

CORRELATION OF REGULATORY REQUIREMENTS AND REGULATORY ELEMENTS OF PROOF FOR 10 CFR PART 60

**Systematic Regulatory Analysis
Synopsis Report
WSE&I Intermediate Milestone No. 20-3702-031-103**

Prepared for

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1. INTRODUCTION

This letter report is submitted as part of an activity of Task 1 of the Waste Systems Engineering & Integration Program Element as identified in the Center for Nuclear Waste Regulatory Analyses (CNWRA) FY91-92 Operations Plans for the Division of High-Level Waste Management (HLWM). It is identified as WSE&I Intermediate Milestone No. 20-3702-031-103 and its specific purpose and content are described below.

1.1 PURPOSE

This deliverable transmits the results of a systematic analysis of the logical relationships present in 10 CFR Part 60. It conveys both the individual Regulatory Requirements and the Subordinate Regulatory Elements of Proof which comprise them. These are presented in text form and as logical hierarchies. The purpose of this deliverable is to provide information that will allow the Nuclear Regulatory Commission (NRC) staff the opportunity to prioritize further Systematic Regulatory Analysis (SRA) work on specific Regulatory Requirement (RR) topics of 10 CFR Part 60. For this purpose, the information that is being supplied in the individual Regulatory Requirement/Regulatory Elements of Proof (RR/REOP) Synopsis packages contains only the hard copy information, extracted from the Program Architecture Database (PADB), in a reader-friendly Regulatory Requirement Synopsis format, that will be of immediate value to that decision process. Other related information is yet to be developed.

2. CONTENT

The attendant volumes (1-5), containing 78 RR/REOP Synopses packages, constitute all of the DOE related RR Topics the Center identified when TOP 001-04 (Rev. 1), "Selection of Regulatory Topics for Program Architecture Analysis," was used to analyze 10 CFR Part 60. The 12 Regulatory Requirement topics defined as "NRC self-regulations," (specifically, RR0053, RR0061, RR0062, RR0064, RR0065, RR0069, RR0076, RR3004, RR3007, RR3009, RR3010, and RR3011) are not yet in the database and are not included in this report per agreement. Information contained herein was developed in accordance with the latest revisions of the following CNWRA technical and quality assurance 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
TOP-001-05	Implementing the Systematic Regulatory Analysis Process
QAP-002	Review and Approval of Technical Reports

In this report each RR/REOP Synopsis package, found at the numerically sequenced "tabbed" locations within Volumes 1-5, contains the following SRA information extracted from the Program Architecture database:

- A Regulatory Requirement Synopsis Table of Contents (identifying the RR number and title).
- A Requirements section, including:
 - Regulatory Requirement Citations (Primary, Associated, Referenced and Related Regulatory Text Citations).¹
 - Regulatory Elements of Proof (with their associated PASS identifier and title).

¹NOTE: If potential uncertainties related to this RR have been identified in the "Identification and Evaluation of Regulatory and Institutional Uncertainties in 10 CFR Part 60" (CNWRA 90-003), they are included in this RR Synopsis package by Program Architecture Support System (PASS) Identification numbers and topics only. All such identifiers are located immediately after the Primary Regulatory Text Citation. This is not to infer that the uncertainty(ies) has/have arisen from the Primary Regulatory Text alone, but is only to indicate during the NRC review for prioritization that this RR has potential uncertainty(ies) associated with it.

- Rationale for Logical Relationships of Regulatory Elements of Proof Sets.
- Overall Comments/Observations.
- An Appendix that includes the Regulatory Requirement Text and associated Rationales.
 - Included Regulatory Texts:
 - Primary (with rationale for selection as Primary).
 - Associated (with rationale if appropriate).
 - Referenced (with rationale if appropriate).
 - Included Related Regulatory Texts.
 - Excluded Regulatory Texts:
 - Excluded Related Regulatory Texts.
 - Overall Comments/Observations.
- A logic diagram reflecting the logical relationships of the Regulatory Elements of Proof Set.

3. DEFINITIONS

The following definitions of terms are important to an understanding of the report content. (These definitions are based on TOP-001-02, Program Architecture Relational Database Work Instruction, Attachment A, PA Relational Database -- Definitions and Contents of Record. Where necessary, the definitions in TOP-001-02 have been amplified herein to clarify the specific information in this report.)

CITATION - A citation is an element of a statute, regulation or other source that has the force of law, at or above the lowest level to which an alphanumeric identifier has been assigned (e.g., 42 U. S. C. 10133(b)(1)(A)(i) or 10 CFR 60.131(a)(1)). In this report, citations are associated with quotations from statutes, regulations or other sources which are called "regulatory texts" (see the definition of Regulatory Text below).

LINKAGE - Linkage refers to a relationship between two or more records in the PADB. Linkages may be one-to-one, one-to-many, many-to-one, or many-to-many.

LOGIC STRUCTURE - Logic structure is the textual or graphic representation of the logical interrelationships between Program Architecture elements of the same type. Logic structures are developed, in this report, for the Regulatory Elements of Proof. For each Regulatory Requirement and its associated Regulatory Elements of Proof presented in this report, there is included a logic structure diagram which defines the logical linkage between the Regulatory Elements of Proof. The logic structure diagram may also be viewed in the computer-based PADB. This report also provides a textual description of the logic structure and the manner in which it was developed in each "Rationale for Logical Relationships" section.

OVERALL COMMENTS AND OBSERVATIONS - The overall comments/observations section contains comments, observations and similar notes that are applicable to the Regulatory Requirement as a whole. This includes, for example, the citations of court decisions related to the subject Regulatory Requirement. These notes must be germane to the overall content and must make a positive contribution to the analysis. General observations are avoided.

PASS IDENTIFICATION NUMBER - The PASS Identification Number is an index number assigned from blocks of numbers provided by the Center to the developers of Regulatory Requirements. It serves as a means to identify, relate and retrieve Regulatory Requirements and associated Program Architecture Database records. The form for a Regulatory Requirement is always RRxxxx, where xxxx is a four-digit number with leading zeros, if necessary. For other PADB records, the form is always RRxxxx/YYxxxx where YY is a standard, two-letter code for the type of record (e.g., EP for individual Regulatory Element of Proof, UN for an individual Uncertainty).

RATIONALE - Rationale texts are found in several places throughout the RR/REOP Report. They contain a brief explanation of the rationale, criteria, assumptions and any other bases for decisions made in the process of identifying the specific element of text which they follow. Comments and observations may be included provided that they are (1) germane to the structure or overall content, and (2) they make a positive contribution to the analysis.

REFERENCES - These sections cite the references used in the preparation of the text sections they follow.

REGULATORY ELEMENT OF PROOF (REOP) - Regulatory Elements of Proof are what must be demonstrated to support a conclusion that the Regulatory Requirement has been met. Regulatory Elements of Proof must be directly stated in the Regulatory Requirement itself. The Regulatory Elements of Proof are identified by a unique topic in the synopsis report and the Logic Structure.

REGULATORY ELEMENTS OF PROOF SET (PS) - The Regulatory Elements of Proof Set is the group of Regulatory Elements of Proof contained in a single Logic Structure ("hierarchy"). The Regulatory Elements of Proof Set is the complete group of Regulatory Elements of Proof derived from a single Regulatory Requirement.

REGULATORY REQUIREMENT (RR) - A Regulatory Requirement is a statement of a requirement pertaining to the Nuclear Waste Policy Act nuclear waste management system, as quoted from one or more statutes, regulations or other sources which have the force of law. Each such quotation is a complete Regulatory Text. Thus, a Regulatory Requirement is composed of one or more closely related Regulatory Texts. Regulatory Requirements are the cornerstones of the Program Architecture. The Regulatory Requirements are identified by a unique topic in the synopsis report and the Logic Structure.

REGULATORY TEXT - A Regulatory Text is an element of a statute, regulation or other source that has the force of law at or above the lowest level to which an alphanumeric identifier has been assigned (e.g., 42 U. S. C. 10133(b)(1)(A)(i) or 10 CFR 60.131(a)(1)). There are several categories of Regulatory Text contained in this report. They are defined as follows:

1. **INCLUDED REGULATORY TEXT** - Included Regulatory Text consists of the citation and statutory basis of each individual requirement (i.e., each Regulatory Text) that makes up the Regulatory Requirement. A section of the authorizing statute is included only if it contains a requirement not included in the source regulation.
 - a. **PRIMARY REGULATORY TEXT** - The Primary Regulatory Text is that Included Regulatory Text which provides the primary definition of the criteria or requirements of the source regulation or statute.
 - b. **ASSOCIATED REGULATORY TEXT** - The Associated Regulatory Text is that Included Regulatory Text which contains lower-level implementation requirement (e.g., design criteria) texts that (a) are contained in the same regulation or statute as the Primary Regulatory Text or are from the statute that is the basis of authority for the regulation (e.g., NWPAA), (b) detail, explain or qualify the Regulatory Requirement or the means of demonstrating compliance with it, and (c) are logically related to the Primary Regulatory Text.
 - c. **REFERENCED REGULATORY TEXT** - The Referenced Regulatory Text is that Included Regulatory Text which is incorporated into the Primary or Associated Regulatory Texts by reference.
2. **EXCLUDED REGULATORY TEXT** - Excluded Regulatory Text is any Regulatory Text which was seriously considered for inclusion in the Regulatory

Requirement, and then excluded. When text is present, rationale is provided for such exclusion.

3. **RELATED REGULATORY TEXT** - Related Regulatory Text is that Regulatory Text from (1) other agencies that is applicable to NWPA high-level waste, (2) analogous NRC regulations not directly applicable to NWPA high-level waste, or (3) statutes not referenced in the primary source regulation, provided it has relevant technical content. It includes Regulatory Text concerned with hardware, software and operational interfaces and/or interactions. This includes interfaces and interactions with the Defense Waste Production Facility, the Transportation System and, if approved, the Monitored Retrievable Storage (MRS) facility.
 - a. **INCLUDED RELATED REGULATORY TEXT** - Included Related Regulatory Text is that Regulatory Text which is related to the topic of the Regulatory Requirement but not suitable for inclusion in the Regulatory Requirement.
 - b. **EXCLUDED RELATED REGULATORY TEXT** - Excluded Related Regulatory Text is that Regulatory Text which was seriously considered for inclusion as a Related Regulatory Text, and then excluded. When text is present, rationale is provided for such exclusion.

UNCERTAINTY (UN) - An uncertainty is associated with a perceived insufficiency in a particular item. There are three types of uncertainties: technical, regulatory and institutional. This report contains only the topics of potential regulatory and institutional uncertainties identified in "Identification and Evaluation of Regulatory and Institutional Uncertainties in 10 CFR Part 60" (CNWRA 90-003, 1990).

4. SUMMARY

The data in the PADB supporting each of the supplied RR/REOP packages making up this report was developed and approved in accordance with TOP 001-05 (Rev.0) "Implementing the Systematic Regulatory Analysis Process" and its referenced procedures to meet CNWRA Quality Assurance requirements. This report is designed to provide information to the NRC to support prioritizing further SRA work on specific Regulatory Requirement topics of 10 CFR Part 60.