SECY-96-103

May 17, 1996

FOR: The Commissioners

FROM: James M. Taylor /s/
Executive Director for Operations

SUBJECT: REGULATORY ISSUES IN LOW-LEVEL RADIOACTIVE WASTE PERFORMANCE ASSESSMENT

PURPOSE:

(1) To inform the Commission about proposed staff approaches on principal regulatory issues in low-level waste (LLW) performance assessment (PA) and to discuss comments on these issues from the LLW PA workshop, and (2) to obtain Commission approval for staff to publish, for public comment, a draft Branch Technical Position (BTP) that states staff's position on addressing these issues.

BACKGROUND:

The Low-Level Radioactive Waste Performance Assessment Development Program Plan (SECY-92-060) was developed in response to a June 14, 1991, Staff Requirements Memorandum. Stated goals of this plan were to enhance in-house capability and to develop regulatory guidance for LLW PA based on existing state-of-the-art technology. To accomplish these goals, staff is conducting test case modeling for LLW PA and completing a "BTP on PA of LLW Disposal Facilities."

A preliminary draft BTP was prepared and distributed for comment to all LLW sited and host Agreement States, the Advisory Committee on Nuclear Waste (ACNW), the U.S. Department of Energy (DOE EXIT), the U.S. Environmental Protection Agency (EPA EXIT), and the United States Geological Survey (USGS EXIT). Staff briefed the ACNW in March 1994 and the Commission in April 1994. It also evaluated State and Federal agency comments on the preliminary draft of the BTP, revised certain sections of the BTP, and organized two public workshops on the BTP and LLW PA. Staff has evaluated the comments from these workshops and is preparing a revised draft BTP for public comment. Staff also briefed the ACNW on the four key regulatory issues and workshop comments on March 16, 1995. This SECY paper provides the Commission with information about concerns and issues raised at the LLW PA workshops, presents considerations, and recommends staff approaches for resolving the four key regulatory issues in the BTP.

DISCUSSION:

A summary of the basis and recommended approach for each of the four key regulatory issues presented in the BTP is presented below (a fuller discussion may be found in the Attachment to this paper):

1. Timeframe for LLW PA

A technical analysis is required in 10 CFR 61.13a to demonstrate compliance with the performance objective in 10 CFR 61.41. However, Part 61 does not specify a time of compliance for meeting the overall performance objective in 10 CFR 61.41. It is important for NRC to provide guidance on an appropriate compliance period to ensure consistency in application of Part 61 in the national LLW program (North Carolina has recently requested NRC staff guidance regarding compliance period for performance assessment). Thus, the BTP provides technical concerns with selecting a performance period and recommends a compliance period.

One important concern with establishing an appropriate timeframe is that release and transport are sensitive to a number of uncertain site- and facility-specific parameters (e.g., the degradation rate of engineered barriers, and estimates for geochemical retardation in soils). This can result in order-of-magnitude uncertainties in the predicted time of peak dose at an off site receptor point. Specification of a particular compliance period needs to consider a timeframe appropriate for evaluating the performance of both the site and engineered barriers in meeting the performance objective given the types (i.e., half-life and mobility) of radionuclides being disposed. Staff considers a time of compliance of 10,000 years sufficiently long to capture the peak dose from the more mobile long-lived radionuclides, which will tend to bound the potential doses at longer times and demonstrate the relationship of site suitability to compliance with the performance objective. An assessment of the impacts of disposal of large quantities of uranium or transuranics (e.g.; uranium inventories which result in a radium dose at 10,000 years indicative of a potential for a radium dose in excess of the performance objective beyond 10,000 years) may be necessary in the site environmental evaluation to ensure that unacceptably high doses will not occur beyond 10,000 years.

Staff considers short compliance periods, such as the 1000-years being used in dose assessments of decommissioning facilities, to be generally inappropriate for assessments of LLW facilities because they could rely primarily on the performance of engineered barriers for meeting the performance objective and not provide sufficient evaluation of the performance of the site. Unlike decommissioning facilities, where the number and quantity of radionuclides of concern are generally limited, the inventory and variety of long-lived radionuclides for LLW facilities can be large. Accordingly, the range of parameters that governs the mobility of these long-lived radionuclides will be much larger than that typically found at facilities undergoing decommissioning. In addition, release of radionuclides from LLW disposal units can be delayed for hundreds of years due to the presence of engineered barriers. Therefore, truncation of PA analyses for LLW facilities, at 1000 years, would not fully evaluate the performance of the site in meeting the performance objective when the peak dose occurs beyond 1,000 years. For typical LLW disposal site inventories, staff generally does not expect doses from long-lived radionuclides at any time to exceed 100 mrem TEDE.

2. Considerations of Future Site Conditions, Processes, and Events

The 10 CFR Part 61 siting requirements emphasize site stability, waste isolation, long-term performance, and defensible modeling of future site behavior. To help achieve these ends, the requirements stipulate avoiding sites where the frequency and extent of geologic processes and events will adversely affect performance of an LLW disposal facility or preclude defensible modeling of long-term performance. Therefore, it should be possible to establish a set of natural conditions, processes, and events that comprise the "reference natural setting" to be used in PA. It is important to emphasize that the goal of the analysis is not to accurately predict the future but to test the robustness of the facility against a reasonable range of potential outcomes. Additionally, consideration of societal changes would result in unnecessary speculation and should not be included in performance assessments.

Some workshop participants stated that they were concerned about: (1) the need to specify which site conditions should or should not be analyzed; and (2) the ability to model long-term dynamic or transient site conditions. Staff recommends use of ranges of assumptions and parameters that effectively represent conditions of the site as encompassed in the reference natural setting and tend to bound dynamic site behavior. To capture the variability in natural processes and events, the span of siting assumptions and data should be sufficient to understand the relevance to performance of distinct events as well as long-term trends in natural phenomena acting on the site. Staff emphasizes that the siting requirements are intended to: 1) assist determination of a reasonable range of site conditions, processes, and events to be considered in evaluating long term performance; and 2) eliminate unnecessary speculation in LLW PA.

3. Performance of Engineered Barriers

Engineered barriers affect the overall facility performance by limiting the influx of water into disposal units and reducing the release of radionuclides from the disposal unit. Significant uncertainty exists in predicting long-term design life and degradation rates of engineered barriers. Staff recommends that typical engineered barriers be assumed to be physically degraded after 500 years after site closure. Beyond 500 years the barriers are assumed to be in a degraded condition and function at performance levels considerably less than design expectations. The staff's proposed position on the 500-year design life for the engineered barriers has met with mixed reactions from the Agreement States and recent workshop participants. The reactions have ranged from concerns that the recommended design life is too generous and potentially in conflict with more stringent State regulations that limit performance of engineered features to 100 years, to opinions that the 500-year design life limit is unreasonably short and unsupported by analysis.

The recommendation is generally to limit the design life of the water-repelling characteristics of engineered barriers to 500 years (guidance does allow a longer period of performance if it can be supported). The position allows taking credit for longer periods of time for structural stability and chemical buffering effects. The position recognizes that after about 500 years the radionuclides remaining in "typical" commercial LLW tend to have such long half-lives that no physical barrier can reasonably be assumed to continue to function as designed while the remaining radionuclides decay.

4. Treatment of Sensitivity and Uncertainty in LLW PA

Uncertainty is inherent in all PA calculations, whether they are deterministic or probabilistic, and regulatory decision-makers need to consider how uncertainty associated with the models and parameters translates into uncertainty in demonstrating compliance with the performance objective. The staff has recommended that formal sensitivity and uncertainty analyses be conducted in support of compliance determination calculations. Staff has considered a range of different approaches for acceptable compliance demonstrations. On one end of the spectrum is a deterministic estimate of system performance that clearly and demonstrably bounds the potential doses and on the other end is a probabilistic approach with a distribution of potential outcomes for system performance.

When compliance with the performance objective in 10 CFR 61.41 is based on a single estimate of performance, the applicant is relying on the demonstration of a conservative nature of the analysis, rather than a quantitative analysis of uncertainty. Therefore, a single estimate of performance must be at or below the performance objective in 10 CFR 61.41. In cases where a formal uncertainty analysis is performed and a distribution of potential outcomes for system performance is provided, the staff recommends that the mean of the distribution be less than the performance objective and the 95th percentile of the distribution be less than 1 mSv (100 mrem) to consider a facility in compliance. The BTP on PA implements the Commission's Final Policy Statement on the use of probabilistic risk assessment methods in nuclear regulatory activities by recommending the use of sensitivity and uncertainty analyses which could reduce unnecessary conservatism.

The BTP, which includes the recommendations on the four policy issues, is intended to provide guidance in performance assessment. It also serves to provide guidance for use by Agreement State regulatory agencies having LLW regulatory responsibilities. The guidance is not mandatory, but provides one acceptable approach for demonstrating compliance with the performance provisions of Part 61. The staff has been sensitive to concern that the guidance not be disruptive to state licensing activities. After the LLW PA Workshop, an informal poll of 13 states was conducted to better understand how publication of the BTP might affect their licensing activities. The majority (10) indicated the BTP would either have no adverse effect or a positive impact on their licensing activities. Three states raised concerns that the guidance comes too late and could be used to challenge license applications in the near term (i.e., current PA approach versus BTP). Publication of the Draft BTP will allow all interested parties to provide formal comments to the Commission. Consideration of a full range of comments will provide a better perspective to determine the appropriateness and adequacy of the guidance.

RECOMMENDATION:

Staff intends to publish in the Federal Register, for public comment, the draft "BTP on PA for LLW Disposal Facilities," containing staff preferred positions on the four key policy issues, unless otherwise directed within ten business days from the date of this paper.

NOTE:

Detailed staff considerations during development of the BTP are provided as an attachment. The staff recognizes that conformance with the guidance in the BTP is not required; however, the staff considers use of the BTP guidance as an acceptable approach to LLW PA. The staff would accept for review any performance assessment that addresses the information requirements in 10 CFR Part 61.

COORDINATION:

The Office of the General Counsel has reviewed this paper and has no legal objection.

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Attachment: As stated

ATTACHMENT

STAFF CONSIDERATIONS IN THE DEVELOPMENT
OF
THE BRANCH TECHNICAL POSITION
FOR
LOW-LEVEL RADIOACTIVE WASTE PERFORMANCE ASSESSMENT

INTRODUCTION

The Low-Level Radioactive Waste Performance Assessment Development Program Plan (SECY-92-060) was developed in response to a June 14, 1991, Staff Requirements Memorandum. The plan was divided into two phases. The goals of Phase I were to enhance in-house capability and to develop regulatory guidance for low-level waste performance assessment (LLW PA) based on existing state-of-the-art technology. To accomplish these goals, staff is conducting test case modeling for LLW PA and completing a "BTP on PA of LLW Disposal Facilities." This effort is being carried out by the Performance Assessment Working Group, which is composed of U.S. Nuclear Regulatory Commission (NRC) staff from both the Division of Waste Management, Office of Nuclear Material Safety and Safeguards, and the Waste Management Branch, Office of Nuclear Regulatory Research.

A preliminary draft branch technical position (BTP) was prepared and distributed for comment to all LLW sited and host Agreement States, the Advisory Committee on Nuclear Waste (ACNW), the U.S. Department of Energy (DOE), the U. S. Environmental Protection Agency (EPA), and the United States Geological Survey (USGS). Staff briefed the ACNW in March 1994 and the Commission in April 1994. It also evaluated State and Federal agency comments on the preliminary draft of the BTP, revised certain sections of the BTP, and organized two workshops on the BTP and LLW PA. The first was a 2-day workshop on the BTP and test case held at NRC Headquarters on November 16-17, 1994. The second was a half-day workshop that focused on certain technical issues in LLW PA and was held at the 16th Annual DOE/LLW Management Conference on December 13-15, 1994. Staff has evaluated the comments from these workshops and is preparing a revised draft BTP for public comment. Staff also briefed the ACNW on the four key regulatory issues and workshop comments on March 16, 1995. This background paper provides information concerning the four key regulatory issues by addressing pertinent comments raised at the LLW PA workshops, staff considerations for resolution of the four issues, and recommended staff approaches for resolving the four key regulatory issues in the BTP.

DISCUSSION:

1. BTP Approach to LLW PA

In 1987, the NRC began formulating a PA strategy, that promotes a modular approach to LLW facility systems modeling, which quantifies the potential release and transport of radionuclides through significant environmental pathways. The performance assessment methodology (PAM) that was developed around this strategy embodies a generalized conceptual model of a LLW disposal facility and environs, for doing PA analyses, and is sketched conceptually in Figure 1. The PAM is divided into individual sub-models representing different components of the analysis, including: (1) infiltration; (2) source term; (3) engineered barriers; (4) transport via ground water, surface water, and air; and (5) dose. This modular approach allows a mix of both complex and simple models to be used in the overall PA.

In developing the BTP guidance, staff considered a number of desirable attributes and goals for an iterative PA process to implement the PAM. A flow chart of the iterative PA process is presented in Figure 2. The process starts with relatively simple conservative models, using both generic and site information, and becomes more facility- and site-specific, as required, to demonstrate compliance with 10 CFR 61.41 or to rule out a site. The PA process is intended to be integrated with site characterization and facility design activities, so that information necessary for demonstrating compliance with the 10 CFR 61.41 performance objectives is developed as an intrinsic part of site characterization. Initial screening analyses identify the more important issues and data needs. As more site and design information is collected, modeling assumptions, conceptual models, and data needs are reevaluated. Revisions to the site characterization and design program are made to obtain data needed to reduce uncertainty and defend assessment results. The process helps build confidence in the PA results insofar as reasons for modifying assumptions, models, and conditions are well-documented and supported by data amassed from site investigations and assessments. The approach also incorporates the treatment of sensitivity and uncertainty as an intrinsic part of PA decision-making.

2. Preferred Staff Approaches to Regulatory Issues

In developing regulatory guidance for LLW PA, staff has identified four key regulatory issues pertaining to interpreting and implementing Part 61 performance objectives and technical requirements. These issues affect how PA's are conducted and evaluated. The regulatory issues are: (1) timeframe for LLW PA; (2) considerations of future site conditions, processes, and events; (3) performance of engineered barriers; and (4) treatment of sensitivity and uncertainty in LLW PA. Recommended staff positions on these four policy issues are presented below. The level of guidance provided is general, since individual factors for any particular disposal site must be addressed on a specific basis.

2.1 Timeframe for LLW PA

A technical analysis is required in 10 CFR 61.13a to demonstrate compliance with 10 CFR 61.41 performance objectives. Some parts of Part 61 specify times for analysis of particular aspects of a facility (e.g., a minimum 500 years for evaluating site characteristics). However, Part 61 does not specify a time of compliance for meeting the overall performance objective of 10 CFR 61.41. One important concern with establishing an appropriate timeframe is that release and transport are sensitive to a number of uncertain site- and facility-specific parameters (e.g., the degradation rate of engineered barriers and estimates of geochemical retardation in soils). This can result in order-of-magnitude uncertainties in the predicted time of peak dose at an off site receptor point (as well as the values of peak dose). Another issue is that significant quantities of long-lived radionuclides (e.g., uranium) are being disposed of as LLW, which were not considered in the Draft Environmental Impact Statement (DEIS) for 10 CFR Part 61. The presence of large quantities of uranium at an LLW disposal site may cause the site to exceed the performance objectives at very long timeframes, because the dose potential of decay products is significantly higher than the parent and the concentration of decay products continuously increases with time until equilibrium with the parent is established (about 1 to 2 million years). Given the long half-lives of certain radionuclides, the objective of specifying a time period for PA is to provide a period of analysis sufficiently long to demonstrate, with reasonable assurance, compliance with the performance objectives and to determine if site-specific inventory limits for potentially mobile radionuclides may need to be established as part of overall site safety (10 CFR 61.7(b)(2)). In determining an appropriately long period of analysis, consideration needs to be given to evaluating the relationship of site suitability to meeting the performance objective.

In the preliminary draft BTP that was sent to States, DOE, EPA, and USGS for comment in January 1994, staff recommended that peak dose is appropriate for demonstrating compliance. However, after 10,000 years the applicant would have the option of demonstrating compliance without having to continue the calculations; for example, through arguments related to solubility limits for certain radionuclides, or that the trace amounts of remaining radionuclides would not cause significant doses at longer time periods. Discussion of the timeframe issue at the LLW PA workshop included: (1) concerns about the uncertainties associated with projections over long time periods; (2) worry that the credibility of "predictions" at long times are not sufficient to support licensing decisions; and (3) belief that early timeframes are more important than longer timeframes for addressing uncertainties in scenarios, parameters, and knowledge limitations. Some workshop participants stated a preference for 1000 years (e.g., in decommissioning or uranium mill tailings assessments) as an appropriate timeframe. The DOE PA Task Team, in early comments on timeframe, noted that it is considering a 10,000-year time of compliance. However, both EPA and USGS thought peak dose appropriate for long-term protection, rather than arbitrary assessment cutoff times.

In its LLW PA test-case calculations for a humid site, staff has gained a number of useful insights on the timeframe issue. Staff used 20,000 years as a typical calculation time. Staff has also carried out some calculations to 100,000 years to evaluate the transport of radionuclides with relatively large retardation coefficients and to evaluate impacts from the ingrowth of uranium daughter products, principally radium-226 (^{226}Ra). The test-case simulations show that for most radionuclides, the magnitude of the peak dose decreases with the time at which the peak occurs (i.e., for a particular radionuclide the peak dose will be reduced as the time of the peak is delayed). This is caused by the combined effects of dispersion in the ground-water system, radionuclide decay, and depletion of the inventory. In addition, the test-case simulations confirm that mobile long-lived radionuclides (e.g., carbon-14 (^{14}C), chlorine-36 (^{36}Cl), technetium-99 (^{99}Tc), and iodine-129 (^{129}I)) tend to bound the peak doses for other radionuclides in LLW. Thus a time of compliance that is sufficiently long to capture the peaks from the more mobile radionuclides (i.e., 10,000 years) will tend to bound the potential doses for longer timeframes (>10,000 years). However, specific exceptions include: (1) daughter ingrowth at long timeframes for large inventories of uranium ($>\sim 3.7 \times 10^{13}$ Bq [>~1000 Ci]); and (2) peak doses from large inventories of long-lived transuranics at humid sites.

The preferred staff position is a time of compliance of 10,000 years (see Figure 3). The PA analysis (including sensitivity and uncertainty analyses) within this timeframe would be used as a basis of determining compliance with 10 CFR 61.41. A time of compliance of 10,000 years is sufficiently long to capture the peak dose from the more mobile radionuclides, which will tend to bound the potential doses at longer times, and to demonstrate the relationship of site suitability to meeting the performance objective. This approach recognizes that parameter uncertainty analyses at long timeframes can only capture a very small portion of the overall uncertainty in future conditions and does not attempt to use dose calculations at very long timeframes as a basis for compliance. In general, large-scale geosphere changes would not be anticipated in this 10,000-year timeframe at sites that meet the stability and suitability requirements of 10 CFR Part 61. Staff recognizes that the assumptions and conditions of the analysis may not predict "real" conditions at long timeframes. However, the express purpose of such a calculation is to provide a measure of potential impacts given the current state of knowledge.

An assessment of the impacts of disposal of large quantities of uranium or transuranics (e.g.; uranium inventories which result in a radium dose at 10,000 years indicative of a potential for a radium dose in excess of the performance objective beyond 10,000 years) may be necessary in the site environmental evaluation to ensure that unacceptably high doses will not occur beyond 10,000 years. The approach recognizes that parameter uncertainty analyses at long timeframes can only capture a very small portion of the overall uncertainty in future conditions and allows regulatory judgment in interpreting dose limits at long timeframes. Nevertheless, it provides some estimate of the possible impacts from the disposal of large amounts of long-lived radionuclides. The staff believes there should be discussions with DOE and EPA about the appropriateness of disposing of very large quantities of uranium at near-surface LLW disposal facilities.

Staff considers shorter compliance periods, such the 1000-years being used in dose assessments of decommissioning facilities, to be generally inappropriate for assessments of LLW facilities because they rely almost exclusively on the performance of engineered barriers for meeting the performance objective and do not provide sufficient evaluation of the performance of the site. Unlike decommissioning facilities, where the number and quantity of radionuclides of concern are generally limited, the inventory and variety of long-lived radionuclides for LLW facilities can be large. Accordingly, the range of parameters that governs the mobility of these long-lived radionuclides will be much larger than that typically found at facilities undergoing decommissioning. In addition, release of radionuclides from LLW disposal units can be delayed for hundreds of years due to the presence of engineered barriers. Therefore, truncation of PA analyses for LLW facilities, at 1000 years, would not fully evaluate the performance of the site in meeting the performance objective when the peak dose occurs beyond 1,000 years. For typical LLW disposal site inventories, staff does not expect doses from long-lived radionuclides to exceed 100 mrem TEDE.

2.2 Considerations of Future Site Conditions, Processes, and Events

The natural site contributes to overall disposal system performance by providing a stable environment for waste disposal, and by precluding or retarding the movement of radionuclides offsite through transport media such as ground water, surface water, or air. The Part 61 siting requirements emphasize site stability, waste isolation, long-term performance, and defensible modeling of future site behavior. To help achieve these ends, the requirements stipulate avoiding sites where the frequency and extent of geologic processes and events will adversely affect performance of an LLW disposal facility or preclude defensible modeling of long-term performance. This means that sites should be selected where natural processes are occurring at consistent and definable rates such that PA models will represent both present and anticipated site conditions. Sites where serious concerns exist over catastrophic disruptions to facility performance should be avoided. Thus, the need to speculate about future site conditions, processes, and events over thousands of years is substantially eliminated from LLW PA analyses. To further ensure that the disposal facility will not be severely disrupted during the period when the waste is most hazardous, facilities are to be built to withstand certain design-basis, natural events, such as the maximum credible earthquake and the probable maximum flood.

Comments were expressed at the workshop concerning the proposed position on evaluating site characteristics for PA modeling. Some workshop participants stated that they were concerned about: (1) the need to specify which site conditions should or should not be analyzed; and (2) the ability to model long-term dynamic or transient site conditions. The staff guidance in the BTP is consistent with the philosophy and approach used in developing Part 61 and establishes a basis from which site conditions can be evaluated and represented in PA models. The staff will not be prescribing sets of conditions that should or should not be considered in PA, except as described below. Under the siting requirements of Part 61, sites that exhibit extreme transient or dynamic conditions are not suitable for waste disposal.

In choosing a site, Part 61 requires that site characteristics should be considered in terms of the indefinite future and be evaluated for at least a 500-year timeframe. The 500-year timeframe is related to the potential hazard of the moderately high-activity, short-, and intermediate-lived radionuclides that are mostly present in Class B and C wastes. It also coincides with the expected performance lifetimes for engineered features, such as multi-layered cover designs, concrete vaults, and intruder barriers. The primary design function of these engineered features is to provide stability and limit infiltration of water into the waste to minimize leaching and release of radionuclides into the environment (principally to ground water), and to provide protection for inadvertent intruders over the time that the waste is most hazardous (500 years). For features such as stabilized B and C waste forms and high-integrity containers, Part 61 requires stability lifetimes, to the extent practicable, for 300 years. Service lifetimes on the order of a few hundred years for engineered features are considered credible, but beyond 500 years, natural site features and degraded engineered barriers should be relied on to isolate the remaining inventory of mostly long-lived radionuclides.

As stated above, Part 61 emphasizes selecting sites based on site stability, waste isolation, long-term performance, and defensible modeling. Therefore, it should be possible to establish a set of natural conditions, processes, and events that comprise the "reference natural setting." Ranges of assumptions and parameters should be used to effectively represent conditions of the site as encompassed in the reference natural setting. To capture the variability in natural processes and events, the span of siting assumptions and data should be sufficient to understand the relevance to performance of distinct events as well as long-term trends in natural phenomena acting on the site. It is important to emphasize that the goal of the analysis is not to accurately predict the future but to test the robustness of the facility against a reasonable range of potential outcomes.

In consideration of a site's biological environment, it is acceptable to assume that current biological trends continue unchanged throughout the duration of analyzed performance. This is also the case for human behavior, where, for example, it may be assumed that current land and water use practices will be followed in the future. To do otherwise would be highly speculative. Nevertheless, in the PA the analyst should clearly state the basis for not incorporating biosphere and human behavior changes into the models.

In the future, some disposal site regions may be affected by glaciation or an interglacial rise in sea level in response to global climate changes. These types of events are envisaged disrupting the disposal site, and its regional environment and human population. Therefore, it is believed that the population near a LLW facility will leave such affected areas as glaciation advances. Accordingly, an appropriate assumption would be that under conditions of glaciation no one would be living close enough to the facility to receive a significant dose. In addition, the hazard from the inventory remaining in typical LLW after about 500 years is expected to be low. Staff believes that an applicant can use similar reasoning to explain how potential effects of glaciation will not render the site unsafe.

For disposal sites where the impacts of global climate change primarily consist of changes from present-day meteorologic patterns, ascertaining the nature, timing, and magnitude of related meteorological processes and events (i.e., regional consequences) and their effects on disposal site performance is highly uncertain. However, a key aspect of a LLW PA is determining how variations in precipitation result in varying rates of percolation into the disposal unit(s) and recharge to the water table (infiltration). Increased infiltration, for example, could cause either an increase or decrease in calculated doses, depending upon other factors in the analysis. Therefore, it is important for an analyst to consider how variations in infiltration will affect dose calculations. The proposed staff approach recommends establishing a broad range of infiltration rates based upon historical and current weather data and other site information (e.g., field tests). This range of infiltration rates is statistically sampled through repeated simulations. During any particular simulation, the sampled infiltration rate is held constant throughout the entire simulation period. Since sampled infiltration rates are held constant throughout a given simulation, sampled values that are below and above the mean infiltration value will simulate conditions that are drier and wetter than average current conditions. Further, since it is recommended that multiple simulations be made, a range of site conditions will be considered in the LLW PA. Sensitivity analyses performed as part of the LLW PA will provide some insight into the effects that such variations could have on the dose calculations. Staff believes that the proposed treatment of infiltration in this manner will allow an analyst to consider the effects of a range of site conditions, without the need for making unbounded speculations on what changes in climate may occur.

2.3 Performance of Engineered Barriers

In the January 1994 draft BTP, the NRC staff recommended that typical engineered barriers be assumed to be physically degraded after 500 years after site closure. Beyond 500 years the barriers would be assumed to be in a degraded condition and function at performance levels that would be considerably less than design expectations. This degradation would be limited by the properties of the durable constituent materials that would remain. The staff's proposed position on the 500-year design life for the engineered barriers has met with mixed reactions from the Agreement States and recent workshop participants. The reactions have ranged from concerns that the recommended design life is too generous and potentially in conflict with more stringent State regulations that limit performance of engineered features to 100 years, to opinions that the 500-year design life limit is unreasonably short and unsupported by analysis. The importance of the performance period for engineered features is reinforced by results in the staff's test case, where the barrier's physical impacts are shown to significantly affect estimated doses in the PA analyses. The importance of this large impact on the outcome of dose estimates in PAs causes developers to claim the longest possible period of successful performance for the proposed engineered barriers.

Additional comments received on the role of engineered barriers, as described in the preliminary draft BTP, included: (1) cautions not to limit chemical buffering effects created by barrier materials to 500 years, since these could continue long after the engineered barriers would physically degrade; and (2) requests for guidance in determining what credit could be given to redundant engineered features, and where sophisticated monitoring programs are installed, that could provide confidence in the continuing safe performance of the engineered barriers. The staff plans to respond to these comments by completing revisions to the BTP, which will seek to provide the desired clarifications. A clear distinction is made, in the revisions to the BTP, between the physical characteristics of engineered barriers that would tend to limit the design life because of the degradation processes, and the chemical functioning of the barriers, which could continue well beyond 500 years because of the chemical environment that would result from the remaining constituent materials. In addition, the revised BTP addresses considerations related to the redundancy of engineered features and discusses the intended objectives of monitoring programs.

For the types of engineered barriers that are currently being proposed for near-surface low-level radioactive waste disposal facilities, there does not appear to be a sound, technical basis for accepting design level performance that would preclude water percolation into the waste disposal units for periods well beyond 500 years. At present, there is a lack of supporting data for performance of such engineered barriers beyond 500 years. Further, performance of these barriers beyond this period is questionable given known degradation forces, which can cause unavoidable and unpredictable deterioration of engineered barriers. Although some materials proposed for use in engineered barriers will endure as physically recognizable materials long after 500 years, the barrier as a whole may not continue to function as designed because essential but less durable components may have degraded. Without perpetual maintenance, soil covers at the surface will ultimately degrade because of the penetrations from roots and burrowing animals that will alter the integrity of the soil cover. Reinforced concrete structures will experience degradation that can result in localized cracking or opening of joints, followed by disintegration of portions of the concrete sections.

The preferred staff position, that will be incorporated into the BTP, is to generally limit the design life of the water-repelling characteristics of engineered barriers to 500 years. The position allows taking credit for longer periods of time for structural stability and chemical buffering effects. The staff recommendation acknowledges the limitations of information and performance records that are presently available and recognizes the large future uncertainties about processes and events that may affect performance. The recommendation is also based in part on understanding what was intended in the documents supporting the development and promulgation of Part 61. The "Final Environmental Impact Statement" in NUREG-0945, Issue D-50-9, clearly recognizes a time limit on the physical performance of engineered features and a need to ultimately place sole reliance on the characteristics of the disposal site itself, to continue to isolate the remaining waste. The staff position is also based on engineering judgment as to a period of design performance that is reasonable and acceptable to the engineering profession, for the materials typically being proposed. Staff considers this position to be defensible in licensing hearings. Finally, the position recognizes that after about 500 years the radionuclides remaining in "typical" commercial LLW tend to have such long half-lives that questions exist as to whether any physical barriers can reasonably be assumed to continue to function as designed while the remaining radionuclides decay. Thus, the 500- year time period is sufficiently long to allow the potential LLW inventories of shot-lived radionuclides to decay to insignificant levels and represents a reasonable upper limit for engineered design life. The guidance, however, does allow a longer period of performance, if it can be supported. Any period of time claimed for performance will need to be supported by suitable information and justification and would be evaluated on a case-by-case basis.

2.4 Treatment of Sensitivity and Uncertainty in LLW PA

The primary objective of the performance assessment is the quantitative estimation of system performance for comparison with the performance limit concerning radiological protection contained in 10 CFR 61.41. Since the promulgation of Part 61, a number of computer models have been developed to provide precise estimates of performance in support of a compliance determination. However, uncertainty is inherent in all PA calculations, whether they are deterministic or probabilistic, and regulatory decision-makers need to consider how uncertainty associated with the models and parameters translates into uncertainty in demonstrating compliance with the performance objective. An acceptable compliance demonstration will need to appropriately consider the uncertainties in the calculations.

Uncertainties are caused by factors such as: (1) limitations and assumptions of the conceptual and mathematical models; (2) uncertainties with respect to site conditions and processes over the performance period; (3) variations in parametric values used in the models; and (4) lack of knowledge supporting parameter values and/or conceptual models. Analyses, which use both simple and complex models of natural features and engineered systems, typically include a large number of variables, each of which encompasses a range of probable values. Different, but reasonable, combinations of these values can lead to a range of possible results. Sensitivity analysis is an important tool in determining the most critical parameters and assumptions (i.e., those that have the largest effect on the model result). Uncertainty analysis provides a tool for understanding and explaining the influence or impact of the assumptions and parametric values on the compliance demonstration. Compliance demonstration strategies can vary based on site-specific conditions, engineering design, and inventories. Therefore, the staff attempted to provide guidance in the BTP on approaches that were flexible, yet still provided the information necessary to make a sound regulatory decision.

Comments were raised during the BTP workshop about the usefulness and desirability of performing sensitivity and uncertainty analyses in support of a compliance determination. The main topics of discussion were: (1) uncertainties associated with PA calculations; (2) appropriate techniques for assessing the uncertainty in PA calculations; (3) benefits of using a single deterministic calculation, based on "reasoned point values," for demonstrating compliance, versus probabilistic approaches that produce a range of possible outcomes; (4) difficulties in explaining a distribution of results to the public; and (5) need for NRC guidance to offer a simple, transparent approach, for demonstrating compliance, that bolsters public confidence.

The NRC staff agreed with the concerns regarding the need for understandable and defensible demonstrations of compliance, to ensure public confidence and support for licensing decisions. The BTP provides guidance on approaches to sensitivity and uncertainty analyses. Insight gained from the application of these approaches will help provide a understandable and defensible demonstration of compliance and support for licensing decisions. The staff guidance is intended to encourage flexibility in the selection of approaches to accommodate diverse site characteristics and facility designs. Some workshop participants perceived the guidance to be more rigid than was intended. The guidance has been revised to provide more explicit examples of the types of analyses that would be considered appropriate and to better articulate the intended flexibility in applying sensitivity and uncertainty techniques in PA.

The staff has recommended that formal sensitivity analyses be conducted to identify the conceptual models and parametric values that most influence the performance calculation. This is consistent with existing guidance in NUREG-1199 and NUREG-1200. A variety of approaches can be used to identify key sensitivities in the PA analysis, including: (1) calculations in which a few parameters or one parameter related to a single feature or process (i.e., cover performance, source term, or ground-water flow) is varied over a reasonable range of values; (2) calculations in which many parameters or all parameters that can not be reasonably set to a constant are varied over a reasonable range of values; and (3) calculations for alternative conceptual models.

The selection of an appropriate approach for uncertainty analysis must be based on individual site characteristics, engineering designs, and the uncertainties of key parameters and conceptual models identified in the sensitivity analysis. For example, an analysis that relies predominantly on very long transport times in the unsaturated zone (typical of some arid environments), may focus on extensive site characterization and infiltration tests to understand and bound infiltration rates and unsaturated zone properties. In contrast, an analysis that relies on the combined performance of a number of facility attributes such as long-term performance of multi-layer covers and concrete vaults, diffusional release of radionuclides from cement waste forms, and solubility limits and retardation factors (as may be typical in some humid environments), may need to consider the relationships among parameters, as well as consider alternative conceptual models, to build confidence in the understanding of system performance. The applicant may decide to reduce the uncertainty associated with a conceptual model or parameter range by further site characterization activities, engineering design enhancements, and modeling improvements. Regardless of the additional effort it is important to acknowledge that residual uncertainties will remain. (A licensing decision does not require the **complete** removal of uncertainty.)

Staff has considered a range of different approaches for acceptable compliance demonstrations. Because PA analyses for any particular site may involve a spectrum of models of differing complexity, the most appropriate methods for evaluating uncertainty need to be tailored to the complexity of the analysis and the nature of the uncertainties being analyzed. On one end of the spectrum is a deterministic estimate of system performance that clearly and demonstrably bounds the potential doses. For this type of PA, the applicant provides a single estimate of performance that is believed to bound the performance. Defendability of this type of analysis requires the applicant to demonstrate that the PA models and parameters are bounding, especially with respect to any key uncertainties in the analysis. On the other end of the spectrum is a probabilistic approach with a distribution of potential outcomes for system performance. For this type of PA, the applicant uses the distribution of results as a representation of the effect of uncertainty on the performance. Such a PA, which relies on more realistic estimates of performance for multiple system components, requires the applicant to defend the representation of the uncertainty (defendable parameter ranges, appropriate random selection, and combination of parameters, etc.). In any approach, it is essential that the applicant present a reasonable, comprehensive, and persuasive understanding of the disposal system and provide interpretation of the results consistent with that understanding. The applicant needs to support the rationale for the analysis and the basis supporting the uncertainties considered and not considered in the PA.

There was considerable discussion at the workshop about how the results from the above two approaches for dealing with uncertainty would be used in determining compliance. When compliance with the dose standards in 10 CFR 61.41 is based on a single estimate of performance, the applicant is relying on the demonstration of the bounding nature of the analysis, rather than a quantitative analysis of uncertainty. A single estimate of performance does not provide a reviewer with insight into the quantitative margin of safety provided by the bounding analysis. Therefore, a single estimate of performance must be at or below the dose standards in 10 CFR 61.41.

In cases where a formal uncertainty analysis is performed and a distribution of potential outcomes for system performance is provided, the staff considered a number of aspects of the analysis to gain insight into appropriate measures for determining compliance based on the results of the uncertainty analysis. Appropriate statistical measures of a distribution were initially considered. The mean value of the distribution, as a representation of the central tendency of system performance or the "best model estimate" of performance, was considered the most reliable statistic of the distribution and therefore a logical choice for the point for compliance determination. The staff also considered a need for more assurance that the dose standards would not be exceeded than is provided by the mean of the distribution. For example, if the 95th percentile of the distribution were specified as a criterion for meeting the dose standards in 10 CFR 61.41, the staff believes there is high probability that the dose standards would not be exceeded (see Figure 4). The staff also considered the case for the entire distribution being in compliance with the dose standards. The staff believes this last option would only provide a marginal increase in confidence over the 95th percentile criterion and could result in excessive effort by the applicant to eliminate a few outliers in the tail of the distribution for a limited reduction in risk.

The approach to PA modeling discussed in the BTP is designed to ensure that the model results provide a conservative bias compared with actual disposal system and site performance. Based on the above considerations, the staff recommends that the mean of the distribution be less than the dose standards and the 95th percentile of the distribution be less than 1 mSv (100 mrem) to consider a facility in compliance with the dose standards of 10 CFR 61.41. Thus, a compliance determination makes use of the central tendency of the model (the mean is below the dose standard) and additional assurance is provided by demonstration that the 95th percentile is below 1 mSv (100 mrem). This compliance determination approach, involving a faithful representation of the uncertainty, is sufficient for making sound regulatory decisions. NRC staff believes that the use of the mean of the parameter uncertainty analyses for defensible conceptual models for the site and facility design provides confidence that the performance objectives will be met by the disposal system.