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**Regulatory Compliance
for a Yucca Mountain Repository:
A Performance Assessment Perspective**

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Abstract

The U.S. Department of Energy's Yucca Mountain Site Characterization Project is scheduled to submit a License Application in the year 2002. The License Application is to show compliance with the regulations promulgated by the U.S. Nuclear Regulatory Commission which implement standards promulgated by the U.S. Environmental Protection Agency. These standards are being revised, and it is not certain what their exact nature will be in terms of either the performance measure(s) or the time frames that are to be addressed.

This paper provides some insights pertaining to this regulatory history, an update on Yucca Mountain performance assessments, and a Yucca Mountain Site Characterization Project perspective on proper standards based on Project experience in performance assessment for its proposed Yucca Mountain Repository system.

The Project's performance assessment based perspective on a proper standard applicable to Yucca Mountain may be summarized as follows: a proper standard should be straightforward and understandable; should be consistent with other standards and regulations; and should require a degree of proof that is scientifically supportable in a licensing setting. A proper standard should have several attributes: (1) propose a reasonable risk level as its basis, whatever the quantitative performance measure is chosen to be, (2) state a definite regulatory time frame for showing compliance with quantitative requirements, (3) explicitly recognize that the compliance calculations are not predictions of actual future risks, (4) define the biosphere to which risk needs to be calculated in such a way as to constrain potentially endless speculation about future societies and future human actions, and (5) have as its only quantitative requirement the risk limit (or surrogate performance measure keyed to risk) for the total system.

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Introduction

The U.S. Department of Energy's (DOE's) Yucca Mountain Site Characterization Project (YMP) is scheduled to submit a License Application in the year 2002. The License Application is to contain a Safety Analysis Report that demonstrates compliance with the regulations promulgated by the U.S. Nuclear Regulatory Commission (NRC). The NRC regulations, in turn, implement standards promulgated by the U.S. Environmental Protection Agency (EPA). These standards are being revised, and it is not certain, at this point, what their exact nature is to be in terms of either the performance measure(s) or the time frames that are to be addressed.

At the request of the U.S. Congress, the National Academy of Sciences (NAS) made recommendations to the EPA to aid their effort at writing standards applicable specifically to a Yucca Mountain repository. This NAS report was issued in August 1995. [1] The DOE has expressed its views on this report by the NAS in written comments and recommendations to both the NAS and the EPA¹. The EPA effort at creating a draft standard for a Yucca Mountain repository is in progress. A summary of the DOE/YMP perspective on the NAS recommendations to the EPA has been presented elsewhere [2] in terms of issues important to the regulatory framework for Yucca Mountain, namely (a) regulatory time frame, (b) risk/dose limit, (c) definition of the reference biosphere, (d) human intrusion, and (e) natural processes and events.

This paper provides some insights pertaining to this regulatory history, an update on Yucca Mountain performance assessment activities, and a DOE/YMP perspective on proper standards. The DOE/YMP perspective presented here is based on the project's experience in implementing and evaluating performance assessments for its proposed Yucca Mountain Repository system.

Need for a New Site-Specific Standard for the Yucca Mountain Site

The DOE/YMP performance assessment perspective on the need for a standard for the Yucca Mountain Site is simply that there was a conceptual mismatch between the processes determining performance at the unsaturated Yucca Mountain site, located in a closed basin, and the 1985 EPA standard. [3] This conceptual contrast was masked by the fact that early calculations of system performance by both the EPA and the DOE showed negligible risks for the specified regulatory time frame. The basis for this mismatch lies at the heart of the approach of the EPA in setting the 10,000 year cumulative release limits of their 1985 standard. The EPA approach was to assume a generic conceptual model and then to use it to determine allowable releases from a repository system by calculating backwards from allowable health effects for a global population:

- a decision was made that 1,000 health effects per 100,000 metric tons of heavy metal over 10,000 years for a 10 billion person global population was an allowable population risk (a comparison was made with the same calculation for natural background radiation that suggested 6,000 premature cancer deaths per year, in the U.S., illustrating the conservative nature of this standard: it represents a cancer risk allowance of about 10^{-8} times the global background)
- the 10 billion-person population was divided by a health-effects to dose conversion factor for radionuclides in the spent-fuel inventory (no low-dose threshold)
- a maximum allowable population dose for each radionuclide, per 1,000 metric tons of heavy metal, was thus obtained

¹ Letter from S. J. Brocrou (DOE), to R. Clark (EPA), 29 March 1996, re: Additional recommendations to the Environmental Protection Agency Standard for Yucca Mountain

- a table of radionuclide-specific release limits was created, with a formula to assure cumulative releases will not exceed a total dose resulting in the allowable excess deaths in the global population.

The EPA's rationale for the selection of this low allowable risk factor and approach was in part that "it provides a level of protection that appears reasonably achievable by the various options being considered within the national program for commercial wastes." Because of expected uncertainties, however, individual and groundwater protection requirements also were made part of this standard.

Except for its degree of conservatism, there was nothing wrong with the EPA approach for sites that resemble the conceptual model on which the standard was based. For Yucca Mountain, however, there is a great conceptual mismatch: there is no radionuclide transport mechanism leading to a global dose.

It was the degree of conservatism and the conceptual misfit between Yucca Mountain and the EPA's 1985 standard that led to questions of the general applicability of this standard to Yucca Mountain. These questions eventually resulted in the Congress directing the EPA to write a site-specific standard for Yucca Mountain. A slightly revised version of the 1985 EPA standard still applies to U.S. disposal facilities for high-level waste, spent nuclear fuel, and transuranic wastes other than Yucca Mountain, however.

Recent Developments in Yucca Mountain Performance Assessment

Since the Total System Performance Assessment of 1995 (TSPA 1995)[4], several improvements have been made to the models used to evaluate system performance. First, an order of magnitude improvement of system performance has been realized through improved thermal-hydrology calculations together with more sophisticated assumptions about the likelihood that water may directly flow over the waste form. Even if there is dripping water falling on waste packages, drips are not likely to directly contact the waste form since "failure" openings are very small and are expected to be filled with corrosion products. These assumptions are thought to be more realistic, but require verification through confirmatory testing.

Second, a compensating decrease in system performance is the likely result of a new understanding of water flux in the unsaturated zone. The revised mean-value estimate of percolation flux is up to 4.5 mm/year for the area modeled, with about 7 mm/year over the repository block underlying the higher topography, with higher fluxes during pluvial periods. This larger flux may be compared with the TSPA-1995's average ambient flux for its high range of 1.25 mm/year. Pluvial periods were estimated to have flux increases from 0 to 4 times ambient, with an average increase of 3 times ambient (some recent estimates of precipitation increases accompanying the start of a pluvial within 10,000 years are about 2.5 times the current annual precipitation).

To evaluate the new flux distribution estimates, preliminary system calculations were performed using the version of TSPA 1995 also updated for the thermal hydrology and engineered barrier performance improvements described above. No climate-change flux-multiplier has yet been included, but a simplified pluvial case was evaluated.

For 100,000 years, drinking-water-only peak annual doses to a person obtaining 2-liters water per day in the contaminant plume 20 km from the repository, given current, non-pluvial conditions, were about 10 mrem/year, from I and Tc. Peak annual doses (drinking-water only at 20 km) were about 14 mrem/year, for the hypothetical pluvial case which assumed pluvial fluxes for all of the 100,000 year period [Figure 1].

If a new standard requires the calculation of total dose rather than just drinking water dose, the multiplier on the drinking water dose may be roughly 10, depending on the radionuclide of interest, its pathways in the environment and into the individual, and the behavior of the individual (mainly the extent of consumption of

homegrown agricultural products). Perhaps the new regulatory requirements will stipulate that the likely location of the potentially affected individual is to be where water is reasonably accessible to an individual agricultural household. This may be 30 km from the repository, since this is presently where most area residents are located who are practicing agriculture to some degree [Figure 2]. This could lower doses approximately 25-fold (more than an order of magnitude) [Figure 3].

Recent scoping calculations have suggested that taking credit for cathodic protection (waste package failure rate reduction), cladding life (waste form degradation rate reduction), and perhaps an insulating backfill (waste package failure rate reduction) can each contribute an order of magnitude reduction in doses over the long term (convolution may reduce that to two orders of magnitude, perhaps). Thus, new, more optimistic calculations may yield 100,000 year peak annual doses of about 0.0001 mrem/year for the agricultural individual scenario at 30 km, and a 10,000-year peak annual dose of 0.0 mrem/year for that same individual. [Figure 4]

Reasonable bounds on maximum infiltration and accompanying water-table elevation changes still need to be determined. However, it is not clear what the effect would be because increased dilution may at least partly balance the effects of greater releases and shorter travel times.

Performance Assessment Perspectives on Regulatory Standards

Standards Need to Acknowledge Irreducible Uncertainties

The U.S. Nuclear Regulatory Commission (NRC), in its 1983 regulation [5] governing the disposal of high-level radioactive waste and spent nuclear fuel stated: "Analyses and models ... shall be supported using an appropriate combination of such methods as field tests, in situ tests, laboratory tests which are representative of field conditions, monitoring data, and natural analog studies." These activities are part of what is necessary to provide "reasonable assurance" in the "demonstration of compliance."

An NRC elaboration on "Reasonable Assurance," (10 CFR Part 60 Statements of Consideration, 48 FR 28222 6/21/1983), suggested there will be irreducible uncertainties in long-term predictions: ... "there will be no opportunity to carry out test programs that simulate the full range of relevant conditions over the periods for which waste isolation must be maintained."

The U.S. Environmental Protection Agency (EPA) in its 1985 regulation on the disposal of spent nuclear fuel, high-level waste and transuranic waste, [3] stated: "Performance assessments need not provide complete assurance that the requirements ... will be met. ... what is required is a reasonable expectation, on the basis of the record before the implementing agency, that compliance ... will be achieved." In its introductory statements the EPA stated that "unequivocal numerical proof of compliance is neither necessary nor likely to be obtained." Thus, both the EPA and the NRC have recognized that there will be irreducible uncertainties in projections of system behavior over very long times.

The U.S. National Academy of Sciences' (NAS) National Research Council pointed out in a position statement that "there are certain irreducible uncertainties about future risk." [6] The Council acknowledged that "the EPA standards and the USNRC regulations recognize and accept a certain level of uncertainty," but "the discussion to date of the application of these standards and regulations does not warrant confidence in the acceptance of uncertainty in the licensing process." This statement appears to say that in the opinion of the National Research Council, regulators may have expectations of a degree of proof in licensing that exceeds "reasonable assurance" in the face of irreducible uncertainty. These high expectations on the part of regulators may, in part, reflect experience in the adjudicatory licensing process which tends to push an applicant toward greater than necessary conservatism.

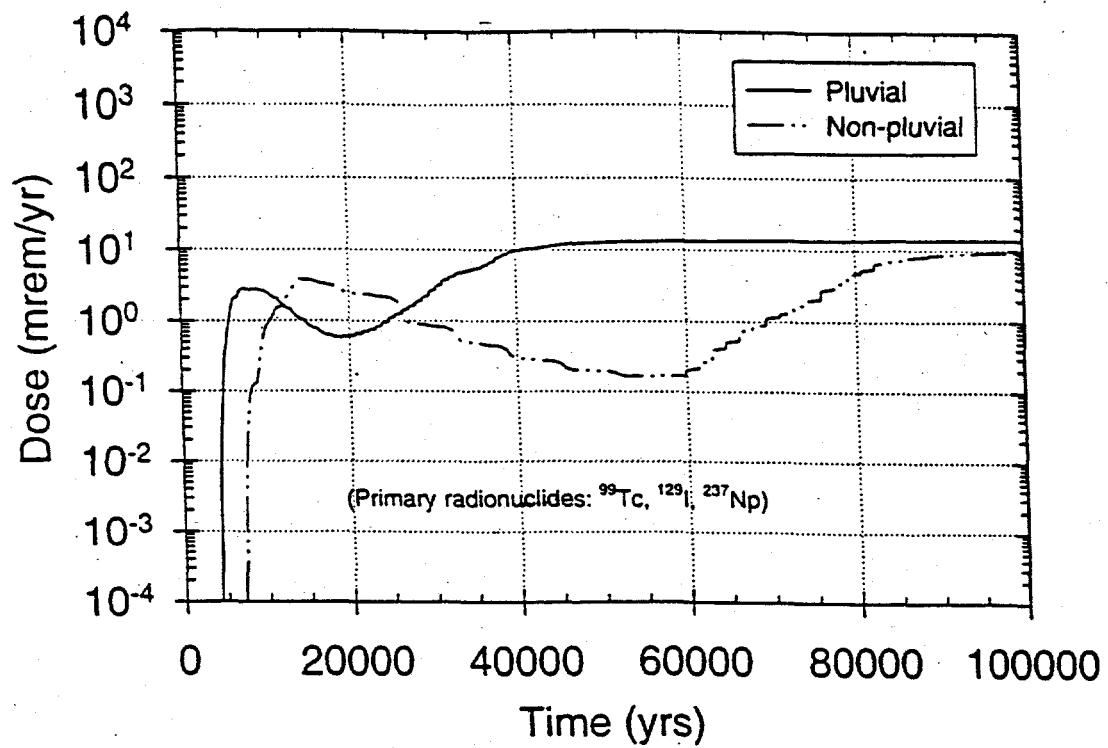


Figure 1. Sensitivity study comparing drinking water dose histories for a conservative case at 20 km assuming current and pluvial groundwater fluxes for 100,000 years.

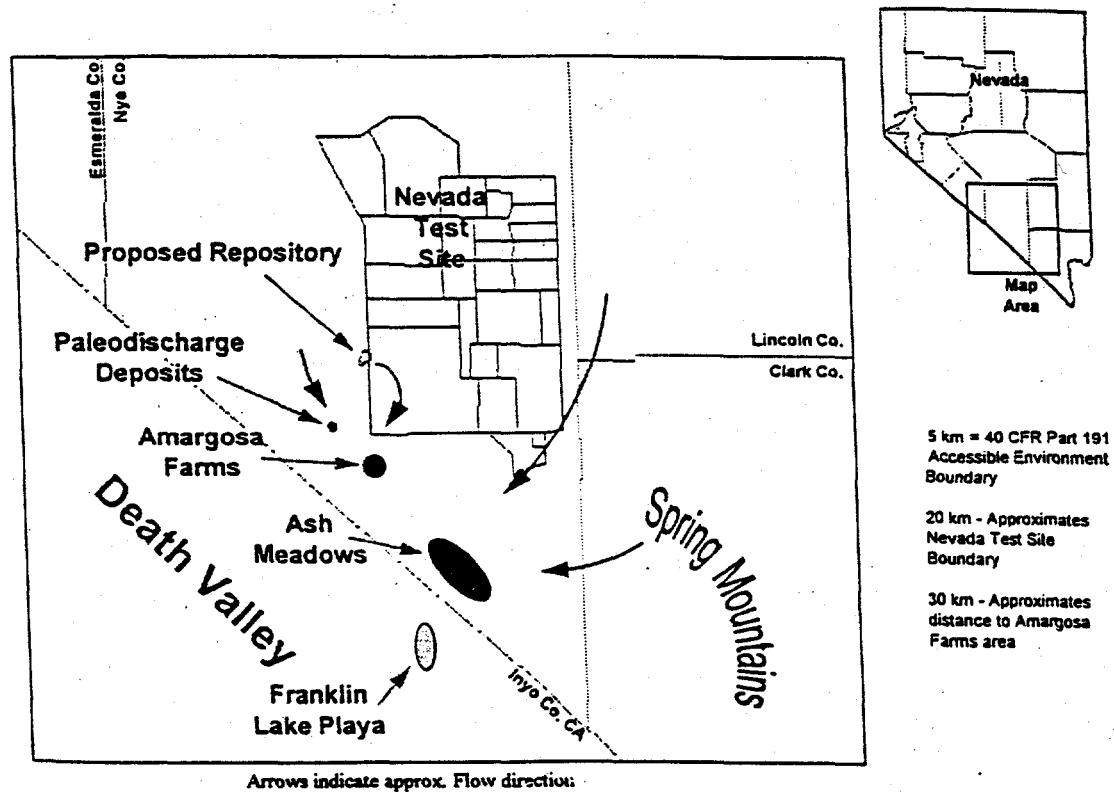


Figure 2. Approximate direction of groundwater flow in the Yucca Mountain vicinity.

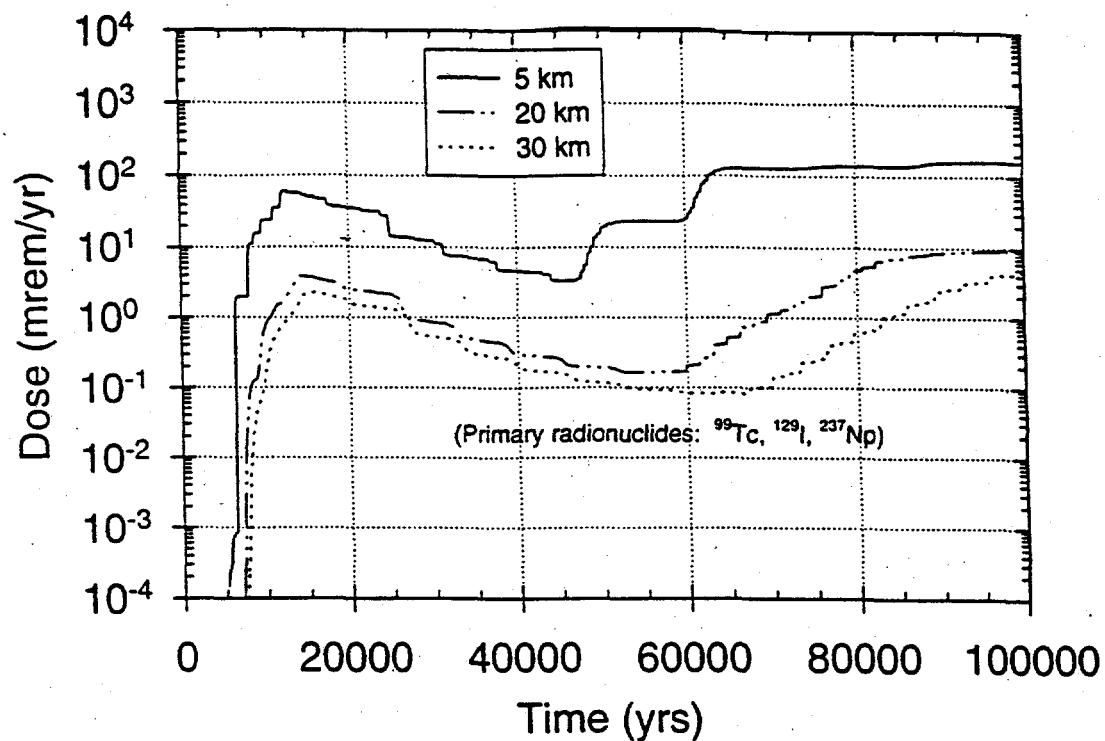


Figure 3. Conservative case, non-pluvial drinking water dose histories for three locations over 100,000 years.

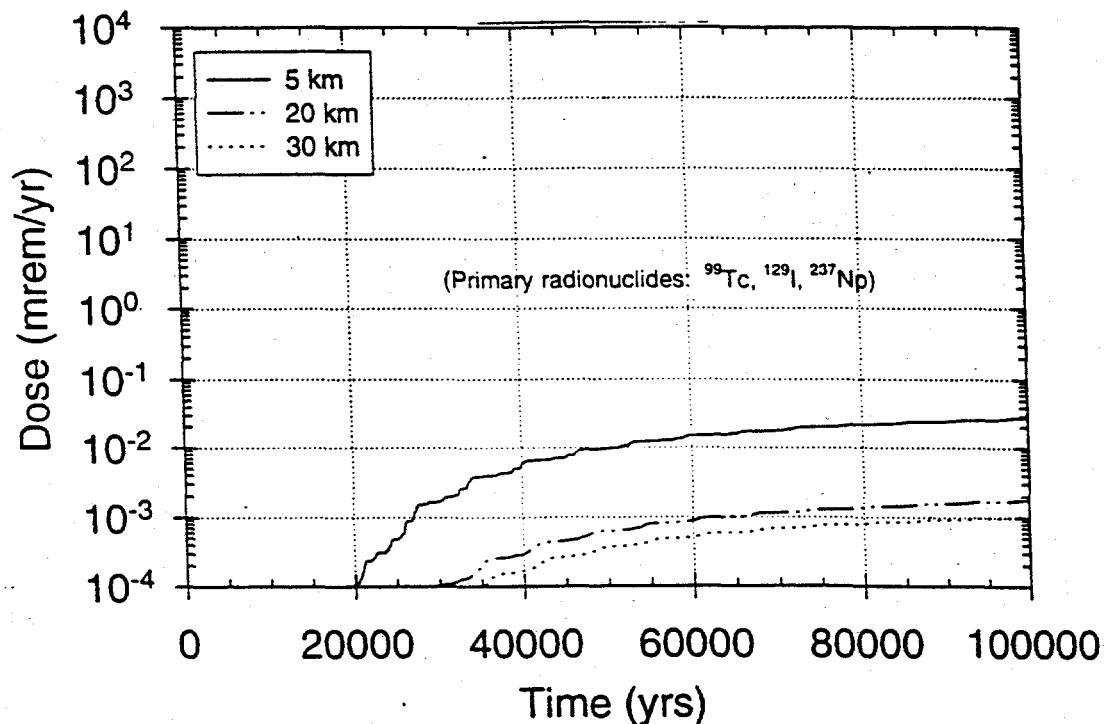


Figure 4. Optimistic case, non-pluvial drinking water dose histories for three locations over 100,000 years.

The Adjudicatory Licensing Process

An adjudicatory licensing process is comparable with a hearing in a court of law. In discussing "The Scientist and Engineer in Court," Bradley [7] observed that legal decisions "are generally made on the 'weight of evidence'." When modeling is involved, the evidence consists of 1) the "scientific studies and research" aspect [ie: the model development phase], and 2) the "field justification" aspect [ie: the field calibration and subsequent application phases].

The application phase requires field data for calibration and separate sets of field data for establishing credibility, and affords room for challenge. Vulnerability may be minimized by 1) assuring that the model user is familiar with the development of the model and the conditions for which it was designed to be used, 2) assuring the modeler is very familiar with the data used, its nature, limitations, etc., and 3) assuring results are carefully and competently interpreted, and that limitations are recognized but not exaggerated.

The typical legal challenge to a modeling exercise includes detailed questioning of the supporting field sampling program and its data. Thus, modeling confidence can not be divorced from its basis in adequate site characterization, system design, and component testing programs. The way scientific modeling is likely to be treated in the licensing process is a challenge to the regulator writing a standard for permanent radioactive waste disposal. The standard must adequately protect public health and safety, and yet not make licensing impractical.

Protecting Public Health and Safety Through Regulations

One implication of the way that modeling is likely to be challenged in the adjudicatory process is that the value of the quantitative performance measure being addressed should not be unnecessarily conservative or based on what simplified generic models indicate to be achievable. A regulatory performance measure needs to reflect a societal judgement of a permissible risk level, and therefore is a governmental policy decision.

If a regulation or standard is unrealistically conservative, a site may be disqualified even though it is adequate in terms of protecting public health and safety. The National Research Council's opinion on this matter calls for a process that may be needed "to determine whether DOE's inability to meet a particular requirement is due to a disqualifying deficiency in the site or to an unreasonable regulatory demand, one that is unlikely to be met at any site and is unnecessary to meet public health." [6]

The portion of the Council's statement that says "one that is unlikely to be met at any site" seems to still partake of the assumption that all acceptable sites are roughly comparable in terms of operative processes. It may be, however, that some performance measure that can be met by hypothetical repositories in one class of geologic settings may simply not apply in other geological settings because different processes control performance. It does not follow that there is necessarily an adverse effect on public health and safety if there is a disconnect between the conceptual understanding that underlies a standard and the conceptual model that describes a specific site. However, it is not in a society's best interest to preclude a site offering acceptable performance because a standard requires that a threshold not be exceeded, if that threshold is not meaningful in terms of public health and safety.

For example, in the YMP's earliest evaluations of an idealized system placed into a simplified Yucca Mountain, releases were vanishingly small for the first ten-thousand years because the flux of water through the mountain was postulated to be extremely low, based on simplified interpretations of the available evidence. [8] Similar analyses were done by the EPA in support of their 1985 standard. [9] Both the YMP and EPA analyses were accompanied by caveats and sensitivity studies showing that if fluxes are higher than expected, releases and thus risks would be higher.

As has been noted above, site characterization results are supporting estimates of fluxes through the unsaturated zone significantly higher than estimated for the earlier, idealized calculations. Using these higher flux values in the former, simplified calculations suggests that the Yucca Mountain system could result in substantial releases and risks. However, a better understanding of the site coupled with a more complete engineered system design have allowed more sophisticated evaluations that show system performance has a high likelihood of being non-threatening to public health and safety even if there are higher fluxes through the unsaturated zone than previously anticipated.

These new results also illustrate that selecting an important process such as groundwater flux for added regulatory attention by creating a subsystem requirement for its rate, based on a very simple preliminary system model, reflects on the adequacy of that simplistic system model more than it reflects on the adequacy of a system designed for an actual location. This again underscores the need for a standard to be based on a societal judgement of acceptable risk and not on what is achievable by an idealized hypothetical system evaluated through simplistic modeling.

Conclusions: Attributes of Reasonable Standards and Regulations to Govern Disposal of High-Level Radioactive Waste and Spent Nuclear Fuel at a Yucca Mountain Repository

Standards, and their implementing regulations, should have as their overriding purpose the protection of public health and safety. These standards and regulations should be implementable, meaning that demonstrating compliance with such standards and regulations should be possible even in the confrontational settings that may be expected as part of an adjudicatory licensing process. To be implementable, a regulation or standard should be straightforward and understandable, should be consistent with other standards and regulations, and should require a degree of proof that is scientifically supportable in a licensing setting.

Several attributes would suggest an implementable standard. The first attribute of an implementable standard would be having a reasonable risk level as a basis, whatever the quantitative performance measure is chosen to be. The risk-level basis should reflect an acceptable level of health-risk to a defined population or to defined representative individuals. This requires a societal decision as to the level of an acceptable risk. It may be tempting to base a standard upon idealized calculations of what a conceptual repository is capable of meeting. This is not an appropriate approach because it is necessarily dependent on a limited conceptual understanding of a site and a preliminary idea of the engineered system to be emplaced in that site. The understanding of a site after characterization, coupled with more complete designs, may lead to an estimate of repository performance in that site that may fail to meet the idealized system standard, leading to the rejection of what may in fact be an effective and safe solution for society.

The second attribute would be a definite regulatory time frame for showing compliance with quantitative requirements. An undefined time frame, as would result from a requirement to meet quantitative limits at the time of peak dose, may not be implementable in an adjudicatory licensing process. As a qualitative goal, however, these types of speculative calculations may help the licensing authority make a more informed decision on the quantitative compliance argument.

A third attribute that would aid implementation is for the standard to explicitly recognize that the compliance calculations are not predictions of actual future risks. Instead, they are stylized, to an extent prescribed, sequences of methodology applications that provide the means for making societal-risk decisions. Results of compliance calculations are meant to provide reasonable assurance to a regulatory authority, recognizing that there are limitations to the analyses. The analyses incorporate assumptions that can not be verified, but that can be shown to reflect reasonable expectations or to reasonably bound those expectations.

A fourth attribute positively affecting implementation is for a standard to define the biosphere to which risk needs to be calculated in such a way as to constrain potentially endless speculation about future societies and future human actions. Prescribing stylized calculations for human intrusion scenarios is one approach, prescribing limits on human intrusion frequency is another. Prescribing the size, location, and characteristics of a nearby population, based on a cautious interpretation of the present, is also desirable. As a general principle, it is desirable to focus on the protection of nearby populations rather than the global population.

A final attribute is simplicity. The only quantitative requirement should be the risk limit (or dose or other surrogate performance measure keyed to risk) for the total system. Subsystem performance requirements that seem to add assurance have the drawback of being based on specific conceptual models of system performance that incorporate assumptions that allocate system performance to subsystems and components. This could limit the applicability of a standard to sites that fit the preconceived engineered system design and site conceptual model, and thus either drive site selection to overlook suitable alternatives, or require the creation of a site specific standard.

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