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A PERFORMANCE ASSESSMENT METHODOLOGY FOR LOW-LEVEL RADIOACTIVE WASTE DISPOSAL FACILITIES: RECOMMENDATIONS OF NRC'S PERFORMANCE ASSESSMENT WORKING GROUP

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ABSTRACT

The relationships between the overall 10 CFR Part 61 data and design requirements, and detailed low-level radioactive waste (LLW) performance assessment needs, are not directly apparent from the existing U.S. Nuclear Regulatory Commission (NRC) guidance documents. To address this concern, NRC's Performance Assessment Working Group (PAWG) has prepared this technical report as a means of providing information and recommendations on performance assessment methodology as it relates to the objective concerned with the radiological protection of the general public – 10 CFR 61.41. Specifically, this information includes the PAWG's views on: (a) an acceptable approach for systematically integrating site characterization, facility design, and performance modeling into a single performance assessment process; (b) five principal regulatory issues regarding interpreting and implementing Part 61 performance objectives and technical requirements integral to an LLW performance assessment; and (c) implementation of NRC's performance assessment methodology. Moreover, the PAWG does not expect separate intruder scenario dose analyses would be included in an LLW performance assessment because 10 CFR 61.13(b) requires that analyses of the protection of individuals from inadvertent intrusion must include a demonstration that there is reasonable assurance the waste classification and segregation requirements will be met and that adequate barriers to inadvertent intrusion will be provided.

Finally, this technical report attempts to share with the Agreement States and LLW disposal facility developers some of the PAWG's experience and insights, as they relate to the use of LLW performance assessments. In this regard, these groups may also find this technical report useful, as they proceed with the implementation of their respective programs.

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EXECUTIVE SUMMARY

1. INTRODUCTION

Performance assessment for low-level waste (LLW) disposal facilities is a quantitative analysis used in connection with demonstrating compliance with the 10 CFR Part 61 post-closure performance objective governing radiological protection of the general public (10 CFR 61.41). This technical report provides extensive information on conducting performance assessments for LLW disposal facilities. It describes a comprehensive process within which site characterization, facility design, and performance assessment are conducted concurrently so that assessment results can be used to identify additional information needs and direct the course of subsequent information-gathering activities. The report also addresses certain LLW regulatory issues concerning how to interpret and implement the Part 61 technical requirements pertaining to performance assessment. These regulatory issues are: (a) treatment of future site conditions, processes, and events; (b) performance of engineered barriers; (c) timeframe for an LLW performance assessment; (d) treatment of sensitivity and uncertainty; and (e) the role of a performance assessment during operational and post-closure periods. Finally, this technical report describes the Performance Assessment Working Group's (PAWG's) views on acceptable modeling approaches for implementing the U.S. Nuclear Regulatory Commission (NRC) performance assessment methodology (PAM).

Finally, this technical report also attempts to share with the Agreement States and LLW disposal facility developers some of the PAWG's overall experience, expertise and insights as they relate to the use of LLW performance assessments. In this regard, these groups may also find this Technical report useful as they proceed with the implementation of their respective programs.

2. LLW PERFORMANCE ASSESSMENT PROCESS

The goal of the performance assessment process is to develop a supportable demonstration of compliance. The approach presented in this technical report provides a process to defensibly and transparently address uncertainty when analyzing future LLW disposal site performance. In developing an effective performance assessment process, several attributes and objectives are considered essential. *The central attribute of the process is that it is to be conducted* ***iteratively*** *– starting with a combination of generic and limited site-specific information in support of relatively simple conservative models and analyses, and progressing to more realistic, site-specific and detailed analyses,* ***as necessary****, to reduce uncertainty in assessing performance of an LLW disposal facility.* Initial screening analyses identify the most important issues and data needs, and as more site and design information is collected, modeling assumptions, conceptual models, and data needs are reevaluated. Site characterization and design bases are then revised to obtain data or modify the design as needed to reduce uncertainty and defend assessment results. The process is intended to be open and transparent in that all data, assumptions, and models should be well-documented and explained. Moreover, the reasons for any subsequent modification of assumptions and models should also be documented and supported by an appropriate combination of site investigation and assessment data, valid technical reasoning, and professional judgment. The process incorporates a formal treatment of uncertainty to provide a basis for performance assessment decision-making, provides a technical basis for identifying the completion of site characterization, and helps build confidence that the disposal site meets the performance objective.

3. RECOMMENDED APPROACHES TO REGULATORY ISSUES

The PAWG has identified five Part 61 performance assessment issues that it believes need to be addressed. These regulatory issues are: (a) consideration of future site conditions, processes, and events; (b) performance of engineered barriers; (c) timeframe for an LLW performance assessment; (d) treatment of sensitivity and uncertainty in LLW performance assessments; and (e) role of performance assessment during operational and closure periods. The PAWG's positions on these five issues recommend general approaches to addressing them in the context of an LLW performance assessment.

3.1 Consideration of Future Site Conditions, Processes, and Events

The Part 61 siting requirements emphasize site stability, waste isolation, long-term performance, and defensible modeling of future site behavior. To help achieve these goals, 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 define a set of natural conditions, processes, and events that comprise the "reference geologic setting" to be used in an LLW performance assessment. 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 possibilities. The PAWG recommends the use of realistic assumptions and ranges of parameters to effectively reflect the reference geologic setting for the site. To capture the variability in natural processes and events and dynamic site behavior, the range of siting assumptions and data should be sufficient to understand the long-term trends in natural phenomena acting on the site. The PAWG emphasizes that there should be a limit on the range of possible site conditions, processes, and events to be considered in an LLW performance assessment and that unnecessary speculation in the assessment should be eliminated.

Additionally, consideration of societal changes would result in unnecessary speculation and therefore should not be included in a performance assessment.

3.2 Performance of Engineered Barriers

Engineered barriers are typically used to enhance overall facility performance by limiting the flux of water that comes into contact with the waste and the subsequent release of radionuclides from disposal units. However, significant uncertainty exists concerning predicting the service (i.e., design) life and long-term degradation rates of most engineered barriers, and concerning demonstration of their long-term performance. The PAWG recommends that an applicant assign and justify the credit given to engineered barrier performance. Any period of time claimed for performance of engineered barrier should be supported by suitable information and technical justification evaluated on a case-by-case basis.

However, to limit unnecessary speculation as to their performance, the PAWG believes that materials typically used in engineered barriers can alternatively be assumed to have physically degraded after 500 years following site closure. Thus, at 500 years and beyond, the engineered barriers can be assumed to function at levels of performance that are considerably less than their optimum level, but credit for structural stability and chemical buffering effects may be taken for longer periods of time.[1] For timeframes longer than 500 years, it is unreasonable to assume that any physical engineered barrier such as a cover or a reinforced concrete vault can be designed to function long enough to influence the eventual release of long-lived radionuclides such as carbon-14 (half-life: 5300 years); technetium-99 (half-life: 213,000 years); and iodine-129 (half-life: 15,700,000 years), if they are present. However, credit for structural stability and chemical buffering effects may be taken for the long-term provided that the applicant provides suitable information and justification. But again, this would have to be evaluated on a case-by-case basis.

3.3 Timeframe for an LLW Performance Assessment

Part 61 does not specify a time of compliance for meeting the post-closure performance objective of 10 CFR 61.41. Specification of a period for analysis needs to consider a timeframe appropriate for evaluating the performance of both the engineered barriers and geologic barriers with consideration given to the types (i.e., activity, half-life, and mobility) of radionuclides being disposed of as LLW. The key concern is that release and transport are sensitive to a number of uncertain site-specific parameters such as the degradation rates of physical barriers, and estimates for geochemical retardation in natural soils, backfills and infills (chemical barriers), and intact and degraded physical barriers. This sensitivity can result in order-of-magnitude uncertainties in the predicted time of peak dose at an off-site receptor point. To reduce unnecessary speculation regarding the performance assessment, a period of 10,000 years (i.e., the period of regulatory interest or concern) is sufficiently long to capture the peak dose from the more mobile long-lived radionuclides and to demonstrate the relationship of site suitability to the performance objective. Shorter periods, such as the 1000 years being used in dose assessments for site decommissioning, are considered generally inappropriate for assessments of LLW facilities. The PAWG is concerned that reliance on shorter compliance periods may result in an over-reliance on engineered barriers, to an extent that the performance of the natural setting would not be sufficiently evaluated, and would not consider peak dose, should it occur beyond the 1000-year period. Assessments beyond 10,000 years can be carried out, to ensure that the disposal of certain types of waste does not result in markedly high doses to future generations, or to evaluate waste disposal at arid sites with extremely long ground-water travel times. However, assessments of doses occurring after 10,000 years are not recommended for use as a basis for compliance with the performance objective.

3.4 Treatment of Sensitivity and Uncertainty in an LLW Performance Assessment

Uncertainty is inherent in all performance-assessment calculations, whether they are

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1 For "typical" commercial LLW, the inventory of short-lived radionuclides decays to insignificant quantities at about 500 years.

deterministic or probabilistic, and regulatory decision-makers need to consider how the uncertainty associated with the models and parameters translates into uncertainty in performance measures. The PAWG recommends that formal sensitivity and uncertainty analyses be conducted in support of performance assessment calculations. The PAWG considered two different approaches for representing system performance in the context of the post-closure performance objective. One approach provides a single bounding estimate of system performance supported by data and assumptions that clearly demonstrate the realistic nature of the analysis. The other approach provides a quantitative evaluation of uncertainty with regard to system performance represented by a distribution of potential outcomes.[2]

When compliance, as measured against the 10 CFR 61.41 performance objective, is based on a single (deterministic) estimate of performance, the applicant is relying on the demonstration of the conservative nature of the analysis, rather than a quantitative analysis of uncertainty. Therefore, if it is to be used as a performance measure, a single estimate of performance should be at or below the 10 CFR 61.41 performance objective. In cases where a formal uncertainty analysis is performed and a distribution of potential outcomes for system performance is provided, the PAWG recommends that the peak of the mean dose as a function of time be less than the performance objective, and a plot of the upper 95th percentile of doses at each discrete time be less than 1 mSv (100 mrem), to consider a facility in compliance.

3.5 Role of Performance Assessment during the Operational and Closure Periods

Part 61 requires that final LLW site closure plans demonstrate the long-term safety of the facility, and include any additional geologic, hydrologic, or other disposal site data obtained during the operational period pertinent to the long-term containment of waste, and the results of tests, experiments, or analyses pertaining to long-term containment of waste. This could include testing of assumptions about the performance of engineered aspects of the facility that are amenable to confirmation during operations. The site closure requirements suggest a need to keep performance assessments up to date as new information brings into question the bases of earlier assessments of LLW site safety.

4 RECOMMENDED ANALYTICAL APPROACHES TO MODELING ISSUES

NRC formulated a performance assessment strategy in 1987 that promotes a modular approach to modeling LLW disposal facility systems. The PAM, which was subsequently developed around this strategy, embodies a generalized conceptual model of an LLW disposal site, necessary for undertaking performance assessment analyses. The purpose of the PAM is to provide a basic set of system component models for conducting LLW performance assessments. The PAM

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[2] Probabilistic approaches encompass a wide range of analysis techniques and methods. For the purposes of this technical report, the probabilistic approach being recommended refers to the use of a formal, systematic uncertainty analysis to quantify the uncertainty in performance estimates caused by uncertainty in models and parameters. Although LLW disposal facility developers are free to screen scenarios and assign them probabilities (which is characteristic of some probabilistic approaches), the PAWG believes that the siting guidelines found at Section 61.50 obviate the need for this step.

considers disposal system component models for: (a) infiltration; (b) source term; (c) engineered barriers; (d) transport via (i) groundwater, (ii) surface water, and (iii) air; and (e) dose. The PAM's modular structure allows a mix of both complex and simple models to be used in the overall LLW performance assessment. Given the technical uncertainty of modeling LLW site performance and the diversity of sites and facility designs being considered by various States and compacts, flexibility to select appropriate subsystem models and codes is an important PAM attribute.

This technical report identifies technical issues and describes analytical approaches for modeling disposal system components set out in the PAM. Although it is possible to implement the PAM manually, creating input to one subsystem model based on the results of another, this document discusses the potential benefits of automating subsystem model or code inputs and outputs with an overall "system" code. The benefits of an automated system code over manually linked subsystem models may include: (a) increased ability to step through successive iterations of the performance-assessment process and perform uncertainty and sensitivity analyses; (b) a higher degree of quality assurance; (c) explicit recognition of assumptions that might be vague or addressed inconsistently; and (d) use of consistent parameters and values among subsystem models. However, no matter how model integration is performed, it is important that analysts scrutinize and understand the intermediate model results. Although specific models and codes may be discussed or referenced in this document, PAWG does not endorse the use of any particular models or codes for an LLW performance assessment.

TABLE SHOWING ENGLISH/METRIC CONVERSION FACTORS

The preferred system of measurement today is the "Systèm Internationale (SI)," or the metric system. However, for some physical quantities, many scientists and engineers prefer the familiar and continue to use the English system (inch-pound units). With few exceptions, all units of measure cited in this NUREG are usually in the metric system.

The following table provides the appropriate conversion factors to allow the user to switch between the English and SI systems of measure. Not all units nor methods of conversion are shown. Unit abbreviations are shown in parentheses. All conversion factors are approximate.

Multiply Inch-Pound Units	*By*	*To Obtain SI Units*
	Length	
inch (in)	2.54	centimeter (cm)
feet (ft)	0.3048	meter (m)
mile (mi)	1.609	kilometer (km)
	Area	
square mile (mi^2)	2.590	square kilometers (km^2)
	Flow	
cubic feet per second (ft^3/sec)	0.02832	cubic meters per second (m^3/sec)
gallon (U.S.) per minute (gal/min)	0.06309	Liter per second (L/sec)
	Transmissivity	
foot squared per day (ft^2/day)	0.0929	meter squared per day (m^2/day)
	Temperature	
degree Celsius (°C)	9/5 °C + 32 = °F	degree Fahrenheit (°F)

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Brookhaven National Laboratory
California State University
Idaho National Engineering and Environmental Laboratory
National Institute of Science and Technology
Oak Ridge National Laboratory
Pacific Northwest National Laboratory
Princeton University
Massachusetts Institute of Technology
Sandia National Laboratories
University of California

Staff from these institutions do not necessarily approve, disapprove, or endorse the views expressed in this document.

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Lastly, the PAWG also wishes to thank staff in NRC's Office of State Programs and the Idaho National Engineering and Environmental Laboratory staff, for helping to organize the public workshop on LLW Performance Assessment held in November 1994; members of the Advisory Committee on Nuclear Waste, for their continuing encouragement and support along the way toward completion of this document; and the Sandia National Laboratories' staff, for their assistance in the evaluation of public comments.

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FOREWORD

This technical report was developed by the Performance Assessment Working Group (PAWG), which was composed of U.S. Nuclear Regulatory Commission (NRC) staff, from the Division of Waste Management, Office of Nuclear Material Safety and Safeguards (NMSS), and the Waste Management Branch, Office of Nuclear Regulatory Research (RES). PAWG members were recognized NRC staff experts in the area of performance assessment and allied sciences.

In January 1994, a preliminary draft of this document was first prepared as a draft Branch Technical Position (BTP) and distributed for comment to all low-level radioactive waste (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; and the U.S. Geological Survey. The PAWG briefed the ACNW and the Commission, respectively, in March and April 1994. PAWG also evaluated State and Federal agency comments on the preliminary draft of the document, revised certain sections of the document, and organized two workshops on the draft BTP and LLW performance assessment. The first was a 2-day workshop on the draft 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 performance assessment and was held at the 16th Annual DOE/LLW Management Conference on December 13-15, 1994. The PAWG also briefed the ACNW on key regulatory issues and its evaluation of the workshop comments on March 16, 1995. This technical report reflects the PAWG's consideration of comments received during those interactions as well as specific direction received from the Commission.[1]

In a *Federal Register* notice dated May 29, 1997 (62 *FR* 29164), the NRC staff announced the availability of the draft BTP for (formal) public comment. In addition to the *Federal Register* notice, more than 200 copies of the draft BTP were distributed to former NRC LLW workshop participants and other targeted groups. A copy of the draft BTP was also made available on the NRC State Programs' external web page. As a result of these efforts, the staff received comments from 17 organizations and agencies. These comments and PAWG's responses thereto have been included as Appendix B found later in this technical report. It should also be noted that Appendix B includes a list of new references and information developed since the draft BTP was issued for public comment that has now been incorporated into the text of the final document. These additions and updates, as well as some recent editorial revisions, do not change the recommendations and advice provided earlier by the staff.

As a result of the public comment process, a number of commenters expressed concern that the proposed guidance, particularly in the area of the recommended policy approaches (Section 3.2 of this technical report), once finalized, would be viewed by LLW disposal facility developers and other regulatory entities as *defacto* NRC standards by virtue of their codification in the form

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[1] See U.S. Nuclear Regulatory Commission, "Regulatory Issues in Low-Level Radioactive Waste Performance Assessment," Washington, D.C., Commission Paper, SECY-96-103, May 17, 1996.

of a BTP. This was not the staff's intent. The recommended technical and policy approaches in this NUREG were not intended as substitutes for NRC's regulations, and compliance with these recommendations was never intended to be obligatory. To avoid the potential for future confusion in this area, the staff no longer refers to this document as the draft BTP; it is now simply a *technical report*, representing the views and recommendations of NRC's PAWG. Nonetheless, PAWG believes that methods and solutions differing from those set out in this NUREG should be acceptable to the NRC staff if they provide a sufficient basis for the findings requisite to the issuance of a permit or license by the Commission.

Finally, it should be noted that a motivating factor influencing the development of this technical report was the desire to share with the Agreement States and LLW disposal facility developers (as potential applicants) some of the PAWG's experience and insights, as they relate to the use of LLW performance assessments in a regulatory context. The extent to which the Agreement States or other regulatory entities implement the recommended approaches found in this document is, of course, a matter for their consideration and decision. The PAWG believes that rigid adherence to the specific concepts/steps proposed in this technical report is not sought so much as the use of a consistent process that produces an accurate and properly documented assessment.

ACRONYMS AND ABBREVIATIONS

ACNW	Advisory Committee on Nuclear Waste
AGV	above-ground vault
ALARA	as low as is reasonably achievable
ALIs	annual limits on intake
ANSI	American National Standards Institute
ASTM	American Society for Testing and Materials
BGV	below-ground vaults
BLT	breach, leach, and transport (computer code)
BTP	Branch Technical Position
CFR	*U.S. Code of Federal Regulations*
CEDE	committed effective dose equivalent
CNS	Chem-Nuclear Systems, Inc.
DACs	derived air concentrations
DCFs	dose conversion factors
DEIS	Draft Environmental Impact Statement
DOE	U.S. Department of Energy
DUST	disposal unit source term (computer code)
DQO	data quality objectives (process)
EIS	Environmental Impact Statement
EMCB	earth-mounded concrete bunkers
EPA	U.S. Environmental Protection Agency
FEPs	features, events, and processes
FEIS	Final Environmental Impact Statement
FR	*Federal Register*
HDPE	high-density polyethylene
ICRP	International Commission on Radiation Protection
LLW	low-level radioactive waste
LSA	low-specific activity (steel liners)
MCL	maximum concentration levels
HIC	high-integrity container
HLW	high-level radioactive waste

NAPA	National Academy of Public Administration
NAS	National Academy of Science
NEA	Nuclear Energy Agency
NEI	Nuclear Energy Institute
NEFTRAN	network flow and transport (computer code)
NRC	U.S. Nuclear Regulatory Commission
PAM	performance assessment methodology
PAWG	Performance Assessment Working Group
PDCFs	pathway dose conversion factors
PRA	probabilistic risk assessment
QA	quality assurance
RIP	repository integration program (computer code)
SDWA	Safe Drinking Water Act
TEDE	total effective dose equivalent
USGS	U.S. Geological Survey

1 INTRODUCTION

The U.S. Nuclear Regulatory Commission's (NRC's) licensing and related regulatory authority are provided by the Atomic Energy Act of 1954 (Public Law 83-703), as amended, and the Energy Reorganization Act of 1974 (Public Law 93-438). Before 1983, the NRC regulated the disposal of low-level radioactive waste (LLW) using a collection of generic regulations specified in 10 CFR Parts 30, 40, and 70. In response to the needs and requests of the public, the States, industry and others, the Commission promulgated specific requirements for licensing the near-surface land disposal of LLW. NRC's requirements are in the form of 10 CFR Part 61 (NRC, 1982; 47 *FR* 57446).[1] Part 61 establishes licensing procedures, performance objectives, and technical criteria for licensing facilities for the land disposal of LLW.

Since 1983, the NRC staff has developed several documents intended to aid in the implementation of Part 61. Foremost among these are: the "Environmental Standard Review Plan for the Review of a License Application for a Low-Level Radioactive Waste Disposal Facility" – NUREG-1300 (NRC, 1987); the "Standard Format and Content of a License Application for a Low-Level Radioactive Waste Disposal Facility" – NUREG-1199 (NRC, 1991); and the "Standard Review Plan for the Review of a License Application for a Low-Level Radioactive Waste Disposal Facility" – NUREG-1200 (NRC, 1994). However, in terms of measuring performance against the Part 61 performance objectives, the guidance provided by these documents is general and many specific implementation issues and acceptable approaches for resolving them are not addressed. Moreover, the relationships between the overall Part 61 data and design requirements, and specific LLW performance assessment needs, are not explicitly addressed by the existing guidance documents. Previously, site characterization, facility design, and performance modeling were activities that heretofore were considered separate. To clarify these issues, the NRC Performance Assessment Working Group (PAWG) has prepared this technical report as a means of providing detailed information and recommendations, to potential applicants,[2] in this area, as it relates to the performance objective concerned with the radiological protection of the general public – 10 CFR 61.41.

1.1 Background

A primary consideration of a decision to authorize a license to operate an LLW disposal facility will be whether the site and design meet the performance objectives and technical requirements contained in Subparts C and D, respectively, of Part 61. A potential licensee must characterize

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[1] Under Section 274 of the Atomic Energy Act, NRC can relinquish portions of its LLW regulatory authority to the States. "Agreement States" are those States whose Governors have entered into limited agreements with the Commission to assume this authority and are permitted to license new disposal facilities under comparable regulations.

[2] In addition to potential Part 61 applicants, existing LLW licensees, operating under comparable Agreement State regulations, may also find the recommended approaches in this technical report useful as they proceed with the implementation of their respective programs. (See Section 1.8.)

the site and provide a demonstration that the disposal site and design will comply with explicit standards. There will be unavoidable uncertainties in predicting the long-term performance of an LLW disposal facility. Conclusions as to the performance of the disposal facility and of particular barriers over long periods of time, by necessity, will be based largely on inference, as it will not be possible to carry out test programs of sufficient duration or that simulate the full range of potential conditions expected over the period of regulatory concern. Given these uncertainties, it will be necessary for a potential licensee to adopt a variety of design features, develop models, perform tests, acquire data, and undertake other measures to be able to demonstrate, with reasonable assurance, that the performance objectives will be met.

For its part, in reaching a potential LLW licensing decision, the Commission can be expected to apply the standard of "reasonable assurance," based on the record before it, that the Part 61 performance objectives and technical criteria will be met. Performance assessments are one mechanism for providing reasonable assurance, and, therefore, are expected to play an important role in any potential LLW licensing proceeding.

1.2 Overview of LLW Disposal Concepts, Performance, and Technical Issues

A *land disposal facility* is the land, buildings, and equipment necessary to carry out the disposal of LLW. A *disposal site* is that portion of a land disposal facility that is used for the disposal of waste. It consists of a number of covered disposal units surrounded by a buffer zone. A *disposal unit* is a discrete portion of the disposal site into which waste is placed for disposal. Near-surface disposal units may range from earthen trenches to concrete vaults. They may be covered with simple earthen caps or complex multi-layer systems of drainage layers, capillary breaks, and moisture wicks (see Cartwright *et al.*, 1987; Schulz *et al.*, 1988 and 1997; Smyth *et al.*, 1990; Bennett, 1991; Bennett and Horz, 1991; and Bennett and Kimbrell, 1991). The *buffer zone* is that portion of the disposal site that is controlled by the licensee and which lies under and between the disposal units and any disposal site boundary. The buffer zone provides controlled space to establish monitoring locations that are intended to provide an early warning of radionuclide movement.

The *natural site* in which an LLW disposal facility is located consists of: (a) the geosphere and hydrosphere (i.e., geologic and hydrogeologic systems, including surface water); (b) the surrounding atmosphere; and (c) the biosphere. The natural characteristics of an LLW disposal site should promote disposal site stability and attenuate the transport of radionuclides away from the disposal site into the general environment. Although engineered barriers can be used to improve or enhance disposal site performance, the natural (geologic) setting must be relied on, in the long term, for safety. Minimum characteristics that a disposal site must have to be acceptable for near-surface disposal of LLW are specified in the technical requirements of 10 CFR 61.50. Sites generally must possess the following characteristics: (a) relatively simple geology; (b) well-drained soils free from frequent ponding or flooding; (c) lack of susceptibility to surface geological processes such as mass wasting, erosion, slumping, landslides, and weathering occurring with such frequency or to such an extent as to significantly affect disposal site performance; (d) a water table of sufficient depth so that groundwater will not periodically intrude into the waste or discharge on site; (e) lack of susceptibility to tectonic processes such as folding, seismic activity, and volcanism with such frequency or to such an extent as to significantly affect disposal site performance; (f) no known potentially exploitable natural resources; (g) limited future population growth or development; and (h) capability of not being adversely impacted by nearby facilities or activities.

Engineered barriers (both physical and chemical) are man-made structures or devices designed to improve or enhance the site's natural ability to isolate and contain waste, and to minimize releases of radionuclides to the environment. The engineered barrier system operates in conjunction with the characteristics of the natural site to form an integrated waste disposal system. Figure 1 depicts an example of an engineered barrier system consisting of various engineered system components, including: (a) a layered earthen cover; (b) a disposal vault; (c) a drainage system; (d) waste forms and containers; (e) back-fill material; (f) infill material; and (g) an interior moisture barrier and low-permeability membrane. Covers are required to be designed to prevent significant quantities of water from contacting the waste [10 CFR 61.51(a)(4)] and they also must provide shielding from direct gamma exposure [10 CFR 61.52(a)(6)]. Cover performance depends on site stability and many of the technical requirements governing facility design, operation, and siting are directed at promoting waste package and cover stability. Most of the disposal facilities proposed by States and compacts will use concrete vault systems to help isolate waste from the accessible environment. Concrete vault systems include below-ground vaults (BGVs); earth-mounded concrete bunkers (EMCBs – i.e., above-grade, but covered with earthen material); and above-ground vaults (AGVs) with no earthen covers (see Bennett *et al.,* 1984; Warriner and Bennett, 1985; Bennett and Warriner, 1985; Miller and Bennett, 1985; Bennett, 1985; and Denson *et al.,* 1987 and 1988).

The transient nature of surficial (i.e., geomorphic) processes, which are influenced by patterns of weather and long-term climatic variability, and soil heterogeneity, contribute to uncertainty in modeling the movement of water into and through disposal unit covers. Furthermore, given the sparsity of data on the long-term durability of engineered materials – how effectively physical barriers perform over time, to limit the flux of water into the disposal units – is a major uncertainty that must be addressed by relying primarily on the nature of the design, construction and associated quality assurance and control (QA/QC), monitoring and maintenance data and analyses, and engineering judgment.

Source term refers to the radionuclide flux leaving the disposal units. Releases of radionuclides from an LLW disposal unit are caused by a number of physical and chemical processes that occur primarily in the presence of water. Water enters the disposal unit covers

Figure 1. Example of engineered barrier system for an LLW disposal facility.

because a portion of the precipitation that impinges on disposal unit covers passes through them. Water is the primary medium for mobilizing radionuclides from disposed LLW. Therefore, container degradation and waste-form leaching, by infiltrating water, must occur before significant releases of radionuclides from the facility develop. {Note that small amounts of gas may exist in the waste [e.g., krypton-85 (^{85}Kr)], or be generated in the absence of water [e.g., radon-222 (^{222}Rn)], but generation of large amounts of carbon-14 (^{14}C) or tritium (^{3}H), as gaseous species(e.g., $^{14}CO_2$, $^{14}CH_4$, etc.) generally occurs in the presence of infiltrating water.} Backfill material placed around waste containers for structural stability may also be engineered to have chemical and physical properties that enhance radionuclide retention.

Significant uncertainty in modeling the source term arises from variations within waste types, waste forms, waste containers, and the many complex physical and chemical interactions occurring among them and with the backfill material. These uncertainties are encountered when: (a) characterizing a site-specific waste inventory by waste class (A, B, and C), waste stream, and waste form; (b) determining credible container lifetimes (especially for high- integrity containers for B/C Classes of waste); (c) identifying waste-form-specific release mechanisms; and (d) ascertaining chemical considerations, such as solubility limits, that may be included in source-term modeling.

Site-specific environmental transport media should be characterized and appropriate exposure pathways, scenarios, and receptor locations identified. Principal transport media at LLW disposal sites include groundwater, surface water, and air. Groundwater is typically the most important transport medium from a subsurface disposal facility because radionuclides are mobilized by infiltrating water and convected and dispersed in groundwater moving beneath the site. The most important ground-water exposure pathways are linked to well water used for drinking and crop irrigation. Transport of contaminants to surface water via seepage and springs, and subsequent exposure through other pathways, are considered of secondary importance, because of the extent of dilution that generally occurs in surface-water systems. However, for an AGV facility subject to degradation by surficial processes, direct transport in surface runoff could be significant, particularly in humid regions. Air exposure pathways are typically of secondary importance relative to exposure from ground- and surface-water-related pathways. However, air exposure pathways may be significant for particular designs, such as AGVs with no earthen cover (Kozak *et al.*, 1993), or if specific chemical and physical conditions at the facility (e.g., at arid sites) promote generation of gases containing ^{14}C and ^{3}H that are released to the atmosphere. Significant uncertainty is inherent in collecting and interpreting data on site conditions, and in setting initial model boundary conditions and selecting model input parameters for analyzing radionuclide transport. Uncertainty also exists in selecting appropriate site-specific exposure scenarios and pathways, and human receptor locations.

Radiation doses to humans from radionuclides transported through environmental media are typically calculated using a linear relationship between the dose and the time-dependent concentration of radionuclides at human access locations. Human exposure to radiation occurs through internal and external dose pathways. Internal doses result from radionuclides being incorporated into the body primarily through inhalation of contaminated air, and by ingesting contaminated food and water. External doses occur from direct radiation sources outside the body, such as contaminated surfaces and air. The sum of the doses from all the radionuclides in all significant exposure pathways is the total dose to individual members of the general population. Calculations of radiological exposures to any member of the general population should be made in terms of the average member of the critical group. For the purposes of this technical report, the *critical group* is defined as the group of individuals reasonably expected to receive the greatest exposure to radiological releases from the disposal facility over time based on realistic but reasonable exposure assumptions and model parameter values.

1.3 What is LLW Performance Assessment ?

LLW performance assessment is a type of systematic (risk) analysis that addresses: (a) what can happen; (b) how likely it is to happen; (c) what the resulting impacts are; and (d) how these impacts compare to regulatory standards (see Eisenberg *et al.*, 1999)? The essential elements of a performance assessment for an LLW disposal site are: (a) a description of the site and engineered system; (b) an understanding of events likely to affect long-term facility performance; (c) a description of processes controlling the movement of radionuclides from LLW disposal units to the general environment; (d) a computation of doses to members of the general population; and (e) an evaluation of uncertainties in the computational results. [Also see DOE *et al.* (1992).] Quantitative estimates of LLW site performance are matched to need: deterministic, bounding analyses for simple problems; and probabilistic analyses for more complex problems, with large uncertainties. Performance assessment ties disposal site performance to site characterization and facility design alternatives so that disposal system knowledge is obtained and integrated in a systematic and efficient way. This approach also helps in establishing a record to support the technical basis and written documentation of model assumptions and data needed for a successful compliance demonstration, as required by 10 CFR 61.13.

Consistent with the first sentence in the paragraph above, an LLW performance assessment thus (quantitatively) evaluates "potential" doses, not "actual" doses, to potential receptors. Although the Commission does not require an "accurate" prediction of future states in the estimation of disposal facility performance, uncertainty in a performance assessment estimate cannot be so great that the Commission would not have reasonable assurance that the postclosure performance objectives will be met. There will always be uncertainties in numerical estimates, even for fairly rigorous analyses, because of uncertainties in analyzing the complex behavior of engineered and natural systems, over long periods of time. However, the existence of these uncertainties does not preclude an applicant from conducting a defensible performance assessment. The key to a defensible analysis, therefore, is to identify and understand which aspects of the site and design have the greatest influence on the performance and what assumptions or parameters if changed could lead to a different licensing decision.

To integrate site characterization and facility design activities, LLW performance assessment should be performed iteratively. For example, simple screening calculations can provide insights on the performance of proposed sites and conceptual designs to enhance the prospects of selecting a suitable site. Moreover, in designing an LLW facility, performance assessment can be used to optimize disposal facility design to achieve potentially higher levels of performance for the overall system. In characterizing a site, initial screening analyses should help the performance assessment analyst to identify important issues and data needs that must be factored into any program to investigate and evaluate a candidate site. As more site information is collected, the analyst should reevaluate modeling assumptions, conceptual models, and data needs, and revise the site characterization program accordingly, to obtain data identified as most needed to reduce uncertainty and defend assessment results. The site-specific nature of performance assessment will dictate the type and amount of feedback between performance assessment and site characterization. The process intrinsically builds confidence in performance assessment results because the reasons for modifying assumptions, models, and conditions are well-documented and supported by data amassed from preceding site investigations and assessments. If at some point it appears likely that very extensive and/or expensive site characterization will be needed to continue the process, the developer may decide to consider evaluation of another site. Such a decision would reflect practical implementation of the 10 CFR 61.50(a)(2) requirement that "The disposal site be capable of being characterized, modeled, analyzed and monitored."

To provide a defensible result, uncertainty analysis needs to be part of the LLW performance assessment. Analyses of uncertainty and sensitivity drive the performance assessment process toward a defensible final decision on site compliance. The most commonly cited sources of uncertainty in performance assessment are uncertainty about conceptual models (model uncertainty), which may include doubts about future site conditions, processes and events, and uncertainty regarding data, parameters, and coefficients used in models (parameter uncertainty). The objective of uncertainty analysis is to assess the degree of variability in calculated results as a function of the variability in model and input parameters. The treatment of model uncertainty necessitates analyzing those conceptual model alternatives not refuted by site data. Methods for treating parameter uncertainty are usually based on establishing the degree of belief in a value or range of values for each parameter selected for model input. The objective of sensitivity analyses is to focus attention on important parameters by determining the relative contributions of input variables to the resulting dose. Sensitivity studies on the intermediate results from sub-system models (infiltration, source term, transport media, etc.) also may provide valuable insight on those factors that most influence the performance of the overall system. Before a compliance demonstration can be made, a number of data collection and assessment iterations may need to be undertaken to refute some of the alternative conceptual models and to narrow parameter ranges. Gauging uncertainty through formal validation exercises, such as model calibration, history matching, and prediction, is not possible because of the inherent nature of uncertainty in performance assessment modeling. What is important, however, is being able to build confidence that the models perform as they are designed, capture relevant features and processes of the disposal system being modeled, and reflect the uncertainty in system knowledge.

Finally, LLW performance assessments can be used to provide site-specific inventory limits for certain long-lived radionuclides in those cases where the performance assessment results do not meet the performance objective. Radionuclides of concern include such long-lived radionuclides as iodine-129 (^{129}I); technetium-99 (^{99}Tc); ^{14}C, chlorine-36 (^{36}Cl); and thorium (Th); uranium (U); and their daughter products. The concept of site-specific inventory limits for controlling radionuclide releases through the ground-water pathway is part of the supporting analysis for Part 61 presented in the *Draft* and *Final Environmental Impact Statements* (DEIS and FEIS, respectively – see NRC, 1981 and 1982) and the Commission is authorized, under 10 CFR 61.7(b)(2), to establish maximum radionuclide inventories. Because of the site-specific nature of potential impacts of radionuclide migration in groundwater, which are a function of the total inventory of particular radionuclides disposed of at the facility, the NRC did not establish generic inventory or concentration limits for the protection of individuals off-site. Rather, each disposal facility must be analyzed on a case-by-case basis and, depending on site environmental conditions and the design of the disposal facility, maximum site inventories may be imposed by license condition for certain radionuclides. Even if initial inventories of long-lived radionuclides are projected to be low, knowing the potential site-specific disposal limits for these radionuclides, through some type of LLW performance assessment, would ensure site safety should unforeseen disposal needs arise.

1.4 Previous PAWG Activities in the Area of LLW Performance Assessment

Traditionally, all commercially generated LLW in the United States has been disposed of at the near-surface, using shallow land burial (SLB) methods. This disposal method relies on relatively simple engineering designs to isolate wastes from infiltrating water – the natural (geologic) characteristics of the site are the principal attenuators of any radioactivity that might be released to the accessible environment. SLB facilities for LLW at Barnwell, South Carolina, and Richland, Washington, are currently operational and are based on these somewhat simple designs. In conjunction with the development of Part 61 and after its publication in 1982 (NRC, 1982; 47 *FR* 57446), the PAWG began to undertake a variety of performance assessment-related projects that primarily addressed SLB facilities. These projects were initiated in such areas as waste package performance and leaching, hydrogeological and hydrogeochemical characterization and modeling, and cover performance. The PAWG also began to investigate alternatives to SLB and developed guidance for the licensing of new disposal facilities (see NRC, 1991,1994).

To address the need for a more integrated approach to LLW performance assessment, NRC's PAWG formulated an overall LLW performance assessment strategy in 1987 (Starmer *et al.*, 1988). This strategy recommended a modular approach for modeling LLW disposal facility system performance by quantifying potential release and transport of radionuclides through significant environmental pathways. An LLW performance assessment methodology (PAM) based on this strategy was subsequently developed by the Sandia National Laboratories (SNL), at the request of the PAWG, and published in a five-volume series as NUREG/CR-5453.[3]

Concurrently, the staff published its LLW Research Program Plan (O'Donnell and Lambert,

[3] See Shipers (1989); Shipers and Harlan (1989); Kozak *et al.* (1989a,b); and Kozak *et al.* (1990a,b).

1989), which presents the staff's strategy for LLW research. The development of the research program plan reflected the staff's interactions at the time with the Agreement States, regional compacts, the U.S. Department of Energy (DOE), and its technical assistance contractors.

In the early 1990s, the PAWG began developing an LLW performance assessment program plan (see NRC, 1992). This program had two primary goals: (a) to enhance the staff's capability to review and evaluate new LLW license applications; and (b) to develop the in-house capability needed to prepare the necessary guidance. This plan was begun in response to needs identified by Agreement States and the staff through interactions with prospective applicants, the review of DOE prototype license applications, and in response to specific performance assessment issues raised by the States. It was also during this time that the staff formed the PAWG to ensure the inter-office coordination of the respective LLW performance assessment efforts within the Agency.

Since the early 1990s, the staff has continued to enhance its LLW performance assessment expertise and capability, consistent with its 1992 program plan, through a variety of measures. For example, PAWG members and its technical assistance contractors have been involved with a number of LLW performance assessment modeling exercises and analyses. (Many of these efforts are cited in "References," Section 4).[4] As part of this work, in 1992, PAWG began to develop this NUREG and also initiated computer simulations of a test case problem of a hypothetical LLW disposal system. Using actual site data representative of a humid environment and a staff-generated facility design and source term inventory, the PAWG: (a) tested a number of models that could used in conducting an LLW performance assessment; and (b) gained experience with the use and limitations of LLW performance assessment modeling. The PAWG's efforts to enhance its performance assessment expertise and capability have also benefited from related work in the area of high-level radioactive waste – HLW [see Codell *et al.* (1992) and Wescott *et al.* (1995)]. Finally, it should be noted that the PAWG has gained additional performance assessment experience and insight through workshops and meetings with interested States; other Federal agencies [the DOE; the U.S. Environmental Protection Agency (EPA); and the U.S. Geological Survey (USGS)]; comparable regulatory entities in foreign countries (France, Spain, and Germany); and international organizations, such as the International Atomic Energy Agency (IAEA) and the Nuclear Energy Agency (NEA).

1.5 NRC's LLW PAM

As noted earlier, the staff first formulated a general performance assessment strategy in 1987. This strategy recommended a modular approach to the modeling of LLW disposal facility system performance (Starmer *et al.,* 1988). This approach, represented graphically in Figure 2, logically divides the disposal system into separate modeling areas:

— Infiltration and unsaturated (vadose) zone flow;

[4] For an extensive summary of NRC-sponsored technical assistance work performed before 1990, see Dunkelman (1987).

- Engineered barrier performance (coupled with infiltration analysis to calculate the water flux into disposal units);

- Radionuclide releases from waste forms and the bottoms of disposal units (container failure, leaching, and near-field transport);

- Transport media – groundwater, surface water, and air;

- Plant and animal uptake (food chain); and

- Dose to humans.

Given the constraints imposed by site-specific conditions, the modular approach allows a mix of both complex and simple models to be used to capture the critical interactions among important processes affecting disposal site performance. Generally, complex models require more abundant and detailed input data than less sophisticated models, which rely more on simplifying assumptions and generalized information. The appropriate degree of modeling complexity within a module is determined by the purpose of the modeling, and the availability of suitable data and associated data uncertainty.

Over a 3-year period from 1988 through 1990, the NRC, through its technical assistance contractor, SNL, developed the PAM. The PAM is a suite of models and codes suitable for analyzing the various disposal system modules set out in the staff's performance assessment strategy and was produced in five steps:

Figure 2. **Conceptual model showing processes to be considered in an LLW performance assessment (modified from Kozak *et al.*, 1990b).** Numbers next to the process blocks correspond to the recommended approaches described in Section 3.3 of the text. Solid lines correspond to water flow pathways, and the dashed lines correspond to radionuclide transport pathways. The "source-term" process block, "Section 3.3.5," corresponds to the LLW disposal cell(s).

Step 1 – Identifying potential human exposure pathways.

Step 2 – Assessing the relative significance of exposure pathways.

Step 3 – Selecting and integrating system component models.

Step 4 – Identifying and recommending computer codes for solving the models.

Step 5 – Implementing and assessing the performance of recommended codes.

In the course of developing the PAM, a number of significant policy and technical issues were identified and described but not addressed (Kozak *et al.*, 1993), and although the PAM addresses the mechanics of analyzing and modeling LLW disposal system performance, it does not constitute a way of systematically conducting, documenting, and preparing performance assessments acceptable for licensing.

Since 1990, the PAWG has gained many insights into resolving these LLW performance assessment issues; conducted a realistic test case performance assessment modeling study for a hypothetical site; interacted with Agreement States on site-specific performance assessment issues; conducted a performance assessment workshop for Agreement States; conducted NRC research and technical assistance contractor studies; and participated in international programs. These include: (a) an IAEA project on LLW site performance assessment (IAEA, 1996); (b) various international symposiums on the verification and validation of geosphere performance assessment models (Statens Kärnkraftinspektion (SKI), 1988; SKI/Organisation for Economic Co-operation and Development (OECD) NEA, 1991; and OECD NEA, 1995); and (c) the International Cooperative Project on Geosphere Model Validation (INTRAVAL) Project (SKI, 1993). The advice, information, and recommendations contained in this document reflect consideration of these other efforts.

1.6 Purpose of this Technical Report

As noted in Section 1.2, a range of land disposal technologies has been developed, in addition to SLBs, that could be applied toward the disposal of LLW. They include BGVs, EMCBs, AGVs, mined cavities, and augured holes. Most of the designs being considered for future LLW facilities center on improved engineering enhancements, such as concrete vaults and multi-layered covers, to help isolate waste from the accessible environment. Based on the State and PAWG experiences, it is believed that advice and recommendations are needed not only on how to analyze and model natural systems, but also on analyzing the performance and reliability of more complex engineered barriers over the long term. Several areas have thus been identified where recommendations on how to conduct an LLW performance assessment may be needed. These areas include:

— An overall understanding of the performance assessment process;

— The relationship between site characterization and performance assessment data collection;

— Modeling of infiltration rates, source-term releases, and concrete and engineered barrier degradation;

— Transport of radionuclides in the environment;

— Verification and validation of computer models;

— The use of generic data in performance assessment; and

— Uncertainty and sensitivity analyses.

The information and recommendations presented in this technical report is intended to be generally applicable to any method of land disposal; however, only technical issues that specifically are attributable to the performance of near-surface disposal technologies are addressed. Technical issues related to land disposal in AGVs or disposal deeper than 30 meters (mined cavities and augured holes) will need to be evaluated and addressed separately.

As noted earlier, performance assessments are expected to play an important role in any potential LLW licensing proceeding under Part 61. The purpose of this technical report, therefore, is to provide information and recommendations on an acceptable overall approach for conducting an LLW performance assessment to demonstrate compliance with the performance objective defined in 10 CFR 61.41. Specifically, this advice includes the PAWG's views on:

(a) An example of an acceptable approach for systematically integrating site characterization, facility design, and performance modeling into a single performance assessment process;

(b) Policy issues with respect to interpreting and implementing Part 61 performance objectives and technical requirements as they may pertain to LLW performance assessment; and

(c) Ways to implement NRC's PAM.

Moreover, this technical report augments existing LLW performance assessment guidance currently contained in NUREG-1199 (NRC, 1991) and NUREG-1200 (NRC, 1994).

However, the recommended approaches in this technical report are not intended to address safety issues that are recommended to be addressed in any *Safety Analysis Reports*[5] submitted as part of a potential Part 61 license application. For example, operational performance issues (Subpart C),

[5] As suggested in NUREG-1199 (NRC, 1991; pp. xi).

and the necessary technical analyses to address them (10 CFR 61.13), are not considered, within the context of this document, unless particular aspects of disposal facility operations might have an impact on the long-term performance of the disposal site. In addition, issues relating to site characterization [10 CFR 61.12(a)], including the design and construction of a disposal facility [10 CFR 61.12(b)-(i)] are not discussed except as they relate to assessing the post-closure performance of the disposal site (Subpart C). Moreover, the recommended performance assessment approach described in this technical report is not intended to address radiation safety. For example, issues related to demonstrating compliance with the Part 61 performance objectives governing protection of inadvertent intruders (10 CFR 61.42)[6]; protection of individuals during operations (10 CFR 61.43); and stability of the disposal site after closure (10 CFR 61.44), are beyond the scope of this document. Operational practices, emergency responses to accidents, and monitoring programs, as described in the radiation safety program for control and monitoring of potential operational releases [10 CFR 61.12(k)], should provide assurance that individuals on and off-site are protected from routine operations and from accidents that may occur when waste handling, storage, and disposal activities would occur. Environmental monitoring programs [10 CFR 61.53(c)], including proposed plans for corrective measures [10 CFR 61.12(l)], will provide early warning of radionuclide releases from the disposal facility, before they leave the site boundary. If necessary, operational procedures may be modified or other mitigating actions taken to ensure that operational releases of radioactivity are maintained within the individual dose requirements of 10 CFR 61.41 (which are incorporated by reference in 10 CFR 61.43).

Section 2 of this technical report summarizes the principal regulatory requirements and policy considerations that relate to this topic. The PAWG's technical advice and recommendations are listed in Section 3. Section 3 also includes a discussion of the supporting rationale behind each statement of position. Definitions of key terms used in the technical report are provided as Appendix A.

1.7 This Technical Report as Guidance

This technical report is provided to describe, and make available to the public and Agreement States, methods PAWG believes that may be acceptable to the staff, for implementing specific

[6] Separate intruder scenario dose analyses are not envisioned to be included in an LLW performance assessment. Rather, 10 CFR 61.13(b) requires that "...analyses of the protection of individuals from inadvertent intrusion must include demonstration that there is reasonable assurance the waste classification and segregation requirements will be met and that adequate barriers to inadvertent intrusion will be provided...."

That being said, separate intruder scenario analyses may be necessary in cases where the projected waste spectra are fundamentally different from those considered in the technical analyses supporting any Part 61 draft environmental impact statement (DEIS – see NRC, 1981). For example, an intruder analysis might be necessary if the waste form(s) proposed for disposal contain anomalous quantities and concentrations of certain long-lived radionuclides (e.g., uranium or thorium) such that the intruder cannot reasonably be protected by the waste classification and intruder barrier requirements of Part 61. To the extent that there may be a need for guidance on how to perform an intruder consequence analysis at an LLW disposal facility, disposal facility developers and/or other regulatory entities should consult NRC’s DEIS on Part 61 (NRC, 1981).

parts of the Commission's regulations, and to provide advice to regulated entities. The recommended technical and policy approaches in this document are not intended as substitutes for regulations, and compliance with them is not required. PAWG believes that methods and solutions differing from those set out in this document should be acceptable if they provide a sufficient basis for the findings requisite to the issuance of a permit or license by the Commission. Finally, nothing in this technical report constitutes a commitment to issue any authorization or license, or in any way affects the authority of the Commission, the Atomic Safety and Licensing Boards, other presiding officers, or the Director, in any such proceeding.

1.8 Use of this Technical Report by Other Regulatory Entities

A motivating factor influencing the development of this technical report was the desire to share with the Agreement States and LLW disposal facility developers (as potential applicants) some of the PAWG's experience and insights, as they relate to the use of LLW performance assessments in a regulatory context. The extent to which the Agreement States or other regulatory entities implement the recommendations found in this technical report is, of course, a matter for their consideration and decision. The PAWG believes that rigid adherence to the specific concepts/steps proposed in this document is not sought so much as the use of a consistent process that produces an accurate and properly documented assessment. Moreover, the PAWG believes that effective implementation of a good LLW performance assessment cannot guarantee acceptance of the technical conclusions; however, use of a flawed process or improper implementation of a good process cannot help but cast serious doubt on the quality of the conclusions. However, as other regulatory entities consider the application of these recommended approaches to their respective programs, it is useful to discuss how performance assessment contributes to regulatory decision-making.

The burden of demonstrating compliance with the applicable disposal regulations resides with the potential license applicant. Thus, once a potential applicant decides that adequate analyses have been conducted, it is anticipated that it would be documented and submitted as part of an overall license application. For its part, it will be the job of the regulatory body to independently evaluate the license application to ensure that it provides the technical data and analyses necessary to support a regulatory conclusion that the proposed LLW disposal facility can operate safely.

In this regard, the recommended process described in Section 3.1 of this technical report provides a useful guide. This recommended process emphasizes the selection of important items of information that are useful in defending why a particular LLW performance assessment is sufficient and is likely to be an acceptable indicator of disposal site performance. The recommended process focuses attention on: (a) selection of assumptions and conceptual models; (b) basis for model input data selection; (c) appropriateness of computer model application; (d) integration of subsystem models; and (e) analysis of uncertainties and sensitivities of data and assumptions. Questions raised about any aspect of the performance assessment would constitute feedback to the developer. Based on this feedback, it is intended that the developer re-evaluate the data and assumptions, and perform further iterations, through the performance assessment process, as necessary, to answer the questions. As suggested above, it is important to the regulatory staff that the license application provide comprehensive documentation of the performance assessment. Once the review process is completed and the application found to be technically acceptable, the regulator's findings and supporting independent assessments are documented. It is through this documentation that the regulator's conclusions and findings are communicated to the public.

Thus, it may be desirable to make the site characterization-performance assessment process participatory, where interested parties would be encouraged to participate in developing and refuting conceptual models as the disposal site is being characterized and evaluated. An open process can be expected to improve the technical breadth and defensibility of performance assessments, and eliminate the perception of applicant bias toward more optimistic results. The performance assessment process should readily accommodate a wide variety of alternative approaches for public participation and openness. A final consideration also related to the defensibility of performance assessment analyses is that the entire performance assessment process, including all iterations, should be thoroughly documented to enable independent auditors to trace the modeling results, thereby demonstrating that they can be reproduced.

Finally, in preparing the advice and recommendations contained in this technical report, it was not the PAWG's intent to imply that other regulatory entities need to independently undertake comprehensive, corroborating LLW performance assessments of their own or precisely repeat every part of the recommended overall process. Other regulatory entities may, however, decide to conduct independent performance assessment modeling for the entire system or for selected subsystem areas, to corroborate certain aspects of the reported results. The amount of modeling should be based on technical judgment; the level of confidence the respective regulatory staff has in the data, assumptions, models, and codes used by the developer; and the relative significance of subsystem modeling results to the overall compliance demonstration.

As is the case with the geologic disposal of HLW, one way to improve the credibility and confidence in an LLW performance assessment would be through the use of *peer reviews*. Usually, peer reviewers are recognized experts in the domain of interest as evidenced by their (comparable) scientific/engineering qualifications. Because they are independent and possess no unresolved conflicts-of-interest, the peers may comment freely on the validity of the assumptions, the appropriateness and limitations of the methodology and procedures, the accuracy of the calculations, the validity of the conclusions, and the uncertainty of the results and consequences of the work. They may also offer alternative explanations of the results and comment on the adequacy of the information and data used to obtain them.

In addition to the independent (critical) evaluation provided, peer reviews can aid in the public confidence in and acceptance of an LLW performance assessment itself as well as the conclusions drawn from it. Peer review has been suggested by some observers as the best assurance that quality technical criteria will prevail over social, economic, and/or political considerations. However, the fundamental decision regarding the use of a peer review process ultimately rests with consenting Agreement States and/or LLW disposal facility developers, and not with the NRC.

2 REGULATORY FRAMEWORK

As noted earlier, the Commission's regulations found in Part 61 address the licensing of near-surface land disposal of LLW. There are several requirements in Part 61 that provide a basis for the conduct of an LLW performance assessment. These requirements can be found in Subparts C, B, D, and G. In Subpart C, for example, one of the major performance objectives is described in 10 CFR 61.41 ("Protection of the General Population from Releases of Radioactivity") of the regulations. During and after facility operations, 10 CFR 61.41 requires that:

> Concentrations of radioactive material which may be released to the general environment in groundwater, surface water, air, soil, plants, or animals must not result in an annual dose exceeding an equivalent of 25 millirems [0.25mSv] to the whole body, 75 millirems [0.75 mSv] to the thyroid, and 25 millirems to any other organ of any member of the public. Reasonable effort should be made to maintain releases of radioactivity in effluents to the general environment as low as is reasonably achievable.

The specific technical information needed to demonstrate compliance with 10 CFR 61.41 is described in Subpart B (content of license application). Section 61.13(a) requires that the following three information needs be met:

— That "...the pathways analyzed in demonstrating protection of the general population from releases of radioactivity must include air, soil, groundwater, surface water, plant uptake and exhumation by burrowing animals";

— That "...the analyses must clearly identify and differentiate between the roles performed by the natural disposal site characteristics and design features in isolating and segregating the wastes"; and

— That "...the analysis must clearly demonstrate that there is reasonable assurance that the exposure to humans from the release of radioactivity will not exceed the limits set forth in 10 CFR 61.41."

Additional requirements are set forth in Subpart D. Section 61.50(a)(2) requires that "The disposal site shall be capable of being characterized, modeled, analyzed, and monitored." The intent of this requirement is to provide a criterion for site suitability that is aimed at minimizing the complexity of the site and the associated uncertainty in the technical analyses of site safety, including an assessment of the site's performance. Section 61.53 requires that during the operational and post-operational periods, a licensee is responsible for conducting an environmental monitoring program. Measurements and observations must be made and recorded to provide data to evaluate potential health and environmental impacts and long-term effects of the facility.

In Subpart G, 10 CFR 61.80 requires licensees to maintain records, by waste class, of activities and quantities of radionuclides disposed of, and report to the Commission the results of environmental monitoring and any instances in which observed site characteristics were significantly different than those described in the license application.

Finally, in a license application amendment to close an LLW disposal facility, 10 CFR 61.28(a) of Subpart B requires that the final site closure plans should include any additional hydrologic or other site data obtained during the operational period of the site, and the results of tests, experiments, or analyses pertinent to the long-term containment of emplaced radioactive wastes.

NUREGs-1199, 1200, and 1300 provide some guidance on performance assessment-related issues. NUREG-1200 provides guidance applicable to evaluating a performance assessment and presents the process that would be used by staff in reviewing a license application. NUREG-1199 details the necessary components and information needed in a license application for an LLW disposal facility required under Part 61. In both documents, Chapter 6, "Safety Assessment," deals with the technical analyses required to demonstrate compliance with Part 61 performance objectives. Section 6.1, "Release of Radioactivity" (Subsections 6.1.1 - 6.1.5.4) specifically deals with meeting 10 CFR 61.41 requirements and is primarily concerned with performance assessment. However, the performance assessment guidance provided refers to only general issues, and many specific issues or recommended means for resolving them are not addressed.

Chapters 2 ("Site Characteristics") and 3 ("Design and Construction") of NUREGs-1199 and 1200 describe information related to meeting the Part 61 siting and facility design requirements. However, some of the site and design data identified would be used for purposes other than performance assessment, such as for establishing site monitoring networks, or demonstrating operational safety and stability in design. One of the goals of this technical report is to provide a linkage between overall data and design requirements, and specific performance assessment needs, which may not be directly obvious from NUREGs 1199 and 1200.

With respect to QA, 10 CFR 61.12(j) describes the requirements for a QA program, to be included in any potential license application, that are necessary to meet the performance objectives and technical criteria set forth in Part 61. NUREG-1293 (Pittiglio and Hedges, 1991) provides specific guidance on how to meet the Part 61 requirements.[7] Additional QA guidance for potential applicants is provided in Chapter 9 of NUREGs-1199 and 1200. NUREG-1383 (Pittiglio, *et al.*, 1990) should be consulted for QA guidance related to site characterization activities, when necessary.

In addition to the aforementioned, the PAWG has drawn on experience and guidance obtained from other NRC regulatory programs that can be applied analyzing future LLW disposal site

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[7] The criteria described in NUREG-1293 are similar to the criteria contained in Appendix B of 10 CFR Part 50. Although Appendix B to Part 50 is not applicable to NRC's LLW disposal regulation, the criteria it contains are basic to any nuclear regulatory QA program.

performance.[8] These areas are discussed below.

Peer Reviews: Much of scientific and engineering development is subjected to the normal review process of critical evaluation by colleagues in various venues. These so-called *peer reviews* are typically documented, critical reviews that evaluate the acceptability and adequacy of some particular form of original research, performed by peers who are independent of the work being reviewed but, nonetheless, still have comparable technical competence to perform the review. In addition, peer reviews may be employed as part of the independent actions necessary to provide public confidence in the technical work being conducted and/or the interpretation and meaning of its results.

A peer review can be conducted by obtaining input separately from a number of peers or by convening a panel to conduct the review. (Also, discussions among the panel members can generate useful information not available from a set of independent reviews.) The most common peer review process typically uses informal *expert judgment* to evaluate scientific methods and results. NUREG-1297 (Altman *et al.*, 1988) provides guidance on: (a) areas where peer reviews may be appropriate; (b) the selection of peers; and (c) the conduct and documentation of the peer review process itself.

Expert Judgment: Nearly every aspect of site characterization and performance assessment will involve significant uncertainties. The primary method to evaluate, and perhaps reduce, these uncertainties should be collection of sufficient data and information during site characterization. However, factors such as temporal and spatial variations in the data, the possibility for multiple interpretations of the same data, and the absence of validated theories for predicting the performance of a disposal facility for thousands of years, will make it necessary to complement and supplement the data obtained during site characterization with the interpretations and subjective judgments of *technical experts* (i.e., expert judgments). The NRC expects that subjective judgments of individual experts and, in some cases, groups of experts, will be used to interpret data obtained during site characterization and to address the many technical issues and inherent uncertainties associated with predicting the performance of an LLW disposal system for thousands of years.

NUREG-1563 (Kotra *et al.*, 1999): (a) provides general guidelines on those circumstances that may warrant the use of a formal process for obtaining the judgments of more than one expert (i.e., expert elicitation); and (b) describes acceptable procedures for conducting expert elicitation when formally elicited judgments are used to support a demonstration of compliance. (In NUREG-1563, the staff also provides an expanded definition of peer review over that provided earlier in NUREG-1297.)

Model Validation: Validation (or confidence building) should be an important aspect of the regulatory uses of mathematical models in the safety assessments of geologic/engineered systems

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[8] Although this guidance was developed for the purposes of the HLW management program, the PAWG believes it can also be applied to LLW.

for the disposal of radioactive wastes. A substantial body of literature exists indicating the manner in which scientific validation of models is usually pursued. Because models for a geologic repository performance assessment cannot be tested over the spatial scales of interest and long time periods for which the models will make estimates of performance, the usual avenue for model validation – that is, comparison of model estimates with actual data at the space-time scales of interest – is precluded. Further complicating the model validation process are the uncertainties inherent in describing the geologic complexities of potential disposal sites, and their interactions with the engineered system, with a limited set of generally imprecise data, making it difficult to discriminate between model discrepancy and inadequacy of input data. A successful strategy for model validation, therefore, should attempt to recognize these difficulties, address their resolution, and document the resolution in a careful manner. The end result of validation efforts should be a documented enhancement of confidence in the model to an extent that the model's results can aid in regulatory decision-making. The level of validation needed should be determined by the intended uses of these models, rather than by the ideal of validation of a scientific theory.

NUREG-1636 (Eisenberg *et al.*, 1999) presents a model validation strategy that can be implemented in a regulatory environment. This document should not be viewed as, and is not intended to be, formal guidance or a staff position on this matter. Rather, based on a review of the literature and previous experience in this area, this *White Paper* presents regulatory views regarding how, and to what degree, validation might be accomplished in the models used to estimate the performance of a geologic disposal facility.

3 PAWG VIEWS ON LLW TECHNICAL ISSUES

It is the PAWG's position that a potential license applicant should develop and use a defensible methodology to demonstrate LLW disposal facility design compliance with the performance objective set forth in 10 CFR 61.41. In that regard, an example of an acceptable approach is described in Section 3.1 of this technical report. Section 3.2 provides information on assessing site conditions, processes and events, and the long-term performance of engineered barriers that need to be considered when demonstrating compliance with 10 CFR 61.41. Section 3.3 describes the PAWG's views on some general technical issues related to the conduct of a performance assessment that should be considered when analyzing disposal site subsystem components.

3.1 Example of an Acceptable Approach for Demonstrating Compliance with 10 CFR 61.41

The activities recommended for an integrated LLW performance assessment are depicted in Figure 3. The process is designed to build confidence in model estimates of LLW disposal site performance by providing a useful decision-making framework for evaluating and defending the appropriateness of data, assumptions, models, and codes used in a performance assessment to demonstrate compliance with the post-closure performance objective of 10 CFR 61.41. Moreover, the PAWG believes that this process systematically brings together, as a single endeavor, all aspects of site data, facility design, and waste characterization information needed for assessing disposal site performance. If properly implemented, it will direct the applicant, through uncertainty and sensitivity studies, to identify data and assumptions that contribute most to disposal site performance. In successive iterations of this process, additional site data are collected, auxiliary analyses[8] or laboratory modeling are performed, alternative conceptual models are evaluated, and/or modifications to the facility design are made as needed to reduce parameter and model uncertainty. By building confidence in performance assessment results in this fashion, issues concerning model validation are addressed to a reasonable degree. However, because the goal of the LLW performance assessment analysis is intended to develop a supportable demonstration of compliance, *the applicant need only undertake a depth of analysis and conduct as many iterations as necessary to show that the performance objective has been met.* Thus, the PAWG expects that the extent to which the recommended process depicted in Figure 3 is followed will be tempered according to the complexities of the LLW disposal system being modeled, uncertainties surrounding system performance, and the estimated risk.

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8 In a number of places in this technical report, the PAWG is recommending that auxiliary analyses be conducted as part of the investigations described to examine specific processes and factors that may be important to system performance. Auxiliary analyses support the LLW performance assessment by using more detailed models to: (i) provide greater insight into cause-and-effect relationships; (ii) evaluate conservatism of model assumptions; (iii) evaluate alternate modeling approaches; and/or (iv) interpret field and laboratory data.

Figure 3. **Section 3.1: Detail to the "Example of an Acceptable Process for Demonstrating Compliance with 10 CFR 61.41."** The activities shown by the dotted lines depict the compliance review the NRC staff is expected to perform.

The integrated performance assessment process depicted in Figure 3 consists of nine process steps. Certain steps in the process may be performed concurrently, particularly in the initial assessment stages. Steps 1 through 9 are carried out by the applicant, in meeting its responsibility to demonstrate that the LLW disposal facility will comply with the post-closure performance objective in 10 CFR 61.41. These nine steps are discussed below. As noted above, the process is intended to be iterative inasmuch as the applicant should go through this process as many times as necessary to demonstrate compliance. The activities also loop back to the applicant through questions posed by the staff about the performance assessment or disposal site adequacy. Because an overall LLW disposal system performance assessment is composed of subsystem models (i.e., infiltration, source term, transport media, and dose), the following discussions apply, as appropriate, to subsystems' models as well. As noted in Section 2, it should be understood that approaches to site characterization undertaken for meeting non-performance assessment-related regulatory requirements, such as for establishing monitoring networks, are outside the scope of the LLW performance assessment process.

Step No. 1 – Conduct Initial Data Evaluation of Information Needed to Describe the LLW Disposal System Environment

An LLW disposal facility is a complex system comprised of numerous natural and engineered features. The complexity of the system can be further complicated by many different waste species, containers, and forms that may be disposed of in it. Therefore, the first step should be to identify and consider every credible factor or key process that could contribute to effecting a radionuclide release, including changes to the disposal site over time from natural processes and events. In other words, the notion behind this first process step is to develop a complete view of how the disposal system might actually perform, including consideration of possible alternative hypotheses. To be as complete as possible, a multidisciplinary physical/engineering science team approach is recommended. Although this description is primarily qualitative in nature, it should highlight deficiencies in the overall level of knowledge about the disposal site from which to begin the process of evaluating site-specific technical issues and data needs. The disposal site description (and accompanying database) provide the basis for the initial set of site-specific conceptual models appropriate for the mathematical analyses performed later.

At this stage of the process, much of the information used to describe the disposal system will need to be generic. Subjective judgments about the performance of the disposal system – based on information drawn from the fundamental principles of chemistry, physics, geology, and the engineering sciences, and past experience or data from similar sites, precedent, and professional judgment[9] – are also appropriate. However, reliable information on waste characteristics and amounts, as well as a detailed facility conceptual

[9] Professional judgment would be, for example, the technical experts' evaluations and interpretations of some scientific knowledge base, to the extent that the knowledge base exists. Also referred to as *engineering judgment* for the purposes of this technical report – see Section 3.3.4.6. Also refer to Meyer and Booker (1990, p. 3).

design, should be available. There should be sufficient site and regional data available to at least describe the general nature of the facility's natural setting. It is important to note that there is always some performance-assessment-relevant information available about all parts of the United States. For instance, geologic maps, regional hydrologic data, and meteorologic statistics are generally available and, in many cases, more detailed information may also be available from other engineering projects. NUREG-1199 (NRC, 1991) contains detailed guidance on basic data needs, suggested sources for published and unpublished reports, and records of specific information on natural site characteristics.

Step No. 2 – Describe Initial Conceptual Models and Parameter Distributions

The detailed disposal system description, including all initially available data and information (Step No. 1), should next be used to develop site-specific conceptual models. Conceptual model development involves abstracting the system description into a form that can be mathematically modeled. This generally means imposing a number of simplifying assumptions to approximate the behavior of the disposal site while accounting for all of the processes and features judged to be important to site safety. Although clearly not a trivial task, deciding on the necessary level of complexity should depend on the purpose of the analysis. For example, initial "screening" assessments may be very simple; however, more realism and complexity will likely be needed as the performance assessment process progresses. The analyst should be able to describe, in words, conceptual model assumptions and their technical bases, including how the models incorporate or account for important disposal site features and processes.

At this initial stage, conceptual models and parameter distributions should be as broad as necessary to reflect the level of uncertainty in the behavior of the system. This does not mean that knowledge about the system is ignored. Conceptual models should include only those assumptions or conditions that cannot be refuted by site information or data, and parameter distributions should assume the broadest ranges possible within the limits of available information. The result is that at this stage of the process, when only sparse or generic data are prevalent for many parts of the analysis, conceptual models and parameters would bound a greater range of possible conditions than would likely be the case when more site-specific information is made available.

Step No. 3 – Formulate Mathematical Model(s) and Select Code(s)

At this stage in the performance assessment process, the analyst formulates mathematical representations of the conceptual models based on site-specific physical and chemical process considerations. The mathematical models may be solved numerically or in the form of analytical approximations. However, representations of conceptual models should not be constrained by the limitations of a particular computer code simply because a code is available or easy to use. This means that the analyst may have to develop a computer code for the express purpose of evaluating a particular conceptual model. However, it is not expected that this level of effort usually will be necessary, because a large number of computer codes exist that can be used to represent a broad range of potential conceptual models. As when developing conceptual models, the analyst should identify and describe, in words, all assumptions embedded in mathematical models and codes. As noted in NUREG-0856 (Silling, 1983), it is important that codes and databases used in the analysis be properly verified and documented according to a rigorous QA/QC program.

Step No. 4 – Conduct Consequence Modeling

The purpose of consequence modeling is to calculate site performance for credible conceptual models. Because uncertainty is inherent in all performance assessment calculations, analysts need to consider how uncertainty associated with the models and parameters translates into uncertainty in consequence modeling. The amount of information and the level of analysis needed for treating uncertainty will vary from facility to facility because of significant differences among site characteristics, engineering designs, and radionuclide inventories. Section 3.3.2 provides a discussion of approaches for addressing uncertainty in compliance demonstrations.

Step No. 5 – Perform Sensitivity Analysis

Sensitivity analysis is performed on the consequence analysis results (Step No. 4) to evaluate which models, assumptions, and combinations of parameters were most significant in producing the resulting doses. Sensitivity analysis allows the analyst to carefully scrutinize what most affects analysis results to: (a) optimize characterization efforts by specifying information to be collected to most reduce uncertainty; (b) better explain and defend the meaning of the performance assessment results; and (c) provide information that assists in the selection of an appropriate approach for the compliance demonstration. (See Section 3.3.2 for additional information.)

Step No. 6 – Evaluate Disposal Site Adequacy

Step No. 6 is a decision point to determine whether the LLW performance objective has been met. The evaluation to take place here should be a simple comparison between the consequence analyses (Step No. 4) and the 10 CFR 61.41 performance objective. If the comparison shows that the performance objective has been met, it would be documented and submitted for review as part of a Part 61 license application. (An important issue relating to the evaluation of site adequacy is to determine what part of the output distribution of doses should not exceed the 10 CFR 61.41 performance objective. This policy issue is addressed in Section 3.2.4.)

If the comparison indicates that the performance objective has not been met, the applicant should proceed to Step No. 7. However, as noted previously, because the goal of the LLW performance assessment analysis is to develop a supportable demonstration of compliance, the applicant need only undertake a depth of analysis and conduct as many additional iterations as necessary (Step Nos. 7 through 9) to show that the performance objective has been met. In this regard, the PAWG expects that the need for additional iterations in the analysis will be tempered according to the complexities of the LLW disposal system being modeled, uncertainties surrounding system performance, and the estimated risk.

Step No. 7 – Reevaluate Data and Assumptions
From the sensitivity studies conducted in Step No. 5, to identify those data and assumptions having the greatest influence over the calculated results (Step No. 6), the analyst may be faced with a number of choices related to how best to reduce uncertainty further in additional performance assessment iterations. Uncertainty may be reduced in any or a combination of several ways, including: obtaining new data from additional site investigations; performing adjunct modeling studies with new or existing data; and/or making changes to facility design. Thus, at this stage of the performance assessment process, the analyst should be concerned with how to optimize the allocation of resources for obtaining the information and data needed to reduce uncertainty and demonstrate compliance. Entering into this evaluation would be the relative uncertainties of assumptions and data, the degree that uncertainty was accounted for in the preceding analysis, and the cost of producing more or better data. This has been called "data-worth analysis" in decision-making models (Kozak *et al.*, 1993; Bear *et al.*, 1992; and Freeze *et al.*, 1990). If, however, the analyst determines that extensive additional data are needed to continue the process, owing to site complexity or other factors, it may be more cost-effective for the developer to reject the site altogether and proceed to another site.

Step No. 8 – Collect New Information and/or Change Design
Having completed the data-worth analysis (in the preceding step), the information identified at this time as being the most beneficial to reducing uncertainty should be gathered. As stated in Step No. 7, above, information developed can be of one type or a combination of several possible types, including site characterization data, changes to facility design, and adjunct modeling studies. Based on the sensitivity studies performed in Step No. 5, any of these sources of new information may significantly affect the subsequent consequence analysis iteration. A developer may, for example: (a) obtain new disposal site data with the goal of eliminating a conceptual model from consideration or narrowing a parameter range; (b) change the facility design to influence how barrier degradation is modeled, or confine problem radionuclides through the addition of special backfills; and/or (c) perform sophisticated modeling of geochemical conditions inside of disposal units, including cement buffering, to lower the source-term release.

Step No. 9 – Update Assumptions
Assumptions and conceptual models are modified in this step, based on the new information and/or design changes obtained from performing Step No. 8, above. The principles to be applied in this step are the same as those for the initial data evaluation and conceptual model development (Steps 1 and 2, above). Subsequent model formulation may involve elimination of a conceptual model, modification of a conceptual model, or introduction of new models, as suggested by additional information. A smaller range of potential outcomes will result when models are updated to reduce uncertainty. As shown by the process flow chart (Figure 3), mathematical representations of the updated models are formulated (Step No. 3) for the next performance assessment

iteration. Every successive iteration of the performance assessment should provide a rationale for the goals of the next iteration, such as the evaluation of new information (data) or improved conceptual models. Models, assumptions, and data may not be rejected simply because the analyst does not like the results of the current iteration or believes for insupportable reasons that it is too conservative.

3.2 PAWG Views on Policy Issues Regarding 10 CFR Part 61 Performance Objectives and Technical Requirements

Technical policy issues represent fundamental questions pertaining to the interpretation and implementation of specific Part 61 performance objectives and technical requirements. The PAWG identified five areas in the regulation that pertain to LLW performance assessment and that this supplemental advice should, therefore, address. These areas are:

— Consideration of future site conditions, processes, and events;

— Performance of engineered barriers;

— Timeframe for LLW performance assessment;

— Treatment of sensitivity and uncertainty in LLW performance assessment; and

— Role of performance assessment during the operational and closure periods.

The views expressed here are intended to be general and related technical issues will need to be addressed by applicants on a site-specific basis. Recommendations on how to address technical issues as well as on conducting site-specific analyses is set out in Section 3.3.

3.2.1 Role of the Site and Consideration of Site Conditions, Processes, and Events

3.2.1.1 Site Selection

The natural site contributes to overall disposal system performance by providing a stable environment for waste disposal, and by attenuating the movement of radionuclides off-site through environmental transport media (groundwater, surface water, and air). The minimum characteristics of an acceptable near-surface LLW disposal site are specified by the site suitability requirements of 10 CFR 61.50. The requirements emphasize site stability, in connection with engineered barriers; waste isolation, in terms of rates of radionuclide mobilization and transport; and long-term performance, with respect to defensible modeling of future site behavior. The siting requirements in 10 CFR 61.50(a)(9) and 60.51(a)(10) stipulate the need to avoid sites where the frequency, rate, and extent of geologic processes and events will adversely affect performance of an LLW disposal facility or preclude defensible modeling of long-term performance. The requirements are intended to eliminate, to the extent practicable, areas having characteristics that are known to, or highly likely to, produce problems over the long term (NRC, 1981). This means that sites should be selected where natural processes are occurring at consistent and definable rates, such that performance assessment models will represent both present and anticipated site conditions (NRC, 1982). Thus, a site carefully selected, to reduce uncertainty about its characteristics and behavior, adds to the credibility of performance assessment results.

In choosing a disposal site, 10 CFR 61.7(a)(2) requires that site characteristics should be considered in terms of the indefinite future and evaluated for at least a 500-year timeframe. The 500-year timeframe corresponds to the period when the hazard from moderately high-activity, short- and intermediate-lived radionuclides contained in Classes B and C waste is greatest, and when the ensuing need for achieving long-term stability of engineered features, such as multi-layered covers, concrete vaults, high-integrity waste containers (HICs), stabilized waste forms, and intruder barriers to Class C waste is greatest. The main design function of these engineered features is to limit infiltration of water into the waste so as to minimize leaching of radionuclides into the environment, and to provide protection to an inadvertent intruder. Part 61 requires stability lifetimes on the order of 300 to 500 years for B/C Class waste forms, HICs, and intruder barriers. The timeframe previously recommended for considering design bases, natural events, or phenomena for engineered barrier performance was 500 years (NRC, 1982). As discussed in Section 3.2.2 ("Role of Engineered Barriers"), service lives for engineered barriers, on the order of a few hundred years, are still considered credible, if justified by adequate technical analyses and data.

Beyond the specified service life for engineered barriers,[10] and into "the indefinite future," the focus of performance is on the continued isolation of long-lived radionuclides in the waste. At this time, the performance of the "physical" constituents of the engineered barriers can no longer be assumed and reliance must be placed primarily on the engineered barrier’s "chemical characteristics" as well as the site's natural (geologic) qualities to continue to limit environmental releases of long-lived radionuclides. In evaluating site suitability, the PAWG suggests refraining from excessive speculation about the extremely distant future, and recommends limiting evaluations of the natural site's geologic evolution to the next 10,000 years. This 10,000-year timeframe is the time period of regulatory concern recommended by the PAWG (see Section 3.2.3, "Timeframe for LLW Performance Assessment Analyses"). All significant conditions, processes, and events that are of concern to the ability of the engineered disposal system and natural site to meet the performance objectives need to be considered. However, it is not necessary to demonstrate that the stability of natural site features, including those primarily intended for achieving stability of engineered barriers, will continue to be met beyond 500 years.[11]

3.2.1.2 Site Conditions in Performance Assessment Models

At the time scale appropriate to assessing LLW disposal, natural site conditions may range from being relatively static to highly dynamic, depending on the influence of processes that are driven by the forces of tectonics and climate. Natural events occurring at a site, which at times may be catastrophic, are tangible manifestations of these active processes. However, as stated above, Part 61 emphasizes selecting sites based on geologic stability, waste isolation, long-term performance, and defensible modeling. Therefore, it should be possible to develop a set of reasonably anticipated natural conditions, processes, and events to be represented in site

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[10] As determined by the LLW disposal facility developer, with adequate technical justification.

[11] 10 CFR 61.7(a)(2) requires that in selecting a disposal site, "...site characteristics should be considered in terms of the indefinite future and evaluated for at least a 500-year timeframe...."

conceptual models (e.g., distribution of infiltration to account for variation in rainfall, and a service life for concrete that bounds the impact of degradation processes). The overall intent is to discourage excessive speculation about future events and the PAWG does not intend for analysts to model long-term transient or dynamic site conditions, or to assign probabilities to natural occurrences.[12] In developing this "reference natural setting," changes in vegetation, cycles of drought and precipitation, and erosional and depositional processes should be considered; future events should include those that are known to occur periodically at the site (e.g., storms, floods, and earthquakes). It must be emphasized that the goal of the analysis is not to accurately predict the future, but to test the robustness of the disposal facility against a reasonable range of potential outcomes. Accordingly, the parameter ranges and model assumptions selected for the LLW performance assessment should be sufficient to capture the variability in natural conditions, processes, and events.

Consistent with the above, consideration given to the issue of evaluating site conditions that may arise from changes in climate or the influences of human behavior should be limited so as to avoid unnecessary speculation. It is possible that, within some disposal site regions, glaciation or an interglacial rise in sea level could occur in response to changes in global climate. These events are envisaged as broadly disrupting the disposal site region to the extent that the human population would leave affected areas as the ice sheet or shoreline advances. Accordingly, an appropriate assumption under these conditions would be that no individual is living close enough to the facility to receive a meaningful dose. In addition, the hazard from the inventory remaining in typical LLW after about 500 years is expected to be relatively low. The PAWG believes that an applicant could use similar reasoning to explain how potential effects of glaciation will not render a disposal site unacceptable. Therefore, the PAWG recommends that new site conditions that may arise directly from significant changes to existing natural conditions, processes, and events do not need to be quantified in LLW performance assessment modeling.

For disposal sites where the impacts of global climate change consist primarily 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 an LLW performance assessment is determining how variations in precipitation result in varying rates of percolation into disposal units and of recharge to the water table. The PAWG recommends using historical and current weather data, and other site information (e.g., field tests) to establish a broad range of infiltration

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[12] By virtue of the siting guidelines found at Section 61.50, developers need to site LLW disposal facilities in geologic settings that are essentially stable (quiescent) or, alternatively, in areas in which active features, events, and processes will not significantly affect the ability of the site and design to meet the Subpart C performance objectives. In practical terms, the effect the Section 61.50 requirements have on the LLW performance assessment scenario selection methodology is that, after site characterization, the candidate site be defined in terms of its expected geologic evolution, where all likely scenarios are accounted for in the performance assessment model and treated equally, with a probability of (1). If the results of site characterization conclude that, geologically, there is the potential for low-probability scenarios – say on the order of 10^{-4} per year, in frequency of occurrence, or lower – they can be considered unimportant and thus screened out of the site model (and the subsequent analysis). In this fashion, uncertainty in the future system state of the disposal system is accounted for in the analysis.

rates that may be used to simulate both wetter and drier conditions than the current average. Sensitivity analyses performed as part of the LLW performance assessment will provide some insight into the effects that such variations could have on the dose calculations. The PAWG believes that the treatment of infiltration in this manner will allow an analyst to consider the effects of broad variations in weather, without the need for speculating on how climate might change.

Given the uncertainty in projecting the site's biological environment beyond relatively short periods of a few hundred years, it is sufficient to assume that current biological trends remain unchanged throughout the period of analyzed performance. Similarly, consideration of societal changes would result in unnecessary speculation and should not be included in performance assessments. With respect to human behavior, it may be assumed that current local land-use practices and other human behaviors continue unchanged throughout the duration of the analysis. For instance, it is reasonable to assume that current local well-drilling techniques and/or water use practices will be followed at all times in the future. Finally, the disruptive actions of an inadvertent intruder do **not** need to be considered when assessing releases of radioactivity off-site.

Assurance about site performance into the far future is also provided by limiting the amounts of long-lived radionuclides that may be disposed of at an LLW disposal facility, including those shown by analysis to be significant only after tens of thousands of years have passed. The effect of placing inventory limits on long-lived radionuclides is to mitigate, given what is foreseeable today, the potential consequences of waste disposal to generations in the distant future. See Section 3.2.3 for a discussion of timeframes for dose calculations in LLW performance assessments and inventory limits on long-lived radionuclides.

3.2.2 Role of Engineered Barriers

The term engineered barrier as defined in Section 61.2 means "... a man-made structure or device that is intended to improve the land disposal facility's ability to meet the performance objectives in Subpart C...." As such, engineered barriers are usually designed to inhibit water from contacting waste, limit release of radionuclides from disposal units, or mitigate doses to potential human intruders. Materials composing the "physical" constituents of the engineered barriers may range from purely (geo)synthetic membranes to natural soils to concrete vaults that are reconfigured to impart some characteristic or property enabling it to perform as an engineered barrier. Examples of physical engineered barriers are surface drainage systems and cover systems, concrete vaults, HICs, backfills, infills, etc. Engineered barriers improve LLW disposal facility performance by physically limiting the amount of water that can contact disposed-of waste and/or chemically retarding the release of radionuclides to the environment. Specific features to include as engineered barriers, and how they should be designed are site-specific decisions left to the discretion of the disposal facility developer. Although engineered barriers may be used to improve facility performance, it is nonetheless expected that the disposal characteristics of the site itself will meet the suitability requirements of 10 CFR 61.50.

The Final Environmental Impact Statement (FEIS) for Part 61 (NRC, 1982) clearly recognized that in time a disposal site's natural characteristics must be relied on to isolate waste. A later study of LLW disposed of in the United States from 1987 through 1989 (Roles, 1990) shows that although most of the activity in initial waste inventories resides in Class C waste, Class A waste typically contains the largest quantity of long-lived radionuclides (radionuclides with half-lives greater than 100 years). This means that within about 1000 years after disposal, the higher-activity short- and intermediate-lived radionuclides of B/C Class waste will have decayed to the point where most of the remaining activity will be from Class A waste. The remaining radionuclides in Class A waste will have such long half lives that it is unreasonable to assume that any physical barrier can be designed to function long enough to influence, through radioactive decay, the amount of long-lived radionuclides eventually available for release.

The PAWG has reviewed, and in some cases studied, the long-term performance of certain natural and man-made constituents of engineered barriers currently being proposed for near-surface LLW disposal facilities. Available information and performance records on some of these materials (concrete, plastics, natural soils, etc.) are limited and there are large uncertainties about how natural processes and events may affect their longevity and performance. The PAWG concluded that some constituent materials of engineered barriers are likely to remain physically distinct and structurally stable long after the 500 years intruder barriers are required to perform by 10 CFR 61.52. However, given natural forces likely to cause unavoidable and unpredictable deterioration of physical barriers, no compelling evidence was found to suggest that physical barriers, such as natural covers and reinforced concrete vaults, will perform at anticipated design levels, indefinitely. For example, the integrity of soil covers will ultimately be compromised by penetrating tree roots and burrowing animals, and reinforced concrete structures are subject to localized cracking or opening along joints followed by partial disintegration of concrete sections.

The PAWG recommends that an applicant assign and justify the credit given to engineered barrier performance. Any period of time claimed for performance of engineered barrier should be supported by suitable information and technical justification evaluated on a case-by-case basis. This information should include, but not be limited to specific engineered barrier designs, construction practices and associated QA/QC, analysis of maintenance/monitoring data, etc. In the degraded condition, at the end of its intended service life, an engineered barrier (e.g., reinforced concrete vault, engineered subsurface drainage system, etc.) can still perform a function, but the (diminished) function would be established by the applicant based on the assumed properties of its constituent materials.[13] In general, the parameter values for hydraulic conductivity and other physicochemical properties of the engineered barrier used in the performance assessment should represent its changed/degraded condition.

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[13] By relying on more robust engineered materials, such as those being proposed for HLW repositories, longer periods of engineered barrier performance can be justified – on the order of 10^3 years or greater. However, these more robust engineered materials have not been considered for LLW disposal facilities to date because of their relatively high unit construction costs and the commensurate increase in technical sophistication typically required to evaluate their performance.

For example, considering site conditions, it may also be possible to justify that the engineered barriers will maintain their structural stability and chemical buffering capacity considerably longer than 500 years that intruder barriers are required to function. Also, credit may be taken for redundant engineered systems if it can be demonstrated that they perform sequentially. Otherwise, individual barrier performance should be assumed as being concurrent with the performance of other barriers. The PAWG recommends that the applicant should assume that engineered barriers begin to degrade following site closure unless there is on-going monitoring and maintenance. Section 3.3.4 ("Engineered Barriers") provides a detailed discussion on modeling physical behavior of engineered barriers from their intended design condition through complete degradation. Analyses of several other site and design-engineering issues related to meeting the long-term stability requirements of 10 CFR 61.44 (i.e., surface drainage and erosion protection, stability of cover slopes, and settlement and subsidence) are typically evaluated independently of performance assessment.[14]

3.2.3 Timeframe for LLW Performance Assessment Analyses

The PAWG recommends a time period of 10,000 years for analyzing performance with respect to 10 CFR 61.41. In specifying the timeframe of regulatory interest, the PAWG considered several issues related to the nature of LLW and how engineered barriers and the site contribute to isolating radionuclides from the general environment. Figure 4 depicts the timeframes of importance to performance assessment of LLW disposal facilities.

Part 61 specifies compliance times for particular aspects of LLW disposal – B/C Class waste form stability is required for 300 years; intruder barriers must last 500 years; and site characteristics are to be evaluated for a minimum of 500 years. However, the regulation does not specify a time of compliance for meeting the overall performance objective of 10 CFR

[14] Alternatively, the applicant may choose to simplify the analysis of engineered barrier performance by assuming that engineered barriers will maintain their structural integrity for no more than 500 years after site closure, following which time it will be assumed that they will have physically degraded. In addition, considering site conditions, it may be reasonably assumed that the (degraded) engineered barriers will maintain their chemical buffering capacity periods considerably longer than 500 years. If the applicant chooses to rely on these alternative performance assumptions (i.e., 10^2 years versus 10^3 years or greater), it will still need to provide suitable (albeit simpler) information and technical justification, which would also be evaluated on a case-by-case basis.

Figure 4. Timeframes to be considered in an LLW performance assessment. [Adopted from NRC (1989, p. 2c).]

61.41. Disposal site performance is determined by activity, half-life, and mobility of radionuclides in the waste inventory; and processes and conditions that control engineered barrier degradation, water infiltration and leaching of waste, and release and transport of radionuclides to the general environment. The objective of specifying a regulatory timeframe is to ensure that all these determinants are fully evaluated with respect to achieving compliance with the performance objective. If the timeframe is too short, the performance objective could be met primarily through reliance on engineered barriers and site performance would not be adequately evaluated. On the other hand, strict application of the performance objective, for an extremely long compliance period, may not be meaningful given the amount of long-lived radioactivity in typical LLW, and the uncertainties inherently associated with the analysis.

Many mobile radionuclides in LLW – ^{14}C, ^{36}Cl, ^{99}Tc, and ^{129}I – have half-lives greatly exceeding the time when engineered barriers can reasonably be relied on to isolate waste from the environment. In addition, immobile uranium is being disposed of as LLW in quantities exceeding what was considered in the Part 61 DEIS (NRC, 1981). The dose potential from the progenies of uranium decay is significantly higher than that of uranium, and the concentrations of the progenies increase continuously until equilibrium with the parent uranium is established after 1 to 2 million years. Because analyses of total system performance are sensitive to uncertain site-specific disposal parameters (e.g., degradation rates of engineered barriers and estimates of geochemical retardation in soils), order-of-magnitude uncertainties in the time of peak dose, at off-site receptor points, are possible. Manipulation of these variables within relatively conservative ranges can readily shift the calculated peak uranium daughter products, principally radium-226 (^{226}Ra). The test-case simulations show that, for multiple realizations, the magnitudes of the peak doses, for most radionuclides, decreases asymptotically beyond a certain period of time (i.e., the distribution of peaks versus time is skewed to lower doses, at longer timeframes). The decay products of uranium are an exception to this trend.

Through its LLW performance assessment test-case calculations for a humid site, the PAWG has gained some useful insights into this issue. Twenty-thousand years constituted a typical calculation time, but some calculations were carried out to 100,000 years, to include the transport of radionuclides with relatively large retardation coefficients, and the ingrowth of 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 tend to indicate that mobile long-lived radionuclides (e.g., ^{14}C, ^{36}Cl, ^{99}Tc, and ^{129}I) generally bound the peak doses for other LLW radionuclides. Thus, a time of compliance that is sufficiently long to capture the peaks from the more mobile long-lived radionuclides (i.e., 10,000 years) will tend to bound the potential doses at longer timeframes (greater than 10,000 years). However, specific exceptions include: (a) ingrowth of daughter products from large inventories of uranium [greater than ~3.7×10^{13} becquerel (~1000 curies)]; and (b) peak doses at humid sites from large inventories of long-lived transuranics.

The PAWG believes that a period of 10,000 years is sufficiently long to: (a) evaluate performance of both engineered barriers and the site; (b) capture the peak doses from the most mobile long-lived radionuclides; and (c) bound the potential peak doses at longer times. In examining shorter periods, such as the 1000 years being used for decommissioning facilities, it should be recognized that at facilities undergoing decommissioning, the number and quantity of long-lived radionuclides of concern are generally limited and the parameters controlling their mobility less uncertain. The release of radionuclides also will not be delayed for hundreds of years by the presence of engineered barriers. Should analyses indicate failure to meet the performance objective is caused by a release of a long-lived radionuclide(s), a 10,000-year period is generally sufficient for setting a site-specific inventory limit for that radionuclide, under 10 CFR 61.7(b)(2). Generic inventory limits for protection of individuals off-site, analogous to the waste classification system for intruder protection, are not provided in the rule because of the site-specific nature of radionuclide migration in groundwater. The technical analysis done in the Part 61 DEIS (NRC, 1981; p. 5-73) identified ^{3}H and three long-lived radionuclides of particular concern for migration in groundwater (^{14}C, ^{99}Tc, and ^{129}I), but others may also be important, depending on the particular radionuclides that are projected to be in the inventory.

However, it should be noted that for performance assessments carried out beyond 10,000 years, it may be necessary to ensure that the disposal of certain types of waste will not result in markedly high doses to individuals living at any time in the future. Potentially high doses relative to the performance objective could occur within a timeframe longer than 10,000 years, from disposing of large quantities of uranium or transuranics, or possibly by mobile long-lived radionuclides at arid sites with long ground-water travel times. If, at 10,000 years, a radionuclide shows evidence of breakthrough below a peak, the calculation should be continued, assuming the same set of conditions, processes, and events considered significant over the initial 10,000 years, until the radionuclide's peak dose is reached regardless of when that occurs. For example, a uranium-238 (^{238}U) inventory resulting in a ^{226}Ra dose at 10,000 years may indicate a potential ^{226}Ra dose in excess of the performance objective beyond 10,000 years. The PAWG recommends that assessments beyond 10,000 years not be used for determining regulatory compliance with the performance objective. However, as a basis for making judgments about the magnitude of the estimated dose relative to the performance objective and its time of occurrence beyond the regulatory compliance period, such assessments may provide an important contribution to the site environmental evaluation. If, after considering the magnitude and time of the dose, and associated uncertainty, the regulatory authority decides that the dose is unacceptably high, either inventory limits would have to be imposed or the problem waste is not suitable for disposal as LLW at the site.

3.2.4 Treatment of Sensitivity and Uncertainty in LLW Performance Assessment

The objective of the LLW performance assessment is to quantitatively estimate disposal system performance for comparison with the performance objective in 10 CFR 61.41. Uncertainty is inherent in all LLW performance assessment calculations and regulatory decision-makers need to consider how uncertainties within the analysis translate into uncertainty in estimates of performance. Uncertainty denotes imprecision in the analysts' knowledge (or available information) about the input parameters to the models, the models themselves, or the outputs from such models. Uncertainties come from a variety of sources, some of which, given the present state of the art, cannot be quantified at this time, although there are methods for addressing them in an LLW performance assessment (as discussed below). To understand their influence on the compliance demonstration, performance assessment practitioners rely on *sensitivity* and *uncertainty analyses. Sensitivity analysis* identifies which assumptions and parameters affect the quantitative estimate of performance by changing input variables and model structures. By contrast, *uncertainty analysis* provides a tool for understanding and explaining (in quantitative terms) the influence (or impact) of imprecision in performance estimates, caused by imprecisely formulated models and/or imprecisely formulated known input variables.

Uncertainties in a performance assessment may be generally classified as: (a) *parameter uncertainty*; and/or (b) *model uncertainty*. Although this classification is neither precise nor exhaustive, it facilitates discussion of uncertainties related to estimated performance of an LLW disposal facility over long periods of time. *Parameter uncertainty* describes the variability of physicochemical properties over spatial scales of interest and the incomplete knowledge of the natural system because of necessarily sparse measurement. Parameter uncertainty is expected to be described in the LLW performance assessment by distributions of variables, such as hydraulic conductivity, porosity, or the retardation coefficient.

Model uncertainty describes the limited knowledge inherent in applying predictive models: (a) over long periods of time for which direct validation is precluded; and (b) to complex systems for which measurement and characterization are limited. These uncertainties are expected to be described: (a) by consideration of reasonable range of fundamental conditions, processes, or events to test the robustness of the facility; and (b) by distributions of parameters describing the manifestations of these conditions, processes, or events. Therefore, analysis of these model uncertainties may involve evaluation of the variation in parameters and/or the use of different conceptual models. For example, variation of the parameter used for estimating the degradation rate of a disposal unit cover could also be used to represent uncertainty in the degradation of the engineered materials of the cover in the environment because of uncertain conditions, processes, and events (e.g., erosion, freeze-thaw action, tree root penetration, etc.). Although some model uncertainty may be parameterized, performance estimates based on a reasonable range of the alternative models considered may be more applicable for particular modeling approaches (e.g., consideration of the uncertainties of chemical buffering of a cementitious waste form on solubility limits may require comparison of analyses that use chemical buffering with analyses which do not use chemical buffering, rather than an analysis that varies the solubility limits over a range of values which encompasses chemical buffering to no buffering).

3.2.4.1 Role of Sensitivity and Uncertainty Analyses

Sensitivity and uncertainty analyses are integral parts of the LLW performance assessment process, and are often used to assist in interpreting results and to optimize strategies for building confidence in compliance demonstrations. As noted above, sensitivity analysis is used in identifying parameters and assumptions that have the largest effect on the modeled result. The insights from this analysis can be used to assist in developing and refining LLW performance assessment models and approaches. Zimmerman (1990) identified that sensitivity analysis results can be used to justify the use of a simple model as a surrogate for a more complex model, without loss of important detail, define priorities for data acquisition, and reduce the number of parameters for the uncertainty analysis.

Uncertainty analysis provides a tool for understanding and explaining the influence or impact of the assumptions and parametric values on the variability of the quantitative estimate of performance. An uncertainty analysis propagates the uncertainty in model inputs and assumptions through the analysis to the output. Model output can then be displayed in a variety of ways such as scatter plots, histograms, or cumulative distribution functions, to graphically display the effect of input uncertainty on model output (performance measure). Additionally, statistical attributes of output distributions such as mean, median, and variance can be evaluated to provide the analyst with quantitative measures for the influence of uncertainty on system performance.

Insights gained from sensitivity and uncertainty analysis assist both the staff, as the regulating body, and potential applicants. An applicant can use these insights to optimize resources and focus on supporting approaches/assumptions that are key to the compliance calculation.

3.2.4.2 Recommended Approaches for Sensitivity and Uncertainty Analyses

Because LLW performance assessment analyses for any particular site may involve a spectrum of models of differing complexity, the most appropriate methods for evaluating sensitivity and uncertainty need to be tailored to the complexity of the analysis and the nature of the uncertainties being analyzed. Early in the performance assessment process, sensitivity analysis can provide valuable insights to assist further model development and data collection. The PAWG recommends that sensitivity analysis be conducted to identify the conceptual models and parametric values that most influence the performance calculation. A variety of approaches can be used to identify key sensitivities in the LLW performance assessment analysis, including: (a) calculations in which 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, while holding all other parameters constant; (b) calculations in which many parameters are varied simultaneously over a reasonable range of values; and (c) calculations considering multiple conceptual models. Sensitivity analysis results should be used to help explain and ensure how conceptual models and parameter values provide a reasonable test of the robustness of the facility, and to help select an appropriate approach for analyzing uncertainty in the context of the compliance demonstration.

The PAWG has considered a range of different approaches for evaluating uncertainty in LLW performance calculations. 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* which quantitatively depicts system performance as a distribution of potential outcomes based on variation in models and parameters. For example, a bounding analysis relies predominantly on very long transport times in the unsaturated zone (typical of some arid environments). It may focus on site characterization and infiltration tests to understand and bound uncertainty associated with infiltration rates and unsaturated zone properties, for use in calculating a single, *deterministic estimate* of performance. 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 use a *probabilistic approach* to quantify the uncertainty in system performance. In this latter case, 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. (Note: Probabilistic approaches encompass a wide range of analysis techniques and methods. For this technical report, probabilistic approach refers to the use of a formal, systematic uncertainty analysis to quantify the uncertainty in performance estimates because of uncertainty in models and parameters. Assigning probabilities to scenarios, which is characteristic of some probabilistic approaches, is **not** recommended for LLW performance assessments.)

In any approach, it is essential that the applicant present a reasonable, comprehensive, and persuasive understanding of the disposal system performance 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 LLW performance assessment.

3.2.4.3 Compliance Determination

Variations in approaches for demonstrating compliance with the LLW performance objectives require appropriate flexibility in the selected approach for determining compliance. The PAWG has considered compliance determination approaches appropriate for deterministic (characterized by a single estimate for performance) and probabilistic (characterized by a distribution of potential outcomes of system performance) analyses based on distributions of input.

For a deterministic approach to LLW performance assessment, the applicant should provide a single estimate of performance that is believed to bound performance. Dependability of this type of analysis requires the applicant to demonstrate that the performance assessment models and parameters are bounding, especially with respect to any key uncertainties in the analysis. The applicant is relying on the bounding nature of the analysis, rather than a quantitative analysis of uncertainty. A single estimate of performance does not provide insight into the quantitative margin of safety provided by the bounding analysis. Therefore, a single, deterministic estimate of performance should be at or below the performance objective defined in 10 CFR 61.41.

For a probabilistic approach to LLW performance assessment, the applicant should conduct a formal uncertainty analysis and provide a distribution of potential outcomes for system performance. This type of assessment, which relies on more realistic estimates of performance for multiple system components, should be supported by a demonstration by the applicant that justifies the representation of the uncertainty (defendable parameter ranges, appropriate random selection, and combination of parameters, etc.). The PAWG recommend that the whole distribution of results be evaluated to gain insights into the possible disposal facility performance. The PAWG considered a number of aspects of the analysis to gain insight into appropriate measures for determining compliance based on a distribution of results. The *peak of the mean dose curve* (i.e., dose as a function of time) provides the best representation of the central tendency of system performance, at any specific time and thus potential risks to an average member of the critical group, and therefore the most reliable statistic of the distribution. Accordingly, the PAWG considers this to be a logical choice for the point for compliance determination. The PAWG also considered a need for more assurance that the performance objective in 10 CFR 61.41 would not be exceeded than is provided by the mean of the distribution. The PAWG recommends that the peak of the plot of mean doses over time be less than the performance objective and a plot of the upper 95th percentile of doses at each discrete time be less than 1 millisievert (mSv) [100 millirem (mrem) total effective dose equivalent (TEDE)] to consider a facility in compliance with the performance objective in 10 CFR 61.41.

It is recognized that the quantified uncertainty in the analysis may represent both uncertainty reflecting the analyst's degree of belief (epistemic uncertainty) and uncertainty due to spatial and temporal variability (aleatory uncertainty). It is important to point out this distinction because aleatory uncertainty can be reduced through additional data collection; whereas, epistemic uncertainty cannot. The PAWG recommending the use of the mean in determining compliance could be misinterpreted by some that little, if any, additional data collection should be undertaken to reduce uncertainty due to spatial and temporal variability. However, as previously stated, insights gained from sensitivity and uncertainty analysis can be used to optimize resources and focus effort on supporting approaches and assumptions necessary to collect additional data to reduce the uncertainty due to spatial and temporal variability in key parameters that are important to demonstrating compliance.

In addition to meeting the numerical limits in 10 CFR 61.41, an applicant must employ reasonable effort to maintain releases of radioactivity in effluents to the general environment "as low as is reasonably achievable" (ALARA). ALARA analyses should weigh the costs and benefits of design alternatives in meeting the performance objective. These analyses may be either quantitative or qualitative. Quantitative analyses may make use of the performance assessment process to compare releases from the design alternatives (from comparing the time and rate of release to comparing collective doses). The various benefits of any design should be weighed against the costs (e.g., additional worker dose or occupational hazards or additional costs or resources use). In general, the ALARA analysis should use the guidance in Chapter 7 ("ALARA Analysis") of the *NMSS Decommissioning Standard Review Plan* (NRC, 2000).

3.2.5 Role of LLW Performance Assessment during Operational and Closure Periods

In receiving a license to receive, possess, and dispose of LLW, disposal facility developers will have used the performance assessment analysis (initially) to show that, with reasonable assurance, the operation of the LLW disposal facility will not constitute an unreasonable risk to the health and safety of the public. During the construction, operation, and post-operational periods of the LLW disposal facility *per se*, performance assessment can continue to play an important role in determining compliance with the performance objectives found in Subpart C.

For example, Section 61.53 of the regulations requires that, during the construction, operation, and post-operational periods, a licensee is responsible for conducting an environmental monitoring program. Measurements and observations must be made to evaluate potential health and environmental impacts and long-term effects of the disposal facility and, if necessary, corrective actions taken to mitigate the potential effects of radionuclide releases. In addition, Section 61.28(a) requires that the final revision to site closure plans should contain any additional geologic, hydrologic, or other disposal site data obtained during the operational period pertinent to the long-term containment of waste, and the results of tests, experiments, or analyses pertaining to long-term containment of waste. Site closure will be authorized if the final site closure plan provides reasonable assurance of the long-term safety of the facility.

One way to address these requirements is to revise and update the performance assessment model used in the initial license application (Subpart B) submittal with the new information from these monitoring programs. These new site data may confirm or validate the key parameters or model assumptions used in the earlier performance assessment or call them into question. The level of confirmation (i.e., validation) needed should be determined by the intended regulatory uses of the models and assumptions, rather than the ideal of validation of a scientific theory.

3.3 Recommended Approaches to LLW Performance Assessment Modeling Issues

3.3.1 Introduction

The PAM, introduced in Section 1.4 of this technical report, provides a basic set of component models and analytical approaches for conducting LLW performance assessments. Although the conceptual models and related uncertainties documented in the PAM have not changed, the analytical approaches recommended (i.e, position statements) in the following pages have evolved from the PAWG and NRC contractor insights obtained from applying the PAM to a site-specific test case problem. Consistent with the overall structure of the PAM, the recommended approaches in this section of the technical report include suggested analytical approaches for each of the recommended system components and/or processes. These modeling areas (and the PAWG's corresponding views and recommendations) are as follows:

— Uncertainty and Sensitivity Analysis: *Section 3.3.2*

— Infiltration and unsaturated zone flow: *Section 3.3.3*

— Engineered barrier performance (coupled with infiltration analysis to calculate the water flux into disposal units): *Section 3.3.4*

— Radionuclide releases from waste forms and disposal units: *Section 3.3.5*

— Transport media – groundwater, surface water, and air: *Section 3.3.6*

— Plant and animal uptake: *Section 3.3.7*

— Dose to humans: *Section 3.3.7*

Because understanding and addressing uncertainty are vital to the supporting basis of any compliance demonstration, recommendations and advice on approaches for treating uncertainty and for performing parametric sensitive analyses is included in Section 3.3.2. These recommendations identify the various sources of uncertainty within LLW performance assessment analyses and discusses how these uncertainties should be addressed and translated by the analyst into uncertainty about decisions on regulatory compliance. Because there is no "best" approach to demonstrating compliance, the recommendations are flexible, to include a simple, bounding deterministic as well as a more complex, probabilistic approach to uncertainty, as warranted by specific disposal site conditions.

To implement the PAM, the PAWG has found that it is necessary to develop a proper method of integrating the multiple computer codes used to analyze the respective subsystem models. It is possible to step through the PAM manually, where analysts submit input to one subsystem module based on the results (output) of another. This approach enables the output of an individual subsystem code to be critically reviewed before its use as input to subsequent subsystem codes. At the other extreme is a purely automated approach in which computer codes (in the form of a "system manager") are used to run (execute) the various subsystem computer codes in the proper sequences and thereby permit the extraction of relevant output automatically as input to succeeding subsystem modules without the benefit of any type of review. Intermediate approaches might automate the process to a lesser degree, for example, by using a program to extract relevant code output and process it as usable input to a specific subsystem code that the analyst then runs manually. However, regardless of the method of model integration used, the PAWG believes that it is important for analysts to have the ability to scrutinize and thereby understand the intermediate model results during any phase of an LLW performance assessment (i.e., Section 3.1) and to understand the relationship of the results to the overall analysis, and to analyze parameter uncertainty and sensitivities.

For working the performance assessment test-case problem, the PAWG developed an overall "systems" code to automate the execution of the individual subsystem modules (and computer codes) as well as their linkages. Developing the systems code resulted in a considerable amount of problem-dependent computer code that had to be written. However, the code enabled the PAWG to efficiently run the multiple model realizations needed for analyzing parameter uncertainty probabilistically. Generally, the benefits derived from automating the PAM, over linking and running subsystem codes manually, appear to be significant and include:

(a) Greatly enhanced ability to step through successive iterations of the performance assessment process described in Section 3.1 (see Figure 3), thereby making uncertainty analyses and assessing sensitivity and robustness of the system much easier;

(b) Most likely, obtainment of a higher degree of QA;

(c) Explicit recognition of assumptions that might be vague or addressed inconsistently; and

(d) Better assurance that parameters and values are consistent among subsystem models.

Although specific models and computer codes may be discussed or referenced in the technical report to follow, the NRC does not endorse the use of any particular models and/or codes for an LLW performance assessment. Moreover, as noted in Section 2.1, it is important for potential applicants to have established a rigorous QA program at the beginning of the performance assessment process, and to provide an appropriate technical basis (e.g., justification and documentation) regarding the particular models and/or computer codes used in the analysis.

Finally, to better understand the approaches to the issues described in the following technical areas, the reader should be familiar with the PAWG's positions on the policy issues described in Section 3.2 of this technical report.

3.3.2 Uncertainty and Sensitivity Analysis

Uncertainty is inherent in all performance assessments, and regulatory decision-makers need to consider how uncertainties within the analysis translate into uncertainty in modeling results used to measure performance. The amount of information and level of analysis needed for treating uncertainty will vary from facility to facility because of significant differences among their site characteristics, engineering designs, and radionuclide inventories. To accommodate these differences, flexibility in analyzing uncertainty is necessary. Section 3.2.4 discusses the role of sensitivity and uncertainty analysis in performance assessment and presents two possible approaches for treating uncertainty. One approach provides a single bounding estimate of system performance supported by data and assumptions that clearly demonstrate the conservative nature of the analysis. The other approach provides a quantitative evaluation of uncertainty and its impact on system performance represented by a distribution of potential outcomes. This "probabilistic" approach will likely involve more calculational effort than will the bounding "deterministic" approach, and should be used in complex situations where a single estimate of performance is difficult to defend. Regardless of the particular approach used, the supporting basis for demonstrating compliance should include an uncertainty analysis.

3.3.2.1 Sources of Uncertainty

Distinct sources of uncertainty in performance assessment modeling include: (a) uncertainty regarding abstracting a real system and its evolution into a form that can be mathematically modeled (i.e., model uncertainty); and (b) uncertainty, in the data, parameters, and coefficients used in the models (i.e., parameter uncertainty – see Kozak *et al.*, 1993; and Davis *et al.*, 1990).

3.3.2.1.1 Model Uncertainty

Model uncertainty results from limitations in models used to represent complex system behavior, including the system's evolution (future site conditions, processes, and events), for a specific site and engineering design. This includes uncertainty about the interpretation and use of data (e.g., parameter variability in space and time), and assumptions about system dimensionality, isotropy, and initial boundary conditions (Kozak *et al.*, 1993). Although model uncertainty may be difficult to quantify in a rigorous numerical fashion, these sources of uncertainty may be significant and should not be neglected in the analysis.

Treating model uncertainty requires making credible assumptions about likely processes and events, and expressing them through selection of appropriate conceptual models and input variables. Although system and subsystem models are designed to be "reasonably realistic," credible alternative models may be possible, given: (a) limitations in available site data; (b) ambiguities in interpreting site features; and (c) inadequacies in understanding processes (e.g., physical, chemical, geologic, and meteorologic) relevant to long-term performance of engineered barriers and the site. In considering model uncertainty in demonstrating compliance, the LLW disposal facility developer should use the conceptual model that can be best defended based upon what is known about the site. Additional data may need to be collected to defend the selected model. Alternatively, it may be preferable to choose the most conservative conceptual model for demonstrating compliance. However, the evaluation should be performed in the context of providing a reasonable range of potential outcomes – incredible events, highly unlikely combinations of parameters, and unreasonable modeling assumptions should not be used. Additionally, it is important to recognize that the assumed future state of the system is not intended to correspond to all possible future site conditions, but is intended to test the robustness of the facility against a reasonable range of potential outcomes.

3.3.2.1.2 Parameter Uncertainty

Parameter uncertainty is connected with the data, parameters, and coefficients used in mathematical models and computer codes. This uncertainty originates from a number of sources, including: uncertainty associated with laboratory and field measurements (e.g., standard error in analytical techniques, sampling bias errors, etc.); uncertainty in determining parameter and coefficient values used in a model (e.g., assumptions used to determine degradation rates of engineered barriers); and uncertainty associated with the intrinsic heterogeneity of natural systems (e.g., spatial variability of measured hydraulic conductivities and distribution coefficients within a geologic unit, and variability of source-term release rates).

Parameter uncertainty is more readily quantified than model uncertainty. There are numerous approaches for dealing with data, parameter, and coefficient uncertainty (see Peck *et al.*, 1988; Maheras and Kotecki, 1990; Zimmerman *et al.*, 1990; Meyer *et al.*, 1997; and Meyer and Gee, 1999); all involve some degree of quantitative treatment. The main types of approaches for treating parameter uncertainty quantitatively are: (a) analytical methods, including stochastic approaches and Bayesian analyses (Meyer *et al.*, 1997); and (b) Monte Carlo methods, which include random and Latin Hypercube Sampling (LHS) techniques (Iman and Shortencarier, 1984). For these probabilistic approaches, ranges and/or distribution functions should be specified for the data, parameters, and coefficients.

3.3.2.2 Issues

The sophistication of the compliance calculation depends on facility-specific characteristics such as: inventory and waste form characteristics; infiltration rates; engineered barriers; and hydrogeologic properties of the site. Questions that should be addressed before selecting an approach for demonstrating compliance are:

— What are the key uncertainties?

— What are the key sensitivities?

— Is a simple, deterministic approach justified?

— If needed, what is the most appropriate method for quantitatively evaluating uncertainty?

There are no simple generic answers to these questions. They should be addressed at the initial stages of the LLW performance assessment process by identifying and evaluating the strengths and weaknesses of facility attributes relative to possible approaches for measuring performance.

3.3.2.3 Recommended Approach

There is no "best" approach for measuring the performance of an LLW disposal facility. Selection of an appropriate approach needs to begin with developing a general understanding of how the facility will perform by conducting systematic evaluation to identify important facility attributes and their relationships to performance. This initial analysis should be used to probe assumptions and uncertainties to determine the sensitivity to facility performance. The PAWG recommends using simple approaches that encourage broad examination of uncertainties (parameter and model) including an evaluation of the degree to which the uncertainties should be addressed and represented in assessment results. Although simple approaches are envisioned, it is anticipated that alternative models as well as parameter variations should be used to provide sufficient information to determine whether a probabilistic or deterministic approach is a more appropriate measure of performance.

3.3.2.3.1 Deterministic Analysis

Single estimates of performance often can be evaluated easily, but the selection of appropriate models and parameter values may be difficult. [The PAWG's views on policy issues (Section 3.2) provide important information on what is and is not expected in developing models and parameter values.] When performance is measured against a single estimate, uncertainty is addressed by providing reasonable assurance that this estimate conservatively bounds performance. Given the uncertainties inherent in an LLW performance assessment, it is expected that bounding analyses will use simple modeling approaches, assumptions, and parameters that readily can be demonstrated as being conservative.

One approach would be to use bounding values in key areas of performance such as the amount of water entering the disposal units, release of radionuclides from disposal units, transport to receptor locations, and dilution of radionuclides within exposure pathway. Although it is not required that the bounding analysis use the most conservative values for all parameters and the most conservative models, a demonstrably conservative or bounding analysis should not make use of parameters and models that cannot readily be shown as leading to conservative results. Although the bounding analysis is expected to be a simple calculation involving a limited number of parameters and simple models, the support necessary to defend a bounding analysis will vary based on the characteristics of the facility and the nature of the analysis.

For example, at a facility relying on small releases and slow transport in the unsaturated zone (typical of some arid environments), site characterization and infiltration tests could be performed to understand and bound uncertainty associated with infiltration rates and unsaturated zone properties. This site information could be used to select a conservative infiltration rate and radionuclide solubility limits that, when combined with appropriate models for radionuclide transport and uptake, can be shown to provide a single conservative estimate of performance. At a different facility, where reliance may be placed on having a design with significant amounts of cementitious material to create a high pH environment lasting long periods of time, geochemical experiments could be performed to understand and bound uncertainty associated with near-field solubility limits. Again, this information could be used to select conservative near-field radionuclide solubility limits for transport models to provide a single conservative estimate of performance.

3.3.2.3.2 Probabilistic Analysis[15]

Simple, bounding analyses may not always be an appropriate measure because of the need to rely on conservatism in the analysis as a replacement for quantitatively evaluating uncertainty. As the complexity of the analysis and the number of parameters increase, it becomes very difficult to select a defensible single estimate of performance. An alternative approach is to develop more sophisticated models and more realistic parameter ranges that more explicitly quantify the uncertainty in performance estimates. In contrast to what may be appropriate for simple deterministic approaches, understanding the uncertainty associated with the results from more sophisticated models may require more sophisticated approaches for analyzing the uncertainty in results of the assessment. A formal, systematic uncertainty analysis (characteristic of probabilistic approaches) provides a tool to probe the conceptual models and parametric values, and furnishes a foundation for understanding and explaining the influence or impact of the assumptions and parametric values on the calculation of consequences.

The representation of parameter uncertainty is perhaps the most easily and commonly analyzed uncertainty. Parameter uncertainty is often evaluated using a Monte Carlo analysis or LHS where the input variables representing parameter uncertainty and the output of the model(s) are in the form of distribution functions (see Davis *et al.*, 1990). A plot of the mean dose versus time is obtained by taking the mean dose at each discrete time increment for each vector (run), within the analysis, using sets of input values based on random or Monte Carlo sampling of the input distributions. This approach is shown conceptually in Figure 5 and can be represented mathematically as follows:

[15] Probabilistic approaches encompass a wide range of analysis techniques and methods. For the purposes of this technical report, probabilistic approach refers to the use of a formal, systematic uncertainty analysis to quantify the uncertainty, in performance estimates, caused by uncertainty in models and parameters. The PAWG does **not** recommend assigning probabilities to scenarios, which is characteristic of some probabilistic approaches.

Figure 5. Overall approach to uncertainty analysis in an LLW performance assessment (after Kozak *et al.*, 1993).

$$\text{Max}\left[\text{Mean}(t)\right] \leq \textit{Regulatory Limit}$$

where:

$$\textit{Mean}(t) = \frac{\sum_{k=1}^{N} \textit{Dose}_k(t)}{N}$$

$\text{Dose}_k(t) \equiv$ doses *at time t, for run k*

$N \equiv$ *number of Monte Carlo runs*

$t \equiv$ *time*

This type of formal approach, however, does not necessarily require extreme amounts of site-specific data to specify parameter distributions. The specification of the parameter distribution should reflect the knowledge of the parameter or "degree of belief" rather than concentrate on rigorous statistical efforts to determine distributions. Precisely defined distribution functions may not provide significantly better insights than can be obtained using distributions that are selected using qualitative means such as expert opinion combined with a knowledge and understanding of available generic and site-specific data. This type of approach is most appropriate for an analysis with many parameters and can provide additional insights beyond analyses that vary a single parameter only. (Although single-parameter variations can be useful in examining model sensitivity, their use in evaluating uncertainty in analyses involving many parameters is limited. The results of uncertainty analysis using single-parameter variations can be misleading when the sensitivity of one parameter is not independent of the value of another parameter and the sensitivity of the output may not be constant over the range of variability of a particular parameter.)

Uncertainty in conceptual models is more difficult to evaluate. It is not generally possible to informally and *a priori* identify models and their associated parameter values that prove to be conservative throughout the performance assessment analysis. This is because of the complex relationships that exist within and between subsystem models of the system and the counter-intuitive relationships between parameters. When there are two or more equally reasonable and plausible conceptual models for the site, results of different conceptual models need to be compared and analyzed. Comparison of the results from different conceptual models provides a quantitative basis for evaluating the uncertainty and conservative nature of competing conceptual models.

The analyst must weigh the results of all analyses and cogently present the evidence and arguments supporting or rejecting each model. Since the staff can be expected to evaluate the overall performance of the system, in part on the basis of the applicant's performance assessment (as well as on the basis of independent analyses), it is PAWG's view that it is essential that the applicant present a reasonable, comprehensive, and persuasive interpretation of the results, in the context of the applicant's understanding of the site and disposal system. Thus, an uncertainty analysis that propagates parameter uncertainty through each credible model of the system, using

Monte Carlo analyses or some similar technique, can provide a comprehensive examination of uncertainty and its effect on compliance demonstrations. Figure 6 (modified from Hoffman and Gardner, 1983) depicts how the results of analyzing multiple conceptual models and parameter sets are compared and used to make a decision on how adequately the design meets the requirements. When more than one model is derived and cannot be refuted based upon the available data and information, additional data may need to be collected to provide a basis for accepting one model as oppose to the other credible models. Alternatively, the conceptual model that provides the most conservative result can be used to measure performance and thus possibly obviating the need for additional data collection. However, as noted in Section 3.3.2.1.1, on model uncertainty, incredible events, highly unlikely combinations of parameters, and unreasonable modeling assumptions should not be used.

3.3.2.4 Parametric Sensitivity Analysis

Sensitivity analysis plays an important role in performance assessment by identifying which model parameters are most important to performance calculations. This type of information can be useful in interpreting the results of uncertainty analyses. Similar to uncertainty analyses, sensitivity analyses can be performed at different levels of sophistication. The method should be selected based on the types of questions being asked and the sophistication of the models being examined.

The objectives of uncertainty and sensitivity analyses are different. The objective of the sensitivity analysis is to determine which parameters affect the model results most, whereas the objective of an uncertainty analysis is to determine how the uncertainty in model parameters affects the model results. Sensitivity analysis provides extremely useful input to uncertainty analysis by identifying the important parameters and assumptions in the models that can be used to focus the scope of the uncertainty analysis. For complicated modeling analyses, where there are many parameters and potential for counter-intuitive results, a better understanding of model sensitivities should be used before selecting a particular approach for analyzing uncertainty. For sensitivity analyses, it is suggested that the distribution of calculated doses at the time of the peak mean dose be used as the dependent variable in analyzing the relative sensitivity of the input parameters. This allows an assessment of sensitivity of parameters consistent with the part of the analysis used for determining compliance; therefore, those parameters that most influence the compliance demonstration can be identified. In addition, it is recommended that the sensitivity of input parameters against the distribution of peak doses (i.e., the peak dose over time for each simulation) be considered. This will help to determine if there are key parameters controlling the time when the peak mean dose occurs and whether additional pathways and parameters are important to the compliance demonstration.

3.3.3 Infiltration

The primary objective of the performance assessment infiltration analysis is to determine the

Figure 6. **Probabilistic approach for treating model and parameter uncertainty in an LLW performance assessment (after Kozak *et al.*, 1993).**

amount of water entering the disposal unit, and the amount of water available for replenishing the ground-water system (i.e., natural recharge). Determining the amount of water infiltrating into the disposal unit is needed in the source-term analysis to determine the release rate of determining the upper boundary condition for the ground-water flow and transport analysis. radionuclides from the disposal unit. Knowledge of recharge in the natural system is needed in determining the upper boundary condition for the ground-water flow and transport analysis. Infiltration is commonly defined as the entry of water into the soil profile or the cover surface of the disposal unit. However, as described in this document, the infiltration analysis also includes the subsequent movement of water through the soil profile or cover system and into the disposal unit, itself, and/or the ground-water system.

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Figure 7, which reflects commonly used terminology, shows the various processes to consider in performing the infiltration analysis. Climate, soil properties, and vegetation are a few of the important parameters controlling infiltration. Each can vary spatially and temporally, and trying to account for this variability over the period of regulatory concern will involve a considerable amount of uncertainty. Several important considerations to weigh in undertaking the infiltration analysis are discussed below, followed by a general approach to the analysis that is designed to address these considerations without having to treat them in full.

3.3.3.1 Key Considerations in the Analysis

3.3.3.1.1 Temporal Variation in Processes and Parameters

Infiltration is influenced by highly transient processes of precipitation, runoff, drainage, evapotranspiration, and snowmelt that create special problems in analyzing infiltration in an LLW performance assessment. Capturing the true interaction of these highly transient processes may require an analysis at small time increments; however, this is problematic for performance assessment analyses that may cover many hundreds of years. Water budget analyses, which are commonly based on average monthly values, may underestimate the mean annual infiltration rate because months where evapotranspiration exceeds precipitation are assumed to have zero infiltration, even though there may be significant precipitation during parts of the month. Similarly, concluding that recharge at arid sites will be negligible because, on average, annual evapotranspiration exceeds annual precipitation, is not conservative. This is because it is entirely possible for some recharge to occur after episodes of high-intensity precipitation. An analysis based on too large a time discretization could also lead to over-estimates of the infiltration rate because larger time intervals allow more time for the soil profile to receive a given influx of water. These examples highlight the importance of using short time intervals in the infiltration analysis. Smyth *et al.* (1990) reported that 1-hour or 6-hour incremental data may be required to define the subsurface response to climate, vegetation, and near-surface soils. However, it can be easily seen that even for an analysis

Figure 7. **Schematic showing an LLW disposal facility in relation to the components of the hydrologic cycle.**

using data on 6-hour increments, the data requirements will be substantial for an analysis carried out for many hundreds of years. Even if the analysis is carried out at small time increments, consideration must be given to selecting the appropriate climatological, or sequence of climatological data, to use in the analysis. A hydrologic evaluation methodology was developed by the Pacific Northwest National Laboratory for estimating water movement through natural materials and engineered covers at commercial LLW sites (Meyer *et al.*, 1996).

Because site conditions and the physical properties of engineered barriers will not remain the same throughout the period covered by the performance assessment analysis, infiltration into the disposal unit may increase over time. For example, infiltration may be enhanced if the site experiences a change or loss in vegetation (Gee *et al*., 1992; and Smyth *et al*., 1990) and cover performance may be reduced by plant and animal intrusion, settling and slumping, or erosion. In addition, man-made materials such as concrete are expected to degrade over time in response to physical, chemical, and/or mechanical processes (Walton *et al*., 1990). Thus, an analysis based solely on as-built and current site conditions may be unrealistic and, therefore, some assumptions must be made about the performance of engineered barriers (see Section 3.2.2), and future states of the site (Kozak *et al*., 1990b). In addition, assumptions about how the site may change or engineered materials degrade are expected to affect the type of analysis required. For example, assuming that the concrete will degrade through fracturing may require consideration of fracture flow.

3.3.3.1.2 Spatial Variation in Parameters

Soil properties are expected to vary spatially over the area covered by the infiltration analysis. Variability in the physical properties of soil is important in determining infiltration rates. Gee *et al.* (1992) show how spatial variation in soil texture influences recharge. Variation in soil physical properties, unless accounted for, increases the level of uncertainty in the performance assessment infiltration analysis. Even for relatively uniform soils – for example within units of an engineered cover – physical properties can vary greatly from one place to another. As an example, hydraulic conductivity values measured in radon barriers of three Uranium Mill Tailings Radiation Control Act (UMTRCA) projects varied spatially between 1 to 2 orders of magnitude (Smyth *et al.*, 1990). Variations in natural soils may be even higher. Information on natural soil variability is provided in Meyer *et al.* (1997). This information is taken from the U.S. Department of Agriculture data base known as *UNSODA* – UNsaturated SOil Database – see Leij *et al.* (1996).

The dimensionality of the analysis should also be considered. Assuming strictly vertical, one-dimensional (1-D) flow should be conservative for most situations because it does not account for lateral drainage; however, under some conditions, this assumption may not be conservative. Covers designed for LLW disposal facilities likely will incorporate one or both of the following design features: a sloped surface to enhance runoff; and a sloped subsurface interface of coarse-to-fine grained soil to enhance lateral drainage. Under some circumstances this design could actually enhance water flux into the disposal unit. For example, Smyth *et al.* (1990) reported that surface runoff has been observed at the cover edge of several UMTRCA projects. If this accumulated water migrates back toward the disposal unit, which it could under some circumstances, the flux of water into the disposal unit will be larger than that assumed under strictly vertical, 1-D flow.

3.3.3.2 Recommended Approach

3.3.3.2.1 General Strategy

The approach the PAWG recommends for the infiltration analysis is to start with a simple conceptualization of the engineered system and the unsaturated (vadose) zone of the natural setting and progress to more complicated analyses, as appropriate, for measuring performance and evaluating the design. For example, in developing a conceptual model of the cover, the analyst may choose not to take credit for liners that may have a short life-span; such liners may provide an extra measure of protection, but may not be needed for demonstrating compliance. A simple analysis will facilitate testing several conceptual models over a range of parameter values. Figure 8 diagrams one approach that is similar to the integrated numerical model approach described by Smyth *et al.* (1990) and later revised in Meyer *et al* (1996). The approach is designed so that sites with favorable hydrologic conditions can take advantage of these favorable conditions, whereas sites with less favorable hydrologic conditions will require greater reliance on the engineered system.

As discussed in Section 3.3.2.1.2, a broad range of values should be used to characterize each parameter in the analysis. A range of values is used to capture the uncertainty in the parameter. Soil characterization methods, for use at LLW sites, is provided in Wierenga *et al.* (1993). To determine hydrologic properties and simple vertical percolation values, a model is provided in Hills and Meyer (1995). Ranges in parameter values, taken from a national database and other sources of information to determine hydrologic properties, are provided in Meyer and Gee (1999). For a bounding-type deterministic analysis, the analyst will have to determine the appropriate values to use in the infiltration analysis so as to bound the performance assessment results. The use of extreme values may not be conservative when placed in the context of the overall performance assessment analysis. That is, although a particular value may be conservative for the purpose of the infiltration analysis, it may not be conservative for the overall performance assessment results.

A key feature of the approach is how progressive stages of cover performance degradation over time are captured in the infiltration analysis by using ranges of percolation rates and hydraulic parameters for engineered materials. At each stage of cover degradation, hydraulic parameter values for engineered materials are developed to represent the state of cover degradation for the stage. Ranges are sampled based on their assumed statistical distributions, and the values taken are assumed to remain constant throughout the stage. At each subsequent stage, a new set of parameter distributions is sampled. The calculated percolation rate, based on the parameter distribution sampling, is assumed to remain constant during the particular stage of the analysis. Determining sets of values for both percolation and hydraulic properties of engineered materials may require auxiliary analyses performed outside the integrated

Figure 8. Recommended approach to the LLW infiltration analysis. (Numbers next to the process blocks refer to the recommended approaches found in Section 3.3.2.2.2 of the text.)

performance assessment analysis.

3.3.3.2.2 Analysis

The infiltration analysis can be viewed as consisting of two primary components. First, highly variable (temporal) processes are considered in determining a steady-state percolation rate. As depicted in Figure 8, this can be represented as a range of values. As previously stated, it may be best to determine this range through analyses outside the integrated performance assessment analysis. Second, the steady-state percolation rate is used as an upper boundary condition to model moisture movement through the cover and the ground-water system; this is depicted as the bottom, middle box in Figure 8.

Given the potentially long periods over which the performance assessment analysis is likely to be carried out, use of a constant percolation rate is desirable. Use of a constant percolation rate is justified because as water moves below the zone of influence of plant roots, the requirement for capturing the transient nature of the hydrologic processes occurring near the land surface (e.g., precipitation, evapotranspiration, runoff, etc.) becomes less important; as a result, the flux of water below this zone can be assumed to be at a steady rate. Therefore, in the proposed approach, this "steady rate" of water or percolation is used in determining the upper boundary condition of the flow analysis. This percolation rate can be considered as equivalent to natural recharge and can therefore be used to establish the upper boundary condition for the ground-water flow and transport analysis.

Because of uncertainty in the determined percolation rate, the analyst should consider a range of parameter values in the analysis. The range will need to be broad enough to represent the analyst's confidence in the value. Once the range and distribution are established, values can be sampled for use in the flow analysis.

In determining the range of percolation rates, the analyst should consider the effects that discrete high-intensity events, and various prolonged wet periods might have on the mean annual percolation rate. In general, prolonged periods (i.e., seasonal or annual) of higher than normal precipitation have been found to result in more infiltration than short-duration, extremely high-intensity storms. However, the effects of high-intensity, short-duration storms should not be overlooked, because in some settings they may be the principal source of infiltration. The analyst should consider the effects melting snow that accumulated on the site may have on infiltration. The analyst should also try different conditions to determine the melting effect of snow on the percolation rate. Because of the uncertainty in predicting climatic changes, the PAWG does not recommend considering long-term climatic changes in the analysis (see Section 3.2.1.2); however, variations in weather conditions should be considered, as discussed above. Finally, the analyst should consider the effects of having no vegetation on the cover surface of the disposal unit, in case the vegetation later dies off. To analyze for variable infiltration rates because of climate change, recommended approaches are outlined in Meyer and Gee (1999) and Timlin *et al.*(2000).

One suitable method for determining the range and distribution of percolation rates is the method used by Smyth *et al.* (1990) in their analytical stochastic analysis of an UMTRCA cover. In their analysis, percolation rates were assumed to be uniformly distributed. The range in values was derived by estimating the minimum and maximum possible recharge rates. In general such an approach should be conservative (for the infiltration analysis) since recharge rates are expected to have either a gamma or log-normal distribution, based on previous works that have shown climatic data to be best represented by a gamma distribution (Richardson and Wright, 1984), and both hydraulic conductivities and infiltration rates to be approximately log-normally distributed (Cook *et al*., 1989).

Another suitable method, especially for arid areas, is to use the natural recharge rate determined from field tests conducted at the site. Gee and Hillel (1988) discuss a number of methods for determining natural recharge and some of the considerations of each method. Of these methods, lysimetry and tracer tests appear to be most reliable for estimating natural recharge at an arid site. These methods could provide an estimate of the expected recharge or percolation rate; however, the analyst will have to establish a justifiable range about this expected value, especially for sampling in a probabilistic performance assessment analysis. Kozak *et al.* (1990b) recommend using several field methods, as opposed to a single method. If real-time, near-continuous measurements of soil-water content are needed to estimate percolation and recharge, recommended methods and instrumentation are provided in Timlin *et al.* (2000). Each method used should have data input independent of the other methods.

For humid sites (i.e., greater than 500 millimeters/year of precipitation), a range of percolation rates can be estimated through the use of water balance analyses. For such analyses, the analyst should use National Weather Service and/or the USGS climatological data from nearby stations to augment site data. The data record for the analysis should cover 20 to 50 years (Smyth *et al*., 1990). It is recommended that the time interval for water balance analyses be no greater than average daily values (i.e., water balance analyses based on average monthly or annual input values are not recommended). The average of the mean annual infiltration rates, determined from the water balance calculations, can be used as an estimate of the percolation rate to be used in the analysis. Statistical deviations about this mean value can be used in determining an appropriate range. The analyst should ensure that the sequence of the climatological data used in determining the range in percolation rates is appropriate considering the timeframe of the analysis (i.e., selection of climatological data that represent significant dry periods is not advised). In general, results from water balance calculations are more sensitive to uncertainties in the input components for sites in arid and semi-arid areas than for sites located in humid areas (Gee and Hillel, 1988). Therefore, it is advisable to exercise considerable caution in using water balance calculations for sites located in arid or semi-arid areas.

Lastly, when the cover is assumed to be intact, the amount of water transmitted through the cover may be sufficiently small so that the analysis can be simplified with some conservative assumptions. For example, the analyst may assume full saturation for the clay barrier and use the saturated hydraulic conductivity of the barrier as an estimate for the percolation rate.

For the second step in the analysis, the steady rate of water, determined from the percolation/

natural recharge analysis, establishes the upper boundary condition for analyzing flow through the remainder of the cover. For the native soils, recharge can be used directly in establishing the upper boundary condition for the ground-water flow and transport analysis (see Section 3.3.6.1). Because of the expected spatial variation in hydrologic properties of cover materials, the analyst should use a range of values. Distributions for the parameters for the engineered system should be based on specific values representing the median of the respective parameter distributions for each of the three phases of facility performance [i.e., design, degrading, and degraded performance (as applicable), discussed in Section 3.3.4.4]. The selection of the functional form of the distribution should be based on the type of distribution typically observed for that parameter. Values can be sampled from the assumed distribution and treated as an effective parameter in the analysis. Because the potential number of parameters to be sampled could become fairly large (depending on the complexity of the cover system), the analyst should carefully consider the correlation of the various parameters. If parameters are correlated, it may be possible to use a lumped parameter in the analysis and reduce the number of parameters to be sampled. Parameters that can be specified can be described by constants.

The cover material is expected to degrade with time (see Section 3.2.2, "Role of Engineered Barriers"); therefore, the hydrologic parameters used in the analysis should also encompass expected temporal changes. In the approach outlined in Figure 8, degradations of materials are handled through changes in their hydraulic properties. The material hydraulic can be conductivities are assumed to change (as evidenced through some new statistical distribution) and new parameter values are sampled to reflect a progression in degradation of the physical engineered components of the disposal unit.

The PAWG recommends treating some materials as an equivalent porous continuum; therefore, explicit modeling of fracture flow is not required for materials that are susceptible to fracturing. For materials expected to undergo fracturing, the degree of fracturing expected should be captured by the range of hydraulic parameters assumed when these materials are expected to degrade. Treating the material as an equivalent porous continuum eliminates the need for making detailed predictions about the geometry and nature of the fractures. In addition, assuming an equivalent porous continuum is in general agreement with the approach recommended for analyzing the source term, whereby it is assumed that the influx of water into the disposal unit comes into contact with the bulk of the waste.

In considering degradation of engineered components of the barrier, the analyst will need to consider the degradation of not only the clay barrier, but also the degradation of other constituents within the cover that are important to limiting infiltration (i.e., a concrete vault, if included). For example, over time, drainage layers may become clogged, and therefore lose their effectiveness in transmitting water away from the disposal unit.

The analyst should consider the influence of multi-dimensional flow; this is needed to ensure that accumulated water at the cover edge does not reach the disposal unit. Accumulated water at the edge may produce a larger flux of water into the disposal unit than that occurring vertically at the top of the disposal unit. Determining the potential occurrence of such a phenomenon will likely require a multi-dimensional analysis. However, once it has been determined that such accumulated water could migrate into the disposal unit, the effects of this can be accommodated within a simple 1-D or quasi 2-D analysis used as part of the performance assessment analysis.

3.3.4 Engineered Barriers

The objective of the engineered barrier analysis in an LLW performance assessment is to establish model representations of the physical dimensions and characteristics of designed engineered features, and to determine the ranges of parameter values that would reasonably represent the behavior of the features with the passage of time. The following discussion addresses the major issues relevant to evaluating the performance of engineered barriers, and describes a process that can be used to establish parameter values of materials in engineered barriers for use in an LLW performance assessment. A methodology for evaluating the characteristics and modeling engineered barriers in the performance assessment is depicted in Figure 9.

3.3.4.1 Features and Dimensions of Engineered Barrier Systems

Engineered barriers are components and systems designed to improve the waste retention capability of a land disposal facility. The considerations related to physically describing the features of the engineered barriers in performance assessment are the same as those inherent in their actual design. These design considerations are described in detail in Chapter 3 of NUREG-1200 ("Design and Construction"), and are controlled primarily by the requirements of established engineering practice and building codes. The design concept of a disposal unit for an LLW disposal facility (layout and physical dimensions of a vault system, etc.) is typically documented and depicted in sketches and drawings. The descriptions should identify the materials and their arrangement in a disposal unit including spatial variations (i.e., horizontally and vertically). This information defines the spatial relationships among the various types of materials that are used in a facility and provides the information that is needed to model the physical dimensions of engineered barriers. Not all design features will necessarily be reflected in, or qualify for, consideration in performance assessment as engineered barriers. The applicant should define which components and associated materials are intended to help meet the performance objective and thus are being considered as engineered barriers in the performance assessment. It is likely that the results of preliminary (auxiliary) analyses will be used to assess the need for additional performance enhancements that may, in turn, dictate the use of improved or additional engineered barrier systems (e.g., the performance modeling of reinforced concrete vaults, soil covers, etc.). In this manner, design features and engineered barriers would evolve from important conclusions arising from performance assessment results.

Figure 9. Recommended approaches to LLW performance assessment modeling – methodology for modeling engineered barriers performance. (Numbers next to the process blocks refer to the specific sections of text in this technical report.)

3.3.4.2 Integration and Interaction of Materials

An understanding of the nature of materials in engineered barriers, their make-up, and their interactions is needed in performance assessment, for estimating material longevity and for developing parametric values that represent the behavior of engineered barriers with time. Once the various materials that make up the engineered barriers and their spatial relationships are described, it will be necessary to evaluate how their integration into the composite system affects facility behavior. Presumably, each material that constitutes part of the design is selected either for fulfilling the regulatory requirements or for some utilitarian purpose such as constructability. Factors that need to be considered in this process include: (a) compatibility among materials that may come in contact with each other, either directly or indirectly through material transport processes within the engineered barrier system; (b) the manner in which the disposal facility is to be constructed, including how construction joints, changes in geometry, penetrations, etc., may affect system behavior; (c) the effect that failure of a design feature or some portion of an engineered barrier would have on the overall behavior of the barrier; and (d) how the degradation of material properties affects barrier performance over time. The purpose of this integration step is to begin a logical design process, to ensure that all relevant materials and conditions that could affect the behavior of the waste disposal system, over the service life of the engineered barriers, are considered.

3.3.4.3 Construction Quality and Testing[16]

The quality level to be required and maintained during the design and construction of a disposal facility should be reflected in the parametric values for engineered barriers derived for use in performance assessment. Before construction of the disposal facility, the quality level of the various material and construction specifications that will be documented in the license application can be used by the analyst. It would be necessary, however, to conclude that the quality level being proposed is attainable and that it is supported by an acceptable QA program. Provisions also should be made in performance assessment for the fact that the actual level of quality achieved in the field (i.e., as-built conditions) may be different and possibly lower than that assumed during the design and analysis phase of the project. If this has not been considered in the original design, by allowing for design margins, appropriate parameter distributions in a performance assessment will need to be modified to reflect as-built conditions. For example, it is expected that the permeability of physical engineered barriers will be a key parameter in the performance assessment. Therefore, it may be necessary for appropriate controls to be initiated in the field during and after construction, including testing, to verify permeability values for design and in performance assessment. The testing need not be done on the actual facility but could be done on a replicate cover or disposal unit constructed at the site being assessed. Testing of in-place reinforced concrete barriers, for example, including areas with discontinuities, should include tests for hydraulic conductivity. Field permeability testing should also be performed on other materials and engineered barriers that are relied on in performance assessment.

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[16] In-situ or as-built testing should be conducted when it is practicable to do so.

3.3.4.4 Model Input

After proceeding through the initial three steps of this methodology, discussed above (in Sections 3.3.4.1 through 3.3.4.3), the analyst should have sufficient information on the characteristics of engineered barriers from which to base reasonably bounding estimates of their material properties necessary for the performance assessment. These steps include: (a) identifying engineered barriers, systems, and materials used in the disposal unit; (b) appraising compatibility and interactions among materials; (c) evaluating material quality and durability, and system behavior; and (d) assessing the effect of construction quality. In carrying out the recommended methodology, the analyst should review sources of information on engineered barrier material properties and performance to be certain that they include:

(a) comparable historical laboratory and field service data, including consideration of:
- (i) compatibility with current LLW disposal conditions; and
- (ii) compatibility of the test methods and procedures; and

(b) the analytical methods for projecting service life performance, including:
- (i) capability of addressing synergistic effects; and
- (ii) the ability to extrapolate service life and performance characteristics.

In determining the service life of physical engineered barriers, including the parameter values and the confidence levels in those parameters influencing physical performance, previous engineering experience and knowledge about the application and long-term behavior of specific materials need to be considered. Some materials, such as synthetic waterstops, are generally believed to have service histories of no more than 100 years. The service histories of other materials (e.g., clay, sand, and gravel) is well known from their behavior in the environment and from proven service experience.

The ranges of parameter values to represent the performance of engineered barrier materials, over time, may be determined by dividing engineered barrier performance into three phases. The first phase is the service life or performance period, when engineered barriers would perform as designed. The occurrence of certain natural events (e.g., seismic and meteorological) and resulting imposed loads that the facility must be designed to withstand, are factored into the design of the disposal facility (so-called "design-basis" natural events are defined in Chapter 3 of NUREG-1200). Once it has been determined that the requirements for disposal site stability have been met, it can be assumed that engineered barriers will remain stable against design basis events for the duration of their intended service life. The second phase, after the service life period, represents a time of decreasing engineered barrier function from ongoing processes of degradation. The third or final phase represents performance where complete degradation has occurred. Complete degradation means loss in intended design function and a return to those constituent materials shown to be resistant to physical, chemical, or biological processes, and is not meant to imply total structural instability and the creation of void spaces. For example, complete degradation of reinforced concrete vaults would assume a return to the constituent sand and gravel aggregates, whereas, for a degraded clay-cover soil, the clay soil particles would remain in-situ, but at a loss in intended engineering properties (e.g., increased hydraulic conductivity). The selection of parameters for model input for a degraded barrier is very much influenced by the availability of information and data on material quality and durability. Because the performance assessment timeframe is much longer than actual material performance records, engineered design lives, and the period of active institutional control, it is necessary to assume conservative material properties for degraded engineered barriers.

It is expected that, in the first phase, the service life periods of different barriers will vary significantly because of the inherent diversity and variability of materials used to construct engineered barriers. This would need to be accounted for in performance assessment. As an example, based on engineering judgment, the hydraulic conductivity for the low-permeability portion of the cover, such as a clay layer, may range from 1×10^{-8} to 1×10^{-7} centimeters/second over its service life. Its service lifetime may be established at 500 years , for example, because it is determined that site conditions would ultimately allow tree roots to penetrate the clay layer at 500 years. Similarly, the hydraulic conductivity over the service life of a reinforced concrete vault may be estimated to range from 1×10^{-11} to 1×10^{-9} centimeters/ second. If, for example, it is determined that site conditions could lead to slowly developing differential settlement, under structural loading[17] and ensuing concrete cracking 100 years after site closure, then the service life of the disposal vault would be chosen at 100 years. [Calculations by Snyder and Clifton (1995) indicate that 50-micron cracks extending through a concrete member, spaced about one meter intervals, can change the hydraulic conductivity of bulk concrete by several orders of magnitude.]

For the second and third phases of performance after the service life phase, new sets of parameter values would be established for barrier materials, first to represent engineered barriers in the process of degrading and then to represent them after they have completely degraded. It should be recognized that in some materials (e.g., concrete vaults), the time between initial undegraded conditions and completely degraded conditions may be quite short in terms of changes in hydraulic conductivity. Thus, to represent variations in the behavior of clay after 500 years, when tree roots are likely to have penetrated, or of a cracked concrete vault beyond 100 years, additional hydraulic conductivity distributions for the respective barriers would have to be determined. In preliminary modeling of engineered barriers, the time increment can be considered as a step function by introducing, at the beginning of each phase of barrier performance, the set of unique parameter distributions representing the performance of the barrier over the respective phase. In later iterations of the performance assessment, continuous time functions may be established, based on as much actual data as are available.

Finally, in performing the necessary calculations, it should be noted that for some materials (e.g., concrete), the timeframe between the onset of initial degraded conditions and that of complete (physical) degradation may be quite short (in terms of terms of changes in hydraulic

[17] Other scenarios could include concrete failure due to sulfate attack, carbonization, corrosion of reinforcing steel, alkali-aggregate reactions, biological effects, etc. Depending on the particular failure mode selected, the hydraulic conductivity parameters values would need to be adjusted to represent the new, degraded condition.

conductivities).

3.3.4.5 Post-Construction Monitoring and Evaluation

The range of values used in design must also reflect what is achievable in the field after various materials, configurations, and resulting engineered barriers are integrated into the disposal facility. Once a disposal unit is ready for operation, it will be necessary to verify that the actual as-built parameter values are within the design range used in the performance assessment. If the as-built values are less favorable and outside the range considered as initial conditions in the design, additional supporting studies to update the performance assessment may be required. The monitoring of a facility's post-construction behavior is typically intended to build confidence in fulfillment of design expectations, by obtaining confirmatory records of the disposal facility's successful performance. Monitoring to verify satisfactory performance is accepted practice and is not normally meant to allow a licensee to take greater credit and to reduce safety margins. During the design and construction stage of facility development it may be necessary to plan for and implement physical arrangements and instrumentation needed for monitoring the relevant parameters previously defined by the designer (White *et al.*, 1990; and Marts *et al.*, 1990). The development of monitoring strategies, for regulatory determining compliance, can use the information found in Young *et al.*(1999a and b). The selection of field instrumentation and analysis methods need to be site-specific (Young *et al.*, 1996).

3.3.4.6 Use of Engineering Judgment

Predicting the service life of the engineered features of the LLW disposal facility will, by necessity, be based partially on the results of accelerated material testing and mathematical modeling. The PAWG does not expect potential applicants to independently develop this information. Rather, the PAWG expects that an applicant will carefully review the literature and select values (or ranges in values) for the material property parameters to be considered as part of the LLW performance assessment. Thus, in selecting the values for the needed engineering parameters, the applicant is expected to evaluate and interpret the scientific knowledge base as it relates to materials performance, to the extent that this knowledge base exists. For the purposes of this document, the analysts' efforts to synthesize sometimes disparate and often conflicting sources of information (or data) on materials performance into an integrated picture can be referred to as *engineering judgment.*

As with all complex technical analyses, engineering judgment, usually informal and implicit, is used routinely to supplement and interpret this information – indeed, even to determine how to obtain the data or perform the analyses. The PAWG believes that the ability to evaluate a potential LLW license application will, in large measure, depend on the transparency with which data are collected, analyzed, and interpreted, and safety-related decisions are made. Therefore, the PAWG believes that it is important for the analyst to document the rationale and basis for the engineering judgments. The reasons for documenting these engineering decisions are: (a) to indicate the current state of knowledge about material properties and service life; (b) to demonstrate that the parameter values selected are reasonable and conservative, and consistent with the current state of knowledge; (c) to permit the analysis to be independently confirmed; and (d) to provide a basis for updating assessments to reduce uncertainty in the analysis.

3.3.5 Source Term and Waste Type

The objective of a source term analysis is to calculate radionuclide releases from the LLW disposal units as a function of time. These radionuclide release rates can then be used as input for transport models that estimate offsite releases for the facility. Radionuclide releases from LLW facilities are typically liquid or aqueous releases; however, release of certain radionuclides disposed of at LLW facilities can occur in the gaseous phase. Although liquid releases can be significantly constrained by considerations of the flux of water entering a disposal unit, gaseous releases are relatively unconstrained because of the significantly higher rates for gaseous diffusion and advection compared with diffusion and advection of radionuclides in the liquid phase. Gaseous and liquid releases will often be analyzed separately in LLW performance assessment analyses because of the significant differences in the nature of the releases, and because the limited impact on performance of the gaseous release readily lends itself to a simple bounding analysis. Therefore, source-term modeling of liquid and gaseous releases are discussed separately.

Gaseous release of radionuclides, for those waste streams with gaseous radionuclides, will be governed by the container lifetime and design (e.g., container vents could allow gas to diffuse out). Section 3.3.5.7.2 presents approaches for bounding calculations of gaseous release to be used to determine if further consideration is warranted. The remaining views and advice in this section concentrates on more sophisticated approaches and assumptions used for understanding liquid release processes. The source-term analysis for liquid release uses the flux of water into the disposal unit, calculated from the infiltration analysis, to estimate radionuclide releases (the source term) from the disposal unit(s), which are then used to analyze environmental transport.

When selecting modeling approaches for estimating the liquid releases, one must consider a number of disposal unit features and environments such as the radionuclide inventory, waste types, waste form and type, waste containers, backfill, and chemical conditions. Estimates of releases that rely on specific performance from these features will require data and technical support commensurate with their importance to performance. Simple modeling approaches, which are based on the general behavior of the waste form and a general understanding of the chemical environment within the disposal unit, will require less sophisticated analyses and support than approaches that put more reliance on understanding complex processes. It is recommended that a screening analysis, which identifies the important radionuclides that need to be included in the analysis for comparison with the regulatory limit, should be performed to limit the scope of radionuclides to be considered. A schematic depicting the general considerations or decisions that could be required in a source-term analysis is shown in Figure 10. The following discussion provides recommendations and advice on the simple approaches that can be used to address these general considerations.

3.3.5.1 Inventory of Radionuclides in LLW

3.3.5.1.1 Issues

Assumptions regarding the characteristics of the radionuclide inventory can have a significant impact on the determination and selection of modeling approaches appropriate for representing the source term. Radionuclide inventories need to be addressed on a facility-specific basis. That is, the anticipated distribution of specific radionuclides in the LLW disposal facility inventory must be estimated by waste class (Classes A, B, and C); waste type; waste form; waste stream; and waste container type. This information provides a basis for selecting an initial approach for source term modeling. The necessary level of detail of this information will need to vary with the modeling approaches under consideration. For example, the distribution of radionuclides among different waste types (e.g., dewatered ion-exchange resins, activated metals, dry solids, dry active wastes, etc.) can be very important because of the potential for significant variation in release rates from the various waste types. In addition, the solubilities and half-lives of the radionuclides under consideration can affect the selection of source term models. Also, consideration of specific waste containers (e.g., HICs) which can be relied on to delay initial releases of radionuclides, might be effective for reducing the releases of short-lived radionuclides.

3.3.5.1.2 Recommended Approach

The applicant should provide a description of the inventory, waste form, waste type, and waste container assumptions used in the performance calculation. Moreover, the applicant should use assumptions consistent with LLW expected to be disposed of at its site. Despite the uncertainty in predicting future inventories, waste streams, and disposal practices, the performance assessment needs to contain a thorough description of the LLW quantities and disposal assumptions.

Significant radionuclides present in LLW should be provided by volume and activity levels and identified by: waste class; waste type (e.g., ion-exchange resins, dry active wastes, and dry solids); waste form (e.g., cement-solidified, activated metals); waste stream; and waste container for each type of generator (e.g., utility, medical, academic). LLW containing chelating agents (e.g., decontamination waste) needs to be identified separately, because of the concerns of 10 CFR 61.2 and 61.20 regarding waste forms containing chelating agents. Particular attention should also be given to: identifying long-lived radionuclides with a high potential for mobility [e.g., ^{14}C, ^{36}Cl, ^{99}Tc, ^{129}I, and certain alpha-emitting transuranics such as plutonium-239 (^{239}Pu) and neptunium-237 (^{237}Np)]. In addition the inventory needs to include radionuclides with a relatively high dose conversion factor (DCF) and/or significant ingrowth

Figure 10. Calculational considerations in estimating LLW source term releases. (Note that the calculational steps and parameters can be specific to a waste class, waste type, and stream, or to an individual radionuclide.)

of daughter radionuclides [e.g., ^{238}U and thorium-232 (^{232}Th)].

Information on commercially generated radionuclide distribution by waste generators, waste class, waste stream, and waste form is available from shipping manifests (see Roles, 1990, and Cowgill and Sullivan, 1993) and from DOE's *National Information Management System* managed by the Idaho National Engineering and Environmental Laboratory (INEEL).[18] Specific inventory information for a performance assessment may be obtained from surveys of waste generators within the compact or State and projections of changes in waste streams over the lifetime of the facility (e.g., for anticipated reactor decommissioning). The Commission recently amended its regulations at 10 CFR Part 20 to improve LLW manifest information and reporting (NRC, 1995). Guidance to complete NRC's uniform LLW manifest is presented in NUREG/BR-0204 (NRC, 1995).

3.3.5.2 Screening Methods to Identify Significant Radionuclides

3.3.5.2.1 Issues

The objective of preliminary screening of the LLW facility inventory is to identify radionuclides to be included in the performance assessment and eliminate insignificant radionuclides from further analysis. The use of a screening approach to determine these key radionuclides could involve a number of possible approaches and also will likely involve disciplines other than the source term (e.g., ground-water transport and dose). A tiered approach, which starts with the highly conservative inventories and releases mechanisms and progresses to a less conservative approach, is recommended. Regardless of the approach, justification would be required to explain the rationale for eliminating radionuclides from the analysis.

3.3.5.2.2 Recommended Approach

The following are acceptable screening approaches to determine which radionuclides in the facility inventory need to be considered further in the LLW performance assessment.

(a) Eliminate radionuclides, with half-lives less than 5 years, that are not present in significant activity levels and do not have long-lived daughter products (or are themselves not daughters of a longer-lived parent).

(b) Perform a dose calculation that assumes the waste container, waste forms, backfill, or other retardation methods are completely ineffective in delaying or retaining radionuclides within the disposal units. All radionuclides are assumed to be available for radionuclide transport in soil to the ground-water system, and with subsequent transport to the average member of the critical group by all exposure pathways, including drinking water. Important radionuclides will be determined by calculating the transport of the radionuclides in soil and groundwater, with an acceptable radionuclide transport model, using conservative, radionuclide distribution coefficients to retard radionuclide

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[18] Administered by the National Low-Level Radioactive Waste Management Program, INEEL, P.O. Box 83415, Idaho Falls, ID 83415. The system administrator is currently Ron Fuches, Telephone: 208/526-9717.

movement in the soils. Radionuclides with an estimated maximum dose less than one percent of the Part 61 dose requirements can be eliminated from further performance assessment calculations. Appropriate computer models, such as *PAGAN* (Chu *et al.*, 1991), would be useful to make this type of screening calculation. To ensure that important radionuclides are not inadvertently screened out of the assessment, it is important to confirm that the dominant exposure pathways (i.e., those contributing the most to the calculated dose) in the screening calculation are consistent with those in the final performance assessment analysis.

3.3.5.3 Waste Form and Waste Type

The physicochemical properties of the waste form and waste type will determine the release mechanism(s) for a given radionuclide inventory. Aqueous release, once the container degrades, is controlled primarily by the waste form and waste type. Radionuclide release from various waste forms such as cement-solidified waste (diffusional release) and activated metals (dissolutional release) may vary significantly from waste forms that have only surface contamination and are characterized by a "wash-off" or rinse release. Understanding specific release mechanism(s) that retard release from specific waste forms can be extremely important, depending on the inventory, in developing appropriate source-term release models.

3.3.5.3.1 Issues

The minimum requirements that all waste forms must meet, to be acceptable for near-surface disposal, are given in 10 CFR 61.56(a). In addition to these minimum requirements, certain wastes (i.e., Classes B and C wastes, and Class A waste that is to be co-disposed of with Classes B and C waste) must be stabilized (structurally) and meet the requirements of 10 CFR 61.56(b). Stability is defined in terms of the ability to keep dimensions and form under disposal conditions. Stability can be provided by the waste form (e.g., activated metals); by processing the waste to an acceptable form (e.g., cement solidification); placing the waste in a HIC; or by the disposal unit itself (e.g., vault disposal). Note that stability does not imply that the waste form will not release radionuclides, nor that its container is water-impermeable for the same length of time that it is stable. Waste form stability is a component of the systems approach, to Part 61, that supports the goal of minimizing water contact with waste. However, the relationship of waste form stability requirements and release rate from the waste form is not necessarily straightforward. Assumptions with respect to the release of radionuclides need to be justified based on properties of the waste form and chemical environment in the disposal unit.

The PAWG is aware of the following four broad categories possible for characterizing the release of radionuclides from the waste form: (a) rinse release; (b) diffusional release; (c) dissolutional release; and (d) sorption coefficient or K_d release. A rinse release or wash-off occurs when infiltrating water removes or washes radionuclides from the surface of the waste form (e.g., appropriate for Class A waste consisting of lab trash, clothing, plastics, etc.). A diffusional release results when the release of radionuclides is limited by diffusion through a porous waste form such as cement (e.g., cement-stabilized waste form). A dissolutional release occurs when the release is controlled by the corrosion rate of a metal waste form (e.g., activated metals). Certain waste types may be characterized by a K_d or sorption release when a radionuclide is bound or sorbed onto a surface such that radionuclide release is characterized by a distribution coefficient or K_d (e.g., ion-exchange resins that are selected for their sorption properties). Additionally, all releases can be moderated to some degree by solubility limits for the particular radionuclide and particular chemical environment of the disposal unit (see Section 3.3.5.6 of this technical report for discussion on solubility limits).

The variation of waste forms and waste types both within and between the waste classes can result in significant variation in overall releases from the facility. Applicants should, therefore, identify the waste generators and waste streams anticipated for disposal, to make appropriate assumptions regarding inventory waste forms and waste types. During facility operation, waste form and waste type assumptions should be updated and the performance assessment calculations redone if significant deviations occur between these assumptions and the characteristics of waste being disposed. At the time of facility closure, the performance assessment calculation will use the actual inventory and disposal methods based on manifest data to update the waste form and waste type assumptions.

3.3.5.3.2 Recommended Approach

LLW inventories will typically involve a large variety of waste forms and waste types, which may complicate the selection of an appropriate approach for estimating waste form release. A simple, conservative approach for the performance of waste forms and waste types should be used initially. A more sophisticated, less conservative, approach could be used for particular waste streams and radionuclides where the simple approach produced unacceptable results. Less conservative analyses generally will involve more support to justify their use for a particular application and therefore should be used on an as-needed basis. Homogenization of the disposal unit, by allowing globally assigned percentage releases by the various mechanisms and radionuclides (e.g., 60 percent rinse release and 40 percent diffusional release for a particular radionuclide), is an example of a simple approach that is acceptable if it is supported by site-specific inventory information. The wash or rinse release model would generally be conservative in all cases; however, the very conservative nature of this approach limits its overall utility. Knowledge about the particular waste forms and waste types being disposed of may be useful for selecting approaches that limit waste form release because of consideration of specific characteristics of the waste form and waste type such as low permeability of a cement-solidified waste, corrosion rate of activated metals, and sorption on an ion-exchange resin.

Generally more is known about the releases of radionuclides for Classes B and C waste forms than for Class A, particularly for solidified waste streams where a diffusional release may be appropriate. For solidified waste forms, release of radionuclides may be diffusion- controlled and can be quantified by the American National Standards Institute/American Nuclear Society (ANSI/ANS) leach test (ANSI/ANS, 1986) that is incorporated in NRC's technical position on waste form (NRC, 1991c). However, the effectiveness of diffusion control of waste form release rates over long time periods (hundreds of years) will be limited by the eventual degradation of a cementitious waste form and subsequent increase in the diffusion coefficient.

Ion-exchange resins and activated metals are examples of waste forms that require a chemical reaction before release of radionuclides from the waste form. Ion-exchange resins were selected by industry because of their sorption properties, and they probably wouldn't freely release all their sorbed nuclei at once (i.e., in a rinse release). However, little is known about the release of nuclei from these materials over long timeframes, in a setting such as an LLW disposal site. Release of radionuclides from the ion-exchange resin is often estimated by considering the distribution coefficient for the individual radionuclide in the ion-exchange resin (Roberson, 2000a). However, to take credit for some kind of partitioning properties for the resins, while seemingly reasonable, would be highly uncertain over extended timeframes without specific experimental and site-specific chemical data. Release of radionuclides from activated metals could be controlled by the corrosion rate of the metal except where the surface has removable contamination.

Solubility limits are an extremely important consideration when selecting specific modeling approaches. Solubility limits, especially in the high-pH environment of a cement-buffered disposal unit, may be very useful in limiting release of radionuclides and thus reducing the need for characterizing waste form release rates. [See Krupka and Serne (1998) for a discussion of the influence of pH and other chemical factors on solubility limits.] However, the complex and transient nature of the waste types and of the disposal unit chemistry exacerbates the difficulties in obtaining reliable solubility limits and requires that uncertainties must be addressed. Selection of the solubility limits, for important radionuclides (i.e., those that contribute significantly to dose), should span a realistic range and distribution of values for the anticipated physicochemical conditions in the disposal units. (See Section 3.3.5.6, below, for a discussion of the recommended approach.)

3.3.5.4 Waste Container

3.3.5.4.1 Issues

Waste containers can improve overall performance by delaying the release of radionuclides, allowing short-lived radionuclides to undergo significant decay, while the container remains leak-proof. Containers for LLW typically consist of carbon-steel drums, low-specific activity (LSA) steel liners, or HICs. Each container will have its own characteristic lifetime, during which it would be considered "leak-proof," which would have to be justified for the particular application. Manifest information can provide data on the distribution of LLW by waste container type(s). In some cases, it may be possible to estimate or infer LLW distribution by container. For example, Class A wastes are generally disposed of in LSA boxes or "55-gallon" drums; Class B wastes are generally disposed of in HICs; and Class C wastes are generally disposed of in liners (e.g., activated metals) or HICs.

The structural stability requirement of 10 CFR 61.56(b) can be provided by processing the waste (e.g., solidified in cement) or placing the waste in a container (e.g., HIC) that provides the stability. Examples of materials used in construction of HICs include: Ferralium-255; stainless steels; metallic fiber-reinforced concrete with polyethylene inner shell; polymer-impregnated concrete; metallic reinforced concrete with a polyethylene inner shell; high-density polyethylene (HDPE); or combinations of these. HDPE HICs, containing Classes B and C wastes, are placed in concrete overpacks for additional stability.

There is considerable uncertainty and argument as to the length of time that these containers will provide isolation from the environment. Initial performance assessment analyses should investigate the impact, on facility performance, of the length of time HICs would provide integrity against water penetration. The uncertainty concerning the "leak-proof" performance lifetime of the HICs would tend to increase as the performance lifetime increases. Assumptions regarding long-term "leak-proof" performance of containers will need to be justified for the chemical characteristics of the disposal unit and the container design. Additionally, the importance of the integrity of a container to keep water out must be viewed relative to the effectiveness of other engineered barriers (e.g., cover and concrete vault) to reduce infiltration into the disposal unit. An assumed long container lifetime for a HIC could have a profound effect on the facility performance when its lifetime significantly exceeds the effective lifetime of other barriers to infiltration, such as the cover. On the other hand, the lifetime of other containers (e.g., 55-gallon steel drums), with relatively shorter lifetime compared with HICs, could have very little effect on performance, because they will have degraded long before engineered barriers are compromised relative to water flow. Disposal of Class A waste containers in concrete overpacks, particularly where grout backfill is used, may have a positive impact on the stability and lifetimes considered for this type of waste container.

3.3.5.4.2 Recommended Approach

Estimations of container lifetimes generally focus on HICs that are made of corrosion-resistant materials or carbon-steel containers (e.g., 55-gallon drums, LSA boxes). For carbon-steel containers, a time-averaged corrosion rate has been proposed as one possible approach for estimating container lifetime (Sullivan, 1993). However, general corrosion failure of carbon-steel containers is anticipated to result in short lifetimes (i.e., mean lifetimes on the order of tens of years), which provides little performance enhancement. Therefore, it is recommended that carbon-steel containers be given no credit for delaying releases because of the anticipated short lifetime relative to either the lifetime of other engineered barriers such as the cover or the institutional control period. Additionally, significant justification might be necessary to support long lifetimes (e.g., lifetimes greater than 50 years) for carbon-steel containers, without commensurate benefit to overall performance. For example, the chemistry of corrosion processes in soil is generally based on a generic database, the use of which could lead to large uncertainties in the predicted corrosion rates (see Sullivan and Suen, 1989). The effects of internal corrosion by the waste streams would also have to be considered when determining container lifetime. The placement of containers in concrete overpacks and the use of grout backfills may be considered in terms of the stability and longevity of the waste packages. The LLW disposal facility developer would need to develop a reasonable range and distribution of container and overpack lifetimes provided there is a sufficient technical basis for the degradation of concrete overpacks and the impact of grout or other backfills on the corrosion properties of the containers.

The length of time a HIC provides isolation of the waste from the environment could be substantially longer than carbon-steel container lifetimes as well as other engineered barriers and thus potentially be an important factor in delaying releases. Justification will be necessary to support the length of time credit is taken for water not contacting waste inside the HIC. After this period of performance, a conservative assumption would be that the container can no longer prevent releases of radionuclides. Generally, a simple model for HICs will treat HICs as a group such that there are no releases before water entering the HICs and after this "failure" time, the HICs do not offer any reduction in radionuclide releases. Thus, the technical basis for defining the waste container "failure" time needs to be provided. For example, an adequate technical basis could include: (a) an NRC-approved topical report[19] or other technical basis document that has undergone an independent peer review subject to the guidance set forth in Altman *et al.* (1988); (b) specific information on the features that inhibit water movement into the HIC; and (c) specific information on the HIC that relates its designed stability properties to its ability to keep water out of the waste. Sophisticated models, which attempt to take credit for the distributed or partial failure of individual containers, may result in lower estimates for release rates, but will require the applicant to provide additional details supporting the technical basis for the assumed credit.

Similar to the approach recommended for partitioning the release mechanisms, it would be acceptable to "homogenize" the waste containers of the disposal unit by assigning a percentage of containers by waste class (e.g., for Class C waste, 60 percent are contained in HICs and 40 percent are contained in liners), if it were supported by site-specific inventory information. The location of LLW within a disposal facility, by waste class, may also be an important consideration in any LLW performance assessment. However, the locations and relative positions of individual containers within each waste class in the disposal facility need not be considered in any performance assessment, unless an applicant believes this level of detail is important.

3.3.5.5 Source-Term Models

Selection of appropriate modeling approaches for estimating radionuclide releases from the disposal unit will need to consider the processes affecting container lifetime, release rates, and solubility limits. Any particular approach should be tailored to the characteristics of the facility and the level of sophistication necessary to demonstrate compliance. For example, one facility may require only solubility limits to demonstrate compliance, whereas another may need to consider a release rate and solubility limits. The appropriateness of any particular approach is not a generic issue and can only be determined based on the characteristics of the facility (i.e., inventory, design, and site). Once a modeling approach is selected, both generic and site-specific information may be useful in assigning parametric values within the model(s) and supporting specific approaches.

Various source-term models have been developed in recent years and are compared and discussed in the following references: Kozak *et al.* (1990a, 1989a, 1989b); Sullivan (1991); and Kozak *et al.* (1993). ***BLT*** (**B**reach, **L**each, and **T**ransport) and **DUST** (**D**isposal **U**nit **S**ource **T**erm) were developed for NRC by the Brookhaven National Laboratory (Sullivan and Suen, 1989; Sullivan, 1993; MacKinnion, 1995; and Sullivan, 1996) to provide comprehensive

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[19] Or, in the case of LLW disposal facilities licensed by Agreement States, following the guidance established by the designated regulatory authority.

analytical capabilities (e.g., individual containers within a disposal unit can be evaluated) and to consider container lifetimes, release rates, and solubility limits. Both ***BLT*** and **DUST** have been applied to evaluating the releases of radionuclides in soils from low-level radioactive waste (McConnell, 1998). *NEFTRAN II* (**NE**twork **F**low and **TRAN**sport – Olague *et al.*, 1991) can be used to implement a simpler approach, which considers the entire disposal unit rather than individual containers, to account for the effects of container lifetime (a single lifetime for all containers in a disposal unit); release rate (a single leach rate for all waste); and solubility limits (solubility limit is element-specific).

Solubility limits for radionuclides are common to all three models mentioned above. The solubility of radionuclides may be applied to two chemical environments for the source term in LLW performance assessments (Krupka and Serne, 1998). In one environment, the composition of the leachate migrating from the disposal vault is assumed to be controlled by the dissolution of the cement hydrate phases (i.e., "cement buffered" case). These conditions would correspond to the initial stages of water infiltration into the LLW disposal facility where the pore water volume may be considered small compared to the available reactive concrete. In the second environment, the leachate composition is assumed to be controlled by reactions with the site soils and therefore equivalent to the local ground-water composition (i.e., "ground-water buffered" case). This case would correspond to an advanced state of degradation of the LLW disposal system when the available reactive concrete is insufficient to affect pore fluid compositions. The ground-water buffered case also corresponds to conditions in the far-field where the ground-water composition would not be affected by cementitious materials of the waste disposal facility. It is extremely important to use solubility limits appropriate to the facility being analyzed. Because of its potential importance to performance, Section 3.3.5.6.1, below, provides a detailed discussion on this subject.

3.3.5.6 Chemical Environment

The chemical environment within the waste disposal facility may have significant, long-term impacts on the releases of radionuclides from the waste and subsequent transport out of the disposal unit. Consideration of this chemical environment is important for two specific areas within the source-term model: (a) if credit is being taken for solubility limits of radionuclide species in the aqueous phase; and (b) if credit is being taken for retardation coefficients specific to the materials within the disposal units. An understanding of the chemical environment within the disposal units is also important if the source term model is based on empirically derived radionuclide release rates or other release mechanisms from laboratory or field studies. Another important consideration is that a disposal system could be engineered to have specific chemical properties that will buffer, over long time periods, the overall chemical state of the system, which would result in facility-specific radionuclide solubilities and retardation coefficients for the performance assessment.

3.3.5.6.1 Considerations and Issues

Application of source-term models, which make use of release rates or solubility limits to improve the radionuclide containment of the facility, can be highly uncertain because of a lack of knowledge of the chemical conditions that might occur inside a disposal unit. Chemical considerations that are important for assessing the releases of radionuclides from the LLW disposal facility include: (a) chemical conditions inside the disposal units that could affect solubilities, diffusion, corrosion rates, and sorption properties of radionuclides (e.g., pH; redox potential; ionic strength; buffer capacity; chemical composition; speciation; complexation; etc.); and (b) potential chemical changes (e.g., oxidizing to reducing conditions) over time, that could affect releases of long-lived radionuclides.

One key issue is to develop an understanding of the chemical environment that may occur in the disposal units so that reasonable and conservative assumptions with respect to radionuclide solubility limits or retardation coefficients for the backfill material may be made. The chemical environment at different points within a disposal unit could be highly uncertain over the performance period, because of the heterogeneous nature of LLW. However, depending on the design of the disposal facility and the methods used to stabilize and dispose of the LLW, a concrete vault disposal system could contain large amounts of calcium hydroxide and calcium silicate mineral phases in various components of the system (e.g., cementaceous waste forms, concrete overpacks, grout backfill, and the structure itself) which could have a strong buffering effect on the overall chemical state of the system. Thus, uncertainty of specific solubility limits and/or retardation coefficients might be reduced in a performance assessment for such a system.

A second key issue is the applicability to vault systems of existing data on solid phase/aqueous phase partition coefficients derived from existing field and laboratory studies. This is important, because most States and compacts are developing concrete vault disposal facilities rather than trench disposal facilities. Geochemical field, laboratory, and modeling studies, that have been carried out for LLW trench disposal sites, show that, in general, the solutions are reduced relative to ambient groundwater, and that significant increases in major ion concentrations, and dissolved organic species occur (Serne *et al.*, 1990; and references therein). A better understanding of the potential chemical conditions that may exist in a concrete vault will help determine if empirically based release models derived from studies of: (a) trench systems; or (b) field lysimeter studies (Rogers and McConnell, 1993; McConnell *et al.*, 1994; McConnell *et al.*, 1996; and McConnell *et al.*, 1998); and/or (c) laboratory leaching experiments using actual LLW (Akers *et al.*, 1994a,b; and Serne *et al.*, 1996) are conservative for a performance assessment of a concrete vault system.

A third key issue is to determine if certain materials, such as a specialized backfill or special concrete formulations, can be used to chemically condition the environment within disposal units. The goal in such an approach would be to chemically engineer the system to have certain specific properties that limit the potential mobility of particular radionuclides, especially radionuclides that may be present in releases as anions (e.g., ^{129}I and ^{99}Tc).

Uncertainties in the mechanisms for release of radionuclides from some LLW could result in unanticipated releases of radionuclides. This would depend upon the specific waste type and waste form involved, and the environment within the disposal facility. These may include: (a) cellulose impacts on release and sorption (Van Loon and Glaus, 1999; and Askarieh *et al.*,2000); and; (b) microbial effects on radionuclide releases (Rogers *et al.*, 1996); and (c) radionuclides in activated metals that are not listed in 10 CFR Part 61.55 and may not be considered in LLW performance assessments (e.g., beryllium-10; ^{36}Cl; molybdenum-93; and silver-108m – see Robertson, 2000b).

Empirical release models based on partition coefficients derived from trench disposal systems are not appropriate for concrete vault systems. The Part 61 DEIS (NRC, 1981) used release factors (i.e., partition coefficients) based on ratios of measured radionuclide leachate concentrations, to estimated radionuclide inventories in disposal trenches at Maxey Flats (Kentucky) – for ^{3}H; cobalt-60 (^{60}Co); strontium-90 (^{90}Sr); cesium-137 (^{137}Cs); $^{238/239}Pu$; and americium-241 (^{241}Am) – and West Valley (New York) – for ^{14}C; and ^{238}U (Oztunali *et al.*, 1981). The use of the Maxey Flats/West Valley partition coefficients implies a certain set of chemical conditions, for the disposal units, that must be justified in terms of conditions that are likely to occur in the system(s) being analyzed. For the Maxey Flats/West Valley trench leachates, near neutral pH and strongly anoxic conditions result in the leachates being supersaturated with respect to certain carbonate and sulfide phases (Dayal *et al*., 1986; and Weiss and Colombo, 1980). Thus, if these systems have achieved a state of equilibrium, then the concentrations of radionuclides in solution represent both mobilization from the waste forms and removal as precipitates in secondary solid phases. A different set of chemical conditions or waste types may result in significantly different equilibrium concentrations of radionuclides in solution than would be predicted from the ratios. For example, the trench leachate concentrations of ^{238}U at West Valley are consistent with U(IV) solubilities in a reducing environment. If it is likely that oxidizing conditions will eventually prevail in a proposed disposal system, then the Maxey Flats/West Valley partition coefficients are not appropriate since as solubilities of U(VI) are several orders of magnitude higher than for U(IV). Similar arguments apply to other radionuclides that are relatively immobile under reducing conditions, but relatively mobile under oxidizing conditions.

Another related problem is that the Maxey Flats/West Valley partition coefficients for certain radionuclides are derived from other radionuclides. Thus, ^{129}I and ^{99}Tc are assumed to be 10 percent of the ^{3}H ratio; nickel and iron are assumed to be the same as Co; niobium is assumed to be 75 percent of Co; and neptunium and curium are assumed to be the same as for Pu. The applicant would have to justify these assumptions and show that they are appropriate and conservative for the potential chemical conditions inside the proposed disposal units.

A more critical problem area for using the Maxey Flats/West Valley partition coefficients is that the true waste inventories in the trenches are considerably uncertain and the waste types disposed of at Maxey Flats/West Valley are not typical of current wastes. If the waste inventories are overestimated then the partition coefficients may be underestimated by large amounts. Therefore, even if the chemical environment issues discussed above can be resolved, the use of the Maxey Flats/West Valley ratios presupposes a knowledge base about the radionuclide inventories that cannot be supported.

3.3.5.6.2 Recommended Approach

Initial analysis should make use of simple, conservative models and assumptions before implementing more sophisticated techniques, which may require additional information to justify a less conservative approach. Conservative solubility limits could be set within reasonable bounds, given some consideration to the waste form and water quality chemical factors such as pH. After initial calculations, it might prove useful to examine in further detail the chemical conditions of the system (e.g., redox state, chemical composition, and ionic strength of water) to better understand the influence on solubility limits, corrosion rates, and release rates. Section 3.3.5.6.3.2 provides information on available models for performing geochemical calculations.

The following technical approaches are acceptable for treating chemical characteristics in LLW performance assessments:

(a) A rinse-release model is used and no credit is taken for engineered controls on chemical characteristics, including backfill, chemical barriers, and geochemistry considerations. This is the most conservative approach.

(b) Credit is taken for the chemical conditions inside the disposal units to justify specific solubility limits, retardation coefficients, and corrosion rates. Sufficient justification must be presented for specific chemical conditions (e.g., redox conditions, pH). The justification may be based on experimental data, and/or the use of field data, where appropriate, in conjunction with geochemical modeling.

(c) If backfill materials or chemical barriers are used to retard the release of radionuclides to the groundwater, sufficient justification must be provided that the sorptive properties of the material would be appropriate for the chemical environment of the disposal facility. The justification may be based on the distribution coefficient approach, experimental studies such as field lysimeter investigations, or laboratory studies, combined with geochemical modeling.

3.3.5.6.3 Development of Site-Specific Parameters and Models

There are several issues and concerns that need to be addressed in developing site-specific values and geochemical models for use in source-term analyses. Similar considerations also apply to developing site-specific K_ds and geochemical models for input to the ground-water transport analysis. Of particular importance for the latter are the conditions and properties and models of the geologic strata most likely to be involved in radionuclide transport to the average member of the critical group.[20]

3.3.5.6.3.1 Radionuclide Distribution Coefficients

In general, performance assessments take credit for retardation in the transport of radionuclides. Development of retardation or K_ds for a specific application, whether inside the disposal units or in the unsaturated and saturated zones, should use an iterative approach. In recent years, literature reviews of K_d information for a large number of radionuclides and conditions have been

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[20] The critical group is defined as the group of individuals reasonably expected to receive the greatest exposure to radioactive releases from the disposal facility over time, given the circumstances under which the analysis would be carried out. See Section 3.3.7.1.

developed (Baes and Sharp, 1983; Berry, 1992a,b,c; Isherwood, 1981; Looney *et al.*, 1987; Sheppard and Thibault, 1990; Turner, 1995; and EPA, 1999). The information from these and other K_d databases and reviews will be useful in developing an initial range of K_ds appropriate for the site and disposal units. A two-volume EPA report (1999) describes the assumptions underlying the use of K_ds in transport codes and the use of the K_d parameter and geochemical aqueous and sorbent properties that are most important in controlling adsorption/retardation behavior of selected radionuclides. In the early stages of the iterative process, these initial ranges may be overly conservative but will be useful for identifying the most important radionuclides. In the latter stages of the iterative process, site-specific data could be developed for key radionuclides and would supplement information in the literature. Methodologies and approaches for measuring and estimating K_ds are discussed in detail in Krupka and Serne (1998) and EPA (1999).

For sites where soil geochemistry will dominate the near-field environment compilations of soil, K_ds will be useful (e.g., Baes and Sharp, 1983; Sheppard and Thibault, 1990; and EPA, 1999). Detailed information on K_ds reported in the Sheppard and Thibault paper are published in an Atomic Energy of Canada Report (see Thibault *et al.*, 1990). For disposal systems where large amounts of cementitious materials will be present, the applicant may need to consider K_d values measured on these types of materials. This will be a more limited dataset than for soils and rocks, but information is available in a variety of publications and abstracts (e.g., Allard, 1985; Berry, 1992a,b,c; and Krupka and Serne, 1998). In addition, NRC staff have recently compiled information on sorption coefficients, in the high-pH environment, that are likely to dominate for long periods of time in a concrete/grout disposal system (Krupka and Serne, 1996 and 1998).

Because the K_ds reported in these databases cover many orders of magnitude, it will be important to evaluate the specific information on the experimental conditions, soil types, and other variables under which the K_ds were measured. This type of information will be important in determining the appropriateness of applying these "generic" K_ds to the specific site conditions and will help in narrowing the ranges of values. A number of parameters reported for the measured K_ds may need to be considered and evaluated to bound the uncertainty in the K_d values. These parameters are likely to be facility-dependent, but may include: time of the experiment; solution pH; redox poise of the solution; nuclide concentration; major ion concentration and ionic strength; reduced iron content; vault-water versus ground-water chemistry; water/soil ratio; backfill and structural material variations; soil mineralogy and composition (e.g., clay content); batch experiments versus column experiments; and filtration method versus centrifugation.

There are chemical and environmental effects that could enhance the transport of radionuclides in soil and ground water. Chelating agents from the decontamination of reactor piping and cores could react with radionuclides to form radionuclide-chelating complexes that may increase the mobility of radionuclides by affecting the radionuclide/soil sorption mechanism (Serne *et al.*, 1996 and 1999). Organic complexation and radiocolloids could play a role in the transport of radionuclides in ground water (Robertson, 2000c; and Brey *et al.*, 1998). The environmental behavior of ^{14}C, near LLW disposal sites, is affected by uptake in vegetation (Link, 1999). In addition, desorption of radionuclides from soils may be possible under the environmental conditions that would affect the transport of radionuclides in ground-water/soil systems (Schell and Sibley, 1982; EPA, 1999; and Kaplan, 1999). Moreover, the upward migration of ^{137}Cs, ^{134}Cs, and ^{90}Sr has been observed in sandy soils with fine roots following releases from radioactive waste (Sanford *et al.*, 1998).

Facility- and site-specific K_ds can be determined for a few radionuclides when necessary to help bound the uncertainty in the literature data with respect to specific site and facility conditions. Experiments would be carried out to measure these specific K_ds in the site characterization phase of the program. Representative vault water (if the anticipated chemical composition differs from that of the groundwater) and representative disposal unit materials (e.g., concrete; backfill; etc.) will need to be used in the experiments. In general, either batch or column experiments would be appropriate [(e.g., ASTM D-4319-83 (American Society of Testing and Materials, 1984)]. However, detailed recommendations or advice on measuring K_ds under appropriate experimental conditions for site-specific applications is not provided in this document.

3.3.5.6.3.2 Geochemical Modeling of an LLW Disposal Facility
It is difficult to predict, *a priori*, what the aqueous chemistry inside a disposal unit will be without some knowledge of the main reactive components of the disposal system. The applicant needs to develop a conceptual model of the chemical conditions inside the disposal unit, if credit is being taken for a release model that is dependent on specific chemical conditions. For example, if the applicant wishes to take credit for specific solubility limits and/or sorption coefficients, then the values selected must be consistent with the conditions that are likely to occur in the disposal units.

As noted above, chemical conditions in concrete vaults may not be similar to trench conditions from which the leachate/solid partition coefficients were developed for the Part 61 *IMPACTS* analysis methodology (Oztunali and Roles, 1986). In general, if the applicant is relying on a source-term model, in the performance assessment, that is based on field and/or laboratory data for radionuclide releases, then there is a need to develop sufficient justification to support the application of such data toward a specific site and facility. If the applicant is relying on a chemically engineered disposal system to retard specific radionuclides, then it must present information and modeling results that support the designed properties of the proposed system.

Geochemical modeling of expected disposal facility chemical conditions, determination of the potential chemical state in the disposal units, and comparison with models of and data from field and laboratory studies, can be done to build confidence in the use of specific release models. Site characterization data [e.g., water chemistry; soil; backfill chemistry; etc. – see Chapter 2.6 ("Geochemical Characteristics") in NUREG-1200] must be obtained for both the natural site and engineered facility. Geochemical calculations (e.g., speciation, solubilities, and sorption) may be carried out using presently available codes such as *MINTEQ* (Felmy *et al.*, 1984); *MINTEQA2* (Allison *et al.*, 1991); *EQ3/6* (Woolery, 1992a,b; Woolery and Daveler, 1992c; and Daveler and Woolery, 1992); *PHREEQE* (Parkhurst *et al.*, 1980); *PHRQPITZ* (Plummer *et al.*, 1988); and *WATEQ4F* (Ball and Nordstrom, 1991). For a review of these codes and confirmatory studies see Bassett and Melchior (1990). The purpose of this type of modeling is to support the use of specific values and ranges of values within the performance assessment source-term model.

3.3.5.7 Gaseous Releases

Some of the radionuclides present in LLW can be released from the LLW disposal facility in the gas phase. Gaseous radionuclides would be available for release immediately and completely after breach of the container, or may be released more slowly if the HIC design incorporates vents. For LLW buried below the ground, advective and diffusive migration to the ground surface and subsequent release to, and transport in the atmosphere, to locations downwind from the disposal facility, may conceivably contribute a non-trivial fraction of the TEDE for the average member of the critical group.

3.3.5.7.1 Considerations

The most important radionuclides that must be considered and evaluated for gaseous release include: ^{14}C; ^{85}Kr; ^{222}Rn; ^{3}H; and ^{129}I. These five radionuclides may be present in LLW facilities in a variety of waste streams and waste forms. Carbon-14 is expected to be present in dry solids, DAW (dry active waste), sorbed aqueous liquids, activated metals, and animal carcasses (Roles, 1990). Tritium is expected to be present in dry solids, DAW, sorbed liquids, oils, and animal carcasses. Both ^{14}C and ^{3}H could be released in the gaseous phase by several mechanisms, including: (a) microbial degradation of specific waste streams; (b) changes in oxidation/reduction conditions within the disposal facility over time; or (c) by leaching and volatilization mechanisms involving varying pH and other water chemistry considerations. Krypton-85 is disposed of as gas in sealed containers that will degrade over time. Radon-222, having a half life of only 3.8 days, is present in the disposal facility as a daughter product of ^{226}Ra ($t_{½}$ = 1600 years). The latter is present both from disposal of waste containing ^{226}Ra, and from the decay of ^{238}U in LLW.

3.3.5.7.2 Recommended Approach

A screening method is recommended to determine if gaseous release of the radionuclides ^{14}C, ^{85}Kr, ^{222}Rn, ^{3}H and ^{129}I in the disposal facility inventory might contribute significantly to the dose to the average member of the critical group. The screening approach would assume: (a) all the containers simultaneously fail, resulting in a puff release; and (b) the entire inventory of ^{14}C, ^{3}H, ^{85}Kr, ^{222}Rn, and ^{129}I in the disposal facility is available for release in the gaseous phase to the surface in a short period of time that conservatively bounds the problem (e.g., 1 year). If ^{14}C and ^{3}H appear to be important contributors to the TEDE to the average member of the critical group, it may be possible to estimate the fractions of ^{14}C and ^{3}H released through the gaseous pathways relative to the total inventories of these radionuclides. The decay of short-lived radionuclide (e.g., ^{85}Kr, ^{3}H) inventory activities to much lower activity levels over the 300-year lifetime of the BGVs and EMCBs is also acceptable for screening. Details on the transport of gaseous radionuclides in the atmosphere can be found in Section 3.3.6.3 ("Air Transport").

Because the screening analysis does not account for partitioning of radionuclides between gas and liquid phases, the entire inventory of radionuclides released to the atmosphere would still have to be considered available for groundwater transport. A realistic and defensible generation rate and partitioning between gaseous and aqueous radionuclide species would have to be justified if the applicant desires to take credit for partitioning as a means of reducing the inventory available for release to either groundwater or air.

If needed, more realistic release rates for ^{14}C, ^{3}H, ^{85}Kr, ^{222}Rn, and ^{129}I might be obtained from a study of mechanistic gas phase releases of radionuclides from individual LLW streams (Yim, 1994). This study simulates the evolution and production of radionuclide gas from LLW and estimates release rates to the atmosphere from LLW. Release rates may also be obtained from actual gaseous release data for the West Valley LLW disposal site (see Matuszek, 1982; Matuszek and Robinson, 1983; and Kunz, 1982, and references therein). However, a number of assumptions must be evaluated to determine the applicability of these release rates to a specific facility. For any particular LLW facility, the chemical conditions that govern the release processes and chemical form of the radionuclides are most likely different from the conditions at the West Valley trenches (Francis *et al.*, 1980; Kunz, 1982; and Dayal *et al.*, 1986). Partitioning of radionuclides between air and water is not explicitly considered; however the release rates based on the West Valley trench data implicitly take this into account. The release rates for West Valley (Kunz, 1982), when properly scaled, may represent a conservative estimate of release for a range of future LLW facilities, based on the significant differences in West Valley waste disposal practices and anticipated facility designs (e.g., concrete vaults) and the forms and types of waste disposed of. Nevertheless, the applicant would have to justify such an assumption. This can be done by examining the waste streams or waste forms to identify the extent of LLW most likely to undergo physical or chemical changes that would result in gas-phase release of radionuclides.

More complicated analyses may include: determining radionuclide gaseous production rates by waste class, waste stream, and waste form from the LLW inventory; more sophisticated consideration of container failure; consideration of different mechanisms influencing gaseous releases (e.g., microbial, aerobic, anaerobic, radiolytic); and partitioning of the radioactive gases between aqueous and gas phase. In a concrete vault disposal system with a large amount of internal concrete (e.g., in overpacks; grout backfill; and so forth), the applicant may need to consider the effects of the high pH and large amounts of calcium (Ca) present to take credit for the precipitation $^{14}CO_2$ as calcium carbonate ($CaCO_3$).

3.3.6 Transport Media

Radionuclides released from an LLW disposal site are transported in the general environment by groundwater, surface water, air, and biota (e.g., rodents; insects; etc.). Transport media may be linked to radionuclide doses directly, such as through the consumption of contaminated well water, or indirectly, through pathways composing the food chain. How radionuclide transport should be analyzed is influenced by the requirement for assessing annual dose to the average member of the critical group. This requirement implies: (a) selecting the maximum concentrations over the entire time and spatial domain of interest in the general environment that might be inhabited by a member of the critical group; and (b) integrating radiation exposures over a period of one year, rather than deriving a dose rate from radionuclide concentrations at specific times.

Approximations of properties and behaviors of complex radionuclide transport systems are depicted in site-specific conceptual models for analyzing radionuclide transport at LLW facilities. The complexity of conceptual models – features and processes modeled and how they are represented – and solution approaches to site-specific modeling, should be based on compliance-demonstration needs. Development of conceptual models is the second step in the recommended LLW performance assessment process described in Section 3.1 of this technical report. Recommendations and advice presented in Section 3.1, and in Sections 3.3.2.1.1 and 3.3.2.1.2 (on treating model and parameter uncertainty) should be considered when analyzing media transport.

3.3.6.1 Groundwater

The objective of the ground-water flow and transport analysis is to assess radionuclide concentrations in the groundwater at receptor points (i.e., human-access locations) consistent with the exposure pathway assumptions for assessing the TEDE to the average member of the critical group.

3.3.6.1.1 Considerations

Available hydrogeologic and geochemical site characterization data must be evaluated and abstracted to form a simplified representation of the groundwater flow and transport system. This abstraction should consider all relevant conditions, processes, and events present at the site as well as any cause-effect relationships. Geometry of a modeled system will be defined by site geologic and hydrogeologic characteristics such as stratigraphy, faults, ground-water flow boundaries, and zones of groundwater recharge and discharge. Processes modeled will be selected from among the physical and chemical phenomena affecting ground-water flow and transport. Physical processes represented in a conceptual model may include advection, dispersion, and diffusion. Although advection will probably be the predominant means of transport – dispersion is probably not very important at disposal site scale – the analyst may decide to account for dispersion in the analysis. Geochemical processes include sorption, precipitation, complexation, and redox reactions. However, the influence of some of the geochemical processes on transport may be extremely difficult to evaluate.

In simplifying the analysis, the analyst will have to determine how best to represent the spatial variation of hydrologic parameters used to characterize features and processes included within the analysis and some consideration must be given to the appropriate analytical approach and dimensional representation to include. Detailed ground-water flow and transport modeling may be performed as needed to provide the analyst with sufficient insight to support simplification of the conceptual flow system while retaining features important to overall performance. These modeling activities commonly are called auxiliary analyses because they support, but are not part of, the final systems model.

In assessing the dose to the average member of the critical group, the analyst will have to consider radionuclide concentrations in groundwater at all potential points downgradient from the disposal unit where a human could come into contact with the contaminated water. This means that both existing (i.e., current) and hypothetical ground-water discharge points will have to be considered. Such discharge points could include streams, pumping wells, springs, and seeps. An analysis based solely on existing discharge points will likely be non-conservative because, over the long timeframes covered by the analysis, additional human-access locations may develop closer to the disposal unit. Therefore, the analysis will likely involve a hypothetical well, and the analyst will have to make some assumptions in terms of where to assume that the well is located. In addition, the analyst will have to make certain assumptions regarding pumping well design and construction. Design features, such as well depth and screen length, are important in terms of determining how much water is available for dilution and how much of the plume will be captured by the well.

3.3.6.1.2 Recommended Approach

For this analysis, the PAWG recommends using the approaches to developing conceptual models discussed in Section 3.1, and approaches treating model and parameter uncertainty discussed in Sections 3.3.2.1.1 and 3.3.2.1.2. Auxiliary analyses may be useful in identifying important processes to be considered in the conceptual model as well as in filling-in data gaps. Although regulatory compliance is based on the annual dose to the average member of the critical group, the PAWG recommends that the ground-water transport analysis provide concentrations in well water at the site boundary that would have the composite concentrations of radionuclides resulting in the highest dose. For conservatism, the analyst should consider all points on the disposal site boundary as potential pumping well locations. The analyst can assume that the design of the pumping well is consistent with the design of other wells common to the region in which the site is located. Because the well is treated as a pumping well,[21] the analyst should initially assume that the well will yield sufficient water of adequate quality to provide the annual water requirements assumed as part of the overall dose analysis. For example, if the well is assumed to supply water for irrigation and drinking, the amount and quality of water assumed to be pumped should meet the need of these two requirements. If analyses of the hydrogeologic system suggest that a well would not satisfy the water requirements of the hypothetical user, the scenario controlling the annual water requirements may need to be adjusted by considering the availability of water from other sources.

As a generally applicable approach for simulating radionuclide transport in groundwater, the PAWG recommends streamtube analyses. This approach envisions a family of steady-state streamtubes connecting discrete radionuclide sources (i.e., disposal units) to the water table, the pumping well, and possibly any other location where groundwater discharges to surface water. As an example, Figure 11 depicts a hypothetical disposal system and hydrogeologic environment, including two aquifers and a pumping well. For this hypothetical example, the streamtubes associated with each discrete source (a disposal vault) consist of a vertical segment from the disposal vault to the water table, continuing through Aquifer 1 to Aquifer 2. For sites with relatively thin unsaturated zones, travel time from the disposal vault to the water table will not afford a significant amount of radioactive decay. Therefore, the analyst may ignore the travel

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[21] As opposed to a monitoring well – with a capture zone that can be assumed to be at steady-state conditions.

time through the unsaturated zone. The streamtubes should more or less correspond with the direction of regional ground-water flow. To justify the location and properties of streamtubes, auxiliary analyses of the ground-water flow system may be needed. In this example, the vertical extent of one streamtube and a portion of another are intercepted by the pumping well. Within streamtubes, solute transport is modeled as advection with the moving water, and dispersion in the direction of flow. Typically, the analysis should account for radioactive decay and daughter in-growth.

Figure 11. Conceptualization showing potential streamtube pathways to pumping well in ground-water flow and transport analysis.

The radionuclide flux from each source is diluted by the flux of clean groundwater within each streamtube. Transport through streamtubes ignores reduction in the concentration of radionuclides from dispersion normal to the flow direction (transverse dispersion). The significance of transverse dispersion is limited by the short distance between the radionuclide source and the pumping well, and because the analysis evaluates the concentration of radionuclides in water discharged by a pumping well rather than at points within the aquifer. Groundwater captured by the pumping well may consist of both a portion of a plume or plumes contaminated with radionuclides and uncontaminated water. The concentration of radionuclides in water discharged by the pumping well may therefore be diluted with uncontaminated water. Auxiliary analyses should be conducted to estimate the contribution of radionuclides derived from the total volume of water withdrawn by the pumping well. In other words, the pumping well averages the concentration, based on the relative proportions of contaminated and uncontaminated water pumped. Thus, proper treatment of how the pumping well influences ground-water flow captures contaminant plumes is essential to approximating radionuclide concentrations in water pumped from the well.

For modeling site-specific conditions, in which the hydrologic and transport parameter variability is known, stochastic approaches , such as the ones described in Gelhar *et al.*(1994) and Talbot and Gelhar (1994), may be useful. For modeling infiltration through the unsaturated zone, and subsequent transport, the approaches in Meyer (1993) and Rockhold (1993) may also be useful. In general, the level of complexity in estimating ground-water flow will determine which of the recommended approaches is appropriate for assessing transport to the receptor. For example, if vapor-phase transport of radionuclides, such as ^{14}C and ^{3}H is of a concern, then the approach recommended in Binning *et al.* (1995) may be useful.

Analysts, most likely, will wish to account for radionuclide retardation in the ground-water system. Soil and rock characteristics such as pH, organic content, texture, and mineralogy control radionuclide retardation in groundwater. K_ds, which express the partitioning of an ion species between the solution and the solid adsorbing phase, are commonly used to describe radionuclide migration rates in transport analyses. Because of the general significance of retardation to the results of radionuclide transport analyses, use of site-specific K_d values for important radionuclides is recommended. However, retardation will, in most cases, have a minimal effect in reducing doses from long-lived radionuclides, because of their half-life and the short distance traveled. For the most part, radioactive decay of the short-lived radionuclides can be achieved before they leave the disposal unit. Thus, their decay through the ground-water pathway should have a minimal effect in reducing doses. Therefore, to account for specific geochemical processes that lower radionuclide concentrations in groundwater, especially those that permanently remove radionuclides from groundwater (i.e., irreversible sorption and chemical precipitation), supporting auxiliary analyses in geochemistry will likely be needed. Therefore, it is recommended that analysts not consider such processes when performing ground-water transport analyses unless their inclusion would be highly beneficial to making a successful demonstration of compliance with the dose requirement. Sections 3.3.5.6.3.1 and 3.3.5.6.3.2 provide additional recommendations on the use of K_ds and geochemical modeling in performance assessment.

3.3.6.2 Surface Water

The objective of the surface-water transport analysis is to assess radionuclide concentrations in surface water at human-access locations consistent with exposure pathway assumptions for assessing the TEDE to the average member of the critical group. Furthermore, the surface-water analysis needs to be consistent with the water use and pathway exposure assumptions considered in assessing the TEDE from groundwater. For example, if groundwater is shown to be the principal domestic water-use pathway for the disposal site, then the amount of surface water used for domestic purposes should account for the amount of groundwater already incorporated into the analysis. As in assessing dose for the ground-water pathway, the average member of the critical group resides at or near the disposal site boundary.

For purposes of this document: (a) a facility that is constructed above natural grade and mounded with earth (an EMCB) is considered to perform as a BGV; and (b) the design of covers for below-ground disposal facilities will preclude exposure of waste at the surface by erosion where it would be subject to overland transport.

3.3.6.2.1 Considerations

Surface-water bodies can become contaminated with radioactivity by overland flow across a disposal site after exposure of the waste by erosion, or by the discharge of seeps and springs contaminated with leachate percolating from an LLW disposal facility (see Figure 12). For radionuclide transfer overland, contaminated runoff entering a stream may undergo immediate dilution; however, radionuclides deposited on the ground may become incorporated into plant or animal tissue, or be subject to further overland transport through successive episodes of erosion and deposition. The transfer of radionuclides via overland flow is generally not considered to be significant to the performance of below-ground disposal facilities (i.e., BGVs) constructed according to Part 61 requirements.

In surface water, radionuclides can occur in either the water column itself or in association with sediment. Partitioning among forms that remain in solution, suspension, or settle to the bottom is controlled by the surface-water body's geochemical environment. Radionuclide concentrations in water normally will be reduced by continued dilution with non-contaminated water or by adsorption onto bottom sediment.

When a stream is joined by a tributary, complete mixing usually is not instantaneous. Often, the water from the influent stream flows unmixed for a distance alongside water in the major stream until dispersion, diffusion, and turbulence cause the waters to mix. When the influent stream is contaminated with radioactivity, the specific activity level is not fully diluted until mixing is complete. Therefore, in assessing doses from drinking water withdrawn from a stream, it may not be conservative to assume that complete mixing has occurred. Instantaneous complete mixing is also unlikely when stream flow enters a retardant body of

Figure 12. Conceptualization showing potential surface water contamination pathways. (All radionuclides distributed in the aquifer, in the vicinity of the surface-water body, are discharged into it.)

water such as a lake, reservoir, wetland, or tidal body. Turbulence can contribute to mixing, but thermal or density stratification may instead serve to impede such mixing if the influent stream flows as a tongue along the bottom or at some elevation in the water column. Slow flushing in a wetland or a tidal water body may also serve to concentrate radionuclides; moreover, precipitation of radionuclides may occur if entry into a brackish or saline environment affects solubility. In any of these water bodies, there is likelihood that aquatic plants and animals will concentrate whatever radionuclides are made available to them.

The point of exposure for the surface water pathway will normally be at the nearest downstream location from the site where surface water contact or withdrawal is feasible. Potential dose pathways for surface water analysis may include domestic use and irrigation; livestock ranching, with or without bioaccumulation; water-contact activities such as recreation, when there may be direct gamma radiation from exposure to contaminated sediments; and consumption of fish taken from contaminated surface water bodies (see Section 3.3.7.2.1). It is unlikely that any surface water pathway analysis would need to include all these water uses. For example, gamma-emitting radionuclides in bottom sediments are generally incapable of producing significant external doses, except possibly in low-velocity areas where sediments may accumulate. In addition, the DCFs for eating fish implicitly account for bioaccumulation in bottom-feeding aquatic organisms. Therefore, a simple screening-level analysis may permit the exclusion of radionuclides in bottom sediments from further analyses.

The nature and extent of surface water transport analyses will depend on whether the facility is constructed above or below the ground surface. For below-ground disposal facilities (i.e., BGVs and EMCBs), eventual disposal unit degradation will result in radionuclide releases to groundwater, but would not necessarily result in direct exposure of waste at the surface. Because radionuclide concentrations in contaminated groundwater would be diluted by surface water, surface-water transport is not considered to be significant at below-ground disposal facilities (BGVs). Above-ground disposal facilities (i.e., AGVs), however, rely entirely on engineered barriers to isolate waste from the surface environment. Eventual disposal unit degradation and erosion will expose the waste and subject it to redistribution by surface processes. Therefore, surface-release pathways, including surface water, are more significant to the performance of above-ground disposal facilities and are potentially more difficult to analyze as well. In assessing the performance of a degraded AGV, it may be necessary to estimate the proportion of radionuclides released that directly enter surface water from overland flow and transport and the proportion that enters surface water via groundwater through seeps or springs. Depending on the particular times of travel and dilution en route, the two transfer mechanisms to surface water may each have significance for human exposure, over entirely different timeframes.

3.3.6.2.2 Recommended Approach

As noted above, the significance of the surface-water pathway will depend on the extent that erosion and overland transport of waste are relevant to the particular site under consideration. Although actual site conditions and disposal cell design should be evaluated (e.g., erosion resistance of EMCB design), generally, site selection and cover design for below-ground disposal will minimize the likelihood of erosion and overland transport of radionuclides being a problem.

Since there currently are no plans for an above-ground disposal facility in the United States, the PAWG's recommended approach is to evaluate radionuclide concentrations in surface water resulting from the discharge of contaminated groundwater.

3.3.6.2.2.1 Below-Ground Disposal Facilities

As the most important transfer mechanism of radionuclides from a BGV to surface water, the interaction between groundwater and nearby surface water bodies should be assessed. The surface water model can be based on a conservative assumption that all radionuclides distributed in the aquifer in the vicinity of the nearby surface water body are discharged into it. The discharge should be assumed to occur as a point (seep or spring) at the shore; assuming a diffuse laterally distributed ground-water plume entering the surface water would be less conservative.

The PAWG recommends that an initial approach to calculating surface-water concentrations involves diluting the ground-water concentration at the point of release (i.e., spring) by the ratio of the surface-water discharge to the volumetric ground-water flux associated with the contaminant plume (i.e., the volumetric flux that infiltrates the disposal site). For example, if the volumetric infiltration at the site is greater than the surface-water discharge (i.e., stream flow) then there is no dilution of the concentration in the surface water. However, if the volumetric infiltration at the site is half the surface-water discharge, then the concentration in the surface water is reduced by a factor of 2. To calculate the radionuclide concentration and ground-water discharge rate at the spring, a 1-D streamtube analysis, as described in Section 3.3.6.1.2 (calculating ground-water concentrations at the site boundary), is recommended. It should be noted that the determined coincident stream flow and volumetric ground-water flux of the plume should be based on a common meteorological database and analysis.

If radionuclide transport away from the initial point of surface-water contamination is an important site-specific consideration in the performance assessment, the PAWG recommends that the next step should be use of a site-specific surface-water transport model. For example, where appropriate, the *GENII* model can be used for a river or lake (Napier *et al*., 1988). The surface-water model within *GENII* assumes that the flow depth, convective velocity, river width, and lateral dispersion coefficient are constant; the river channel is straight and the point discharge of contaminants is continuous (Kozak *et al*., 1990a). Other examples of analytical models used to calculate surface-water concentrations in streams subject to mixing and dispersion are provided in Regulatory Guide 1.113 (NRC, 1977c) and these models are contained in the *GENII* computer code. However, these example models are for short-term transient releases and may need to be modified to consider chronic long-term contaminant releases.

The important water pathways in LLW performance assessment usually are evaluated for only dissolved radionuclides; consequently, radionuclide interactions with sediments frequently are neglected. The usual effect of neglecting sediment sorption is to produce conservative estimates of exposure via the food chain (National Council on Radiation Protection and Measurement, 1984). A simple approach to sorption of radionuclides onto sediments is included in *GENII* and can be used if needed.

3.3.6.2.2.2 Above-Ground Disposal Facilities

In conducting an LLW performance assessment for an AGV, an applicant will be expected to address the technical concerns about above-ground disposal raised above, to the extent that those surface-water issues apply.

3.3.6.3 Air Transport

The objective of the air transport analysis is to assess the contribution of radionuclides released to the atmosphere to the TEDE to the average member of the critical group. The following section discusses analysis of gaseous releases from the disposal facility. In some cases, an applicant may need to evaluate particulate releases caused by wind erosion, if there is a credible way the waste could be exposed; the following are recommendations are still valid for these cases.

Several radionuclides present in LLW could be released from the LLW disposal facility in the gas phase and transported in the atmosphere by dilution and advective dispersion mechanisms to locations downwind from the disposal facility where they would be inhaled and conceivably contribute a non-trivial fraction of the dose to the average member of the critical group. In addition, radionuclides released to the atmosphere could contribute to the ingestion dose to the average member of the critical group through the ingestion of radionuclides that become incorporated in plants and animals and through radionuclides that accumulate in the soil by either dry or wet deposition and are subsequently taken up by plants and animals to become part of the food-chain pathway. For vapor-phase transport through the ground-water pathway, the reader should refer to Section 3.3.6.1.2 (Recommended Approach"), which outlines acceptable approaches for determining vapor-phase transport [see Binning *et al.*(1995)].

3.3.6.3.1 Considerations

Generally, the important radionuclides that must be considered as gaseous source terms and evaluated in air transport modeling for LLW performance assessments are ^{14}C, ^{129}I, ^{85}Kr, ^{222}Rn, and ^{3}H. Further details on source-term releases of gaseous radionuclides can be found in Section 3.3.5.7 ("Gaseous Releases").

Important atmospheric transport considerations for determining the impacts of gaseous radionuclides downwind from their release include: (a) atmospheric plume model parameters such as gaseous-release source height (ground level or elevated) from the surface; wind speed, wind direction; atmospheric stability class; and annual rainfall rate; (b) radionuclide removal mechanisms such as rainfall, dry deposition, and radioactive decay that reduce the activity levels in the atmosphere; and (c) general topography of the land near the disposal facility.

As the radionuclides travel from their release point, several processes could reduce their concentrations below those predicted by atmospheric transport and diffusion alone. These removal mechanisms include radioactive decay, dry particulate deposition, and rainfall scavenging removal. At most LLW disposal facilities, rainfall is expected to occur during a small percentage of the hours in a year, so that the dose calculation to the individual who could be affected by wet deposition may not be significantly changed by consideration of wet deposition. At best, it is estimated that as little as two percent of the radionuclides released to the atmosphere would be deposited on the surrounding soil from rainfall at an LLW disposal facility.

Radionuclide transport in the atmosphere is generally modeled using Gaussian plume transport equations (Slade, 1968; and Randerson, 1984) and Pasquill-Gifford atmospheric stability parameterization (Pasquill, 1974; and Culkowski and Patterson, 1976) to determine the dispersion and diffusion factors for estimating the concentrations of radionuclides at distances downwind from the disposal facility. Regulatory Guides 1.111 (NRC, 1977b) and 1.145 (NRC, 1983) as well as NUREG/CR-3332 (Brenk *et al.*, 1983) recommend approaches for estimating radionuclide concentrations in the atmosphere using dispersion and diffusion factors.

Determining atmospheric transport, dispersion, and inhalation and ingestion doses to the average member of the critical group, from gaseous radionuclides, can be performed by hand calculations or with an assortment of computer codes that can either compute dose in single directions from point source releases, or, for more sophisticated computer models, obtain doses from area releases and from multi-directions from the disposal facility. A summary of atmospheric transport and diffusion models, for monitoring or predicting the transport of gaseous materials that have been developed by Federal agencies, has been prepared by the National Oceanic and Atmospheric Administration (NOAA) (Department of Commerce/NOAA, 1993). Oak Ridge National Laboratory has evaluated the performance of several computer codes to determine atmospheric transport and human exposure from an atmospheric release of radionuclides (Fields and Melescue, 1994). Models for calculating ingestion doses from radionuclides released to the atmosphere may be found in Regulatory Guide 1.109 (NRC, 1977a)

3.3.6.3.2 Recommended Approach

A simple bounding screening approach that uses conservative radionuclide releases, local meteorological conditions, conventional atmospheric transport models, and standard dose calculations is recommended to determine if releases of the gaseous radionuclides to the atmosphere would significantly contribute to the committed effective dose equivalent (CEDE) or TEDE. If the results of the screening analysis turn out to be significant, more detailed analysis would be required to demonstrate that the radionuclide releases to the atmosphere would not be of regulatory concern.

3.3.6.3.2.1 Screening Approach

The recommended approach for screening would include: (a) release of the entire inventory of ^{14}C, ^{129}I, ^{85}Kr, ^{222}Rn, and ^{3}H in the disposal facility to the surface over a one-year period; (b) atmospheric plume dispersion to estimate radionuclide concentrations downwind; and (c) inhalation and ingestion pathways to calculate dose. If other radionuclides are considered by the applicant in the air pathway analysis, sufficient justification should be provided.

The decay of short-lived radionuclide (e.g., ^{85}Kr, ^{3}H) inventory activities to much lower activity levels over the lifetime of the BGVs and EMCBs is also acceptable for screening. Radon-222 activity levels can be obtained from the ^{238}U decay series at the year the performance assessment is maximized (e.g., 10,000 years). The chemical form of the radionuclide should be the most conservative, volatile species. Consideration of the food-chain pathway would be necessary where radionuclides could be taken up by plants grown and animals grazed near the disposal facility. The dose to the average member of the critical group may be estimated, using a total gaseous radionuclide release over 1 year and conservative meteorological conditions for wind speed, atmospheric stability class, and atmospheric diffusion. The applicant will need to provide justification for the conservatism of meteorological assumptions and parameters used. Because the screening analysis does not account for partitioning of radionuclides between gas and liquid phases, the entire inventory of radionuclides released to the atmosphere would still have to be considered available for ground-water transport.

For screening purposes, the gaseous radionuclides can be released as either a point source or an area source. Because an LLW disposal facility would typically occupy a large area, a more realistic determination of dose to the average member of the critical group from radionuclides released to the atmosphere may be obtained by using an area or virtual point source-release model instead of point source-release models. Wind directions can be either single-directional downwind from the center of the disposal facility, or multi-directional radiating outward from the center of the disposal facility. Ground-level release of the radionuclides should be assumed and Gaussian plume models with Pasquill-Gifford dispersion parameters can be used to provide the ground-level atmospheric diffusion factor X/Q for radionuclide concentrations. Doses can be calculated for the inhalation and ingestion pathways, except for ^{85}Kr, where external exposure is the dominant pathway.

An atmospheric stability Class B or C and wind velocity of three meters/second can be used for the initial screening calculations. These atmospheric stability classes and surface wind speed meteorological data reflect conventional practice for assessing impacts from radionuclides released to the atmosphere in the absence of site-specific data. Except in those cases in which applicants or licensees provide acceptable alternative conditions based on regional or site-specific meteorological data, PAWG believes they will be used by the staff in evaluating submittals for an operating license.

Air pathway CEDE or TEDE may be calculated from standard methods involving atmospheric diffusion, breathing rates, and DCFs. Single-directional ground-level releases from a point source along the plume centerline or across a 22.5°-wind-sector average are acceptable for determining doses at downwind distances from the disposal facility. For single-direction air pathway calculations, the atmospheric diffusion factor, X/Q (seconds/cubic meter), for ground-level releases, may be calculated from standard equations involving wind speed, atmospheric stability conditions, lateral plume speed, and vertical plume speed (NRC, 1977a; NRC, 1982; Brenk *et al.*, 1983; and Turner, 1970), or from atmospheric transport computer codes such as *DWNWKE-PC* (Fields and Howe, 1993). A chronic breathing rate, inhalation DCFs for ^{14}C, ^{129}I, ^{3}H, and ^{222}Rn, and an external DCF for ^{85}Kr can be used to estimate the dose commitment to the average member of the critical group downwind from the disposal facility. Computer models, such as *PRESTO-II* (Fields *et al.*, 1986) or *PRESTO-EPA-POP* (Fields *et al.*, 1987), that contain Gaussian plume dispersion and dose determination subroutines may be used to calculate dose directly to the average member of the critical group. Uniform-area source releases to the atmosphere can be modeled with *CAP88-PC* (Chaki and Parks, 2000), a computer code that uses a Gaussian plume model to estimate inhalation and ingestion doses and risks from radionuclide emissions to the atmosphere.

The applicant should use local or site-specific data, such as wind rose, and local geography, for the initial screening. Assumptions concerning exposure time and inhalation rate should be based on Appendix B to Part 20[22] for the initial screening analysis. DCF selection should be based on the recommendations made in Section 3.3.7 ("Dose") of this technical report. For ^{222}Rn, a conservative estimate of 100 percent equilibrium with daughter products is appropriate for the initial screening. The applicant may propose alternate equilibrium levels with proper justification.

3.3.6.3.2.2 Detailed Approaches

If the overall performance assessment indicates that the dose to the average member of the critical group exceeds the dose standard, and results of the air pathway screening analysis turn out to be significant, the analyst may need to consider a more detailed air pathway analysis to demonstrate compliance. The analyst may wish to consider longer periods for gaseous radionuclide inventory to be released (e.g., entire inventory released over 100 years); other smaller annual gaseous release rates; or more complicated analyses involving the waste streams and waste forms in the disposal facility. For example, the fraction of the total inventory of each gas-phase radionuclide released to the atmosphere could be estimated by examining each waste stream or waste form and determining the most likely ones that would release radionuclides in the gas phase. Detailed studies involving the LLW inventory disposal practices and facility designs, or references to published literature may provide adequate justification for alternative gaseous release rates or partitioning. Such studies or references to published data and information should examine: (a) LLW streams and forms most likely to undergo physical or chemical changes that would release gaseous radionuclides at some smaller fraction or rate; and (b) consideration of the transport of gases through the soils overlying the LLW disposal facility. Recent studies (Yim *et al.*, 1993a; Yim, 1994; and Yim *et al.*, 1996b) of the releases of gaseous radionuclides to the atmosphere from LLW disposal facilities provide methods for determining

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[22] "Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage."

mechanisms of the formation of gas-phase radionuclides from LLW radionuclide inventories, estimating radionuclide gaseous generation and production rates in LLW disposal facilities, modeling gas-phase radionuclides release from LLW disposal facilities, and calculating dose. More realistic gas-generation rates and partitioning between gaseous and aqueous radionuclide species may be considered as a means of avoiding having to double-count the inventory of radionuclides transported in both groundwater and air. Additional information on that analysis of gaseous releases may be found in Section 3.3.5 ("Source Term").

More complex analysis involving the transport of gaseous radionuclides through soils overlying the LLW disposal facility may also be needed to demonstrate compliance. Movement of gaseous contaminants through air-filled pores in unsaturated materials overlying LLW disposal cells would depend on the pneumatic properties of the overlying materials. Coincident infiltration and air movement, as a function of transient soil moisture contents and pressure gradients, need to be determined for gas ventilation models. However, ventilation models are complex, and the effects of infiltration and transient soil moisture contents on ventilation create large uncertainties (Binning *et al.*, 1995). Ideally, simultaneous vapor and solute transport modeling could be conducted using numerical simulators such as those described by Binning *et al.* (1995) and Celia and Binning (1992). Establishing boundary conditions for air-phase transport is important because they control the direction of air flow and velocity field variations (Celia and Binning, 1992).

Detailed atmospheric transport modeling may also include reliance on better defining site-specific meteorological conditions and a more thorough assessment of dose from the food chain. For example, radionuclides removed from the plume by precipitation scavenging and dry particulate deposition may be directly taken up into the food chain. Further advice on a recommended pathway analysis can be found in Section 3.3.7 ("Dose"). Also, additional information on modeling deposition can be found in Till and Meyer (1983).

3.3.7 Dose

The objective of dose modeling in an LLW performance assessment is to provide estimates of potential doses to humans, in terms of the average member of the critical group, from radioactive releases from an LLW disposal facility, after closure. In this role, dose modeling integrates the information from the various modeling areas.

3.3.7.1 Considerations

Dose modeling for performance assessment includes the transfer of radionuclides through the human food chain and human dosimetry. The goal of this technical report is to aid in understanding important issues related to human impacts from potential releases of radionuclides from an LLW disposal facility. In addition, this technical report will provide some discussion of the calculations necessary to assess these potential doses.

The information and recommendations in this technical report supplements the pathway and dosimetry guidance provided in Section 6.1.6 ("Safety Assessment: Assessment of Impacts and

Regulatory Compliance") of NUREG-1200 (NRC, 1994). That guidance, along with other generally applicable pathway identification and dose calculation recommendations (referenced below), provides the foundation for the PAWG's views described below.

There are two specific areas to consider in the assessment of doses to humans. First, the mechanisms of radionuclide transfer through the biosphere, to humans, needs to be identified and modeled. This is termed the *pathway analysis*. Second, the dosimetry of the exposed individual must be modeled (e.g., a *dose assessment*). Dose models and analytical solutions for both types of calculations are discussed below. However, this technical report does not endorse any specific computer code nor computational solution to be used in an LLW performance assessment. The applicant is responsible for providing sufficient support and documentation for any codes and/or mathematical solutions used in its compliance demonstrations. The applicant should, therefore, be familiar with the models and methodologies and provide sufficient information to allow an independent determination as to the adequacy of any codes and models used.

Pathway and dose assessment, in the context of an LLW performance assessment, is a process that consists of more than just calculating potential dose values from environmental concentrations. These processes integrate information from other sub-modeling areas and feed information back to this and other sub-modeling areas. This process is consistent with the iterative nature of performance assessment. In addition, the simplified models and analysis suggested in this section of this technical report support an iterative modeling approach.

Pathway analysis consists of pathway identification and pathway modeling, both of which are discussed further in this section. Pathway identification, at an early stage of the performance assessment process, is very important. As per Section 61.13(a) of the regulation, pathways that must be considered include air, soil, groundwater, surface water, plant uptake, and exhumation by burrowing animals. Results of the pathway analysis should show the contribution from each major pathway to the total dose estimate.

Pathway analysis should result in the determination of the total intake of radionuclides by the average member of the critical group. The critical group is defined as the *group of individuals reasonably expected to receive the greatest dose from radioactive releases from the disposal facility over time, given the circumstances under which the analysis would be carried out.* For example, in a rural environment, a family farm adjacent to an LLW disposal facility may be the targeted critical group. The average member of the critical group is that individual who is assumed to represent the most likely exposure situation, based on cautious but reasonable exposure assumptions and parameter values. It is generally not practicable, when analyzing future potential doses, to calculate individual doses for each member of a critical group and then re-calculate the average dose to these same members. In general, it is more meaningful to designate a single hypothetical individual, representative of that critical group, who has habits and characteristics equal to the mean value of the various parameter ranges that define the critical group. In this fashion, the dose to the "average member" of the critical group approximates the average dose obtained if each member of the critical group were separately modeled and the results averaged.

In contrast to the situation during operations, where public doses normally result from activities that are carefully prescribed and controlled, and it is possible to update, or keep track of, who might likely receive the highest exposure, the public doses, from releases in the future from the disposal facility, may result from a variety of activities for which the maximally exposed individual is much more difficult to precisely define. Therefore, the PAWG believes it is more prudent to use the average member of the critical group for assessing TEDE from releases post-closure because this provides a reasonably conservative estimate of public risk without attempting to speculate on which specific individual may be expected to receive the highest dose.

The practice of defining and using the critical group concept when assessing individual public dose from low levels of radioactivity is proposed in Section 3.3.6.1 of the 1990 recommendations of the International Commission on Radiation Protection – ICRP (ICRP, 1990), and has been tentatively adopted by both the EPA (1994) and the NRC (1994).

Pathway analysis results in a calculation of the total exposure of the individual to radionuclides. The *dose assessment* converts both the internal exposure, through ingestion and inhalation, and the external exposure to a single TEDE for the individual's annual exposure. For radionuclides that are ingested or inhaled, calculations of the dose to organ, systems, and tissues of the body, and an effective dose equivalent are accomplished through the use of biokinetic models of the transfer of elements in the body and radionuclide-specific information. For external exposures, calculations of the effective dose equivalent from the time-weighted external exposure to contaminated materials include geometry assumptions, and radionuclide-specific information (such as radiation type, half-life, and energy of particle or gamma ray).

3.3.7.1.1 Pathway Identification and Modeling

Various considerations should be taken into account when analyzing the transport of radionuclides through the biosphere (to humans). These considerations should include:

(a) Modeling the movement of radionuclides through the food chain, adequately reflecting complex symbiotic systems and relationships;

(b) Considering how isotopes are uptaken; and

(c) Identifying usage, production, and consumption parameters, for various food products and related systems, that may vary widely, depending on regional climate conditions, local or ethnic diet, and habits.

In addition to the above concerns, one must be concerned with both the complexity and conservatism of a model. Also, unique issues may emerge, based on site-specific conditions, that the applicant needs to consider in the analysis. Section 3.3.7.1.1 provides information and advice on a recommended general approach to pathway modeling.

3.3.7.1.2 Internal Dosimetry

The NRC performance objective set forth in Section 61.41, is based on the ICRP 2 dose methodology (ICRP, 1959), but current health physics practices follow the dose methodology used in Part 20, which is currently based on ICRP 30 methodology (ICRP, 1979). The license application will contain many other assessments of potential exposures (e.g., worker exposure, accident exposures, and operational releases) that will need to use ICRP 30 dose methodology. For internal consistency in the application, it is recommended that the performance assessment be consistent with the methodology approved by the NRC in Part 20 for comparison with the performance objective. Therefore, PAWG believes that calculation of a TEDE for the LLW performance assessment – a summation of the annual external dose and the CEDE – is acceptable for comparison with the performance objective.

As a matter of policy, the Commission considers 0.25 mSv/year (25 mrem/year) TEDE as the appropriate dose limit to compare with the range of potential doses represented by the older limits that had whole-body dose limits of 0.25 mSv/year (25 mrem/year) (NRC, 1999, 64 *FR* 8644; see Footnote 1). Applicants do not need to consider organ doses individually because the low value of the TEDE should ensure that no organ dose will exceed 0.50 mSv/year (50 mrem/year).

3.3.7.1.3 External Dosimetry

The impact of external gamma dose from potential releases from an LLW facility depends on the facility design and the exposure pathways of concern. There are three general external exposure pathways related to an LLW facility: (a) exposure to soils contaminated by air or water deposition; (b) submersion exposure from air releases; and (c) direct exposure from the facility. Doses from the external exposure pathways would be added to the CEDE calculated by the ingestion and inhalation exposure pathways, resulting in the TEDE to the individual of interest. In general, pathway analysis should indicate the possibility of build-up of radionuclides in sediment via water-borne pathways, including via irrigation, and assess the build-up, if appropriate. If releases from the facility to the atmosphere are significant (as discussed in Section 3.3.6.3, "Air Transport"), air concentrations from releases can cause external exposure by two pathways: ground shine from deposition on soil, and exposure by submersion in the plume. These air pathways need to be explored and assessed, if appropriate. In addition, direct external exposure from the LLW facility may need to be assessed depending on the design of the facility and assumed future events.

3.3.7.2 Recommended Approach

The recommended approach is to use pathway dose conversion factors (PDCFs) for calculating doses via the potential exposure pathways. The PDCFs should convert radionuclide concentrations in an environmental locale (i.e., ground-water concentration at the pumping well, or air concentration over the crops) to a TEDE to the average member of the critical group. The PDCF combines both the pathway analysis and the dosimetry methodology in multiplication factors (e.g., multiplying the concentration at the pumping well by the appropriate pathway analysis conversion factor to calculate the total intake from that pathway, and then, multiplying an appropriate DCF to give the CEDE from that pathway). This approach is described in greater detail in the DEIS for Part 61. An applicant should document and justify, on a site-specific basis, the use of its PDCFs.

The approach outlined in Figure 13 is a generalization of an acceptable approach to modeling the potential pathways and doses to humans. This approach is consistent with the iterative approach identified in Section 1.2 of this technical report. The figure reveals that many of the considerations concerning pathways and parameter values need to be integrated with other modeling areas for overall consistency of the performance assessment. The approach is explained in greater detail below.

3.3.7.2.1 Pathway Identification

The applicant should apply a "current conditions" philosophy to determine which pathways are to be evaluated. That is to say that current regional land use and other local conditions in place at the time of the analysis will strongly influence pathways that are considered to be significant. The applicant should explicitly identify and document the pathways considered in its LLW performance assessment, at an early stage in the performance assessment process. The identification of pathways should be consistent with the types of transport in the conceptual model. Figure 14 shows generalized pathways to consider for releases from an LLW facility. Pathway identification is discussed in various literature sources, such as Volume 1 of NUREG/CR-5453 (Shipers, 1989) and NUREG-1200 (NRC, 1994). An applicant must consider each of the general pathways discussed in Section 61.13 of the regulation. Consistent with the guidance found in Section 6.1 of NUREG-1200 ("Safety Assessment: Release of Radioactivity"), if any of the pathways studied are found to contribute less than five percent of the total dose, that pathway need not be evaluated in detail[23]. If there are alternative, equally credible conceptual models for a particular site, then separate, different pathway will be need to be screened and analyzed, for each conceptual model. This approach is needed because pathways determined to be insignificant, based on one conceptual model, may not be insignificant for other, equally credible alternative conceptual models When the pathways discussed in Section 61.13 of the regulations are not evaluated in detail, PAWG believes that the applicant should provide some justification for the basis not to consider them

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23 This guidance for screening out pathways assumed the use of a deterministic analysis for carrying out the assessment. A different approach may be required for probabilistic analyses such as evaluating the contribution of the total dose attributable to each pathway for each run at the time of the peak mean dose.

Figure 13. **Section 3.3.7: Recommended approach for modeling potential exposure pathways and dose to humans.**

Figure 14. Example of potential dose pathways to be considered in an LLW performance assessment. [Determination of appropriate pathways depends on site-specific information (i.e., habits of the critical group). Adapted from EPA (1972).

(e.g., design considerations, five percent screening models, etc.).

3.3.7.2.2 Model Identification and Identification of Parameter Values

Pathway modeling for dose assessment is discussed in a wide array of literature sources (Till and Meyer, 1983; and Nicholson and Parrott; 1998[24]). The models suggested for pathway analyses, in this technical report, are simple mathematical formulations to reflect transfer compartments in the environment. These formulations are documented in various places and are based on models described in Regulatory Guide 1.109 (NRC, 1977a), and NUREG/CR-5512 (Kennedy and Strenge, 1992). Recent research and its applications have focussed on dose assessment models. Information on these models is provided in Buck *et al.* (1997) and Nicholson and Parrott (1998). Figure 14 shows the overall recommended approach for developing PDCFs and the interactions with other submodeling areas.The following items should be considered in developing a pathway modeling approach and selection of parameter values.

(a) One acceptable approach for modeling the transport of radionuclides through the biosphere employs steady-state transfer factors and bioaccumulation factors. An applicant should document the sources of soil-to-plant, plant-to-animal, and other transfer factors used. Regulatory Guide 1.109 (NRC, 1977a) provides conservative values for a variety of these factors. Regional or local parameters (ranges of parameters) should be used if these data are available, as discussed below. Generic parameter values found in the literature need to be documented as to their applicability to the expected site conditions and the applicant should attempt to represent a best estimate of the actual values at the site. A minimum number of sources of generic data should be used to maintain internal consistency.

(b) For disposal facilities with potentially significant releases of ^{3}H, a specific-activity model may be useful. The radionuclide appears to be widely distributed in the environment, and if released, rapidly form compounds with its stable elements counterparts in the nature. Thus, a specific-activity model is generally used to describe its movement through the terrestrial biosphere, is generally conservative, and may be acceptable for dose assessment. The specific-activity methodology assumes that an equilibrium states exists between the tritium concentrations in the water, food products, and body tissues, for the specified location. For AGVs or other disposal facilities where the atmospheric pathways are predominate, it may be useful to use a specific-activity model for ^{14}C. A specific-activity model should not be used for pulse releases of either ^{3}H or ^{14}C, or for ^{14}C released through the ground-water pathway. More information on specific-activity models can be found in Till and Meyer (1983).

(c) Because of the site-specific nature of performance assessment for LLW facilities, the applicant should obtain the best available data for regional food generation and

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[24] The *RESRAD, MEPAS, DandD, PRESTO* and *FRAMES* dose modeling (computer) codes are presented, with references. The decision methodology for dose modeling at decommissioning sites is also presented, which was later documented in NUREG-1549 (NRC, 1998).

consumption rates, irrigation rates and durations, and other significant parameters used in pathway analysis. Regional food production and consumption rates are generally available through a variety of sources, including U.S. census information and other site-specific studies (e.g., Baes *et al.*, 1984). Typical regional values of consumption rates and exposure durations should be used, rather than maximum regional rates. Regulatory Guide 1.109 (NRC, 1977a) values may be acceptable, but may be highly conservative for certain food pathways, because of changes in dietary habits since its compilation. Use of generic data, such as those in Regulatory Guide 1.109, needs to be justified in the application.

The PAWG recognizes the conservatism in these models; however, in the absence of more sophisticated modeling, which may be justified on a case-by-case basis, this approach is suggested. The applicant should perform a sensitivity analysis on the pathways and parameters used in the performance assessment. The sensitivity analysis may indicate that more complex modeling may be appropriate for certain pathways. If more complex models are used, they should be developed to allow the sensitivities and uncertainties associated with the models to be evaluated.

An acceptable general approach to resolving unique issues discussed above is a tiered approach, consistent with the overall iterative approach of the performance assessment. First, simple models and single parameter values are to be used for modeling the potentially complex systems (e.g., Kennedy and Strenge, 1992). If this approach is not sufficient to demonstrate compliance, next, simple models and parameter ranges should be considered, which encompass all realistic parameter values and quantify the range of consequences associated with the parameters. This approach should also identify the sensitivity of the model to significant parameters.

3.3.7.3 Dosimetry

The applicant should document the dosimetry methodology used in the application. Considerations that should be addressed by an applicant include: (a) internal dosimetry methodology and calculation; and (b) external dosimetry methodology and calculations. Other considerations that influence model or parameter choice should be documented, as appropriate.

The applicant should show the contribution from each major pathway to the TEDE to the average member of the critical group. Generally, these pathways can include the drinking water, food crops, meat products, external dose, aquatic foods, and inhalation.

3.3.7.3.1 Internal Dosimetry

The simplified approach of calculating doses using DCFs will assist in conducting a performance assessment. The EPA has published DCFs for inhaled and ingested intakes of radionuclides for most isotopes in Eckerman *et al.* (1988). This publication, designated as *Federal Guidance Report 11*, provides a simple intake to dose ratio for most isotopes considered in an LLW performance assessment. Internal doses should be calculated with the internal DCFs provided by the EPA (in *Federal Guidance Report 11*) to give the CEDE to the average member of the critical group. These DCFs represent the dose per unit intake values calculated, using the

ICRP 30 methodology discussed above. Assumptions regarding human activity and uptake rates and human organ weighting factors are also identified in *Federal Guidance Report 11* and in Part 20. In general, an applicant should use the most conservative of the internal DCFs for CEDE calculations for radionuclides with multiple DCFs based on chemical form, unless the applicant can justify a particular chemical form for the element (e.g., analog studies).

3.3.7.3.2 External Dosimetry

The PAWG recommends the use of dose rate conversion factors for evaluating external doses. Potential doses can be calculated using tabulated dose rate conversion factors (e.g., Eckerman and Ryman, 1993). Shielding from potential overburden and/or buildings should be considered. The use of dose rate conversion factors can be easily incorporated in the development of pathway DCFs. The external pathway DCFs should calculate the external dose to the whole body based on the assumptions for the critical group. The TEDE is the summation of the CEDE from all the other pathways and the external dose to the whole body from the external pathway.

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APPENDIX A
GLOSSARY

As used in this technical report:

"Area source" means the release of gaseous radioactive material over the uniform area of the disposal facility.

"Atmospheric diffusion factor" (*X/Q*) is the relative concentration of gaseous radioactive materials normalized for wind speed, atmospheric stability, and distance from the source. The diffusion factor is used to compute normalized estimates of time-integrated air concentrations of radioactive gases at a given distance from their release.

"Atmospheric dispersion" is the combined influences of diffusion and transport affecting the behavior of an airborne plume of radioactive gases.

"Auxiliary analyses" are analyses performed to provide the bases for model simplifications, or to support or provide data for input to models.

"Committed dose equivalent" is the dose equivalent to organs or tissues of reference that will be received from an intake of radioactive material by an individual during the 50-year period following the intake.

"Committed effective dose equivalent" (CEDE) is the sum of the products of the weighting factors applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to these organs or tissues.

"Conceptual design" refers to those descriptions, sketches or initial plans describing the disposal facility (e.g., physical layout, vault disposal, multi-layered cover, and subsurface drainage system) to provide a preliminary overall definition of a facility. The conceptual design would not typically include detailed design features based on complex engineering analyses.

"Conceptual model" is a qualitative description of the processes, geometry, and boundary conditions associated with a disposal site or site sub-system component (i.e., ground-water system, flow-through covers, source term, etc.). Conceptual model development includes abstracting system, or sub-system, descriptions into more simplified forms that can be mathematically modeled.

"Critical group" is a group of individuals reasonably expected to receive the greatest exposure to releases over time, given the circumstances under which the analysis would be carried out.

"Deep-dose equivalent" (applies to external whole-body exposure) is the dose equivalent at a tissue depth of 1 centimeter (1000 milligrams/square centimeter).

"Degradation" is a process of gradual reduction in the physical capability of materials used in the construction of low-level waste disposal facilities to limit water infiltration and the release of radionuclides; the physical decline of an engineered barrier following the service life, when important physical characteristics of an engineered barrier progress from an expected design value to the degraded condition.

"Degraded barrier" is an engineered barrier that has fully undergone the process of degradation resulting in reduced material and performance characteristics: a degraded barrier could still perform a function limited by the properties of the remaining durable constituent materials.

"Diffusion release" is a release mechanism that is characterized by the movement of radionuclides in the direction of their concentration gradient (e.g., diffusion of radionuclides out of a cementitious waste form).

"Dissolution release" is a release mechanism that is characterized by the breakdown of a solid in a liquid or the corrosion rate of the waste type (e.g., the corrosion rate for activated metals).

"Dose" (or radiation dose) generically refers to absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, or total effective dose equivalent.

"Dry deposition" is the process of removal of airborne radioactive materials from gravitational setting or through contact with surfaces, ground, vegetation, or other ground cover.

"Durability" is the ability to retain important physical characteristics over a long span of time.

"Engineered barrier" is a man-made structure or device designed to improve the land disposal facility's ability to meet the performance objectives of 10 CFR Part 61 described in Subpart C, meaning the ability to isolate and contain waste, to retard and minimize possible release of radionuclides to the environment.

"Flux" is the specific discharge of a fluid equal to the volumetric flow rate per unit cross-sectional area through which the flow occurs.

"Gaussian plume" is a mathematical model commonly used to predict atmospheric diffusion of gases and particulates. The model is based on assumptions of statistically normal or Gaussian plume dispersion, modified by empirical dispersion coefficients.

"High-integrity container" is a container that provides the structural stability required by 10 CFR 61.56(b) for Classes B and C low-level radioactive waste (LLW). Guidance on demonstrating this structural stability is given in NRC (1991).

"Infiltration" is the net water intake into the native soils at the site or into a disposal unit(s) through the land or cover surface(s).

"Liner" is a vessel used in a transportation package or disposal container to facilitate transportation and/or disposal operations. Sometimes a liner is also used as the disposal container.

"Member of the public" refers to an individual in a controlled or unrestricted area. However, an individual is not a member of the public during any period in which the individual receives an occupational dose.

"Model uncertainty" occurs because perfect models cannot be constructed. Models of physical processes generally have many underlying assumptions and often are not valid for all possible cases. Often, there are alternative models proposed by different analysts, and it is not known which, if any, of the models is the most appropriate one (each alternative will have its own deficiencies). Probabilistic risk assessment (PRA) models themselves, such as event trees and fault trees, can be constructed in different ways, and these alternative constructions can change the results. [Taken from PRA Working Group (1994, p. 150).]

"Natural recharge" is the entry of water into the saturated zone.

"Nonstochastic effect" is a health effect, the severity of which varies with the dose and for which a threshold is believed to exist. Radiation-induced cataract formation is an example of a nonstochastic effect (also called a deterministic effect).

"Parameter uncertainty" results from the lack of knowledge about the correct inputs to models being used in the analysis. The parameters of interest may be inputs to either the PRA models themselves or a variety of physical and process models that influence the PRA process. [Taken from PRA Working Group (1994, p. 150).]

"Pathway analysis" refers to an analysis of radionuclide transport in the biosphere, along pathways that result in a receptor's internal or external exposure (i.e., groundwater-forage-cow-milk-man).

"Pathway dose conversion factor" is a conversion factor that translates a radionuclide concentration at a potential receptor location in the environment (i.e., a well) and the resultant total effective dose equivalent to an individual, considering the various potential modes of ingestion, inhalation, and exposure to the radionuclide (i.e., drinking the water, irrigating crops, contaminated dust in the air, direct exposure to contaminated soils).

"Rad" is a special unit of absorbed dose. One rad is equal to an absorbed dose of 100 ergs/gram or 0.01 joules/kilogram.

"Radionuclide inventory" is the isotopic distribution of radioactive materials by waste class, waste form, and waste container disposed of in the facility and potentially available for release to the environment.

"Radionuclide removal mechanisms" refer to wet and dry deposition processes and radioactive decay that deplete the atmosphere of gases and particulates.

"Reference natural setting" is in reference to a set of natural conditions, processes and events, based on geologic, hydrologic, and other knowledge about the site, that is used in conceptual models to represent the site for quantitative predictions of performance. The reference natural setting includes a range of features and events, and associated parameters, that bound both current conditions at the site and those likely to occur over the period of performance. The reference natural setting does not account for highly uncertain natural phenomena or human behavior based on unreasonable speculation.

"Rem" is a special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rems is equal to the absorbed dose in rads multiplied by the quality factor.

"Rinse release" is a release of radionuclides from a waste form the instant water contacts the waste form or waste type (i.e., a "wash-off" of radionuclides). (Although release from a waste form is considered instantaneous, the dissolution of radionuclides in groundwater will be moderated by solubility limits and retardation for the particular geochemical conditions appropriate for the disposal unit being analyzed.)

"Screening process" is the process of performing a simple, overly-conservative calculation for the expressed purpose of eliminating certain radionuclides from consideration in a performance assessment or eliminating the need for further more complicated analysis (e.g., the screening calculation results meet the regulatory requirements).

"Service life" is a reasonably obtainable and expected length of time over which an engineered barrier performs as designed.

"Scenario uncertainty" refers to the inability to accurately identify, describe, and/or select current and future conditions (e.g., features, events, and processes – FEPs) relevant to the evaluation of the performance of the engineered and natural components of an LLW disposal system. These FEPs can be classified as: naturally occurring geologic events, events caused by the actions of humans, or events caused by man-made components of the disposal system itself. [Adopted from Ekberg (1995, pp. 8- 11).]

"Solidified waste form" refers to liquid or wet-solid wastes, or encapsulated solid wastes (e.g., filter cartridges) that have been mixed with cement, bitumen, or vinyl-ester styrene to meet the requirements of the disposal facility and 10 CFR Part 61. A solidified waste form that meets the requirements of 10 CFR 61.56(b), and the associated guidance in NRC (1991), is a **stabilized** waste form.

"Solubility limit" is the maximum amount of a radionuclide (solute) that can be dissolved per unit of liquid (solvent) under specified conditions (e.g., temperature, pH).

"Sorption coefficient" (K_d) is the ratio of the mass of solute on the solid phase per unit mass of solid phase to the concentration of solute in solution. The validity of this ratio requires that the reactions that cause the partitioning are fast and reversible (e.g., chemical equilibrium is achieved) and the sorption isotherm is linear.

"Source term" is the quantity of radionuclides expected to be released over time out of a clearly identified boundary (such as the waste form, container, disposal unit, or facility).

"Stability" is a structural stability term and refers to the physical stability of the waste and the disposal site so that once waste is emplaced, backfilled, and covered, water access to the waste over time is minimized to achieve long-term stability.

"Stability class" (diffusion category) is a classification scheme that describes an atmospheric turbulence condition in terms of boundary layer atmospheric stability. Diffusion categories are generally grouped in six classes, ranging from Class A, very unstable, to Class F, very stable.
"Stochastic effects" are health effects that occur randomly and for which the probabilities of the effects occurring, rather than their severity, are assumed to be linear functions of doses without thresholds. Hereditary effects and cancer incidences are examples of stochastic effects.

"Streamline" is a line whose tangent at any point in a fluid is parallel to the instantaneous velocity of the fluid at that point.

"Streamtube" is an analytical model of ground-water flow; a streamtube may be used to represent the set of streamlines that originate from a distinct source (i.e., a specific waste vault) and end at a particular discharge point (i.e., a well or surface-water body).

"Total effective dose equivalent" is the sum of the deep-dose equivalent (for external exposures) and the *committed effective dose equivalent* (CEDE) (for internal exposures). As per 10 CFR Part 20 (see Appendix B for a discussion of Table 2), non-stochastic organ-specific limits are not necessary when using the Part 20 dose methodology because "...non-stochastic effects are presumed not to occur at the dose levels established for individual members of the public...." [International Commission on Radiation Protection (ICRP), 1979] In addition, in the ICRP 30 dose methodology, human organs have been assigned weighting factors, based on the risks of stochastic effects to the organ, to evaluate the calculated committed dose equivalent to an organ with a value of CEDE that represents the same risk of stochastic effects to the whole body.

"Waste form" refers to the physical and chemical properties of the radioactive waste (e.g., liquid, cement, metal) without its container or packaging.

"Waste stream" is the origin of a low-level waste type or combination of waste types with a particular radionuclide content and distribution independent of its physical characteristics.

"Waste type" refers to those radioactive materials such as cloth, wood, plastic, glass, or metal, or other substances obtained from radioactive waste treatment systems, industrial processes, or research experiments. Some examples of waste types are dry solids, dry active waste, ion-exchange resins, sorbed liquids, filter cartridges, and activated metals.

"Weighting factor" (organ or tissue) is the proportion of the risk of stochastic effects resulting from irradiation of that organ or tissue to the total risk of stochastic effects when the whole body is irradiated uniformly.

"Wet deposition" is a type of deposition resulting from the scavenging of particles and gases by falling precipitation.

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APPENDIX B
DISPOSITION OF PUBLIC COMMENTS ON MAY 29, 1997, DRAFT NUREG-1573, INCLUDING UPDATES TO TECHNICAL REFERENCES

In response to a request in the *Federal Register* (62 *FR* 29164-29165) for public comments on draft NUREG-1573, the PAWG received comments from the 17 organizations and agencies listed below. The following table is intended to show where these comments can be found in Section B.1 of this appendix.

As a result of the public comment process, a number of commenters expressed concern that the earlier proposed guidance, particularly in the area of recommended policy approaches (Section 3.2 of this document), once finalized, would be viewed by low-level radioactive waste (LLW) disposal facility developers and other regulatory entities as a *defacto* NRC standards by virtue of their codification in the form of a BTP. This was not the staff's intent. The recommended technical and policy approaches in this document were not intended as a substitute for NRC's regulations, and compliance with these recommendations was never intended to be obligatory. To avoid the potential for future confusion in this area, the staff no longer refers to this NUREG as the *draft BTP* but simply as a *technical report.* Moreover, what were formerly *staff positions* or *technical positions* in the draft BTP are now referred to as *recommended approaches*, *attributes of an acceptable approach*, *staff advice*, or words to that effect by the PAWG.

In addition to the changes made in response to public comments described in Section B-1, the PAWG determined that the final version of this document needed to be updated to incorporate new references and information developed since the draft BTP was issued for public comment. Most of the new information is from NRC's research programs, although other sources are included. The list of new technical references added to the final version of this document can be found in Section B-2 of this appendix. These additions do not change the recommendations and advice provided earlier by the staff.

Finally, in the same *Federal Register* notice, the NRC also requested comment on the appropriateness of discounting potential doses, from a hypothetical LLW disposal site, to future generations. To the extent that public comments were received, these comments were forwarded to the Commission for its information and are not addressed in this technical report.

B-1.1 AGREEMENT/NON-AGREEMENT STATE COMMENTS

Commonwealth of Massachusetts
LLW Management Board

Specific Comments on the Suitability of Approaches for Measuring the Performance of LLW Disposal Facilities

The Management Board staff agrees with the overall content and scope of the [draft] BTP. The Board's staff offers some relatively minor comments for U.S. Nuclear Regulatory Commission (NRC) staff consideration.

1. The meaning of the last sentence in [Section] 3.2.1.1 is not clear. It seems that the sentence could read, "...However, it is not necessary to demonstrate that **the stability of natural site features, including those** primarily intended for achieving stability of engineered barriers, will continue to be met beyond 500 years...." The prior sentence refers to both natural site features and the engineered disposal system.

Response
The PAWG agrees that the meaning of the sentence in question could be improved and has subsequently modified the technical report, in the manner described above. The PAWG's intent with this sentence was to communicate the notion that in defining the reference geologic setting to be used in an LLW performance assessment, it is possible to predict with some precision the nature and rates of geomorphic processes acting therein. See Bull (1991) and Goudie (1995) for additional discussion of geomorphic rate prediction and geologic responses thereto.

2. The many cases allowing exemption of certain scenarios and phenomena from performance assessment analyses, the many areas cited where significant uncertainty exists in predicting performance, and the methods recommended for addressing sensitivity and uncertainty are understandable and acceptable from an engineering and technical basis, and are consistent with engineering and scientific approaches to design processes used for other technologies. However, these techniques and ground rules may be very difficult to explain to policy makers, the public, or those involved in a licensing proceeding or adjudication. NRC may wish to consider summarizing these "limitations" of performance assessments, including a clear and concise rationale for their acceptability, in a separate section of this technical report or in a separate document.

Response
In response to this and other subsequent public comments, Section 1.3 of the technical report ("What is LLW Performance Assessment ?") has been modified to clearly (and concisely) state that a key limitation of any performance assessment is addressing the uncertainty in the assessment, which is an inherent aspect of the analysis that must be addressed to provide a defensible basis for accepting the results. This modification consists of the following new paragraph:

> Consistent with the first statement in the paragraph above, an LLW performance assessment (quantitatively) evaluates "potential" doses, not "actual" doses, to potential receptors. Although the Commission does not require an "accurate" prediction of future states in the estimation of disposal facility performance, uncertainty in a performance assessment estimate cannot be so

great that the Commission would not have reasonable assurance that the postclosure performance objectives will be met. There will always be uncertainties in numerical estimates, even for a fairly rigorous analyses, because of uncertainties in analyzing the complex behavior of engineered and natural systems, over long periods of time. However, the existence of these uncertainties does not preclude an applicant from conducting a defensible performance assessment. The key to a defensible analysis therefore is to identify and understand which aspects of the site and design have the greatest influence on the performance.

In addition to that clarification, the PAWG also wishes to add the following to the record, to address this specific comment.

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 Section 61.41of the regulation. Since the promulgation of 10 CFR Part 61, a number of computer codes have been developed to provide precise estimates of performance in support of a compliance determination. However, uncertainty is inherent in all performance assessment 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.

As noted in this technical report, uncertainties are caused by factors such as: (a) limitations and assumptions of the conceptual and mathematical models; (b) uncertainties with respect to site conditions and processes over the performance period; (c) variations in parametric values used in the models; and (d) 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, possible engineering designs, and radionuclide inventories. Therefore, the PAWG attempted to provide advice on preferred approaches that were flexible, yet still provided the information necessary to make a sound regulatory decision.

Comments were also raised during the 1994 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: (a) uncertainties associated with performance assessment calculations; (b) appropriate techniques for assessing the uncertainty in performance assessment calculations; (c) 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; (d) difficulties in explaining a distribution of results to the public; and (e) need for NRC guidance to offer a simple, transparent approach, for demonstrating compliance, that bolsters public confidence.

The PAWG agreed with the concerns regarding the need for understandable and defensible demonstrations of compliance, to ensure public confidence and support for licensing decisions. This technical report provides recommendations and advice 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. This technical report is intended to encourage flexibility in the selection of approaches to accommodate diverse site characteristics, possible engineering designs, and radionuclide inventories. Some workshop participants perceived the PAWG recommendations to be more rigid than was intended. The technical report 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 performance assessment.

In this technical report, the PAWG 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 (NRC, 1991) and NUREG-1200 (NRC, 1994). A variety of approaches can be used to identify key sensitivities in the performance assessment analysis, including: (a) 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; (b) calculations in which many parameters or all parameters that cannot be reasonably set to a constant are varied over a reasonable range of values; and (c) calculations for alternative conceptual models.

The selection of an appropriate approach for uncertainty analysis must be based on individual site characteristics, possible 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 LLW disposal facility developer 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 that may be needed in these areas, it is important to acknowledge that residual uncertainties will remain. (A licensing decision does not require the **complete** removal of uncertainty.)

The PAWG has considered a range of different approaches for acceptable compliance demonstrations. Because performance assessment 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 performance assessment, the LLW disposal facility developer provides a single estimate of performance that is believed to bound the performance. Dependability of this type of analysis requires the LLW disposal facility developer to demonstrate that the performance assessment 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 performance assessment, the LLW disposal facility developer uses the distribution of results as a representation of the effect of uncertainty on the performance. Such a performance assessment, 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 LLW disposal facility developer present a reasonable, comprehensive, and persuasive understanding of the disposal system and provide interpretation of the results consistent with that understanding. The LLW disposal facility developer also needs to support the rationale for the analysis and the basis supporting the uncertainties considered and not considered in the performance assessment.

There was considerable discussion at the 1994 BTP 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 Section 61.41 is based on a single estimate of performance, the LLW disposal facility developer 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 regulatory decision-makers 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.[1]

In cases where a formal uncertainty analysis is performed and a distribution of potential outcomes for system performance is provided, the PAWG 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 of doses at any particular time, as a representation of the central tendency of system performance or the "best model estimate" of performance at that point in time, was considered the most reliable statistic of the distribution. Therefore, the peak of these means is a logical choice for the point for compliance determination. The PAWG also considered a need for more assurance that the dose standards would not be exceeded than is provided by the peak of the mean doses. For example, if the 95th percentile of the distribution of doses at any particular time were specified as a criterion for meeting the dose standards in 10 CFR 61.41, the PAWG believes there is high probability that the dose standards would not be exceeded (see Figure B-1).

The approach to performance assessment modeling discussed in this technical report is designed to ensure that the model results provide a conservative bias compared with actual disposal system and site performance.

Comments on Proposed Staff Positions on Certain LLW Regulatory Issues

1. *Consideration of future site conditions, processes, and events*. The Management Board staff concurs that "extreme" events or conditions, such as glaciation, should not be considered for performance assessments; nor should long-term societal changes (such as changes in local land-use practices, well drilling methods, or water-use practices) or biological changes.

Response
This comment is noted. No specific modification of this technical report is called for in this comment.

2. *Performance of engineered barriers*. The Management Board staff agrees that engineered barriers and other engineered features should not be relied on for more than 500 years, for performance assessment evaluations, without substantial and convincing documentation in support of extended design lives.

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[1] It should also be noted that although (deterministic) bounding analyses are a good starting point for determining regulatory compliance, demonstration using a single, deterministic result may be difficult to prove technically. For probabilistic analyses, it is only necessary to demonstrate that the mean dose does not exceed the regulatory criterion. A single, deterministic calculation using the mean values of the input parameters is unlikely to result in the generation of a mean dose.

Figure B-1. Hypothetical distribution of the results from an uncertainty analysis showing both the mean and the 95th percentile of the distribution.

Response
This comment is noted. No specific modification of this technical report is called for in this comment.

4. *Time frame for an LLW performance assessment.* The Management Board staff agrees with NRC staff analysis regarding the use of a 10,000-year timeframe for a performance assessment analysis.

Response
This comment is noted. No specific modification of this technical report is called for in this comment.

5. *Treatment of sensitivity and uncertainty*. The Management Board staff agrees with the staff's proposed methodology for handling sensitivity and uncertainty in a performance assessment.

Response
This comment is noted. No specific modification of this technical report is called for in this comment.

6. *The role of performance assessment during the operational and closure periods*. The Management Board staff agrees that it would be appropriate to verify performance assessment parameter validity during the post-operational phase of the facility and prior to final site closure, or to re-run performance assessments based on revised data accumulated or measured during the operating and post-operating periods.

Response
This comment is noted. No specific modification of this technical report is called for in this comment.

Commonwealth of Pennsylvania
Department of Environmental Protection
Bureau of Radiation Protection
Division of Nuclear Safety

General Comments

The [draft] BTP provides a general outline of the performance assessment process and discusses several issues that must be dealt with in the context of the analysis. This material is rather basic to people active and experienced in the performance assessment arena, but may be helpful for inexperienced assessors to sort out many of the details of the performance assessment process.

The NRC tip-toes through most of the major issues in a very non-committal fashion. In general, the NRC touches upon all sides of a given issue and vaguely recommends how to proceed. However, most of the vague recommendations are followed by a suggestion that alternative approaches may be warranted or appropriate.

The [draft] BTP generally reinforces the [draft] Staff Technical Series (STS) report on performance assessment developed by the Commonwealth of Pennsylvania (Pennsylvania Department of Environmental Protection, 1997).[2] It outlines similar steps for conducting the analyses, although some differences do exist (see specific comments below). Furthermore, the [draft] BTP emphasizes the iterative nature of the performance assessment process and stresses the interplay of performance assessment with site characterization, facility design, operational, and closure activities.

The emphasis on uncertainty in the early part of the [draft] BTP is misguided. For example, page xi of the *Executive Summary* states that "The goal of the performance assessment process is to defensibly and transparently address uncertainty ...." While that is a worthwhile secondary objective, it is not the primary goal of performance assessment in the LLW disposal facility licensing process. The NRC is assuming that the health-related performance objectives, (e.g., the 25 mrem/year peak annual dose) are real doses, and that the objective of the performance assessment process is to address the uncertainties in predicting these real-world peak doses. This is clearly not the case.

The 25 mrem/year peak dose is a design objective. Therefore, the numerical value has minimal relationship to the real world – the goal of an acceptable performance assessment is not to address the uncertainty in predicting a real dose. Rather, it is to demonstrate compliance through a consistent process intended to give regulators and other interested parties a qualitative understanding that the long-term performance of the facility is acceptably safe and stable.

Page 3-10 of the [draft] BTP allows that "It is sufficient to assume that current biological trends remain unchanged throughout the period of the analyzed performance." This allowance eliminates the performance assessment dose as a prediction of future doses and emphasizes [it] as an estimate of the uncertainty of the potential future doses.

Incidentally, page 3-1 states that "The goal of the LLW performance assessment analysis is intended to develop a supportable demonstration of compliance. While this goal may be

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[2] A copy of this draft report (dated June 1997) was included with this State's public comments and has been placed in NRC's Puplic Document Room (PDR).

reconciled with the goal given in the *Executive Summary*, the two goals initially appear to be different and cause confusion.

The *Introduction* to the document places too much focus on the uncertainty aspects of performance assessment. Compliance to the design standard need not rest on detailed uncertainty analysis or, particularly, the formal probabilistic risk assessment (PRA). The detailed discussion of uncertainty for the traditional contaminant release and transport portion of the performance assessment contrasts starkly [with] the simplistic prescriptions allowed and even encouraged for the engineered concrete barriers portion of the performance assessment. This difference in emphasis is unfortunate and not helpful.

Responses
First, the PAWG does not agree with the *Commonwealth of Pennsylvania's* first set of *General Comments*. Despite the number of active and experienced performance assessment practitioners suggested, the PAWG's view is that at best, the LLW disposal site development process record in the U.S. is mixed because of earlier problems in the siting, design, and/or performance of these facilities (e.g., Yalcintas and Jacobs, 1982; Yalcintas, 1983a and 1983b; National Research Council, 1995; U.S. General Accounting Office, 1999). Rather than address any of the specific short-comings that can be found in this earlier history, or criticize the expertise that may have contributed to it, the PAWG will simply note that one of the principal motivations behind the development of this NUREG was to make the LLW disposal facility devloment process more efficient and effective in the future. To this end, the PAWG decided to return to "first principles" in this technical report as it relates to both NRC's Part 61 regulation, and performance assessment as an analytical tool.

Next, the *Executive Summary* has been modified to address the second overall *General Comment* expressed by the *Commonwealth of Pennsylvania* related to uncertainty (see Section 2 – "LLW performance Assessment Process," Paragraph 1, Sentence nos. 1 and 2) and in doing so, reflect the broad notion that the overall goal of the LLW performance assessment, as outlined in this technical report, is to develop a supportable demonstration of compliance with10 CFR 61.41 of the regulations. However, it should be noted that addressing uncertainty is a key aspect of providing defensible basis for the demonstration, and the approach presented in this technical report is intended to provide a process to acceptably address it in the analysis. This goal has now been rephrased in Section 3.2.1.2 of this technical report ("Site Conditions in Performance Assessment Models"), to emphasize that the purpose of the analysis is not to accurately predict the future, but to test the robustness of the disposal facility against a reasonable range of potential outcomes. Therefore, the PAWG is clearly not assuming that the calculated doses would, in fact, represent "real" (or true) doses that an individual receptor would potentially receive. Rather, these calculated doses are intended to be used as a measure of potential compliance with the regulations. Because they are used in this manner, the PAWG believes that it is important to ensure that one does not underestimate the "calculated doses" in relationship to the standard. That is to say, to ensure that the regulatory standard will be met, with reasonable assurance, the LLW disposal facility developer will need to have sufficient margin (conservatism) integrated into the analysis.

As regards to the portion of the comment concerning the relative "balance" between the contaminant transport and engineered barrier portions of this technical report, we are reminded that the acknowledged most likely process for moving radioactive waste from the disposal facility, through the biosphere, to potential receptor locations, is transport by groundwater. We are also reminded that the man-made portions of the disposal system will ultimately fail in their waste containment role (regardless of how much "engineering" takes place) and that the "site" (i.e., the geosphere) will provide for the isolation of the wastes for the remaining time period of regulatory interest. Although preparing a predictive model of contaminant transport might appear relatively simple based on an understanding of the theory, there are still large gaps in knowledge of the behavior of these systems (e.g., National Research Council, 2000). For these reasons, the PAWG believes that the balance of information contained in this technical report is appropriate.

Lastly, as regards to the portion of the *Commonwealth of Pennsylvania General Comment* that questions the "predictive value" of a performance assessment in public health and safety decision-making, the PAWG agrees that performance assessments do not "predict" future LLW disposal facility performance. Rather, in the PAWG's view, performance assessment (when correctly performed) is a type of systematic risk (or safety) analysis (or PRA, using the *Commonwealth of Pennsylvania*'s terminology) that is intended to address: (a) what can happen; (b) how likely it is to happen; (c) what the resulting impacts are; and (d) how these impacts compare to regulatory standards (see Eisenberg *et al*., 1999)? Finally, based on previous NRC staff and international experience, it is unlikely that future anthropogenic or biologic changes can or could be predicted with any degree of reliability. Moreover, the PAWG believes that such projections would be highly speculative, subject to significant conjecture, and difficult to scientifically defend. Thus, consistent with prevailing International opinion and practice [e.g., International Commission on Radiation Protection (ICRP), 1990; Nuclear Energy Agency (NEA), 1996], the PAWG has assumed, in its performance assessments, that the "reference biosphere" is constant over the time period of regulatory concern. However, having taken this position, the PAWG does not believe the predictive value of the analysis is diminished. (Later in the appendix, the PAWG provides more commentary on this issue in its responses to *Golder Associates General Comment No.* 5 and *DOE Specific Comment No. 3.)*

Specific Comments

1. Developing the performance assessment methodology (PAM) (refer to page 1-11) seems without purpose if "...it does **not** constitute a [emphasis added] way of systematically conducting, documenting, and preparing performance assessments acceptable for licensing...." If the PAM does not serve this purpose, its utility is questionable.

Response
This comment suggests that there should be correspondence between the approach for demonstrating compliance with 10 CFR 61.41 (Section 3.1) and NRC's PAM (Section 3.3). In general, the PAWG agrees with this comment and believes there is an appropriate level of correspondence. In examining this correspondence, we are reminded that the two technical areas in question are attempting to convey two different concepts, at different levels of detail. Section 3.1, the example of approach for demonstrating compliance with 10 CFR 61.41, describes a broad decision-making framework that a LLW disposal facility developer can use to evaluate and defend an LLW performance assessment used to demonstrate compliance with NRC's LLW post-closure performance objective. In the PAWG's view, guidance is not needed on how to conduct most of the activities described in this framework. However, for some of the activities described, because of the uniqueness of the LLW performance assessment methodology, the PAWG undertook development of the PAM. For its part, PAM (Section 3.3) describes some basic models and approaches that can be used to evaluate specific disposal system components and/or processes – some of which may or may not need to be considered in the LLW performance assessment analysis itself because of differences in site characteristics, possible engineering designs, and radionuclide inventories. Considered together, what the PAWG hopes is that LLW disposal facility developers will discover that important decisions need to be documented about the appropriateness of the data, assumptions, models, and computer codes used in the analysis.

2. Determining parameter distributions should not be a part of the second step of the performance assessment process, as stated on page 3-4. At most, estimates of ranges of the parameters should be attempted at this stage.

Response
The PAM described in Section 3.1 of this technical report ("Example of an Acceptable Approach for Demonstrating Compliance with 10 CFR 60.41") is intended to be an iterative process. A preliminary screening assessment, using broad parameter ranges, may initially be used in screening analyses. However, it is expected that more refined parameter ranges would be used on subsequent iterations as more site-specific information becomes available. Assigning parameter distributions is needed to

facilitate the use of the Monte Carlo approach for evaluating uncertainty. Parameter distributions can be assigned even for sparse data through the use of such procedures as “maximum entropy formalism” (see Harr, 1987; pp. 92-96).[3]

3. Requiring the applicant to formulate the mathematical models for his/her conceptual models before consulting available computer codes, as recommended on page 3-4, seems questionable. One can examine the areas of validity and applicability of computer codes to represent particular conceptual models without formulating the exact mathematical expressions of the conceptual models.

Response
This technical report does not state or intend to imply that LLW disposal facility developers should blindly formulate new mathematical models and computer codes without first evaluating existing computer codes. These computer codes implement numerical methods that can be applied directly to the mathematical model selected by the analyst. The point being made is that existing computer codes should not be used when they do not appropriately represent the conceptual model(s) formulated for the particular site, as discussed under *Step No. 2* of Section 3.1.[4] Under certain circumstances, it is possible that a new computer code may need to be developed for a particular site and design so as to better represent the conceptual model identified by the analyst. However, as stated in this technical report, it is not expected that this level of effort will usually be necessary because of the large number of computer codes, already in existence, that could be modified to meet the analysts’ needs.

4. Step No. 6 of the performance assessment process, described on page 3-5, refers to the "distribution of output doses", but previous steps only require a deterministic analysis and sensitivity analyses using the deterministic modeling. Sensitivity analyses [are] usually understood to show the sensitivity of variations in a single parameter at a time. However, on page 3-10, the [draft] BTP includes formal probabilistic approaches in sensitivity analysis. The use of formal probabilistic analyses as a standard step needed to demonstrate disposal site adequacy is not appropriate, especially when the applicable performance objective is deterministic. This emphasis takes the performance assessment approach of the high-level radioactive waste (HLW) program too seriously and is counterproductive to establishing safe LLW disposal facilities.

Responses
First, the PAWG does not believe that the *Commonwealth of Pennsylvania*’s statement is correct when it says that *Step Nos. 1* through *5,* of Section 3.1, only require a “deterministic analysis.” The process steps described in this portion of the technical report do not specifically address the use of either deterministic or probabilistic analyses. Although *Step No. 4* would tend to favor the use of a probabilistic analysis, as stated in Sections 3.2.4 (“Treatment of Sensitivity and Uncertainty in LLW Performance Assessment”) and 3.3.2 of this technical report (“Uncertainty and Sensitivity Analysis”), the PAWG has taken the position in this technical report that either deterministic or probabilistic analyses can be used to demonstrate compliance with 10 CFR 61.41.

Second, the PAWG does not agree that sensitivity analyses are usually understood to be limited to looking at variations in a single parameter at a time. Most practitioners will tend to agree that sensitivity

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[3] Based on Shannon’s (1948) so-called “information entropy,” this formalism allows the analyst to pick the parameter distribution, based on the kinds of information available on the parameter, to assure that the result is the least biased. For example, if only the range in data is known, then a uniform distribution between the range is the least-biased form of distribution.

[4] If this step is not performed, then the computer codes simply become “black boxes.”

analyses can be performed on either deterministic or probabilistic calculations. Sensitivity analyses are performed to identify the input variables that are the primary contributors to the variation in the output. A number of methods have been developed for performing sensitivity analyses, including individual-parameter perturbation methods (i.e., where the sensitivity of the variation of a single parameter is considered one at a time) to determining partial derivatives (e.g., Taylor Series expansions; response surface methods; etc.). Incorporating the sensitivity analysis into a probabilistic analysis has the advantage of allowing the simultaneous evaluation of the interaction of multiple parameters. The use of probabilistic analysis simply recognizes and quantifies the inherent uncertainty in the assessment.

Finally, the PAWG takes exception with the last portion of this comment, that suggests that probabilistic methods are "...counterproductive to establishing safe LLW disposal facilities...." And as a technology, probabilistic or PRA methods has been in place for many decades and lately, have enjoyed greater use and acceptance in both nuclear and non-nuclear applications (e.g., DOE *et al.*, 1992). In recognition of the growing use and acceptance of PRA in evaluating reliability engineering and system safety, the Commission issued a *Policy Statement,* in 1995, on the use of PRA methods in its regulatory activities (see Appendix C). Today, PRA technology supports the Commission's risk-informed regulatory philosophy in several areas of the nuclear fuel cycle (PRA working Group, 1994). Consequently, the PAWG believes that it is appropriate to apply these methods to the area of LLW management.

5. For all intents and purposes, the NRC places a 500-year limit on the effective life of engineered barriers (including concrete structures) when they can be relied upon to perform all intended functions. The NRC states that "... at 500 years and beyond, the engineered barriers should be assumed to function at levels of performance that are considerably less than their optimum level...." In many places in the [draft] BTP, discussions about barrier performance appear to be largely disassociated with performing detailed modeling to determine a reasonable lifetime of the facility (although page 3-11 states that a technical basis must be provided for whatever lifetime is assumed). The use of this (apparently) arbitrary cutoff time serves no useful purpose. The applicant should simply be required to justify the lifetime of the barrier, without placing real or imagined performance limits on the system beforehand.

Response

In this comment, as well as in other comments, some members of the public have expressed views and opinions that demonstrate a certain degree or level of confusion on the PAWG's view regarding engineered barriers. Some public comments were directed primarily toward the expected performance of engineered barriers, particularly with the proposed 500-year performance period that is discussed in this technical report (Sections 3.2.2 and 3.3.4). It was stated that the NRC failed to provide justification for a 500-year limit on engineered barrier performance. Moreover, no credit is given for high-performance barriers that exceed PAWG's proposed 500-year performance limit. In addition, it is suggested that this technical report fails to acknowledge or consider progressive degradation of engineered barriers, which, in the view of some commenters, makes the performance assessment of an LLW site somewhat difficult to defend.

Aside from the 500-year requirement to protect against human intrusion, there is no explicit numerical requirement in Part 61 regarding engineered barrier performance. However, the importance of the performance period for engineered features was recognized (and reinforced) by results in the PAWG's LLW test case, where the engineered barrier's contribution to waste containment are shown to significantly affect estimated doses. The importance of this impact on the outcome of dose estimates in the performance assessment could lead to over-reliance on the performance of the engineered barriers. For the types of engineered barriers that are currently being proposed for near-surface 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 or the transport of radionuclides from them, indefinitely. At present, there are limited supporting data for the performance of such engineered barriers beyond 10^2 years.[5] Further, performance of these barriers beyond this period is questionable given known degradation forces, which can cause unavoidable and unpredictable deterioration. Although some materials proposed for use in engineered barriers will endure as physically recognizable materials long after 10^2 years, the barrier as a whole may not continue to function as designed because essential but less durable components may have degraded. For example, without perpetual maintenance, soil covers at the surface will ultimately degrade because of the penetrations from tree 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.

Consequently, this technical report had initially recommended that for time periods of up to 500 years, LLW disposal facility developers need to demonstrate (with supporting technical analyses) that the engineered barrier *system*[6] will remain intact, providing the ability to divert percolating groundwater away from the disposal units. For timeframes on the order of 10^2 years, it is the PAWG's view that the engineered barrier system will begin to degrade, but still remain structurally intact and allow for some chemical buffering effect. After timeframes on the order of 10^2 years, the less than one percent of a typical LLW inventory remaining will have such long half-lives that no physical barrier can reasonably be assumed to continue to function as designed while the remaining radionuclides decay (that is to say that some of the inventory will outlast the engineered barriers). The site (geologic setting) will then be relied on to subsequently provide isolation of the remaining wastes.

Thus, the question arises as to how rapid is the engineered barrier degradation rate, and how much water, and at what rate, will ultimately come into contact with the waste? The PAWG recommendation thus acknowledges the limitations of information and performance records that are presently available and recognizes the large uncertainties about future processes and events that may affect engineered barrier performance. The recommendation is also based in part on understanding what was intended in the documents supporting the development and promulgation of Part 61. Issue D-50-9 in the Final Environmental Impact Statement (FEIS) 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 wastes. The PAWG recommendations are 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. However, it is incumbent on the LLW disposal facility developer to make this determination, supported by an adequate technical justification, which would be evaluated by the staff on a case-by-case basis.

The PAWG recognizes that some members of the public may have misunderstood or misinterpreted the adopted position. On review of this and other comments, the PAWG believes that its stated position needs to be clarified. Succinctly stated, the PAWG's views on engineered barrier performance are:

- Any time period can be claimed for the performance of engineered barriers. However, the time period claimed should be supported by an adequate technical justification.[7, 8] Such a justification

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5 Which are needed to influence the eventual release of certain long-lived radionuclides such as carbon-14 (^{14}C), chlorine-36 (^{36}Cl), technetium-99 (^{99}Tc), and iodine-129 (^{129}I).

6 Generally consisting of natural and/or man-made cover materials as well as some type of concrete vault/ and or cap.

7 Because of the significance of groundwater as a degradation and transport mechanism, the selection of the duration of the service life should be based on the ability of the engineered barriers to isolate the waste from ground water.

8 By relying on more robust engineered materials, such as those being proposed for geologic repositories for high-level radioactive waste (HLW), longer periods of engineered barrier performance can be justified – say on the order of 10^3 years or greater. However, these more robust engineered materials have generally not been considered for LLW disposal facilities to date because of their relatively high unit construction costs

would be evaluated on a case-by-case basis.

- It should be assumed that engineered barriers will have physically degraded at some point in time. In the degraded condition, an engineered barrier can still perform a function, but the function would be established based on the assumed properties of the constituent materials and be supported by an adequate technical justification. Such a justification would be evaluated on a case-by-case basis.

- At a minimum, the performance of engineered barriers must be analyzed for 500 years, to assure protection against human intrusion (and be supported by an adequate technical justification).

- The capability of the engineered barriers to repel water versus conditioning of the waste (i.e., high pH) can have different times of applicability, provided that there is adequate technical justification.

- Alternatively, a time period of 500 years for engineered barrier performance can be used, but it still must be technically justified by the repository developer.[9] Such a justification would be evaluated on a case-by-case basis.

Consistent with the aforementioned statements, the PAWG has made limited editorial changes to the technical report in Sections 3.2.1.1 ("Site Selection"), 3.2.2 ("Role of Engineered Barriers"), 3.3.3 ("Infiltration"), and 3.3.4 ("Engineered Barriers") to better express its views and recommendations in this area.

6. The [draft] BTP does not provide clear guidance on the time of compliance but settles, without justification, on 10,000 years as a reasonable period of time. This stance is in general agreement with the Pennsylvania [draft] STS on performance assessment. Similarly, both documents include discussions showing why it is wise to understand the magnitude of the peak dose, regardless of when it occurs. However, the [draft] BTP hints at the possibility that if these doses are unacceptably high (no matter when they occur), measures may be required to limit the amount of waste placed in the facility (page 3-14).

Response
Based on this and other public comments received, the PAWG understands that the public has a wide variety of views on its proposed 10,000-year time period of regulatory concern. These views range from requesting a shorter timeframe of compliance, to agreeing with the PAWG's position, to continuing the performance assessment calculation until the time peak dose occurs, without a time constraint.

Before responding to this comment, it is important to first note that the overall goal of the performance assessment analysis is to test the robustness of the LLW disposal facility against a reasonable range of potential outcomes. Although the overall aim of the performance assessment is to demonstrate compliance with the regulation, the goal is not to obtain a true prediction of doses that some individual in a potential receptor group will receive. Therefore, there is no requirement for making accurate predictions out to 10,000 years.

10 CFR 61.13(a) requires a technical analysis to demonstrate compliance with the performance

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and the commensurate increase in technical sophistication typically required to evaluate their performance.

[9] 500 years also happens to be the timeframe when most of the radioisotopes of concern will have decayed to insignificant levels. Therefore, PAWG believes that, in general, it is not necessary for LLW disposal facility developers to spend large amounts of resources trying to justify performance over periods beyond 500 years.

objective set forth in 10 CFR 61.41. Elsewhere in the regulation, some portions of Part 61 specify duration times for analysis of particular aspects of an LLW disposal facility (e.g., a minimum 500 years for evaluating site characteristics). However, Part 61 does not specify a time of compliance (or compliance period) for meeting the performance objective of 10 CFR 61.41. One important concern when defining an appropriate compliance time for the analysis is the recognition that the release and transport of radionuclides are sensitive to a number of uncertain site- and facility-specific parameters (e.g., estimates of geochemical retardation in soils or the degradation rate of engineered barriers). This sensitivity can result in order-of-magnitude uncertainties in the predicted time of peak dose at some off-site receptor location (as well as the values of the peak dose, itself). Another issue to consider is that significant quantities of certain long-lived, potentially mobile radionuclides (e.g., uranium and thorium) are being disposed of as LLW, which was not considered in the Part 61 *Draft Environmental Impact Statement* (DEIS) when it was prepared. For example, the presence of large quantities of uranium or other transuranics may cause an LLW disposal site to exceed the performance objective, at very long times, since the dose potential because of the decay products is significantly higher than that of 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 for uranium).[10] Thus, in determining what an appropriate time period of regulatory interest for the regulation should be, consideration needs to be given to evaluating the relationship of site suitability and design, and how they both contribute to the containment and isolation of LLW, given the types of radionuclides being disposed of (i.e., their half-lives and mobility).

In the January 1994 preliminary draft BTP that was released for informal comment,[11] PAWG recommended that the mean peak dose was an appropriate statistic for demonstrating compliance with 10 CFR 61.41. However, under the PAWG's proposal, after 10,000 years, the applicant (i.e., the LLW disposal facility developer) would have the option of demonstrating compliance without having to continue the dose calculations – for example, through arguments related to solubility limits for certain radionuclides, or through statements that the trace amounts of remaining radionuclides would not cause significant doses at longer time periods. Discussion of the compliance time issue at the 1994 LLW performance assessment workshop included: (a) concerns about the uncertainties associated with projections over long time periods; (b) worry that the credibility of "predictions," at long times, are not sufficient to support licensing decisions; and (c) belief that early timeframes are more important than longer timeframes for addressing uncertainties in scenarios, parameters, and system-knowledge limitations. Some workshop participants stated a preference for 1000 years (e.g., in decommissioning or uranium mill tailings assessments) as an appropriate compliance time. In its early comments, for example, DOE's *Performance Assessment Task Team* noted that it was (independently) considering a 10,000-year time period of regulatory interest for its compliance demonstrations. However, staff representing both the EPA and the USGS thought peak dose appropriate for long-term protection, rather than arbitrary assessment cutoff times.

In its LLW performance assessment test-case calculations for a hypothetical disposal site, the PAWG gained a number of useful insights on the compliance time issue. In its test-case calculations, PAWG

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10 Given the long half-lives of potentially mobile radionuclides, site-specific inventory limits for certain radionuclides may need to be established as part of overall design strategy for the site. See last sentence in 10 CFR 61.7(b)(2).

11 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); the U.S. Environmental Protection Agency (EPA); and the United States Geological Survey (USGS). The PAWG 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 proposed guidance, revised certain sections of the proposed guidance, and organized two workshops on the draft BTP and LLW performance assessment. The first was a 2-day workshop on the draft 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 performance assessment and was held at the *16th Annual DOE/LLW Management Conference* on December 13-15, 1994. The PAWG evaluated the comments received during these various interactions and revised the draft BTP, before it was **formally** issued for public comment.

used 20,000 years as a typical time period for the analysis. The PAWG 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 showed 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 LLW inventory. In addition, the test-case simulations confirmed that mobile long-lived radionuclides – e.g., ^{14}C, ^{36}Cl, ^{99}Tc, and ^{129}I – tend to bound the peak doses for other LLW radionuclides. Thus, a compliance time 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 (greater than 10,000 years). However, specific exceptions include: (a) daughter ingrowth at long timeframes for large inventories of uranium (greater than ~3.7 x 10^{13} Becquerel [greater than~1000 Curie]); and (b) peak doses from large inventories of long-lived transuranics at humid sites.

In light of the aforementioned, the PAWG recommends a compliance time of 10,000 years (see Figure 4 in this technical report). The performance assessment analysis (including sensitivity and uncertainty analyses) conducted within this timeframe would be used as a basis of determining compliance with the requirements set forth in 10 CFR 61.41. Members of PAWG believe that a compliance time of 10,000 years is sufficient: (a) to capture the peak dose from the more mobile radionuclides, which will tend to bound the potential doses at longer times; and (b) to demonstrate the relationship of site suitability to meeting the performance objective. This approach also recognizes that analyses of parameter uncertainty, at long timeframes, can only capture a very small portion of the overall uncertainty in future system states 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 Part 61. In this regard, the PAWG recognizes that the assumptions and conditions of the analysis may not predict "real" conditions at very long timeframes. However, the purpose of such an analysis 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 that 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 PAWG staff believes there should be discussions with both the DOE and the EPA about the appropriateness of disposing of very large quantities of uranium at near-surface LLW disposal facilities.

The PAWG considers shorter compliance times, such as the 1000 years being used in dose assessments for facility decommissioning, to be generally inappropriate for assessments of LLW facility performance because they would 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 decommissioned 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 greater than that typically found at facilities being decommissioned. In addition, the release of radionuclides from LLW disposal units can be delayed for hundreds of years because of containment within engineered barriers. Therefore, truncation of performance assessment 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 1000 years. For typical LLW disposal site inventories, the PAWG does not expect doses from long-lived radionuclides to exceed 100 mrem *Total Effective Dose Equivalent* (TEDE).

Further, the recommended 10,000-year time period of regulatory concern is consistent with the time periods cited in draft or final NRC (10 CFR Parts 60 and 63), DOE (10 CFR Parts 960 and 963), and EPA (40 CFR Part 191) HLW disposal regulations. From a policy perspective, the EPA has already codified a 10,000-year compliance period in Part 191 for a radioactive waste disposal system (EPA, 1993; 58 *FR* 7924). Moreover, this compliance time is consistent with the approach recommended by the National Radiological Protection Board (NRPB) for assessing land-based disposal of solid radioactive waste (NRPB, 1992).

Finally, as a matter of regulatory policy, the PAWG believes that it may not be practical to determine the level of confidence in a compliance demonstration based on projections of hundreds-of-thousands of years into the future. A large and cumulative amount of uncertainty is associated with numerical projections over very long time-scales as additional scenarios and parameters are added to the analysis. These longer compliance periods would require the specification of exposure scenarios that would, potentially, be based on arbitrary assumptions, rather than on current scientific knowledge or reasonable (defendable) projections. In addition, reliable modeling of potential human exposures may be untenable and regulation to the time of peak dose could become arbitrary over extremely long compliance periods. In light of the cumulative uncertainty for calculation over an extremely long time frame, the PAWG believes that it is more appropriate to consider, in regulatory decision-making, assessments of disposal system performance over such times in a qualitative manner. Recognizing that the highest dose for some facilities may result from less mobile radionuclides, which may result in the peak dose occurring after 10,000 years, the PAWG also advocates that the LLW disposal facility developer perform a qualitative evaluation of dose beyond 10,000 years, if needed, to identify any potential significant deficiencies, in the performance of the facility, that may require ameliorating action (e.g., inventory limits, deeper disposal).

7. The NRC is still a major supporter of using probabilistic uncertainty analysis to understand the uncertainties associated with performance assessments, although they have backed off their earlier "all or none" approach by offering up a deterministic, bounding approach in addition to the probabilistic uncertainty analysis. Not much is made of the fact that considerably more data may be required to conduct the probabilistic analysis, and that the choice of approach should consider data availability (to which page 3-24 alludes). The approach taken should be left up to [the] applicant, with the applicant realizing that they will have to convince the regulators that they understand the disposal system adequately. In its defense, the [draft] BTP does state on page 3-17 that, regardless of the approach taken to understand uncertainties, the applicant needs to demonstrate "persuasive understanding" of the disposal system performance.

Response
As stated in Section 3.3.2 of this technical report (“Uncertainty and Sensitivity Analysis”), there is no “best” approach for measuring the performance of an LLW disposal facility; consequently, both deterministic and probabilistic analysis are recommended by the PAWG. As correctly noted in this comment, the decision regarding the selection of “when, where, and how” to apply either of these analytical approaches resides with the LLW disposal facility developer.

8. For the reasons given in *Specific Comment No. 4,* above, the 100 mrem/year dose should not be required to satisfy the 95th percentile test, contrary to the discussion presented on pages 3-17 and 3-18.

Response
A key issue that must be addressed in the treatment of uncertainty in an LLW performance assessment analysis is specifying how to interpret the results in the context of the regulatory limit; that is, what metric of the distribution of calculated doses (e.g., the mean or some other statistical measure) should be used in determining compliance. As a result of both policy and technical considerations, the PAWG considers

the use of the *peak of the mean dose* [12] *versus time (curve)* to be an appropriate measure for demonstrating compliance with the regulation, for three major reasons.

First, there is existing precedent for using the “best estimate” of the dose outcome distribution, in the form of the mean (e.g., 40 CFR Part 191, 10 CFR Part 60, and proposed 10 CFR Part 63). Based on this previous regulatory experience, the PAWG believes that the use of the peak of the mean dose would provide a reasonable measure of the (expected) central tendency of the performance of an LLW disposal system and is the most direct measure of risk. See Figure B-2. Further, placing a limit on the upper 95th percent confidence of the dose distribution provides additional assurance of the acceptable performance of the site – constraining the 95^{th} percentile of the distribution to 1.0 milliSievert (mSv) [100 millirem (mrem)], as shown in Figure B-2. [In response to this and other comments, the PAWG staff have modified Paragraph No. 2 of Section 3.3.2.3.2 of this technical report (“Probabilistic Analysis”) to describe how the mean dose as a function of time can be derived mathematically, consistent with Item (a), shown in Figure B-2.]

Second, a mean dose is calculated for each discrete time-step in the analysis. In general, the mean dose for any particular time-step will be influenced by a few large results. Accordingly, the peak of the mean dose will generally be greater than the peak of the median dose (i.e., 50^{th} percentile) at each time-step. This effect will tend to provide a conservative bias in the results. Additional conservatism in the assessment is introduced when the conceptual models and scenarios used are themselves conservative.

Third, in the context of using reasonably realistic models and scenarios, this approach also provides a conservative estimate of the potential risk posed by an LLW disposal site and thus is consistent with the Commission’s risk-informed, performance-based regulatory philosophy (see Appendix C) in evaluating such risks. With regards to the final question concerning demonstration of the PAWG’s preferred approach, whether it can be demonstrated that sites will comply with the regulations, in a generic context, was previously addressed in the development of the Part 61 regulation; therefore, it is not necessary for this technical report to state generically whether it is possible to demonstrate compliance with the rule. Through its test-case exercise, the PAWG is convinced that approaches proposed in this technical report can be implemented. This was a key reason for undertaking the exercise.

9. The [draft] BTP indicates that the mean dose from the probabilistic uncertainty analysis should be used to judge compliance (the 95th percentile annual dose must also be less than 100 mrem). This tends to diverge from other approaches to compliance evaluation, which tend to use the 90th or 95th percentile of the distribution as the decision point. The suitability of using the mean value may be expected to vary with the disposal system under consideration, and may not be reasonable. Overall, it is probably not wise to place generic constraints on the compliance point.

Response
See response to *Commonwealth of Pennsylvania Specific Comment No. 8.*

10. The [draft] BTP does a good job of emphasizing the iterative nature of the performance assessment and the interplay between the analysis and the design, construction, operation, and closure of the disposal facility. The report reinforces the material provided in the Pennsylvania STS report on performance assessment and should help convince the applicant of the continuing importance of performance assessment.

Response
The comment is so noted. No specific modification of this technical report is called for in this comment.

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12 The **mean dose** is the arithmetic average of a dose distribution as a function of time.

Figure B-2. PAWG-recommended approach to calculating the peak of the mean dose.

(A) Current approach in the technical report. The following equation shows how the mean dose as a function of time can be derived. For ***N*** Monte Carlo realizations (or runs):

Essentially, a mean dose is determined at each discrete time-step in the analysis. A plot is then made of these means versus time. The mean dose provides the "best estimate" of dose at each discrete time. The overall peak of these best estimates is then used to determine compliance with the regulation.

(B) Proposed approach during May 1997 public comment period.

11. The [draft] BTP specifically states that intruder dose projections need not be performed as part of the performance assessment (footnote on page 1-13). Rather, the applicant must provided assurance that the waste classification limits will be met and that adequate barriers will be provided to protect intruders. This aspect of the performance modeling approach is in direct contrast to the exposure scenario discussion in the Pennsylvania STS report on performance assessment. The Pennsylvania STS report indicates that several intruder scenarios should be considered in devising exposure scenarios.

Response
The observation that the intent of this technical report is not to provide guidance on how to perform a human intrusion scenario calculation is correct. The assumption in Part 61 is that if the LLW disposal facility developer can demonstrate that the waste form classification criteria of 10 CFR 61.55 are met, then no separate intruder analysis is required. In the LLW DEIS (NRC, 1981), the NRC staff performed a generic analysis of inadvertent human intrusion and showed that, by complying with 10 CFR 61.55, the general population, workers, and inadvertent intruders would be protected from exposures. Thus, this technical report and the Pennsylvania report are inconsistent in this regard.

Should LLW disposal facility developers and/or regulators need future advice on how to perform an intruder analysis, the following statement to Footnote No. 6, found in Section 1.6 of this technical report ("Purpose") has been added:

> "...To the extent that there may be a need for guidance on how to perform an intruder consequence analysis at an LLW disposal facility, LLW disposal facility developers and/or other regulatory entities should consult NRC's DEIS on Part 61 (NRC, 1981)...."

12. The [draft] BTP mentions in several places that iterations of the performance assessment need to be undertaken only until the performance objective has been met (e.g., page 3-1). While demonstrating compliance is the ultimate objective, care should be taken in applying this philosophy. Under some conditions, compliance may be able to be demonstrated using limited site-specific data and/or "conservative" estimates of several parameters. While the facility may (apparently) comply, a real understanding of how the disposal system functions may not emerge. Thus, major conceptual errors in model formulation and application may go unnoticed. Therefore, it is suggested that, regardless of whether compliance is demonstrated or not, the applicant be required to display an adequate understanding of how the disposal system performs in protecting members of the general public, potential inadvertent intruders, and facility workers.

Response
The PAWG agrees with the observations contained in this comment on the need for balance. Although the principal goal of the LLW performance assessment is to demonstrate compliance with 10 CFR 61.41 of the regulation, as noted in the last sentence of Paragraph 3 of Section 1.3 of this technical report ("What is LLW Performance Assessment ? "), we are also reminded that the performance assessment analysis should:

> "...capture relevant features and processes of the disposal system being modeled, and reflect the uncertainty in system knowledge...."

Thus, it is incumbent on the LLW disposal facility developer to be able to defend the assumptions and parameter values used in the performance assessment. This technical report does not suggest using simple, unrealistic modeling assumptions. Clearly, the modeling assumptions relied on must be credible and consistent with the results of site characterization. In this technical report, PAWG is attempting to steer practitioners away from the notion of collecting data and information solely for the purpose of gaining an increased scientific knowledge about the site and the performance of a particular facility design. Such data and information-gathering efforts can easily become open-ended. Instead, this technical report describes a comprehensive process where site characterization, facility design, and performance assessment are conducted concurrently (and iteratively) so that the analysis results can be used to direct and focus future data-gathering activities, as needed.

13. The performance assessment flow chart in the [draft] BTP (Figure 1) and the chart shown in the Pennsylvania report on performance assessment (Figure 3-1 – see Pennsylvania Department of Environmental Protection, 1997) are in good agreement with one another.

Response
The PAWG agrees that there is good correspondence between the two flow charts. However, the one area for which there is a discrepancy between the two flow charts, and thus the two documents is the explicit recognition, in the NRC's technical report, that, following one or more performance assessment iterations, it may be concluded that a candidate site is not suitable to host an LLW disposal facility. The Pennsylvania report does not address this possibility.

14. In its [draft] BTP discussions about uncertainty, the NRC does not clearly suggest that the applicant provide a best estimate of facility performance (dose) in conjunction with dose estimates adjusted for uncertainties. It is a valuable exercise for all involved to understand the "expected" performance of the disposal system, in addition to understanding the impacts of uncertainties. This estimate should be considered, along with the results of the uncertainty analysis, in the compliance evaluation stage of the process.

Response
For probabilistic analyses, this technical report recommends that the peak of the mean dose curve (i.e., mean dose as a function of time) be used to evaluate compliance with the performance objective in 10 CFR 61.41. As noted in its response to *Commonwealth of Massachusetts Specific Comment No. 2*, the PAWG believes that this statistic provides the "best model estimate" of system performance in terms of demonstrating compliance with the regulations. For deterministic analyses, it is difficult to say that the calculated dose is truly the "best estimate," even when "best estimate" parameter values are used in the analysis, because use of "best-estimate" parameter values may not ensure a "best-estimate" of the dose. Accordingly, it is recommended that the analysis conservatively bound the estimate of performance.

15. In its discussion of the deterministic uncertainty approach, the [draft] BTP indicates that the bounding dose should not exceed the performance objective. This highlights the importance of the best estimate of dose. For instance, one might have a different level of assurance if the best estimate and bounding estimate are 10 and 98 percent of the limit, respectively, rather than if these values were 75 and 98 percent of the limit, respectively.

Response
See the PAWG's response to *Commonwealth of Pennsylvania's Specific Comment No. 14,* above. In addition, the commenter needs to consider that in a deterministic analysis, only a single estimate of dose is reported (i.e., no measure of uncertainty is provided). The PAWG agrees that use of the mean could result in different percentiles of the distribution used for demonstrating compliance. However, the PAWG does not agree that this could ever result in the 10^{th} percentile of the dose distribution being used for such purposes. Because PAWG advocates the use of the arithmetic average in determining the mean (see response to *Specific Comment No. 9, above*), it will never be less than the 50^{th} percentile of the distribution. In most cases, it will be near the upper end of the distribution.

16. Modeling of engineered barrier performance is oversimplified by the [draft] BTP based on the discussion on page 3-39. Taken at face value, a concrete structure is assumed to function

perfectly for its design life, at which point it begins to be less effective. In fact, a structure may be able to continue to meet its intended functions beyond the design life, as safety factors are usually included in the design. Furthermore, it is not clear whether the NRC realizes that the processes that lead to functional failure actually commence within the design life of the structure. Overall, the [draft] BTP portrays the engineered barriers as functioning in a step-wise manner, when the degradation processes are definitely continuous and progressive in nature (although the discussion on page 3-40 does allude to this fact). This could lead to some confusion when it comes time for the applicant to conduct the modeling.

Response

PAWG agrees that *conventional* structures (buildings, bridges, retaining structures, etc.) may be able to continue to meet their intended functions well beyond their expected service (design) life by incorporating safety factors into the design process. In theory, these *minimum* safety factors have been established through experience and regulation for civil engineering systems as a means of ensuring that no failures[13] occur during service life or, if there are failures, they are tolerable – say in the neighborhood of one to five percent (Harr, 1987; p. 157). There are several considerations that contribute to determining the magnitude of the safety factor itself,[14] including the opportunity for regular inspections and maintenance (which, coincidentally, are generally recognized to also have a major impact on defining the service life of concrete). Thus, although physicochemical degradation processes are continuous and progressive in nature, as noted in this comment, with the opportunity for regular inspections, maintenance, and/or rehabilitation, conventional structures should be able to be perform, as intended, during their design life.

However, unlike conventional structures, whose implied service life is typically on the order of 10^2, the engineered barriers for an LLW disposal facility are required by virtue of the regulation to have a service life of at least 10^3 years (or greater), with no opportunity for inspections, maintenance, or rehabilitation, after the first 100 years of service. In addition, the regulations envision that there should be *no service failures* of the LLW engineered barrier system during this 10^2-year timeframe, or, if there are failures, their consequences should be such that the Subpart C performance objectives would not be exceeded. Thus, in the example of a concrete structure cited in this comment, the challenge for LLW disposal facility developers is twofold: (a) how to *model* the physicochemical degradation of concrete over 10^2 years when there is only about 150 years or so of modern service history[15]; and (b) based on the performance models developed, how to subsequently *design* the concrete barrier (system) using *modified* safety factors that reflect a much longer, 10^2-year service life.

Finally, in its earlier response to *Commonwealth of Pennsylvania Specific Comment No. 5,* PAWG has clarified its views on what level of performance is expected from engineered barriers. However, neither in that response, nor in this technical report itself, has the PAWG taken a position on how the engineered barriers themselves are expected to perform over time (i.e., “stepwise versus continuous” as noted in this comment). As noted in PAWG’s response to *the Commonwealth of Pennsylvania*, the decision on how best to depict (model) engineered barrier performance over time rests with the LLW disposal facility developer.

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13 Failures generally being defined as an inability to perform the intended design function.

14 Bowles (1977, pp. 141-143) has identified a number of considerations (parameters) that contribute to defining safety factors ***F***. In addition to inspections and maintenance these include reliability of (or uncertainty in) design data, accuracy of design methods/analyses, quality of and tolerances in construction, magnitude (i.e., consequence) of potential design failure, relative costs of increasing/decreasing ***F***, and the relative change in design failure by increasing/decreasing ***F***.

15 As a construction material, concrete was first introduced in Roman times (Briggs, 1956; p. 405). Although some of the structures built back then still exist today, it wasn’t until the late 1800s that concrete, as a modern construction material, was “rediscovered” and came into widespread use (Hamilton, 1958; pp. 483-491).

17. The screening approach discussed on [draft] BTP pages 3-44 and 3-45 needs to be considered in terms of what iteration of the performance assessment is being conducted. If it is an early iteration, based on sparse, generic data, it may be dangerous to conduct radionuclide screening. One could needlessly eliminate radionuclides that may pose a significant risk from further consideration, even though the conceptual and mathematical models will evolve with the collection of more and better information.

Response

The recommended approach under Section 3.3.5.2.2 of this technical report ("Screening Methods to Identify Significant Radionuclides – Recommended Approach") specifically states that all radionuclides and all dose pathways should be considered when screening out insignificant radionuclides. As long as the dominant dose pathways (i.e., those contributing the most to the calculated dose) remain the same in the final analysis as those first observed in the initial screening analysis, it is unlikely for a radionuclide to have be erroneously screened out. Item (b) of Section 3.3.5.2.2 has been modified to clearly point out the need for ensuring that the dominant pathways are the same between the screening analysis and the final compliance demonstration analysis by the addition of the following sentence to the end of the paragraph in question:

> "To ensure that important radionuclides are not inadvertently screened out of the assessment, it is important to confirm that the dominant exposure pathways (i.e., those contributing the most to the calculated dose) in the screening calculation are consistent with those in the final performance assessment analysis."

18. The discussion about selecting pathways for consideration in modeling (page 3-73) may permit faulty conclusions. The text states that pathways that will not contribute at least five percent of the total dose need not be evaluated in detail. The cumulative effect of ignoring such pathways could be a significant portion of the overall dose. Furthermore, final screening of pathway in this way does not address potential uncertainties associated with the pathway. Errors introduced by uncertainties for pathways eliminated from consideration in the screening process could be considerably greater than those for other apparently more significant pathways. Pathways should not be permanently eliminated from consideration early in the performance assessment process, when sufficient information of adequate quality does not exist to support such an action.

Response

As stated in Section 3.3.7.2.1 of this technical report ["(Dose) Pathway Identification"], the LLW disposal facility developer must consider each of the general pathways discussed in Section 61.13 of the regulation (i.e., air, soil, groundwater, surface water, plant uptake, and exhumation by burrowing animals). To show that the dose from the dominant pathway is less than 25 mrem/year TEDE, the combined dose from the remaining pathways (assuming they each contribute five percent to the total dose) would be only 0.0625 mSv/year (6.25 mrem/year). Therefore, the PAWG believes that it is unlikely that the cumulative effect of ignoring such dose pathways would be significant.

With regards to the concerns about addressing potential uncertainties associated with such pathways, this technical report states that consideration of model uncertainties (i.e., different conceptual models) should be made through evaluation of the variation in parameters and/or the use of different conceptual models. Therefore, a separate or different screening of pathways will be required for each conceptual model; that is, it is not reasonable to assume that the screening of pathways based on one conceptual model is appropriate for another conceptual model. Section 3.3.7.2.1 has been modified to clearly reflect this PAWG view in this area by the addition of the following sentence to the paragraph in question:

> "If there are alternative, equally credible conceptual models for a particular site, then separate, different pathway will be need to be screened and analyzed, for each conceptual model. This

approach is needed because pathways determined to be insignificant, based on one conceptual model, may not be insignificant for other, equally credible alternative conceptual models.”

State of Illinois
Department of Nuclear Safety
Division of Radioactive Materials

The Illinois Department of Nuclear Safety (the Department) hereby submits its comments on the above-identified document. The document is intended to provide detailed LLW performance assessment guidance to potential applicants for an NRC license. The NRC has requested specific views on both the suitability of approaches presented in the draft BTP, for measuring the performance of LLW disposal facilities, as well as the NRC staff's proposed positions on certain LLW regulatory issues: (a) consideration of future site conditions, processes, and events; (b) performance of engineered barriers; (c) timeframe for an LLW performance assessment; (d) treatment of sensitivity and uncertainty; and (e) the role of performance assessment during the operational and closure periods.

Several of the Department's five current comments are similar to those we submitted to the NRC in response to a preliminary draft of the BTP that was issued in January 1994. In particular, we remain very concerned about the potential disruptive effects that the BTP will have on our and other Agreement States' regulatory programs, and we still maintain that the proposed 10,000-year compliance period is excessive and unwarranted.

General Comments

Section 1.8 of the [draft] BTP states that "[t]he extent to which Agreement States or other regulatory entities implement the recommended technical position statements found in the NUREG is, of course, a matter for their consideration and decision." In spite of that disclaimer and assurances that the BTP is intended only to supplement other guidance documents, and compliance with it is not required, BTP positions may become defacto standards. In some cases, this may have already occurred. For example, in an April 18, 1997, letter to the South Carolina Division of Radioactive Waste Management, the NRC cited the 10,000-year time-frame proposed in the preliminary draft of [the] BTP as the basis for urging that South Carolina require dose projections for longer time periods. There is no need for the NRC to establish independent guidance that Agreement States will be coerced to apply during licensing.

Response
The PAWG does not believe that citing this technical report as the basis for recommended positions or as guidance on recommended approaches invalidate alternative positions (or approaches) adopted by the Agreement States provided they have a sound technical basis. As discussed in Section 1.8 of this technical report, the extent to which Agreement States or other regulatory entities apply this technical report to their respective programs is a matter for their consideration and decision. Moreover, we are reminded that the PAWG has undertaken the development of this technical report as a means for closure on acceptable procedures for conducting a performance assessment used to support demonstration of compliance with NRC's LLW disposal regulations. The PAWG believes that rigid adherence to the specific concepts/steps proposed in this technical report is not sought so much as the use of a consistent process that produces an accurate and properly documented assessment. Moreover, the PAWG believes that effective implementation of a good LLW performance assessment cannot guarantee acceptance of the technical conclusions; however, use of a flawed process or improper implementation of a good process cannot help but cast serious doubt on the quality of the conclusions. The key, therefore, to the adoption of alternative positions to those set forth in this document, will be their technical/scientific defensibility.

This being said, other commenters have expressed the general concern that the proposed advice, particularly in the area of recommended policy approaches (Section 3.2 of this technical report), once finalized, would be viewed by LLW disposal facility developers and other regulatory entities as a *defacto* NRC standards by virtue of their codification in the form of a BTP. This was not the staff's intent. The recommended technical and policy approaches in this document were not intended as a substitute for NRC's regulations, and compliance with these recommendations was never intended to be obligatory. To avoid the potential for future confusion in this area, the staff no longer refers to this NUREG as the *draft BTP* but simply as a *technical report.* Moreover, what were formerly *staff positions* or *technical positions* in the draft BTP are now referred to as *recommended approaches*, *attributes of an acceptable approach*, *staff advice*, or words to that effect in final version of this NUREG.

> In the March 7, 1997 memorandum to the Executive Director for Operations, "Staff Requirements – COMSECY-96-055," the NRC Secretary noted that Agreement States have commented that the [draft] BTP is "unnecessary and disruptive." The staff was directed to "...inform the Commission how it plans to resolve such comments prior to a decision to finalize the [draft] BTP...." We are not aware of any action by the staff to comply with this directive to date. We agree with the Commission that the concerns expressed by Agreement States must be resolved before the final BTP is issued.

Response
NRC's earlier Direction-Setting Issue (DSI) 5 concerns LLW, and it asked, among other things, whether the staff should proceed to finalize its (earlier proposed) guidance (in the form of a BTP) on LLW performance assessments. In asking this question (specifically Question 3), background to the DSI noted that the staff had previously issued the draft BTP for public comment and that the public comments were "mixed." Moreover, this background also stated that the draft BTP was considered "unnecessary and disruptive." The staff believes that, in both of these instances, the background to Question 3 of DSI 5 mischaracterizes the influence the earlier draft guidance has had on the national program.

To begin with, the LLW BTP had not been previously issued for public comment. In January 1994, a **preliminary draft** of the LLW BTP was distributed informally for comment to all LLW-sited and host Agreement States; the ACNW; the DOE; the EPA; and the USGS. Many written comments were received; most of these were constructive and consistent with the type of technical comments typically received by members of PAWG. (Then as now, many of the comments concerned the basis for the PAWG's position on a proposed 10,000-year timeframe for an LLW performance assessment, the use of the mean in the dose calculation, and the 500-year lifetime for engineered barriers.) However, none of the comments received suggested that the draft BTP was "unnecessary and disruptive." The PAWG also received additional, constructive feedback on the draft BTP during a November 1994 LLW performance assessment workshop from Agreement State regulators and LLW site developers who participated in the workshop. Draft NUREG-1573 reflects the PAWG's consideration of comments received during those interactions. In fact, in light of these interactions and consideration of the workshop comments received thus far, the PAWG believes that there has been a substantial improvement to the January 1994 preliminary draft version of this technical report.

The PAWG believes that this strategy, to provide an advance copy of the earlier proposed guidance (i.e., the January 1994 preliminary draft) to those regulatory groups most likely to implement it, was successful, inasmuch as PAWG members have been able to consider their early views, and recommendations of other LLW performance assessment practitioners, before it formulated its positions to be ventilated for formal public comment.

In a Staff Requirements Memorandum (SRM) dated August 7, 1996, the Commission directed the staff to proceed with issuing the draft guidance for public comment. Included in this process was a review by the Office of the General Counsel, to ensure that it had no legal objection to it being issued. Moreover, because the staff has a continuing interest in addressing the concerns of potential users, more than 200 copies of the draft LLW BTP were mailed to cognizant regulatory authorities in each State, former BTP workshop participants, and the aforementioned Federal agencies, as part of the current public comment period.

In conclusion, because no **formal** public comments have been received at this time, it is not clear what the views of the public were on an earlier draft of this document.

Detailed Comments

1. *Timeframe for an LLW Performance Assessment.* Neither the NRC regulation on LLW disposal (Part 61) nor the Department's equivalent rule describing the "Licensing Requirements for Land Disposal of Radioactive Waste" (32 Ill. Adm. Code 601) explicitly requires a regulatory compliance period for an LLW facility. Clearly, the principal performance objective regarding protection of the general public from releases of radioactivity (10 CFR 61.41; 32 Ill. Adrn Code 601.190) does not direct that doses be evaluated over a specified time period. These rules – without a mandated compliance period – have been determined by the State of Illinois and the NRC to be adequately protective of public health and safety. The Department maintains that there is neither a need nor a basis for the NRC to impose a specific regulatory compliance period now.

   A timeframe of 500 years is sufficiently long to evaluate doses to determine compliance with performance objectives. Although we note again that there is no specified compliance period in the rules, there are provisions that indicate the adequacy of a 500-year timeframe:

   (a) Class C waste must be disposed of with intruder barriers designed to protect against an inadvertent intrusion for at least 500 years.

   (b) Site characteristics should be considered in terms of the indefinite future and evaluated for at least 500 years.

   These provisions can be interpreted to mean that the regulatory compliance period for an LLW facility is 500 years, but they do not require an explicit demonstration that an LLW disposal facility will meet performance objectives for 500 years. There is no way to infer that an applicant must demonstrate compliance for 10,000 years.

   In 1992, the Department reviewed performance assessment modeling efforts associated with the proposed Martinsville LLW site. Each parameter and its corresponding sensitivities and uncertainties were studied. It became apparent that trying to credibly predict radiation doses to theoretical populations in light of the complex variables inherent in a 500-year period was pushing the limit of technical credibility. There have been no new technological advances in the last five years that would now allow credible predictions of performance over much longer time periods.

   Given the current state of the art in performance assessment and what is known about the value of key parameters, we maintain that a 500-year time frame is adequate for a credible performance assessment to be conducted and defended for an LLW disposal facility. Evaluation of potential doses due to long-lived radionuclides, for longer time frames, may be warranted to increase understanding of site-specific performance, but using time periods in excess of 500 years for the purpose of demonstrating compliance with performance objectives lacks meaning.

Response
See PAWG's response to *Commonwealth of Pennsylvania Specific Comment No. 6.*

2. *Compliance Determination.* There is the general requirement in 10 CFR 61.40 that there must be "reasonable assurance" that performance objectives will be met. The equivalent Department rule, 32 Ill. Adm Code 601.10, also requires assurance that limits established in the performance objectives are not exceeded. The NRC staff has apparently quantified the level of assurance required. When probabilistic performance assessments are done, according to the [draft] BTP, the median value of the distribution of results is the value that should be used to determine compliance. Thus, assurance is evidently defined to be 50 percent uncertainty. If the median value is at the performance objective limit, half of the results exceed the limit, the other half are below it). Although the median result is the most probable, there should be greater justification given for the position that a 50-50 chance that a performance objective will be met is adequate "assurance."

Response

Contrary to the view expressed in this comment, the PAWG is not attempting to quantify the degree of assurance required to demonstrate compliance with Part 61. Instead, the PAWG recognizes that in advocating the use of a probabilistic approach, the appropriate metric of the distribution used for determining compliance must be specified. For the purposes of demonstrating compliance with Part 61, the PAWG recommends the use of the *peak of the mean dose versus time*. (See the PAWG's response to *Commonwealth of Pennsylvania Specific Comment No. 8* on how the mean value of the performance assessment results should be interpreted.)

Moreover, it is also recognized that not all sources of uncertainty, even in a probabilistic analysis, will be quantified. Ultimately, the decision on whether reasonable assurance has been provided will be made by the decision-maker. In this regard, the Commission has clearly articulated that probabilistic assessments should be conducted to assist the Agency in its mission of protecting public health and safety, and the environment. The Commission's *PRA Policy Statement* (see Appendix C) states that the use of PRA methodology, which includes performance assessment for waste management systems, should: (a) reduce unnecessary conservatism; and (b) be as realistic as practicable, when supporting regulatory decisions (NRC, 1995; 42628-42629). However, numerical compliance with the postclosure performance objective alone is not sufficient for the Commission to have "reasonable assurance" that there is no unreasonable risk to the health and safety of the public in any LLW licensing decision. 10 CFR 61.23 of the regulation also requires that other technical requirements must be met (i.e., the regulations in Subparts D and E).

3. *Site Selection*. Section 3.2.1.1 of the [draft] BTP, entitled "Site Selection," should be eliminated. The process by which a potential site is selected has no bearing on performance assessment analysis of a disposal facility. The siting requirements and performance objectives in 10 CFR Part 61 and in 32 Ill. Adm Code 601 relate to site suitability, not to the method by which the site is identified. In fact, the last two paragraphs of this three-paragraph section have nothing to do with site selection. They deal with engineered barriers and time frames, topics discussed at length elsewhere in the document. The first paragraph, however, attempts to equate several technical requirements to selection, and concludes with the sentence:

> "...Thus, a site carefully selected, to reduce uncertainty about its characteristics and behavior, adds to the credibility of performance assessment results...."

The validity of a performance assessment should be unrelated to whether a site is selected carefully. Site selection procedures may influence public acceptability of the performance assessment results, but that does not render the assessment more technically credible. Public acceptance issues should be outside the scope of this [draft] BTP.

Response
The PAWG does not agree with the *State of Illinois* views on this subject. In responding to this comment we first need to be reminded of the role of the “site” in the performance of an LLW disposal system. For all intents and purposes, the “site” of an LLW disposal facility consists of two features: (a) the disposal units themselves – in which the LLW is physically placed; and (b) the geosphere – being that portion of the land (and natural system), surrounding the disposal units, which provides for the long-term isolation of the wastes after the disposal units cease to perform their waste-containment function. In addition, we know that based on a waste form classification system, the Part 61 disposal concept also requires reliance on deep emplacement depths and other certain engineered (and natural) barriers, to reduce radiation exposures and further minimize the potential that individuals might inadvertently come into contact with the waste. Thus, because the “engineered” features will, at some point, no longer be relied on to ensure public health and safety, NRC’s regulations require that the site, by virtue of certain favorable physical characteristics, will need to provide for slower migration and/or greater retardation in radionuclide transport away from the disposal units to the accessible environment.

Having said this, it is not clear to the PAWG how the site-selection process for an LLW disposal facility can or could be separated from the need to understand how effective the geologic setting at the candidate site would be in containing and isolating LLW. By virtue of the technical criteria found at 10 CFR 61.50, developers need to site LLW disposal facilities in geologic settings that posses generally favorable physicochemical characteristics (e.g., Lutton *et al.,* 1982) so as to ensure compliance with the Subpart C performance objectives; engineering cannot compensate for a site with unfavorable or ineffective containment and waste isolation characteristics. In practical terms, the effect these requirements have on siting decisions is that following preliminary reconnaissance, if the LLW disposal facility developer cannot reasonably expect a candidate site to contribute (significantly) to meeting the performance objectives, then the site should be withdrawn from further consideration.

State of Nebraska
Department of Regulation and Licensing

Members of the Nebraska LLW Program Team have reviewed the Draft of NUREG-1573. The team wishes to congratulate you on the preparation of a well written and useful document.

The two comments generated for your consideration are listed below:

1. Page xvi, Unit Conversion Table, all the conversion factors are the reciprocal of the correct values with three exceptions. The two temperature conversions are correct and the conversion for acres to kilometers should be 1 acre = 0.004047 km^2.

Response
In response to this and other public comments, the PAWG has modified the *Unit Conversion Table* and adopted the one used by the USGS in its publications.

2. Page 3.75, Figure 14, this figure contains an unusual label [sic] "Fishing and Sports Gear." If this level of specificity was used uniformly throughout the diagram it may become too cluttered to be useful.

Response
The PAWG agrees with this comment. Figure 14 has been revised accordingly.

State of New Jersey
LLW Disposal Facility Siting Board

General Comment

In general, the draft BTP provides helpful guidance regarding the position of the NRC staff on several important technical issues associated with [LLW] performance assessment. We agree with the common-sense approach of the NRC to assessing the impact of ‘future site conditions, such as climate change, technological changes, and land-use changes. Also, we agree with the prescriptive approach to demonstrating compliance with the inadvertent intruder performance objective, rather than attempting to assess performance under hypothetical inadvertent intruder scenarios.

Response
This comment is noted. No specific modification of this technical report is called for in this comment.

Specific Comments

1. *Role of Engineered Barriers.*

The discussion on the role of engineered barriers is helpful and seems to reflect a reasonable approach, given the confines of Part 61, but we would appreciate additional more specific guidance. Since the NRC apparently evaluated various materials and designs to reach the conclusion that applicants may assume that engineered barriers can be relied upon for up to 500 years, we recommend that you make these evaluations public.

It would be very helpful to New Jersey, and perhaps other non-agreement states, to have the benefit of your specific knowledge in this area as we begin to design a disposal facility. A range of years for which the NRC expects various types of engineered barriers to function as designed, along with the technical information necessary for the applicant to successfully rely on the performance of the engineered barrier, would be of great assistance to potential license applicants and other members of the public.

Response
To provide a broad analytical base for the Part 61 regulation and its accompanying EIS, the NRC held four regional workshops during the early 1980s that provided state officials, industry representatives, waste generators, interest groups, and private citizens the opportunity to comment on NRC’s LLW regulatory decision-making.

As part of this process, the PAWG sought input from the public on what level of performance should be expected from engineered barriers. Engineered and other (natural) barriers[16] affect overall facility performance by limiting the influx of groundwater into waste disposal units and reducing the subsequent release of mobile radionuclides to the geosphere. However, over time, the barriers will physically degrade and, because the long timeframes of concern exceed conventional engineering experience,

[16] As shown in Figure 1 of this technical report, following the cover material, formed concrete is the principal “man-made” component of the engineered barrier system for an LLW disposal facility (see Otis, 1986). Other man-made components may include geomembranes, earthen materials, and asphaltic materials.

there is uncertainty regarding predicting their durability and thus defining their service (design) life.[17] Thus, when analyzing the performance of an LLW disposal facility, the question has been how much credit (i.e., what time limitation) should be attributed to their effectiveness? In addressing this question, we are reminded that for an LLW disposal facility, the engineered barriers serve two functions. First, they contain and isolate the waste over the time period of regulatory concern. Second, engineered barriers are expected to reduce the potential impact from inadvertent human intrusion by serving as a physical barrier between intruders and the waste.

Before convening the public workshops, the PAWG had not independently evaluated the performance of various engineered materials, particularly reinforced concrete, although it did rely on recommendations informally solicited from knowledgeable experts who, at the time, were providing technical assistance to PAWG members.[18] In providing these opinions it was noted that there are only about 150 years or so of modern service history with concrete, and few, if any, of these structures have had implied design lives of more than 50 years. By contrast, there are several man-made analogues, built during Roman times, that are still structurally intact today (Halstead, 1971).

In spite of this paradox, there appeared to be general agreement at the public workshops that 500 years seemed to be a reasonable performance period so long as the exposure (environmental) conditions that the concrete barriers were subjected to were not too severe (NRC, 1981a; pp. 25, 27). For the purposes of this NUREG, the design life for concrete barriers applies to its as-designed, in-situ hydraulic characteristics (i.e, its ability to shed groundwater away from the disposal vault). It is believed that this function could be achieved with using low-permeability concrete (Atkinson *et al.*, 1986), or by incorporating geomembranes (Koerner, 2000) and/or asphaltic materials (National Research Council, 1997) into the barrier design. [For these three examples, it is also believed that service lives on the order of about 10^3 years can be achieved (*Op cit.*)]. In addition, it is believed that credit for longer periods of time (greater than 10^3 years) for structural stability and chemical buffering effects of the concrete disposal vaults could also be allowed. However, at some point in time, the properties of the engineered system, under degraded function and condition, would be based on the properties of the durable constituent materials that remain. As noted in the PAWG's response to *CNS Technical Comment No. 2*, the PAWG's position is that the developer will need to provide adequate technical justification for the service life selected for the engineered barriers as part of the documentation process for the LLW performance assessment.

With regard to the question related to the PAWG's evaluation of performance of particular engineered barrier designs, some "generic" design concepts were considered and evaluated for the purposes of the 1981 DEIS (NUREG-0782), and the commenter is referred to that document for a description of those designs. In addition, the commenter should consult the transcripts for the November 1994 two-day public workshop on the NRC LLW test case, in which the PAWG described the basic engineered barrier design concept used in its analysis.[19] [Other references to consult would include the series of reports prepared by the U.S. Army Corps of Engineers/Waterways Experiment Station – by Bennett (and others) – now cited in Appendix C of this technical report.] Subsequent to the publication of the final Part 61 rule and final EIS (NRC, 1982), the NRC sponsored a number of applied research activities in the area of barrier material performance. In the area of concrete performance, for example, the PAWG was particularly interested developing approaches to the design and evaluation of concrete compositions with a 500-year service life (Clifton and Knab, 1989; Clifton *et al.*, 1995). On behalf of the NRC, the National Institute of Standards and Technology (NIST) has developed a computer program

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17 *Serviceability* is defined as the capability of a product, component, or construction to perform the functions for which it is designed and constructed (American Society for Testing and Materials, 1982).

18 Drs. R. Schulz/University of California (Berkely) and J.R. Clifton/National Institute of Science and Technology (Gaithersburg, Maryland).

19 A concrete vault with a multi-layer, low-permeability earthen cover (consisting of clay, sand, and gravel) to shed percolating groundwater away from the disposal facility.

that predicts the degradation of concrete with time. This computer program, entitled *4SIGHT* (Snyder and Clifton, 1995; and Snyder, 2000), conducts a performance assessment of LLW disposal facilities that use concrete in engineered barriers.[20] Schulz *et. al.* (1988) provides a literature review of the performance of various natural cover materials, and Schulz *et al.* (1997) provides the results of more than a decade of material cover testing, including unsaturated flow properties, at a humid site. For those technical assistance activities bearing results to date, and which have been published, the commenter is referred to the bibliography now found in Appendix D of this technical report.

Finally, in the context of a geologic repository for HLW at Yucca Mountain, the DOE has considered integrating reinforced concrete into its geologic repository design (see DOE, 1998). As a result, the DOE has also evaluated concrete performance-related issues. To the extent that results of DOE-sponsored work in this area have been published, they have also been cited in Appendix D.

2. Iterative Performance Assessment Approach.

We agree with the overall iterative performance assessment approach advocated in the [draft] BTP. We believe, however, that it is neither helpful nor necessary to use performance assessment to calculate dose before initial site characterization and facility design efforts are completed. If the exercise were strictly academic, there would be nothing technically wrong with the approach of coupling site characterization and facility design with performance assessment dose calculations. However, performance assessment is not a strictly academic exercise. We believe that any dose calculations performed prior to site characterization and facility design would be premature and counterproductive. Such calculations may bound the problem, but the proverbial ballpark thus created would be far too large to be useful.

We realize the intent is to iteratively reduce uncertainty by coupling the performance assessment to site characterization efforts, facility design, and development of waste acceptance criteria. However, performance assessment dose calculations are not necessary or useful to guide site characterization or facility design efforts. Site characterization is best guided by modeling potential pathways of contaminant transport using traditional modeling methods.

The initial site characterization data collection should be aimed at satisfying the requirements for designing an effective and defensible environmental monitoring system. The environmental data needed for this are more extensive than the environmental data needs for performance assessment, especially for highly engineered disposal facilities. Natural site characteristics are relied upon to safely isolate long-lived radionuclides long after the short-lived nuclides have decayed to safe levels and the engineered barriers are presumed to be physically degraded. It is very likely that simple analytical bounding calculations will be used to demonstrate that the maximum individual dose from the radioactivity remaining after presumed degradation of engineered barriers is less than the performance objective for individual dose. Facility design, on the other hand, is best guided by site-specific engineering calculations aimed at minimizing contact of water with waste.

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[20] It should be noted that the *4SIGHT* computer code is an analytical tool for evaluating the performance of concrete and its main output are estimates of hydraulic conductivity. Its applicability is not LLW-specific. The *4SIGHT* computer code could be integrated into an overall LLW performance assessment system code, or in the support of an LLW auxiliary analysis as part of a broader LLW performance assessment. It is not intended to serve as a stand-alone computer code for evaluating the total system performance of an LLW disposal facility.

We recommend, therefore that the performance assessment dose calculations begin with initial site characterization data and at least a preliminary disposal facility design. The process may still be iterative, but the results will have much greater meaning. Furthermore, the performance assessment results would then not be likely to require collecting additional data as to the flow characteristics of the site. Instead, performance assessment would be more likely to be iterative with respect to waste form performance data, waste acceptance criteria decision (such as inventory limits), and possible facility design modifications.

In our opinion, beginning performance assessment after initial site characterization and facility design would not compromise either site characterization or facility design technically. It would provide a far more productive use of both time and financial resources for license applicants, and would lead to license applications that would be easier to follow and evaluate, both for your agency and for other interested individuals and groups.

Response
The PAWG does not agree with the commenter that performance assessment dose calculations are not necessary or useful in guiding site characterization or facility design efforts. The iterative performance assessment approach described in this technical report provides a process for systematically bringing together major aspects of site characterization, facility design, and waste characterization into a defensible demonstration of disposal facility performance. Because the overall goal of the LLW performance assessment is to develop a supportable demonstration of compliance, an applicant only needs to undertake an analysis of sufficient depth to show that the performance objective has been met. Accordingly, the performance assessment can be used to direct data collection or facility design efforts toward those aspects that are key to demonstrating compliance. In this way, resources are optimized (as well as conserved) by focusing on the most important aspects of the facility performance and not in data collection and information-gathering activities that have little or no importance to the compliance demonstration.

Finally, the recommended approach set forth in this technical report describes a process that should build confidence in the performance assessment results because the reasons for modifying assumptions, models, and parameters are well-documented and supported by data and information from preceding site investigations. Finally, in this technical report, the PAWG has attempted to steer practioners away from the notion of collecting data and information solely for the purpose of increasing scientific knowledge about a particular site, as this can easily lead to an open-ended process with no clearly defined stopping point.

State of South Carolina
Department of Health and Environmental Control
Division of Radioactive Waste Management
Bureau of Land and Waste Management

Our office has reviewed the draft BTP, and provides the following comments.

1. The methodology presented in the [draft] BTP is not the appropriate methodology for demonstrating compliance of existing sites, such as the Barnwell (South Carolina) site, that received waste prior to the implementation of 10 CFR Part 61. However, some parts of the [draft] BTP may be appropriate in evaluating existing sites.

Response
The PAWG wishes to note that there is no provision in this technical report that it should be used to evaluate existing LLW disposal sites. That decision rests solely with the cognizant regulatory authorities in the affected Agreement States. As discussed in Section 1.8 of this document, the extent to which the Agreement States or other regulatory entities apply the recommendations contained in this NUREG to their respective programs is a matter for their consideration and decision. Nonetheless, the PAWG believes that this technical report serves an important and useful purpose in the area of LLW performance assessment and hopes that it assists both disposal facility developers and regulators as they implement their respective programs.

That being said, however, as a *validation exercise* and to the extent that resources permit, LLW disposal facility developers are free (and encouraged) to implement any or all aspects of this NUREG, as a way of confirming their earlier or current decisions regarding disposal facility performance.

2. The [draft] BTP should recognize that the performance assessments which have been prepared for new sites, and have been reviewed and received approval from Agreement States should not be reevaluated using the [draft] BTP. Reopening these approved performance assessments will needlessly prolong the development of new sites.

Response
As noted in the response above, any decision to implement any or all of the PAWG recommendations outlined in this NUREG with respect to existing, approved sites is the prerogative of the cognizant regulatory authorities in the affected Agreement States, not the NRC.

As regards the suggestion that the re-examination of approved performance assessments "...will needlessly prolong the development of new sites...," the PAWG takes issue with this suggestion. One of the major strengths of this technical report is the standardized and comprehensive approach, recommended by the PAWG regarding the conduct of an LLW performance assessment. In PAWG member's experience, the existence of such guidelines in regulatory contexts helps to keep the public debates focused (appropriately) on the acceptability of the technical conclusion rather the acceptability of the analytical approach.

3. The [draft] BTP does present a method for developing a technically defensible performance assessment; however, it is questionable whether it would be defensible in court.

Response

A LLW performance assessment is a type of PRA.[21] And as a technology, PRA has been in place for many decades, and lately, has enjoyed greater use and acceptance in both nuclear and non-nuclear applications (e.g., DOE *et al.*, 1992). In recognition of the growing use and acceptance of PRA in evaluating reliability engineering and system safety, the Commission issued a *Policy Statement* in 1995 on the use of PRA methods in its regulatory activities (see Appendix C). Today, PRA technology supports the Commission's risk-informed regulatory philosophy in several areas of the nuclear fuel cycle (PRA Working Group, 1994). While these applications have not been challenged in the courts, the PAWG recognizes that challenges may occur in adjudicating complex licensing issues. A strong technical basis assists in defending regulatory decisions. The PAWG recognizes the burden that must be undertaken in litigation to justifying the views and recommendations made when demonstrating compliance with Part 61. Finally, it is recognized that approaches other than those advocated in this technical report may be used to demonstrate compliance with Part 61.

[21] In PRA parlance, it is mainly a *Level 2* (analyzing container failure) and *Level 3* (analyzing release, transport, and dose) type of a PRA.

State of Texas
LLW Disposal Authority

General Comment

The staff of the Texas Low-Level Radioactive Waste Disposal Authority has reviewed the [draft] BTP. As with [earlier] drafts of the document, we find much with which we can agree and support. There is still one provision of the guidance with which we disagree and will take exception to in our use of this guidance document.

Before discussing specific observations and comments on the document, we would like to restate our position that the development of this guidance document fulfills a need that has existed in the LLW program for many years. During the last 15 years, all of the subjects in this [draft] BTP have been thoroughly discussed. Decisions have been made based upon formal and informal guidance received from the staff of the NRC, state regulators, and other individuals. This document incorporates many of these concepts and methodologies and its publication will be of assistance to all those who must conduct a performance assessment.

We appreciate the opportunity to comment on this [draft] BTP throughout its development, and we hope to see a complete and final NUREG document available in the near future.

Response
The comment is so noted. No specific modification of this technical report is called for in this comment.

Specific Comments

1. We strongly support the guidance presented in the [draft] BTP regarding the assumptions on the long-term conditions to be considered. We agree that speculation should be minimized and that only conditions which can reasonably be assumed to occur should be evaluated. This is critically important in the area of societal changes. If you do not assume that the land use and population distribution around the disposal site remain generally the same as they are today, it will be difficult to demonstrate that long-term population growth and land use pressures will not adversely affect site performance. Following in this same vein, the guidance document recommends that major changes in site conditions resulting from global climatic change need not be considered as long as reasonable and justifiable variations in site conditions are considered. A similar statement regarding the assumptions made on biological conditions surrounding the site is also made. We agree with both of these positions because they will eliminate needless speculation regarding changes in conditions which would be impossible to quantify in any defensible manner. The bounding of assumptions regarding future conditions is essential if we are to avoid being forced into an analysis of "what if" scenarios which will lead to proving that no site is suitable for disposal if certain assumptions are made in the modeling effort.

Response
The comment is so noted. No specific modification of this technical report is called for in this comment.

2. We are in agreement with the general methodology outlined in the guidance document. We interpret the methodology as a reinforcement of the long-standing guidance that simple models which yield realistic and conservative results are preferable. The performance assessment

process should be iterative so that only as much as is required to defensibly support the conclusion that the performance criteria will be met is done.

Response
The PAWG agrees with this comment. No specific modification of this technical report is called for in this comment.

3. The recommendation that an applicant should assume that engineered barriers have physically degraded 500 years after site closure is, in our opinion, one of the least conservative recommendations made in the [draft] BTP. Although not specifically stated, it seems to imply that one can depend on the performance of an engineered barrier for 500 years before having to assume a degraded condition. We can agree that the chemical buffering capacity can be depended upon for a significantly longer period of time. We have questions about whether the structural stability of a reinforced concrete structure will remain constant over 500 years. Depending upon the site conditions, it may be of no practical impact since the long-lived mobile radionuclides will remain significant for a period of time orders of magnitude longer than anyone could reasonably depend on a concrete structure. On the other hand, short-lived radionuclides which are received in much larger quantities can be eliminated from consideration by making assumptions regarding the life of a man-made barrier. Great care should be exercised when evaluating the service life of a man-made barrier, and these assumptions and the justifications for making them should be clearly documented and supported.

Response
See PAWG response to *State of New Jersey Specific Comment No. 1.*

4. The 10,000 year time period for analyzing performance seems to be a reasonable compromise between the 300 to 500 year period advocated by some and the calculation of dose from the peak concentration of each radionuclide. The [draft] BTP does a reasonable job of justifying the time period; however, we recommend that a discussion of the meaning of the results at 10,000 years be included. While not long in the sense of geologic time, a 10,000 year period is very long when compared to the recorded history of man. It is difficult to convince educated people who have some knowledge of the methods being employed in the assessment that there is meaning in the results of these types of analyses. It is also difficult to convince members of the general public that any events occurring over such periods of time can be analyzed. A key to acceptance must be an admission up front that the performance assessment is not a predictive tool, and that no one really expects that the exact values for concentration or dose calculated during performance assessment will be measurable at the future time and place determined by the evaluation. We believe that a longer discussion of performance assessment as a tool to be used along with professional judgment in the demonstration of reasonable assurance that the performance standard will be met should be included in the [draft] BTP.

Response
In its earlier response to *Commonwealth of Pennsylvania Specific Comment No. 6,* the PAWG has addressed the issue regarding the meaning of the performance assessment results at 10,000 years.

Next, the PAWG agrees that the performance assessments are not predictive tools. Nonetheless, the PAWG does believe that performance assessment results provide a quantitative means of demonstrating compliance with the regulation, taking into account uncertainties and limitations in the analysis itself. As noted in its earlier response to *Commonwealth of Massachusetts Specific Comment*

No. 3, Section 1.3 of this technical report has been modified to more clearly reflect this point.

Lastly, because of the importance of professional judgment in performance assessment decision-making activities, the staff agrees with the recommendation to expand the discussion of its use in the final version of this document. Specifically, the staff has now included some additional discussion regarding the use of *peer reviews, (formal) expert judgment,* and *model validation* in the LLW performance assessment process, in Section 2 ("Regulatory Framework") of this technical report. See the staff response to *Mel Silberberg and Associates Specific Comment No. 3* for a description of these additions.

5. The one issue with which we continue to disagree is the treatment of uncertainty and sensitivity. The Texas LLW Disposal Authority submitted in its application for a license a deterministic performance assessment where the final dose calculation is compared with the regulatory standard. We believed, and continue to believe, that this is the only way we can obtain a license in the current socio-political climate. The "probabilistic approach" described in the [draft] BTP is an invitation to failure. Our position on this issue should not be taken as disagreement with the scientific and mathematical principles employed in the suggested methodology. They are accepted and proven methods of analysis, and in a society where technical correctness was the only criterion for licensing, we could be very supportive of the concept. Our opposition to the use of this method derives from the suggested interpretation of the results.

   As we read this guidance, the NRC staff is proposing that once the analysis has been completed the resultant distribution of probable outcomes should be compared to the regulatory requirements in a two-step process. First, the mean of the distribution should be compared to the regulatory standard. Second, the 95th percent confidence value of the distribution should be less than 100 mrem. The results could then be interpreted as, "We are certain that under most conditions evaluated, the system would meet the criteria for dose contained in Part 61 and that we are 95 percent confident that under almost all but the most extreme and unlikely situations, the system would result in a dose that meets the general population standard of 100 mrem contained in other regulations." Unfortunately, this will be interpreted by the opposition as, "...on the average you think you will meet the standards and that there is a five percent chance that you will greatly exceed the standards....." Because this is just the type of comment which is being made regarding the results of our evaluation of other issues where probability has been considered, we cannot support the use of a probabilistic approach to performance assessment.

Responses

As regards the first portion of the *State of Texas* comment, the PAWG is sensitive to the issue being raised here but, nonetheless, disagrees with the observation here that use of the probabilistic approach is "...an invitation to failure...." Generally, there is wide recognition that there is considerable uncertainty in performance assessment analyses. Given this recognition, it is important that these uncertainties be openly addressed, to better understand their influence on the compliance demonstration. The probabilistic approach described in this technical report provides a way of quantifying these uncertainties, in an open and transparent manner, thus building confidence in the results. Through sensitivity analyses, the important aspects of the site performance can be clearly identified. Site investigation and data-gathering activities can then be directed at supporting these key assumptions and parameters. The PAWG believes that this (probabilistic) approach should provide a more transparent demonstration of compliance than currently achieved through deterministic methods.

The PAWG wishes to address one additional point with respect to the use of probabilistic methods. The Commission has concluded that probabilistic methods can be useful in regulating both nuclear and non-nuclear applications. In recognition of the growing use and acceptance of probabilistic methods, or PRA,in evaluating reliability engineering and system safety (e.g., DOE *et al.*, 1992), the Commission issued a *Policy Statement* in 1995 advocating the use of PRA methods in its regulatory activities (see

Appendix C). As a consequence, PRA technology supports the Commission's risk-informed regulatory philosophy in several areas of the nuclear fuel cycle today (PRA Working Group, 1994).

As regards the second portion of this comment, on the use of the mean, see the PAWG's response to *Commonwealth of Pennsylvania Specific Comment No. 8* on this subject.

6. Our final comment is one which probably cannot be totally addressed in the [draft] BTP. In the discussion of dose, it is clear that, in recommending the use of *Federal Guidance [Reports] 11 and 12* published by the EPA (see Eckerman *et al.,* 1988; and Eckerman and Ryman, 1993, respectively), the staff is recommending that dose be calculated as committed effective dose equivalent. This is consistent with the current dose standards set out in 10 CFR Part 20 and the equivalent State regulations in Texas. Since the dose standards set out in Part 61 have never been changed there is currently a difference in the regulations [that] is difficult to explain. It would be useful, we believe, for the staff to present a method [that it] would find acceptable for comparing the calculated doses based on the methods suggested in the [draft] BTP to the dose standards contained in Part 61.

Response
The PAWG is aware of the potential confusion in this area and has modified Section 3.3.7.1.2 of this technical report ("Internal Dosimetry") to clarify the PAWG's intent in this portion of the document. The following paragraph has been added to the end of the section.

> As a matter of policy, the Commission considers 0.25 mSv/year (25 mrem/year) TEDE as the appropriate dose limit to compare with the range of potential doses represented by the older limits that had whole body dose limits of 0.25 mSv/year (25 mrem/year) (NRC, 1999; 64 *FR* 8644, see Footnote 1). Since stochastic risks (e.g., cancer) are controlled by the TEDE dose limit, the role of an organ limit in the TEDE dosimetry system is to prevent non-stochastic effects to that organ. As noted in Appendix B of 10 CFR Part 20, consideration of non-stochastic effects is unnecessary at the dose levels established for members of the public, because the organ dose can never reach the organ limit for non-stochastic effects of 0.5 Sv/year (50 rem/year) without the TEDE dose being greater than the public dose limit. Therefore, when the applicant calculates the TEDE dose, the organ limits are ignored.

B-1.2 OTHER ORGANIZATIONS'/AGENCIES' COMMENTS

Chem-Nuclear Systems, Inc.

Overall Comments

1. The following are Chem-Nuclear System's (CNS') consolidated comments on the draft BTP, designated NUREG-1573. CNS' primary concern is the 10,000-year compliance timeframe. Credible predictions, far into the future, using guidelines recommended by the NRC staff, are not possible. While the analytical tools for the approach are certainly available, CNS does not think the data are available to apply the tools and endure public and technical review.

Response
See PAWG response to *Commonwealth of Pennsylvania Specific Comment No. 6.*

2. The [draft] BTP is being developed as guidance to assess [the performance of] potential new [disposal] site[s]. Another significant concern is the fact that the guidance is unclear and a number of the staff recommendations have not been justified. It is CNS' recommendation that the NRC should provide a demonstrable example of the use of the [draft] BTP approach including complete documentation as would be expected in a license application. This example could be used to verify' that the process can be implemented and be a guide for site developers.

Response
The results of NRC's so-called "LLW test case" were presented at a November 1994 two-day public workshop. The test case was an analysis undertaken by the PAWG of the performance a hypothetical LLW site and design to evaluate the implementability of the approaches being recommended in the draft NUREG. In the PAWG's view, the results of this test case do demonstrate that the approaches being recommended can be implemented – or "verified," using CNS' terminology. Although the PAWG was able to successfully complete the test case analyses, and demonstrate the implementability of the approaches recommended, because of resource constraints within the Agency, PAWG has not been able to complete the final test case documentation. It is unlikely the requested documentation will be completed before the finalization of this technical report.

As participants to the public workshop, CNS will recall that transcripts of the workshop were prepared, including discussions of the PAWG's test case presentation, and subsequently provided to all workshop participants. These transcripts are also available for inspection and/or copying in NRC's Public Document Room (PDR).[22] In general, the PAWG agrees with this *Overall Comment* that it have been useful to have the test case documentation published in parallel with the issuance of the draft technical report for public comment. Nonetheless, we are reminded the test case was generic in nature and was intended to illustrate **one approach** to implementing the PAWG's recommendations. The PAWG believes that rigid adherence to the specific concepts/steps proposed in this technical report is not sought so much as the use of a consistent process that produces an accurate and properly documented assessment. Moreover, the PAWG believes that effective implementation of a good LLW performance assessment cannot guarantee acceptance of the technical conclusions; however, use of a flawed process or improper implementation of a good process cannot help but cast serious doubt on the quality of the conclusions.

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[22] In addition to the meeting transcripts, preliminary results from the LLW test case have been presented by Cady and Thaggard (1994), Campbell (1994), Campbell and McCartin (1994), and Krupka and Serne (1998).

General Comments

1. There continues to be an emphasis on an iterative analysis beginning with simple generic models, progressing to more site-specific and detailed analyses, where these analyses continue as necessary to reduce uncertainty. Similarly, there is great emphasis on the uncertainty analysis; however, the specification showing how adequate uncertainty is attained is not provided. Formal "quantitative" uncertainty methodologies acceptable [to] the NRC need to be provided to support the staff's positions.

Response
The amount of information and level of analysis needed for treating uncertainty will vary from one facility to another because of significant differences among site characteristics, possible engineering designs, and radionuclide inventories. Therefore, it is necessary to allow flexibility in approaches for analyzing uncertainty. Section 3.3.2 of this technical report ("Uncertainty and Sensitivity Analysis") **does** discuss overall approaches that would be acceptable to NRC. However, if more detail is needed than that provided in this technical report regarding specific analysis methodologies, the commenter is referred to Appendix C.6 ("Uncertainty and Sensitivity Analyses") of NUREG-1498 – "A Review of NRC Staff Uses of Probabilistic Risk Assessment" (PRA Working Group, 1994). The reader can also refer to Zimmerman *et al.* (1990) for more information.

2. The [draft] BTP, in general, is devoid of specifics which provide information on how the NRC staff selected specific time periods. It is recommended that NRC provide an example (with numerical values) of a complete performance assessment performed with a generic inventory and design. By this example, NRC can show [its] expectation in a performance assessment [that] follows the recommendation of the [draft] BTP.

   The example should include the following key elements using realistic data which could be related to or could be obtained from the current literature. The example should include elements such as:

   - Prediction of water infiltration rates.
   - Example of assumptions which can be taken for the performance of waste containers and other features of the disposal technology.
   - Based on the current trends of waste generation, include a justification for differentiating between Class A, Class B, and Class C waste in the inventory projections.
   - Example of reasonable waste to leachate partitioning ratios resulting in radioactivity releases from waste.
   - Example showing how site-specific values are to be obtained so these values are used in a transport model which includes uncertainty and sensitivity analyses.
   - Dose calculations showing which dose pathway conversion factors could be used and how these factors adapt to uncertainty analyses. The example should include NRC acceptable boundary and receptor locations.

Response

The basic thrust of this comment is to repeat the request made in *CNS Overall Comment No. 2*, above, that the staff present an example (with specific numerical values) of a complete LLW performance assessment. As noted in the PAWG's earlier response, we cannot comply with this request at this time. However, as noted earlier, some of the requested information on the test case was already presented at NRC-sponsored workshops in 1994.

In addition, CNS is reminded that examples of parameters values or ranges of parameter values for key elements of an LLW performance assessment were published earlier in both the DEIS and FEIS for Part 61 [see NRC (1981 and 1982), respectively].

3. Also related to specifics, our general review shows that the NRC has provided what amounts to the opinion of staff without the benefit of providing the justification or staff analysis which led to these opinions. CNS believes these analyses are important because future licensees and agreement state regulators need to understand the basis of NRC's position. This kind of information will be most important during the licensing process and when intervenors are challenging the state regulator and the licensee. Therefore, CNS believes that some type of analysis should be provided and peer-reviewed before allowing the publication of the [draft] BTP to continue. Some of our specific examples are as follows:

   — The NRC staff recommends a time period of 10,000 years. There is no clear justification for the selection of this time period. Further, this time frame conflicts with the current waste classification table which is based on an analysis conducted with a time period of 500 years.

Responses

In response to the first portion of this comment – that the NRC staff has provided what amounts to an opinion without the benefit of providing justification or staff analysis in support of its recommended approaches – the PAWG does not agree, for several reasons. First, each of the PAWG views and recommendations **is supported** with an appropriate rationale that usually includes reference to some form of technical-basis document. Although the referenced technical-(basis) work is often NRC-sponsored research, the work itself is often performed by another independent Federal Agency or one of the pre-eminent National laboratories. A second source of information contributing to the formulation of the PAWG's views and recommendations is the staff's earlier work on the DEIS and FEIS for Part 61. CNS should note that the EIS development process, including the staff's approaches to the evaluation of potential environmental impacts, was available for earlier review and comment by the public. A third major source of information is the much-requested NRC LLW test case, the results of which were presented at an earlier public meeting. The final major source of information contributing to the formulation of the PAWG's views and recommendations was the (complementary) performance assessment expertise acquired by the some staff from its work in other radioactive waste management areas – specifically HLW and decommissioning. Although this work applies to regulatory contexts other than LLW, there are many common technical issues and analytical approaches among these risk assessment areas.

As regards the request that the PAWG, using this NUREG, present an example (with specific numerical values) of a complete LLW performance assessment performed with a generic inventory and design, the staff cannot comply with this request at this time. Again, see the PAWG response to *CNS Overall Comment No. 2,* above.

Finally, with respect to that portion of the comment related to the recommended 10,000-year period of regulatory interest, this issue was responded to by the PAWG in its response to *Commonwealth of Pennsylvania Specific Comment No. 6*. In addition, the PAWG wishes to note that a 10,000-year time period does not conflict with the way the waste classification table was derived. As noted in the background information to the DEIS and the proposed Part 61 rule, radionuclide concentrations in the waste classification tables are intended to ensure that the waste remaining in the disposal facility after 500 years will not pose significant hazards to inadvertent human intruders. Nonetheless, because the exposure would be expected to be temporary or of a short-term nature and limited to only a few individuals [see NRC (1982, Vol. 1)], the Commission has taken the position in its rule that allowable doses to inadvertent intruders can be (considerably) higher than the allowable dose to the general public. Compliance with the waste classification system was not intended as a means of providing demonstration of long-term protection of the general public. In the DEIS, the commenter should recall that an assessment of 10,000 years was used to evaluate potential long-term radiological impacts on the general public.

— The NRC staff recommends means of the distribution be less than the performance objective and the 95th percentile of the distribution be less than 1 millisievert (mSv). This recommendation has not been justified by the NRC staff. We have several related questions regarding this recommendation. First, what is the basis of the selection for 95th percentile of the distribution to be less than l mSv? Is it possible to demonstrate this standard deviation in a real license application?

Response
See PAWG response to *Commonwealth of Pennsylvania Specific Comment No. 8*

• In separate communications and in the [draft] BTP, we are aware that the NRC staff has made test case calculations. These test cases [calculations] have not been published so potential users of this methodology can review these findings. The review of the NRC [test case] methodology should be allowed to proceed before the [draft] BTP becomes official to help determine the feasibility of the NRC's approach for it is possible that not all test cases could be implemented in a practical manner.

Response
The PAWG does not agree with this recommendation. As noted in the response to *CNS' Overall Comment No. 2*, the test case was intended to illustrate **one approach** to implementing the proposed recommendations, and as a stand-alone technical product, it illustrates the staff's capability to both conduct and review LLW performance assessments. This being said, the PAWG had not intended to solicit public comment on it.

— Staff indicates that it may be necessary for performance assessments to be carried out beyond 10,000 years. However, the staff does not recommend regulatory compliance determination beyond 10,000 years. It is not clear why and for what reason this recommendation exists.

Response
See response to *Commonwealth of Pennsylvania Specific Comment No. 6.*

— To the extent possible, a licensee would like to follow the methodology used by the regulator in a license application. We make this statement because the implementation guidance, in the [draft] BTP, in its current form is not in sufficient detail to trace the methodology acceptable to the NRC. A good example of a generic calculation should help define the NRC's position.

Responses
The PAWG does not agree that there is insufficient detail in this technical report to trace the LLW performance assessment methodology acceptable to the staff. For example, Section 3.1 of the technical report describes the PAWG's views on an acceptable approach for demonstrating compliance with 10 CFR 61.41 of the regulation. To provide additional detail regarding how to implement the specific process steps described in Section 3.1 (and depicted in Figure 3), the PAWG presents NRC's *Performance Assessment Methodology* (PAM), as Section 3.3. Lastly, to the extent that there are policy questions related to the interpretation and/or implementation of NRC's regulation (as it relates to an LLW PAM itself), Section 3.2 was prepared as a means of providing yet additional PAWG views and recommendations to LLW disposal facility developers on certain technical and policy issues. The commenter is reminded that rigid adherence to the specific concepts/steps proposed in this technical report is not sought by the PAWG so much as the use of a consistent process that produces an accurate and properly documented assessment, as recommended in this document.

Finally, the PAWG cannot comply with the request to complete the test case documentation at this time. See the PAWG's response to *CNS Overall Comment No. 2.*

— Based on the [draft] BTP, the NRC now recommends the [LLW] performance assessment have [sic] a formal and systematic [sic] analysis to quantify the range [of uncertainty] in [the] performance assessment. This recommendation is sufficiently vague that the NRC needs to perform such an analysis on a "generic site," to show how the NRC believes such an [uncertainty] analysis should be conducted in support of the [draft] BTP. The example should use real data from existing literature to show the following:

(a) How the results could be related to compliance.

(b) Support NRC staff recommendations in the [draft] BTP with "realistic data."

(c) What level of detail quantification of uncertainty is adequate.

(d) How a complete and acceptable methodology works. Further, the methodology should be subjected to the same peer reviews expected for a site developer.

(e) An example of a probabilistic approach that might be reasonable to the current NRC staff.

The generic analysis should be like the "Final Environmental Impact Statement on 10 CFR Part 61" because staff recommendations made in the [draft] BTP do not show developers how to perform licensing calculations. Finally, without this supporting analysis, the [draft] BTP places an additional level of complexity on the process of performance assessment and specifies additional unclear requirements on site developers.

Response
This comment raises a number of issues but all of them are essentially tied to the basic request that NRC perform a generic analysis to demonstrate that its proposed LLW performance assessment methodology is implementable. As noted earlier, the PAWG believes that the proposed approach is implementable. See the PAWG's response to *CNS Overall Comment No. 2.*

Specific Comments

1. Page iii; Paragraph 1; Line 8(a). Change "an acceptable approach" to "a reasonable approach...."

Response
The PAWG does not agree with this recommendation. As noted in Section 1.7 of this technical report, the PAWG recommendations "...describe, and make available to the public and Agreement States, **methods that may be acceptable to the staff**, for implementing specific parts of the Commission's regulations, and to provide regulatory recommendations to regulated entities...." [emphasis added]

2. Page iii; "Abstract," Paragraph 2. What collective staff experiences? The fact is there has been only one successful use of performance assessment in Part 61 licensing practice in an environment. Success, in CNS' opinion, means that the method proposed has been successful and can be reasonably implemented under the current regulatory environment. In this regard, the NRC staff are overstating their experience.

Response
Within the Division of Waste Management there are many staff involved in the development and application of performance assessment (analytical) techniques to radioactive waste management issues. Although some of this expertise has been acquired outside of the LLW/Part 61 regulatory venue (e.g., in the HLW/Parts 60 and 63, and Decommissioning/Part 72 programs – see Eisenberg *et al.,* 1999), the PAWG believes that many of the issues and analytical approaches to performance assessment methodologies for LLW, HLW, and decommissioning share common technical issues, albeit in different regulatory contexts. The use of the phrase "collective staff experience" in the *Abstract* of the draft BTP was intended to acknowledge this ability and its judicious application to LLW. Thus, the PAWG does not agree with the *CNS'* opinion that NRC's experience in performance assessment is "overstated," as well as the value of this analytical technique to LLW decision-making. Nonetheless, to avoid further debate on this matter, the PAWG has deleted the term "collective" from the final version of this technical report.

3. Page xi; "Executive Summary," Section 1; Paragraph 1; Line 15. Change ‘‘acceptable modeling ... to "...reasonable modeling...." The statement appears as if NRC is dictating how modeling is to be conducted.

Response
The PAWG does not agree with the recommended change. See the PAWG's response to *CNS Specific Comment No. 1,* above.

4. Page xi; "Executive Summary," Section 2; Line 7. When is the "as necessary" satisfied?

Response
Use of the phrase "as necessary" in this portion of the text is intended to reflect the notion that owing to parameter and/or model uncertainty, simple (conservative) or bounding types of analyses may not be adequate and there may be the need to conduct certain analyses with more technical sophistication (i.e., to a greater level of detail). Because the propagation of uncertainty in LLW performance assessments can be quantified (statistically), the "as necessary" concept is satisfied when the uncertainty in the analysis is reduced to an acceptable level – that is to say the pertinent performance objectives have been met with the high (statistical) confidence needed to make the reasonable assurance determination.

5. Page xii; "Executive Summary," Section 3.1; Paragraph 1, Line 6. What is the "reference geologic setting?" Here is where a "generic" example or an "impact" methodology calculation could be useful.

Response
In conducting an LLW performance assessment, an important question to be addressed is what phenomena and components of the disposal system can and should be dealt with (quantitatively). In the technical literature, this problem is usually referred to as "scenario development" and the phenomena and components – the things to be modeled and their alternatives – are both the current and future conditions, processes, and events that comprise the disposal system [see Galson and Swift (1994; p. 1)]. The phrase "reference geologic setting" in this document refers to a set of reasonably anticipated natural conditions, processes, and events that should be represented in site conceptual models used in the LLW performance assessment. The emphasis of the analysis is thus to test the robustness of the disposal facility against a reasonable range of potential outcomes.

Because there are many diverse geologic/geomorphic settings in the United States (Bally and Palmer, 1989; and Graf, 1987) and thus potentially many different "scenarios," it is not clear how the development of a generic example (i.e., test case calculation) would be useful. What may be more useful is for the NRC staff to work with potential LLW disposal facility developers, on a site-by-site basis, as part of NRC's *Technical Assistance Program* to the States, if need be, to help them define their respective reference geologic settings.

6. Page xii; "Executive Summary," Section 3.1; Paragraph 2. Societal changes will probably determine the probability of a receptor encountering radioactivity from the disposal site.

Response
Although this statement is correct, the fundamental question to consider in any dose calculation is how and to what extent will lifestyles and habits of society change in the future, and to what extent will these changes affect the location of potential receptors? The view among most experts is that for time scales beyond decades, these changes cannot be predicted with any degree of reliability [see Buser (1997, p. 29)]. Thus, in developing this technical report, to avoid questionable speculation about the behavior of future human society, the PAWG has taken the position that "current conditions" are to apply when conducting the requisite dose calculations [see Section 3.3.7.2.1 – "(Dose) Pathway Identification"].

7. Page 1-3; "Introduction," Paragraph 1; Line 2. Why does Part 61 not allow water table discharge on site? If groundwater discharge is addressed in performance assessment and compliance is achieved, then why should this [criterion] exist? Must this [criterion] be shown to be achieved for [the] 10,000-year performance assessment period? If not, then how long?

Response
As stated in Section 61.50(a) of the regulation, the primary emphasis in disposal site suitability is long-term waste isolation. Discharge of groundwater within the disposal site, from the hydrogeologic unit used for disposal, could provide a rapid transport pathway to potential receptors. In choosing a disposal site, 10 CFR 61.7(a)(2) requires that site characteristics be considered in terms of the indefinite future and evaluated for at least a 500-year timeframe. However, as stated in Section 3.2.1.1 of this technical report ("Site Selection"), the PAWG recommends refraining from excessive speculation about the distant future when evaluating site suitability, and recommends limiting evaluations of the natural site's geologic

evolution to the next 10,000 years.

8. Page 1-5; "Introduction," Paragraph 3; Line 10. The statement, "...for an AGV facility... direct transport [radionuclides] in surface runoff can be significant." Why is this pathway allowed while water table discharge at surface is not?

Response
The PAWG's intent in this statement was to note that significant surface runoff from above-ground-vault-type facilities was neither desirable nor allowable. However, to avoid future confusion on this point, the PAWG has modified this technical report to say that "...surface runoff **could** be significant...."

9. Page 1-7; "Introduction," Paragraph 2. By statements made in this paragraph, it appears that NRC is going to allow performance assessment to restrict the concentrations/waste form of certain radionuclides on a site-specific basis. The implications are:

   (a) not all sites will allow same kinds of waste; and
   (b) concentrations of some radionuclides may need to be restricted so certain sites cannot accept these waste streams.

   These restrictions will affect current compacts for there is a potential for not all sites to be equal or equivalent in items of waste acceptance. Is this the intent of this paragraph'?

Response
Current NRC regulations in Part 61 effectively place limits on radionuclide concentrations/waste forms types by virtue of the respective performance objectives. In evaluating the performance of an LLW disposal facility, what the performance assessment needs to show is compliance with those performance objectives. In addition, because the analysis is system-based, the performance assessment can illustrate the contribution (and effectiveness) of the various engineered and natural barriers to radionuclide containment and waste isolation. Finally, maximum radionuclide concentrations/ waste form types permissible for a given LLW site and design can be "backed-out" of the performance assessment analysis based on radionuclide concentration levels that permit compliance with the performance objectives. The concept of developing site-specific inventory limits for controlling radionuclide releases was also part of the supporting analyses for Part 61, as presented in the DEIS and FEIS.

10. Page 1-12; "Introduction," Paragraph 4. Change "an acceptable approach ..." to "a reasonable approach...."

Response
The PAWG does not agree with the recommended change. See the PAWG's response to *CNS Specific Comment No. 1.*

11. Page 3-2; "Branch Technical Positions (With Discussion)," Figure 3. Where does the option of limiting radionuclide inventory fit into this flow chart? Limits on radionuclide inventory may change a disposal site's rating from "inadequate" to "satisfactory."

Response
In *Step No. 1* of Section 3.1, information on waste form characteristics and amounts would be factored into the initial description of the LLW disposal facility *system*. Later, in *Step No. 6*, following evaluation of compliance with the performance objective, if it is determined that there is non-compliance, the

analyst would proceed through *Step Nos. 7* through *9* , and in doing so, reduce the initial radionuclide inventory and repeat *Step Nos. 3* through *6*, and then re-evaluate compliance with the performance objectives. Through this iterative process, the analyst should be able to determine what the maximum allowable radionuclide inventory is for a particular site and design.

12. Page 3-10; "Branch Technical Positions (With Discussion)," Paragraph 4; Line 12. Performance assumed for engineered barriers, even in the long term, directly impacts conclusions about suitability of site characteristics. The amount of infiltration assumed can lead to [a] "bathtub" [effect] and discharge of water at the surface in an otherwise suitable site. This condition can occur when engineered barriers and drains are badly degraded.

Response
The PAWG agrees that engineered barriers and site characteristics need to be properly integrated into an overall "design concept" to ensure the long-term containment and isolation of wastes. The point this technical report is attempting to communicate is that engineered enhancements cannot be used to compensate for a site with unfavorable or ineffective containment and waste isolation characteristics (e.g., one that provides for fast radionuclide migration and/or little-to-none retardation in radionuclide transport). In other words, a candidate site should not be selected that does not meet the site suitability requirements set forth in 10 CFR 61.50 of the regulations. Engineered enhancements should not be used to overcome recognized deficiencies that would rule out a site from meeting the Part 61 performance objectives.

As regards the specific comment about the potential for the "bathtub effect," the PAWG believes that prudent measures should be taken to preclude this from occurring. For example, the installation of liners, at an arid site, might lead to the bathtub effect, should the cover fail. Specific requirements under 10 CFR 61.44, 61.51(a)(3), 61.51(a)(4), and 61.51(a)(6) of the Commission's regulations are intended to achieve long-term containment and isolation of wastes, and thereby obviate the need for continuing active maintenance after site closure. Thus, as a potential failure mode, the PAWG would expect LLW disposal facility developers to recognize and anticipate the potential for defective trench caps to occur and factor some level of redundancy into the design in recognition of this possible design basis event. In addition, Section 61.50(a)(5) requires that the disposal site must be generally well drained. In general, this would not be achieved for a site with impermeable soils, located in a humid environment.

13. Page 3-11; "Branch Technical Positions (with Discussion)," Technical Position 3.2.3. There appears to be no basis for this time frame/recommendation.

Response
See PAWG response to *Commonwealth of Pennsylvania Specific Comment No. 6.*

14. Page 3-13; "Branch Technical Positions (with Discussion)," Technical Position 3.2.3, Paragraph 3; Line 10. Change "...simulations confirm that..." to "...simulations tend to indicate...." Computer simulations do not confirm anything [for] which NRC has no data on.

Response
The PAWG has no objection to making the requested change but does not agree with the CNS' suggestion that the PAWG has no LLW performance assessment data. The commenter is referred to the PAWG response to the second *Overall CNS Comment* which talks about the status of NRC's LLW test case documentation. The commenter is also referred to NRC's previously published DEIS and FEIS, which contain data of the type previously requested by the commenter.

15. Page 3-14; "Branch Technical Positions (with Discussion)," Technical Position 3.2.3, Paragraphs 2 and 3; General Comment. The NRC staff is making recommendations that 10,000 years be used as the time period for analysis. It is not clear what happens if uranium inventory shows peak dose may potentially occur beyond 10,000 years. For example, what is the basis of judgment for compliance beyond 10,000 years should the peak dose [be] projected to be 50 millirem per year for a potential receptor?

Response
See PAWG response to *Commonwealth of Pennsylvania Specific Comment No. 6.*

16. Page 3-15; "Branch Technical Positions (with Discussion)," Technical Position 3.2.3, last line in the last paragraph; Where does this information come from?

Response
In this section of the document, the PAWG had intended to say that, based on past disposal practices, in general, we do not think there will be significant doses from long-lived radionuclides beyond 10,000 years. Nonetheless, the PAWG agrees with the commenter that there is not much documented (technical) support for this position, at this time. For this reason, the sentence in question has been deleted from the final version of this technical report.

17. Page 3-16; "Branch Technical Positions (with Discussion)," Technical Position 3.2.3, Paragraph 3; General Comment. The NRC is making general statements indicating there is no knowledge about what is governing releases of radioactivity. Much about what is most important is already known to the NRC and the insight gained is really not an accurate statement.

Response
Neither the technical issue in question (nor the NUREG, in general) states or implies that there is a lack of knowledge about the key (physicochemical) processes governing releases of radioactivity from a disposal facility. However, because of significant differences among site characteristics, possible engineering designs, and radionuclide inventories, site-specific sensitivity and uncertainty analyses are recommended to gain insights into the assumptions and parameters controlling the performance of a specific LLW disposal facility. It is the PAWG's view that LLW disposal facility developers should use these insights to optimize resources by focusing on supporting key design assumptions and parameters.

18. Page 3-16; "Branch Technical Positions (with Discussion)," Section 3.2.4.2, General Comment. This is a new approach toward performing performance assessment analysis. In description, the approach appears simple; however, the assignment of ranges and assignment distribution characteristics bring another level of complexity to the performance assessment approach. The data requirement for this approach to support the extent of formal uncertainty analysis is not clearly defined. Simply spoken, when does the [LLW] performance assessment analysis end?

Response
The goal of the LLW performance assessment and the focus of the approach described in this technical report are to demonstrate compliance with the performance objectives set forth in NRC's regulations. The PAWG believes that LLW disposal facility developers will need to explain how uncertainties (in both engineered and natural systems) propagate through the overall analysis and how they subsequently

affect the compliance demonstration.

The PAWG believes that Section 3.1 of this technical report ("Example of an Acceptable Approach for Demonstrating Compliance with 10 CFR 61.41") describes a process that systematically brings together the types of information and analyses needed for adequately assessing disposal facility performance. In addition, because of its iterative nature, the PAWG believes this proposed process helps the LLW disposal facility developer to identify important parameter (data) needs and modeling assumptions critical to this assessment. Consistent with its risk-informed, performance-based regulatory philosophy, the PAWG believes that the required resources and technical effort necessary to achieve this understanding can be channeled into those areas where the uncertainty affecting performance is greatest, as opposed to a potentially open-ended program of site characterization, engineering design, and waste classification with poorly defined goals.

In practice, the PAWG believes that the approach outlined in Section 3.1 of this technical report (and depicted in Figure 3) should result in a supportable demonstration of compliance with 10 CFR 61.41. *Step No. 6* of the process is the logical ending point for the required assessment; specifically, having performed the necessary sensitivity analyses (*Step No. 5*),[23] if the analysis shows that the performance objective will be met, then no additional data would be needed and the analysis can be documented and submitted for review. On the other hand, if the analysis shows that the performance objective will not be met, then the LLW disposal facility developer would proceed to *Step Nos. 7* through *9*, and collect more data or perform additional analyses. In summary, the LLW disposal facility developer would need to iterate, through the process described, as many times as necessary, to show that the performance objective has been met.

19. Page 3-18; "Branch Technical Positions (with Discussion)," Section 3.2.4.3, Paragraph 1; Last Sentence. What is the basis of this recommendation? Where is the proof that this recommendation is achievable?

Response
See PAWG response to *CNS' General Comment No. 3*.

20. Page 3-44; "Branch Technical Positions (with Discussion)," Section 3.3.5.2.2. Change "The following are acceptable screening approaches ..." to "The following are reasonable screening approaches...."

Response
The PAWG does not agree with this recommendation. See the PAWG's response to *Commonwealth of Pennsylvania Specific Comment No. 6.*

21. Page 3-49; "Branch Technical Positions (with Discussion)," Section 3.3.5.4.2. Paragraph 1; Line 7. We believe that NRC-approved topical reports will not be used in the future; therefore, this option may not be available.

Response
At the present time, this comment correctly notes that the staff is not considering and reviewing Topical Reports. Nonetheless, the PAWG believes that this option should still be left open should

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[23] And assuming that the uncertainties are acceptable and that no more can be done to reduce them.

circumstances change in the future. However, to address the concern raised here, the PAWG has modified this portion of this technical report to read as follows:

> "...(a) an NRC-approved topical report[14] or other technical basis document that has undergone an independent peer review subject to the guidance set forth in Altman *et al.* (1988)...."

22. Page 3-52; Paragraph 5; Line 1. Change "The following technical approaches are acceptable..." to "The following technical approaches are reasonable...."

Response
The PAWG does not agree with this recommendation. See the PAWG's response to *Commonwealth of Pennsylvania Specific Comment No. 6.*

23. Page 3-52; Section 3.3.5.6.2 – "Recommended Approach" (on solubility). Given the impossibility of predicting the chemical conditions in a disposal unit 10,000 years in the future, the rinse-release model seems to be the only acceptable approach.

Response
As potential licensees, the PAWG believes that LLW disposal facility developers should have flexibility in deciding how chemical conditions within disposal units are treated in the analysis. Solubility limits, retardation coefficients, and corrosion rates used in the performance assessment will have to be justified in consideration of the length of time that the specific conditions are expected to occur. If chemical conditions within disposal units are not expected to remain constant throughout the time period of regulatory concern, it may be possible to select different parameter values to represent the transient chemical conditions during the various phases (periods) of the disposal unit's service life.

24. Page 3-53; Paragraph 1. This option may not be cost-effective. Field lysimeter investigations generally take many years to produce results.

Response
The PAWG agrees that the use of field lysimeters can be expensive and could require several years of operation to acquire representative site data. However, reliance on backfill materials or chemical barriers to retard the release of radionuclides is still considered to be a viable design option to control the release of radionuclides from the disposal system. The use of field lysimeters is only one approach that can be used to provide an appropriate justification for this particular design option. As noted in this technical report, another approach that could be used is to determine the distribution coefficients through laboratory studies. However, lysimeters are ideal because they allow the waste system to be evaluated under actual environmental (in-situ) conditions.

25. Page 3-57; "Branch Technical Positions (with Discussion)," Section 3.3.6.1.1 – "Considerations on Transport." The combination of the 10,000 year time frame with the requirement to "consider... at all potential points down-gradient..." results in placing a well directly in the waste to maximize dose. For most locations, this will result in unacceptable doses. Additionally, the analyst is faced with predicting water well screen length and pumping rates at 10,000 years.

Responses
As noted in Section 3.3.6.1of this technical report ("Groundwater"), the intent of the ground-water flow and transport analysis is to access radionuclide concentrations (i.e., dose) at likely receptor locations

within some reference biosphere that encompasses the LLW disposal facility and its environs. Difficulties in forecasting the characteristics of future society, especially those influencing exposure, though, will lead to large uncertainties in the estimates of who will be exposed, by how much, where, and when. To avoid unbounded speculation about future human lifestyles and habits caused by the uncertainty in predicting future human behavior, the PAWG has assumed that the reference biosphere for a performance assessment is constant over the time period of regulatory concern. That is to say by relying on **cautious but reasonable assumptions**, the critical group used in the LLW performance assessment would be defined using **present knowledge** about the LLW disposal site. In defining the characteristics of such a group, the PAWG's view is that it would be a community comparable to that found in and around the location of the LLW disposal facility today. This assumption is consistent with prevailing national and international opinion and practice (e.g., ICRP, 1990; and National Research Council, 1995).

As regards the comment that the performance assessment analyst is faced with the problem of predicting well depths, well screen locations and lengths, pumping rates and volumes, etc., when defining pumping scenarios at the receptor locations, consistent with the aforementioned philosophy, the PAWG believes that the needed information can be determined based on present knowledge in an area for which an LLW disposal facility may be sited. Likely sources of this information would include State geologic surveys, State or local municipal engineers offices, local well drilling contractors and/or engineering firms, and interviews with local residents. Regardless of which of these sources or approaches are used, the LLW disposal facility developer needs to document the basis for his or her decision-making.

Finally, if, as this comment suggests, the doses calculated using this overall approach are found to be too high (i.e., they exceed the regulation), then the LLW disposal facility developer has several choices. To name a few, they would include: (a) re-examining the LLW inventory and re-evaluating whether more can be done to stabilize the waste form itself; (b) determining what enhancements can be made to the engineered barrier design to provide additional radionuclide containment and waste isolation; (c) re-examining the assumptions underpinning the dose calculation itself – the characteristics of the well and pumping scenarios, dosimetry models, ingestion pathways, and the like; or (d) siting the disposal facility in a more favorable geologic setting – one that provides slower migration and/or greater retardation in radionuclide transport.

26. Why is the NRC attempting to produce another BTP on performance assessment when, in fact, the current-old existing disposal sites have not been subjected to compliance-related issues due to dose to a real receptor? Experiences gained by existing sites show:

    (a) Practical improvements have reduced [the] quantity of radioactivity released from existing sites;
    (b) Areas around these sites can be managed effectively to estimate real dose to a receptor; and
    (c) Adding yet another level of complexity does not contribute to the success of complexity or [a] reasonable performance assessment.

Responses
The PAWG does not share CNS' optimism regarding the operating record of older or existing LLW disposal sites. At best, the LLW disposal site development process record in the U.S. is mixed because earlier problems in the siting, design, and/or performance of these facilities. Rather than address any of the specific short-comings that can be found in this earlier history, the PAWG will simply note that one of the principal motivations behind the development of this NUREG was to make the LLW disposal facility development process more effective in the future.

Finally, contrary to what is stated in this comment, there are no other NRC guidance documents, in the form of technical positions, on LLW performance assessment methodology. The commenter is referred to the *Foreword* of this NUREG for a discussion of the history of its development.

Enviocare of Utah

> Enviocare has reviewed the above-referenced document and considers it to be a thoughtful and complete treatment of the matters addressed. The guidance it provides will be useful to licensees, and we appreciate the NRC's efforts in this area.

Response
The comment is so noted. No specific modification of the technical report is called for in this comment.

Golder Associates, Inc.

Overall Comments

At the most general level, Golder Associates believes that the draft BTP represents a major step forward in terms of setting out clear, rational expectations for what will be required to demonstrate the long-term safety of a disposal facility. Golder Associates notes that the proposed approach is quite similar to that currently envisioned for high-level waste (HLW) disposal, and concur that there is no valid underlying rationale to hold LLW facilities to a lower standard of safety than those for HLW. For short-lived [radioactive] wastes the proposed approach will not be onerous. However, for longer-lived wastes, it will provide a fundamental challenge to many of this country's basic assumptions regarding site suitability and facility design.

Golder Associates also notes that the NRC staff expect, appropriately, to require applicants to provide a high level of scientific justification of any assumptions regarding the long-term behavior of a facility, and that they clearly reject some 'traditional' assumptions, such as a limited time-frame for compliance, and simplistic release calculations.

Notwithstanding our overall positive reaction, there are some aspects of the [draft] BTP with which Golder Associates do not fully concur or otherwise wish to comment on, and which we will address briefly below. We have also attached a list of specific editorial comments on the draft text.

General Comments

1. The 10,000 Year Time Frame. The [draft] BTP remains quite unclear on exactly what it is recommending, other than that compliance should be demonstrated for at least 10,000 years. In our opinion, if the assumed reference case, based on current environmental processes, showed compliance at 10,000 years and significant non-compliance at a later time, it would violate NRC's public credibility to issue a license, and in fact the Commission would not do so. The [draft] BTP should take a stronger position in this regard.

Response
See response to *Commonwealth of Pennsylvania Specific Comment No. 6.*

2. *The Basis of Dose Calculations.* The [draft] BTP recommends using a conventional TEDE calculation for comparison to the Part 6l Standard. However, the standard explicitly calls for a different, older methodology (ICRP 2 – ICRP, 1959). It won't do an applicant much good to argue that the NRC staff recommended one method when faced with an intervenor at a judicial hearing. At a minimum, if a TEDE approach is still recommended, the [draft] BTP should provide quite direct guidance on whether and how to do the calculations for compliance with the regulatory limits on doses to organs.

Response
As noted in *State of Texas Specific Comment No. 6*, a paragraph has been added to Section 3.3.7.1.2 of this technical report ("Internal Dosimetry") to clarify what the appropriate dose limit is when demonstrating compliance with Section 61.41.

3. *Conservatism.* A facility designer has to follow two essentially parallel paths in evaluating the

safety of a proposed facility. If it is to be licensed, it should be demonstrably safe using simple, conservative calculations. However, if its performance is to be optimized to the best of the designer's ability, he or she must use true, best-estimate probability distributions for the input parameters and processes. The [draft] BTP presents a valid iterative process to develop a licensable facility, but it should acknowledge that during the processes of site selection, site characterization, and design, the developer should be seeking the best possible understanding of how the facility will perform, not just making simple, conservative assumptions.

Response

The PAWG agrees with this comment and believes that Section 1.3 of this technical report ("What is LLW Performance Assessment") does make the point that through the performance assessment process, "...the developer should be seeking the best possible understanding of how the facility will perform...," but does so using more words. (Also see the PAWG response *to Commonwealth of Pennsylvania Specific Comment No. 12.*)

4. *Alternative Conceptual Models.* In our experience, we have never run into a case where there were alternative, equally-credible models for a significant performance assessment process. However, we have frequently encountered alternative, equally-incredible numerical models, where we knew that none of the models was more than a rough approximation of reality. This raises the critically important issue of evaluating model uncertainty and somehow incorporating it into probabilistic performance assessment calculations. This is a major shortcoming of most performance assessment exercises, both probabilistic and deterministic, which often end up as lengthy, expensive exercises to establish the correct inputs to demonstrably incorrect models!

Responses

The PAWG agrees with *Golder Associates'* concern about the importance of appropriately assigning a mathematical model to represent the conceptual model developed for a site. However, the PAWG find it hard to believe the comment that equally credible, alternative conceptual models cannot generally be developed for a particular site. Given limitations in available site data, ambiguities in interpreting site features, and inadequacies in understanding physicochemical processes, it is possible (perhaps even likely) that a site could be conceptualized in more than one way. Because of broad differences at the process level, each of these (alternate) conceptual models could then be abstracted with a unique mathematical model. To the extent there is uncertainty in the development in any aspect of this "hierarchy of models," consistent with this recommendation, it should be acknowledged and accounted for in the sensitivity and uncertainty analysis so as to understand what effect, if any, it has on compliance with the performance objective.

5. *The Critical Group.* To our knowledge, there is still no credible prescription for identifying a critical group. It seems incongruous to assume that a population 5000 or more years in the future would magically restrict themselves to drilling their wells outside of the periphery of the former disposal site. At the same time, it seems unreasonably harsh to assume they would emplace their wells directly within the wastes. Some no-nonsense regulatory guidance on this issue would be most helpful.

   The [draft] BTP's discussions about using current conditions as a basis for future projections, and its discussion on page 3-70 about "the targeted critical group", almost sound as if the staff recommend literally using the current population to define the affected group. Is this in fact intended? What if a disposal facility currently had no residents nearby? The discussion on page 3-58 implies that the critical group should be based on a drinking water well at the worst location on the former site boundary.

Response
As regards the first portion of this comment, the PAWG agrees that there are no justifiable methods or procedures for forecasting human habits or lifestyles in the future (i.e., the very long term). For this reason, the PAWG subscribes to the recommendations (and guidance) of the ICRP on how to define a critical group for the requisite dose calculations in a performance assessment.

The ICRP is an international standard-setting body that provides general guidance on the widespread use of radiation sources caused by developments in the field of nuclear energy. In one of its guidance documents, ICRP 46 – "Radiation Protection Principles for the Disposal of Solid Radioactive Waste,"[24] the following is noted concerning the definition of a critical group:

> The critical group should be representative of those individuals in the population expected to receive the higher dose equivalent, and should be relatively homogenous with respect to the location, habits, and metabolic characteristics that affect the doses received. It may comprise existing persons, or a future group of persons who will be exposed at a higher level than the general population. When the actual group cannot be defined, a hypothetical group or representative individual should be considered who, due to location and time, would receive the greatest dose. The habits and characteristics of the group should be based [on] present knowledge using cautious, but reasonable, assumptions. For example, the critical group could be a group of people who might live in an area near a LLW disposal facility and whose water would be obtained from a nearby underground aquifer. Because the actual doses in the entire population will constitute a distribution for which the critical group represents the extreme, this procedure is intended to ensure that no individual doses are unacceptably high. (ICRP, 1985; paragraph 46, p. 9)

In practical terms, what ICRP 46 says is that there are difficulties in forecasting the characteristics of future society, especially those influencing exposure, that will lead to large uncertainties and unbounded speculation in the estimates of who will be exposed, by how much, where, and when. To overcome these uncertainties, the PAWG interprets ICRP 46 to mean that we are to assumed that the reference biosphere for an LLW performance assessment is to remain constant over the time period of regulatory concern. Relying on **cautious but reasonable assumptions**, the lifestyles and habits of the critical group used in the performance assessment would be defined using **present knowledge** about the LLW disposal site.[25]

In defining the characteristics of such a group, the PAWG's view is that it would be a community comparable to that found in and around the location of the LLW disposal facility today, as suggested in this comment. Consistent with this interpretation, the PAWG believes that the needed information can be determined based on present knowledge in an area for which an LLW disposal facility is to be sited. Information on population, land use, agricultural activity, ground-water availability, water-use practices, and the like can be obtained from census statistics, geologic surveys, State or local municipal engineers' offices, and interviews with local residents. Consistent with the overall transparency and traceability theme in this NUREG, the LLW disposal facility developer needs to document the technical basis for his or her decision-making regarding how the critical group was defined.

If, as this comment notes, the doses calculated using this overall approach, at a water well, are found to be too high, then the LLW disposal facility developer has several choices. To name a few, they would include: (a) re-examining the LLW inventory and re-evaluating whether more can be done to stabilize the

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[24] The NRC staff contributed to ICRP 46.

[25] The reader is also referred to International Atomic Energy Agency (1996) for additional discussion.

waste itself; (b) determining what enhancements can be made to the engineered barrier design to provide additional radionuclide containment and waste isolation; (c) re-examining the assumptions underpinning the dose calculation itself – the characteristics of the well and pumping scenarios, dosimetry models, ingestion pathways; or (d) siting the disposal facility in a more favorable geologic setting – one that provides slower migration and/or greater retardation in radionuclide transport.

Finally, with respect to the portion of this question concerning how the critical group approach would be implemented if there were no residents near a candidate disposal site, the PAWG expects that the LLW disposal facility developer would identify some analog site, of comparable geology and climate, and define the critical group in terms of the analogue site. Again**,** the LLW disposal facility developer needs to document the technical basis for his or her decision-making – regarding how both the analogue site was selected and the critical group subsequently defined.

6. *The Regulatory Process.* The huge costs and long time-frames required for waste-disposal programs have led to the evolution of a new paradigm for the Regulator's role, which is now being experimented with in the North Carolina program. Essentially, it involves the Regulator in the iterative process discussed in the [draft] BTP, providing real-time feedback to the Developer, as opposed to waiting until the end to criticize the entire process. This has been tried in earlier projects, and failed, because the Regulator's staff were unable or unwilling to subsequently stand by the agreements reached during the siting/characterization process. It would be valuable if the [draft] BTP discussed the role that a Regulatory agency could/should play in the process. After all the goal of both sides should be the same, to proceed efficiently to develop a safe, publicly-acceptable disposal facility.

Response
The PAWG is sensitive to the concern being raised in this comment. However, the PAWG believes that it would be inappropriate for it to tell other regulators how they should conduct themselves with potential licensees. Nonetheless, in its own interactions with potential licensees, NRC's staff is sensitive to the impact of regulation on the various waste management programs, and has consequently relied on informal, pre-licensing consultations as a way of avoiding imprudent program expenditures and delays, particularly in areas with long lead-time procurement actions. This approach attempts to reduce the number of, and to better define, issues that could be potentially litigated, by obtaining input and striving for consensus from the technical community, interested parties, or other targeted groups, on such matters.

In this regard, the PAWG has undertaken the development of this NUREG as a means for closure on acceptable procedures for conducting a performance assessment used to support demonstration of compliance with NRC's LLW disposal regulations. The PAWG believes that rigid adherence to the specific concepts/steps proposed in this technical report is not sought so much as the use of a consistent process that produces an accurate and properly documented assessment. Moreover, the PAWG believes that effective implementation of a good LLW performance assessment cannot guarantee acceptance of the technical conclusions; however, use of a flawed process or improper implementation of a good process cannot help but cast serious doubt on the quality of the conclusions.

7. *The Part 61 Regulation.* In fact, the NRC should seriously consider updating of the regulation (perhaps subsequent to EPA's 40 CFR Part 191 replacement, if it is ever promulgated):

   — The Part 61 dose standard is antiquated;

   — A risk-based standard would be better in any case, as it appears highly likely that dose-to-risk conversion factors will change significantly in the next few years. A risk-based standard would not need to be updated in such an event, although staff guidance would need to be updated;

— The siting guidelines are based on unstated assumptions that an above-grade or near-surface facility will be employed. Some of these guidelines would actually be counter-productive for a deeper, higher-performance facility, such as may be required in order to meet the [draft] BTP's expectations.

Responses
Although no specific request has been made to modify this technical report, in response to this comment, the PAWG wishes to note the following:

- To the extent that *Golder Associates* believes that NRC's Part 61is "antiquated" and in the need of modification and/or revision, the staff will inform the Commission of its views.

- As regards the comment concerning the dose-to-risk conversion factors, it should be noted that the Commission prefers a standard stated in terms of annual dose to ensure consistency among all its regulations. Necessary revisions to those other regulations (including Part 61) will be evaluated when there is a rulemaking to change the dosimetry system described in Part 20.

- With respect to that portion of the comment concerning the Part 61 siting guidelines, the siting guidelines found in 10 CFR 61.50 are not predicated on "unstated assumptions" that an above-grade or near-surface facility will be employed; both Part 61 and the LLW EIS explicitly acknowledge that LLW disposal facilities would be located above-grade or near-surface (e.g., generally less than 30 meters below the ground surface). The PAWG agrees that the guidelines are not intended to apply to deeper, higher-performance types of facilities such as the kind that may be needed for the disposal of HLW.

Detailed Comments

The following comments refer to specific text locations where we have comments.

1. Page xii:, Half lives: the values [reported] are not quite correct; [they] should be 5730 years, 213,000 years, and 1,5700,000 years.

Response
In the draft BTP, the PAWG had originally rounded-off the half-lives of the radionuclides in question – ^{14}C, ^{99}Tc, and ^{129}I. However, in the interest of maintaining scientific accuracy, the PAWG agrees to revise this technical report as requested.

2. Page xiv:, The deterministic, conservative approach typically requires not just a single bounding estimate, but a separate estimate for each of a number of scenarios, demonstrating compliance for all cases. [This comment] also applies to Page 3-17.

Response
The PAWG agrees that for a deterministic assessment, there could be any number of plausible scenarios potentially considered and presumably a different analysis would be needed to evaluate the consequences of each. However, consideration of alternative future system states, related to human behavior, could be quite speculative with no single scientifically or technically defensible answer. To avoid unbounded speculation in this area (as well as the potential for multiple outcomes), as noted in its

earlier responses to the *Commonwealth of Pennsylvania General Comment* and *Golder Associates' General Comment No. 5*, the PAWG recommends the use of the average member of the critical group be used to define the exposure scenario for the analysis using present knowledge about the LLW disposal site. By relying on the use of cautious but reasonable assumptions, the PAWG believes that the average member of the critical group selected should represent the most likely exposure scenario for the analysis. The PAWG also believes that this provides a reasonable approach to selecting the scenarios considered in the analysis – regardless of whether the analysis is deterministic or probabilistic. (Later in the appendix, the PAWG provides more commentary on this issue in its responses to *DOE Specific Comment No. 3.)*

3. Page 1-2, Paragraph 3, the terminology presumes a near-surface disposal facility.

Response
This observation is correct. Most or all LLW disposal facilities are expected to be at or near the surface.

4. Page 1-5, Paragraph 1, looks like it should read "... large amounts of carbon-14 (^{14}C) or tritium (^{3}H) as gaseous species (e.g. ...) generally can occur only in the presence of infiltrating water)...."

Response
The PAWG agrees with this comment and has revised this technical report as recommended.

5. Page 1-6, Paragraph 1, the definition of the critical group as "...the group of individuals..." implies some knowledge of the actual population in the region. This is appropriate for an existing facility, but not so for one thousands of years in the future.

Response
The PAWG does not agree with this comment regarding the inappropriateness of the critical group approach. See the PAWG's earlier response to *Commonwealth of Pennsylvania's Specific Comment No. 5.*

6. Page 1-13, Footnote No. 6. This looks pretty ominous... what is implied here?

Response
Under NRC's regulations, LLW disposal facility developers must meet the waste form classification criteria found at 10 CFR 61.55 of the Commission's regulation. These criteria are intended to ensure that the general population, workers, and inadvertent intruders would be protected from exposures. In the specific case of inadvertent human intrusion, no separate consequence analysis is required by the applicant so long as the criteria found at 10 CFR 61.55 are met.

This footnote alerts disposal facility developers to the fact that if the LLW waste spectra envisioned for a particular facility do not meet the criteria found at 10 CFR 61.55, then it will be incumbent on the developer to perform a separate human intrusion consequence analysis to ensure that Part 61, Subpart C's performance objectives are met. Should there be the need for some future guidance on how to perform such an analysis, the PAWG has added the following statement to the footnote in question:

> "...To the extent that there may be a need for guidance on how to perform an intruder consequence analysis at an LLW disposal facility, disposal facility developers and/or other regulatory entities should consult NRC's DEIS on Part 61 (NRC, 1981)...."

7. Page 1-15, Paragraph 3. We strongly concur, and hope that the regulators are able to participate in such a process without compromising their objectivity. This might be indicated on Figure 3 [Technical Position 3.1: Detail to the "Example of an Acceptable process for Demonstrating Compliance with 10 CFR 61.41"], if appropriate.

Response

As noted in the response to *Golder Associates' General Comment No. 6*, the PAWG believes one of the tenants of good and effective regulation is to interact early and frequently with potential licensees. With this philosophy in mind, the NRC staff (or any other State regulatory authority) would, at the request of potential licensees, interact on any or all of the LLW performance assessment process steps described in Figure 3.

8. Page 3-13, Paragraph 2, Insert "Many" in front.

Response

The PAWG agrees with this comment and has revised this technical report as recommended.

9. Page 3-15, Main Paragraph, last 7 lines: confusing...

Response

There are basically three sources of uncertainty in evaluating the performance of a radioactive waste disposal facility (Bonano and Apostolakis, *1990; p. 106) – future system state uncertainty, data and parameter uncertainty, and model* uncertainty. In this portion of the technical report (Section 3.2.4 – "Treatment of Sensitivity and Uncertainty in LLW Performance Assessment"), the PAWG has attempted to describe how to treat parameter (and data) uncertainty and model uncertainty, and explain how they would be accounted for in an LLW performance assessment of the type envisioned by this document. As noted in the PAWG's response to *DOE Specific Comment No. 3,* found later in this appendix*,* compliance with the siting guidelines found at 10 CFR 61.50 of the regulation, in effect, obviate the need for disposal facility developers to consider scenario uncertainty for these requirements, and thus oblige disposal facility developers to site LLW disposal facilities in geologic (geomorphic) settings that: (a) have essentially been quiescent for the last 10,000 years; and (b) are geologically easy to interpret, thereby eliminating the potential for multiple geologic interpretations (a major source of scenario uncertainty).

To address the potential for further confusion in this area and improve the readability of this technical report, the narrative in this section of this technical report has been subdivided into three paragraphs, with what is now the first paragraph re-written as follows (see bold type):

> The objective of the LLW performance assessment is to quantitatively estimate disposal system performance for comparison with the performance objective in 10 CFR 61.41. Uncertainty is inherent in all LLW performance assessment calculations and regulatory decision-makers need to consider how uncertainties within the analysis translate into uncertainty in estimates of performance. **Uncertainty denotes imprecision in the analysts' knowledge (or available information) about the input parameters to the models, the models themselves, or the outputs from such models. Uncertainties come from a variety of sources, some of which, given the present state of the art, cannot be quantified at this time, although there are methods for addressing them in an LLW performance assessment (as discussed below). To understand their influence on the compliance demonstration, performance assessment practitioners rely on *sensitivity* and *uncertainty analyses. Sensitivity analyses* identify which assumptions and parameters affect the quantitative estimate of performance by changing input variable and model structures. By contrast, *uncertainty***

***analysis* provides a tool for understanding and explaining (in quantitative terms) the influence (or impact) of imprecision in performance estimates, caused by imprecisely formulated models and/or imprecisely formulated known input variables.**

In addition, the following footnote has been added to the first paragraph of Section 3.2.1.2 of the technical report ("Site Conditions in Performance Assessment Models") to address how scenario uncertainty is accounted for in the LLW performance assessment process:

> By virtue of the siting guidelines found at Section 61.50, developers need to site LLW disposal facilities in geologic settings that are essentially stable (quiescent) or, alternatively, in areas in which active features, events, and processes will not significantly affect the ability of the site and design to meet the Subpart C performance objectives. In practical terms, the effect the Section 61.50 requirements have on the LLW performance assessment scenario selection methodology is that, after site characterization, the candidate site be defined in terms of its expected geologic evolution, where all likely scenarios are accounted for in the performance assessment model and treated equally, with a probability of (1). If the results of site characterization conclude that, geologically, there is the potential for low-probability scenarios – say on the order of 10^{-4} per year, in frequency of occurrence, or lower – they can be considered unimportant and thus screened out of the site model (and the subsequent analysis). In this fashion, uncertainty in the future system state of the disposal system is accounted for in the analysis.

Finally, definitions for *parameter uncertainty, model uncertainty,* and *scenario uncertainty* have been added to the *Glossary*.

10. Page 3-26, Second paragraph, "In practice, the most conservative results should be used to measure performance" seems to violate the entire purpose of a probabilistic approach!

Response
The PAWG does not believe that its recommendation to use the most conservative results to measure LLW disposal facility performance violates the intent of this technical report's probabilistic approach. However, the document has been modified to make it clearer that the LLW disposal facility developer can use any conceptual model to demonstrate compliance that can be appropriately defended. In some cases this may necessitate additional data collection efforts. As an alternative, the conceptual model that provides the most conservative results can be used which may obviate the need for additional data collection. It should be noted that research is currently underway to look at quantifying conceptual model uncertainty. The technical report has been modified to now read as follows:

> When more than one model is derived and cannot be refuted based upon the available data and information, **additional data may need to be collected to provide a basis for accepting one model as oppose to the other credible models. Alternatively, the conceptual model that provides the most conservative result can be used to measure performance and thus possibly obviating the need for additional data collection**.

11. Page 3-26, last paragraph, fourth line, should probably read "...which parameter uncertainties affect the model results most....". The value of gravity might affect the model a lot, but we don't care because it is not uncertain.

Response
The PAWG agrees and the recommended correction has been made to this technical report.

12. Page 3-[31], Paragraph 3, lines 7-8, "...The sampled percolation rate remains the same throughout all stages of the analysis..." seems contradictory to the earlier discussion.

Response
To avoid future confusion in this area, the text has been corrected to say that "...the calculated percolation rate is assumed to remain constant during the particular stage of the analysis...."

13. Page 3-[31], last paragraph, last sentence. Confusing terminology: the figure uses the term "infiltration" for the flow impinging on the cover; the text seems to use it otherwise.

Response
To avoid confusion and facilitate the use of the technical report, the PAWG has adopted terminology commonly used by performance assessment practitioners. However, some of this adopted terminology may not always be used in a manner that is technically correct (e.g., the use of the term "infiltration" to describe water percolating into disposal units). Nonetheless, Section 3.3.3 of this technical report states that the definition for "infiltration" is being broadened for the purposes of this document. Figure 7, though, uses the correct terminology.

14. Page 3-34, Paragraph 2, seems to assume identical soil/vegetation properties for the cover and for the rest of the site.

Response
This observation is correct. Ambient recharge is considered an acceptable surrogate for estimating the amount of percolation into disposal units because it is reasoned that over time, similar biological, chemical, and physical processes responsible for the properties of native soils and vegetation used as cover will result in the formation of similar soils and vegetation throughout the balance of the waste disposal site.

15. Page 3-36, Paragraph 2. The concept of 'ignoring' system components that are not "...being taken credit for..." may lead to conceptually illogical scenarios, which can make the performance assessment just an elaborate fiction. This really happens. Instead, the approach should be to make credible assumptions for the rapid degradation of certain types of component, and then model the system including the properties of the degraded components. Logical inconsistencies ("this piece of concrete degrades because the regulations don't allow us to take credit for it" but that adjacent piece of concrete does not) should not be permitted.

Response
The PAWG agrees that ignoring system components could result in the formulation of illogical conceptual models. However, this technical report does not advocate ignoring these system components. In formulating conceptual and mathematical models for the performance assessment, it is recognized that some simplifications will have to be made. As in the development of conceptual and mathematical models for the natural setting, for example, (unimportant) low-probability features, events, or processes (FEPs) may be excluded from the analysis. (This would also apply to rare events, highly unlikely combinations of parameters, and unreasonable or speculative modeling assumptions.) Although these FEPs may not be included in the analysis, it is still important for the analyst to know that they exist and why they have been excluded from further consideration, for a reason.

16. Page 3-38, Paragraph 2. Testing in-situ reinforced concrete for hydraulic conductivity may not always be possible. It would be nice to add [the phrase] "where practicable" after most testing recommendations. (Obviously, if a component is untested, the performance assessment should allow for an increased probability of leakage).

Response
The PAWG agrees with this comment and, as recommended, has added the following footnote to the section in question:

> "In-situ or as-built testing should be conducted, when it is practicable to do so."

17. Page 3-40; Section 3.3.4.6; Paragraph 1; line 2. Insert "partially" after " be based."

Response
The PAWG agrees with this comment and has revised this technical report as recommended.

18. Page 3-42; Section 3.3.5.1.1; Paragraph 1; Line 6. Change "waste container" to "waste container type"

Response
The PAWG agrees with this comment and has revised this technical report as recommended.

19. Page 3-50; Section 3.3.5.5; Paragraph 2. Where the [draft] BTP gives examples of suitable codes for specific applications, we would appreciate reference to Golder's Repository Integration Program (RIP) model, a major [computer] program that was specifically developed to support exactly the types of analyses recommended by the [draft] BTP.

Response
In this technical report, the PAWG has attempted to avoid endorsing specific computer codes. When computer codes are referenced, it is for illustrative purposes only. Moreover, for those computer codes cited, because they occur in the public domain, they are generally free to potential users (although there may be a modest duplicating fee charged).

The staff is generally familiar with this *Golder's* RIP model and is aware that DOE has evaluated this particular computer code in the context of the potential performance of a geologic repository for HLW at Yucca Mountain, Nevada (see Intera, Inc., 1993). Although it is likely that with appropriate modification, this computer code could be used in LLW performance assessment applications, of the type proposed in this technical report, RIP is a *proprietary property* of Golder Associates, Inc. (1997), and as such, it would be inappropriate for the PAWG to endorse the use of it or any other commercially available commuter code. Decisions on the use of specific computer codes ultimately rests with the individual LLW disposal facility developers.

20. Page 3-55, Paragraph 3. Half-life of ^{226}Ra is 1600 years in our data.

Response
In the draft NUREG, the PAWG had originally rounded-off the half-lives of certain radionuclides. However, in the interest of maintaining scientific accuracy, the PAWG agrees to make the recommended revision.

21. Page 3-57, Paragraph 1. Add rodents, insects, etc., to the list of transport media?

Response
Biotic transport has been added to the first sentence of the paragraph in question. It now states:

> "Radionuclides released from an LLW disposal site are transported in the general environment by groundwater, surface water, air, and biota (e.g., rodents, insects, etc.)."

22. Page 3-61, Paragraphs 3-4. Our analyses have found very significant differences between an earth-mounded concrete bunker (EMCB) and a below-ground vaults (BGV), and we would not treat them as equivalent. In particular, in-depth analysis of erosional issues suggests that they are hard to discount, and can lead to controlling dose levels via overland erosion and/or dust.

Response
As stated in Section 3.3.6.2 of this technical report ("Surface Water"), in assuming that a EMCB facility performs similar to a BGV facility, the PAWG is also assuming that the cover for the EMCB facility is designed to preclude exposure of waste at the surface. Accordingly, the LLW disposal facility developer will need to confirm that exhumation of the disposal vault by geologic/geomorphic processes is unlikely before assuming that an EMCB facility can be modeled like a BGV facility.

23. Page 3-63, Paragraph 3. It is unreasonably onerous to assume that all releases from a multi-acre disposal facility would be concentrated at a single point of discharge, unless a specific hydrologic pathway was credible (and karst is not permitted on the site).

Response
The PAWG recognizes that this is a conservative assumption. For most LLW sites, the surface water pathway is not expected to be a significant exposure pathway; therefore, the recommended approach is intended to allow an easy and yet defensible means of incorporating the surface water pathway in the performance assessment analysis. This approach is also intended to be consistent with the approach recommended for analyzing the ground-water pathway. However, a more realistic analysis that uses a multidimensional ground-water transport analysis can be used, if it is needed. The text has been modified to make it clearer that use of the proposed approach is not required, as follows:

> "The surface-water model can be based on a conservative assumption that all radionuclides distributed in the aquifer in the vicinity of the nearby surface-water body are discharged into it."

24. Page 3-65, Paragraph 5. Wind erosion of exposed wastes can be important.

Response
The PAWG believes that it is very unlikely for wind erosion of exposed waste to be a significant dose pathway for disposal facilities properly designed and constructed in accordance with Part 61 requirements. In particular, the technical requirements found at 10 CFR 61.51of the regulation are intended to achieve the long-term containment and isolation of LLW by ensuring that facility designs are capable of resisting degradation by surficial geologic/geomorphic processes and/or biologic activity, thereby obviating the need for continuing active maintenance after site closure.

25. Page 3-67, Paragraph 3. Refers to "300-year lifetime of the BGVs and EMCBs." Where did this

come from?

Response
The 300-year lifetime requirement [Section 61.7(2) of the regulation] applies to the structural stability of waste forms and waste containers for Class B and C types of waste and not the overall structural stability of the disposal facility itself. To avoid future confusion in this area, the text has been modified to remove the reference to the 300-year lifetime.

26. Page 3-72, Paragraph 2. What should be done about Part 61's thyroid/organ limits?

Response
This section of this technical report (Section 3.3.7.1.2) has been clarified to note that if the applicant calculates the TEDE, separate organ limits are not necessary with the addition of the following paragraph:

> As a matter of policy, the Commission considers 0.25 mSv/year (25 mrem/year) TEDE as the appropriate dose limit to compare with the range of potential doses represented by the older limits which had whole body dose limits of 0.25 mSv/year (25 mrem/year) (NRC, 1999; 64 *FR* 8644, see Footnote 1). Since stochastic risks (e.g., cancer) are controlled by the TEDE dose limit, the role of an organ limit in the TEDE dosimetry system is to prevent non-stochastic effects to that organ. As noted in Appendix B of 10 CFR Part 20, consideration of non-stochastic effects is unnecessary at the dose levels established for members of the public, because the organ dose can never reach the organ limit for non-stochastic effects of 0.5 Sv/year (50 rem/year) without the TEDE dose being greater than the public dose limit. Therefore, when the applicant calculates the TEDE dose, the organ limits are ignored.

Also see the PAWG response to *Golder Associates' General Comment No. 2*, "The Basis of Dose Calculations."

27. Glossary: Add HMCB, BGV, DCF, CEDE, TEDE.

Response
The PAWG agrees with this comment and has revised this technical report as recommended.

Medical University of South Carolina
College of Health Professionals
Department of Environmental Health Sciences

Overall Comment

This preliminary draft of the BTP is poorly conceived and technically flawed. Furthermore, it is not responsive to comments made on the 1994 draft BTP or to the comments made at the Commission's Workshops on the [draft] BTP and Performance Assessment held November 16-17, 1994 and December 13-15, 1994. The NRC has not published a formal response either to comments made on the 1994 draft BTP or to comments provided by participants at the workshops that interested parties took the time and expense to prepare for and attend in 1994. A transcript of the workshop was published, but the resulting comments have yet to be addressed formally by the Commission or staff. It is improper to offer a revised [draft] BTP that does not systematically address previous public comments.

Response
The PAWG does not agree with the comment that characterizes this technical report as poorly conceived and technically flawed. This comment, taken in the context of the other public comments received, is a minority opinion, and the PAWG would refer to the reader the other public comments contained in this appendix which, on balance, offer a different and more positive view.

As regards the comment that this technical report does not systematically address previous public comments, the PAWG again does not agree with this comment. In the *Foreword* to this technical report, the PAWG has attempted to explain the history of the development of this document and in doing so, acknowledge that the earlier draft BTP has undergone substantial revision during the 1994-96 period as a result of the many interactions and informal reviews that took place on earlier, preliminary versions of the draft document. By design, the staff-sponsored public interactions were intended to foster open and candid discussions between potential LLW disposal facility developers/regulators, the interested outside scientific community, and the NRC staff on the many technical/policy issues related to the conduct of an LLW performance assessments. The PAWG's intent has always been clear in this regard. Until it was officially issued for public comment (in May 1997), the draft BTP was considered essentially a work in progress. Meeting transcripts were maintained so as to keep a complete and accurate record of participant views. The PAWG would review the transcripts and consider participant views but not (formally) respond to views that happened to differ from those of members of the PAWG, although it should be noted that, in some places in this appendix, the PAWG has acknowledged certain areas for which there are differing points of view. To the extent that there were these earlier differing views, the PAWG relied on the transcripts to identify areas in this technical report where, perhaps, additional technical justification/explanation was warranted. In summary, the PAWG believes that it gave careful and conscientious consideration to the external comments received thusfar, although some public commenters may not agree with any or all of the PAWG's proposed approaches.

Specific Comments

Not withstanding the flaws in the process of revising the 1994 draft BTP, the following (specific) comments are made to offer constructive improvements in guidance that the Commission offers regarding the performance assessment of developing LLW disposal facilities.

1. A significant deficiency that the draft BTP does not address properly is its lack of consistency among the dosimetric methods used to calculate compliance with 10 CFR 61.41, 10 CFR 61.43

(10 CFR 20.1201) and 10 CFR 20.130. The current regulations state:

- *§61.41 Protection of the general population from releases of radioactivity.*
  "Concentrations of radioactive material which may be released to the general environment in groundwater, surface water, air, soil, plants, or animals must not result in an annual dose exceeding an equivalent of 25 millirems to the whole body, 75 millirems to the thyroid, and 25 millirems to any other organ of any member of the public. Reasonable effort should be made to maintain releases of radioactivity in effluents to the general environment as low as is reasonably achievable."

- *§61.42 Protection of individuals from inadvertent intrusion.*
  "Design, operation, and closure of the land disposal facility must ensure protection of any individual inadvertently intruding into the disposal site and occupying the site or contacting the waste at any time after institutional controls over the disposal site are removed."

- *§61.43 Protection of individuals during operations.*
  "Operations at the land disposal facility must be conducted in compliance with the standards for radiation protection set out in Part 20 of this chapter, except for releases of radioactivity in effluents from the land disposal facility, which shall be governed by §61.41 of this part. Every reasonable effort shall be made to maintain radiation exposures as low as is reasonably achievable."

- *§61.44 Stability of the disposal site after closure.*
  "The disposal facility must be sited, designed, used, operated, and closed to achieve long-term stability of the disposal site and to eliminate to the extent practicable the need for ongoing active maintenance of the disposal site following closure so that only surveillance, monitoring, or minor custodial care are required."

10 CFR Part 61.41 and 10 CFR Part 61.43 (10 CFR 20.1201) are inconsistent. The method for calculating and accumulating internal dose and adding internal and external dose together has changed. National and international recommending bodies and the Commission have adopted the methods described in ICRP Publications 26 and 30. These recommendations have been codified in 10 CPR 20.1201 for exposure to workers and 20.1301 for members of the public. The principal public protection standard in 10 CFR 61.41 is still an out-of-date annual-limit standard. An annual dose of 25 millirem to the whole body, 75 millirem to the thyroid, and 25 millirem to any other organ (based on the methodology published in 1959 in ICRP Publication 2) does not readily translate to a CEDE of 25 millirem for internal emitters. Neither is it clear how to add internal and external doses with this older methodology. A re-evaluation of the form and numerical value for 10 CFR 61.41 is required. Further, the standard calls out specific organ doses that are inconsistent with the calculation of CEDE and TEDE for workers. No attempt is made in the draft BTP to resolve this problem effectively.

The public dose standard currently in force in 10 CFR 20.1301, applied for a reasonable institutional control period, would be a rational substitute and would resolve this conflict.

- *§20.1301 Dose limits for individual members of the public.*

  (a) Each licensee shall conduct operations so that-

(1) The total effective dose equivalent to individual members of the public from the licensed operation does not exceed 0.1 rem (1 millisievert) in a year, exclusive of the dose contributions from background radiation, any medical administration the individual has received, voluntary participation in medical research programs, and the licensee's disposal of radioactive material into sanitary sewerage in accordance with §20.2003.

Response

The PAWG agrees that there are conflicting dose methodologies in Part 61. The draft BTP did attempt to address this point by recommending the use of *Federal Guidance Report Number 11* (Eckerman *et al.,* 1988) in Section 3.3.7.1.2 (pg. 3-72). Nonetheless, as noted in the response to the *State of Texas Specific Comment No. 2,* the PAWG has now revised the section in question to attempt to better clarify the intent of the technical report and avoid future confusion in this area. This technical report now explains the Commission's position in this area, which is that a 0.25-mSv (25-mrem) TEDE annual dose limit is an appropriate limit to use when showing compliance with limits using older dose methodologies that have a whole body annual dose limit of 0.25 mSv.

2. The recommendation on page xi of the *Executive Summary* states:

> "The central attribute of the process is that it is to be conducted iteratively starting with a combination of generic and limited site-specific information in support of relatively simple conservative models and analyses, and progressing to more site-specific and detailed analyses, as necessary, to reduce uncertainty in assessing performance of an LLW disposal facility."

There is a key problem with this approach. It in no way offers an applicant any guidance on how to conduct and **conclude** the process of performance assessment. The process of assessment must lead to a conclusion. Unfortunately in both the HLW and LLW management programs, the Commission's regulatory process has lead only to indecision. This draft BTP offers no coherent way to make a deterministic decision based on analysis of future events.

Response

See the response to *CNS' Specific Comment No. 18*.

3. It is stated on page xii [under "Consideration of Future Site Conditions, Processes, and Events"] that:

> "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 possibilities."

What is meant by "robustness of the facility"? How does an applicant assess this? What is the acceptable standard of robustness? How does an applicant determine robustness for the recommended 10,000-year evaluation period? Without clear and extensive definition, the term "robustness" has absolutely no meaning.

Response

In siting and designing an LLW disposal facility, the disposal facility developer will need to identify, analyze, and screen those scenarios – possible future system states (conditions, features, events, and processes) – that are expected to affect long-term facility performance during the time period of regulatory concern (i.e., up to 10,000 years). Scenarios are screened out of the analysis if their probabilities are sufficiently low or if it determined that they will have little impact on performance. For those scenarios retained, the LLW disposal facility developer will need to take them into account when designing the engineered components of the disposal system to confirm that the barriers will perform as intended. In either case, the LLW disposal facility developer will need to document his or her decision-making.

As illustrated in Figure 4 of this technical report, during the first several hundred (10^2) years, LLW disposal facility performance focuses principally on the behavior of the engineered components of the disposal facility. During this time frame, the LLW disposal facility developer can determine that the proposed disposal facility design concept is "robust" if compliance with the pertinent Part 61 performance objectives can be demonstrated. For the longer timeframes, say on the order of 10^3 to 10^5 years, this technical report assumes there will be an onset of the degradation in the engineered components of the disposal facility, and the focus of facility performance shifts to examining how the geologic features of the disposal site limit radionuclide migration. If the overall performance assessment shows that the disposal facility, now consisting of the site (and, albeit, degraded engineering), can meet the performance objective set forth in 10 CFR 61.41 of the regulation, then the disposal facility developer can conclude the disposal system is "robust."

4. Further in the same paragraph, it is stated:

> "The staff recommends the use of conservative assumptions and ranges of parameters that could effectively bound the reference geologic setting of the site. To capture the variability in natural processes and events and bound dynamic site behavior, the range of siting assumptions and data should be sufficient to understand the long-term trends in natural phenomena acting on the site. The staff emphasizes that there should be a limit on the range of possible performance assessment and that unnecessary speculation in the assessment should be eliminated."

This guidance is too vague to be useful. The staff should follow up and provide specific numerical values for the ranges to be evaluated for the technical performance criteria listed in 10 CFR Part 61, Subpart D below.

§61.51 Disposal site design for land disposal.

(a) Disposal site design for near-surface disposal.

(1) Site design features must be directed toward long-term isolation and avoidance of need for continuing active maintenance after site closure.

(2) The disposal site design and operation must be compatible with the disposal site closure and stabilization plan and lead to disposal site closure that provides reasonable assurance that the performance objectives of subpart C of this part will be met.

(3) The disposal site must be designed to complement and improve, where appropriate, the ability of the disposal site's natural characteristics to assure that the performance objectives of subpart C of this part will be met.

(4) Covers must be designed to minimize to the extent practicable water infiltration,

to direct percolating or surface water away from the disposed waste, and to resist degradation by surface geologic processes and biotic activity.

(5) Surface features must direct surface water drainage away from disposal units at velocities and gradients which will not result in erosion that will require ongoing active maintenance in the future.

(6) The disposal site must be designed to minimize to the extent practicable the contact of water with waste during storage, the contact of standing water with waste during disposal, and the contact of percolating or standing water with wastes after disposal.

Response
The stated intent of this technical report is to provide the PAWG's views on an acceptable approach for conducting a performance assessment to demonstrate compliance with 10 CFR 61.41 of the Commission's regulations. It is not intended to provide guidance on the design and construction of disposal facilities or guidance on how to demonstrate compliance with the design requirements found at 10 CFR 61.51. Specific guidance on design and construction of facilities and meeting 10 CFR 61.51 requirements has been provided previously in NUREG-1200 (NRC, 1994).

5. The staff and the Commission should provide some leadership and develop a generic set of parameter values and ranges for typical geohydrologic regimes that should be considered by a licensee. If this were done and indexed to each of these technical requirements, much confusion could be avoided.

Response
As a regulatory agency, the PAWG believes that it would not be appropriate for the NRC staff to develop a generic set of parameter values and ranges for typical geohydrologic regimes that should be considered by a licensee in an LLW performance assessment. Rather, in any licensing context, the disposal facility developer should be performing this task for it needs to be able to justify and defend its siting and design decisions, including its decision-making related to design basis selection.

Reaching these types of decisions should not be an arduous task for disposal facility developers. In fact, there already exists detailed geohydrologic information abundantly in the literature. Some generic information has been already summarized and published by NRC (e.g., Mercer *et al.,* 1982), and others (Dunne and Leopold, 1978). Nationally, the USGS has taken the lead in preparing data compilations (i.e., the *Regional Aquifer-System Analysis Series*). Individual State geologic surveys and their sister agencies have also published information on local aquifers. In addition, disposal facility developers can canvas the refereed technical journals for geohydrologic data (e.g., *Advances in Water Resources, Geological Society of America Bulletin, Ground Water, Journal of Contaminant Hydrology, Journal of Hydraulic Engineering*). Also, it is expected that disposal facility developers will be employing the services of licensed geotechnical engineers and geologists as part of site characterization activities. These professionally registered individuals typically possess extensive local knowledge about geohydrologic conditions at potential disposal sites and should prove to be an invaluable resource in defining or estimating parameter values and ranges. For example, it is very likely that detailed, site-specific geohydrologic information is already being integrated into local decision-making (e.g., septic tank and water well-permitting; environmental monitoring; foundation design and construction; and the like).

6. The recommendation to extend performance assessment over a 10,000-year period is without

foundation. It is true that if dose values are calculated for periods of time beyond 1000 years, using typical assessment codes and constant parameter values, the calculated doses increase at long times. This should not be a surprise. In **any** assessment of the near surface behavior where primordial radionuclides from the uranium and thorium decay chains are present this calculational artifact will occur. It is presumptuous and without benefit to public health and safety to attach meaning to these results. There is no basis for the selection of 10,000 years as the time period for assessment for LLW. In fact, at 500 years, less than one percent of a typical LLW inventory will remain. The currently available assessment tools are not capable of estimating doses in a credible way for a 10,000-year time interval in the near-surface environment. It is not possible, nor is it necessary, to predict behavior or near surface disposal systems for LLW. Calculated doses from assessments of disposed uranium and thorium as LLW are inconsistent with background doses in the vicinity of naturally occurring materials where there are much higher quantities of uranium and thorium in equilibrium with [their] natural setting. While in geologic time 10,000 years is short, it is inappropriate to assume that natural surface phenomena will remain constant over such a time interval which most models assume. Such estimates are likely to be uncertain by several orders of magnitude, rendering them useless. A realistic time frame for assessment is 500 years. Primordial radionuclides can be assessed by comparison to natural analogs.

Response
See PAWG response to *Commonwealth of Pennsylvania Specific Comment No. 6.*

7. The guidance offered on page xiv of the *Executive Summary* states:

> "When compliance, as measured against the 10 CFR 61.41 performance objective, is based on a single (deterministic) estimate of performance, the applicant is relying on the demonstration of the conservative nature of the analysis, rather than a quantitative analysis of uncertainty. Therefore, if it is to be used as performance measure, a single estimate of performance should be at or below the 10 CFR 61.41 performance objective. 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 percentile of the distribution be less than the performance objective [10 CFR 61.41] and the 95th percentile of the distribution be less than 1 mSv (100 mrem) to consider a facility in compliance."

This recommendation is helpful in its attempt to advise a licensee when performance assessment can be successfully concluded. It is not acceptable in its present form. It suffers from the inconsistent dose standard issue mentioned above. Further, the recommendation to use uncertainty analysis does not explicitly indicate that doses can be calculated that will exceed the standard, albeit with low probability, and that this outcome is acceptable. Without specific guidance regarding parametric analysis and specific modeling approaches and tools, the argument merely shifts from whether or not the calculated outcome is correct to whether or not the input values used to create the distribution [are correct]. The staff and Commission have the obligation to develop more specific guidance on the entire performance assessment process.

Response
See the PAWG's response to *Medical University of South Carolina's Comment No. 1*, above. In addition, the fact that the standard is 0.25 mSv and yet this technical report says that the 95th percentile of the distribution should be less than 1 mSv (100 mrem) clearly implies a recognition that some of the

calculated dose may exceed the standard. In terms of the concerns about defending the probability distributions, this is a common concern expressed in the use of probabilistic analyses. However, there are several good sources of information, readily available on assigning probability distributions; these include: Harr (1987); Evans *et al.* (1993); and National Council on Radiation Protection and Measurements (1996).

8. In its current form, the [draft BTP] further confuses the Commission's guidance regarding the process of site performance assessment for an LLW disposal site. The staff has not addressed obvious inconsistencies in the basic dose standards and has created a vague framework for developing performance assessment information to support a license application. This draft needs to be withdrawn and significant work must occur to develop consistent and clear guidance regarding performance assessment necessary to demonstrate the licensability of LLW disposal sites.

Response

The PAWG disagrees with this comment. As noted in its response to the *State of Texas Specific Comment No. 6* and *Medical University of South Carolina's Comment No. 1*, the PAWG members did attempt to resolve the inconsistencies in the conflicting dose methodologies. This technical report now recommends that disposal facility developers use the **dose methodology consistent with Part 20**, rather than the dose methodology that would inherently be used to demonstrate compliance with the dose limits set forth in 10 CFR 61.41 of the regulation.

Mel Silberberg and Associates [26]

General Comments

The draft BTP represents a significant milestone in the development of the technology and regulation of LLW disposal facilities in the United States. The NRC staff of the *Performance Assessment Working Group* and its contractors are to be commended for developing a high quality document which exemplifies traditional NRC standards of technical and regulatory excellence. The issuance of this document in final form should receive a high priority along with the development and use by the NRC staff of a workable strategic plan for rapid deployment of this guidance; assurance of its implementation by licensees and Agreement States; adequate oversight of [draft] BTP applications by users under the *Integrated Materials Performance Evaluation Program*; and updating by incorporation of new information, results from related research, and user experience. The public deserves the full and wholehearted support of the Commission in helping the NRC staff bring this important process to fruition. In this regard, it is essential for the Commission to accelerate its deployment and implementation by the Agreement States.

Response

This comment is noted. However, as regards the specific recommendation that "...the Commission ... accelerate its deployment and implementation by the Agreement States...," the PAWG does not (nor does the Commission) have the authority to impose its views and recommendations on the Agreement States. This point was recognized earlier by the PAWG in Section 1.8 of this technical report ("Use of this Technical Report by Other Regulatory Entities"), where it is noted:

> "...The extent to which the Agreement States or other regulatory entities implement the recommendations found in this technical report is, of course, a matter for their consideration and decision...."

The commenter is reminded that the motivation in developing this document was the desire to share with the Agreement States and LLW disposal facility developers (as potential applicants) some of the PAWG's experience and insights, as they relate to the use of an LLW performance assessment in a regulatory context.

Specific Comments

1. *BTP on LLW Performance Assessment: Useful Guidance or Essential Guidance?*

— Given the central importance of the LLW performance assessment process, as set forth in the draft BTP, and the key role that this process must play in the entire life of an LLW disposal

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[26] These comments reflect a review of Draft NUREG-1573 from the commenter's perspective as a former member of NRC management which initiated and implemented the program for the development of this guidance in response to a SRM issued by the Commission in June 1991. He was the Senior Executive Service manager in the Office of Nuclear Regulatory Research responsible for developing staff capability and guidance in LLW performance assessment, in coordination with his counterparts from the Office of Nuclear Material Safety and Safeguards (NMSS). During his tenure, the preliminary draft of the [draft] BTP was completed and distributed to selected parties for comment in January 1994; he retired from NRC in February 1994 and has since followed the progress of the draft BTP and other activities in LLW with considerable interest.

facility, from site selection to the post-operational period, the Commission should give strong consideration to upgrading the guidance in the draft BTP to a Regulatory Guide or other appropriate measures needed to engender a bona fide commitment of technical excellence by Agreement States and their licensees for demonstrating compliance with 10 CFR 61.41.

Response

The PAWG has previously noted that rigid adherence to the specific concepts/steps proposed in this technical report is not sought so much as the use of a consistent process that produces an accurate and properly documented performance assessment. Consistent with this notion, Paragraph 1 of Section 1.7 of this technical report ("This Technical Report as Guidance") states that:

> "...Methods and solutions differing from those set out in this technical report should be acceptable if they provide a sufficient basis for the findings requisite to the issuance of a permit or license by the Commission...."

Inasmuch as the PAWG has used this NUREG to reinforced its long-standing interest in technically defensible analyses that are transparent and traceable, it is not clear how upgrading this document to a Regulatory Guide, as suggested in this comment, would require more than that which is already (or would be) expected from potential licensees.

— In the Introduction of the *Executive Summary* (on page xi) and the [second] footnote to Section 1, *Introduction*, on page 1-1, the staff uses the phrase "...**may** also find the guidance in this NUREG **useful** as they proceed with the implementation of their respective programs...." (emphasis added), in referring to potential Part 61 applicants and existing LLW licensees, operating under comparable Agreement State regulations. In the *Federal Register* Notice of May 29, 1997,the staff noted what could be perceived as additional equivocation of their position on the performance assessment guidance with the statement, "...When finalized, the BTP **may** contain information that **may** be **useful**...." (emphasis added) Taken together, these statements and the discussion in Section 1.8, are not sufficiently proactive to give the Agreement State regulator the incentive or authority to motivate or require adequate demonstration of compliance with Part 61.41 based upon sound, comprehensive technology. We have considerable difficulty understanding the reasoning and philosophy behind the NRC's apparent, ongoing, passive stance towards Agreement State guidance and oversight in LLW. Agreement States need sufficient tools, assistance and guidance to adequately regulate LLW disposal facilities. We recommend that the staff strengthen the [draft] BTP by at least substituting the word "will" for "may."

Response

For a number of years, NRC has figured prominently in the national LLW management program. NRC has promulgated the requisite disposal regulations (Part 61) accompanied by the necessary regulatory guides and other documentation needed to implement those regulations [e.g., NUREG-1199 (NRC, 1991); NUREG-1200 (NRC, 1994); NUREG-1293 (Pittiglio and Hedges, 1991); NUREG-1300 (1987); and NUREG-1383 (Pittiglio *et al.*, 1990)]. In addition, when there has been a need, NRC has sponsored basic and applied scientific research to address many of the technical issues that underpin the management of LLW; the results of these efforts are the many publications cited in Section 4 ("References") of this NUREG. In fact, about half of the references cited in this NUREG are NRC-sponsored products.

Nonetheless, the intent of the Low-Level Radioactive Waste Policy Act of 1980, as amended, was to empower the States to figure more prominently in LLW decision-making and management. Consistent with Congressional direction in this regard, NRC technical efforts in the area of LLW management have been scaled back in recent years, and are now limited to oversight and some basic (generic) waste management research sponsored by NRC's Office of Nuclear Regulatory Research. To the extent that Agreement States need "...sufficient tools, assistance, and guidance to adequately regulate LLW disposal facilities...," as suggested by this comment, the PAWG is issuing this technical report as a means of providing some needed/requested information and/or direction. In addition, the PAWG is not aware of any outstanding requests for technical assistance by the Agreement States. Future requests for the development of analytical tools, individual technical assistance, and/or regulatory guidance will be evaluated if and when they are received.

Lastly, as regards the recommendation to strengthen this document in the aforementioned sections by substituting the word "will" for "may," the PAWG does not agree with this editorial recommendation.

— On page 1-1, the [draft] BTP clearly states the deficiencies in existing NRC staff LLW guidance documents with respect to: measuring performance requirements against Part 61 performance objectives; explicitly addressing the relationship between the overall Part 61 data and design requirements and specific LLW performance assessment needs; and consideration of site characterization, facility design, and performance modeling in isolation. In addition, the relationship between performance assessment and environmental monitoring during operational and post-operational periods (10 CFR 61.53) needs to be included in this list. Since the detailed guidance in the [draft] BTP corrects these deficiencies and clarifies all of these issues, it surely deserves to be deployed in a regulatory form that will ensure broad acceptance, durable application, and regulatory continuity.

Response
The principal focus of this NUREG is to discuss what is needed to demonstrate compliance with NRC's requirements found at 10 CFR 61.41 as part of any potential LLW license application (see Subpart B). This comment correctly points out that there will be an environmental monitoring program (10 CFR 61.53) during the construction, operational, and post-operational periods, to collect data to ensure that the performance objectives of Subpart C are met. What this technical report is silent on [in Section 3.2.5 ("Role of LLW Performance Assessment during Operational and Closure Periods")] is how these and other design data [(10 CFR 61.28(a)] would be factored into the disposal facility developer's decision-making regarding the compliance determinations to be made, during the operational and post-operational periods, with respect to 10 CFR 61.41.

The PAWG believes that the decision-making apparatus used to confirm compliance with 10 CFR 61.41 during the operational and post-operational periods would be the same performance assessment model used in the initial license application submittal. The environmental monitoring program data [10 CFR 61.5(a)] are intended to confirm (or validate) that there is reasonable assurance that the performance objectives will be met. Nevertheless, to better express this view, Section 3.2.5 of this technical report has been re-written, as follows:

> **3.2.5 Role of LLW Performance Assessment during Operational and Closure Periods**
>
> In receiving a license to receive, possess, and dispose of LLW, disposal facility developers will have used the performance assessment analysis (initially) to show that, with reasonable assurance, the operation of the LLW disposal facility will not constitute an unreasonable risk to the health and safety of the public. During the construction, operation, and post-operational periods of the LLW disposal facility *per se*, performance assessment can continue to play an important role in determining compliance with the performance objectives found in Subpart C.
>
> For example,10 CFR 61.53 of the regulations requires that during the construction, operation, and post-operational periods, a licensee is responsible for conducting an environmental monitoring program. Measurements and observations must be made to evaluate potential

health and environmental impacts and long-term effects of the disposal facility and, if necessary, corrective actions taken to mitigate the potential effects of radionuclide releases. In addition, 10 CFR 61.28(a) requires that the final revision to site closure plans should contain any additional geologic, hydrologic, or other disposal site data obtained during the operational period pertinent to the long-term containment of waste, and the results of tests, experiments, or analyses pertaining to long-term containment of waste. Site closure will be authorized if the final site closure plan provides reasonable assurance of the long-term safety of the facility.

One way to address these requirements is to revise and update the performance assessment model used in the initial license application (Subpart B) submittal with the new information from these monitoring programs. These new site data may confirm or validate the key parameters or model assumptions used in the earlier performance assessment or call them into question. The level of confirmation (i.e., validation) needed should be determined by the intended regulatory uses of the models and assumptions, rather than the ideal of validation of a scientific theory.

2. *Test Case of a Hypothetical LLW Disposal System*.

— On pages 1-9 and 3-13, reference is made to a staff[‘s] performance assessment test case of a hypothetical LLW disposal system. Regardless of the form of performance assessment guidance issued by the NRC staff, it is highly desirable, and even essential, that the documentation of this test case be available concurrently with the final draft of the BTP. Should the Commission decide to upgrade the [draft] BTP to a Regulatory Guide, concurrent publication of the test case document would be mandatory. The test case document will also serve to help demonstrate the importance of and need for employing flexible performance assessment methodology to adequately address key LLW issues. The test case and performance assessment guidance documents are essential tools for the transition of the NRC and Agreement States to a risk-informed, performance-based approach to LLW regulation, and for improved communication to the public of LLW disposal facility risk, and the demonstration of compliance with regulatory requirements.

Response
The PAWG agrees that it would be highly desirable for the test case documentation to be available. However, as noted in its earlier response to *CNS’ Overall Comment No. 2,* the PAWG cannot complete the requested documentation at this time. Until the necessary resources become available, interested parties are referred to the transcript of the NRC-sponsored November 16-17, 1994, workshop on the draft BTP and test case, for information on the test case.

3. *Ensuring Sound Defensible Performance Assessment: An Element of Regulatory Excellence.*

— The role of sound, defensible performance assessment guidance, such as the [draft] BTP, in building credibility in the community at large, is discussed in a recent paper on the need for and approach to assuring Agreement State regulatory excellence (see Silberberg, 1997[27]). The paper also notes that the [draft] BTP would provide a single vehicle to test and evaluate updates and improvements in performance assessment methodology, as well as experience gained from the performance assessment user community, worldwide. An additional point is that it is more

[27] A copy of this paper (Silberberg, 1997) was included in Mr. Silberberg’s public comments and has been placed in NRC's PDR.

> cost-effective and strategically sound to promote consistency using an approach, such as the [draft] BTP or its equivalent, to focus on priority issues and to allocate scarce resources in a coordinated way. The [final] BTP should include an appropriate statement on the advantages and prudence of achieving consistency in methodologies among LLW performance assessment users, available in the BTP, for facilitating comprehensive comparisons, technical communication, including peer review, within the regulatory and regulated LLW community, and as a vehicle for incorporating new data, improvements in methodology, and the results of ongoing, relevant research.

Response
The PAWG agrees with the view expressed in this comment that there should be open communication among interested practitioners (both regulators and LLW disposal facility developers) as a means of exchanging information and knowledge about "LLW performance assessment technology." However, because of differences among existing and proposed LLW disposal sites (i.e., physical settings and/or designs), there will be practical limits on the extent to which the various individual performance assessments themselves can or could be compared.

Nonetheless, after considering the concepts discussed in this comment (and other subsequent comments), the PAWG believes that its intent with respect to the issues raised in this comment could be further explained by making the following addition to Paragraph 1 of Section 1.8 of this NUREG ("Use of this Technical Report by Other Regulatory Entities" – see bold type):

> A motivating factor influencing the development of this technical report was the desire to share with the Agreement States and LLW disposal facility developers (as potential applicants) some of the PAWG's experience and insights, as they relate to the use of LLW performance assessments in a regulatory context. The extent to which the Agreement States or other regulatory entities implement the recommendations found in this technical report is, of course, a matter for their consideration and decision. **The PAWG believes that rigid adherence to the specific concepts/steps proposed in this document is not sought so much as the use of a consistent process that produces an accurate and properly documented assessment. Moreover, the PAWG believes that effective implementation of a good LLW performance assessment cannot guarantee acceptance of the technical conclusions; however, use of a flawed process or improper implementation of a good process cannot help but cast serious doubt on the quality of the conclusions.** As other regulatory entities consider the application of these recommended approaches to their respective programs, the PAWG also thought it useful to discuss how performance assessment contributes to regulatory decision-making.

In addition, the PAWG agrees with the concept of using *peer reviews*, as suggested by this comment, as a means of establishing/advancing the technical foundation underpinning LLW performance assessment methodology. Peer reviews are currently being used in the HLW management program by both the developer (DOE) and the regulator (NRC) [see Whipple *et al.,* (1999) and Center for Nuclear Waste Regulatory Analyses (1999), respectively] as a means of providing independent technical review of the adequacy of its respective performance assessment programs.[28] However, in the context of the LLW management program, the fundamental decision regarding its use ultimately rests with consenting Agreement States and/or disposal facility developers, and not with NRC. Nonetheless, to better express the PAWG's views in this area, the following paragraph has been added to Section 1.8:

> As is the case with the geologic disposal of HLW, one way to improve the credibility and confidence in an LLW performance assessment would be through the use of *peer reviews.*

[28] In addition, other Federal agencies rely extensively on the use of peer reviews to independently evaluate their programs. See U.S. General Accounting Office (1999).

Usually, peer reviewers are recognized experts in the domain of interest as evidenced by their (comparable) scientific/engineering qualifications. Because they are independent and possess no unresolved conflicts of interest, the peers may comment freely on the validity of the assumptions, the appropriateness and limitations of the methodology and procedures, the accuracy of the calculations, the validity of the conclusions, and the uncertainty of the results and consequences of the work. They may also offer alternative explanations of the results and comment on the adequacy of the information and data used to obtain them.

In addition to the independent (critical) evaluation provided, peer reviews can aid in the public confidence in and acceptance of an LLW performance assessment itself, as well as the conclusions drawn from it. Peer review has been suggested by some observers as the best assurance that quality technical criteria will prevail over social, economic, and/or political considerations. However, the fundamental decision regarding the use of a peer review process ultimately rests with consenting Agreement States and/or LLW disposal facility developers, and not with NRC.

To ensure consistency between these additions and the *Regulatory Framework* section of this technical report (as well as to address other public comments), the PAWG is also adding the following discussion to Section 2:

In addition to the aforementioned, the PAWG has drawn on experience and guidance, obtained from other NRC regulatory programs, that can be applied to analyzing future LLW disposal site performance.[29] These areas are discussed below.

Peer Reviews: Much scientific and engineering development is subjec to the normal review process of critical evaluation by colleagues in various venues. These so-called *peer reviews* are typically documented, critical reviews that evaluate the acceptability and adequacy of some particular form of original research, performed by peers who are independent of the work being reviewed but, nonetheless, still have comparable technical competence to perform the review. In addition, peer reviews may be employed as part of the independent actions necessary to provide public confidence in the technical work being conducted and/or the interpretation and meaning of its results.

A peer review can be conducted by obtaining input separately from a number of peers or by convening a panel to conduct the review. (Also, discussions among the panel members can generate useful information not available from a set of independent reviews.) The most common peer review process typically uses informal *expert judgment* to evaluate scientific methods and results. NUREG-1297 (Altman *et al.*, 1988) provides guidance on: (a) areas where peer reviews may be appropriate; (b) the selection of peers; and (c) the conduct and documentation of the peer review process, itself.

Expert Judgment: Nearly every aspect of site characterization and performance assessment will involve significant uncertainties. The primary method to evaluate, and perhaps reduce, these uncertainties should be collection of sufficient data and information during site characterization. However, factors such as temporal and spatial variations in the data, the possibility for multiple interpretations of the same data, and the absence of validated theories for predicting the performance of a LLW disposal facility for thousands of years, will make it necessary to complement and supplement the data obtained during site characterization with the interpretations and subjective judgments of *technical experts* (i.e., expert judgments). NRC expects that subjective judgments of individual experts and, in some cases, groups of experts, will be used to interpret data obtained during site characterization and to address the many

[29] Although these guidance documents being cited were developed for the purposes of the HLW management program, the PAWG believes it can also be applied to LLW.

technical issues and inherent uncertainties associated with predicting the performance of an LLW disposal system for thousands of years.[30]

NUREG-1563 (Kotra *et al.,* 1999): (a) provides general guidelines on those circumstances that may warrant the use of a formal process for obtaining the judgments of more than one expert (i.e., expert elicitation); and (b) describes acceptable procedures for conducting expert elicitation when formally elicited judgments are used to support a demonstration of compliance. (In this NUREG, the PAWG also provides an expanded definition of peer review over that provided earlier in NUREG-1297.)

Model Validation: Validation (or confidence building) should be an important aspect of the regulatory uses of mathematical models in the safety assessments of geologic/engineered systems for the disposal of radioactive wastes. A substantial body of literature exists indicating the manner in which scientific validation of models is usually pursued. Because models for a geologic repository performance assessment cannot be tested over the spatial scales of interest and long time periods for which the models will make estimates of performance, the usual avenue for model validation – that is, comparison of model estimates with actual data at the space-time scales of interest – is precluded. Further complicating the model validation process are the uncertainties inherent in describing the geologic complexities of potential disposal sites, and their interactions with the engineered system, with a limited set of generally imprecise data, making it difficult to discriminate between model discrepancy and inadequacy of input data. A successful strategy for model validation, therefore, should attempt to recognize these difficulties, address their resolution, and document the resolution in a careful manner. The end result of validation efforts should be a documented enhancement of confidence in the model to an extent that the model's results can aid in regulatory decision-making. The level of validation needed should be determined by the intended uses of these models, rather than by the ideal of validation of a scientific theory.

NUREG-1636 (Eisenberg *et al.,* 1999) presents a model validation strategy that can be implemented in a regulatory environment. This document should not be viewed as, and is not intended to be, formal guidance or as a staff position on this matter. Rather, based on a review of the literature and previous experience in this area, this White Paper presents regulatory views regarding how, and to what degree, validation might be accomplished in the models used to estimate the performance of a geologic disposal facility.

4. Timeliness.

A large number of sited and host Agreement States are far along in their site characterization and performance assessment process [i.e., South Carolina, Washington, Utah (Envirocare), California, Texas, North Carolina, and Nebraska]. It is not clear how the Commission will motivate or encourage the acceptance and use of the [draft] BTP guidance in these States. The final BTP should address this situation and provide the basis for the subsequent development of a strategy to assist these States in deploying the BTP into their ongoing process, through a suitable, orderly transition.

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[30] Based on their increasing use in seismic hazard analysis [e.g., Bernreuter *et al.* (1980-83, 1985, and 1989) and Seismicity Owners Group/Electric Power Research Institute (1986), and Senior Seismic Hazard Analysis Committee (1995)], geologic disposal performance assessments [e.g., Tschoepe and Abramson (1992), DeWispelare (1993), Trauth *et al.* (1993)], and other nuclear applications [e.g., Harper *et al.* (1995), Brown *et al.* (1997), Goossens *et al.* (1997), Haskin *et al.* (1997), Little *et al.* (1997), and Goossens *et al.* (1998)].

Response
See PAWG response to *State of South Carolina Comment No. 1.*

5. *Participation of Interested Parties.*

— We strongly endorse the staff's suggestion that the site characterization/performance assessment process be made participatory for interested parties and that the performance assessment process readily accommodate a wide variety of alternative approaches for public participation and openness. This practice would help build and enhance public confidence in LLW disposal, a fragile commodity which is badly needed at the present time. Exclusion of a suitable public participation process only serves to fuel the public perception (real or apparent) that the applicant and regulator are hiding something.

In the final BTP the staff should give strong consideration to the recommendation of the National Research Council (see National Research Council, 1995) regarding the concept of using a peer review oversight panel for Ward Valley activities, as part of the iterative process of site characterization, monitoring, and performance assessment. [NRC's] Advisory Committee on Nuclear Waste (ANCW) endorsed the recommendations of the Council and extended it to all LLW facility programs, by recommending that the NRC staff issue guidance on the formation of such expert review panels (see Kotra *et al.*, 1996) (sic). We recommend that the staff incorporate, in the [final] BTP, the concept of the use of expert review panels in performance assessment and related activities, as noted in the referenced ACNW recommendation.

Response
A recurring theme in a number of comments received on this document, albeit subtle, is the issue of public and regulatory acceptance of the methods used in and the conclusions drawn from an LLW performance assessment. The PAWG agrees with the spirit of this recommendation – namely, that one way to bolster public confidence and acceptance of the LLW performance assessments would be through the use of *peer reviews.* (Also see PAWG response to *Mel Silberberg and Associates' Specific Comment No. 2,* above.) However, the fundamental decision regarding their use ultimately rests with the Agreement States and not the NRC.

Nonetheless, the PAWG has made specific changes to this technical report to encourage the use of peer reviews. See the PAWG's response to *Mel Silberberg Associates Specific Comment No. 3* for a description of where these changes have been made.

6. *Staff Resolution of Previous Comments on the Preliminary Draft BTP.*

— In SRM COMSECY-964 -55- LLW(DSI 5) March 7, 1997, the Commission directive regarding the draft BTP on performance assessment [for] LLW sites requested the staff "...to inform the Commission on how it plans to resolve previous comments on the [draft] BTP prior to a **decision to finalize the BTP**" (emphasis added). In the last paragraph of the SRM, the Commission stated "Agreement State comments on the ...8th... stated that the 13th is unnecessary and disruptive...." A similar statement appeared in the Strategic Assessment Issue Paper DSI-5 (page 16) issued for public comment on September 16, 1996. A review of comments on the public record from Agreement States, since the initial release of the preliminary draft BTP on January 19, 1994, to LLW sited and host Agreement States for comment, and after several public workshops held by the NRC staff and several ACNW meetings on the 13th, does not support the

Commission's SRM statement, particularly when it calls into question the finalization and issuance of this badly needed guidance.

To my knowledge, based on the public record, there was no consensus from the host Agreement States to support the charge that the 13th is "unnecessary and disruptive." Furthermore, the use of this exact phrase could not be found. A publicly-disclosed, negative Agreement State comment on the 13th was made by the State of Illinois in comments provided to the Organization of Agreement States (OAS) for their October 21, 1996, letter on the DSI papers, including DSI 5. In their comments Illinois references their December 5, 1995, letter to Mr. James Kennedy, NMSS, which refers to the [draft] BTP as "...ill-conceived and serves no benefit to the individual state responsible for licensing a LLRW disposal facility...." However, no basis was offered to support this conclusion. In fact, this statement and several others made orally by a few representatives of State organizations and LLW site developers (who might be biased to view the BTP unfavorably), at several public meetings on the preliminary draft BTP, were largely subjective in nature and without substantiation. It is interesting to note that in their 1994 comments on the [draft] BTP, [the State of] Illinois did not offer a similar conclusion. Should Commission policy be unduly influenced by a few individuals, especially if their contention does not have a valid basis nor is [not] indicative of a clear consensus from [other] State regulators?

The Commission's directive in the March 7, 1997, SRM does not contribute to the timely issuance process needed for this important guidance. Without adequate guidance from the NRC, all host LLW disposal facilities will probably be using different performance assessment methodologies.

Will this help contribute to consistency, compatibility and cost-effectiveness in an era of scarce resources? Can a downsized NRC LLW Program adequately oversee and assess Agreement State performance in this area without the timely issuance of guidance of the type to be found in the [draft] BTP? We believe these are serious questions that need to be addressed by the Commission.

Over the years, the Commission has placed a high priority on the quality of information it receives to support Commission and staff decisions; we trust that SRM COMSECY-96-055 does not represent a departure from that practice.

Response

See PAWG response to *State of Illinois Second Overall Comment.*

Nuclear Energy Institute

Overall Comment

The following comments are provided by the Nuclear Energy Institute (NEI) on behalf of the nuclear energy industry in response to the subject notice. The industry appreciates the opportunity to provide input on the draft BTP.

The draft BTP is solid technical guidance. NRC's Performance Assessment Working Group has done an admirable job in identifying the critical elements of a supportable performance assessment and establishing a clear staff position on each of these critical elements. With the exception of eight specific technical comments (described below), the following comments do not question the sound technical basis upon which these positions are founded; rather they identify concerns on how the public will accept performance assessments conducted prior to this guidance and future performance assessments based upon it.

Response
This comment is noted.

General Comments

1. One disposal site license has been issued in draft, subject to an on-going adjudicatory hearing and two facility license applications are under regulatory review. These applications were developed prior to the availability of the subject BTP. The industry is concerned that the public may not accept the issuance of a license that is based on a performance assessment that differs from the BTP in areas such as time of compliance determination or critical population determination.

Response
The PAWG agrees that, potentially, this could be an issue with the public. However, as stated in Section 1.7 (“This Technical Report as Guidance”), this document is only intended to identify and describe methods or approaches that the PAWG recommends that would be acceptable to staff for demonstrating compliance with the regulations. Other methods or approaches can be used provided there is a sufficient basis for the preferred (alternative) approach. However, irrespective of the method or approach used by the LLW disposal facility developer, the PAWG has previously noted that rigid adherence to the specific concepts/steps proposed in this technical report is not sought so much as the use of a **consistent process that produces an accurate and properly documented performance assessment.** The PAWG believes that effective implementation of a good LLW performance assessment cannot guarantee acceptance of the technical conclusions; however, use of a flawed process or improper implementation of a good process cannot help but cast serious doubt on the quality of the conclusions.

That being said, the staff does not know, and thus cannot comment on, how often regulatory authorities , in Agreement States, have used alternatives, to the compliance times or critical groups, this technical report recommends. However, the PAWG does note that, consistent with the theme expressed in the previous paragraph, the low-level radioactive waste disposal facility developer needs to provide a well-documented, technically defensible basis for the positions, including those different from the ones recommended in this NUREG, taken in its performance assessment.

Finally, as noted in the PAWG’s response to *Mel Silberberg and Associates Specific Comment No. 3*, one way to improve the credibility and confidence in an LLW performance assessment would be through the use of *peer reviews.* The PAWG believes that this recommendation would also be useful in those instances when LLW disposal facility developers adopt alternative positions/approaches to those recommended by the staff in this technical report.

2. In addition, the operating facilities at Barnwell (South Carolina) and Hanford (Washington) were licensed prior to Part 61 and it's not clear how the guidance found in this [draft] BTP would be applied by these Agreement States in future operation and pre-closure activities. The staff addressed these concerns in part by stating in Section 1.8 of the [draft] BTP: "The extent to which the Agreement States or other regulatory entities implement the recommended technical position statements found in this NUREG is, of course, a matter for their consideration and decision...." The NRC could further help the public understand and accept licensing decisions involving existing facilities and pending applications by direct participation in and support of those Agreement State licensing decisions.

Response

Under Section 274 of the Atomic Energy Act, when NRC enters into an agreement with a State, to permit the State to assume regulatory authority for the regulation of LLW, the Commission's responsibility is discontinued, and the Agreement State, not the NRC, is now responsible for implementing the Commission's regulations and reaching the necessary licensing decisions. Under such an arrangement, the Agreement States have performed essentially all the licensing decisions for LLW disposal facilities during the last two decades. For its part, NRC has provided significant technical assistance to the Agreement States in the past, to ensure that their programs are effective, and continues to budget resources in this area to support future technical assistance needs. The NRC staff also periodically reviews Agreement State LLW programs to ensure that they are adequate and compatible with NRC's LLW regulatory framework. In addition, there are a number of mechanisms whereby the State and the NRC staffs routinely interact to exchange information, such as meetings of the Conference of Radiation Control Program Directors, the LLW Forum, the Organization of Agreement States, and State Liaison Officers.

The PAWG agrees that public understanding of and confidence in the Agreement States' LLW regulatory programs is essential for the continued operation of existing LLW disposal facilities and the development of new ones, and the staff has an interest in ensuring that the States' respective LLW agreement programs are a success. However, the PAWG believes that the framework described above is sufficient for the identification of regulatory or technical issues of mutual interest, for discussion by the respective staffs. With the completion of this technical report, the PAWG expects this dialogue to continue. However, the PAWG believes that if the NRC staff were to directly or indirectly participate in Agreement State licensing decisions, as suggested in this comment, it would have the effect of undermining the regulatory authority of those Agreement States.

3. For future license applications based on this BTP, a key concern is the public acceptance of a probabilistic approach to performance assessment compliance determination based on the "mean value" of a distribution. The industry concurs that this is a technically sound, statistical approach for determining compliance while addressing the uncertainty inherent in modeling complex systems. Our challenge is how to successfully communicate this concept to the public.

Response

In response it should be noted that the Commission has also concluded that probabilistic methods can be useful in regulating both nuclear and non-nuclear applications. In recognition of the growing use and acceptance of probabilistic methods, or PRA, in evaluating reliability engineering and system safety (e.g., DOE *et al.*, 1992), the Commission issued a *Policy Statement* in 1995 advocating the use of PRA methods in its regulatory activities (see Appendix C). As a consequence, PRA technology supports the Commission's risk-informed regulatory philosophy in several areas of the nuclear fuel cycle (PRA Working Group, 1994).

The PAWG recognizes the challenges associated in communicating with the public on the use of new decision-making concepts, such as those associated with probabilistic methods, and has worked hard to introduce and explain this technology. For example, the PAWG hopes that its responses to public comments contained in this appendix will contribute to this understanding (e.g., the PAWG's response to *Mel Silberberg and Associates Specific Comment No. 3*), as well as its earlier sponsored public workshops related to the LLW PAM, overall, and the Commission's *PRA Policy Statement* now attached to this technical report, as Appendix C.

4. The staff must appreciate the difficulty faced by an applicant who must respond to a siting opponent, in front of a judge, and support a compliance determination based on a distribution where nearly 50 percent of the probable outcomes could exceed the dose limits to the critical group. The NRC must be prepared to provide expert testimony that clearly explains and supports the use of this complex method.

Response
See PAWG's response to *NEI General Comments Nos. 2 and 3*. Furthermore, the NRC staff generally does not participate in non-NRC litigations. In this regard, requests for NRC staff participation may be made in accordance with the procedures set forth in 10 CFR Part 9, Subpart D.

5. The industry believes that the public would benefit from some targeted NRC sponsored workshops that deal directly with specific radiation dose limits and acceptable methods of determining compliance with them. In this way the NRC could expand public participation and provide interested parties an integrated overview of radiation protection standards, how they are developed, and how compliance determination is demonstrated.

Response
As noted in the response to *NEI General Comment No. 2*, the Agreement States have performed essentially all the licensing activities related to LLW disposal over the last two decades. By contrast, NRC's resources in this area have generally declined although the staff continues to provide technical assistance to the States, when needed. Nonetheless, in recent years, NRC staff participating in the PAWG have been actively involved in identifying approaches and developing acceptable methods for demonstrating compliance with its LLW regulations, as evidenced by the preparation of this NUREG.

In addition to PAWG efforts in the area of LLW, the NRC staff has held a number of public workshops on the license termination rule for decommissioning (Part 20, Subpart E) and its associated guidance, the proposed rule for the disposal of HLW at Yucca Mountain, Nevada (Part 63), and the proposed clearance rule for radioactive materials (NRC, 1999; 61 *FR* 35090).

To ensure that the public has an opportunity to review and comment on **all** the Commission's regulatory activities, the draft rules and guidance in the various program areas have been published in the *Federal Register,* for public comment. In addition, NRC maintains a "Technical Conference Forum" on the *Internet* to facilitate public input to NRC's regulatory development process. In general, the PAWG believes that NRC regulations and guidance are consistent with prevailing National and International opinion and practice for responsible radioactive waste management.

Technical Comments

1. Page 3-10: "Class A waste contains the largest quantity of long-lived radionuclides (radionuclides with half-lives greater than 100 years)." This is not true in all cases. For some of the key long-lived radionuclides, Class C waste contains the largest quantity, e.g., 53.1 percent of ^{14}C and 45.3 percent of ^{99}Tc. This is based on the shipping manifest information collected at Barnwell (South Carolina) from 1989-1994.

Response
The statement in question in this technical report is based on a study covering waste disposal in the United States from 1987 through 1989 (NUREG-1480 – Roles, 1990). Another study (NUREG/CR-5911– Cowgill and Sullivan, 1993) covering the same period, confirms that Class C waste at existing facilities do contain higher percentages of certain long-lived radionuclides. Therefore, the PAWG agrees with the *NEI's* comment, and accordingly, the text of this technical report in Section 3.2.2 ("Role of Engineered Barriers" – paragraph No. 2) has been modified (see bold type) to acknowledge that the largest quantity of long-lived radionuclides may not be contained in Class A waste, as follows:

> "...Study of LLW disposed of in the United States from 1987 through 1989 (Roles, 1990; **Cowgill and Sullivan, 1993**) shows that although most of the activity in initial waste inventories resides in Class C waste, Class A waste **typically** contains the largest quantity of long-lived radionuclides (radionuclides with half-lives greater than 100 years)...."

2. Page 3-11: "The staff recommends that an applicant should assume that engineered barriers have physically degraded after 500 years following site closure." The lifetime of engineered barriers will have a major impact on performance assessment. While the prediction of the service life of engineered barriers is difficult, research continues to improve the performance of engineered barriers and their predictability. The BTP should not discourage these efforts or place limitations on the use of future advances in this field.

Response
PAWG agrees that the prediction of the service life of engineered barriers is a difficult technical issue and it welcomes research on improving their performance as well as the predictability of their performance. PAWG's intent is not to discourage those efforts. Rather, in estimating engineered barrier service life, the LLW disposal facility developer will need to provide adequate technical justification for the service life selected as part of the performance assessment documentation process. [As noted in response to the *State of New Jersey Specific Comment No. 1*, the staff have introduced some editorial changes to the final version of this technical report to make it clearer that: (a) it is incumbent for LLW disposal facility developers to select the time period of performance for engineered barriers; and (b) credit for longer time periods of performance (i.e., greater than 10^2 years) can be taken.] The emphasis on the need for such justification should actually help to encourage research in this important area.

3. Page 3-21, Section 3.3.2.1.1 ("Model Uncertainty"): "...and choose the most conservative conceptual model for demonstrating compliance...." As discussed in page 3-46 (Section 3.3.5.3.2: "Waste Form and Waste Type – Recommended Approach"), the most conservative model could be unrealistic and produce unacceptable results. Use of more sophisticated models could avoid overly conservative approaches and should be allowed for demonstrating compliance.

Responses

The PAWG wishes to address two points in its response to this comment – one is general and the other is specific. First, as a general observation, decisions regarding the amount of conservatism to be applied to modeling activities ultimately rests with the LLW disposal facility developer. Under ideal circumstances, and with unlimited budgets, LLW disposal facility developers can collect large quantities of data that can be expected to produce sophisticated, predictive models. However, the budgets for most disposal programs are usually finite and knowledge of LLW disposal system behavior is imprecise, and thus results in a natural tension in deciding how much data to collect and where, and how simple or bounding (e.g., conservative) to make the subsequent modeling activities, based on these data. The Commission's risk-informed regulatory framework recognizes this dilemma and affords the facility developer flexibility in how to assemble an acceptable safety case – that is to say flexibility in how it demonstrates compliance with the regulations. As part of this process, in describing their analyses, LLW disposal facility developers will need to explain how conservative the constitutive modeling is, and how the residual uncertainty associated with the modeling propagates through the analysis and subsequently affects compliance with the standards. Therefore, the amount of conservatism applied to the modeling for a particular condition, feature, event, or process should be base, in some fashion, on how sensitive disposal facility performance is to that particular parameter. Once the limitations (i.e., the extent of conservatism in the analysis[31]) and the uncertainties have been identified, the Commission will determine if it can find, with "reasonable assurance," that the performance objectives can be met.

Having said this, the PAWG believes that examples cited by NEI, in their *Specific Comment,* reinforce these views, albeit in two different contexts. The first cited example (from Section 3.3.2.1.1) concerns the treatment of model uncertainty in scenarios. As a result of site characterization, it may be possible for equally credible, multiple conceptual models to emerge because of the temporal and spatial variations in the data, the possibility for multiple interpretations of the same data, and the absence of validated theories for predicting the performance of LLW disposal systems for thousands of years. (In this regard, the PAWG has taken the position that rare events, highly unlikely combinations of parameters, and unreasonable or speculative modeling assumptions, should not be used.) Consequently, it is possible (perhaps even likely) that a condition, feature, event, or process could be conceptualized in more than one way – i.e., amenable to multiple interpretations. Each of these (alternate) conceptual models could thus be implemented in a unique mathematical model. The PAWG has taken the position that the LLW disposal facility developer should use the conceptual model to demonstrate compliance that can be best defended based upon what is known about the site. See the PAWG response to *Golder Associates, Inc. Detailed Comment No. 10*.

On the other hand, in the second cited example (from Section 3.3.5.3.2), the issue here concerns the treatment uncertainty in the estimation of the source term used in dose assessments. Because of the differences in the kinds of waste form and waste types could be potentially disposed of in an LLW facility, it is recommended that simple, conservative model can be used initially in the assessment. This could reduce the burden of justifying the use of more sophisticated, realistic release models that typically require more data and information to support their use..

4. Page 3-44: "Information on commercially generated radionuclide distribution by waste generators, waste class, waste stream, and waste form is available from shipping manifests (see Roles, 1990; and Cowgill and Sullivan, 1993)." The cited references provide a good framework for inventory characterization. But the actual details of inventory distribution in various waste

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31 In general, the NRC staff does not (nor does the Commission) have quantitative standards on what level of conservatism in an analysis is tolerable. For some LLW disposal conditions, features, events, or processes, conservative analyses may suffice because their effect on a parameter or performance is marginal or because additional characterization is not likely to improve the LLW disposal facility developer's understanding in that area. The challenge for LLW disposal facility developers is to decide where conservative analyses will suffice and where they will not.

forms and streams are based mainly on the Richland (Washington) site data. The Richland site data are not, in all cases, representative and should not be used for general inventory characterization.

Response

The cited references are provided as examples of the use of shipping manifests and are not intended as a source for characterizing the inventory at a specific site. Section 3.3.5.1.2 of this technical report ("Source Term and Waste Type – Recommended Approach") specifically states that assumptions regarding inventory, waste form, and waste type should be consistent with the LLW specifically expected to be disposed of at the site.

5. Page 3-46: "Certain waste types may be characterized by a K_d or sorption release when a radionuclide is bound or sorbed onto a surface such that radionuclide release is characterized by a distribution coefficient or K_d (e.g., ion-exchange resins that are selected for their sorption properties)."

   Page-47: "However, little is known about the release of nuclei from these materials over long timeframes, in a setting such as an LLW disposal site. Release of radionuclides from the ion-exchange resin is often estimated by considering the distribution coefficient for the individual radionuclide in the ion-exchange resin. However, to take credit for some kind of partitioning properties for the resins, while seemingly reasonable, would be highly uncertain over extended timeframes without specific experimental and site-specific chemical data."

   Use of K_d or sorption release for ion-exchange resins may be acceptable for radionuclides with relatively high K_d values. For radionuclides with low K_d values (such as ^{14}C and ^{129}I), use of sorption release model is not realistic with currently suggested K_d values (~0.01) for these radionuclides. The radioactivity in ion-exchange resins is not surface contamination. Release of radionuclides from ion-exchange resins is controlled by the ionic strength of the contacting water and the transport within the bulk pore water of the medium. The [draft] BTP should allow the use of more sophisticated models or the first-order chemical reaction model based on relevant data for these low K_d long-lived radionuclides. This issue is important because large quantities of low K_d long-lived radionuclides exist in ion-exchange resins.

Response

The recommended approach for modeling releases from ion-exchange resins does not preclude the use of more sophisticated models or first-order chemical reaction models, provided sufficient justification is provided on the specific chemical conditions (e.g., redox conditions, pH) assumed in the analysis. This technical report recommends that distribution coefficients or K_ds should be used for modeling releases from waste types where the radionuclides are bound or sorbed onto the surface of the waste. Ion-exchange resins are included as an example of waste type where this might be applicable. NRC has recently sponsored research evaluating the adsorption property of ion-exchanging resins for a range of radionuclides and water chemistries (e.g., Robertson *et al.,* 2000). Results from this research offer insights on the adsorption behavior of ion-exchange resins. For example, radionuclide sorption onto ion exchange resin from reactor coolant and liquid radwastes at nuclear power stations is a combination of true ion exchange of soluble ions onto the functional groups of the resins, and physical adsorption of insoluble hydrous metal oxides (e.g., Fe, Mn, Ni oxides) onto which radionuclides are incorporated. Therefore, the sorption is a surface phenomenon. In addition, desorption of the radionuclides from the resin is more than just a function of the ionic strength of the solution and the transport within the bulk pore water of the medium. The composition of the solution is more important than just the total ionic strength because of the competing ion effect for ions of similar size and charge.

With regards to the statement about the low K_d values for ^{14}C and ^{129}I, while it is true that ^{14}C can have relatively low K_d values less than one (for inorganic carbon), reported K_ds for ^{129}I have always been very high (e.g., thousands to hundreds of thousands L^3/M) for ion exchange resins (mixed-bed and anion resins).

6. Page 3-48: "...Therefore, it is recommended that carbon-steel containers be given no credit for delaying releases because of the anticipated short lifetime relative to either the lifetime of other engineered barriers such as the cover or the institutional control period...." This is true in a soil-backfilled facility. But, in a cement-backfilled system, the lifetime of carbon-steel containers (liners) could be significantly extended if availability of oxygen at the interface of cement and steel surfaces is limited.

Response
Although the PAWG agrees with *NEI's* observation regarding the performance of carbon-steel containers, it questions how long one can rely on the cement backfill to remain intact (e.g., how long will it be durable)?[32] Once the cement backfill is degraded, the PAWG expects the carbon-steel components of the system to oxidize from the exposure to oxygen. The discussion in Section 3.3.5.4.2 of this technical report ("Waste Container– Recommended Approach") is intended to reflect this possibility.

7. Page 3-53: "If backfill materials or chemical barriers are used to retard the release of radionuclides to the groundwater, sufficient justification must be provided that the sorptive properties of the material would be appropriate for the chemical environment of the disposal facility. The justification may be based on the K_d approach, experimental studies such as field lysimeter investigations, and laboratory studies, combined with geochemical modeling." Does the justification require all of the approaches (distribution coefficient approach, experimental studies such as field lysimeter investigations, and laboratory studies, combined with geochemical modeling)? If not what is the acceptable minimum to justify the use of backfills to retard the release? Should the "and" between investigations and laboratory be changed to "or"?

Response
The PAWG did not intend to imply that all of the listed approaches should be implemented, to provide adequate justification for retardation. Accordingly, the text has been corrected, as suggested, as follows:

> "The justification may be based on the distribution coefficient approach, experimental studies such as field lysimeter investigations, **or** laboratory studies, combined with geochemical modeling."

8. Page 3-76: "For facilities with potentially significant releases of ^{3}H and ^{14}C, specific-activity models may be useful. Specific-activity models should not be used for pulse releases or for ^{14}C in water." In performance assessment, the dominant exposure pathway is ground-water

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[32] *Durability* is defined as the capability of a material, product, component, assemblage of components, or a complete construction system to maintain its serviceability over a specific period of time, under specific chemical, physical, and mechanical environmental conditions (National Materials Advisory Board, 1987; p. 22).

contamination. Therefore, realistically, the use of a specific-activity model is not appropriate for ^{14}C except for the gaseous release. A little more clarification is desired.

Response

As noted in Section 1.2 of this technical report ("Overview of LLW Disposal Concepts, Performance, and Technical Issues"), although waterborne release is typically the dominant pathway, certain situations may require evaluation of potential releases to air because "...air exposure pathways may be significant for particular designs, such as AGVs with no earthen cover...." To better express the PAWG's views in this area, additional clarification has been added to Paragraph (b) of Section 3.3.7.2.2 ("Model Identification and Identification of Parameter Values"). The paragraph now reads as follows:

"(b) For disposal facilities with potentially significant releases of ^{3}H, a specific-activity model may be useful. The isotope appears to be widely distributed in the environment, and if released, rapidly mixes, with its stable elements, counterparts in nature. Thus, a specific-activity model is generally used to describe its movement through the terrestrial biosphere, is generally conservative, and may be acceptable for dose assessment. The specific-activity methodology assumes that an equilibrium state exists between the tritium concentrations in the water, food products, and body tissues, for the specified location. For AGVs or other disposal facilities where the atmospheric pathways are predominate, it may be useful to use a specific-activity model for ^{14}C. A specific-activity model should not be used for pulse releases of either ^{3}H or ^{14}C, or for ^{14}C released through the ground-water pathway. More information on specific-activity models can be found in Till and Meyer (1983)."

Oak Ridge National Laboratory
Chemical Technology Division

> [The following] are Oak Ridge National Laboratories' (ORNL's) comments on the draft of NUREG-1573. The [BTP] fills a long-standing need and is well written. There is one omission in the [draft guidance] that needs to be addressed – nuclear criticality. Nuclear criticality is important because if a nuclear criticality event occurred in a disposal site it would: (1) generate added radioactivity; and (2) generate heat. The additional radioactivity would change the source term of the disposal site. More significantly, a criticality event would generate heat that can accelerate waste package degradation, accelerate degradation of engineered barriers, and cause movement of water and air by thermal convection. Water and air movement provide the mechanisms for radionuclide transport to the environment.
>
> In principle, nuclear criticality can occur in any disposal site containing more than one critical mass of fissile materials. An LLW disposal site that contains significant quantities of wastes from nuclear fuel fabrication facilities is likely to contain more than one critical mass of material. Nuclear criticality is unlikely in an LLW disposal site; but not impossible. Normal geochemical cycles (oxidizing rainwater and chemically reducing wastes) tend to separate and concentrate uranium from most other elements in a shallow-land disposal site. It is these mechanisms that creates the possibility for a nuclear criticality event either inside or beyond the boundary of the disposal site. As such, the potential for nuclear criticality should be explicitly addressed. There are multiple methods to ensure that nuclear criticality is not a practical concern.
>
> It is noted that the NRC is currently undertaking studies on the potential for nuclear criticality at LLW disposal facilities, including the Barnwell site in South Carolina and the Envirocare site in Utah. Furthermore, the American Nuclear Society is conducting a topical meeting in September 1997 in Chelan, Washington, that includes multiple papers on criticality control in disposal facilities.
>
> Several of these papers address nuclear criticality control in LLW disposal facilities. These papers include the enclosed paper that [an ORNL staff member is] presenting on this subject.[33] [This] paper discusses one strategy to minimize risks from nuclear criticality events in disposal sites, including shallow-land disposal sites. These sources of information provide a good information base to address this issue.
>
> Based on the above considerations, ORNL recommends that: (1) either the [BTP] directly address the issue of nuclear criticality in LLW disposal facilities; or (2) the [BTP] acknowledge the issue and make appropriate reference to planned or future activities to address this issue.

Response
The PAWG agrees with the commenter that nuclear criticality is unlikely in an LLW disposal facility. In fact, independent work by the NRC staff indicates that the potential for nuclear criticality in an LLW disposal facility is extremely remote, but not necessarily impossible (Toran *et al.,* 1999; pp. 47-49). The PAWG believes that appropriate measures (i.e., controls on waste handling and disposal practices) will be taken during the facility operation to preclude post-closure criticality.

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[33] A copy of this paper (Forsberg, 1997) was included with ORNL's public comments and has been placed in NRC's PDR.

U.S. Department of Energy
Office of Environmental Policy and Assistance
Division of Air, Water, and Radiation

General Comments

The Department has reviewed the draft "BTP which the NRC made available for public comment. We are assembling a Department-wide consolidated set of comments which we will provide in the near future as a supplement to the enclosure.[34]

There are aspects of the draft BTP that are good and others that are not. The endorsement of the use of probabilistic analysis as a decision tool is generally positive. Compared with deterministic analyses, probabilistic analyses can provide additional, quantified information to decision-makers and thus facilitate a judgment regarding "reasonable assurance." The Department also supports many of the specific performance assessment recommendations such as the assumption of undisturbed (by humans) performance, use of current technologies, and the critical group.

However, the [draft] BTP contains various flaws that would make an adjudicatory licensing process far more difficult without any substantive improvement in health and safety or site performance. Certain recommendations in the [draft] BTP may cause a proliferation of many small waste sites (due to the [draft] BTP effectively limiting site inventories) where fewer larger sites may possibly be more (or at least as) protective of the public welfare. Other recommendations act to effectively punish the use of superior disposal sites. A fundamental problem is the uncertain role of active and passive institutional controls in assuring long-term safety and compliance with regulatory requirements.

Given these issues and the enclosed comments, the [draft] BTP should be reconsidered. NRC needs to precisely articulate its fundamental tenets and assumptions regarding institutional controls in light of current law and regulation, and then develop its recommendations based on this foundation.

We believe that assurance of protection of the public and the environment requires the continuation of active and passive institutional controls at waste disposal sites until such time as they can be safely released (applying appropriate decommissioning criteria to the disposed waste in addition to ancillary surface facilities).

Although the draft BTP makes some good points, it is seriously flawed. The fundamental problem is the uncertain role of active and passive institutional controls in assuring long-term compliance with regulatory requirements. The Part 61 rulemaking record is contradictory with respect to this critical issue.

Part 61 requires a regulatory prediction that doses to members of the public will not exceed specified dose limits. On what basis, ultimately, will NRC justify this prediction? If active institutional controls end in the future, then NRC must rely very heavily on performance assessments to provide the required prediction of compliance with specified dose limits. But if active institutional controls form an essential component of assurance of long-term safety, then

[34] DOE has subsequently indicated that it intends to submit no further comments on this NUREG.

the prediction about long-term compliance with dose limits depends more significantly on a site-specific assessment of the adequacy of the long-term... institutional control provisions, including funding mechanisms. Performance assessments serve a planning rather than a predictive role. (Although for planning purposes one may calculate hypothetical public doses assuming that the future site custodial agency does not act to preclude the doses from occurring, such inaction is actually not intended and may be inconsistent with legal or regulatory requirements.)

Because the long-term role of institutional controls is not clearly established, the role of performance assessments in making decisions, and the interpretation of performance assessment results and limitations, is also not clear. The [draft] BTP reflects this lack of clarity, and reads as if the authors simultaneously believe, and do not believe, that performance assessment calculations represent real doses to real people.

Response

In its opening comments, the Department raises a number of issues, which it repeats later in more detail in its *Specific Comments* below. However, the one unique comment presented here concerns the need for maintaining (active) institutional controls at LLW disposal sites. In its comment, DOE states that the "...long-term role of institutional controls is not clearly established..." and questions the "predictive value" of a performance assessment in public health and safety decision-making. Alternatively, DOE recommends that institutional controls should be in place for as long as the wastes pose a radiological hazard.

As DOE correctly notes, an important consideration in the long-term performance of an LLW disposal facility concerns the need to prevent inadvertent human intruders from performing activities (farming, construction, exploration, mining, well drilling) that could result in unknowingly expose such individuals to doses or result in the increased migration of radionuclides off-site. In its regulation, the Commission proposed two measures to address these concerns – institutional controls and specific design requirements.

Institutional Controls: The Commission has taken the position that institutional controls can be used to prevent society from having contact with the disposed waste and affecting the integrity of a disposal site. In addition, the Commission believes that such controls [10 CFR 61.59(b)] can be relied on for no more than 100 years (NRC, 1982; 47 *FR* 57446) and after this time, passive controls, such as government ownership of the disposal site (10 CFR 61.59) would be relied on to preserve knowledge about the site and thus reduce the potential for inadvertent intrusion by limiting the types of activities that could take place there.

Design Requirements: In its regulations, the Commission also has other requirements directed at achieving the long-term stability and isolation of the wastes following the end of active institutional controls (NRC, 1982; 47 *FR* 57446). The specific design requirements found at 10 CFR 61.52 require emplacement depths and other certain engineered (and natural) barriers to reduce radiation exposures and further minimize the potential that individuals might inadvertently come into contact with the disposed of waste. The specific design requirements are tied to a waste classification system (10 CFR 61.55) which segregates wastes based on their activity after 100 years. Under this system, wastes with higher activities, over longer periods of time, require deeper (geologic) disposal and/or reliance on more durable engineered barriers (NRC, 1982; 46 *FR* 38091) to ensure that potential exposures to inadvertent intruders are reduced after active institutional controls have expired.

This regulatory proposal was issued for public comment as part of the earlier rulemaking process for Part 61(NRC, 1982; 46 *FR* 38081) and the accompanying DEIS (NRC, 1981a-d). Although the choice of a time period for relying on institutional controls is completely a matter of judgment, the Commission based its decision on the consensus that developed as a result of the following (NRC, 1982; p. B-140):

(a) NRC-sponsored regional workshops on Part 61 and the DEIS, and the public comment period that followed; and (b) earlier work by EPA on the subject (EPA, 1978; 43 *FR* 53265).[35] What the rulemaking record also indicates is that although "active" institutional controls would end at 100 years, NRC does not assume that government oversight would end; rather, certain "passive" institutional measures would be relied on to limit the potential for future human intrusion (NRC, 1982; 46 *FR* 38085). This would include land ownership by the government as well as the existence of certain types of institutional information – records, deed restrictions, and covenants (NRC, 1982; p. B-42) – which, based on the historic record (Jensen, 1993), can be expected to convey archived information about the potential hazard present at an LLW disposal site for many hundred of years. In closing , because, in DOE's view the existing Part 61 regulatory framework still needs to be amended, the staff will inform the Commission of the Department's views.

Finally, as regards that portion of the DOE comment that questions the "predictive value" of a performance assessment in public health and safety decision-making, the PAWG agrees that performance assessments do not "predict" future LLW disposal facility performance. Rather, in the PAWG's view, performance assessment methodology (when correctly performed) is a type of systematic safety analysis that is intended to address: (a) what can happen; (b) how likely it is to happen; (c) what the resulting impacts are; and (d) how these impacts compare to regulatory standards (see Eisenberg *et al.*, 1999)? Because of the hazardous nature of radioactive wastes and the long time periods of concern, there is general consensus, within the international community, that disposal facility developers and regulators will rely on mathematical models, numerical methods, and computer codes, as part of a performance assessment process (Nuclear Energy Agency, 1991). That being said, there are some question as to the value of these predictive methods in earth science applications (e.g., Kitts, 1976; de Marsily and Merriam, 1982; Oreskes *et al.*, 1994; Konikow and Ewing, 1999). However, it is the PAWG's view that the performance assessment methodology, of the type outlined in this NUREG, can be used with confidence in regulatory decision-making when a model validation strategy (Eisenberg *et al.*, 1999) has been employed, as now recommended in this technical report. (See the PAWG's response to *Mel Silberberg and Associates Specific Comment No. 3.*)

Specific Comments

Among other concerns, we note:

1. The [draft] BTP lacks, but needs, a clear process that would enable NRC to arrive at a licensing decision on a timely basis, considering and accounting for uncertainties. NRC seems to be hoping that all decisions could be made at the time of license issuance, and is compensating for expected data limitations and analytical uncertainties by calling for either a highly conservative bounding analysis or compliance with an abstract numerical formula. We believe, however, that as the [draft] BTP is written, it discourages a timely licensing process, particularly if adjudicatory hearings are contemplated. Assuming that new disposal facilities are ultimately approved, the [draft] BTP recommendations could result in decision-making based on grossly conservative and misleading performance assessments, a situation that promotes large numbers of disposal facilities, each containing only small quantities of waste.

Responses

The PAWG disagrees with the observations made in this comment. LLW performance assessments are a type of a PRA, and as a technology, PRA has been in place for many decades and lately has enjoyed greater use and acceptance in radioactive waste management applications (e.g., DOE *et al.*, 1992). Because of the hazardous nature of radioactive wastes and the long time periods of concern, there is

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[35] After public comment, in its final rule, EPA adopted the 100-year limitation on reliance on active institutional controls (EPA, 1985; 50 *FR* 38080).

general consensus within the international community (i.e., Nuclear Energy Agency, 1991) that disposal facility developers and regulators will need to rely on mathematical models, numerical methods, and computer codes as part of the performance assessment process.

In the specific case of LLW disposal, the PAWG has attempted to outline in this technical report the attributes of an acceptable performance assessment methodology. When properly implemented (and documented), this methodology should provide decision-makers with information on the extent to which data limitations and analytical uncertainties affect estimates of performance. In the first instance, LLW disposal facility developers can evaluate the effects such limitations and uncertainties have on siting, design, and/or performance, and decide where and how adjustments[36] are to be made. For their part, independent regulators can then judge the quality of the overall disposal concept and determine whether this concept would adequately protect the public health and safety and the environment.

Finally, the PAWG disagrees with the notion that this technical report will discourage a timely licensing process. As alluded to in the paragraph above (and discussed in more detail in this technical report itself), essentially all the fundamental siting and design decisions rest with the LLW disposal facility developer and not with the regulator (i.e., NRC). Simply stated, disposal facility developers should not be requesting license applications to receive and dispose of LLW until they have confidence that a particular disposal concept is capable of meeting NRC's regulation. Contrary to DOE's view in this area, the PAWG does not expect to rely on the LLW performance assessment process to compensate for a poorly conceived LLW disposal concept.

Consistent with its views on risk-informed, performance-based regulation, the PAWG has outlined in this document an iterative approach designed to ensure that site characterization and facility design activities are focused in those areas most important to disposal facility performance. As a consequence, the PAWG believes that approaches outlined in this document should greatly facilitate any future licensing process.

2. NRC needs to develop and set forth a decision process that clearly and honestly confronts the need for a licensing decision based largely on judgment, considering a site-specific data record that covers only a few years.[37] For this, the general principles of the *Data Quality Objectives* (DQO) *Process* may be helpful. The decision process should be established so that initial regulatory decisions are reviewed at appropriate follow-up intervals for as long as the waste presents a sufficient hazard to be of concern, consistent with a long-term "responsible control" approach to LLW management.

Responses

In its comments, DOE is recommending that the application of the *DQO Process,* currently used in radiological decommissioning surveys to demonstrate compliance with dose- or risk-based regulation, be applied to the LLW performance assessment process outlined in this technical report. In summary, the *DQO Process* is intended to ensure that early consideration be given to the kinds and amounts of

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[36] As described in Section 3.1 and depicted in Figure 3 of this document, the LLW disposal facility developer can collect additional site data, make the disposal system design more robust through additional engineering enhancements, reduce the proposed radionuclide inventory intended for disposal, or select an alternative disposal site with more favorable waste isolation characteristics.

[37] As part of preparing and reviewing performance assessments for its own LLW disposal facilities, DOE frequently identifies sources of significant technical uncertainty, even though DOE has been operating some of its sites, and collecting data, for over 50 years. Assuming that DOE authorizes an LLW disposal facility, significant technical uncertainties must be addressed as part of required performance assessment maintenance programs, in recognition of the need for continuous long-term management of LLW disposal facilities.

data needed to be collected to support a potential licensing decision, before actual data collection commences. In its comment, the Department suggests that the *DQO Process* may help to address the concern that LLW licensing decisions are based on data-sets covering timeframes significantly less than the 10,000 years of regulatory concern.

The *DQO Process* is described in the *Multi-Agency Radiation Survey and Site-Investigation Manual* (EPA, 1997). This process consists of a series of planning steps based largely on the so-called "scientific method" for establishing criteria for data quality and quantity developed during radiation survey designs (see EPA, 1987a and b, 1994; and American Society for Quality Control, 1995). The PAWG supports the underlying principle of the *DQO Process* – to ensure that data collecting activities appropriate to support decision-making have taken place. However, for the purposes of the LLW program, the PAWG has taken the view that additional "assurance" measures are needed to provide confidence in the performance assessment results. As noted in the response to *Mel Silberberg and Associates Specific Comment No. 3*, the PAWG is now recommending the use of *peer reviews, (formal) expert judgment,* and *model validation* be integrated into the LLW performance assessment process. It is believed that the application of these concepts to the recommended approach set forth in this technical report will be useful in addressing the generic issue of how limitations in the short-term data (collection) record can be overcome when reaching long-term regulatory decisions.

Finally, as regards that potion of the comment related to the need for "follow-up" activities in the area of data collection, the Department is referred to Section 3.2.5 of this technical report ("Role of LLW Performance Assessment during Operational and Closure Periods") which clearly suggests that additional assessment be made of the site performance before site closure, based on data and information gained during the operational period.

3. NRC provides insufficient justification for recommendations about performance assessment assumptions for undisturbed performance, current technologies, land use practices, and biological trends. Also, NRC provides no justification regarding its recommendation to avoid "unnecessary speculation" in performance assessments, nor guidance (e.g., examples) in interpreting the recommendation. Uncertainty about these matters can be detrimental to achieving a timely licensing process, particularly if adjudicatory hearings are contemplated. The rule requires reasonable assurance about protection of a member of the public, and is silent about conditions on that protection. On what basis would NRC justify not considering an unlikely or speculative scenario (e.g., disturbed performance) in a performance assessment? A "calculational inconvenience" argument may not be compelling, even though one can argue that anthropogenic processes and biological trends are difficult to project beyond a very short period of time. [We believe the needed justification for these concerns must be largely based on institutional control considerations. Some issues may be appropriate for expert elicitation with recommendations reviewed on a periodic basis (such as every 25 years) as part of a long-term responsible control approach to waste management.]

Responses
This comment essentially raises three issues: (a) the LLW performance assessment scenario selection methodology; (b) the definition of the critical group; and (c) the role of institutional controls.

First, with respect to scenario selection, the siting guidelines found at 10 CFR 61.50, in effect, obviate the need for LLW disposal facility developers to consider highly speculative and low-frequency events. In addition, they discourage disposal facility developers from siting potential LLW disposal facilities in areas that are geologically active as well as those areas whose geologic history is complex, subject to multiple, mutually exclusive interpretations. Under 10 CFR 61.50, LLW disposal facility developers are also obliged to site disposal facilities in geologic (geomorphic) settings that are essentially stable or, alternatively, in areas in which active features, events, or processes will not significantly affect the ability of the site and design to meet the Subpart C performance objectives. In practical terms, to meet this requirement the LLW disposal facility developer will need to locate the disposal facility in an area that is geologically quiescent. Moreover, in characterizing the site, the LLW disposal facility developer will need to assure itself that the characterization process itself is of sufficient precision (e.g., Schumm, 1991) so as to not miss evidence of the potential for disruptive events to possibly occur sometime during the next 10,000 years, based on an interpretation of the past geologic record.

Having done these things, any low-probability scenarios identified – say on the order of 10^{-4} per year, in frequency of occurrence, or lower – would be screened out of the site model (and the subsequent analysis), for the requirements in 10 CFR 61.50 argue that they do not need to be considered. As for the remaining scenarios, because all are credibly likely – that is to say they reflect the expected geologic evolution of the disposal site, they would be accounted for in the performance assessment model and treated equally, with a probability of one (1).

Second, concerning the Department's comment on definition of the critical group, based on previous NRC staff experience, it is unlikely that future anthropogenic or biologic changes can or could be predicted with any degree of reliability – irrespective of (formally elicited) expert opinion. Moreover, the PAWG believes that such projections would be highly speculative, subject to significant conjecture, and difficult to scientifically defend. Thus, consistent with prevailing International opinion and practice (e.g., ICRP, 1990; NEA, 1996), the PAWG has assumed in its performance assessments that the "reference biosphere" is constant over the time period of regulatory concern. The PAWG has previously commented on this issue in its response to *Golder Associates General Comment No.* 5.

Finally, the PAWG is aware of DOE's views as they relate to institutional controls. The Department is referred to the PAWG's response to DOE's *General Comments*, above.

4. BTP recommendations on time of compliance are contradictory and reflect an ambivalence about the role and limitations of performance assessments in making licensing decisions. NRC seems to be trying to compensate for analytical uncertainty by increasing the level of uncertainty. The [draft] BTP acknowledges the large uncertainties associated with performance assessments, and notes that uncertainties can increase with time (e.g., the [draft] BTP notes the uncertainties associated with projecting a "site's biological environment..beyond...a few hundred years...," and also with other factors such as human technology changes, glaciation, and climate change). Yet the [draft] BTP recommends analyses to 10,000 years and beyond, and even suggests that applicants consider restricting inventories based on such analyses. NRC is therefore asserting that such calculations far in the future have predictive validity. This assertion is highly questionable.

Response
See the PAWG response to *Commonwealth of Pennsylvania Specific Comment No. 6.*

5. NRC also states that shorter time periods, such as 1000 years, would be generally inappropriate for assessments of LLW disposal facilities. But a requirement to extend compliance times beyond 1000 years requires analyses that have such large uncertainties that they are just as likely to lead to wrong decisions as right ones. Furthermore, such extended analyses effectively punish "good" sites. It would be easier under the BTP to license a site based on a performance assessment that projected a dose of 10 mrem per year over 300 of the first 500 years, than it would [be] to license a site based on a performance assessment that projected zero release over 1000 years but a spike of 40 mrem in year 5600. This is intuitively wrong. It would be highly unreasonable to treat highly suspect dose projections thousands of years in the future with the same level of concern as projections over the first few hundreds of years.

. NRC should therefore incorporate the concept of information quality into the [draft] BTP. One approach would be for an applicant to provide an assessment of his or her confidence in the analytical projections as a function of time. Those aspects of a confidence estimate pertaining to physical, measurable parameters (e.g., the geological and hydrological data record) should be considered separately from those pertaining to anthropogenic processes or biologic trends, recognizing that the one influences the other.[38]

Responses

This comment raises several important themes. First, the PAWG agrees with this comment to the extent that the analyst needs to be able to express his or her confidence in the quality of the data being used to support the analysis. However, contrary to the opinion expressed in this comment, the PAWG believes that it already has incorporated the concept of "information quality" into this technical report. The reader is reminded that, in general terms, the need for information quality and documentation of decision-making related to data selection is already addressed in the following sections of this technical report: 1.8 ("Use of this Technical Report by Other Regulatory Entities"), Paragraphs 4 and 5; 3.1 ("Example of an Acceptable Approach for Demonstrating Compliance with 10 CFR 61.41"), Step No. 1; 3.2.4 ("Treatment of Sensitivity and Uncertainty in LLW Performance Assessment"); and 3.3.2.1 ("Sources of Uncertainty"). As a means of further elaborating its views on the value of data qualification, the PAWG has added language to this technical report encouraging the use of *peer reviews, expert judgment,* and *model validation*, when appropriate, as part of the performance assessment process. See the PAWG's response to *Mel Silberberg and Associates Specific Comment No. 2* for a discussion of these additions.

Also with respect to the data quality theme, this comment suggests that the PAWG (or the performance assessment analyst himself/herself) should distinguish between physical parameters that can be measured today (and likely to remain fixed/constant) as opposed to those parameters subject to change because of anthropogenic processes and/or biological trends (i.e., natural evolution and selection). Based on previous NRC staff performance assessment experience, it is unlikely that future anthropogenic or biologic changes can or could be predicted with any degree of reliability. Moreover, the PAWG believes that such projections would be highly speculative, subject to significant conjecture, and difficult to scientifically defend. Thus, consistent with prevailing International opinion and practice (e.g., ICRP, 1990; NEA, 1996), the PAWG has assumed in its performance assessments that the "reference biosphere" is constant over the time period of regulatory concern.

6. NRC seems undecided about the purpose(s) of performance assessments. Although the [draft] BTP makes statements (p. xii) such as "The goal of the analysis is not to accurately predict the future," it makes other statements that contradict this premise. For example, in Section 1.3 the [draft] BTP states that "Low-level waste performance assessment is a type of systematic (risk) analysis that addresses what can happen, how likely it is to happen, and what are the resulting impacts." Another example is the discussion about the goal of performance assessment being to "defensibly and transparently address uncertainty." But although presenting defensible analysis in a clear manner is necessary, the process is intended to address more than uncertainties.

Response

[38] One may have a high confidence that, given an assumption of current conditions, and an assumption for calculational purposes, that a custodial agency takes no corrective actions, one can project (bound) the release and transport of radionuclides to the environment. However, one may have a low confidence that current conditions (reflecting current anthropogenic and biologic processes) can be projected over a few hundred years. The result can be that one may have a high confidence that he or she understands the current physical processes affecting a disposal facility, and the likely release and transport pathways based on these current processes, but a low confidence in the future public "dose" implied by the analysis beyond a time that "current conditions" can be reasonably projected.

The PAWG sees nothing inconsistent with this technical report's statements that DOE is questioning. As noted in the PAWG's earlier response to *DOE's Overall Comment*, performance assessments do not "predict" future LLW disposal facility performance. Rather, a performance assessment is a type of systematic safety analysis that is intended to address: (a) what can happen; (b) how likely it is to happen; (c) what the resulting impacts are; and (d) how these impacts compare to regulatory standards (see Eisenberg *et al.*, 1999)? Moreover, in order to have a defensible result, that is to say how do the performance assessment results compare with the applicable regulatory standards, the PAWG's view (position) is that uncertainty and sensitivity analyses need to be intrinsically part of the performance assessment analysis methodology.

7. The [draft] BTP often gives the impression that one must evaluate uncertainty in the model outcome and investigate the parameters and assumptions that affect this uncertainty for their own sake. However, uncertainties in the results of performance assessment are important only to the extent that they affect a decision about regulatory outcome. The [draft] BTP lacks, and should provide, guidance about "rolling up" the uncertainty analysis into an overall assessment of the quality of the information used in and provided by the analysis.

Response

The PAWG does not intend to imply that uncertainties should be evaluated solely for their "own sake." Performance assessments, as with any type of analysis, have a certain amount of inherent uncertainty because of how the models were constructed, how the input parameters for those models were selected, and how to the interpret the outputs from such models. Uncertainty, therefore, denotes imprecision in the analysts' knowledge or available information with respect to any or all of these factors. In addition, understanding uncertainty, as a performance assessment output, is important for both the LLW disposal facility developer and regulators to understand because it can have an impact on decision-making related to siting and design (i.e., Section 3.1). For example, if decision-makers compare analytical results against the standard, whether there can be a determination made that the regulation will be met, with reasonable assurance, depends on how prevalent the uncertainties in the analysis are and how sensitive the outcome is to these uncertainties. However, just having performance assessment results expressed in terms of uncertainty is not enough.

Thus, the PAWG have taken the position in this technical report that LLW disposal facility developers will need to explain what the uncertainties are, how they propagate through the analysis, and how they subsequently affect compliance with the Part 61 performance objective. **Although it is recognized that some of the assumptions and data used in the assessment may be based on limited information, the quality of this information should be known by the analyst.** If the analyst is uncertain about the quality of the information used, it will be difficult to provide a defensible basis for the conclusions of the assessment. Therefore, to avoid further confusion in this area, Section 3.2.4 of this technical report ("Treatment of Sensitivity and Uncertainty in LLW Performance Assessment") has been modified (see bold type), as indicated below:

> The objective of the LLW performance assessment is to quantitatively estimate disposal system performance for comparison with the performance objective in 10 CFR 61.41. Uncertainty is inherent in all LLW performance assessment calculations and regulatory decision-makers need to consider how uncertainties within the analysis translate into uncertainty in estimates of performance. **Uncertainty denotes imprecision in the analysts' knowledge (or available information) about the input parameters to the models, the models themselves, or the outputs from such models. Uncertainties come from a variety of sources, some of which, given the present state of the art, cannot be quantified at this time although there are methods for addressing them in an LLW performance assessment (as discussed below). To understand their influence on the compliance demonstration, performance assessment practitioners rely on *sensitivity* and *uncertainty analyses. Sensitivity analyses* identify which assumptions and parameters affect the quantitative estimate of**

performance by changing input variable and model structures. By contrast, *uncertainty analysis* provides a tool for understanding and explaining (in quantitative terms) the influence (or impact) of imprecision in performance estimates from imprecisely formulated models and/or imprecisely formulated known input variables.

8. The [draft] BTP is confusing and contradictory in its treatment of deterministic analyses. On the one hand, it appears to say that an applicant need not be concerned about uncertainties, such as human activities, that are difficult to project over time. On the other hand, the [draft] BTP appears to say that if an analytical parameter value is based on a measurable physical process, then a bounding analysis must be "clearly demonstrated" (i.e., conservative at all costs). We have several concerns.

— First, how can one truly provide a bounding analysis if one does not consider all uncertainties, including those associated with anthropogenic influences? These influences can have a large effect on disposal facility performance, but are difficult to predict or to model. There seems to be no justification for excluding uncertainties associated with anthropogenic influences without institutional controls sufficient to forestall or mitigate them.

— Second, the [draft] BTP admonishes the reader to **demonstrate** that models, parameters, and calculated doses are bounding. But although in some cases, a bounding assumption can be demonstrated (e.g., one could ignore decay for long-lived fission or activation products), in many cases, a "demonstration" of a bounding assumption is really an argument based on the judgment of the analyst considering available data. One cannot "demonstrate" the future in a manner consistent with a dictionary definition of the word.

— Third, if one is depending on a bounding analysis to help reach a licensing decision, then the question should be whether the overall analysis is likely to be bounding (subject to initial assumptions and predictive limitations). It does no good to assume a high degree of conservatism for each parameter in a model, so that conservatisms are propagated through the analysis, leading to grossly misleading results. With enough conservative assumptions, perhaps no site could meet the requirements of the performance objectives. Realism, not conservatism, must be encouraged in LLW performance assessments.[39]

— Finally, the [draft] BTP provides no useful guidance about the level of protection required to be identified as acceptably conservative. There can be an extremely wide range in definitions of what is conservative depending on the person or organization conducting the assessment.[40]

Responses

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[39] NRC implies the need for analytical realism by suggesting that applicants avoid unnecessary speculation, but contradicts this suggestion by recommending highly conservative analyses.

[40] If parameters are viewed probabilistically, one can quantify a definition of conservatism (e.g., a specified confidence level). There is often not a large difference in the data needed to identify a conservative or bounding parameter and the data needed to identify a probability distribution for the parameter. The difference is that the amount of conservatism applied to the bounding parameter is unspecified.

First, as regards the Department comment on the need to consider anthropogenic influences in the dose calculations, the PAWG has commented on this issue in its earlier responses to *Golder Associates General Comment No. 5* and *DOE Specific Comment Nos. 3 and 5.*

Second, concerning DOE's comments on the use of bounding assumptions in an LLW performance assessment, the PAWG agrees that a high degree of conservatism (i.e., a safety margin) may be needed when the analysis is deterministic, especially to demonstrate that the calculated dose is at or below the regulatory standard – hence "bounding." However, this is one of the major limitations to the use of this particular methodology. Because a deterministic analysis provides only a single estimate of performance, no information is provided on the margin of safety associated with the calculation – the difference between the calculated dose and the allowable dose. This is important to know for the analyst needs to demonstrate that it is unlikely that the "true" (or actual) dose could be higher than the single reported estimate. In addition, the use of conservative values for parameters is not the only means of demonstrating that the results are conservative. It may be possible to demonstrate that the results are conservative based on the use of conservative models and/or scenarios. In fact, the use of bounding parameter values does not ensure a conservative result, when optimistic models and/or scenarios are used. Thus, to achieve the "realism" sought for in this comment in the performance assessment results, the PAWG has taken the view that probabilistic approaches are the preferable methodology to be used when conducting an LLW performance assessment.

Finally, the PAWG does not believe additional guidance is needed to define the acceptable level of conservatism required. A conservative analysis by its very definition means that it is unlikely that the dose to an average member of the critical group will be underestimated. As noted in the PAWG's response to *NEI Technical Comment No. 3*, the amount of conservatism needed to support any demonstration of compliance with the standards should be made in the overall context of the analysis itself, by the LLW disposal facility developer.

9. NRC recommends that "...where a formal uncertainty analysis is performed and a distribution of potential outcomes for system performance is provided, the mean of the distribution ... [should] 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."

Although we appreciate that NRC is attempting to provide a numerical measure of "reasonable assurance" as an aid in making a licensing decision, we must point out that use of such a formula would not relieve NRC from the need to exercise judgment in this decision. Although a probabilistic approach may help to organize and present information in a way that hopefully leads to better-informed judgments, it cannot be used to create data. There is often not a black and white distinction between the deterministic approach and the probabilistic approach. When a performance assessment is performed probabilistically, some parameters are still either fixed or based on arguably bounding assumptions. Also, the recommendation appears to be limited to the uncertainties associated with those aspects of a performance assessment pertaining to natural conditions, processes, and events. As noted, NRC has not provided a justification for its recommendations pertaining to future anthropogenic, climatological, and biological processes. Although there are techniques for estimating probabilities or bounds for these processes, the estimates must be based on current knowledge and therefore require periodic reassessment.

Responses

The fact that there are uncertainties in analyzing the performance of an LLW disposal facility was clearly recognized at the time Part 61 was promulgated. Part 61 requirements for siting disposal sites in locations that are geologically quiescent as well as the need to employ multiple engineered (or natural) barriers suggests that both the staff and Commission were well aware of the desire to reduce potential sources of uncertainty (e.g., Bonano and Apostolakis, 1990; p. 106) in the required compliance demonstrations, to the extent practicable. Nevertheless, previous experience suggests that such uncertainties will be present in any analysis, whether it be deterministic or probabilistic.

In this technical report, the PAWG has advocated the use of either deterministic or probabilistic approaches. In the PAWG's view, for deterministic analyses, no attempt is made to quantify uncertainty which, in the PAWG's view, limits the amount of information provided by the assessment.[41] By contrast, uncertainty analysis is a major constituent of probabilistic analyses (PRA Working Group, 1994). However, regardless of which approach is used, though, the PAWG believes that LLW disposal facility developers will need to explain how uncertainties (both engineered and natural system states) propagate through the analysis and how they subsequently affect compliance with the Part 61 performance objective. From a public health and safety perspective, neither the staff (nor the Commission) have quantitative standards on what level of uncertainty in the analysis is tolerable. As noted above, that decision, in the first instance, rests with the LLW disposal facility developer. Once the uncertainties and the limitations to the analysis are identified, the Commission can then determine if it can find, with "reasonable assurance," the performance objectives can be met. Thus, contrary to DOE's comment, the PAWG is not attempting to provide a numerical measure of "reasonable assurance." As noted above, that determination rests with the Commission. (Also see the PAWG's response to *NEI General Comments Nos. 2 and 3* and *State of Illinois Detailed Comment No. 2*.)

Lastly, the PAWG agrees with the commenter that assumptions about future anthropogenic, climatological, and biological processes should be based on current knowledge. Specifically, see the PAWG's earlier response to *CNS' Specific Comment No. 6*.

10. NRC's blanket recommendation to not perform probabilistic evaluations of scenarios is inconsistent with its endorsement of a probabilistic approach to performance assessments. It would be reasonable to consider scenarios, or at least to identify the critical group, for performance assessment, that [is] appropriate for the site under consideration. One cannot do so without at least a qualitative assessment of probabilities. Remote sites in the desert southwest are very different from sites in more populated areas (such as the west coast or east of the Mississippi River), and exposure scenarios that may be most appropriate for one site may be inappropriate for another.

Response

The PAWG does not believe that this technical report is inconsistent, particularly as it relates to the selection of scenarios for consideration in the performance assessment. By virtue of the siting guidelines found at 10 CFR 61.50 of the regulations, developers need to site LLW disposal facilities in geologic settings that are essentially stable (quiescent) or, alternatively, in areas in which active FEPs will not significantly effect the ability of the site and design to meet Subpart C performance objectives. In practical terms, what affect the 10 CFR 61.50 requirements have on the LLW performance assessment scenario selection methodology is that after site characterization, the candidate site be defined in terms of its expected geologic evolution, where all likely scenarios are accounted for in the performance assessment model and treated equally, with a probability of one (1). If the results of site characterization conclude that, geologically, there is the potential for low-probability scenarios – say on the order of 10^{-4} per year, in frequency of occurrence, or lower – they would be screened out of the site model (and the subsequent analysis). In summary, the LLW performance does require a probabilistic evaluation of scenarios as part of the site characterization process, but only as a screening device. The PAWG believes that this approach is effective and efficient given the nature of the LLW hazard and the time periods of concern.

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41 Deterministic analyses, such as engineering design calculations, typically rely on safety factors to account for uncertainty. See PAWG response to *Commonwealth of Pennsylvania Specific Comment No. 16.*

With respect to DOE's comments related to physical parameters used to define the critical group, the PAWG recognizes the potential for different geologic settings (with correspondingly different scenarios) to influence its definition. The Department is referred to the PAWG's response to *Golder Associates Specific Comment No. 5.*

10. There is no justification for NRC's guidance about the 500-year limit on the performance of engineered barriers. Why not merely require that all assumptions be justified, and that projections of performance be consistent with existing data, designs, and material parameters? There is nothing unique about engineered barriers as compared to natural site conditions that should cause engineered barriers to be considered separately. Alternatively, NRC could consider an option, through institutional control mechanisms, to ensure maintenance or repair of engineered barriers for as long as may be needed. One could estimate a bounding time for barrier performance, estimate costs for assumed major repairs at prescribed intervals, and establish sufficient funds in an interest-bearing account to make the repairs. Such an approach would be allowable under Part 20 requirements for restricted release; we see no reason why a similar provision could not be considered for LLW disposal facilities.

Response

Earlier, in its response to *State of New Jersey Specific Comment No. 1*, the PAWG explained its basis for its earlier recommendation regarding the proposed 500-year design life for engineered barriers. In summary, the proposed 500-year timeframe for the selection of engineered barrier performance resulted from earlier public comment (and general agreement) on NRC's draft Part 61 regulation (NRC, 1981; p. 27). Moreover, the PAWG has now amended its earlier proposed position and reminds readers that credit for periods of performance greater than 500 years can be claimed. In either case, and consistent with DOE's comment that "... all [design] assumptions be justified...," this technical report **does** require that LLW disposal facility developers provide an adequate technical justification (supported by documentation) for whatever time period credit is attributed to engineered barrier performance.

As regards the DOE observation that there is nothing unique about engineered barrier performance compared to natural site conditions such that the performance of the former would need to be considered separately, it would appear that the Department may have failed to recognize the important role engineered barriers serve in an LLW disposal system. In simple terms, the PAWG's views concerning the service life for engineered barriers responds to the need to isolate a "typical" LLW radionuclide inventory during the period of time when it is most hazardous and mobile. After 500 years, less than one percent of a typical LLW inventory will remain and the geologic setting (the site) will be relied on to subsequently provide isolation of the remaining wastes. Thus, by partitioning the LLW disposal system, taking into account the waste classification requirements (10 CFR 61.55), the PAWG sought to exploit the ability to design certain features – the engineered barriers – as differentiated from those features that it could not – the geologic setting.

Finally, as regards the DOE alternative proposal, as part of some institutional control mechanism, to permit inspections, maintenance, and repair (when needed) of the engineered barriers to ensure that they perform as intended, it is not clear how this proposal would conform to the existing concept and regulatory framework for LLW disposal. Under this concept and framework, which was based on earlier public consensus (NRC, 1981a; p. 28), Part 61 recognizes a period of active institutional controls of only 100 years after facility closure [10 CFR 61.7(a)(4)]. Thus, after waste emplacement operations are complete, the LLW disposal facility would be closed, which includes sealing and covering the disposal units. For a period of 5 years thereafter [10 CFR 61.7(c)(3)],[42] the licensee will remain at the site conducting observations and maintenance, as necessary, to ensure that the site is stable and ready for institutional control. After this five-year period, the license will be transferred and the 100-year period of

[42] The Commission may approve shorter or require longer periods, if conditions warrant [10 CFR 61.7(c)(3)].

institutional control will begin with site monitoring, surveillance, and minor custodial activities [10 CFR 61.7(c)(4)]. It is the PAWG's view that minor custodial activities described in the rule do not include the potential for *perpetual* engineered barrier inspection, maintenance, and repair, as proposed by the Department.

11. NRC's recommendations on intruder dose analyses have not been given the level of regulatory analysis that is required. Several issues must be addressed and resolved, such as the costs and benefits of implementing the recommendation, appropriate scenarios and dose or risk criteria, the disposition of wastes determined to be unacceptable for near-surface disposal, whether larger concentration limits could be determined for some radionuclides (e.g., Ni-59, Ni-63), and whether a probabilistic or deterministic analysis should be used. Considering that the Part 61 rulemaking record indicates that NRC consciously discounted ingrowth of uranium progeny when it established the classification system, an amendment to the rule may be needed to implement the recommendation.

Response
The PAWG does not agree with DOE's comment that its intruder analyses have "...not been given the level of regulatory analysis that is required...." The Department is reminded that NRC's proposed approach to inadvertent human intrusion is predicated on its waste form classification system (Section 61.55). Both the waste form classification system and the approach to the treatment of inadvertent human intrusion were outlined and discussed previously in NRC's draft Part 61 rule (NRC, 1981a) and the accompanying DEIS (NRC, 1981b). Following earlier requests for public comment on the two, NRC's respective responses to both documents can be found in NUREG-0945 (NRC, 1982).

In summary, under NRC's regulations, LLW disposal facility developers must demonstrate how they meet the waste form classification criteria found at 10 CFR 61.55. These criteria are intended to ensure that the general population, workers, and inadvertent intruders would be protected from potential radiation exposures. In the specific case of inadvertent human intrusion, no separate consequence analysis is required by the applicant so long as the criteria found at 10 CFR 61.55 are met. If the LLW waste spectra envisioned for a particular facility do not meet the criteria found at 10 CFR 61.55, then the disposal facility developer is required to perform a separate human intrusion consequence analysis to ensure that Part 61, Subpart C's, performance objectives are met.

Because, in DOE's view, the existing Part 61 regulatory framework may need to be amended in this area, the staff will inform the Commission of the Department's views.

12. Although the critical group concept is worthwhile for performance assessments, the [draft] BTP lacks justification for the recommendation. Section 61.41 refers to "...any member of the public...," not to an average member of a critical group. (NRC may consider that if institutional controls continue, performance assessments are clearly planning documents; performance assessment results do not constitute actual doses to any member of the public, adult or child.)

Response
The PAWG does not agree with the Department's observation that NRC's critical group approach lacks justification. For the purposes of Part 61, PAWG considers the critical group to be defined as the group of individuals reasonably expected to receive the greatest exposure to radioactive releases from the disposal facility over time, given the circumstances under which the analysis would be carried out. (See Section 3.3.7.1 of the technical report). In summary, the principal governing the PAWG's critical group approach is that the same levels of protection should be provided for future generations as are being provided for the current generation. Moreover, the critical group approach recommended for implementation by PAWG is consistent with International opinion and practice (see ICRP, 1985; NEA, 1996). Also see the PAWG's response to *DOE's General Comments* and *Golder Associates General*

Comment No. 5.

13. The [draft] BTP should address uncertainties in estimates about the radiological, physical, and chemical inventories in waste. If NRC is assuming that LLW shipment manifests can be used for these estimates, NRC should evaluate the accuracy [of] these manifests in that many manifest citations have been questionable in the past.

Response
In designing an LLW disposal facility, a key design area will be the disposal facility developer's ability to make certain basic assumptions about the types, kinds, and amounts of LLW that are to be disposed of. As with any design decision, the LLW disposal facility developer will need to document its decision-making in this area so that it is not only transparent and traceable, but technically defendable as well. The Commission currently has in place regulations found at Part 20 which have detailed reporting requirements for licensees to comply with. The PAWG expects that LLW disposal facility developers will rely on the information contained in these records (or some comparable source) when it develops parameter distributions as part of the disposal facility design process (*Step No. 2* in the approach described in Section 3.1 of this document). Contrary to the Department's assertion in its comment, the PAWG is not aware of significant problems with respect to the Part 20 reporting requirements for shipping manifests such that, on balance, the overall accuracy of the information contained in these records would be called into question.

That being said, the PAWG does not believe that it is necessary for it to provide guidance on how one should address potential uncertainties in the disposal facility developer's estimates of the radiological, physical, and chemical characteristics of LLW destined for disposal. That responsibility rests with the developer, as is the case with any other derived design parameter. In general, it is the PAWG's view that uncertainties in waste inventory characterization, including future waste steams, can be treated in the same fashion as the treatment of uncertainties for other important design parameters – in the event of significant uncertainty, the LLW disposal facility developer should select conservative design parameters. [To a limited extent, Sections 3.3.5.1.2 ("Source Term and Waste Type – Recommended Approach") and 3.3.5.2 ("Waste Form and Waste Type – Recommended Approach") of this technical report touch on this issue and the commenter is referred to those discussions.]

14. The [draft] BTP is repetitive and scattered, as if it was two or three documents at once, and the language is imprecise. This [latter] condition reflects a root uncertainty about the basic principles driving the recommendations.

Response
As regards the first portion of this comment, DOE correctly observes what has been already acknowledged in the document itself, specifically that this technical report is in fact a collection of three separate (but related) LLW performance assessment issues.[43] Because the broad topic areas are closely related, the PAWG though it would be more appropriate to issue them together in one document rather than individually, in separate documents. Thus, as the Department comment correctly notes, there is a certain amount of repetition among the three broad area, but the PAWG believes such

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[43] We are reminded that Section 3.1 describes an acceptable approach for systematically integrating site characterization, facility design, and performance modeling into a single performance assessment process that would be used to show compliance with 10 CFR 61.41 of the regulation. Section 3.2 addresses five principal technical policy issues that are integral to the conduct of an LLW performance assessment activities described in Section 3.1. Finally, Section 3.3 concerns recommended analytical approaches for each of the system components and/or processes that comprise NRC's performance assessment methodology described earlier in Section 3.1. Section 3.3 also addresses some of the technical policy issues set out earlier in Section 3.2.

(limited) repetition is necessary and desirable to ensure internal consistency among the respective approaches being recommended. However, to the extent that there is repetition in this technical report, overall, the PAWG believes that it is not as great as it would be if PAWG's recommended approaches themselves were issued separately.

As regards the DOE comment regarding imprecision and uncertainty in this technical report, although the Department is free to express this view, the PAWG does not believe this to generally be the case. Moreover, to the extent that it is perceived that there may be imprecision, ambiguity, or the need for additional clarification related to one or more of the PAWG's recommendations and advice, the public comment process on this technical report is where DOE and the rest of the technical community have the opportunity to identify such areas for subsequent elaboration/clarification by the PAWG, as documented by this appendix.

15. The [draft] BTP lacks, and should provide, guidance on compliance with the "as low as reasonably is achievable" (ALARA) requirement in Section 61.41.

Response
The PAWG agrees and the following discussion of compliance with the ALARA requirement has been included at the end of Section 3.2.4.3 ("Compliance Determination"). To keep the LLW disposal facility developer focused on the modeling of the doses that can be used in evaluating ALARA rather than the other risks and costs that must be analyzed, the reader has been referred to the *NMSS Decommissioning Standard Review Plan* :

> "In addition to meeting the numerical limits in 10 CFR 61.41, an applicant must employ reasonable effort to maintain releases of radioactivity in effluents to the general environment "as low as is reasonably achievable" (ALARA). ALARA analyses should weigh the costs and benefits of design alternatives in meeting the performance objective. These analyses may be either quantitative or qualitative. Quantitative analyses may make use of the performance assessment process to compare releases from the design alternatives (from comparing the time and rate of release to comparing collective doses). The various benefits of any design should be weighed against the costs (e.g., additional worker dose or occupational hazards or additional costs or resources use). In general, the ALARA analysis should utilize the guidance in Chapter 7 ("ALARA Analysis") of the *NMSS Decommissioning Standard Review Plan* (NRC, 2000)."

16. Although it would be desirable to use effective dose equivalent for compliance with Section 61.41, it would not be consistent with the rule as it is stated.

Response
See the response to *Golder Associates General Comment No. 2,* "The Basis of Dose Calculations."

DOE Recommendation

NRC should reconsider the [draft] BTP. NRC should precisely articulate its fundamental tenets and assumptions for active and passive institutional controls, and then develop its recommendations based on this foundation and in terms of a long-viewed, responsible control" approach to LLW management. Such an approach would be consistent with the recommendations of a 1994 workshop held by the National Academy of Public Administration (NAPA) on intergenerational equity issues. An initial licensing decision can be based on a limited but acceptable amount of site-specific data. Technical uncertainties in assessments of disposal system performance can be addressed using performance monitoring and research programs conducted over the life of the disposal facility. Difficult questions involving anthropogenic processes could be addressed and periodically reassessed through techniques such as formal expert elicitation.

The elements of a "responsible control" approach could be as follows:

— A site selection process directed toward sites expected to result in minimal costs for long-term maintenance, or for correction if needed (e.g., the site suitability requirements of 10 CFR 61.50)

— Design of disposal facilities[44] directed toward passive disposal systems requiring minimal maintenance over time (and avoiding water accumulation and management problems). An initial licensing decision subject to follow-up review for as long as the waste presents a sufficient hazard to be of concern.[45]

— An initial assessment (basis for licensing) that would be updated and amended as needed. The assessment could address adherence to generic design requirements or to [sic] adherence to a performance standard such as a dose limitation assessed using a performance assessment.

— A system of physical, legal, and administrative controls to ensure operational and long-term protection of the public and the environment. Controls would include limitations on public access and use, performance monitoring (including vadose monitoring) and environmental surveillance, periodic assessments of real-time public dose, markers and public records, contingency plans, periodic reassessments of the licensing basis, assured funding mechanisms, and so forth.

— Identification of parties legally responsible for inspections, oversight, corrective action, if necessary, etc.

Under this approach, primary assurance of public and environmental protection is derived from the continuation of passive and active institutional controls, including access controls, environmental monitoring and surveillance, and periodic assessments (and reporting) of public dose. Because an entity will be present or responsible for ensuring that actual doses to the public are within requirements, the consequences of a "bad" licensing decision are essentially economic. Should there be unanticipated or unallowed radionuclide release from the disposal facility, the realistic impacts are the costs (above a baseline of custodial costs) required to remedy the problem.

Therefore, one would design disposal facilities to be sufficiently robust (given current knowledge) to tolerate a reasonable envelope of variations from expected conditions without

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[44] Design" is used generally, to include considerations (as appropriate) such as engineered barriers, waste form, size of buffer zone, or waste concentration or inventory.

[45] Depending on the situation (e.g., short-lived radionuclides disposed of in an arid environmental setting), one might determine that it would be safe in the future to reduce the levels of oversight and control, and possibly to release the site on either a restricted or unrestricted basis applying appropriate decommissioning criteria to the of disposed waste in addition to ancillary surface facilities.

requiring human intervention. Those variations occurring outside this envelope would be left to the custodial agency to address. The possibility that a future society would be burdened with a large expense could be reduced by: (a) expanding the envelope of variations to be considered, and modifying the design accordingly; or (b) augmented financial assurance and oversight mechanisms.[46] The proper balance of these and related tradeoffs (e.g., the design life) is not easy to decide. Some could be decided on a generic basis and others on a site-specific basis. Decision tools will need to be applied.

A performance assessment is therefore seen in the context of a tool used to assist in design of disposal facilities, to characterize radionuclide release and transport pathways, to identify and characterize significant assessment uncertainties, to develop monitoring programs (including "performance" monitoring), and to plan for contingencies.[47] A performance assessment represents a best estimate at a point in time of disposal system performance, given a technically defensible conceptual model, site-specific characterization data, surface and subsurface process definitions, exposure scenarios, and a host of assumptions about factors in the future. It is through definition of the assumptions, quantification of the data, uncertainty and sensitivity analysis, and a realistic assessment of the collective error of the performance assessment results that performance assessment usability and reliability are determined. Decisions and actions based on performance assessment results are data- and site-specific and should be evaluated in a graded approach.

Performance assessments have limitations as decision tools. Factors that contribute to variable performance assessment results include input data quantity and quality, period of record of the data, data trends and interpretations, robustness of the conceptual model, steady-state versus transient modeling assumptions, numerical versus analytical modeling, the period of projection for the model runs, and so on. Changes in the steady-state ground-water gradient due to regional or local ground-water withdrawals can invalidate model projections. Likewise, a 20-year input data record can propagate very large uncertainties in steady-state or transient calculations over 10,000 years.

For these reasons, the reliability of the performance assessment calculations should be assessed and documented. A *value of information analysis* should be included in a performance assessment "results and interpretations section" to inform the reader of deficiencies or limitations in the performance assessment projections, and to describe how these concerns affect performance assessment usability. (In this regard, deterministic performance assessment methods do not provide the analyst with as detailed or sensitive a set of tools to describe and quantify uncertainty as do probabilistic methods.) performance assessments are based on a set of steady-state assumptions that represent a snapshot in time that is carried forward for many years. Because data estimate reliability erodes over time, depending largely on the period of record of

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[46] If one postulates that a potentially disruptive event might occur within – say 500 years, one could estimate the costs required to remediate the site in current dollars, and establish sufficient funds (assuming long-term interest and inflation levels) in an interest-bearing account to address the problem if and when it occurs.

[47] Performance assessments would be used to provide decision-makers with a reasonable expectation that corrective action would not be needed, over a specified design time horizon and consistent with "current conditions" assumptions, to assure compliance with applicable dose limits and constraints. To do this, the performance assessment could be conducted based on the design assumption that, should releases from a disposal facility hypothetically occur, the custodial agency would take no action to prevent public dose. This approach is similar to, but not the same as, one that would prohibit "...any considerations from active institutional controls ..." in the manner stated in Part 191.

the input data, it may be inappropriate to assume that the analyses can provide reasonable assurance of system performance for more than several tens of years. Hence, iterative update through a formal performance assessment maintenance program is needed. Significant limitations or uncertainties in performance assessment assessments (e.g., data limitations) should be identified during the licensing process, prioritized, and addressed during the disposal facility life.

Responses
Although, in its *Summary Recommendation,* DOE is asking the PAWG to reconsider the need for the NUREG, the Department is also questioning some of the fundamental provisions of the Part 61 regulation itself.

To begin with, the PAWG wishes to remind DOE (and others) that the Commission engaged in a long and deliberate process when it promulgated Part 61. This included NRC sponsorship of four regional workshops on the scope of the DEIS and the proposed rule, the publishing of a DEIS and draft proposed rule for public comment, and the publishing of a final rule and EIS, which included the staff's response to the public comments received during this process. The Department participated in this process by providing its comments. Thus, having completed this process, which included taking into account several of what DOE has referred to generally as "responsible control elements" for LLW disposal, the Commission has in place a regulatory framework it believes is sufficient to protect public health and safety and the environment. Moreover, this framework is consistent with the Commission's risk-informed, performance-based approach to nuclear regulation as well as the Commission's views on the use of PRA methods in its regulatory activities (NRC, 1995; 60 *FR* 42622).

To ensure that this framework is implemented efficiently and effectively, the PAWG has addressed some of the major policy issues important to demonstrating compliance with Part 61's post-closure performance objective. Having addressed these issues in this technical report, the PAWG finds no compelling reason to revisit the regulatory framework, contrary to DOE's recommendation. Because, in the Department's view, the existing Part 61 regulatory framework may need to be amended in this area, the staff will inform the Commission of DOE's views.

Nonetheless, having said all this, the PAWG believes that there are some specific points it needs to respond to based on *DOE's (Summary) Recommendation*:

- Contrary to DOE's view, the PAWG does not expect "bad" licensing decisions to result as a consequence of a performance assessment of the type outlined in this document. Both in the regulation and in this technical report there are provisions sufficient to ensure that necessary analytical assessments[48] are conducted, that they are adequately documented, and that the limitations to the assessments themselves are fully understood. To the extent that there may be the potential for unanticipated events to occur during the timeframe of regulatory interest, the PAWG expects disposal facility developers to site and design an LLW disposal facility in such a way that allowances (or what DOE has described as an "envelope") are made for uncertainties in the performance of engineered barriers and/or geologic knowledge related to features, processes, and events. Having taken into account these and other types of uncertainties, in addition to now proposing that disposal facility developers employ the concepts of *peer review, expert judgment,* and *model validation* into the LLW performance assessment process (see the PAWG's response to *Mel Silberberg and Associates Specific Comment No. 3*), the PAWG sees no compelling reason to periodically update and repeat the performance assessment.

- NRC's regulation does not specifically identify the need for a *value of information analysis*, as recommended by DOE in its *(Summary) Recommendation*. However, NRC's requirements at 10 CFR 61.12(j) do require that a quality assurance (QA) program be applied to site

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[48] Performance assessments, in the view of the PAWG.

characterization and design activities. In describing this program, the PAWG expects that LLW disposal facility developers to address their confidence in the quality of their information (e.g., the data, models, and codes) supporting their analyses of disposal facility design and performance. In the context of the performance assessment, the PAWG expects LLW disposal facility developers to also address how the uncertainties in the analysis translate to uncertainties in the estimation of performance. [See Sections 3.2.4 ("Treatment of Sensitivity and Uncertainty in LLW Performance Assessment") and 3.3.2 ("Uncertainty and Sensitivity Analysis").] The PAWG expects LLW disposal facility developers, by meeting these expectation, to be able to describe as well as quantify the limitations in their performance assessment analyses.

Having identified the level of uncertainty in the analysis of performance, the PAWG believes that LLW disposal facility developers will need to determine how uncertainties propagate through the analysis and how they subsequently affect compliance with the Part 61 performance objective. From a public health and safety perspective, neither the staff (nor the Commission) has quantitative standards on what level of uncertainty in a performance assessment is tolerable. That decision rests in the first instance with the LLW disposal facility developer. Once the uncertainties and the limitations to the analysis are identified, the Commission will determine if it can find, with "reasonable assurance," the performance objectives can be met. Thus, the PAWG does not agree with DOE's proposal that "...limitations or uncertainties in performance assessment assessments should be identified during the licensing process, prioritized, and addressed during the disposal facility life ..." (presumably) by the LLW disposal facility developer. In the PAWG's view, if uncertainties cannot be reduced to acceptable levels, as part of the design process, then the LLW disposal facility developer needs to consider alternative designs and/or sites [e.g., the decision point between process *Step Nos. 7* and *8*, as set forth in Section 3.1 (and depicted in Figure 3)]. Because Part 61 has a one-step licensing process, there are no provisions, in the rule, for the conduct of confirmatory testing or monitoring during LLW facility construction, as a licensing condition to confirm design assumptions, as is the case in NRC's HLW regulations.

- As regards DOE's comment on the need for active and passive institutional controls to legally and administratively restrict access to LLW disposal sites, the PAWG's views on this subject can be found in its earlier response to *DOE's Overall Comment.* Concerning the Department recommendation for the need for financial assurances to ensure institutional oversight, NRC's regulations (10 CFR 61.63) already require such assurances, but for only 100 years, consistent with the Commission's views, in the context of Part 61, that *active* institutional controls, in the context of Part 61, are effective for only a period of 100 years. Lastly, the Commission's regulations do have requirements for restricting physical access to LLW disposal sites (10 CFR 61.23), as recommended by the Department, which are expected to include site makers, fences, and the like, but these are only expected to last 100 years, again consistent with the Commission's views on the effectiveness of active institutional controls. After 100 years, the Commission expects certain passive measures (e.g., governmental ownership, archival records) to restrict the types of activities that could take place at an LLW disposal site.

- DOE recommends that NRC's approach to LLW management should be consistent with the 1994 recommendations by NAPA on intergenerational equity issues. The PAWG is familiar with these recommendations,[49] which generally propose that public decisions and actions take into account the risks, benefits, and costs of those decisions and actions. Moreover, the NAPA recommendations emphasize the need to protect successive generations from immediate hazards rather than those which are long-term and (potentially) hypothetical in the future. The generic NAPA principles differ sharply from those followed by the Commission in the area of nuclear regulation. In its decision-making, the guiding principle the Commission has adhered to

[49] This workshop, entitled "Deciding for the Future: Balancing Risks, Costs, and Benefits Fairly," was held in Washington, D.C., on June 26-28, 1994. The results of this workshop were published by NAPA as Finger *et al.* (1997).

consistently is one in which the level of radiological protection provided to future generations (at any time) should be the same as that provided to the current generation. [See ICRP (1985) and NEA (1996).] More recently, this and other guiding principles influencing the staff's decision-making in the area of radioactive waste management and regulation have been codified in the form of a *Collective Opinion* (see Nuclear Energy Agency, 1995).

Finally, contrary to other NAPA recommendations, which advocate the use of cost-benefit analyses to decide how to best use the government's resources in Federally sponsored programs, NRC's LLW program is derived from Congressional direction found in the *Low-Level Radioactive Waste Policy Act of 1985*, as amended.

U.S. Ecology, Inc.

General Comment

U.S. Ecology has reviewed draft NUREG-1573. U.S. Ecology believes that the principles and guidelines contained in the draft BTP are for the most part consistent with the site-specific performance assessments completed or in progress by developers in several agreement states and reviewed by state regulators with NRC oversight. These site-specific performance assessments, both prospective (e.g., California, Texas and Nebraska) and retrospective (e.g., South Carolina, Nevada and Washington), are consistent with the regulatory requirements of 10 CFR Part 61 and previous relevant NRC guidance. The subject BTP both builds upon, in a generic sense, and complements these site-specific performance assessments performed by developers and reviewed by Agreement State regulatory officials with oversight from NRC technical staff. U.S. Ecology would welcome an explicit acknowledgment of the above circumstances in the *Introduction* or preamble to the [final] BTP.

Response
The NRC staff oversight of the LLW performance assessments referred to in this comment was not as extensive as *U.S. Ecology* would suggest. Based on the staff's limited reviews of these analyses and because of the lack of consistency among the analyses' respective methodologies and the interpretation of the Commission's regulation, the PAWG undertook development of this technical report. Consequently, because of limitations both collectively and individually, that PAWG believes that it would be an overstatement to say that this document "builds on and complements" on the performance assessments performed thus far.

Specific Comments

Additionally, we have the following specific comments on the draft text:

1. On pages 1-1 and 4-13, the reference to NUREG 1200 (NRC, 1991b) Revision 2 is incorrect. The current revision to NUREG 1200 is Revision 3, dated April 1994.

Response
The correct reference should be to *Revision 3* of NUREG-1200. The PAWG has corrected this technical report as recommended

2. On page 2-2, last paragraph to ["Regulatory Framework"], the reference to NUREG-0856 providing QA guidance appears to be in error. The reference should be to NUREG-1293. Additional QA guidance for site characterization activities is contained in NUREG-1383.

Response
The correct reference should be to *Revision 1* of NUREG-1293, prepared by Pittiglio and Hedges. The PAWG has corrected this technical report as recommended and has added the following reference to Section 4:

> Pittiglio, C.L., Jr., and D. Hedges,"Quality Assurance Guidance for a Low-Level Radioactive Waste Disposal Facility," U.S. Nuclear Regulatory Commission, NUREG-1293, Revision 1, April 1991.

In addition, the PAWG will include the following sentence to the last paragraph of the "Regulatory Framework," as follows:

> "...NUREG-1383 (Pittiglio, *et al.*, 1990) should be consulted for QA guidance related to site characterization activities, when necessary....."

The following reference to NUREG-1383 will also be added to Section 4:

> Pittiglio, C.L., Jr., R.J. Starmer, and D. Hedges,"Guidance on the Application of Quality Assurance for Characterizing a Low-Level Radioactive Waste Disposal Site: Final Report," U.S. Nuclear Regulatory Commission, NUREG-1383, October 1990.

3. On page xvi, the conversion factor column is confusing. Conversion factors are in units such as "inches/centimeter" rather than just "centimeters." The table should either provide the correct units or provide a unitless number along with instructions such as "multiply metric unit by conversion factor to obtain inch-pound unit. See the *Radiological Health Handbook* for an example of this format.

Response
In response to this and other public comments, the PAWG has modified the *Unit Conversion Table* and adopted the one used by the USGS in its publications.

4. On page 1-5, last paragraph, it may be helpful mention radiation from waste units themselves as a potential (though not significant) contributor to external dose. This exposure pathway is mentioned in Section 3.3.7.1.3.

Response
The comment is noted, but the PAWG believes that the waste disposal units could be considered under the general example "contaminated surfaces" that is already in the sentence in question. Addition of a example, such as the waste disposal units (vaults) themselves, would not be consistent with the level of detail in the other examples included in the same paragraph.

5. On page 3-44, the [draft] BTP states that a performance assessment should provide significant radionuclides by volume and activity levels and identify waste class, waste type, waste stream, and waste container for each type of generator. Since the [draft] BTP is intended to be useful to "...existing LLW licensees, operating under comparable Agreement State regulations...," it should be noted that this level of detail will not be available for previously disposed waste at existing facilities.

Response
This comment is noted. No modification of this technical report is necessary.

6. Page 3-45 suggests eliminating radionuclides with half-lives less than five years, that are not present in significant activity levels and do not have long-lived daughter products (or are not themselves daughters of a longer-lived parent). For the ground-water pathway, it would be more meaningful to choose a half-life cutoff based on calculated minimum travel times. Five years is

unnecessarily conservative for arid sites, where migration time through the vadose zone may be on the order of 1000 years.

Response
Two approaches are proposed in Section 3.3.5.2. ("Screening Methods to Identify Significant Radionuclides") of this technical report for screening out radionuclides. The first approach, as noted by the commenter, allows for certain radionuclides to be screened-out that have half-lives less than five years. The second approach proposed would allow radionuclides to be screened out considering their relative transport travel time through the environment. This second approach would allow the screening out of certain radionuclides, in arid sites, where the transport travel time through the vadose zone could be significant. Finally, the PAWG does not agree that this screening analysis should be limited to a 1000-year time period; instead, the screening analysis should be carried out over a time period consistent with that for the overall performance assessment.

7. On Figure 14, the mechanism by which exposure is received by the individual (i.e., ingestion, inhalation, direct radiation) is identified in italics for some but not all of the pathways depicted. Specifically, the milk and meat pathways at the bottom of the figure should specify "ingestion," and the fishing and sports gear category and sand and sediments category should specify "direct radiation "if that is the intent.

Response
Figure 14 has been revised based on these comments.

U.S. Environmental Protection Agency
Office of Radiation and Indoor Air
Radiation Protection Division

Overall Comments

The Radiation Protection Division within the Office of Radiation and Indoor Air, is pleased to offer the enclosed review comments.

The draft BTP presents useful, systematic and logical guidance on the crucial subject of performance assessment as related to projecting the behavior of low-level radioactive waste disposal sites. This version reflects numerous improvements that speak more directly to important issues such as compliance determination and regulatory time frame.

EPA's primary concerns relate to ground-water protection and the role of ALARA in performance assessment. With respect to ground-water protection, EPA is concerned that meeting the numerical limits of 10 CFR 61.41 (e.g., 25 millirems per year to the whole body) may allow people to drink water exceeding the maximum contaminant levels (MCLs) of the *Safe Drinking Water Act* (SDWA – Public Law 93-523). For example, the MCLs for beta particle and photon-emitting radionuclides is [are] 4 millirems per year to the total body or any internal organ. The [draft] BTP should provide advice for dealing with this situation, such as encouraging the applicant to consider alternative designs to mitigate this concern. EPA is concerned that such a site may require Superfund remediation at the expense of those neither responsible for, nor benefitting from, the disposal site. Concerning ALARA, although it is not a numerical requirement, the concept of ALARA is embodied in 10 CFR 61.41. The draft BTP should address how performance assessment might be used as a tool to demonstrate that a waste disposal system design is ALARA.

Response
In the response to this and other comments on the application of ALARA principles to an LLW performance assessment, the PAWG has provided additional discussion to the end of Section 3.2.4.3 of this technical report. See the PAWG's response to *DOE's Specific Comment No. 5* for a description of this addition.

With regards to the comments about ground-water protection, these comments relate primarily to the regulations rather than to possible approaches for demonstrating compliance with the regulations, and are thus largely outside the scope of this technical report. Nonetheless, the PAWG views the suggestion for a separate requirement for ground-water protection are neither needed nor necessary for the goal of public health and safety. The PAWG believes that such an approach could lead to inconsistent and unreconcilable results, which may cause confusion and diminish public confidence in the process. For example:

- Although MCLs were considered reasonable standards at the time of their development in 1975, current understanding of the risk posed to individual organs by radiation exposure demonstrates that the MCLs for individual radionuclides provide a level of protection that varies significantly. For example, consider the annual risk of developing a fatal cancer from drinking water that contains neptunium-237 (^{237}Np) and ^{129}I, at each one's respective MCL. The risk of developing a fatal cancer from ingestion of ^{237}Np at its MCL is 30 chances in one million (3×10^{-5}), whereas the risk from ingestion of ^{129}I at its MCL is 0.07 chance in one million (7×10^{-8}). More than a 400-

fold difference exists between the risk levels prescribed for these two radionuclides. Therefore, this simple comparison shows an application of MCLs that results in nonuniform risk levels, which are likely to lead to greater confusion about the level of risk which is acceptable and attainable, rather than confidence that the health and safety of the public are being protected.

- The PAWG believes that recent Congressional direction[50] and National Academy of Science (NAS) guidance (National Research Council, 1995), provided under that direction, are germane to setting acceptable risk levels for radionuclides received through the ground-water pathway. The 1996 Amendments to the SDWA (Public Law 104-182) directed EPA to withdraw drinking water standards proposed for radon in 1991 that would have established an acceptable risk level for radon (a naturally-occurring isotope, not generally regulated by NRC) comparable to current MCLs for other radionuclides. The same amendments called for EPA to arrange for the NAS to conduct an individual risk assessment for radon in drinking water. Based on the results of that assessment, EPA was further directed to develop an alternative MCL that would represent a risk comparable to that incurred from naturally-occurring radon in outdoor air. The PAWG calculates that such an alternative MCL, for a single radionuclide, would correspond to an annual risk of 3.8×10^{-5} or more than twice that arising from exposure to an all-pathway, all-nuclide limit of 0.25 mSv (25 mrem). As noted in the first bullet (above), the risk from ingestion of ^{129}I at its MCL is 0.07 chance in 1,000,000 (7×10^{-8}) or nearly 2000 times more restrictive than the annual risk of 3.8×10^{-5}.

- The MCLs were based on an analysis of treating contaminated water in public drinking water systems subject to the SDWA and not on an analysis of technology and costs of remediating groundwater at actual sites. EPA proposes to apply the same MCLs to ground-water supplies **before** treatment, as required by the SDWA. In the absence of an appropriate and comprehensive cost-benefit analysis, there is little justification for requiring actions to prevent potential contamination of groundwater that may require treatment before use.

- The EPA has selected, as its limits for the protection of groundwater, the limits specified for drinking-water supply systems. The risk estimates for the MCLs consider only a single pathway (i.e., the direct ingestion of the water as drinking water) and do not consider any other uses for the water. For some elements, such as iodine and technicium, other pathways, such as consumption of irrigated crops, can result in doses an order of magnitude or more higher than the drinking-water dose. Therefore, classification of using the MCLs as “ground-water protection” is a misnomer since it does not account for any other uses of the groundwater except for drinking it. An all-pathway dose limit, by its very nature, ensures that risks from all radionuclides and all exposure pathways, including the ground-water pathway, are acceptable and protective.

- A limit of 0.25-mSv TEDE, received in a year by the average member of the critical group, would limit the dose received from all possible pathways to the critical group, including direct exposure, drinking of contaminated water, eating food that was irrigated with contaminated groundwater or grown in contaminated soil, and exposure to airborne releases. The Commission established the 0.25-mSv annual dose limit as the overall safety objective for both decommissioning of nuclear facilities (at 10 CFR 20.1402) and for LLW disposal facilities (at 10 CFR 61.41). It is within the range of international constraints that allocate doses from HLW disposal to between 0.1 and 0.3 mSv (10 and 30 mrem) per year.

Finally, as a matter of record, it should be noted that in providing its public comments on the draft proposed rule establishing disposal requirements for LLW (Part 61), EPA had earlier stated that it was **inappropriate** to apply drinking water standards to 10 CFR 61.41 (NRC, 1982; 47 *FR* 57446).

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[50] Under the Energy Policy Act of 1982 (Public Law 102-486).

General Comments

1. Section 1.2, "Overview of LLW Disposal Concepts, Performance and Technical Issues" (p. 1-5); Section 3.1, "Example of an Acceptable Approach for Demonstrating Compliance with 10 CFR 6l.41" (p. 3-1); Section 3.2.4.3, "Compliance Determination" (pp. 3-17, 3-18); Section 3.3.6.1.1, "Considerations" (p. 3-58); Section 3.3.6.1.2, "Recommended Approach" (p. 3-58); Section 3.3.7.2.1, "Pathway Identification" (p. 3-73); and Section 3.3.7.3, "Dosimetry" (p. 3-77).

   Cumulatively, these sections relate to the general concepts and detailed approaches for demonstrating compliance with the numerical limits embodied in 10 CFR 61.41. Meeting only the numerical limits of 10 CER 61.41 may not assure protection of the public health as related to groundwater protection and the drinking water that may be used by individuals and populations in the future.

   Concerning the approach to ground-water transport analysis, EPA applauds the NRC in its recommendations of Section 3.3.6.1.1 ("Considerations") that both existing and hypothetical ground-water discharge points should be considered in assessing the dose to the average member of the critical group. Section 3.3.6.1.2 ("Recommended Approach") goes on to advise that all points on the disposal site boundary should be considered as a location for a pumping water well. These recommendations assure that potential sources of drinking water be evaluated in the ground-water transport analysis. Section 3.3.7.2.1 ("Pathway Identification") , however, recommends that a "current conditions" philosophy be applied to determine which pathways should be evaluated. Limiting consideration strictly to current conditions could jeopardize any consideration of potential drinking water sources. Considering the long time frames applicable to performance assessment, EPA recommends that the [draft] BTP provide clear and consistent guidance that existing and potential drinking water pathways be evaluated.

Response
The PAWG is sensitive to the concerns expressed in this comment. However, the PAWG believes that this technical report has provided clear and consistent advice as it concerns the evaluation of potential drinking water pathways. In response to this and other comments on the use of the critical group approach and possible drinking water sources for the requisite dose calculations (e.g., *CNS Specific Comment Nos. 6, 7,* and *25*), the PAWG has taken the position that difficulties in forecasting the characteristics of future society, especially those influencing exposure, could result in unbounded speculation on who will be exposed, by how much, where, and when. To avoid such unbounded speculation about future human lifestyles and habits, the PAWG recommends the use of the critical group approach along with assuming that the reference biosphere is constant over the time period of regulatory concern (i.e., 10,000 years). That is to say by relying on cautious but reasonable assumptions, the critical group, and the particular exposure scenario used in the LLW performance assessment, would be defined using present knowledge about the LLW disposal site. These assumptions would apply equally to defining existing and so-called “hypothetical” ground-water discharge points. In light of national and international practice on such matters, the PAWG considers this approach appropriate and reasonably conservative.

Finally, in describing this framework, It must be emphasized that the goal of the analysis is not to accurately predict the future, but to test the robustness of the disposal facility against a reasonable range of potential outcomes. Although the overall aim of the performance assessment is to provide a clear demonstration of compliance with the regulation, the goal is not to obtain a true prediction of doses that some member of the critical group would receive.

2. Section 3.1 ("Example of an Acceptable Approach for Demonstrating Compliance with 10 CFR 61.4.1") and Section 3.2.4.3 ("Compliance Determination") advise that an applicant need only demonstrate through performance assessment that the numerical limits of 10 CFR 61.41 are met. Section 3.3.7.3 ("Dosimetry") advises further that the applicant should show the contributions from each major pathway to the total dose to the average member of the critical group. Section 1.2, ("Overview of LLW Disposal Concepts, Performance, and Technical Issues") cites groundwater as typically the most important transport medium for subsurface disposal and also cites drinking water as one of the most important pathways. Thus, it would appear that any applicant demonstrating compliance with 10 CFR Part 61 would be expected to evaluate the drinking water pathway for its contribution to the total dose, which would then be compared to the numerical limits of 10 CFR 61.41. The [draft] BTP does not address the possibility that meeting the numerical limits of 10 CFR 61.41 may still allow individual well users and customers of present or future public water suppliers to drink water exceeding the applicable MCLs. The MCLs are the health-based limits defining safe drinking water under the *Safe Drinking Water Act* (EPA, 1976; 41 *FR* 28402). For radionuclides, one of the MCLs applies to man-made beta particle and photon-emitting radionuclides and is 4 mrem per year to the total body or any internal organ; this compares to 25 mrem per year to the whole body, 75 mi11irem per year to the thyroid, and 25 mrem per year to any other organ for 10 CFR 61.41.

   Should an LLW disposal site result in contaminated drinking water exceeding the MCLs, important institutional issues are raised. Such a site may fall under the purview of the *Comprehensive Environmental Response, Compensation and Liability Act* (CERCLA), or Superfund, and require expensive remediation by those having neither the responsibility nor benefits of such a disposal site. EPA's ground-water protection strategy – *Protecting the Nation's Ground Water: EPA's Strategy for the 1990s* (EPA, 1991) – endorsed the [use of] MCLs as the primary reference point for pollution prevention activities, such as the development of waste disposal sites.

   The [draft] BTP should address the situation whereby the performance assessment for an LLW disposal site shows the potential for exceeding the MCLs for radionuclides while still meeting the numerical limits of 10 CFR 61.41. In such a situation, the applicant needs to demonstrate adequate financial capability for cleanup. Further, the applicant should be advised to consider alternative disposal designs to minimize the potential for exceeding the MCLs for the drinking water pathway.

Responses
These comments relate primarily to the content of the regulations, the commenter is referred to the PAWG response to *EPA's Overall Comments*.

3. Section 3.1, "Example of an Acceptable Approach for Demonstrating Compliance with 10 CFR 61.41 (p.3-1); and Section 3.2.4.3, "Compliance Determination" (pp. 3-17, 3-18).

   These sections discuss the various activities directed at an integrated LLW performance assessment whose goal is to build a supportable demonstration of compliance. The applicant is advised to "...only undertake a depth of analysis and conduct as many iterations as necessary to show that the performance objective has been met...." (p. 3-1) This appears to indicate that the applicant need only meet the numerical limits set forth in 10 CFR 61.41 (i.e., annual doses of 25 mrems to the whole body, 75 mrems to the thyroid, and 25 mrems to any other organ of any member of the public). This is not enough.

In addition to meeting these numerical limits, 10 CFR Part 61.41 also requires the applicant to employ "reasonable effort" to maintain releases of radioactivity in effluents to the general environment "as low as is reasonably achievable." The ALARA concept is an integral component of prudent radiation protection programs and this is evidenced in NRC's fundamental radiation protection regulation, 10 CFR Part 20 at Section 20.1101(b) and is endorsed by EPA in proposed *Federal Guidance* (Recommendation 3 – see EPA, 1994; pp. 66420-66421). The present draft of NRC's technical position does not appear to address the issue of ALARA as related to performance assessment. The applicant should be required to show that the performance assessment process has been used to examine alternative approaches or designs to arrive at an "optimal" disposal system design. Such a design would both meet the applicable numerical limits with some margin to spare and fulfill the requirement to employ the concept of ALARA. Ultimately, the applicant may discover a more cost-effective design assuring compliance and this should be encouraged.

Response

In the response to this and other comments on the application of ALARA principles to an LLW performance assessment, the PAWG has added more discussion at the end of Section 3.2.4.3 of this technical report. See the PAWG's response to *DOE's Specific Comment No. 5* for a description of this addition.

4. Section 3.2.4.3, "Compliance Determination" (pp. 3-17,3-18).

This section recognizes that applicants may select different approaches for determining compliance with the numerical limits in 10 CFR 61.41. Along these lines, 10 CFR 61.40 advises that "reasonable assurance" should exist that the numerical limits of 10 CFR 61.41 are met. For the deterministic approach, NRC recommends that performance should be "...at or below the performance objective defined in 10 CFR 61.41...." An applicant that selects a probabilistic approach to LLW performance assessment is advised to conduct a formal uncertainty analysis and provide a distribution of projected outcomes for system performance. As now written, the technical position advocates the use of the mean of the distribution as the benchmark for comparison with the numerical limits of 10 CFR 61.41. Further, the 95th percentile of the distribution must also be less than 100 millirems (per year?) TEDE. This means that a significant number of outcomes may exceed the numerical limits of 10 CFR 61.41 when the probabilistic approach to compliance is used. This may give the impression that compliance using a probabilistic approach is more lenient than if one were to use a deterministic analysis, where the result **must** not exceed the numerical limits. Presumably, whatever approach is selected should provide a similar degree of confidence, or "reasonable assurance," that the numerical limits are met. NRC's regulations at 10 CFR Part 60 for the disposal of HLW in geologic repositories, for example, go so far as to describe the degree of confidence, or "reasonable assurance," required for meeting applicable performance objectives [10 CFR 60.101(a)(2)]. The [draft] BTP could provide guidance as to what constitutes reasonable assurance that the numerical limits of 10 CFR 61.41 are met, irrespective of the performance assessment methodology used to demonstrate compliance.

The last two sentences of this section advise that the performance assessment be updated. During operations, waste form and waste type assumptions are to be updated but no guidance is provided as to how this may be accomplished. For closure, it is recommended that the performance assessment use the information extracted from manifest data. Given past problems with using manifest data for performance assessments, resulting in extremely conservative radionuclide inventories for certain key long-lived mobile radionuclides, are there not other sources of information that might be used to update the inventory data both during operations and at closure? Manifest data is reported for transportation purposes, not disposal site performance assessment purposes. Will the waste generators be required to perform any QA to substantiate the radionuclide content of the waste packages they are sending to the disposal facility? Do the disposal site operators perform any independent evaluation of the waste content of waste packages that would aid performance assessment? Disposal site operators should be encouraged to take steps to better define the radionuclide content of waste they accept for, among other reasons, to improve the performance assessment process as a whole.

Responses

First, as regards the recommendation in this comment that this technical report could define what is necessary to meet the reasonable assurance "test" when complying with 10 CFR 61.41 of the regulation, the PAWG does not believe that it is appropriate for it to do so; that determination would rest with the Commission – or for the purposes of the Agreement State program, some other regulatory entity. As noted in the PAWG response to *DOE Specific Comment No. 9*, regardless of which approach is used, the PAWG believes that LLW disposal facility developers will need to explain how uncertainties propagate through their analysis and how they subsequently affect compliance with the performance objectives. From a public health and safety perspective, neither the staff (nor the Commission) has quantitative standards on what level of uncertainty in an analysis is tolerable. That decision rests in the first instance with the LLW disposal facility developer. Once the uncertainties and the limitations to the analysis are identified, the cognizant regulatory authority will determine if it can find, with "reasonable assurance," that the performance objectives can be met. Although the PAWG believes that the reasonable assurance decision will rely on traditional lines of scientific evidence, the decision itself will not necessarily be based on strict scientific standards of proof (e.g., McGowan, 1983). However, consistent with what has been done previously for HLW [e.g., 10 CFR 60.101(a)(2)], it should be noted that the Commission's LLW regulations at 10 CFR 61.23(b) **do** describe the types of information needed to support a reasonable assurance finding.

Second, as regards the commenter's observation that demonstrating compliance using probabilistic approaches may be a more lenient approach than if one were to use a deterministic approach, the PAWG does not agree. As noted earlier by the PAWG, a key limitation regarding using deterministic analyses is that they provide no information to the decision-maker on the uncertainty in the reported result. By contrast, probabilistic analyses do provide the decision-maker with some information on the degree of uncertainty in the reported result. Although the same regulatory standard is applicable in either case, it is likely that the developer may need to do more (i.e., collect more data, have more redundant containment systems, spend more time validating and verifying process models) to convince decision-makers that the deterministic analysis is bounding so that there is confidence that expected doses do not exceed the regulatory limits. Consequently, reliance on deterministic analyses may lead LLW disposal facility developers to suboptimal (and more expensive) siting and design decisions.

Second, in its response to *CNS' General Comment No. 3*, PAWG discusses why it considers the use of the mean to be an appropriate measure of compliance for probabilistic analyses.

Next, as regards the commenter's comment about the last two sentences of Section 3.2.4.3, it should be noted that Section 3.2.4.3 of this technical report does not address the issue of updating the performance assessment. Section 3.2.5 ("Role of LLW Performance Assessment during Operational and Closure Periods") does note that one way to address the site closure requirements of 10 CFR 61.28(a) is to update the performance assessment with new information obtained during the operational period. Section 3.3.5 ("Source Term and Waste Type") addresses issues related to characterizing the

waste form, waste type, and inventory for the performance assessment. Therefore, the PAWG does not believe there is a need to provide specific advice, in Section 3.2.4.3, on the need for updating the performance assessment.
Finally, with regard to the concerns raised about the use of manifest data, the implementation and requirements on using a uniform manifest [i.e., 10 CFR 20.2006(a)(2)] should improve current and future LLW information and reporting. The PAWG agrees that in the past, reporting activities for some radionuclides have been conservatively reported by using detection limits. However, this should not represent a problem in terms of demonstrating compliance with the regulations because it simply provides additional conservatism and confidence that the dose limits will not be exceeded. If licensee's see the need for developing more refined or less conservative inventory estimates for their analyses, they can be expected to do so. In some cases, this has already been done through the use of the *3R-STAT computer code*[41] (see Nelson, 1995). With regards to the question as to whether waste generators are required to perform QA checks to verify the radionuclide content, they are required, under Appendix G of Part 20, to conduct a QA program to assure compliance with 10 CFR 61.55 and 61.56. The commenter also asked whether disposal site operators perform an independent evaluation of the waste content. Under 10 CFR 61.81, LLW disposal facility developers are required to perform any test deemed appropriate or necessary for administrating the regulation under Part 61. These can include tests of the radioactive waste, radiation-detection and monitoring instruments, and other equipment. The PAWG understands that such tests have been performed to varying degrees at existing LLW facilities.

5. Section 3.3.6.2.1, "Surface Water. Considerations" (p. 3-61): The first sentence of this section references Figure 13. Figure 12 appears to be the more appropriate reference.

Response
The PAWG has corrected this technical report as recommended.

6. Sections 3.3.6.2.1, "Considerations" and 3.3.6.2.2, "Recommended Approach" (pp. 3-61 to 3-63).

   Another possible source of surface water contamination from below-ground disposal facilities may result from the well-known "bathtub effect." This has been well-documented at the Maxey Flats site in Kentucky. Given a defective trench cap over a disposal trench located in impermeable soil in a humid environment, it is possible for the trench to fill with water and overflow, leading to surface contamination. This section of the [draft] BTP should address this issue and explain, for example, how the requirements of 10 CFR Part 61 prevent the bathtub effect being a source of surface water contamination.

   Finally, it is not clear how the applicant uses either the deterministic or the probabilistic approach to performance assessment to address the ALARA requirement of 10 CFR 61.41. The applicant should be advised to employ performance assessment as a tool in deriving the disposal system design that provides a level of protection as far within the applicable numerical limits as the ALARA process will allow.

Response
NRC's Part 61 regulation was not in place when Maxey Flats was designed and constructed. The PAWG believes that it is unlikely for the bathtub effect to occur at disposal facilities designed and

41 3R-STAT is a proprietary computer code developed by *Vance and Associates* of Ruidoso, New Mexico.

constructed according to Part 61's requirements. See the PAWG's response to *CNS Specific Comment No. 12* on this same subject.

As regards the comment concerning ALARA, the commenter is directed to the PAWG's earlier response to *DOE's Specific Comment No. 15*, above.

7. As an aid to the reader, a list of acronyms would be very helpful.

Response
In response to this and other public comments, the PAWG has modified this technical report to include a list of acronyms.

Specific Comments

1. Section 1.3, "What is LLW Performance Assessment?" (p. 1-6): In Item (b) of the first paragraph of this section, "effect" should be "affect." Item (b) should read: "...(b) an understanding of events likely to affect...."

Response
The PAWG has corrected this technical report as recommended.

2. Section 3.3.5.2.2, "Recommended Approach" (pp. 3-44, 3-45): First, it is not clear whether the screening approaches recommended in paragraphs (a) and (b) are mutually exclusive approaches, or may be applied in sequence. This should be clarified.

   Second, Paragraph (b) advises a screening methodology whereby the applicant would calculate the transport of radionuclides in soil and groundwater but places no minimum time on the calculation period. Considering that Section 3.2.3 ("Timeframe for LLW Performance Assessment Analyses") recommends a 10,000 year analysis period for most situations, any screening calculation should generally be carried out for 10,000 years as well.

Response
This technical report has been modified to clearly indicate that the two approaches are intended to be mutually exclusive. Further, the text has been changed to reflect that the screening analysis should be carried out over a timeframe consistent with that for the overall assessment.

3. Section 3.3.5.3.1, "Issues" (p. 3-45). The middle of the first paragraph makes reference to an "HIC." This appears to be the first time the term is used and should therefore be spelled out.

Response
"HIC" refers to high-integrity container and the text has been modified accordingly.

4. Section 3.3.6.3.1, "Considerations" (p. 3-65): The first paragraph references Technical Position 3.3.3.7 ("Gaseous Releases"). It appears the appropriate reference would be to Technical Position 3.3.5.7 at page 3-55.

Response
The PAWG has corrected this technical report as recommended.

5. Section 3.3.7.1, Considerations (page 3-69): The last paragraph on page 3-70 discusses the critical group, the group of individuals who receives the highest doses. This discussion defines the average member as that individual "...assumed to represent the most likely exposure situation...." While this may be one way to define the average member of the critical group, it should be pointed out that in terms of regulatory compliance, ICRP 46 (Paragraph 45) for example, recommends that it is the "average dose in the critical group" that is to be compared to the regulatory limits. The [draft] BTP should discuss and clarify this issue in the final technical position.

Response
The section of this technical report in question has been revised to be consistent with the critical group definition found in Part 20 and the *Statements of Consideration* for Subpart E of Part 20 (NRC, 1997; 62 *FR* 39058). The following statement has been added to the end of paragraph 6 of Section 3.3.7.1 (“Dose – Considerations”) :

> It is generally not practicable, when analyzing future potential doses, to calculate individual doses for each member of a critical group and then re-calculate the average dose to these same members. In general, it is more meaningful to designate a single hypothetical individual, representative of that critical group, who has habits and characteristics equal to the mean value of the various parameter ranges that define the critical group. In this fashion, the dose to the “average member” of the critical group approximates the average dose obtained if each member of the critical group were separately modeled and the results averaged.

6. Section 3.3.7.2, "Recommended Approach" (p. 3-73). The first sentence of the last paragraph should exclude the [repeated] phrase "...is a generalization of an...."

Response
The PAWG has corrected this technical report as recommended.

B-2 ADDITIONAL TECHNICAL REFERENCES

The following list of references identifies where new, updated references that have been added to this NUREG. In most cases, the addition of the new reference(s) is usually accompanied some ancillary textual material, found necessary to place the cited references in the appropriate context. These new references are organized, by section, according to where they have been added to the NUREG.

Section 3.3.2.1.2, "Uncertainty and Sensitivity Analysis – Parameter Uncertainty"

Meyer, P.D., M.L. Rockhold, and G.W. Gee, "Uncertainty Analyses of Infiltration and Subsurface Flow and Transport for SDMP Sites," U.S. Nuclear Regulatory Commission, NUREG/CR-6565, September 1997.

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Section 3.3.3, "Infiltration – Key Considerations in the Analysis"

Leij, F.J, W.J. Alves, and M.T. van Genuchten, "The UNSODA Unsaturated Soil Hydraulic Data User's Manual Version 1.0," Cincinnati, Ohio, U.S. Department of Agriculture/ Agricultural Research Service and the U.S. Environmental Protection Agency, EPA/600/R-96/095, August 1996.

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Timlin, D., et al., "Comparison of Estimated Ground-Water Recharge Using Different Temporal Scales of Field Data," U.S. Nuclear Regulatory Commission, NUREG/CR-6653, April 2000.

Wierenga, P.J. *et al.*, "Soil Characterization Methods for Unsaturated Low-Level Waste Sites," U.S. Nuclear Regulatory Commission, NUREG/CR-5988, February 1993.

Section 3.3.4.5, "Engineered Barriers – Post-Construction Monitoring and Evaluation"

Young, M.H., *et al.*, "Field Testing Plan for Unsaturated Zone Monitoring and Field Studies," U.S. Nuclear Regulatory Commission, NUREG/CR-6462, July 1996.

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Young, M.H., *et al.*, "Comparing Monitoring Strategies at the Maricopa Environmental Monitoring Site, Arizona," U.S. Nuclear Regulatory Commission, NUREG/CR-5698, June 1999.

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Rogers, R.D., *et al.*, "Microbial Degradation of Low-Level Radioactive Waste," U.S. Nuclear Regulatory Commission, NUREG/CR-6341, June 1996.

Section 3.3.5.6.1, "Chemical Environment"

Askarieh, M.M., *et al.,* The Chemical and Microbial Degradation of Cellulose in the Near Field of a Repository for Radioactive Waste," *Waste Management*, 20:93-106 [2000].

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APPENDIX C
BIBLIOGRAPHY ON ENGINEERED AND NATURAL BARRIERS FOR A LOW-LEVEL RADIOACTIVE WASTE DISPOSAL FACILITIES

In response to public comments, the PAWG has prepared a limited bibliography of publications that relate to the properties, design, construction, and performance of materials that could be relied on as engineered and natural barriers for low-level radioactive waste (LLW) disposal facilities. Many of the publications cited were developed as a result of the LLW technical assistance programs sponsored by the U.S. Nuclear Regulatory Commission's Offices of Nuclear Material Safety and Safeguards and Nuclear Regulatory Research. This list is not intended to be comprehensive nor complete.

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APPENDIX D
FINAL COMMISSION *POLICY STATEMENT* ON THE USE OF PRA METHODS IN NUCLEAR REGULATORY ACTIVITIES [1]

D-1 INTRODUCTION

The following statement presents the policy that the U.S. Nuclear Regulatory Commission (NRC) will adopt in the use of probabilistic risk assessment (PRA) methods in nuclear regulatory matters. This policy was developed because the Commission believed that the potential applications of PRA methodology could improve public health and safety decision-making while promoting stability and efficiency in the regulatory process and reducing unnecessary burdens on licensees. After a public workshop, the *Policy Statement* was published in draft form in the *Federal Register* (NRC, 1994; 59 *FR* 63389). On receipt and consideration of public comments, it was published in final form (see NRC, 1995; 60 *FR* 42622).

D-2 THE COMMISSION POLICY (at 60 *FR* 42628)

1. The use of PRA technology should be increased in all regulatory matters to the extent supported by the state of the art in PRA methods and data and in a manner that complements NRC's deterministic approach and supports NRC's traditional defense-in-depth philosophy.

2. PRA and associated analyses (e.g., sensitivity studies, uncertainty analyses, and importance measures) should be used in regulatory matters, where practical within the bounds of the state of the art, to reduce the unnecessary conservatism associated with current regulatory requirements, regulatory guides, license commitments, and staff practices. Where appropriate, PRA should be used to support the proposal for additional regulatory requirements in accordance with 10 CFR 50.109 ("Backfit Rule"). Appropriate procedures for including PRA in the process for changing regulatory requirements should be developed and followed. It is, of course, understood that the intent of this policy is that existing rules and regulations shall be complied with unless these rules and regulations are revised.

3. PRA evaluations in support of regulatory decisions should be as realistic as practicable, and appropriate supporting data should be publicly available for review.

4. The Commission's safety goals for nuclear power plants and subsidiary numerical objectives are to be used with appropriate consideration of uncertainties in making regulatory judgments on the need for proposing and backfitting new generic requirements on nuclear power plant licensees.

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[1] It should be noted that this NUREG was developed prior to the adoption of risk-informed, performance-based regulation at the NRC. However, the iterative approach to performance assessment promoted in the NUREG, which includes explicitly addressing uncertainty and the development of increasingly realistic models and parameters to support more complex modeling are consistent with NRC’s risk-informed, performance-based philosophy outlined in this policy statement.

D-3 REFERENCES

U.S. Nuclear Regulatory Commission, "Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities [Proposed Policy Statement]," *Federal Register*, Vol. 59, No. 235, November 8, 1994, pp. 63389 – 63391.

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APPENDIX E
DISPOSITION OF ACNW COMMENTS

(RESERVED)

APPENDIX F
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