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AT THE

SYMPOSIUM ON RADIOACTIVE WASTE REPOSITORY LICENSING  
NATIONAL ACADEMY OF SCIENCES  
NATIONAL RESEARCH COUNCIL

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"REPOSITORY PERFORMANCE -- THE REGULATORY CHALLENGE"

INTRODUCTION

Good morning, ladies and gentlemen. It is a pleasure and indeed a distinct honor for me to have this opportunity to deliver the keynote address this morning, opening what I consider to be a most timely and important symposium on a subject of great interest to all of us, the licensing framework for radioactive waste repositories.

This Symposium comes at an important time in the waste disposal program, with the regulatory agencies -- the Environmental Protection Agency (EPA) and we at the Nuclear Regulatory Commission (NRC) -- currently focusing our attention, respectively, on EPA's ongoing efforts to establish the basic health and safety framework that will govern the licensing of a geologic repository and, following that, on NRC's efforts to conform our more detailed licensing requirements to those EPA standards.

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In July of this year, the Board on Radioactive Waste Management of the National Research Council released a report entitled "Rethinking High-Level Radioactive Waste Disposal", which examines a wide range of issues concerning the licensing process for geologic repositories. This report, together with a number of other recent analyses and commentary, have served to focus increased attention -- and, in some quarters, concern -- on the regulatory standards and process for the licensing of a geologic repository. It is this subject that I would like to focus on in my remarks here this morning.

In so doing, however, -- and particularly in view of my training as a lawyer and not a scientist -- what I propose to do is to step back from many of the detailed technical issues that occupy those who work in this arena on a day-to-day basis -- issues such as APES and UPEs, CCDFs, and the like -- and instead focus on what I think are the broader policy questions that have arisen with regard to the regulatory framework, beginning first with an examination of EPA's approach to establishing a generally applicable environmental standard; then focusing on the relationship between EPA's standard and NRC's implementing regulations -- what I will refer to as the technical nexus; and then, finally, turning my attention to the approach taken by the NRC in its implementing regulations and, specifically, the approach that we have taken to subsystem performance criteria.

Perhaps before I begin -- and again, reflecting my own personal background and biases -- let me turn first to the Nuclear Waste Policy Act for a brief but important reminder of what the statute itself says about the regulatory framework for geologic repositories: Section 121 of the Act directs EPA to establish generally applicable standards for protection of the general environment from offsite releases from radioactive material in repositories; that same section goes on to direct the NRC to establish the detailed technical requirements, including a system of multiple barriers, for the licensing of such repositories.

Importantly, the approach used here was one that Congress had used elsewhere: EPA was to set the generally applicable environmental standards, reflecting their conclusion as to what would be required to protect the public health and safety; and NRC, in turn, was to establish the detailed technical requirements, defining how, specifically, one would go about meeting EPA's general standards.

I emphasize this distinction not simply because it exists, but because it is an important one -- and one that I will return to when I discuss the relationship between EPA's standards and NRC's implementing regulations.

## EPA STANDARDS

With that by way of general background, let me now turn to the first of the three issues that I would like to address this morning, the subject of EPA's generally applicable environmental standard. As I indicated at the outset of my remarks, EPA is currently in the midst of repromulgating its general standard, responding to a court remand of July of 1987.

It is in this context that the opportunity has arisen, once again, for those within EPA who are responsible for the development of this standard, as well as those of us outside the agency who have an interest in this matter, to reexamine not just that part of the standard that was the subject of the court remand, but to consider as well the entire range of issues, including the containment requirements, that have been so controversial over the years.

Two issues, in particular, have arisen as a result of the pending review: First, the overall stringency of the EPA standard; and second, the feasibility of implementing the probabilistic portion of the standard. Neither of these two issues, of course, is new and, for that reason, I don't propose to review the lengthy history associated with either one here this morning.

But what I do think is important here and what ought to be emphasized is the continuing and unresolved debate over both of these issues. Indeed, it was this very point that the NRC made in our letter of August 27, 1990, commenting on EPA's Working Draft Number 2. With regard to the stringency of the proposed standard, the letter observed, and I quote:

"There continues to be considerable controversy regarding the stringency of [EPA's standards]. This controversy results, at least in part, from concerns over the very low levels of risk which underlie release limits imposed by EPA's standards, particularly when compared to other federal health and safety standards. We are concerned that a clear understanding and acceptance of the standards will not be achieved until EPA has explicitly documented the acceptable risk level that underlies the release limits of the standards and the way in which the release limits were derived from that risk level."

With regard to the ability to implement the EPA standards, the NRC letter of comment indicated that:

"[T]he Commission continues to be concerned about the workability of standards that require numerical probability estimates for very unlikely processes and events."

In my judgment, the debate over the stringency of the standards will continue, perhaps notwithstanding whatever explanation EPA might provide. Nevertheless, as the Commission emphasized in its comment letter, the basis for the proposed standards should be thoroughly documented and, more importantly, explained in the context of regulatory standards that have been imposed for other risks experienced by society, so that those who might wish to evaluate the stringency of the EPA standard will have a framework within which to do so.

Of greater concern, at least in my personal judgment, is the continuing controversy over the ability to implement and apply probabilistic standards as a basis for licensing a geologic repository. This issue, as I indicated, is not new either. Indeed, it was first raised by the Commission in 1978, when the Commission, in commenting on this matter to EPA, said, and I quote:

"We feel strongly that a deterministic method should be used to regulate nuclear facilities. We are aware that you are considering a substantially different type, a probabilistic standard which requires quantitative risk assessment. Based on our understanding of the virtues and the weaknesses of quantitative risk assessment, we are convinced that it can and should be used to provide insight on the quality and effectiveness of HLW disposal regulation, but it cannot be the explicit basis of the regulation . . ."

The discussion of this most important issue continued over the next several years, culminating in EPA's promulgation of its standard -- with its basic probabilistic framework intact -- in September of 1985. Importantly, the standard included the following proviso:

"Performance assessments need not provide complete assurance that the requirements of [this standard] will be met. Because of the long time period involved and the nature of the events and processes of interest, there will inevitably be substantial uncertainties in projecting disposal system performance. Proof of the future performance of a disposal system is not to be had in the ordinary sense of the word in situations that deal with much shorter time frames. Instead, what is required is a reasonable expectation, on the basis of the record before the implementing agency that compliance with [the standard] will be achieved."

It was based upon the inclusion of this language in the final EPA standard, that the staff advised the Commission at the time that EPA's probabilistic standards can, indeed, be implemented in a licensing review.

Four years later, in October of last year, the staff came back to the Commission, once again raising the implementation issue -- this time in the context of EPA's now-ongoing response to the court's remand. Acknowledging that EPA had endeavored to address this issue in its 1985 standard in the fashion recommended at the time by the NRC, the staff noted this past October that:

"[W]hile the language added by EPA to the rule and in the Supplementary Information [in 1985] tends to recognize qualitative considerations, an acceptable approach to implementation is still ambiguous and the governing standard is still the probabilistic numerical standard."

Thus, we find ourselves today -- nearly 12 years after the NRC first identified the difficulties associated with implementation of a probabilistic standard in a licensing context -- facing what I consider to be a most unfortunate situation: We have yet to identify a clear and unambiguous approach to implementing EPA's standard in our licensing review.

What we do about this situation, of course, is the challenging question -- and with your forbearance, this is a topic that I intend to address shortly, when I turn my attention to the NRC regulations and their relationship to the EPA standards. I would emphasize at this point, however, that if the EPA standards are to serve as an independent regulatory basis for licensing the repository, a clear and unambiguous resolution of this issue is essential and urgent.

#### RELATIONSHIP OF NRC REGULATIONS TO EPA STANDARDS

Lest it appear that the EPA standards are the source of my greatest concern, let me now turn my attention to the remaining two issues that I would like to discuss this morning -- both of which more directly involve our approach at the NRC to establishing detailed implementing regulations -- beginning first with the relationship between EPA's standards and NRC's regulations.

As I indicated at the outset, the Nuclear Waste Policy Act envisions that EPA would establish generally applicable environmental standards, setting forth the general offsite limits necessary to protect the public health and safety, with the NRC in turn establishing the detailed technical requirements necessary to achieve those standards.

This approach, as I indicated, is one that Congress had used in other contexts -- and, specifically, in the Uranium Mill Tailings Radiation Control Act of 1978. In addition, it draws directly upon the authority that was transferred to EPA, when that agency was

first established, to promulgate generally applicable environmental standards.

In view of the division of responsibility between the respective agencies -- EPA setting the overall standards, NRC establishing the implementing regulations to achieve those standards -- you can imagine that it came as quite a surprise to me when, in the context of a recent Commission meeting -- where the Commission and the staff were discussing the difficulty of demonstrating compliance with EPA's probabilistic standard in our licensing proceeding -- I learned for the first time that one did not necessarily comply with the EPA standards by demonstrating compliance with the NRC regulations. Indeed, as it turns out, the same result attaches to the converse: one does not necessarily comply with the NRC regulations by demonstrating compliance with the EPA standards.

While it is true that compliance with the NRC regulations makes it more likely that the applicant will satisfy the EPA standards, the technical nexus that I was searching for -- and that, in my judgment, the concept of a generally applicable environmental standard contemplates -- was not sufficiently well-established to permit one to reach the legal conclusion that compliance with the NRC regulations could be deemed to constitute compliance with the EPA standards.

The advantage of such a nexus is obvious: One need not litigate the underlying EPA standard, with all of the attendant difficulties associated with its probabilistic character, if the deterministic NRC regulations were based upon a clear technical nexus to the EPA standard. But unfortunately, that is not the situation that we have today.

One can quite readily understand, historically, why this technical nexus between EPA's standards and NRC's regulations does not exist -- recall that in the late '70s and the early '80s, NRC was endeavoring to convince EPA of the problems associated with a probabilistic standard and, indeed, had its own deterministic standard out on the streets, in final form, before the EPA standards were promulgated. Unable to convince EPA to abandon the probabilistic approach when it finalized its standards in 1985, we now have what amounts to two legally distinct licensing standards -- NRC's deterministic requirements in 10 CFR Part 60, and EPA's probabilistic standards in 40 CFR Part 191.

I recognize, as the staff concluded in NUREG-0804 and its subsequent appendices, that compliance with NRC's regulations does indeed make it more likely that EPA's standards will be met. However -- and perhaps here I view this issue more through the eyes of a lawyer reflecting upon the challenge that the applicant will face in a licensing proceeding -- absent a technical nexus that would permit one to conclude that compliance with NRC's regulations can be deemed to constitute compliance with EPA's standards, I fear

that the applicant will face the challenge of demonstrating that both the NRC regulations and the EPA standards have been satisfied.

In short, while we may have reduced the technical uncertainty with such an approach, we have increased the legal uncertainty, perhaps to the point where the various requirements that the applicant must demonstrate compliance with in a licensing context -- and particularly those that involve probabilistic elements of proof -- will overwhelm whatever technical advantage might otherwise exist in such an approach. Indeed, as Pogo once observed, we may be facing insurmountable opportunities.

What is the solution? One obvious answer would be for the NRC to reevaluate its subsystem performance criteria, following promulgation of the EPA standard, with an eye towards restructuring those criteria in a manner that would permit one to establish the technical nexus that I referred to earlier. We already know, for example, that one of the three subsystem performance criteria -- the 1,000 year groundwater travel time -- is not only a poor surrogate for radionuclide transport, but moreover, does not appear to have a clear nexus to the EPA standard and, for this reason, may not be necessary in 10 CFR Part 60.

I suggest such an approach recognizing that the conclusion of an analysis such as this may well be that the subsystem performance criteria should be made more stringent -- but with the caveat that if this pushes these criteria beyond the bounds of what is technically achievable, then it seems to me that this indirectly raises a question about the stringency of the underlying EPA standard -- which, you recall, was based upon a view at the time as to what could be feasibly achieved. In the event that such a situation comes to pass, this, it seems to me, is a matter that we should then pursue directly with EPA.

The benefit of such an approach, I emphasize, is that the licensing framework for the geologic repository would be based upon deterministic considerations, rather than the very difficult and perhaps intractable considerations that we would face in applying -- and litigating -- a probabilistic licensing standard.

#### NRC SUBSYSTEM PERFORMANCE CRITERIA

With the time remaining, let me now turn to the third topic that I'd like to cover this morning -- the specific approach that we at the NRC have taken in establishing subsystem performance criteria for the repository. And here what I would like to focus on -- as distinct from the relationship of our regulations to EPA's standards -- is the somewhat narrower question of the approach that we have taken to establishing specific subsystem performance

criteria and the flexibility contained in the application and implementation of those criteria.

As I reviewed the report "Rethinking High-Level Radioactive Waste Disposal", one of the more insightful comments of that report, in my judgment, was its call for a certain amount of flexibility in the implementation of regulatory requirements. And indeed, it is in the context of the NRC's subsystem performance criteria that this recommendation, in my view, appears most appropriate.

As many of you know, we currently have three subsystem performance criteria, set forth in 10 CFR Part 60, each of which represents a minimum requirement and each of which must be satisfied as a prerequisite to issuance of a construction authorization: a release rate for any radionuclide from the engineered barrier system of one part in 100,000; a groundwater travel time criterion of 1,000 years; and a package lifetime criterion of 300 to 1,000 years.

I emphasize, each of these criteria constitutes a minimum requirement and each must be satisfied independent of the others.

That, of course, raises the question as to whether, for example, we would be satisfied with an application that relied to a greater degree on one of the criteria -- say, package lifetime, for instance -- and, based upon that enhanced performance, we would perhaps take that into account in evaluating compliance with any of the other criteria.

I emphasize here that the regulation specifically authorizes the Commission, on a case-by-case basis, to approve some other radionuclide release rate, designed containment period, or groundwater travel time, "provided that the overall system performance objective is satisfied."

But there are two aspects of this provision -- which requires an affirmative Commission decision to implement -- that I would like to emphasize here. First, as I indicated, this provision requires an affirmative decision by the Commission, in order to permit the applicant to depart from the specific subsystem performance criteria defined in the regulation; rather than allowing the applicant, on its own initiative, to determine how best to strike the balance between these three subsystem performance criteria and then to demonstrate that the overall level of protection sought by the Commission has been provided.

Purely as a practical matter, I think it highly unlikely that as we get closer to the licensing process, with the intense public scrutiny that will no doubt exist at that time, the Commission will be in a position to approve the kind of tradeoff that might make sense -- to take one example, greater reliance on the engineered waste package, with perhaps lesser reliance on groundwater travel

time -- if that results in the applicant being allowed to meet a less demanding showing on any of the criteria. This is particularly true, in my judgment, when one recalls that these individual subsystem performance criteria were based upon a conclusion as to what is technically feasible, not necessarily what is required to protect the public health and safety. Are we to allow DOE, the argument will go, to do less than what is feasible?

Beyond the practical problem, the second concern that I have with our ability to apply these criteria in the flexible manner that I think was originally intended is that these criteria were not based upon some well-defined overall health and safety goal -- established either in the body of NRC's regulations or, alternatively, in EPA's general standards. Indeed, as I just indicated, these criteria reflect an agency judgment as to what is feasible, not necessarily what is required to protect the public health and safety. Thus, whether DOE is allowed the flexibility to strike its own balance or NRC is required to take some affirmative action to approve an alternate approach, the problem that we have in either case is the same: How do we define the overall system performance objective -- the standard for evaluating any alternative approach that DOE might propose -- when -- (i) an unambiguous technical nexus to the EPA standard is lacking; and (ii) the subsystem performance criteria were formulated to reflect that which is feasible, rather than with an eye toward an overall safety objective?

Here, it seems to me that the answer to this problem, again, lies in establishing a firm technical nexus between the NRC regulations and the EPA standard -- and then allowing the applicant, without the need for affirmative Commission action, to decide what emphasis to place on individual subsystem performance criteria, so long as the Commission determines that the overall performance objective -- ideally the EPA standard -- is satisfied. Indeed, I think you will find that this approach is very much akin to the philosophy reflected in the Commission's recently-approved implementation plan for applying the Safety Goal to commercial nuclear power plants, where less emphasis has been placed on specific subsystem criteria, so long as the overall safety objectives established in that policy are satisfied.

#### CONCLUSION

Let me conclude my remarks with the following observation: It is my hope that the remarks that I have delivered here this morning will serve to stimulate a healthy discussion over the next two days about how we might improve the regulatory process for licensing a repository in this country. I do not count myself among those who believe that we must reinvent the wheel; but at the same time, perhaps because of the legal perspective that I have on some of

these issues, I see opportunities to improve that process. I wish you a most successful Symposium and I thank you for your thoughtful attention.