Department of Energy
Carlsbad Area Office
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Carlsbad, New Mexico 88221

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MAY 12 1994

Dear Colleague:

Enclosed is the *WIPP Regulatory Compliance Strategy and Management Plan for Demonstrating Compliance to Long-Term Disposal Standards* (RCSMP) (DOE/CAO-94-2003) and the *Format and Content Guide for Title 40 CFR 191 and Title 40 CFR 268.6 Compliance Reports* (FCG) (DOE/CAO-94-2004).

The RCSMP was originally distributed to stakeholders in November 1993 for review and comment. Stakeholder review resulted in an improved document which sets forth a comprehensive strategy for compliance with the Long-Term Disposal Standards codified in 40 CFR 191 and 40 CFR 268.6.

The FCG has also been through a similar review and was used as the general outline for the format and contents of the *Compliance Status Report* completed in March 1994. The FCG will also be used for subsequent compliance submittals expected in 1995 and 1996.

As a commentor on the draft versions of these documents, you will also receive the enclosed Document Review Record which details the Department of Energy response to all comments. As evident by the revisions and by the responses to comments, both documents have been improved by the review process. I thank you for your effort and input.

If you have any questions regarding either of these documents, please contact Dr. James A. Mewhinney of my staff at (505) 234-7480.

Sincerely,

George E. Dials

George E. Dials
Manager

Enclosures

940502.5

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DOE/CAO-94-2003

WIPP Regulatory Compliance Strategy and Management Plan for Demonstrating Compliance to Long-Term Disposal Standards

May 1994

United States Department of Energy
Waste Isolation Pilot Plant

Carlsbad Area Office
Carlsbad, New Mexico

This document supercedes DOE/WIPP 86-013.

DOE/CAO-94-2003

WIPP Regulatory Compliance Strategy and Management Plan for Demonstrating Compliance to Long-Term Disposal Standards

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Carlsbad, New Mexico

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ACRONYMS

ASME	American Society of Mechanical Engineers
BIR	Baseline Inventory Report
CFR	Code of Federal Regulations
DOE	Department of Energy
EPA	Environmental Protection Agency
FCG	Format and Content Guide
LDRs	Land Disposal Restrictions
LWA	Land Withdrawal Act
NEPA	National Environmental Policy Act
NMD	No-Migration Determination
NMVP	No-Migration Variance Petition
PTB	Project Technical Baseline
QA/QC	Quality Assurance/Quality Control
QMP	Quality Management Plan
RCRA	Resource Conservation and Recovery Act
TRU	Transuranic
WIPP	Waste Isolation Pilot Plant

Introduction

1. INTRODUCTION

1.1 BACKGROUND

The U.S. Department of Energy (DOE) was authorized by the Department of Energy National Security and Military Applications of Nuclear Energy Authorization Act of 1980, Public Law 96-164 (U.S. Congress, 1980) to develop a facility for demonstrating the safe disposal of transuranic (TRU) radioactive wastes generated in national defense activities. This facility, known as the Waste Isolation Pilot Plant (WIPP), has been constructed in southeastern New Mexico, 26 miles east of Carlsbad. The site encompasses 10,240 acres in a sparsely populated area. The surrounding land is used for livestock grazing, potash mining, and oil and gas production.

The enactment of Public Law 96-164 initiated the phased development of the WIPP. Phased development began with a siting phase during which several sites were evaluated and a preferred site selected based upon the geotechnical setting. During this phase, the host rock and the depth of the facility were selected considering geologic, hydrologic, geochemical, and rock-mechanics properties. In the next phase, the site and preliminary design validation phase, two shafts were constructed; an underground testing area was excavated; and geologic, hydrologic, and geotechnical investigations were continued to gain further information on the site's characteristics. Also during this phase, methods for assessing long-term performance were evaluated and advanced. The construction phase followed during which the WIPP facility was constructed, additional data about the site were collected, and the tools needed for assessing performance were developed and refined. Surface structures were built and additional underground areas were excavated for further experimentation. At the conclusion of the construction phase, the DOE proposed to proceed into a test phase that would include testing with TRU waste. Although the DOE has recently announced that the WIPP will not conduct radioactive tests in the WIPP underground, information needs regarding a compliance demonstration have not changed.

The WIPP facility is composed of surface structures, the planned underground repository, and four connecting shafts. The underground excavation is 2,150 feet below the surface in bedded salt. The underground repository currently comprises a 12-acre area excavated for conducting scientific investigations and experiments in which no waste is used, a mining area with equipment and maintenance facilities, and four major interconnecting tunnels that are used for ventilation and traffic. The planned waste disposal area will cover 100 acres and will contain eight

separately excavated panels each containing seven separate disposal rooms of 100 ft. x 33 ft. x 13 ft. One of the eight panels has been excavated to date.

A significant development during the construction phase was the promulgation of environmental standards for the management and disposal of TRU wastes by the U.S. Environmental Protection Agency (EPA) (EPA, 1985). In addition, the EPA ruled that facilities that manage radioactive mixed waste are subject to the regulations implementing the Resource Conservation and Recovery Act (RCRA)(U.S. Congress, 1976).

In October 1992, through the WIPP Land Withdrawal Act (LWA), Public Law 102-579 (U.S. Congress, 1992), Congress transferred jurisdiction of the land from the U.S. Bureau of Land Management to the DOE and reserved the land for the use of the DOE for the WIPP Program. The LWA also provided additional authorization to continue the activities initiated by Public Law 96-164. The LWA requirements (Sec. 6) focus on the test phase and the criteria for certification of compliance with the long-term disposal regulations developed by EPA (Sec. 8). While the Test Phase will not be conducted, many requirements such as the development of certification criteria by the EPA, and other requirements necessary to begin disposal are still applicable. For example, the LWA also requires periodic recertification and verification of continuing compliance with applicable regulations during disposal operations.

The LWA and its provisions are as central to regulatory compliance as are the regulations themselves in that the LWA mandates certain schedules, reviews, approvals and limitations. As a result, an updated flexible regulatory compliance strategy that more fully integrates WIPP Project elements and ensures the sufficiency of information to document compliance is needed. This flexible compliance strategy is also necessary to ensure that the WIPP can accommodate the changing TRU waste inventory resulting from increased decommissioning and decontamination of facilities, environmental restoration activities, the dismantlement of weapons, and newly generated TRU waste that will result from treatment of low level wastes. Table 1-1 provides a comparative listing of significant factors affecting the compliance strategy. As can be seen, recent changes affecting the WIPP support the need to revise the compliance strategy at this time.

Table 1-1

Factors Affecting WIPP Regulatory Compliance Strategy

FACTORS IN 1989	FACTORS IN 1994
WIPP Compliance Strategy for 40 CFR Part 191, DOE-WIPP 86-013 (DOE, 1986)	WIPP Regulatory Compliance Strategy and Management Plan, DOE/CAO-94-2003 (1994)
Final disposal standards, 40 CFR Part 191 Subpart B (EPA, 1985) in remand; no external regulatory agency[1]	Passage of WIPP Land Withdrawal Act, revised 40 CFR Part 191 Subpart B in effect; Subpart C added (EPA, 1993a); external certifier identified; certification criteria to be developed under 40 CFR Part 194 (EPA, 1993b)
Single compliance demonstration; all TRU waste; disposal operations commence	Initial compliance demonstration; performance-based waste inventory envelope; disposal operations commence; periodic documentation of continued compliance
TRU waste source and type from 10 major generator/storage facilities	TRU waste source and type from 10 major generator/storage facilities plus other sources identified in the Federal Facility Compliance Act Inventory report
TRU waste defense-production based	TRU waste defense-related based; waste inventories and forms affected by DOE complex reconfiguration
Compliance focused on radioactive waste component	Compliance focused on mixed-waste aspects of the waste
Waste Acceptance Criteria based on transportation, operational safety, and permit conditions	Performance-Based Waste Acceptance Criteria based on transportation, operational safety, permit conditions, and repository performance

[1] Previous to the passage of the LWA, the DOE was defined as the implementing agency for the standards in 40 CFR 191. In this capacity, DOE is considered to be self-regulating, particularly with regard to determining when compliance to the standards is achieved. The LWA, while it did not specifically change DOE's responsibilities, assigned certain responsibilities to the EPA regarding 40 CFR 191 compliance. Specifically, the EPA is required to certify that the DOE will comply with the final disposal regulations. This strategy does not attempt to define the extent of EPA's responsibility or authority in this regard. However, it is assumed that DOE's responsibilities and authorities remain the same.

1.2 PURPOSE

The primary purpose of this document is to provide a strategy by which the WIPP will demonstrate its ability to perform as a deep geologic repository. To achieve this, the document will: (1) communicate to WIPP Project participants, regulatory agencies, and other stakeholders, the DOE's understanding of the regulations related to long-term repository performance; and (2) provide the most efficient strategy that a) integrates WIPP Project elements, b) ensures the sufficiency of information, and c) provides flexibility for changes in the TRU waste generation system to facilitate the disposal of defense-generated TRU wastes.

In addition, this document forms a focal point between the DOE and its various external regulators as well as other stakeholders for the purpose of arriving at compliance decisions that consider all relevant input.

- As a compliance strategy that integrates WIPP Project elements, it will enhance mutual understanding between the DOE, its contractors, and its stakeholders resulting in a cost effective and environmentally sound disposal decision.
- As a flexible strategy to accommodate changes in the TRU waste system, it will assure that WIPP's stakeholder's interest are represented in the decision-making process that affects the future of the TRU waste system.
- As a compliance strategy that ensures sufficiency of information, it will foster discussions between DOE, its contractors, and its stakeholders regarding the data used to support a technically sound disposal decision.

1.3 SCOPE

This document conveys the DOE's compliance demonstration strategy relative to the long-term performance of the repository system. This focus is provided because it is the long-term performance portions of the various regulations that require WIPP-specific interpretation and for which the compliance programs at the WIPP are precedent setting. It focuses on those regulations that directly impact the WIPP program and shows the necessary information-gathering, experimental and test activities, and programmatic aspects necessary to complete a demonstration of compliance.

This is not to say that other regulations and/or agreements are less important. For example, the Agreement for Consultation and Cooperation (and associated modifications) between the DOE and the State of New Mexico contain numerous commitments made by the DOE on the basic premise that the DOE will consult and cooperate with the State of New Mexico with respect to public health concerns. These commitments include items such as monitoring requirements, operational prerequisites, and on-site monitoring by the State. Such commitments and activities are implicitly included in this document to the point that they overlap the long-term disposal standards specifically targeted for discussion.

As such, the following statutes and/or regulations are considered in this document:

- WIPP Land Withdrawal Act (U.S. Congress, 1992)
  - Section 6. Test Phase Activities
  - Section 7. Disposal Operations
  - Section 8. EPA Disposal Standards

- 40 CFR Part 191. Environmental Radiation Protection Standards for Management and Disposal of Spent Nuclear Fuel, High-Level and Transuranic Radioactive Wastes (EPA, 1985). Specifically:
  - Subpart B. Environmental Standards for Disposal; and
  - Subpart C (proposed). Environmental Standards for Ground-Water Protection.

  (Subparts B and C are referred to as the Final Disposal Standards.)

- 40 CFR Part 194.[2] Criteria for the Certification of Compliance with Environmental Radiation Protection Standards for the Management and Disposal of Spent Nuclear Fuel, High-Level and Transuranic Radioactive Wastes (advance notice of proposed rulemaking)(EPA, 1993b).

- 40 CFR Part 264. Standards for Owners and Operators of Hazardous Waste Treatment, Storage and Disposal Facilities (referred to as the RCRA TSDF Standards)(EPA, 1980). Specifically:
  - Subpart G. Closure and Post-Closure; and
  - Subpart X. Miscellaneous Units.

- 40 CFR Part 268. Land Disposal Restrictions (referred to as the RCRA LDRs)(EPA, 1986). Specifically:
  - 40 CFR 268.6. Petitions to allow land disposal of a waste prohibited under Subpart C of Part 268.

[2] The LWA §8(c) requires the EPA to issue certification criteria for the Administrator's certification of compliance with the final disposal regulations. The issuance of these criteria is critical to the successful completion of the activities in this strategy related to 40 CFR 191. The milestones and target dates for the completion of this strategy are dependent on a timely issuance of these criteria as mandated by the LWA.

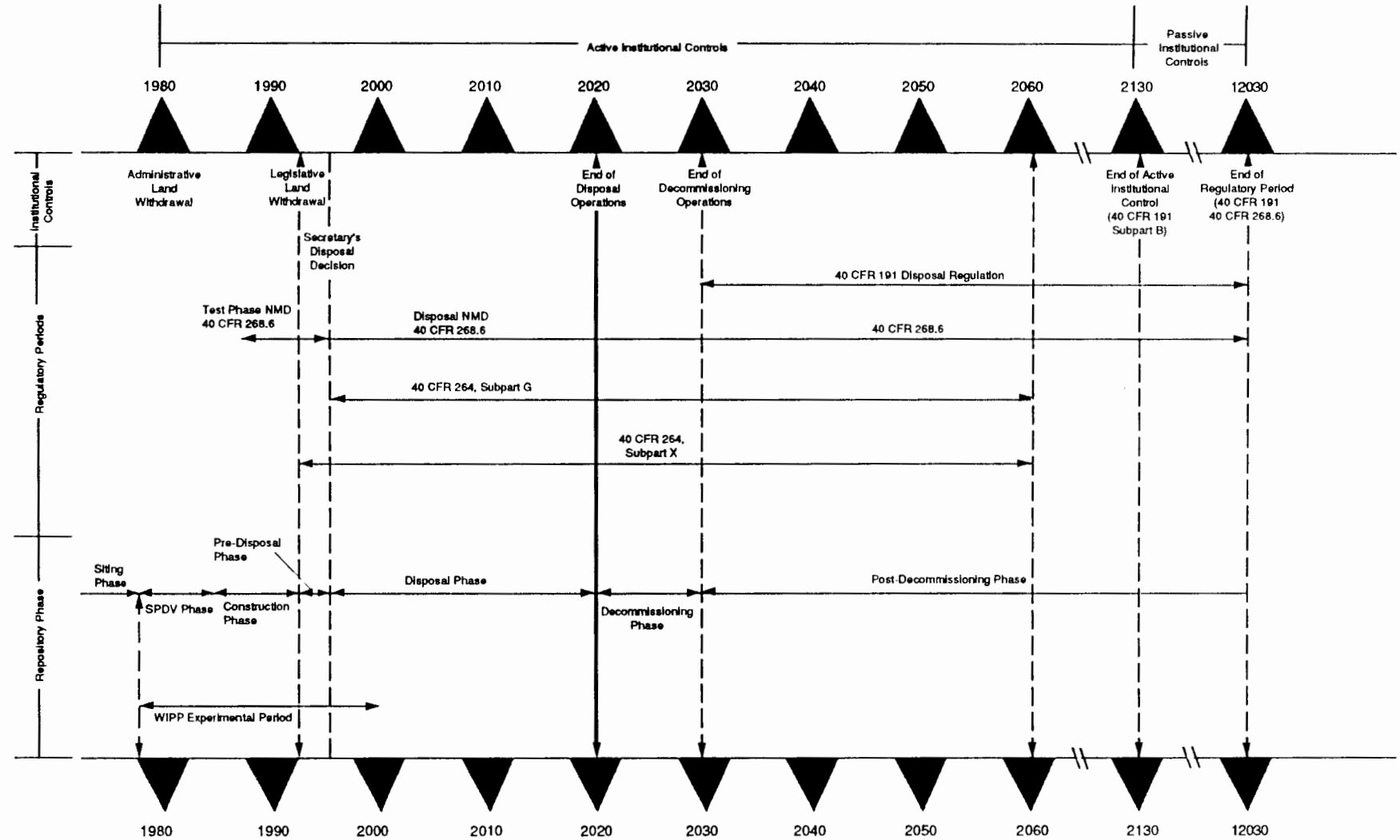
- 40 CFR Part 270. EPA Administered Permit Program: The Hazardous Waste Permit (EPA, 1980). Specifically:
  - Subpart A. General Information
  - Subpart B. Permit Application
  - Subpart C. Permit Conditions

The DOE has fashioned this strategy based on its understanding of the EPA's expectations regarding compliance documentation. This understanding is based on the text of the applicable standards, guidance documents and regulatory precedent where available, EPA documentation (such as the preambles to rulemakings), and communication with the EPA. Recent interaction with the State of New Mexico relative to the recent RCRA permitting process has also provided additional insight into the strategy set forth in this document.

In addition, the compliance strategy considers project elements that are derived from provisions of the Atomic Energy Act and relevant DOE orders, and are pertinent to the scope of this document. Within this scope, several key compliance activities are addressed, including:

- waste characterization
- performance assessment modeling and analysis relative to long-term performance in compliance with the Final Disposal Standards and the RCRA LDRs
- design development
- performance-based waste acceptance criteria
- periodic recertification as required by Section 8(f) of the LWA
- decommissioning and post-decommissioning

The regulations addressed in the compliance strategy and the WIPP phases to which they apply are shown in Figure 1-1. Section 2, Strategy, discusses the programmatic strategy to demonstrate compliance with the regulations and program elements discussed previously in this section. Section 3, Roles and Responsibilities, discusses the compliance and support activities of the DOE, its Management and Operating Contractor, and its Scientific Advisor. Section 4, Planning for Compliance, discusses future compliance planning documentation.



NOTE: This schematic is meant to show sequence; the years are identified to indicate relative timing and should not be interpreted as a schedule.

Figure 1-1
Regulatory Periods and WIPP Project Phases

Strategy

2. STRATEGY

2.1 INTRODUCTION

As discussed in Chapter 1, the site selection and construction phases are complete. The WIPP is now facing the transition from pre-disposal activities to the disposal phase. In order to reach the disposal phase in the most efficient and timely manner, the WIPP has established a "compliance target." The compliance target is based on the Secretary of Energy's announcement that the Department will submit a draft compliance application to the EPA for review by spring 1995. The purpose of the compliance target is to document the WIPP Project's determination of compliance with the disposal regulations through an evaluation of uncertainties, "trade-off" analyses, and, if required, future actions to reduce uncertainties through performance confirmation. In support of this compliance target, the following milestones have been identified.

- **Issue this *Regulatory Compliance Strategy and Management Plan***

- **Complete the *Format and Content Guide***
  This guide is an annotated outline which generally outlines the contents of the 40 CFR 191 and 40 CFR 268.6 compliance submittals as well as the Compliance Status Report (see below).

- **Develop Performance Assessment Input**
  Currently, certain performance assessment input lacks refinement, and as such, performance assessment reports have been preliminary. Once refined, this information will be used in the assessment of the Project's status with regard to demonstrating compliance to the long-term performance regulations.

- **Implement Project Technical Baseline**
  The Project Technical Baseline (PTB) is a compendium of the current technical data, approaches, and assumptions about the WIPP Project that will be included in upcoming compliance submittals.

- **Evaluate Quality Assurance Program Regarding Compliance Status Data**
  In order to accurately assess the status of the compliance program, numerical results will be used for comparison to performance standards. Confidence in these numerical results will be a function of the amount and quality of the information that were used in their calculation.

- **Complete Compliance Status Report**
  This report will be a "snapshot" of the status of regulatory compliance programs for 40 CFR 191 and RCRA long-term regulations. This Report will be transmitted to the EPA, the New Mexico Environment Department (NMED), and WIPP Project stakeholders in order to begin dialogue regarding issues associated

with the compliance approach prior to submitting the previously mentioned compliance documentation (spring 1995). This is a proactive effort to assure that the compliance documentation will be adequate to result in certification by the EPA.

- **Define Quality Assurance Corrective Action and Implement**
  If problems are detected in the area of data quality, a plan for rectifying the problem will be defined and implemented.

- **Implement DOE Approval Process**
  The DOE will be responsible for the approval of WIPP's demonstration of compliance with the requirements of 40 CFR 191. Pending DOE's approval decision, the compliance documentation will be forwarded to the EPA for certification.

- **DOE Approve 40 CFR 191 Compliance Documentation**
  The DOE will provide public notification of its approval decision relative to WIPP compliance with the standards in 40 CFR 191.

- **Submit Compliance Certification Package**
  The DOE must submit a package to the EPA which addresses all of the criteria specified in 40 CFR 194. This is the package in which EPA will base their certification. Similar packages will be submitted to EPA Office of Solid Waste to demonstrate compliance to 40 CFR 268.6 and to the NMED to satisfy RCRA permitting requirements.

In order to meet each of these milestones and ultimately demonstrate compliance with the regulations discussed in Section 1.3 consistent with the compliance target, this document includes two major areas of focus: (1) continued phased development of the WIPP; and, (2) a compliance-based approach to satisfy each applicable regulatory requirement in a consistent and integrated manner. Figure 2-1 illustrates the programmatic elements and sequence of this compliance strategy. The double-ended arrows in Figure 2-1 associated with the technical activities imply two features of this compliance strategy. First, the strategy is applied in an iterative fashion such that if compliance determinations (Compliance Assessment block) result in less confidence of compliance than desired, then technical activities will be initiated or enhanced to further address key parameters that may affect compliance. Second, the strategy is flexible in that it allows trade-offs between technical activities to achieve compliance. For example, engineered alternatives (Facility Information block) may be used to account for uncertainty in waste information.

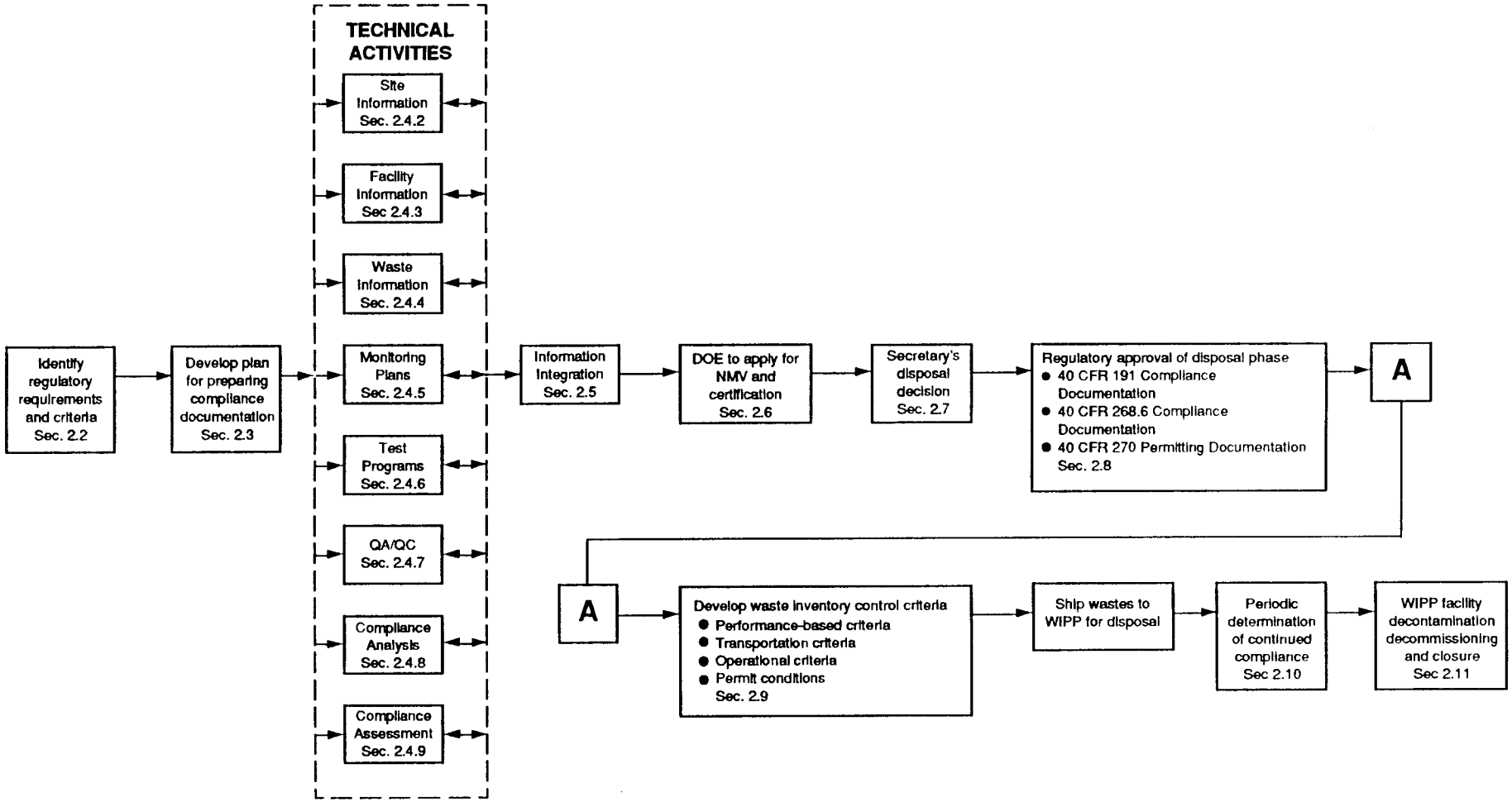


Figure 2.1
WIPP Programmatic Compliance Strategy

2.1.1 Phased Development

The phased development of the WIPP is supported by the LWA, which addresses the time period from initiation of pre-disposal activities through periodic recertification of compliance and eventual facility closure. The primary LWA provisions that support the continued phased development of WIPP include: (1) the requirement that the EPA review and approve DOE documents which detail any tests at the WIPP which use radioactive waste as well as Waste Retrieval Plans for such tests and, ultimately, certify compliance with the final disposal regulations; (2) recognition of the continued development of performance assessment modeling and analysis via submission of biennial reports; (3) periodic recertification with the final disposal standards; and (4) provisions for facility decommissioning and post-decommissioning management.

In response to these LWA provisions, key programmatic elements of the compliance strategy are identified in Figure 2-1. These elements are linked sequentially and illustrate DOE's compliance path, beginning with the identification of regulatory requirements and criteria that affect the design and conduct of pre-disposal operations activities and, in turn, generate and provide compliance documentation. The data collection/evaluation activities and the information integration activity are iterative based on the sufficiency of the information collected.

For statutory reasons, the processes used to obtain permits, determinations, and certifications must be repeated to some extent periodically. With this in mind, the DOE's strategy includes demonstrating continued compliance with the regulations. Recertification to the Final Disposal Standards is required every 5 years in accordance with the LWA. Both the RCRA Standards (40 CFR 268.6 and 40 CFR 270) require the submittal of a new application every 10 years. Additional data collected during operations will be used as appropriate to verify previous compliance demonstrations or as the basis for modifying those demonstrations and/or identifying new information for inclusion in the new applications.

When the facility reaches full capacity limits imposed by the LWA, the facility will be decommissioned and closed. The key strategic element in Figure 2-1 is the "information integration" block. The activities in this block are aimed at assuring the sufficiency of data and information for making compliance declarations and integrating input from all participants, including the DOE, contractors, regulators, and other stakeholders into the final compliance documentation.

The remainder of this section describes the specific features of the DOE's strategy for compliance. Where appropriate, additional logic is provided to detail the decisions that must be made to support the submittal of compliance documents.

2.2 REGULATORY REQUIREMENTS

2.2.1 Strategic Summary

The DOE's strategy includes the satisfying of each of the applicable regulations in an integrated and consistent manner, referred to as an integrated compliance approach. This integrated approach considers the interpretative, analytic, and substantive differences in the regulations and yet allows, for example, the development of the PTB, and the development of a single set of compliance "tools" (i.e., performance assessment) to be used for demonstrations of compliance. The PTB will contain information, data, and analyses that are relevant to determining repository capability to isolate TRU and TRU-mixed waste for the period of regulatory interest. The PTB is discussed in detail in Section 2.5.4.

The DOE's approach focuses on interpretation of such requirements as "reasonable expectation" and "reasonable degree of certainty." This will be accomplished through frequent dialogue with the EPA. Most importantly, this approach also recognizes that such a regulatory understanding must be accomplished at a sufficient level of detail early enough to provide the appropriate programmatic direction necessary to meet the compliance target of spring 1995.

2.2.2 Regulatory Applicability

While compliance with all applicable regulations is essential, this strategy emphasizes the concepts necessary for demonstrating compliance with the disposal requirements that govern the DOE's ability to receive and dispose of TRU wastes at the WIPP. The disposal of TRU wastes at the WIPP is subject to a number of requirements intended to protect public health and safety, and the environment. The DOE strategy recognizes, however, that certain differences exist among the requirements of the regulations. Compliance with 40 CFR Part 191, for example, focuses on achieving confidence in the results from long-term predictions of repository behavior, rather than specifying prescriptive program requirements. By contrast, the RCRA regulations are

generally more detailed, and focus on specific aspects or components of the system that must be used in compliance evaluations.

In general, the applicable regulations are those intended to set protective standards for the management and disposal phases of the repository. During these phases, the emphasis is more on the operation of the facility and not on its characteristics as a geologic repository. These are:

- 40 CFR Part 191, Subpart A
- 40 CFR Part 268 (certain portions)
- 40 CFR 264[3]

Also applicable are those regulations related to post-closure and long-term containment of wastes within the repository during the post-decommissioning phase. During this period of time, emphasis has shifted from operational characteristics to those provided by the geologic setting and man-made barriers. These are:

- 40 CFR Part 191, Subpart B and C
- 40 CFR 268.6
- 40 CFR 264, certain portions including Subparts G and X

The aforementioned regulations are cited here because they pertain to the long-term disposal aspect of compliance, and, they are relatively general, lacking specificity with regard to implementing guidance.

For these regulations, the WIPP is subject to certification and permitting requirements administered by the EPA (40 CFR Parts 191 Subparts B and proposed C, and 268.6) and the State of New Mexico (40 CFR Part 264). The DOE intends to demonstrate that there is a "reasonable expectation" (40 CFR Part 191) or "reasonable degree of certainty" (40 CFR Part 268.6) that compliance over a 10,000 year period can be achieved. A successful demonstration will be dependent on assessment and projection of total repository system performance and must show that the generally applicable standards for the protection of the public and the environment will be met. The regulations require consideration of natural and engineered barriers, as well as the characteristics and forms of the disposed wastes and waste interactions with the system.

[3] The State of New Mexico operates its own hazardous waste program in lieu of the Federal RCRA program under authority granted by the EPA. The State has incorporated the federal standards into the New Mexico Hazardous Waste Management Regulations (HWMR). The HWMR, which was last amended in 1992 (HWMR-7), consists of nine parts corresponding to 40 CFR 260 (Part I) through 40 CFR 270 (Part IX). HWMR-7 incorporates 40 CFR 264. The RCSMP uses the federal nomenclature when referring to these regulations.

The DOE's approach is to identify features of each regulation that are similar and address these provisions in similar ways. Features of the regulations that are not similar will be addressed differently. The DOE plans to interact with EPA to assure that this approach will facilitate a demonstration of compliance. The DOE will communicate similarly with the State of New Mexico for hazardous waste permitting activities.

In summary, the activity identified by the DOE as "Identify Regulatory Requirements" includes:

- Identification of specific applicable requirements
- Definition/interpretation of terminology and requirements that are site specific or whose definition is left to the applicant
- Identification of common requirements within the applicable regulations
- Discussion of conclusions with regulators

2.3 DEVELOP PLANNING DOCUMENTS

2.3.1 Strategic Summary

Planning documents are prepared to meet the needs of different organizations. This is best illustrated in the Document Hierarchy Logic shown in Figure 2-2.

At the highest level, the DOE states its overall goals regarding regulatory compliance. In addition, the DOE provides department-wide interpretation of EPA guidance, federal regulations, and regulatory terminology to assure consistent implementation. An example of such a document is the Draft *Regulatory Criteria Document for the Disposal of Defense Transuranic Mixed Waste in a Geologic Repository* (DOE, 1992a).

At the next level the DOE merges the general guidance with any site-specific regulations. For example, while 40 CFR 191 and the RCRA apply universally throughout the DOE, the WIPP LWA has added requirements for the DOE to meet that are specific to the WIPP Program. An example of a document at this level is this *Regulatory Compliance Strategy and Management Plan*.

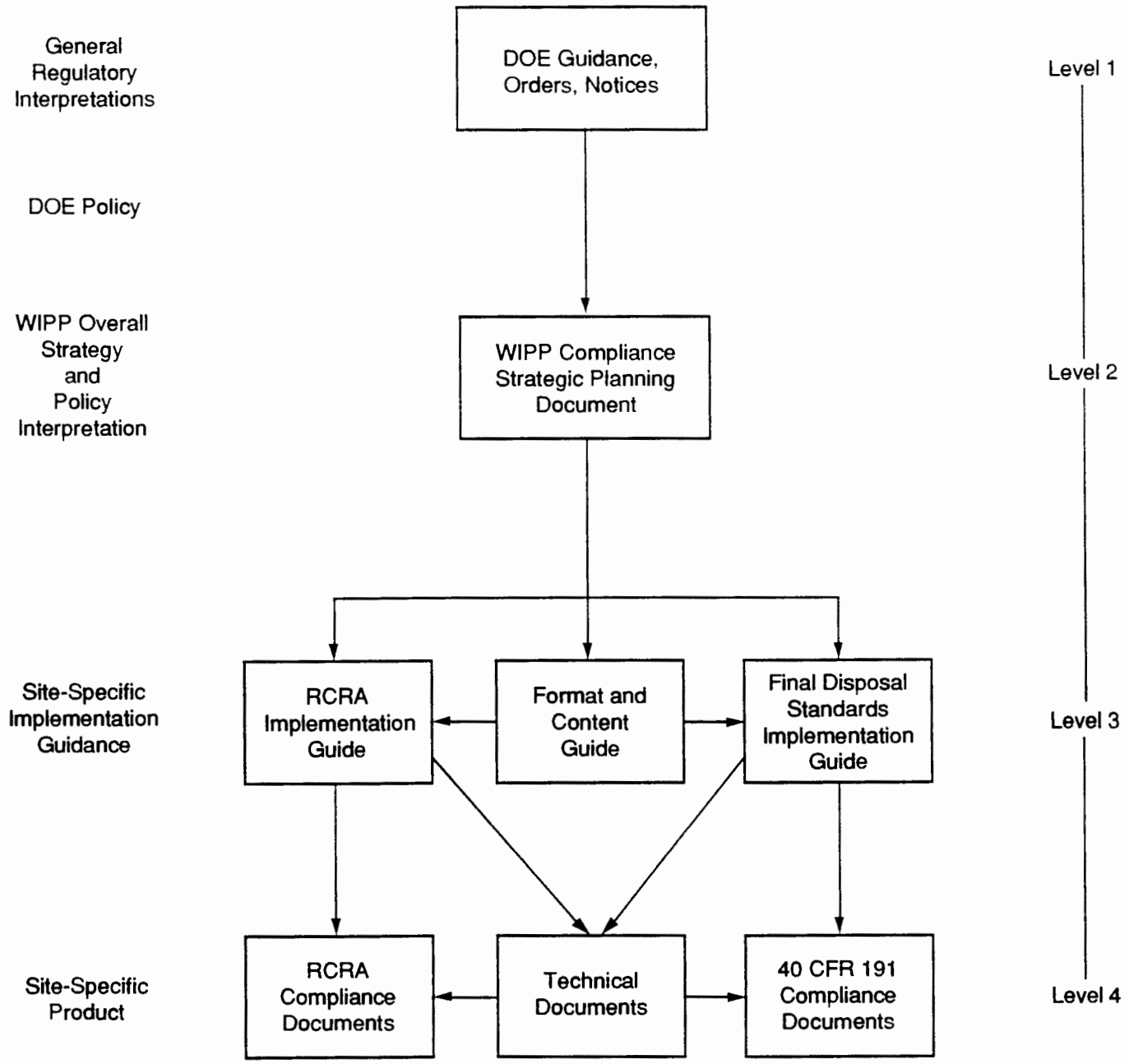


Figure 2.2 Document Hierarchy Logic Diagram

Documents at the third level are generally regulation, waste, and site specific. They include detailed guidance to project participants whose activities support compliance demonstrations. These documents are currently being prepared.

The final level of hierarchy includes applications that will be submitted to regulatory agencies for their decision making. These are an application for certification under 40 CFR 191, a permit application (or permit modification) under 40 CFR 264, and a petition under 40 CFR 268.6.

Supporting this final level is a large collection of technical documents. These include scientific studies, engineering studies, site evaluations, monitoring results, waste information, and others as required to support the demonstration of compliance. Although Level 1 documents are often submitted for public comment, such comment is generally obtained at Levels 2 and 4.

The DOE has identified a group of "stakeholders" for the WIPP Project. These stakeholders, who range from the citizens of Carlsbad to oversight and advocacy groups are invited to provide input into the DOE's decision making process. This would include documents at Level 2.

Level 3 documents typically constitute internal working documents and do not normally undergo external (stakeholder) review.

Level 4 documentation, as a regulatory submittal, is reviewed by the public at the discretion of the regulatory agency. It is assumed that all DOE regulatory submittals for the WIPP will undergo a rulemaking process that involves public comment.

2.4 TECHNICAL ACTIVITIES

The DOE has described its compliance process in terms of technical activities described in this section. For consistency, the DOE has adapted this list from the activities that are typically used in preparing facility-specific safety analysis documentation, National Environmental Policy Act (NEPA) documentation, permit applications, and petitions under various environmental regulations including RCRA.

2.4.1 Strategic Summary

The DOE will use input from the following eight technical activities to prepare the compliance documentation.

- *Site Information*
- *Facility Information*
- *Waste Information*
- *Monitoring Plans*
- *Test Programs*
- *Quality Assurance/Quality Control*
- *Compliance Analysis*
- *Compliance Assessment*

It is the DOE's intent to provide sufficient data, analyses, and records to allow the regulator to evaluate WIPP compliance. Data will be reliable and will conform to acceptable quality standards.

The regulations of interest consist of a mixture of technical and performance standards. By way of technical standards, the EPA has specified actions that the owner/operator of a facility must take to satisfy the requirements. Technical standards include requirements for waste characterization and facility monitoring. To compliment these actions, the EPA requires, by way of performance standards, that the owner/operator use predictive modeling to show that the air, water, and soil pathways are adequately protected during the operation and after closure of the facility.

2.4.2 Site Information

The EPA expects a thorough discussion of the facility's natural environment since the natural setting is crucial for the demonstration of compliance. Sufficient detail must be presented to allow an assessment of the degree of waste isolation achievable. Moreover, background water, soil, and air quality must be determined to facilitate an adequate evaluation of the impacts of disposal.

Geological descriptions must discuss both regional and local geology including structure, subsurface geology, geomorphology, geologic stability, soils, and topography. Site specific information should be provided to whatever extent possible.

Groundwater hydrology must include a comprehensive description of regional, local, and site specific groundwater features. The types of information should include identification of aquifers, confining layers, and perched water tables; characteristics including thickness, porosity, permeability, hydraulic conductivity, and storage; groundwater elevations and seasonal variations; aquifer interconnections; flow rates, directions, and recharge/discharge areas; groundwater quality; and locations of all wells that withdraw groundwater from the vicinity of the facility. The location of producing and non-producing gas and oil wells, monitoring wells, and water injection wells will be provided as well.

Surface water hydrology information, like groundwater, must include the regional, local, and site features that influence surface water movement. Of particular interest are floodplain maps and the facility features that control run off and run on.

Meteorological and climatological information includes sufficient data to evaluate the influence of these factors on compliance. Since the WIPP facility uses meteorological information in modeling off-site releases, a significant amount of meteorological information is anticipated.

Finally, as part of the site description, the EPA requests a description of the background environmental quality. This includes air, soil, and water quality and any other factors that are appropriate for the particular setting of the facility. For the most part, the information needed to meet this requirement has been collected. Extensive site characterization was initiated in the early 1970's and continues through the present. Current activities are addressing specific characteristics of the Rustler Formation affecting the migration of contaminants such as the ability of the rock to adsorb contaminants.

2.4.3 Facility Information

EPA requests that the owner/operator provide enough detail to acquaint the reviewer with the facility and its overall operation. Information includes location, points of contact, the nature of the businesses served by the facility (that is the generators of the waste), detailed design, layout, and operating plans. Also included in this section is the description of the waste isolation features of the facility, including both natural and engineered barriers.

In addition, the EPA expects information on other facility features including: procedures employed to prevent hazards, contingency plans, personnel training plans, closure plans, and post-closure plans.

With the exception of a few experimental programs to resolve technical issues, facility characterization is complete. Remaining activities include the description of any engineered features that may be implemented in order to provide greater assurance of compliance or to monitor facility performance.

The DOE's definition of design development includes active and passive institutional controls, repository design and engineered barriers, and engineered alternatives. Design development both supports and is guided by performance assessment in iterative development of specific design elements. In this context, the DOE's approach is to modify design elements in response to performance assessments to improve confidence in the disposal system by mitigating uncertainty. The final facility design will become a portion of the PTB used in compliance demonstrations.

The DOE will use an iterative process, as appropriate, to reach conclusions regarding the development and application of additional engineered barriers and alternatives. This process is depicted by the logic diagram in Figure 2-3. The selection of additional engineered features will be made carefully to assure that such enhancements are justified. Potential alternatives will be evaluated for efficacy and analyzed based on cost, the benefit derived, and the detrimental impacts of implementation. Accordingly, the need for such alternatives will be based on the results of the performance assessment described in Section 2.4.8.

The LWA, § 8(c), requires the DOE to use both engineered and natural barriers, and waste form modifications, to the extent necessary to comply with the final disposal regulations. In this regard, the DOE and the EPA have reached agreement on two items. First, the DOE has agreed to perform a detriment/benefit study of engineered alternatives that may be appropriate for the WIPP. This study will be documented in a written report. Second, the DOE has agreed to include this study in its certification application for information purposes since the requirement to perform this study does not stem from 40 CFR 191.

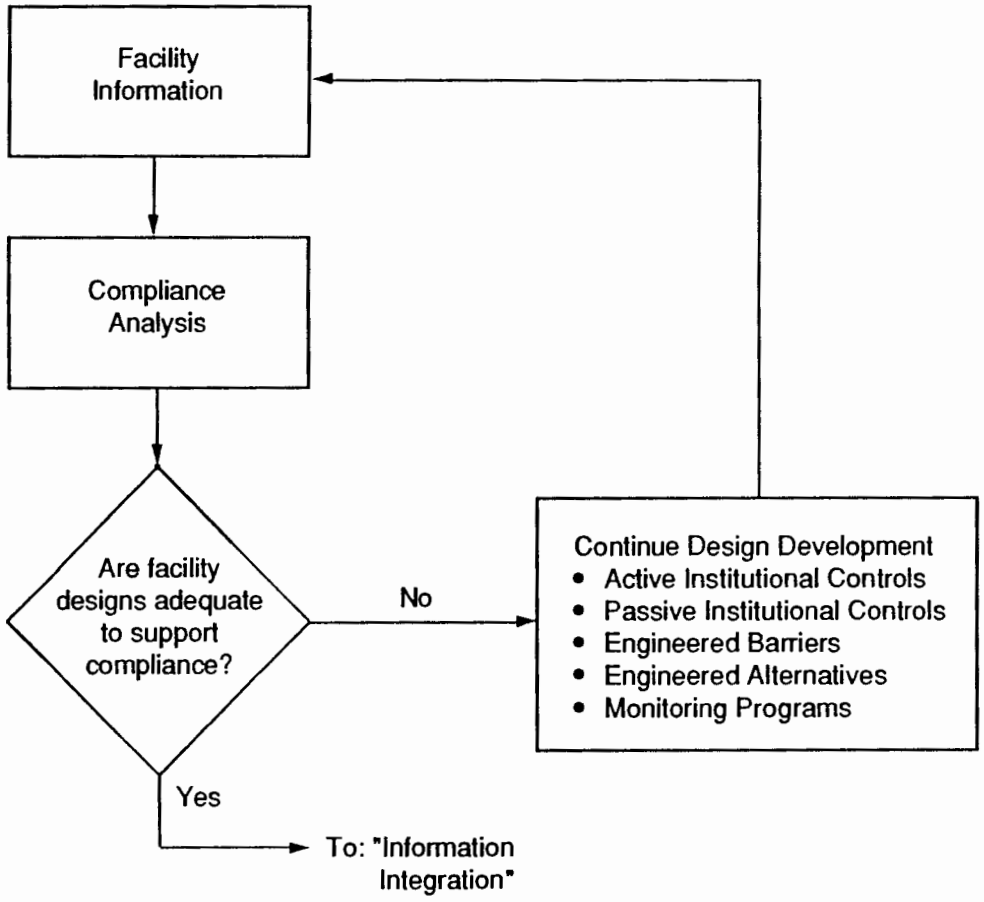


Figure 2.3
WIPP Compliance Decision Network for Additional Facility Information

2.4.4 Waste Information

Information is necessary to help assure that the waste programs and repository system will protect human health and the environment. Waste information may be obtained through any or all of the following characterization methods: radioassay, radiographic examination, visual examination, headspace sampling and analysis, and process knowledge.

Waste information will be used as test and model input data. The physical and chemical characteristics of the waste must be identified in order to test and model interactions of the various waste forms, interactions of the waste with the repository environment, and movement of waste constituents along various pathways in the repository. For hazardous waste, the EPA recommends evaluating the following mechanisms of waste transformation: biodegradation, photodegradation, hydrolysis, oxidation/reduction, and volatilization. For radioactive waste, it would also be proper to discuss potential transformations induced by radiation.

The DOE will have to ensure that the waste accepted for disposal has been included in compliance documentation. This will be accomplished through the development of a set of Waste Acceptance Criteria (WAC) that are based on and bounded by the performance evaluation of the facility (i.e., performance-based WAC, see section 2.9) and adequate characterization to ensure that the wastes meet these criteria prior to acceptance at WIPP for disposal.

To assure that consistent waste characterization data are gathered, the DOE requires that each generator/storage facility implement a program based on the Waste Characterization Program Plan (DOE, 1992b) prior to certifying and shipping waste to the WIPP for disposal. These programs will be implemented through site-specific Quality Assurance Project Plans. This will help assure quality waste characterization data, which will be used in performance assessment to determine a performance-based WAC.

2.4.5 Monitoring Plans

It is incumbent on the owner/operator of the facility to provide sufficient information to justify the design and to assure the reviewers that the monitoring locations will detect migration from the unit at the earliest practicable time.

For the WIPP facility, monitoring will most likely continue to concentrate on the air pathway during facility operations. Long-term monitoring will be defined to address facility performance as opposed to the detection of specific contaminants.

Some amount of testing and evaluation is anticipated to support the development of monitoring programs. Demonstrating that monitoring can be successfully accomplished will support the compliance demonstration(s).

2.4.6 Test Programs

The purpose of this element is to develop and conduct programs to provide data to support the disposal phase compliance demonstration. The drivers for collecting additional information may be the need to reduce the uncertainty in model assumptions, the identification of model parameters not previously considered, or the existence of new data not used in previous models. Detailed programs for collecting data have been initiated. Included are field and laboratory studies. A key feature of this compliance strategy is the close coupling of compliance determinations and test programs. Test programs serve three fundamental purposes. These are as follows:

- Provide primary data for compliance modeling
- Provide data to reduce uncertainty in the modeling
- Provide data to confirm modeling assumptions when scaling from laboratory to repository scale applications

2.4.7 Quality Assurance and Quality Control

It is the DOE's strategy to implement an effective quality assurance program which will ensure that research, testing, design, construction, and other operating activities are conducted in accordance with existing guidance. This guidance will reflect sound, accepted scientific and engineering principles, and provide assurance that those activities meet or exceed the established project objectives and regulatory requirements.

2.4.7.1 DOE Quality Management Requirements

The WIPP Project implements DOE Order 5700.6C, "Quality Assurance," (DOE, 1991) as the foundation of its quality management requirements document. This DOE Order is organized into three major categories: Management, Performance, and Assessment. Each category is further subdivided into several criteria, each prescribing quality management controls.

- The Management section requires establishing and maintaining a formal quality management program, personnel training, quality improvement, and control of documents and records.
- The Performance section requires achieving quality objectives while accomplishing work activities. These requirements include control of work processes; design and planning; procurement; and inspection and testing.
- The Assessment section requires determining how effectively work activities are accomplished at the management and employee level.

As directed by DOE Order 5700.6C, documented quality management procedures specific to each functional activity will be developed, reviewed, approved, and implemented to reflect applicable Project quality requirements.

Additional guidance regarding Quality Assurance Programs includes the American Society of Mechanical Engineers (ASME) endorsed standard, NQA-1, "Quality Assurance Program Requirements for Nuclear Facilities," (ASME, 1989) and EPA QAMS-005/80 "Interim Guidance and Specifications for Preparing Quality Assurance Project Plans," (EPA, 1983) which provides guidance for ensuring the quality of environmental data.

A new Quality Assurance standard, ANSI/ASQC-E4 "Quality Systems Requirements for Environmental Programs," (ASQC, 1992) will emphasize the Total Quality Management philosophy of "planning, performance, and assessment," and is the first industry standard designed to satisfy the requirements of DOE Order 5700.6C by integrating the appropriate elements of both NQA-1 and QAMS-005. ANSI/ASQC-E4 has not yet been finalized.

2.4.7.2 WIPP Quality Management Applications

Application of the WIPP quality management program will begin with the development of a project Quality Management Plan (QMP) aimed at strategically addressing applicable criteria to

meet the requirements of DOE Order 5700.6C. Working within the framework of the QMP, management will perform evaluations focused on the identification of quality-affecting activities. These activities are the tasks and processes that will provide confidence (*i.e.,* contribute to a "reasonable expectation") that the repository, its facilities, and associated programs will be studied, evaluated, characterized, designed, developed, and operated in accordance with applicable requirements.

As project quality-affecting activities are identified, the quality management requirements applicable to each activity will be defined. The complexity, inherent risk, and significance of the activities to the overall project and to public safety will be key factors in determining applicable quality management requirements.

Management

A quality management program will be documented to ensure that the identified quality-affecting activities are controlled. This includes the definition of the quality management program, personnel training and qualification requirements, quality improvement objectives, and provisions for documents and records to ensure objective evidence exists to demonstrate regulatory compliance. Records and documents will be controlled during all stages of Project compliance activities.

Performance

For quality-affecting activities, plans and procedures commensurate with the nature of the specific actions involved will be developed to control the performance of work and to ensure compliance with all applicable regulations. As during the initial WIPP characterization and design stages, the test and modeling stages will require Project-specific quality management plans and procedures to be developed and implemented. Management will approve these plans and procedures prior to their implementation.

Assessment

The quality management program will provide managers responsible for accomplishing compliance tasks with guidance for conducting ongoing assessments. These assessment activities will provide management with information related to the quality of organizational operations.

Worker, management, and independent assessments (all three types comprising "self-assessments") will be part of the continual evaluation program that assists in the attainment of quality objectives and continuous improvement.

2.4.7.3 Implementation

A quality assurance/quality control (QA/QC) plan that addresses all aspects of the compliance documentation must be prepared and included in the submittal. For RCRA it must be approved by the EPA. Quality goals and approaches to meet the goals should be included for the following aspects of the demonstration:

- Waste and environmental monitoring, sampling, and analysis activities
- Field measurements of the facility site
- Where appropriate, validation of computations, codes, models, and methods used in calculating critical facility parameters
- Control of construction activities and evaluation of construction materials

QA/QC goals are to be set for each of the following:

- **Data Representativeness** -- the degree to which data accurately and precisely represent characteristic populations, etc
- **Data Accuracy** -- the degree to which data agree with accepted reference or true values
- **Data Precision** -- the measure of mutual agreement between comparable data
- **Data Completeness** -- a measure of the amount of data collected versus the amount that was anticipated

The EPA has stated that it will give greatest credence to data collected under approved QA/QC programs.

2.4.8 Compliance Analysis

Consistent with an integrated approach to preparing compliance documentation, the DOE's strategy includes the development of a flexible performance assessment process to evaluate repository performance relative to the long-term standards. The DOE's approach is to use the

PTB as the basis for conceptual model and modeling system development (see Section 2.5.4). This developmental and iterative process will: (1) assess repository performance under various undisturbed and disturbed conditions (i.e., scenarios and associated probabilities); (2) ascertain the sensitivity of repository performance to various parameters; and (3) estimate uncertainties.

The DOE's strategy is to use the results from performance assessment modeling as a means to prioritize experimental activities, and to evaluate the need for and effectiveness of enhancements to repository design and engineered barrier systems. The WIPP Project may also use these results to modify or initiate experimental programs and provide guidance to the TRU-waste generators to modify the content of newly generated waste and the packaging.

The DOE's strategy for performance assessment modeling supplements the quantitative predictions of waste containment with the compilation of the PTB, which will provide information to support a compliance demonstration. The DOE's approach is to ensure that the compliance database of site and waste characteristics (contained within the PTB) will be sufficient to: (1) satisfy regulatory requirements relative to these items; (2) demonstrate an adequate understanding of natural processes and their interrelationships; (3) define and defend conceptual models of natural processes; (4) provide ranges and distributions of parameters for use in the calculations; and (5) assess interaction processes between the repository contents and the host-rock. The approach is also intended to ensure that the PTB will be sufficient to provide confidence that the repository design and engineered barrier systems will contribute to waste isolation.

It is the DOE's strategy to use performance assessment modeling and analysis to develop a waste inventory envelope. The approach is to identify waste inventory parameters that may adversely impact waste isolation and to establish the widest acceptable range of these parameters that will still support a demonstration of compliance. In this way, waste parameter criteria will be selected to form an envelope with a primary goal of disposing of as much TRU and TRU-mixed waste as possible. Additional details of the waste inventory envelope are contained in Section 2.9.

The EPA provides no specific technical standards for modeling. Instead, the performance standard of demonstrating compliance at the regulatory boundary is specified. In meeting this performance standard, the EPA expects the owner/operator to use modeling techniques in the demonstration. The EPA provides general guidance regarding modeling methods. The EPA specifies that the models be accurate and representative for the waste constituents being

considered, and that all reasonable pathways to the unit boundary be examined. Models may need to include both the transport of contaminants and the performance of natural and engineered barriers. Models, input data, and relevant documentation used in compliance documents should be available for the EPA upon request without restriction. The following QA/QC information is requested by the EPA for each model used:

- **Model Confirmation and Calibration** -- Comparing the results of analytical and numerical models with field results. Calibration in this context refers to adapting the model to the specific conditions of a facility's location.
- **Justification of Assumptions** -- All assumptions must be properly justified. Reasonable conservatism should be demonstrated.
- **Sensitivity Tests** -- Models should show greatest sensitivity to the most influential parameters.
- **Model Accuracy Assessment** -- The owner/operator must demonstrate the model reasonably represents the actual physical system; there are no computational errors in the numerical code; and there is a high degree of correlation between the calculations and the measured data.

The EPA discourages the use of proprietary models, since the models selected will be closely scrutinized to determine their reasonableness and accuracy. In addition, the models will be submitted for public comment.

Compliance analysis is an iterative process with the goal of demonstrating a reasonable expectation that long-term performance will be in compliance with the standards. The iterative process is depicted in Figure 2-4. In a recent rulemaking, EPA determined that "...the "reasonable degree of certainty" standard requires that a petitioner provide reasonably trustworthy information and data such that the totality of the facts and circumstances within the Agency's knowledge are sufficient, given its scientific and technical expertise, to warrant "a firm belief" that no migration of hazardous constituents from the [unit] will occur so long as the waste remains hazardous. The petition requirements at 40 CFR 268.6 ensure that the Agency is presented with the appropriate information, data, and modeling predictions upon which to make a no-migration determination" (EPA, 1993c). (For the purposes the of this document, a "reasonable degree of certainty" is held to be equivalent to a "reasonable expectation.") The criteria for determining when a "reasonable expectation" has been achieved will be defined on a regulation specific basis in the guidance manuals for preparing compliance documentation (see Section 2.3).

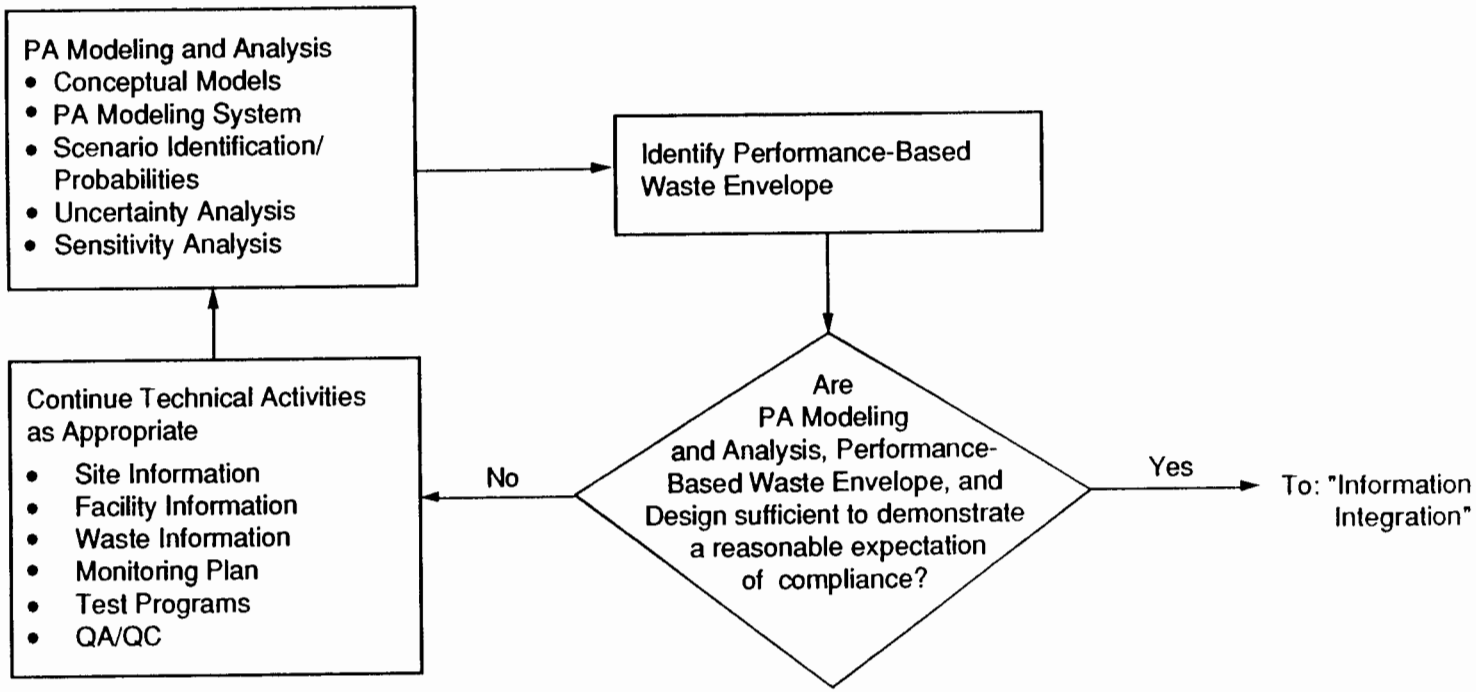


Figure 2.4
WIPP Compliance Decision Network for Compliance Analysis

2.4.9 Compliance Assessment

The compliance assessment, simply stated, is the comparison of the analysis results to the appropriate regulatory standards. This in essence constitutes the demonstration of compliance. The EPA has provided the appropriate standards in 40 CFR 191 Subparts B and proposed C, 40 CFR 264 Subparts G and X, and 40 CFR 268.6.

In addition, the EPA has specified that analyses be conducted to identify and quantify the sources of uncertainty in the compliance demonstration. As part of the uncertainty analysis, the EPA requires the consideration of predictable future events such as earthquakes, floods, droughts, and other natural phenomena. Further, reasonably expected man-made events should also be considered. In applying the "reasonably expected" criterion to RCRA compliance, the DOE has ruled out direct human intrusion into the repository as long as certain active and passive controls are exerted over the facility's location. The EPA has accepted this for the purpose of no-migration modeling under RCRA (EPA, 1990). In guidance for 40 CFR 191 however, the EPA stipulates that institutional controls cannot rule out the possibility of inadvertent human intrusion.

2.5 INFORMATION INTEGRATION

2.5.1 Strategic Summary

Once the technical information has been collected through testing, or determined through the evaluation of experts, it will be summarized and integrated into compliance documentation. This documentation has several key components. These include:

- *Compliance submittals consisting of applications and/or petitions submitted to regulatory authorities*
- *Administrative record consisting of data and information that are used in determining compliance and in preparing compliance submittals*
- *PTB consisting of all pertinent descriptions of the facility and its components as used in preparing compliance submittals*
- *Compliance database consisting of data supporting the descriptions contained in the PTB. The compliance database and the PTB will be combined in one document.*

Figure 2-5 provides greater detail on the content of the PTB, the administrative record, and the compliance submittals. As shown in this figure, the submittal of applications will proceed when the DOE has determined it has sufficiently completed all three aspects defined by this activity.

2.5.2 Compliance Submittals

Documents that are required for submittal to regulatory authorities are defined under RCRA as a "permit application" and a "petition." The form and content of these documents have been established and are included in Appendix A.

The form and content of documents for demonstrating compliance to 40 CFR 191 and for seeking certification of compliance from the EPA are not specifically defined in the regulations. Consequently, the DOE has prepared a Format and Content Guide (FCG) for these submittals. A simplified version of the FCG is included in Appendix A. The FCG for 40 CFR 191 is based on the guidance used under RCRA for No-Migration Variance Petitions.

The details of preparing compliance submittals will be included in subsequent documentation as described in Section 2.3.

2.5.3 Administrative Record

When a regulatory agency begins the decision-making process regarding an application for a compliance decision (permit, certification, or determination), it uses two principle sources of information. These are the application itself and the record that supports the application. This record is referred to as the "administrative record" and includes all information the applicant believes is necessary to support rulemaking.

The administrative record comprises the comparison of the final calculated performance measures against the requirements, the results of quantitative and qualitative reviews, the collection of new or additional data, and the PTB (see Section 2.5.4). The administrative record includes information on specific parameters or processes and the results of quality assessments of these data. As part of this strategy, the DOE will define the nature and extent of the administrative record and the process by which it is controlled. This definition will be reviewed with the regulatory agencies and with project stakeholders to assure fair and accurate treatment of all topics and reporting of relevant information to the regulatory agencies.

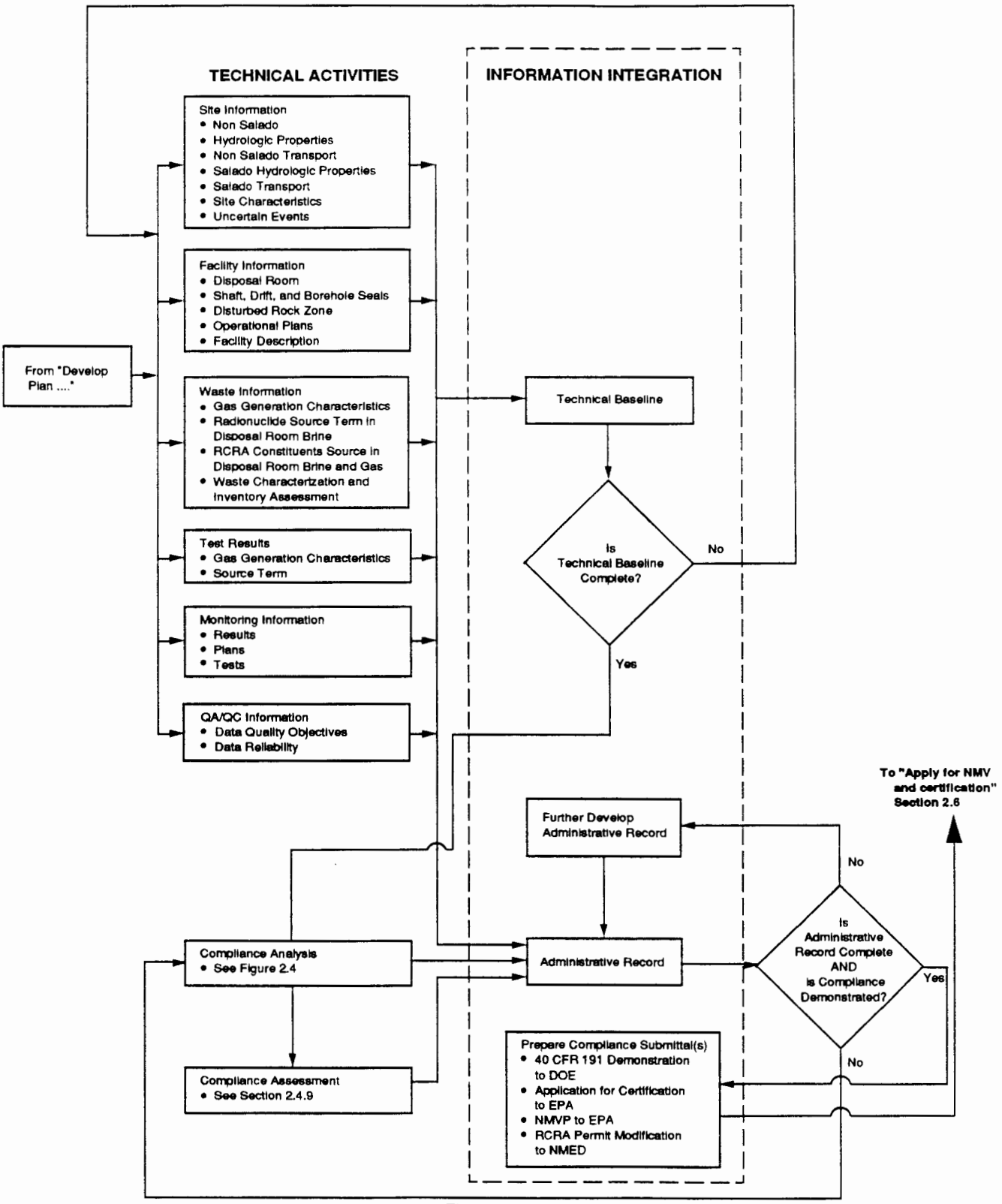


Figure 2.5
Compliance Decision Network for Information Integration

2.5.4 Project Technical Baseline

The PTB document will contain a compendium of technical facts, approaches, and assumptions, and will serve as the description of the WIPP which has been accepted by the project participants. The PTB document will be a tool used by the DOE to consolidate this information for use in future performance calculations. By consolidating this information, the DOE can ensure that the technical information, approaches, and assumptions used in performance calculations and compliance applications for 40 CFR 191 Subparts B and C, 40 CFR 268.6, and 40 CFR 264 Subpart X are consistent and accurate. The document will contain information on the following topics:

- Site Characterization
- Facility Description
- Waste Description
- Monitoring
- Transportation
- Regulatory Compliance
- Obligations
- Quality Assurance

2.6 COMPLIANCE DEMONSTRATION

Performance assessment will be used as part of an assessment of compliance with the long-term performance standards. The compliance documentation will address the requirements in the regulations and record the process and subsequent findings.

A determination of reasonable expectation that the standards will be met will be formulated based on the degree of confidence in the repository design, engineered barriers, the data, scenarios and associated probabilities, performance assessments, and on discussions with regulators. Documentation of independent reviews, the technical reports, information, and quality assurance files will become a part of the administrative record available to support the compliance demonstration.

Four submittals will be required. These are defined as follows:

- 40 CFR 191 compliance demonstration to DOE for approval
- 40 CFR 191 application for certification to EPA
- 40 CFR 268.6 petition for a determination of no-migration to the EPA
- 40 CFR 270 application for a hazardous waste permit to the NMED

In addition, the DOE will comply with NEPA in its decision-making process regarding disposal operations at WIPP.

2.6.1 Strategic Summary

The DOE's strategy for compliance demonstration to obtain initial certification under the Final Disposal Standards and to obtain a no-migration variance under the RCRA LDRs is to perform a self-assessment of the administrative record. The administrative record is comprised of the comparison of the calculated performance measures against the requirements, the results of quantitative and qualitative reviews, the collection of new or additional data, and the PTB. This formal self-assessment is necessary for DOE to arrive at both a reasonable expectation and a reasonable degree of certainty based upon the degree of confidence in the repository design, engineered barriers and alternatives, the data, uncertain events such as human intrusion, and various performance measures.

2.7 SECRETARY'S DISPOSAL DECISION

2.7.1 Strategic Summary

Central to the strategy is the common understanding of the term "Secretary's Disposal Decision" (see figure 2-1). The Secretary's Disposal Decision means that the DOE internal organizations agree that the WIPP Project has demonstrated to their satisfaction that WIPP meets the requirements of 40 CFR 191, and is ready to ask the EPA to agree with (certify) the DOE position. Upon making the disposal decision, the DOE will submit their determination on 40 CFR 191 to the EPA, the petition for a disposal phase no-migration variance (40 CFR 268.6) to the EPA, and RCRA permit application or modification (40 CFR 264) to the NMED.

2.8 REGULATORY APPROVAL OF DISPOSAL PHASE

2.8.1 Strategic Summary

The regulatory process for the RCRA regulation is well defined and is illustrated generically in Figure 2-6. This process involves the basic elements of interaction between the regulator and the DOE, the public, and decision makers. The EPA will manage all information, including communications with the DOE and other stakeholders through the establishment of a docket.

The LWA provides a partial basis for defining the regulatory process for 40 CFR 191 in that it requires the EPA to certify the DOE's compliance determination. The exact definition of "certify" and the process by which the EPA will complete this task is undefined at this time. The EPA will define its certification criteria in 40 CFR 194 which is anticipated as a proposed rule early in calendar year 1994. Final rulemaking is not expected until early 1995. It is assumed for planning purposes that a process similar to that depicted in Figure 2-7 will be used for 40 CFR 191.

2.9 PERFORMANCE-BASED WASTE INVENTORY

2.9.1 Strategic Summary

The DOE's strategy includes the integration of the performance assessment activity and the identification of the waste inventory for disposal. The approach is to use performance assessment analysis as one tool to identify the range of waste parameters that are acceptable to the WIPP. Based on the sensitivity of these parameters relative to repository performance, an envelope of acceptable waste will be identified and appropriate waste acceptance criteria developed. The criteria are referred to by the DOE as performance-based waste acceptance criteria. The waste acceptance criteria will be based on the results of the performance assessment models, operational assessments, and possible conditions that may be imposed as part of the regulatory process. The application of these waste acceptance criteria to the TRU-waste inventory defines a "performance-based inventory" (i.e., the inventory acceptable for disposal).

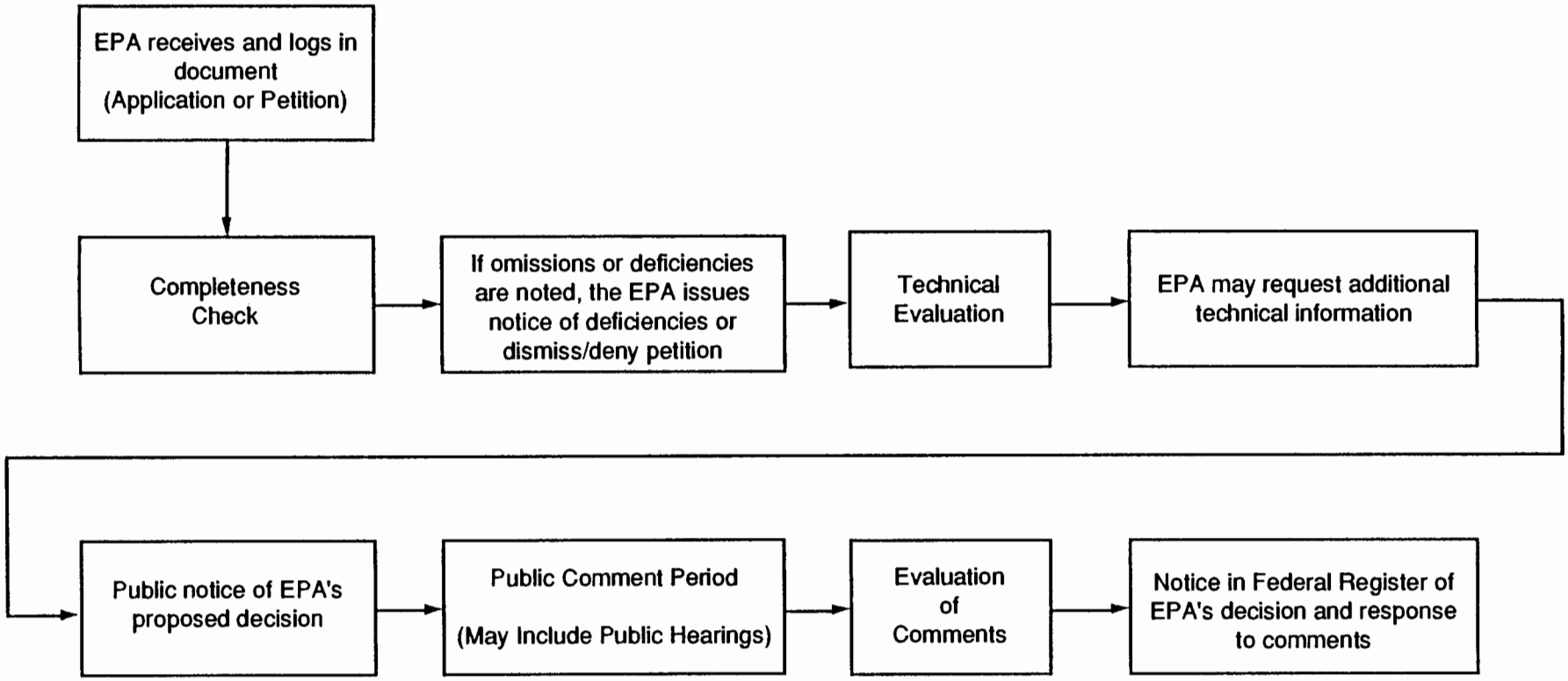


Figure 2.6
Major Elements of the EPA's RCRA (No-Migration Determination) Review Process

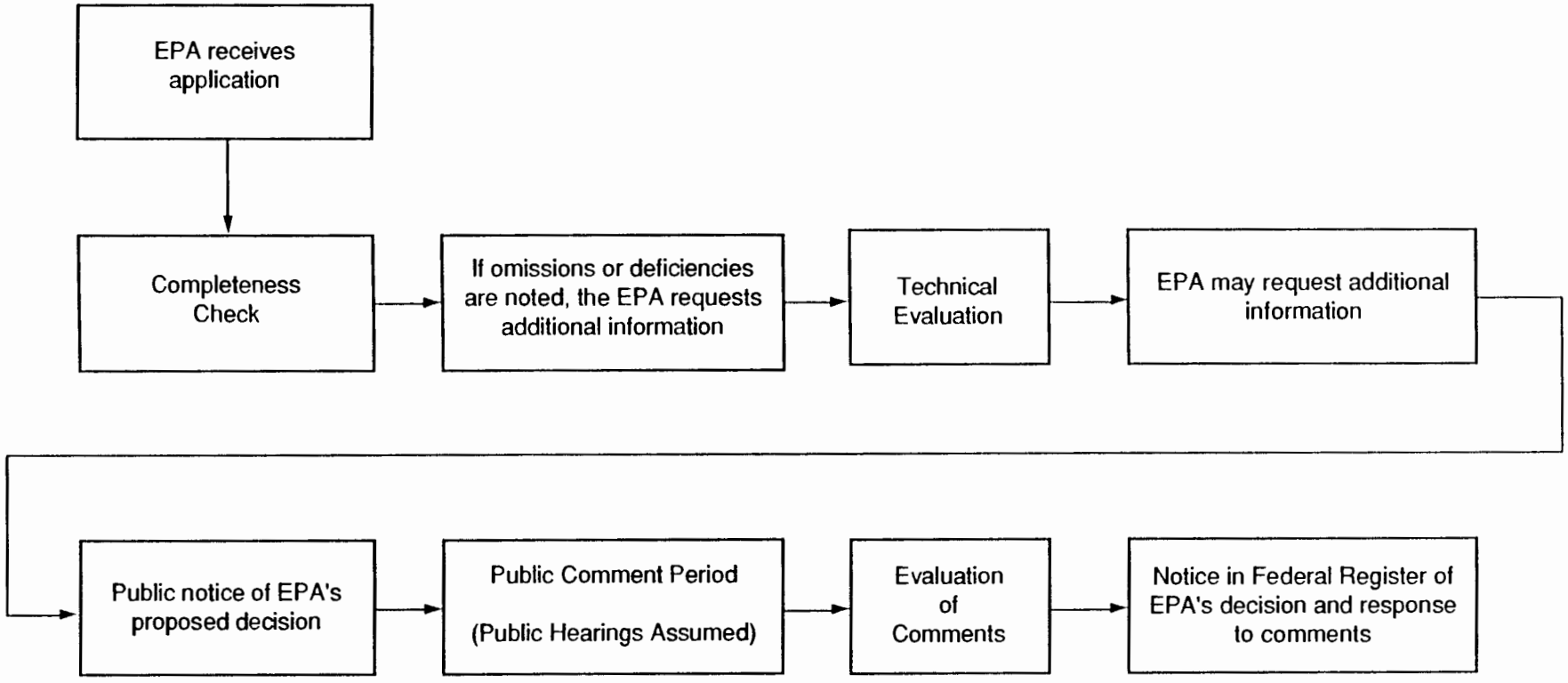


Figure 2.7
Major Elements of the EPA's Certification Application

2.9.2 Baseline Inventory Assessment

Prior to the development of a performance-based waste inventory, a baseline inventory assessment must be prepared. The inventory assessment will consist of the process knowledge and previous sampling and analysis data available for the waste inventory. The DOE has defined this to include knowledge of the processes and materials that lead to the generation of the waste and the results of sampling and analyses. The baseline inventory assessment will be consolidated into a report to include all associated waste stream assumptions and cross-correlations. This report will be titled the Baseline Inventory Report (BIR).

The DOE will conduct this assessment by evaluating prior data-gathering campaigns and by considering quality control measures and reporting consistency. Data from the WIPP No-Migration Variance Petition (DOE, 1990) and the Federal Facility Compliance Act Inventory Report (DOE, 1993) will be the basis for the initial inventory assessment. Additional information that supports parameters identified as important to compliance, such as recent characterization data from the Idaho National Engineering Laboratory and the Rocky Flats Plant, will be considered in this assessment as appropriate. The BIR will be periodically updated as new waste information becomes available through sampling and analysis activities and as newly generated wastes are documented.

2.9.3 Performance-Based Waste Envelope

The performance-based waste envelope identifies the bounding characteristics of wastes acceptable for the WIPP based on repository performance. This envelope considers only the physical and chemical form of the waste and its interaction with the repository. Information used to formulate and identify this envelope will likely include characterization data, process knowledge, and modeling. It is anticipated that some waste forms or constituents will be identified which may require additional quantitative analysis through waste characterization or additional experimental evaluation prior to their inclusion in the performance-based waste envelope.

In an effort to expand the performance-based waste envelope, and consistent with phased compliance, the evaluation of additional data including waste characterization information, engineered alternatives, and packaging options, will be used in subsequent compliance submittals

to reduce restrictions as appropriate and accept newly generated waste types which will likely result from decontamination and decommissioning activities.

2.10 THE RECERTIFICATION AND REAPPLICATION PROCESS

2.10.1 Strategic Summary

The DOE's strategy for recertification and reapplication is to use information obtained from ongoing testing and operations during disposal operations to confirm and/or update performance assessment modeling and analysis and to develop a compliance demonstration record. The DOE is required to demonstrate, on a periodic basis, continued compliance with the Final Disposal Standards and the RCRA LDRs. In addition, the DOE must submit a new hazardous waste permit application every 10 years. This demonstration will consist of a repeating five-year recertification with the Final Disposal Standards (required by the LWA), and a 10-year permit reapplication for the no-migration variance petition (required by the RCRA). This process as applied to the Final Disposal Standards (depicted in Figure 2-8) is designed to evaluate additional data collected during ongoing operations and lead to a determination that the original basis for compliance has not changed or, if it has, to evaluate the significance of the change.

2.10.2 Recertification and Reapplication Approach

The LWA requires recertification that the WIPP remains in compliance with the Final Disposal Standards during the disposal phase. The RCRA also requires renewal of the no-migration determination and hazardous waste permit, both of which can be issued for no more than 10-years (reapplication). The DOE's strategy is to evaluate new data to determine if significant changes have occurred that may affect continued compliance with the applicable regulations.

Documentation for recertification and reapplication will include the information required by the regulators in addition to an assessment of information gained through ongoing operations and data collection.

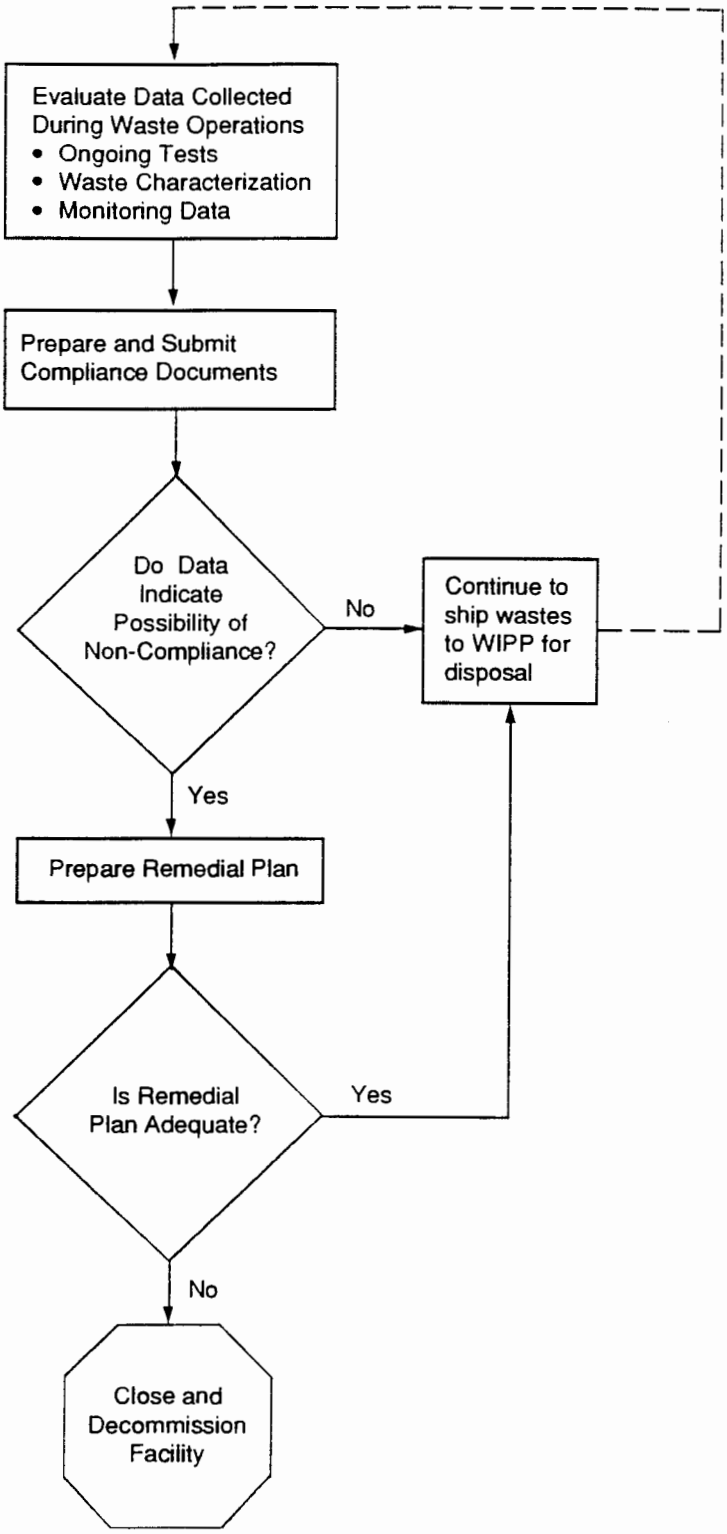


Figure 2-8

Periodic (5 year) Recertification Process

(Applies to the Final Disposal Standards)

2.11 DECONTAMINATION, DECOMMISSIONING, AND CLOSURE

2.11.1 Strategic Summary

It is the DOE's strategy to conduct decontamination, decommissioning, and closure activities in accordance with applicable guidance and regulation. The LWA (Section 13) provides two specific requirements related to decontamination and decommissioning planning. These are:

- *Prepare and submit a plan for decommissioning to the Congress, the State of New Mexico, the Secretary of the Interior, and the EPA*
- *Develop a post-closure land management plan*

The Final Disposal Standards, RCRA, and DOE Orders provide specific requirements for decontamination and decommissioning implementation. Regarding the Final Disposal Standards, the "Assurance Requirements" have been specified by the EPA to assure that cautious steps are taken by the implementing agency to reduce the uncertainties in projecting the behavior of natural and engineered components for long periods of time. Similar requirements are applicable to the long-term performance standards 40 CFR 268.6.

The hazardous waste standards require, through the RCRA permitting process, Closure/Post-Closure Plan be prepared and submitted to the State of New Mexico prior to disposal operations. This Plan details the action to be taken to close or partially close the hazardous waste facility. It is to be implemented once the facility has reached its capacity.

DOE orders specify decontamination and decommissioning activities following operations and generally require site reclamation, equipment decontamination and salvage, and the removal of radioactive residues if such contamination could be released to the environment. For WIPP, activities will include shaft sealing, emplacement of markers and monuments, notation in appropriate records, and appropriate performance monitoring.

Roles and Responsibilities

3. ROLES AND RESPONSIBILITIES

The WIPP's strategy for the development, management, and implementation of the compliance approach discussed in Section 2.0 is to ensure that the development of performance tools, such as performance assessment, is directed by the compliance needs. The DOE, therefore, obtains its primary source of compliance support from its Management and Operating Contractor and its primary source of analytic and experimental support from its Scientific Advisor.

3.1 DEPARTMENT OF ENERGY

The DOE has implemented the WIPP Project in a phased manner consistent with Public Law 96-164. The Project is well along in its transition to disposal operations and long-term waste isolation. As the owner and operator of the WIPP, the DOE has the ultimate responsibility and legal liabilities for all Project activities, including regulatory compliance. In recognition of these responsibilities and liabilities, the DOE provides the leadership and integration of the necessary resources to ensure that the goals of the strategic approach to regulatory compliance (discussed in Section 2.0) are met expeditiously.

In response, the DOE has designed a regulatory compliance management process that:

- Results in an integrated, focused approach to compliance task planning and execution
- Provides clear guidance and direction to its Management and Operating Contractor and Scientific Advisor
- Assures that guidance and direction will be commensurate with available resources
- Assures that duplication of effort will not occur and
- Assures that fundamental elements of the compliance strategy, such as an integrated database common to all demonstrations of compliance and similar quality assurance and quality control programs, will be designed, developed and implemented consistent with compliance expectations

- Assures ongoing and timely coordination with the waste generators with regard to waste characterization activities need to both determine and to assure regulatory compliance

3.2 MANAGEMENT AND OPERATING CONTRACTOR

The DOE's approach is to assign primary compliance support responsibilities to the Management and Operating Contractor. The Management and Operating Contractor performs compliance activities based upon direction and guidance issued by the DOE. The range of compliance activities that are representative of the types of compliance support provided to the DOE include:

- The identification and interpretation of regulatory requirements and criteria. As discussed in Section 2.0, aspects of the regulations often require interpretation beyond that which is provided by EPA to ensure that common understandings of compliance approaches are reached in an expeditious manner.

- The development of compliance strategies for identified regulatory needs. Appropriate compliance strategies involve an integrated, consistent approach in such aspects as analytical methods and modeling concepts, recommended guidance for various experimental projects, and the development of the DOE's administrative record.

- The development of format and content guidance for regulatory documents

- Acting as compliance focal point for interfaces with regulatory agencies. In supporting the DOE, a compliance focal point assists in the development of guidance and will undertake planning and logistics interfaces between the WIPP Project participants and regulatory agencies to ensure effective and efficient participatory interchange.

- The recommendation of modifications to experimental programs consistent with regulatory interpretation. Modifications to existing experimental programs or the creation of new programs within a prioritized framework is necessary to ensure that outcomes and quantitative results are directly relevant to demonstrations of compliance.

- The development and maintenance of the compliance database, as well as associated documents which are integral to the compliance demonstration process.

3.3 SCIENTIFIC ADVISOR

The DOE recognizes that the Scientific Advisor, in providing analytic and experimental program support, must do so in a manner that provides outcomes and results that are directly relevant to demonstrations of compliance with the source regulations. In addition, the Scientific Advisor must provide this support to the DOE in an organizational structure that allows for, encourages, and accepts the research and development environment of the Nation's first geologic disposal facility and, yet, is tempered by the recognition that the WIPP Project has become one of regulatory compliance. Thus, it is the DOE's approach to merge the regulatory interpretations into a priority-based analytic and experimental program. The following tasks are representative of the scope of those activities to be undertaken by the DOE's Scientific Advisor to fulfill the requirements of this approach:

- Development and implementation of experimental programs and modification of existing programs. The DOE's approach is to focus its current experimental program and to develop and implement new programs that are directly relevant to determinations of compliance with the regulations.

- Interpretation and analysis of data obtained from the conduct of the experimental programs. These data and analyses form the basis for the conceptual understandings of the natural and engineered barriers interactions with the waste inventory.

- Development of conceptual models. The development of conceptual models that adequately describe repository behaviors, and natural and engineered barrier systems and that are applicable to all regulations is necessary to fulfill the overall strategic approach to compliance.

- Application of numerical models and analytic codes. Numeric models and computer codes that reflect reasonably expected phenomena, as captured by the conceptual models, are necessary elements of the DOE's compliance documentation.

Planning for Compliance

4. PLANNING FOR COMPLIANCE

4.1 INTRODUCTION

This strategy is intended to present an upper-level approach and logic for integration and demonstration of compliance with selected key regulations for the disposal of TRU-mixed waste. The strategy is structured to provide a process flow that clearly indicates the interactions among the various project components from which output will be required to satisfy key project decision points and initiate key activities. Since it is intended to provide an upper-level perspective of the compliance strategy, this document does not address implementation details, nor does it attempt to resolve specific issues and uncertainties relative to the key regulations considered.

This strategy should need to be revised only in those instances where major changes in the applicable legislation, regulations, or other upper-level considerations make adjustments appropriate. In effect, the strategy may be considered a baseline from which to proceed with more explicit analyses.

In order to effectively implement the strategy, the on-going program must: (1) be sensitive to the needs and expectations of the regulators, and (2) have mechanisms in place by which the DOE can direct and monitor the technical and administrative aspects of the program that are relevant to the demonstrations of compliance. Programmatic considerations exist which reinforce the need for detailed, integrated, and baselined compliance documentation. These are: (1) program complexity, (2) the use of data to demonstrate compliance with more than one regulation, and, 3) the differing levels of regulatory guidance and precedent that are available. In addition, a management capability to assess the impact of regulatory or technical program changes on the upper-level compliance strategy, as well as on individual project plans and activities, must be available. With these objectives in mind, two documents designed to supplement this strategy will be prepared:

- An annotated format and content outline for the preparation of the 40 CFR Part 191 Subparts B and C (proposed) certification application. The intent is to provide upper-level guidance for TRU-waste disposal that is equivalent to the guidance and precedent that are already available for the hazardous waste component.

- A detailed implementation document. This document will provide a baselined compendium of the approaches that are being, or will be, used to provide the information needed to complete variance petitions, and certification applications, in accordance with the overall regulatory compliance strategy, the annotated outline for the 40 CFR Part 191 certification application, and the available precedent and guidance for No-Migration Variance Petitions.

4.2 ANNOTATED OUTLINE FOR CERTIFICATION APPLICATION

Appendix A provides a generic Table of Contents for the 40 CFR Part 191 and 40 CFR Part 268.6 compliance documentation. In the case of the 40 CFR Part 191 certification application and the 40 CFR Part 268.6 No-Migration Variance Petition, the two submittals should be as consistent as possible, as indicated in Table A.2, even though internal details and approaches may differ.

In order that the annotated outline be of the most value to the Project, the DOE will actively support a continuing dialog with the EPA during the preparation and review processes. Additionally, the DOE will request EPA concurrence of the final outline as an acceptable concept for the certification application.

Appendix A
Recommended Format and Content for Compliance Documentation

APPENDIX A

RECOMMENDED FORMAT AND CONTENT FOR COMPLIANCE DOCUMENTATION

This appendix provides recommended summary level outlines for structuring the primary documentation that will be submitted to the responsible regulatory agencies for permitting, certification, or variance petitions as required by RCRA and the Final Disposal Standards. Consistent with the scope of this strategy document, the outlines provided in this appendix do not emphasize operational safety and other requirements imposed on DOE by regulation, DOE orders, or legislation. Compliance with other applicable requirements will be demonstrated as specified in Section 9 of the LWA, and will be documented separately.

Significant precedent exists for the preparation of applications for RCRA permits, including the availability of detailed checklists outlining EPA and New Mexico information requirements and format concepts. The EPA has defined the WIPP as a Miscellaneous Hazardous Waste Management Unit, which subjects it to the requirements of 40 CFR Part 264, Subpart X. Compliance with Subpart X will be documented in Part B of the RCRA permit application for the disposal phase. Further guidance has been provided by EPA for the 40 CFR Part 268.6 No-Migration Variance Petition (NMVP) format and content. Finally, effective precedent has been set, for the WIPP Project, by the successful application for the NMD for the test phase; a precedent that should be followed for the NMVP for the disposal phase. No precedent exists for the 40 CFR Part 191 certification application. The EPA is currently developing certification criteria that will be proposed as 40 CFR Part 194; however, these criteria will not be available in final form for some time and, even then, will provide only partial guidance relative to the content of the certification application.

The 40 CFR Part 191 certification application and the NMVP will be submitted to EPA headquarters, the Office of Radiation and Indoor Air and the Office of Solid Waste and Emergency Response, respectively. Conversely, permitting under RCRA is the responsibility of the State of New Mexico. Thus, DOE compliance documentation must address the specific interests of three separate regulatory organizations while maintaining an appropriate level of consistency in the documentation provided to the regulators.

Tables A.1 and A.2 provide summary outlines of content for the 40 CFR Part 264 permit application, and the 40 CFR Part 268.6 NMVP and 40 CFR Part 191 Subparts B and C

(proposed) applications, respectively. Separate documents will be required for each application or petition.

In an effort to maintain as much consistency as possible, and because of the relative content similarities, the 40 CFR Part 191 certification application outline and the NMVP outline are considered to have the same upper-level structure (Table A.2). This structure reflects EPA guidance for NMVP preparation and should, pending additional guidance for the certification application, serve as a useful starting point. However, it must be recognized that the guidance provided in this appendix is intended solely to provide a generalized concept for the preparation of the documents. At the detailed, "annotated outline" level, format and content adjustments will be required, not only to more fully reflect available guidance, but also to accommodate the differing perspectives imbedded in the regulations themselves (see Section 2.0). The requirements resulting from the 40 CFR Part 194 rulemaking process must ultimately be incorporated in any detailed format and content guidance for the certification application. However, it is expected that the individual certification criteria will fit within the generalized outline recommended in this appendix.

Similar information is required for all three documents, although the level of detail and emphasis will vary based on the requirement being addressed. For example, it is expected that the descriptions of site properties and general design information will be essentially identical for both the NMVP and the certification application, while performance assessment content will require application/petition specific approaches to conform to the regulatory guidance in 40 CFR Part 268.6 and 40 CFR Part 191. In all cases, however, data and analyses must be consistent unless regulatory requirements dictate otherwise. Where there are differences in assumptions or usage, the justification for such differences must be available, although not necessarily called out specifically in the permit/certification documentation itself. Of particular importance is the DOE position that conceptual models for long-term performance of the natural and engineered systems must be consistent in all cases.

TABLE A.1

OUTLINE FOR RCRA PART B PERMIT APPLICATION

1.0 FACILITY DESCRIPTION

- General Description
- Topographic Map
- Location Information
- Traffic Information

2.0 WASTE ANALYSIS PLAN

- Facility Description
- Identification of Waste to be Managed
- Boundary Conditions and Process Tolerance Limits
- Parameters, Rationale, and Test Methods
- Waste Sampling Plan and Data Analysis
- Waste Shipment Screening and Verification
- QA/QC Program

3.0 FACILITY AND PROCESS INFORMATION

- Containers
- Miscellaneous Unit
  - Description of the Miscellaneous Unit
    - a. Site Characteristics
      - Climate
      - Geology
      - Groundwater Hydrology
      - Surface Water Hydrology
      - Soils
      - Air Quality
      - Biological Community Structure
    - b. Process Description
      - Description of Experimental Waste

- TRU Mixed Waste Management Operations

c. Facility Design and Construction

- Site Security
- Waste Handling Building
- TRU Mixed Waste Handling Equipment
- Shafts and Subsurface Facilities
- Repository Subsurface Structures
- Containers

- Waste Characterization
- Environmental Performance Standards for the Miscellaneous Unit

a. Protection of Groundwater and Subsurface Unit

b. Protection of Surface Water, Wetlands, and Soil Surface

c. Protection of the Atmosphere

- Monitoring, Inspection, and Reporting

a. Monitoring

b. Inspection

c. Reporting

4.0 GROUNDWATER MONITORING

- Compliance with Groundwater Protection Requirements

5.0 PROCEDURES TO PREVENT HAZARDS

- Security
- Inspection Schedule
- Waiver or Documentation of Preparedness and Prevention Requirements
- Preventive Procedures, Structures, and Equipment
- Prevention of Reaction of Ignitable, Reactive, and Incompatible Waste

6.0 RCRA CONTINGENCY PLAN

- General Information
- Incident Response Personnel
- Implementation
- Emergency Response Method
- Emergency Equipment
- Coordination Agreements

- Evacuation Plan
- Required Reports
- Location of the Contingency Plan and Plan Revision

7.0 PERSONNEL TRAINING

- Outline of the Training Program
- Implementation of Training Program

8.0 CLOSURE PLANS, POST-CLOSURE PLANS, AND FINANCIAL REQUIREMENTS

- Disposal Phase Closure Plan
- Post-closure Plan/Contingent Post-closure
- Notices Required for Disposal Facilities
- Closure Cost Estimate
- Financial Assurance Mechanism for Closure
- Post-closure Cost Estimate
- Financial Assurance Mechanism for Post-closure Care
- Liability Requirement

9.0 CORRECTIVE ACTION FOR SOLID WASTE MANAGEMENT UNITS

- Solid Waste Management Units
- Releases

10.0 OTHER FEDERAL LAWS

11.0 NO MIGRATION DETERMINATION

- Compliance with Conditions of the Determination

12.0 CERTIFICATION

ACRONYMS

GLOSSARY

APPENDICES

TABLE A.2

GENERIC TABLE OF CONTENTS FOR 40 CFR PART 268.6 NO MIGRATION VARIANCE PETITION AND 40 CFR PART 191 CERTIFICATION APPLICATION

The following is a summary outline for the preparation of the NMVP and 40 CFR Part 191 certification application, with the intent of making the formats of the two documents as consistent as possible to simplify the preparation and review processes while minimizing the potential for unrecognized inconsistencies. Separate applications will be submitted for the NMVP and the certification application and detailed annotation will be required to address the 40 CFR Part 191 demonstration of compliance with the specific requirements of the applicable regulations.

1.0 INTRODUCTION

Provide general information to the reader on the purpose of the facility, its current status, and the regulatory basis for the submittal.

- Waste Isolation Pilot Plant Overview
- Regulatory/Legislative Basis and Authorities

2.0 SITE DESCRIPTION/CHARACTERIZATION

Describe the site and regional geologic, hydrologic and meteorological environment. As appropriate to the regulation being addressed, emphasize the natural system in terms of barriers to radionuclide or hazardous material releases over the 10,000-year regulatory period, including evaluation of past and future geologic conditions. Cite applicable test and analysis information.

- Geology
  - Geologic history
  - Stratigraphy
  - Geomorphology
  - Structural and Tectonic setting/stability
  - Surface and subsurface features
  - Geochemistry/sorption
  - Geomechanical characteristics
- Surface and Groundwater Hydrology
  - Precipitation, evaporation, flooding
  - Hydrologic characteristics of formations, transmissivities, flow rates

- Brine characteristics, geochemistry
- Dissolution

- Resources
- Background Environmental Conditions
- Climatology and Meteorology
  - Current
  - Past conditions
  - Future Projections
- Summary of the Natural System
  - Conceptual assessment of site conditions through the 10,000-year compliance period
  - Summary of natural events and processes
  - Summary of conceptual models
  - Summary of natural barrier performance

3.0 FACILITY DESCRIPTION

Describe the WIPP engineered facility and the engineered barriers intended to prevent or mitigate the release of radioactive and/or hazardous wastes. Cite test and analysis information.

- Facility As-built Design Description
- Facility Design Specifications
- Facility Boundaries
- Facility Design and Operation
  - Surface structures and operations
  - Underground structures and operations
- Engineered Barriers
  - Shafts
  - Seals and plugs
  - Backfill
- Engineered system behavior during disposal and decommissioning phases: brine inflow, response to gas generation, disturbed rock zone, creep closure, etc.

- Summary of the engineered system behavior after decommissioning
  - Conceptual assessment of the undisturbed performance during the regulatory period of concern
  - Summary of processes occurring in the underground
  - Summary of conceptual models
- Waste Retrieval
- Contingency Planning
  - Retrieval
  - Emergency response
- Training
- Engineered Facility Closure and Decommissioning Plans
  - Monitoring provisions
  - Reclamation and recovery
  - Active and passive controls
  - Summary of engineered barrier system performance

4.0 WASTE DESCRIPTION

Describe current and future waste inventories intended for emplacement. Provide sufficient information, including waste characterization data, and other experimental information to enable application in the repository performance assessment.

- Waste Types and Characterization Data
  - Contact-handled TRU and TRU mixed waste
  - Remote-handled TRU and TRU mixed waste
- Waste Analysis Methods
- Waste Interactions in the Disposal Environment
  - Physical response
  - Chemical response
  - Interactions with the engineered and natural barrier systems
- Waste Acceptance Criteria
  - Repository performance based bounds
  - Inventory control

5.0 MONITORING PLANS

Describe monitoring plans, objectives, and limitations.

- Operational monitoring
- Confirmatory monitoring
- Post-closure monitoring

6.0 COMPLIANCE ANALYSIS

Describe the performance assessment and evaluation techniques used to support the assessment of compliance (Section 7). Emphasis and scope will vary depending on the regulatory basis for the document (certification application or NMVP).

- Describe the Analytical Methodology Used for Performance Assessment
  - Conceptual models
  - Models and codes, including validation and verification
  - Statistical techniques
  - Scenario selection
  - Calculation of performance measures specified by the requirement
  - Uncertainty and sensitivity analysis
- Development of Reasonable Expectation/Reasonable Degree of Certainty
  - Expert judgment
  - Alternate scenarios and conceptual models
  - Documentation of assumptions
- Data Supporting Compliance Assessment

7.0 ASSESSMENT OF COMPLIANCE

As appropriate to the NMVP or the 40 CFR Part 191 requirements, this section will provide the demonstration of compliance with the individual specifications of the regulation. The demonstration will draw on preceding sections and cited references as necessary. In the case of 40 CFR Part 191, specific reference will be made to the 40 CFR Part 194 certification criteria.

- Demonstration of Compliance for Individual Requirements, such as, but not limited to:
  - Containment or releases at the compliance boundary (both regulations)
  - Groundwater and individual protection (40 CFR Part 191)
  - Human intrusion (40 CFR Part 191
  - Unlikely events and processes (both regulations)

- Assurance requirements (40 CFR Part 191)
- Limitations, if any, imposed to increase the expectation that requirements will be satisfied
- Monitoring (40 CFR Part 268.6)
- Waste acceptance criteria

8.0 DESCRIPTION OF QUALITY ASSURANCE/QUALITY CONTROL PROGRAMS

- Describe past and current quality assurance programs in sufficient detail to demonstrate the acceptability of the information used in the application for its intended purpose.
- Describe QA/QC programs that will be implemented during the disposal and closure phases.

APPENDICES

As required, appendices will be used to provide supplementary information, data, analyses, and other material too detailed, voluminous, or otherwise inappropriate for inclusion in the text of the petition/application. Examples include:

- Plans and Procedures
- Data listings and manipulation
- Code and Model details
- Waste characterization data

Appendix B
Glossary

GLOSSARY

40 CFR Part 191

This regulation sets environmental radiation protection standards for management (Subpart A) and disposal (Subparts B and C) of spent nuclear fuel, high-level and transuranic radioactive wastes.

40 CFR Part 194

This regulation, required by the LWA, will provide EPA's criteria for certifying compliance with the final disposal standards.

40 CFR Part 264

This regulation establishes minimum national standards which define the acceptable management of hazardous waste.

40 CFR 264, Subpart G

This subpart of 40 CFR Part 264 defines closure and post-closure requirements pertaining to hazardous waste management units.

40 CFR 264, Subpart X

This regulation specifies requirements that apply to owners and operators of facilities that treat, store, or dispose of hazardous waste in miscellaneous hazardous waste management units.

40 CFR Part 268

This regulation restricts the land disposal of hazardous wastes and specifies treatment standards and/or treatment technologies that must be met or applied before hazardous wastes may be land disposed. Section 268.6 provides for petitioning to allow land disposal of untreated hazardous waste if it can be demonstrated to a reasonable degree of certainty that there will be no migration of hazardous constituents from the disposal unit for as long as the waste remains hazardous.

40 CFR Part 270

This regulation establishes provisions for the Hazardous Waste Permitting Program under Subtitle C of RCRA. This regulation and the associated State of New Mexico regulation require the permitting of the WIPP as a hazardous waste management unit.

Active Institutional Control

(1) Controlling access to a disposal site by any means other than passive institutional controls; (2) performing maintenance operations or remedial actions at a site, (3) controlling or cleaning up releases from a site, or (4) monitoring parameters related to disposal system performance.

Administrative Record

All information and data used in the preparation and support of compliance submittals. The administrative record becomes the "record before the implementing agency."

Baseline Inventory Assessment

An assessment of the total waste inventory currently existing in the DOE TRU system. This assessment includes previous sampling and analysis data and knowledge of the processes and materials that lead to the generation of the waste.

Barrier

Any material or structure that prevents or substantially delays movement of water or radionuclides toward the accessible environment. For example, a barrier may be a geologic structure, a canister, a waste form with physical and chemical characteristics that significantly decrease the mobility of radionuclides, or a material placed over and around waste, provided that the material or structure substantially delays movement of water or radionuclides.

Certification Application

A document to be prepared by the DOE which will contain the information necessary to demonstrate that the WIPP has complied with the disposal regulations contained in 40 CFR 191 Subparts B and C (proposed).

Compliance Database

A compendium of information, data, and analyses that will be used for compliance determination and defense to ascertain repository capability to isolate TRU waste for the period of regulatory interest. This database will be included in the Project Technical Baseline.

Compliance Status Report

A report of the status of the WIPP Project relative to compliance with 40 CFR 268.6 (RCRA) and 40 CFR 191. This document will be provided to the EPA and other stakeholders to identify those areas where compliance with the requirements are believed to be met, as well as those areas where additional activities are required to make a determination of compliance. This document is not a statement or determination of compliance.

Conceptual Model

A conceptual model is a set of qualitative assumptions used to describe a system or subsystem for a given purpose. At a minimum, these assumptions concern the geometry and dimensionality of the system, initial and boundary conditions, time dependence, and the nature of the relevant physical and chemical processes. The assumptions should be consistent with one another and with existing information within the context of the given purpose. Alternative conceptual models are alternative sets of assumptions that describe the same system for the same purposes, where each set of assumptions is consistent with the existing information. Conceptual model uncertainty is the lack of knowledge about the system resulting from limited information available to support or refute alternative conceptual models.

Contact-Handled Transuranic (CH-TRU) Waste

TRU waste that has a measured radiation dose rate at the container surface of 200 millirems per hour or less and the filled containers can be safely handled without special equipment when drummed.

DOE Approval Process

The process by which the DOE evaluates all the available information including performance assessment results, and agrees to go forward with a determination of compliance. This decision referred to as the "Secretary's Disposal Decision" means that the facility is ready to proceed with statements of compliance to the appropriate regulatory agency. This is not the decision to initiate disposal operations, which requires a significant number of prerequisites as identified on the Disposal Decision Plan.

Decommissioning

Actions taken upon abandonment of the repository to reduce potential environmental, health, and safety impacts, including repository sealing, as well as activities to stabilize, reduce, or remove radioactive materials or to demolish surface structures.

Decommissioning Phase

The period of time beginning with the end of the disposal phase and ending when all shafts at the WIPP repository have been back-filled and sealed.

Disposal Decision Plan

A plan listing significant milestones that must be completed prior to disposal operations at the WIPP.

Disposal System

Any combination of engineered and natural barriers that isolate spent nuclear fuel or radioactive waste after disposal (40 CFR 191.12[a]). The WIPP disposal system comprises the repository/shaft system and controlled area.

Disposal Phase

The period of time during which transuranic waste is being emplaced in the WIPP, beginning with the initial emplacement of transuranic waste underground for disposal and ending when the last container of transuranic waste, as determined by the Secretary of Energy, is emplaced underground for disposal.

Engineered Alternatives

Potential modifications to the design or operation of the WIPP or to waste forms that, if adopted, will provide increased assurance that the WIPP will perform in compliance with environmental protection and safety requirements.

Engineered Barriers

Backfill, seals, and any other manmade barrier components of the disposal system.

Event

A phenomenon that occurs instantaneously or within a short time interval relative to the time frame of interest.

Federal Facility Compliance Act (FFCA)

An amendment, promulgated in 1992, to the Solid Waste Disposal Act. Title I of the FFCA grants the U.S. EPA administrative enforcement authority against any department, agency, or instrumentality of the executive, legislative, or judicial branch of the Federal Government. In regard to mixed wastes, sovereign immunity for federal agencies is waived, consistent with a schedule provided in the Act. In addition, the Act requires that the DOE prepare an inventory of mixed wastes and mixed waste treatment capacities and technologies. For those mixed wastes for which treatment capacities or technologies do not exist, the DOE must prepare plans for the development of the capacities or technologies.

Final Safety Analysis Report (FSAR)

A safety document providing a concise but complete description and safety evaluation of the site, the design, normal and emergency operations, potential accidents, and predicted consequences of such accidents, and the means proposed to prevent such accidents or to mitigate the consequences of such accidents. An FSAR documents the adequacy of safety analysis for a nuclear facility to ensure that the facility can be constructed, operated, maintained, shut down, and decommissioned safely and in compliance with applicable laws and regulations.

Hazardous Waste

Solid waste that exhibits any of the characteristics of hazardous waste identified in New Mexico Hazardous Waste Management Regulations (HWMR-7), Part II, Subpart C; is listed in Part II, Subpart D; or is a mixture of a solid waste and a hazardous waste.

Human Intrusion

Potential inadvertent human disruptions of a mined geologic repository. The most severe disruption would occur through inadvertent or intermittent intrusion by exploratory drilling (into the repository) for resources.

Institutional Controls

Human actions to control a waste management facility such as the WIPP. Institutional controls are described as "active" and "passive." Active institutional controls are defined in 40 CFR 191.12(f) as: (1) controlling access to a disposal site by any means other than passive institutional controls, (2) performing maintenance operations or remedial actions at a site, (3) controlling or cleaning up releases from a site, or (4) monitoring parameters related to disposal system performance. Passive institutional controls are defined in 40 CFR 191.12(e) as: (1) permanent markers placed at a disposal site, (2) public records and archives, (3) government ownership and regulations regarding land or resource use, and (4) other methods of preserving knowledge about the location, design, and contents of a disposal system.

Isolation

Refers to inhibiting the transport of radioactive material so that the amounts and concentrations of this material entering the accessible environment will be kept within prescribed limits.

Mixed Waste

Mixed waste contains both radioactive and hazardous components, as defined by the Atomic Energy Act and the Resource Conservation and Recovery Act, respectively.

Natural Barriers

The repository host rock and surrounding geologic structures and formations. The natural barriers extend from the engineered barrier to the compliance boundary.

New Mexico Hazardous Waste Act

The New Mexico legislation which establishes the state hazardous waste management program. The state law is no less stringent than the federal law.

New Mexico Hazardous Waste Management Regulations (HWMR-7)

The New Mexico Hazardous Waste Management Regulations implement the provisions of the New Mexico Hazardous Waste Act. The regulations are consistent with the federal RCRA regulations, 40 CFR Parts 260 through 270.

No-Migration Determination for Test Phase

The term "No-Migration Determination" means the Final Conditional No-Migration Determination for the Department of Energy Waste Isolation Pilot Plant published by the Environmental Protection Agency on November 14, 1990 (55 Fed. Reg. 47700), and any amendments thereto, pursuant to the Solid Waste Disposal Act (42 U.S.C. 6901 et seq.).

Passive Institutional Control

(1) Permanent markers placed at a disposal site, (2) public records and archives, (3) government ownership and regulations regarding land or resource use, and (4) other methods of preserving knowledge about the location, design, and contents of a disposal system

Performance Assessment

A term used to denote all quantitative activities carried out to: 1) evaluate the long-term ability of WIPP to effectively isolate the waste and ensure long-term health and safety of the public by complying with 40 CFR 191 and 40 CFR 268.6; and 2) supply data/information to the compliance analysis for demonstrating regulatory compliance.

More specifically with regards to 40 CFR 191, Performance Assessment is an analysis that (1) identifies the processes and events that might affect the disposal system; (2) examines the effects of those processes and events on the performance of the disposal system; and (3) estimates the cumulative releases of radionuclides, considering the associated uncertainties, caused by significant processes and events. These estimates shall be incorporated into an overall probability distribution of cumulative releases to the extent practicable.

Performance Assessment Input

Any information used in a performance assessment, including (but not limited to) regulatory guidance, modeling techniques and tools, and site specific data and general knowledge used to construct values for model parameters.

Performance-Based Waste Acceptance Criteria

Criteria based on the results of performance assessment models, operational assessments, and possible conditions which may be imposed as part of the regulatory process.

Performance-Based Waste Envelope

The bounding characteristics of wastes acceptable for the WIPP based on repository performance.

Performance-Based Waste Inventory

That portion of the waste inventory which will meet the Performance-Based Waste Acceptance Criteria.

Post-Closure Phase

A designated period of time beginning with the end of the Decommissioning Phase and extending through the end of the regulatory time frame of 10,000 years. Performance assessment modeling of repository behavior will be conducted within this time frame with the exception of possible human intrusion events which will not be modeled until 100 years after decommissioning.

Process

A phenomenon that occurs over a significant portion of the time frame of interest.

Public Law 96-164

The U.S. Department of Energy National Security and Military Application of Nuclear Energy Act of 1980. Public Law 96-164 directed the DOE to proceed with the design and development of the WIPP.

Quality Assurance

All those planned and systematic actions necessary to provide adequate confidence that a structure, system, or component will perform satisfactorily in service.

Quality Control

Those quality assurance activities that provide a means to control and measure the characteristics of a structure, system, or component to established requirements.

Remote-Handled Transuranic (RH-TRU) Waste

TRU wastes that have a measured radiation dose rate at the container surface of between 200 millirems per hour and 1000 rem per hour and, therefore, must be shielded for safe handling.

Repository

The portion of the WIPP repository/shaft system within the Salado Formation, including the access drifts, waste panels, and experimental areas, but excluding the shafts.

Repository/Shaft System

The WIPP underground workings, including shafts, all engineered barriers, and the altered zones within the Salado Formation and overlying units resulting from construction of the underground workings.

Salado Formation

A geologic formation of Late Permian age located in southeastern New Mexico. At the WIPP site, it is composed of salt beds with minor amounts of anhydrite (45 numbered anhydrite marker beds, MB 101 through MB 145) and clay. It is the host unit for the WIPP repository.

Scenario

A combination of naturally occurring or human-induced events and processes that represents realistic future changes to the repository, geologic, and geohydrologic systems that could cause or promote the escape of radionuclides from the repository.

Sensitivity Analysis

Methods for computing the effect of changes in the input parameters on the model predictions.

Source Term

The kinds and amounts of radionuclides (per 40 CFR Part 191) or hazardous wastes (per 40 CFR 268.6) that can be mobilized for transport.

Project Technical Baseline

The Project Technical Baseline document includes the technical facts, approaches, and assumptions necessary to support demonstrations of compliance with 40 CFR 191 Subpart B and C, 40 CFR 268.6, and 40 CFR 264, Subpart X. As such, the document will serve as a basis for the conceptual model of the WIPP repository by explaining the parameters affecting the performance of the repository. It will include the compliance database consisting of technical data supporting compliance demonstrations.

Transuranic Waste (TRU Waste)

Waste containing more than 100 nanocuries of alpha-emitting transuranic isotopes per gram of waste, with half-lives greater than 20 years, except for:

(A) High-level radioactive waste;

(B) Waste that the Secretary has determined, with the concurrence of the Administrator, does not need the degree of isolation required by the disposal regulations; or

(C) Waste that the Nuclear Regulatory Commission has approved for disposal on a case-by-case basis in accordance with 10 CFR Part 61.

Uncertainty Analysis

1) An evaluation to determine the uncertainty in model predictions that results from imprecisely known input variables. 2) Determination of the degree of uncertainty in the results of a calculation based on uncertainties in the input parameters and underlying assumptions. Such an analysis requires definition of a system, description of the uncertainties in the factors that are to be investigated, and the characteristics of the system that is to be simulated.

Waste Acceptance Criteria (WAC)

A set of conditions established for permitting transuranic wastes to be packaged, shipped, managed, and disposed of at the WIPP facility.

Waste Characterization

Sampling, monitoring, and analysis activities to determine the extent and nature of the waste.

Waste Parameter

A characteristic or property of the waste which may have the potential to affect the calculated repository performance. Specifically, they may be used as input to performance assessment in defining the performance-based waste acceptance criteria (PBWAC).

WIPP

The Waste Isolation Pilot Plant project authorized under section 213 of the Department of Energy National Security and Military Applications of Nuclear Energy Authorization Act of 1980 (P.L. 96-164; 93 Stat. 1259, 1265) to demonstrate the safe disposal of radioactive waste materials generated by atomic energy defense activities (P.L. 102-579).

WIPP Land Withdrawal Act

Public Law 102-579. The Act withdraws the land at the WIPP site from "entry, appropriation, and disposal," transfers jurisdiction of the land from the Secretary of the Interior to the Secretary of Energy, and reserves the land for activities associated with the development and operation of the WIPP.

Appendix C
References

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Document Review Record

for the

WIPP Regulatory Compliance Strategy and Management Plan

and the

Format and Content Guide for Title 40 CFR 191 and Title 40 CFR 268.6 Compliance Reports

May 1994

WASTE ISOLATION PILOT PLANT (WIPP)
REGULATORY COMPLIANCE TASK FORCE

DOCUMENT REVIEW RECORD

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REVISION:	Revision 1, Draft (dated November 1993)
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COMMENTS THAT ARE ANNOTATED WITH AN (*) ARE MANDATORY AND REQUIRE RESPONSE AND RESOLUTIONS

SECTION/ PARA	COMMENT	RESPONSE
	New Mexico Energy, Minerals, and Natural Resources Department Comments	
General A-1	The State of New Mexico strongly supports DOE's recent efforts to reorient the WIPP program to more clearly reflect a compliance-driven approach. This approach, which focuses predominantly on meeting applicable statutory and regulatory requirements, must be fully embraced by DOE and emphasized as the primary mechanism to be used in guiding WIPP's future development. Adherence to such a strategy will keep the WIPP program on track in fulfillment of its mission: determining the repository's suitability as a permanent disposal facility for defense transuranic wastes. By demonstrating top management's stated commitment to regulatory compliance, DOE may currently enhance its credibility--a positive step toward regaining the public's trust and confidence.	No response necessary.

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SECTION/ PARA	COMMENT	RESPONSE
General (Type 1: Regulatory Scope) A-2	The draft WIPP RCSMP represents a determined effort to outline the process by which WIPP will demonstrate its ability to perform as a deep geologic repository. The strategic planning process for demonstrating long-term performance of the WIPP system is of paramount importance and must be given unparalleled priority attention. Notwithstanding this, the scope of the Plan is limited in that it does not address a number of key laws and regulations governing WIPP, its activities and operations. Compliance with these other requirements will also determine, albeit to a lesser extent, whether and when certain wastes can be disposed at WIPP. [These] laws, regulations, and other requirements must be addressed in the WIPP RCSMP or another similar document if DOE intends its "compliance-driven approach" to the WIPP program to be a comprehensive, integrated approach. At a minimum, the Plan should cite these important regulatory requirements, briefly discuss their salient elements, and then reference where additional detail can be found.	The intent and scope of the RCSMP was not designed to address ALL applicable regulations to the WIPP. Instead, it was meant to present the strategy for compliance with key long-term disposal standards. These standards, for the most part, lack regulatory guidance and/or precedent for compliance. As such, the RCSMP is focused on these regulations. Other regulations, though no less important, have regulatory precedents, official guidance documents, or both, such as the National Environmental Policy Act, the Clean Air Act, and the Clean Water Act. The WIPP has maintained compliance with these as well as many other regulations for some time. The regulations identified in the RCSMP are not as "common" and therefore require a comprehensive, dedicated strategy and approach for compliance. This is the primary reason for the regulatory emphasis and focus of the document. Since this comment was made by several reviewers, the following has been done to clarify this point in the document. First, the title has been revised to the "The [RCSMP] for Demonstrating Compliance to Long-Term Performance Standards." Second, the introduction has been edited to clarify the limited scope of the document.

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SECTION/ PARA	COMMENT	RESPONSE
A-3	Another concern about the draft Plan relates to how it addresses interactions with the State of New Mexico versus other stakeholders. The document clearly emphasizes the necessity to solicit from the U.S. Environmental Protection Agency (EPA) early and continuing input on regulatory compliance issues. However, the need for comparable State involvement does not come across as strongly, and is considered essential. It appears as if the State of New Mexico is included as an "afterthought" in many of the discussions. As host state for the project and a key regulator of repository operations, meaningful and productive involvement and interaction with the State is essential. Toward this end, the Plan should be revised to better reflect DOE's commitment to maintaining an early proactive dialog with the State of New Mexico on matters pertaining to WIPP's compliance with all applicable laws, regulations, and other requirements.	The DOE agrees that it is imperative that the State, both as the implementing agency for RCRA, and as the host state for the WIPP project be involved in the ongoing, proactive dialogue with the Project regarding compliance issues. Text has been added as appropriate to illustrate the vital role of the state and the importance of this dialogue with the State.
General A-4	With respect to waste characterization, the Plan does not adequately stress the importance of characterization and related activities. To date, only the Idaho National Engineering Laboratory and Rocky Flats Plant have made definitive progress in this area. Significantly, remote-handled (RH) waste characterization facilities do not yet exist within the DOE complex. For these reasons, the document must focus priority attention on those measures and capabilities required to perform accurate sampling and detailed analyses of the existing TRU waste inventory. It should emphasize the critical need for data on those waste inventory parameters identified as important to compliance.	The value and need for adequate and accurate waste characterization is indeed great. We do not feel, however, that the characterization program should be detailed in this document. Detailed information of this type belongs in the many lower-tiered (level 3; see figure 2.2 in the RCSMP) documents. For example, the characterization program is detailed in the Waste Characterization Program Plan. We regret that the document appears to underemphasize the importance of characterization. Additional emphasis has been added to the text.

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SECTION/ PARA	COMMENT	RESPONSE
General A-5	[Several] directives make clear that engineered barriers are to be integral components of the WIPP disposal system. What is not clear, however, are DOE's plans for evaluating the various available alternatives, and then determining the appropriate combination of barriers and, if necessary, waste form modifications to meet the applicable long-term disposal regulations. The State of New Mexico believes the results of the WIPP Performance Assessment must be used to guide the decision-making process on selection of engineered barriers and waste form modifications. For these reasons, the Plan should discuss in greater detail how DOE intends to address the issue of engineered barriers and waste form modifications within its regulatory compliance framework.	The DOE understands the attractiveness of engineered barriers and alternatives. However, the decision to select and implement any such barriers must be made carefully to assure that such barriers are needed, that implementation is beneficial, and that costs are justified. The DOE has a three step approach in arriving at a responsible decision. First, viable alternatives will be identified and evaluated for efficacy. Second, a cost/benefit/detriment study will be performed. Third, the need will be evaluated using performance assessment. More detail on this strategy has been included in the RCSMP.
Table of Contents p.iv A-6	The caption for Figure 2-6 should read: "Major Elements of the EPA's RCRA (No-Migration Determination) Review Process." This recommended change, along with similar ones throughout the text, will help distinguish among the various RCRA regulations applicable to WIPP.	Comment incorporated.

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SECTION/ PARA	COMMENT	RESPONSE
p. 1-2 3rd para A-7	This section discusses the need for flexible compliance strategy "...to ensure that the WIPP can accommodate the changing TRU waste inventory resulting from increased decommissioning and decontamination of facilities, environmental restoration activities, and newly generated TRU waste that will result from treatment of low level wastes." Although the amount of TRU waste resulting from nuclear weapons dismantlement is estimated by DOE officials to be relatively small, this activity should nevertheless be mentioned here as a potential source of waste destined for the WIPP repository.	Text modified to read "....inventory resulting from increased decommissioning and decontamination of facilities, environmental restoration activities, the dismantlement of weapons, and newly generated TRU waste that will result from treatment of low level wastes."
p. 1-4 Section 1.3 Scope A-8	This section states that the Plan "...focuses on those regulations that directly impact the WIPP program." However, the laws and regulations listed earlier in this correspondence "...directly impact the WIPP program." This is particularly true for WIPP repository and transportation operations, including worker safety, during the disposal phase. The DOE is encouraged to adopt our previously stated recommendations on this issue (i.e., "cite these important regulatory requirements, briefly discuss their salient elements, and the reference where additional detail can be found."	As stated in the first two sentences in Section 1.3, the document conveys the compliance strategy "relative to the long-term performance of the repository." The logic behind the current scope is set forth as well: "This focus is provided because it is the long-term performance portions of the various regulations that require WIPP-specific interpretation and for which the compliance programs at the WIPP are precedent setting." Based on this focus, other regulations are not included in this Strategy. Refer to response of comment A-2.

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SECTION/ PARA	COMMENT	RESPONSE
p. 2-2 middle para A-9	This paragraph discusses "compliance margins" in the context of initiating or enhancing certain technical activities to further address key parameters that may affect such margins if they (compliance margins) are less than DOE desires. It is unclear what DOE is trying to convey here. Clarifying language should be added to better delineate DOE's message. Nonetheless, arbitrary compliance margins should not be established and self imposed by DOE. The appropriate regulatory agency must be the entity providing guidance in this area.	This section has been reworded to eliminate the term "margins" while conveying the intended concept. In essence, what is being addressed in this context are the measures that DOE adopts to mitigate some of the uncertainty associated with 10,000 year predictions. For example, DOE may choose to characterize waste to an extent beyond that required to minimally comply with the standards as a means of providing additional assurance of compliance. Similarly, DOE may opt to implement certain engineered enhancements as a means of providing additional assurance that the disposal system will perform as predicted. Such actions are not intended to build a numerical "margin," instead, they are to build confidence among the DOE, the regulators, and the public that compliance will be achieved.
p. 2-5 Section 2.2.2 Regulatory Applicability A-10	This section states that "...this strategy emphasizes the concepts necessary for demonstrating compliance with the disposal requirements that govern the DOE's ability to receive and dispose of TRU wastes at the WIPP." Again, there are other requirements excluded from the draft Plan that govern DOE's ability to receive and dispose of TRU wastes at WIPP. These requirements must be addressed along the lines recommended in this correspondence.	See response to comments A-2 and A-8.

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SECTION/ PARA	COMMENT	RESPONSE
p. 2-6 middle paras A-11	It is recommended these two paragraphs be revised to clarify that DOE intends to interact as closely with the State of New Mexico as with the EPA on compliance issues. Comparable interactions with the State are advisable due to the interrelated nature of the applicable regulations.	These two paragraphs are related to the task of demonstrating compliance with the long-term disposal standards of 40 CFR 191 and 268.6. Discussion of the important dialogue associated with the RCRA permitting process does not follow with the intent of the text. Interactions with the State regarding C & C commitments and RCRA permitting activities are equally as important as those interactions with the EPA and will be conducted similarly.
p. 2-10 3rd full para A-12	This paragraph lists the types of site information to be presented in DOE's demonstration of compliance with the applicable disposal requirements. The listing includes "...locations of all wells in the vicinity of the facility." Both operable and inoperable wells, including water wells, monitoring wells, oil/gas wells, and others, should be noted in this submission to facilitate the regulators' assessment.	Groundwater hydrology is the focus of this paragraph. Therefore, it is logical to list the locations of wells supplying groundwater data. It does not mean, either explicitly or implied, that no other wells will be considered or identified. To correct this misinterpretation, additional text has been added that states "the location of wells, including gas/oil, water, monitoring, etc. will be provided..."
p.2-11 last two paras A-13	These paragraphs discuss "engineered alternatives" and "engineered barriers." Does DOE make any distinction between these two terms? (Note: The glossary at the end of the document defines "barrier" and "engineered barrier," but not "engineered alternative.") Clarification should be provided here and in the glossary.	Clarification has been provided.

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SECTION/ PARA	COMMENT	RESPONSE
p. 2-30 1st full para A-14	This paragraph talks about "...phased, flexible compliance." While the DOE's "compliance strategy" may be flexible, "compliance" itself is not. Also, in discussing newly generated waste types, include as potential sources environmental remediation and weapons dismantlement activities.	We agree that compliance is not flexible. Text has been modified to clarify this point. In addition, weapons dismantlement has been addressed (see response to comment A-7). It should be added that the uncertainty over the volumes and physical forms of wastes that will come from remediation and dismantlement are, in fact, the very reason the term "flexible" is included in the RCSMP in this context.
p. A-7 Appendix A Table A-2 A-15	Section 3.0 FACILITY DESCRIPTION list "Shafts" as "Engineered Barriers." Clarify shaft seals and plugs are engineered barriers--not the shafts themselves.	It was not intended to imply that "shafts" were engineered barriers. This sub-topic has been deleted from the document.
p. B-1 et seq Appendix B A-16	GLOSSARY: Add the following terms and their definitions to the Glossary: 40 CFR 264 Subpart G; 40 CFR 270; New Mexico Hazardous Waste Act; New Mexico Hazardous Waste Management Regulations (HWMR-7); Contact-Handled Transuranic (CH-TRU) Waste; Remote-Handled Transuranic (RH-TRU) Waste; Disposal System; Final Safety Analysis Report (FSAR); Federal Facilities Compliance Act (FFCA).	Comment incorporated.

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SECTION/ PARA	COMMENT	RESPONSE
	New Mexico Attorney General Comments	
General B-1	The documents suggest a growing appreciation of the challenge of regulatory compliance at WIPP and are to be commended for that. However, in their present form, the documents fail to examine specifically how, if at all, various of the broadly-stated objectives can be achieved and, thus, raise more questions than they answer.	DOE's purpose behind the RCSMP is not to demonstrate an appreciation for the challenge of regulatory compliance at WIPP. Instead, the DOE is acknowledging the importance of having a well defined strategy that involves regulators and stakeholders from the outset. In this way the challenge will be met. Within this perspective, the RCSMP is intended to be a "upper-tiered" document which sets forth the overall strategy for compliance with the Final Disposal Standards and that portion of RCRA that requires demonstrating long-term performance. As a *Strategy* document, the RCSMP is somewhat general in nature and is designed to foster discussion and consensus on overall goals and objectives. For example, the strategy of using PA as a key process in evaluating WIPP is a generally accepted objective. Its details for implementation are relegated to lower-tiered documents, the audience for which is likely to be far more focused and far more technical.
p. 2-1 & 2-2 B-2	There is no schedule or adequate description of the content of most of the "milestone" items listed on pages 2-1 and 2-2. For instance, the specific content and delivery date for the "Performance Assessment Input," "Technical Baseline," the quality assurance evaluation, and documents involved with DOE's approval of a compliance demonstration are unstated. Thus, the practical problems of feasibility and the interrelationship of tasks are not addressed.	Additional detail has been added. However, no schedule is included since the objective is to represent a sequence of events or combination of activities to achieve a compliance demonstration. Schedules are dealt with external to the RCSMP.

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SECTION/ PARA	COMMENT	RESPONSE
p. 2-5 B-3	There is reference on page 2-5 to "frequent dialogue" between the DOE and EPA. More should be said to assure the public that such dialogue will be publicly conducted and recorded.	The RCSMP was intended to assure stakeholders that their participation is important. Additional emphasis has been placed on this point in the final version (See also response to comments A-3 and A-11).
p. 2-11 B-4	The document contains the cursory conclusion that "[a]s with site characterization, facility characterization is, for the most part complete." Given the number of unresolved technical issues, such a statement cannot fairly be made. For example, the nature of brine flow in the Salado, the anticipated fracture behavior of the anhydrites, the transport model appropriate to the Culebra, and the gas generation model remain unresolved.	This statement was not intended to minimize the importance of any experimental studies aimed at resolving modelling uncertainties. However, the observation that site and facility characterization are now down to a few specific topics and not the broad studies required initially underscores the point being made here. This statement has been clarified in the RCSMP.

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SECTION/ PARA	COMMENT	RESPONSE
p. 2-11 B-5	It is said that DOE shall "modify design elements in response to performance assessments to improve confidence in the disposal system by mitigating uncertainty." If this means, as appears, that DOE will only initiate efforts to design engineered barriers and alternatives in response to perceived noncompliance or a specified level of uncertainty in a performance assessment, the approach is too narrow. Such design efforts should not be tied to the outcome of a performance assessment, because to date the performance assessments have been limited by arbitrary constraints, such as the nature of anticipated exploratory drilling, adopted to create an objective test of compliance. These are arbitrary limitations upon the broad range of possible future events, and engineered barriers and alternatives should be designed to anticipate the possible future, rather than an artificially limited conception of the future. Further, if it is proposed that some particular level of uncertainty shall trigger work on engineered barriers and alternatives, the document should explain how and when such uncertainty will be identified. At the latest quarterly meeting there was discussion of a broader approach to engineered barriers and alternatives, and, if DOE intends to follow through on such an approach, such a discussion should appear in this document.	Additional descriptions have been added regarding the selection and use of engineered enhancements. The DOE believes that all will agree that to be arbitrary in the selection of engineered enhancements is irresponsible. Due to the high cost of implementing such decisions (both in terms of dollars and radiation dose), the DOE must have a deliberate process for decision making. As a minimum, enhancements will be considered, if appropriate, to achieve compliance. Further, they may be implemented to provide additional assurance of compliance, once again, if appropriate. These additional assurances will be implemented depending on the nature of uncertainty associated with whatever limits are placed on possible future events. Furthermore, the DOE is committed to perform the evaluations and to make the decisions in a manner that includes stakeholder participation. In this manner, involved and affected members of the public will understand the tradeoffs that the DOE is making and the basis for the tradeoffs. Further, the stakeholders have the opportunity to influence those decisions through their participation.

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SECTION/ PARA	COMMENT	RESPONSE
pp. 2-18 and 2-29 - 2-30 B-6	There are discussions on pages 2-18 and 2-29 through 2-30 of performance-based waste acceptance criteria; however, the development process is not described with sufficient concreteness to determine whether it is even feasible to develop usable waste acceptance criteria from the performance assessment process. For example, it is not clear whether the present level of conceptual model development is deemed sufficient to create performance based waste acceptance criteria or further experimental work, performance assessments, and sensitivity analyses are necessary before this can be done. It is not stated whether the waste acceptance criteria will include some idea of "loading" or distribution of various types of waste. We are not told how and when the preliminary "baseline inventory assessment" will be carried out (p. 2-29). Further, how the performance-based waste acceptance criteria will be integrated into an initial and subsequent compliance demonstrations -- which must be based on waste characterization data of some sort -- is not explained.	While additional information on a PBWAC is included, the detail requested is beyond the scope of the RCSMP. The concept of a PBWAC is not dissimilar to the waste profile or waste envelope approach used by RCRA facilities and regulators to assure only wastes compatible with the facility and its processes are placed in the facility. At WIPP, the application is complicated by the long regulatory time frame and the mandated human intrusion considerations. Consequently, a process like PA must be used to define the PBWAC.
p. 2-24 B-7	The content and timing of the technical baseline document (p. 2-24) is unstated. It is not explained exactly how the content will be determined nor how the preparation of this document relates to the existing process whereby the performance assessment program itself requests data from research groups.	Further detail has been added to the RCSMP.

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SECTION/ PARA	COMMENT	RESPONSE
p. 2-25 B-8	The document suggests that a RCRA permit for disposal may be obtained by modification of a prior permit (page 2-25). Given the large differences between a disposal RCRA permit and any conceivable test plan RCRA permit, it would seem that a modification procedure is not available.	The DOE feels that a permit based on a modification of the current application would be in the best interest of both the WIPP Project and the taxpayers. Much work on the behalf of both the DOE and the NMED is represented in the current draft permit. DOE feels there is still great value in continuing the present permitting process to assure a vehicle for dialog with the NMED regarding outstanding permitting issues.
p. 2-26 B-9	There is reference to an internal DOE determination of compliance with 40 CFR 191 and perhaps other regulations (page 2-26). It is not stated by what process and which "DOE internal organization" (p. 2-26) such a determination would be made. It was a continuing problem before Pub. L. 102-579 that DOE did not identify the internal organizations that would determine compliance. The problem persists.	DOE has established an internal milestone of mid-1994 to identify their process.
Format & Content Guide General: B-9	The Format and Content Guide has been drafted, obviously, prior to the issuance in final form of the disposal regulations, 40 CFR 191, or the compliance criteria, 40 CFR 194. As such, it is plainly premature.	Although the F&CG will be released prior to the issue of 40 CFR 194, the EPA has made a generally favorable statement regarding the document. The F&CG was fashioned after EPA's guidance for No-Migration Variance Petitions, and enhanced by information which we feel would be valuable in certifying to 40 CFR 191.

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SECTION/ PARA	COMMENT	RESPONSE
Format & Content Guide pp. 14-16 B-10	The purpose of the Guide is not clear; thus, it is not possible to evaluate the sufficiency of the information outlined to achieve such purpose. For example, the discussion of Compliance Analysis under 40 CFR 191 (pp. 14-16) consists largely of a paraphrase of the terms and guidance issued by EPA in 1985. Such discussion is unobjectionable but leaves open questions such as how much of the content of test results, models, uncertainty and sensitivity analyses and the like will be contained in the 1994 and 1995 showings or made available with them. There is a great need for full disclosure of information underlying the statements in performance assessment reports. If the 1994 'snapshot' (for example) will reveal little more than is contained in the performance assessment reports now in preparation, what is its purpose?	The basis for any submittal to a regulator (in terms of how much) will depend on the specific guidance provided by that regulator. For example, 40 CFR 194 will provide specific submittal requirements in terms of content. The submittal will be written to meet these specific requirements.
General B-11	There is an omission between pages 15 and 16.	The phrase "These program elements will feed the compliance database and the compliance technical ...." has been inserted at the beginning of page 16.

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	NMED Comments	
General C-1	The New Mexico Environment Department (NMED) is a stakeholder in WIPP related activities from the pre-disposal through the proposed disposal phases at the site. NMED's areas of interest include environmental protection and safety standards relating to the emplacement of transuranic radioactive waste and mixed hazardous radioactive waste at the WIPP site for long-term disposal. Comments on the draft documents are offered from the stakeholder perspective.	No response necessary.
General C-2	The WIPP Regulatory Compliance Plan addresses "trade off" compliance with disposal regulations through an evaluation of uncertainties. NMED, as a regulatory agency, needs to have a better understanding of this proposed strategy by the U.S. Department of Energy (DOE) in meeting regulatory requirements. NMED assumes that the "trade offs" apply to methodologies in meeting regulatory requirements and not to "trade offs" of regulatory requirements themselves. This strategy should be explicit in the document.	The NMED is correct in assuming that the "trade offs" apply to methodologies in meeting regulatory requirements and not to "trade offs" of regulatory requirements themselves. As stated in Section 2.1, page 2-2, "...the strategy is flexible in that it allows trade-offs between *technical activities* to achieve compliance (emphasis added). For example, engineered alternatives may be used to account for uncertainty in waste information." This is not intended to imply that compliance will be compromised.

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General C-3	This document states that "a compliance based approach to satisfy each applicable regulatory requirement" will be used to demonstrate compliance with regulations in Section 1.3. NMED believes that specific activities proposed by DOE to address "each applicable" regulatory requirement should be discussed with the appropriate regulatory agency and stakeholders to assure that the proposed activities address regulatory requirements.	The Compliance Status Report (CSR) will address each applicable regulatory requirement for 40 CFR 191 and 40 CFR 268.6. The CSR, through external review will be the vehicle through which the appropriate regulatory agency(s) and stakeholders may address regulatory requirements. The RCSMP, however, is not the appropriate place for such detailed regulatory discussions.
General C-4	The document states that DOE's strategy includes demonstrating continued compliance with the regulations through re-application of (RCRA) processes. This concept as stated is unclear to NMED. Does this statement mean that DOE will resubmit an application for permit of the disposal RCRA regulated wastes to include documentation on meeting RCRA requirements. This language should be specific and explicit in explaining DOE's intent.	The intent is only to acknowledge that the term of the NMD and the RCRA permit is limited to 10 years. This has been clarified in the text.
General C-5	The document refers to decommissioning of the facility prior to the facility being closed. NMED is unclear as to the decommissioning activities relative to regulatory requirements. DOE should explain the decommissioning activities as they relate to regulatory requirements.	Text has been added that describes decommissioning activities per 40 CFR 191, and closure, partial closure, and final closure related to RCRA.

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General C-6	The document cites regulations which DOE considers to be applicable. DOE cites "40 CFR 264, Subpart X (certain portions)". NMED believes that 40 CFR 264 in its entirety is applicable and that "applicable portions of 40 CFR 264 and Subpart X" should be the statement of choice. NMED believes that 40 CFR 268 requirements must be included as a part of the 264 submittal requirements for a Part B RCRA permit application.	This text has been clarified. The DOE agrees with regard to the two points raised by the NMED. However, only the Subpart X requirements are included in the RCSMP because they meet the criteria for inclusion; namely lack of significant precedent and unique application for WIPP.
General C-7	The document cites long term monitoring as being developed to address facility performance. RCRA requires ability to detect specific contaminants, this is specifically the case when discussing closure plans for a RCRA regulated site. There also, is no clear indication that long term monitoring will address media other than air as a transport medium. RCRA closure plans usually require soil and water long term monitoring for specific constituents.	This comment underscores one of the fundamental differences between the "operational" standards such as 40 CFR 264 and the "long-term" standards such as 40 CFR 191 and 40 CFR 268.6, as they apply to the WIPP facility. Because of the nature of the WIPP facility and the regulatory requirements for containment, travel times for contaminants are on the order of thousands of years, consequently, monitoring for contaminants is not considered to be meaningful. It is for this reason long-term monitoring guidance is aimed at evaluating overall disposal system performance to determine, in a reasonable period of time, if there is a significant or detrimental deviation from expected performance. During operations, on the other hand, travel times are relatively short and meaningful monitoring for contaminants can be performed. During operations, based on WIPP's design, the only reasonable pathway is airborne. Therefore the operational monitoring is developed around the air pathway. Part of DOE's strategy is to develop an approach regarding RCRA closure between operational and long-term. This approach will be geared to show that even during the RCRA post-closure period, soil and groundwater pathways remain inconsequential.

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General C-8	Language within the RCSMP document is unclear as to whether "testing" refers to actual tests to be conducted in the underground WIPP locations or if testing refers to sampling and monitoring activities for release constituents. DOE should clarify language used in the document to avoid miscommunication.	The text is purposely vague on the location of testing because the DOE will select the best available location based on testing needs. What can be stated, however, is that the DOE will not conduct any testing with radioactive waste in the underground at the WIPP prior to obtaining all needed permits and certification per the LWA.
General C-9	The Format and Content Guide for Title 40 CFR 191 and Title 40 CFR 268.6 Compliance Reports document is intended to be on outline for a report to be completed in mid 1995. The current document provides only broad direction in preparing the proposed 1995 document. NMED suggests that DOE implement a participatory procedure for stakeholders, to include regulatory agencies, in addressing the specific content of the actual compliance and management strategy document.	The FCG will not only guide the 1995 draft compliance submittal, but also the Compliance Status Report (CSR). The CSR will be submitted to stakeholders and regulators during the Spring of 1994. One of the purposes of the CSR is to initiate the dialogue suggested in the RCSMP. By submitting the FCG and the RCSMP for stakeholder review, we are in essence "addressing the specific content of the actual compliance strategy document" with interested parties.
General C-10	NMED thanks DOE for this opportunity to comment on DOE draft documents but suggests a longer comment period on such documents. Comments on these drafts are minimal based on the short turn around time on request for comments. NMED suggests a 30-60 day comment period on documents of such great regulatory concern and impact to the varied regulatory agencies and stakeholders.	Comment noted.

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General C-11	NMED suggests that DOE include identification of contacts whom stake-holders may contact on an informal basis as these documents are developed and finalized. This will facilitate agency and stakeholder participation in the development process.	Comment noted.

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	SRIC Comments	
General D-1	Your November 9, 1993, letter states: "DOE is aware that there are differences in the manner in which compliance must be demonstrated to support the 40 CFR 191 certification application and the 40 CFR 268.6 variance petition." SRIC is pleased that DOE now recognizes that two separate processes will be required.	Comment noted.
General D-2	There are additional compliance requirements that must be met before WIPP can receive wastes, including a RCRA permit from the State of New Mexico (listed on p. 1-5 and briefly discussed on pages 2-6 and 2-7 -- but see specific comment #4 below), a supplemental Environmental Impact Statement (EIS), and compliance with other federal laws as required by Section 9 of the WIPP Land Withdrawal Act (LWA). Neither of those latter two requirements are mentioned in the plan. SRIC would urge that future revisions of the document reflect those additional requirements. Thus, this plan falls far short of providing "a strategy by which the WIPP will demonstrate its ability to perform as a deep geologic repository." (p. 1-2) Rather, it seems to be only for regulatory compliance with some EPA regulations, rather than being a plan for all regulatory compliance or a plan for all compliance requirements.	The intent and scope of the RCSMP was not designed to address ALL applicable regulations to the WIPP. Instead, as indicated by the words "performance as a deep geologic repository" it was meant to present the strategy for compliance with key long-term disposal standards. These standards, for the most part, lack regulatory guidance and/or precedent for compliance. As such, the RCSMP is focused on these regulations. Other regulations, though no less important, have regulatory precedents, official guidance documents, or both, such as the National Environmental Policy Act, the Clean Air Act, and the Clean Water Act. The WIPP has maintained compliance with these as well as many other regulations for some time. The regulations identified in the RCSMP are not as "common" and therefore require a comprehensive, dedicated strategy and approach for compliance. This is the primary reason for the regulatory emphasis and focus of the document. A clarifying statement has been added.

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General D-3	The document states that "WIPP can accommodate the changing TRU waste inventory resulting from increased decommissioning and decontamination of facilities, environmental restoration treatment of low level wastes." (p. 1-2) Neither the WIPP LWA nor the Supplement EIS provide for such an expanded mission. If DOE is proposing such a mission change, SRIC believes that DOE must now initiate NEPA compliance. Moreover, future revisions of the Plan should indicate that such activities have not yet been approved. The regulatory compliance strategy also must better reflect the major unknowns that result from such activities.	The document states that "...*a flexible compliance strategy* is necessary to ensure that the WIPP can accommodate...." Merely by accepting wastes from decommissioning and decontamination activities does not constitute a change in WIPP mission. The waste produced by these activities is still considered weapons- or defense-related and is believed to be similar to waste already in the WIPP "inventory." What is meant by this statement is that these wastes may take on different (larger) physical forms, i.e., hot cell components. The iterative nature of this *flexible* strategy would allow the Performance Base Waste Acceptance Criteria (PBWAC) to be modified, as additional information becomes available, to accept such waste forms. There is no intent, stated or implied to change the WIPP mission with the RCSMP.

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p. 2-1 D-4	SRIC questions DOE's ability to develop an adequate draft compliance application by Spring 1995 (p. 2-1). For example, SRIC believes that engineered barriers and waste form modifications must be developed, and we have seen no DOE plan that shows such activities being complete by 1995. Moreover, SRIC doubts that an adequate draft compliance application can be developed so quickly after EPA's final compliance criteria are issued (presently proposed for early 1994). Rather than establishing arbitrary deadlines for important documents, SRIC believes that the plan should reflect DOE's activities and schedules and the agency's current understanding of EPA's schedules.	The WIPP will use engineered alternatives only if needed for compliance. It has not been proven that they are indeed needed. The same goes for waste form modifications. These options exist, but shouldn't be adopted or pursued unless absolutely necessary for *compliance.* The regulations themselves consider and incorporate provisions for protection of human health and the environment. Therefore, compliance with the letter of the law is adequate for safety. Until proven necessary for compliance, developing alternatives which go "above and beyond" the regulatory requirements is not responsible use of taxpayer dollars. Regarding the imposition of "schedules", the DOE has established several key dates for program planning purposes. If certain prerequisites are not complete such as the issuance of certification criteria in 40 CFR 194, or the completion of experimental activities, the DOE will not submit regulatory compliance documentation for agency consideration.

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SECTION/ PARA	COMMENT	RESPONSE
pp. 2-1 - 2-2 D-5	Several of the milestones listed on pages 2-1 and 2-2 are not adequately defined. For example, what are "Performance Assessment Input," "Technical Baseline," Compliance Status Report," and "DOE Approval Process?" Only the second term is even listed in the glossary and no references are listed that seemingly reflect the needed detailed information. The "Format and Content Guide" does provide some additional information about the March 1994 Compliance Status Report (p. 1), but it is not specifically referenced (and the "Guide's" discussion is too truncated to be very helpful). How does that report compare with the annual performance assessment reports done by Sandia Labs?	These terms have been added to the glossary. The PA reports assess repository performance in the general sense. The CSR draws from the PA reports, but makes a *compliance assessment* for the specific requirements in 40 CFR 191 and 268.6. The CSR will identify areas where more information is needed to achieve compliance, and provide appropriate program direction based on these areas.
p. 2-5 D-6	[This page] states that DOE will have "frequent dialogue with the EPA." The document should provide some information about how the public will be involved in such dialogue.	The EPA has committed, and the DOE has agreed to conduct all transactions in a public forum. Both agencies have maintained this position since the inception of EPA's regulatory program in late 1992.
pp. 2-7 and 2-25 D-7	[These] mention a "permit modification" possibility for a RCRA permit from the State of New Mexico. The New Mexico Environment Department has stated on several occasions that a new permit application must be submitted to cover disposal. SRIC agrees with that position. Thus, all references to "permit modification" should be deleted from the plan.	Discussions are still ongoing regarding the status of the RCRA permit. Once a formal decision has been made, the document will reflect that decision. It is important to note, however, that the NMED's statement was in the context of a new permit for disposal as opposed to a modified permit for disposal. Since a test phase permit was never issued, this statement is moot.

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SECTION/ PARA	COMMENT	RESPONSE
pp. 2-7 and 2-9 D-8	[These pages] indicate that Level 3 documents are internal and do not undergo stakeholder review. SRIC questions why such documents should not undergo stakeholder review and believes that all such documents must be publicly available.	These documents are "available" to the public, but will not be included in a formal stakeholder review. These documents are "working" documents and may undergo frequent revision. A stakeholder review would unnecessarily slow the revision process, and would result in little added value due to their technical nature.
p. 2-11 D-9	[This page] states "facility characterization is, for the most part complete." SRIC believes that neither site nor facility characterization is complete for the range of waste types and forms that DOE appears to be planning to bring to WIPP. Thus, we would request that either that language be deleted or that the plan reflect that some stake-holders question that statement.	This statement was not intended to minimize the importance of any experimental studies aimed at resolving modelling uncertainties. However, the observation that site and facility characterization are now down to a few specific topics and not the broad studies required initially underscores the point being made here. This statement has been clarified in the RCSMP. Past facility characterization has been conducted for a specific range of waste types and only wastes that coincide with those considered are permitted in accordance with the WAC.
p. 2-11 D-10	[This page] states that DOE will use an iterative process to determine what engineered barriers will be used. SRIC strongly disagrees that engineered barriers can be based on performance assessment results. Rather, engineered barriers are necessary at WIPP, just as they will be required at any other repository by Nuclear Regulatory Commission licensing regulations (10 CFR 60.113). DOE should not propose a lesser requirement at WIPP.	Engineered barriers will be used at the WIPP. The question is, "to what extent?" The text plainly states "...[the use of] *additional* engineered barriers..." The text does not say or imply that engineered barriers will not be used at all. As stated in comment response D-4, only those engineered barriers and alternatives needed for compliance will be considered. This position does not represent a compromise in safety or compliance. Furthermore, comparison to the requirements of the NRC is not appropriate because of the significant differences in the wastes that are dealt with (TRU versus high-level waste and spent nuclear fuel).

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pp. 2-18 and 2-29 - 2-30 D-11	[These pages] briefly discuss "performance-based waste acceptance criteria." Much more detailed information about such criteria is required before DOE can assume that they will be adequate for regulatory compliance. For example, will the "bounding characteristics" use existing models or those being developed? What levels of uncertainty are considered acceptable? What sensitivity analyses will be used? Will existing or new waste containers be assumed? In short, such criteria are high-risk. DOE must go through a much more rigorous, public discussion about such criteria before it commits to using them. Revisions of the plan should reflect this uncertainty and how DOE will address it.	The DOE agrees that before a concept such as PBWAC is settled on, a significant amount of additional detail is needed and significant stakeholder and regulator input is needed. The concept is introduced here to begin this process and to indicate that the DOE understands the importance of reconciling repository performance with waste characteristics.
p. 2-21 D-12	[This page], modified by your letter of November 19, 1993, briefly discusses DOE's views on human intrusion. The plan must reflect the position of stakeholders, such as SRIC, who believe that human intrusion at WIPP must be assumed to be a certainty. The plan and other DOE performance assessment documents must reflect the position that DOE must fully analyze the effects of human intrusion scenarios.	There is little uncertainty, as far as the DOE is concerned, regarding the treatment of human intrusion under 40 CFR 191. The standard states that institutional controls alone cannot rule out the possibility. In keeping with this guidance, the DOE includes intrusion in its performance assessment for 40 CFR 191. For RCRA, however, the EPA does not require consideration of such events so long as passive controls remain.
p. 2-26 D-13	[This page] discusses the "Secretary's disposal decision," but provides no detail about the process that will be used, including how the public will be involved. SRIC believes that DOE's internal decision-making should involve the public.	The DOE has committed to prepare a Supplement Environmental Impact Statement (SEIS) to support the decision to begin disposal operations. Public involvement is mandated by this process.
p. 2-27 D-14	[This page] should be changed to reflect that public hearings are assumed, since the public will certainly request such hearings and EPA's past history is to conduct them.	The diagram does not preclude the opportunity for public hearings. It does provide for public hearings (if needed) during the public comment period.

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p. 2-32 D-15	[This page] and the letter of November 19, 1993, briefly discuss assurance requirements of 40 CFR 191.14. DOE must provide much more detail about how it will demonstrate compliance with the assurance requirements as well as how it will implement them.	As specified in the RCSMP, this level of detail regarding implementation will be provided in various plans as required in the Land Withdrawal Act. This document is not intended to provide implementing details.

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SECTION/ PARA	COMMENT	RESPONSE
	Carlsbad Department of Development Comments	
Format & Content Guide, p. 15 1st sen 1st para E-1	It is not clear why active controls cannot be assumed after 100 years. It seems reasonable that the DOE would want active controls for the whole 10,000 year period. No one can predict whether or not this is possible so it should be assumed that it will be monitored. Recent history indicates that communications between the people and their institutions are improving at a rapid rate and that the likelihood for any misunderstanding will decrease over time. However, some form of passive controls should be developed and utilized just in case.	This statement merely states the EPA requirement that no credit can be taken for active controls beyond 100 years. If active controls could be assumed to remain intact and effective forever, human intrusion could be ruled out completely. However, in keeping with EPA guidance, they (active controls) are only considered to work for 100 years. EPA's rationale for limiting credit for active control to 100 years is their desire to have repositories provide adequate protection without dependance on positive actions by future generation. The DOE intends to perform performance assessments that exclude active controls after 100 years. However, the DOE also has committed to maintain active controls for as long as such controls are beneficial.
Format & Content Guide, p. 15 3rd para E-2	The third paragraph on page 15 discusses inadvertent drilling. This would have to occur with drillers who would not know that the WIPP facility exists and would require that nobody else would know. The likelihood of this seems extremely remote, if not impossible. The following undetected mishaps related to this type of intrusion is very unlikely.	The DOE agrees that inadvertent intrusion will be unlikely. Furthermore, the DOE will implement passive controls that will effectively reduce the likelihood of intrusion. These measures not withstanding, the EPA standards maintain such controls cannot be assumed to eliminate such intrusions. Consequently, the DOE must consider the effects of such intrusion, although unlikely, as specified in the regulations.
General E-3	One area that is not well covered is the establishment of an independent monitoring center such as the Carlsbad Environmental Monitoring and Research Center. Funding has been provided for the center operations but not for physical facilities. It is critical that these facilities are in place in time to get needed background information. To get a building built in time requires immediate funding.	The operation of an independent monitoring center will indeed provide useful environmental data as the WIPP progresses through the operational, closure, and post-closure phases. However, such a facility is not required for compliance with the long-term disposal standards discussed in this document. The argument for timely development of such a facility should occur outside this document.

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	EEG Comments	
General F-1	The RCSMP meets the need for an updated compliance strategy consonant with the requirements of the 1993 WIPP LWA. The notion and codification of a compliance-based approach is commendable. The time line given in Figure 1-1 of the RCSMP is probably the best that can be done at present to incorporate flexibility into a schedule, though the schedule seems ambitious. However, the plan proposed is weak in several respects. The comments that follow are based on other Federal regulatory agencies' experience with similar projects and documents. In completing the RCSMP, both DOE and EPA are well advised to avail themselves such experience.	Comment noted.

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General F-2	**The plan anticipates EPA regulations that, in some cases, have not been promulgated.** In the case of WIPP, EPA is the agency that decides and directs the determination of compliance, because EPA's regulations are the ones to be complied with. A clearer nexus is needed between EPA's needs and DOE's plans. While DOE's plans to outline the agency's approach and strategy to EPA indicates good communication, the RCSMP and the Format and Content Guide (FCG) may have to be rewritten after promulgation of 40 CFR 194, because 40 CFR 194 will form the basis for these documents. The RCSMP omits some topics, like engineered barriers, that received extensive comment in the Advance Notice of proposed Rulemaking for 40 CFR 194. Although the outline of the RCSMP is sufficiently broad and flexible to encompass other topics like engineered barriers. DOE should be ready to accommodate EPA in such amendments. Even procedures relating to compliance, like quality documentation, and data collection are properly directed by the regulatory, EPA, rather than by the applicant. Section 2 requires considerable input and direction from EPA. Issuing these documents in anticipation of EPA's promulgation may inadvertently give the impression that DOE will define the regulatory process. Moreover, any compliance requirements that exist in the WIPP LWA (PL102-579) should be incorporated into the RCSMP.	As the *certifier* for 40 CFR 191, it is clear the EPA has implementation responsibilities with regard to this standard and its application at the WIPP. Under the strategy outlined, the DOE will make a determination of compliance with 40 CFR 191, and submit this determination to the EPA for *certification* (40 CFR 194). Upon issue of 40 CFR 194, modifications to the RCSMP and the F&CG will be made as appropriate. Issuing these documents prior to the final issue of 40 CFR 194 should not be interpreted as an attempt to define the regulatory process, but rather as a proactive means to initiate dialogue with the regulator and as a means of implementing DOE's responsibilities under the various regulations. Compliance requirements stemming from the Land Withdrawal Act are not within the scope of these documents and will not be discussed unless they are directly related to the long-term disposal standards (40 CFR 191 & 268.6).

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SECTION/ PARA	COMMENT	RESPONSE
General F-3	**The proposed plan should recognize the preliminary performance assessments published by Sandia National Laboratories (SNL).** Considerable work has already been done and published on parts of a RCSMP. In 1989, SNL issued a preliminary compliance strategy document (SAND88-1452, Bertram Howery et al 1989) that covers much of the same ground as this strategy document, but is not even cited. SAND88-1452 was subsequently improved, following comments by EEG and others. These improvements are reflected in the 1992 Preliminary Performance Assessment for the WIPP (SAND92-0700, SNL 1993). SAND92-0700 responded adequately to comments on previous performance assessment, and demonstrates that the performance assessment process is on track. Although these documents concern themselves only with performance assessment modeling, they nonetheless provide a very good outline of how performance assessment should be used to demonstrate compliance with 40 CFR 191. Much of SAND88-1452 has been superseded by the more recently developed data and models of SAND92-0700. The following sections of SAND88-1452 are particularly relevant to the compliance strategy and should be incorporated in it:	While the DOE agrees the documents cited have been useful for the purposes for which they were intended, they only satisfy a part of the DOE's strategy for compliance. For example, data and code quality, which are not assessed by the PA are also of great importance. Likewise, waste characterization is significant. The RCSMP addresses these and other topics at a high level to illustrate their role in the overall strategy for achieving compliance.

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(cont. from previous page)	Table 2-1 and related text on methods of reducing uncertainty in performance assessment. The sections of Chapter III that discuss the overview of the philosophy and method of scenario selection and performance assessment. Although specific scenarios have been, and may be added, deleted, or altered, the philosophy of constructing scenarios of various processes and events as bases for performance assessment remains a valid part of the compliance strategy. The references and glossary. Volume 1 of SAND 92-0700 is also a good template for a compliance strategy, and a good summary of the methods used in assessing performance with respect to 40 CFR 191. This volume also includes a cogent and pertinent discussion of the meaning of "reasonable expectation of compliance" (p. 3-20) Volumes 1 and 2 should be incorporated by reference into the RCSMP.	

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General F-4	**The relationship between the proposed compliance strategy and the regulation is not clear, nor is a clear scheme presented for dealing with regulatory uncertainties.** Two components of a compliance strategy are particularly important: (1) determination and exposition of compliance determination methods - the ways by which compliance will actually be determined, and (2) a method for identifying and resolving regulatory uncertainties. Both of these may be addressed by a systematic regulatory analysis. One example of a regulatory analysis is presented below (See attachment to letter dated January 7, 1994, from Robert Neill of EEG). In the discussion that follows, the <u>organization</u> of a compliance strategy is being addressed rather than the specific content of the strategy.	Without having access to the full text of the NRC's work, it is difficult to put the EEG's comments into context. What does appear obvious is a disagreement over what constitutes an acceptable "compliance determination method." The PA methodology, by itself, does not satisfy all of the requirements in the standards. For example, PA does not address data and code quality, waste characterization, or monitoring requirements. In addition, if PA alone were used to make decisions regarding engineered alternatives, it could be misleading since such decisions must also consider cost, time, radiation exposure, environmental impacts and overall impacts on the disposal system. As stated in the RCSMP, the PA methodology, when applied with realistic data and assumptions, is a vital part of the compliance decision-making process. The DOE agrees that a systematic approach to developing and implementing a compliance program is important. The DOE is using an approach somewhat different the NRC's approach. DOE believes its approach will be effective for the WIPP. Briefly, DOE's approach differs from NRC's in two areas. First, DOE prepared a single, generic document, the Regulatory Criteria Document (RCD) which addresses regulatory uncertainty. The RCD is the basis for negotiating major regulatory issues with the regulators. Second, the DOE is using significantly more stakeholder involvement in their process. This assures that regulatory issues are given proper discussions and the basis for decisions is well publicized.

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p. 2-5 F-5	**The RCSMP is focused on regulatory uncertainties rather than on their resolution.** On page 2-5, the plan states that "DOE's approach focuses on an interpretation of such requirements as 'reasonable expectation' and 'reasonable degree of certainty.'" The two phrases represent uncertainties in requirements, not the requirements themselves. The focus of the plan should be on demonstrating compliance with statutory and regulatory requirements. Moreover, determining what constitutes a "reasonable degree of certainty" is EPA's province. DOE can and could identify regulatory uncertainties but their resolution is EPA's responsibility. Resolution can be achieved in a number of ways: informal consultation, EPA staff technical positions, guideline documents, and as a last resort, rulemaking. A prime example of an existing regulatory uncertainty is the question of human intrusion; if the forthcoming promulgation of 40 CFR 194 does not resolve the question of human intrusion adequately, EPA may consider a rulemaking, since this is such an important uncertainty. As was mentioned above, SAND92-0700, Volume 1 quotes EPA extensively on resolution of the uncertain language "reasonable expectation of compliance." EPA has gone to considerable lengths to clarify what it means by "reasonable expectation."	The DOE is not in full agreement with this comment. While the LWA has assigned certain responsibilities to the EPA, the DOE also has similar responsibilities. It must be acknowledged that the DOE is the "expert" agency with regard to the management of nuclear waste and the EPA is the "expert" agency with regard to the protection of the environment. Consequently, it is incumbent on the DOE to use its expertise in determining what constitutes a "reasonable expectation" or a "reasonable degree of certainty" and to justify that determination. The EPA has the responsibility to judge if the DOE "determination" of reasonable expectation provides an adequate degree of protection of the public and the environment. Obviously, both agencies have to deal with uncertainty which EPA admits is inherent in long-term predictions of performance. DOE must demonstrate that in spite of uncertainty the repository is expected to perform adequately and the EPA must be convinced that uncertainty is sufficiently bounded for them to render a positive decision. In this context, the DOE believes it is important to address both quantifiable and unquantifiable uncertainty. Quantifiable uncertainty can be handled through the PA process and can be considered adequate when the analysis results in compliance with numerical performance standards. Unquantifiable uncertainty, such as that associated with the characteristics of future societies can only be addressed by implementing measures that complement the containment ability of the repository. Such measures are addressed through the assurance requirements of 40 CFR 191.

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General F-6	**The plan does not make the clear and necessary distinction between compliance with 40 CFR 191 and RCRA compliance.** The two regulations require separate compliance strategies and separate guides for format and content of the application. Moreover, a detailed regulatory analysis of 40 CFR Parts 264, 268, and 270 could, and should, have been done as part of the Compliance Strategy and Management Plan. DOE should undertake such an analysis, preferably in the format suggested heretofore, as a prelude to identification of CDMs for 40 CFR Parts 264, 268, and 270. The application of 40 CFR Parts 264, 268, and 270, to the WIPP reveals major and marked regulatory uncertainties that can and must be resolved now. RCRA compliance must be addressed in documentation distinctly separate from compliance with 40 CFR Parts 191 and 194. Moreover, DOE should not assume that much of the existing No-Migration Determination (NMD) and Part B of the RCRA Permit Application can apply to the disposal phase at WIPP. The NMD, published by EPA in 1990, was for the Test Phase, and the permit application was only for the dry bin tests of the Test Phase. While the volatile organic compounds (VOCs) considered are clearly the same, the total quantities of these compounds emplaced in the WIPP and the calculation of concentrations of VOCs in the accessible environment are entirely different. Moreover, their behavior at pressures increasing to lithostatic, and their dilution by gas generated over thousands of years is	It is agreed that 40 CFR 191 and RCRA are quite different, and that compliance submittals should also be different. However, there are numerous similarities as well. The current Format and Content Guide was modified slightly from guidance for no-migration petitioners to accommodate 40 CFR 191 as well. EPA Office of Radiation and Indoor Air (ORIA) suggested in its letter from Margaret Oge to Jill Lytle that "...the Format and Content Guide prepared by DOE is a significant improvement over the current PA organization" and that the guide provides "a good starting point for discussions between the EPA, DOE, and other interested parties." It is initiating this dialogue that DOE hoped to accomplish with the FCG. Regulatory uncertainties in the regulations listed in this comment have been addressed in the RCD and discussions with the EPA were conducted. The RCD was used in preparing the CSR which is to be issued in April 1994. The CSR states the DOE position on many of the issues raised in this comment. Where such a position is lacking, dialogue and interaction with the Agency will provide valuable input to the formulation of such project positions and approaches. This dialogue is emphasized in the RCSMP.

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(cont. from previous page)	also different from behavior at atmospheric pressure and dilution by ventilating air. Moreover, the 1990 NMD states that "EPA generally believes that the issue of human intrusion is a long term question, not relevant to the short-term operation of the WIPP during the test and operational phases. In the short-term, DOE management of the site and RCRA permit controls will ensure limited access. Long-term issues would be addressed at the time a petition is considered for permanent disposal" (EPA 1990, p. 20, emphasis added). The promulgated NMD was a conditional NMD, and provides a clear indication that the question of human intrusion -- presently a prominent uncertainty in the RCRA regulation -- will have to be considered in detail for the disposal phase of WIPP. There are many other differences between the requirements met in the NMVP and an analogous petition for a No-Migration Variance for the disposal phase. Table 1 summarizes the most important of these (see attachment to letter dated January 7, 1994, from Robert Neill of EGG. Details of these differences will not be commented on here.	

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	EEG Comments on Format and Content Guide	
General F7	DOE is to be commended for including a Format and Content Guide (FCG); the 1989 Compliance strategy did not include one. However, this FCG does not include existing information and detail that are presently available to DOE. For example, the format and content of the RCRA permit application and No-Migration Variance Petition (NMVP) are not included. Much of the RCRA format and content guides have already been determined in the sense that EPA has issued a No-Migration Determination (NMD), and the New Mexico Environment Department did issue a draft RCRA permit, for the bin and alcove tests. The contents of the NMVP and the RCRA Permit application for the disposal phase will be quite different, but the nature of the information -- the format -- will most likely be the same. This being the case, the subject FCG for RCRA permitting should be much more specific as regards the particular VOCs that are the subject of the applications and the particular concentrations of these VOCs that are not to be exceeded, how the calculations of compliance are to be made, and how compliance is to be monitored. The format and content of a new NMVP and a new RCRA Permit application should be clearly distinct and separate from that of the certification application under 40 CFR Parts 191 and 194.	This FCG is general by design. While information exists for RCRA compliance submittals, the same cannot be said for 40 CFR 191 or 194. It would be presumptuous for the DOE to develop a FCG for 40 CFR 191 when no guidance yet exists. As such, this FCG is general in its content to provide a means of opening dialogue with the regulator on this topic. As you have stated, RCRA format and content guides have in essence been determined due to the fact that EPA has issued a No-Migration Determination (NMD), and the New Mexico Environment Department did issue a draft RCRA permit for the bin and alcove tests. As mentioned above and in the response to comment F6, the current FCG is derived from RCRA No-Migration Variance Guidance. Its content, therefore, should be suitable to the EPA for the purposes of a NMVP for disposal. In addition, and as mentioned above, ORIA seems to agree with the preliminary approach as well. Whether or not a final FCG should incorporate NRC FCGs will depend on dialogue with EPA and their requests to do so.

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(cont. from previous page)	The final FCG will be the product of considerable dialogue between the regulator (EPA in this case) and the applicant (DOE). In cases where the Nuclear Regulatory Commission (NRC) has been the regulator, it has taken the lead in formulating the FCG. DOE's ideas on the FCG are valuable, but the leading role in issuing the document obviously belongs to EPA. NRC has several FCGs codified as NUREG documents, and both EPA and DOE would be well advised to consult these. Comments on particular sections of the FCG follow.	
Sections 1.0, 2.0, and 3.0 F-8	These sections, that deal respectively with project overview, the site selection process, and the regulatory framework, are appropriate and acceptable. However, the outline consists almost exclusively of major headings, and has limited value. Section 1.3, that deals with regulatory framework of compliance, should include complete citations and precise quotations of applicable statutes and regulations. As has already been noted, while the extant RCRA Permit application and NMVP demonstrate and appropriate level of detail for the FCG, the relevant information needed for the disposal phase is quite different from that needed for the bin and alcove tests. The information in the extant RCRA Permit application and NMVP is, in fact, mostly irrelevant to the disposal phase, and the extant applications will require extensive modification and additions; they will have to be completely redone.	While the NMVP for disposal will be a completely new petition, the guidance for its preparation has not changed. This guidance, as mentioned above, has been provided by the EPA in the "RCRA No-Migration Petition Guidance." The content will be somewhat different, but will still follow the available guidance which is also reflected in the current FCG. The DOE disagrees with the comment that the current application is mostly irrelevant. If this were the case, the DOE would not be insisting that the existing application be modified as opposed to completely rewritten. The DOE has requested that the current Draft Permit be maintained and that provisions for disposal be incorporated through a revision process. The NMED has yet to make a decision regarding this proposal.
Section 4.0 F-9	DOE already has a great deal more information than is reflected in the outline of this section. Some specific suggestions for more detail are [as follows].	Comment noted.

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Section 4.1 F-10	Section 4.1 should identify the fraction of CH and RH wastes yet to be generated, and must allow for a rationale as to why any waste not yet generated should be mixed waste.	The section headings within each chapter are intended to serve as minimum topics. In the case of Chapter 4, a logical addition to a compliance submittal would be, as you have pointed out, a discussion on future waste inventory projections, and would likely become Section 4.1.3. Clearly, the FCG will not limit the content of a compliance submittal, but rather become the foundation for the presentation of all relevant material needed to certify (40 CFR 191) or make a determination of no migration (RCRA).
Section 4.2 F-11	Section 4.2 should include the fractions of CH and RH wastes that are mixed waste.	Same response as above applies. The suggestion of including the fractions of CH and RH mixed wastes in Section 4.2 may indeed be necessary in a complete statement of compliance. This decision will be made during the preparation of the petition/application based on the added value to the compliance argument.
Section 4.3.2 F-12	Section 4.3.2 can be very specific about information still needed to characterize VOCs in the waste.	Comment noted.
Section 4.3.3 F-13	Section 4.3.3 can even now specify the analytical methods by characterized, and quantified: gas chromatography, GC-mass spectrometry, etc.	Comment noted.
Section 4.3.3.2 F-14	Section 4.3.3.2 should specify the analytical data: the specific actinides and quantities thereof, and the specific VOCs and quantities thereof.	Comment noted.
New Section 4.4.3 F-15	A new section 4.4.3 -- "Reactions Among Waste Components" -- is needed to describe gas generation reactions, evaporation of VOCs, migration of VOCs through the container, etc.	Comment noted.

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Sections 4.4.1.1 and 4.4.1.2 F-16	The specific physical and chemical processes referred to by the titles of Sections 4.4.1.1 and 4.4.2.2 could be identified and listed.	Comment noted.
General F-18	A few of the requested specifics are discussed but this discussion needs considerable expansion. Wherever possible and feasible, the FCG should repeat information given in documents referred to, rather than citing the documents, particularly when the documents in question are obsolete or have been superseded.	As discussed previously, the DOE's intent was not to make the FCG a comprehensive document. Instead, it was to identify major topical areas for inclusion in an application, suggest a logical order for those topics, and initiate discussion. The compliance submittals will include such information, rather than by reference only. This is done in an attempt to provide all relevant information needed for the regulator to make a determination or certification.
Section 5.0 F-19	The FCG clearly intends that "monitoring" in Sections 5.2 and 5.3 be read as "environmental monitoring." However, particularly in radiation and health physics, "monitoring" can mean other things as well; e.g., personal or individual monitoring, that will doubtless be included in Section 5.1 on operational monitoring. Clarification is needed. Moreover, EPA should determine, in consultation with DOE, the monitoring program and data that it develops, as well as the format used for reporting. This section as written could have contained specific detail. DOE has environmental and occupational monitoring systems in place now, both on-site and, in the case of environmental monitoring, in the surrounding communities. Moreover, EEG has had an environmental monitoring program in place since 1985, and its reports are valuable in this regard. Finally, DOE should already have some designs and plans for post-closure monitoring; these could have been included to expand the outline of this section.	As mentioned in the response to comments F-7, the FCG is relatively general by design. Indeed, much more detail regarding the monitoring program exists, but the DOE chooses not to include such detail in the guide. As previously mentioned, one of the primary purposes of the guide is to initiate dialogue with the regulator. The general format provides a basis for such interaction.

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Section 6.0 F-20	Section 6.0 should be devoted to future test programs (Section 10.0 in the FCG, that should be deleted); the ongoing and completed test programs should not be a separate section. Test and experimental programs have been under way for some years, and some new programs are being undertaken, in order to produce information needed for certification. Descriptions of the tests and experiments, and the analyzed results, should be included in the appropriate sections. Section 6.0 should be devoted to descriptions of future tests.	In addition to providing an outline for compliance submittals for 40 CFR 191 and 40 CFR 268.6, the FCG was used as the template for the Compliance Status Report (CSR) completed in March of 1994. As stated in the Executive Summary of the FCG, the CSR will show a status of the WIPP compliance program. In order to do this effectively, Chapter 6 was used as a "roadmap" to the historical experimental program. This background is necessary to proceed through the Compliance Analysis and Regulatory Compliance Assessment sections (Chapters 8 & 9 respectively). Once a historical perspective is drawn and related to the status of compliance, future tests are identified (Chapter 10) that are needed to bring the Program into compliance. In simple terms, the CSR will 1) show where we have been, 2) show where we are, 3) identify the delta between where we are and where we need to be, and 4) show how we will get there. The current outline in the FCG is appropriate for accomplishing this task.
Section 7.0 F-21	Section 7.0 should include or cite the appropriate QA/QC schemes currently employed by various DOE projects.	The DOE feels that the compliance submittal should contain the items you suggest, but not the FCG. Lower level, site-specific implementing documents will specify information reflective of this level of detail, and in turn, will be included in the appropriate compliance document (RCRA or 40 CFR 191).

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Section 8.0 F-22	Section 8.0 should be divided; it is particularly important that there be <u>two</u> sections on compliance analysis: one for 40 CFR parts 191 and 194, and one for RCRA. The rationale for this recommendation is discussed in the comments on the RCSMP. The outline of the present Section 8.0 of the FCG is applicable to performance assessment for compliance with 40 CFR Parts 191 and 194, but not for compliance with RCRA. An attempt to force RCRA compliance evaluation into this mode will distort the NMVP and the RCRA Permit application. RCRA compliance determination does not require the use of complex transport models or algorithms; the conservative approach assumes gas phase equilibrium and one is mostly just calculating gas dilution. It is important to note that the gas generation model (Brush et al 1993, Molecke and Lappin 1990, USDOE 1992) is not a model of VOC generation but of hydrogen, methane, and CO_2 generation, and its results affect RCRA considerations only to the extent that generated gas dilutes the VOC vapors present or forces movement of VOCs through the geologic medium. The only model developed that predicts VOC performance is that developed by Leikhus et al (1993) to represent VOC transport within a TRU waste drum. Moreover, RCRA compliance does not require a specific time frame, like 10,000 years. Formal elicitation of expert judgment need play little or no role in RCRA compliance. Fewer and far simpler alternative release scenarios and conceptual models apply.	As stated previously, the FCG was derived from RCRA Guidance for No-Migration Petitioners. It would follow that its content would be suitable for a RCRA-related compliance submittal. In addition, and as stated previously, the FCG is general in order to provide the latitude to the authors of compliance submittals to include all pertinent information necessary for a determination of compliance, without violating the format recommended in the FCG. The DOE plans to adapt this guide, as necessary, to satisfy the specific requirements of the standards. The FCG is only considered to be an indication of general content and format.

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F-22 continued from previous page	In sum, RCRA compliance needs a format and content guide all its own, that addressed RCRA compliance and does not confuse it with compliance with 40 CFR 191 and 194. The discussion on page 12 of the FCG promises that "DOE will describe waste mobility modeling techniques employed to complete and support demonstration of no migration." DOE is apparently planning to model and test assumptions about how VOCs move through the lithosphere until a model is found that shows no migration. This approach appears to be overly complex and most likely unnecessary. The conservative assumption of gas equilibrium, combined with the use of the soil standards for VOCs (Rosnick 1993) shows compliance. In any case, the equilibrium assumption is conceptually and algorithmically simpler, adequately conservative, and should be used, or at least used first. Moreover, any transport models available are understood and developed now, and should be specified in this discussion. Further, the statement beginning "The EPA will require..." could be read as gratuitous. The entire section on RCRA compliance should be rewritten by, or in consultation with, EPA.	The DOE agrees that with the recent statements by the Office of Solid Waste regarding the compliance points (i.e., soil based standards), the likelihood of a demonstration of compliance to the no-migration standard is extremely high. However, the DOE will seek to assure consistency in its compliance approaches used for 40 CFR 268.6 and 40 CFR 191 to the extent such consistency is appropriate. For example, the conceptual models may be different (that is, the RCRA model may be simpler than the 40 CFR 191 model) as long as they are not inconsistent.

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F-22 continued from previous page	Insofar as Section 8.0 addresses 40 CFR 191 and 194 compliance it is a reasonable, though excessively vague, outline of performance assessment. The cited report by Bertram-Howery et al (1989) and the 1992 performance assessment (SNL 1993) provide both better outlines of performance assessment and better and more pertinent discussions of its application. The ongoing performance assessments published annually and, from now on, biennially, by SNL provide an excellent basis and format for this section on the FCG. The discussion on page 14 mentions 40 CFR 191.13, 191.15, and 191.16, but does not mention 40 CFR 191.14. Compliance with 40 CFR 191.14 is nowhere mentioned. While performance assessment calculations will not be used to demonstrate compliance with 40 CFR 191.14, compliance must be demonstrated nonetheless. This section of the FCG should include discussion of active and passive institutional controls, and should incorporate the notion of use of engineered barriers to compensate for the existence of natural resources (40 CFR 191.13(e)).	

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Section 9.0 F-23	DOE might consider integrating the summary of regulatory compliance assessment, now relegated to Section 9, into the two sections that are given as Section 8. Integration into the relevant subsections of Section 8 would be desirable, and Section 9 could then serve as a summary that compares the results of compliance assessment with the applicable regulations and standards. In every case, precise regulatory citations should be given. Section 9.7 should adopt the NRC language -- "anticipated and unanticipated processes and events" -- because there is considerable literature on the meaning and interpretation of this phrase. The phrase "infrequent events and processes" is not defined in regulation and introduces a major regulatory uncertainty that would require resolution. If the term "reasonableness" is used in compliance determination, as is suggested on pp. 17-18, both DOE and EPA leave themselves open to the charge of fitting regulations to the existing situation rather than ensuring compliance. It is preferable to implement appropriate criteria rather than invoking "reasonableness."	The reasoning behind the level of detail present in the current FCG has been addressed numerous times in this response.
Section 10.0 F-24	Future test programs -- should become Section 6.0.	Previously addressed in comment F-20.
Section 11.0 F-25	Dealing with other Federal laws and agency regulations -- is appropriate as it stands.	Comment noted.
General F-26	DOE should not feel bound or limited to the number and nature of the appendices listed at the end of the FCG. More and different appendices may be necessary.	Comment noted. As you have stated, additional appendices may be necessary as supportive information to a compliance submittal. Information which clarifies and/or supports will be included if appropriate.

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SECTION/ PARA	COMMENT	RESPONSE
EPA ORIA COMMENTS		
General G-1 (RCSMP)	The document appears to address many of the appropriate areas related to regulatory compliance, however, it does not accomplish its stated purpose to clearly communicate DOE's understanding of the regulations and strategy it plans to use at WIPP.	The DOE believes the commentor is confusing "understanding" of the regulations with "interpretation" of the regulations. In this context, the former term is used to describe the DOE's overall view of the standards and the process by which compliance may be demonstrated and certified. For example, as illustrated in Section 2.4, the DOE understands that compliance will require the integration of technical information from a number of topical areas including the site, the facility, and the waste.

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SECTION/ PARA	COMMENT	RESPONSE
General G-2 (RCSMP)	First, the document needs to delete references to or clarify the use of the Test Phase as the basis for its compliance strategy since the radioactive wastes won't be tested at the WIPP site as contemplated in the WIPP LWA. Second, the document lists the applicable RCRA and 40 CFR 191 long-term disposal regulations, but does not provide DOE's understanding and interpretation of the regulations or recognize EPA's role in certifying compliance with 40 CFR 191. Other Federal laws, such as the Federal Facilities Compliance Act, are not addressed as might be appropriate given the document's title.	The first reference to the test phase, on Page 1-1, states that the "...DOE has recently announced that the WIPP will not conduct radioactive tests in the WIPP underground..." This statement adequately explains the DOE's position regarding the Test Phase. However, pursuant to this comment, the text citing Section 6 of the LWA, "Test Phase Activities," has been modified to reflect the Project's redirection regarding the Test Phase. The text also clearly recognizes the EPA's role as certifier for 40 CFR 191. For example, on Page 2-1 (bottom) the text states "...to assure that the compliance documentation will be adequate to result in certification by the EPA." and also in Section 2.1.1, where it is stated that the LWA provides "...the requirement that the EPA review and approve DOE documents which detail any tests at the WIPP which use radioactive waste as well as Waste Retrieval Plans for such tests and, **ultimately, certify compliance with the final disposal regulations;**" As mentioned in responses to other commentors, other Federal Laws (including the FFCA) are not discussed due to the limited scope of this document. Only those laws specifically relating to the permanent disposal of TRU mixed wastes are germane to the topic. As such, the title of the RCSMP has been modified to "The [RCSMP] for Demonstrating Compliance to Long-Term Performance Standards." See also comment A-2.

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General G-3 (RCSMP)	While the document stated that the purpose was to communicate to DOE management and external stakeholders, it needs to be revised to account for the disparate audience. For an audience of more than DOE management, the document should better define terms that have been developed by DOE and could be interpreted differently by different groups. Several examples are "compliance margin," Waste parameter," and "engineered barriers." In addition, the organization of the document could be changed to provide more of a step-by-step discussion. Suggestions about this are presented in the specific comments (later).	"Engineered barriers" has been defined in the Glossary. Reference to "compliance margin" has been adequately defined in the text. "Waste parameter" has been added to the Glossary.

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General G-4 (RCSMP)	Figure 1-1 is useful in identifying some internal DOE milestones, but some important items have been omitted, including the expected promulgation of the Compliance Criteria (40 CFR 194) in 1995 and EPA's determination of compliance or non-compliance. The strategy could identify DOE's ideal (but realistic) schedule for applying for certification, plus the major milestones listed at the beginning of section 2. The schedule and the document should also include as a milestone the completion of the total system performance study of potential engineered barriers, as agreed to by Margo Oge and Jill Lytle. In addition, DOE should make the commitment that the scheduled dates will be altered according to scientific and regulatory needs, such as the Administrator's decision on the application of certification, which may take from one to three years.	Figure 1-1 is intended to depict proposed phases and not specific milestones unless those milestones either begin or end a phase. Neither of the milestones mentioned in this comment qualify for inclusion on Figure 1-1. Caveats in the RCSMP already state that the information presented is not intended to be a "schedule," except for those dates established by Congress (per the LWA) and the Secretary of Energy. The milestones discussed need to completed to achieve compliance. An approximate timeframe is shown which, in met, will assure success to the Secretary of Energy's disposal decision date. The DOE acknowledges the importance of the promulgation of 40 CFR 194 and has included the following discussion as a footnote associated with the second bullet (40 CFR 194) on page 1-5: "The LWA §8(c) requires the EPA to issue certification criteria for the Administrator's certification of compliance with the final disposal regulations. The issuance of these criteria is critical to the successful completion of the activities in this strategy related to 40 CFR 191. The milestones and target dates for the completion of this strategy are dependent on a timely issuance of these criteria as mandated by the LWA." The following paragraph has been added at the end of Section 2.4.3: "The LWA, §8(c), requires the DOE to use both engineered and natural barriers, and waste form modifications, to the extent necessary to comply with the final disposal

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G-4 Continued		regulations. In this regard, the DOE and the EPA have reached agreement on two items. First, the DOE has agreed to perform a detriment/benefit study of engineered alternatives that would be appropriate for the WIPP. This study will be documented in a written report. Second, the DOE has agreed to include this study in its certification application for information since the requirement to perform this study does not stem from 40 CFR 191.
General G-5 (RCSMP)	Where feasible, the document ought to identify measures that can be used to demonstrate success to internal DOE management and to the rest of the audience. An example would be achieving a certain level of knowledge about waste at each waste generating facility. It would also be useful for the document to identify the milestones DOE plans to accomplish before applying for certification and in what timeframe before the application submission they will be completed (e.g., all laboratory studies completed and analyzed by (date), computer models available one year before application submission, etc.).	As a high-level document, this level of detail was not included. This type of information should be included in lower-tier implementing documents (see Figure 2-2). One of the key elements of this strategy is that of flexibility. Stating details such as this would compromise this element. This is not to say that such information is not presented elsewhere. For example, the milestones and dates you have suggested are documented in tools such as the Disposal Decision Plan.
General G-6 (RCSMP)	Lastly, section three does not substantially describe DOE's role in the process. This could be facilitated by a better delineation of DOE's role in the previous sections. What are the respective roles of the DOE Headquarters and Carlsbad offices? The section also omits a discussion of the waste generators' role and responsibilities. It would be valuable to include this information because presumably the waste generators will have a large role in waste characterization and other activities crucial to the performance of the repository.	DOE's role is described in Section 3.1 by such terms as "owner and operator," "ultimate responsibility and liability," "leadership," and "integration." The roles of the various DOE branches is not relevant since all responsibility for compliance at WIPP lies with the CAO. While the degree of discussion regarding the generators requested by this comment is beyond the detail of the RCSMP, the following bullet has been added to Section 3.1. "Assures ongoing and timely coordination with the waste generators with regard to waste characterization activities need to both determine and to assure regulatory compliance."

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General G-7 (FCG)	The FCG presents a good outline that appears to cover most of the areas of concern. It should prove useful in ongoing discussions between the DOE and the EPA. Although we do have some comments on the outline in the attachment, our comments are primarily on the implementation of the outline.	Comment noted.
General G-8 (FCG)	A major concern is the appropriate use of references. EPA recognizes that references will need to be used to substantiate materials in the PA, but a review of the PA should allow the reader to understand DOE's entire process and rationale, without having to continuously go back to the references.	The CSR, which is not a statement of compliance nor a demonstration of compliance, will reference those materials used to make statements regarding regulatory **status**. Subsequent submittals such as the draft Compliance Application in 1995 and Compliance Application in 1996 will be submitted with <u>all</u> pertinent information used to draw regulatory conclusions. This information will be attached as appendices, included with the submittal as separate documents, or both. It is in the best interest of both the DOE and the EPA to include this type of material with the regulatory submittal(s).
General G-9 (FCG)	We are also concerned about the general QA guidelines and the incorporation of the guidelines to the PA inputs. Specifically, how are QA/QC going to be determined, and how will this information be reflected in the PAs? DOE may want to provide the QA information early in the process as a separate document. However, it would still be appropriate for the final compliance package to address this QA/QC information as its own section. Individual sections should also include discussion of specific QA issues.	Generally, Chapter 7 of the CSR discusses the establishment of QA/QC programs. The DOE will provide the EPA with the results of QA/QC activities such as assessments of older data, audits of ongoing programs, and the implementation of QA/QC programs whenever specifically requested. In addition, the DOE will include this information at an appropriate level of detail in the compliance documents.

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General G-10 (FCG)	While the FCG does encompass much of the information discussed in the Compliance Criteria, DOE should keep in mind, that the compliance criteria expected to be promulgated by the end of 1995 will represent the main guidelines for the DOE compliance application. The FCG may therefore need to modified after the Compliance Criteria are finalized.	Comment noted. The DOE realizes that the FCG will likely need revision after the final Compliance Criteria are issued.
General G-11 (FCG)	A final suggestion is for DOE to develop an example section that could be reviewed by EPA for content, level of detail and the use of references. By starting early with a small section, we could save time and effort in the future.	To a degree, the March 1995 draft submittal will be such a document. It is doubtful that an "example" chapter could be prepared any sooner that the 1995 draft. Therefore, the draft would in essence be the example you suggest.

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Specific G-12 (RCSMP)	**Re: Organization** The level of detail provide in the document and organization fall short of DOE's goal. In addition, the strategy should identify and discuss the regulations that apply to WIPP and provide a step-by-step discussion of how DOE intends to comply with those regulations specifically for the WIPP facility. Instead the document provides the following information in the order given: a. list of applicable regs. b. short discussion of the different levels of DOE documents c. basic discussion of general facility topics d. general description of the PA process e. general discussion of how information is documented (e.g. administrative record) f. very general discussion of the RCRA permitting process and radiation certification process g. very general discussion of the re-certification process h. very general discussion of DOE's roles and responsibilities i. summary of intent Items a, f, g, h, and i could have been presented first and in more detail. Items b, c, and d should be included in a more expanded step-by-step discussion of how DOE intends to show compliance.	The DOE has noted this comment and appreciates the input. However, the detail requested is best handled in regulation-specific documents.

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Page 2-2 G-13	What is the compliance margin discussed on page 2-2? DOE may be publicly establishing a de facto standard.	This section has been reworded to eliminate the term "margins" while conveying the intended concept. In essence, what is being addressed in this context are the measures that DOE adopts to mitigate some of the uncertainty associated with 10,000 year predictions. For example, DOE may choose to characterize waste to an extent beyond that required to minimally comply with the standards as a means of providing additional assurance of compliance. Similarly, DOE may opt to implement certain engineered enhancements as a means of providing additional assurance that the disposal system will perform as predicted. Such actions are not intended to build a numerical "margin," instead, they are to build confidence among the DOE, the regulators, and the public that compliance will be achieved. (See also comment A-9)
Page 2-1, 2-2 G-14	The document proposes that DOE will assess data quality, submit a CSR, and then develop and implement a plan to resolve identified data quality problems. Since the purpose of the CSR is to begin dialogue between the DOE and EPA regarding issues associated with the compliance approach and results, it seems logical that any data quality problems should be included in the CSR.	The DOE is in the process of evaluating data QA/QC. This process is not complete and therefore the conclusions cannot be incorporated into the CSR. The CSR, regarding data QA/QC, states that a new DOE Carlsbad Area Office document entitled the Quality Assurance Requirements and Description (QARD), is expected to be issued in August 1994. This document will establish the minimum QA requirements for the WIPP Program. This document will be consistent with EPA QA requirements. The QARD will provide controls for activities which assess the quality of previous work. If data of indefensible quality have a significant impact on compliance, corrective action will be implemented.
Page 2-10 G-15	It would be useful to present a table that lists the baseline measurements and the percentage of baseline measurements completed.	Information of this type should be included in a status document like the CSR. The status of a site characterization or baseline program should not be included in a *strategy* document.

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Page 2-11 G-16	Define and describe all "natural and engineered barriers." 40 CFR 191 defines the term "barrier" to include repository modifications and waste treatments.	The term "engineered barriers" has been added to the glossary.
Page 2-13 G-17	The last statement of section 2.4.4 concerning the implementation of the Waste Characterization Program Plan appears to be inconsistent with current practices. It is our observation that each generator/storage facility has its own procedures for dealing with the waste, and that waste characterization needs of the WIPP program are not currently recognized by at least some of the waste generators. It would be useful to include a description of how DOE plans to use the performance evaluation to drive waste acceptance. Perhaps this could be combined with section 2.9 on the inventory.	The text has been modified to read, "...implement a program based on the Waste Characterization Program Plan (DOE, 1992b) prior to certifying and shipping waste to the WIPP for disposal. These programs will be implemented through site-specific Quality Assurance Project Plans." Additional information regarding the interaction between PA and waste acceptance has been added to Section 2.9.
Page 2-13 G-18	What is the expected time-frame for having the waste characterized according to the WAC?	Waste characterization and waste certification should not be confused. Waste characterization is required by a number of regulations, some of which are strictly generator site requirements (such as the on-site storage of hazardous waste). In this context, characterization is an ongoing process. Once the final waste "envelope" is established for the WIPP, the generators will use their characterization data to evaluate whether or not the waste can be shipped. The process for screening waste for shipment is incorporated through the WAC. In this regard, the WAC process needs to be operating before the first shipment.

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Page 2-13 Section 2.4.5 G-19	The discussion regarding Monitoring Plans should be expanded. The document provides little information regarding DOE's intentions on this issue. There should be information on the short-term monitoring (required under RCRA for the haz. waste permit) and long-term monitoring (required under RCRA for the NMD and 40 CFR 191 requirements). DOE should also note that monitoring associated with the remediation of Solid Waste Management Units specified in the RCRA permit may be required for WIPP. The document states that the long-term monitoring will not address the detection of specific contaminants. This is unclear and DOE should expand on this statement. The detection of specific contaminants is <u>indicative</u> of any facility's performance. If DOE intends to conduct other types of monitoring for WIPP, then some general statements regarding the monitoring should be given in this section.	Short-term monitoring details are not within the scope of this document, since they are not relevant to long-term requirements. The monitoring associated with SWMUs per the RCRA permit is not included for the same reason.
Page 2-14 Section 2.4.7 G-20	This section should include a discussion of the process DOE intends to use to QA/QC the older data. What is the strategy should this data fail QA/QC?	This strategy is provided in the QARD, as mentioned in the response to comment G-14.
Page 2-19 Section 2.4.8 G-21	The last paragraph includes a quote of a recent EPA rulemaking. No regulatory cite is provided. Is the rule the same as cited later (EPA 1993c)?	There is only one quote taken from the reference. The text is correctly referenced. However, in the interest clarity, the quoted material has been set off by left and right indents.

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Page 2-19 Section 2.4.8 G-22	DOE states that models, input data, and relevant documentation should be available for the EPA upon request without restriction. This has not been the case so far. This is a good example of why schedules would be needed to evaluate whether or not this strategy is realistic in terms of achieving the compliance target date.	The text has been clarified to indicate the statements in this section apply to models used in compliance submittals. The issue raised by the comment has to do with models used for purposes other than compliance (such as preliminary calculations). The availability of these codes and data are not specifically included in this RCSMP since this issue is procedural and not regulatory. It is not obvious what is meant by the comment regarding schedules relative to evaluating the strategy.
Page 2-24 Section 2.5.4 G-23	DOE should clarify the relationship between the PA documents and the PTB.	The term is now being called the "Project Technical Baseline" or PTB. This term is first mentioned and defined in the RCSMP. The PTB document will contain the information upon which repository compliance analyses and compliance demonstrations will be based. WIPP PA reports were based on information obtained from a variety of sources. The Project Technical Baseline document will be a tool used by the DOE to consolidate this information for use in future performance calculations. By consolidating this information, the DOE can ensure that the technical information, approaches, and assumptions used in performance calculations and compliance applications for 40 CFR 191 Subparts B and C, 40 CFR 268.6, and 40 CFR 264 Subpart X are consistent and accurate.
Page 2-24 Section 2.5 G-24	The document should address DOE's information transfer and management system(s). Without an effective way of addressing information flow, the review process could be delayed.	Process details such as this should be included in lower-level implementing documents rather than an overall strategy.

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Page 2-29 Section 2.9 G-25	While the RCSMP appropriately concentrates on the WIPP facility, it provides very little information on activities (such as waste characterization) at the waste generating facilities that are an important part of the WIPP compliance. This section is unclear because the terms, such as "waste parameters" could have various interpretations. What is the goal that DOE has in mind here? Is the goal that DOE will make sure that the waste placed in the repository will not violate the standard, and that the PA will be used to look at various waste scenarios to see what "waste parameters" would violate the standard?	Section 2.9 coupled with Section 2.4.4 provide the framework for both including waste information and providing feedback to the generators with regard to acceptable waste forms, etc. This is consistent with the level of detail adapted for the RCSMP.
Page 2-29 G-26	The introduction to section 2.9 is an example of a passage that is awkwardly written and unclear at first reading. Much of the lack of clarity is due to use of terms undefined to non-DOE reader, such as "waste parameter," and which may have different interpretations. The following passage is our understanding of what DOE intends to communicate: "DOE's strategy is to use PA to ensure that the waste meets regulatory requirements. PA analysis will be used to determine the waste parameters (e.g., curie content of a drum, stacking of drums, solubility, waste form, etc.) that will provide acceptable performance. The PA results, operational considerations, and regulatory requirements will be used to develop criteria for accepting waste so that the repository will meet the standard and DOE's compliance margin goal. These PBWAC define a "performance-based inventory" or waste that is acceptable for disposal at WIPP. Is this passage consistent with the ideas that DOE wished to convey?	The suggested text is partially consistent with the DOE's intent. The first sentence of the suggested text is incorrect. PA cannot ensure that the waste meets regulatory requirements. PA can, however, identify wastes that are not expected to jeopardize the performance of the repository, thus helping to ensure that the *repository* meets regulatory requirements.

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Page 2-29 Para. 2 G-27	Will this inventory assessment be complete enough to truly and completely represent the total waste potentially provided by the generator complex?	If this comment is asking if we will know all the answers ahead of time, the answer must be "no" since all of the waste won't be (and needn't be) characterized a priori. However, the DOE will know enough about facility performance and what is acceptable in terms of waste characteristics to logically and rationally address any unanticipated results from future waste characterization activities.
Page A-5 G-28	Should the first bullet be the **Disposal** Phase Closure Plan?	The text has been revised to read, "Closure Plan." Reference to the test phase has been removed.
FCG (Other general comments) G-29	The discussions provided in the compliance analysis section, (pp. 12 - 16) would also be useful as part of the compliance discussion given in the RCSMP.	Much of the compliance analysis information in the RCSMP does in fact come directly from the FCG. The FCG contains more detail to assist in the production of regulatory documents. The DOE feels that such detail would be inappropriate in a strategy document such as the RCSMP.
G-30	The compliance analysis section should include analysis of conditional scenarios in addition to the final CCDF.	The analysis will discuss what reasonable alternatives were screened out and why. However, only one reasonable conceptual model is required by the standards.
G-31	DOE needs to provide information on how the March 1994 CSR will be used for the 1995 report and point out the differences between the two documents.	Additional information has been placed in the Executive Summary which clarifies the differences between the CSR and the draft submittal in 1995.

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G-32	The waste description section should include both existing and to-be generated waste, and each one should be discussed separately. A discussion on alternative engineered barriers should also be added to the waste description section in order to review alternatives to mitigate the impact of a drilling intrusion.	Both existing and to-be generated wastes are included since they both constitute the waste "inventory." The only differences between these wastes has to do with the characterization program needed to assure acceptability to WIPP. Legacy waste will have to be shown to be acceptable through an appropriate sampling and analysis program. Future waste can be controlled (through the generator process) to be acceptable with appropriate verification characterization. This difference is discussed in a separate section (Section 4.3.5). If alternative waste forms are selected through the compliance process, then these waste forms would be discussed under Section 4.3.
G-33	Since this project covers many disciplines, it would be useful for DOE to provide a glossary of the terms it is using in the documents. This would help prevent conflicting interpretations between EPA and DOE.	The CSR Glossary includes many of the terms unique to the DOE and its contractors. This glossary is consistent with the glossary in the RCSMP, although it contains more terms. Due to the numerous stakeholders and audience of the document(s), it is important to clarify these terms, as you have stated, to prevent misinterpretations between the EPA and DOE, as well as with other stakeholders (members of the public). In addition, and along the same lines, a list of "regulatory assumptions" has been included as an appendix to the CSR. This too will serve to reduce misinterpretations and to initiate dialogue between the EPA and the DOE.

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SECTION/ PARA	COMMENT	RESPONSE
Specific Comments on FCG Page 2 G-34	Please indicate how much material is going to be referenced and how much will be provided in the CSR? Are the references going to be submitted along with the report or are they readily available to the EPA?	The CSR will reference most data and information (most of which is derived from the 1992 PA Report) rather than include it. This is done primarily because it represents the current **status** of the WIPP Project relative to compliance with the long-term disposal standards. If the CSR was intended to be a statement of compliance, such information and data would be included. In presenting the current status, the DOE has the opportunity to state many of the assumptions and basic thinking used to identify areas of the program that are considered complete, and those areas which require additional testing or work. This is intended to focus dialogue with the stakeholders on the approach and rationale used to draw conclusions, rather than the information itself. An assessment of data QA/QC will determine the adequacy of information prior to the compliance application of 1996.
Page 3 Discussion G-35	It is assumed that the site description and characterization text will be accompanied by the appropriate table and graphical representations of the data.	Such tabular data will be referenced in the CSR, but will be included documents that make a declaration of compliance rather than status.
Page 3 Discussion G-36	(Paragraph 2) Please clarify if the site-specific information will include a discussion of the sampling and analysis methodologies and field work conducted to obtain the information.	In the CSR, sampling methods and descriptions of field work will not be included. If appropriate, a reference may be provided. In compliance documents like the draft application in 1995 and the submittal of 1996, this type of information will be included with or in the document itself.
Page 3 Section 2.3 G-37	This should include a history of resource use of the Delaware Basin.	"History" has been added to the content of section 2.3.

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SECTION/ PARA	COMMENT	RESPONSE
Page 3 Section 2.4 G-38	The CSR and/or the PA should clarify which chemicals and/or elements were or will be sampled for determining the Background Environmental Conditions in each of the media (ground water, surface water, air soils).	The CSR will not include this level of detail. This information will be included documents that make a declaration of compliance.
Page 4, Line 1 G-39	The information should identify water bearing units that could be potential aquifers.	"Potential aquifers" are implicitly included by identifying "...confining layers, and perched water tables;"
Page 4, Discussion, Para. 1. G-40	The hydrogeology section should include a discussion of the known and projected brine pockets located in the area. Information regarding the frequency of the occurrence, rate of flow, possible interconnections, mineralogy, etc....should also be included for all geologic units above the Salado and the Salado Formation.	The FCG will be modified to state that known and projected brine pockets will be discussed in compliance submittals. It is implied, however, that such information, as well as many other site characteristics will be discussed in detail. Adequate information must be supplied for the regulator to make a determination or certification statement without going through several iterations such as Notice of Deficiencies (NODs), requests for information, or other similar requests. Therefore, it is in the best interest of the DOE to supply the proper and necessary information which allows the regulatory agency to make a decision in a timely manner.
Page 5, last line G-41	Add after last line: "Each individual components' characteristics will be described in detail, with its performance requirements and its addition to the total confinement capability of the repository."	Because the FCG is intended as guidelines for both the CSR and compliance applications and demonstrations, the suggested text cannot be incorporated as written. This is because, as stated previously, the CSR will not include this level of detail. As such the following will be added: "For compliance submittals, each individual components' characteristics may be described in detail, with its performance requirements and its addition to the total confinement capability of the repository."

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SECTION/ PARA	COMMENT	RESPONSE
Page 7, Section 4.3.2 G-42	The 1992 FFCA requires that DOE prepare Site Treatment Plans for mixed wastes at the various generator sites throughout the country. Implementation of the plans may result in alterations to the waste form which ultimately is emplaced in WIPP. DOE may wish to note this as a possibility.	A statement has been added to reflect that implementation of the Site Treatment Plans required by the FFCA may result in waste forms which have not been considered in PA analyses. Comment incorporated.
Page 7 G-43	Need to include a Section 4.5 on the impact of alternative engineered barriers and the goal and objective of their potential use, e.g., meet standard by x margin, decrease respirable particles, decrease solubility, etc.	Engineered barriers are appropriately discussed in Sections 3.3 and 3.4. Stating a quantitative goal or objective is not appropriate, nor is quantifying "margin." The goal is compliance and nothing more. Margin, however, may be intrinsic of a certain engineered barrier or alternative. In such a case, the alternative which provides the most "margin" above other alternatives may be selected, provided cost and time of implementation are not prohibitive. The "Total System Performance Study" will provide detail on potential engineered barriers and alternatives and, while not required in 40 CFR 191 for compliance purposes, will be included as an appendix as supportive information.
Page 7 G-44	Discuss the waste parameters that DOE is evaluating. What are they and how are they expected to affect performance?	Section 4.2.1, "Bounding Criteria Based on Projected Disposal System Performance" will discuss the waste parameters and their impact (or more appropriately the lack thereof) to the repository.
Page 7 After last para., after line 2 G-45	add: "This demonstration will include a comparison of waste expected from all generator facilities. This comparison will consist of common waste characteristics and differences in waste form."	This comment potentially restricts the compatibility determination to something less than what is required by RCRA.

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SECTION/ PARA	COMMENT	RESPONSE
Page 9 G-46	The following statement is misleading and taken out of context: "The EPA has stated in the Test-Phase NMD that the only credible release pathway from the unit is by way of airborne emission." EPA's conclusion was applicable to only the release of hazardous constituents during the Test-Phase and did not include the Operational Disposal Phase as DOE is implying in this discussion. The following are excerpts from the WIPP Notice of the Final NMD that address monitoring: "Because of the nature of the tests that will be conducted in the WIPP and their relatively short duration, EPA has concluded that releases of hazardous constituents from the unit through brine, salt, or other geological media is implausible during the test phase. (55 FR 47703) ...EPA has concluded that the only possible migration pathway during the test phase is through the exhaust shaft. (55 FR 47709)	The qualifying statement in the sentence preceding the EPA statement is important here: "For the **operational** timeframe, monitoring will appropriately be focused on the air pathway." The DOE feels that the basis for EPA's statement was that the short duration of test phase would not allow enough time for migration through any other mechanism. The operational timeframe is not significantly different from the test phase when considering migration pathways other than air. Other monitoring methods would not be meaningful during disposal operations.

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SECTION/ PARA	COMMENT	RESPONSE
Page 9 Para. 1, lines 7-11 G-47	It is stated that, "The WIPP has already ... demonstrated that the equipment can be operated as required ..." We do not agree with this statement. The "demonstration" has not been made to the EPA Region 6 NESHAP standards or any environmental air monitoring activities.	For migration of hazardous constituents, the air monitoring system was evaluated during the 1993 Operational Readiness Review and was verified as meeting the requirements of the test-phase NMD. From a radioactive NESHAPS standpoint however, we agree with your comment in that the WIPP has not demonstrated the operational efficacy of the monitoring system to Region 6 of the EPA. This is consistent with the WIPP position on Radionuclide NESHAPS as defined in WIPP Compliance with 40 CFR Part 61 (Subpart H) for Airborne Particulate Emission (March 1994), which states that the WIPP will not release more than 1% of the standard (Subpart H) and therefore need only conduct periodic confirmatory measurements for compliance. Text has been modified to correctly reflect the extent of the monitoring system "demonstration."
Page 9 Para. 1, last line G-48	40 CFR 191.14 (b) states clearly that long-term monitoring is required to, "detect substantial and detrimental deviations from expected performance." Also this monitoring, "shall be conducted until there are no significant concerns to be addressed by further monitoring." This line should be added after the last line of paragraph one, "Post-closure monitoring procedures will be described with sufficient detail to show complete compliance with the 40 CFR 191 Assurance Requirements."	Comment incorporated.

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SECTION/ PARA	COMMENT	RESPONSE
Page 10 G-49	Discussion. Since the basis of the compliance demonstration is the experimental program, it is advised that DOE provide more of an emphasis than is implied in this section of the Guide. Add after the last line, "This discussion will include a list of all experiments done, date completed, all parameters measured or derived from experiments done, all range values derived, and a statement of the true confidence in these values."	Comment incorporated.
Page 11 G-50	In the QA/QC program outline, there should be a separate discussion on existing and to-be generated waste, and the target data quality objectives (DQOs) should also be listed. There should also be a discussion of the relationship between DQOs and the PA.	These details will be covered in the compliance documents as appropriate.

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SECTION/ PARA	COMMENT	RESPONSE
Page 12 Para. 2 G-51	DOE states that all reasonable pathways to the unit boundary will be examined. Define reasonable.	The use of subjective terms such as "reasonable" is common in dealing with long-term regulations such as 40 CFR 191 and 40 CFR 268.6. The reality is that absolute proof of compliance is not possible. In response to comments for the Final Rule of 40 CFR 191 (1985), the EPA states in clarifying the term "reasonable expectation" that "*unequivocal numerical proof of compliance is neither necessary nor likely to be obtained.... The use of this test of judgement is meant to acknowledge the unique considerations likely to be encountered upon implementation.*" The DOE agrees with this interpretation of the term and feels it is appropriate to use the term "reasonable" to qualify the extent of migration scenarios to be considered. The shafts present reasonable pathways to examine in a compliance analysis. Inadvertent human intrusion will also be considered as a pathway. An example of an unreasonable pathway would be a fracture created through the geology due to tectonic movement. This would be determined as unrealistic based on the seismic history of the area. Other phenomena such as a catastrophic meteor impact to the repository is considered unreasonable as well.
Page 13 Para. 1 G-52	Examples of benchmark tests of the models should be included to assist independent evaluation of each model.	Comment noted.

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SECTION/ PARA	COMMENT	RESPONSE
Page 13 Last Para. G-53	DOE states that for purposes of no-migration modeling, EPA has accepted that direct human intrusion into the repository will not occur during the time period in which active and passive controls are in place. DOE should provide the EPA reference from which this statement was derived. The WIPP Notice of the Final NMD (55 FR 47720) merely states that during the short-term test phase, DOE management and RCRA permit controls will ensure limited access, therefore making human intrusion irrelevant during the test phase.	In stating that, "during the short-term test phase, DOE management and RCRA permit controls will ensure limited access, therefore making human intrusion irrelevant during the test phase" it would also follow that applying this to the period of disposal is not inconsistent with the intent of the EPA.
Page 14 Para. 1, Line 1 G-54	"...parts 191.13, 191.15, and 191.16 for Subpart B..." is incorrect, it should be parts 191.13, 191.15 for Subpart B, and Subpart C.	Comment incorporated.
Page 14 Para. 2, last line G-55	The last line states, "The EPA also acknowledges that no procedures for demonstrating compliance have been provided or tested." What does this mean?	This means that 1) demonstrating compliance with 40 CFR 191 has never been done before (i.e., no precedent), and 2) the EPA hasn't clearly defined what will be needed to do so. It is understood that 40 CFR 194, when final, will provide helpful guidance.
Page 14 Para. 4, line 2 G-56	Any events omitted from the evaluation must be clearly explained. The reason why events are omitted must be given and the probability derived must be explained.	The text has been modified to reflect that releases omitted from the PA will be explained.
Page 14, Last Para. G-57	The statement, "(e.g., the mean or the median)" is incomplete. The complete statement from the guidance is, "(e.g., the mean or the median of the appropriate distribution, whichever is higher)." [Note that this standard may be changed in the compliance criteria.]	Comment incorporated.
Page 15 G-58	Note that the third paragraph will change with compliance criteria.	Comment incorporated.

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SECTION/ PARA	COMMENT	RESPONSE
Page 15 G-59	There is missing information between 15 and 16.	The phrase "These will feed the compliance database and the compliance technical ...." has been inserted at the beginning of page 16. See also comment B-11.
Page 15 Para 5, line 3 G-60	Please clarify "technical baseline?"	The term is now being called the "Project Technical Baseline" or PTB. This term is first mentioned and defined in the RCSMP. The PTB document will contain the information upon which repository compliance analyses and compliance demonstrations will be based. WIPP PA reports were based on information obtained from a variety of sources. The Project Technical Baseline document will be a tool used by the DOE to consolidate this information for use in future performance calculations. By consolidating this information, the DOE can ensure that the technical information, approaches, and assumptions used in performance calculations and compliance applications for 40 CFR 191 Subparts B and C, 40 CFR 268.6, and 40 CFR 264 Subpart X are consistent and accurate.
Page 17 Para. 9.6 G-61	Section to be added, "9.6.1, 40 CFR 191.14(b)"	It is understood that there will be monitoring associated with 40 CFR 191.14. In the CSR, these are addressed in Section 9.5, Assurance Requirements, and more specifically, Section 9.5.2 "Monitoring." As written, the FCG portrays Section 9.6 "Monitoring Requirements" more generally related to those monitoring requirements associated with 40 CFR 268.6.
Page 20 G-62	It may be appropriate to include compliance with the requirements of the 1992 Federal Facilities Compliance Act here as well.	The FFCA was not identified here because it is not specifically related to human health, or the environment.

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REVIEWED BY	
James A. Murphy 10 May 94 Signature Date	5/10/94 Signature Date

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Format and Content Guide for Title 40 CFR 191 and Title 40 CFR 268.6 Compliance Reports

May 1994

United States Department of Energy
Waste Isolation Pilot Plant

Carlsbad Area Office
Carlsbad, New Mexico

DOE/CAO-94-2004
Format & Content Guide for
Title 40 CFR 191 + Title 40
CFR 268.6 Compliance Report
May 94

DOE/CAO-94-2004

Format and Content Guide for Title 40 CFR 191 and Title 40 CFR 268.6 Compliance Reports

May 1994

United States Department of Energy
Waste Isolation Pilot Plant

Carlsbad Area Office
Carlsbad, New Mexico

FORMAT AND CONTENT GUIDE FOR TITLE 40 CFR 191 AND TITLE 40 CFR 268.6 COMPLIANCE REPORTS

I. INTRODUCTION

This Format and Content Guide was followed in preparing the WIPP Compliance Status Report submitted in March 1994 and will be used for the compliance documents scheduled for submittal in the Spring of 1995. The Compliance Status Report was issued to stakeholders in March 1994 and describes the status of associated activities on compliance with the requirements in Title 40 CFR 268.6 and Title 40 CFR 191. The Compliance Status Report focuses on 1) the information required for a demonstration of compliance, 2) preliminary results, 3) the areas of the WIPP program that are either not currently mature enough, or do not provide adequate margin for a demonstration of compliance, and 4) the areas of the WIPP program that will be focused upon to provide the remaining necessary information for use in the 1995 compliance demonstration reports. The Compliance Status Report is not intended to constitute a statement of compliance or a demonstration of compliance. It is intended to report the status of progress made to date in project efforts to achieve the required level of data/information necessary for the required compliance demonstrations. Comments on the Compliance Status Report from stakeholders will likely result in a modified Format and Content Guide, as will the promulgation of the EPA's Compliance Criteria for WIPP (40 CFR 194).

The March 1994 Compliance Status Report was designed to fill several project needs including the following:

1. Focusing the WIPP project on the compliance program and any relevant needs

2. Putting the DOE in a position to receive valuable stakeholder input relative to the appropriateness of the compliance documentation approach and completeness, the appropriateness of the proposed compliance driven experimental programs, and the ability to defend areas where the DOE believes it can demonstrate compliance

3. Establishing a direct link between the proposed experimental programs and needs identified in the compliance evaluation process

The Compliance Status Report differs from subsequent compliance submittals in that the Compliance Status Report does not make a declaration of compliance. Therefore, the

Compliance Status Report does not provide the exhaustive detail and supporting information that a compliance submittal would need in order for a regulator to make a certification or determination of compliance. The Compliance Status Report focuses on the status of the Project, acknowledging that compliance is not yet documentable. This status involves identifying the areas and system components relevant to compliance, briefly discussing results of the compliance analyses associated with the area/component, and in areas where compliance is not yet achievable, identifying the future action(s) needed to achieve compliance.

II. TABLE OF CONTENTS

1.0 INTRODUCTION

1.1 Project Overview
1.2 Site Selection Process
1.3 Regulatory Framework

DISCUSSION:

The project overview will include a discussion of the history of the WIPP project. Appropriate information to fulfill this requirement can be referenced in several existing WIPP documents.

The site selection process will be summarized to document that acceptable criteria were used and the appropriate factors were assessed in selection of the WIPP site. The required information can be referenced in the Final Environmental Impact Statement for the WIPP (DOE/EIS-0026), Appendix D.

This section will summarize the requirements of 40 CFR 191, Subparts B & C and 40 CFR 268.6, and discuss how the document is structured to address these requirements.

2.0 SITE DESCRIPTION/SITE CHARACTERIZATION

2.1 Geology

2.1.1 History
2.1.2 Stratigraphy
2.1.3 Geomorphology
2.1.4 Structural and Tectonic Setting
2.1.5 Surface and Subsurface Features
2.1.6 Geochemistry
2.1.7 Geomechanical Characteristics

2.2 Surface and Groundwater Hydrology

2.2.1 Geochemistry
2.2.2 Hydrological Characteristics
2.2.3 Applicable Natural Processes

2.3 Resources

2.3.1 Resource History
2.3.2 Natural, Extractable, Economic, Cultural

2.4 Background Environmental Conditions

2.5 Climatology and Meteorology

2.5.1 Historical Conditions
2.5.2 Current Conditions
2.5.3 Future Projections

2.6 Summary of Natural Processes

2.6.1 Conceptual Assessment of Future Site Conditions
2.6.2 Summary of Natural Events and Processes
2.6.3 Summary of Projected Performance of Natural Barriers

DISCUSSION:

This section will include a thorough discussion of the facility's natural environment, since the natural setting is critical to an assessment of adequate repository performance.

Geological descriptions must include both regional and local geology including structure, subsurface geology, geomorphology, geologic stability, soils, and topography. Site-specific information will be provided to the extent possible. Discussions of groundwater hydrology must include a comprehensive description of regional, local, and site-specific groundwater features. The information shall include identification of aquifers, confining layers, and perched water tables; hydraulic conductivity and storage; groundwater elevations and seasonal variations; aquifer interconnections; flow rates, directions of flow, and areas of recharge/discharge; and locations of wells that withdraw groundwater in the vicinity of the facility.

Surface water hydrology descriptions, like groundwater, will include regional, local, and site features that influence surface water movements. Maps depicting flood plains and relevant facility features serving to control run on and run off will be of particular interest to the regulator(s) performing the evaluation. Background air, soil, and water quality must be determined and discussed to allow for an assessment of the short-term and long-term impacts of the facility on the environment. The necessary information can be referenced in Chapter 4 of the NMVP; with supporting information located in Appendices J and L and in Addendum 4.0. More current information can be referenced in Chapters B and E of the WIPP RCRA Permit Application.

Applicable, naturally occurring processes that could affect projected repository performance must be described. These discussions must include a summary of applicable historical events and processes, projections of future site conditions, and a summary of the expected performance of the facility relative to natural barriers.

3.0 FACILITY DESCRIPTION

3.1 Design Specifications

3.1.1 DOE Facility Acquisition Process

3.2 As-built Design
3.3 Facility Boundaries
3.4 Engineered Barriers

3.4.1 Seals and Plugs
3.4.2 Backfill

3.5 Performance of Engineered Systems

3.5.1 Disposal Phase
3.5.2 Decommissioning Phase
3.5.3 Closure/Post-Closure Phase

3.6 Operations

3.6.1 Disposal Operations
3.6.2 Decommissioning
3.6.3 Closure/Post-Closure Operations
3.6.4 Contingency Planning and Emergency Response
3.6.5 Waste Removal
3.6.6 Waste Management and Safety Training
3.6.7 Reclamation and Restoration Activities
3.6.8 Active and Passive Controls

DISCUSSION:

The DOE will provide adequate detail to acquaint the reviewer with the overall facility and its operations. The information included will consist of a detailed facility design, the facility layout, a discussion of operating plans, the nature of the services to be provided by the facility, the location of the facility, and appropriate points of contact. In addition, a discussion of the level of independent review that the DOE obtains through its facility acquisition process will be included. The information provided will include a description of procedures designed to prevent hazards, contingency plans for addressing hazardous situations that may occur, personnel training plans, facility closure and post-closure plans, decommissioning plans, waste removal operations, and reclamation and restoration activities. The DOE will also include a description of the anticipated performance of the repository and applicable waste isolating features of the repository to include both natural and engineered barrier system components. For compliance submittals, each individual components' characteristics may be described in detail, with its performance

requirements and its addition to the total confinement capability of the repository.

The WIPP design development process will be described. The development of the WIPP repository long-term design is managed by making iterative assessments of planned active and passive institutional controls, repository design and engineered barriers, and potential engineered alternatives. The iterative process of long-term design development provides input to, and receives input from, the performance assessment, which supports the consideration of and potential development of specific modified design elements. This approach will allow for the modification of specific design elements in response to results of performance assessments to mitigate uncertainties where necessary and/or appropriate. The eventual final facility design will become a portion of the facility technical baseline to be used in compliance demonstrations.

The relevant information and appropriate level of detail that will be included is similar to that in Chapters B, D, F, G, H, I, and J of the WIPP RCRA Permit Application, and in Chapters 1, 2, and 3 of the NMVP. Appendices C and J, and Addendum 1.4 contain some additional supplementary information that will likely be useful. The information in the RCRA Permit Application will require some modification as it currently addresses the WIPP Test Phase only.

4.0 WASTE DESCRIPTION

4.1 Waste Inventory

4.1.1 CH Wastes
4.1.2 RH Wastes

4.2 Waste Envelope

4.2.1 Bounding Criteria Based on Projected Disposal System Performance
4.2.2 Inventory Control

4.3 Waste Characterization

4.3.1 Plans and Programs Summary
4.3.2 Waste Forms
4.3.3 Analytical Methodologies
4.3.4 Waste Characterization Information Summary

4.3.3.1 Process Knowledge Information
4.3.3.2 Analytical Data

4.3.5 Future Waste Characterization Activities

4.4 Waste Related Processes in the Repository Environment

4.4.1 Interactions With Natural Barrier Systems

4.4.1.1 Physical Processes
4.4.1.2 Chemical Processes

4.4.2 Interactions With Engineered Barrier Systems

4.4.2.1 Physical Processes
4.4.2.2 Chemical Processes

DISCUSSION:

This section will include identification and discussion of the specific family of wastes to be managed at the facility. A demonstration that the wastes are compatible with one another and with the facility will also be provided. The DOE will include specific information relative to the waste types and the sources of the wastes, applicable RCRA waste codes, descriptions of the waste generating processes, anticipated waste quantities, and any other relevant chemical and/or physical properties of the wastes that may affect the performance of the repository. A summary of the analytical methodologies to be used in waste characterization activities will also be

provided. This will be supported by discussions documenting the DOE's knowledge of the waste generating processes and/or hard analytical data where required. A discussion of future plans for waste characterization activities will also be discussed. For example, implementation of Site Treatment Plans as required by the Federal Facilities Compliance Act may result in waste forms which have not been considered in PA analyses, and would be considered in such a discussion of future waste characterization activities.

It will be necessary to discuss the Performance-Based Waste Envelope, the Performance-Based Waste Acceptance Criteria, and their relation to the phased approach and projected repository performance. It will also be necessary to discuss any strategies relative to waste inventory control and load management that may be employed to enhance repository performance while maintaining as flexible a set of Waste Acceptance Criteria as possible. Waste characterization program descriptions will be sufficiently detailed to allow for 1) an assessment demonstrating that the proposed acceptable wastes are compatible, 2) modeling of waste/waste and waste/repository interactions, and 3) modeling potential waste constituent migration pathways and rates of migration toward the boundary of the unit. The assessments will address projected chemical and physical processes involved in interactions between the wastes and both the natural and engineered barrier system components. The DOE will discuss the potential(s) for leachate formation and potential volatilization of organics such that transport/migration toward the unit boundary is feasible. The waste compatibility assessments will also address the potential solubilization and mobilization of hazardous constituents, and must include all components of the waste disposal system. Mechanisms, particularly where waste-related transformations could result in alterations to the original waste toxicity and/or mobility must also be addressed. These mechanisms shall include, at a minimum, biodegradation, hydrolysis, oxidation/reduction, and volatilization. Transformations related to, or driven by the presence of radiation must also be considered.

Relevant information can be referenced in Chapter 3 of the NMVP, Appendices B and N of the NMVP, and Chapter C of the WIPP RCRA Permit Application. The EPA has indicated that additional information, above what was provided in the Test Phase NMVP, will be required in the Disposal Phase NMVP. The required additional information is detailed in Section 7 of the Conditional No-Migration Determination (NMD) for the WIPP.

5.0 MONITORING

5.1 Operational Monitoring
5.2 Confirmatory Monitoring
5.3 Post-closure Monitoring

DISCUSSION:

Sufficient discussion will be included to justify the proposed design of the monitoring systems and the monitoring program. The operational systems and program shall be adequately described and defended to convince the reviewer that any migration of hazardous constituents and/or radionuclides from the unit will be detected at the earliest time possible. For the operational time-frame, monitoring activities will appropriately be focused on the air pathway. The EPA has stated in the Test-Phase No-Migration Determination that the only credible release pathway from the unit is by way of airborne emission. The WIPP has already installed the appropriate equipment, demonstrated operationally that the appropriate monitoring programs can be implemented, and demonstrated that the equipment can be operated as required to ensure any potential airborne emissions of both radioactive and/or hazardous constituents will be detected as early as is feasible. Long-term activities shall be described that assess facility performance rather than detecting potential contaminant migration via the soil and/or water pathways as equipment and methodologies do not exist that would make these types of monitoring options technologically or economically practical. Post-closure monitoring procedures will be described with sufficient detail to show complete compliance with the 40 CFR 191 Assurance Requirements.

Appropriate monitoring information can be referenced in Chapter 2 of the NMVP, NMVP Appendices H, I, J, and K, and NMVP Addendum 6.0. Chapter D of the WIPP RCRA Permit Application also contains some discussion of monitoring programs that will require some modification to address disposal operations.

6.0 TEST PROGRAMS

6.1 Status of Experimental Program Relevant to a Compliance Demonstration

DISCUSSION:

Discussions in this section will include a history of the WIPP experimental programs relevant to a compliance demonstration. This will include a listing of the experimental programs to date that have generated data/information that are used in the compliance evaluation(s). This discussion will include a list of experiments done, date completed, parameters measured or derived from experiments done, range values derived, and a statement of the true confidence in these values.

7.0 QUALITY ASSURANCE/QUALITY CONTROL PROGRAM

7.1 Waste Characterization Program
7.2 Models and Codes
7.3 Experimental Programs
7.4 Facility Data Collection Programs

7.4.1 Monitoring
7.4.2 Site Characterization

7.5 Facility Operations

DISCUSSION:

A QA/QC plan that addresses all aspects of the compliance evaluation shall be prepared and included in the compliance documentation and must be approved by the EPA. Quality goals and the approaches used to meet the goals will be included for the following aspects of the compliance demonstration:

- Waste sampling and analysis activities
- Environmental monitoring activities
- Field measurements of the facility setting
- Validation of computations, codes, models, and methods used in calculating critical facility parameters, and assessing compliance with the standards
- Control of construction activities and evaluation of construction materials.

QA/QC goals are to be set for each of the following:

Data Representativeness: The degree to which data accurately and precisely represent characteristic populations.

Data Accuracy: The degree to which data agree with accepted reference or true values.

Data Precision: A measure of mutual agreement between comparable data.

Data Completeness: A measure of the amount of data collected versus the amount that was expected to be collected.

The EPA has stated that it will give greatest credence to data collected under approved QA/QC programs. Relevant QA/QC program discussions can be referenced in the NMVP in Chapters 2 and 3.

8.0 COMPLIANCE ANALYSIS

8.1 Methodology Used for Assessing Disposal System Performance

8.1.1 Conceptual Models
8.1.2 Numerical Models and Codes

8.1.2.1 Validation
8.1.2.2 Verification

8.1.3 Statistical Techniques
8.1.4 Scenario Selection
8.1.5 Calculation of Regulatory Performance Measures
8.1.6 Uncertainty and Sensitivity Analyses

8.2 Reasonable Expectation/Reasonable Degree of Certainty

8.2.1 The Role and Use of Expert Judgement
8.2.2 Alternative Scenarios/Conceptual Models
8.2.3 Documentation of Assumptions

8.3 Summary of Compliance Determination Data

DISCUSSION:

Title 40 CFR 268.6 Requirements

The EPA does not provide any specific technical standards for the methodologies to be used in performing waste mobility modeling for demonstrations of no migration. It is, however, specified that the Disposal Phase NMVP must demonstrate, to a reasonable degree of certainty, that there will be no migration of hazardous constituents from the disposal unit for as long as the wastes remain hazardous. The DOE will describe waste mobility modeling techniques employed to complete and support the demonstration of no migration. The EPA provides general guidance regarding the use of waste mobility modeling techniques, and lists the minimum requirements for completeness of a demonstration of no migration. These completeness requirements are addressed in other sections of this table of contents.

It will be demonstrated that the chosen models are accurate and representative of the relevant waste constituents, and that all reasonable pathways to the unit boundary have been examined. Models, input data, and relevant documentation shall be discussed, substantiated, and made available to the EPA upon request and without restriction. The EPA will require that the

following QA/QC information be used for each model employed in the assessment:

Model Confirmation and Calibration: A comparison of the results of analytical and numerical models with measured field results. Calibration in this context refers to adapting the model to the specific conditions of a facility relative to its location.

Justification of Assumptions: All assumptions will be properly justified. Reasonable conservatism will be used and must be demonstrated.

Sensitivity Tests: Models will be chosen that are influenced the most by the most important parameters.

Model Accuracy Assessment: The DOE will demonstrate that the model reasonably represents the actual physical system; there are no computational errors in the numerical codes employed; and that there is a high degree of correlation between the calculations and the measured data.

The EPA discourages the use of proprietary models, since the models selected will necessarily be closely scrutinized to determine their reasonableness and accuracy. In addition, the models will be submitted for public comment. The selected models shall be designed to accommodate two phase movement (that is, liquid and gas), and will be relatively simple models that can be used easily by the regulator to check the DOE's calculations. The key input parameters that the models use will be listed and discussed.
Relevant discussions of Waste mobility modeling are included in Chapters 4 and 5 of the NMVP.

Operational assessments were performed for use in the NMVP using models. Both the long-term and the short term versions of the model were used to calculate exposures due to routine operations and during short term events such as accidents. The model used must be re-evaluated to determine its appropriateness for the disposal phase operations.

An assessment of environmental impacts, simply stated, is a comparison of the modeling results to the appropriate health based standards for exposures to humans. This environmental assessment of potential impacts in essence constitutes the evaluations required for demonstrations of no migration. The EPA provided the appropriate health-based standards for the Test-Phase

NMD since there were no published standards. The EPA has since proposed a set of health based standards as part of the RCRA Subpart S rulemaking (40 CFR 264, Subpart S). The appropriateness of using the proposed Subpart S health based levels in WIPP assessments for disposal operations will be discussed with the EPA. Descriptive information relevant to the evaluation of environmental impacts can be referenced in Chapters 4 and 5 and Appendices J and M of the NMVP.

The EPA has specified that the potential for infrequent events during the period of time that the wastes will remain hazardous must be examined and the impacts assessed. Reasonably expected man-induced events will also be considered. In applying the "reasonably expected" criterion, the DOE has ruled out direct human intrusion into the repository as long as certain active and passive controls are exerted at the site of the facility. The EPA has accepted this for the purposes of no-migration modeling. The prediction of infrequent events and associated uncertainty analyses will be included and can be referenced in Chapter 6 of the NMVP.

Title 40 CFR 191 Requirements

The DOE will determine compliance with parts 191.13, 191.15, for Subpart B and Subpart C by evaluating long-term predictions of disposal system performance. The evaluation of compliance will be made through the use of performance assessments. The EPA defines a performance assessment as an analysis that identifies processes and events that could impact the performance of the disposal system, examines the potential impacts of any such events on performance, and estimates the cumulative releases of radionuclides while considering the associated uncertainties caused by significant processes and events. The estimates will be incorporated into an overall probability distribution of cumulative release to the extent practicable.

The EPA acknowledges that it is appropriate to use rather complex computational models, analytical theories, and expert judgement, as available. The EPA recognizes that sole reliance on the numerical predictions of the models may not be appropriate and that qualitative judgements may be used to supplement such predictions for compliance determinations. The EPA also acknowledges that no procedures for demonstrating compliance have been provided or tested.

The EPA assumes that when predicting disposal system performance, reasonable projections of the expected level of protection from engineered and natural barrier systems will be considered. The only portions of the disposal system that the implementing agency may disregard are portions

of the system that make negligible contributions to the capability of the system to isolate the wastes. This will likely be difficult to defend without actually performing the calculation(s) to demonstrate negligibility.

The performance assessment will consider only those events that have a probability greater than one in 10,000 of occurring over a 10,000 year time period. Some release events may be omitted from the performance assessment if there is a reasonable expectation that the remaining probability distribution of cumulative releases will not be changed significantly by the omission. Omissions will be clearly explained and justified.

In the Title 40 CFR 191 Appendix B guidance, the EPA assumes that when practical the performance assessment results will be assembled into a Complementary Cumulative Distribution Function (CCDF) that indicates the probability of exceeding various levels of cumulative release. When the parametric uncertainties are considered, their effects can be incorporated into a single CCDF. If this single CCDF meets the 191.13(a) containment requirements, the disposal system will be considered in compliance.

In assessing compliance with the requirements of 191.15 and 191.16, "best estimates" (e.g., the mean or the median of the appropriate distribution, whichever is higher) for radiation exposures or radionuclide concentrations may be used.

The EPA clearly states that credit for active institutional controls in performance assessments cannot be taken after the first 100 year period. The EPA allows for the use of passive controls, but stipulates that they can never be assumed to eliminate the chance of inadvertent and intermittent human intrusion into disposal sites.

The EPA acknowledges that the most speculative potential disruptions are inadvertent human intrusions scenarios. The EPA also states that they believe that the most productive consideration of inadvertent intrusion concerns those realistic possibilities that may be usefully mitigated by repository design, site selection, or the use of passive controls.

The EPA specifies that the likelihood for inadvertent and intermittent drilling should be determined on a site-specific basis and should not be greater than 30 boreholes per square kilometer of repository area per 10,000 years for repositories that are situated close to sedimentary rock formations. The EPA also specifies that the consequences of such inadvertent

drilling need not be assumed to be more severe than a direct release of all the available groundwater in the repository horizon that would promptly flow through the borehole to the surface driven by natural lithostatic pressure (or 200 cubic meters of groundwater if pumping is required), and creation of a pathway for groundwater flow typical of a borehole filled by indigenous gravel/soils that might be expected to settle into such a borehole over time had it been left open. These requirements may change with the promulgation of the Compliance Criteria for WIPP (40 CFR 194).

As required in the 40 CFR 268.6 standard, the EPA in general will require a demonstration that the implementing agency can reasonably expect that the repository will perform adequately to meet the 191 environmental protection standards for radionuclide contaminants. The methodologies used in assessing repository performance are not required to provide complete assurance. The models for 40 CFR 191 assessments, like those for 40 CFR 268.6 assessments, will be made available to the EPA without restriction. The required QA/QC information will likely be the same level required for 40 CFR 268.6 assessments as well. The conceptual models for 40 CFR 191 and 268.6 assessments will be identical. The conceptual models will be closely scrutinized by the EPA and the public.

The DOE will describe an integrated approach to compliance document preparation. A flexible performance assessment process will be used to evaluate long term compliance with the standards. The compliance database and technical baseline will be used as the bases for conceptual model and model system development. The process will assess repository performance and identify and estimate parametric uncertainties.

Results from performance assessment modeling will be used in compliance analyses for prioritization and focusing of the experimental programs. The performance assessment results may also be used to modify existing experimental programs and/or to provide guidance to the generator facilities relative to repository waste envelope fluctuations that may allow for the use of innovative technologies in waste generation process modifications to ensure that future generated wastes will meet the WIPP Performance Based Waste Acceptance Criteria.

Performance assessment modeling will supplement the projections of repository performance. These program elements will feed the compliance database and the compliance technical baseline for the facility which will be used in supporting demonstrations of compliance. The compliance

database will be revised until it is sufficiently mature to satisfy the regulatory requirements, demonstrate a thorough understanding of the natural processes and their interrelationships, define and defend the conceptual models of the naturally occurring processes, provide ranges and distributions of parameters for use in the calculations, and assess interactive processes between the repository contents and the repository geology.

The results of the performance assessment will be compared to the 40 CFR 191 release limits. If the 40 CFR 191 guidance for assessments of repository performance is adhered to and the DOE is reasonably certain that the facility will perform as expected, the compliance demonstration will be at hand.

9.0 REGULATORY COMPLIANCE ASSESSMENT

9.1 Containment of Releases

9.1.1 40 CFR 191
9.1.2 40 CFR 268.6

9.2 Human Intrusion

9.2.1 40 CFR 191
9.2.2 40 CFR 268.6

9.3 Groundwater Protection

9.3.1 40 CFR 191

9.4 Individual Protection

9.4.1 40 CFR 191

9.5 Assurance Requirements

9.5.1 40 CFR 191

9.6 Monitoring Requirements

9.6.1 40 CFR 268.6

9.7 Infrequent Events and Processes

9.7.1 40 CFR 191
9.7.2 40 CFR 268.6

9.8 Program/Facility Modifications Designed to Increase Compliance Margin

9.9 Waste Acceptance/Waste Compliance

DISCUSSION:

The assessment of compliance will entail comparing available relevant information to the 1) appropriate health-based standards for the purposes of 40 CFR 268.6, and 2) appropriate radiation protection standards for the purposes of 40 CFR 191.

The results of the comparison of projected repository performance values to the regulatory requirements, while employing tools such as "reasonableness," will identify areas where

compliance can be demonstrated and substantiated with information already available. It will also identify some areas where remaining uncertainties relative to repository performance are "unacceptable" and/or "unreasonable." The DOE will provide a logical, defensible, and substantiated argument for those areas where compliance is to be demonstrated. For those areas when the compliance assessment indicates unacceptable levels of uncertainty and/or unacceptable substantiating evidence for a "reasonable" argument that compliance can be achieved, additional data/information will be pursued. A potential alternative to additional data/information gathering activities is modification(s) to the program or facility that may increase compliance margin to an acceptable level. Risk screening techniques will be employed by the implementing agency in choosing the most feasible approaches. Waste related modifications may also be considered, as appropriate.

10.0 FUTURE TEST PROGRAMS

10.1 Summary of Future Experimental Activities Necessary to Support a Compliance Demonstration

DISCUSSION:

This section will include a listing and description of the current experimental programs that are expected to provide data/information relevant to a current need identified in the compliance evaluation. The discussion will also include a listing of data/information needs driven by unacceptable levels of uncertainty and/or inadequate compliance margin that were identified in the compliance evaluation. Other potential drivers for additional information may be the need to reduce uncertainty relative to model assumptions, the identification of important model parameters not previously considered, results of sensitivity analyses indicating that parameters previously believed to be insignificant are potentially more significant than originally believed, or the emergence of new data not previously used in modeling activities. Any relevant schedule information shall be included as appropriate.

11.0 OTHER FEDERAL LAWS

DISCUSSION:

This section will include information relative to the facility's overall environmental protection program to ensure that the applicable regulations can be effectively and efficiently implemented and enforced at a single facility. For example, rules enforced by the Occupational Safety and Health Administration (OSHA) are complementary to the protective measures that the DOE and the EPA might impose on operations of a regulated facility. The discussion here will be similar to that in Chapter K of the WIPP RCRA Permit Application (DOE/WIPP 91-005) and Chapter 2 of the WIPP No-Migration Variance Petition (DOE/WIPP 89-003).

APPENDICES

1. Relevant Plans and Procedures
2. Code and Model Details
3. Experimental Program Data, Manipulations, Calculations
4. Waste Characterization Data