

o include for each reference, as applicable:
- document title
- publication (e.g., Federal Register, NUREG-0804)
- author
- originating agency (e.g., NRC)
- beginning and ending page numbers of the specifically relevant material

Rationale(s) for Information Requirement(s) of NC0100 [see TOP-001-02, Sec 20h, pg A155]

IRxxxx [Topic of first IR of subject NC in lower case - see TOP-001-02, Sec 20c, pg A153]

o rationale, criteria, assumptions and other bases for decisions made in developing or selecting the IRs

o germane and positive comments/observations

o denote references used by inserting "(Reference n0)" immediately after material obtained from another document

o end Rationale with name of analyst and date of analysis

IRxxxx [Topic of second IR of subject NC in lower case - see TOP-001-02, Sec 20c, pg A153]

[Continue as above for each individual IR of the subject NC]

Reference(s) for Information Requirements and Rationales [see TOP-001-02, Sec 20i, pg A156]

- o list and number references in order cited above
- o include for each reference, as applicable:
  - document title
  - publication (e.g., Federal Register, NUREG-0804)
  - author
  - originating agency (e.g., NRC)
  - beginning and ending page numbers of the specifically relevant material

[Continue as above for all Information Requirements for the subject Compliance Determination Method]

NCxxxx -- [Topic of second individual Compliance Determination Method in lower case - see TOP-001-02, Sec 12d, pg A87]

[Continue as above for all Compliance Determination Methods. There is at least one NC for each EP and each RC.]

POTENTIAL UNCERTAINTY(IES)

Included Potential Uncertainty(ies)

UN0001 -- [Topic in lower case - see TOP-001-02, Sec 14c, pg A106]

Parent Record: [If parent is a Reg Text, enter its citation in standard format. If parent is a NC or an IR, enter its complete PASS ID number, see TOP-001-02, Sec 14b, pg A106]

Uncertainty Type: [Institutional, Regulatory or Technical, see TOP-001-02, Sec 14a, pg A107]

Text of the Potential Uncertainty [see TOP-001-02, Sec 14k, pg A108]

- o if practical, state in a single sentence:
  - what is uncertain

- what is needed to correct the uncertainty (e.g.; clarification; further definition; interpretation; generic, high-order criteria)
- why the uncertainty needs to be corrected

o statement is to be positive -- what is needed, rather than what may not have been done adequately or what is not now available

Rationale for Inclusion [see TOP-001-02, Sec 14l, pg A109]

o rationale, criteria, assumptions and other bases for decision
o minimum search includes:
  - Source Federal Register notices
  - Statements of Consideration
  - NUREG-0804
o germane and positive comments/observations with contributor name and date
o denote references used by inserting "(Reference n0)" immediately after material obtained from another document
o end Rationale with name of analyst and date of analysis

UN0002 -- etc. [See Text and Rationale instructions above]

Reference(s) for Uncertainty Text(s) and Inclusion Rationale(s)
[for all Included Potential UN - see TOP-001-02, Sec 14m, pg A110]

o list and number references in order cited above
o include for each reference, as applicable:
  - document title
  - publication (e.g., Federal Register, NUREG-0804)
  - author
  - originating agency (e.g., NRC)
  - beginning and ending page numbers of the specifically relevant material

Excluded Uncertainty(ies)

UN000x -- [Topic of first Excluded Uncertainty in lower case - see TOP-001-02, Sec 14c, pg A106]

Parent Record: [If parent is a Reg Text, enter its citation in standard format. If parent is a CDM, enter its complete PASS ID number, see TOP-001-02, Sec 14b, pg A106]

Excluded Uncertainty Text [see TOP-001-02, Sec 14k, pg A108]

- o if practical, state in a single sentence:
  - what is uncertain
  - what is needed to correct the uncertainty
  - why the uncertainty needs to be corrected
- o statements are to be positive -- what is needed, rather than what may not have been done adequately or what is not now available

Rationale for Exclusion [see TOP-001-02, Sec 141, pg A109]

- o rationale, criteria, assumptions and other bases for decision
- o minimum search includes:
  - Supplementary Information (Federal Register notice)
  - Statements of Consideration
  - NUREG-0804
- o germane and positive comments/observations with contributor name and date
- o denote references used by inserting "(Reference n0)" immediately after material obtained from another document
- o end Rationale with name of analyst and date of analysis

UN000y -- [Topic of second Excluded Uncertainty in lower case]

[See Text and Rationale instructions above]

Reference(s) for Uncertainty Text(s) and Exclusion Rationale(s)
[for all Excluded Potential UN - see TOP-001-02, Sec 14m, pg A110]

- o list and number references in order cited above
- o include for each reference, as applicable:
  - document title
  - publication (e.g., Federal Register, NUREG-0804)
  - author
  - originating agency (e.g., NRC)
  - beginning and ending page numbers of the specifically relevant material

APPENDIX. REGULATORY REQUIREMENT TEXTS AND RATIONALES

Included Regulatory Text(s)

Primary Regulatory Text [see TOP-001-02, Sec 3, Background, pg A5]

[Citation in non-std format] [Revision date]

[Full text of cited primary Regulatory Text]

Rationale for Selection as Primary [See TOP-001-002, Sec 3.5c, pg A14]

- o rationale, criteria, assumptions and other bases for decision
- o identify related parts of Supplementary Information, responses to public comments, and similar sources
- o for 10 CFR 60, related parts of Statements of Consideration and NUREG-0804
- o germane and positive comments/observations with contributor name and date
- o denote references used by inserting "(Reference n0)" immediately after material obtained from another document

Associated Regulatory Text(s) [see TOP-001-02, Sec 3, Background, pg A5]

[Citation in non-std format] [Revision date]

[Full text of cited Regulatory Text]

Rationale for Inclusion [see TOP-001-02, Sec 3.5c, pg A14]

- o rationale, criteria, assumptions and other bases for decision
- o identify related parts of Supplementary Information, responses to public comments, and similar sources
- o for 10 CFR 60, related parts of Statements of Consideration and NUREG-0804
- o germane and positive comments/observations with contributor name and date
- o denote references used by inserting "(Reference n0)" immediately after material obtained from another document

[Citation in non-std format] [Revision date]

[Continue as above for each Associated Regulatory Text]

Referenced Regulatory Text(s) [see TOP-001-02, Sec 3, Background, pg A5]

[See Text and Rationale instructions for Associated Reg Text]

Reference(s) for Inclusion Rationale(s) [for all Included R e g Texts, see TOP-001-02, Sec 3.5d, pg A15]

- o list and number references in order cited above
- o include for each reference, as applicable:
  - document title
  - publication (e.g., Federal Register [including volume and number], NUREG-0804)
  - author
  - originating agency (e.g., NRC)
  - beginning and ending page numbers of the <u>specifically</u> relevant material

<u>Excluded Regulatory Text(s)</u> [see TOP-001-02, Sec 3.6, pg A16]

[Citation and revision date of first Excluded Regulatory Text]

Rationale for Exclusion [see TOP-001-02, Sec 3.6b, pg A16]

- o rationale, criteria, assumptions and other bases for decision
- o germane and positive comments/observations with contributor name and date
- o denote references used by inserting "(Reference n0)" immediately after material obtained from another document

[Citation and revision date of second Excluded Regulatory Text]

[Continue as above for each Excluded Regulatory Text]

Reference(s) for Exclusion Rationale(s) [for all Excluded Reg Texts]

- list and number references in order cited above
- include for each reference, as applicable:
  - document title
  - publication (e.g., Federal Register [including volume and number], NUREG-0804)
  - author
  - originating agency (e.g., NRC)
  - beginning and ending page numbers of the <u>specifically</u> relevant material

2. INSTRUCTIONS FOR PREPARATION OF ADDENDA TO SRA SYNOPSES

[NOTE: The following sections identify the records and the Additional SRA information that are required in addition to the current synopsis formats to complete the analysis (i.e.; RR, EP, associated Regulatory and Institutional UN and RC) called for by TOP-001-02 and the DW4 load sheets for the Program Architecture Data Base.]

2.1 ADDITIONAL SRA INFORMATION -- REGULATORY REQUIREMENTS

The following information is required for the completion of the DW4 input forms for the Program Architecture Database (PADB). <u>This additional information is not to be included with a Synopsis used for any other purpose. The paragraph numbers for the remainder of Section 2.1 reflect the record numbering system from the load sheets.</u>

3.2 Regulatory Requirement Keywords

- o only for topics that receive <u>meaningful</u> treatment in subject RR.
- o sufficiently specific to the content of the subject RR to isolate it from other RRs.
- o terms <u>database users</u> would most likely have in mind when performing a search for the subject RR.
- o maximum size: 50 characters per keyword or phrase.
- o see TOP-001-02, pg. A8, for additional guidance.

3.3 Regulatory Requirement Applicable Period

- o phases of the program during which the subject RR applies.
- o see TOP-001-02, pg A9, for definitions of the program phases and additional guidance.

3.4 Regulatory Agency

- o agency with <u>compliance determination authority</u> for the subject RR.
- o see TOP-001-02, pg. A11, for additional guidance.

3.5b Statutory Basis

- section citation(s) of the authorizing statute that is the basis for each Included Regulatory Text of the subject RR.
- all citations in nonstandard format [see TOP, Att. A, Section 2].
- if no identifiable statutory basis for given Reg Text, enter "See Rationale" and explain in Section 3.5c, Rationale for ... Statutory Basis.
- see TOP-001-02, pg. A14, for additional guidance.

3.5c Rationale for ... Statutory Basis
[This record is shared with rationale for inclusion of regulatory text]

- rationale, criteria, assumptions and other bases for decisions made in determining statutory basis of each Included Reg Text.
- if no identifiable statutory basis, explanation of attempt to identify same.
- see TOP-001-02, pg. A14, for additional guidance.

3.7 RELATED REGULATORY TEXT

Records 3.7.1a through 3.7.1d are to be repeated for each Regulatory Text selected for inclusion as a Related Regulatory Text. The texts are to be listed in the alphanumeric order of their citations.

3.7.1a Included Related Regulatory Text Citation

- single citation in nonstandard format (see TOP-001-02, sec 2).
- include revision date.
- see TOP-001-02, pg. A18, for additional guidance.

3.7.1b Rationale for Inclusion

- rationale, criteria, assumptions and other bases for decisions made in selecting the subject Related Regulatory Text.
- comments/observations may be included.
- see TOP-001-02, pg. A18, for additional guidance.

3.7.1c References for Rationale

- o references used in Rationale for Inclusion (by TDI number with beginning and ending page numbers).
- o VERIFY THAT TDI IDENTIFIER IS FOR CORRECT AMENDMENT, DATE, EDITION AND/OR REVISION.
- o see TOP-001-02, pg. A19, for additional guidance.

3.7.1d Related Regulatory Elements of Proof

[This record will be completed by the PASS computer -- see TOP-001-02, pg. A19]

Records 3.7.2a through 3.7.2c are to be repeated for each individual Regulatory Text that was seriously considered for inclusion as a Related Regulatory Text and then excluded. The texts are to be listed in the alphanumeric order of their citations.

3.7.2a Excluded Related Regulatory Text Citation

- o single citation in nonstandard format (see TOP-001-02, sec 2).
- o include revision date.
- o see TOP-001-02, pg. A20, for additional guidance.

3.7.2b Rationale for Exclusion

- o rationale, criteria, assumptions and other bases for decisions made in the process of excluding the subject Related Regulatory Text.
- o comments/observations may be included.
- o see TOP-001-02, pg. A20, for additional guidance.

3.7.2c References for Rationale

- o references used in Rationale for Exclusion (by TDI number with beginning and ending page numbers).
- o VERIFY THAT TDI IDENTIFIER IS FOR CORRECT AMENDMENT, DATE, EDITION AND/OR REVISION.
- o see TOP-001-02, pg. A20, for additional guidance.

3.8 Overall Comments/Observations

- o comments, observations and similar notes applicable to the Regulatory Requirement as a whole.
- o must be germane and make a positive contribution to the analysis.
- o GENERAL OBSERVATIONS ARE TO BE AVOIDED.
- o see TOP-001-02, pp. A20-21, for additional guidance.

3.9 References for Comments/Observations

- o references used in Overall Comments/Observations (by TDI number with beginning and ending page numbers).
- o VERIFY THAT TDI IDENTIFIER IS FOR CORRECT AMENDMENT, DATE, EDITION AND/OR REVISION.
- o see TOP-001-02, pg. A21, for additional guidance.

2.2 ADDITIONAL SRA INFORMATION -- REGULATORY ELEMENTS OF PROOF SET (PS)

The following information is required for the completion of the DW4 input forms for the Program Architecture Database (PADB). <u>This additional information is not to be included with a Synopsis used for any other purpose. The paragraph numbers for the remainder of Section 2.2 reflect the record numbering system from the load sheets.</u>

5.4 Regulatory Elements of Proof Set Keywords [see TOP-001-02, pg. A30]

[This record will be completed by the PASS computer using the same keywords as the Regulatory Requirement]

5.5 Cognizant Element Code

- o Choose one: EB___ GS ___ QA___ RD___ WS___ PA___
- o see TOP-001-02, pg. A30

5.6 When Action Required

- o milestone(s) by which NRC staff must be satisfied that the technical material for Compliance Determination for the subject PS is complete and available.

- o latest point that would avoid impacting overall program schedule.
- o IDENTIFIED BY MILESTONE OR A TIME RELATIVE TO (i.e., "DISPLACED" FROM) A MILESTONE (e.g., license application submittal minus one year).
- o see TOP-001-02, pg A30.

Milestone _____ (25 character max)

Displacement _____ (30 " ")

5.7 Rationale for When Action Required

- o rationale, criteria, assumptions and other bases for decisions made in determining when action required.
- o comments/observations may be included.
- o see TOP-001-02, pg A31.

5.8 References for "When Action Required" Rationale

- o references used in determining "When Action Required" (by TDI number with beginning and ending page numbers).
- o VERIFY THAT TDI IDENTIFIER IS FOR CORRECT AMENDMENT, DATE, EDITION AND/OR REVISION.
- o see TOP-001-02, Sec 5.10, pg A33

5.13 Overall Comments/Observations

- o comments, observations and similar notes applicable to PS records.
- o must be germane and make a positive contribution to the analysis.
- o GENERAL OBSERVATIONS ARE TO BE AVOIDED.
- o see TOP-001-02, Sec 5.12, pg A34.

5.14 References for Overall Comments/Observations

- o references used in Overall Comments/Observations (by TDI number with beginning and ending page numbers).
- o VERIFY THAT TDI IDENTIFIER IS FOR CORRECT AMENDMENT, DATE, EDITION AND/OR REVISION.
- o see TOP-001-02, Sec 5.13, pg A34.

2.3 ADDITIONAL SRA INFORMATION -- REGULATORY ELEMENTS OF PROOF (EP)

The following information is required for the completion of the DW4 input forms for the Program Architecture Database (PADB). This additional information is not to be included with a Synopsis used for any other purpose. The paragraph numbers for the remainder of Section 2.3 reflect the record numbering system from the load sheets.

5.15b Parent Regulatory Element of Proof

- o PASS ID number of the EP that appears in the Hierarchy in the position of a parent to the subject EP.
- o for EP0100 (the EP for the Primary Reg Text), identify the "Parent EP" to be PS0001.
- o see TOP-001-02, Sec 5.14b, pg A35

5.15d Individual Regulatory Element of Proof Keywords

- o only for topics that receive meaningful treatment in subject EP.
- o sufficiently specific to the content of the subject EP to isolate it from other EPs.
- o terms database users would most likely have in mind when performing a search for the subject EP.
- o maximum size: 50 characters per keyword or phrase.
- o see TOP-001-02, Sec 3.2, pg A8

5.15g Comments/Observations

- o comments, observations and similar notes applicable to the individual EP.
- o must be germane and make a positive contribution to the analysis.
- o GENERAL OBSERVATIONS ARE TO BE AVOIDED.
- o see TOP-001-02, Sec 5.14g, pg A36

5.15h References for Comments/Observations

- o references used in Comments/Observations (by TDI number with beginning and ending page numbers).
- o VERIFY THAT TDI IDENTIFIER IS FOR CORRECT AMENDMENT, DATE, EDITION AND/OR REVISION.
- o see TOP-001-02, Sec 5.14h, pg A37

2.4 ADDITIONAL SRA INFORMATION -- TECHNICAL REVIEW COMPONENTS SET (TS)

The following information is required for the completion of the DW4 input forms for the Program Architecture Database (PADB). This additional information is not to be included with a Synopsis used for any other purpose. The paragraph numbers for the remainder of Section 2.4 reflect the record numbering system from the load sheets.

6.2 Parent Individual Regulatory Element of Proof

- o PASS ID number of the end-point EP from which the subject Technical Review Component Set (TS) was derived.
- o must correspond directly to the PASS ID of the parent EP (e.g., if set PASS ID is RRxxxx/TS0400, the PASS ID of end-point EP is RRxxxx/EP0400)
- o see TOP-001-02, Sec 6.2, pg A42

6.4 Technical Review Components Set Keywords

- o only for topics that receive meaningful treatment in subject RC.
- o sufficiently specific to the content of the subject RC to isolate it from other RCs.
- o terms database users would most likely have in mind when performing a search for the subject RC.
- o maximum size: 50 characters per keyword or phrase.
- o see TOP-001-02, Sec 3.2, pg A8

6.5 When Action Required

- o milestone(s) by which NRC staff must be satisfied that the technical material for Compliance Determination for the subject TS is complete and available.
- o latest point that would avoid impacting overall program schedule.
- o IDENTIFIED BY MILESTONE OR A TIME RELATIVE TO (i.e., "DISPLACED" FROM) A MILESTONE (e.g., license application submittal minus one year).
- o see TOP-001-02, Sec 6.5, pg. A43

[NOTE: This schedule point can be no later than that contained in record 5.6, "When Action Required" for the PS]

Milestone _____ (25 character max)

Displacement _____ (30 " ")

6.6 Rationale for When Action Required

- o rationale, criteria, assumptions and other bases for decisions made in determining when action required.
- o comments/observations may be included.
- o see TOP-001-02, Sec 6.5, pg A43

6.7 References for "When Action Required" Rationale

- o references used in determining "When Action Required" (by TDI number with beginning and ending page numbers).
- o VERIFY THAT TDI IDENTIFIER IS FOR CORRECT AMENDMENT, DATE, EDITION AND/OR REVISION.
- o see TOP-001-02, Sec 5.9, pg A33

6.11 Overall Comments/Observations

- o comments, observations and similar notes applicable to TS records.
- o must be germane and make a positive contribution to the analysis.
- o GENERAL OBSERVATIONS ARE TO BE AVOIDED.
- o see TOP-001-02, Sec 6.10, pg A45

6.12 References for Overall Comments/Observations

- o references used in Overall Comments/Observations (by TDI number with beginning and ending page numbers).
- o VERIFY THAT TDI IDENTIFIER IS FOR CORRECT AMENDMENT, DATE, EDITION AND/OR REVISION.
- o see TOP-001-02, Sec 6.11, pg A45

2.5 ADDITIONAL SRA INFORMATION -- TECHNICAL REVIEW COMPONENTS (RC)

The following information is required for the completion of the DW4 input forms for the Program Architecture Database (PADB). This additional information is not to be included with a Synopsis used for any other purpose. The paragraph numbers for the remainder of Section 2.5 reflect the record numbering from the load sheets.

6.13b Parent Technical Review Component

- o PASS ID number of the RC that appears in the Hierarchy in the position of a parent to the subject RC.
- o for those RC at the first level of the set, identify the PASS ID of the "Parent RC" to be that of the set (i.e., TSxxxx).
- o see TOP-001-02, Sec 6.12b, pg A47

6.13d Individual Technical Review Component Keywords

- o only for topics that receive meaningful treatment in subject EP.
- o sufficiently specific to the content of the subject EP to isolate it from other EPs.
- o terms database users would most likely have in mind when performing a search for the subject EP.
- o maximum size: 50 characters per keyword or phrase.
- o see TOP-001-02, Sec 3.2, pg A8

6.13f References for Technical Review Component Text

- o references used in developing the individual Technical Review Component text (by TDI number with beginning and ending page numbers).
- o VERIFY THAT TDI IDENTIFIER IS FOR CORRECT AMENDMENT, DATE, EDITION AND/OR REVISION.
- o see TOP-001-02, Sec 6.12g, pg. A49

6.13i Technical Review Component -- Issue Correlation

- o the identification number(s) (where assigned) and the complete text(s) of issues identified by the DOE and affected parties that correspond with the subject RC.
- o see TOP-001-02, Sec 6.12h, pg. A49

6.13j Comments/Observations

- o comments, observations and similar notes applicable to the individual RC.
- o must be germane and make a positive contribution to the analysis.
- o GENERAL OBSERVATIONS ARE TO BE AVOIDED.
- o see TOP-001-02, Sec 6.12i, pg A49

6.13k References for Comments/Observations

- o references used in Comments/Observations (by TDI number with beginning and ending page numbers).
- o VERIFY THAT TDI IDENTIFIER IS FOR CORRECT AMENDMENT, DATE, EDITION AND/OR REVISION.
- o see TOP-001-02, Sec 6.12j, pg A50

3. INSTRUCTIONS FOR USE OF THE LOGIC STRUCTURE INPUT FORMS.

3.1 Element Linkage Input Form

3.1.1 This form (Figure 3-1) is to be completed by the analyst when completing SRA on Regulatory Elements of Proof Sets (PS) and Technical Review Component Sets (TS). It identifies relationships between parent and node elements for binary logic diagrams and indicates binary logic linkage and relationships between elements.

3.1.2 Completed Element Linkage Forms are verified by the Element Manager prior to the Program Architecture Review Committee (PARC) technical review and are then forwarded to the WSE&I Element for pre-PARC entry in the Program Architecture Data Base (PADB).

3.2 Cross Linkage Input Form

3.2.1 The analyst completes the Cross Linkage Input Form (Figure 3-2) when showing the linkage between a Regulatory Element of Proof (EP) and a Compliance Determination Method (NC) and between a Technical Review Component (RC) and a NC.

3.2.2 Completed Cross Linkage Input Forms are verified by the Element Manager during the pre-PARC technical review and are then forwarded to the WSE&I Element for pre-PARC entry in the PADB.

ELEMENT LINKAGE INPUT FORM (07/16/90)

>>>(G2.1) FORMAT: <LINKAGE.V05>

>>>(G2.2) ANALYST NAME: < > < > < >

>>>(G2.3) ORIGINAL SUBMISSION DATE: < > / < > / < >

>>>(G2.4) REVISION DATE: < > / < > / < >

>>>(G2.5) INPUT FILE NAME: < >

>>>(G2.6) INPUT FILE VERSION (EXTENSION): < >

>>>(G9.1) ELEMENT LINKAGE AND LOGICAL RELATIONSHIPS:

LEFT ARGUMENT ID	LOGICAL OPERATOR	RIGHT ARGUMENT ID	PARENT ELEMENT ID
< >	< >	< >	< >
< >	< >	< >	< >
< >	< >	< >	< >
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Figure 3-1 Element Linkage Input Form

```
CROSS LINKAGE INPUT FORM                                    (07/16/90)
>>>(G2.1) FORMAT: <CROSSLNK.V05>
>>>(G2.2) ANALYST NAME: <                    >    < > < >
>>>(G2.3) ORIGINAL SUBMISSION DATE: <  > / <  > / <    >
>>>(G2.4) REVISION DATE: <  > / <  > / <    >
>>>(G2.5) INPUT FILE NAME: <        >
>>>(G2.6) INPUT FILE VERSION (EXTENSION): <   >
```

```
>>> CROSS LINKAGE DEFINITIONS:
REOP OR TRC ELEMENT ID | NRC CDM ELEMENT ID
<RR0000/XX0000>        | <RR0000/XX0000>
<              >       | <              >
<              >       | <              >
<              >       | <              >
```

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES TECHNICAL OPERATING PROCEDURE	Proc. TOP-001-05 Revision 0, CH 1 Page 1 of 39

Title TOP-001-05 IMPLEMENTING THE SYSTEMATIC REGULATORY ANALYSIS PROCESS

EFFECTIVITY AND APPROVAL

Revision 0 of this procedure became effective on 3 December 1990. This procedure consists of the pages and changes listed below.

Page No.	Change	Date Effective
1	1	1 January 1991
2-4	-	3 December 1990
5	1	1 January 1991
6-39	-	3 December 1990

SUPERSEDED

by TOP-001, Revision 2, Effective 10/17/91

Supersedes Procedure No. TOP-001-05, Rev 0

Approvals

Written By	Date	Technical Review	Date
P. Mackin	1/31/91	T. Romine	1/31/91
Quality Assurance	**Date**	**Cognizant Director**	**Date**
B. Mabrito	1/31/91	B. Sagar	1/31/91

CNWRA Form TOP-1

structure diagrams and the Logic Structure Input Forms generated by the analysts within the Element to ensure that the original relationships are correct and that the proper relationships have been maintained.

4.6 Following concurrence by the PARC that SRA information is ready for entry into the PADB, Quality Assurance verification shall be completed in accordance with the Center Quality Assurance Manual (CQAM). If necessitated by the results of the Quality Assurance verification, the SRA information shall be returned to the PARC for remedial action.

4.7 Certified SRA products shall be released to the PADB by the WSE&I Element, and change control shall be initiated.

5. RECORDS

5.1 The SRA sign off sheet, the associated main frame computer printout and the plotted logic diagram (as appropriate) constitute QA records for this TOP in accordance with CQAM Section 17.

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

TECHNICAL OPERATING PROCEDURE

Proc. TOP-001-05

Revision 0, CH 1

Title TOP-001-05 IMPLEMENTING THE SYSTEMATIC REGULATORY ANALYSIS PROCESS

EFFECTIVITY AND APPROVAL

Revision 0 of this procedure became effective on December 3, 1990. This procedure consists of the pages and changes listed below.

Page No.	Change	Date Effective
1	1	1/1/91
2-4	-	12/3/90
5	1	1/1/91
6-39	-	12/3/90

THIS PROCEDURE IS SUPERSEDED BY TOP-001, REVISION 2, EFFECTIVE

Supersedes Procedure No. None

Approvals

Written By	Date	Technical Review	Date
Patrick C. Mackin	10/8/91	Ted Romine	10/8/91
Quality Assurance	**Date**	**Cognizant Director**	**Date**
Bruce Mabrito	10/11/91	Wes C. Patrick	10/11/91

CNWRA Form TOP-1