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Introduction

The last five years have been an interesting period in the regulation and development of the Nation's high-level radioactive waste disposal system. Recently, long after Congress mandated promulgation of standards, there has been a plethora of guidance and advice from numerous committees and scientific groups. Since EPA is required to reissue the disposal provisions of our standards, it is an appropriate time for us to receive this advice. Much of the advice, however, concerns major changes in well established provisions of laws and regulations that would require in-place systems be torn down and new ones built. There certainly needs to be a careful analysis made of the present system's viability and a consensus reached before such a drastic and expensive step is taken. Personally, at least from a regulatory perspective, I am not convinced such steps are necessary.

In my remarks today I do not intend to discuss the larger societal and philosophical issues involved in disposal of high-level radioactive waste. Rather, in the first portion of this talk I will discuss some of the regulatory advice offered in recent reports and will indicate EPA's views on the issues involved. While we in EPA agree with most of the recent advice, there are at least several areas in which we disagree. I will focus my final remarks on three of these issues.

Highlights of Reports

ICRP 46-Radiation Protection Principles for the Disposal of Solid Radioactive Waste (1985)

In 1985, the ICRP issued a report that discussed how the principles of radiation protection could be applied to the problem of radioactive waste disposal. They pointed out that the principles of justification and optimization should be retained, that normal releases should be subject to annual dose limits, and that some exemptions from disposal regulations were appropriate. These are all views that we generally agree with. However, the committee also called for probabilistic risk limits to be applied

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to individual annual radiation doses. This is one of the areas of disagreement that I will address in more detail later.

NEA PAAG/DOC(90)4 Disposal of Radioactive Waste-Review of Safety Assessment Methodologies

This document, developed by the Committee on Radioactive Waste Management and still undergoing final review by the OECD/NEA, reviews the performance assessment capabilities for radioactive waste disposal. Although much of the report discusses techniques that are beyond the scope of this presentation, some of its findings are worth highlighting here.

The task group noted that "performance assessment is multi-disciplinary and iterative in approach." They also noted that "the calculated long term consequences of a repository must be considered with respect to their probability of occurrence." In this context they also stated, "However, in most cases of probability estimates, human judgement has to be used in conjunction with incomplete or only partially relevant data and observations." Like so many others, they also indicated that more work needs to be done and that "It is not obvious, however, how compliance should be demonstrated for the long term safety of repositories."

NEA RWM/DOC(90)2 RWMC Collective Opinion on Safety Assessment

The same NEA committee has followed up its review of methodologies to develop this draft collective opinion. In carrying out this effort they considered whether 1) disposal systems and their impacts on people and the environment could be sufficiently understood, 2) specialist and regulatory authorities could be convinced that the predicted behavior is representative of what might actually happen, and 3) the potential impacts and means of estimating these can be illustrated transparently for a wider audience. They concluded that "...safety assessment methodologies exist today to illustrate the long-term radiological impacts that a proposed radioactive waste disposal system could have on man and his environment."

GAO NUCLEAR WASTE-Quarterly Report as of December 31, 1989- (Published April 1990)

This General Accounting Office (GAO) quarterly report is particularly pertinent to today's discussion. The report reflects some NRC staff concerns as to whether the EPA containment requirements may make it difficult, if not impossible, to satisfactorily demonstrate compliance in an NRC licensing proceeding. GAO notes that "Specifically, the staff believes that the standard can be implemented successfully in a licensing proceeding only if the inherent uncertainties involved

in making long-term projections of repository performance, can be satisfactorily taken into account." They further note, however, that "NRC's staff believes that meaningful, though not statistically rigorous probability estimates can be developed and reasonably defended for repository sites that are not complex or unusually geologically active. In fact, the staff believes that the required probability estimates will help determine how well a site is understood and, therefore, how much confidence can be placed in its future performance as part of a repository."

This subject of concern over uncertainties and how they are handled in an NRC licensing forum is the second of the three areas I will discuss later.

NRC Advisory Committee on Nuclear Waste letter to Chairman Carr of May 1, 1990; Subject: CRITIQUE OF THE ENVIRONMENTAL PROTECTION AGENCY'S STANDARDS FOR DISPOSAL OF HIGH-LEVEL WASTES

This NRC advisory committee has been conducting a review of the EPA High-level Radioactive Waste Standards over an extended period. They, too, indicate concern over showing compliance in the context of an NRC licensing hearing. Also, as in some of the other advisories, they state: "Although lower level standards can be stated probabilistically, they should be expressed in terms of annual risk limits from a disposal facility in an undisturbed and a disturbed state." This is, of course, an area where I have already noted I will have further comments.

This committee has also made several other specific suggestions concerning the EPA standards. We have evaluated those suggestions and have asked for clarification on several of them.

IAEA Safety Series No. 99- Safety Principles and Technical Criteria for Underground Disposal of High-Level Radioactive Wastes (1989)

This report reflects a number of the precepts that have become the basic criteria for high-level waste disposal. One of the overlying objectives noted the largely accepted approach to the intergenerational question and the role of institutional controls. The report states that the objective is "to isolate high-level wastes from the human environment over long time-scales without relying on future generations to maintain the integrity of the disposal system, or imposing upon them significant constraints due to the existence of the repository."

For limits on exposure from gradual processes, the document recommends the application of upper-bound dose limits that are less than the ICRP recommended 100 millirems per year. This is to prevent the overall limit from being exceeded by multiple sources. This is the approach that EPA has taken.

The report recommends considering the risks of disruptive events in a probabilistic approach using individual risk based on the ICRP-46 approach. The recommended limit for these events is a health effects risk increase of one in a hundred thousand per year. This is a higher risk than the EPA usually uses. The report also differs, as have many of the others, from the EPA decision to use total releases rather than annual dose for the probabilistic criteria.

National Research Council Board on Radioactive Waste Management Position Statement "Rethinking High-Level Radioactive Waste Disposal" (1990)

This document is critical of the whole U.S. high-level radioactive waste program. It basically calls for redoing the entire system beginning with the law. Concerning regulations, the statement implies that we would be better off without so much quantitative regulation and that we should just move forward studying the matter and doing the best possible job. This is the third area I will be specifically addressing later.

This report does contain some recommendations that are in line with suggestions we have made. For instance, it calls for performance assessments to be done on an iterative basis, an area we had suggested to DOE regarding their WIPP assessment. We further agree that one should not expect to get an analysis right the first time. Indeed, one of the major purposes of early site assessments should be to ascertain the significant areas requiring further examination.

The report makes three specific recommendations for EPA's consideration:

1) We should reconsider the detailed performance standards to determine how they will affect the level of health risks that will be considered acceptable.

We are doing this as a part of our repromulgation effort. It includes a comparison of the standard with other risk management standards EPA has promulgated in the last five years.

2) We should reexamine the use of quantitative probabilistic release criteria and examine what will constitute a reasonable level of assurance.

This is an area we are reviewing, but it should be realized that this is only partly our responsibility, since it largely falls to the NRC in their licensing process. Our standards authority is restricted to general applicability, and most of this determination is clearly related to site-specific issues. One of the issues that I will discuss later will highlight how

EPA has considered this matter of "reasonable assurance" in the drafting of its standards.

3) The report notes that all other countries use only a dose requirement and that the EPA should consider doing the same.

This, again, is the area where we most consistently disagree with many of the recommendations that have been made.

The Nuclear Waste Technical Review Board- First Report to the U.S. Congress and the U.S. Secretary of Energy (March, 1990)

This is the first in what can be expected to be a series of reports from this statutorily created advisory panel. It contains many excellent suggestions on the subjects that need to be examined during the assessment of potential repositories. It points out the critical need for preliminary performance assessments to see if the computations are possible for a site and whether any characteristics that would disqualify the site have been detected.

The report contains a listing of six different comments based on a review of a preliminary draft of EPA's reproposal of 40 CFR 191. We are adding several statements to clarify the areas that the report found ambiguous. We are also giving special attention to comments that call for changes in the standard. As the report suggests, we have already decided to drop the ALARA requirement from the next draft. We are also exploring the ¹⁴C release issue, and we agree that this needs to be understood.

EPA Issues

As I mentioned earlier there are then at least three areas where EPA has differences with some of these advisories. First, should there be quantitative standards before a repository is developed; second, what level of compliance assurance does EPA believe to be appropriate; and third, why have we chosen to express the probabilistic-related part of our standard in terms of total releases rather than individual annual dose? I will now explore these issues in more depth.

The Need For Quantitative Probabilistic Standards

Probabilistic standards are necessary because of the long time period over which one must judge the repository's suitability. Without taking the probability of events into consideration, a standard has no meaning for these types of facilities. If a site has any type of geological integrity at all, and all proposals certainly indicate this will be the case, the releases from undisturbed performance are not expected to be the ones of major concern. As we extend the analysis into the

thousands and tens of thousands of years, we realize releases of some kind are indeed possible, despite the geological integrity. The releases that might occur in the longer term are dependent on disturbed performance and, therefore, are not susceptible to the classic type of standard that prescribes limits on "routine releases." Nor can they be brushed aside as of no consequence. The releases of concern for any reasonably considered geology usually result from such things as human intrusion or seismic disturbances. To ignore this reality is to develop standards that have no effect on the releases of concern.

If we take the disturbances into consideration and apply only deterministic standards, we have only two choices for the possible events: we assume they either will or will not occur. If we assume they will occur, it will be difficult to find a repository that can pass the test. If we assume they will never occur, or ignore consideration of these events, we will have abandoned having a meaningful standard. If we do not state these criteria in some type of quantitative terms, we will have no yardstick for decision. This will invite litigation.

Another reason we think that a quantitative standard is necessary is that it provides a criterion against which to measure success or failure. We are very much aware of the potential contentious nature of the forthcoming repository licensing process. Without quantitative standards in place that have gone through a public review and promulgation process, each proposed site will require extensive justification, much of which will be subjective. This could result in an adversarial situation. By having an existing quantitative measure, much of the contention could be avoided since both the licensing board and any subsequent court will have a yardstick against which to judge the arguments.

The final reason for quantitative standards is that we do not believe that the disposal of high-level radioactive waste can be approached on the basis of just doing the best job that we can. Even the most experimental of engineering designers must have in mind some design goal. The country started out on this approach, which resulted with a proposed repository at Lyons, Kansas, that most now agree would not have been adequate. Furthermore, we do not believe that the public is willing to accept a nonquantitative standard as adequately protective of their health and the environment.

Also, reference Congressional mandate for itds in NUPA as evidence of public Compliance Assurance drive for acceptability benchmark.

The determination of whether a proposed repository complies with the EPA standard will not be made through measurement, monitoring, or inspection. For these facilities, we must depend

on mathematical models to carry out the long-term predictions of performance upon which the decisions will be made. Again, we realize that this will be taking place in a rather contentious setting. We are also aware that there is no way to make these types of predictions over such extended time periods and have total certainty as to their correctness. In fact, we would expect that there would be a good deal of uncertainty. We have dealt with this issue by indicating in our standard that we are looking for the analysis to show only a reasonable expectation of the standards being met. We purposefully avoided using the term "reasonable assurance" because it has been extensively used in the licensing of nuclear reactors and has acquired connotations that could complicate the waste repository decision. We have not developed any quantitative definition for "reasonable expectation" because we felt that it was both premature and that it was the responsibility of the NRC to do it in its licensing process.

Although we did not numerically define "reasonable expectation", there were other areas in the 1985 promulgation of the EPA standards in which we gave guidance on how we would handle uncertainty. For instance, in discussing how the implementing agencies might assure compliance where predictions of performance are made, we said:

Substantial uncertainties are likely to be encountered in making these predictions. In fact, sole reliance on these numerical predictions to determine compliance may not be appropriate; the implementing agencies may choose to supplement such predictions with qualitative judgments as well.

Also, to assure that there is appropriate truncation to the probabilistic analysis, we included the following guidance:

The Agency assumes that such performance assessments need not consider categories of events or processes that are estimated to have less than one chance in 10,000 of occurring over 10,000 years. Furthermore, the performance assessments need not evaluate in detail the releases from all events and processes estimated to have a greater likelihood of occurrence. Some of these events and processes may be omitted from the performance assessments if there is a reasonable expectation that the remaining probability distribution of cumulative releases would not be significantly changed by such omissions.

Because it was clear that uncertainties were very much a part of the analysis, we included some thoughts on how they might be handled with guidance that:

When the uncertainties in parameters are considered in a performance assessment, the effects of the uncertainties considered can be incorporated into a single such distribution function for each disposal system considered. The Agency assumes that a disposal system can be considered to be in compliance with 191.13 if this single distribution function meets the requirements of 191.13(a).

And similarly, regarding the analysis of undisturbed performance, we said:

When the uncertainties in undisturbed performance of a disposal system are considered, the implementing agencies need not require that a very large percentage of the range of estimated radiation exposures or radionuclide concentrations fall below limits established in 191.15 and 191.16, respectively. The Agency assumes that compliance can be determined based upon "best estimate" predictions (e.g., the mean or the median of the appropriate distribution, whichever is higher).

Also, relative to inadvertent intrusion, we wanted to appropriately limit the discussion when we included the following in our guidance:

The Agency believes that the most productive consideration of inadvertent intrusion concerns those realistic possibilities that may be usefully mitigated by repository design, site selection, or use of passive controls (although passive institutional controls should not be assumed to completely rule out the possibility of intrusion).

As further substantiation that EPA fully understood the uniqueness of the repository venture and the uncertainties that went with it, we provided a mechanism for calling for alternative provisions (section 191.17). In describing the purpose of this provision in the preamble to the rule, EPA wanted to go on record to provide perspective for any future reviewer, such as a licensing board or court. In this context, following are some of the examples of statements we made in the preamble:

In developing the disposal standards, the Agency has had to make many assumptions about the characteristics of disposal systems that have not been built, about plans for disposal that are only now being formulated, and about the probable adequacy of technical information that will not be collected for many years.

Thus, although the Agency believes that the disposal standards being issued today are appropriate based upon current knowledge, we cannot rule out the possibility that future information may indicate needs to modify the standards.

There are several areas of uncertainty the Agency is aware of that might cause suggested modifications of the standards in the future. One of these concerns implementation of the containment requirements for mined geologic repositories. This will require collection of a great deal of data during site characterization, resolution of the inevitable uncertainties in such information, and adaptation of this information into probabilistic risk assessments. Although the Agency is currently confident that this will be successfully accomplished, such projections over thousands of years to determine compliance with an environmental regulation are unprecedented. If--after substantial experience with these analyses is acquired--disposal systems that clearly provide good isolation cannot reasonably be shown to comply with the containment requirements, the Agency will consider whether modifications to Subpart B were appropriate.

As we have proceeded in repromulgating this standard, the area of guidance for implementation is one that we have given particular attention to. This is especially true where misunderstanding or lack of clarity has been pointed out to us. It should be clear, however, from these references to the 1985 version, that we never intended "absolute proof", as some have contended.

Individual Annual Dose versus Total Release

Probably the area in which we have had the most consistent difference with the various advisories is that of probabilistic-related assessment. Although we have set individual annual exposure levels for the undisturbed performance over a 1,000 year period, we have taken the approach of setting limits on total releases over 10,000-years for the probabilistic-related standards. When we started this standard setting effort, it was our inclination to use individual dose, since that was how radiation standards had always been set. It was only after we examined what it would mean to have to comply with such a provision that we switched to our present approach. We believe that approach is much more appropriate in view of the long time periods and uncertainties involved. The easiest way to show why we came to this decision is through reference to Figure 1.

Figure 1 shows two symbolic spheres representing the boundary line around two repositories and the defined "accessible

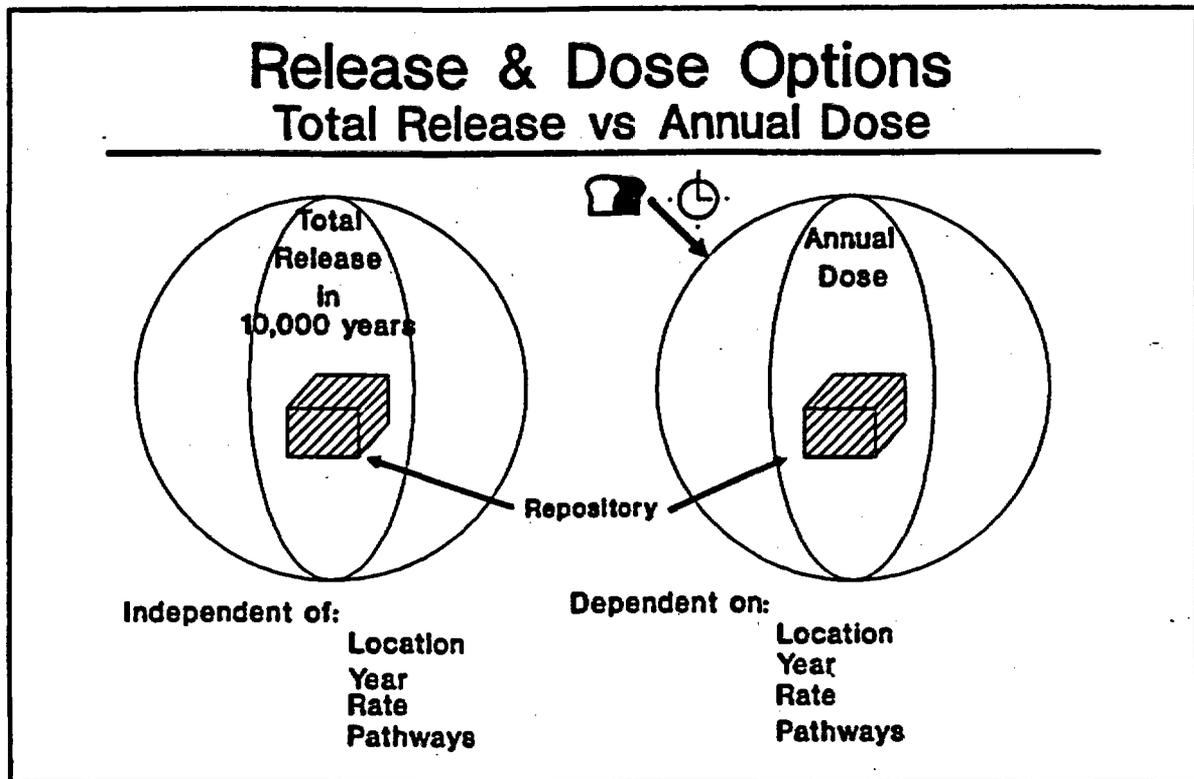


Figure 1: Total release and annual dose alternatives

environment". The sphere on the left represents the compliance case if you have the current structure of the EPA standards for probability related releases. In this instance, the release limits have been determined using fairly simple models related to the overall objective of having no greater than 1,000 health effects in 10,000 years. Under these circumstances, one only needs to estimate the probability and quantities of releases of radioactive material across this boundary at any time during the 10,000-year period. To demonstrate compliance, it is not necessary to identify where on that boundary sphere the release occurs (Location), when the release starts or stops during that 10,000 year period (Year), the time-related frequency of the amounts released (Rate), or how this material might interact with people and how they might be exposed (Pathways).

If we were to pursue the second alternative, annual individual dose, as depicted by the sphere on the right of Figure 1, we have a much more difficult analytical task. It is no longer sufficient to just estimate how much radioactivity is likely to cross the boundary. We now must also estimate where (arrow) on that boundary it will occur and whether it is close to people. That would be only the beginning of the analytical chore, however. Since we must calculate an annual dose, we must know when the release starts and ends (clock) and how much will be released on an annual basis (time-related factors on an annual

basis). While we think all this is more than should be asked of a probabilistic analysis, it would not be sufficient. We would still be required to go on from that point and speculate on how this material might interact with people (pathway-bread?) at this specific location and what the subsequent annual dose might be. These are speculations we believe are feasible for the analysis of the undisturbed repository but that are beyond what should be considered reasonable for the probabilistic analysis,

Why? Does this really mean just 1,000 years versus 10,000 years?

CONCLUSION

There is no doubt that the country has set itself a considerable challenge in seeking to establish a high-level radioactive waste repository. Yet, we must do it. In our evaluation of the regulatory aspects of this issue we do not see the system as broken beyond repair. Certainly, the political and sociological issues appear to be much greater deterrents to success than do the technical requirements of an EPA standard. We have noted a large number of advisories concerning how these facilities should be regulated, some of which we have highlighted here. There are many ideas in these advisories that we agree with and have adopted. We find a few ideas we do not agree with, and we have pointed out our reasons for disagreeing at this meeting. We think that more such interchanges should take place and that improved communications would be helpful in resolving differences. In many ways we have an advantage because everything we do is subject to public review, generating comments from many sectors. It would be much more difficult to create responsible public policy from discussions among ourselves. We appreciate the opportunity to have participated in this exchange.