- MEMORANDUM FOR: John T. Larkins, Acting Executive Director Advisory Committee on Nuclear Waste
- FROM: B. J. Youngblood, Director Division of High-Level Waste Management Office of Nuclear Material Safety and Safeguards
- SUBJECT: TRANSMITTAL OF OVERALL REVIEW STRATEGY FOR THE NUCLEAR REGULATORY COMMISSION'S HIGH-LEVEL WASTE REPOSITORY PROGRAM

In accordance with the Memorandum of Understanding between the Advisory Committee on Nuclear Waste (ACNW) and the Executive Director for Operations (EDO) enclosed for your information and use are 12 copies of the "Overall Review Strategy for the Nuclear Regulatory Commission's High-Level Waste Repository Program" (ORS), which is being prepared for publication as a NUREG report. The preparation of this ORS was dependent on significant contributions from the Office of Nuclear Material Safety and Safeguards (NMSS), the Center for Nuclear Waste Regulatory Analyses (CNWRA), the Office of Nuclear Regulatory Research (RES), and the Office of General Council (OGC).

The primary purpose of ORS is to give guidance to the staff in conducting the license application and pre-license application reviews. In addition, it describes the strategy for developing our review capability which consists of the License Application Review Plan, performance assessment and other technical analysis capability, and research results.

Presenting all these strategies together in ORS also improves the identification, prioritization, and integration of major review and review capability development activities being conducted by both NMSS and RES.

Please feel free to contact me if you have any questions regarding the ORS. B. J. Youngblood, Director Division of High-Level Waste Management Office of Nuclear Material Safety and Safeguards

Enclosure: As stated

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# **OVERALL REVIEW STRATEGY FOR THE NUCLEAR**

# **REGULATORY COMMISSION'S HIGH-LEVEL**

# WASTE REPOSITORY PROGRAM

February 1993

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Robert L. Johnson

Division of High-Level Waste ManagementOffice of Nuclear Material Safety and SafeguardsU.S. Nuclear Regulatory CommissionWashington, D.C. 20555

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OVERALL REVIEW STRATEGY FOR THE NUCLEAR REGULATORY COMMISSION'S HIGH-LEVEL WASTE REPOSITORY PROGRAM

#### **1.0 INTRODUCTION**

# 1.1 <u>Purpose</u>

The primary purpose of the Overall Review Strategy (ORS) is to give general guidance to the Nuclear Regulatory Commission staff in conducting its license application (LA) and pre-LA reviews in support of the Commission's construction authorization decision for a geologic repository for the disposal of high-level radioactive waste (HLW). In addition, it generally describes the strategy for developing the LA and pre-LA review capability. These strategies for review and development of review capability both contribute to a more effective and efficient LA review process. This will contribute significantly to meeting the overall goal of the program: help ensure that the Commission can make its construction authorization decision within the 3-year statutory mandated time period.

The ORS, its complementary Regulatory Strategy (RS) (NRC, 1988), and two updates (NRC, 1991 and NRC, 1992) provide a consistent planning basis for the NRC HLW program for licensing a repository. The ORS guides the specific planning for reviews, review capability development, and research to support the annual Five-Year Plan and Budget preparation. In addition, the ORS establishes strategies that will, in particular, improve the identification, prioritization, and integration of Office of Nuclear Material Safety and Safeguards (NMSS) and Office of Nuclear Regulatory Research (RES) activities.

This document also will help inform other parties, such as NRC's Advisory Committee on Nuclear Waste (ACNW), U.S. Department of Energy (DOE), and the State of Nevada, about how the staff intends to conduct its reviews. Although the staff recognizes the value in other parties better understanding the staff's program, it should be clearly understood that the purpose of this document is not formal guidance to DOE. In particular, the review strategies given in this document are for staff use and should not be interpreted to provide direction for DOE's program and LA preparation. Clearly, it is DOE's responsibility, independent of the review priorities of the NRC staff, to provide in the LA a complete demonstration of compliance with the pertinent requirements of 10 CFR Part 60.

#### 1.2 <u>Background</u>

NRC programmatic requirements for a geologic repository are given in NRC's Five-Year Plan. This is the Commission policy document for carrying out NRC's overall statutory and regulatory responsibilities related to high-level nuclear waste regulation. It includes mission statements, policy guidance, and descriptions of major activities. One of the programs included in the Five-Year Plan is the NMSS High-Level Nuclear Waste Repository Program. As shown on Figure 1, this program consists of seven activities, of which four are being conducted during the present 5-year planning period of the pre-LA phase. The remaining three will be conducted during the LA review phase. These seven activities together make up the NMSS licensing activities important to the development of the ORS.

In October 1988, the staff prepared the initial RS and updated it in 1990 and 1991. The RS and its updates are important for two reasons. First, they help implement one of the goals of the program, by describing how the overall program would identify and resolve potential licensing issues. Potential licensing issues were defined as regulatory, institutional, and technical uncertainties. Second, they focus on how rulemakings and formal guidance documents such as regulatory guides, staff positions, and staff technical positions can be used to reduce uncertainties. These rulemakings and guidance documents are prepared under the Development of Regulatory Requirements and Guidance activity, which is one of the eight program activities cited above. Therefore, the RS gives guidance to the staff for conducting work in this one activity.

Although the RS also recognizes the contributions that pre-LA reviews make to identifying and reducing uncertainties, the staff considered that it would be useful to expand the descriptions of the activities related to these reviews as well as development of review and technical assessment capability. Therefore, the staff decided to develop the ORS to describe the staff's approach to implementing the four pre-LA and LA program activities dealing with reviews and developing review and technical assessment capability (i.e., Site Characterization and Pre-licensing Reviews, Quality Assurance, Technical Assessment Capability, Systematic Regulatory Analysis, and Conduct LA Review).

It is the staff's intent, therefore, that the RS and ORS complement each other in providing strategies for implementing all the activities of NMSS' High-Level Nuclear Waste Repository Program in the Five-Year Plan. Figure 1 illustrates the relationship of the two strategy documents to the program's activities, and Table 1 lists the program's products associated with the two strategy documents. Finally, these two strategy documents also help guide the activities of RES' Assessing the Safety of High-Level Waste Disposal Program that support rulemaking and guidance development, as well as licensing reviews (see Figure 1).

# 1.3 <u>Scope</u>

The ORS addresses both the staff's pre-LA review and LA review activities up to, and including, the completion of the Safety Evaluation Report (SER) and those pre-LA activities needed to develop the review and technical assessment capability for conducting the reviews. Therefore, it does not address the staff's subsequent activities during the licensing proceedings or subsequent licensing phases. Its present focus is on the reviews needed for the staff to make its safety finding in the SER. It does not cover, at the present time, the reviews that will be needed for adopting DOE's Final Environmental Impact Statement (FEIS), consistent with the Nuclear Waste Policy Act of 1982 (NWPA) and 10 CFR Part 51. However, in the future, the ORS might be revised to include a section on reviews related to adopting DOE's FEIS. The ORS is the staff's general strategy for the pre-LA and LA reviews that will guide the preparation of more specific review strategies for each of the requirements of 10 CFR Part 60. These specific review strategies will be included in the License Application Review Plan (LARP).

Consistent with NRC's responsibilities under NWPA, the ORS is concerned only with activities of and information relevant to DOE's Civilian Radioactive Waste Management Program at the Yucca Mountain site. Although DOE's Waste Isolation Pilot Plant is not within the scope of NRC's regulatory responsibility, the staff anticipates some transfer of technology and experience, particularly in the area of performance assessments. Review of DOE's compliance with the Resource Conservation and Recovery Act (RCRA) also is not within NRC's responsibility and, therefore, not within the scope of the ORS.

Finally, since the ORS supports NMSS' High-Level Nuclear Waste Repository Program, it is applicable only to the overall repository system, its subsystems (e.g., natural system and engineered barrier system) and the effects on the repository system from other repository interface systems, such as interim storage, waste producers, and transportation.

# 1.4 <u>Content</u>

The ORS consists of four sections in addition to this introduction. Section 2.0 summarizes the statutory and regulatory requirements, NRC policy guidance, and assumptions that form the foundation of the ORS. Section 3.0 describes the review objectives and strategies for both LA and pre-LA reviews. Section 4.0 describes the strategies for developing the LA and pre-LA review capability, and Section 5.0 describes how all the strategies will be implemented.

# 2.0 SUMMARY OF EXISTING REQUIREMENTS, POLICY, AND ASSUMPTIONS APPLICABLE TO THE OVERALL REVIEW STRATEGY

Statutory requirements of NWPA, and the NWPA, as amended in 1987, together with regulatory requirements of 10 CFR Part 2 and Part 60, provide a basis for the ORS. In addition, regulatory guidance and existing policy in the form of NRC's Five-Year Plan, RS and updates, existing review plans, and procedural agreements with DOE contribute to the ORS. Many of the specific strategies described in Sections 3.0 and 4.0 are based on existing requirements and policy. The applicable requirements and policy are summarized below and discussed in more detail in Appendix A.

#### 2.1 <u>Summary of Applicable Statutory Requirements</u>

NRC's licensing and related regulatory authority is defined by the Atomic Energy Act of 1954, as amended. This authority is made applicable to DOE (as successor to the Energy Research and Development Administration) under Section 202 of the Energy Reorganization Act of 1974. Congress further defined the NRC's role as it related to the disposal of HLW in geologic repositories in NWPA, as amended. The staff's LA review is based on the NWPA requirement that the Commission make a construction authorization decision within 3 years following DOE's required submittal of the LA to NRC. A provision allows for a 1 year extension, if necessary.

The staff's pre-LA reviews are also based on NWPA provisions for: 1) commenting on DOE's Mission Plan, Site Characterization Plan, and sufficiency of site characterization analyses and waste form proposal; 2) concurring on the need, if proposed, for DOE use of radioactive materials in site characterization; and 3) providing input to DOE's Project Decision Schedule (PDS).

Important to both pre-LA and LA reviews is the NWPA provision for allowing State and Indian Tribe participation. Finally, NWPA, as amended, directed DOE to characterize only one candidate site, the Yucca Mountain site in the State of Nevada, and terminate site-specific activities at all other candidate sites and all work related to a second repository. This has resulted in focusing NRC's reviews on DOE's repository program at the Yucca Mountain site.

Statutory requirements of particular relevance to the ORS are further described in Appendix A.

#### 2.2 <u>Summary of Applicable Regulatory Requirements and Guidance</u>

The Commission has promulgated regulations dealing with all aspects of the disposal of HLW in geologic repositories. These regulations are contained principally in 10 CFR Part 60, but also include provisions in Part 2 relating to procedural aspects of the LA review process and provisions in Part 51 pertaining to implementation of the National Environmental Policy Act (NEPA). The regulations, which conform to the requirements of Section 121 (b) of NWPA, address certain pre-LA reviews as well as the consideration of the LA. Other regulations that might influence the design of the HLW repository are 10 CFR Parts 71 (transportation) and 72 (fuel cycle facilities). These regulations could influence the design of the HLW repository through the natural interfaces among the transportation and interim storage facilities and the repository, particularly with regard to the design requirements of 10 CFR Part 60. Appendix A provides further descriptions of applicable regulatory requirements and guidance.

# 2.3 <u>Summary of Applicable Existing Policy</u>

NRC's existing policies related to reviews exist in many documents, including the Five-Year Plan, RS and updates, Division of High-Level Waste Management (HLWM) review plans, and the NRC-DOE procedural agreements. In addition, general agency and HLWM practice has also been a major contributor to formulating the ORS. Much of the ORS is built upon this foundation of policy and practice that has evolved over years of program implementation.

# 2.4 <u>Major Assumptions</u>

The degree to which the four major assumptions listed below are actually achieved will contribute to the effectiveness of the ORS.

1. Much of the information in the LA and references supporting the LA (including interfaces between the repository and other systems) will be developed and documented by DOE during the pre-LA phase and, therefore, will be available, in preliminary form, for the staff's pre-LA review. This includes complete access to data and documents prepared by DOE, consistent with the NRC-DOE procedural agreements. This assumption is based on DOE's intentions expressed in its Site Characterization Plan (SCP) (DOE, 1988) and its plans for developing the LA Annotated Outline (AO) and topical reports (Roberts, 1992);

2. DOE's preliminary performance allocations and performance assessments will be available for pre-LA reviews;

3. The staff's review guidance and interactions with DOE will be successful in leading DOE to resolve staff concerns and reflect resolution in the LA (resolution of concerns is at the staff level and such concerns can be raised in licensing);

4. The State of Nevada and other interested parties will participate technically so that the staff will be able to consider technical concerns of other parties during its pre-LA and LA reviews.

**3.0 OBJECTIVES AND STRATEGIES FOR PRE-LA AND LA REVIEWS** 

#### 3.1 <u>Objectives</u>

All the staff's reviews should be consistent with the applicable statutory and regulatory requirements and should not delay the implementation of DOE's program (in the absence of unresolved safety concerns). In particular, LA and pre-LA reviews should support the objectives stated below. Objectives for LA reviews are given first to emphasize the importance of the LA reviews in guiding other program activities.

#### LA Review Objectives

Conduct a review to determine the completeness and acceptability of DOE's LA and document the findings with respect to compliance with 10 CFR Part 60 in the SER within the first 18 months from when the LA is docketed so that the Commission can make its construction authorization decision within the last 18 months, in order to comply with the 3-year NWPA-mandated time period.

#### Pre-LA Review Objectives

1. Conduct reviews that support streamlining the LA acceptance and compliance reviews.

2. Conduct reviews and provide comments required by NWPA and 10 CFR Part 60 (i.e., SCP, Mission Plan, PDS, and preliminary site characterization sufficiency reviews);

3. Conduct reviews requested by DOE or agreed to between the staff and DOE (e.g., study plan reviews);

4. Conduct reviews to identify concerns that might be potential licensing issues and comment on DOE's resolution of these concerns to help ensure that DOE submits a complete LA that will be acceptable for docketing and conducting the LA review;

5. Conduct reviews to identify concerns with DOE's compliance with the site characterization requirements of Subpart B of 10 CFR Part 60 (e.g., use of radioactive materials and adverse effects on waste isolation capability of the site).

# 3.2 <u>Strategies</u>

This section discusses the LA and pre-LA strategies that the staff will use to achieve the objectives stated above. Strategies for LA review are given first to emphasize the importance of the LA review in guiding other program activities.

#### LA Review Strategies

The following five strategies will be used by the staff in its review of the LA:

1. Conduct a two-phase review consisting of an initial acceptance review followed by a compliance review;

2. Use compliance reviews to verify the acceptability of DOE's compliance demonstrations;

3. Use results of the pre-LA reviews and supporting investigations;

4. Use a systematic, audit approach for compliance reviews and prioritize these reviews by focusing on areas most important to repository performance (i.e., compliance with 10 CFR Part 60 performance objectives);

5. Select from four types of compliance reviews, including staff analyses and testing for the systematic, audit approach;

A description and rationale for each strategy is given below.

1. Conduct a two-phase review consisting of an initial acceptance review followed by a compliance review. Upon submittal of the LA by DOE, the staff will conduct an acceptance review to determine if the LA is complete and acceptable for docketing. This review will focus on the inclusion, in the LA, of those technical and procedural elements that are defined in 10 CFR 60.21 and 60.22 that may affect the issuance or denial of a construction authorization. If the LA is not complete, docketing will be denied, or DOE will be requested to provide such additional information as may be required for the LA to be docketed. This review will determine if the LA is consistent with the staff's preliminary sufficiency/acceptance findings (see pre-LA Review Strategy 5).

The staff's use of the acceptance review is required by 10 CFR 2.101 (f). In addition, the acceptance review is expected to contribute significantly to meeting the NWPA-mandated 3-year licensing time period by not starting the 3-year process until DOE submits the information needed for a complete and acceptable LA.

Once the LA is docketed, the staff will conduct a compliance review to determine the acceptability of DOE's demonstrations of compliance. The results of the compliance review will be documented as staff evaluation findings in the staff's SER. See Figure 2 for the LA review phases.

2. Use compliance reviews to verify the acceptability of DOE's compliance demonstrations. This review strategy recognizes that the staff will conduct the reviews and supporting activities needed to gain the confidence that DOE's compliance demonstrations are acceptable, rather than duplicate all of DOE demonstrations. It is not the staff's responsibility to demonstrate compliance, rather, it is DOE's statutory responsibility. The staff's compliance reviews will lead to evaluation findings shown in Figure 3. Staff's evaluation findings are further discussed in Section 2.1 of Appendix A.

This strategy is consistent with NRC's statutory licensing role (see Section 2.1) and NRC's general licensing philosophy that the safe operation of any nuclear facility is the responsibility of the licensee (i.e., DOE for the HLW program).

3. Use results of the pre-LA reviews and supporting investigations. Reports referenced in the LA will include a substantial amount of detailed technical information such as data, methodologies, detailed analyses, and data interpretations. The staff will conduct pre-LA reviews of some of these supporting reports. Therefore, where information in these reports has been reviewed and found acceptable, it will ordinarily not need to be reviewed again during the LA compliance review, unless additional information calls into question the staff's earlier reviews. However, the staff will review how the information is used in demonstrating compliance. In addition, quality assurance (QA) reviews and audits conducted during the pre-LA phase will give confidence that the information in the LA was obtained under an acceptable QA program. The staff's pre-LA technical and QA activities will be the basis for making preliminary sufficiency/acceptance findings (as described in pre-LA strategy 5) at the end of the pre-LA phase.

This strategy should streamline the acceptance review and result in compliance reviews that focus less on detailed supporting information and methodologies and focus more on how the detailed information was used to demonstrate compliance. Therefore, this strategy will contribute to the effectiveness and efficiency of the LA review and is considered essential for the staff to be able to conduct its LA review in 18 months. 4. Use a systematic, audit approach for compliance reviews and prioritize these reviews by focusing on areas most important to repository performance (i.e., compliance with 10 CFR Part 60 performance objectives). This review strategy consists of conducting a complete compliance review of the broad level of information in the LA and more detailed reviews on an audit basis (in selected areas), to determine if the detailed information supports DOE's demonstrations in the LA. This strategy can be envisioned as a "vertical slice" through a program area from broad to very specific levels.

This strategy describes a method to prioritize the review by identifying the higher priority areas that will receive more attention by the staff (see LA Review Strategy 5, below). Areas selected for detailed review will be primarily focused on technical uncertainties judged to be most important to repository performance. The staff has developed and will apply criteria to systematically identify the technical uncertainties most important to repository performance (i.e., technical uncertainties that pose a risk of noncompliance with one or more of the performance objectives of 10 CFR Part 60). These are referred to as key technical uncertainties (see Figure 3, which lists the selection criteria, and Appendix B, which describes the selection criteria, and defines the terms "technical uncertainty" and "key technical uncertainty"). The staff's judgment in applying these criteria will be supported by insights gained from reviews of DOE's program, staff performance assessments, and the work by other parties, including the concerns they raise.

This strategy also recognizes that because of the nature and complexities of the repository program, some flexibility must be maintained while conducting the staff's review. Therefore, the staff has flexibility in how it applies the LARP at the time of review; however, the intent is to follow the LARP unless there is a justified change that has been approved by management. Therefore, the areas and types of reviews described in the LARP are the minimum review that the staff would do. Changes to refocus a review might be justified to respond to new information, comments raised by other parties, or to go into more detail in order to adequately review a particular issue. In addition, some additional review areas also will be selected, at random, to avoid the possibility that DOE might concentrate its efforts in those areas where it knows the staff will focus its detailed reviews.

This review strategy not only ensures that the staff will conduct a complete review at a broad level, but also directs the staff to focus detailed attention on those areas most important to performance and that will likely be the areas most difficult to consider in licensing. Therefore, this strategy is intended to enhance the effectiveness and efficiency of the staff's review.

5. Select from four types of compliance reviews, including results of staff analyses and testing for the systematic, audit approach. The staff will select the type(s) of reviews from four different types of compliance reviews and supporting investigations appropriate for the review priority determined by the systematic, audit approach described above, to determine compliance with 10 CFR Part 60. These review types are described in detail in Appendix B and are shown in Figure 4. Therefore, the "vertical slice" of LA information will be reviewed in greater detail and further evaluated and verified, using the results of staff investigations. These investigations might include analyses where the staff uses the results of its own performance assessments by applying either available numerical models or models it has developed independently. It should be emphasized that the burden is completely on DOE to provide the data and assessments to support its performance assessments in the LA. In most cases, the staff will rely on DOE data, independently reviewed by the staff, as input to the staff's performance assessments. In addition, the results of staff field or laboratory testing might also be used to either verify some of DOE's results or simply to gain an independent understanding of a condition or process, to enhance the staff's ability to conduct detailed review. Such testing will be done by NRC's research program, which is further discussed in Section 4.0.

The technical reviews discussed above will be complemented by reviews of the QA information given in the LA and the results of the staff's QA reviews and audits conducted during the pre-LA phase (see LA Review Strategy 2, above). These reviews are intended to give confidence that the information in the LA was developed under an acceptable QA program.

Finally, the variety of reviews and independent staff investigations described above will provide evaluations of DOE's program from different perspectives and different levels of detail, resulting in complementary lines of evidence regarding the acceptability of DOE's compliance demonstrations in the LA. Therefore, this strategy should improve the effectiveness of the staff's verification and thus increase the staff's confidence in making findings.

#### <u>Pre-LA Review Strategies</u>

The following seven strategies will be used by the staff in its pre-LA reviews:

1. Conduct reviews consistent with the general phases and schedule of DOE's program;

2. Use a systematic, audit approach and focus technical reviews on supporting the Pre-LA review objectives;

3. Conduct focused QA reviews and QA audits;

4. Conduct reviews of DOE's issue resolution strategy and performance allocation process;

5. Conduct reviews of DOE's AO for the LA and make preliminary sufficiency/acceptance findings;

6. Support reviews by documenting concerns as open items and tracking DOE resolution of these open items, using a computer data base.

7. Support reviews with open interactions with DOE and other parties, together with considering concerns of other parties.

A description and rationale for each strategy is given below.

1. Conduct reviews consistent with the general phases and schedule of DOE's activities. During the pre-LA phase, DOE's activities can be grouped into three general phases, sequentially progressing through 1) planning; 2) testing, design, and preliminary performance assessments; and 3) preparing the LA, FEIS, and Site Recommendation Report. It is recognized that activities in these three phases overlap and many are repetitive (e.g., annual preliminary performance assessments). The staff's reviews will generally follow these three phases and, therefore, will initially emphasize reviewing DOE plans such as the SCP and study plans. As DOE begins to implement these plans in its testing and design activities, the emphasis of the staff's reviews will shift accordingly. Finally, even though testing, design, and preliminary performance assessments continue, the emphasis in the third phase will be reviewing DOE's final synthesis of information into final positions to be documented in topical reports, the AO for the LA, and Site Recommendation Report. The staff's preliminary site characterization sufficiency review, required by NWPA, will be important, in this phase, to identify potential insufficiencies that should be resolved by DOE. These comments will be based on the staff's preliminary sufficiency/acceptance findings that document the final results of its pre-LA reviews.

Phased reviews consistent with DOE's schedules are needed so the staff can give timely guidance and avoid delaying DOE's program.

2. Use a systematic, audit approach and focus technical reviews on supporting the pre-LA review objectives. Technical reviews should focus on each of the pre-LA review objectives identified in Section 3.1. The staff will not review all of DOE's activities nor all the data collected nor information developed by DOE. Instead, the technical reviews intended to support the LA reviews should take an audit approach and be prioritized, like the LA reviews, on those key technical uncertainties most important to repository performance (see LA Review Strategy 4). They should also use similar types of reviews and supporting investigations, as in LA Review Strategy 5. Supporting investigations, like the staff's iterative performance assessment (IPA) activities conducted during the pre-LA phase, either provide results that can be used in the LA reviews, or provide preliminary results supporting the staff's pre-LA reviews. Table 2 gives some examples to guide the staff in selecting the types of pre-LA reviews and investigations that would support the different types of LA reviews. As part of this strategy, the staff will also review DOE's resolution of the concerns documented by the staff (see pre-LA Review Strategy 6 on open item tracking). Furthermore, concerns documented as a result of technical reviews, and that might lead to the staff not docketing the LA (i.e., objections to LA submittal) if not resolved by DOE, also will be considered by the staff, in preparing its preliminary site characterization sufficiency comments required by NWPA.

Focused pre-LA reviews will be the basis for making preliminary sufficiency/ acceptance findings that will be used in preparing the preliminary site characterization sufficiency comments required by NWPA. The preliminary sufficiency/acceptance findings will act as preliminary LA acceptance findings. This will allow streamlining the acceptance review by confirming that the LA is consistent with what was reviewed in the pre-LA phase. Furthermore, the reviews will streamline the LA compliance reviews, where detailed information in reports that will be referenced by the LA can be reviewed before LA submittal. Furthermore, even reviewing preliminary information that is expected to change before being presented or referenced by the LA will both familiarize the staff with the information and improve the staff's capability to review this material during the LA review. Both of these benefits will further contribute to streamlining the staff's LA review.

3. Conduct focused QA reviews and QA audits. This strategy consists of reviewing DOE's QA plans, auditing DOE's program, observing DOE's audits, and conducting surveillances. These reviews and audits are for determining the acceptability of DOE's QA plans and obtaining confidence that the overall QA program is being implemented by DOE in an acceptable manner. In addition, the observation audits and surveillances give the staff an opportunity to judge the effectiveness of DOE's audits of its own QA program. The staff's approach of accepting DOE QA programs requires DOE to first pass judgment on the acceptability of any QA program it wants the staff to accept. In this way, the staff is ensuring that DOE retains responsibility for ensuring that the repository QA program is being conducted in an acceptable manner. All of these activities are aimed at ensuring that for safety/waste isolation activities, DOE has an acceptable QA program in place before the activity is started, and that DOE will acceptably implement its QA program throughout the pre-LA phase.

Audits or surveillances will not be performed for DOE's complete program; instead parts of DOE's program will be the focus of staff attention. To some extent, audits and surveillances will be focused in the same areas as the technical reviews, so there is technical involvement with QA audits, and for efficient use of staff resources. In addition, reviews of selected administrative procedures and their implementation will be conducted in such areas as sample management, data base access and control, and document control. Finally, this strategy includes evaluating concerns documented from technical reviews, to determine if they are indicative of concerns with the overall QA program.

This strategy has numerous benefits. First, based on years of reviews and audits, the staff will have confidence that DOE's compliance demonstrations in the LA have been prepared under acceptable QA programs. Second, confidence in the acceptability of DOE's QA program complements the audit approach of both the pre-LA technical reviews and the LA compliance reviews. Finally, accepting DOE's QA programs before work begins will avoid unnecessary costs or schedule delays that would result if testing had to be repeated to replace data that were unacceptable because of QA problems.

4. Conduct reviews of DOE's issue resolution strategy and performance allocation process. DOE's issue resolution strategy and performance allocation process described in DOE's SCP is intended to be a decision-aiding process by which DOE assigns performance goals and desired levels of confidence in those goals to each of the repository system, subsystem barriers, and their components, and eventually determines if enough information has been collected and adequately assessed to achieve those goals at the desired level of confidence. This process was agreed upon by the staff and DOE as the principle mechanism to make sure DOE exercises its responsibility for site characterization and demonstrating compliance with 10 CFR Part 60, in the LA. In addition to agreeing with DOE's issue resolution strategy and reviewing it in the SCP, the staff will review any revisions to the strategy, together with the implementation of the strategy throughout the pre-LA phase. Such reviews will help ensure that DOE's LA is based on a sound and well-documented technical decision-aiding process. The results of the focused technical reviews in the pre-LA Review Strategy 3 will help determine how well DOE's process is being implemented.

5. Conduct reviews of DOE AO for the LA and make preliminary sufficiency/ acceptance findings. DOE has started its iterative development of the AO for the LA, which will evolve into a draft of a potential LA (Roberts, 1992). It will be revised periodically throughout the pre-LA phase based on new information and NRC staff guidance. The AO will provide the staff with DOE's understanding and interpretation of the applicable regulatory requirements, the implementation of these requirements, and understanding of the format and content of the LA, as expressed in the staff's regulatory guide "Format and Content of the License Application for the High-level Waste Repository" (FCRG) (NRC, 1991). Therefore, the staff's review of DOE's AO will be an important way to give DOE timely guidance regarding how DOE is interpreting the applicable regulatory requirements and regarding what information is needed to prepare a complete and acceptable LA. Although the staff's AO reviews will use the draft LARP, the reviews will not be to determine compliance with 10 CFR Part 60, but will be to review the sufficiency of information necessary for a complete and acceptable LA. Therefore, near the end of the pre-LA phase, the staff will make preliminary sufficiency/acceptance findings based on the AO reviews and supporting technical reviews and QA audits. These findings will be confirmed in the LA acceptance reviews and by so doing will streamline the LA acceptance review. These preliminary sufficiency/acceptance findings will also be the basis for NRC's preliminary site characterization sufficiency comments required by NWPA.

Support reviews by documenting concerns as open items and tracking DOE 6. resolution of these open items, using a computer data base. This strategy involves documenting, in letters to DOE, the concerns identified by technical and QA reviews and QA audits. These concerns are also referred to as open items. 10 CFR 60.18 provides the staff with the responsibility to identify both objections and comments to DOE, throughout the pre-LA phase. To implement this provision, the staff has defined four kinds of open items related to concerns with DOE's program: start work objections, LA submittal objections, comments, and questions (see Appendix C for the definitions of these concerns). In its review of the SCP, the staff documented open items in its SCA (i.e., objections to DOE starting specific site characterization activities, comments, and questions). Throughout the pre-LA phase, the staff will continue to identify open items, comparable to those in the SCA, as it reviews other DOE documents, such as semi-annual SCP progress reports, study plans, technical reports, and topical reports. All open items are important for DOE to resolve. However, the staff might also consider some comments and questions to be critical to the staff's LA review, because lack of acceptable DOE resolution would prevent the staff from conducting a meaningful review, or the Commission from making a decision regarding construction authorization, within the 3-year statutory time period. For this reason, the staff considers this type of concern to be an objection to LA submittal. Concerns that would need a long time to resolve, such as new or additional testing or development of new or revised analytical methods, are examples of this type of objection.

After the staff has documented a concern with DOE's program as an open item. it is DOE's responsibility to resolve each open item. The staff will track DOE's resolution of these open items as part of the focused technical and QA reviews discussed above. When DOE has resolved an open item in a manner acceptable to the staff, the staff will document its agreement with DOE that the open item has been resolved. New information may require further consideration of an open item, causing it to be reopened. It is important to emphasize that, consistent with 10 CFR 60.18, such resolution of open items is only at the staff level, and therefore, can be raised in licensing. The staff expects that DOE will make every effort to resolve all the staff's concerns, particularly those identified as objections to LA submittal. However, it is possible that reaching an agreeable resolution for some objections could be difficult. Therefore, as part of the acceptance review of the LA and before a decision on docketing the LA, the staff will evaluate the effect of any unresolved objections to LA submittal, both individually and in combination with others, on the staff's ability to conduct a meaningful review and make a decision regarding construction authorization within the 3-year statutory time period. Unresolved objections to LA submittal would also be considered by the staff in preparing NRC's preliminary site characterization sufficiency comments, which are required by Section 114(a)(3) of the NWPA, and which will be submitted as part of the President's Site Recommendation to Congress.

The staff will track these open items using a computerized data base referred to as the Open Item Tracking System (OITS). Included in this data base for each open item will be a statement of the item, basis for the concern, resolution history, pertinent references, and cross references to applicable 10 CFR Part 60 sections and individual review plans in the LARP. The status of open items will be formally reported on in two ways. First, an annual summary report will be prepared, of the status of all open items, and included in the quarterly progress report to the Commission, for the last reporting period for each fiscal year. This report will also be given to DOE and other interested parties. Second, a status report will also be included in the staff's comments to DOE on the SCP progress reports.

This strategy implements the provision of 10 CFR 60.18 for identifying comments and objections, and thereby standardizes how these review concerns are documented, tracked, and resolved. Furthermore, it is consistent with the staff's established review practice, as expressed in the RS and updates, SCP review plan (NRC), and draft FCRG. The staff expects that this strategy will improve the efficiency of documenting the staff's pre-LA reviews and improve communication of staff concerns to DOE. It also is intended to focus the attention of both the staff and DOE on resolving concerns before LA submittal. Finally, this strategy will help streamline the staff's LA review by making available all the concerns, how DOE resolved them, how the staff reviewed and closed them, and associated references, on a computerized data base, for rapid search and retrieval by the staff. 7. Support reviews with open interactions with DOE and other parties, together with considering concerns of other parties. This strategy includes supporting the technical and QA reviews with a variety of open interactions with DOE, such as technical meetings, management meetings, technical exchanges, and site visits. These interactions are for exchanging information, discussing resolution of open items, and generally improving communications and understanding among all parties. The schedules for these interactions are made available by written notice and telephone recording. The State of Nevada, affected Indian Tribes, and affected units of local government representatives are invited to participate, and other parties can attend as observers. Each interaction is documented in minutes signed by the staff and DOE and made available to interested parties and NRC's Public Document Room. In addition, NRC's onsite licensing representative office will continue to provide prompt information exchange and consultation with DOE.

This strategy also includes staff consideration of comments by other parties about DOE's program, as well as considering comments that other parties might have on the staff's concerns with DOE's program. If appropriate, the staff might initiate a review to follow up on such comments.

This strategy contributes to implementing requirements of NWPA and 10 CFR Part 60, agreements between NRC and DOE, and agency policies and procedures for openness. The benefit of this strategy is to facilitate resolution of concerns, improve communications, and help ensure that the staff is aware of, and considers pertinent views of other parties, while conducting its reviews.

# 4.0 STRATEGIES FOR DEVELOPING THE LA AND PRE-LA REVIEW CAPABILITY

The following strategies will be used, during the pre-LA phase, to develop both the LA and pre-LA review capability:

1. Develop the LARP to guide the staff's LA review. Develop the LARP early and revise it iteratively, based on new information and implementation experience;

2. Use the principles of systems engineering to develop the LARP.

3. Use existing pre-LA review plans and develop additional review plans, to use in conjunction with the LARP, to guide the pre-LA reviews;

4. Develop a performance assessment and other technical analysis capability early and revise it iteratively, based on new information and implementation experience;

5. Conduct research to develop data, understanding, and methods necessary to support the reviews.

A description and rationale for each strategy are given below.

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1. Develop the LARP to guide the staff's LA review. Develop the LARP early and revise it iteratively, based on new information and implementation experience. The LARP will be developed early in the pre-LA phase, to focus in a timely manner on what is needed in the LA to improve the basis for pre-LA reviews and resulting guidance to DOE. Early development is also needed to allow time to prepare and refine the LARP and supporting analyses and research investigations. The staff recognizes the exploratory and evolving nature of the repository program, as well as the need for flexibility under these conditions. Because of this, the staff expects to develop the LARP iteratively. The staff's initial judgments and products will be reevaluated annually, and updated as needed, based on pre-LA review experience, input from DOE and other parties, new information, new insights, or the availability of new analytical methods. For example, the staff's initial judgments in identifying technical uncertainties that pose a high risk of non-compliance will eventually need to be evaluated more quantitatively by using sensitivity analysis methods developed by the IPA activity (discussed below). Any changes that result may lead to changes in the review strategies or review methods.

The draft LARP will be developed, starting in FY92 and ending in FY98 with a revision each year, to incorporate new and revised sections as they are prepared by the staff.

2. Use the principles of systems engineering to develop the LARP. The LARP will be developed using the Systematic Regulatory Analysis (SRA). In general, the SRA is a formal, systematic, and documented process specifically developed to apply the principles of systems engineering to the needs of the staff's HLWM program. SRA is a process that helps focus, in a consistent and documented manner, the staff's technical and programmatic judgments. This process is particularly well suited for dealing with some of the challenging aspects of the repository licensing program (e.g., it is complex, first-of-akind, multi-disciplinary, and of long duration). The SRA will help identify, prioritize, and integrate the LA review. As a result, the staff will have greater confidence that all the necessary reviews are done, that the reviews are done in a consistent and integrated manner, that the reviews are done as efficiently as possible, and that the review plans and supporting rationales are sufficiently documented to preserve a record for future staff reference.

Specifically, using the SRA first involves developing a common organizational structure between the individual review plans making up the LARP and the grouping of 10 CFR Part 60 requirements into the system/subsystem structure of the FCRG. A common structure among the LARP, FCRG, and DOE's LA should facilitate the staff's LA review and enhance pre-LA guidance and consultation with DOE.

Using the SRA for developing the LARP also involves developing the content of each review plan, following procedures prepared and approved for use, under the Center for Nuclear Waste Regulatory Analyses' (CNWRA's) QA program to apply criteria in Appendix B to select the type of LA review that is appropriate for each regulatory requirement of 10 CFR Part 60 that is related to the LA. Consistent with LA Review Strategies 4 and 5, described in Section 3.2, criteria are used to select five standard types of reviews, which involve different levels of detail and different review methods (see Appendix B). The type of review is used to develop the specific review strategy that will be included in each individual review plan dealing with the regulatory requirement. The review strategy gives the general scope and approach that will help the staff streamline its work and optimize its resources during the LA review. It does this by focusing the staff work on those technical uncertainties most important to performance (i.e., key technical uncertainties) and where more detailed reviews and rigorous methods of review will be conducted. In addition, the review strategy will help identify what research, model development, and pre-LA reviews are needed to prepare for the staff's LA review.

Further development of the LARP involves using the SRA to develop, within the bounds of the review strategy already developed, the review methods, acceptance criteria, implementation, and example evaluation findings. This information gives more detailed guidance to the staff for determining the adequacy of DOE's LA and making evaluation findings for each regulatory requirement of 10 CFR Part 60.

Finally, the SRA process and implementing procedures also require that rationales and supporting references be documented for the review strategies, review methods, and acceptance criteria. All of this information is entered into a computer data base, (the Program Architecture Relational Database) which will facilitate the staff's storage, search, and retrieval of background information relevant to the staff's LA review.

3. Use existing pre-LA review plans and develop additional review plans to use, in conjunction with the LARP, to guide the pre-LA reviews. Pre-LA reviews of DOE's plans will be guided by already existing review plans and procedures for the SCP Progress Reports, study plans, technical reports, and QA program. These existing review plans will be revised, where needed to, implement the pre-LA review strategies. Additional review plans will be developed, as needed, for reviews of other documents, such as topical reports. Acceptance criteria in the LARP will be used, where applicable, to assist in pre-LA reviews, in particular the reviews of DOE's AO and topical reports.

4. Develop a performance assessment and other technical analysis capability early and revise it iteratively, based on new information and implementation experience. To support the detailed LA and pre-LA reviews, the staff will develop a performance assessment capability, IPA, as well as other technical analysis methods, such as thermomechanical modeling and tectonic modeling.

IPA will enhance the staff's capability to perform an effective review of DOE's performance assessment, which will be the principal way that DOE will demonstrate compliance with the performance objectives of 10 CFR Part 60 in the LA. IPA is an iterative process of technical analyses primarily using predictive models and computer codes to obtain quantitative estimates of repository performance. More specifically, IPA consists of developing system descriptions and supporting databases, together with conducting scenario analyses, consequence analyses, performance measure calculations, sensitivity and uncertainty analyses, and comparisons to the performance objectives of 10 CFR Part 60. These analyses are repeated as new data and increased understanding from NRC-supported or other research becomes available. Through this iterative process, progressively refined capability and resulting assessments of repository performance as it relates to the performance objectives in 10 CFR Part 60, may be obtained.

Development of computer models and codes will be an ongoing activity, with models and codes continuously being refined as improved information is obtained during site characterization. Moreover, development of models and codes is only a part of IPA. Of equal or greater importance is development of the staff expertise, and familiarity with the Yucca Mountain site, sufficient to allow identification of the key phenomena important for repository performance; formulation of conceptual models of the phenomena and their effects on repository performance; and completion of sensitivity and uncertainty analyses, to determine the importance of individual parameters, on the overall repository system. Such information will be used to support the staff judgments regarding the significance of key technical uncertainties identified during LARP development using the SRA process. Furthermore, it is important to emphasize the iterative nature of IPA. Each iteration will provide the information needed to provide comments to DOE, regarding priorities for site characterization to ensure that necessary site information is collected, to refine the models and codes describing repository performance. The sensitivity and uncertainty analyses of IPA, together with the LARP, are expected to provide much of the technical basis for reviewing DOE's progress in characterizing the Yucca Mountain site.

IPA also provides a tool for technical integration, because it provides the structure for examining couplings between phenomena that might not be adequately evaluated, within the limits of a specific technical discipline. In addition, the multi-disciplinary involvement with data inputs, assumptions, and code development more clearly defines activities and interfaces of the many disciplines involved, In this way, IPA also contributes to programmatic integration.

IPA and other technical analyses complement the SRA process used to develop the LARP, by feeding the results of integrated technical analyses back into the SRA process. As mentioned previously, knowledge gained through IPA will be used to reevaluate the significance of technical uncertainties important to performance and thereby provide a quantitative basis for determining the need to revise these key technical uncertainties and associated review strategies. Sensitivity analysis will be conducted to evaluate all key technical uncertainties identified in the SRA, to confirm the staff's initial judgment in identifying these key technical uncertainties. As the SRA process is used to develop the LARP, it will help to ensure that IPA activities are appropriately focused to contribute in a logical fashion to the LARP and LA review.

Appendix D gives the Performance Assessment Strategy, which describes in more detail the development phases of the IPA.

5. Conduct research to develop data, understanding, and methods needed to support reviews. To support the review strategies and methods in the LARP, the results of the staff's research will be used. In addition, results of research will be useful in conducting pre-LA reviews. For example, research

can develop independent understanding of basic processes and develop licensing tools such as models and codes, data, and other information that will contribute to the technical basis necessary for the staff to judge the adequacy of the LA. In addition, research can also provide limited confirmatory information. For results of research to be available for the staff's LA review, research must be conducted in a timely manner, throughout the pre-LA phase. As the LARP is developed using the SRA, and as IPA is conducted, the staff will also use this information to identify and prioritize needed research. As previously mentioned, the review strategies in the LARP will allow the staff to identify areas that are judged most important to compliance (i.e, key technical uncertainties). For some of these key technical uncertainties, detailed safety reviews of the LA will rely on use of research results. Such identification will help the staff revise its research user needs in a more systematic and comprehensive way that is more directly linked to its LA review needs and those areas that are most important to repository performance and determinations of compliance. In addition to importance to performance and LA review, other factors are also considered: programmatic needs, timing, and resource constraints. The research needs identified as a result of the SRA/IPA review strategy development will be compared to the ongoing research program, and necessary adjustments will be made. As research work progresses, the staff will evaluate the results, as part of the SRA process, to determine if additional research is needed to satisfy review needs.

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#### 5.0 IMPLEMENTING AND UPDATING THE OVERALL REVIEW STRATEGY

To implement the ORS, the staff will use the objectives and strategies described above, to guide its development, each year of the Five-Year Plan and Budget. In these broad agency planning documents, general activities, schedules, and resource needs for 5 and 3-year planning periods, respectively, will be developed for conducting reviews and developing review capability. For HLWM activities needed for developing LARP, IPA, and other technical analyses, more detailed implementation will be accomplished by developing both long-range, strategic development plans, and periodic development plans for each of these activities. The long-range, strategic development plans will give general plans and schedules for the full capability development period, whereas the periodic plans will give additional detailed guidance for a single fiscal year for LARP and about 18 months for IPA and other technical analyses. Where possible, development schedules will be chosen to support pre-LA reviews of DOE site characterization program activities. The activities and schedules, in the periodic plan, along with pre-LA review activities, will be implemented and tracked, using the staff's HLWM Operating Plan. Figure 5 illustrates the relationship described above between ORS, the long-range strategic development plans, the periodic development plans, and the HLWM Operating Plan. The initial long-range, strategic development plans and periodic plans will be prepared in FY93. For RES activities, more detailed implementation will be accomplished through the Research Program Plan.

Finally, the ORS will be evaluated annually and updated as needed.

## 6.0 REFERENCES

- 1. Nuclear Regulatory Commission, "Regulatory Strategy and Schedules for the High-Level Waste Repository Program," Commission Paper SECY-88-285, October 5, 1988.
- 2. Nuclear Regulatory Commission, "First Update of the Regulatory Strategy and Schedules for the High-Level Waste Repository Program," Commission Paper SECY-90-207, June 7, 1990.
- 3. Nuclear Regulatory Commission, "Format and Content for the License Application for the High-Level Waste Repository," Office of Nuclear Regulatory Research, Draft Regulatory Guide, DG-3003, November 1990.
- 4. Nuclear Regulatory Commission, "Second Update of the Regulatory Strategy and Schedules for the High-Level Waste Repository Program," Commission Paper SECY-91-225, July 29, 1991.
- 5. Roberts, J. P., U.S. Department of Energy, letter to J. J. Holonich, Nuclear Regulatory Commission, July 20, 1992.
- 6. U.S. Department of Energy, "Site Characterization Plan, Yucca Mountain Site, Nevada Research and Development Area, Nevada," DOE/RW-0199, December 1988.

# HIGH-LEVEL WASTE LICENSING PROGRAM ACTIVITIES

#### **PRE-LA PHASE ACTIVITIES**

#### LICENSING PHASE ACTIVITIES



Figure 1 Relationship of strategy documents to the licensing and research program activities.

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Calendar Year

Figure 2 General schedule of pre-La and licensing phases.

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Figure 3 General logic structure of staff evaluation findings in the safety evaluation report.

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EVALUATION FINDINGS FOR 10CFR 60.31

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SUPPORTING EVALUATION FINDINGS FOR LARP CHAPTERS

# TYPES OF LA-REVIEW (SELECTION CRITERIA)







Figure 5 Plans for guiding the development of LA review capability during the pre-LA phase.

Table 1. Products Associated With the Regulatory Strategy and Overall Review Strategy

# Regulatory Strategy

Rulemaking

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Regulatory guides

Staff positions

Staff technical positions

# Overall Review Strategy

Site Characterization Plan (SCP) Review Plan

SCP Progress Report Review Plan

Study Plan Review Plan

Generic Document Review Plan

Topical Report Review Plan

Early Site Suitability Evaluation Review Plan

LA Review Plan

Iterative performance assessment reports

Staff review guidance letters

Summaries of NRC-DOE meetings and technical exchanges

Preliminary Site Characterization Sufficiency Comments

Safety Evaluation Report

Table 2. Pre-LA Reviews a Reviews	and Supporting Activities Applicable to lypes of LA
Types of LA Review	Applicable Pre-LA Review and Supporting Activities
Type 1	Annotated Outline reviews
Type 2	Annotated Outline reviews
Туре 3	Annotated Outline reviews Topical report reviews Major design report reviews Annual performance assessment reviews SCP review (completed) SCP progress report reviews QA plan reviews QA audits, observation audits, and surveillances Study Plan reviews Meetings and technical exchanges
Туре 4	Detailed study plan concerns Detailed technical report reviews Data reviews Site/lab visits QA audits, observation audits, and surveillances Meetings and technical exchanges Iterative performance assessment and technical analyses using available methods Lower priority research
Type 5	Same as Type 4 activities Iterative performance assessments, and technical analyses using staff developed methods Higher priority research

## APPENDIX A

# SUMMARY OF STATUTORY AND REGULATORY REQUIREMENTS AND POLICY APPLICABLE TO THE OVERALL REVIEW STRATEGY

#### **1.0 STATUTORY REQUIREMENTS**

The Nuclear Regulatory Commission's licensing and related regulatory authority is defined by the Atomic Energy Act of 1954, as amended. This authority is made applicable to the U.S. Department of Energy (DOE), as successor to the Energy Research and Development Administration, under Section 202 of the Energy Reorganization Act of 1974. Congress further defined NRC's role as it relates to the disposal of high-level radioactive waste in geologic repositories in the Nuclear Waste Policy Act of 1982 (NWPA) and NWPA, as amended in 1987. The requirements of NWPA, as amended relevant to the Overall Review Strategy (ORS) are summarized below.

#### 1.1 Promulgation of Regulations

The Commission has promulgated regulations dealing with all aspects of the disposal of high-level radioactive waste in geologic repositories. These regulations are contained principally in 10 CFR Part 60, but also include provisions in 10 CFR Part 2 relating to procedural aspects of the license application review process, and provisions in 10 CFR Part 51, pertaining to implementation of the National Environmental Policy Act (NEPA). The regulations, which conform to the requirements of Section 121(b) of NWPA, address certain pre-license application (LA) reviews, as well as the consideration of LAs.

## 1.2 <u>Review of DOE's Mission Plan</u>

Consistent with Section 301(b)(1) of NWPA, the Commission will review and comment on any amendments to DOE's Mission Plan. This plan provides an informational basis sufficient to permit informed decisions to be made in carrying out the repository program and the research, development, and demonstration programs under the NWPA. This provision is important to the ORS because it requires the staff to consider and comment on fundamental, broadscale programmatic factors that contribute to successful DOE program operation.

#### 1.3 Inputs to DOE's Project Decision Schedule (PDS)

Consistent with Section 114(e) of NWPA, DOE must prepare and update, as appropriate, in cooperation with all affected Federal agencies, including NRC, a PDS that portrays the optimum way to attain the operation of the repository involved, within the time periods specified in the NWPA. This schedule must include a description of objectives and a sequence of deadlines for all Federal agencies required to take action, including an identification of the activities in which delay in the start, or completion, of such activities will cause a delay in beginning repository operation. This provision requires that a specific report be provided by any Federal agency, including NRC, if the agency determines it cannot comply, or fails to comply, with any deadline in the PDS. This report, submitted to DOE and to the Congress, would include the reason why the agency could not reach an agreement with the DOE, the estimated time for completion of the activity(ies), and the associated effect on its other deadlines in the PDS and any recommendation or actions to mitigate the delay involved.

The PDS (Revision 1), issued in June 1991, identifies many future NRC actions, of which the actions below are relevant to the ORS and proposed by DOE (and agreed to by NRC) to be subject to the reporting requirements of Section 114(e) of NWPA, described above. Those identified by NWPA are NWPA required actions.

- Comment on Sufficiency of Site Characterization Analysis (NWPA)
- Complete Acceptance Review of License Application (LA)
- Report Status to Congress of LA Review and Construction Authorization Decision (NWPA)
- Complete LA Review
- Issue Construction Authorization (NWPA)

The schedules given in the PDS for the above NRC actions necessitate that the ORS identify and update schedules for these required actions and major milestones supporting these actions. More importantly, the ORS itself has been developed to help ensure meeting the above required actions.

#### 1.4 <u>Review and Comment on Plans for DOE's Site Characterization Program</u>

Consistent with Section 113(b)(1)(A) of NWPA, before proceeding to sink shafts at any candidate sites, DOE must submit a general plan for site characterization (i.e., Site Characterization Plan (SCP)) for such candidate site, to the Commission, for its review and comment.

Consistent with Section 113(c)(2)(A), DOE may not use any radioactive material at the candidate site, during site characterization, unless the Commission concurs that such use is necessary to provide data for the preparation of the required environmental reports and an application for a construction authorization for a repository.

# 1.5 <u>Preliminary Comment on Sufficiency of DOE's At-Depth Site</u> <u>Characterization Analysis and Waste Form Proposal</u>

Consistent with Section 114(a)(1)(E) of NWPA, preliminary comments will be prepared by the Commission, concerning the extent to which the at-depth site characterization analysis and the waste form proposal for such site seem to be

sufficient for inclusion in any application DOE submits for licensing a site as a repository. DOE will publish these comments in its Site Recommendation Report to the President.

Items 4 and 5, together, give a statutory basis for conducting pre-LA reviews of the plans and results of DOE's program supporting the development of the LA, along with those activities necessary to prepare for these reviews.

### 1.6 <u>State and Tribal Participation</u>

Consistent with Section 117(a)(1) of NWPA, the Commission must provide to the Governor and legislature of a potential repository State, and to the governing body of any affected Indian tribe, timely and complete information regarding determinations or plans made with respect to site characterization, siting, development, and decommissioning of such repository.

#### 1.7 <u>Status Report on LA Review to Congress</u>

Consistent with Section 114(c), not later than 1 year after the date on which an application for a construction authorization is submitted, and annually thereafter until the date on which the authorization is granted, the Commission shall submit a report, to Congress, describing the proceedings undertaken through the date of the report, with regard to the application.

#### 1.8 Licensing Decision for Construction Authorization

Consistent with Section 114(d), the Commission shall consider an application for a construction authorization for a repository and shall issue a final decision approving or disapproving the issuance of a construction authorization, within 3 years after the date of submission of the application, unless the Commission extends such time period by not more than 12 months as specified in NWPA.

This provision is the most important one to the ORS, because it sets a very ambitious statutory schedule for licensing. This statutory time period, in turn, is the reason for certain review and review capability development strategies being taken, to help meet the 3-year licensing period.

#### 1.9 Focus on the Yucca Mountain Site

Pursuant to NWPA, as amended, DOE is directed to focus its site characterization activities only on the Yucca Mountain site. This, in turn, has focused NRC's ORS also on the Yucca Mountain site.

#### 2.0 APPLICABLE REGULATORY REQUIREMENTS AND GUIDANCE

# 2.1 <u>LA Review</u>

Of particular importance to the staff's LA review is 10 CFR 60.31. This section describes the three determinations that the Commission will make in considering whether to authorize construction. These determinations are: 1) safety, 2) common defense and security, and 3) environmental. The staff's LA

review is related to the Commission's safety and common defense and security determinations; the staff's findings for each of these will be the primary findings documented in its safety evaluation report (SER) for consideration by the Commission. (The staff's review of DOE's Environmental Impact Statement would be documented elsewhere and, therefore, not in the SER.)

10 CFR 60.31 also lists six considerations that the Commission will use in making its safety determination for a construction authorization decision. Similarly, the staff's LA review will make secondary evaluation findings for each of these six considerations, to support its primary safety evaluation finding. These six considerations include compliance with specific 10 CFR Part 60 requirements given in the technical criteria of Subpart E, the quality assurance requirements of Subpart G, the personnel training criteria of Subpart H, and the emergency plan criteria of Subpart I. Two other considerations are whether DOE has described the proposed geologic repository and planned repository operations. 10 CFR 60.21 further specifies these and other required descriptions, together with the assessments to be included in the LA.

Procedural requirements for repository licensing are given in 10 CFR Part 2. A few of these requirements are of specific importance to the LA review. First, 10 CFR 2.101(f) requires the staff to determine if the DOE's LA is complete and acceptable for docketing. This determination is based on the results of what is referred to as an acceptance review (see Section 3.2 for further discussion). Second, 10 CFR 2.102 indicates that the staff may request additional information from the applicant and can confer informally with any party during its review of the LA. Finally, although not specified in 10 CFR Part 2, itself, in the statement of considerations supporting the rule on the Submission and Management of Records and Documents Related to the Licensing of a Geologic Repository for the Disposal of High-Level Waste, the Commission gave a model schedule for the licensing proceedings for general guidance in meeting the statutory 3-year time period for the Commission to make its construction authorization decision. This schedule includes 18 months for the staff to review the LA and prepare its SER.

#### 2.2 Pre-LA Review

In addition to requirements for the LA review, 10 CFR Part 60 also gives procedural requirements for DOE important to the staff's pre-LA reviews. In particular, 10 CFR 60.15 requires DOE to conduct a program of site characterization consistent with a number of specific requirements for testing, limiting adverse effects of testing on long-term repository performance, and coordinating testing with repository design and construction. In addition, 10 CFR 60.16 requires DOE to prepare a SCP consistent with the content requirements given in 10 CFR 60.17. DOE is also required, by 10 CFR 60.18(g), to provide semiannual progress reports to the Commission, regarding site characterization activities, as well as repository and waste package design. The contents for these progress reports are specified in 10 CFR 60.18.

Procedural requirements for the NRC staff's review of DOE's site characterization activities also are included in 10 CRF 60.18. In summary, 10

CFR 60.18 requires the Nuclear Material Safety and Safeguards (NMSS) Director (and supporting staff) to review DOE's SCP and prepare a Site Characterization Analysis (SCA); this review has been completed. In addition, the Director may comment any time in writing to DOE on any aspect of DOE's site characterization program. Objections or recommendations can be included. If appropriate, the Director's comments should include a determination regarding whether the Commission concurs that DOE's proposed use of radioactive material is necessary for site characterization. To support any of its reviews, the staff may invite and consider the views of other parties. In addition, all the Director's comments will be made available in NRC's Public Document Room and will be sent to the appropriate State and Indian Tribes. The Director shall invite public comment on any comments the Director makes to DOE. Finally, the NRC staff is permitted to visit site characterization locations, and observe in-situ testing activities, excavations, and borings.

In addition to the procedural requirements important to pre-LA reviews, the technical requirements of 10 CFR Part 60 that DOE must comply with in its LA and that the staff will review and make findings for in its SER, will also be the focus of the staff's pre-LA reviews.

Finally, Draft Regulatory Guide DG-3003: "Format and Content for the License Application for the High-Level Waste Repository" (FCRG) provides a format and content for the LA that would be acceptable to the staff. This FCRG also is the organizational structure for the staff's License Application Review Plan (LARP).

# 3.0 APPLICABLE EXISTING NRC POLICY

# 3.1 <u>Five-Year Plan</u>

A primary source of Commission policy guidance is the Five-Year Plan. The Five-Year Plan objectives most significant to the staff's reviews are:

1. Statutory requirements will be met;

2. In the absence of unresolved safety issues, staff reviews will not hold up DOE's program;

3. Continue pre-LA reviews, based on DOE's schedule, to ensure timely regulatory guidance on technical issues, and timely identification and resolution of issues;

4. Develop LA review capability, including licensing criteria and evaluation methods;

5. The NRC will continue an active program of interaction and cooperation with the State of Nevada, affected counties and Indian tribes, and interest groups;

6. Guidance for resolving licensing issues (e.g., including the LARP) will be developed by FY 1998; this work will be prioritized so that those most

important to DOE site characterization and NRC meeting the 3-year licensing review are given the highest scheduling priority;

7. Reviews and development of review capability will be coordinated with NMSS, Office of Nuclear Regulatory Research (RES), and the Office of General Counsel (OGC); and

8. Formalize procedures for documenting agreements between the NRC and DOE staffs, on the resolution of technical issues, in advance of the LA review.

General activity descriptions in the Five-Year Plan also give additional guidance applicable to pre-LA reviews. In these descriptions, it is recognized that detailed study plan, document reviews, and quality assurance (QA) audits will be limited to a sample in selected areas. For example, only 20 percent of DOE's 106 study plans can be reviewed in detail, given the present resources. It is also recognized that the LARP, which will be developed during the pre-LA phase, will assist the staff in conducting its pre-LA reviews. Finally, the Five-Year Plan recognizes that staff reviews will be supported by independent performance assessments and other investigations, such as those conducted by RES.

#### 3.2 <u>Regulatory Strategy</u>

The staff's Regulatory Strategy (RS) (SECY-88-285) and updates (SECY-90-207 and SECY-91-225) establish a number of staff policies important to the ORS. Strategies for identifying and resolving technical uncertainties (as well as regulatory and institutional uncertainties, which are not the focus of the ORS) are discussed. In particular, pre-LA reviews are one important way the staff will use to identify technical uncertainties. In addition, the staff considers that it is DOE's responsibility to reduce technical uncertainties through site characterization activities and pre-LA consultations with NRC, the State of Nevada, and other parties. Furthermore, it is the staff's responsibility to give guidance to DOE on reducing technical uncertainties, before DOE submits its LA. This guidance will be primarily in the form of pre-LA review guidance, but for a few selected cases, staff technical positions will be used. The RS also establishes the intent of the staff to identify, during the course of its pre-LA reviews, objections that if not resolved by DOE, would prevent the staff from conducting a meaningful review or the Commission from making a decision regarding construction authorization within the 3-year statutory time period. Such objections, therefore, might result in the staff not docketing the LA. The benefits of resolving objections to the staff's LA review and the Hearing is discussed. Any unresolved objections would also be factored into NRC's Preliminary Site Characterization Sufficiency Comments required by NWPA. This policy is further described in the staff's draft FCRG. The RS also mentions that the staff would use an Open Item Tracking System to track resolution of objections and other concerns identified in the staff's pre-LA reviews. The first and second updates to the RS also express the staff's intent to identify key technical uncertainties, which are those technical uncertainties that are most significant to performance. These key technical uncertainties will be useful in prioritizing those technical areas where the staff would develop its

modeling capability, conduct research, and conduct detailed pre-LA reviews. Finally, the updates to the RS explain that the staff would be using the Systematic Regulatory Analysis (SRA) to develop a well-integrated review capability in the LARP.

# 3.3 <u>SCP Review Plan</u>

The SCP Review Plan also establishes review policy important to identifying and documenting concerns with DOE's program in a consistent manner, following three kinds of defined concerns. The three concerns defined are: objections to starting work, comments, and questions. The staff's intent to establish an Open Item Tracking System is also discussed.

#### 3.4 <u>NRC-DOE Procedural Agreements</u>

NRC and DOE have two procedural agreements. The Morgan-Davis Procedural Agreement of August 25, 1983, ensures that an information flow would be maintained between NRC and DOE, so as to facilitate each agency's accomplishment of its responsibilities under NWPA. Specific provisions are made for open meetings, exchange of information, and access to data and samples. The Site-Specific Agreement of September 18, 1984, implements Section 6 of the Procedural Agreement, which requires a site-specific agreement. This agreement provides for public notice of schedules and agendas for technical and management meetings, and for NRC and DOE to jointly prepare meeting reports and distribute them to the affected parties, in a timely manner. An opportunity is also provided for the affected parties to include their positions in the meeting report. Special provisions are included, under Appendix 7, for interactions among the NRC On-site Representatives and DOE. (Note that changes to these procedural agreements are presently being negotiated by the staff and DOE).

#### APPENDIX B

## SELECTION CRITERIA AND TYPES OF LICENSE APPLICATION (LA) REVIEW

#### **REVIEW TYPE SELECTION CRITERIA**

#### Type 1 - LA-Related

These are the 10 CFR Part 60 requirements for which the U.S. Department of Energy (DOE) must demonstrate compliance in its LA, or which directly affect the content or submittal of the LA. These are also the requirements that would be addressed in the staff's compliance review of the LA and for which findings will be made in the staff's Safety Evaluation Report.

Excluded from these requirements would be those not related to the LA, whether DOE requirements (e.g., Site Characterization Plan requirements in 10 CFR 60.16 and 10 CFR 60.17), Nuclear Regulatory Commission requirements (e.g., review of site characterization activities in 10 CFR 60.18 and construction authorization in 10 CFR 60.31(a)), or other procedural requirements (e.g., participation of State governments and Indian tribes in 10 CFR Part 60, Subpart C).

#### Type 2 - General Information-Related

These are the general information requirements contained in 10 CFR 60.21(b), and for which compliance is necessary to make a safety determination for construction authorization as defined in 10 CFR 60.31(a). Additionally, this review type is for requests for information in the license application which are not based on specific regulatory requirements from 10 CFR Part 60 but which support the staff's reviews and overall finding with respect to safety, as stated in 10 CFR 60.31(a).

Type 3 - Radiological-Safety and Waste-Isolation Related

These are 10 CFR Part 60 requirements for which compliance is necessary to make a safety determination for construction authorization, as defined in 10 CFR 60.31. These include those requirements that embody Subparts E, G, H, and I.

Type 4 - High Potential Risk of Non-Compliance with a Performance Objective of 10 CFR Part 60

These 10 CFR Part 60 requirements are the subset of all the radiological health-and-safety or waste-isolation-related requirements for which

there is a high potential risk of non-compliance with one or more of the performance objectives in 10 CFR 60.111, 112, or 113.

The high potential risk of non-compliance comes from the existence of key technical uncertainties.

A key technical uncertainty is a technical uncertainty that poses a high risk of non-compliance with a performance objective of 10 CFR Part 60. It may also be associated with reducing a high risk of non-compliance with a performance objective.

For example, a key technical uncertainty exists where there is a lack of certitude about a methodology that is needed to either demonstrate compliance with a performance objective (e.g., scenario analysis methods are necessary to demonstrate compliance with the containment requirement of 40 CFR Part 191). A key technical uncertainty also exists where (1) there is a lack of understanding about a condition or process, and (2) it is credible that the condition or process exists (or will exist) and could have either a significant adverse or favorable effect on repository performance.

Type 5 - High Potential Risk of Non-Compliance and Most Difficult to Resolve

These 10 CFR Part 60 requirements, a subset of the requirements that pose a high potential risk of non-compliance, pose the highest potential risk because the risk is judged to be the most difficult to reduce. Therefore, there might be a high residual risk of non-compliance, because very little can be done to reduce the risk or compensate for the risk using, for example, favorable site conditions or engineered features.

#### **REVIEW TYPE DESCRIPTION**

Type 1 - Acceptance Review

This type of review is to determine if the LA is complete and acceptable for docketing and for conducting the compliance review in an effective and timely manner. This is not a review to determine adequacy.

#### Compliance Reviews

Type 2 - General Information Review

This type of review is to determine the adequacy of compliance with the general information requirements of 10 CFR Part 60 and with those requests for information in the license application which are not based on specific regulatory requirements from 10 CFR Part 60, but which support the staff's review and overall finding with respect to safety, as stated in 10 CFR 60.31(a).

## Type 3 - Safety Review

This type of review is to determine the adequacy of the compliance demonstrations and associated system descriptions that are related to radiological health and safety or waste isolation. The focus of this review is primarily on the LA itself, although some references might also be reviewed if they contain essential compliance demonstration information. Generally, however, the detailed information supporting the compliance demonstration in the LA references will not be the focus of this type of review. The safety review might also be supported by simple verifications, using handbooks, standard formula, or "back-ofthe-envelope" calculations. However, detailed verifications using complex numerical modeling should not be used. A Type 3 review might eventually be changed if new information leads to a key technical uncertainty.

#### Type 4 - Detailed Safety Review Supported by Analyses

This review is an expansion or extension of the Type 3 Safety Review in that it is a detailed review of the adequacy of selected detailed information supporting the compliance demonstration in the LA (i.e., "vertical slice" reviews of data, analyses, methods, and technical procedures). Specifically, Detailed Safety Reviews would focus on the level(s) of detail appropriate for the assessment of the key technical uncertainty(ies) and how the key technical uncertainty should be reduced, compensated for, or remedied by DOE.

The Detailed Safety Review should be supported, if relevant and needed, by analyses conducted by the staff of specific key technical uncertainties. Such analyses could include use of complex numerical models. Unless justified, based on the unique nature of the key technical uncertainty, the detailed analyses methods would not be developed by the staff. Instead, the staff would use methods, developed by DOE or other parties, that have been reviewed and found acceptable by the staff. Although this type of review requires the staff to obtain and become proficient in using a particular method or making minor modifications to the method, it does not require, for most cases, the extensive resources needed for the staff to develop its own independent method. (For special cases, such as where the staff may have concerns with DOE's data interpretation or method of analysis, the staff could modify DOE's method or use another party's method.) Independent investigations, including research, can also support Type 4 reviews if justified; however, these investigations would be lower priority than those supporting a Type 5 review.

Type 5 - Detailed Safety Review Supported by Independent Tests, Analyses, or Other Investigations

This type of review further supports the Detailed Safety Review with either analyses, tests (laboratory or field), other investigations conducted by the staff or using methods (e.g., numerical modeling) independently developed by the staff. Such independent investigations could focus on all or a part of a specific key technical uncertainty. This type of review might also further supplement the Detailed Safety Review by verifying some of the LA data or descriptions of conditions or processes with data collected by the staff or the understanding of conditions and processes obtained by the staff's own investigations (e.g., results of the research program). Furthermore, the understanding of processes may also support the staff's independent model development. In addition to analyses and tests, this type of review could, if appropriate, be supported by other kinds of investigations, such as expert panel solicitations. The specific type of supporting investigations selected should be based on what is technically needed to address the key technical uncertainty(ies).

It should be emphasized, however, that the independent investigations conducted by the staff are for verification purposes and are not a substitute for data or analyses that DOE should be providing to support its compliance demonstration in the LA.

Finally, it is important to note that a review type might eventually be changed to a lower or higher type should new information or lack of information either reduce the key technical uncertainty causing the risk of non-compliance, or lead to identifying a new key technical uncertainty.

#### APPENDIX C

#### DEFINITIONS OF STAFF CONCERNS WITH DOE'S PROGRAM

**Start-Work Objection:** A concern with the U.S. Department of Energy (DOE) program related to either:

1) potential adverse effects on repository performance;

•. .

2) potential significant and irreversible/unmitigatable effects on characterization that would physically preclude obtaining information necessary for licensing;

3) potential significant disruption to characterization schedules or sequencing of studies that would substantially reduce the ability of DOE to obtain information necessary for licensing; or

4) inadequacies in the quality assurance (QA) program that must be resolved before work begins.

Start-work objections are reserved primarily for concerns with activities that, if started, could cause significant and irreparable adverse effects on the site, the site characterization program, or the eventual usability of the data for licensing (programmatic fatal flaws). Because of this irreparable nature of objections, the Nuclear Regulatory Commission would recommend that DOE not start work until the objections are satisfactorily resolved.

License Application (LA) Submittal Objection: A concern with the DOE program critical to the staff's LA review because lack of acceptable DOE resolution would prevent NRC from conducting a meaningful review and making a decision regarding construction authorization within the 3-year statutory time period. Concerns that would need a long time to resolve, such as new or additional testing or developing new or revised analytical methods, are examples of this type of objection.

Comment: A concern with the DOE program as presented in any DOE document that would result in a significant adverse effect on licensing if not resolved, but would not cause irreparable damage if site characterization started before resolution. The DOE program could be modified in the future, with some risk to not having the necessary information for licensing; the adverse effects would be primarily related to the program schedule. Therefore, for these concerns, DOE could start work at its own risk before resolving such concerns with NRC. NRC would recommend timely resolution of comments. If resolution is not achieved in a timely manner, comments might evolve into LA submittal objections.

Question: A major concern with the presentation of the DOE program in any DOE document, such as missing information that should be in the documents, level of detail, contradictions, and ambiguities that preclude understanding a part

of DOE's program, thereby preventing the staff from being able to comment. NRC would recommend DOE clarify such questions. If a question is related to a potential start-work objection, satisfactory resolution should be accomplished before work begins. If a question is not related to a start-work objection, then DOE could choose to proceed with work at its own risk, and resolve the questions in future reports. Questions should be reserved for major items; minor inconsistencies should not be included.

#### APPENDIX D

# NRC POST-CLOSURE PERFORMANCE ASSESSMENT STRATEGY FOR A HIGH-LEVEL NUCLEAR WASTE REPOSITORY

#### **1.0 INTRODUCTION**

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In its broadest sense, any qualitative or quantitative estimation of the isolation capability (pre- and post-closure) of the high-level nuclear waste (HLW) repository constitutes a performance assessment (PA). In this paper, however, PA is restricted to mean only quantitative post-closure estimates of the repository's isolation capability. Furthermore, the quantitative estimates are restricted to those that are called for in relevant regulations, primarily 10 CFR Part 60 and 40 CFR Part 191.

The U.S. Department of Energy (DOE) is required, by regulation, to provide a comprehensive PA in its license application. The law requires the Nuclear Regulatory Commission to review the license application before granting, or denying, a construction authorization. As a part of the review process, NRC will form its own estimates of the potential performance of the repository described in the license application. If it determines that it is necessary and appropriate to do so, NRC may use independent calculations in forming these estimates. It should be understood that PA is only one input, albeit important, into NRC's decision-making process, as will be made clear in the much broader Overall Review Strategy (ORS). It is also worth noting that at no time during the life cycle of the repository is NRC expected to carry out its own site investigations or perform any engineering design. It will, however, provide guidance to DOE on both site characterization and engineering design.

The general question considered in this paper is how should NRC use PAs in implementing its proactive and reactive regulatory program? This breaks down to the following issues: (1) where in its review of DOE's license application should NRC perform independent PAs, and (2) how should PA be used in the overall program? In essence, what should be NRC's PA strategy, taking into account its mission and resource availability.

#### 2.0 REGULATORY BASIS FOR PERFORMANCE ASSESSMENT

The regulatory requirements for the geologic repository are codified in 40 CFR Part 191 (U.S. Environmental Protection Agency (EPA)) and 10 CFR Part 60 (NRC) - two complementary, but independent regulations. Part 191, the "generally applicable standards for protection of the general environment from off-site releases from radioactive material in repositories" (Nuclear Waste Policy Act (NWPA), Sec. 121) is concerned with the acceptable level of performance of the overall repository system. It specifies three broad quantitative performance objectives: (1) limiting the cumulative release at the accessible environment boundary over 10,000 years; (2) individual protection objectives for the first 1000 years; and (3) requirements for protection of special sources of ground water for the first 1000 years. (For purposes of this document, it is assumed that 40 CFR Part 191, though vacated by Court Order, will be repromulgated without material change.)

In contrast, Part 60, the "Disposal of High-Level Radioactive Wastes in Geologic Repositories" is more comprehensive in its scope. The generally applicable environmental standards of 40 CFR Part 191 are incorporated into 10 CFR Part 60 by reference. In addition, consistent with the mandate of NWPA, as amended, 10 CFR Part 60 makes it explicit that a repository include a system of multiple barriers. This concept of multiple barriers is enforced by establishing three minimum subsystem performance objectives, namely, the substantially complete containment performance objective for the waste package; the release rate performance objective for the engineered barriers; and the ground-water travel time performance objective for the site. In addition to performance objectives, siting and design criteria (for waste package and engineered barriers) are also specified in 10 CFR Part 60. However, the subsystem performance objectives of 10 CFR 60.113(a), for the engineered barriers, apply only with respect to the "anticipated processes and events." An additional flexibility with respect to the subsystem standards is included in 10 CFR 60.113(b). So long as the total system performance objective is met for anticipated processes and events, NRC can approve or otherwise specify a radionuclide release rate, containment time, or groundwater travel time other than the nominal values stated in 10 CFR 60.113(a).

With regard to judging compliance with these objectives (including the EPA standard) and criteria, 10 CFR Part 60 states:

Proof of the future performance of engineered barrier systems and the geologic setting over time periods of many hundreds or many thousands of years is not to be had in the ordinary sense of the word. For such long-term objectives and criteria, what is required is reasonable assurance, making allowance for the time period, hazards, and uncertainties involved, that the outcome will be in conformance with those objectives and criteria.

In the Supplementary Information Statement, the Commission explained that the subsystem performance objectives of 10 CFR Part 60 are meant to provide confidence in meeting the overall system performance objective. Technical support is provided in NUREG-0804, Part C, by evaluation of the extent to which compliance with the three subsystem performance objectives increases the likelihood of compliance with EPA's overall system performance criteria. Additional analyses of how the three subsystem performance objectives increase the likelihood of compliance with EPA's overall performance criteria are given in NUREG/CR-3111. This technical support was prepared before promulgation of 40 CFR Part 191. An early working draft of 40 CFR Part 191 was used to carry out the evaluation. EPA is currently in the process of reissuing 40 CFR Part 191, and changes from the earlier working draft and the remanded final version are uncertain. A PA capability will allow NRC not only to reevaluate the extent to which the subsystem performance objectives will provide additional confidence of compliance with EPA's standards, but it also will identify refinements to the subsystem objectives that might be appropriate.

Because of the long period of regulatory concern (10,000 years set by EPA) and large spatial scales (tens of cubic kilometers), the future subsystem and total system performance of the repository are expected to be projected by way of mathematical models. Direct performance testing of either the total system or its subsystems over such scales is not possible. DOE has the responsibility to develop, validate, and implement, to the degree appropriate, these models and to provide a complete description of the PAs in its license application. NRC, on the other hand, has the responsibility of ensuring that the licensed repository will adequately protect public health and safety. In performing its regulatory function, the approach to be taken will be one of reviewing DOE's entire PA at a broad level of detail and doing more detailed reviews in the most significant areas. NRC must, therefore, decide which selected parts should include independent verification through independent PAs. NRC will adopt the strategy described below in applying PAs in its HLW work.

#### 3.0 NEED FOR NRC'S PAs

Many relatively complex technical issues of a multi-disciplinary nature are involved in assessing the future performance of the geologic repository. To meet the NRC mission of protecting public health and safety, the NRC staff must, during the licensing process, take positions on the potential performance of the repository as it relates to the performance objectives. In addition, NRC will comment on and provide guidance to DOE on the completeness and adequacy of the site characterization program and engineering design, as well as on DOE's plans to construct, operate and close the repository. Thus, NRC has a definite role to play throughout the life cycle of the repository.

It is conceivable that the NRC staff can form an opinion about the performance of the repository without independent calculations. However, because of the complexity of the system and in the absence of accumulated historical experience, such an opinion will not be sufficiently well-founded to support licensing decisions. Therefore, NRC should conduct its own PAs. NRC must devise a plan based on this strategy to select critical portions of DOE's license application for intensive review by independent PAs. This strategy should also help NRC in meeting its obligations to provide guidance to DOE during site characterization, construction, operation and closure. This strategy will be implemented by all the NRC organizations involved in PA aspects of the High Level Waste Program and their contractors.

#### 4.0 STRATEGY FOR PA

The key features of NRC's PA strategy are derived from a few basic considerations: the complex and interdisciplinary nature of PA; its potential use in both the reactive and proactive programs; the top-down approach to guide resource utilization by identifying components important to repository performance; the integration of technical work performed on how the subsystems work; and keeping the NRC staff knowledgeable in PA methodology. These features are discussed below.

#### 4.1 <u>General Program</u>

Assessing performance of a geologic repository requires execution of a number of steps. These include conceptualizing the system in terms of its identifiable components, the formulation of mathematical models representing all important processes, the translation of the mathematical models into computer programs, the verification, and to the extent possible, validation of the models, the analyzing of field and laboratory data to extract model parameter values, the executing of computer programs, performing sensitivity and uncertainty analyses, and, finally, analyzing results to draw conclusions.

Although all parts of the PAs presented by DOE will be reviewed at some level. critical parts will be selected for in-depth review (see ORS for definitions of various review types). In reviewing DOE's PAs, the NRC staff will not need to duplicate the work done by DOE. DOE will perform these calculations under an auditable quality assurance (QA) program. As part of its reactive HLW licensing program, the NRC will conduct audits as needed. The NRC staff will perform, at least at a rudimentary level, a calculation to check all the DOE estimates of performance. In addition, the NRC staff will use independent calculations to evaluate the significance of key assumptions regarding conceptual models, process models, and parameter values included in DOE's PAs. This evaluation will draw heavily from the proactive work described below. Other applications of PA in the review of DOE's program will include determination of the adequacy of performance allocations and other facets of the DOE's site characterization program. Particular attention will be given to evaluating DOE's evolving iterative PA program. Auxiliary analyses done as part of independent PAs will also provide a technical foundation for evaluating alternatives with respect to conceptual models, process models, parameter values, and sensitivity analyses presented by DOE, and to identify those that may not be considered adequately in DOE's work. Such work will provide technical credibility to recommendations that the NRC will make to DOE for its investigations. The NRC HLW research program will generate scientific information to support staff positions on whether alternatives have been adequately explored by DOE.

Special attention will be paid to uncertainties involving the assumptions that form the basis of models, future states of nature, and estimation of parameter values that are fed into PA computer programs. Again, one may assume that DOE's raw data will be collected under an approved QA program. The interpretation of these data leading to model parameter values not only will be spot-checked, but NRC, itself, will interpret selected data sets for critical parameters. It is in the interpretation of these data that alternate hypotheses or inferences may be identified that were not adequately considered by DOE. Special attention may be directed to issues identified by external reviewers, as well as those identified by the NRC staff.

The primary aim of NRC's proactive PA program will be to evaluate its regulations, develop sound technical guidance, train and keep its staff current, and develop appropriate technical review methods in the License Application Review Plan (LARP). NRC will use the DOE-developed computer codes, if available, provided that these codes have enough flexibility to also allow NRC evaluation of DOE assumptions about conditions that may have public health and safety implications and the sensitivity of DOE's conclusion to these assumptions. Otherwise, NRC will develop its own codes or modify existing codes to suit its purpose. The proactive program will be also supported through NRC's HLW research program (see draft NUREG-1406). PA issues that are related directly to NRC's regulatory function of technical review will be addressed through NRC's HLW research program. Such issues will include: (1) understanding processes that affect HLW repository performance; (2) understanding coupling among processes that affect HLW repository performance; (3) techniques for probability estimation; (4) assessing reliability of long-term mathematical predictions; and (5) numerical methods (if needed).

Because PA of nuclear waste repositories is a relatively new field and because it is interdisciplinary in nature, very few formal educational opportunities exist to train staff in this aspect. Although NRC has developed a course on PA, learning through experience, by conducting limited PAs, is the best and most efficient method for training of the NRC and contractor staffs. Insights gained by NRC staff will allow development of meaningful regulatory guidance and review procedures. Together with the NRC's Systematic Regulatory Analysis (SRA) program, PA modeling also will help in evaluating current regulations regarding their interrelationships, completeness, and sufficiency in providing assurances that public health and safety will be protected.

#### 4.2 Integration of Subsystems

NRC's regulations require that the total repository system should include engineered and natural barriers. These regulations also require that each of several barriers attain a certain performance objective. Therefore, these subsystem performance objectives have an important role in ensuring that the multiple barrier concept is maintained and thereby provide additional confidence that public health and safety goals are met. In view of this, the DOE is expected to develop a repository system that will be comprised of engineered and natural barriers. Because of potential complex interactions between these barriers under future environmental states, the net impact of individual barriers on the total system performance is not known <u>a priori</u>. Therefore, it is natural and necessary to account for all these barriers in conducting PAs of the total system.

It has recently been suggested that there is a need to reevaluate the relationship between the subsystem performance requirements of 10 CFR Part 60 and the EPA HLW standard. As discussed previously, the staff will do this reevaluation in connection with repromulgation of the EPA standards. This reevaluation will examine the extent to which meeting subsystem requirements of 10 CFR 60.113 relates to compliance with the EPA standards. The data and analyses needed for compliance determination with requirements of 10 CFR 60.113 will also be examined.

The relative contribution of each barrier in meeting the total system performance objective can be determined only after such an assessment of total system performance is conducted. Therefore, from the PA view, there is no natural hierarchy to subsystems, that is, all subsystems will be considered during PAs of the total system. Depending on their relative importance, which will be determined during initial iterations, eventually and for certain purposes (e.g., sensitivity analyses) some subsystems may be treated in more detail than others.

Irrespective of the relative importance of any barrier in meeting the EPA standard for the total system performance, subsystem PAs will be conducted to judge whether the subsystem performance objectives of Part 60 are met. As stated before, the subsystems do not perform independently of each other; that is, the performance of the engineered barriers is determined by the site conditions and vice versa. Also, due to large time and space scales inherent in the subsystem performance objectives, like the total system, the subsystem PAs will also require mathematical modeling. In view of the above, it is possible that the assessments of the subsystems can become a part of the total system PAs. However, it is also possible to investigate the performance of these subsystems in greater detail by isolating them within properly selected boundaries. Initially, both options will be followed by the NRC staff. However, eventually the subsystem PA efforts and the total system performance efforts will be thoroughly integrated. This will be done by implementing an "interdisciplinary team approach" in conducting the PAs. The members of the various teams will be drawn from various NRC branches involved with the HLW program's offices and subcontractors. Suitable management controls will be designed and implemented for the success of the team approach.

#### 4.3 <u>Timing and Iterative Nature of Assessments</u>

There are two different approaches to decide upon the right time to carry out a PA. In the first approach, one waits until the computational tools are fully developed and the collection of site-specific data is complete before attempting a PA. In the second approach, iterative PAs are carried forward with the help of available data at a given time with computational tools available at that time. From a regulatory perspective, the second approach should receive the highest priority by the NRC staff. This approach should apply to both the subsystem and the total system PAs.

Performance assessment of geologic repositories, including engineering barriers, is inherently iterative in nature. Because different conceptual models must be explored, the effect of various simplifications must be assessed, and uneven and sparse data must be dealt with. The selection of iterative PAs as the primary NRC staff approach is based on the fact that NRC has responsibility to make a series of judgments during site characterization and license review, for which PA is needed. Additionally, in making these judgments, it is axiomatic that complete scientific understanding of processes, fully validated computational tools, and complete and unambiguous site-specific data are objects to be strived for, but are unable to be achieved. Therefore, NRC recognizes that judgments will be made under conditions of substantial uncertainty, and that it is necessary to learn to use less than perfect computational tools and incomplete data sets.

There are several other reasons why the iterative PA approach will be followed. Iterations will be invaluable in pointing out the shortcomings in existing models and data, and will also indicate topics in need of further investigations or research. We will strive for incremental improvements in understanding of processes, computational tools, and data, in each iteration. It is also imperative that the iterative PAs perform a technical integration function by being truly inter-disciplinary. Thus, the concepts developed for the engineered subsystem and the natural subsystem must be brought together in each iteration of the PA.

#### 4.4 <u>Top-Down Approach to Resource Allocation</u>

Iterative PA will provide an important input to deciding work priorities in both the Nuclear Material Safety and Safeguards (NMSS) and Nuclear Regulatory Research offices, in order to best use limited resources. This input will be in the form of problems identified during iterative PAs that need a solution. In addition to identification of problems, iterative PA, especially sensitivity and uncertainty analyses, will show which specific uncertainties contribute most to uncertainties in performance and, therefore, might pose a threat of noncompliance with the performance objectives (referred to as key technical uncertainties). Such key technical uncertainties are addressed in the ORS and LARP. Obviously, priorities indicated by PA should be considered in conjunction with needs identified by other means.

#### 4.5 <u>Training of Staff</u>

Iterative PAs combined with participation in international performance assessment programs such as INTRAVAL will keep the NRC staff current on pertinent methodologies. This is an essential step in providing assurance that the staff will have at its disposal the needed skills to review critically DOE's PAs at the time of license application review. Of equal importance, it will provide the staff with needed tools for developing regulatory guidance and additional reactive work, such as review of prelicense submittals, including site characterization data and interactions with DOE, State of Nevada, and affected parties.

#### 5.0 PROGRAMMATIC PRIORITIES

Highest priority in the near term will be given to developing staff and contractor technical capabilities in the conduct of PAs. Progress has already been made, as indicated by the recently released staff report entitled, "Phase I Demonstration of the Nuclear Regulatory Commission's Capability to Conduct a Performance Assessment for a HLW Repository" (April, 1990). The second phase of this effort has been initiated and is intended primarily to combine the knowledge of specialized technical disciplines (engineering and earth sciences) with those of the system modelers, to produce integrated PAs. Special attention will be directed toward improvements in methodology for scenario identification and screening, retardation phenomena, mechanistic treatment of radionuclide release and near-field coupled effects, disruptive consequences, and alternative sensitivity and uncertainty analysis methods. Of equal importance in this effort is a planned evaluation of the effects of the NRC subsystem requirements on EPA Standard compliance.

Skills acquired in the Phase-I development exercise and the planned second phase will have immediate applicability to the other two principal areas of PA work: support to the DOE program review and the development of regulatory guidance for use by the staff and DOE. The staff Phase I effort has already had substantial influence in dealings with DOE in its site characterization activities and led to the staff's first formal technical exchange with DOE on PA (November 27-29, 1990). Immediate benefits also accrue to the regulatory guidance efforts under the SRA program, which is investigating technical uncertainties related to model validation, scenario identification, data uncertainty, and use of expert judgment. Depending on SRA program results, rulemaking may also be warranted.

In the future iterations, high priority will be given to integration of the subsystem PA work with the total system PA and assessment of key technical uncertainties identified by the staff consistent with ORS. In the present organizational structure, important work on the subsystems, including compliance determination with respect to the siting and design criteria of 10 CFR Part 60, is being funded separately. Irrespective of the funding mechanisms, a plan to implement a team approach for integration of work with respect to each one of the subsystem PAs will be developed. To be successful, each team must be comprised of experts from different disciplines interested in a particular subsystem and the total system. The compositions of the teams, the responsibilities of the team leader, relation of the teams to line management, and funding of the work of the teams will be the subject of the "NRC Performance Assessment Implementation Plan."

#### **6.0 UPDATING OF STRATEGY**

The NRC PA strategy will be reviewed periodically (once a year) and updated based on possible program redirection. This applies especially to the updating of programmatic priorities stated in the last section. The proportion of reactive and proactive PA work may also change from year to year depending upon the extent and nature of DOE's pre-license submittals.