STEP-WISE REPOSITORY LICENSING
-IMPLEMENTING THE SCIENTIFIC AND LEGISLATIVE VISION FOR THE NEXT PHASE OF THE YUCCA MOUNTAIN PROJECT

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ABSTRACT

International scientific consensus backing geologic disposal as the preferred method of long term management of used nuclear fuel and defense high level radioactive waste has existed since the 1950s. Furthermore, many believe that geologic disposal programs should be implemented in a staged or 'step-wise' approach. These principles have also been at the root of US waste management policy for which a regulatory framework for site selection, and the licensing of a site once selected, is set forth in a series of legislation.

The US program has now matured to the point where these regulatory components are now in place. Sufficient data has also been gathered and evaluated to support a site recommendation decision. This decision – on whether or not to proceed with a repository site at Yucca Mountain, Nevada – is about to be put before the US President and Congress. If made in the affirmative, the decision would initiate the next phase in the US disposal process as originally envisioned by Congress – a three-step repository licensing process (Construction, Operation, & Closure).

This paper explores the many facets of the licensing process that may lie ahead. Approaches that could be deployed to effectively implement this process are discussed and opportunities to optimize the process, by capitalizing on its evolutionary nature to assure that the best available science is always applied to the protection of public health and safety, are identified. Focus is also placed on a key prerequisite to the accomplishment of this goal – the definition of the level to which post closure repository performance must be addressed at each stage of the licensing process.

INTRODUCTION

The U.S. Department of Energy (DOE) is currently embarked on a program to evaluate the suitability of a candidate spent fuel and high-level radioactive waste (HLW) repository at Yucca Mountain, Nevada. DOE has conducted extensive testing, both in situ and in the lab, of the properties of the natural system and the underground engineered barrier system (EBS). Other field observations worldwide from "natural analog" sites have provided additional information on the potential long-term behavior of the candidate repository at the Yucca Mountain site. These laboratory and field data and observations have been used to develop detailed conceptual and numerical models of subsystem and total system behavior. In turn, these models have been used to develop projections of the potential long-term radiological exposures to a hypothetical population living downstream of the candidate repository due to the presence of the HLW repository. DOE now has over 15 years of data collection and modeling experience behind them at Yucca Mountain.

If DOE determines that the site is suitable, the anticipated release of the "Site Recommendation" report will mark a change in roles for DOE. The Department will, at that time, shift from being only a site investigator to actively seeking to use the site for permanent HLW disposal. The intent of the "Site Recommendation" (SR), as defined by the Nuclear Waste Policy Act (NWPA), is to formally recommend the Yucca Mountain site to Congress and the President for their approval to proceed into licensing. Assuming DOE receives this approval from Congress and the President the next step will be for DOE to submit a license application (LA) to the U.S. Nuclear Regulatory Commission (NRC) to begin construction and loading of the repository.

The LA process and documentation will be extensive. In order to enable this process to effectively manage uncertainty in the projections of consequences over large time scales, both NRC and the U.S. Environmental Protection Agency have instituted a risk-based approach to demonstrating, with reasonable expectation, that future human health in the Yucca Mountain vicinity will be adequately protected. It is also why the NWPA prescribes a three-step licensing process. NRC will be required to make separate determinations on whether or not to authorize DOE to first construct, then operate and finally close the repository. These determinations will be spaced many years apart. In the intervening time between decision-points DOE's data and modeling projections will evolve and improve. They will submit and re-submit, under rigorous quality assurance standards, increasingly detailed analyses of the processes upon which the original SR was based. NRC will conduct rigorous reviews of all of this information and they will ask many questions that DOE will be required to answer.

Assuming that the Yucca Mountain Site Recommendation is approved by the President and confirmed by Congress, DOE will need to develop appropriate approaches to collecting and analyzing data, and producing a license application for construction, followed perhaps by license amendments to load the repository and site closure. A clear vision of how to proceed in a step-wise fashion in both the scientific/technical and regulatory arenas is required.

BASES FOR STEP-WISE REPOSITORY DEVELOPMENT

The National Academy of Sciences, in its 2001 report, *Disposition of High-Level Waste and Spent Nuclear Fuel*, recommended, "For both technical and societal reasons, national programs should proceed in a phased or stepwise manner, supported by dialogue and analysis" (1). In supporting this, its 'Principle Recommendation #3, the Academy went on to say "The justification for a phased process is that knowledge and understanding are developing in both the technical and societal areas." Consideration of the evolving nature of both scientific knowledge and societal views is a key aspect of a repository development process that, by its very nature, must play out over extremely long time frames. This was explicitly recognized in the Nuclear

Waste Policy Act that defined a multi-step approach consisting of site characterization, site approval by the President and Congress, followed by three separate NRC licensing decisions (construction, operations, closure) (2).

The NRC in developing its final regulation for Yucca Mountain, 10 CFR Part 63 (3), also recognizes that knowledge about the site will increase throughout the time the repository remains open. NRC also notes it has developed its regulation accordingly:

> [P]art 63 provides for a multi-staged licensing process that affords the Commission the flexibility to make decisions in a logical time sequence that accounts for DOE collecting and analyzing additional information over the construction and operational phases of the repository. The multi-staged approach comprises four major decisions by the Commission: (1) [c]onstruction authorization; (2) license to receive and emplace waste; (3) license amendment for permanent closure; and (4) termination of license. The time required to complete the stages of this process (e.g., 50 years for operations and 50 years for monitoring) is extensive and will allow for generation of additional information. Clearly, the knowledge available at the time of construction authorization will be less than at the subsequent stages. However, at each stage, DOE must provide sufficient information to support that stage. … The Commission believes the regulations, as proposed, provide the necessary flexibility for making licensing decisions consistent with the amount and level of detail of information appropriate to each licensing stage.
> (2, pg. 55739)

Because the NRC licensing process will govern the full range of repository operations (from initial emplacement to eventual closure) and take place over a period of time that will stretch for decades if not centuries, this phase encompasses the greatest opportunities for learning. DOE's licensed activities must be capable of taking full advantage of these opportunities while, most importantly, assuring that public health and safety is protected every step of the way. Accomplishing this will require that both applicant and regulator adopt innovative, forward-thinking approaches to constructing, developing, and maintaining the facility's licensing basis. Fortunately, NRC's risk- and performance-based licensing regulation (3) is well suited to this purpose. This regulation calls for two separate safety cases to be developed – for pre-closure and post-closure repository performance – and further requires a performance confirmation program that will facilitate incorporation of scientific advances to inform the evaluation of the latter while work is still being conducted in accordance with the former.

STEP-WISE REPOSITORY LICENSING

Effective application of 10 CFR Part 63 will require both DOE and NRC to think well outside the paradigm of nuclear reactor licensing, while still learning from that experience (4). As required by 10 CFR 63.131 (3), the repository performance confirmation program must provide data that indicate whether actual subsurface conditions "are within the limits assumed in the licensing review" and whether natural and engineered barriers "perform as intended and anticipated." Tests and experiments intended to meet these requirements should be accompanied, from the outset, by detailed plans describing what will be done with the information gained through these activities. In order for this to be effective, the designers of the tests need to 'pre-think' where further scientific exploration might lead. There are five key components to this type of pre-thinking.

1. A definition of what analysis will be conducted with the data collected;

2. Acceptance criteria for determining whether or not the data 'confirm' the originally expected performance;

3. Plans for responding to data that do not confirm the originally expected performance (particularly important for tests and experiments designed to challenge the safety case);

4. Decision points in time where the defined analytical program will be revisited and can be revised in response to new information if necessary; and

5. Outlines of potential design improvements, or changes to the analyses or safety case that can be implemented if new information indicates repository performance will be different than expected. These should include modifications that can be made to improve the efficiency of the repository if performance is found to be better than expected.

All of these pre-thinking components need to be clearly established as part of the repository's licensing basis. They must be sufficiently broad in scope and fully defined to meet both key requirements of 10 CFR Part 63.131 by both verifying and challenging the repository system.

In a licensing context, this pre-thinking can take on a very specific form, molded after the example of reactor Technical Specifications. Of necessity, where significant uncertainty exists over extremely long time frames, the ability to further evaluate assumptions made in the safety case with additional information over time (and make adjustments when the assumptions can no longer be supported) must take the place of a certainty of knowledge. There is actually a strong precedent for this approach in reactor licensing. Although there is much less uncertainty in the reactor world, a reactor license does not rely on absolute certainty in predicting how the plant will be operated. Instead, a Reactor license is based on Technical Specifications that establish 'Limiting Conditions of Operation' (parameters within which the plant must be operated) and 'Surveillance Requirements' (test that verify that the plant is within the bounds of these 'limiting conditions').

There are several levels to the license that can exist for the construction, testing, operation and closure of Yucca Mountain (using nuclear power station and ISFSI licensing as a guide). For nuclear power stations, licensing has, among other conditions, the following elements that are of relevance to the Yucca Mountain repository (assuming DOE proceeds to licensing):

1. A *Site License* provides a very high level and usually general statement of conditions for operation of the facility.

2. *Technical Specifications* will provide *Safety Limits* with accompanying applicable *operational conditions and required actions* when these limits are exceeded. Tech Specs also provide the *Bases* for these Safety Limits. These Safety Limits compose the upper tier of operating limits. They are defined based on the reactor's safety analysis (or in the repository case the performance assessment) as the regulatory points that assure that the facility is operating within the conditions of its license (i.e. post-accident or post-closure doses are assured to be within regulatory limits). If these limits are exceeded, then prompt action to

move the facility to a safer configuration and immediate notification of the regulator must be undertaken. Tech Specs also provide Limiting Conditions for Operation (LCO) and Surveillance Requirements (SR) for the LCOs. These LCOs range from electrical distribution, instrumentation, to cooling systems. LCOs are the tolerances set beneath the regulatory limits to assure that the systems are operating as expected. If these tolerances are exceeded, equipment will be declared inoperable and actions that must be taken to either restore operability or transition the facility into a safer configuration. As long as these actions are followed as outlined in the Tech Specs, no regulatory response is required. Finally, Tech Specs covers some key administrative aspects such as staffing and key facility design features.

3. The *Safety Analysis Report* provides a detailed description of the facility that includes the local environs as well as each system. The design basis events are also described. System performance testing not part of Tech Spec SRs is included in the SAR. Whether or not a given type of testing is included in the Tech Specs or simply left to the SAR is a function of how important the equipment being tested is to public health and safety. In a reactor, equipment such as the reactor vessel and emergency core cooling systems would be covered by Tech Specs while radwaste systems and ventilation in non-critical parts of the plant would not. In the repository case, what is and what is not appropriate for inclusion in Tech Specs will be driven by the relative importance of things in the performance assessment.

The NRC process from construction license approval to repository closure can be segregated into a number of milestones. Each of these has a specific meaning when viewed in the context of step-wise repository development (reflected in italics below):

a. Construction – Material receipt testing is performed per the construction test program. Structures, Systems and Components important to safety are assembled and tested prior to final receipt by the owner (DOE).
   Step-wise repository implementation: Before NRC authorizes construction at Yucca Mountain, there must be reasonable assurance that pre-closure safety objectives will be met. Also, irreversible aspects of repository design (tunnel diameter, location, orientation, etc.) will need to be fixed. This means a reasonable expectation will also need to be reached on a very limited set of attributes of the post-closure safety case (mostly having to do with natural systems as engineered barriers can be changed).

b. Start up testing – Integrated system testing without irradiated or contaminated materials is performed as part of acceptance testing.
   Step-wise repository implementation: This phase should primarily focus on confirming pre-closure performance so that there is assurance subsequent repository operations can be performed safely. Post-closure confirmatory programs for which tests not requiring actual fuel/waste and for which results are desired early in the pre-closure period may also be initiated. Furthermore, certain testing on engineered barrier performance should also be initiated from the outset. For example, while it may be possible to make modifications later to some components, it would not be desirable (either from an economic or worker exposure standpoint) to do so. This is particularly true where there is a relationship between pre- and post-closure performance (such as in the case of container lid welds).

c. Low capacity testing – Spent nuclear fuel is introduced in a fraction of full operational capacity to demonstrate the functional capability of the integrated facility. Capacity is increased in stages to full capacity bringing additional systems and features on line.
Step-wise repository implementation: Yucca Mountain's initial operating license should allow for a flexible design. This phase of operations should allow for a range of tests to further define the design (for example, some fuel can be placed in hotter drifts while other fuel is placed in cooler drifts to better assess temperature effects, at the same time fuel received and stored at the surface can be accurately catalogued to better define the actual thermal profile of the incoming waste stream). This approach needs to be implemented in a highly dynamic fashion, while it may affect waste emplacement and surface staging it cannot do so at the expense of the repository's primary mission – to receive waste from reactor and defense sites. All of these programs must be aligned with waste acceptance schedules to which the repository is already committed.

d. Full capacity testing – Additional testing (performance confirmation), including some tests that may be considered operational transients are included in this period.
Step-wise repository implementation: This point is not likely to be reached at Yucca Mountain for many decades. By this time significant data from waste emplaced in tunnels, as appropriate in accordance with "low capacity" testing, will have been evaluated and a significant inventory will also likely have been accumulated on the surface. Economies of scale will dictate that uniform large-scale waste emplacement should be underway. The design will be largely fixed at this point, although it will still be possible to make changes or even reverse course if new information is received that is significantly contrary to what was expected (outside technical specifications).

e. Normal operations – Continued testing occurs such as those tests required by Technical Specifications (SR) and the SAR.
Step-wise repository implementation: For a facility designed to protect public health and safety with no active intervention, the state of "normal" operations is not reached until the point of repository closure. It is in issuing the license to close that a final determination that a "reasonable expectation" exists that post-closure safety objectives will be accomplished. Although monitoring of the repository may continue, and future generations may make all sorts of choices (for example to mine and reopen the facility), it will no longer be appropriate at this point to take licensing credit for information that can be obtained in the future (as it should be at each of the previous stages of the repository's life).

Along the way, 10CFR Part 63.44 allows for changes to facility design which includes the physical design, analysis methods and changes to the license (Technical Specifications, SAR). Some changes, depending on the significance of the change and its importance to the safety case, may not require prior NRC approval.

The performance confirmation program of a repository is, in fact, quite analogous to the Technical Specification surveillance program of a reactor (4). Reactor surveillance verifies that reactor equipment is operable – i.e. will perform its intended function as described in the plant's safety analysis. The 'Limiting Conditions of Operation' prescribe what equipment must be operable for the plant to continue to function safely and define actions to be taken if equipment important to safety is found not to be operable. These actions typically have time frames assigned for their completion, either the operability of the specific equipment in question must be restored, or the entire plant must be placed in a safer configuration (up to and including shutdown). The time frames are typically on the order of hours, days, or months depending on how important a specific component is to safety. Repository Technical Specifications should be designed in a similar manner by rigorously employing the performance confirmation program. In the case of a repository, operability refers to confidence that a natural system or engineered barrier will perform as assumed in the performance assessment upon which the licensing review is based.

In the repository license, specific tests and experiments should be designed to both confirm and challenge the reasonably expected inputs to the performance assessment. Specific 'limiting conditions' should be placed on the results of these tests. If the results of the test or experiment fall outside these limits, a given natural or engineered barrier should be considered inoperable. In this case, the Repository Technical Specifications should call for specific actions to be taken to either restore confidence in the 'operability' of the barrier in question or make adjustments to the repository configuration. These actions could range from additional testing to restore confidence in the barrier, to design modifications to restore confidence through other means, up to halting or reversing the disposal operation.

What is meant by a natural or engineered feature being inoperable and what actions are required in such an event must be carefully defined and will be highly specific to the individual feature being addressed. There will also likely be different degrees of "inoperability" and different levels of response called for. This will require a highly sophisticated and risk-informed approach to prioritizing which barriers are most important to safety and what attributes of each barrier are the most important indicators of its performance. In other words, a graded approach should be taken to constructing repository 'limiting conditions of operation'. In some cases, a parameter going out of tolerance would merely be a call for action to do additional testing. In many of these cases the time allowed before more significant action needed to restore operability could be quite long (perhaps decades). In other cases, a more direct call for action to modify the barrier or add additional barriers might be in order. In the most risk significant cases, such an action statement might also require emplacement to be halted until this could be done (or even require bringing already emplaced waste back out). Also, declaring an individual barrier to be inoperable does not imply any change in the status of other barriers, which opens up another range of options – making up for out of tolerance performance in one area by taking credit for improved performance in another. For example, if the performance confirmation program on the geology is learning that it performs better than expected, while the program on the waste packages is showing performance not meeting expectations (outside limits), then a potential response would be to simply rerun the TSPA to credit the improved natural barrier performance while taking less credit for the engineered barrier. In such a case, the Technical Specifications would then be modified (via a license amendment) to relax operability requirements for the waste package while tightening requirements for the natural system.

By taking a graded approach, and adaptively managing a flexible set of Technical Specifications, this licensing concept can be quite valuable in compensating for long-term scientific uncertainty through the addition of near-term process certainty. The key difference between repository

Technical Specifications and reactor Technical Specifications is in the time frames allowed for responding to information outside the 'Limiting Conditions of operation. As opposed to time frames of hours to months, repository operators may have years to decades to respond to non-confirming information regarding the repository's long-term performance. This is appropriate because the long-term performance of the repository need not be confirmed finally until the risk of non-performance is actually being assumed – which does not ultimately occur until closure. Between initial operations and closure, confirmation would be a matter of degree with additional confidence being continually added as the performance confirmation program moves through successive stages. Accordingly, for many components of the safety case (for example saturated zone parameters that do not become relevant until after the waste packages have degraded) action completion times can be quite significant, with some extending all the way to repository closure.

Building long-term repository technical specifications on the performance confirmation program places a heightened importance on performance confirmation (4). It also relieves the operators of the repository from the impossible task of achieving unreasonably accurate long-term predictions. Confidence that the disposal operation will never be allowed to go beyond the limiting conditions of its license can then replace confidence that 10,000-year predictions are 'correct' with present day science in forming the basis for regulatory approvals.

Here the staged nature of repository development takes on a greater meaning. A reactor is not permitted to start up unless it can be shown to be within the limits of its Technical Specifications. For a repository designed to isolate nuclear materials for thousands of years, the act equivalent to reactor start-up is that of repository closure. Everything up to that point is equivalent to construction, maintenance, testing or outage operations (these also have a very specific set of requirements that must be met to assure safety). At start-up, the operators of a reactor are taking on the risk of a sustained nuclear chain reaction that will continue until actively stopped. At closure, the operators of a repository are taking on the risk of sustained waste isolation that will continue unless a future civilization actively intervenes to undo the repository. DOE and NRC should recognize this as they develop and regulate the repository's licensing basis. Throughout the several stages of repository development that will occur between initial operations and closure, the level of expectation should be ever increasing in step with the level of knowledge. Care should be taken to not set expectations to high at the outset (requiring an unnecessary and hard to achieve level of knowledge about long-term processes long before such knowledge is really needed) or to let the tightening of expectations wait too long toward closure (perhaps leaving future society with an expensive repository that it is unable to close). What is 'reasonably expected' at any point in time should be consistent with the level and nature of risk being assumed at that point in time. The extent of knowledge of long-term performance that is required should be allowed to progress as repository development progresses over the decades of emplacement operation – through the performance confirmation program. Care should be taken to not place excessive expectations on the amount of knowledge that must be acquired in the early stages of the repository development process.

Licensing Stages

As mentioned above, a key attribute of the repository licensing process is that it occurs in stages. 10 CFR Part 63 lays out three specific stages, construction authorization, operating license approval, and approval of a license amendment to close the repository. The time between the 2nd and 3rd stage is likely to be on the order of decades if not centuries. An active performance confirmation program, developed in accordance with the regulation, will be ongoing throughout this time and will likely gain significant new information while at the same time the overall capabilities of science to understand and evaluate such information will also be advancing considerably. The transition from the 2nd to the 3rd phase is therefore more likely to be an iterative process that progresses over several small steps as opposed to one giant leap. Use can be made of the requirement in Part 63 to report data and their significance at least every two years (3) to support this iterative process. Therefore, the entire process should be viewed as many-stepped, not just three-stepped. Care should be taken not to place too much emphasis on what is known at the first two steps in making licensing decisions because doing this might preclude opportunities to enhance public health and safety protection through the learning that will occur over several subsequent steps.

To most effectively apply a step-wise approach, care should also be taken to preserve flexibility in repository design to the maximum extent possible for as long as possible. While many parameters will need to be fixed early on to facilitate the timely initiation of waste emplacement (such as surface facility design and tunnel configuration), many others (such as waste package spacing and ventilation flow rates) can readily be varied later in repository life. Some parameters (such as engineered barrier materials choices) may be variable, but with some difficulty (requiring major modification or back fit that could only be justified if the benefit were great). Nevertheless, there is a wide range of repository design parameters for which building significant flexibility into early repository designs will enhance the project's capability to apply more advanced scientific information – that can be gained at later steps – toward the ultimate protection of public health and safety.

Risk-Informed Regulation

The risk- and performance-based platform for repository licensing provided by 10 CFR Part 63 provides a strong foundation for the effective implementation of step-wise licensing. This regulation requires that DOE demonstrate a 'reasonable expectation' that the radiation exposure and contaminant levels of EPA's Yucca Mountain radiation protection standard (40 CFR 197, or "Part 197") (5) will be met using a probabilistic assessment of the repository's future performance. The term "reasonable expectation" takes on a very fluid meaning in the context of a many stepped, iterative, licensing process. EPA (5) notes that "reasonable expectation" means:

- "Best estimate" or "realistic" analyses should be conducted instead of "conservative" or "bounding" analyses;
- It is inappropriate to leave repository features, events, or processes (FEPs) out of the analyses simply because they are difficult to calculate; and
- Appropriate use of expert elicitation is allowed.

Scientists will have a much stronger 'expectation' for what will happen post-closure as the performance confirmation program gains increasingly more information over the many years that precede repository closure (4). Accordingly, early in the licensing process, more confidence should be placed on what is believed to be true about post-closure repository performance with knowledge that this belief can be tested over time, while later in the process regulatory confidence will be based on additional knowledge that has been collected over time.

In calling for a probabilistic safety case, NRC has gone a step beyond the risk-informed regulatory approaches currently applied to reactors. In the reactor case, probabilistic analysis is applied to make judgments about what elements of reactor licensing are most risk significant. These judgements are then applied to set priorities for the application of deterministic methods to demonstrate that safety goals are met. However, in the repository case, the probabilistic analysis *itself* is used to demonstrate compliance with safety goals. This difference is essential to ensuring the success of the many-stepped process that will characterize the repository case – where the amount of knowledge supporting projections of post-closure performance is ever increasing. Unlike deterministic analyses that are often used to bound possible future outcomes, probabilistic analyses are designed to combine the full range of potential outcomes with an estimate of the likelihood of each possible outcome. This approach allows the licensing case to manage the uncertainties that are inherent in a project that seeks to project performance of a heterogeneous system over many thousands of years. The results of this research, along with concurrent advances in scientific capability, will periodically reshape and redefine both the likelihood and range of potential outcomes – i.e., what is 'expected'. As this occurs, the repository will advance, step-by-step, towards closure with increasing confidence that public health and safety will be protected (or waste emplacement will be halted or reversed).

Historically, the nuclear industry has used a mixed approach in models used to support licensing activities– combining expected behavior and conservative assumptions –. However, it is **always** necessary to develop an expected behavior model **first** such that unbiased risk insights can be drawn. Any conservatisms that are applied should be done after discussing the implications of doing so with the regulator. All subsequent conservatisms that are added must be clearly identified along with the impact of applying such conservatisms on biases in the relative importance of particular FEPs, the risk results, and available margin.

A similar approach is also desirable in the repository case, however some fundamental adjustments need to be made to account for the more directly 'risk-informed' nature of repository licensing. Specifically, we believe that, for a repository, use of both approaches separately is most appropriate – so long as the 'expected behavior' model is developed first. Any conservative models developed later should be constructed so as to make readily apparent applied conservatisms, how the conservatisms introduce biases and impact the results, and use of engineering/scientific judgement. In general, the parts of the calculations in which 'expected behavior' models and data have been used are those for which adequate frequency data are available, the system is relatively well defined in both behavior and spatial extent, and for which there is little spatial or temporal variability in the properties or processes of interest. The 'conservative' parts of the calculations are those for which more limited data are available, the system is more poorly understood in general, or for which there is more spatial or temporal variability.

For the development of reactor PRAs, EPRI's current recommendation is to first develop as completely as possible an 'expected behavior' approach. This is because it is necessary to understand the 'true' sensitivities and relative importance of each component of the system regarding its contribution to safety. Adopting conservative approaches early in an assessment has been found to skew the relative importance of particular components of the system. A skewed assessment may lead to sub-optimal expenditure of resources for maintaining safety. Only after the important components of the system have been identified using an 'expected behavior' model, may one then adopt some conservative assumptions for the purposes of licensing where robust defensibility is required for public acceptance and NRC approval. The initial 'expected behavior' model can then be used to provide an estimate of the degree of conservatism introduced in the 'conservative' model used for licensing.

While there are many similarities between licensing nuclear reactors and licensing the proposed Yucca Mountain facility, there are also a few differences that may require a somewhat different approach. Both systems involve many thermal, mechanical, structural, chemical, and radiological processes. Both systems have base case and 'off normal' or 'accident' scenarios that require analyses. Yet the degree of heterogeneity, time, and spatial scales for the Yucca Mountain system are much larger than that for nuclear reactors. Because the time and spatial scales are so great at Yucca Mountain, there are little to no direct frequency data for many of these processes. Natural analogue information will be necessary in many cases to supplement the active data acquisition program that DOE is conducting. Furthermore, it will likely be necessary to collect additional data over a longer period of time (tens to hundreds of years) to 'confirm' some of the models used to defend the safety of the Yucca Mountain system.

Thus, while a somewhat more conservative approach may be necessary in a repository licensing case than in a reactor licensing case (due to greater long term uncertainties and less data), the modeling approach in an NRC-regulated environment for a repository is still fairly similar to that EPRI recommended for nuclear reactors. That is, a dual modeling approach should be used. An 'expected behavior' model should be developed first using a combination of data (wherever available), analogue information, and engineering/scientific judgment. A second modeling approach, using conservative assumptions in those areas where it may be difficult to accurately define the 'expected' conditions, may then be developed for licensing purposes. The 'expected behavior' model can then be used to inform NRC and the public about the relative degree of conservatism in the 'conservative' model used for licensing. The intent is that the 'conservative' model would form the main basis for the licensing decision, while the 'expected behavior' model would be used to provide additional insight. Thus, the 'conservative' model would need to be based on data and models entirely within the NRC requirement for quality assurance for licensing purposes. While the 'expected behavior' model may use many of the same models and data developed under the full QA program, some of the data and perhaps some of the models will be based on more engineering/scientific judgment that could not be validated and verified to the extent typically required in nuclear QA programs.

While the level of conservatism required for a repository licensing case may be greater than for a reactor licensing case, it is important that the level of conservatism not be allowed to grow too high. Excessive conservatism could make what is in reality a perfectly safe repository, impossible to license. It could also add unnecessary complexity and costs that would not be in the best interests of protecting public health and safety. This is why a dual model approach is so valuable, for only by starting first with a best estimate model and then constructing a conservative model can one truly appreciate the level of conservatism applied (and assess whether or not it is excessive). In combination with this approach, there are two fundamental elements to keeping conservatism in proper perspective - knowledge already gained and knowledge that can be learned over the 50-300 year period that the repository will be open. DOE should make maximum use of both the data it has collected and its performance confirmation program in applying a balanced approach to the use of conservatism in its licensing case. Obviously, the more data that exists, the less conservatism is needed. However, the opportunity to gain additional data in the future is of equal importance for a repository. This is one key difference between repository licensing and reactor licensing. The longer time frames being considered in the repository case provide greater opportunity for learning from and adjusting to future information than that which exists at a reactor.

The technical bases in a repository licensing case are far more likely to survive the rigorous scrutiny of the regulatory process if they are backed by a well thought out performance confirmation program (4). Using the combination of the 'expected behavior' and 'conservative' modeling results to provide information about what areas a long-term R&D program would have the most benefit. Conversely, taking a step-wise approach can help guide decision-making about where and to what degree conservatism should be applied. In areas where a rigorous confirmatory research, or surveillance program, can be put in place, and where adjustments can be readily made if that program yields unexpected results, it may be advantageous to gravitate more towards "expected behavior' in the licensing case. In areas where such a program would be difficult to implement or where unexpected information would be difficult to accommodate, it might be more prudent to base the licensing case on conservative modeling. In such cases, the confirmatory program could then be designed to investigate whether or not such conservatism is really necessary, hence providing potentially valuable margin in future steps.

Pre-Closure versus Post-Closure Safety

What has been discussed thus far refers largely to how post-closure repository performance can be addressed in a step-wise licensing process. Pre-closure performance is more akin to reactor licensing (particularly at fuel storage and handling facilities related to reactors) such that direct analogies to current reactor licensing approaches are much more appropriate. Pre-closure operating risk will be assumed at the time repository emplacement operations begin and thus a licensing determination that risk is acceptable cannot wait for 'future' information. NRC's risk informed 'Integrated Safety Analysis' approach in 10 CFR Part 63 represents a substantial advance over regulatory philosophies applied in the commercial world. However, this approach is not so different that it would justify a significant deviation from what is currently practiced at similar commercial facilities. In this case both NRC and DOE should actively apply lessons learned from the commercial world. While the approaches described elsewhere in this paper will still have some value (as fuel handling technologies advance) in effecting process improvements, they do not in any way relieve the responsibility of the licensee to assure pre-closure safety up-front in the initial license application.

SCIENTIFIC INQUIRY IN LICENSING HEARINGS

As in any NRC licensing process, submittal of a repository license application will be followed by formal public hearings. As a matter of policy, formal, trial-type, adjudicatory proceedings – with the right to present and rebut evidence, and cross-examine witnesses – are not particularly well suited to the task of reaching a decision on complex technical and scientific issues. When honest, intellectual disagreements among scientists and engineers are removed from the world of objective inquiry and thrust into an adjudicatory arena, the very nature of the investigation will undergo a substantive change. The result can be that a methodical application of scientific principles and enlightened debate degenerates into a full-blown trial to find out who is "telling the truth" when, in reality, the scientific process is based on interpretation of data. Such an outcome would be especially problematic in the case of repository licensing, where science is being employed to objectively address matters that include both studies of events that occurred several centuries in the past and projections about events that may occur several centuries in the future.

NRC should carefully consider how to tailor application of its formal hearing procedures to allow both those who are working to demonstrate the safety of the repository and those who are challenging such work to more openly communicate the rationale for their arguments. Such procedures should recognize the step-wise nature of the process and allow a graded approach to be taken to the degree of proof needed at each stage. Correspondingly, it will be important for DOE to be highly rigorous in its incorporation of performance confirmation into the license application where it intends for such confirmation to stand as an effective counter to uncertainty in the ad judicatory process.

Tailored implementation of NRC's formal hearing process would provide a logical follow-on to the technical dialogue that has already been established ahead of the licensing process through the use of external peer review. The NRC pre-licensing process for Yucca Mountain, defined in the "*Agreement Between DOE/OCRWM and NRC/NMSS Regarding Prelicensing Interactions*" dated November 16, 1998**,** is already being effectively applied to facilitate this dialogue. In NUREG-1297, "Peer Review for High-Level Nuclear Waste Repositories" (Feb. 1988), the NRC has documented a proven and effective way to deal with resolving complex technical and scientific issues through scientific inquiry. This NUREG was adopted and formally codified by EPA for WIPP (see 40 CFR 194.27, "Peer Review"), and was implemented successfully by DOE at WIPP.

NRC has already provided a solid foundation for a tailored hearing process with recent changes to 10 CFR Part 2, which established an Internet-based Licensing Support Network to improve access to licensing information for all interested parties. Enhanced access to information and carefully tailored hearings should work hand in hand to facilitate an effective scientific dialogue on Yucca Mountain licensing.

CONCLUSIONS AND RECOMMENDATIONS

The final regulations for Yucca Mountain will provide an effective platform for assuring adequate protection of public health and safety. Demonstration of compliance with these regulations through a probabilistic performance assessment will provide reasonable assurance that the overall health risk objective is met. Implementation of the following recommendations will facilitate the accomplishment of this objective in the most effective and timely manner possible:

- The repository licensing process should be viewed as a many step process. Construction, operations, and closure approval are the most obvious steps. However, for the post-closure safety case there will also be many additional steps between operations and closure as science advances incrementally over time.

- The degree of 'proof' required of the licensee at each stage in the process should be consistent with the level of risk being taken at that stage.

- A well-planned performance confirmation program, thoroughly integrated into the repository license, will facilitate a smooth and effective transition through the various steps of the process.

- Clear distinctions should be made between the licensing approach for pre-closure operations and that applied to the post closure safety case. In each case, there are important and unique differences between repository and reactor licensing that must be made clear.

- Design flexibility should be preserved to the maximum extent possible so that the step-wise development of a repository is able to capitalize on continuing advances in science to assure public health and safety protection.

- A soundly tailored hearing process that recognizes the unique aspects of repository licensing is the most effective way to publicly discuss and scrutinize the extensive and complex scientific and technical information related to repository licensing.

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