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REGULATORY ANALYSES**

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Revision 1

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Title

TOP-001-04 SELECTION OF REGULATORY TOPICS
FOR PROGRAM ARCHITECTURE ANALYSIS

EFFECTIVITY AND APPROVAL

Revision 1 of this procedure became effective on August 18, 1989. This procedure consists of the pages and changes listed below.

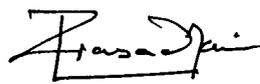
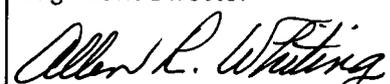
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SUPERSEDED

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Approvals

Written By 	Date 8/17/89	Technical Review 	Date 8/17/89
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**TOP-001-04 SELECTION OF REGULATORY TOPICS
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1. PURPOSE AND SCOPE

The purposes of this procedure are to (a) document the method previously used to select the Regulatory Topics for 10 CFR Part 60 Subparts B and E and (b) provide consistent guidance for the selection of additional Regulatory Topics associated with 10 CFR Part 60 and other primary regulations and/or statutes that are subject to Program Architecture analysis.

Regulatory Topics for Subparts B and E of 10 CFR Part 60 were selected to support an acceleration in the development of the Program Architecture. Since the process used in the initial selection was effective for those Regulatory Topics that were previously identified, it is documented here (fulfilling the requirements of the current Center Quality Assurance Manual) and is used as the basis for subsequent selections.

2. DEFINITIONS

2.1 REGULATORY TOPIC

The Regulatory Topic is an assigned word or phrase that uniquely identifies the subject of the Regulatory Requirement. Such Regulatory Topics are based on the Primary Statute or Regulation, and are assigned by means of implementing this procedure.

2.2 REGULATORY REQUIREMENT

A Regulatory Requirement is a statement of a requirement pertaining to the Nuclear Waste Management System, as quoted from one or more statutes, regulations, or other sources which have the force of law. Each such quotation, which is called a Regulatory Text, is an element of a source at or above the lowest level to which an alphanumeric identifier has been assigned. See TOP-001-02 for expanded, current definition of Regulatory Requirement.

2.3 PRIMARY STATUTE OR REGULATION

Primary Federal statutes and regulations are those which

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the NRC has direct regulatory authority to implement and enforce. Examples include 10 CFR Part 60, 10 CFR Part 71, and 10 CFR Part 72. Note that most items falling into the "Primary" category are regulations; there are relatively few cases where the NRC has not developed regulations to implement its statutory authorized responsibilities. From an analytical perspective, the Primary Regulations and Statutes are those used to derive both the Regulatory Topics, and the Regulatory Requirements that are the foundation of the Program Architecture development process.

2.4 INCORPORATED BY REFERENCE STATUTE OR REGULATION

The pertinent parts of statutes and regulations that are incorporated by reference (IBR) are treated as an integral part of the base Primary Federal Statute or Regulation. To be considered as "incorporated by reference", the statute or regulation must (a) be directly cited by number in a Primary Statute or Regulation, (b) be cited as part of the "Authority" for a Primary Statute or Regulation, and/or (c) be clearly referred to in a Primary Statute or Regulation. Examples include pertinent portions of 10 CFR Part 20, 10 CFR Part 51, and 40 CFR Part 191 that are IBR into 10 CFR Part 60, and portions of 49 CFR Parts 173-178 that are IBR into 10 CFR Part 71. Note that items incorporated by reference are typically regulations, rather than statutes. With regard to analyses, any regulation incorporated by reference into a Primary Regulation is treated as an integral part of that Primary Regulation for purposes of analysis; the portion of the regulation becomes part of the Regulatory Requirement that is analyzed.

2.5 STATUTORY AUTHORIZATION

Statutes that authorize the NRC to conduct the various parts of its regulatory mission fall under this definition. Examples include the NWPA, NWPA, and the Atomic Energy Act. Statutes may be used in the analyses in three different ways. First, these Federal statutes may contain the specific requirements which must be complied with by the affected agency. In this case, the pertinent part of the statute would be treated as part of the Primary Statute or Regulation and would be included in the Regulatory Requirement. Second, they may provide the basis for evaluation of the consistency and completeness of the regulation with its respective authorizing legislation. Third, statutes are compared with one another and with pertinent regulations to evaluate potential Institutional and/or Regulatory Uncertainties.

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In the latter two cases, the authorizing legislation is treated as a Related Statute for purposes of Program Architecture analysis, i.e. it is not embodied in part or in whole in a Primary Statute or Regulation and such things as Regulatory Elements of Proof are not developed for it.

2.6 RELATED STATUTES AND REGULATIONS

Statutes and regulations that relate topically to the Primary or IBR items, that are used by the NRC to regulate other nuclear facilities with similar functions, or that are used by other agencies to guide or regulate either high-level nuclear waste facilities or other nuclear facilities are included in this category. Sections of such statutes and regulations may be included as Related Regulatory Text, as appropriate. Examples include 10 CFR Part 72 in the context of 10 CFR Part 60, and vice versa.

2.7 OTHER

Other definitions are as contained in TOP-001 "Program Architecture Development and Maintenance," TOP-001-01 "Guidance to the Program Architecture Review Committee, Review and Revision of WSE&I Major Milestone No. 12," TOP-001-02, "Program Architecture Relational Database Work Instruction," and TOP-001-03 "Submission and Verification of Program Architecture Database Entries."

3. RESPONSIBILITY

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

3.2 All other responsibilities regarding this procedure are as described in TOP-001, Section 3.

4. CRITERIA

The following criteria apply to the selection of Regulatory Topics for subsequent Program Architecture analysis.

4.1 The principal subject matter for a Regulatory Topic must be found in a Primary Statute or Regulation, and shall clearly and concisely convey the essence of the underlying Regulatory Requirement.

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Applicable text from incorporated by Reference statutes and/or regulations is to be included in the Regulatory Requirement.

4.2 The subject matter of Related Statutes or Regulations shall not be used as the basis for Regulatory Topics.

4.3 Each Regulatory Topic shall embody a complete Regulatory Requirement (see TOP-001-02, Attachment A). That is, the cited portion of the statute or regulation taken by itself shall comprise a distinct requirement which will require an independent proof of compliance.

4.4 Each Regulatory Topic shall contain a single Regulatory Requirement (see TOP-001-02, Attachment A). That is, a Regulatory Topic should not apply to two or more requirements, unless more than one requirement exists at a level below the lowest designated subdivision of the statute or regulation that is being analyzed. (See Section 2.2, definitions of Regulatory Requirement and Regulatory Text.)

4.5 Each Regulatory Topic shall be unique. That is, it should not duplicate an existing Topic.

5. PROCEDURE

5.1 The WSE&I Element Manager may elect to implement this procedure on the whole of a Primary Statute or Regulation, or for an appropriate subdivision of such Statute or Regulation. Such decision to select Regulatory Topics for a subdivision of a Primary Statute or Regulation shall be documented by the WSE&I Element Manager.

Note: Historically, Regulatory Topics were selected for Subparts B and E of 10 CFR Part 60 to support an accelerated development of the Program Architecture. The remaining Subparts of 10 CFR Part 60 and all other Primary Regulations will be analyzed using this procedure to select a unique set of Regulatory Topics.

5.2 The WSE&I Element Manager, with the concurrence of the Director of Systems Engineering and Integration, shall identify a team of analysts who will work together to select the Regulatory Topics for the identified Primary Statute or Regulation or subdivision thereof. The team shall include members from the senior technical staff, regulatory analyst, and legal staff (if such legal expertise is not

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present in the regulatory analyst). Identification of the team and statements of their qualifications (by means of Professional Data Sheets or the equivalent) shall be documented.

5.3 Team members shall study the Primary Statute or Regulation or subdivision thereof and appropriate supporting documentation such as the Supplementary Information of the Federal Register notice of the rulemaking, the Statements of Consideration, NUREG-0804 (applicable to 10 CFR Part 60, only), Statutory Authorizations, Congressional Record, etc. to become familiar with the statute or regulation, as well as the legislative and regulatory intent associated with it.

5.4 Using the criteria given in Section 4 of this procedure, an initial list of Regulatory Topics shall be developed comprising each distinct requirement that is present in the regulation. The process of identifying distinct requirements and naming of specific Regulatory Topics may be assisted by considering the following factors.

- A. A section or paragraph of the statute or regulation may call out a specific program requirement or technical criteria, and examination of that section may show that it contains only one distinct requirement. In this case, the section or paragraph identifies the Regulatory Topic. Furthermore, the title of that section or some modification thereto can be used to name the Regulatory Topic.

For example, 10 CFR Section 60.21 "Content of application" produced the Regulatory Topic "License Application and Content."

- B. A section or paragraph of the statute or regulation may appear to call out a specific requirement but examination of that section may show that it contains several distinct Regulatory Requirements that are logically interrelated. In this case, the content of the section or paragraph must be further divided to identify each of the several unique Regulatory Requirements (but never lower than the lowest level of alphanumeric identifier used in the regulation). The names selected for the Regulatory Topics may be developed from a combination of the title of the

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section of the regulation and the topical material contained in the pertinent text of the regulation.

For example, 10 CFR Section 60.122(c) "Potentially adverse conditions" produced 24 Regulatory Topics of the form "Adverse Condition - Flooding," "Adverse Condition - Drilling," etc.

- C. A section or paragraph of the regulation may call out a specific requirement but examination of that section may show that it contains several distinct Regulatory Requirements that are not logically interrelated. In this case, the content of the section or paragraph must be further divided to identify each of the several unique Regulatory Requirements (but never lower than the lowest level of alphanumeric identifier used in the regulation). Furthermore, the names selected for the Regulatory Topics must be developed from the topical material contained in the pertinent text of the regulation.

For example 10 CFR Section 60.113 "Performance of particular barriers after permanent closure" produced the three Regulatory Topics "EBS Performance after Permanent Closure," "EBS Release of Radionuclides after Permanent Closure," and "Groundwater Travel Time."

Following tentative identification under Step 5.4, each Regulatory Topic shall be evaluated according to Steps 5.5 through 5.8 of this procedure to determine whether it has been correctly identified.

5.5 Each Regulatory Topic shall be carefully evaluated to ensure that it (a) clearly and concisely conveys the essence of the underlying Regulatory Requirement, (b) embodies a complete Regulatory Requirement (i.e. the cited portion of the regulation taken by itself comprises a distinct requirement), and (c) does not group two or more distinct Regulatory Requirements. Each Regulatory Topic shall be checked against the then current list of such Topics to ensure that it does not duplicate or only minimally supplements any existing Topic.

5.6 The set of Regulatory Topics shall be compared with the results of a functional analysis of the system that is subject to the

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regulation from which the Regulatory Topics were developed (e.g., 10 CFR Part 60 for the repository "system") to (a) determine the inter-relationships among the hierarchy of the specific Regulatory Requirements and (b) evaluate whether the regulation, taken in total, is sufficient and complete to support the NRC repository licensing mission. This comparison should include "rolling up" or consolidating the individual requirements to successively higher levels until, at the highest level, the requirements for the entire system are identified. The functional analysis may be performed independently of this procedure and be used here as the basis for comparison.

5.7 The Primary Regulation or subdivision thereof that is being analyzed shall be compared with the set of Regulatory Topics to ensure that each portion of the text is included in one or more Regulatory Topics. Portions of regulations such as general guidance, concepts, discussions of regulatory intent, and definitions should not be included in Regulatory Topics (See TOP-001-02, Attachment A, Section 3 for detailed criteria).

5.8 The Regulatory Topics resulting from use of this procedure are subject to subsequent review by a Program Architecture Review Committee (PARC), in accordance with TOP-001-03 "Submission and Verification of Program Architecture Database Entries." Any changes recommended by a PARC are subject to approval at or above the level of the Director of Systems Engineering and Integration.

6. RECORDS

Records shall be developed and maintained in accordance with Sections 4.A.4.3 through 4.A.4.6 and 4.A.4.8 of TOP-001, and the general provisions of Chapters 5, 6, and 17 of the Center Quality Assurance Manual (CQAM). Appropriate records shall also be maintained of Quality Assurance surveillance, reviews, and/or audits performed on the activities conducted under this procedure.

7. QUALITY ASSURANCE

This procedure has been developed and shall be controlled in accordance with Chapters 5 and 6 of the CQAM.

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Other Quality Assurance requirements for this procedure shall be implemented in accordance with the provisions of Sections 4.A.4.7 and 4.A.4.8 of TOP-001 and the general provisions of the CQAM. Either electronic or hard-copy objective evidence is acceptable for independent verification of the acceptability of activities performed in accordance with this procedure.

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1-9	0	8/18/89

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

SUPERSEDED

Supersedes Procedure No. None

Approvals

Written By <i>Patrick C. Mackin</i> Patrick C. Mackin	Date <i>10/8/91</i>	Technical Review <i>DTT 2</i> Ted Romine	Date <i>10/8/91</i>
Quality Assurance <i>Bruce Mabrito</i> Bruce Mabrito	Date <i>10/14/91</i>	Cognizant Director <i>Mes C. Patrick</i> Mes C. Patrick	Date <i>10/11/91</i>