UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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PUBLIC MEETING - A FACILITATED ROUND TABLE DISCUSSION ON DEFENSE IN DEPTH AS APPLIED TO A POSSIBLE HIGH-LEVEL WASTE REPOSITORY AT YUCCA MOUNTAIN, NEVADA

Alexis Park Hotel

375 E. Harmon

Las Vegas, Nevada 89109

Tuesday, November 2, 1999

The above-entitled meeting commenced, pursuant to notice, at 1:37 p.m.

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PROCEEDINGS

[1:37 p.m.]

MR. CAMERON: Good afternoon, everyone. Nice to see so many familiar faces again, both around the table and in the audience.

My name is Chip Cameron. I'm the Special Counsel for Public Liaison at the Nuclear Regulatory Commission, and I'm going to provide some facilitation assistance to all of you today on the discussion of the multiple barrier concept that's in the NRC's proposed rule on the Yucca Mountain repository, 10 CFR, Part 63, and as I understand it, the NRC has three goals today, one of which is to clarify the NRC approach to multiple barriers, to explain the rationale for that approach and the assumptions that underline that approach.

Secondly, the NRC wants to clearly understand any concerns that all of you have or may have with the multiple barrier approach, and obviously, the rationale for that approach and the assumptions on which it is based, and a third goal is to discuss possible alternatives that might perhaps address the concerns that you have, and I'm going to try to help you to meet those goals by assisting you in a number of different ways, one of which is to keep the discussion relevant and focused to ensure that we all understand what everybody else is saying about this

particular issue, to make sure that everybody has an opportunity to speak, to try to keep us on schedule, and to keep track of any action items or recommendations on this flipcharts.

The good news is that we have a great turnout for the meeting.

I guess the bad news is that we don't have probably enough time to get into a real indepth discussion on everything, and along those lines, the focus of the discussion is going to be with the people who are sitting up here at the table, but we are going to go out to all of you in the audience periodically for comment and question, and I guess that I would ask all of you, the people around the table and the people in the audience, that if you could try to be concise in your comment, that would be very helpful, because this is sort of an unusual meeting in that it is only a halfday meeting, so we really do need to try to pay attention to the time.

Now, I think everybody at the table, or most of you, has been through the ground rules on this before.

If you have something to say, please turn your name tent on end.

I think Mal, could you test this? Yeah, that's what I was afraid of. All right. Good. Congratulations.

Now we're going to go to the full if you could

turn your name tent up on end like that, and then I'll call you, and that will help our stenographer to keep a clean transcript.

We're going to go around for introductions, around the table, at least, in a minute.

The stenographer is going to note where you're sitting, and so, you won't have to say your name every time that you talk, at least for the people around the table.

When we go out to the audience for questions, I'm going to bring this talking stick out to you, and if you could just give your name and affiliation, if appropriate, for the transcript, before you ask your question or make your comment.

Okay.

I think we're getting our everybody that's supposed to be up here at the table up here, and we're getting some extra chairs for those of you who don't have any seats, and what I'd like to do now is, before I do an agenda overview, is to go around the table and have each of you introduce yourself, what your affiliation is, and one or two sentences, if you like, in terms of what your interest or concern on this multiple barrier issue, and that is what we're going to be discussing, not all of Part 63 but the multiple barrier issue, and anything that you think is related to that, too, as well, and let's start over here

with Rick.

MR. CRAUN: Okay. I'm Richard Craun. I'm with the Department of Energy. Concerns on the multiple barrier I like multiple barriers, so I don't know that I have any concerns to put on the table at this time.

I do like the fact that Part 63 has gotten away from the subsystem requirements and has gone forward and allowed the licensee to define those elements or attributes of performance that are important to the repository. I think that was an important step forward and quite a transition from Part 60.

MR. CAMERON: Okay. Thank you very much, Rick.

Christiana?

MS. LUI: I'm Christiana Lui. I work in the Nuclear Regulatory Commission, in the Division of Waste Management. My purpose here today is to basically clarify what NRC's current thinking of multiple barriers is, and my presentation will be following Dr. McConnell's presentation.

MR. BECKMAN: My name is Don Beckman. I'm the Acting Manager of Licensing for DOE's M&O contractor at Yucca Mountain.

My principle interest in attending today's meeting is very similar to Rick's. We're also very glad that the regulations have driven in the direction that they have, and we're interested in understanding the NRC's developing and

current position on the implementation of those regulations.

MR. CAMERON: Thanks.

MR. McCONNELL: I'm Keith McConnell. I'm with the NRC staff. I'm the Section Chief for what's called the Performance Assessment and Integration Section, and it's the section that has the principle responsibility for developing our sitespecific rules.

So, we're here in the process of responding to public comments on Part 63, and we are here to get your input on this particular issue as we finalize Part 63.

MR. FRISHMAN: I'm Steve Frishman with the Nevada Agency for Nuclear Projects, and many of you know that I have a concern with the way thinking and defense in depth has been going, and I guess the only example that I can give of the depth of my concern is I'm going lower myself to use a couple of viewgraphs today to show you what I'm talking about.

MS. TREICKEL: My name is Judy Treickel. I'm with the Nevada Nuclear Waste Task Force, and I'm here as a public advocate, because the public here in Nevada is very concerned that the rules are being sort of developed as site characterization goes on, and there's a real fear that the rules are being developed to fit the mountain, and that wouldn't provide defense in depth.

MR. CAMERON: Thanks, Judy.

MR. BECHTEL: My name is Dennis Bechtel. I'm a Planning Manger for the Department of Comprehensive Planning, Nuclear Waste Division, in Clark County, Nevada, and I'm here because I'm interested in I've tracked this program for a number of years and concerned about the fact that the defense in depth the interpretation has sort of changed. I think the tenor seems to be changing, and that concerns me.

MR. CAMERON: Okay. Thanks, Dennis.

Rex?

MR. MASSEY: I'm Rex Massey with Lander and Churchill Counties.

I guess one of my principle concerns is pretty much how the TSPA, now we call LA, or the models are used to predict an outcome that is then shown to satisfy the new criteria.

MR. CAMERON: Okay. Thanks, Rex.

And let's go over to Mike.

MR. BAUGHMAN: Yes. My name is Mike Baughman. I'm here representing Lincoln County.

I guess my principle interests and interest of the county is it's kind of a question that we're interested in pursuing, and that is are we spending our limited resources in the right areas to achieve public health benefits, and I guess I'm really interested in the risk benefit, the kind of

cost equation, with defense in depth kinds of questions and certainly the regulations that are on the table.

MR. CAMERON: Okay. Thanks, Mike.

Janet?

MS. KOTRA: I'm Janet Kotra. I'm with the Division of Waste Management, also, and one of the principle authors of the proposed Part 63, and as we prepare to analyze the more than 100 comments, written comments, and many more other comments that we've received in our public meetings, defense in depth and the requirement for multiple barriers has been one of the more significant ones, and I am here today because I want to hear people's reaction to our current state of thinking on how we make meaningful our statutory obligation to provide for a system of multiple barriers in our regulations, and we welcome that opportunity.

MR. CAMERON: Mal?

MR. MURPHY: I'm Mal Murphy. I'm the Regulatory and Licensing Advisor to the Nye County Nuclear Waste Repository Project Office.

I don't have any particular concerns about the Commission's proposed defense in depth positions, so I guess the reason I'm here is that Nye County closely watches everything that DOE and the NRC do.

So, I'm here to listen and contribute what I can.

MR. CAMERON: Okay. Thanks, Mal.

Yes, sir.

MR. BAILEY: I'm Jack Bailey. I'm the Regulatory and Licensing Director for the M&O contractor to the DOE.

Like Mal, I'm not particularly concerned, if you will, about the rule, but I am interested in a discussion and where the rule will ultimately take us and where the discussion of defense in depth requirements will ultimately come down.

MR. CAMERON: Okay. Thank you.

Cynthia?

MS. SOCHOR: I'm Cynthia Sochor with the NRC. I don't have any comments.

MR. CAMERON: If you could just make sure that you put the microphone close to you and speak in its direction, then everybody will be able to hear.

Well, we have a lot of expertise and interest around the table, and what we're going to start off with I'm just going to go through this agenda that I think everybody, hopefully, has a copy of.

Keith McConnell is going to give us an overview on this particular issue, and that's more or less to set the context for you, and I know that we're all going to want to leap into the discussion after he's done with that, but I would ask you to just hold the discussion.

If there is some ambiguity or something that you want to ask to clarify something, we'll take some clarifying questions for Keith after he's done, but then we're going to move on to Christiana, who is going to give us our segue into the first discussion topic, which you see at 2:30, and that's what is the best way to achieve repository defense in depth, and I think that goes to the heart, at least, of some of the threshold issues that Steve and some others have been referring to, and any questions for Christiana, we can deal with in that roundtable discussion.

The second major category we have on the 2:30 segment is, if you assume that the performancebased approach that the NRC is calling its approach in Part 63 is going to be the approach ultimately selected in the final rule, then there's a discussion about what's the best way to try to implement that, and at 4:30, we're going to have a summary and next steps, what the schedule is, but keep in mind, I am going out to the audience for comment, although we're going to have to keep everything sort of concise so we can get through this.

Any questions on the agenda?

MR. MURPHY: Did you forget to put in a break?

MR. CAMERON: No, I didn't forget. There is no break, Murphy.

No, we can take a let's see how we feel when we

get down to a couple hours down the road or so, and then we will take a break. It's just a question of when we most need it, and that may come sooner for some people than others, but

Keith, are you ready to go?

MR. McCONNELL: Yes.

MR. CAMERON: Okay.

MR. McCONNELL: Okay.

On behalf of the NRC, I'd like to express our appreciation for everybody coming out this afternoon. We know that there have been a lot of meetings in the past, recent past, by us, the Department of Energy and the EPA and that there are more scheduled for the future and that these meetings can become quite resourceintensive for you all, also.

However, I think there are two reasons why we think this meeting this particular meeting is important.

First and foremost, I think that, as others have indicated during the public comment period for Part 63, there were a number of comments on this particular issue, defense in depth, made by the State of Nevada and others, and also in other venues, similar comments were made.

The most visible to us was when the Commission held a meeting on DOE's viability assessment, these issues about defense in depth, and how the staff was treating them

in Part 63 also came up.

The second reason we think it's important to have this meeting is, back in June, Bill Reamer, who's the Branch Chief for the HighLevel Waste Branch back at NRC, made a commitment that NRC wouldn't regulate from 3,000 miles away, that we would be out here talking about the various issues, and this meeting today is one of a number of attempts that we're going to have and make to fulfill that commitment that Bill made back in June.

What I'd like to do, as Chip mentioned, is to kind of give an overview or background on some information, and then Ms. Christiana Lui will talk about some of the specifics, and we're just laying this information out ont he table to stimulate the discussion.

So, with that, what I'm going to do is, first of all, talk about some definitions for terms.

In the discussions we have on this topic back at NRC, it's quite apparent that sometimes we're not all on the same page when we talk about various issue. So, we'd like to talk about definitions.

Second, we'll briefly mention the statutory requirement for multiple barriers. There is only one. We'll talk about what's in the old rule, and by "the old rule," I mean the generic regulation NRC has called 10 CFR, Part 60.

We'll talk about what's in our proposed rule, 10 CFR, Part 63, look at what are some of the commonalities between the two rules and what are some of the differences, and then, by way of introduction, we'll talk about some of the reasons why we changed our approach between the two rules.

First of all, definitions of terms.

Defense in depth is a key philosophical point at the NRC. It's part of its safety philosophy. It's applied to all facilities that we regulate, and therefore, it's going to be applied to a repository should that ever come to fruition.

Second, defense in depth includes multiple barriers and other elements of a repository system, including things like emergency planning, administrative controls, and things like that.

The area we're going to discuss today, in principle, is multiple barriers, not the whole concept of defense in depth but specifically multiple barriers.

Defense in depth is applicable to operations, during the operational period of a repository, should that occur, as well as after it's closed.

After closure, the key element of the defense in depth philosophy is multiple barriers, and again, that's what we're going to be focusing on today.

The statutory requirement again, there is only one. It's in the Nuclear Waste Policy Act of 1982, as amended, and it directs us to provide for a system for the use of a system of multiple barriers. That's specifically the only statutory guidance we have, and we think we have applied it in both Part 60 and Part 63; it's just how it's being implemented.

In the old rule, Part 60, there were two major objectives, basically an overall system performance objective, which was the EPA standard, and then a set of subsystem performance objectives for particular barriers, and there were three of those.

First, there was a 300 to 1,000year containment period in the waste packages. There were restrictions on the release rate for any radionuclide. It was one part in 100,000 per year of the inventory at 1,000 years. And then, finally, there was a ground water travel time subsystem performance objective, and it was termed the prewaste emplacement ground water travel time should be at least 1,000 years.

Now, all of these subsystem performance objectives could be changed either by the Commission or independently or by the Commission based on a request from DOE. So, there was flexibility in these requirements in Part 60.

What's in the proposed rule? Again, two overall

objectives first of all, the individual protection standard, which, right now, in the proposed Part 63, is 25 millirem. Should the EPA standard be finalized, we would conform whatever conform our regulation to whatever is int he final EPA standard.

There's also a second requirement or objective, and that's requirements for barriers, or multiple barriers, and within the existing Part 63, there are four specific requirements.

First of all, DOE has to identify any barrier they intend to use for their safety analysis. What are they going to rely on to demonstrate that the facility is safe?

Second, there has to be diversity in barriers. They have to have both engineered and natural; they can't have only engineered and they can't have only natural barriers. And there has to be at least one of each.

They have to define the capability, and define it in quantitative terms, of those individual barriers. They have to say what is providing that margin of safety that says public health and safety will be protected.

And then, finally, they have to provide the technical basis, what's the arguments that say what they're saying is correct and that health and safety will be protected?

Some of the common features to between Part 60

and Part 63.

First of all, in both of them, there is a goal to manage uncertainty. There was a recognition both in 60 and 63 that uncertainty would be present in the analysis, and so, we needed an additional assurance that the overall protection limit would be met, and so, in both cases, the way to manage that uncertainty was the implementation of multiple barriers.

There was also the assumption both Part 60 and Part 63 that, at some point, radionuclides would be released from the facility at safe levels.

Also, there was common between Part 60 and Part 63 was that there would be engineered and natural, that you couldn't rely on one, you had to have both, and that basically addresses the fourth issue or common feature.

Some of the differences quantitative subsystem performance goals. Part 60 has them, the proposed rule does not, and there are a number of reasons which we'll talk about in the next slide why we have changed that.

The effect of barrier interactions considered. In the old Part 60, basically you looked at one part of the barrier or one barrier and did an analysis, you didn't consider how those barriers might interact and how that might affect the outcome of the analysis and what impact that might have on public health and safety.

In Part 63, we've tried to address that, to look at barrier interactions.

And then, finally, the relationship to the overall system performance. In Part 60, one of the principle criticisms of the subsystem performance objectives was that there was no nexus or clear tie to the public health and safety goal, which is the individual protection requirement.

In the proposed rule, we think we've addressed that by tying the individual the multiple barrier analysis to the demonstration of the overall system performance, again making sure that we look at the interaction between barriers.

Now, the issue is why did we change our approach between early 1980 and, I guess, 1999, and there are a number of reasons.

One is that, over the last couple of years, we've had a number of recommendations made to the staff on how we should approach multiple barriers in our proposed rule.

Both the National Academy of Sciences panel as well as the Advisory Committee on Nuclear Waste recommended to us that we not include quantitative subsystem performance objectives in the proposed Part 63.

We also wanted to incorporate progress and methods in how we analyze uncertainty, how we do probabilistic risk assessments. All of that has progressed quite substantially

over the last 10 years, and we wanted to incorporate that thought process in the proposed Part 63.

Also, the Commission, over the last couple of years, has changed its approach to regulation, going to more performancebased approach to regulation, and we wanted to make sure that that was incorporated into our proposed Part 63, and then, finally, we wanted to provide for a comprehensive performance evaluation, one that considered the barrier interaction and one that focused our effort on those issues that are most important to safety, and again, we think that the quantitative subsystem performance objectives in Part 60 did not necessarily do that, and so, that's why perhaps we've changed our approach, one of the more principle reasons why we changed our approach.

So, with that, Chip, I'll turn it back over to you.

MR. CAMERON: Okay. Thanks a lot, Keith.

Does anybody have any questions, clarification on Keith's presentation, what the NRC was trying to do in this proposed rule?

[No response.]

MR. CAMERON: Okay.

We're going to do a short very short audience and these are questions, Sally.

MS. DEVLIN: Thank you, Keith.

I have a very serious question to ask you. You're talking about multiple barriers inside the repository, and you have no design for a repository. You have nothing, and you're talking multiple barriers. Now, why?

MR. McCONNELL: Well, it's DOE's responsibility to define the design, but what they have to do is demonstrate that that design does incorporate multiple barriers and that the requirements that we're trying to specify in our proposed Part 63 are met.

So, NRC doesn't have a design, because that's not our role. What we're trying to do is lay out what DOE has to do to define multiple barriers, if that's clear. It's a difference in role.

MR. CAMERON: Okay. Well, we're going to get more into this aspect a little later. We just want to make sure that everybody understands the multiple barrier concept at this point.

Grant?

MR. HUDLOW: Hi, Keith.

I got a letter from Keith and talked about the Nelson limits, and I have some more information I'll give you on that later.

The thing that I'm glad to see that the NRC is stepping up to the plate and looking into the details of these multiple barriers.

The DOE has demonstrated that they don't follow rules. So, if you put out a rule, it's not going to get followed.

That's a long history of DOE doing that, and so, it's incumbent upon you to check these details, and I'm kind of puzzled about how you expect to deal with the DOE where they don't bother to follow the rules. That throws, to me, a monkey wrench in the way you usually operate.

Usually, if somebody doesn't follow the rules, you shut them down and they scream because they're making a million dollars a day and you cost them that. If you shut the DOE down, their paycheck continues anyway and they don't care.

How are you going to shift and their M&Os are the same way. How are you going to shift so you can be more involved in the process to make sure the details are taken care of?

MR. CAMERON: Okay. That's perhaps an issue for wrapup, okay, and for Yucca Mountain review plan, at this point, and I would just ask everybody the real intent right now is, if you don't understand something, ask a question, but let's hold our comments at this point so we can get into the discussion.

If you could just state your name and affiliation for the transcript.

MR. CRAIG: I'm Paul Craig of the Nuclear Waste Technical Review Board, and I'd like some clarification on the first item on your list, namely the shift from quantitative subsystem goals to nonquantitative subsystem goals.

How does one go about thinking about barriers if you don't apply numbers?

MR. McCONNELL: It's not that we're not requiring a quantitative analysis. What we're not doing is putting goals into the regulation that could, in essence, end up suboptimalizing the repository system.

In other words, by specifying particular goals for particular barriers, because we're looking at a system rather than individual barriers, we don't want to arbitrarily define goals for those individual elements and potentially, you know, take the flexibility out of DOE hand to design for something they need to design for to protect public health and safety.

MR. CRAIG: Well, does that mean that, after you talk about a goal and look at the overall optimization, you will then talk about what numbers do apply to that particular barrier?

MR. McCONNELL: Yes. The answer and I think Christiana will talk about the specifics is that we will require a quantitative analysis, and we will also provide

acceptance criteria in our review plan as to what we find to be an acceptable quantitative analysis to demonstrate multiple barriers has been implemented, and I guess I'd defer to Ms. Lui to respond.

MR. CAMERON: Okay. I think this probably would be a good point to go to Christiana Lui for her presentation, and then we'll get into the first discussion area up here at the table.

Christiana?

MS. LUI: Thank you, Chip.

My name is Christiana Lui, and good afternoon. Thank you for coming to the roundtable discussion, and we will be very happy to hear your comments, and we will try to address them, if not today then during the process of finalizing the proposed Part 63.

First I would like to basically just summarize what we have heard from the public.

As Janet Kotra has stated previously we received approximately 100 sets of comments from the public, written comments from the public during the Part 63 public comment period, and we also have her comments during the public meetings that we held out in Nevada.

Roughly 20 sets of comments were addressing the topic of defense in depth or multiple barriers. These 20 sets of comments can roughly be categorized into three

different types.

The first type is use the approach in the old rule, the second type would be we like what you're doing in the proposed Part 63, and the third type of comments is the approach in the proposed Part 63 sounds reasonable, however we need more clarification.

Dr. McConnell has basically, in his presentation, summarized the differences between the old rule and what's in the proposed rule. What I'm going to talk about today I will be focusing on the third group of comments.

Following Dr. McConnell's presentation, just to clarify what is the intent of the multiple barriers requirement, as Dr. McConnell has stated, it is part of the NRC safety philosophy to require defense in depth, and the true intent of the multiple barriers is really how we can compensate imperfect knowledge. So, it is a way to manage uncertainty.

What we require DOE to do is a safety assessment or a compliance demonstration to include all the known uncertainties, but what we do with the unknowns is going to be dependent on what lines of evidence DOE can provide, and we're going to require DOE to do some whatif calculations. I'm going to elaborate on this a little bit more during the latter part of my presentation.

What is required of DOE to demonstrate multiple

barriers?

In the proposed rule, at this point, we require DOE to assess all the significant negative impact on safety in a socalled performance assessment, or a more easytounderstand term would be a compliance demonstration, to demonstrate the repository can actually meet the individual protection requirement, and in that particular compliance demonstration calculation, we want DOE to identify all the positive aspects or all the credits that DOE are taking in assessing repository safety, and next, we will ask DOE or DOE is required to describe the capabilities of all these barriers in a quantitative manner.

What we want to do, which may not be as clear in the current proposed rule, is we will require we are thinking about requiring DOE to perform an additional calculation to show that safety does not depend on any single barrier.

For example, even though, in a safety assessment, DOE showed that, within a compliance period, most of the performance comes from waste package or the engineered barrier, we want DOE to perform an additional calculation to show what if that particular engineered barrier does not perform as expected.

The rest of the system will still have enough capacity to compensate for that particular barrier of the

performance or to show that the natural system, indeed, contribute to a repository safety.

And lastly, whatever assertion DOE is going to make, they will have to provide sufficient technical basis to support that assertion.

Now, we're switching gears to what particular approach can DOE use to demonstrate multiple barriers?

In the proposed rule, currently, the definition of barrier is a element in the repository system that could prevent or substantially delay the delay water or radioactive material movement.

We are contemplating adding to that particular definition to otherwise enhance safety.

So, it's not just focusing on water or radionuclide or radioactive material; it's really the overall repository safety that we are after here.

As I stated before, we are contemplating requiring DOE to perform a separate analysis to quantify the reserve capacity of the barriers by assuming underperformance.

Underperformance here is really in comparison to the amount of credit that DOE is taking in the compliance demonstration, and we want DOE to perform whatif analysis, and one barrier at a time, and the degree of underperformance should really be commensurate with the evidence that DOE has to support a particular barrier's

capability in its safety assessment.

So, if DOE has a lot of evidence to support the claimed capability of a barrier, its safety assessment, the amount of underperformance is not going to be a great degree, but if DOE does not have as much evidence to support the capability it's claiming in safety assessment, then the amount of underperformance will certainly need to be greater.

In general, what is the NRC's review?

NRC will look at all the technical work that has been conducted by DOE.

We will basically be tearing DOE's safety case apart and analyze piece by piece and determine whether all these different pieces are acceptable, and in addition to that, NRC will be performing independent confirmatory of the calculations to see if we can actually agree with DOE's conclusion, DOE's approach, and assessing DOE's demonstration of compliance.

In particular, what is in NRC's evaluation of DOE's multiple barriers?

Multiple barriers, as in one of the earlier slides, is really an assurance requirement. So, we will start from the point of DOE's safety assessment.

We will look at the data that has been collected by DOE and whether DOE has followed and implemented an

acceptable QA procedure, and we will look at the conceptual models, the assumptions that has gone into the safety assessment.

We will also look at the mathematical models that DOE has put together to do the computation.

We will look at how the data, the models all link together, so all the interactions between the various subsystems are appropriately quantified in DOE's safety assessment.

And lastly, until we have confidence that all the different pieces that has gone into the safety assessment is acceptable, is transparent, then we can make a determination of DOE's conclusions and results.

To continue, first and foremost, the repository will have to meet all the applicable regulations, and for multiple barriers, in particular, DOE will have to show that both the engineered barriers and natural barriers contribute to safety.

So, we have diversity of the barriers, and the safety of the repository does not come from just one particular barrier, and we will also look at DOE's additional calculation to make sure that the repository has enough capacity to compensate for imperfect knowledge as a way to manage uncertainty, in case a particular barrier underperforms, the repository will still be safe.

In summary, what we attempt to do here today is to clarify the intent of the multiple barriers and to basically present to you the current thinking of NRC the current NRC thinking, how DOE can demonstrate multiple barriers, and most importantly, because multiple barrier is an assurance requirement, if DOE does not demonstrate multiple barriers in NRC's evaluation, if DOE does sufficiently demonstrate multiple barriers, DOE will not get a license to the repository.

Thank you.

MR. CAMERON: Thank you very much, Christiana.

I think you can see that the two presentations that we heard pretty well match up with the two main discussion areas, the first one being what approach should be used to multiple barriers by the NRC, and Keith gave us a number of assumptions and rationale on which that approach is based, and that's going to be our first discussion topic, and I think that the NRC would be particularly interested in your perspectives or comments on the assumptions that that new performancebased approach is based on, and the second major discussion area was mainly focused on by Christiana, which is implementation issues, and there probably will be a lot of concerns there.

It will be interesting to see if there are some connections between some of the concerns on approach,

whether those concerns might be mitigated by the approach that NRC takes to implementation, but both of them are wide open for comment.

We're going to begin with the approach, and let's take our time with that, an hour, and then we'll take a break after we go out to the audience, finally, for discussion of that, but who would like to start us off on the threshold issue of approach?

Steve, I was going to sort of put you on the spot, if you're ready.

MR. FRISHMAN: Yeah, I am, and I think maybe it's useful to get an alternative on the table, and I guess I've been getting more and more practice lately in trying to clarify what my problem is with the approach that the not only the NRC is taking but also, quite clearly, the one that the department is taking by the way it talks about defense in depth and tries to apply it in its program, and a couple of things maybe need to be presented so we can get everything in context first and then I can tell you exactly where my problem is.

It's probably best if I use a couple of viewgraphs.

I had a long discussion with Janet the other day, and I figured out that, if I can put something in front of your face, maybe you can understand it, and also, if you can

look at a picture, maybe it better describes where my problem is than if I try to describe it myself.

MS. KOTRA: I'm glad you think we're teachable.

MR. FRISHMAN: Well, I'm not sure you are.

First you heard that from Keith that there's a statutory basis for defense in depth, and that statutory basis is in the 1982 Waste Policy Act.

That term wasn't invented by Congress. It was a term that NRC has been using in the past, and it's also a term that was introduced into highlevel waste disposal concepts in the one document that we have that is the basis for the policy established in the waste policy act in 1982.

That one document is one that has been forgotten by many people in this program, that final environmental impact statement in 1980, and the 1982 act used this as the basis for making the policy decision that, in this country, we will attempt to use the concepts of geologic disposal to deal our highlevel waste and spent fuel.

It's the only document that is out there that was intended to be a basis for a policy, and Congress took that up.

So, when they said defense in depth in the Nuclear Waste Policy Act, we only have one place to go to find out what defense in depth means relative to highlevel waste disposal in a geologic repository, and here's where we go.

This is page 51 out of that, and I think you need to read section 51 and you'll see the beginnings of what I'm getting at. I'm not sure you can read it. I'll read it to you. It's probably not that difficult.

"Geologic disposal of radioactive waste, as used in this statement, is the disposal of radioactive waste in a conventionally mined repository deep within geologic formations of the earth. Included is the concept of multiple barriers to provide a series of independent barriers to the release of radionuclides to the biosphere. The multiple barriers that could contain nuclear waste in deep mined repositories fall into two categories: geologic or natural barriers and engineered barriers. Geologic barriers are expected to provide isolation of the waste for at least 10,000 years after the waste is emplaced in the repository and probably will provide isolation for millennia thereafter. Engineered barriers are those designed to assure total containment of the waste within the disposal package during an initial period during which most of the intermediate live fission products decay. This time period might be as long as 1,000 years, in which case the radiation levels and heat generation rates of the total waste will drop by factors of approximately 1,000 and 100 respectively."

This is the basis for multiple barriers, and if

somebody knows of some other basis other than in statements of consideration that all sort of fall below this level of basis for policy, I'd like to know where that is.

So, what we're looking at is the sort of some of the underpinnings of what the NRC has done, and that's defense in depth in all other approaches that the NRC uses it, speech in terms of independence and redundancy. I noticed in the discussion of the proposed rule, it sort of says, well, for geologic repositories, that independence and redundancy really is kind of a mushy thing, it's hard to get at.

It might be in the sense of the interaction between barriers, but it's also difficult for me to see that the interaction of barriers, in very many cases, if I can even think of any, would, in fact, enhance safety.

It looks to me like everything that is being done in terms of trying to analyze barriers, when you look at the interactions, it's to keep performance from going down rather than trying to enhance that or trying to find something that will enhance the performance.

We keep looking at things like, well, what's the effect of cement? Well, cement is a real problem. It's a detractor. What's the effect of part of the natural barrier, which is the water on the metal? It's a detractor.

I have a hard time finding places where the

interaction between barriers enhances performance. Maybe you can tell me of some that I haven't thought of, and I'd like to know if there are so that I can figure out whether it's really an enhancement or not.

Now, having put this together as a basis for defense in depth and multiple barriers, I think what we ultimately are going to have to do, or what you will have to do in this rule, is not only write your four things in section 114 that the department has to do, somebody's got to decide how much each barrier contributes and when.

It's not good enough just to say write down everything you know, what you think it will do, how you think it will do it, prove to me that you have a basis for what you say it will do.

Somebody's got to make the decision somewhere of what is appropriate behavior to be relied upon for each one of these barriers and when.

Here, in the EIS, it's pretty clear what the policy is based on. They tell you what the different barriers are expected to do and when, and if you go even deeper into the system, you can find and I hate to bring this up, because all it will do is nudge the DOE system along a little bit more.

In DOE's guidelines, they talk about the intent of including engineered barriers was not to compensate for an

inadequate site; rather, engineered barriers are intended to enhance the natural system's containment and isolation capacities to the extent that is practicable.

This approach is consistent with multiple barrier approach endorsed by EPA and NRC. DOE agrees, however, that engineered barriers are secondary to the natural system with respect to longterm isolation.

Consequently, the postclosure guidelines are premised explicitly on a recognition of the primacy of natural barriers.

So, we sort of established that, and until information about Yucca Mountain came along, everybody was happy with it. People thought they understood what defense in depth meant.

People thought they after some what I think were pretty entangled discussions years ago about what substantially complete containment meant and Joe Bunting, most of us remember, was in charge of trying to figure out what that meant, but on the side, he was always says it's real simple.

What substantially complete containment means is nothing gets out for 1,000 years, and the big question is how do you prove that?

But there were many arguments about what substantially complete containment really means.

Now, the problem that I have in specific is in the definition of barrier, and I know that definition's been around for a long time, but it never seemed to have the importance that it does now, and that's that a barrier is to prevent or delay, and it's delay that I have the problem with.

If you look at the subsystem performance requirements, you have the aside from the ground water travel time, you have substantially complete containment, and what that means is that you need to demonstrate and if the engineered barrier, as to this EIS, is the way you do it, you do that.

Now, the other one, having to do with the rate of release, rate of release to be no more than one 100,000th of the inventory at 1,000 per year delay has crept in and intended to sort of be in place of that, but stop and think about it.

The subsystem performance assessment set a limitation on the rate. Delay is a time function, it's not a rate function.

So, the best way to illustrate this, using an illustration from a presentation the department made to the Nuclear Waste Technical Review Board last January and I don't want to get in an argument about whether the numbers are right, but I want you to look at whether the argument

makes any sense.

This is an illustration of one of the things that, Keith, you say they're going to have to do in their safety analysis. They're going to have to do what they refer to as the oneoff exercises.

Well, this is a oneoff exercise where the waste package was neutralized.

Now, you can take the waste package away, and you can see that it has a very large effect, but that's not what I'm looking at right now.

What I'm looking at is, with or without the waste package, the peak dose is essentially the same.

With the waste package, according to DOE's performance assessment, the peak dose is right about here and forget about the superpluvial spikes or whatever. It's just about here, and that's out there at, oh, a couple to three hundred thousand years.

If you don't have the waste package, the peak dose is just about the same, but it happens within a thousand or two years.

So, what we have here, if we're using the waste package as the engineered barrier, all it's doing is delaying when the peak dose occurs from here to here. It's not saying anything about the system itself isolating waste.

All it's saying is that you have a system that

relies heavily on the container to tell you when that peak dose is going to arrive, not that the peak dose is ultimately the level of the peak dose is ultimately affected.

Now, conventionally, people like to draw this line at 10,000 years, so you never see this problem, and this is part of my argument about why 10,000 years is wrong, as well, because what it does is it masks the what I believe is the wrong definition of multiple barriers and defense in depth.

Ten thousand years allows you to get away with looking at nothing other than the fact that you can put together a metal container that you think can contain the waste for 10,000 years, and it's obvious from this somebody else thinks so, too.

We'll use another one of those, much maligned.

This is another one that came out and sort of work people up that same day. All it is is a bargraph illustration of part of what we just saw.

Now, what this does is it moves on, and it says it was delayed, but it's still the most important barrier, and in this case, it's most important to the extent of being potentially over 99 percent of the barrier.

I know some people's calculations may disagree with this, but it's still way big compared to anything else.

So, this comes back full circle to where I started, and that's you can tell them what they have to show you in those safety analyses, make them tell how they know it, how they arrived at that, what method they used to apply it.

Somebody's got to tell them whether this is acceptable or not, the importance of each barrier and what time, because if we're really talking about, as Christiana said, you're thinking of adding enhancing safety to the definition of barrier, you haven't with the kind of approach that you're allowing, without saying putting some kind of requirement on what is the relative importance of barriers at what time, you're not enhancing safety if you're allowing delay as part of it.

The ultimate result, the ultimate safety is the same. You get a real high dose. It's just when you get it, and it's no more or less safe in 10,000 years or 200,000 based on the uncertainties in the calculation anyway.

I'm not worried about talking 200,000 years, because it's sort of an impossible thing to think out that far.

It's also sort of impossible to think that the kinds of curves we're looking at right here, that this enormous difference is all on the extrapolation of some experiments on metal over a short period of time.

This line is representative of a belief, and it could be close to right, it could be way wrong, and we'll never know.

If you're talking about safety, that's just as unsafe as that, and that's my argument.

MR. CAMERON: Thanks, Steve.

You covered a lot of ground there, and when you were sitting down, you suggested that you might have an alternative on this, and before we go to the rest of the roundtable for comment on what you said, do you have a specific alternative that you think the NRC should consider that we should discuss at some point?

MR. FRISHMAN: Yes.

I don't have it's just like DOE's repository plan, it's conceptual, but what I did find out in talking with Janet recently and other people is that there are certain words that elicit kneejerk reactions and make people stop thinking, like subsystem performance requirements and substantially complete containment, but I think if we can talk about the concepts and you notice that I talked about somebody has to decide what level of or what relative importance of barriers needs to be applied, and you notice I said "and when," and this comes dangerously close to a subsystem performance requirement, but I still think, if we can think about it in other terms, there might be a way of

getting at this question of what is the required relative range of relative performance of engineered versus natural barriers through time, and if you look at that EIS, you understand what the real function of engineered barriers was intended to be originally, and that was to protect from the effect of released fission products. The site is supposed to do the rest.

If we want to change this whole approach, then I think it's going to take more than an NRC rulemaking, and I think that position may prevail at some time if the NRC tries to independently change the meaning of defense in depth, as required in the Waste Policy Act.

MR. CAMERON: Okay.

So, just to clarify this this is sort of the basis of someone needs to decide how much does each barrier contribute and when, in other words to think about it in those terms. That's the conceptual alternative that we can discuss at some point.

MR. FRISHMAN: Somebody has to decide what it has to do.

MS. KOTRA: Not what it does but what it's required to do.

MR. FRISHMAN: At the risk of sounding really foolish, I'd love to have the EPA do it.

MR. CAMERON: Okay. We'll come back to this, and

we would love to have EPA here, too, I guess.

MS. KOTRA: We would.

MR. CAMERON: Okay. We'll come back to this, but let's go to discussion.

I see there are some tents up, and I'd be particularly interested Steve put an excerpt from the 1980 environmental impact statement up, and I'd be curious as to whether people around the table think that that excerpt is in immutable conflict with the approach that's being taken in Part 63, and if there is a conflict, does that 1980 document, as I think Steve suggests, provide some sort of a constitutional, if you would, foundation that can't be changed in future regulatory documents.

So, I think that it might be useful to explore that.

Janet?

MS. KOTRA: Before we get to that, can I ask Steve some clarifying questions about what he's put out, which I found quite helpful.

I want to assure you that those of us who have been writing this rule have been thinking very hard for quite some time about all of these concepts, and there's no words that are verboten, but I do appreciate the time and effort you took pursuant to our discussion a couple of weeks ago to sharpen up, you know, your I understand a lot better

based on what you said this afternoon.

One thing that I wanted to ask you about, though, is that, when the old Part 60 requirements were issued, the NRC got a great deal of criticism, because they were interpreted, particularly with regard to substantially complete containment, as providing a disincentive for the applicant to design the best container they could.

We went to some lengths, as you may recall, as a student of this program longer than I, to say no, that's not what we meant, but I guess the question I would put to you is why would we as regulators not want the department to design the best container it could?

I mean what you're suggesting here, you know, could be interpreted as doing exactly that, and that's what we were trying to get away from in terms of these arbitrary ultimately arbitrary limits that don't have a direct tie to health and safety.

So, I would just ask you that.

MR. FRISHMAN: Well, I'm not saying that there shouldn't be the best container possible. What I'm saying is that belief in the performance of the container goes down through time and you can say that you have built the best container, but then, if you follow this sort of prescription of this EIS, that after about 1,000 years, you have to be able to rely on the geology.

If you've built the best container, then you do have defense in depth, because if you misfigure the geology somewhat, the engineering will cover it.

If the container is really as good as you say or is not as good as you say, then the geology will take care of it.

It's like a fairly simple thing that seems so obvious I shouldn't even have to say it, and that's that, if you go to that subsystem performance requirement for substantially complete containment, let's say what do we think defense in depth is within that.

What defense in depth says, within that, to me, is that you rely on the metal container for essentially no releases to the accessible environment in 1,000 years, but if you're wrong, the site will take care of it; there still will not be releases in 1,000 years.

So, let's apply it a little bit farther out.

You build a container that, if you're right about, yes, we've got really good defense in depth. If you're wrong about it, the geology will still take care of it, and none of us will know the answer, and by the time you could know the answer, nobody will want to know the answer anyway, probably, but it's the concept that I'm looking for, and a good container is great. A good container leads you to defense in depth.

MS. KOTRA: Well, I think you've raised some embedded issues here, and I want to just put those on the table for others to discuss, that a delayed dose is no more safe than a prompt dose. I disagree with that personally.

I believe for the people who live for the next 20,000 or 200,000 years, that delayed dose definitely is meaningful, but I think that's something we might need to discuss here, and the value of that.

The other thing I would point out is that the statutory basis is for a multiple barrier requirement. It does not speak to defense in depth, and I think that Keith went to great lengths, I think, in his presentation to make clear that defense in depth is an overall NRC philosophy.

The law requires us to provide for the use of a system of multiple barriers, and that's what we're trying to discuss, and I want to keep that concept straight in people's mind, that multiple barriers is just one aspect of an overall philosophy that includes a lot of other things.

MR. FRISHMAN: That's why I didn't wander around in that EIS to see what they say about defense in depth, because they're not very clear about it. That's why I went directly to multiple barriers.

MS. KOTRA: So, you're saying we've learned something since the 1988 EIS that I've reviewed thanks to your discussion.

MR. FRISHMAN: I think it's been a decline on the learning curve, and I think the data from Yucca Mountain is the reason for it.

Yucca Mountain, as a site, doesn't perform at a level that would be acceptable under any standard, and it's the engineered barrier that's being relied upon, and what I'm saying is that, as regulators, you should not be writing a regulation that doesn't set a hurdle someplace that adheres to the concept of multiple barriers, as is the basis in the law that told you to write the rule.

MS. KOTRA: Okay. I think I understand.

MR. CAMERON: Okay. And we'll come back to that concept of must set a hurdle.

Mal?

MR. MURPHY: Thanks, Chip.

Let me just explain I indicated earlier that I don't have any particular concerns about defense in depth, and I should probably explain that for the benefit of those at the table and everybody else in the room, because Steve makes some excellent points.

He's made them before, and he's going to make them again in this program, I'm sure, and every one of those points that the department and the NRC are going to have to address in licensing.

My approach is that I don't see, based on my

understanding of what 10 CFR 60 provides and requires, I don't see any significant difference in terms of system performance requirements, subsystem performance requirements, defense in depth, multiple barriers, however you want to express it I don't see any significant difference between Part 63 and Part 60 with respect to how the regulation will influence the ultimate result, and that is, you know, here's your ticket, go and construct a repository.

I don't think Part 63 is going to have a significantly relaxed effect in that respect, and let me try to briefly explain why.

As Keith pointed out, in Part 60, the current generic regulation, which Congress has said must be changed to so that it becomes Yucca Mountain sitespecific, in conformance or consistent with the EPA standards when they're finally promulgated, but Part 60 has an overall system performance requirement, which is the EPA standard, as Keith pointed out.

It then has three large, you know, big subsystem performance requirements. Keith pointed them out on his viewgraph, as well, each one of which is changeable by the Commission.

In other words, we've talked for years in this program and my thinking here is not you know, 10 CFR 63

didn't focus this thinking, for example. I have expressed exactly these same thoughts in a paper delivered to a highlevel waste conference here in Las Vegas several years and in a presentation to the TRB several years ago, but we've focused for years in this program on the socalled 1,000year ground water travel time standard.

Well, there is no 1,000year ground water travel time standard. The standard in Part 60 is the prewaste emplacement ground water travel time shall not exceed 1,000 years from the repository to the accessible environment unless the Commission says it can be a different number.

The release rate has to be one part in 100,000 of the inventory at 1,000 years unless the Commission establishes a different number.

Well, the reason, in my view, my personal view, the reason the Commission would establish a different number than the 1,000year ground water travel time is if the Department of Energy demonstrates with a large margin of safety if DOE demonstrates compliance with the overall system performance requirement, with the EPA standards.

In other words, it is inconceivable to me, and has been for 15 years, that the NRC would deny a construction authorization if the department could clearly demonstrate that they would meet the EPA standards just because one or more of the subsystem performance requirements were not met.

Therefore, what licensing would be all about and what site characterization has been all about and what the whole prelicensing interaction between DOE and the NRC and the State of Nevada and Nye County and Lincoln County and everybody else has been all about is can DOE meet a total system performance requirement? What is their TSPA going to show?

We've been screaming for years, can we finally see numbers from DOE? What is your TSPA going to show?

Consequently and let me throw out another qualifier Nye County does not have an unlimited amount of money to oversee this program. We will not have an unlimited amount of money to litigate issues in an NRC licensing proceeding.

We, like everybody else in this program, have got to focus on the highpriority issues which we feel most directly affect the health and safety of the people of Nye County.

So, consequently, because, in my view, the main and, indeed, really the exclusive driver in licensing will be and always has been compliance with the overall system performance requirement, I would prefer that we not waste our time worrying about subsystem performance requirements in and of themselves and look at them, as Keith pointed out and Christiana pointed out, how they you know, the

synergistic effect, if you will, of those various barriers or subsystem performance elements and how they interact with each other and either detract from or add to the ability of the site to isolate waste.

Additionally, what Janet has pointed out has always been a very strong factor in my mind.

Because we know that the site is not perfect and it's becoming less perfect over time, as we can see, but we've known for years that the site is not perfect.

It's always been my philosophy that we don't want the regulations to do anything whatsoever, even remotely to do anything which would give the department the slightest motivation not to design the strongest, most robust system of engineered barriers that they possibly could.

So, for that reason, I don't you know, as I say, I don't have any concern about defense in depth. I think the multiple barrier requirements are still there. They were there in Part 60.

I don't see them changing significantly at all in Part 63, so they don't concern me, but I need to add this strong qualification.

The problems in the general approach about how you know, is the site good or bad, how much reliance are we going to place on the site, is the geology going to provide any benefit to the public whatsoever out here at Yucca

Mountain those are all very legitimate concerns, and the department is still going to have a very strong burden to demonstrate in licensing that there is some reliance, not just some but a significant reliance at Yucca Mountain on the natural geologic barriers, and whether or not they're going to be able to meet that burden is an open question, but I just don't see that Part 63, if adopted, is going to change that significantly.

MR. CAMERON: Mal, it seems what you're saying is that, based on the examples you gave from the Commission's discretion, is that the end result might end up the same, but you're also saying that the proposed approach may have some benefits to it of the type of thing that Mike Baughman suggested, and I know he's going to he has his card up, he's going to talk.

There might be some benefits in terms of where resources, where the effort is focused.

MR. MURPHY: Right, exactly.

The other thing I should point out is that we for those of us who have been in this program a long time, without making it explicit or saying as much in so many words, the kind of approach that Keith and Christiana have put up on the board about how the NRC staff is going to analyze whether or not DOE is complying with its requirements has I mean the staff, in all of its

interactions, in its various iterations of a review plan and all of the things that they've been working on with DOE and with all of the rest of us over the last 10 years or so has been moving in that direction.

So, it seems to me that, since the staff was going to analyze DOE's license application, its total system performance assessment and its demonstration of compliance with subsystem requirements in this way, the way that we were just shown on the viewgraphs, why not put it in the rule?

Why not make it explicit so that everybody, up front, you know, knows what the rather than waiting for a revision, you know, 14 of the NRC's license application review plan, so that we all know right up front that this is going to be sort of an interactive you know, they're going to look at barriers and how they interact with each other, etcetera.

Basically, we've got a limited number of resources. We're not going to have anymore money to conduct I'm going to feel fortunate if my poor client, Nye County, has as much money to participate in the licensing proceed two, three, four years from now as they have today.

We can't afford to look at every single conceivable, you know, issue that's involved in this process.

So, hopefully, others and everybody together will look at all the important issues, but we want to focus on the key drivers for safety, what are the key issues that directly affect the potential health and safety of the people in southern Nye County, and I've always thought that that was total system performance requirements because that's the decision that is the demonstration that would drive the NRC's ultimate decision with respect to whether or not to grant a construction authorization.

MR. CAMERON: Okay. Thank you.

We're going to go to Judy and then to Rex and Mike and come over to Rick.

But Steve, I would ask you to be thinking about the question of how does your alternative differ from the at least two alternatives that Keith put on the table for us, which very basically were we have the subsystem, quantitative subsystem approaches in the existing rule we probably shouldn't call it the old rule yet in the existing rule, and then we have the approach that's in the proposed rule.

So, at some point, I'd like to come back to you to get a clarification about how your alternative differs from either of those two approaches.

Judy?

MS. TREICKEL: It's my view that, if you have

limited resources, what you certainly would want would be a checklist, much like the old subsystems performance, and possibly even more, like DOE's current guidelines, like these performance requirements, where you check it out. It either does that or it doesn't do that, and if you look in things like and there's many sources for this, but I was going over it last night the technical basis report, most countries have that, and there isn't an existing repository in the world.

Nobody can look around at a whole bunch of other repositories that are out there working and say, well, that one does this, that one does that. This is a firsttime thing, and we're going to have to be awfully sure, because I, for one, will never accept the idea that you can undo it.

I know people are trying about retrievability, and I will never go for that.

But you have to have if you ever hope to have the first inkling of public confidence, you have got to have checkoff points where you can say we set up these rules and it meets these rules, and that's been the basis for the screaming that has gone on in Nevada and is being picked by people across the country on the fact that this mountain seems to be setting its own rules, and those rules all should been in there, but I think you're going to have to we, for years, have asked the department, okay, what would

you find out there?

If you're studying this site, what's the thing you would find out there that would make you say, okay, Mr. Secretary, you're going to have to go back to Congress, this thing's a dog, we found the showstopper, and nobody can tell us that.

Well, I would like to see those quantitative subsystem performance requirements that you can say, okay, if it didn't if you can't show that it does this, it's out of there.

MR. CAMERON: Judy, let me ask you

MR. MURPHY: Let me just follow up a bit.

I agree with you, Judy, but my point is that we don't have them in Part 60, so that there's not that big a difference between Part 63 and the NRC's approach I mean that big a difference between Part 60 and the NRC's approach under Part 60.

MS. TREICKEL: Well, you said the Commission could change it.

MR. MURPHY: Right. There's always been flexibility in the subsystem performance requirements.

MS. TREICKEL: I don't like flexibility, and if they were to change them, you would have the same battle you'd have right today.

MR. MURPHY: Sure. Perhaps what we ought to be

talking about is not Part 63 but another part where we not only go back to Part 60 but to go back to Part 60 without the flexibility.

MS. TREICKEL: Fine.

MR. MURPHY: That's what you want.

MS. TREICKEL: Perfect. Yes.

MR. MURPHY: My only point is that the more perfect or the better regulatory scenario that you think is necessary to give the public confidence, we haven't had anyway. It didn't exist in 1983, '82.

So, what the NRC is proposing to adopt here isn't that big a difference.

MR. CAMERON: Let me ask for clarification on that and I think that perhaps we can assume that, even though the Commission had discretion under the current rule to change those subsystem requirements, that certainly the way the existing rule reads now, in comparison to the proposed rule, is that there's more of an initial burden on DOE to demonstrate something, and I guess that, at some point, I'd like to get some impressions of Judy's statement that the quantitative subsystem goals promote public confidence, and I guess the question for Judy is are you in saying that, in saying that there should be quantitative subsystem goals, are you also saying that those subsystem goals should be the ones that are currently in Part 60 or should they be a

different or, in fact, have to be a different set of subsystem goals because of the overall health standard that might be in Part 63?

MS. TREICKEL: I want the toughest ones you're going to get, and the only way we seem to be moving at this point is toward weaker, so I'll go with what's there right now.

MR. CAMERON: Okay. And we'll come back to revisit this issue, but let's go to Rex.

MR. MASSEY: My concerns just lie, again, with total systems performance assessment. I just wanted to touch on one thing that Mal had talked about.

At the end of this process, we're going to have in place a system that tells us, yes, the repository meets the standard or no, it doesn't meet the standard, and I find it, at this point, hard to buy into any model of any type or any predictive capability that is going to be that accurate, to come out and say that it's going to be 10 millirems, we're going to meet the standard, aren't having problems, and I think what I'd like to see NRC do is go back and I know you guys touched on it, on the underperformance, but look at each barrier and look at what the potential for the underperformance is in each barrier and how, when you add up the underperformance, how it ultimately affects the total systems performance and what the implications are, because

there's got to be at the end of the this TSPA, there's really got to be a range of what can happen, and it doesn't strike me that anybody can hit right on the head and predict, 1,000 years out, 10,000 years out, 100,000 years out, what exactly is going to happen with models.

So, I think we've got to take a real close look at what the underperformance is, perhaps what the uncertainties are with each barrier system, and factor that into how much of an effect on performance that we can have.

And then the last thing that I wanted to say is I just kind of wanted to bring up a concern I have about you know, we're setting up this new standard where these folks in Amargosa Valley become the thing we measure, in a sense, the performance by. I know this is pretty simplistic.

Then we've created a barrier of distance, a natural distance between the repository and Amargosa Valley that I'm not really sure will exist in 1,000 years, and I think that NRC ought to take that barrier into consideration, whether or not we have to rely on someone sitting in Amargosa Valley to be affected, or is it someone that's closer than Amargosa Valley to be affected.

So, it really brings into question whether that distance from the repository to Amargosa Valley should be considered as a barrier, a natural barrier.

MR. MURPHY: I don't think that distance will

exist in 50 years, much less 1,000.

MR. CAMERON: Okay.

Let me just jump over to Keith, not to ask him what he has to say because his card is up.

But Keith, you heard Rex's suggestion not on the 20 kilometer or whatever it is, but is that pretty how does what he suggested about what should be done match up with your conception of what's in the proposed rule as the approach?

MR. McCONNELL: Well, what I heard him say was that we should look at or ask DOE to look at each barrier, add up the underperformance, and then see the effect on the total system, and I think that we may not have articulated it effectively, but that, in essence, is what we're asking them to do, is to do that analysis, put it out on the table so everyone in the affiliations here have the opportunity to look at it, review it, comment on it, give comment to the Commission, the five Commissioners who will actually rule on this, and that way, everybody has an equal or almost equal part in what's going on, and it facilitates your review, in essence.

DOE has to provide all this information, lay it on the table, and you don't have to spend all the time digging into the analysis.

So, I think the bottom line on that particular

issue is that we're trying to address it.

MR. CAMERON: Okay.

Janet, did you want to add anything quickly to that?

MS. KOTRA: Along the same lines, you had made a statement Rex made a statement that all that was going to be produced would be, yes, it meets the standard, everything's going to be fine, and I think if you look closely in the proposal, we have laid out a great deal of requirements for what that analysis showing that compliance must do in order to meet our requirements, and those include the things that Keith mentioned.

There's not just one model. There are many, many models, and the models that DOE relies on, and the technical data that go into those models all of that has to be part and parcel of a competent and transparent performance assessment, and those requirements are spelled out in Part 63 in far more detail than they were ever addressed in the old Part 60.

The burden is on us, I think, to explain better that we're not just looking for, yeah, thumbs up, thumbs down, you know, yeah, it will meet it, no, it won't. I think there's a great deal more involved in the demonstration that is expected of DOE under Part 63.

MR. CAMERON: And we'll get more into that in our

second discussion area.

Let's go to Mike and over to Rick and then we'll come over to Keith and Steve.

Mike?

MR. BAUGHMAN: Just a couple of observations.

I guess one would be I think the information Steve presented was really quite fascinating. I would hope, though, that we would not feel constrained by a knowledge base that's 20 years old, and certainly, if there is reason to think we can do things differently now that will result in enhanced protection to public health and safety, we ought to certain pursue that.

I did note, with the graph you had up there, and the two peak dose periods, where his argument that basically we are delaying or the engineered barriers might, in effect, result in a delay he makes a very good point.

However, I wonder, though, whether we ought not to encourage the NRC to give credit for that kind of delay, because in one perspective, a dose at what I take to be really quite small levels 10,000 years from now probably is a more acceptable dose or could be a more acceptable dose then would be the same level of dose today, just because of technology, and if you think out 200,000 years, which is pretty hard to do, that same level of dose 200,000 years from now, with advanced technology, you know, may be even

more acceptable, and so, there is reason, perhaps, to give credit for delay, and I don't know how you do that, but there may be some value to that.

I also then with regard to the engineered barriers and the notion that you have to have well, the requirement that you have to have one of each and I wonder, you know, with regard to Yucca Mountain and the natural side of the house, how do we you know, there are multiple aspects to the natural barriers, single aspects to the natural barrier. It is a block of rock, and so, it really seems to be one natural barrier that maybe does a variety of things.

If that rock doesn't work the way you predicted, then you really don't have both types of barriers. You have an engineered barrier, but you have a natural barrier that's not performing the way you thought it was. And I guess I'm wondering you know, it gets back to this gentleman's question.

At that point, you know, you don't have two types of barriers, a natural and an engineered, and do we shut the facility down at that point? And I suspect, you know, that these regulations ought to anticipate that kind of an outcome.

I guess, finally, I would just encourage that we ought to perhaps give weight or value to those barriers,

whether they be natural or engineered, which tend to reduce uncertainty in our understanding of how they would perform, and that's maybe what Rex was getting at in terms of the calculations and all that, but I don't know that the regulations themselves would encourage one to use one over the other if that one tends to reduce the uncertainty about its performance and the resultant, then, public health benefit, and it strikes me as though that there may be some value in that.

MR. CAMERON: Okay. Thanks, Mike.

You've raised a number of issues, and one that I just would sort of bring back up for people around the table to consider is one that Steve brought up, the whole issue of the inadequate site and what Steve referred to as the primacy of natural barriers, and I would be curious to hear what others around the table have to say about whether the NRC proposed approach is really eliminating the or allowing for the possibility that the site is going to be inadequate and that the reliance would be on engineered barriers.

I don't know if I articulated that the way it should be, but I think that you may know what I'm talking about at any rate, but Rick, why don't you go ahead?

MR. CRAUN: Well, I'm just going to just basically share some thoughts as I was looking at Steve's charts that he put up there.

I recognized some of them from the VA design, and I think the really good examples of the concepts that are trying to be embraced by Part 63, and that is to base decisions on riskinformed, risk information, and as it was shown up there, the waste package, when I believe those were neutralization analysis curves that you put up there when the waste package is neutralized, that, in fact, it does have a substantial change in the performance of the repository.

I think, as Christiana pointed out, that maybe neutralizations may not be the correct thing that we look at. It may be more appropriate for us to look at the degree of underperformance that's reasonable for us to really assess the a barrier and its capability.

So, what was, I think, a good example of a design that we need to kind of step across and step beyond, and that is really what we have done.

Since the VA, we've looked at changing the design so that that reliance on a single barrier in Part 63 draft that, really, the intent is not to rely on a single barrier.

So, we are looking at designs, changes that would distribute that reliance over multiple barriers, not only engineered barriers but natural barriers.

So, I think that risk information that you showed or put up on the table is really valid information for us to

look at, to consider when evaluating the overall performance of the repository, and I really think that's what Part 63, at least in my mind, is wanting the department to do, and that is to look at the overall assessment of the performance of the repository, identify what barriers are key to that performance, why we feel they're key, and how they participate in that performance, and then look at and this is the area where the department has really tried a couple of different approaches look at whatif scenarios, what if we're wrong, what if the waste package doesn't perform as we expect it to perform, what if, in the current design, the drip shield or the backfill doesn't perform as we expect it to perform, or what if the unsaturated zone underneath the repository doesn't does not perform as we expect, and those whatif scenarios, I think, have been in the last yearandahalf, or thereabouts, that we've been running them, whether they be complete neutralization analyses or sensitivity analyses, those have been very informative and have helped us take the design to the next level, so to speak, to the next stage, and I see that process as continuing, and as we build our compliance, start building our compliance arguments, we'll find some areas where they may be weak, and that may result in either, then, the need for either more data to get a better understanding of the natural system or, in some cases, an alteration to the

engineered feature to get it to perform better.

So, I just wanted to kind of add I thought your examples that you put up there were really very good examples of a system that needed to be looked at very carefully, and that's what I think we are in the process of doing, and I think that's what 63 wants us to do. It puts the burden on the DOE.

MR. CAMERON: Steve, what would you add to how do you react to what Rick said? What would you ideally add into his formula?

MR. FRISHMAN: I'm aware of their thinking of more design stuff, and I don't care how many engineered barriers you apply to the thing, it's still a question of where the reliance is and what is the relative reliance at what time? What is performance really all about? And it's really all about which are the important radionuclides at what time and how much, when you finally get to it, because you have different things happening in different times.

So, it doesn't particularly bother me that you're working on new engineered barriers. It's a concept of what you're relying on, because it comes back to whether, in fact, you're able to rely on the site or not.

Let me give you an example that sort of may clarify why I said I don't care about 200,000 years. If you look at at least in the viability assessment, you look at

the sensitivity of performance to juvenile failures, there's enough information there granted, there's not a lot, but there's enough information there that tells you, if you instead of having one juvenile failure, if you have maybe about 100 juvenile failures out of 11,000 packages and those occur sometime in the first two or three thousand years and we may not be calling them juvenile failures, we may be calling them unanticipated failures, but if you have about 100 of them so, you're still you're down around the 1percent level.

If you have that many, within 10,000 years, you would exceed the standard.

So, the uncertainty is such that I say I don't care about 200,000 years, and a peak dose at 200,000 years that's the same as one at 8,000 years is equally unsafe, it's because you could have the 200,000year predicted condition happen within 10,000 years on something that you can't tell me with any assurance would not happen, and you say it's fine to spread those doses out, but I'm saying it's not necessarily that those doses are going to get spread out.

You can have the equivalent of the 100,000year dose within 10,000 years just by twiddling how many juvenile failures you have or how many unanticipated failures, and it's still a very, very low number of failures very early in

the life of the repository performance.

MS. KOTRA: That's an excellent point in terms of how those failures are treated and when they occur, but I did not say it was okay to spread that out.

I was saying, you know, is there a difference and Mike addressed this with the same dose with reasonable assurance occurring early versus it occurring much later, and I think that's something that, you know, I want to hear other people's opinion on, but I did not say, either for myself as an individual or representing NRC, that it was okay.

MR. FRISHMAN: Well, I guess the point that I'm making is all of this information sort of put together tells me that we're dealing with a characteristic of the site that allows, under not unreasonable predictions, doses within a very short period of time relative to the hazard of the waste, doses to people within a relatively short period of time that would be totally unacceptable if they were proposed to be allowable today, and that would be up around the 1remperyear level, at least according to the calculations we have available to us.

MR. CAMERON: Steve, in terms of how your alternative and I don't want to put too heavy a pressure on you about your alternative, but how does that differ from the existing approach versus the proposed approach?

MR. FRISHMAN: The existing approach sets at least some levels of compliance. The proposed approach says how you how they must analyze, but it does not provide for a level of compliance, and the question was out earlier about, well, what if it turned out that the reliance was very heavily on the engineered barriers, and under the proposed rule, that would be just fine, because it doesn't say it can't be.

It says we're going to analyze whatever it is you provide, we require that there be engineered and natural barriers, but it doesn't say anything about the level of reliance that would be considered acceptable, and I think this last example I gave is one that, even knowing this, based on the analysis requirement, without setting any kind of limits on levels of reliance, something like that you could license a repository with something like the juvenile failure scenario being perfectly acceptable within the considerations for a license.

MR. CAMERON: Okay.

MR. FRISHMAN: Because it doesn't say what the regulator believes is a reasonable level of reliance on the performance of the site and the performance of the engineered barrier.

MS. KOTRA: So, you're saying that the regulator, in this case, should specify numerically or in qualitative

terms? What are you saying?

MR. FRISHMAN: I'm saying that the regulator should at least specify what we see in that 1980 EIS and what we see DOE wrote in its own guidelines based on the knowledge of that statement, wrote in its own guidelines before it found out what Yucca Mountain was, and that's that, after an initial period of protecting however you must protect from the risks of shortlived fission products, the geologic barrier site must be primary.

MR. CAMERON: Okay.

Can I just step in here to this is an important issue in terms of Steve is suggesting maybe that there is a at least a qualitative statement, if I could use that term.

MR. FRISHMAN: Well, primary says more than 50 percent.

MR. CAMERON: Right. In other words, you wouldn't have these same specific subsystem performance goals, but there needs I'm just trying to figure out how this differs between the old approach, and I think that it's stating some requirement of reliance, and Rick has something to say on that.

MR. FRISHMAN: The old approach establishes at least some type of a standard. The proposed approach only says you will analyze how DOE has analyzed its compliance with the need for multiple barriers.

MR. CAMERON: Okay.

Rick?

MR. CRAUN: You're proposed, if I understand what you're saying, a predefinition of a balance between the natural and engineered systems.

MR. FRISHMAN: It's been defined already. I'm not proposing a predefinition. It's there. The rule doesn't satisfy it.

MR. CRAUN: If we were to look in that direction, I would suggest that we look at more than just the isotopes that are involved in the charts that you put up on the table, which are those that are highly soluble and transportable, and look at how the site functions on 99 percent of the remainder of the isotopes.

MR. FRISHMAN: That curve is not based on just iodine technesium. It's based on all of the isotopes used in the viability assessment.

MR. CRAUN: So that we look at the total picture of those at the site, basically, that are not transportable, not soluble and not transportable in the site, and I think that gives, then, a balanced perspective of how the site's performing as compared to how the engineered barrier systems are performing, and the second point I wanted to I'll just stop there for now.

MR. FRISHMAN: I have to respond again and make

clear, that curve is based on all of the radionuclides that are used in the TSPA, total system performance in other words, a selection, I think, of about key ones, some of which are more soluble than others, but it's apparently the reference suite that is used for performance assessment. It is not selective of only those that are highly soluble, only those that don't absorb.

MR. CAMERON: Okay.

MR. FRISHMAN: I was not doing a selective curve. I was using the same suite that the department uses.

MR. CAMERON: Let's get off this particular issue right now and go back to some of these broader issues, and if we need to get back into this specific discussion, we'll get into it later on, and we can get some comment, too, from Grant on that.

But Dennis, let's go to you you've been waiting patiently and then go to Keith, and I inartfully added Steve's alternative, perhaps, in up here, and we can flesh that out and see what the rest of you think about something like that.

Dennis?

MR. BECHTEL: Just the years I've worked this program, I've seen very much a shift between a lot of discussion about the environment and more discussion about the engineered barrier system, and you know, starting off

just with a caster and now fill and drip shields and things like that, and I think the concern I have is that we're kind of straying from the I see a definite shift to emphasis on engineered barriers, and I think we're straying from the fact that this stuff is going to be a lot more dangerous than the life of a container, and so, I think I would hope that the NRC does not get too far away from where this whole thing seems to be going and relying on something that has a finite engineering life, and so, I'm hoping that this I feel, as Steve does, that the natural barrier system is really the meets the failsafe.

We have we need the public needs to rely on that, and as time goes on, I see more and more problems appearing with the site, which leads me into my next part.

I understand, in your review, you're going to look at data and models, and a number of us have quite a bit of concern about just the level of data that's available and the use of models that will not, as I understand it, be able to be validated.

So, I guess I would throw a question back to the NRC.

I notice, in part of your policy papers, that such an approach will require the Department of Energy to provide greater transparency of how multiple barriers contribute to overall performance and associated uncertainty.

How do you feel now, given the fact that this is very much a scheduledriven program, and whether, in fact, you will be able to make decisions based on the fact that there may not be enough data, and probably will not be enough data available, and some very models are as good as data, and where does that put you?

I mean, in my mind, that would throw me back into wanting more information about the environment, because there's very little available now.

So, I guess my question to Keith and perhaps others is where do you see this going?

MR. CAMERON: Is this the question that some of the commenters on the rule raised, that performance assessment is although, as the NRC pointed out, there may have been great strides since the original Part 60, but there's still we're still not there with performance assessment.

So, shouldn't we be doing something in terms of quantitative subsystem requirements to make up for that lack in the state of the art, so to speak?

Keith and then Janet and Christiana any of you want to respond to Dennis' question?

MR. McCONNELL: Well, I think it puts us in a difficult situation in the sense that, you know, certainly what we're requiring in the rule is sufficient information

to make the case that the citizens in Nevada are protected from this facility, but I think what we're done we're not trying to think into the future that far as to what DOE might provide for to us.

What we're saying was we're laying out the requirements of what's necessary.

We have expressed concern, most recently in our letter to the department on our review of the viability assessment, that some information that is key to demonstrating compliance with what is in the proposed Part 63 might not be there.

Particular areas where we've raised questions are the performance of the waste package, as Steve has pointed out, and also the quality and quantity of the data on the natural barrier.

So, I think, you know, we're aware, we're concerned, and we've expressed this concern to the department, that you know, to receive a license application, this analysis has to be full and complete, and I guess that's as far as I can go.

MR. CAMERON: Okay.

I think that we probably need to go to the audience, take a break, and do some talk about the bulk of Christiana's presentation on implementation, but I guess I would just like to see if there's any comments out there

about you know, there were a number of reasons given by the NRC about why there were moving to the new approach.

What do people and take the way I characterize Steve's alternative with a lot of grains of salt, and you know, some of them coming from the fact that we haven't articulated it yet, but how would you feel about this particular alternative?

In other words, you don't have the specific subsystem performance requirements, but you have some statement in terms of how important the natural barrier subsystem should be.

Does that throw into a cocked hat all of the reasons why the NRC was trying to do this, and you know, there's reasons of giving flexibility to DOE in the design, etcetera, etcetera.

That's one question, and the other question is I think Mal agreed with Judy on this, and maybe this is something that's just obvious, but what do people think about the statement that the subsystem goals promote public confidence in the licensing decision.

Janet, go ahead.

MS. KOTRA: Well, I don't disagree with the second one.

I understand that point, and I think that's something we need to take back, that perhaps we need to look

at putting additional something into the rule that will make it easier for the public to see what constitutes success and what constitutes failure, if I understand Judy correctly on that.

She mentioned the word "a checklist." I think there are some aspects checklist aspects that are in there now, but maybe we haven't done a good enough job to put more in. That I understand.

With regard to the other issue, I am intrigued by this alternative. I believe that there has to be a basis, a technically justifiable basis more than just, in some DOE document now, 20plus years old, you know, it said it used the word "primacy," or you used the word "primacy," what is the basis that we could use to derive that relative contribution of the natural system and the engineering system?

How would we do something other than being totally arbitrary, I guess, is what I'm asking.

MR. CAMERON: Let's go to Steve and then Judy.

MR. FRISHMAN: I can give you another basis in law, the same law.

MS. KOTRA: I'm asking for a basis in science.

MR. FRISHMAN: Let me give you the basis in law first, because that's the one a judge will understand.

In the Nuclear Waste Policy Act, not only does it

require multiple barriers and require you to write rules, it also requires the department to write guidelines for recommending sites with which the Commission concurs.

The Commission concurred in the guidelines that were written, because its only basis for concurrence was Part 60.

In Part 112(a), where DOE is told to write guidelines, it says geologic factors this is for qualifying and disqualifying sites geologic factors shall be primary. That should be sufficient basis for you. Whether you want a scientific basis for that or not, you've got the law to follow.

MR. CAMERON: Okay. And there may be a public confidence basis in that, as you might have been suggesting.

MR. FRISHMAN: I also think the word "primary," if we're going to use a word, is far preferable to "substantial" or "significant," because I don't want to get back into the Joe Bunting syndrome about what "substantially" means and what "significant" means and spend lots of time and money arguing over something that should be pretty obvious to people.

MR. CAMERON: Right.

MR. FRISHMAN: "Primary," I could convince a judge, I believe, means more than 50 percent, I believe.

MR. CAMERON: Okay.

The question is, if people agree that maybe there's some value to following this concept but have problems with "primary," is there some way to address this concept besides doing that? I don't know.

MR. FRISHMAN: I think I gave the basis for it. The law says "primary."

MR. CAMERON: Okay.

Judy.

MS. TREICKEL: I think we play sort of fast and loose when you get into the lab on this kind of thing.

Number one, it needs to be said before, during, and after this whole discussion, we don't have to build a repository. A repository is not something this isn't a comet that's coming toward the earth and we've got to do something, like a kids' film that makes it all survive.

We don't have to do this, and most of the world isn't planning to do this very soon. So, just keep that in mind.

But when you talk about dosing future people and very cavalierly say that they may in much better shape to take a dose, this gets right back to informed consent, and you can't suppose that sort of thing, and I don't think we have the right to do that.

I'm very glad that some people a long time ago didn't set us up for a surprise like that.

Last week, we also or about 10 days ago learned a whole new term, and it was flying all over TV for an entire day, while a Lear jet was flying with a whole batch of dead people in it, and they were talking about that, and they called it redundant failures, because they talked about how the Lear had all of the the reason you pay the extra money is because you were going to get fallbacks for things that could go wrong.

So, they started using this term "redundant failures," and I think that's something that could fit in here, and I find it very strange that this kind of discussion takes place when you're talking about a site that's being forced.

Nevadans have not agreed to be a repository site. This is forced siting, and to not have that checklist or to take just a kind of casual attitude about where what barriers are and who defines them and maybe where boundaries are and that sort of thing, this is a forced site, and it's got to be something that can really prove itself.

It's not something that people say, well, yeah, we'll take a chance, we really want to do this, like going up in an airplane or a rocket or whatever.

So, it has to be a tighter system than what you're talking about.

MR. CAMERON: Okay. Thanks, Judy.

Let's take Mike and then Keith and then go to the audience.

Mike?

MR. BAUGHMAN: Well, I guess, as a Nevadan who isn't particularly concerned one way or the other with the repository, I would say, at this point, because I think the jury is still out, I would be particularly troubled with a requirement for putting emphasis on a natural barrier without some technical basis or knowledge that it does, in fact, provide a risk reduction benefit.

Having said that, I also think that, if I wanted the repository to go somewhere else, then I would emphasize and seek to emphasize natural barriers, knowing that it might be a barrier to the repository itself, but I would quickly worry, though, that if I am also suggesting that we keep the waste onsite, that that almost entirely depends upon the use of engineered barriers, and so, if I'm willing to accept engineered barriers for onsite storage for some unknown specified period of time, but yet I'm not willing to accept engineered barriers to contain radioisotopes at Yucca Mountain, I think my argument would quickly sneak around and bite me.

I didn't know quite what to say about this, but I worry about just kind of saying, hey, we've got to put more emphasis on it, because unless there's a reason, public

health and safety reason, I don't think it makes a whole lot of sense.

MR. CAMERON: So, your basic point is that there has to be some rationale in risk reduction, public health and safety from making the statement that the natural barrier should be the primary barrier, is what you're saying.

MR. BAUGHMAN: Yeah. And if Nevada is going to get the repository, it's not going to be for scientific reasons. If there's anybody in this room that thinks that this project is going to come here purely because of science I mean we're not foolish.

So, that means that, if we rely upon natural barriers, put overemphasis on natural barriers, and still get the project, we would be safer. I'm not so sure.

MR. CAMERON: I guess the law depending on the law can cut both ways, can't it?

Steve, quick comment before we go to Keith, and then we're going to come out here.

MR. FRISHMAN: I guess, for Janet's purposes, I want to emphasize that she has a legal basis to do it, and that's good enough, but of course there's a scientific basis for it. It's just what I showed on those curves. When the engineered barrier goes away, you get an unacceptably high dose.

MS. KOTRA: That's true of any site.

MR. FRISHMAN: Not necessarily. I guess what I told Bill Kane the other day, speaking on this same subject, was that I still have a you know, some level of thought that says geologic isolation is not impossible, but what we're doing is setting up a system here to assure that it never gets a fair test, and geologic disposal as has been discussed since the '50s had a heavy reliance on geologic barriers, natural barriers. Why? Because we knew we could not engineer a system that would contain actinides for their dangerous lifetime.

MR. CAMERON: Okay. I'm going to go to Keith now because we really I'm sorry, we really do need to move on here.

Keith, final comment?

MR. McCONNELL: The discussion seems to be turning to the fact that NRC is not going to require any level of performance from a natural barrier, and I just want to make it clear that that's not the case, that we do and the proposed Part 63 will require that the natural barrier do provide a measure of performance that is going to be protective of public health and safety, but other than that, I'll defer anything else.

MR. CAMERON: Okay.

Let's go out here.

Yes, sir. And could you state your name and affiliation for the record, please?

MR. METLAY: My name is Dan Metlay. I'm on the staff of the Nuclear Waste Technical Review Board.

I raise this comment in response to a remark by Steve at the beginning of his presentation about are there other documents that sort of reflect on this consideration with respect to how you design repository systems, and I, perhaps, show my years.

There is, in fact, another document that was developed in parallel with the GEIS in the late 1970s, and that was done by the InterAgency Review Group of the Carter administration, and I had a little hand in that, unfortunately, because it was a long time ago.

The key point of the IRG group, which was endorsed by President Carter, was that the repository had to be looked at as a system, and there was very clear understanding in the work of that group that no particular type of barrier would be morally superior to another type of barrier, and what counted was the total system performance.

Having said that, I should also note that, at that point, which was 20 years ago, there was the general expectation that engineered barriers simply could not provide the level of confidence for periods beyond much beyond 1,000 years.

Whether that's changed now is a question that the DOE and the NRC will have to wrestle with, but at least the IRG made a very clear statement that it's the system that does count, and I just say this to add to the historical record.

MR. CAMERON: Okay. Thank you very much. I think that was useful for people to hear.

We're going to go to the gentleman in the back over here.

MR. MORTENSON: I'm Harry Mortenson. I'm a legislator, and I'm also the ViceChair of the HighLevel Nuclear Waste Committee at the legislature.

Steve had mentioned one rule that exists where the NRC said that they would not okay a repository in which the mechanical barriers had to make up for inferior geology. That was one of the statements that NRC made.

When Rick was talking about doing studies, whatif studies, I just had a great idea, I thought. While you're doing whatif studies, I think it would be a wonderful idea if you threw in some whatif's if we were going to consider the natural barriers of something like Sandstone and David Canyon in Utah or the salt barriers in New Mexico or the basalt in Hanford.

I think they would be very illuminating in some whatif studies, to look at the total performance of the

system and the contribution of those natural barriers. I think we know the transports in those materials pretty well for nuclides.

MR. CAMERON: Okay. Thank you very much.

Grant.

MR. HUDLOW: I'd like to mention that you're talking about doing models, studies, and so forth. The DOE has already done a study on the transport of nuclides in tuft like Yucca Mountain. In Los Alamos, it drilled a hole in the tuft, dumped some radioactivity in it, and within a couple of months, it was in Cochiti Lake, and the reason we all knew about it was because you had to shut down fishing in the lake; the fish were inedible due to the radioactivity.

Fortunately, they apparently used a shortlived radionuclide, and sometime later, why it was okay again to eat the fish.

It was 10, 15 years that happened in 1980. It was 10, 15 years before we understood the mechanism of what happened there, and the mechanism turned out to be that the colloid transport.

So, when you're talking about the waste material in Yucca Mountain, there is no such thing as some waste that is not transportable. The colloids will absolutely transport all of it or any of it.

The other thing that I'd like to mention, back to the approach again, one of the things that I hear people dancing all around with this approach is how do you get the confidence of the public, and that also includes the NRC commission itself.

They don't have the technical background to understand the details, and according to academia, only 4 percent of the population has the background to understand the details.

My experience in industry is that it's much higher than that.

People that don't have a chemical or science or engineering degrees are capable of understanding and contributing a great deal to these technical problems if there's somebody around that can translate what they have to say, and so, you know, Christiana is giving the DOE the terminology that maybe they can get a license if they quote her words and say we're going to do this and we're going to do this and we're going to do this and we're going to do this.

That does not get to the technical performance at all, not even close, and those kind of words, not backed up by technical performance, will guarantee a spectacular failure.

We have them in industry all the time when we have

nontechnical people using those kind of words and there's no technical background behind it.

MR. CAMERON: Okay. Thanks, Grant.

I probably should add for Christiana that I don't think she was suggesting that.

MS. LUI: I just wanted to clarify that. In my presentation, I did emphasize that any assertions that DOE is going to make, they have to provide a technical basis to back up that assertion.

MR. CAMERON: Okay.

MS. LUI: So, just laying out a particular process or steps that DOE could follow does not undermine the need for all the technical basis and background that DOE would have to support this approach.

MR. CAMERON: Okay.

Corbin?

MR. HARNEY: My name is Corbin Harney. I'm a Shoshone from Nevada here.

I'm really concerned about my land, because my forefathers lived here for thousands and thousands of years on this land, and today, what you guys are doing, you forgot this nuclear industry started within just 50someodd years ago, and today, it seems to me that you guys are buffaloed. You don't know what to do with it.

I think each and every one of us understand our

people have died from cancer caused by radiation. It's happening throughout the country. When are we as a people going to come to and say the nuclear industry should look at something else besides nuclear power?

Today, we're suffering throughout the world. I think most of you people understand that we are running out of things.

Our mother, my mother I don't know whose mother you guys belong to, but my mother is suffering. They don't have no food out there for the animal life or the bird life, because new this new industry we call nuclear energy is wiping out the life of all living things.

This is my concern. This mother earth of mine, my forefathers survived here probably a million years before you guys ever decide to come in this part of the world. I hope you guys will make a decision here, Yucca Mountain is not safe place. I think each and every one of you know that.

It's a mountain they call rolling hills, but it moves all the time. It will continue to move. Somebody, when you put nuclear rods in it, how many rods in the cave it's going to be in, how hot it's going to be.

We already know, each and every one of you, it's got water in it, that nuclear rods heats up water. It's going to blow Nevada out of site when it does blow, maybe

half of this mother earth of ours.

You don't have to be a scientist to know that. You don't have to be welleducated to know those things. It's here with us, gentlemen ladies and gentlemen. Think about it.

Think about your grandchildren. How are they going to survive now that we're running out of water throughout the country?

Today, things are changing so fast. We have to do something. Instead of sitting here spending money, let's get ahead of this and say one way or the other. Let's change the nuclear weapons, nuclear energy to more safe energy that our scientists can develop, instead of wasting money here.

We've been talking about for 50someodd years. What are we going to do with the nuclear waste? Now nuclear waste is going to be coming here to Nevada from throughout the world.

Is it going to be safe on the highway, railroad? Do you think you're going to be safe? What about your young people, the future generation as we call it?

I hope that we do make sense, make sense for the younger generation so they have a place to stay, a place to live, a place to enjoy, instead of destroying our mother, is not the way.

Thank you.

MR. CAMERON: Okay. Thank you, Corbin, for that message.

Let's take a break now, and we'll come back and talk about implementation issues. Try to be back by about 10 after. That gives us about 15 minutes or so.

Thank you.

[Recess.]

MR. CAMERON: We're going to focus on implementation right now.

I just wanted to remind you of something that Keith said at the end of our previous session about the fact that we heard Steve talk about all that's required now is an analysis.

I think Keith pointed out that there's more to it than that, but now we're going to talk about, if you assume the proposed approach goes forward and I suppose that this would be relevant could also be relevant to other approaches that would be selected besides the one in the proposed rule.

What is DOE going to be what type of analysis is going to be required?

You heard a lot in Christiana's presentation about implementation issues. We do have a issue over here in the paddock that we'll bring out on the track, so to speak, and

I think this was Mal Murphy's issue about put the acceptance criteria that are going to be the Yucca Mountain review plan, put that directly on the rule. Okay?

Mal, just quickly, did I get that right? Is that what you were suggesting?

MR. MURPHY: No, you didn't.

MR. CAMERON: All right.

MR. MURPHY: What I was saying is that, since the ultimate acceptance decision or the ultimate licensing decision will be based on compliance with a total system performance requirement and compliance will be demonstrated by a total system performance assessment, then let's put that in the rule, let's have the rule, as does proposed Part 63, focus on the overall system performance and TSPA rather than on details which could be overridden, which are not ultimate determinants of licensing in the first place.

MR. CAMERON: Okay.

MR. MURPHY: What I was saying is that, under the proposed Part 63, I think that the acceptance criteria is in the rule, by focusing on overall system performance.

MR. CAMERON: All right.

MR. MURPHY: That's not to say that the rest of the stuff isn't important, but I've always been convinced that the ultimate decision will be based on overall system performance, and let's have the rule make that clear at the

outset.

MR. CAMERON: Okay. Thank you.

We're going to stay up here at the table, and we'll be going out to the audience after we have a discussion up here.

Let's lead it off with Steve Frishman.

Steve?

MR. FRISHMAN: I'd like to point out a discussion that Dan Metlay and I had after he announced that, yeah, there is another document out there, and recognize that it's a document not in the EIS.

It's a report of a interagency review group that was going on about the same time that that EIS was being written, and he said that they understood, at that time, in that group, that system performance was going to be an important consideration.

The point that I made to him was that they didn't say how long the system had to function, and part of the point I was trying to make today is, if you truncate at 10,000 years, you're not looking at the true question of the safety of the system, and that group did not talk about a truncation of how long the system had to function.

So, I think Mal can talk fine about putting the requirement in the rule or the understanding in the rule that ultimate performance is the safety standard, and

whatever the criteria might be, if we know something about performance, then we can decide whether it passes or fails some kind of a test, but you have to look at the total performance, and part of my message here is that we're artificially truncating the safety question by putting a 10,000year limit in, and I think it's fine you can say that, Mal, but at the same time, if we're not looking at what we know to be performance beyond 10,000 years that only gets worse, then we're not really getting at the question.

MR. MURPHY: But I'm not saying we don't look at performance beyond 10,000 years.

MR. FRISHMAN: You were careful not to, just as the IRG was.

MR. MURPHY: The question of whether or not of how you measure performance do you measure the worth the value of the repository by looking at overall system performance or by looking at subsystem performance requirements individually is totally separate from the 10,000 years versus peak dose.

I mean whether you're going to measure the performance of the requirement at 1,000 years, 10,000 years, or 250,000 years, what I'm saying is that the proposed approach in Part 63 makes me feel more comfortable than looking at subsystem performance requirements individually.

It's an entirely different issue, and you've got

some strong arguments about whether or not, you know, the regulatory period should be 10,000 years or some longer period. That's in my mind, those issues are completely separate.

MR. CAMERON: Okay. I'm sorry that I unwittingly, by mischaracterizing what Mal said, led us back to the future or whatever, but we would like to have some discussion on implementation, and I'm going to I guess I'm going to ask the ask Christiana, perhaps, to put an implementation issue out on the table for us, but one issue you should keep in mind is that there will be perhaps I'll ask Christiana to talk about what's going to be in the Yucca Mountain review plan, and keep in mind that this review plan is a document that you probably will want to have some input into.

Christiana?

MS. LUI: Okay.

What's going to be in the Yucca Mountain review plan?

The intent of Yucca Mountain review plan is really to pull a lot of the technical detail that would be consistent with what's going to be in the final rule, in the final Part 63.

Yucca Mountain review plan will have the acceptance criteria and review methods of how we intend to

review DOE's compliance demonstration in accordance to what we publish in the final rule.

At this point in time, in terms of the postclosure safety evaluation, NRC has been doing issue resolution status report of various technical disciplines in the past two years, and we are doing a comprehensive review of all the acceptance criteria and review methods in the issue resolution status report and integrate the acceptance criteria and review methods under the framework of what's in the proposed Part 63.

In terms of what we have presented here today, the fundamental concept is going to be clarified in the rule, in the final rule, but in terms of how we're going to do a lot of the detailed analysis such as NRC's independent confirmatory of the calculation type of issue will be in the Yucca Mountain review plan rather than in the rule.

MR. CAMERON: Okay. Thank you.

I guess, based on that, I would ask if people around the table have suggestions for NRC about what should be in the plan in terms of the acceptance criteria or concerns about what the acceptance criteria might look like.

Janet?

MS. KOTRA: I just wanted to speak to the philosophy behind the placing of some of these technical details of implementation in the review plan, as opposed to

in the regulation itself.

One of the things we're trying to avoid is to have we recognize that there will be a period of time this has been an evolving project and that the state of the art is not a fixed point in time, but we did not want to tie ourselves or, for that matter, DOE down to a particular technique of demonstration to foreclose the possibility of better techniques that may emerge between and when, ultimately, the final licensing decision would be made.

We wanted to focus on what is important for safety in the regulation and allow some flexibility in demonstration of that in particular disciplines, in particular areas where there will be improvement.

So, there is a split there.

The reason for that is that we want to have, for the sake of public confidence, some sense of stability in what we believe is important for protecting public health and safety but also a recognition that it is the review plan is a work in progress, it will be updated, and as we get more information, it will evolve with time, with ample opportunities for public input.

MR. CAMERON: I don't know if we have said this yet, but the status of a review plan is similar to a regulatory guide. Could you just talk about what the regulatory status in terms of compliance is of the review

plan, for people who don't understand how these documents work?

MS. KOTRA: Keith, would you want to take that one?

Certainly, yes, it's comparable to a reg guide.

MR. McCONNELL: Right. What the review plan would constitute would be the way the staff one way the staff could use is acceptable for demonstrating compliance.

So, if DOE comes in with a particular approach for demonstrating multiple barriers, they can take the staff's acceptable approach and probably benefit from doing it that way in efficiency of review.

However, it doesn't preclude DOE from doing something different as long as they demonstrate compliance with the overall safety objective.

MR. CAMERON: Okay. Good. I think it's important that people understand that.

Christiana?

MS. LUI: I just want to add that the review plan is really the guidance to staff at NRC, but indirectly, it will become an acceptable way to demonstrate compliance for the applicant.

MR. CAMERON: Okay.

MS. LUI: Keith has pointed out that, if the applicant has alternative ways which will better demonstrate

compliance, again, it's a guidance document, it's not regulation.

MR. CAMERON: Okay.

Let's go to Steve, and then I might ask Don or Rick if they have anything at all to say on these implementation issues.

Steve?

MR. FRISHMAN: One of the very large implementation issues in my mind it's a really fundamental one, that somehow the staff is going to have to come to grips with and I know they've tried to, and it's almost nobody's thrown up their hands, but nobody knows how to do it, and that's how will the regulator deal with the issue of model validation, because if you have a performancebased rule and performance assessment is the measure, then throwing up our hands and saying all of this stuff goes out so far and has so many known unknowns and unknown unknowns, that you can't validate a model as you might be able to validate some models under different circumstances.

I think the staff is going to have to be very clear in its implementation on how it deals with that, because most of the people in the country now are sufficiently computerliterate to know one thing, and that's computers will give you any answer you want and models will give you any answer you want. They know that.

MS. KOTRA: Are you comfortable with that assuming we can come to a point where we can deal with that acceptably, are you comfortable with that being in the review plan, recognizing that reasonable people can disagree over what's acceptable for dealing with model validation.

MR. FRISHMAN: I don't know, because I don't know what you could put in a rule about it, since we know it can't be done to the level of expectation. We know that models just can't be validated to the level of at least some people's expectations, and you say part of the reason for having this shift in regulatory approach is that we've gotten so much better at doing things that we didn't think we could very well back in 1980 to '82.

Well, in this case, yeah, we've gotten better at building much bigger, much more sophisticated models and, as I told the Technical Review Board not too long ago, models where the perpetrator says I thought of everything, and we know that can't be the case, somebody will always think of something else.

So, putting that in the rule I'm not sure really does anything.

I think it's much better to have it clear what is going to be the basis of at least the staff's judgement of the extent to which these models reflect anything other than the latest techniques in modeling. They don't reflect

reality. We know that.

MR. CAMERON: Can we get some feedback from Christiana or Keith on how the acceptance criteria or the review plan is going to deal with the issue of model validation? Is there anything that we can say about that at this point?

MS. LUI: Since the Yucca Mountain review plan is still in the making, I would use what's in the total system performance assessment and integration issue resolution status report as an example at this point, because we did try to model that particular issue resolution status report after the concept in the proposed Part 63.

There is one particular acceptance criteria that may not be exactly what Steve is looking for in terms of model validation, but we have laid out an approach where basically we ask DOE to verify the model output in the total system performance assessment by comparing against the data that has been collected or any other natural analogs that are applicable to the Yucca Mountain site.

MR. CAMERON: When we talk about verification versus validation, for all of the laymen here, can someone tell us what the difference is between the term "model verification" and "model validation." Anybody want to take that on?

MS. LUI: It's interesting that you actually ask

this particular question, because I intended the Nuclear Waste Technical Review Board meeting back in September. Basically, they had a panel discussion on model validation. I believe, if my recollection is correct, model validation means different things to different people.

MR. CAMERON: It seems like that runs through this program, doesn't it?

MS. LUI: So, instead of using a word as validation, I believe the sort of the consensus that came out of that particular panel discussion is to describe exactly what we would ask DOE to do, rather than just lump everything together under the phrase of model validation.

MR. CAMERON: Okay.

Janet, do you want to add on to that?

Keith?

MR. McCONNELL: I think that the terminology is changing to a certain extent based on some of the work in the international community to more confidence building, that you become more confident that the models that you're using to predict performance actually do estimate or I guess adequately estimate what the performance is.

So, it's more of a process of confidence building than the effort of validation, which I think does have many different definitions.

MR. CAMERON: Okay.

Janet wants to add something and then Mike, and then let's go over to Don.

Janet?

MS. KOTRA: I just wanted to note that we have with us from the Center for Nuclear Waste Regulatory Analysis Gordon Wittmeyer.

Gordon, did you want to add something?

MR. CAMERON: Gordon has been hiding back here, and he's an expert.

MR. WITTMEYER: I think the point that Christiana made about validation being many things to different people is true, and in recent times, I think the emphasis internationally has been on building confidence, and I think the way of looking at building confidence is kind of piece by piece, looking at different parts of a total system performance assessment code and comparing, say, a release model to what you might see at a natural analog site for uranium.

Techniques like that are approaches that can be used for building confidence in parts of a TPA code.

MR. CAMERON: Okay.

Mike.

MR. BAUGHMAN: Well, I guess I don't know, I'm just kind of struck by the you know, Steve asked a legitimate question, you know, and then this whole thing,

how are you going to validate these models, and they can't validate them, and obviously, I think I anticipate a great deal of controversy about the models, and what do they mean, what they don't mean, you know, the algorithms.

We can argue about algorithms, we can argue about data, we can argue about results, we can argue about interpretation results. Everything about them is going to be argued, and there's some confusion here at the table even about, you know, the difference between validation and verification.

You know, you folks are in deep trouble. I mean I can tell you, from the public's perception and Judy's the public expert, supposedly, but I represent the public, as well.

This is not the kind of thing that people are going to want to hear, and it's not going to help to build public confidence to hear that we don't necessarily know what the difference is between these terms or, you know, it's an evolving term of art and this is what we think we do.

Let me just throw a suggestion on the table.

It seems to me that, in this program and other complex technological programs, when we want to have someone render a judgement as to the technical suitability of the problem at hand, we go to a group like the NAS or somebody

like that and say take a look at this and tell us what you think, and there are those that will refute the findings of the NAS or a group like that, but the refuting doesn't go very far.

It generally falls pretty much on deaf ears, and I think that the public does look to entities like that as kind of, well, hey, this is a group of people that, you know, I certainly can't match wits with, and if they're comfortable with it, well, you know, perhaps I can live a little bit better with it.

They're not going to trust the state, they're not going to trust the NRC, they're not going to trust DOE, the EPA, because quite frankly, you don't know, but they may trust a group such as the NAS or some other peer panel like that to render some conclusions.

So, when we think about validating, I would certainly discourage you from trying to do that inhouse. You don't seem too prepared to do a convincing job, and even if you thought you were, I don't think you can convince the people that need to be convinced.

MR. CAMERON: Mike, the independent third party would look at what? The ultimate conclusion that the NRC reached from looking at the models?

MR. BAUGHMAN: They might actually be asked to do the validation process.

MR. CAMERON: Okay.

MR. BAUGHMAN: It's a process of building confidence. Let the panel come together and cogitate on the models or whatever we're trying to establish some sense of comfort with and let them reach some sense of confidence.

MS. KOTRA: In the rule, we speak to peer review, and we have guidance on the street that probably needs to be at least we need to examine whether it needs to be updated, but we expect that DOE will provide that kind of peer review of its own work.

We have a role, but model validation for every one of DOE's models is not that role. Our role is to provide an oversight and a review of those elements of DOE's safety case that we believe are most important, and we are prepared and we do have the capability to do that, but we fully expect, as part of this process, that there will be peer review, and the extent to which it relies on the National Academy or other widelyrespected bodies to do that, I think we are not prescribing that, but we expect that that will happen.

MR. MURPHY: People shouldn't forget that that's one of the purposes of the licensing hearing process, too, is to test all of any applicant's license applicant's assumptions and theories, etcetera.

In a sense, the threetofouryear adjudicatory

process before the NRC is going to be a process of model validation, and everybody is going to have a chance to shoot at it.

MR. CAMERON: That's a good point, Mal.

MR. MURPHY: That's not to say that Mike's suggest for independent NAS review isn't that's a good idea.

MR. BAUGHMAN: My worry is, when we get in the licensing process, which will be heavily debated and contested, that's all going to be advocacy science. There's just no getting around it.

MR. CAMERON: Indeed, the suggestion you have may help to mitigate some of that.

Don.

MR. BECKMAN: Thank you.

Just a couple of data points in order to avoid perhaps an incorrect impression of where the project is headed on the subject of model validation.

We have recently undergone a couple of fairly substantial changes to our quality program and procedures to address some concerns that we're hearing around the table, to both better document what we're doing and its basis, the methods and bases, and to demonstrate the ways that we're attempting to improve the confidence, as Keith had mentioned, and included in that documentation, in each of the major analysis packages that we're preparing is an

intrinsic part of the analysis.

So, we're very sensitive to what you're saying, and we're increasing our efforts in that area to address the kinds of questions or concerns that you have. That's underway even as we speak.

MR. CAMERON: Okay. Thanks, Don.

Rex.

MR. MASSEY: I just want to clarify one thing on Mike's recommendation about going to an independent group to validate the models. That can be fine, but I understand that NRC has its own models and is working with DOE models, and I think that's an important part of the process, that they understand how the models work, and I wouldn't want to see NRC getting away from looking at those and handing that off to an independent group and relying upon an independent group.

I understand the mechanisms of the models is really vital for the NRC staff.

MR. CAMERON: Okay. I think that that point is well taken.

Anything else on implementation issues, or do you really need to see what's going to be in the acceptance criteria on this before you can really make any comment on it?

Just for the NRC, the acceptance criteria will not

be finalized until after the rule is finalized? Can you just tell us, Christiana, what the relationship is on some of these implementation issues?

MS. LUI: I do have one last slide on schedule and future activities. Maybe this is the right time to put that on. Or do you want me just to speak to it?

MR. CAMERON: Well, maybe it is the right time, because I think I'm not sure that there is a whole lot that else that people need to say. How's that?

Go ahead, Christiana.

MS. LUI: As the first line there indicates, the current schedule is to have the final rule and Rev. 0 of the Yucca Mountain review plan go to the Commission by March 31, 2000, and Rev. 0 of the Yucca Mountain review plan will only be focusing on the post closure safety issue.

We do have two other substantial sections that are currently under development. One part speaks to the preclosure safety issue. The other part speaks to the programmatic and administrative requirements. Those will be fully developed come Revision 1 of the Yucca Mountain review plan.

So currently the staff is working on both finalizing the rule and have a proposed as Janet has indicated, the Yucca Mountain review plan is a work in progress.

So, we will work right now, we are working in parallel with the development of the final rule for Revision 0 of the Yucca Mountain review plan, but once the final rule is in place, the future revision of the Yucca Mountain review plan will basically develop piece by piece to further implement what's in the final rule, and Rev. 1 is due out by the end of September 2000, and Rev. 2 currently is planned for a year after Rev. 1, and we will be formally inviting public comments on Revision 1 and Revision 2 of the Yucca Mountain review plan.

MR. CAMERON: Okay.

Before we go out to the audience, let me ask people around the table if there are concerns with or questions with this schedule, relationships between the rule and the review plan.

Let me ask this question. If the approach to multiple barriers was changed somewhat dramatically, whatever, from what's in the proposed rule, what would that do to your schedule on the review plan?

MS. LUI: In terms of Rev. 0, the Yucca Mountain review plan is going to reflect what goes into the final rule. Unless the Commission denies what the staff has proposed in the final rule, then the Yucca Mountain review plan is not really going to change.

However, the bottom line is, if there's going to

be any changes to the approach, our thinking on the multiple barriers is going to be reflected in the next iteration of the Yucca Mountain review plan.

MR. CAMERON: Okay. I just wanted people to know that we're not the NRC is not it's being locked into the review plan. It doesn't mean that the development of the draft final rule doesn't have room for change in terms of the multiple barrier concept.

Keith, do you want to add to that?

MR. McCONNELL: No, because I'm not sure exactly what the point is.

MR. CAMERON: Okay.

MR. MURPHY: If the final rule or if a new version of the rule changes too substantially the approach toward multiple barriers, you're going to have to put it back out for further notice and comment, and I would imagine the Yucca Mountain review plan and everything else will just have to be held in abeyance until that's done.

MR. McCONNELL: I would agree with Mal.

If we make major changes to what's in the proposed Part 63, then there is the distinct potential we'd have to go back out for public comment on those particular aspects, but I think that we are anxious to get some of the information that we're developing in the Yucca Mountain review plan out on the table so all the parties can look at

it.

So, we might still try to narrow the scope of what's in the review plan to the extent that you know, if they're still in contention as far as Part 63. Those might not be in the review plan, like multiple barriers, for example, but the rest of the information will be out there.

So, we do want to get the information out for public comment as soon as we can.

MR. CAMERON: Okay. Thank you.

Any other concerns or comments around the table on this?

Mike?

MR. BAUGHMAN: I don't know if this is the appropriate time, Chip. Maybe it comes under next steps, but you asked us to come here today, we came, we're sharing ideas. I would certainly hope that the final rule has room for revision. Otherwise, I feel like I wasted my time.

Second of all, I think we would all benefit as we go to leave here today perhaps hearing from you, from the staff, or perhaps DOE, you know, what did you hear today, and this is certainly nonobligatory on your part in terms of any commitment.

So, what did you hear today that has caused you to do some serious thinking?

MR. CAMERON: I think that's a real legitimate

point, and I was sort of stumbling with the idea that I don't want people to leave here and think that this was an empty exercise in terms of, well, we're locked into what's in that proposed rule and that's not going to change.

So, I think Mike did it much more succinctly than I did.

Keith, do you want to give us an impression?

MR. McCONNELL: I want to kind of preface my remarks first.

I think that what we're not trying to do here is reopen the public comment period for Part 63. I think what we heard here today is probably very close to what we heard in the public comment period anyway.

So, for that respect, we're basically here to, I think, improve what we heard or what we've done in the proposed rule.

What I heard is that the staff still has not, even in what we presented today, gone sufficiently forward in communicating what we expect as far as performance from individual barriers and how that will ensure that the overall system performance objective, as Mal has pointed out, would be met, and how important that is in demonstrating that the overall system performance objective is met.

MR. MURPHY: Let me just follow up on that for

just a second.

I think we can't lose sight of the ultimate test for licensing, and that is the reasonable assurance standard.

However you phrase this, whatever we say here today, the Commission is going to have to arrive at a decision with respect to whether or not they have a reasonable assurance that whatever the standard is, the overall system performance standard, whether it's 15 millirem, 25 millirem, you know, the maximum contaminant levels in a ground water standard, whatever they have to be reasonably assured that they're going to meet it.

Hypothetically and this is a vast oversimplification, but hypothetically, if the department were going to come in with a TSPA that shows 2percent reliance on the natural geology at Yucca Mountain and 98percent reliance on engineered barriers, some of which and some of that reliance of which relies only on 22 years worth of testing on C22 or whatever it is, it seems to me there would be some strong arguments that the Commission cannot feel reasonably assured that this mountain is going to produce compliance with an overall system performance standard under those conditions.

So, you know, in that sense, there is always an ultimate multiple barrier requirement, you know, that sort

of adheres in however you express the rule, and that is you've got to be reasonably assured that there are going to be two contributing, or more than, multiple contributing barriers so that that comfort level, that reasonable assurance can ultimately be arrived at, and you know, one barrier producing 90, 95, 98 percent of the isolation seems to me does not in my mind, at least, it doesn't produce reasonable assurance, and I would expect the Commission would probably arrive at the same conclusion. I would hope so, anyway.

MR. CAMERON: I guess it might depend which barrier it was.

Judy.

MS. TREICKEL: It seems to me that you're probably going to miss that first date with the final rule anyway, because you've got to comply with EPA, and I think their target date is right around that time.

So, there is going to be some compliance stuff going on, and I don't know if it's just the writing of the numbers or what would be entailed in complying, but it looks to me like well, I don't know. There are so many cart and horse things going on in this whole process.

I guess I feel more comfortable when things are in stone that have to do with regulating this program before the program goes ahead.

So, I would like to see a review plan and see how that works.

MR. CAMERON: Okay. Thanks, Judy.

Janet, do you want to clarify the EPA issue?

MS. KOTRA: I also wanted to address Mike's comment.

MR. CAMERON: Yeah, I think we need to address that a little bit more.

MS. KOTRA: With regard to the EPA, the last I had heard was that they are on target for an August 2000 final. The directions that we are operating on in the NRC staff is that we have a deadline to produce a package for the Commission, and as I understand it, if the Commission votes to move forward with a final rule, the intent is that, when a final EPA standard is issued, then there will be a conforming rulemaking that will make conform it to the EPA standard, recognizing that there are large portions of Part 63 that are really unaffected by the EPA standard, that we want to get out there and in place with regard to, you know, requirements for retrievability, quality assurance, preclosure activities, all the types of things that our regulations are required to address that are not EPA's purview.

That's what I wanted to add. So, from a tiny point of view, if a conforming rulemaking is necessary, the

Commission is prepared to do that.

On Mike's question, I did want to say that, as one of the rule writers here not rulemaker, that's the Commission, but as one of the rule writers, I have found this session to be extremely valuable.

I think I come away with a great deal of deeper understanding behind the written comments that we've received.

All of the stakeholder groups that I see represented here at the table and in the audience have issued comments. We've been studying those comments.

I think this meeting has helped me focus what are some reasonable options to put forward to the decisionmakers about how to make real the multiple barrier requirements.

I think Keith is correct. I think we need to do a better job in making clear what the Commission expects, and I think one of the things I'm taking back with me is the need to generate inhouse options that address that. But I certainly feel that this type of dialogue has been extremely important.

Keith is correct this is not an extra public comment period. It is a way to help us make more clear what we've put out in our proposal and to understand better the comments that we've received, and we are, by law, required to address in issuing a final.

So, I'd thank all of the participants, because I think that this is a very important part of our rulemaking process.

MR. CAMERON: Okay. Thank you for adding that, Janet.

Let's go to Rick, and then we'll go to Mike and Mal.

Rick?

MR. CRAUN: I just wanted to add, I think from the standpoint of the transition from 60 to 63, again, it's important that the licensee be given the opportunity to identify clearly what's important, and that's kind of the basis of 63.

In doing that, in identifying what's important, what I haven't really heard is a lot of discussion on the fact that not only those barriers that we feel are principle but all of the barriers will be addressed in the overall assessment of TSPA in how we identify each of the roles, and I think it's important that we remember we're not just going to look at one or two of the principle barriers, we're going to look at all of the barriers that are involved and credited, and I think that system approach is a much more complete way of looking at it and will identify why, in that process, we need to identify the basis for giving credit to certain barriers and which barriers that we will be relying

on, and as we go down this process, I think it would be we need to kind of maintain that focus of letting the DOE define via the TSPA and the riskinformed basis why we want to rely on certain barriers and how we want to do that, and I think, as we start identifying subsystem requirements, or if we go in that direction, I think that's counterproductive to where we are now with the current regulation.

MR. CAMERON: Okay.

Mike?

MR. BAUGHMAN: I guess I'd just in reaction to the March 31st that was cast as a deadline on the Commission. Is that selfimposed? Is it a legal deadline?

MS. KOTRA: It is the deadline the Commission has put on the NRC staff.

MR. BAUGHMAN: Okay. So, it's a discretionary deadline.

I would suggest that you might want to consider that if, on March 31st, or soon thereafter, the Commission votes to adopt a proposed standard which is a lower threshold than the pending EPA standard, which is well traveled, out on the streets, the public's very aware of it, and generally, I think, you know, those that are predisposed to be opposed to the repository, you know, or just showing concern about public health and safety, are saying, hey, EPA's standard looks a lot better than NRC's standard, if

you adopt the NRC standard, as proposed, I worry about what message does that send to the public, then, about how you really feel about the EPA standard which you will then just go through the motions to conform yourselves to, and will you really, as a regulatory agency, you know, enforce that? I mean, obviously, you'll have to, but I'm just not sure the public's going to feel real good about the fact that the NRC kind of thumbed their nose, in a sense.

What's the hurry? I would suggest you consider waiting. Let the EPA standard issue be resolved and then have the Commission take it up.

MR. CAMERON: Okay. Thank you for that caution, and I think that's on a lot of people's minds.

Janet, go ahead.

MS. KOTRA: The Commission, from the beginning, has stated that it will comply with and implement final EPA standards, as the law requires, and I am acutely aware, particularly after attending all of EPA's public hearings on its standard, the breadth and the depth of the feeling about this very public disagreement between the two agencies.

I think that the best I can say as a member of the Commission staff is that and we obviously are not the decisionmakers; we work for the Commissioners who are appointed by the President that they are very sincere in their commitment to carry out those responsibilities, but

part of the process of EPA issuing final standards is to collect comment, and we are a commenting agency, and until those standards are final, we are expressing as an agency our considered opinion on what is necessary for protection of public health and safety.

The Commissioners are about to issue their comments on EPA's proposal, and they're participating in the process, as they also feel obligated to do, but at the end of the day, when there is a final EPA standard in place, as is required by law, the Commission is also very sincere in carrying that out, and I think that what I hear you saying is that one way that they could demonstrate that sincerity would be to hold in abeyance.

MR. BAUGHMAN: There's no reason to adopt the regulation in March.

MS. KOTRA: And that comment, as well as all of the other very fine comments that we've heard today, will be carried back.

MR. CAMERON: Okay. Thank you, Janet.

Mal.

MR. MURPHY: I logically am compelled to agree with Mike but with a cautionary word, though, that the EPA is not the international model for perfunctory rulemaking. I mean, you know, we could wait 10 years before they finalize their standard.

I say this only partly in jest, but why not you know, it seems to me there might be two approaches. One is to adopt two alternative standards, adopt 15 millirem as an individual protection requirement, with a proviso that, if the EPA final standard is different, then it supersedes the 15 millirems and becomes whatever the EPA says.

I don't know whether, as a matter of Federal drafting requirements and guidelines, etcetera, we at the state level, we do that all the time. I mean states constantly adopt regulations and refer and adopt by reference Federal regulations, and if the Federal regulation changes and goes up a tick or down a tick, it's automatically picked up by the state regulations. I don't know whether your General Counsel's office will let you do that or not, Chip.

But the other alternative, Janet, is just to adopt 15millirem, and if the EPA comes in later with 25, then you maybe have to change it.

MR. CAMERON: Could even go to 10.

MR. MURPHY: Plus the 4millirem maximum contaminant levels for ground water, sure. Why not just adopt them, and then, if the EPA goes your direction later on, well, then, you might have to change. Just a suggestion.

MR. CAMERON: Okay. Thanks a lot, Mal.

There are some problems with the Office of Federal Register in terms of trying to

MR. MURPHY: Have them give me a call.

MR. CAMERON: adopt and I will tell them.

Claudia, do you still have your phone?

Okay. Let's go out in the audience.

I think, Sally, didn't you want to ask a question.

MS. DEVLIN: I'm Sally Devlin from Nye County, Nevada, and I'm so delighted to be here except that this meeting should be in Pahrump.

It should be in Nye County, and of course, nobody wants to go to Nye County, and I can't blame them because of all our problems. I hope everybody's been reading about them.

But what my distress is and I have to say it to Janet and to the rest of you is you're talking about standards of EPA of 15 millirems over background, or 25 millirems, and yet you'll allow workers 5,000 millirems.

Now, this blows my mind. Where's Bill Vasconi to stand here for workers? He's not here today, but you've heard him many times.

How can you do something little like that when you don't even know? And I brought cancer studies with me, because I've been trained in radiobiology, to say that nobody knows why I was at Hiroshima and I'm dead and you

were in Hiroshima and you're alive.

This is such an arbitrary thing, and as I mentioned at the meeting up in Beatty, when you were kind enough to come, and insulted the people from Amargosa, calling them strange people of strange habits, which was in the Federal Register, that was not kind, and they're very disturbed about it. You better get some answers in there.

If the tortoises could talk from Death Valley, they might say something, too, but anyway, what I'm saying is these things are so arbitrary, and these things are very serious.

We have discussed how many times the measurements in the air, that the processes that are now in place are not working, they're not efficient, they're not anything.

You've got to get the halfapicocurie of plutonium measured, and where it is, or the twoandahalf picocurie per gram, or the 500 picocuries that's up at Plutonium Hill, and I'm looking around me, and I always ask a question, because I see so many new faces, it's delightful.

How many of you have been out to Yucca Mountain? Anybody raise hands? How many of you have been out there? How many have been out there for any length of time outside of a tour? How many have been out there when it was 120 degrees with a wind storm of 125?

All right. Then you know what I'm talking about

when I talk about the desert. The public doesn't know this. It is not in your reports. The public doesn't understand what goes on. The public doesn't understand what a picocurie is.

And I'm looking at your thing here, participant discussion. I heard the term and I'm going to get on your case, Christiana, because you put it up there, and that is you said the representative system is sufficiently robust to account for imperfect knowledge.

I'll give you my favorite that they heard me say a dozen times, from Lake Barrett, my arch enemy. Assumed uncertainty, questions that can be answered given the context of the moment. I finally, after all these years, got a definition.

Now, you're hearing what you're saying to the public. I will not accept assumed uncertainty. I will not accept questionable knowledge.

We're talking about the NAS a minute ago. The NAS, according to the Federal Register, doesn't even want public comment. What is the NAS? They're a bunch of egghead professors, in my opinion, and I deal with these professors all the time, because I'm a perpetual student, and it bothers me that they don't want the public to question them.

I'm sorry, but these are very negative things.

But they have to be said. We cannot have assumed uncertainties. We have to get better cancer studies.

You're going to allow workers to get 5,000 millirems; you're going to allow people 15 or 25. What's the difference? It does not interpret for the individual who is going to get it.

The carbon24 that is in the Federal Register is going to mutate children or fetuses and kill them and look at the numbers. Four out of 100 that's not allowed.

We've talked about the misrepresentation of NCI and their reports, when I keep telling you we don't have email, we don't have computers, we don't have the web in Nye County and in half the cow counties.

I was just was with a marketing man. We're a CD. That means nobody wants to come to our counties because we don't have a decent place for them to meet, and this is very true, so that we're the ones that are affected.

My home is 50 miles from Yucca Mountain, and you talk about the 12mile or 25 kilometers for retrievable storage, and I don't even know where it begins or end. I've never even seen a map in any of your publications.

Now, I've read 16 pounds of VA, I've read 14 pounds of EIS, I just read 5 pounds of EPA, and you've sent me a million things, and I've read them, and I've tried to digest them, and what they say to me is there's no

intracommunication between agencies, nobody says, hey, let's think this out and let's think this through.

There's a bunch of people and look around. Where's the public? Here. Most of the people that are here are paid.

Grant and I are not paid. We've never taken a nickel, and we're very serious about this, because the people of Nye County don't realize that this is a death threat and that you're programming us to extinction, and I put it just in those very serious terms, because I do not feel that this is just a ladeeda thing. This is life and death.

I've been screaming about transportation for years, I've been screaming about radiation poisoning, and I've been screaming about a few dozen other things.

Now, the most important thing is how do you get to the public?

The first thing you do is you write those reports in English, not in DOEese or EPAese or NRCese. The language. What is there? Twentythree pages of glossary in the back of this 14pounder. This is ridiculous. You're talking to the people who are going to be affected in the next generation.

Now, I'll give you another example I have in my little thing that I'm giving to Chris and that is regarding

your attitude towards Hanford and giving a $1.7 billion contract to FluorDaniels, and FluorDaniels is saying we don't know how we're going to get the fuel rods out of the water because it's too dangerous and so on, so you give them 40 years to do it.

On the closing of the repositories, you've given them 60 years and can extend it.

Now, what does that tell the public, who can read, a few of us. It tells the public that you're not sure about anything. Give them three generations, give them two generations, but that's the way I look at it.

My greatgrandchildren can die from 1 picocurie of plutonium in the air or of carbon14 or of whatever, strontium.

It's in my report that Chris is getting, how this stuff affects people, so that my plea is, for goodness sake, write in English, talk in English, and don't give me any of this assumed uncertainty. We will not tolerate it.

You are spending a million dollars a day on Yucca Mountain and a million dollars a day on the test site and a million there and a million here. You're in litigation on the nuclear power money. All this stuff is just ladeeda. Are you responsible or are you not, to the public?

The Congress passed what is it? results management, and the people are the regulators. Have you

heard of this? Do you know what it means.

You're smiling, Dan.

The people haven't assumed or asserted themselves in this.

MR. CAMERON: Can I ask you just to wrap up?

MS. DEVLIN: I'll be glad to wrap up.

I'm talking particularly to Rick. He knows me well, and he knows I'm very serious about this, because the more I read, the more horrified I get, and if you want to program us to extinction, you're doing a good job. If you want to program us to enviroworld economics, you're failing miserably, but that's what's going to happen.

We have a choice here, and we're not getting it because of your bureaucratic attitudes, your lack of communication, and all the rest of it, and I will put that in writing, and I hope I get some comment from it, because it's not real.

MR. CAMERON: Okay. Thank you again, Sally.

Do we have other comments? I know Grant wants to say something. Anybody who hasn't had an opportunity to say something about the multiple barrier issue, anybody that we haven't heard from who wants to speak?

Grant?

MR. HUDLOW: Thank you. I'm Grant Hudlow.

I'd like to point out that Rick mentioned that we

need to get a peer review from the NAS, and we are, to some degrees. That's what the NWTRB is supposed to be, but that's far short of a any kind of a reasonable review of a worldclass project.

In an industrial setting, not utilities, like the power companies, the power companies, after deregulation, may turn into industrial.

We see that with the phone company. They've taken longdistance calls from 25 cents a minute down to 7 cents a minute, because they were deregulated and they quit having to play footsie with the government and get some results and put some competition in there.

As we see that with the power companies, we'll see something similar. I can buy power right now for my plants at 2 cents a kilowatt hour. Everybody else pays 5 or 10 cents a kilowatt hour. I have some economic clout with them. The public doesn't.

The other people that can buy power for 2 cents are people that band together into a coop, people that do their own generation, people that get in with some bureaucrats in the Bureau of Reclamation with some of the power that comes out of the hydroplants, the dams and so forth.

But you can't do it up front until there's somebody with industrial experience that takes on this kind

of project, and of course people with industrial experience check with the various professors, but they're certainly far from the last word.

You have another problem in this. There's no way to make money off of the waste other than to charge somebody it's a tax sink or a sinkhole for tax dollars. It's not a moneymaking operation.

If you put this on the basis of somebody has to use that waste, make something useful out of it, make some money out of it, then all of this monkey business goes away. You don't have bureaucrats pontificating about stuff that they don't know anything about it at all.

The reason that I've been talking about the Nelson limits and asked Keith to look them up, the reason I asked for the NRC and the DOE to come up with the test results at Los Alamos for the radiation limit delay, the reason I asked for the NRC and the DOE to come up with the description of the casks that split open in Wisconsin recently, where they got with those, is because there isn't anybody so far in the DOE that even knows what I'm talking about.

Keith is the first one that's dug into it and started to get some of the basic fundamental knowledge of how this stuff works.

Keith got the first step about it's about 90yearold technology that he got ahold of for the Nelson

limits.

When you get up to the early '50s on what the Nelson limits were used for, you're going to find that there is a material that will hold this very dangerous, nasty stuff it's hot and so froth for 20 years, for sure, that I know of, and if some of those plants are still in operation, it will hold it for 40 years, with absolutely no damage, but in not having that knowledge, the kinds of things that have been proposed, put trial balloons up, are totally inadequate.

They're telling me there is nobody in the DOE or anybody in the NWTRB or anybody in any of the M&Os that has a clue about the technology they need to know to contain this stuff.

That's a fatal flaw, and it's legally defensible. You're talking about fraud, and you're talking about fraud because of color of office. These are serious charges.

This is not, as Sally says, ladeeda bureaucratic nonsense, and I need you to take that back to the NRC and get to work and get the DOE to work so you end up with some competent people on this project.

MR. CAMERON: Okay. Thank you very much, Grant.

I would just like to thank everybody who came to the meeting and just echo what Dr. Kotra said about what the NRC heard and the value of the meeting, and I guess, with

that, we will

Judy, go ahead.

MS. TREICKEL: I want to thank you for being sensitive to our time schedules and working so hard.

Christiana, I think that was you, because we had real problems with setting a date, and when you've got that word up there, "continued dialogue," I won't use the word "stakeholder," and I don't want you to use it again either, but if meetings are to continue, just be advised that here we are inundated and our calendars are absolutely full.

MS. LUI: I understand that. That's why, before we set a date for this meeting, I tried to contact most of the people who commented.

MS. TREICKEL: I really appreciate that.

MR. CAMERON: Okay. Thank you, Christiana, for that, and we should thank Judy Goodwin, who helped us with all the details of the meeting from the NRC staff. Thank you very much.

[Applause.]

[Whereupon, at 5:20 p.m., the meeting was concluded.]

REPORTER'S CERTIFICATE

This is to certify that the attached proceedings before the United States Nuclear Regulatory Commission in the matter of:

NAME OF PROCEEDING: PUBLIC MEETING - A FACILITATED ROUND TABLE DISCUSSION ON DEFENSE IN DEPTH AS APPLIED TO A POSSIBLE HIGH-LEVEL WASTE REPOSITORY AT YUCCA MOUNTAIN, NEVADA

CASE NUMBER:

PLACE OF PROCEEDING: Las Vegas, NV

were held as herein appears, and that this is the original transcript thereof for the file of the United States Nuclear Regulatory Commission taken by me and thereafter reduced to typewriting by me or under the direction of the court reporting company, and that the transcript is a true and accurate record of the foregoing proceedings.

Audrey Johnson

Official Reporter

Ann Riley & Associates, Ltd.

November 2, 1999

FINAL AGENDA

ROUND TABLE DISCUSSION ON DEFENSE IN DEPTH AS APPLIED TO A POSSIBLE HIGH-LEVEL WASTE REPOSITORY AT YUCCA MOUNTAIN, NEVADA

1:30 p.m. Welcome, Ground Rules, Agenda Overview and Participant Introduction
Francis "Chip" Cameron, Facilitator

1:50 p.m. Meeting Overview and Purpose
Keith McConnell, Section Chief
Performance Assessment and Integration Section
High-Level Waste and Performance Assessment Branch

1. Purpose of this meeting
2. Statutory requirement on repository defense in depth
3. Commission policy on defense in depth and the risk-informed and performance-based regulatory approach
4. Clarifying Questions
   - Participant discussion
   - Audience comments

2:10 p.m. NRC's Current Thinking on Repository Defense in Depth
Christiana Lui, Systems Performance Analyst
Performance Assessment and Integration Section
High-Level Waste and Performance Assessment Branch

1. Public comments summary
2. NRC's clarification on
   - Intent of the multiple barriers
   - Regulatory requirements
   - Compliance demonstration
3. Clarifying Questions
   - Participant discussion
   - Audience comments

2:30 p.m. Round Table Discussion on Issues Associated with Repository Defense in Depth

1. What is the best way to achieve repository defense in depth?
   - Participant discussion
   - Audience comments
2. How best to implement the performance-based approach for multiple barrier demonstration?
   - Participant discussion
   - Observer comments

4:30 p.m. Summary and Next Steps

- Summary of round table discussion
  Francis "Chip" Cameron, Facilitator
- Schedule and future activities
  Christiana Lui, NRC

5:00 p.m. Adjourn

federal register

Monday
February 22, 1999

Part II

Nuclear Regulatory Commission

10 CFR Part 19 et al.

Disposal of High-Level Radioactive Wastes in a Proposed Geological Repository at Yucca Mountain, Nevada; Proposed Rule

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 2, 19, 20, 21, 30, 40, 51, 60, 61, and 63

RIN 3150–AG04

Disposal of High-Level Radioactive Wastes in a Proposed Geologic Repository at Yucca Mountain, Nevada

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is proposing licensing criteria for disposal of spent nuclear fuel and high-level radioactive wastes in the proposed geologic repository at Yucca Mountain, Nevada. These criteria will address the performance of the repository system at Yucca Mountain, a system that must comprise both natural and engineered barriers. The proposed requirements are designed to implement a health-based, safety objective for long-term repository performance that is fully protective of the public health and safety, and the environment, and is consistent with national and international recommendations for radiation protection standards. Also included are licensing procedures, criteria for public participation, records and reporting, monitoring and testing programs, performance confirmation, quality assurance, personnel training and certification, and emergency planning. The proposed criteria will apply specifically and exclusively to the proposed repository at Yucca Mountain. Consistent with this intent, the Commission proposes to modify its generic criteria for disposal of spent nuclear fuel and high-level radioactive wastes in geologic repositories at 10 CFR Part 60 to make clear that they do not apply, nor may they be the subject of litigation, in any NRC licensing proceeding for a repository at Yucca Mountain.

DATES: Submit comments by May 30, 1999. Comments received after this date will be considered if it is practical to do so, but the NRC is able to assure consideration only for comments received on or before this date.

ADDRESSES: Comments may be sent by mail to the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemakings and Adjudications Staff.

Hand deliver comments to 11555 Rockville Pike, Rockville, Maryland, between 7:30 am and 4:15 pm on Federal workdays.

You may also provide comments via the NRC's interactive rulemaking web site through the NRC home page (http://www.nrc.gov). This site provides the availability to upload comments as files (any format), if your web browser supports that function. For information about the interactive rulemaking site, contact Ms. Carol Gallagher (301) 415–5905; e-mail CAG@nrc.gov.

Certain documents related to this rulemaking, including comments received and the regulatory analysis, may be examined at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC. These same documents also may be viewed and downloaded electronically via the interactive rulemaking website established by NRC for this rulemaking.

FOR FURTHER INFORMATION CONTACT: Timothy McCartin, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone (301) 415–6681; e-mail tjm3@nrc.gov, or Clark Prichard, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone (301) 415–6203; e-mail cwp@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The Nuclear Waste Policy Act of 1982 (NWPA, Public Law 97–425) directed NRC to develop technical criteria for high-level radioactive waste (HLW) disposal, in mined geologic repositories, that: provide for the use of a system of multiple barriers; include restrictions on retrievability, as the Commission deems appropriate; and are not inconsistent with environmental standards promulgated by the Environmental Protection Agency (EPA) pursuant to the NWPA. Existing NRC regulations at 10 CFR Part 60 contain generic criteria governing the licensing of the Department of Energy (DOE) to receive and possess source, special nuclear, and byproduct material at a geologic repository that is sited, constructed, and operated in accordance with NWPA. Procedural requirements at Part 60 were promulgated in 1981 (46 FR 13971; February 25, 1981), and technical criteria were promulgated in 1983 (48 FR 28194; June 21, 1983). These technical criteria were amended in 1985 to add specific criteria for disposal in the unsaturated zone (50 FR 29641; July 22, 1985). Procedural amendments reflecting the passage of the NWPA were published in 1986 (51 FR 27158; July 30, 1986), and procedures for implementation of the National Environmental Policy Act with respect to geologic repositories for HLW were added in 1989 (54 FR 27864; July 3, 1989). In 1996, NRC amended Part 60 to update generic criteria for preclosure activities at repository sites (61 FR 64267; December 4, 1996), incorporating changes that sought, in part, to achieve greater consistency between those criteria and the NRC's licensing requirements for independent storage of spent fuel and HLW at 10 CFR Part 72.

The technical criteria at Part 60 were promulgated initially, in 1983, on the assumption that EPA would issue standards limiting cumulative radionuclide releases from a geologic repository. In 1985, some 2 years after Part 60 was published, EPA issued final standards at 40 CFR Part 191, which contained not only cumulative release limits but also provided criteria for individual and ground-water protection, that had not been included in EPA's rulemaking proposal. In 1986, NRC proposed "conforming amendments" to incorporate the EPA standards into NRC's regulations (51 FR 22288; June 19, 1986). The proposed amendments were abandoned in 1987 when EPA's standards were vacated by the U.S. Court of Appeals. Also, in 1987, Congress amended NWPA, redirecting the national waste program to focus exclusively on the characterization of the Yucca Mountain site as a potential geologic repository.

During the more than 15 years since the initial technical criteria at 10 CFR

Part 60 were promulgated, there has been considerable evolution in the capability of technical methods for assessing the performance of a geologic repository at Yucca Mountain ("TPA 3.1-Sensitivity and Uncertainty Analyses," NUREG/CR-5549, in publication; "Total System Performance Assessment—1995: An Evaluation of the Potential Yucca Mountain Repository," DOE, 1995). These changes allow for the use of more effective and efficient methods of analysis for evaluating conditions at Yucca Mountain than do NRC's existing generic criteria. These new methods were not envisioned when the Part 60 criteria were established, and their implementation for Yucca Mountain will avoid the imposition of unnecessary, ambiguous, or potentially conflicting criteria that could result from the application of some of the Commission's generic requirements at 10 CFR Part 60.

In 1992, Congress directed EPA, at Section 801 of the Energy Policy Act of 1992, Public Law 102-486 (EnPA), to contract with the National Academy of Sciences (NAS) to advise EPA on the appropriate technical basis for public health and safety standards governing the Yucca Mountain repository. On August 1, 1995, the NAS Committee on Technical Bases for Yucca Mountain Standards issued its report, "Technical Bases for Yucca Mountain Standards." In its report, NAS recommended an approach and content that is significantly different from that adopted by EPA for its disposal standards at 40 CFR 191 (no longer applicable to sites characterized under Section 113(a) of NWPA), as well as from that adopted by NRC for its existing generic regulations at Part 60.

EPA is obligated, under EnPA, to issue final public health and safety standards for Yucca Mountain that "prescribe the maximum annual effective dose equivalent to individual members of the public" and that are "based upon and consistent with" the NAS findings and recommendations. According to EnPA, EPA's new health-based disposal standards "* * * shall be the only such standards applicable to the Yucca Mountain site." After establishment of final EPA standards, NRC, under EnPA, has 1 year to modify its technical requirements and criteria under Section 121(b) of the NWPA (i.e., the current Part 60 criteria) to be consistent with new EPA standards, and also to implement certain assumptions that are specified in the EnPA with regard to the effectiveness of postclosure oversight of the repository, to the extent consistent with the NAS report. Following repository closure, EnPA requires that DOE continue its oversight of the Yucca Mountain site to "prevent any activity at the site that poses an unreasonable risk of—(1) breaching the repository's engineered or geologic barriers; or (2) increasing the exposure of individual members of the public to radiation beyond allowable limits." NRC's requirements and criteria are to assume, consistent with the findings and recommendations of NAS, that such oversight will be effective.

Because NRC must carry out a rulemaking to modify its requirements for geologic repository disposal within a very short period of time following EPA publication of final standards for Yucca Mountain, the Commission believes it must undertake its own rulemaking development in parallel with development of EPA's standards. Following publication of the NAS report, NRC staff met frequently with EPA staff to discuss the report and associated issues relating to development of new EPA standards and NRC regulations. NRC is continuing to work with EPA in the development of reasonable and implementable standards for Yucca Mountain that are protective of public health and safety. The Commission believes, as noted below, that it is in the best interest of the national program to proceed with promulgation of its implementing regulations. It is recognized that when EPA issues its final standards, or if new legislation affecting the regulation of the Nation's HLW program is enacted into law, these proposed regulations may need to be amended.

At the same time, the DOE program for characterizing the Yucca Mountain site as a potential geologic repository is continuing. A viability assessment of the site was completed in December 1998. Further, it is expected that DOE will publish a draft environmental impact statement (EIS) in 1999, with a final EIS to be completed in 2000, such that a site suitability recommendation can be made in 2001. Assuming that the Yucca Mountain site can be recommended for development as a geologic repository, DOE would then submit a license application to NRC in 2002.

In order for DOE to commence preparation of a license application and to permit timely and significant public involvement in the development of implementing regulations, the Commission believes it has an obligation to make public now how it would implement dose- or risk-based standards for Yucca Mountain.

As part of its broader efforts to improve the effectiveness of its programs and processes, the Commission has a study of the NRC hearing process underway which includes the process that would be used for repository licensing. If, on the basis of this study, the Commission concludes that changes to the hearing process are warranted, it will propose them for adoption in a separate notice and comment rulemaking. In this rulemaking, the Commission is not seeking comment on potential changes to the hearing process. However, in the interest of openness, the Commission wishes to say that, at present, the Commission is inclined to provide for informal hearings for both construction authorization and licensing to receive and possess waste. No statute requires formal hearings in either case; EPA conducted none in certifying the Waste Isolation Pilot Project; and informal hearings allow for both greater efficiency and greater openness.

II. NAS Conclusions and Recommendations for Yucca Mountain

Pursuant to Section 801(a)(2) of EnPA, the NAS was directed to provide recommendations on reasonable standards for a repository at Yucca Mountain that address the following three issues:

(A) Whether a health-based standard, based on doses to individual members of the public, from releases to the accessible environment, will provide a reasonable standard for protection of the health and safety of the general public;

(B) Whether it is reasonable to assume that a system for postclosure oversight of the repository can be developed, based on active institutional controls, that will prevent an unreasonable risk of breaching the repository's engineered or geologic barriers or increasing the exposure of individual members of the public to radiation beyond allowable limits; and

(C) Whether it is possible to make scientifically supportable predictions of the probability that the repository's engineered or geologic barriers will be breached as a result of human intrusion, over a period of 10,000 years.

On August 1, 1995, NAS published its report entitled "Technical Bases for Yucca Mountain Standards." The report was prepared by a committee organized under the auspices of the National Research Council, which is jointly managed by the National Academy of Sciences and the National Academy of Engineering. The committee, consisting of 15 members representing engineering, geoscience, environmental, and risk disciplines, deliberated for more than 2 years, holding five public sessions in Las Vegas, Nevada, and Washington, DC, between May 1993 and April 1994.

With regard to the three questions posed in the EnPA, the NAS made the following findings:

(A) That an individual protection standard, expressed as a limit on individual risk rather than dose, would provide a reasonable basis for protecting the health and safety of the general public provided that the policy makers and the public are prepared to accept that very low radiation doses pose a negligibly small risk. Further, NAS found that such a standard would be particularly appropriate for the Yucca Mountain site in light of the characteristics of the site.

(B) That it is not reasonable to assume that a system for post-closure oversight of the repository can be developed, based on active institutional controls, that will prevent an unreasonable risk of breaching the repository's engineered barriers or increasing the exposure of individual members of the public to radiation beyond allowable limits.

(C) That it is not possible to make scientifically supportable predictions of the probability that a repository's engineered or geologic barriers will be breached as a result of human intrusion over a period of 10,000 years.

The specific conclusions and recommendations delineated in the Executive Summary of the NAS report (pp. 1 through 14) were:

(1) The standard should set "* * *a limit on the risk to individuals of adverse health effects from releases from the repository." NAS explicitly recommended against quantitative release limits because they provide no additional protection relative to that provided by an individual risk limit. NAS declined to assign the appropriate level of risk, and stated that it views the determination of this level as a crucial policy judgment that should be addressed in a transparent rulemaking process. As a starting point in such a process, NAS suggested that consideration be given to risk levels comparable to those recommended by the International Commission on Radiological Protection (ICRP) (100 mrem/yr (1 mSv/yr) maximum individual dose from all sources, with 10–30 mrem/yr (0.1–0.3 mSv/yr) allocated for high-level waste disposal) (p. 4).

(2) For specifying the individual or individuals for whom the risk calculation is to be made, the NAS recommended that the critical-group approach, as defined by ICRP and modified for individual risk, should be used. The ICRP notes that the critical group concept is intended to ensure that no individual doses are unacceptably high, since the critical group represents the extreme of the dose distribution to the entire population. The critical group risk calculated for comparison with the risk limit established in the standard, according to NAS, should be the mean of the risks to the members of a group whose location and habits are such that they are representative of those individuals expected to receive the highest doses as a result of the discharges of radionuclides. For releases expected to occur in the far future, it will be necessary to define a hypothetical group of individuals by making assumptions about lifestyle, location, eating habits, and other factors. NAS cited the ICRP recommendation that present knowledge and cautious, but reasonable, assumptions be used in defining this group of individuals (pp. 5–6).

(3) NAS recommended that compliance assessment should be conducted over a time frame that includes the period where greatest risk occurs. NAS found there to be no scientific basis for limiting the time period of an individual-risk standard (pp. 6–7).

(4) In response to issue (A) specified at Section 801(a)(2) of EnPA, NAS concluded that "* * * an individual-risk standard would protect public health, given the particular characteristics of the [Yucca Mountain] site, provided that policy makers and the public are prepared to accept that very low radiation doses pose a negligibly small risk." As a suitable starting point for a determination of negligible individual risk, NAS suggested that consideration should be given to the risk equivalent of 1 mrem per year (0.01 mSv per year) as recommended by the National Council on Radiation Protection (pp. 7–8).

(5) NAS concluded that physical and geologic processes affecting Yucca Mountain "* * * are sufficiently quantifiable and the associated uncertainties sufficiently boundable such that performance can be assessed over time frames during which the geological system is relatively stable or varies in a boundable manner." According to NAS, the geologic record suggests this time frame is on the order of a million years (p. 9).

(6) NAS concluded that it is not possible to predict on the basis of scientific analyses the societal factors necessary to define exposure scenarios, and that specification of such scenarios is a policy judgment best accomplished through a public rulemaking process (pp. 9–10).

(7) In response to issue (B) as specified at Section 801(a)(2) of EnPA, NAS concluded that "* * * it is not reasonable to assume that a system for postclosure oversight, based on active institutional controls, can be developed that will prevent an unreasonable risk of breaching the repository's engineered barriers or increasing the exposure of individual members of the public to radiation beyond allowable limits." Despite its conclusion that there exists no scientific basis for judging whether such controls can prevent an unreasonable risk of intrusion, NAS, nonetheless, asserts that "a collection of prescriptive requirements, including active institutional controls, record-keeping, and passive barriers and markers, would help to reduce the risk of human intrusion, at least in the near term" (p. 11).

(8) With regard to issue (C) as specified at Section 801(a)(2) of EnPA, NAS concluded that it is not possible to make scientifically supportable predictions of the probability that the repository's engineered or geologic barriers will be breached as a result of human intrusion over a period of 10,000 years. Because NAS could not find it technically feasible to assess the probability of intrusion into a repository over the long term, NAS concluded that it is not scientifically justified to incorporate alternative scenarios of human intrusion into a fully risk-based compliance assessment (p. 11).

(9) In order to assess whether the repository's performance would be substantially degraded as a consequence of a postulated intrusion, NAS considered a "stylized intrusion scenario consisting of one borehole of a specified diameter drilled from the surface through a canister of waste to the underlying aquifer." NAS recommended that "the estimated risk calculated from the assumption of such an assumed scenario be no greater than the risk limit adopted for the undisturbed-repository case because a repository that is suitable for safe long-term disposal should be able to continue to provide acceptable waste isolation after some type of intrusion" (p. 12).

(10) NAS concluded that "there is no scientific basis for incorporating the ALARA [as low as is reasonably achievable] principle into the EPA standard or USNRC regulations for the repository" (p. 13).

(11) NAS concluded that "because it is the performance of the total system in light of the risk-based standard that is crucial, imposing subsystem performance requirements might result in suboptimal design." This conclusion was directed specifically to NRC, in the context of revisions NRC will need to make to its regulations in order to be consistent with a new risk-based EPA

standard for Yucca Mountain. NRC's existing generic regulations at 10 CFR Part 60 currently contain quantitative limits on the performance of specific subsystems such as those cautioned against by NAS.

III. Development of a New 10 CFR Part 63

As discussed above, the Commission is directed by EnPA to modify its requirements for geologic disposal within a very short time to implement site-specific standards for Yucca Mountain. The legislation also specifies the type of standards NRC is to implement (i.e., standards which limit individual dose, and which are based on and consistent with the NAS recommendations). In view of these constraints, the Commission is proposing to establish a new, separate part of its regulations at 10 CFR Part 63 that will apply only to the proposed repository at Yucca Mountain. The Commission is also proposing to leave its existing, generic regulations at 10 CFR Part 60 in place, modified only to indicate that they do not apply, nor may they be the subject of litigation, in any NRC licensing proceeding for a repository at Yucca Mountain. The Commission believes this to be the most direct and time-efficient approach to the specification of concise, site specific criteria for Yucca Mountain that are consistent with current assumptions, with site-specific information and performance assessment experience, and with forthcoming EPA standards that must also apply solely to Yucca Mountain.

In establishing these criteria, the Commission seeks to establish a coherent body of risk-informed, performance-based criteria for Yucca Mountain that is compatible with the Commission's overall philosophy of risk-informed, performance-based regulation. Stated succinctly, risk-informed, performance-based regulation is an approach in which risk insights, engineering analysis and judgment (e.g., defense in depth), and performance history are used to (1) focus attention on the most important activities, (2) establish objective criteria for evaluating performance, (3) develop measurable or calculable parameters for monitoring system and licensee performance, (4) provide flexibility to determine how to meet the established performance criteria in a way that will encourage and reward improved outcomes, and (5) focus on the results as the primary basis for regulatory decision-making. The Commission believes that the creation of a new part of its regulations to accomplish these objectives is preferable to modifying its generic requirements, given the fundamentally different approach laid out for Yucca Mountain by EnPA and NAS than was contemplated when the generic criteria were promulgated. More specifically, EnPA and NAS have specified an approach that would require the performance of a Yucca Mountain repository to comply with a health-based standard established in consideration of risk to a hypothetical critical group, and, further, that this would be the only quantitative standard for the post-closure performance of the repository. This approach is incompatible with the approach taken in the existing generic criteria which relies on quantitative, subsystem performance standards.

The Commission proposes to leave the existing generic requirements intact and in place, if needed, for sites other than Yucca Mountain. Although their application could be expected to be difficult, the Commission assumes that it would be afforded adequate time and resources in future years to amend its generic regulations for any additional repository site that might be authorized. Other alternatives to this approach have been considered but rejected. The Commission could defer development of proposed regulations until final EPA standards for Yucca Mountain are in place, thereby making it easier for the Commission to conform its regulations to established standards. However, the time schedule for development of the Yucca Mountain repository is aggressive, and DOE has stated that it needs to have implementing regulations in place by 2000. Only by initiating development of these regulations now can this milestone be met. Although the Commission may not know all the details of EPA's final standards at this time, the NAS recommendations with which EPA must be consistent have been public for more than 3 years.

Other options for revising NRC's generic criteria at Part 60, in addition to developing new site-specific standards for Yucca Mountain, were also considered but rejected: (1) creation of a new part for Yucca Mountain while simultaneously updating Part 60, and (2) updating Part 60 in such a way as to include a site-specific subpart for Yucca Mountain. Simultaneously revising generic criteria and developing Yucca Mountain-specific criteria would require more resources than the Commission has available at this time. Furthermore, the Commission can identify no foreseeable need for revised generic requirements and criteria because, among other things, no site other than Yucca Mountain is undergoing characterization as a HLW repository.

IV. Part 63 Technical Criteria

The foundation for the Commission's proposed technical criteria at 10 CFR Part 63 is the specification of overall performance objectives for preclosure and postclosure phases of the repository and requirements that compliance with these overall performance objectives be demonstrated through an integrated safety analysis of preclosure operations, and through a performance assessment for long-term, postclosure performance. This risk-informed, performance-based approach does not include specification of design and siting criteria or quantitative subsystem requirements; however, the Commission is proposing specific requirements for the content of the assessments to ensure their adequacy and the sufficiency of the information provided to the Commission. The Commission believes that its proposed approach ensures protection of public health and safety and provides appropriate flexibility to DOE for demonstrating compliance, while ensuring that the information required to make a licensing decision will be provided to the Commission. The Commission's consideration of specific topics related to the proposed technical criteria is elaborated further in subsequent sections of this notice.

V. Individual Protection Standard for Postclosure Repository Performance

As already stated, the authority and responsibility for setting public health and safety standards for radioactive waste disposal at Yucca Mountain rest with EPA. It is NRC's responsibility to implement those standards in its licensing actions and ensure that public health and safety are protected. The Commission is proposing an individual dose limit which it believes is generally consistent with EnPA and with the conclusions and recommendations of NAS. Although EnPA required that EPA specify a limit based on individual dose, NAS recommended a limit be established on risk to individuals (i.e., the probability that an individual or individuals receive an adverse health effect). An equivalent level of radiation protection is afforded individuals by a standard expressed either as a risk or a dose limit when the evaluation of dose or risk considers the probability of incurring a dose and both limits are based on similar dosimetry assumptions (i.e., consistent dose to health effects conversion). In previous rulemakings, the Commission has used either implicitly or explicitly a constant total effective dose equivalent to health risk

coefficient (i.e., FR 39061; July 21, 1997), and thus, for a given probability of occurrence, the health risk can be related to a unique value of dose. Additionally, the Commission is proposing an individual dose limit because the Commission believes that a dose limit may be more readily understood by the public and is the form of a standard more frequently used to regulate nuclear activities. When EPA issues final standards for Yucca Mountain or if new HLW legislation is enacted into law, the Commission will amend its criteria at 10 CFR Part 63, if necessary, to be consistent with the final standards. As a licensed, operating facility, a repository at Yucca Mountain would be subject to the existing regulations at 10 CFR Part 20 that require, among other things, doses to members of the general public to not exceed a total effective dose equivalent of (TEDE) 1 mSv (100 mrem) per year exclusive of the dose contribution from background radiation, medical procedures, and sanitary sewerage disposals. In addition, prior to permanent closure, repository operations would need to be conducted such that public exposures be maintained as low as reasonably achievable. When the repository is closed, surface facilities must be decommissioned in accordance with 10 CFR Part 20, Subpart E. Finally, during normal operations and anticipated operational occurrences, the annual dose to any real member of the public, located beyond the boundary of the site, shall not exceed a TEDE of 0.25 mSv (25 mrem). This final dose limit, used in this regulation, is adapted from the dose limits specified in 10 CFR Part 72,[1] for effluents and direct radiation during normal operations and anticipated operational occurrences, associated with a monitored retrievable storage installation (MRS). Like an MRS facility, the operations area at Yucca Mountain is expected to be a large industrial facility equipped to handle the loading, unloading, and decontamination of spent fuel and HLW shipping casks; the removal and packaging or repackaging of spent fuel assemblies and HLW canisters; and the sealing, handling, transport, stowage and periodic monitoring of canisters to contain the spent fuel and HLW during operations. Because the activities contemplated for the operations area prior to repository closure pose similar radiological hazards, during normal operations and anticipated operational occurrences, to those posed at an operating MRS, the Commission is proposing that the dose limits for the operations area be comparable to those applicable for the MRS, from planned discharges and from direct radiation during operations. (Radiation from other fuel cycle operations, anticipated for an MRS or independent spent fuel installation (ISFSI) that might be co-located with other operating nuclear facilities, is not anticipated at the operations area, because fuel cycle operations are not likely to be located in the region). The 0.25 mSv (25 mrem) limit also provides consistency with requirements for other waste management facilities (e.g., 40 CFR 191.03(a), 10 CFR 72.104, and 10 CFR 61.40) and for license termination (10 CFR 20.1402). The protection standard is consistent with the national and international recommendations for radiation protection (National Council on Radiation Protection and Measurements and International Commission on Radiological Protection). The final dose limit used in this regulation and the requirement in 10 CFR 20.1101(b) to maintain doses to members of the public that are as low as is reasonably achievable (ALARA) will fully protect the public and the environment.

To identify an appropriate objective for repository performance after permanent closure, the Commission seeks to establish a constraint that, if met, would provide reasonable assurance that doses to members of the general public will remain below acceptable levels. International guidance on dose limits suggests establishing constraint limits for specific sources (such as a HLW repository) to ensure that exposure to members of the public from all sources, excluding background radiation, is less than the public dose limit. In the case of operational releases, compliance with the requirements of 10 CFR Part 20 can be expected, based on Commission experience with its other licensed facilities, to limit effluents far below the public annual dose limit of 1 mSv (100 mrem). For postclosure exposures, the performance of the repository must depend on passive systems limiting the exposure. Therefore, the performance objective for postclosure must be established such that the public would not receive doses, from all possible sources, excluding background radiation, in excess of 1 mSv (100 mrem) per year.

The Commission proposes a limit of 0.25 mSv (25 mrem) to the total effective dose equivalent, received in a single year and weighted by the probability of occurrence, by the average member of the critical group, as the overall system performance objective for the repository, following permanent closure. This criterion would limit the dose received from all possible pathways to the critical group at Yucca Mountain, including direct exposure, drinking of contaminated water, eating food that was irrigated with contaminated groundwater or grown in contaminated soil, exposure to airborne releases, etc. The Commission believes that application of a single, all-pathway standard is protective of public health and safety, and obviates the need for separate, single pathway limits. The Commission established the 0.25 mSv (25 mrem) annual dose limit as the overall safety objective for both decommissioning of nuclear facilities (10 CFR 20.1402) and for low-level radioactive waste disposal facilities (10 CFR 61.41). It is within the range of international constraints that allocate doses from high level waste disposal to between 0.1 and 0.3 mSv (10 and 30 mrem) per year, and is comparable to the risk range recommended by NAS as a reasonable starting point for EPA's rulemaking (a risk range of between 10^{-5} and 10^{-6} per year, approximately equivalent to annual doses between 0.02 and 0.2 mSv (2 and 20 mrem)). The Commission believes that 0.25 mSv (25 mrem) per year is sufficiently below the public dose limit that no members of the public near Yucca Mountain would be expected to receive doses from all sources, excluding background radiation, in excess of 1 mSv (100 mrem) per year. Estimates of potential exposures at Yucca Mountain are expected to be probabilistic because these estimates will consider variability and uncertainty in the features and processes, and a range of events each with specific probability of occurrence over the time period of interest at the site. The Commission proposes that an expected annual dose, based on the probabilistic results, is representative of individual risk and would be compared to the individual protection standard for determining compliance. Calculation of the expected annual dose incorporates the probability that the estimated dose will occur (i.e., annual dose estimates consider the probability of the occurrence of the events and the

[1] As a matter of policy, NRC considers 0.25 mSv (25 mrem) TEDE as the appropriate dose limit within the range of potential doses represented by the current 10 CFR 72.104 limit of 0.25 mSv (25 mrem) (whole body), 0.75 mSv (75 mrem) (thyroid dose), and 0.25 mSv (25 mrem) (to any other critical organ). It is also important to note that the average individual exposure in the U.S. from natural background is approximately 3 mSv (300 mrem) per year or 3 times the Part 20 public dose limit and 12 times the standard proposed for Yucca Mountain.

uncertainty and variability of the parameter values used to describe the behavior of the geologic repository).

VI. Reference Biosphere and Critical Group for Yucca Mountain

In addition to establishing an individual protection limit as an overall system performance objective, as discussed above, it is necessary to specify the individual or individuals for whom the performance calculation is to be made, as well as the environment in which the individual(s) reside, and the relevant pathways for potential exposure. In this regard, the NAS observed that the appropriate objective should be to "protect the vast majority of members of the public while also ensuring that the decision on the acceptability of a repository is not prejudiced by the risks imposed on a very small number of individuals with unusual habits or sensitivities." NAS recommended that the characteristics of the critical group and reference biosphere be defined in regulation. Citing guidance of ICRP, NAS recommended the critical group be representative of those individuals in the population expected to receive the highest dose equivalent, should be relatively homogeneous with respect to the location, habits, and metabolic characteristics that affect the doses received; and the habits and characteristics of the group should be based on present knowledge using cautious, but reasonable, assumptions. Although the ICRP guidance was developed for present day releases to existing populations that could be surveyed, monitored, and screened to find the few actual individuals that would be members of the critical group, the Commission has used the ICRP principles in developing specifications for the critical group and reference biosphere.

Demonstration of compliance with an individual dose limit over thousands of years requires the use of certain assumptions about the characteristics of the individual or group to be protected, as well as the characteristics of the biosphere in which the critical group resides, for purposes of analyzing the performance of the waste disposal facility. Difficulties in forecasting the characteristics of future society, especially those influencing exposure, lead to large uncertainties in the estimates of who will be exposed, by how much, and when.

The Commission is proposing to limit speculation by specifying the assumptions to be used by DOE in developing the assumed critical group and reference biosphere appropriate for Yucca Mountain. The Commission is proposing criteria at §63.115 for identifying a critical group and reference biosphere that the Commission believes provide a reasonable basis for demonstrating compliance and that preclude unbounded speculation. The Commission's intent here is to define characteristics that would otherwise be subject to unlimited speculation, and to identify how available information is to be used by DOE to identify the average member of the critical group. The identification of those individuals expected to receive the highest dose will be most sensitive to attributes such as location, percentage of diet from locally-produced food, lifestyle, and land use. Based on present day knowledge of the habits and characteristics of the local population in the vicinity of Yucca Mountain, §63.115 specifies a farming critical group located approximately 20 km south from the underground facility (i.e., in the general location of U.S. Route 95 and Nevada Route 373, near Lathrop Wells). This section also directs DOE to use current conditions in the region surrounding Yucca Mountain to define the remaining attributes of the critical group.

Based on analysis to date, the Commission considers a farming critical group to be reasonably representative of those individuals expected to receive the highest dose from radionuclides released from a Yucca Mountain repository for a number of reasons. First, farming activities involve more exposure pathways than other known human activities in the region (e.g.; ingestion pathway through consumption of contaminated water, crops, and animal products; inhalation and direct pathways from surface contamination exacerbated by the significant outdoor activity of a farming lifestyle). Second, the relatively large demand for ground water for irrigation increases the likelihood of drawing contaminated water to the surface where human exposures could occur. And third, farming activities currently exist in the Yucca Mountain region.

The 20 km location (near Lathrop Wells) represents an informed assumption regarding the accessibility of groundwater for irrigation considering current irrigation practices, depth to the water table, and the recognition that soil conditions at this location are generally similar to those further down gradient, near Amargosa Valley, where farming is currently practiced. Locations much closer to the proposed repository have soil conditions that are considerably less favorable for farming. Review of current well use information for Nevada suggests that irrigation wells constructed for water table depths greater than 150 meters are rare. Because well cost is related to depth, it is economically preferable to establish irrigation wells in areas where the water table is near the surface. The water table at Yucca Mountain is deep (i.e., greater than 300 meters) and decreases with distance down-gradient, which would also be the eventual path for radionuclide releases in the ground-water pathway. The area near U.S. Route 95 and Nevada Route 373 is the general location where the depth to water is approximately 100 meters with more shallow depths to water occurring further south. Because current farming practices are concentrated in the Amargosa Farms region (approximately 30 km south of Yucca Mountain), the 20 km critical group distance is considered reasonably conservative.

Other activities that currently exist in the area represent more limited potential for exposures (e.g., casino resort/hotel, residential dwellings). Activities such as residential housing are certainly feasible at locations closer than 20 km, where potential release concentrations are likely to be higher. However, the bases for determining precise locations of such groups are likely to be highly speculative, and largely arbitrary, when compared to a farming critical group based on existing living patterns. Additionally, the small water demand of a residential community, and even smaller demand of a single residence, relative to a farming community, further increases the uncertainty of dose estimates. Finally, because releases to the groundwater are expected to be quite variable spatially, due to the characteristics of fractured rock, the likelihood of any particular, randomly selected, withdrawal well intercepting contaminated water, at a specific location, would be quite small.

Exposures to the average member of the critical group will increase with the amount of contaminated water, crops, and animal products consumed, assuming the ground water pathway is the most likely release pathway. Individuals expected to receive the highest dose would be those for whom locally-produced, contaminated food represents a significant fraction of their diet. The Commission is proposing that the consumption of locally produced food for the average member of the critical group be based on the mean of the range of the dietary habits consistent with the current conditions in the Yucca Mountain region. It is reasonable to assume that a farming community of

sufficient size (as opposed to a few isolated farms) would be needed to supply the range of locally produced food that is currently consumed in the Yucca Mountain region. Such a farming community of up to 100 individuals, residing on approximately 15 to 25 farms, is consistent with current conditions of the region (substantially more farms would increase water demand and further decrease radionuclide concentrations in pumped water; substantially fewer farms would restrict the availability of locally-produced food relative to the regional average). Thus, it would be expected that the average member of the critical group resides within a farming community and has dietary habits which will result in the exposures being among the highest.

Exposures to the average member of the critical group will also be affected by the degree to which the locally produced food is contaminated. Variability in farming and water well withdrawal practices, as well as the spatial variability of radionuclide concentrations in ground water, will produce variation in the amount and degree of contamination of locally produced food. The Commission considers it desirable to constrain the determination of the contamination levels of locally produced food because it is not possible to precisely determine concentrations in ground water at specific locations or to avoid speculation regarding individual farm and water well withdrawal practices. The concentration of radionuclides in the water used by a larger farming community, by contrast, can be determined by dividing the annual release of radionuclides to the location of the farming community by the annual water demands of the farming community. For a community of sufficient size, it can be assumed that water demand is large enough to "capture" the entirety of the contaminated plume. Thus, all the locally produced food of the farming community would be considered to be contaminated through the use of contaminated ground water. The Commission considers this reasonable because the average member of the critical group can be assumed to consume contaminated food in all categories of locally produced food. The use of mean values for defining dietary habits ensures that dose estimates would not be unduly biased by unusual habits of a few individuals, and speculation is minimized with respect to where crops are grown relative to the spatial distribution of concentration.

The biosphere in which the critical group resides affects the group's behavior and characteristics and defines how the group could be exposed to radionuclide releases from Yucca Mountain. The precise future state of the biosphere over the time period considered during a performance assessment is highly uncertain. Both natural and man-made processes may affect attributes of the biosphere (e.g., climate, topography, hydrology and soils), and thereby influencing exposure pathways. As noted earlier in this notice, NAS recommended that the assumptions about the biosphere make use of present knowledge and be cautious, but reasonable.

The Commission's proposed implementation of the reference biosphere concept contains four primary requirements. These include that (i) features, events, and processes that describe the reference biosphere shall be consistent with present knowledge and conditions in the region surrounding the Yucca Mountain site, (ii) biosphere pathways shall be consistent with arid or semi-arid conditions, (iii) climate evolution shall be consistent with the geologic record of natural climate change in the region surrounding Yucca Mountain, and (iv) evolution of the geologic setting shall be consistent with present knowledge of natural processes.

Reliance on present knowledge and conditions is considered reasonable for development of exposure scenarios because such exposure scenarios can be based on empirical knowledge rather than unconstrained speculation. The use of current information is intended to place primary emphasis on the provision of a framework for analysis of repository performance, rather than on the precise prediction of possible futures.

Requirements that the biosphere be based on arid or semiarid conditions and that climate evolution be consistent with present knowledge of natural climate change reflect a philosophy that, while societal behaviors cannot be predicted, certain aspects of the evolution of natural systems over long time frames can be predicted based on the geologic record. Climate change studies for the Yucca Mountain region indicate that the Yucca Mountain climate could become cooler and wetter during the next ice age; however, analyses of the fossil records from the previous ice age indicate that the climate in the area south of Yucca Mountain is likely to change, at most, to conditions consistent with a semiarid climate classification. Because the current interpretations of the fossil record support these choices for local climate now and into the future, it is reasonable to limit the scope of assumed climate change to these possibilities. The change from arid to semiarid conditions is not expected to alter the biosphere sufficiently to cause major changes in potential exposure pathways to the critical group. For a farming critical group, a semiarid farming region would be expected to support agricultural crops similar to those grown in present day Amargosa Valley. Although specific biosphere and critical group parameters may change slightly with climate, major changes in behavior and exposure pathways for the critical group are not assumed.

DOE will need to establish and defend the particular characteristics, behaviors and attributes it assumes for the critical group and reference biosphere subject to the requirements and specifications of § 63.115. Then, as suggested by ICRP, a hypothetical individual representing the average member of the critical group, could be established using the mean values of the assumed characteristics, behaviors, and attributes. It is expected that DOE would conduct a habit survey to establish a realistic range of possible characteristics for the critical group, recognizing that its assumptions should be internally consistent and should not be driven by extreme habits. The Commission believes that its proposal of a farming critical group is reasonable for testing the ability of the geologic repository to comply with the performance objective at § 63.113 because it represents cautious, but realistic, assumptions of future living patterns in the vicinity of Yucca Mountain based on patterns observed there today. As this rulemaking progresses, the Commission's ongoing performance assessment analyses will continue to examine the influence of important assumptions such as the characteristics of the critical group including location, lifestyle, diet, and size. As part of this effort, the Commission encourages comments on the appropriateness of its proposed approach to defining the critical group and reference biosphere for Yucca Mountain. In particular, the Commission solicits comments on other candidate population groups, biosphere assumptions and potential exposure pathways that should be considered in the establishment of a "critical group" for Yucca Mountain.

VII. Compliance Period

The NAS recommended that the time over which compliance should be assessed should include the time when greatest risk occurs, within the limits imposed by the stability of the geologic

system. This recommendation was founded on technical considerations only, and, as NAS acknowledged, did not address issues of policy. In selecting the length of time over which the individual dose limit should be applied, a regulatory agency must take into account technical, policy, and legal considerations. In fact, NAS noted that EPA might elect to establish consistent policies for managing comparable risks from disposal of long-lived hazardous materials. From a technical perspective, for example, the time-dependent variation of the hazard, along with the time required to evaluate adequately the waste isolation capability of both engineered and natural barriers, are of significance. From a policy perspective, on the other hand, the practical utility and relative uncertainty of extremely long projections of health consequences, along with the need to maintain a consistent regulatory approach for like hazards, need to be weighed. Having considered both technical and policy concerns, the Commission is proposing the use of 10,000 years for evaluating compliance with the system performance objective at § 63.113. Should EPA issue final standards for Yucca Mountain or Congress enact new high-level waste legislation into law that specify a different compliance period, the NRC will amend its criteria at 10 CFR Part 63, as necessary, to comply with EnPA requirements for consistency with final EPA standards.

The Commission makes its proposal on the basis of three considerations. First, the inherent radiological hazard of spent fuel decreases rapidly and significantly during the initial 10,000 years due to radioactive decay dominated by fission products, with the relative hazard diminished by approximately 90 percent at 100 years, 99 percent at about 1,000 years and 99.9 percent at 10,000 years. At 10,000 years following waste emplacement, the relative radiological hazard is within a factor of ten of the hazard posed by a quantity of 0.2 percent uranium ore equivalent to that which was necessary to produce the spent fuel (Final Environmental Impact Statement on the Management of Commercially Generated Radioactive Waste, DOE, 1980; NRC High-Level Radioactive Waste Program Annual Progress Report; Fiscal Year 1996, NRC, 1997). Beyond 10,000 years, the relative hazard of the disposed waste diminishes very slowly over several hundreds of thousands of years because decay at such late times is controlled by the activity of longer-lived radionuclides. A 10,000-year compliance period corresponds to the time period when the waste is inherently most hazardous.

Second, analysis of repository performance over 10,000 years provides an opportunity to examine the impact of a range of geologic conditions (e.g., seismic events, fault movement, igneous activity, and climate variation on the scale of global changes due to glaciation) on the capability of the engineered and natural barriers to limit radiation exposures below the dose limit. It is possible that DOE may attempt to demonstrate that its engineered barrier system design is sufficiently robust as to preclude any significant releases during a 10,000-year compliance period. The Commission is aware of DOE's efforts to examine a variety of engineered barrier designs that it expects will extend the containment period of the waste package. However, the DOE has not finalized its repository design and thus it is premature, at this time, to assume that the expected lifetime of the engineered barrier system will exceed the compliance period. If, indeed, the waste package can be shown to preclude radionuclide releases beyond the compliance period, a 10,000-year evaluation, it might be argued, would only illustrate the effect of the natural system on the degradation of the engineered barriers and would fail to adequately display the capacity of extant natural barriers to restrict movement of radionuclides following release from the waste packages, and thereby, limit exposures to members of the critical group. The Commission expects that in conducting its performance assessment, DOE will account for the susceptibility of some fraction of the more than 7,000 emplaced canisters to early failures, attributable to such causes as manufacturing defect, lapses in quality assurance programs, etc. The ability of the geologic barriers to retard the transport of radionuclides released as a result of these early failures would clearly need to be evaluated. Furthermore, the assumed intrusion scenario specified at § 63.113(d) and discussed later in this notice requires a stylized analysis of the consequences of a compromised waste package, and will also test the contribution of the geologic barriers to overall performance. Irrespective of the projected lifetime of the waste package design, the capability of the natural barriers to limit exposures would need to be evaluated in the context of the multiple barrier requirement.

Finally, from a policy perspective, EPA has already codified a 10,000-year compliance period at 40 CFR 191 applicable to the Waste Isolation Pilot Plant (WIPP), a similar type of disposal system as that proposed at Yucca Mountain. A 10,000-year performance period is also referenced in EPA guidance on no-migration petitions for facilities seeking exemption from certain land-disposal restrictions for long-lived hazardous, nonradioactive materials. Additionally, a 10,000-year compliance period is specified in NRC's Draft Technical Position on a Performance Assessment Methodology for Low-Level Radioactive Waste Disposal Facilities (62 FR 29164; May 29, 1997). All of these land disposal situations, like HLW disposal, involve disposed wastes containing long-lived, hazardous materials which are of concern, because they can become mobile in the groundwater pathway.

The Commission proposes that a 10,000-year compliance period is appropriate for evaluating a Yucca Mountain repository because it: (1) includes the period when the waste is inherently most hazardous; (2) is sufficiently long, such that a wide range of conditions will occur which will challenge the natural and the engineered barriers, providing a reasonable evaluation of the robustness of the geologic repository; and (3) is consistent with other regulations involving geologic disposal of long-lived hazardous materials, including radionuclides.

VIII. Multiple Barriers and Defense in Depth

The defense-in-depth principle has served as a cornerstone of NRC's deterministic regulatory framework for nuclear reactors, and it provides an important tool for making regulatory decisions, with regard to complex facilities, in the face of significant uncertainties. NRC also has applied the concept of defense-in-depth elsewhere in its regulations to ensure safety of licensed facilities through requirements for multiple, independent barriers, and, where possible, redundant safety systems and barriers. Traditionally, the reliance on independence and redundancy of barriers has been used to provide assurance of safety when reliable, quantitative assessments of barrier reliability are unavailable. The Commission maintains, as it has in the past, that the application of the defense-in-depth concept to a geologic repository is appropriate and reasonable. The Commission now believes, however, that its implementation, in the context of a geologic repository, should be reexamined, in light of the advancement in methods to quantitatively assess the

components of a geologic repository system and with due consideration of the Commission's goal of a regulatory program and associated requirements that are risk-informed and performance-based.

Development of NRC's regulations for geologic disposal in 1983 represented a unique application of the defense-in-depth philosophy to a first-of-a-kind type of facility. While waste is being emplaced, and before a geologic repository is closed, its operation may be amenable to regulation comparable to other operating nuclear fuel cycle facilities licensed by NRC. Application of defense-in-depth principles for regulation of repository performance, for long time periods following closure, however, must account for the difference between a geologic repository and an operating facility with active safety systems and the potential for active control and intervention. A closed repository is essentially a passive system, and assessment of its safety over long timeframes is best evaluated through consideration of the relative likelihood of threats to its integrity and performance. Although it is relatively easy to identify multiple, diverse barriers that comprise the engineered and geologic systems, the performance of any of these systems and their respective subsystems cannot and should not be considered either truly independent or totally redundant.

As stated earlier, NWPA mandated that technical criteria developed by the Commission " * * * shall provide for the use of a system of multiple barriers in the design of the repository." How the performance of those barriers should be assessed, consistent with the Commission's policy of defense-in-depth, was a major issue throughout the development and promulgation of the Commission's generic regulations at 10 CFR Part 60 and continues to be of concern as the Commission contemplates new regulations for Yucca Mountain.

Well before NWPA was enacted, the Commission had considered the appropriate bases for establishing regulations for HLW disposal. In developing proposed generic technical criteria for Part 60, the Commission placed primary emphasis on the need to compensate for the large uncertainty that is inherent in the assessment of the long-term performance of HLW disposal systems. The Commission expressed its view, then, that the state-of-the-art in the earth sciences was such that all the uncertainties related to predicting long-term performance of a repository could not be resolved through consideration of the geologic setting alone.

It should be noted that during the late 1970s and early 1980s, when the Commission was first considering the development of proposed technical criteria for geologic repositories, quantitative techniques for assessing repository performance were in their infancy. The lack of experience with, and confidence in, quantitative methods for addressing the uncertainties associated with estimates of repository performance weighed heavily as the Commission considered options for formulating generic regulations for HLW disposal. As will be discussed later in this statement, the Commission now believes that the application of such methods has matured sufficiently to move away from its earlier approach.

As Part 60 was being developed, the Commission gave serious consideration to a "systems approach," that is, regulation of a repository system through a single figure of merit, that of overall system performance, leaving maximum flexibility for determining the extent and focus of site characterization, and for the designer to make trade-offs among components of the system. It was noted that this approach could include a requirement that the system design incorporate multiple barriers to compensate for uncertainty in overall system performance. It was believed, at the time, however, that compensation for uncertainties in *assessing* the system's overall performance could only be achieved by introducing conservatism. Intentional addition of conservatism, either by making the measure of performance unduly stringent or by using worst-case, bounding assumptions in the evaluation, was argued to be impractical from a regulatory point of view.

Instead, the Commission opted to prescribe minimum performance standards for each of the major system elements (as they were envisioned at the time) as well as to require the overall system to comply with the primary performance objective, namely, whatever standards EPA would eventually establish. This approach was thought to have two advantages over the systems approach, if the barriers were chosen judiciously. It was argued that barriers could be prescribed, generically, which act "independently," and that generic performance measures for these "independent" barriers could be selected that would reduce calculational uncertainty. Identification of such subsystem performance measures was expected to be helpful input to DOE's design process, without being overly restrictive. It is now recognized that NRC attempted to define such criteria on the basis of limited, existing knowledge, without benefit of research and site-specific information that only later was acquired during characterization of a specific site at Yucca Mountain.

The vast majority of comments received on the proposed Part 60 favored a "systems approach." Nevertheless, in publishing its final rule (48 FR 28194; June 21, 1983), the Commission elected to retain the proposed approach, stating that "* * * in simply adopting the EPA standard as the sole measure of performance, it [the Commission] would have failed to convey in any meaningful way the degree of confidence which it expects must be achieved in order for it to be able to make the required licensing decisions' and, further that "* * * The Commission firmly believes that the performance of the engineered and natural barriers must each make a definite contribution in order for the Commission to be able to conclude that the EPA standard will be met."

In support of the final rule, the Commission examined how particular values for the performance of the proposed barriers would assist in concluding that compliance with the EPA standards had been demonstrated, given an assumed set of anticipated processes and events. Final EPA standards still had not been promulgated, so analyses were conducted based on NRC staff assumptions regarding the final standards. These analyses, based on a simplified modeling study for a hypothetical repository located in a variety of saturated geologic media, were documented as NUREG–0804—"Staff Analyses of Public Comments on Proposed Rule 10 CFR Part 60, Disposal of High-Level Radioactive Wastes in Geologic Repositories." For many, but by no means all, of the cases examined, compliance with the proposed subsystem performance objectives did increase the probability of meeting the assumed EPA standards. NRC was not able to demonstrate, however, that compliance with the subsystem criteria alone was sufficient to meet the assumed EPA standards, nor that compliance with the assumed EPA standards would suffice to assure compliance with the subsystem criteria. For the cases analyzed, however, it was asserted that the analyses " * * * demonstrate that compliance with 10 CFR Part 60 can substantially increase confidence that the assumed EPA standard[s] will be met."

Lastly, in order to address concerns that quantitative subsystem performance criteria may unduly restrict the

applicant's flexibility, the Commission modified the proposed rule to explicitly recognize the potential need to change the subsystem objectives to account for unique features of a specific site or design. This flexibility was provided at § 60.113 (b).

Since their promulgation, the subsystem criteria in § 60.113, in particular, have not gained broad acceptance in the technical community. These criteria have been criticized as overly prescriptive, lacking in both a strong technical basis and a clear technical nexus to the overall performance objective (i.e., the EPA standards), and unclear in their wording.

In contrast to the state of performance assessment technology assumed at the time Part 60 criteria were put in place, the NAS Committee on Technical Bases for Yucca Mountain Standards found, in 1995, that the physical and geologic processes relevant to a Yucca Mountain repository: "* * * are sufficiently quantifiable and the related uncertainties sufficiently boundable that the performance [of a repository] can be assessed over timeframes during which the geological system is relatively stable or varies in a boundable manner." As has been described earlier, it was a lack of confidence in this capability to quantify overall performance and adequately bound uncertainty that factored prominently in the Commission's decision to include quantitative subsystem requirements in the Part 60 regulations. Also, as discussed earlier, NAS cautioned against implementation of multiple barriers through the use of subsystem performance requirements. In addition, the Commission's Advisory Committee on Nuclear Waste (ACNW) recently recommended that the Commission implement the concept of defense in depth by ensuring that the effectiveness of individual barriers be identified explicitly in the total system performance assessment (TSPA), but specifically did not endorse the establishment of rule-based subsystem requirements for Yucca Mountain. The ACNW noted that "* * * an overall performance-based regulation in the context of a risk-based standard is a superior tool for promoting safety relative to imposed subsystem requirements. (see letters dated October 31, 1997 and March 6, 1998)."

Upon review of this regulatory history, the Commission is persuaded that much of the basis for NRC's initial development of the specific numerical values for the subsystem criteria was generic judgment with regard to what was (and was not) feasible with regard to the quantitative assessment of long-term repository performance. Because the stated goal was to compensate for uncertainty, there was never any attempt to derive the subsystem performance criteria from a specified dose or risk level or from some projected dose or risk reduction expected to be achieved by their application. Furthermore, after 15 years of experience in working with the requirements of Part 60, the Commission is concerned that, for the Yucca Mountain site, the application of the subsystem performance criteria at § 60.113 may impose significant additional expenditure of resources on the nation's HLW program, without producing any commensurate increase in the protection of public health and safety.

Specifically, when the Part 60 subsystem criteria were selected, they were intended to be separate, "independent," easily-determined measures of subsystem performance, determination of which would require only application of technology that was readily available. Extensive experience with site-specific performance assessment has shown them to be none of these. For example, because container performance, release rate, and groundwater travel time will be derived from the same general data and knowledge base as the TSPA, they are subject to many, if not all, of the same uncertainties. Furthermore, waste package performance and release rate are both a function of available water; therefore, it is arguable whether the existing (or any other) subsystem measures can provide truly independent assurance of total system performance.

Nevertheless, despite its reconsideration of the merits of establishing quantitative criteria for the performance of repository subsystems, the Commission continues to believe that multiple barriers, as required by NWPA, must each make a definite contribution to the isolation of waste at Yucca Mountain, so that the Commission may find, with reasonable assurance, that the repository system will be able to achieve the overall safety objective over timeframes of thousands of years. Geologic disposal of HLW is predicated on the expectation that a portion of the geologic setting will act as a barrier, both to water reaching the waste, and to dissolved radionuclides migrating away from the repository, and thus, contribute to the isolation of radioactive waste. Although there exists an extensive geologic record ranging from thousands to millions of years, this record is subject to interpretation and includes many uncertainties. These uncertainties can be quantified generally and are addressed by requiring the use of a multiple barrier approach; specifically, an engineered barrier system, consisting of one or more distinct engineered barriers, is required in addition to the natural barriers implicit in a geologic setting. Similarly, although the composition and configuration of engineered structures, as well as their capacity to function as barriers, can be defined with a degree of precision not possible for natural barriers, it is recognized that except for a few archaeologic analogues, there is no experience base for the performance of complex, engineered structures over periods longer than a few hundred years. It is expected that DOE will demonstrate that the natural barriers and the engineered barrier system will work in combination to enhance overall performance of the geologic repository.

The Commission believes that this approach to multiple barriers is consistent with the NAS conclusions and recommendations cited above. The Commission also recognizes, and believes it is important to acknowledge that experience and improvements in the technology of performance assessment, acquired over more than 15 years, now provide significantly greater confidence in the technical ability to assess comprehensively overall repository performance, and to address and quantify the corresponding uncertainty. In addition to extensive reviews of evolving TSPAs produced by DOE and its contractors, the Commission, itself, has developed and exercised its own technical capability in the field of repository performance assessment (See, for example, Bonano, E. J., et al., "Demonstration of a Performance Assessment Methodology for High-Level Waste Disposal in Basalt Formation," NUREG/CR-4759, U.S. Nuclear Regulatory Commission, Washington, DC, 1989; "Initial Demonstration of the NRC's Capability to Conduct a Performance Assessment for a High-Level Waste Repository," NUREG-1327, 1992; "NRC Iterative Performance Assessment Phase 2—Development of Capabilities for Review of a Performance Assessment for a High-Level Waste Repository," NUREG-1464, 1995).

Drawing from this experience, the Commission is now proposing to require that DOE evaluate the behavior of barriers important to waste isolation in the context of the performance of the geologic repository. The Commission does not intend to specify numerical goals for the performance of individual barriers. Such an approach will require DOE to provide an analysis that: (1)

identifies those design features of the engineered barrier system, and natural features of the geologic setting, that are considered barriers important to waste isolation; (2) describes the capability of these barriers to isolate waste, taking into account uncertainties in characterizing and modeling the barriers; and (3) provides the technical basis for the description of the capability of these barriers. In implementing this approach, the Commission proposes to incorporate flexibility into its regulations by requiring DOE to demonstrate that the geologic repository comprises multiple barriers but not prescribe which barriers are important to waste isolation or the methods to describe their capability to isolate waste.

DOE could select from a variety of methods in order to demonstrate the capability of barriers to isolate waste. Regardless of the method and the level of quantification, it is expected that the capability of individual barriers to perform their intended function and the relationship of that function to limiting radiological exposure would be described. In parallel with this rulemaking, NRC staff is developing guidance in the form of a Yucca Mountain Review Plan. In this review plan, guidance will be provided on acceptable methods for demonstrating compliance with the multiple barrier requirement that could include, but not necessarily be limited to, performing sensitivity analyses, modeling the behavior of individual barriers, quantifying how individual barriers contribute to performance, and delineating the capabilities of the barriers to isolate waste. The Commission believes that it is appropriate to afford DOE flexibility in selecting the methods to demonstrate the waste isolation capability of the multiple barriers that must comprise its repository design. The proposed requirements will provide for a system of multiple barriers and an understanding of the resiliency of the geologic repository provided by the barriers important to waste isolation to ensure defense in depth and increase confidence that the postclosure performance objective will be achieved.

IX. Performance Assessment

Demonstration of compliance with the postclosure performance objective specified at § 63.113(b) requires a performance assessment that quantitatively estimates the expected annual dose, over the compliance period and weighted by probability of occurrence, to the average member of the critical group. Performance assessment is a systematic analysis of what can happen at the repository after permanent closure, how likely it is to happen, and what can result, in terms of dose to the average member of the critical group. Taking into account, as appropriate, the uncertainties associated with data, methods, and assumptions used to quantify repository performance, the performance assessment is expected to provide a quantitative evaluation of the overall system's ability to achieve the performance objective (§ 63.113 (b)). Consistent with EnPA and the NAS recommendations, the Commission proposes that the results of performance assessment shall be the sole quantitative measure used to demonstrate compliance with the postclosure individual dose limit.

In order to find that issuance of a license will not constitute an unreasonable risk to the health and safety of the public, the Commission must have reasonable assurance that the required performance assessment has demonstrated that, following permanent closure, for the duration of the compliance period and considering the likelihood of occurrence of adverse natural events, expected annual exposures to the average member of the critical group will not exceed the individual dose limit of .25 mSv (25 mrem) TEDE. Although the performance objective for the geologic repository after permanent closure (§ 63.113) is generally stated in unqualified terms, it is not expected that complete assurance that the requirement will be met can be presented. A reasonable assurance, on the basis of the record before the Commission, that the performance objective will be met is the general standard that is required. Proof that the geologic repository will be in conformance with the objective for postclosure performance is not to be had in the ordinary sense of the word because of the uncertainties inherent in the understanding of the evolution of the geologic setting, biosphere, and engineered barrier system. For such long-term performance, what is required is reasonable assurance, making allowance for the time period, hazards, and uncertainties involved, that the outcome will be in conformance with the objective for postclosure performance of the geologic repository. Demonstrating compliance, by necessity, will involve the use of complex predictive models that are supported by limited data from field and laboratory tests, site-specific monitoring, and natural analog studies that may be supplemented with prevalent expert judgment. Further, in reaching a determination of reasonable assurance, the Commission may supplement numerical analyses with qualitative judgments including, for example, consideration of the degree of diversity or redundancy among the multiple barriers of the geologic repository.

Because of the significance of the performance assessment as the sole quantitative measure of compliance, it is essential that the performance assessment be scientifically defensible and transparent. For this reason, the Commission considers it important to specify, at § 63.114, requirements for a complete and high-quality performance assessment. A defensible performance assessment should contain a technical rationale for those features, events, and processes that have been included in the performance calculation, as well as those that have been considered but were excluded. The features, events, and processes (i.e., specific conditions or attributes of the geologic setting; degradation, deterioration, or alteration of the engineered barriers; and interactions between the natural and engineered barriers) considered for inclusion in the assessment should represent a wide range of beneficial and detrimental effects on performance. Features, events, and processes should be considered in light of available data and current scientific understanding, and alternative conceptual models that are consistent with such data and understanding should be evaluated. Inclusion of alternative models should be based, however, on reasonable interpretation of available information, and should not be driven by open-ended speculation. To this end, the Commission is proposing to constrain speculation by defining a lower limit on the probability of events and processes that need to be considered and requiring inclusion of only those features and processes, and higher probability events that significantly change the expected annual dose.

The performance assessment will rely, by necessity, on computer modeling to determine whether a proposed geologic repository meets the performance objectives. Such reliance on computer simulation has become commonplace for determining the likely performance of complex engineered systems. In most applications, it is accompanied by a rigorous testing program, involving model "validation" and "verification," to ensure that the simulated system behavior is sufficiently consistent with empirically observed behavior to meet the need of the application at hand. The Commission expects that DOE will take

reasonable and practical measures to ensure that its performance assessment provides a credible representation of a geologic repository at Yucca Mountain. For example, assurance of the soundness of the performance assessment cannot and will not involve the comparison of simulated behavior of a geologic repository with empirical observation over tens of kilometers and tens of thousands of years. At best, assurance for the performance assessment will involve comparison of simulations with observations drawn from an integrated program of laboratory tests, field tests, and analog studies that starts with site characterization and continues, as appropriate, through the performance confirmation period. To the extent that DOE's performance assessment provides a credible representation of a geologic repository, the Commission expects no more than that and believes that no more is needed. When the NWPA became law in 1982, and when it was revisited in 1987, and again in 1992, the limits on human knowledge that are attendant to confirming performance of a geologic repository were well known. The Commission does not believe that these laws were passed with the intention of creating an impossible task. Accordingly, the Commission has included, at §§ 63.101(a)(2) and 63.101(b), explanations regarding the purpose and nature of the findings it will make.

To be transparent, DOE's performance assessment must contain an evaluation of the performance of the geologic repository relative to compliance with the individual dose limit and an explanation of how the estimated performance was achieved. Section 63.113(b) requires that compliance with the individual dose limit be demonstrated through the calculation of an expected annual dose. The expected annual dose is the expected value of the annual dose considering the probability of the occurrence of the events and the uncertainty, or variability, in parameter values used to describe the behavior of the geologic repository (the expected annual dose is calculated by accumulating the dose estimates for each year, where the dose estimates are weighted by the probability of the events and the parameters leading to the dose estimate). Demonstration of compliance with the individual dose limit will need to include an estimate of the expected annual dose to the average member of the critical group that, for any single year within the compliance period, is below the limit. Explanation of how the estimated performance was achieved should reveal an understanding of the relationship between the performance of individual components or subsystems of the geologic repository and the total system performance. Such understanding would be used to build confidence that the expected annual dose, as asserted in the license application, is a reasonable estimate of the performance of the geologic repository. Consistent with a performance-based philosophy, the Commission proposes to permit DOE the flexibility to select the approach for demonstrating this relationship that is most appropriate to its analysis.

X. Institutional Controls

The Commission is proposing to require DOE to institute active, as well as passive, control measures to reduce the potential for inadvertent human intrusion into the site. Reasonably prudent, active institutional controls, consistent with the requirements of Section 801(c) of EnPA, should be maintained at the site for as long as possible. The Commission is also proposing that DOE's passive control measures should be designed to serve their intended purpose for as long as practicable.

Section 801(b) of EnPA requires that:

* * * the Commission's requirements assume, to the extent consistent with the findings and recommendations of the National Academy of Sciences, that following repository closure, the inclusion of engineered barriers and the Secretary's postclosure oversight of the Yucca Mountain Site, in accordance with Subsection (c) shall be sufficient to:

(A) prevent any activity at the site that poses an unreasonable risk of breaching the repository's engineered or geologic barriers; and

(B) prevent any increase in the exposure of individual members of the public to radiation beyond allowable limits.

However, as was discussed earlier in this notice, NAS concluded that it is not reasonable to assume that a system for postclosure oversight, based on active institutional controls, can be developed that will eliminate entirely, over thousands of years, the possibility of human activity that could degrade the long-term performance of the repository.

XI. Human Intrusion

The geologic record provides a basis for evaluating the likelihood of geologic processes and events, but no similar record of extended duration exists that can be used to constrain either the probability that human intrusion could occur or the characteristics of such intrusion. Although designs can seek to warn potential intruders or to mitigate effects associated with intrusion that does occur, they cannot remove the potential for intrusion to occur. Similarly, repositories cannot be designed to mitigate the full range of possible ways that human intrusion could occur. Therefore, the Commission is proposing to require that DOE take reasonable and prudent steps to reduce the likelihood of human intrusion, and that DOE's repository design must still perform as intended, if an assumed, limited intrusion does occur.

As noted earlier, the NAS also concluded that it is not possible to make scientifically supportable predictions of the probability of human intrusion breaching the repository's geologic or engineered barriers over a period of 10,000 years. The NAS report recommended that human intrusion be excluded from the performance assessment, but that the consequences of an assumed human intrusion scenario should be calculated to determine if repository performance would be substantially degraded as a result of the intrusion.

The Commission agrees with the NAS recommendations to consider human intrusion apart from the risk-based performance assessment. To permit consideration of the potential detriment from human intrusion in the evaluation of repository performance, the Commission proposes that DOE be required to perform a consequence analysis that includes an assumed intrusion scenario as specified at § 63.113(d). This consequence analysis would be identical to the performance assessment, except that a specified human intrusion scenario is assumed to occur. In the event of this assumed scenario, the repository is required to perform such that the expected annual dose to the average member of the critical group is also within allowable limits. Hazards to the intruders themselves (drillers, miners, etc.) or to the public from material brought to the surface by the assumed intrusion should not be included in this analysis, according to NAS. This is because, NAS asserts, analyses of these hazards would be unlikely to provide any useful basis for judging the resilience of a particular repository or design to intrusion.

The Commission does not intend to speculate on the virtual infinity of human intrusion scenarios that could be contemplated, nor does it intend for this analysis to address the full range of possible intrusions that could occur. Rather, the Commission intends that this analysis show that the repository exhibits some resilience to a breach of

engineered and geologic barriers from events that are reasonably of concern. Therefore, the Commission is proposing an assumed human intrusion scenario that results in the breach of both engineered and geologic barriers. The Commission believes that current practices provide a solid basis for establishing properties for the intrusion scenario that avoid speculation. Therefore, the Commission is proposing that DOE use current practices for resource exploration to establish properties (e.g., diameter of the borehole, drilling rate, composition of drilling fluids) for the intrusion scenario. However, because the Commission intends for this analysis to show that the repository can still adequately perform if its barriers are breached, the Commission is requiring DOE to assume that the borehole is not adequately sealed to prevent infiltrating water.

Elsewhere in its regulations (*e.g.*, 10 CFR Part 60), the Commission has limited the extent to which reliance may be placed on active institutional controls to prevent unacceptable radiological exposures from the disposal of other radioactive wastes. Consistent with this approach, the Commission is proposing that the intrusion scenario be assumed to occur 100 years after repository closure.

The Commission is mindful that a single stylized intrusion scenario should not be taken as a prediction of the likely manner or frequency of intrusion. As NAS stated in its report, a "calculation of consequences for such an intrusion removes from consideration a number of imponderables, each of which would otherwise need to be treated separately, including the probability that an intrusion borehole would intersect a waste canister, the probabilities of detection and remediation, and the effectiveness of institutional controls and markers to prevent intrusion. This scenario should not be interpreted as either an optimistic or pessimistic estimate of what might actually occur * * * We believe that the simplest scenario that provides a measure of the ability of the repository to isolate waste and thereby protect the public is the most appropriate scenario to use for this purpose."

Bearing this in mind, the Commission solicits comment on the appropriateness of its proposed intrusion scenario, and the assumed timing of its occurrence, as a reasonable measure for evaluating the consequences of intrusion at a repository at Yucca Mountain.

XII. Preclosure Performance Objective

The Commission is proposing performance objectives at § 63.111 to ensure that the geologic repository operations area is designed and operated to protect against radiation exposures and releases of radioactivity prior to permanent closure. Specifically, protection of the worker and general public is ensured by requiring that (1) the exposure limits codified at 10 CFR Part 20 are maintained, and (2) during normal operations and anticipated operational occurrences, the annual dose to any real member of the public, located beyond the boundary of the site, shall not exceed a TEDE of 0.25 mSv (25 mrem). The 0.25 mSv (25 mrem) limit was included to provide consistency with requirements for the MRS and other waste management facilities (e.g., 40 CFR 191.03(a), 10 CFR 72.104, and 10 CFR 61.40). Additionally, numerical guides for design objectives have been specified for Category 1 design basis events and Category 2 design basis events. Category 1 design basis events are those events that are expected to occur one or more times before permanent closure. Included in Category 1 design basis events are events that occur regularly or moderately frequently, and that are sometimes identified as "normal operations" associated with receiving, handling, packaging, storing, emplacing, and retrieving high-level waste. Also included in Category 1 design basis events are those events that occur one or more times during the operating lifetime of a facility, and that are sometimes identified as "anticipated operational occurrences" or "accidents." Category 2 design basis events are those events that have at least one chance in 10,000 of occurring before permanent closure. For an operational period of 100 years, this corresponds to an annual probability of occurrence of 10^{-6}. Category 2 design basis events are unlikely, but credible and potentially significant events. The Commission incorporated similar definitions of design basis events and associated dose limits in its generic regulations at 10 CFR Part 60 (61 FR 64257) for evaluation of preclosure repository performance. The primary purpose of those most recent amendments to the Commission's generic criteria, in addition to achieving greater consistency with Part 72 requirements, was to improve clarity and sufficiency of the requirements to protect health and safety for the full range of credible conditions or events that could occur at an operating repository, including low-probability events that have potentially serious consequences. The Commission believes that the performance objectives established by these amendments are suitable for inclusion in its proposed criteria for preclosure operation at a Yucca Mountain repository.

XIII. Integrated Safety Analysis of Activities at the Geologic Repository Operations Area

The Commission is proposing that compliance with the preclosure performance objectives would be demonstrated through an integrated safety analysis (ISA) of the geologic repository operations area (GROA). The ISA is a systematic examination of potential hazards at the GROA. It identifies the potential hazards, the potential for initiating event sequences, and describes potential event sequences and their consequences, as well as the site, structures, systems, components, equipment, and activities of personnel intended to mitigate or prevent the accident sequence. Its purpose is to ensure that all relevant hazards that could result in unacceptable consequences have been adequately evaluated and appropriate protective measures have been identified such that the GROA will comply with the preclosure requirements for protection against radiation exposures and releases of radioactive material specified in § 63.111. As used here, integrated means joint consideration of safety measures that, considered separately, might not achieve the overall health and safety protection desired. Such integration would include, but not be limited to, integration of fire protection, radiation safety, criticality safety, and chemical safety measures.

A fundamental aspect of the ISA is the identification and analysis of Category 1 and Category 2 design basis events. Category 1 events as described above represent "normal operations" while Category 2 events represent unlikely but credible events which would challenge the design of the GROA to maintain exposures within allowable limits. The analysis of a specific Category 2 design basis event would include an initiating event (e.g., an earthquake) and the associated combinations of repository system or component failures that can potentially lead to exposure of individuals to radiation. An example design basis event is a postulated earthquake (the initiating event) which results in (1) the failure of a crane lifting a spent fuel waste package inside a waste handling building, (2) damage to the building ventilation (filtration) system, (3) the drop and breach of the waste package, (4) damage to the spent fuel, (5)

partitioning of a fraction of the radionuclide inventory to the building atmosphere, (6) release of some radioactive material through the damaged ventilation (filtration) system, and (7) exposure of an individual (either a worker or a member of the public) to the released radioactive material.

The Commission believes the proposed approach, which does not include specification of general design criteria, is appropriate because prescriptive design criteria may unnecessarily encumber DOE, given the ongoing nature of site characterization of the underground facility and evolution of facility design. The information the Commission needs to make a finding of reasonable assurance that the GROA will comply with the risk-informed, preclosure requirements at § 63.111, will be provided by the ISA. The Commission proposes criteria, at § 63.112, for the content of the ISA.

XIV. Quality Assurance

As is currently required by the generic criteria at 10 CFR Part 60, the Commission is proposing that DOE implement a quality assurance program, for the geologic repository, based on the criteria of Appendix B of 10 CFR Part 50. Although an essentially equivalent quality assurance program for the independent storage of spent nuclear fuel and HLW is specified at Subpart G of 10 CFR Part 72, the Commission believes it to be appropriate to continue to reference Appendix B for the geologic repository at Yucca Mountain for purposes of maintaining continuity between data collected, during site characterization, pursuant to Part 60 requirements and those that will be collected once Part 63 requirements take effect. The Commission is seeking comment on the merits of this approach.

XV. Emergency Planning

When the Commission published final generic criteria for geologic disposal in 1983, licensing requirements for emergency planning were reserved for a later date. On June 22, 1985 (60 FR 32430), the Commission published final amendments to 10 CFR Part 72 that codified generic emergency planning licensing requirements for independent spent fuel storage installations (ISFSIs) and monitored retrievable storage facilities (MRS). These amendments provided for enhanced requirements for offsite emergency planning at MRS facilities (as well as at any ISFSIs that conduct similar operations) because of the broader scope of activities that could be performed at these facilities relative to those conducted at simpler storage installations. Like an MRS facility, a Geologic Repository Operations Area (GROA) at Yucca Mountain is expected to be a large industrial facility equipped to handle the loading, unloading, and decontamination of a large number of spent fuel and HLW shipping casks arriving by rail, heavy haul, and legal weight truck. It will also include facilities to open shipping canisters that are unsuitable for disposal, as well as to package bare fuel assemblies, commercial and defense spent fuel, and commercial and defense HLW in disposable canisters, and seal them for emplacement in the repository. Packaging operations will be conducted in a radiologically-controlled area that can support remote dry and pool-handling operations. At this time, a final GROA design has not been selected by DOE.

In promulgating final amendments at 10 CFR Part 72, the Commission conducted an analysis of potential onsite and offsite consequences of accidental release associated with the operation of an MRS. This analysis is contained in NUREG–1092. Because the activities contemplated for the GROA prior to repository closure pose similar radiological hazards to those analyzed for operations at an MRS, the Commission is proposing that the emergency planning licensing requirements for preclosure operations at the Yucca Mountain repository be comparable to those already codified in § 72.32 (b). Therefore, the Commission is proposing to require, at Subpart I, § 63.161, that DOE develop, and be prepared to implement, a plan to cope with radiological emergencies that may occur at the GROA prior to permanent closure, that is based on the criteria of § 72.32(b).

XVI. Changes, Tests and Experiments

The Commission is proposing to set out, at § 63.44, the bases on which DOE may change the geologic repository operations area or procedures as described in the application, and conduct tests or experiments not described in the application, without prior Commission approval. DOE would be required to maintain records of changes made and tests undertaken pursuant to this section. Comparable provisions exists at 10 CFR 50.59 for licensees of production and utilization facilities (e.g. nuclear reactors) and at 10 CFR 72.48 for licensees of facilities for the independent storage of spent nuclear fuel and HLW. The intent of these requirements is to permit licensees to make changes, or to conduct tests at a licensed facility, provided that: the changes maintain the level of safety documented in the original licensing basis (such as in the safety analysis report); the changes do not alter a license condition; and the changes do not introduce a previously unreviewed safety question.

Recently, the Commission proposed amendments to Parts 50 and 72 (63 FR 56098; October 21, 1998), to address a number of issues concerning the implementation of these provisions for reactors and independent spent fuel storage facilities. In particular, the proposed amendments attempt to revise criteria for determining when an unreviewed safety question exists. The Commission has become concerned that differing interpretations of these requirements as they relate to an increase in the probability of an accident, or an increase in consequences, have contributed to disputed inspection and enforcement findings. Too stringent an interpretation of the meaning of the requirements could result in diversion of licensee and NRC resources for review of inconsequential changes. Too high a threshold for NRC approval could lead to an erosion of safety without explicit NRC review, particularly with respect to the cumulative effect of multiple changes.

The Commission acknowledges that these issues are still under review within the Commission, and may well undergo further modification based upon that review or on public comments received. That being said, the Commission sees merit in the establishment of a uniform policy approach for addressing the change process issue. To this end, at the same time the Commission solicits comment on proposed requirements at § 63.44 that are comparable to existing regulations for other facilities, the Commission also seeks comment on the suitability, for a repository at Yucca Mountain, of an approach substantially equivalent to that proposed last year for nuclear reactors and spent fuel storage facilities. Alternative criteria for § 63.44, that could be used to implement such an approach for a repository at Yucca Mountain, is presented below, and should be viewed as a template for discussion.

Section 63.44 Changes, Tests, and Experiments

(a) Definitions:

(1) *Change* means a modification, addition or removal.

(2) *Final Safety Analysis Report (as updated)* means the Safety Analysis Report for the geologic repository, submitted in accordance with § 63.21, as modified as a result of changes made

pursuant to § 63.44, and as updated in accordance with § 63.24.

(3) *Procedures as described in the Final Safety Analysis Report (as updated)* means information in the Final Safety Analysis Report (as updated) regarding how structures, systems, and components important to safety are operated or controlled and information describing conduct of operations.

(4) *Reduction in margin of safety associated with any license specification* means that the input assumptions, analytical methods, acceptance conditions, criteria and limits of the safety analyses, presented in the Final Safety Analysis Report (as updated), that established any license specification requirement, are altered in a nonconservative manner.

(5) *Tests or experiments not described in the Final Safety Analysis Report (as updated)* means any condition where the geologic repository operations area or any of its systems, structures, and components important to safety, or barriers important to waste isolation, are utilized, controlled, or altered in a manner which is either:

(i) Outside the controlling parameters of the design bases as described in the Final Safety Analysis Report (as updated); or

(ii) Inconsistent with the analyses in the Final Safety Analysis Report (as updated).

(b)(1) DOE may make changes in the geologic repository operations area as described in the Final Safety Analysis Report (as updated), make changes in the procedures as described in the Final Safety Analysis Report (as updated), and conduct tests or experiments not described in the Final Safety Analysis Report (as updated), without obtaining either an amendment of construction authorization pursuant to § 63.33 or a license amendment pursuant to § 63.45, if a change in the conditions incorporated in the construction authorization or license is not required, and the change, test, or experiment does not meet any of the criteria in paragraph (b)(2) of this section.

(2) DOE shall obtain an amendment of construction authorization pursuant to § 63.33 or a license amendment pursuant to § 63.45, prior to implementing a change, test, or experiment if it would:

(i) Result in more than a minimal increase in the probability of occurrence of an event previously evaluated in either the Final Safety Analysis Report (as updated), or in evaluations performed pursuant to this section and safety analyses performed pursuant to §§ 63.33 or 63.45, as applicable, after the last Final Safety Analysis Report was updated pursuant to § 63.24;

(ii) Result in more than a minimal increase in the probability of occurrence of a malfunction of structures, systems, components important to safety, or barriers important to waste isolation, which were previously evaluated in either the Final Safety Analysis Report (as updated), or in evaluations performed pursuant to this section and safety analyses performed pursuant to §§ 63.33 or 63.45, as applicable, after the last Final Safety Analysis Report was updated pursuant to § 63.24;

(iii) Result in more than a minimal increase in the consequences of an event previously evaluated in either the Final Safety Analysis Report (as updated), or in evaluations performed pursuant to this section and safety analyses performed pursuant to §§ 63.33 or 63.45, as applicable, after the last Final Safety Analysis Report was updated pursuant to § 63.24;

(iv) Result in more than a minimal increase in the consequences of malfunction of structures, systems, components important to safety, or barriers important to waste isolation, which were previously evaluated in either the Final Safety Analysis Report (as updated), or in evaluations performed pursuant to this section and safety analyses performed pursuant to §§ 63.33 or 63.45, as applicable, after the last Final Safety Analysis Report was updated pursuant to § 63.24;

(v) Create the possibility for a design basis event, or of a pathway for release of radionuclides, of a different type than any evaluated previously in either the Final Safety Analysis Report (as updated), or in evaluations performed pursuant to this section and safety analyses performed pursuant to §§ 63.33 or 63.45, as applicable, after the last Final Safety Analysis Report was updated pursuant to § 63.24;

(vi) Create the possibility for a malfunction of structures, systems, and components important to safety, or barriers important to waste isolation, with a different result than any evaluated previously in either the Final Safety Analysis Report (as updated), or in evaluations performed pursuant to this section and safety analyses performed pursuant to §§ 63.33 or 63.45, as applicable, after the last Final Safety Analysis Report was updated pursuant to § 63.24;

(vii) Result in a reduction in the margin of safety associated with any license specification;

(viii) Result in a significant increase in occupational exposure;

(ix) Result in a significant unreviewed environmental impact.

(c)(1) DOE shall maintain records of changes in the geologic repository operations area at the Yucca Mountain site and of changes in procedures it has made pursuant to this section if these changes constitute changes in the geologic repository operations area as described in the Final Safety Analysis Report (as updated). DOE shall also maintain records of tests and experiments carried out pursuant to paragraph (b) of this section. These records shall include a written evaluation that provides the bases for the determination that the change, test, or experiment does not require an amendment of construction authorization or license amendment pursuant to paragraph (b)(2) of this section.

(2) DOE shall prepare annually, or at such shorter interval as may be specified in the license, a report containing a brief description of such changes, tests, and experiments, including a summary of the evaluation of each. DOE shall furnish the report to the appropriate NRC Regional Office shown in Appendix D of Part 20 of this chapter, with a copy to the Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Any report submitted pursuant to this paragraph shall be made a part of the public record of the licensing proceedings.

As noted above, the criteria for changes, tests and experiments that a licensee may conduct without prior NRC approval or license amendment continue to be the subject of generic consideration by the Commission, and may change subject to public comment received on this notice, or on the proposed rulemaking for Parts 50 and 72, discussed earlier. For example, in the supplementary information accompanying the latter, the Commission identified a range of possible definitions for what may constitute a "reduced margin of safety," including its deletion as a criterion. Also, it should be noted that, depending on the outcome of the Commission's generic deliberations, it may be necessary to modify §§ 63.44 and 63.46, as proposed in this notice, to eliminate, altogether, the concept of an "unreviewed safety question."

Irrespective of the specific approach and criteria selected, the Commission is also interested in whether criteria for changes, tests and experiments should apply solely to the Safety Analysis Report or to the contents of the entire license application, as proposed.

XVII. Relationship to Generic Criteria at 10 CFR Part 60

The proposed criteria will apply specifically and exclusively to the proposed repository at Yucca Mountain. Consistent with this intent, the Commission proposes to modify its generic criteria at 10 CFR Part 60 to make clear that they do not apply, nor may they be the subject of litigation, in any NRC licensing proceeding for a repository at Yucca Mountain.

Corresponding administrative changes to Parts 2, 19, 20, 21, 30, 40, 51, and 61 are being proposed to reflect the potential of licensing a HLW geologic repository under proposed Part 63 as well as Part 60. In appropriate sections of Parts 2, 19, 20, 21, 30, 40, 51, and 61 where Part 60 is mentioned, a reference to Part 63 is added. [2]

XVIII. Section-by-Section Analysis of Part 63

Subpart A—General Provisions

This subpart, except for § 63.2, "Definitions," contains proposed general provisions that are similar to the provisions of Part 60 with minor wording changes for simplification, clarification, or to refer specifically to the Yucca Mountain site, where appropriate. Definitions have been revised to reflect usage in this part, as appropriate.

Section 63.1 *Purpose and scope.* This section defines the purpose and scope of Part 63 to be limited to the licensing of DOE to receive and possess source, special nuclear, and byproduct material at a geologic repository operations area sited, constructed, or operated at Yucca Mountain, Nevada. It states that generic regulations at Part 60 of this title do not apply, and cannot be the subject of any litigation in any licensing proceeding for the Yucca Mountain site.

Section 63.2 *Definitions.* This section contains definitions of terms as used in this part.

Section 63.3 *License required.* This section prohibits DOE from receiving or possessing source, special nuclear, or byproduct material at a geologic repository operations area at the Yucca Mountain site without having a license issued by the Commission, and prohibits DOE from beginning construction of the geologic repository operations area without authorization from the Commission.

Section 63.4 *Communications and records.* This section describes requirements for communications and reports submitted to the Commission, including appropriate addresses for communications to be forwarded to NRC.

Section 63.5 *Interpretations.* This section specifies when interpretations of the meaning of the regulations in this part by NRC officers or employees will be considered binding on the Commission.

Section 63.6 *Exemptions.* This section states the bases on which the Commission may grant exemptions from the requirements of this part.

Section 63.7 *License not required for certain preliminary activities.* This section allows DOE to possess source, special nuclear, or byproduct material at Yucca Mountain for the purposes of site characterization, and for use in certain construction activities.

Section 63.8 *Information collection requirements: Approval.* This section indicates that the information collection requirements contained in this part have been reviewed and approved by the Office of Management and Budget in accordance with the Paperwork Reduction Act.

Section 63.9 *Employee protection.* This section specifies requirements for protection of licensee or contractor and subcontractor personnel from certain adverse actions by employers.

Section 63.10 *Completeness and accuracy of information.* This section requires information provided to the Commission be complete and accurate. It also requires NRC notification of information having significant public health and safety implications.

Section 63.11 *Deliberate misconduct.* This section prohibits certain licensee activities and describes resulting enforcement action.

Subpart B—Licenses

This subpart, except for § 63.15, "Site characterization," § 63.16, "Review of site characterization activities," and § 63.21, "Content of application," contains proposed provisions that are similar to the licensing provisions of Part 60 with minor wording changes for simplification, clarification or to refer to the Yucca Mountain site, where appropriate. Provisions related to the content of the license application have been developed to be consistent with the proposed technical criteria of Subpart E. Provisions related to site characterization have been simplified from similar sections of Part 60 to reflect the maturity of site characterization at Yucca Mountain. For example, there are no provisions requiring DOE to prepare and submit a site characterization plan to NRC or any requirement for NRC to prepare a specific site characterization analysis in as much as both activities have been completed previously. However, provisions requiring DOE to undertake site characterization and submit semiannual progress reports to NRC and provisions allowing NRC to comment on any aspect of site characterization or performance assessment, at any time, are proposed as indicated in the analysis of pertinent sections of Subpart B that follows.

Section 63.15 *Site characterization.* This section specifies that a program of site characterization is to be conducted prior to submittal of an application and that investigations are to be conducted in a manner that limits adverse effects on the performance of the geologic repository.

Section 63.16 *Review of site characterization activities.* This section specifies that DOE must submit to the Commission semiannual reports on the progress of site characterization, that NRC staff shall be permitted to visit, inspect, and observe site characterization activities at the Yucca Mountain site, and that the Director may at any time comment on any aspect of site characterization and performance assessment. This section also specifies that the Commission will determine whether any proposed onsite testing with radioactive material during site characterization is necessary to provide data for the preparation of the environmental reports required by law and for the license application.

Section 63.21 *Content of application.* This section specifies that the license application must include general information, a safety analysis report, and be accompanied by an environmental impact statement. This section also describes the detailed information to be included in the safety analysis report.

Section 63.22 *Filing and distribution of application.* This section describes requirements for filing and distribution of the license application, amendments to the license application, environmental reports, and related updates and supplements.

Section 63.23 *Elimination of repetition.* This section allows DOE to incorporate by reference information in previous applications, statements, or reports filed with the Commission in its application or environmental statement.

Section 63.24 *Updating of application and environmental impact statement.* This section requires DOE to submit a complete application, to update or supplement the application or environmental impact statement in a

[2] Although the NRC has recently published final rule amendments to update its rules of practice in Subpart J of Part 2 for the licensing proceeding on disposal of HLW at a geologic repository (62 FR 71729; December 30, 1998), any further changes to Subpart J that are necessary to conform to the addition of Part 63 will be deferred until completion of this rulemaking.

timely manner, and certify that updated copies contain current information.

Section 63.31 *Construction authorization.* This section states the bases on which the Commission may authorize construction of a geologic repository operations area at the Yucca Mountain site.

Section 63.32 *Conditions of construction authorization.* This section indicates that the Commission will include conditions in the construction authorization as necessary to protect the health and safety of the public, the common defense and security, and environmental values and describes specific provisions and restrictions that will be included in the construction authorization. This section also indicates that a license will not be issued until DOE has updated its application as required at § 63.24 and the Commission has made the findings stated at § 63.41.

Section 63.33 *Amendment of construction authorization.* This section requires DOE to apply for an amendment of the construction authorization if changes are desired. This section also states the bases on which the Commission may approve an amendment of the construction authorization.

Section 63.41 *Standards for issuance of a license.* This section states the bases on which the Commission may issue a license to receive and possess source, special nuclear, or byproduct material at a geologic repository operations area at the Yucca Mountain site.

Section 63.42 *Conditions of license.* This section indicates that the Commission will include conditions or specifications in the license as necessary to protect the health and safety of the public, the common defense and security, and environmental values. This section also identifies general conditions that will be considered conditions of the license, whether stated in the license or not.

Section 63.43 *License specification.* This section indicates that the Commission will include conditions in the license that are derived from the analyses and evaluations included in the application and amendments made before a license is issued. This section also describes specific categories of restrictions, requirements, and controls that will be included as conditions of the license.

Section 63.44 *Changes, tests, and experiments.* This section states the bases on which DOE may change the geologic repository operations area or procedures as described in the application, and conduct tests or experiments not described in the application, without prior Commission approval. This section also requires DOE to maintain records of changes made and tests undertaken pursuant to this section.

Section 63.45 *Amendment of license.* This section requires DOE to apply for an amendment of the license if changes are desired. This section also states the bases on which the Commission may approve an amendment of the license.

Section 63.46 *Particular activities requiring license amendment.* This section describes specific activities that require amending the license prior to being performed, unless expressly authorized in the license.

Section 63.51 *License amendment for permanent closure.* This section requires DOE to apply for an amendment of the license to permanently close a geologic repository at the Yucca Mountain site. This section also requires DOE to submit an update of the license application and describes the detailed information to be included in the update.

Section 63.52 *License termination.* This section requires DOE to apply for an amendment to terminate the license following permanent closure of the geologic repository and the decontamination or dismantlement of surface facilities at the Yucca Mountain site.

Subpart C—Participation by State Government and Affected Indian Tribes

This subpart contains proposed provisions that are similar to the State and affected Indian Tribe participation provisions of 10 CFR Part 60 with minor wording changes to refer to the State of Nevada and Yucca Mountain site, where appropriate.

Section 63.61 *Provision of information.* This section states that NRC shall provide to the Governor, the Nevada State legislature, and any affected Indian Tribe timely and complete information regarding determinations made by the Commission with respect to the Yucca Mountain site. NRC shall also make this information available to the public and DOE.

Section 63.62 *Site review.* This section states that NRC shall consult with the State of Nevada and affected Indian Tribes regarding site characterization activities.

Section 63.63 *Participation in license reviews.* This section sets forth procedures for State and local governments and affected Indian Tribes to participate in license review activities.

Section 63.64 *Notice to state.* This section notes that if the Governor and legislature of the State of Nevada have designated a joint person or entity to receive information from NRC, NRC will send such information to the jointly designated addressee.

Section 63.65 *Representation.* This section allows the Commission to request that any person acting as a representative of the State, Governor, or legislature of Nevada, or any affected Indian Tribe provide the Commission with the authority basis for such a representation.

Subpart D—Records, Reports, Tests, and Inspections

This subpart contains proposed provisions that are similar to the records, reports, tests, and inspection provisions of Part 60 with minor wording changes for simplification, clarification or to refer to the Yucca Mountain site, as appropriate.

Section 63.71 *Records and reports.* This section requires DOE to make and maintain records and reports as required by conditions of the license or rules, regulations, and orders of the Commission.

Section 63.72 *Construction records.* This section requires DOE to maintain records of the construction of the geologic repository operations area and describes the types of records to be maintained.

Section 63.73 *Reports of deficiencies.* This section requires DOE to notify the Commission of each deficiency found in the characteristics of the Yucca Mountain site and design and construction of the geologic repository operations area, if the uncorrected deficiency could be a safety hazard, represent a deviation from the design criteria or design bases, or represent a deviation from conditions of the construction authorization or license.

Section 63.74 *Tests.* This section requires DOE to perform such tests, or to allow the Commission to perform such tests, as the Commission determines necessary for administration of the regulations in this part. This section also describes the types of tests that may be included under this section.

Section 63.75 *Inspections.* This section requires DOE to afford the Commission opportunity for inspection of the geologic repository operations area and adjacent areas. This section also requires DOE to provide office space for Commission inspection personnel.

Section 63.78 *Material control and accounting records and reports.* This section requires DOE to establish a material inventory system, whereby material and accounting procedures are developed, physical inventories are

performed, loss of special nuclear material, or accidental criticality is reported, and material status and nuclear material transfer reports are generated. This section notes that the material and accounting program is to be the same as that specified at §§ 72.72, 72.74, 72.76, and 72.78.

Subpart E—Technical Criteria

This subpart, except for § 63.101, "Purpose and nature of findings," § 63.102, "Concepts," and § 63.121, "Requirements for ownership and control of interests in land," contains proposed performance objectives for the geologic repository area through permanent closure (preclosure) and the geologic repository after permanent closure (postclosure), and requirements for the analyses used to demonstrate compliance with the performance objectives. The preclosure performance objective is similar to the provisions in Part 60. However, the postclosure performance objective and other requirements differ significantly from Part 60. This subpart proposes compliance to be demonstrated in the context of safety analyses of total system performance and does not prescribe general design or siting criteria, or specific quantitative subsystem performance objectives as was done in Part 60. The Commission is proposing an individual dose limit that is believed to be generally consistent with the Energy Policy Act of 1992 and the findings and recommendations of the National Academy of Sciences' technical bases for Yucca Mountain Standards. When final EPA standards for Yucca Mountain are published, the Commission will amend its regulations to be consistent with the standards, if necessary.

Section 63.101 *Purpose and nature of findings.* This section describes the Commission's expectations for demonstration that the geologic repository will be in conformance with the performance objectives

Section 63.102 *Concepts.* This section provides a functional overview of this subpart.

Section 63.111 *Performance objectives for the geologic repository operations area through permanent closure.* This section requires DOE to design the geologic operations area to comply with the exposure limits given in this section, conduct an integrated safety analysis, permit implementation of a performance confirmation program, and preserve the option for waste retrieval.

Section 63.112 *Requirements for integrated safety analysis of the geologic repository operations area.* This section specifies the requirements for the integrated safety analysis used to demonstrate compliance with the performance objective through permanent closure provided at §§ 63.111(a)(1) and 63.111(a)(2).

Section 63.113 *Performance objective for the geologic repository after permanent closure.* This section requires DOE to include a system of multiple barriers for the geologic repository, comply with the individual annual dose limit, conduct a performance assessment, and assess the consequences of a specified human intrusion event.

Section 63.114 *Requirements for performance assessment.* This section specifies the requirements for the performance assessment used to demonstrate compliance with the individual dose limit specified at § 63.113(b).

Section 63.115 *Required characteristics of the reference biosphere and critical group.* This section specifies characteristics of the reference biosphere and critical group to be used by DOE in their performance assessment.

Section 63.121 *Requirements for ownership and control of interests in land.* This section requires DOE to have permanent control of the site. It states that DOE shall set up controls necessary to prevent adverse human actions that could affect the repository. DOE is required to obtain water rights needed for the repository.

Subpart F—Performance Confirmation Program

This subpart contains proposed provisions that are similar to the performance confirmation provisions of 10 CFR Part 60.

Section 63.131 *General requirements.* This section states the objectives of the performance confirmation program and specifies that the program be started during site characterization and continue until permanent closure.

Section 63.132 *Confirmation of geotechnical and design parameters.* This section requires DOE to monitor subsurface conditions during repository construction and operation to confirm original design assumptions and to ensure that performance of geologic and engineered features is within design limits. DOE is also required to inform the Commission of any design changes needed to accommodate actual field conditions encountered.

Section 63.133 *Design testing.* This section requires DOE to undertake a program of in situ testing of such features as borehole and shaft seals, backfill, and the thermal interaction effects of waste packages, backfill, rock, and groundwater.

Section 63.134 *Monitoring and testing waste packages.* This section requires DOE to establish a program for monitoring and testing waste packages at the geologic repository operations area that is to continue as long as practical up to the time of permanent closure.

Subpart G—Quality Assurance

This subpart contains proposed provisions that are similar to the quality assurance provisions of 10 CFR Part 60.

Section 63.141 *Scope.* This section requires DOE to establish a quality assurance program to be applied at the geologic repository at the Yucca Mountain site.

Section 63.142 *Applicability.* This section indicates that the quality assurance program applies to all systems, structures, and components important to safety, to design and characterization of barriers important to waste isolation, and to activities related thereto.

Section 63.143 *Implementation.* This section indicates that the quality assurance program is to be based on the criteria of Appendix B of 10 CFR Part 50, as applicable and appropriately supplemented as required by § 63.142.

Subpart H—Training and Certification of Personnel

This subpart contains proposed provisions that are similar to the training and certification provisions of 10 CFR Part 60.

Section 63.151 *General requirements.* This section specifies that operations of systems and components important to safety are to be performed only by trained and certified personnel or by personnel under the direct visual supervision of an individual with training and certification in such operations. This section also specifies that supervisory personnel who direct operations that are important to safety are to be certified in such operations.

Section 63.152 *Training and certification program.* This section specifies that a program for training, proficiency testing, certification, and requalification of operating and supervisory personnel is to be established.

Section 63.153 *Physical requirements.* This section specifies physical requirements for personnel certified for operations that are important to safety.

Subpart I—Emergency Planning Criteria

This subpart contains proposed provisions for emergency planning.

Section 63.161 *Emergency plan for the geologic repository operations area through permanent closure.* This section requires DOE to develop and be prepared to implement a plan to cope with radiological emergencies. The section indicates that the emergency plan is to be based on criteria at § 72.32(b).

Subpart J—Violations

This subpart contains proposed provisions that are similar to the violation provisions of 10 CFR Part 60.

Section 63.171 *Violations.* This section specifies actions the Commission may take, including obtaining a court order to prevent a violation, and contains civil penalty provisions.

Section 63.172 *Criminal penalties.* This section specifies criminal sanctions for violations. For purposes of Section 223 of the Atomic Energy Act of 1954, as amended, that provides for criminal sanctions, all regulations in Part 63 are issued under one or more of §§ 161b, 161i, or 161o except for the sections listed in § 63.172(b).

XIX. Section-by-Section Analysis of Changes to Other Parts

Section-by-section analysis of changes to Parts 2,19, 20, 21, 30, 40, 51, and 61.

10 CFR Part 2

Section 2.101 *Filing of applications* is amended to add reference to Part 63 in the procedures for filing of applications.

Section 2.103 *Action on applications for byproduct, source, special nuclear material, and operator licenses* is amended to add reference to Part 63 in the procedures for notification in this section.

Section 2.104 *Notice of hearing* is amended to add reference to Part 63 in the procedures for notification of hearings.

Section 2.105 *Notice of proposed action* is amended to add reference to Part 63 in the procedures for notification of proposed actions in this section.

Section 2.106(c) *Notice of issuance* is amended to provide for public notification of any action with respect to a license application or license amendment pursuant to Part 63.

10 CFR Part 19

Section 19.2 *Scope* is amended to make Part 63 subject to the regulations in Part 19.

Section 19.3 *Definitions* is amended to add Part 63 to the definition of "license."

10 CFR Part 20

Section 20.1002 *Scope* is amended to make Part 63 subject to the regulations in Part 20.

10 CFR Part 21

Section 21.2(a) *Scope* is amended to make Part 63 subject to the regulations in Part 21.

Certain definitions in § 21.3 *Definitions* are amended to include Part 63.

By changes to § 21.21 *Notification of failure to comply or of a defect and its evaluation,* Part 63 is made subject to the regulations for reporting defects and noncompliance.

10 CFR Part 30

Changes to § 30.11 *Specific exemptions* make DOE exempt from Part 30 regulations for activities subject to Part 63.

10 CFR Part 40

Changes to § 40.14 *Specific exemptions* make DOE exempt from Part 40 regulations for activities subject to Part 63.

10 CFR Part 51

Section 51.20 *Criteria for and identification of licensing and regulatory actions requiring environmental impact statements* is amended to add reference to Part 63 under actions requiring environmental impact statements.

Section 51.22 *Criteria for categorical exclusion; identification of licensing and regulatory actions eligible for categorical exclusion or otherwise not requiring environmental review* is amended to add reference to Part 63 in requirements for categorical exclusion from environmental review.

Section 51.26 *Requirement to publish notice of intent and conduct scoping process* is amended to add reference to Part 63 in procedures for receipt of an application and accompanying environmental impact statement from DOE.

Section 51.67 *Environmental information concerning geologic repositories* is amended to add reference to Part 63 in requirements for submission of an environmental impact statement by DOE.

10 CFR Part 61

Section 61.1 *Purpose and scope* is amended to state that the regulations of Part 61 do not apply to disposal of HLW as provided for in Part 63.

Section 61.2 *Definitions,* the definition of "land disposal facility" is amended to clarify that a geologic repository as defined in Part 63 is not considered a land disposal facility.

Section 61.55 *Waste classification* is amended to add reference to Part 63 in the definition of a geologic repository.

XX. Specific Questions for Public Comment

The Commission welcomes comments on all aspects of this proposed rule, and is especially interested in receiving comments on the following:

1. The Commission solicits comments on the appropriateness of its proposed approach to defining the critical group and reference biosphere for Yucca Mountain. In particular, the Commission solicits comments on any other candidate population groups, biosphere assumptions and potential exposure pathways that should be considered in the establishment of a "critical group" for Yucca Mountain.

2. The Commission solicits comments on the appropriateness of its proposed human intrusion scenario, and the assumed timing of its occurrence, as a reasonable measure for evaluating the consequences of intrusion at a repository at Yucca Mountain.

3. The Commission solicits comment on the merits of requiring DOE to implement a quality assurance program for the geologic repository based on the criteria of Appendix B of 10 CFR Part 50.

4. The Commission solicits comments on the suitability of alternative criteria for proposed § 63.44. These alternative criteria are included in the statement of considerations discussion of proposed § 63.44 and are substantially equivalent to that proposed last year for nuclear reactors and spent fuel storage facilities.

5. The Commission solicits comments on whether the approach and criteria for changes, tests, and experiments at § 63.44 should apply solely to the Safety Analysis Report or to the contents of the entire license application, irrespective of whether proposed § 63.44 or the alternative criteria presented in the statement of consideration are selected.

XXI. Plain Language

The Presidential memorandum dated June 1, 1998, entitled "Plain Language in Government Writing," directed that the Federal government's writing be in plain language. The NRC requests comments on this proposed rule specifically with respect to the clarity and effectiveness of the language used. Comments should be sent to the address listed above.

XXII. Finding of No Significant Environmental Impact: Availability

Pursuant to Section 121(c) of the Nuclear Waste Policy Act, this proposed rule does not require the preparation of an environmental impact statement under Section 102(2)(c) of the National Environmental Policy Act of 1969 or any environmental review under subparagraph (E) or (F) of Section 102(2) of such act.

XXIII. Paperwork Reduction Act Statement

This proposed rule contains information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). This rule has been submitted to the Office of Management and Budget for review and approval of the paperwork requirements.

The public reporting burden for this collection of information is estimated to average 121 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. The U.S. Nuclear Regulatory Commission is seeking public comment on the potential impact of the information collection contained in the proposed rule and on the following issues:

1. Is the proposed information collection necessary for the proper performance of the functions of NRC, including whether the information will have practical utility?
2. Is the estimate of burden accurate?
3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?
4. How can the burden of the information collection be minimized, including the use of automated collection techniques?

Send comments on any aspect of this proposed information collection, including suggestions for reducing this burden, to the Records Management Branch (T-6F-33), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet electronic mail at BJS1@nrc.gov; and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-AG04), Office of Management and Budget, Washington, DC 20503.

Comments to OMB on the information collections or on the above issues should be submitted by March 24, 1999. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given to comments received after this date.

Public Protection Notification

If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

XXIV. Regulatory Analysis

The NRC has prepared a regulatory analysis on this regulation. The analysis examines the alternatives considered by NRC. The analysis is available for inspection in the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC. Single copies of the analysis may be obtained from Clark Prichard, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 415-6203, e-mail CWP@nrc.gov.

XXV. Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Commission certifies that this rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. This proposed rule relates to the licensing of only one entity, the Department of Energy, which does not fall within the scope of the definition of "small entities" set forth in the Regulatory Flexibility Act.

XXVI. Backfit Statement

The NRC has determined that the backfit rule, 10 CFR 50.109, does not apply to this proposed rule and, therefore, that a backfit analysis is not required because this rule does not involve any provisions which would impose backfits as defined in 10 CFR 50.109(a)(1).

List of Subjects

10 CFR Part 2

Administrative procedure and practice, Antitrust, Byproduct material, Classified information, Environmental protection, Nuclear materials, Nuclear power plants and reactors, Penalties, Sex discrimination, Source material, Special nuclear material, Waste treatment and disposal.

10 CFR Part 19

Criminal penalties, Environmental protection, Nuclear materials, Nuclear power plants and reactors, Occupational safety and health, Radiation protection, Reporting and recordkeeping requirements, Sex discrimination.

10 CFR Part 20

Byproduct material, Criminal penalties, Licensed material, Nuclear materials, Nuclear power plants and reactors, Occupational safety and health, Packaging and containers, Radiation protection, Reporting and recordkeeping requirements, Special nuclear material, Source material, Waste treatment and disposal.

10 CFR Part 21

Nuclear power plants and reactors, Penalties, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 30

Byproduct material, Criminal penalties, Government contracts, Intergovernmental relations, Isotopes, Nuclear materials, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 40

Criminal penalties, Government contracts, Hazardous materials transportation, Nuclear materials, Reporting and recordkeeping requirements, Source material, Uranium.

10 CFR Part 51

Administrative practice and procedure, Environmental impact statement, Nuclear materials, Nuclear power plants and reactors, Reporting and recordkeeping requirements.

10 CFR Part 60

Criminal penalties, High-level waste, Nuclear power plants and reactors, Nuclear materials, Reporting and recordkeeping requirements, Waste treatment and disposal.

10 CFR Part 61

Criminal penalties, Low level waste, Nuclear materials, Reporting and recordkeeping requirements, Waste treatment and disposal.

10 CFR Part 63

Criminal penalties, High-level waste, Nuclear power plants and reactors, Nuclear materials, Reporting and recordkeeping requirements, Waste treatment and disposal.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; the Nuclear Waste Policy Act of 1982, as amended; and 5 U.S.C. 552 and 553, the NRC is proposing to adopt the following amendments to 10 CFR Parts 2, 19, 20, 21, 30, 40, 51, and 60 and to add the new 10 CFR Part 63.

PART 2—RULES OF PRACTICE FOR DOMESTIC LICENSING PROCEEDINGS AND ISSUANCE OF ORDERS

1. The authority citation for Part 2 continues to read as follows:

Authority: Secs. 161, 181, 68 Stat. 948, 953, as amended (42 U.S.C. 2201, 2231); sec. 191, as amended, Pub. L. 87-615, 76 Stat. 409 (42 U.S.C. 2241); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841); 5 U.S.C. 552.

Section 2.101 also issued under secs. 53, 62, 63, 81, 103, 104, 105, 68 Stat. 930, 932, 933, 935, 936, 937, 938, as amended (42 U.S.C. 2073, 2092, 2093, 2111, 2133, 2134, 2135); sec. 114(f), Pub. L. 97-425, 96 Stat. 2213, as amended (42 U.S.C. 10134(f)); sec. 102, Pub. L. 91-190, 83 Stat. 853, as amended (42 U.S.C. 4332); sec. 301, 88 Stat. 1248 (42 U.S.C. 5871). Sections 2.102, 2.103, 2.104, 2.105, 2.721 also issued under secs. 102, 103, 104, 105, 183, 189, 68 Stat. 936, 937, 938, 954, 955, as amended (42 U.S.C. 2132, 2133, 2134, 2135, 2233, 2239). Section 2.105 also issued under Pub. L. 97-415, 96 Stat. 2073 (42 U.S.C. 2239). Sections 2.200-2.206 also issued under secs. 161 b, i, o, 182, 186, 234, 68 Stat. 948-951, 955, 83 Stat. 444, as amended (42 U.S.C. 2201 (b), (i), (o), 2236, 2282); sec. 206, 88 Stat 1246 (42 U.S.C. 5846). Sections 2.205(j) also issued under Pub. L. 101-410, 104 Stat. 890, as amended by section 31001(s), Pub. L. 104-134, 110 Stat. 1321-373 (28 U.S.C. 2461 note). Sections 2.600-2.606 also issued under sec. 102, Pub. L. 91-190, 83 Stat. 853, as amended (42 U.S.C. 4332). Sections 2.700a, 2.719 also issued under 5 U.S.C. 554. Sections 2.754, 2.760, 2.770, 2.780 also issued under 5 U.S.C. 557. Section 2.764 also issued under secs. 135, 141, Pub. L. 97-425, 96 Stat. 2232, 2241 (42 U.S.C. 10155, 10161). Section 2.790 also issued under sec. 103, 68 Stat. 936, as amended (42 U.S.C. 2133) and 5 U.S.C. 552. Sections 2.800 and 2.808 also issued under 5 U.S.C. 553. Section 2.809 also issued under 5 U.S.C. 553 and sec. 29, Pub. L. 85-256, 71 Stat. 579, as amended (42 U.S.C. 2039). Subpart K also issued under sec. 189, 68 Stat. 955 (42 U.S.C. 2239); sec. 134, Pub. L. 97-425, 96 Stat. 2230 (42 U.S.C. 10154). Subpart L also issued under sec. 189, 68 Stat. 955 (42 U.S.C. 2239). Appendix A also issued under sec. 6, Pub. L. 91-560, 84 Stat. 1473 (42 U.S.C. 2135).

2. Section 2.101 is amended by revising paragraphs (f)(1) and (f)(5) to read as follows:

§ 2.101 Filing of applications.

* * * * *

(f)(1) Each application for a license to receive and possess high-level radioactive waste at a geologic repository operations area pursuant to Parts 60 or 63 of this chapter and any environmental impact statement required in connection therewith pursuant to Subpart A of Part 51 of this chapter shall be processed in accordance with the provisions of this paragraph.

* * * * *

(5)(i) If a tendered document is acceptable for docketing, the applicant will be requested to—

(A) Submit to the Director of Nuclear Material Safety and Safeguards such additional copies of the application and environmental impact statement as the regulations in Part 60 or 63 and Subpart A of Part 51 of this chapter require;

(B) Serve a copy of such application and environmental impact statement on the chief executive of the municipality in which the geologic repository operations area is to be located, or if the geologic repository operations area is not to be located within a municipality, on the chief executive of the county (or to the Tribal organization, if it is to be located within an Indian reservation); and

(C) Make direct distribution of additional copies to Federal, state, Indian Tribe, and local officials in accordance with the requirements of this chapter, and written instructions from the Director of Nuclear Material Safety and Safeguards.

(ii) All such copies shall be completely assembled documents, identified by docket number. Subsequently distributed amendments to the application, however, may include revised pages to previous submittals and, in such cases, the recipients will be responsible for inserting the revised pages.

* * * * *

3. Section 2.103 is amended by revising paragraph (a) to read as follows:

§ 2.103 Action on applications for byproduct, source, special nuclear material, and operator licenses.

(a) If the Director of Nuclear Reactor Regulation or the Director of Nuclear Material Safety and Safeguards, as appropriate, finds that an application for a byproduct, source, special nuclear material, or operator license complies with the requirements of the Act, the Energy Reorganization Act, and this chapter, he will issue a license. If the license is for a facility, or for the receipt of waste radioactive material from other persons for the purpose of commercial disposal by the waste disposal licensee, or if it is to receive and possess high-level radioactive waste at a geologic repository operations area pursuant to Part 60 or 63 of this chapter, the Director of Nuclear Reactor Regulation or the Director of Nuclear Material Safety and Safeguards, as appropriate, will inform the State, Tribal, and local officials specified in § 2.104(e) of the issuance of the license. For notice of issuance requirements for licenses issued pursuant to part 61 of this chapter, see § 2.106(d).

* * * * *

4. Section 2.104 is amended by revising paragraph (e) to read as follows:

§ 2.104 Notice of hearing.

* * * * *

(e) The Secretary will give timely notice of the hearing to all parties and to other persons, if any, entitled by law to notice. The Secretary will transmit a notice of the hearing on an application for a license for a production or utilization facility, for a license for receipt of waste radioactive material from other persons for the purpose of commercial disposal by the waste disposal licensee, for a license under Part 61 of this chapter, for a license to receive and possess high-level radioactive waste at a geologic repository operations area pursuant to Part 60 or 63 of this chapter, and for a license under Part 72 of this chapter to acquire, receive or possess spent fuel for the purpose of storage in an independent spent fuel storage installation (ISFSI) to the governor or other appropriate official of the State and to the chief executive of the municipality in which the facility is to be located or the activity is to be conducted or, if the facility is not to be located or the activity conducted within a municipality, to the chief executive of the county (or to the Tribal organization, if it is to be so located or conducted within an Indian reservation).

5. Section 2.105 is amended by revising paragraph (a)(5) to read as follows:

§ 2.105 Notice of proposed action.

(a) * * *

(5) A license to receive and possess high-level radioactive waste at a geologic repository operations area pursuant to Part 60 or 63 of this chapter.

* * * * *

6. Section 2.106 is amended by revising paragraph (c) to read as follows:

§ 2.106 Notice of issuance.

* * * * *

(c) The Director of Nuclear Material Safety and Safeguards will also cause to be published in the **Federal Register** notice of, and will inform the State, local, and Tribal officials specified in § 2.104(e) of any action with respect to, an application for a license to receive and possess high-level radioactive waste at a geologic repository operations area pursuant to Parts 60 or 63 of this chapter, or for the amendment to such license for which a notice of proposed action has been previously published.

* * * * *

PART 19—NOTICES, INSTRUCTIONS, AND REPORTS TO WORKERS; INSPECTION AND INVESTIGATIONS

7. The authority citation for Part 19 continues to read as follows:

Authority: Secs. 53, 63, 81, 103, 104, 161, 186, 68 Stat. 930, 933, 935, 936, 937, 948, 955, as amended, sec. 234, 83 Stat. 444, as amended, sec. 1701, 106 Stat. 2951, 2952, 2953 (42 U.S.C. 2073, 2093, 2111, 2133, 2134, 2201, 2236, 2282 2297f); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841); Pub. L. 95-601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5851).

8. Section 19.2 is revised to read as follows:

§ 19.2 Scope.

The regulations in this part apply to all persons who receive, possess, use, or transfer material licensed by the Nuclear Regulatory Commission pursuant to the regulations in Parts 30 through 36, 39, 40, 60, 61, 63, 70, or Part 72 of this chapter, including persons licensed to operate a production or utilization facility pursuant to Part 50 of this chapter, persons licensed to possess power reactor spent fuel in an independent spent fuel storage installation (ISFSI) pursuant to Part 72 of this chapter, and in accordance with § 76.60 to persons required to obtain a certificate of compliance or an approved compliance plan under Part 76 of this chapter. The regulations regarding interviews of individuals under subpoena apply to all investigations and inspections within the jurisdiction of the Nuclear Regulatory Commission other than those involving NRC employees or NRC contractors. The regulations in this part do not apply to subpoenas issued pursuant to 10 CFR 2.720.

9. Section 19.3 is amended by revising the definition of License to read as follows:

§ 19.3 Definitions.

* * * * *

License means a license issued under the regulations in Parts 30 through 36, 39, 40, 60, 61, 63, 70, or 71 of this chapter, including licenses to operate a production or utilization facility pursuant to Part 50 of this chapter.

* * * * *

PART 20—STANDARDS FOR PROTECTION AGAINST RADIATION

10. The authority citation for Part 20 continues to read as follows:

Authority: Secs. 53, 63, 65, 81, 103, 104, 161, 182, 186, 68 Stat. 930, 933, 935, 936, 937, 948, 953, 955, as amended, sec. 1701, 106 Stat. 2951, 2952, 2953 (42 U.S.C. 2073, 2093, 2095, 2111, 133, 2134, 2201, 2232, 2236, 2297f), secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846).

11. Section 20.1002 is revised to read as follows:

§ 20.1002 Scope.

The regulations in this part apply to persons licensed by the Commission to receive, possess, use, transfer, or dispose of byproduct, source, or special nuclear material, or to operate a production or utilization facility under Parts 30 through 36, 39, 40, 60, 61, 63, 70, or 72 of this chapter, and in accordance with 10 CFR 76.60 to persons required to obtain a certificate of compliance or an approved compliance plan under Part 76 of this chapter. The limits in this part do not apply to doses due to background radiation, to exposure of patients to radiation for the purpose of medical diagnosis or therapy, to exposure from individuals administered radioactive material and released in accordance with § 35.75, or to exposure from voluntary participation in medical research programs.

PART 21—REPORTING OF DEFECTS AND NONCOMPLIANCE

12. The authority citation for Part 21 continues to read as follows:

Authority: Sec. 161, 68 Stat. 948, as amended, sec. 234, 83, Stat. 444, as amended, sec. 1701, 106 Stat. 2951, 2953 (42 U.S.C. 2201, 2282, 2297f); secs. 201, as amended, 206, 88 Stat. 1242, as amended 1246 (42 U.S.C. 5841, 5846).

Section 21.2 also issued under secs. 135, 141, Pub. L. 97-425, 96 Stat. 2232, 2241 (42 U.S.C. 10155, 10161).

13. Section 21.2 is amended by revising paragraph (a) to read as follows:

§ 21.2 Scope.

(a) The regulations in this part apply, except as specifically provided otherwise in Parts 31, 34, 35, 39, 40, 60, 61, 63, 70, or Part 72 of this chapter, to each individual, partnership, corporation, or other entity licensed pursuant to the regulations in this chapter to possess, use, or transfer within the United States source material, byproduct material, special nuclear material, and/or spent fuel and high level radioactive waste, or to construct, manufacture, possess, own, operate or transfer within the United States, any production or utilization facility or independent spent fuel storage installation (ISFSI) or monitored retrievable storage installation (MRS); and to each director and responsible officer of such a licensee. The regulations in this part apply also to each individual, corporation, partnership, or other entity doing business within the United States, and each director and responsible officer of such organization, that constructs a production or utilization facility licensed for the manufacture, construction, or operation pursuant to Part 50 of this chapter, an ISFSI for the storage of spent fuel licensed pursuant to Part 72 of this chapter, an MRS for the storage of spent fuel or high level radioactive waste pursuant to Part 72 of this chapter, or a geologic repository for the disposal of high-level radioactive waste under Parts 60 or 63 of this chapter; or supplies basic components for a facility or activity licensed, other than for export, under Parts 30, 40, 50, 60, 61, 63, 70, 71, or Part 72 of this chapter.

§ 21.3 [Amended]

14. Section 21.3 is amended by adding the number 63 after "10 CFR Parts 30, 40, 50 (other than nuclear power plants), 61" in paragraph (2) in the definition of *basic components, commercial grade item, dedication,* and in the definition of *substantial safety hazard* between "61" and "70".

15. Section 21.21 is amended by revising paragraphs (d)(1)(i) and (d)(1)(ii) to read as follows:

§ 21.21 Notification of failure to comply or existence of a defect and its evaluation.

* * * * *

(d)(1) * * *

(i) The construction or operation of a facility or an activity within the United States that is subject to the licensing requirements under Parts 30, 40, 50, 60, 61, 63, 70, or 72 of this chapter and that is within his or her organization's responsibility; or

(ii) A basic component that is within his or her organization's responsibility and is supplied for a facility or an activity within the United States that is subject to the licensing requirements under Parts 30, 40, 50, 60, 61, 63, 70, or 72 of this chapter.

* * * * *

PART 30—RULES OF GENERAL APPLICABILITY TO DOMESTIC LICENSING OF BYPRODUCT MATERIAL

16. The authority citation for Part 30 continues to read as follows:

Authority: Secs. 81, 82, 161, 182, 183, 186, 68 Stat. 935, 948, 953, 954, 955, as amended, sec. 234, 83 Stat. 444 as amended (42 U.S.C. 2111, 2112, 2201, 2232, 2233, 2236, 2282); secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246(42 U.S.C. 5841, 5842, 5846).

Section 30.7 also issued under Pub. L. 95-601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5851). Section 30.34(b) also issued under sec. 184, 69 Stat. 954, as amended (42 U.S.C. 2234). Section 30.61 also issued under sec. 187, 68 Stat. 955 (42 U.S.C. 2237).

17. Section 30.11 is amended by revising paragraph (c) to read as follows:

§ 30.11 Specific exemptions.

* * * * *

(c) The DOE is exempt from the requirements of this part to the extent that its activities are subject to the requirements of Parts 60 or 63 of this chapter.

* * * * *

PART 40—DOMESTIC LICENSING OF SOURCE MATERIAL

18. The authority citation for Part 40 continues to read as follows:

Authority: Secs. 62, 63, 64, 65, 81, 161, 182, 183, 186, 68 Stat. 932, 933, 935, 948, 953, 954, 955, as amended, secs. 11e(2), 83, 84, Pub. L. 95-604, 92 Stat. 3033, as amended, 3039, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2014(e)(2), 2092, 2093, 2094, 2095, 2111, 2113, 2114, 2201, 2232, 2233, 2236, 2282); sec. 274, Pub. L. 86-373, 73 Stat. 688 (42 U.S.C. 2021); secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846); sec. 275, 92 Stat. 3021, as amended by Pub. L. 97-415, 96 Stat. 2067 (42 U.S.C. 2022).

Section 40.7 also issued under Pub. L. 95-601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5851). Section 40.31(g) also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Section 40.46 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Section 40.71 also issued under sec. 187, 68 Stat. 955 (42 U.S.C. 2237).

19. Section 40.14 is amended by revising paragraph (c) to read as follows:

§ 40.14 Specific exemptions.

* * * * *

(c) The DOE is exempt from the requirements of this part to the extent that its activities are subject to the requirements of Parts 60 or 63 of this chapter.

* * * * *

PART 51—ENVIRONMENTAL PROTECTION REGULATIONS FOR DOMESTIC LICENSING AND RELATED REGULATORY FUNCTIONS

20. The authority citation for Part 51 continues to read as follows:

Authority: Sec. 161, 68 Stat. 948, as amended, sec. 1701, 106 Stat. 2951, 2952, 2953, (42 U.S.C. 2201, 2297f); secs. 201, as amended, 202, 88 Stat. 1242, as amended, 1244 (42 U.S.C. 5841, 5342). Subpart A also issued under National Environmental Policy Act of 1969, secs. 102, 104, 105, 83 Stat. 853-854, as amended (42 U.S.C. 4332, 4334, 4335); and Pub. L. 95-604, Title II, 92 Stat. 3033-3041; and sec. 193, Pub. L. 101-575, 104 Stat. 2835 (42 U.S.C. 2243). Sections 51.20, 51.30 51.60, 51.61, 51.80, and 51.97 also issued under secs 135, 141, Pub. L. 97-425, 96 Stat, 2232, 2241, and sec. 148, Pub. L. 100-203, 101 Stat. 1330-223 (42 U.S.C. 10155, 10161, 10168). Section 51.22 also issued under sec. 274, 73 Stat. 688, as amended by 92 Stat. 3036-3038 (42 U.S.C. 2021 and under Nuclear Waste Policy Act of 1982, sec. 121, 96 Stat. 2228 (42 U.S.C. 10141). Sections 51.43, 51.67, and 51.109 also issued under Nuclear Waste Policy Act of 1982, sec 114(f), 96 Stat, 2216, as amended (42 U.S.C. 10134 (f)).

21. Section 51.20 is amended by revising paragraph (b)(13) to read as follows:

§ 51.20 Criteria for and identification of licensing and regulatory actions requiring environmental impact statements.

* * * * *

(b) * * *

(13) Issuance of a construction authorization and license pursuant to Parts 60 or 63 of this chapter.

* * * * *

22. Section 51.22 is amended by revising paragraphs (c)(3), (c)(10), and (d) to read as follows:

§ 51.22 Criteria for categorical exclusion; identification of licensing and regulatory actions eligible for categorical exclusion or otherwise not requiring environmental review.

* * * * *

(c) * * *

(3) Amendments to Parts 20, 30, 31, 32, 33, 34, 35, 39, 40, 50, 51, 54, 60, 61, 63, 70, 71, 72, 73, 74, 81, and 100 of this chapter which relate to—

* * * * *

(10) Issuance of an amendment to a permit or license pursuant to Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, 50, 60, 61, 63, 70, or Part 72 of this chapter which—

(i) Changes surety, insurance and/or indemnity requirements; or

(ii) Changes recordkeeping, reporting, or administrative procedures or requirements.

* * * * *

(d) In accordance with Section 121 of the Nuclear Waste Policy Act of 1982 (42 U.S.C. 10141), the promulgation of technical requirements and criteria that the Commission will apply in approving or disapproving applications under Parts 60 or 63 of this chapter shall not require an environmental impact statement, an environmental assessment, or any environmental review under subparagraph (E) or (F) of section 102(2) of NEPA.

23. Section 51.26 is amended by revising paragraph (c) to read as follows:

§ 51.26 Requirement to publish notice of intent and conduct scoping process.

* * * * *

(c) Upon receipt of an application and accompanying environmental impact statement under § 60.22 or § 63.22 of this chapter (pertaining to geologic repositories for high-level radioactive waste), the appropriate NRC staff director will include in the notice of docketing required to be published by § 2.101(f)(8) of this chapter a statement of Commission intention to adopt the environmental impact statement to the extent practicable. However, if the appropriate NRC staff director determines, at the time of such publication or at any time thereafter, that NRC should prepare a supplemental environmental impact statement in connection with the Commission's action on the license application, the procedures set out in paragraph (a) of this section shall be followed.

24. Section 51.67 is amended by revising paragraphs (a) and (b) to read as follows:

§ 51.67 Environmental information concerning geologic repositories.

(a) In lieu of an environmental report, the Department of Energy, as an applicant for a license or license amendment pursuant to Parts 60 or 63 of this chapter, shall submit to the Commission any final environmental impact statement which the department prepares in connection with any geologic repository developed under Subtitle A of Title I, or under Title IV, of the Nuclear Waste Policy Act of 1982, as amended. (See § 60.22 or § 63.22 of this chapter as to required time and manner of submission.) The statement shall include, among the alternatives under consideration, denial of a license or construction authorization by the Commission.

(b) Under applicable provisions of law, the Department of Energy may be required to supplement its final environmental impact statement if it makes a substantial change in its proposed action that is relevant to environmental concerns or determines that there are significant new circumstances or information relevant to environmental concerns and bearing on the proposed action or its impacts. The Department shall submit any supplement to its final environmental impact statement to the Commission. (See § 60.22 or § 63.22 of this chapter as

to required time and manner of submission.)

* * * * *

PART 60—DISPOSAL OF HIGH-LEVEL RADIOACTIVE WASTES IN GEOLOGIC REPOSITORIES

25. The authority citation for Part 60 continues to read as follows:

Authority: Secs. 51, 53, 62, 63, 65, 81, 161, 182, 183, 68 Stat. 929, 930, 932, 933, 935, 948, 953, 954, as amended (42 U.S.C. 2071, 2073, 2092, 2093, 2095, 2111, 2201, 2232, 2233); secs. 202, 206, 88 Stat.1244, 1246 (42 U.S.C. 5842, 5846); secs. 10 and 14, Pub. L. 95-601, 92 Stat. 2951 (42 U.S.C. 2021a and 5851); sec. 102, Pub. L. 91-190, 83 Stat. 853 (42 U.S.C. 4332); secs. 114, 121, Pub. L. 97-425, 96 Stat. 2213g, 2238, as amended (42 U.S.C. 10134, 10141), and Pub. L. 102-486, sec. 2902, 106 Stat. 3123 (42 U.S.C. 5851).

26. Section 60.1 is revised to read as follows:

§ 60.1 Purpose and scope.

This part prescribes rules governing the licensing of the U.S. Department of Energy to receive and possess source, special nuclear, and byproduct material at a geologic repository operations area sited, constructed, or operated in accordance with the Nuclear Waste Policy Act of 1982. This part does not apply to any activity licensed under another part of this chapter. This part does not apply to the licensing of the U.S. Department of Energy to receive and possess source, special nuclear, and byproduct material at a geologic repository operations area sited, constructed, or operated at Yucca Mountain, Nevada, in accordance with the Nuclear Waste Policy Act of 1982, as amended, and the Energy Policy Act of 1992, subject to Part 63 of this chapter. This part also gives notice to all persons who knowingly provide to any licensee, applicant, contractor, or subcontractor, components, equipment, materials, or other goods or services, that relate to a licensee's or applicant's activities subject to this part, that they may be individually subject to NRC enforcement action for violation of § 60.11.

PART 61—LICENSING REQUIREMENTS FOR LAND DISPOSAL OF RADIOACTIVE WASTE

27. The authority citation for Part 61 continues to read as follows:

Authority: Secs. 53, 57, 62, 63, 65, 81, 161, 182, 183, 68 Stat. 930, 932, 933, 935, 948, 953, 954, as amended (42 U.S.C. 2073, 2077, 2092, 2093, 2095, 2111, 2201, 2232, 2233); secs. 202, 206, 88 Stat. 1244, 1246, (42 U.S.C. 5842, 5846); secs. 10 and 14, Pub. L. 95-601, 92 Stat. 2951 (42 U.S.C. 2021a and 5851) and Pub. L. 102-486, sec. 2902, 106 Stat. 3123, (42 U.S.C. 5851).

28. Section 61.1 is amended by revising paragraph (b) to read as follows:

§ 61.1 Purpose and scope.

* * * * *

(b) Except as provided in Part 150 of this chapter, which addresses assumption of certain regulatory authority by Agreement States, and § 61.6 "Exemptions," the regulations in this part apply to all persons in the United States. The regulations in this part do not apply to—

(1) Disposal of high-level waste as provided for in Parts 60 or 63 of this chapter;

(2) Disposal of uranium or thorium tailings or wastes (byproduct material as defined in § 40.4 (a-1) as provided for in Part 40 of this chapter in quantities greater than 10,000 kilograms and containing more than 5 millicuries of radium-226; or

(3) Disposal of licensed material as provided for in Part 20 of this chapter.

* * * * *

29. In Section 61.2, the definition of *Land disposal facility* is revised to read as follows:

§ 61.2 Definitions.

* * * * *

Land disposal facility means the land, building, and structures, and equipment which are intended to be used for the disposal of radioactive wastes. For purposes of this chapter, a "geologic repository" as defined in Parts 60 or 63 is not considered a land disposal facility.

* * * * *

30. Section 61.55 is amended by revising paragraph (a)(2)(iv) to read as follows:

§ 61.55 Waste classification.

(a) * * *

(2) * * *

(iv) Waste that is not generally acceptable for near-surface disposal is waste for which form and disposal methods must be different, and in general more stringent, than those specified for Class C waste. In the absence of specific requirements in this part, such waste must be disposed of in a geologic repository as defined in Parts 60 or 63 of this chapter unless proposals for disposal of such waste in a disposal site licensed pursuant to this part are approved by the Commission.

* * * * *

31. Part 63 is added to read as follows:

PART 63—DISPOSAL OF HIGH-LEVEL RADIOACTIVE WASTES IN A GEOLOGIC REPOSITORY AT YUCCA MOUNTAIN, NEVADA

Subpart A—General Provisions

Subpart B—Licenses

Subpart C—Participation by State Government and Affected Indian Tribes

Subpart D—Records, Reports, Tests, and Inspections

Authority: Secs. 51, 53, 62, 63, 65, 81, 161, 182, 183, 68 Stat. 929, 930, 932, 933, 935, 948, 953, 954, as amended (42 U.S.C. 2071, 2073, 2092, 2093, 2095, 2111, 2201, 2232, 2233); secs. 202, 206, 88 Stat.1244, 1246 (42 U.S.C. 5842, 5846); secs. 10 and 14, Pub. L. 95-601, 92 Stat. 2951 (42 U.S.C. 2021a and 5851); sec. 102, Pub. L. 91-190, 83 Stat. 853 (42 U.S.C. 4332); secs. 114, 121, Pub. L. 97-425, 96 Stat. 2213g, 2238, as amended (42 U.S.C. 10134, 10141), and Pub. L. 102-486, sec. 2902, 106 Stat. 3123 (42 U.S.C. 5851).

Subpart A—General Provisions

§ 63.1 Purpose and scope.

This part prescribes rules governing the licensing of the U.S. Department of Energy to receive and possess source, special nuclear, and byproduct material at a geologic repository operations area sited, constructed, or operated at Yucca Mountain, Nevada, in accordance with the Nuclear Waste Policy Act of 1982, as amended, and the Energy Policy Act of 1992. As provided in § 60.1, "Purpose and scope," the regulations in Part 60 of this chapter do not apply to any activity that is subject to licensing under this part. This part does not apply to any activity licensed under another part of this chapter. This part also gives notice to all persons who knowingly provide, to any licensee, applicant, contractor, or subcontractor, components, equipment, materials, or other goods or services, that relate to a licensee's or applicant's activities subject to this part, that they may be individually subject to NRC enforcement action for violation of § 63.11.

§ 63.2 Definitions.

As used in this part:

Affected Indian Tribe means any Indian Tribe within whose reservation boundaries a repository for high-level radioactive waste or spent fuel is proposed to be located; or whose Federally defined possessory or usage rights to other lands outside of the reservation's boundaries arising out of Congressionally ratified treaties or other Federal law may be substantially and adversely affected by the locating of such a facility; *Provided*, that the Secretary of the Interior finds, on the petition of the appropriate governmental officials of the Tribe, that such effects are both substantial and adverse to the Tribe.

Annual dose means the total effective dose equivalent (TEDE as defined at § 20.1003) received in a single year by the average member of the critical group only as a result of radioactive materials released from the geologic repository.

Barrier means any material or structure that prevents or substantially delays movement of water or radioactive materials.

Commencement of construction means clearing of land, surface or subsurface excavation, or other substantial action that would adversely affect the environment of a site. It does not include changes desirable for the temporary use of the land for public recreational uses, site characterization activities, other preconstruction monitoring and investigation necessary to establish background information related to the suitability of the Yucca Mountain site or to the protection of environmental values, or procurement or manufacture of components of the geologic repository operations area.

Commission means the Nuclear Regulatory Commission or its duly authorized representatives.

Containment means the confinement of radioactive waste within a designated boundary.

Critical group means the hypothetical group of individuals reasonably expected to receive the greatest exposure to radioactive materials released from the geologic repository.

Design bases means that information that identifies the specific functions to be performed by a structure, system, or component of a facility and the specific values or ranges of values chosen for controlling parameters as reference bounds for design. These values may be restraints derived from generally accepted "state-of-the-art" practices for achieving functional goals or requirements derived from analysis (based on calculation or experiments) of the effects of a postulated event under which a structure, system, or component must meet its functional goals. The values for controlling parameters for external events include:

(1) Estimates of severe natural events to be used for deriving design bases that will be based on consideration of historical data on the associated parameters, physical data, or analysis of upper limits of the physical processes involved; and

(2) Estimates of severe external human-induced events, to be used for deriving design bases, that will be based on analysis of human activity in the region, taking into account the site characteristics and the risks associated with the event.

Design basis events means:

(1) Those natural and human-induced events that are expected to occur one or more times before permanent closure of the geologic repository operations area (referred to as Category 1 events); and

(2) Other natural and man-induced events that have at least one chance in 10,000 of occurring before permanent closure of the geologic repository (referred to as Category 2 events).

Director means the Director of the Nuclear Regulatory Commission's Office of Nuclear Material Safety and Safeguards.

Disposal means the emplacement of radioactive wastes in a geologic repository with the intent of leaving it there permanently.

DOE means the U.S. Department of Energy or its duly authorized representatives.

Engineered barrier system means the waste packages and the underground facility.

Expected annual dose means the expected value of the annual dose

considering the probability of the occurrence of the events and the uncertainty, or variability, in parameter values used to describe the behavior of the geologic repository.

Geologic repository means a system that is intended to be used for, or may be used for, the disposal of radioactive wastes in excavated geologic media. A geologic repository includes: The engineered barrier system, and the portion of the geologic setting that provides isolation of the radioactive waste.

Geologic repository operations area means a high-level radioactive waste facility that is part of a geologic repository, including both surface and subsurface areas, where waste handling activities are conducted.

Geologic setting means the geologic, hydrologic, and geochemical systems of the region in which a geologic repository is or may be located.

Groundwater means all liquid water that occurs below the land surface.

High-level radioactive waste or *HLW* means:

(1) Irradiated reactor fuel;

(2) Liquid wastes resulting from the operation of the first-cycle solvent extraction system, or equivalent, and the concentrated wastes from subsequent extraction cycles, or equivalent, in a facility for reprocessing irradiated reactor fuel; and

(3) Solids into which such liquid wastes have been converted.

HLW facility means a facility subject to the licensing and related regulatory authority of the Commission pursuant to Sections 202(3) and 202(4) of the Energy Reorganization Act of 1974 (88 Stat. 1244) [1]

Host rock means the geologic medium in which the waste is emplaced.

Important to safety, with reference to structures, systems, and components, means those engineered features of the geologic repository operations area whose function is:

(1) To provide reasonable assurance that high-level waste can be received, handled, packaged, stored, emplaced, and retrieved without exceeding the requirements of § 63.111(b)(1) for Category 1 design basis events; or

(2) To prevent or mitigate Category 2 design basis events that could result in doses equal to or greater than the values specified in § 63.111(b)(2) to any individual located on or beyond any point on the boundary of the site.

Important to waste isolation, with reference to design of the engineered barrier system and characterization of natural barriers, means those engineered and natural barriers whose function is to provide reasonable assurance that high-level waste can be disposed without exceeding the requirements of § 63.113(b).

Integrated safety analysis means an analysis to identify hazards and their potential for initiating event sequences, the potential event sequences and their consequences, and the site, structures, systems, components, equipment, and activities of personnel, that are relied on for safety. As used here, integrated means joint consideration of safety measures that otherwise might conflict, including, but not limited to, integration of fire protection, radiation safety, criticality safety, and chemical safety measures.

Isolation means inhibiting the transport of radioactive material to the location of the critical group so that radiation exposures will not exceed the requirements of § 63.113(b).

Performance assessment means a probabilistic analysis that:

(1) Identifies the features, events and processes that might affect the performance of the geologic repository; and

(2) Examines the effects of such features, events, and processes on the performance of the geologic repository; and

(3) Estimates the expected annual dose to the average member of the critical group as a result of releases from the geologic repository.

Performance confirmation means the program of tests, experiments, and analyses that is conducted to evaluate the accuracy and adequacy of the information used to determine with reasonable assurance that the performance objective at § 63.113(b) will be met.

Permanent closure means final backfilling of the underground facility, if appropriate, and the sealing of shafts, ramps, and boreholes.

Public Document Room means the place at 2120 L Street NW., Washington, DC, at which records of the Commission will ordinarily be made available for public inspection and any other place, the location of which has been published in the **Federal Register**, at which public records of the Commission pertaining to a geologic repository at the Yucca Mountain site are made available for public inspection.

Radioactive waste or waste means HLW and radioactive materials other than HLW that are received for emplacement in a geologic repository.

Reference biosphere means the description of the environment inhabited by the critical group. The reference biosphere comprises the set of specific biotic and abiotic characteristics of the environment, including, but not necessarily limited to, climate, topography, soils, flora, fauna, and human activities.

Restricted area means an area, access to which is limited by the licensee for the purpose of protecting individuals against undue risks from exposure to radiation and radioactive materials. Restricted area does not include areas used as residential quarters, but separate rooms in a residential building may be set aside as a restricted area.

Retrieval means the act of intentionally removing radioactive waste from the underground location at which the waste had been previously emplaced for disposal.

Saturated zone means that part of the earth's crust beneath the regional water table in which all voids, large and small, are ideally filled with water under pressure greater than atmospheric.

Site means that area surrounding the geologic repository operations area for which DOE exercises authority over its use in accordance with the provisions of this part.

Site characterization means the program of exploration and research, both in the laboratory and in the field, undertaken to establish the geologic conditions and the ranges of those parameters of the Yucca Mountain site, and the surrounding region to the extent necessary, relevant to the procedures under this part. Site characterization includes borings, surface excavations, excavation of exploratory shafts and/or ramps, limited subsurface lateral excavations and borings, and in situ testing at depth needed to determine the suitability of the site for a geologic repository.

Underground facility means the underground structure, backfill materials, if any, and openings that penetrate the underground structure (e.g., ramps, shafts, and boreholes, including their seals).

Unrestricted area means an area, access to which is neither limited nor controlled by the licensee.

Unsaturated zone means the zone between the land surface and the regional water table. Generally, fluid pressure in this zone is less than atmospheric pressure, and some of the voids may contain air or other gases at atmospheric pressure. Beneath flooded

[1] These are DOE "facilities used primarily for the receipt and storage of high-level radioactive wastes resulting from activities licensed under such Act [the Atomic Energy Act]" and "Retrievable Surface Storage Facilities and other facilities authorized for the express purpose of subsequent long-term storage of high-level radioactive wastes generated by [DOE], which are not used for, or are part of, research and development activities."

areas or in perched water bodies, the fluid pressure locally may be greater than atmospheric.

Waste form means the radioactive waste materials and any encapsulating or stabilizing matrix.

Waste package means the waste form and any containers, shielding, packing, and other absorbent materials immediately surrounding an individual waste container.

Water table means that surface in a groundwater body, separating the unsaturated zone from the saturated zone, at which the water pressure is atmospheric.

§ 63.3 License required.

(a) DOE shall not receive nor possess source, special nuclear, or byproduct material at a geologic repository operations area at the Yucca Mountain site except as authorized by a license issued by the Commission pursuant to this part.

(b) DOE shall not begin construction of a geologic repository operations area at the Yucca Mountain site unless it has filed an application with the Commission and has obtained construction authorization as provided in this part. Failure to comply with this requirement shall be grounds for denial of a license.

§ 63.4 Communications and records.

(a) Except where otherwise specified, all communications and reports concerning the regulations in this part and applications filed under them should be addressed to the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. Communications, reports, and applications may be delivered in person at the Commission's offices at 2120 L Street NW, Washington DC, or 11555 Rockville Pike, Rockville, MD.

(b) Each record required by this part must be legible throughout the retention period specified by each Commission regulation. The record may be the original or a reproduced copy or a microform provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, and specifications must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

§ 63.5 Interpretations.

Except as specifically authorized by the Commission in writing, no interpretation of the meaning of the regulations in this part by any officer or employee of the Commission other than a written interpretation by the General Counsel will be considered binding on the Commission.

§ 63.6 Exemptions.

The Commission may, upon application by DOE, any interested person, or upon its own initiative, grant such exemptions from the requirements of the regulations in this part as it determines are authorized by law, will not endanger life nor property nor the common defense and security, and are otherwise in the public interest.

§ 63.7 License not required for certain preliminary activities.

The requirement for a license set forth in § 63.3(a) is not applicable to the extent that DOE receives and possesses source, special nuclear, and byproduct material at a geologic repository at the Yucca Mountain site:

(a) For purposes of site characterization; or

(b) For use, during site characterization or construction, as components of radiographic, radiation monitoring, or similar equipment or instrumentation.

§ 63.8 Information collection requirements: OMB approval.

(a) The U.S. Nuclear Regulatory Commission has submitted the information collection requirements of general applicability contained in this part to the Office of Management and Budget for approval, as required by the Paperwork Reduction Act (44 U.S.C. 3501, *et seq.*). The Office of Management and Budget has approved the information collection requirements contained in this part under control number 3150–XXXX.

(b) The approved information collection requirements contained in this part appear in §§ 63.62, 63.63, and 63.65.

§ 63.9 Employee protection.

(a) Discrimination by a Commission licensee, an applicant for a Commission license, or a contractor or subcontractor of a Commission licensee or applicant, against an employee, for engaging in certain protected activities, is prohibited. Discrimination includes discharge and other actions that relate to compensation, terms, conditions, or privileges of employment. The protected activities are established in Section 211 of the Energy Reorganization Act of 1974, as amended, and in general are related to the administration or enforcement of a requirement imposed under the Atomic Energy Act or the Energy Reorganization Act.

(1) The protected activities include but are not limited to:

(i) Providing the Commission, or his or her employer, information about alleged violations of either of the statutes named in paragraph (a) of this section or possible violations of requirements imposed under either of those aforementioned statutes;

(ii) Refusing to engage in any practice made unlawful under either of the statutes named in paragraph (a) of this section, or under these requirements, if the employee has identified the alleged illegality to the employer;

(iii) Requesting the Commission to institute action against his or her employer for the administration or enforcement of these requirements;

(iv) Testifying in any Commission proceeding, or before Congress, or at any Federal or State proceeding regarding any provision (or proposed provision) of either of the statutes named in paragraph (a) of this section;

(v) Assisting or participating in, or is about to assist or participate in, these activities.

(2) These activities are protected even if no formal proceeding is actually initiated as a result of the employee assistance or participation.

(3) This section has no application to any employee alleging discrimination prohibited by this section who, acting without direction from his or her employer (or the employer's agent), deliberately causes a violation of any requirement of the Energy Reorganization Act of 1974, as amended, or the Atomic Energy Act of 1954, as amended.

(b) Any employee who believes that he or she has been discharged or otherwise discriminated against by any person for engaging in protected activities specified in paragraph (a)(1) of this section may seek a remedy for the discharge or discrimination through an administrative proceeding in the Department of Labor. The administrative proceeding must be initiated within 180 days after an alleged violation occurs. The employee may do this by filing a complaint alleging the violation with the Department of Labor, Employment Standards Administration, Wage and Hour Division. The Department of Labor may order reinstatement, back pay, and compensatory damages.

(c) A violation of paragraph (a), (e), or (f) of this section by a Commission licensee, an applicant for a Commission license, or a contractor or subcontractor of a Commission licensee or applicant may be grounds for—

(1) Denial, revocation, or suspension of the license.

(2) Imposition of a civil penalty on the licensee or applicant.

(3) Other enforcement action.

(d) Actions taken by an employer, or others, that adversely affect an employee, may be predicated on nondiscriminatory grounds. The prohibition applies when the adverse action occurs because the employee has engaged in protected activities. An employee's engagement in protected activities does not automatically render him or her immune from discharge or discipline for legitimate reasons or from adverse action dictated by nonprohibited considerations.

(e)(1) Each licensee and each applicant for a license shall prominently post the revision of NRC Form 3, "Notice to Employees," referenced in § 19.11(c) of this chapter. This form must be posted at locations sufficient to permit employees protected by this section to observe a copy on the way to or from their place of work. Premises must be posted not later than 30 days after an application is docketed and remain posted while the application is pending before the Commission, during the term of the license, and for 30 days following license termination.

(2) Copies of NRC Form 3 may be obtained by writing to the Regional Administrator of the appropriate U.S. Nuclear Regulatory Commission Regional Office listed in Appendix D to Part 20 of this chapter or by accessing the NRC Web Site www.nrc.gov/NRC/FORMS/forms3.html.

(f) No agreement affecting the compensation, terms, conditions, or privileges of employment, including an agreement to settle a complaint filed by an employee with the Department of Labor pursuant to Section 211 of the Energy Reorganization Act of 1974, as amended, may contain any provision that would prohibit, restrict, or otherwise discourage an employee from participating in protected activity as defined in paragraph (a)(1) of this section including, but not limited to, providing information to NRC or to his or her employer on potential violations or other matters within NRC's regulatory responsibilities.

§ 63.10 Completeness and accuracy of information.

(a) Information provided to the Commission by an applicant for a license or by a licensee, or information required by statute, or required by the Commission's regulations, orders, or license conditions to be maintained by the applicant or the licensee shall be complete and accurate in all material respects.

(b) The applicant or licensee shall notify the Commission of information identified by the applicant or licensee as having, for the regulated activity, a significant implication for public health and safety or common defense and security. An applicant or licensee violates this paragraph only if the applicant or licensee fails to notify the Commission of information that the applicant or licensee has identified as having a significant implication for public health and safety or common defense and security. Notification shall be provided to the Administrator of the appropriate Regional Office within 2 working days of identifying the information. This requirement is not applicable to information that is already required to be provided to the Commission by other reporting or updating requirements.

§ 63.11 Deliberate misconduct.

(a) Any licensee, applicant for a license, employee of a licensee or applicant; or any contractor (including a supplier or consultant), subcontractor, employee of a contractor or subcontractor of any licensee or applicant for a license, who knowingly provides to any licensee, applicant, contractor, or subcontractor, any components, equipment, materials, or other goods or services that relate to a licensee's or applicant's activities in this part, may not:

(1) Engage in deliberate misconduct that causes or would have caused, if not detected, a licensee or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation of any license issued by the Commission; or

(2) Deliberately submit to NRC, a licensee, an applicant, or a licensee's or applicant's contractor or subcontractor, information that the person submitting the information knows to be incomplete or inaccurate in some respect material to NRC.

(b) A person who violates paragraph (a)(1) or (a)(2) of this section may be subject to enforcement action in accordance with the procedures in 10 CFR Part 2, Subpart B.

(c) For purposes of paragraph (a)(1) of this section, deliberate misconduct by a person means an intentional act or omission that the person knows:

(1) Would cause a licensee or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation, of any license issued by the Commission; or

(2) Constitutes a violation of a requirement, procedure, instruction, contract, purchase order, or policy of a licensee, applicant, contractor, or subcontractor.

Subpart B—Licenses

PREAPPLICATION REVIEW

§ 63.15 Site characterization.

(a) Before submittal of an application for a license to be issued under this part, DOE shall conduct a program of site characterization with respect to the Yucca Mountain site.

(b) Investigations to obtain the required information shall be conducted in such a manner as to limit, to the extent practical, adverse effects on the long-term performance of the geologic repository at Yucca Mountain.

§ 63.16 Review of site characterization activities.[2]

(a) If DOE's planned site characterization activities include onsite testing with radioactive material, including radioactive tracers, the Commission shall determine whether the proposed use of such radioactive material is necessary to provide data for the preparation of the environmental reports required by law and for an application to be submitted under § 63.22.

(b) During the conduct of site characterization activities at the Yucca Mountain site, DOE shall report not less than once every 6 months to the Commission on the nature and extent of such activities and the information that has been developed, and on the progress of waste form and waste package research and development. The semiannual reports shall include the results of site characterization studies, the identification of new issues, plans for additional studies to resolve new issues, elimination of planned studies no longer necessary, identification of decision points reached, and modifications to schedules, where appropriate. DOE shall also report its progress in developing the design of a geologic repository operations area appropriate for the area being characterized, noting when key design parameters or features that depend on the results of site characterization will be established. Other topics related to

[2] In addition to the review of site characterization activities specified in this section, the Commission contemplates an ongoing review of other information on site investigation and site characterization, to allow early identification of potential licensing issues for timely resolution.

site characterization shall also be covered if requested by the Director.

(c) During the conduct of site characterization activities at the Yucca Mountain site, NRC staff shall be permitted to visit and inspect the locations at which such activities are carried out and to observe excavations, borings, and in-situ tests, as they are done.

(d) The Director may comment at any time in writing to DOE, expressing current views on any aspect of site characterization or performance assessment at the Yucca Mountain site. In particular, such comments shall be made whenever the Director determines that there are substantial grounds for making recommendations or stating objections to DOE's site characterization program. The Director shall invite public comment on any comments that the Director makes to DOE, on review of the DOE semiannual reports, or on any other comments that the Director makes to DOE on site characterization and performance assessment.

(e) The Director shall transmit copies of all comments to DOE made by the Director under this section to the Governor and legislature of the State of Nevada and to the governing body of any affected Indian Tribe.

(f) All correspondence between DOE and NRC, under this section, including the reports described in paragraph (b) of this section, shall be placed in the Public Document Room.

(g) The activities described in paragraphs (a) through (f) of this section constitute informal conference between a prospective applicant and the NRC staff, as described in § 2.101(a)(1) of this chapter, and are not part of a proceeding under the Atomic Energy Act of 1954, as amended. Accordingly, the issuance of the Director's comments made under this section does not constitute a commitment to issue any authorization or license, or in any way affect the authority of the Commission, Atomic Safety and Licensing Boards, other presiding officers, or the Director, in any such proceeding.

LICENSE APPLICATION

§ 63.21 Content of application.

(a) An application shall consist of general information and a Safety Analysis Report. An environmental impact statement shall be prepared in accordance with the Nuclear Waste Policy Act of 1982, as amended, and shall accompany the application. Any Restricted Data or National Security Information shall be separated from unclassified information.

(b) The general information shall include:

(1) A general description of the proposed geologic repository at the Yucca Mountain site, identifying the location of the geologic repository operations area, the general character of the proposed activities, and the basis for the exercise of the Commission's licensing authority.

(2) Proposed schedules for construction, receipt of waste, and emplacement of wastes at the proposed geologic repository operations area.

(3) A detailed plan to provide physical protection of high-level radioactive waste in accordance with § 73.51 of this chapter. This plan must include the design for physical protection, the licensee's safeguards contingency plan, and security organization personnel training and qualification plan. The plan must list tests, inspections, audits, and other means to be used to demonstrate compliance with such requirements.

(4) A description of the material control and accounting program to meet the requirements of § 63.78.

(5) A description of work conducted to characterize the Yucca Mountain site.

(c) The Safety Analysis Report shall include:

(1) A description of the Yucca Mountain site, with appropriate attention to those features, events, and processes of the site that might affect design of the geologic repository operations area and performance of the geologic repository. The description of the site shall include information regarding features, events, and processes outside of the site to the extent the information is relevant and material to safety or performance of the geologic repository. The information referred to in this paragraph shall include:

(i) The location of the geologic repository operations area with respect to the boundary of the site;

(ii) Information regarding the geology, hydrology, and geochemistry of the site, including geomechanical properties and conditions of the host rock;

(iii) Information regarding surface water hydrology, climatology, and meteorology of the site;

(iv) Information regarding the location of the critical group, and regarding local human behaviors and characteristics, as needed to support selection of conceptual models and parameters used for the reference biosphere and critical group.

(2) An integrated safety analysis of the geologic repository operations area, for the period before permanent closure, to ensure compliance with § 63.111(a), as required by § 63.111(c). For the purposes of this analysis, it shall be assumed that operations at the geologic repository operations area will be carried out at the maximum capacity and rate of receipt of radioactive waste stated in the application.

(3) Information relative to materials of construction of the geologic repository operations area (including geologic media, general arrangement, and approximate dimensions), and codes and standards that DOE proposes to apply to the design and construction of the geologic repository operations area.

(4) A description and discussion of the design of the engineered barrier system including:

(i) The principal design criteria and their relationships to the postclosure performance objective specified at § 63.113(b); and

(ii) The design bases and their relation to the principal design criteria.

(5) An assessment to determine the degree to which those features, events, and processes of the site that are expected to materially affect compliance with § 63.113(b)—whether beneficial or potentially adverse to performance of the geologic repository—have been characterized, and the extent to which they affect waste isolation. Investigations shall extend from the surface to a depth sufficient to determine principal pathways for radionuclide migration from the underground facility. Specific features, events, and processes of the geologic setting shall be investigated outside of the site if they affect performance of the geologic repository.

(6) An assessment of the anticipated response of the geomechanical, hydrogeologic, and geochemical systems to the range of design thermal loadings under consideration, given the pattern of fractures and other discontinuities and the heat transfer properties of the rock mass and groundwater.

(7) An assessment of the performance of the proposed geologic repository for the period after permanent closure, as required by § 63.113(c). The assessment shall also include a comparative evaluation of alternatives to the major design features that are important to waste isolation, with particular attention to the alternatives that would provide longer containment and isolation of radioactive materials.

(8) An assessment of the ability of the proposed geologic repository to limit radiological exposures in the event of limited human intrusion into the engineered barrier system as required by § 63.113(d).

(9) An explanation of measures used to support the models used to perform the assessments required in paragraphs (c)(5) through (c)(8) of this section. Analyses and models that will be used

to assess performance of the geologic repository shall be supported by using an appropriate combination of such methods as field tests, in-situ tests, laboratory tests that are representative of field conditions, monitoring data, and natural analog studies.

(10) An explanation of how expert elicitation was used in the assessments required in paragraphs (c)(5) through (c)(8) of this section.

(11) A description of the quality assurance program to be applied to the structures, systems, and components important to safety and to the engineered and natural barriers important to waste isolation.

(12) A description of the kind, amount, and specifications of the radioactive material proposed to be received and possessed at the geologic repository operations area at the Yucca Mountain site.

(13) An identification and justification for the selection of those variables, conditions, or other items that are determined to be probable subjects of license specifications. Special attention shall be given to those items that may significantly influence the final design.

(14) A description of the program for control and monitoring of radioactive effluents and occupational radiation exposures to maintain such effluents and exposures in accordance with the requirements of § 63.111.

(15) A description of the controls that DOE will apply to restrict access and to regulate land use at the Yucca Mountain site and adjacent areas, including a conceptual design of monuments that would be used to identify the site after permanent closure.

(16) A description of the plan for responding to, and recovering from, radiological emergencies that may occur at any time before permanent closure and decontamination or dismantlement of surface facilities, as required by § 63.161.

(17) A description of the program to be used to maintain the records described in §§ 63.71 and 63.72.

(18) A description of design considerations that are intended to facilitate permanent closure and decontamination or dismantlement of surface facilities.

(19) A description of plans for retrieval and alternate storage of the radioactive wastes, should retrieval be necessary.

(20) A description of the performance confirmation program that meets the requirements of Subpart F.

(21) An identification of those structures, systems, and components of the geologic repository, both surface and subsurface, which require research and development to confirm the adequacy of design. For structures, systems, and components important to safety and for the engineered and natural barriers important to waste isolation, DOE shall provide a detailed description of the programs designed to resolve safety questions, including a schedule indicating when these questions would be resolved.

(22) The following information concerning activities at the geologic repository operations area:

(i) The organizational structure of DOE as it pertains to construction and operation of the geologic repository operations area, including a description of any delegations of authority and assignments of responsibilities, whether in the form of regulations, administrative directives, contract provisions, or otherwise.

(ii) Identification of key positions that are assigned responsibility for safety at and operation of the geologic repository operations area.

(iii) Personnel qualifications and training requirements.

(iv) Plans for startup activities and startup testing.

(v) Plans for conduct of normal activities, including maintenance, surveillance, and periodic testing of structures, systems, and components of the geologic repository operations area.

(vi) Plans for permanent closure and plans for the decontamination or dismantlement of surface facilities.

(vii) Plans for any uses of the geologic repository operations area at the Yucca Mountain site for purposes other than disposal of radioactive wastes, with an analysis of the effects, if any, that such uses may have on the operation of the structures, systems, and components important to safety and the engineered and natural barriers important to waste isolation.

§ 63.22 Filing and distribution of application.

(a) An application for a license to receive and possess source, special nuclear, or byproduct material at a geologic repository operations area, at the Yucca Mountain site, that has been characterized, and any amendments thereto, and an accompanying environmental impact statement and any supplements, shall be signed by the Secretary of Energy or the Secretary's authorized representative and shall be filed in triplicate with the Director.

(b) Each portion of such application and any amendments, and each environmental impact statement and any supplements, shall be accompanied by 30 additional copies. Another 120 copies shall be retained by DOE for distribution in accordance with written instructions from the Director or the Director's designee.

(c) DOE shall, on notification of the appointment of an Atomic Safety and Licensing Board, update the application, eliminating all superseded information, and supplement the environmental impact statement if necessary, and serve the updated application and environmental impact statement (as it may have been supplemented) as directed by the Board. Any subsequent amendments to the application or supplements to the environmental impact statement shall be served in the same manner.

(d) At the time of filing of an application and any amendments thereto, copies shall be made available in appropriate locations near the proposed geologic repository operations area at the Yucca Mountain site, for inspection by the public, and updated as amendments to the application are made. The environmental impact statement and any supplements thereto shall be made available in the same manner. An updated copy of the application, and the environmental impact statement and supplements, shall be produced at any public hearing held by the Commission on the application, for use by any party to the proceeding.

(e) DOE shall certify that the updated copies of the application, and the environmental impact statement as it may have been supplemented, as referred to in paragraphs (c) and (d) of this section, contain the current contents of such documents submitted in accordance with the requirements of this part.

§ 63.23 Elimination of repetition.

In its application or environmental impact statement, DOE may incorporate, by reference, information contained in previous applications, statements, or reports filed with the Commission, *provided*, that such references are clear and specific and that copies of the information so incorporated are made available to the public locations near the site of the proposed geologic repository, as provided pursuant to § 63.22(d).

§ 63.24 Updating of application and environmental impact statement.

(a) The application shall be as complete as possible in the light of information that is reasonably available at the time of docketing.

(b) DOE shall update its application in a timely manner so as to permit the Commission to review, before issuance of a license:

(1) Additional geologic, geophysical, geochemical, hydrologic, meteorologic, materials, design, and other data obtained during construction.

(2) Conformance of construction of structures, systems, and components with the design.

(3) Results of research programs carried out to confirm the adequacy of designs, conceptual models, parameter values, and estimates of performance of the geologic repository.

(4) Other information bearing on the Commission's issuance of a license that was not available at the time a construction authorization was issued.

(c) DOE shall supplement its environmental impact statement in a timely manner so as to take into account the environmental impacts of any substantial changes in its proposed actions or any significant new circumstances or information relevant to environmental concerns bearing on the proposed action or its impacts.

CONSTRUCTION AUTHORIZATION

§ 63.31 Construction authorization.

On review and consideration of an application and environmental impact statement submitted under this part, the Commission may authorize construction of a geologic repository operations area at the Yucca Mountain site if it determines:

(a) *Safety.* That there is reasonable assurance that the types and amounts of radioactive materials described in the application can be received, possessed, and disposed of in a geologic repository operations area of the design proposed without unreasonable risk to the health and safety of the public. In arriving at this determination, the Commission shall consider whether:

(1) DOE has described the proposed geologic repository as specified at § 63.21.

(2) The site and design comply with the performance objectives and requirements contained in Subpart E of this part.

(3) DOE's quality assurance program complies with the requirements of Subpart G of this part.

(4) DOE's personnel training program complies with the criteria contained in Subpart H of this part.

(5) DOE's emergency plan complies with the criteria contained in Subpart I of this part.

(6) DOE's proposed operating procedures to protect health and to minimize danger to life or property are adequate.

(b) *Common defense and security.* That there is reasonable assurance that the activities proposed in the application will not be inimical to the common defense and security.

(c) *Environmental.* That, after weighing the environmental, economic, technical, and other benefits against environmental costs, and considering available alternatives, the action called for is issuance of the construction authorization, with any appropriate conditions to protect environmental values.

§ 63.32 Conditions of construction authorization.

(a) A construction authorization for a geologic repository operations area at the Yucca Mountain site shall include such conditions as the Commission finds to be necessary to protect the health and safety of the public, the common defense and security, or environmental values.

(b) The Commission will incorporate, in the construction authorization, provisions requiring DOE to furnish periodic or special reports regarding:

(1) Progress of construction;

(2) Any data about the site, obtained during construction, that are not within the predicted limits on which the facility design was based;

(3) Any deficiencies, in design and construction, that, if uncorrected, could adversely affect safety at any future time; and

(4) Results of research and development programs being conducted to resolve safety questions.

(c) The construction authorization for a geologic repository operations area at the Yucca Mountain site will include restrictions on subsequent changes to the features of the geologic repository and the procedures authorized. The restrictions that may be imposed under this paragraph can include measures to prevent adverse effects on the geologic setting as well as measures related to the design and construction of the geologic repository operations area. These restrictions will fall into three categories of descending importance to public health and safety, as follows:

(1) Those features and procedures that may not be changed without:

(i) 60 days prior notice to the Commission;

(ii) 30 days notice of opportunity for a prior hearing; and

(iii) Prior Commission approval;

(2) Those features and procedures that may not be changed without:

(i) 60 days prior notice to the Commission; and

(ii) Prior Commission approval; and

(3) Those features and procedures that may not be changed without 60 days notice to the Commission. Features and procedures falling in this paragraph section may not be changed without prior Commission approval if the Commission, after having received the required notice, so orders.

(d) A construction authorization shall be subject to the limitation that a license to receive and possess source, special nuclear, or byproduct material at the Yucca Mountain site geologic repository operations area shall not be issued by the Commission until;

(1) DOE has updated its application, as specified in § 63.24; and

(2) The Commission has made the findings stated in § 63.41.

§ 63.33 Amendment of construction authorization.

(a) An application for amendment of a construction authorization shall be filed with the Commission, fully describing any changes desired and following as far as applicable the contents prescribed in § 63.21.

(b) In determining whether an amendment of a construction authorization will be approved, the Commission will be guided by the considerations that govern the issuance of the initial construction authorization, to the extent applicable.

LICENSE ISSUANCE AND AMENDMENT

§ 63.41 Standards for issuance of a license.

A license to receive and possess source, special nuclear, or byproduct material at a geologic repository operations area at the Yucca Mountain site may be issued by the Commission, on finding that:

(a) Construction of the geologic repository operations area has been substantially completed in conformity with the application as amended, the provisions of the Atomic Energy Act, and the rules and regulations of the Commission. Construction may be deemed to be substantially complete for the purposes of this paragraph if the construction of:

(1) Surface and interconnecting structures, systems, and components; and

(2) Any underground storage space required for initial operation, are substantially complete.

(b) The activities to be conducted at the geologic repository operations area will be in conformity with the application as amended, the provisions of the Atomic Energy Act and the Energy Reorganization Act, and the rules and regulations of the Commission.

(c) The issuance of the license will not be inimical to the common defense and security and will not constitute an

unreasonable risk to the health and safety of the public.

(d) Adequate protective measures can and will be taken in the event of a radiological emergency at any time before permanent closure and decontamination or dismantlement of surface facilities.

(e) All applicable requirements of Part 51 of this chapter have been satisfied.

§ 63.42 Conditions of license.

(a) A license issued pursuant to this part shall include such conditions, including license specifications, as the Commission finds to be necessary to protect the health and safety of the public, the common defense and security, and environmental values.

(b) Whether stated therein or not, the following shall be deemed conditions in every license issued:

(1) The license shall be subject to revocation, suspension, modification, or amendment for cause, as provided by the Atomic Energy Act and the Commission's regulations.

(2) DOE shall, at any time while the license is in effect, on written request of the Commission, submit written statements to enable the Commission to determine whether or not the license should be modified, suspended, or revoked.

(3) The license shall be subject to the provisions of the Atomic Energy Act now or hereafter in effect and to all rules, regulations, and orders of the Commission. The terms and conditions of the license shall be subject to amendment, revision, or modification, by reason of amendments to or by reason of rules, regulations, and orders issued in accordance with the terms of the Atomic Energy Act.

(c) Each license shall be deemed to contain the provisions set forth in Section 183 b-d, inclusive, of the Atomic Energy Act, whether or not these provisions are expressly set forth in the license.

(d) A license issued under this part shall be deemed to contain the provisions set forth in Section 114(d) of the Nuclear Waste Policy Act, prohibiting emplacement of a quantity of spent fuel containing in excess of 70,000 metric tons of heavy metal or a quantity of solidified high-level radioactive waste resulting from the reprocessing of such a quantity of spent fuel, until such time as a second repository is in operation, whether or not these provisions are expressly set forth in the license.

§ 63.43 License specification.

(a) A license issued under this part shall include license conditions derived from the analyses and evaluations included in the application, including amendments made before a license is issued, together with such additional conditions as the Commission finds appropriate.

(b) License conditions shall include items in the following categories:

(1) Restrictions as to the physical and chemical form and radioisotopic content of radioactive waste.

(2) Restrictions as to size, shape, and materials and methods of construction of radioactive waste packaging.

(3) Restrictions as to the amount of waste permitted per unit volume of storage space, considering the physical characteristics of both the waste and the host rock.

(4) Requirements relating to test, calibration, or inspection, to assure that the foregoing restrictions are observed.

(5) Controls to be applied to restrict access and to avoid disturbance to the site and to areas outside the site where conditions may affect compliance with §§ 63.111 and 63.113.

(6) Administrative controls, which are the provisions relating to organization and management, procedures, recordkeeping, review and audit, and reporting necessary to assure that activities at the facility are conducted in a safe manner and in conformity with the other license specifications.

§ 63.44 Changes, tests, and experiments.

(a)(1) Following authorization to receive and possess source, special nuclear, or byproduct material at a geologic repository operations area at the Yucca Mountain site, DOE may:

(i) Make changes in the geologic repository operations area as described in the application;

(ii) Make changes in the procedures as described in the application; and

(iii) Conduct tests or experiments not described in the application, without prior Commission approval, provided the change, test, or experiment involves neither a change in the license conditions incorporated in the license nor an unreviewed safety question.

(2) A proposed change, test, or experiment shall be deemed to involve an unreviewed safety question if:

(i) The likelihood of occurrence or the consequences of an accident or malfunction of equipment important to safety previously evaluated in the application is increased;

(ii) The possibility of an accident or malfunction of a different type than any previously evaluated in the application is created; or

(iii) The margin of safety, as defined in the basis for any license condition, is reduced.

(b) DOE shall maintain records of changes in the geologic repository operations area at the Yucca Mountain site and of changes in procedures made pursuant to this section, to the extent that such changes constitute changes in the geologic repository operations area or procedures as described in the application. Records of tests and experiments carried out pursuant to paragraph (a) of this section shall also be maintained. These records shall include a written safety evaluation that provides the basis for the determination that the change, test, or experiment does not involve an unreviewed safety question. DOE shall prepare annually, or at such shorter intervals as may be specified in the license, a report containing a brief description of such changes, tests, and experiments, including a summary of the safety evaluation of each. DOE shall furnish the report to the appropriate NRC Regional Office shown in Appendix D of Part 20 of this chapter, with a copy to the Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Any report submitted pursuant to this paragraph shall be made a part of the public record of the licensing proceedings.

§ 63.45 Amendment of license.

(a) An application for amendment of a license may be filed with the Commission fully describing the changes desired and following as far as applicable the format prescribed for license applications.

(b) In determining whether an amendment of a license will be approved, the Commission will be guided by the considerations that govern the issuance of the initial license, to the extent applicable.

§ 63.46 Particular activities requiring license amendment.

(a) Unless expressly authorized in the license, an amendment of the license shall be required with respect to any of the following activities:

(1) Any action that would make emplaced high-level radioactive waste irretrievable or which would substantially increase the difficulty of retrieving such emplaced waste;

(2) Dismantling of structures;

(3) Removal or reduction of controls applied to restrict access to or avoid disturbance of the site and to areas outside the site where conditions may affect compliance with §§ 63.111 and 63.113;

(4) Destruction or disposal of records required to be maintained under the provisions of this part;

(5) Any substantial change to the design or operating procedures from that specified in the license, except as authorized in § 63.44;

(6) Permanent closure; and

(7) Any other activity involving an unreviewed safety question.

(b) An application for such an amendment shall be filed, and shall be reviewed, in accordance with the provisions of § 63.45.

PERMANENT CLOSURE

§ 63.51 License amendment for permanent closure.

(a) DOE shall submit an application to amend the license before permanent closure of a geologic repository at the Yucca Mountain site. The submission shall consist of an update of the license application submitted under §§ 63.21 and 63.22, including:

(1) An update of the assessment of the performance of the geologic repository for the period after permanent closure.

(2) A description of the program for post-permanent closure monitoring of the geologic repository.

(3) A detailed description of the measures to be employed—such as land use controls, construction of monuments, and preservation of records—to regulate or prevent activities that could impair the long-term isolation of emplaced waste within the geologic repository and to assure that relevant information will be preserved for the use of future generations. As a minimum, such measures shall include:

(i) Identification of the site and geologic repository operations area by monuments that have been designed, fabricated, and emplaced to be as permanent as is practicable;

(ii) Placement of records in the archives and land record systems of local, State, and Federal government agencies, and archives elsewhere in the world, that would be likely to be consulted by potential human intruders—such records to identify the location of the geologic repository operations area, including the underground facility, boreholes, shafts and ramps, and the boundaries of the site, and the nature and hazard of the waste; and

(iii) A program for continued oversight, to prevent any activity at the site that poses an unreasonable risk of breaching the geologic repository's engineered barriers; or increasing the exposure of individual members of the public to radiation beyond allowable limits.

(4) Geologic, geophysical, geochemical, hydrologic, and other site data that are obtained during the operational period, pertinent to compliance with § 63.113.

(5) The results of tests, experiments, and any other analyses relating to backfill of excavated areas, shaft, borehole, or ramp sealing, waste interaction with the host rock, and any other tests, experiments, or analyses pertinent to compliance with § 63.113.

(6) Any substantial revision of plans for permanent closure.

(7) Other information bearing on permanent closure that was not available at the time a license was issued.

(b) If necessary, so as to take into account the environmental impact of any substantial changes in the permanent closure activities proposed to be carried out or any significant new information regarding the environmental impacts of such closure, DOE shall also supplement its environmental impact statement and submit such statement, as supplemented, with the application for license amendment.

§ 63.52 Termination of license.

(a) Following permanent closure and the decontamination or dismantlement of surface facilities at the Yucca Mountain site, DOE may apply for an amendment to terminate the license.

(b) Such application shall be filed and will be reviewed in accordance with the provisions of § 63.45 and this section.

(c) A license shall be terminated only when the Commission finds with respect to the geologic repository:

(1) That the final disposition of radioactive wastes has been made in conformance with DOE's plan, as amended and approved as part of the license.

(2) That the final state of the geologic repository operations area conforms to DOE's plans for permanent closure and DOE's plans for the decontamination or dismantlement of surface facilities, as amended and approved as part of the license.

(3) That the termination of the license is authorized by law, including Sections 57, 62, and 81 of the Atomic Energy Act, as amended.

Subpart C—Participation by State Government and Affected Indian Tribes

§ 63.61 Provision of information.

(a) The Director shall provide to the Governor and the Nevada State legislature, and to the governing body of any affected Indian Tribe, timely and complete information regarding determinations or plans made by the Commission with respect to the site characterization, siting, development, design, licensing, construction, operation, regulation, permanent closure, or decontamination and dismantlement of surface facilities, of the geologic repository operations area at the Yucca Mountain site.

(b) Notwithstanding paragraph (a) of this section, the Director is not required to distribute any document to any entity if, with respect to such document, that entity or its counsel is included on a service list prepared pursuant to Part 2 of this chapter.

(c) Copies of all communications by the Director under this section shall be placed in the Public Document Room, and copies thereof shall be furnished to DOE.

§ 63.62 Site review.

(a) The Director shall make NRC staff available to consult with representatives of the State of Nevada and affected Indian Tribes regarding the status of site characterization at the Yucca Mountain site.

(b) Requests for consultation shall be made in writing to the Director.

(c) Consultation under this section may include:

(1) Keeping the parties informed of the Director's views on the progress of site characterization.

(2) Review of applicable NRC regulations, licensing procedures, schedules, and opportunities for State and Tribe participation in the Commission's regulatory activities.

(3) Cooperation in development of proposals for State and Tribe participation in license reviews.

§ 63.63 Participation in license reviews.

(a) State and local governments and affected Indian Tribes may participate in license reviews as provided in Subpart G of Part 2 of this chapter. The State of Nevada and any affected Indian Tribe shall have an unquestionable legal right to participate as a party in such proceedings.

(b) In addition, a State or an affected Indian Tribe may submit to the Director a proposal to facilitate its participation in the review of the license application. The proposal may be submitted at any time and shall contain a description and schedule of how the State or affected Indian Tribe wishes to participate in the review, or what services or activities the State or affected Indian Tribe wishes NRC to carry out, and how the services or activities proposed to be carried out by NRC would contribute to such participation. The proposal may include educational or information services (seminars, public meetings) or other actions on the part of NRC, such as

establishing additional public document rooms or employment or exchange of State personnel under the Intergovernmental Personnel Act.

(c) The Director shall arrange for a meeting between the representatives of the State or affected Indian Tribe and the NRC staff, to discuss any proposal submitted under paragraph (b) of this section, with a view to identifying any modifications that may contribute to the effective participation by such State or Tribe.

(d) Subject to the availability of funds, the Director shall approve all or any part of a proposal, as it may be modified through the meeting described above, if it is determined that:

(1) The proposed activities are suitable in light of the type and magnitude of impacts that the State or affected Indian Tribe may bear;

(2) The proposed activities:

(i) Will enhance communications between NRC and the State or affected Indian Tribe;

(ii) Will make a productive and timely contribution to the review; and

(iii) Are authorized by law.

(e) The Director will advise the State or affected Indian Tribe whether its proposal has been accepted or denied, and if all or any part of proposal is denied, the Director shall state the reason for the denial.

(f) Proposals submitted under this section, and responses thereto, shall be made available at the Public Document Room.

§ 63.64 Notice to State.

If the Governor and legislature of the State of Nevada have jointly designated, on their behalf, a single person or entity to receive notice and information from the Commission under this part, the Commission will provide such notice and information to the jointly designated person or entity, instead of the Governor and legislature, separately.

§ 63.65 Representation.

Any person who acts under this subpart as a representative for the State of Nevada (or for the Governor or legislature thereof) or for an affected Indian Tribe shall include in the request or other submission, or at the request of the Commission, a statement of the basis of his or her authority to act in such representative capacity.

Subpart D—Records, Reports, Tests, and Inspections

§ 63.71 Records and reports.

(a) DOE shall maintain such records and make such reports in connection with the licensed activity as may be required by the conditions of the license or by rules, regulations, and orders of the Commission, as authorized by the Atomic Energy Act and the Energy Reorganization Act.

(b) Records of the receipt, handling, and disposition of radioactive waste at a geologic repository operations area at the Yucca Mountain site shall contain sufficient information to provide a complete history of the movement of the waste from the shipper through all phases of storage and disposal. DOE shall retain these records in a manner that ensures their usability for future generations in accordance with § 63.51(a)(2).

§ 63.72 Construction records.

(a) DOE shall maintain records of construction of the geologic repository operations area at the Yucca Mountain site in a manner that ensures their usability for future generations in accordance with § 63.51(a)(2).

(b) The records required under paragraph (a) of this section shall include at least the following:

(1) Surveys of the underground facility excavations, shafts, ramps, and boreholes referenced to readily identifiable surface features or monuments;

(2) A description of the materials encountered;

(3) Geologic maps and geologic cross-sections;

(4) Locations and amount of seepage;

(5) Details of equipment, methods, progress, and sequence of work;

(6) Construction problems;

(7) Anomalous conditions encountered;

(8) Instrument locations, readings, and analysis;

(9) Location and description of structural support systems;

(10) Location and description of dewatering systems; and

(11) Details, methods of emplacement, and location of seals used.

§ 63.73 Reports of deficiencies.

(a) DOE shall promptly notify the Commission of each deficiency found in the characteristics of the Yucca Mountain site, and design and construction of the geologic repository operations area that, were it to remain uncorrected, could:

(1) Be a substantial safety hazard;

(2) Represent a significant deviation from the design criteria and design bases stated in the application; or

(3) Represent a deviation from the conditions stated in the terms of a construction authorization or the license, including license specifications.

(b) The notification shall be in the form of a written report, copies of which shall be sent to the Director and to the appropriate Nuclear Regulatory Commission Regional Office listed in Appendix D of Part 20 of this chapter.

§ 63.74 Tests.

(a) DOE shall perform, or permit the Commission to perform, such tests as the Commission deems appropriate or necessary for the administration of the regulations in this part. These may include tests of:

(1) Radioactive waste,

(2) The geologic repository, including portions of the geologic setting and the structures, systems, and components constructed or placed therein,

(3) Radiation detection and monitoring instruments, and

(4) Other equipment and devices used in connection with the receipt, handling, or storage of radioactive waste.

(b) The tests required under this section shall include a performance confirmation program carried out in accordance with Subpart F of this part.

§ 63.75 Inspections.

(a) DOE shall allow the Commission to inspect the premises of the geologic repository operations area at the Yucca Mountain site and adjacent areas to which DOE has rights of access.

(b) DOE shall make available to the Commission for inspection, on reasonable notice, records kept by DOE pertaining to activities under this part.

(c)(1) DOE shall, on requests by the Director, Office of Nuclear Material Safety and Safeguards, provide rent-free office space for the exclusive use of the Commission inspection personnel. Heat, air-conditioning, light, electrical outlets, and janitorial services shall be furnished by DOE. The office shall be convenient to and have full access to the facility and shall provide the inspector both visual and acoustic privacy.

(2) The space provided shall be adequate to accommodate two full-time inspectors, and other transient NRC personnel and will be generally commensurate with other office facilities at the Yucca Mountain site geologic repository operations area. A space of 250 square feet either within the geologic repository operations area's office complex or in an office trailer or other onsite space at the geologic repository operations area is suggested as a guide. For locations at which activities are carried out under licenses issued under other parts of this chapter, additional space may be requested to accommodate additional full-time inspectors. The Office space that is provided shall be subject to the approval of the Director, Office of

Nuclear Material Safety and Safeguards. All furniture, supplies, and communication equipment will be furnished by the Commission.

(3) DOE shall afford any NRC resident inspector assigned to the Yucca Mountain site or other NRC inspectors identified by the Regional Administrator as likely to inspect the Yucca Mountain facility, immediate unfettered access, equivalent to access provided regular employees, after proper identification and compliance with applicable access control measures for security, radiological protection, and personal safety.

§ 63.78 Material control and accounting records and reports.

DOE shall implement a program of material control and accounting (and accidental criticality reporting) that is the same as that specified in §§ 72.72, 72.74, 72.76, and 72.78 of this chapter.

Subpart E—Technical Criteria

§ 63.101 Purpose and nature of findings.

(a)(1) Subpart B of this part prescribes the standards for issuance of a license to receive and possess source, special nuclear, or byproduct material at a geologic repository operations area at the Yucca Mountain site. In particular, § 63.41(c) requires a finding that the issuance of a license will not constitute an unreasonable risk to the health and safety of the public. The purpose of this subpart is to set out the performance objectives and other criteria that, if satisfied, will support such a finding of no unreasonable risk.

(2) Although the performance objective for the geologic repository after permanent closure specified at § 63.113 is generally stated in unqualified terms, it is not expected that complete assurance that the requirement will be met can be presented. A reasonable assurance, on the basis of the record before the Commission, that the performance objective will be met is the general standard that is required. Proof that the geologic repository will be in conformance with the objective for postclosure performance is not to be had in the ordinary sense of the word because of the uncertainties inherent in the understanding of the evolution of the geologic setting, biosphere, and engineered barrier system. For such long-term performance, what is required is reasonable assurance, making allowance for the time period, hazards, and uncertainties involved, that the outcome will be in conformance with the objective for postclosure performance of the geologic repository. Demonstrating compliance will involve the use of complex predictive models that are supported by limited data from field and laboratory tests, site-specific monitoring, and natural analog studies that may be supplemented with prevalent expert judgment. Further, in reaching a determination of reasonable assurance, the Commission may supplement numerical analyses with qualitative judgments including, for example, consideration of the degree of diversity among the multiple barriers as a measure of the resiliency of the geologic repository.

(b) Subpart B of this part also lists findings that must be made in support of an authorization to construct a geologic repository operations area at the Yucca Mountain site. In particular, § 63.31(a) requires a finding that there is reasonable assurance that the types and amounts of radioactive materials described in the application can be received, possessed, and disposed of in a geologic repository operations area of the design proposed without unreasonable risk to the health and safety of the public. As stated in that paragraph, in arriving at this determination, the Commission will consider whether DOE has demonstrated that the geologic repository complies with the criteria contained in this subpart. Once again, although the criteria may be written in unqualified terms, the demonstration of compliance must take uncertainties and gaps in knowledge into account so that the Commission can make the specified finding with respect to reasonable assurance as specified in paragraph (a) of this section.

§ 63.102 Concepts.

This section provides a functional overview of this Subpart E. In the event of any inconsistency with definitions found in § 63.2, those definitions shall prevail.

(a) The HLW facility at the Yucca Mountain site. NRC exercises licensing and related regulatory authority over those facilities described in Section 202 (3) and (4) of the Energy Reorganization Act of 1974, including the site at Yucca Mountain, as designated by the Energy Policy Act of 1992.

(b) The geologic repository operations area. (1) This part deals with the exercise of authority with respect to a particular class of HLW facility—namely, a geologic repository operations area at Yucca Mountain.

(2) A geologic repository operations area consists of those surface and subsurface areas of the site that are part of a geologic repository where radioactive waste handling activities are conducted. The underground structure, backfill materials, if any, and openings that penetrate the underground structure (e.g., ramps, shafts and boreholes, including their seals), are designated the underground facility.

(3) The exercise of Commission authority requires that the geologic repository operations area be used for storage (which includes disposal) of high-level radioactive wastes (HLW).

(4) HLW includes irradiated reactor fuel as well as reprocessing wastes. However, if DOE proposes to use the geologic repository operations area for storage of radioactive waste other than HLW, the storage of this radioactive waste is subject to the requirements of this part.

(c) Stages in the licensing process. There are several stages in the licensing process. The site characterization stage, when the performance confirmation program is started, begins before submission of a license application, and may result in consequences requiring evaluation in the license review. The construction stage would follow, after issuance of a construction authorization. A period of operations follows the Commission's issuance of a license. The period of operations includes the time during which emplacement of wastes occurs; any subsequent period before permanent closure during which the emplaced wastes are retrievable; and permanent closure, which includes sealing openings to the repository. Permanent closure represents the end of the performance confirmation program; final backfilling of the underground facility, if appropriate; and the sealing of shafts, ramps, and boreholes.

(d) Areas related to isolation. Although the activities subject to regulation under this part are those to be carried out at the geologic repository operations area, the licensing process also considers characteristics of adjacent areas that are defined in other ways. There must be an area surrounding the geologic repository operations area, that could include either a portion or all of the site, within which DOE must exercise specified controls to prevent adverse human actions after permanent closure. There is an area, designated the geologic setting, which includes the geologic, hydrologic, and geochemical systems of the region in which the site and geologic repository operations area are located. The geologic repository operations area, plus the portion of the geologic setting that provides isolation of the radioactive waste, make up the geologic repository.

(e) Performance objectives through permanent closure. Before permanent closure, the geologic repository operations area is required to limit

radiation levels and exposures, in both restricted and unrestricted areas, and releases of radioactive materials to unrestricted areas, as specified at § 63.111(a).

(f) Integrated safety analysis. Section 63.111 includes performance objectives for the geologic repository operations area for the period before permanent closure and decontamination or dismantlement of surface facilities. The integrated safety analysis is a systematic examination of the geologic repository operations area's hazards and their potential for initiating event sequences; the potential event sequences and their consequences; and the site, structures, systems, components, equipment, and activities of personnel, to ensure that all relevant hazards that could result in unacceptable consequences have been adequately evaluated and appropriate protective measures have been identified. As used here, integrated means joint consideration of safety measures that otherwise might conflict, including, but not limited to, integration of fire protection, radiation safety, criticality safety, and chemical safety measures. The results of this analysis will support a determination regarding compliance of the geologic repository operations area with the requirements specified at § 63.111.

(g) Performance objective after permanent closure. After permanent closure, the geologic repository is required to limit the expected annual dose to the average member of the critical group, as specified at § 63.113(b).

(h) Multiple barriers. Section 63.113(a) requires that the geologic repository include multiple barriers, both natural and engineered. Geologic disposal of HLW is predicated on the expectation that a portion of the geologic setting will be capable of contributing to the isolation of radioactive waste, and thus be a barrier important to waste isolation. Although there is an extensive geologic record ranging from thousands to millions of years, this record is subject to interpretation and includes many uncertainties. In addition, there are uncertainties in the isolation capability and performance of engineered barriers. Although the composition and configuration of engineered structures (barriers) can be defined with a degree of precision not possible for natural barriers, it is recognized that except for a few archaeologic analogues, there is a limited experience base for the performance of complex, engineered structures over periods longer than a few hundred years considering the uncertainty in characterizing and modeling individual barriers. These uncertainties are addressed by requiring the use of a multiple barrier approach; specifically, an engineered barrier system is required in addition to the natural barriers provided by the geologic setting. It is intended that natural barriers and the engineered barrier system work in combination to enhance the resiliency of the geologic repository and increase confidence that the postclosure performance objective at § 63.113(b) will be achieved.

(i) Reference biosphere and critical group. The performance assessment will estimate the amount of radioactive material released to water or air at various locations and times in the future. To estimate the potential for future human exposures resulting from release of radioactive material from a geologic repository at Yucca Mountain, it is necessary to make certain assumptions about the location and characteristics of a critical group. The environment inhabited by the critical group, along with associated human exposure pathways and dose assessment parameters, make up the reference biosphere. The critical group is selected to represent those persons in the vicinity of Yucca Mountain who are reasonably expected to receive the greatest exposure to radioactive material released from a geologic repository at Yucca Mountain. Characteristics of the reference biosphere and the critical group are to be based on current human behavior and biospheric conditions in the region.

(j) Performance assessment. Demonstrating compliance with the postclosure performance objective specified at § 63.113(b) requires a performance assessment to quantitatively estimate the expected annual dose, over the compliance period, to the average member of the critical group. The performance assessment is a systematic analysis that identifies the features, events, and processes (i.e., specific conditions or attributes of the geologic setting, degradation, deterioration, or alteration processes of engineered barriers, and interactions between the natural and engineered barriers) that might affect performance of the geologic repository; examines their effects on performance; and estimates the expected annual dose. The features, events, and processes considered in the performance assessment should represent a wide range of both beneficial and potentially adverse effects on performance (e.g., beneficial effects of radionuclide sorption; potentially adverse effects of fracture flow or a criticality event). Those features, events, and processes expected to materially affect compliance with § 63.113(b) or be potentially adverse to performance are included, while events of very low probability of occurrence (less than one chance in 10,000 over 10,000 years) can be excluded from the analysis. The expected annual dose to the average member of the critical group is estimated using the selected features, events, and processes, and incorporating the probability that the estimated dose will occur.

(k) Institutional controls. Active and passive institutional controls will be maintained over the Yucca Mountain site, and are expected to reduce significantly, but not eliminate, the potential for human activity that could inadvertently cause or accelerate the release of radioactive material. Because it is not possible to make scientifically sound forecasts of the long-term reliability of such controls, however, it is not appropriate to integrate consideration of human intrusion into a fully risk-based performance assessment for purposes of evaluating the ability of the geologic repository to achieve the performance objective at § 63.113(b). Hence, human intrusion is addressed in a stylized manner as described in paragraph 1 of this section.

(l) Human intrusion. In contrast to events unrelated to human activity, the probability and characteristics of human intrusion occurring many hundreds or thousands of years into the future cannot be estimated by examining either the historic or geologic record. Rather than speculating on the nature and probability of future intrusion, it is more useful to assess how resilient the geologic repository would be against a postulated intrusion as specified at § 63.113(d). Although the consequences of an assumed intrusion event is a separate analysis, the analysis is identical to the performance assessment required by § 63.113(c); except that it assumes the occurrence of a postulated human intrusion event.

(m) Performance confirmation. A performance confirmation program will be conducted to verify the assumptions, data, and analyses that support the performance assessment, and any findings, based thereon, that permitted construction of the repository. Key geologic, hydrologic, geomechanical, and other physical parameters will be monitored throughout site characterization, construction, emplacement, and operation to detect any significant changes in the conditions assumed in the performance assessment that may affect compliance with the performance objective at § 63.113(b).

PERFORMANCE OBJECTIVES

§ 63.111 Performance objectives for the geologic repository operations area through permanent closure.

(a) Protection against radiation exposures and releases of radioactive material.

(1) The geologic repository operations area shall meet the requirements of Part 20 of this chapter.

(2) During normal operations, and for Category 1 design basis events, the annual dose to any real member of the public, located beyond the boundary of the site shall not exceed a TEDE of 0.25 mSv (25 mrem).

(b) Numerical Guides for Design Objectives. (1) The geologic repository operations area shall be designed so that taking into consideration Category 1 design basis events and until permanent closure has been completed, radiation exposures and radiation levels in both restricted and unrestricted areas, and releases of radioactive materials to unrestricted areas, will be maintained within the limits specified in paragraph (a) of this section.

(2) The geologic repository operations area shall be designed so that taking into consideration Category 2 design basis events and until permanent closure has been completed, no individual located on, or beyond, any point on the boundary of the site, will receive the more limiting of a TEDE of 0.05 Sv (5 rem), or the sum of the deep dose equivalent and the committed dose equivalent to any individual organ or tissue (other than the lens of the eye) of 0.5 Sv (50 rem). The lens dose equivalent shall not exceed 0.15 Sv (15 rem), and the shallow dose equivalent to skin shall not exceed 0.5 Sv (50 rem).

(c) Integrated safety analysis. An integrated safety analysis of the geologic repository operations area that meets the requirements specified at § 63.112 shall be performed. This analysis shall include a demonstration that:

(1) The requirements of § 63.111(a) will be met; and

(2) The design meets the requirements of § 63.111(b).

(d) Performance confirmation. The geologic repository operations area shall be designed so as to permit implementation of a performance confirmation program that meets the requirements of Subpart F of this part.

(e) Retrievability of waste. (1) The geologic repository operations area shall be designed to preserve the option of waste retrieval throughout the period during which wastes are being emplaced and thereafter, until the completion of a performance confirmation program and Commission review of the information obtained from such a program. To satisfy this objective, the geologic repository operations area shall be designed so that any or all of the emplaced waste could be retrieved on a reasonable schedule starting at any time up to 50 years after waste emplacement operations are initiated, unless a different time period is approved or specified by the Commission. This different time period may be established on a case-by-case basis consistent with the emplacement schedule and the planned performance confirmation program.

(2) This requirement shall not preclude decisions by the Commission to allow backfilling part, or all of, or permanent closure of, the geologic repository operations area, before the end of the period of design for retrievability.

(3) For purposes of this paragraph, a reasonable schedule for retrieval is one that would permit retrieval in about the same time as that required to construct the geologic repository operations area and emplace waste.

INTEGRATED SAFETY ANALYSIS

§ 63.112 Requirements for integrated safety analysis of the geologic repository operations area.

The integrated safety analysis of the geologic repository operations area shall include:

(a) A general description of the structures, systems, components, equipment, and process activities at the geologic repository operations area.

(b) An identification and systematic analysis of naturally occurring and human-induced hazards at the geologic repository operations area, including a comprehensive identification of potential accident/event sequences that would result in unacceptable consequences (i.e., design basis events).

(c) Data pertaining to the Yucca Mountain site, and the surrounding region to the extent necessary, used to identify naturally occurring and human-induced hazards at the geologic repository operations area.

(d) The technical basis for either inclusion or exclusion of specific, naturally occurring and human-induced hazards in the safety analysis.

(e) An analysis of the performance of the major design structures, systems, and components, both surface and subsurface, to identify those that are important to safety, including identification and description of controls that are relied on to limit or prevent potential accidents or mitigate their consequences, and including identification of measures taken to ensure the availability of identified safety systems. The analysis required in this paragraph shall include, but not necessarily be limited to, consideration of:

(1) Means to limit concentration of radioactive material in air;

(2) Means to limit the time required to perform work in the vicinity of radioactive materials;

(3) Suitable shielding;

(4) Means to monitor and control the dispersal of radioactive contamination;

(5) Means to control access to high radiation areas or airborne radioactivity area;

(6) Means to control criticality;

(7) Radiation alarm system to warn of significant increases of radiation levels, concentrations of radioactive material in air, and increased radioactivity in effluents;

(8) Ability of structures, systems, and components to perform their intended safety functions, assuming the occurrence of design basis events;

(9) Explosion and fire detection systems and appropriate suppression systems;

(10) Means to control radioactive waste and radioactive effluents, and permit prompt termination of operations and evacuation of personnel during an emergency;

(11) Means to provide reliable and timely emergency power to instruments, utility service systems, and operating systems important to safety if there is a loss of primary electric power;

(12) Means to provide redundant systems necessary to maintain, with adequate capacity, the ability of utility services important to safety; and

(13) Means to inspect, test, and maintain structures, systems, and components important to safety, as necessary, to ensure their continued functioning and readiness.

(f) A description and discussion of the design, both surface and subsurface, of the geologic repository operations area, including:

(1) The relationship between principal design criteria and the requirements specified at § 63.111(a) and (b); and

(2) The design bases and their relation to the principal design criteria.

§ 63.113 Performance objective for the geologic repository after permanent closure.

(a) The geologic repository shall include multiple barriers, consisting of both natural barriers and an engineered barrier system.

(b) The engineered barrier system shall be designed so that, working in combination with natural barriers, the expected annual dose to the average

member of the critical group shall not exceed 0.25 mSv (25 mrem) TEDE at any time during the first 10,000 years after permanent closure, as a result of radioactive materials released from the geologic repository.

(c) The ability of the geologic repository to limit radiological exposures to those specified in paragraph (b) of this section shall be demonstrated through a performance assessment that meets the requirements specified at § 63.114, uses the reference biosphere and critical group specified at § 63.115, and excludes the effects of human intrusion.

(d) The ability of the geologic repository to limit radiological exposures to those specified in paragraph (b) of this section, in the event of limited human intrusion into the engineered barrier system, shall be demonstrated through a separate performance assessment that meets the requirements specified at § 63.114 and uses the reference biosphere and critical group specified at § 63.115. For the assessment required by this paragraph, it shall be assumed that the human intrusion occurs 100 years after permanent closure and takes the form of a drilling event that results in a single, nearly vertical borehole that penetrates a waste package, extends to the saturated zone, and is not adequately sealed.

PERFORMANCE ASSESSMENT

§ 63.114 Requirements for performance assessment.

Any performance assessment used to demonstrate compliance with § 63.113(b) shall:

(a) Include data related to the geology, hydrology, and geochemistry (including disruptive processes and events) of the Yucca Mountain site, and the surrounding region to the extent necessary, and information on the design of the engineered barrier system, used to define parameters and conceptual models used in the assessment.

(b) Account for uncertainties and variabilities in parameter values and provide the technical basis for parameter ranges, probability distributions, or bounding values used in the performance assessment.

(c) Consider alternative conceptual models of features and processes that are consistent with available data and current scientific understanding, and evaluate the effects that alternative conceptual models have on the performance of the geologic repository.

(d) Consider only events that have at least one chance in 10,000 of occurring over 10,000 years.

(e) Provide the technical basis for either inclusion or exclusion of specific features, events, and processes of the geologic setting in the performance assessment. Specific features, events, and processes of the geologic setting must be evaluated in detail if the magnitude and time of the resulting expected annual dose would be significantly changed by their omission.

(f) Provide the technical basis for either inclusion or exclusion of degradation, deterioration, or alteration processes of engineered barriers in the performance assessment, including those processes that would adversely affect the performance of natural barriers. Degradation, deterioration, or alteration processes of engineered barriers must be evaluated in detail if the magnitude and time of the resulting expected annual dose would be significantly changed by their omission.

(g) Provide the technical basis for models used in the performance assessment such as comparisons made with outputs of detailed process-level models and/or empirical observations (e.g., laboratory testing, field investigations, and natural analogs).

(h) Identify those design features of the engineered barrier system, and natural features of the geologic setting, that are considered barriers important to waste isolation.

(i) Describe the capability of barriers, identified as important to waste isolation, to isolate waste, taking into account uncertainties in characterizing and modeling the barriers.

(j) Provide the technical basis for the description of the capability of barriers, identified as important to waste isolation, to isolate waste.

CHARACTERISTICS OF THE REFERENCE BIOSPHERE AND CRITICAL GROUP

§ 63.115 Required characteristics of the reference biosphere and critical group.

(a) Reference biosphere. (1) Features, events, and processes that describe the reference biosphere shall be consistent with present knowledge of the conditions in the region surrounding the Yucca Mountain site.

(2) Biosphere pathways shall be consistent with arid or semi-arid conditions.

(3) Climate evolution shall be consistent with the geologic record of natural climate change in the region surrounding the Yucca Mountain site.

(4) Evolution of the geologic setting shall be consistent with present knowledge of natural processes.

(b) Critical group. (1) The critical group shall reside within a farming community located approximately 20 km south from the underground facility (in the general location of U.S. Route 95 and Nevada Route 373, near Lathrop Wells, Nevada).

(2) The behaviors and characteristics of the farming community shall be consistent with current conditions of the region surrounding the Yucca Mountain site. Changes over time in the behaviors and characteristics of the critical group including, but not necessarily limited to, land use, lifestyle, diet, human physiology, or metabolics; shall not be considered.

(3) The critical group resides within a farming community consisting of approximately 100 individuals, and exhibits behaviors or characteristics that will result in the highest expected annual doses.

(4) The behaviors and characteristics of the average member of the critical group shall be based on the mean value of the critical group's variability range. The mean value shall not be unduly biased based on the extreme habits of a few individuals.

(5) The average member of the critical group shall be an adult. Metabolic and physiological considerations shall be consistent with present knowledge of adults.

LAND OWNERSHIP AND CONTROL

§ 63.121 Requirements for ownership and control of interests in land.

(a) Ownership of land. (1) Both the geologic repository operations area and the site shall be located in and on lands that are either acquired lands under the jurisdiction and control of DOE, or lands permanently withdrawn and reserved for its use.

(2) These lands shall be held free and clear of all encumbrances, if significant, such as:

(i) Rights arising under the general mining laws;

(ii) Easements for right-of-way; and

(iii) All other rights arising under lease, rights of entry, deed, patent, mortgage, appropriation, prescription, or otherwise.

(b) Additional controls. Appropriate controls shall be established outside of the site. DOE shall exercise any jurisdiction and control over surface and subsurface estates necessary to prevent adverse human actions that could significantly reduce the geologic repository's ability to achieve isolation. The rights of DOE may take the form of appropriate possessory interests, servitudes, or withdrawals from location or patent under the general mining laws.

(c) Water rights. (1) DOE shall also have obtained such water rights as may

be needed to accomplish the purpose of the geologic repository operations area.

(2) Water rights are included in the additional controls to be established under paragraph (b) of this section.

Subpart F—Performance Confirmation Program

§ 63.131 General requirements.

(a) The performance confirmation program shall provide data that indicate, where practicable, whether:

(1) Actual subsurface conditions encountered and changes in those conditions during construction and waste emplacement operations are within the limits assumed in the licensing review; and

(2) Geologic and engineered systems and components required for repository operation, and that are designed or assumed to operate as barriers after permanent closure, are functioning as intended and anticipated.

(b) The program shall have been started during site characterization and it will continue until permanent closure.

(c) The program shall include in-situ monitoring, laboratory and field testing, and in-situ experiments, as may be appropriate to provide the data required by paragraph (a) of this section.

(d) The program shall be implemented so that:

(1) It does not adversely affect the ability of the geologic and engineered elements of the geologic repository to meet the performance objectives.

(2) It provides baseline information and analysis of that information on those parameters and natural processes pertaining to the geologic setting that may be changed by site characterization, construction, and operational activities.

(3) It monitors and analyzes changes from the baseline condition of parameters that could affect the performance of a geologic repository.

§ 63.132 Confirmation of geotechnical and design parameters.

(a) During repository construction and operation, a continuing program of surveillance, measurement, testing, and geologic mapping shall be conducted to ensure that geotechnical and design parameters are confirmed and to ensure that appropriate action is taken to inform the Commission of changes needed in design to accommodate actual field conditions encountered.

(b) Subsurface conditions shall be monitored and evaluated against design assumptions.

(c) As a minimum, measurements shall be made of rock deformations and displacement; changes in rock stress and strain; rate and location of water inflow into subsurface areas; changes in groundwater conditions; rock pore water pressures, including those along fractures and joints; and the thermal and thermomechanical response of the rock mass as a result of development and operations of the geologic repository.

(d) These measurements and observations shall be compared with the original design bases and assumptions. If significant differences exist between the measurements and observations and the original design bases and assumptions, the need for modifications to the design or in construction methods shall be determined and these differences, their significance to repository performance, and the recommended changes reported to the Commission.

(e) In-situ monitoring of the thermomechanical response of the underground facility shall be conducted until permanent closure, to ensure that the performance of the geologic and engineering features is within design limits.

§ 63.133 Design testing.

(a) During the early or developmental stages of construction, a program for in-situ testing of such features as borehole and shaft seals, backfill, and the thermal interaction effects of the waste packages, backfill, rock, and groundwater shall be conducted.

(b) The testing shall be initiated as early as practicable.

(c) A backfill test section shall be constructed to test the effectiveness of backfill placement and compaction procedures against design requirements before permanent backfill placement is begun.

(d) Test sections shall be established to test the effectiveness of borehole, shaft, and ramp seals before full-scale operation proceeds to seal boreholes, shafts, and ramps.

§ 63.134 Monitoring and testing waste packages.

(a) A program shall be established at the geologic repository operations area for monitoring the condition of the waste packages. Waste packages chosen for the program shall be representative of those to be emplaced in the underground facility.

(b) Consistent with safe operation at the geologic repository operations area, the environment of the waste packages selected for the waste package monitoring program shall be representative of the environment in which the wastes are to be emplaced.

(c) The waste package monitoring program shall include laboratory experiments that focus on the internal condition of the waste packages. To the extent practical, the environment experienced by the emplaced waste packages within the underground facility during the waste package monitoring program shall be duplicated in the laboratory experiments.

(d) The waste package monitoring program shall continue as long as practical up to the time of permanent closure.

Subpart G—Quality Assurance

§ 63.141 Scope.

As used in this part, quality assurance comprises all those planned and systematic actions necessary to provide adequate confidence that the geologic repository and its subsystems or components will perform satisfactorily in service. Quality assurance includes quality control, which comprises those quality assurance actions related to the physical characteristics of a material, structure, component, or system that provide a means to control the quality of the material, structure, component, or system to predetermined requirements.

§ 63.142 Applicability.

The quality assurance program applies to all systems, structures, and components important to safety, to design and characterization of barriers important to waste isolation, and to activities related thereto. These activities include: site characterization, facility and equipment construction, facility operation, performance confirmation, permanent closure, and decontamination and dismantling of surface facilities.

§ 63.143 Implementation.

DOE shall implement a quality assurance program based on the criteria of Appendix B of 10 CFR Part 50, as applicable, and appropriately supplemented by additional criteria, as required by § 63.142.

Subpart H—Training and Certification of Personnel

§ 63.151 General requirements.

Operations of systems and components that have been identified as important to safety in the Safety Analysis Report and in the license shall be performed only by trained and certified personnel or by personnel under the direct visual supervision of an individual with training and certification in such operation. Supervisory personnel who direct operations that are important to safety must also be certified in such operations.

§ 63.152 Training and certification program.

DOE shall establish a program for training, proficiency testing, certification, and requalification of operating and supervisory personnel.

§ 63.153 Physical requirements.

The physical condition and the general health of personnel certified for operations that are important to safety shall not be such as might cause operational errors that could endanger the public health and safety. Any condition that might cause impaired judgment or motor coordination must be considered in the selection of personnel for activities that are important to safety. These conditions need not categorically disqualify a person, so long as appropriate provisions are made to accommodate such conditions.

Subpart I—Emergency Planning Criteria

§ 63.161 Emergency plan for the geologic repository operations area through permanent closure.

DOE shall develop and be prepared to implement a plan to cope with radiological accidents that may occur at the geologic repository operations area, at any time before permanent closure and decontamination or dismantlement of surface facilities. The emergency plan shall be based on the criteria of § 72.32(b) of this chapter.

Subpart J—Violations

§ 63.171 Violations.

(a) The Commission may obtain an injunction or other court order to prevent a violation of the provisions of—

(1) The Atomic Energy Act of 1954, as amended;

(2) Title II of the Energy Reorganization Act of 1974, as amended; or

(3) A regulation or order issued pursuant to those Acts.

(b) The Commission may obtain a court order for the payment of a civil penalty imposed under section 234 of the Atomic Energy Act:

(1) For violations of—

(i) Sections 53, 57, 62, 63, 81, 82, 101, 103, 104, 107, or 109 of the Atomic Energy Act of 1954, as amended;

(ii) Section 206 of the Energy Reorganization Act;

(iii) Any rule, regulation, or order issued pursuant to the sections specified in paragraph (b)(1)(i) of this section;

(iv) Any term, condition, or limitation of any license issued under the sections specified in paragraph (b)(1)(i) of this section.

(2) For any violation for which a license may be revoked under section 186 of the Atomic Energy Act of 1954, as amended.

§ 63.172 Criminal penalties.

(a) Section 223 of the Atomic Energy Act of 1954, as amended, provides for criminal sanctions for willful violation of, attempted violation of, or conspiracy to violate, any regulation issued under Sections 161b, 161i, or 161o of the Act. For purposes of Section 223, all the regulations in this Part 63 are issued under one or more of Sections 161b, 161i, or 161o, except for the sections listed in paragraph (b) of this section.

(b) The regulations in this Part 63 that are not issued under Sections 161b, 161i, or 161o for the purposes of Section 223 are as follows: Sections 63.1, 63.2, 63.5, 63.6, 63.7, 63.8, 63.15, 63.16, 63.21, 63.22, 63.23, 63.24, 63.31, 63.32, 63.33, 63.41, 63.42, 63.43, 63.45, 63.46, 63.51, 63.52, 63.61, 63.62, 63.63, 63.64, 63.65, 63.101, 63.102, 63.111, 63.112, 63.113, 63.114, 63.115, 63.121, 63.131, 63.132, 63.133, 63.134, 63.141, 63.142, 63.153, 63.171, and 63.172.

Dated at Rockville, Maryland, this 12th day of February, 1999.

For the Nuclear Regulatory Commission.

Annette Vietti-Cook,

Secretary of the Commission.

[FR Doc. 99–4022 Filed 2–19–99; 8:45 am]

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POLICY ISSUE
(Information)

July 16, 1999 SECY-99-186

FOR: The Commissioners

FROM: William D. Travers
Executive Director for Operations

SUBJECT: STAFF PLAN FOR CLARIFYING HOW DEFENSE-IN-DEPTH APPLIES TO THE REGULATION OF A POSSIBLE GEOLOGIC REPOSITORY AT YUCCA MOUNTAIN, NEVADA

PURPOSE:

To inform the Commission of the staff's plans to more clearly address the Commission's defense-in-depth philosophy as it pertains to the proposed 10 CFR Part 63 and to the disposal of high-level radioactive wastes in a possible geologic repository at Yucca Mountain, Nevada.

SUMMARY:

This paper provides the staff's plan to address more clearly the U.S. Nuclear Regulatory Commission's (NRC's) defense-in-depth philosophy as it relates to disposal of high-level radioactive wastes. The plan describes a 6-month staff effort that includes conducting an interactive dialogue with stakeholders. The staff plan culminates with a formal response to the Commission on the implementation of defense-in-depth in the NRC's repository regulatory program on November 30, 1999, as part of the package transmitting the proposed final rule at 10 CFR Part 63. Additional milestones beyond November 30, 1999, are identified in the plan for development of more detailed guidance pending Commission approval.

CONTACT: Keith I. McConnell, NMSS/DWM
(301) 415-7289

BACKGROUND:

The Staff Requirements Memorandum, issued on April 12, 1999, directed the staff to evaluate how the NRC could more clearly address repository defense-in-depth to foster a common understanding of this concept, and to inform the Commission of its findings. This paper responds to that direction and provides the staff's plan to clarify its expectations for a demonstration of defense-in-depth for a geologic repository. The staff intends to accomplish this through responses to public comments in the draft final rule for Part 63 and through development of the Yucca Mountain Review Plan (YMRP). In completing Part 63 and the YMRP, the staff will incorporate the Commission's defense-in-depth philosophy as elaborated in the White Paper on Risk-Informed and Performance-Based Regulation, issued on March 1, 1999, and has identified specific activities to involve stakeholders.

DISCUSSION:

The Nuclear Waste Policy Act of 1982 mandated that technical criteria developed by the Commission provide for a system of multiple barriers in the design of the geologic repository. To fulfill this statutory requirement, the Commission, in promulgating its generic regulations at Part 60 (final rule published on June 21, 1983), specified three numerical subsystem performance objectives for repository performance after closure:

1) The length of time radionuclides should be contained in the waste packages (300-1000 years);
2) The rate of subsequent releases from the engineered system (one part in 100,000 per year of the inventory present at 1000 years after permanent closure); and
3) The pre-emplacement ground-water travel time to the accessible environment (at least 1000 years).

Under Part 60, demonstrating compliance with these numerical objectives would constitute compliance with the multiple barrier provision.

In proposing revisions to these objectives in the proposed Part 63[1], 15 years after Part 60 was promulgated, the staff noted that risk-informed, performance-based regulation of geologic disposal, together with advances in performance assessment methods, called for reexamining the imposition of specific numerical subsystem requirements as was done in Part 60. Further, it should be noted that the National Academy of Sciences (NAS) report on the "Technical Bases for Yucca Mountain Standards," published in 1995, opposed the inclusion of subsytem performance objectives. To maintain the Commission's defense-in-depth philosophy, but avoid incorporation of numerical subsystem performance objectives in its site-specific regulation, the staff recommended (SECY-97-300), and the Commission accepted, a proposed regulatory approach that includes assessment of repository barrier performance, without specifying numerical goals for subsystem performance.

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[1]A comprehensive review of the Commission's consideration of multiple barriers and "defense-in-depth" for Part 63 was provided as Attachment 3 to SECY-97-300, "Proposed Strategy for Development of Regulations Governing Disposal of High-Level Radioactive Wastes in a Proposed Repository at Yucca Mountain, Nevada."

Such an approach will require the U.S. Department of Energy (DOE) to provide greater transparency of how multiple barriers contribute to overall performance, and associated uncertainty. The approach does not require compliance with separate performance objectives for individual barriers that are unrelated to the U.S. Environmental Protection Agency standards. As proposed at Part 63.114, DOE must:

1) Identify the design features of the engineered barrier system (e.g., waste package, backfill), and natural features of the geologic setting (e.g., unsaturated zone, saturated zone), that are considered barriers important to waste isolation (63.114(h));

2) Describe the capability of barriers, identified as important to waste isolation, to isolate wastes, taking into account uncertainties in characterizing and modeling the barriers (63.114(i)); and

3) Provide the technical basis for the description of the capability of barriers, identified as important to waste isolation, to isolate waste (63.114(j)).

The staff believes that these requirements for multiple barriers, when combined with requirements for active and passive institutional control, are sufficient to provide for defense-in-depth for post-closure repository performance[2]. However, the staff anticipated that comments would be received on the requirements for defense-in-depth in the proposed Part 63, because they represent a substantially different approach from that taken in Part 60.

In the statement of considerations for the proposed rule, the staff noted that, in parallel with the rulemaking, staff was developing review guidance in the form of a YMRP. The purpose of these statements was to recognize the need to develop additional guidance on how to evaluate compliance with these requirements. Also noted in the proposed rule was the fact that the staff was considering a number of approaches to evaluating DOE's license application including, but not limited to: (1) sensitivity analyses; (2) modeling the behavior of individual barriers; (3) quantifying how individual barriers contribute to performance; and (4) delineating the capability of barriers to isolate waste. Although various approaches exist for aiding the definition of the capability of individual barriers to isolate waste, the identification of which approach or combination of approaches is acceptably transparent in defining the waste isolation attributes of the repository system, without placing undue or non-productive burdens on DOE, is inherently complex. Consequently, developing a common understanding of these complex issues within a risk-informed, performance-based framework will require considerable deliberation and interaction with stakeholders. Therefore, to facilitate development of a common understanding on an acceptable approach(es), the staff has planned a program that includes substantial stakeholder involvement.

The staff's plan focuses on developing detailed guidance for conducting its review of a geologic repository at Yucca Mountain in the YMRP. Interaction with the DOE, the Advisory Committee on Nuclear Waste (ACNW), the Office of Nuclear Reactor Regulation, the Office of Nuclear

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[2]It is expected that defense-in-depth for pre-closure operations would be achieved in a manner similar to that for other operating nuclear facilities.

Regulatory Research, the State of Nevada and Affected Units of Local Government, possibly the Joint Advisory Committee on Reactor Safeguards (ACRS)/ACNW Subcommittee on Risk-Informed Regulation in NMSS, and other stakeholders will occur as the YMRP is developed. The staff intends to include the annotated outline of the review plan when the proposed final Part 63 is submitted to the Commission.

RESOURCES:

The activities described above are part of the efforts to finalize Part 63 and complete Rev. 0 of the YMRP in FY1999 and beyond. Resources to accomplish these activities are included in the current budget.

COORDINATION:

The Office of the General Counsel has reviewed this paper and has no legal objection. The Office of the Chief Financial Officer has reviewed this paper for resource implications and has no objection.

Frank J. Miraglia

for William D. Travers
Executive Director
for Operations

Attachment: As stated

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STAFF APPROACH TO CLARIFYING DEFENSE-IN-DEPTH FOR THE POSSIBLE GEOLOGIC REPOSITORY AT YUCCA MOUNTAIN, NEVADA

WHAT ARE THE UNDERLYING BASES FOR IMPLEMENTING DEFENSE-IN-DEPTH?

- The Commission's "White Paper on Risk-Informed and Performance-Based Regulation," (issued on March 11, 1999) defined the concept of defense-in-depth as follows:

  > Defense-in-depth is an element of the NRC's Safety Philosophy that employs successive compensatory measures to prevent accidents or mitigate damage if a malfunction, accident, or naturally caused event occurs at a nuclear facility. The defense-in-depth philosophy ensures that safety will not be wholly dependent on any single element of the design, construction, maintenance, or operation of a nuclear facility. The net effect of incorporating defense-in-depth into design, construction, maintenance, and operation is that the facility or system in question tends to be more tolerant of failures and external challenges.

- The Proposed 10 CFR Part 63:

  > As reflected in the statement accompanying proposed 10 CFR Part 63, DOE will demonstrate that the natural barrier and the engineered barrier system will work in combination to enhance overall performance of the repository.
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  > In Part 63, a barrier is defined as any material or structure that prevents or substantially delays movement of water or radioactive materials.
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  > Requirements in Part 63 are that the U.S. Department of Energy (DOE) must: 1) identify those design features of the engineered barrier system, and natural features of the geologic setting, that are considered barriers important to waste isolation (e.g., waste package, drip shield, unsaturated zone limiting moisture flux, and saturated zone retarding radionuclide migration); 2) describe the capability of these barriers to isolate waste, taking into account uncertainties in characterizing and modeling the barriers; and 3) provide the technical basis for the description of the capability of these barriers.

HOW WILL STAFF CLARIFY ITS EXPECTATIONS FOR DEMONSTRATING MULTIPLE BARRIERS?

- Based on public comments, we will consider refining regulatory requirements, as needed, to show that multiple barriers are acceptably covered by 10 CFR Part 63 (described under the second bullet under "Proposed 10 CFR Part 63"). However, the goal of avoiding imposition of numerical subsystem performance objectives will be maintained.

- We will describe an acceptable approach(es) for demonstrating the capabilities of multiple barriers to isolate waste in the Yucca Mountain Review Plan (YMRP). Specific

quantitative approaches that will be considered include, but are not limited to: sensitivity analyses, importance analysis, and presentation of intermediate modeling results (e.g., model results that are calculated in support of dose estimates such as waste package lifetime).

WHEN AND HOW WILL CLARIFICATIONS BE MADE AVAILABLE TO STAKEHOLDERS?

- We have presented information on the defense-in-depth regulatory requirements in Part 63 at the DOE/U.S. Nuclear Regulatory Commission (NRC) Technical Exchange (public meeting) on May 26, 1999. The DOE is currently working on approaches to meeting the multiple barriers requirements in Part 63 and presented some of their ideas at the technical exchange.

- We will coordinate with the Advisory Committee on Nuclear Waste (ACNW) on this topic, as we did in briefing the Committee in June of this year on this plan. We will also coordinate with the Offices of Nuclear Reactor Regulation and Nuclear Regulatory Research, and the Joint ACRS/ACNW Subcommittee on Risk-Informed Regulation in NMSS.

- We will hold a public meeting in Las Vegas. In the meeting, we will further clarify the requirements of Part 63 by: 1) discussing our proposed resolution of public comments on defense-in-depth; and 2) presenting example calculations that demonstrate the effectiveness of multiple barriers.

- Based on these interactions, we will finalize guidance in Rev. 0 of the YMRP, due to be completed in March 2000.

WHAT IS THE SCHEDULE OF PLANNED ACTIVITIES FOR CLARIFYING REPOSITORY DEFENSE-IN-DEPTH?

Activity	Completion Date	Purpose
1. DOE/NRC Total System Performance Assessment Technical Exchange at the Center for Nuclear Waste Regulatory Analyses	May 25 - 27, 1999	Preliminary discussion with DOE on the proposed regulatory requirements for multiple barriers (other stakeholders present as observers)
2. Concept Paper on Defense-in-Depth (this Commission Paper)	July 2, 1999	To present the staff's plan for the repository defense-in-depth concept as proposed in Part 63 (in response to the SRM dated April 12, 1999)

Activity	Completion Date	Purpose
3. Presentation to the ACNW	June 28 - 30, 1999	To brief the ACNW on the staff's proposed plan for clarifying the acceptance criteria and review plans for the license application
4. Interactions with the Office of Nuclear Reactor Regulation, Office of Nuclear Regulatory Research, and possibly Joint ACRS/ACNW Subcommittee on Risk-Informed Regulation	July/August 1999	To ensure an appropriately consistent approach for risk-informed and performance-based requirements
5. Meetings with DOE and Public Meetings on Repository Defense-in-Depth in Nevada	August/September 1999	To solicit comments on the staff's approach to repository defense-in-depth; to present possible technical approaches
6. Total System Performance Assessment and Integration Issue Resolution Status Report	September 30, 1999	To provide preliminary draft guidance on possible technical approaches to demonstrate repository design meets applicable regulatory requirements. This guidance will become part of the Yucca Mountain Review Plan (YMRP) or be referenced by the YMRP.
7. Presentation to ACNW	September (after public comment period is over, but before Part 63 is finalized)	To brief the ACNW on staff's proposed positions and strategies on addressing public comments and on the annotated outline of the YMRP
8. Draft final 10 CFR Part 63 to Commission along with Annotated Outline of YMRP	November 30, 1999	To finalize the rule and summarize the approach to defense-in-depth in the YMRP
9. Public meetings in Nevada after finalizing Part 63	January 2000	To present and clarify the final Part 63 and the YMRP, including the requirements for repository defense-in-depth
10. Interactions with DOE	January 2000	To present and clarify the final Part 63 and the YMRP, including requirements for repository defense-in-depth

Activity	Completion Date	Purpose
11. YMRP Rev. 0 (postclosure only)	To the Commission March 31, 2000	To submit to the Commission a risk-informed performance-based YMRP which includes technical guidance and acceptance criteria for conducting the review
12. Future Revisions of YMRP	September 30, 2000; September 30, 2001	To update the YMRP on an annual basis. The last revision would be published 5 months before the current expected Yucca Mountain License Application submission date (March 1, 2002).

Risk-Informed and Performance-Based Regulation

The NRC has established its regulatory requirements, in both reactor and materials applications, to ensure that "no undue risk to public health and safety" results from licensed uses of Atomic Energy Act (AEA) materials and facilities. The objective of these requirements has always been to assure that the probabilities of accidents with the potential for adversely affecting public health and safety are low. For reactors, these probabilities were not quantified in a systematic way until 1975 when the Reactor Safety Study (WASH-1400) was published. For non-reactor activities, the situation is more complex. In some areas, high-level waste disposal and transportation, risk assessment has been in use since the 1970s; in others, such quantification is still evolving. Consequently, most of NRC's regulations were developed without the benefit of quantitative estimates of risk. The perceived benefits of the deterministic and prescriptive regulatory requirements were based mostly on experience, testing programs and expert judgment, considering factors such as engineering margins and the principle of defense-in-depth.

There have been significant advances in and experience with risk assessment methodology since 1975. Thus, the Commission is advocating certain changes to the development and implementation of its regulations through the use of risk-informed, and ultimately performance-based, approaches. The Probabilistic Risk Assessment (PRA) Policy Statement (60 FR 42622, August 16, 1995) formalized the Commission's commitment to risk-informed regulation through the expanded use of PRA. The PRA Policy Statement states, in part, "The use of PRA technology should be increased in all regulatory matters to the extent supported by the state of the art in PRA methods and data, and in a manner that complements the NRC's deterministic approach and supports the NRC's traditional defense-in-depth philosophy."

The transition to a risk-informed regulatory framework is expected to be incremental. Many of the present regulations are based on deterministic and prescriptive requirements that cannot be quickly replaced. Therefore, the current requirements will have to be maintained while risk-informed and/or performance-based regulations are being developed and implemented.

To understand and apply the commitment expressed in the PRA Policy Statement, it is important that the NRC, the regulated community, and the public at large have a common understanding of the terms and concepts involved; an awareness of how these concepts (in both reactor and materials arenas) are to be applied to NRC rulemaking, licensing, inspection, assessment, enforcement, and other decision-making; and an appreciation of the transitional period in which the agency and industry currently operate.

1. **Risk and Risk Assessment**: This paper defines risk in terms that can be applied to the entire range of activities involving NRC licensed use of AEA materials. The risk definition takes the view that when one asks, "What is the risk?" one is really asking three questions: "What can go wrong?" "How likely is it?" and "What are the consequences?" These three questions can be referred to as the "risk triplet." The traditional definition of risk, that is, probability times consequences, is fully embraced by the "triplet" definition of risk.

The first question, "What can go wrong?" is usually answered in the form of a "scenario" (a combination of events and/or conditions that could occur) or a set of scenarios.

The second question, "How likely is it?" can be answered in terms of the available evidence and the processing of that evidence to quantify the probability and the uncertainties involved. In some situations, data may exist on the frequency of a particular type of occurrence or failure mode (e.g., accidental overexposures). In other situations, there may be little or no data (e.g., core damage in a reactor) and a predictive approach for analyzing probability and uncertainty will be required.

The third question, "What are the consequences?" can be answered for each scenario by assessing the probable range of outcomes (e.g., dose to the public) given the uncertainties. The outcomes or consequences are the "end states" of the analyses. The choice of consequence measures can be whatever seems appropriate for reasonable decision-making in a particular regulated activity and could involve combinations of end states.

A risk assessment is a systematic method for addressing the risk triplet as it relates to the performance of a particular system (which may include a human component) to understand likely outcomes, sensitivities, areas of importance, system interactions and areas of uncertainty. From this assessment the important scenarios can be identified.

2. **Deterministic and Probabilistic Analyses**: All safety regulation ultimately is concerned with risk and addresses the three questions discussed in item 1 above. In practice, NRC addresses these three questions through the body of regulations, guidance, and license conditions that it uses to regulate the many activities under its jurisdiction. The current body of regulations, guidance and license conditions is based largely on deterministic analyses and is implemented by prescriptive requirements. As described in the PRA Policy Statement, the deterministic approach to regulation establishes requirements for engineering margin and for quality assurance in design, manufacture, and construction. In addition, it assumes that adverse conditions can exist and establishes a specific set of design basis events (i.e., what can go wrong?). The deterministic approach involves implied, but unquantified, elements of probability in the selection of the specific accidents to be analyzed as design basis events. It then requires that the design include safety systems capable of preventing and/or mitigating the consequences (i.e., what are the consequences?) of those design basis events in order to protect public health and safety. Thus, a deterministic analysis explicitly addresses only two questions of the risk triplet. In addition, traditional regulatory analyses do not integrate results in a comprehensive manner to assess the overall safety impact of postulated initiating events.

PRA and other risk assessment methods (also described in the PRA Policy Statement) consider risk (i.e., all three questions) in a more coherent, explicit, and quantitative manner. Risk assessment methodology examines systems and their interactions in an integrated, comprehensive manner. Probabilistic analysis explicitly addresses a broad spectrum of initiating events and their event frequency. It then analyzes the consequences of those event scenarios and weights the consequences by the frequency, thus giving a measure of risk.

Since risk assessment methods were first used to gain a better understanding of the risk associated with some of the activities and facilities that the NRC regulates, substantial event data and increased sophistication and experience in the use of certain risk assessment methods (e.g., Probabilistic Risk Assessment (PRA), Integrated Safety Assessment (ISA), and Performance Assessment (PA)) have been acquired. Accordingly, there is now the opportunity to enhance the traditional approach by more explicitly addressing risk and incorporating the insights thus gained.

While the traditional deterministic approach to regulation has been successful in ensuring no undue risk to public health and safety in the use of nuclear materials, opportunities for improvement exist. Given the broad spectrum of equipment and activities covered, the regulations can be strengthened and resources can be allocated to ensure that they are focused on the most risk-significant equipment and activities, and to ensure a consistent and coherent framework for regulatory decision-making. The different "risk-informed" and/or "performance-based" approaches to regulation described below, if properly applied singly or in combination, would provide such a framework.

3. **"Risk Insights"**: The term "risk insights," as used here, refers to the results and findings that come from risk assessments. The end results of such assessments may relate directly to public health effects as in the Commission's Safety Goals for the Operation of Nuclear Power Plants. For specific applications the results and findings may take other forms. For example, for reactors these include such things as identification of dominant accident sequences, estimates of core damage frequency (CDF)[1] and large early release frequency (LERF)[2], and importance measures of structures, systems, and components. On the other hand, in other areas of NRC regulation, findings and results include risk curves[3] for disposal facilities for radioactive wastes, frequency of and costs associated with accidental smelting of sealed sources at steel mills, frequency of occupational exposures, predicted dose from decommissioned sites and many others.

Risk insights have already been incorporated successfully into numerous regulatory activities, and have proven to be a valuable complement to traditional deterministic approaches. Given the current maturity of some risk assessment methodologies and the current body of event data, risk insights can be incorporated more explicitly into the regulatory process in a manner that will improve both the efficiency and effectiveness of current regulatory requirements.

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[1] CDF is the frequency of the combinations of initiating events, hardware failures, and human errors leading to core uncovery with reflooding of the core not imminent.

[2] LERF is the frequency of those accidents leading to significant, unmitigated releases from containment in a time-frame prior to effective evacuation of the close-in population such that there is a potential for early health effects.

[3] Risk curves (also known as Complementary Cumulative Distribution Functions (CCDFs) or Farmer curves) are estimates of the probability that a given consequence will be exceeded.

4. **"Risk-Based Approach"**: Regulatory decision-making is required in both the development of regulations and guidance and the determination of compliance with those regulations and guidance. A "risk-based" approach to regulatory decision-making is one in which such decision-making is solely based on the numerical results of a risk assessment. This places heavier reliance on risk assessment results than is currently practicable for reactors due to uncertainties in PRA such as completeness. Note that the Commission does not endorse an approach that is "risk-based"; however, this does not invalidate the use of probabilistic calculations to demonstrate compliance with certain criteria, such as dose limits.

5. **"Risk-Informed Approach"**: A "risk-informed" approach to regulatory decision-making represents a philosophy whereby risk insights are considered together with other factors to establish requirements that better focus licensee and regulatory attention on design and operational issues commensurate with their importance to public health and safety. A "risk-informed" approach enhances the deterministic approach by: (a) allowing explicit consideration of a broader set of potential challenges to safety, (b) providing a logical means for prioritizing these challenges based on risk significance, operating experience, and/or engineering judgment, (c) facilitating consideration of a broader set of resources to defend against these challenges, (d) explicitly identifying and quantifying sources of uncertainty in the analysis (although such analyses do not necessarily reflect all important sources of uncertainty), and (e) leading to better decision-making by providing a means to test the sensitivity of the results to key assumptions. Where appropriate, a risk-informed regulatory approach can also be used to reduce unnecessary conservatism in purely deterministic approaches, or can be used to identify areas with insufficient conservatism in deterministic analyses and provide the bases for additional requirements or regulatory actions. "Risk-informed" approaches lie between the "risk-based" and purely deterministic approaches. The details of the regulatory issue under consideration will determine where the risk-informed decision falls within the spectrum.

6. **"Risk-Informed Approach and Defense-in-Depth"**: The concept of defense-in-depth[4] has always been and will continue to be a fundamental tenet of regulatory practice in the nuclear field, particularly regarding nuclear facilities. Risk insights can make the elements of defense-in-depth more clear by quantifying them to the extent practicable. Although the uncertainties associated with the importance of some elements of defense may be substantial, the fact that these elements and uncertainties have been quantified can aid in determining how much defense makes regulatory sense. Decisions on the adequacy of or the necessity for elements of defense should reflect risk insights gained through identification of the individual performance of each defense system in relation to overall performance.

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[4] Defense-in-depth is an element of the NRC's Safety Philosophy that employs successive compensatory measures to prevent accidents or mitigate damage if a malfunction, accident, or naturally caused event occurs at a nuclear facility. The defense-in-depth philosophy ensures that safety will not be wholly dependent on any single element of the design, construction, maintenance, or operation of a nuclear facility. The net effect of incorporating defense-in-depth into design, construction, maintenance, and operation is that the facility or system in question tends to be more tolerant of failures and external challenges.

7. **"Performance-Based Approach"**: A regulation can be either prescriptive or performance-based. A prescriptive requirement specifies particular features, actions, or programmatic elements to be included in the design or process, as the means for achieving a desired objective. A performance-based requirement relies upon measurable (or calculable) outcomes (i.e., performance results) to be met, but provides more flexibility to the licensee as to the means of meeting those outcomes. A performance-based regulatory approach is one that establishes performance and results as the primary basis for regulatory decision-making, and incorporates the following attributes: (1) measurable (or calculable) parameters (i.e., direct measurement of the physical parameter of interest or of related parameters that can be used to calculate the parameter of interest) exist to monitor system, including facility and licensee, performance, (2) objective criteria to assess performance are established based on risk insights, deterministic analyses and/or performance history, (3) licensees have flexibility to determine how to meet the established performance criteria in ways that will encourage and reward improved outcomes; and (4) a framework exists in which the failure to meet a performance criterion, while undesirable, will not in and of itself constitute or result in an immediate safety concern. The measurable (or calculable) parameters may be included in the regulation itself or in formal license conditions, including reference to regulatory guidance adopted by the licensee. This regulatory approach is not new to the NRC. For instance, the Commission previously has approved performance-based approaches in 10 CFR Parts 20, 50 (Option B, Appendix J and the Maintenance Rule,10 CFR50.65), 60, and 61. In particular, the Commission weighed the relative merits of prescriptive and performance-based regulatory approaches in issuing 10 CFR Part 60.

A performance-based approach can be implemented without the use of risk insights. Such an approach would require that objective performance criteria be based on deterministic safety analysis and performance history. This approach would still provide flexibility to the licensee in determining how to meet the performance criteria. Establishing objective performance criteria for performance monitoring may not be feasible for some applications and, in such cases, a performance-based approach would not be feasible.

As applied to inspection, a performance-based approach tends to emphasize results (e.g., can the pump perform its intended function?) over process and method (e.g., was the maintenance technician trained?). Note that a performance-based approach to inspection does not supplant or displace the need for compliance with NRC requirements, nor does it displace the need for enforcement action, as appropriate, when non-compliance occurs.[5]

As applied to licensee assessment, a performance-based approach focuses on a licensee's actual performance results (i.e., desired outcomes), rather than on products (i.e., outputs). In the broadest sense, the desired outcome of a performance-based

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[5] Not every aspect of licensed activities can or should be inspected using this approach. For example, if a licensee is unsuccessful in meeting the criteria defined by a performance-based regulation, the inspector should then focus on the licensee's process and method, to understand the root cause of the breakdown in performance, and to understand how future poor performance may be avoided.

approach to regulatory oversight will be to focus more attention and NRC resources on those licensees whose performance is declining or less than satisfactory.

8. **"Risk-Informed, Performance-Based Approach"**: A risk-informed, performance-based approach to regulatory decision-making combines the "risk-informed" and "performance-based" elements discussed in Items 5 and 7, above, and applies these concepts to NRC rulemaking, licensing, inspection, assessment, enforcement, and other decision-making. Stated succinctly, a risk-informed, performance-based regulation is an approach in which risk insights, engineering analysis and judgment including the principle of defense-in-depth and the incorporation of safety margins, and performance history are used, to (1) focus attention on the most important activities, (2) establish objective criteria for evaluating performance, (3) develop measurable or calculable parameters for monitoring system and licensee performance, (4) provide flexibility to determine how to meet the established performance criteria in a way that will encourage and reward improved outcomes, and (5) focus on the results as the primary basis for regulatory decision-making.

The definitions and concepts in this paper have proven suitable for application to nuclear power plants and certain non-reactor activities (e.g., PA of geologic repositories). While different in detail, these activities are similar in terms of system complexity and the application of probabilistic methods to the determination of safety. In simpler situations, the concepts and definitions should prove equally suitable provided that NRC adopts a flexible framework for the implementation of risk-informed, and ultimately performance-based, regulation across the full spectrum of the materials, processes, and facilities regulated by the NRC.

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FACT SHEET

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Nuclear Material Safety and Safeguards U.S. Nuclear Regulatory Commission

The U.S. Nuclear Regulatory Commission regulates medical, academic and commercial uses of nuclear materials to protect the public health, safety and the environment and ensure the common defense and security.

The agency issues licenses for nuclear power plants, other types of commercial and research nuclear reactors, the production and use of reactor fuel, and the processing and use of radioactive material produced in reactors. The NRC also certifies packages for the transportation of nuclear materials and regulates the shipment of the materials and the disposal of radioactive wastes.

All non-reactor NRC licensees are regulated by the Office of Nuclear Material Safety and Safeguards (NMSS), one of three major NRC program offices established by law. NMSS's responsibilities fall into six principal areas:

(1) Licensing of fuel cycle facilities
(2) Licensing of nuclear materials for uses other than in reactors
(3) Regulation of the transportation of nuclear materials
(4) Safeguarding of nuclear materials from sabotage and diversion to unauthorized uses
(5) Regulation of radioactive waste disposal facilities and
(6) Regulation of the decommissioning of previously licensed nuclear facilities that are no longer in use.

Some of these functions are carried out by the four NRC Regional Offices.

Fuel Cycle Facilities

The various processing operations required to produce fuel for nuclear reactors are conducted in NRC-licensed fuel cycle facilities. Activities at these facilities include:

- Certain types of uranium mining activities
- Milling and refining uranium ore to produce uranium concentrates
- Production of uranium hexafluoride from uranium con-

centrates to provide feed material for isotopic enrichment of uranium-235 to levels needed for a nuclear reaction
- Isotopic enrichment processing of uranium hexafluoride to produce fuel with a higher percentage of uranium-235 than in natural uranium, which is mostly (99.3%) uranium-238
- Fabrication of nuclear reactor fuel, including converting enriched uranium hexafluoride to uranium dioxide, forming it into pellets, loading the pellets into zircaloy tubes that are fitted with end caps and welded, and assembling the rods into fuel elements and
- Reprocessing spent fuel for recycle. (This step is not performed in the United Sates.)

Most of the manufacturing operations that make up the nuclear fuel cycle are licensed by the NRC. Exceptions are uranium mining and uranium milling in Agreement States.

At the present time there is no reprocessing of commercial nuclear fuel in the United States; spent fuel is being stored for later disposal in a high-level waste repository. However, the NRC is conducting a safety review of DOE's high-level waste solidification activities at the closed-down West Valley, NY, reprocessing facility.

NMSS's Division of Fuel Cycle Safety and Safeguards reviews operational safety, radiation protection and criticality safety programs as part of the licensing process for fuel cycle facilities.

The office also provides policy guidance and technical support to the NRC regional offices and to Agreement States on their licensing and inspection activities and on incident and emergency responses to ensure protection of the public health and safety. At the present time NRC fuel cycle licenses number about 30.

Nuclear Materials

The NRC regulates approximately 8,200 licenses for the possession and use of radioactive materials for purposes other than the generation of electricity or operation of a research reactor. The 29 Agreement States (which are states that have accepted authority, through agreement with the NRC, over the licensing of radioactive materials within the state) regulate about 15,000 radioactive materials licenses.

Most of the over 8,000 NRC materials licenses are administered by the NRC's four regional offices. NMSS's Division of Industrial and Medical Nuclear Safety at headquarters provides national direction to the regional licensing and inspection activities. It also provides technical guidance and support to the regional offices and, upon request, to the Agreement States.

NMSS also takes appropriate actions to control safety issues involving nuclear materials licensees and directs NRC responses to emergencies in this area.

Uses of nuclear materials under these licenses include medical diagnosis and treatment, food irradiation, sterilization of surgical gloves, smoke detection and industrial measurements.

Transportation of Nuclear Materials

Approximately 3 million packages of radioactive materials are shipped in the United States each year. The transportation of these materials is regulated jointly by the NRC and the Department of Transportation (DOT). The responsibilities of the two agencies are generally divided as follows:

DOT—Regulates packages for small amounts of radioactivity, carriers of radioactive material and the conditions of transport (such as routing, vehicle requirements, handling and storage).

NRC—Regulates users of radioactive material and the design, construction, use and maintenance of shipping containers for large amounts of radioactivity.

Requirements for the shipping containers vary according to the amount of radioactivity in the material being transported.

Type B packages

Containers used to transport spent fuel, which is highly radioactive, must be "Type B" packages that are designed to withstand a series of impact, puncture, and fire environments, thereby providing reasonable assurance that the packages will withstand severe transportation accidents. NMSS's Division of Industrial and Medical Nuclear Safety initially reviews the package design to verify its resistance to acci-

dents. An approval certificate must be issued by NMSS before a package, called a "cask," can be used to transport spent fuel.

NRC regulations require that all states located on approved routes be notified by the licensee before a series of spent fuel shipments begins. Under DOT's guidelines, a state may indicate a preferred route through the state other than via an Interstate System highway.

In addition to the protection provided to spent fuel shipments by the Type B shipping container, a physical protection system is applied to minimize the possibilities of radiological sabotage of the shipments, particularly in highly populated areas. Armed escorts must be provided while a shipment travels through urban areas, for example, and state authorities must be notified in advance. NMSS also must approve routes proposed by licensees for shipment of spent fuel to ensure that sabotage concerns are considered.

Type A Packages

Small amounts of radioactivity can be shipped in "Type A" packages. Contents are restricted so that failure of packages containing these materials would not present a serious health problem if the contents were released. Type A packages must be designed to withstand normal conditions of transport, but not accidents.

Most medical isotopes are shipped in Type A packages. Lesser amounts of radioactivity, such as that contained in smoke detectors, may be shipped in ordinary boxes.

Low Specific Activity Packages

Another category, the "Low Specific Activity " package, is used where the radioactivity is low concentration, such as uranium ore or yellowcake. LSA material may be shipped in bulk or packages and presents a minimal health hazard in transport.

NMSS develops policy and guidance for inspection and quality assurance programs to ensure that transportation regulations are followed for nuclear materials shipments. Approximately 1000 individual inspections are performed by the NRC per year—principally by the regional offices.

In case of an accident involving actual or suspected leakage during the transportation of packages of radioactive material regulated by the NRC, the agency's role includes ensuring that affected parties are aware of the event and offering and responding to requests for technical assistance by providing information, advice and evaluations. The Federal Emergency Management Agency is responsible for coordinating federal and state participation in developing emergency response plans. The state government in the affected area is recognized as being responsible for assuming control of the accident scene to protect the public health and safety.

Safeguarding of Nuclear Materials

"Safeguards" refers to (1) measures taken to deter, prevent or respond to the unauthorized possession or use of significant quantities of special nuclear material through theft or diversion and (2) measures taken to protect against radiological sabotage of nuclear activities.

NMSS, in consultation with other Federal agencies, continually reviews the domestic and foreign threat environments and their relationships to NRC's domestic safeguards regulations. The staff also reviews threat-related information on a continuous basis to monitor any change in adversary characteristics and to assess safeguards-related events associated with NRC-licensed facilities and activities.

NMSS's Division of Fuel Cycle Safety and Safeguards develops and implements safeguards policies and the overall safeguards program for licensed nuclear materials, facilities and activities. It recommends improvements for physical security and nuclear materials control and accountability. Protection provided in the commercial sector for weapons-usable "special nuclear material" is comparable to that provided for similar material under government control. (The term "special nuclear material" refers to plutonium, uranium-233, uranium containing more than the natural abundance of uranium-235 or any material artificially enriched in any of these substances.)

The Division also performs international safeguards and foreign physical protection evaluations of nuclear export license applications, coordinates implementation of the United States/International Atomic Energy Agency Safeguards Agreement at NRC-licensed facilities, and provides technical support to strengthen IAEA safeguards through interagency groups and direct assistance.

Safeguards for nuclear power reactors generally stress protection against radiological sabotage—such as a deliberate tampering or breaching of containment that could result in spread of radioactive materials in an uncontrolled fashion—rather than theft or diversion.

Safeguards for licensed nuclear fuel cycle facilities and non-power reactors (such as university or research reactors) emphasize protection against theft or diversion of special nuclear material.

NMSS's Division of Fuel Cycle Safety and Safeguards is responsible for protecting against radiological sabotage and theft or diversion of special nuclear material at nuclear fuel facilities and during transportation. Another NRC office, the Office of Nuclear Reactor Regulation, performs this function for reactors.

Radioactive Waste Disposal

Radioactive wastes generated from commercial uses of radioactive material include high-level and low-level wastes and mill tailings. High-level radioactive waste consists of irradiated nuclear reactor fuel and certain liquid and solid wastes resulting from the reprocessing of irradiated reactor fuel. All other radioactive waste is low-level. The NRC also regulates mill tailings, which are the residues from processing ore to recover uranium and thorium.

High-Level Radioactive Waste Disposal

No facilities are presently available for the permanent disposal of high-level radioactive wastes. In passing the Nuclear Waste Policy Act of 1982 (NWPA), Congress found that a national problem had been created by the accumulation of spent fuel from nuclear reactors, certain materials from the reprocessing of spent fuel, and other highly radioactive materials requiring permanent isolation.

The NWPA provided for the development of repositories for the disposal of high-level radioactive wastes and spent nuclear fuel. In 1987, the NWPA was amended to focus the development of a repository on only one site—Yucca Mountain, Nevada. If the Nevada site does not prove suitable, the Department of Energy (DOE) is mandated to obtain further Congressional guidance.

The NWPA gave DOE the responsibility for siting, constructing, operating and decommissioning the repository under NRC license and regulation. The NRC is charged with evaluating DOE's application for authority to construct a repository and reaching a licensing decision on construction authorization within three years from the receipt of the application. After the repository construction is completed, DOE will apply to NRC for a license to receive and possess the wastes.

DOE will also apply to NRC for license amendments if they intend to permanently close the repository, dismantle surface facilities, remove controls to restrict access to the site or undertake any other activities involving an unreviewed safety question.

The Division of Waste Management within the Office of Nuclear Material Safety and Safeguards manages the NRC's program for licensing, inspecting and regulating the repository. This includes developing a program of pre-licensing interface with DOE, Federal and State authorities and any affected Indian tribes. The aim is to achieve an ongoing understanding of DOE's program and identify repository licensing concerns and issues at an early stage.

Until the repository is approved and constructed, spent nuclear fuel is being stored primarily in specially designed, water-filled basins or dry storage casks at individual reactor sites around the country. Alternative methods for additional storage may include:

Independent Spent Fuel Storage Installations—using wet storage in separate pools or dry storage in casks, modules or vaults off the reactor site. A license of this type has been issued for a wet storage pool at an off-reactor site to General Electric Co., Morris, Illinois.

Monitored Retrievable Storage Facilities—which may be built by the Department of Energy. NMSS is responsible for reviewing applications for such storage facilities and issuing a license to operate, if appropriate.

Low-Level Waste

Two disposal sites in the United States are currently accepting low-level radioactive waste from certain areas of the country. The two sites are located in Barnwell, South

Carolina, and Hanford, Washington. Under a provision of the Atomic Energy Act enabling states to assume certain regulatory responsibilities from the NRC, both sites are licensed by the "Agreement States" in which they are located.

NMSS's Division of Waste Management provides guidance to Agreement States in low-level waste areas.

The Barnwell low-level waste facility accepts waste from the states of Alabama, Florida, Georgia, Mississippi, North Carolina, South Carolina, Tennessee and Virginia. It is slated to close on January 1, 1996. The Hanford facility accepts waste from the states of Alaska, Colorado, Hawaii, Idaho, Montana, Nevada, New Mexico, Oregon, Utah, Washington and Wyoming. States that are not included on either list must store their low-level waste until new sites are opened.

The Low-level Radioactive Waste Policy Act gave the States—rather than the Federal government—responsibility for providing additional disposal capacity for low-level radioactive waste. States are currently working to develop regional compacts to ensure adequate disposal capacity in the future without building a new waste facility in every state. Sites located in non-Agreement States will be regulated by the NRC.

NRC regulations and guides contain performance objectives and technical requirements for the land disposal of low-level wastes. Performance objectives include limits on radioactive material released to the environment and provide for protection against inadvertent intruders after active operations cease.

Technical requirements in NRC's regulations and guides include an examination of site suitability to ensure avoidance of sites with, for example, unacceptable earthquake vulnerabilities and erosion or flooding. Environmental monitoring is required before the site is chosen to provide basic data about the site. Similar monitoring is required during operation to provide early warning of releases of radioactive materials before they leave the site boundary. The regulations also require proper packaging and form of the waste and classifying each package of waste to indicate its radiological hazards, based on the concentration of radioactive materials.

Low-level wastes exceeding the limits of NRC's classification system are to be disposed of by the Federal Government. The Department of Energy is responsible for disposal of these wastes, but has not developed a facility for their storage or disposal. Disposal in the high-level waste repository is one option recognized by the NRC.

The NRC licenses and regulates uranium mills, heap leaching facilities, ore-buying stations, commercial in-situ solution mining operations and uranium extraction research and development projects. The licenses are administered by NMSS's Division of Waste Management. NMSS also reviews the remedial actions to be taken by DOE at 22 inactive mill tailings sites.

Decommissioning

"Decommissioning" means removing a nuclear facility from service and reducing residual radioactivity to a level that permits termination of the license.

For nuclear power reactors, NMSS's Division of Waste Management is responsible for reviewing the decommissioning plan submitted by the utility that operated the reactor and for overseeing the implementation of the plan and the termination of the license when the decommissioning activities are successfully completed.

The NRC group that licenses operating nuclear power plants, the Office of Nuclear Reactor Regulation, also has responsibilities during the initial stages of decommissioning and has complete responsibility for regulating the decommissioning of research and test reactors.

NMSS's Division of Waste Management provides national direction, technical guidance on decommissioning reviews and support for all non-reactor licensees.

The above areas of responsibility evolved from the Energy Reorganization Act of 1974, which established NMSS as one of the three major program offices of the NRC. Under this authority granted by Congress, NMSS has a primary role in ensuring that the NRC performs its mission to regulate the safe use of nuclear materials in the public sector.