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Meeting Title: Briefing on Systematic Regulatory Analysis of High-Level Waste Program

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UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

Title: BRIEFING ON SYSTEMATIC REGULATORY ANALYSIS OF HIGH-LEVEL WASTE PROGRAM

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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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BRIEFING ON SYSTEMATIC REGULATORY ANALYSIS OF HIGH-LEVEL WASTE PROGRAM

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PUBLIC MEETING

Nuclear Regulatory Commission
One White Flint North
Rockville, Maryland

Tuesday, April 26, 1994

The Commission met in open session, pursuant to notice, at 2:00 p.m., Ivan Selin, Chairman, presiding.

COMMISSIONERS PRESENT:

IVAN SELIN, Chairman of the Commission
KENNETH C. ROGERS, Commissioner
FORREST J. REMICK, Commissioner
E. GAIL de PLANQUE, Commissioner

STAFF SEATED AT THE COMMISSION TABLE:

JOHN HOYLE, Assistant Secretary

MARTIN MALSCH, Deputy General Counsel for Licensing and Regulations

JAMES TAYLOR, Executive Director for Operations

MALCOLM KNAPP, Director, Division of Waste Management, NMSS

JOSEPH HOLONICH, Chief, High-Level Waste and Uranium Recovery Project, NMSS

P-R-O-C-E-E-D-I-N-G-S

2:00 p.m.

CHAIRMAN SELIN: Good afternoon, ladies and gentlemen.

The Commission is to receive a briefing this afternoon from the staff on the use of systematic regulatory analysis in the High-Level Waste Program. The staff is applying the systematic technique to help us in the difficult task of developing a first-of-a-kind licensing program for the high-level waste repository. This afternoon we will hear the description of the analysis and how it's being applied to the High-Level Waste Program and the results to date.

The Commission is quite eager to hear the staff's briefing and especially the substantive implications for the program, what have you found so far, et cetera. I would hope it would not be a substance-free procedural presentation, Doctor Knapp.

Commissioners, do we have any comments?

Mr. Taylor?

MR. TAYLOR: As you noted, Mr. Chairman, with me are Joe Holonich and Mal Knapp from NMSS. Mal will be the principal presenter.

Mal?

MR. KNAPP: Thank you.

The overall briefing on systematic regulatory analysis or SRA is going to be -- my support from Joe, who's here for two reasons. His group has done the bulk of the work on this and I plan to give him all of the difficult questions.

CHAIRMAN SELIN: I have to tell you something. When the late President Nixon died, Doctor Kissinger was interviewed and he was asked whether he or President Nixon deserved the credit for the President's foreign policy successes. Doctor Kissinger said, "Since he probably would have taken the blame if they had failed, I think we should give him the credit."

Now is that the type of introduction you've just given?

MR. KNAPP: I think that's good.

This afternoon I hope to talk a fair amount about products. The Commission paper you received a few days ago tends to put more emphasis on process. Today I hope to speak more to specific products.

CHAIRMAN SELIN: Good.

MR. KNAPP: SRA in general is no longer in the development stage. It's complete and we are now

applying it. It provides a discipline, I believe, to the High-Level Waste Program which is pretty important, because it is a complex program and without some sort of a discipline like that which SRA provides I think it would be very hard to have it under control.

One comment on the material I'm about to give you. It is coming in pretty much a logical order, but, in candor, this is not in chronological order. We developed, or, more accurately, Joe and his folks developed and applied at the same time, so there were some false starts. What you'll see today is the logic that we've actually developed over time.

(Slide) The viewgraph on the overview simply shows where I'm headed today. I'm going to talk about what SRA is, why it's needed, what some of its attributes are, what the staff is doing and has done with it, and then I'm going to speak to some of the specific products that have been completed with SRA.

(Slide) In the next slide, what is SRA? Very simply, it's a management process which is a logical way of asking and answering two questions. What should we do? And what order should we do it in? That's really all there is to it. It is applied in

the High-Level Program to two areas.

The High-Level Program consists really of three areas: development of regulations, development of licensing capability, and interaction with DOE. SRA applies to the first two. It helps us develop our regulations. It helps us develop our license review capability. And those in turn help us interact with DOE, but SRA does not directly apply to that third activity.

COMMISSIONER REMICK: Mal, to make sure I understand, you're applying it to the existing Part 60, so you're not really using it to develop regulation, right? Aren't you taking it, in this case where we have a regulation, going through and systematically saying what does this regulation require and trying to follow that through, then, the process? Is that right?

MR. KNAPP: I'll get to that more in a moment, but the quick answer is we applied it to Part 60 after the regulation was complete. We used it in the past to ask some questions such as sufficiency and clarity of the regulation. We've answered those questions and we're now doing things like moving to a rulemaking, in fact one which we proposed last July which I'll also speak about as a product. So we are

not using it to develop Part 60, but we will be using it both to patch up a few of the uncertainties or ambiguities that we found in Part 60.

And as time passes, as we learn more about the site and as we learn more about, for example, our license application review plan, we don't anticipate making changes in Part 60, but, SRA does contain a mechanism which would allow us to reexamine Part 60 and say, in light of the new information, is a change called for.

COMMISSIONER REMICK: Okay. At some point, I would like you to think about and address the question, would this be a useful technique when we are beginning to write the new rule much like, I've come to believe, that a PRA can be very useful during a design process to help you in the design.

We were talking earlier today with the NMSS staff -- I think it was today, or was it yesterday? I lost track of time -- about a systematic approach that they are using, and it seems to me that this enforces or gives you a systematic approach for, if this is what you want to accomplish, how you do it and then how you might follow up with regulatory guide and enforcement and so forth.

MR. KNAPP: To answer your question, yes,

I think it does. In all candor, I started looking at this a few months ago with a certain amount of skepticism. The more I looked at it, the more I became a convert.

And in fact, on about the 17th slide or so, I will talk about a functional analysis which was done. It was actually done by the Center at our request to provide an independent view, but, if I were to start a rulemaking today from scratch, I would start it exactly the way they started the functional analysis. I thought it was a very valuable tool and, as I'll mention later in the discussion, not only was it a great tool to develop the rule, but inasmuch as the National Academy of Science is reconsidering the High-Level Waste Standard and will advise EPA and we will very likely be making some conforming changes to Part 60, that functional analysis has enabled us to support the National Academy in their studies and will make it much easier for us to conform Part 60 to whatever changes EPA makes. So, I've gone from skeptic to convert in about two to three months on this.

To continue briefly what it is, it will direct or does direct planning, organizing, conducting and documenting what we do with respect to development

of regulatory guidance as well as regulation. I would also note that it's derived from systems engineering, and that is in large measure because of the complexity of the repository, the complexity of the regulation.

(Slide) The next slide talks about some of the reasons that we needed some kind of a tool.

This first-of-a-kind repository is a revolutionary as opposed to evolutionary process. We did not have a great deal of information behind us to build on.

The repository itself is physically complex. You get interactions such as the heat generated by the waste which creates a thermal profile which affects what happens to the water, liquid and vapor. Heat could also affect the shrinking or swelling of the rocks. It could affect the geochemistry through phase changes. These all could interact to alter the way the temperature profile behaves. The whole system is pretty complicated, and that's just one aspect of it, but it gets us into an area that goes beyond what I guess I'd call conventional technical application.

Conventionally what I would do would be to take a problem like this and try to simplify it down to a few controlling equations and worry about those

or to try to break it down into a series of individual units which I could analyze and then combine. The repository isn't really that amenable to either one of those, because it's too complicated to use a small set of equations and the individual units that you'd like to break it into, whether physical units or technical concepts, interact enough that you can't really deal with them in a solitary manner. So, you need some sort of a system to decompose it and yet cope with the interactions between the individual pieces.

That also applies to our regulation itself, Part 60. For example, we've got a 1,000 year ground water travel time requirement and a favorable condition to have ground water travel time as long as possible beyond that, and yet at the same time for an unsaturated facility to have a free-draining host rock would be very advantageous. Well, how are we going to balance the relative merit of findings we reach in those two areas? We need to understand how those findings and those concepts would interact so we make for the optimal repository.

And finally, we need it for a pre-licensing program that's prospective, recognizing that we want to be able to get the best application we can from DOE. We want to be able to handle that

application in three years. We need some sort of a system to help us lead DOE, and that means we need a system to tell us what's important and what the priorities are that we should be looking at.

(Slide) SRA has five principal attributes.

It defines a well-organized, I believe well-organized, systematic set of activities, and I'm going to talk about those in the next several viewgraphs.

Through these activities, it helps us prioritize the work.

It also facilitates integration of the program in the manner that I spoke of a moment ago, showing how various segments of the program interact.

As I said a moment ago with respect to Part 60, it will facilitate feedback so that we can upgrade and change guidance, the regulation itself if needed.

It also provides for documentation of results, and we're documenting the results in a relational database. Simply put, that simply looks at a particular topic or perhaps a single review plan within the overall license application review plan and tells us, if we collect data in that area or make

changes in that area, what other parts of the review plan or what other topics might be affected so that we know the relations and the impact of what we do in other parts of the regulation so that it will work as a coherent whole.

(Slide) To return to the first bullet, what is the staff doing with SRA?

We're doing six things, but I'd like to note that you will see that a number of these are in the past tense.

We've already developed program policies.

We've evaluated Part 60 for clarity and sufficiency.

We defined an organizational structure for the license application review plan, the format and content guide.

We are continuing to develop the license application review plan, but I would note that that is presently at the printers and we expect it to be out probably in July. If the move is a little kinder, we might have it out a bit sooner.

We have identified our technical assessment and research needs. We will continue to upgrade that identification as we get results from the license application review plan using SRA.

And finally, we're going to be revising the format and content guide to reflect what we're learning from the review plan.

(Slide) We developed a number of program policies to run the High-Level Waste Program. The policies are largely documented in NUREG-1495, which is currently in-press. I'm going to talk in a little more detail about what that does shortly.

But some of the overall decisions that we've made in the past were to focus our pre-licensing activity on licensing issues, decide what we needed to do at licensing and then before the license application comes in work with DOE to ensure that they are addressing those areas and particularly the areas of greatest uncertainty to us.

We made the decision that we would need some research and some independent modeling, that there are areas out there that are simply too complex and too poorly understood to be able to rely on the technology that is there without doing our own independent work.

We made the decision to integrate the regulation with a system/subject structure. The integration is one of technical areas such as geology, hydrology, engineered system, as opposed to the

regulatory area that would follow the structure of 10 CFR 60. I'll talk more in a moment about why that's effective.

We made the decision that when we did the licensing review we would go through five types of review, from a review that's sufficiently simple that it's just an acceptance review to a review that would take advantage of and would require independent tests and analyses to make it work. That may breed the question, why would we be doing independent tests? Why don't we tell DOE to do that? The answer is we're going to be telling DOE to do those tests in any case, but we believe we need to run a few on such things as corrosion mechanisms so that we can understand the phenomena well enough to review what DOE provides us.

And another policy that we have is, as I mentiored earlier, to give our highest priority to the areas where the uncertainty is the greatest.

(Slide) With these policies in mind, we evaluated Part 60 for clarity and for sufficiency. The evaluation for sufficiency I'll be discussing a little bit under a product, the functional analysis.

The evaluation for clarity is discussed here. This is something we had the Center do for us to provide an independent look at Part 60, and they

identified as many as 54 uncertainties. These were regulatory and institutional uncertainties. Among other things, they felt that we would require 13 major and minor rulemakings to clarify Part 60. I'll be talking about one of those rulemakings, the one from July of last year, later on in this presentation, but that rulemaking provides clarification of siting criteria, definitions of such things as what we mean when we say adequately evaluated.

We also found or rather the Center found that we had 24 items that were unclear that we could simply resolve through regulatory guidance. An example is the definition of the quaternary period. Geoscientists define that, I understand, anywhere from around 1.8 to 2.5 million years. We simply needed to fix a number for purposes of our application. We established it at 2 million years in the license application review plan or LARP.

(Slide) We had one uncertainty that we were able to resolve administratively. This was the concern over the applicability of RCRA to the high-level waste repository. We have not resolved that. It turns out that it is DOE's responsibility to make a decision as to whether or not RCRA is applicable. We agreed that that was the case and we have agreed

that in the event that RCRA is applied that EPA will implement.

Finally, we found that of the uncertainties there were a gang that needed additional discussion within the staff to be able to decide whether we would resolve them by rulemaking, by regulatory change or by other activity. An example of that is substantially complete containment. This is one that we were working on, in fact, even yesterday.

The regulation says that the waste packages shall contain the waste for 300 to 1,000 years. The containment shall be substantially complete. When we wrote the regulation we did that to recognize that we could not achieve perfection, but guidance on exactly what is meant by "substantially complete" appears to need further development.

(Slide) We defined an organizational structure for the regulation. This is the structure that I mentioned a moment ago. We have the same structure in the format and content and, of course, the license application review plan. After working this out with DOE, they have the same structure in their annotated outline for their license application. And as through the years they expand that outline so that it becomes eventually the license application,

they will have the same structure we do. This is, on the face of it, a fairly simple accomplishment, nonetheless it is going to greatly simplify what we do when we go to the review and it's a big step in integrating the two programs.

(Slide) The particular structure that we came up with is shown on the 11th slide. As I mentioned earlier, it goes by subject area. After general information, we talk about the natural systems of the geologic setting, the geologic repository operations area, and so forth.

The organization like this tends to enhance integration of our review of the DOE information that's brought in so that we discuss all of our regulations with respect to, for example, hydrology at the same time and in about the same place. It helps us work so that they interact together and, again, as I mentioned earlier, we don't make a change or a decision in one that has an inappropriate effect on the other.

(Slide) We developed the license application review plan, and again I'll speak more about this as a specific product, but in that development we identified 97 separate individual review plans that would need to be completed. Of the

97, we've identified five kinds of review and each of the plans would fall under one of the five. They go from something as simple as an acceptance review to something as complex as a detailed review th. would have to be supported by independent investigations.

For example, a very simple acceptance review would be applied to the description of the geologic system. That could breed the question, well, why don't we do a compliance review on that? And the answer is, a true SRA, we made the decision that the geologic system is spread across various other areas where we already have review plans. For example, if we want to look at hydrology, we will look at the aspects of the geologic system that drive hydrology there, so that all we need for that particular review plan is an acceptance review.

On the other hand, if we wanted to look at something like a correlation of earthquakes with tectonic features, that would be sufficiently complicated that that would be a type 5 review where we would have independent investigations to support. That's an area which is more or less at the frontier of technology today. How would tectonic features be expected to influence earthquakes and can we gain any information from that? In light of the seismicity

that's out at Yucca Mountain, this is an important area that we need to focus on.

(Slide) From these 12 areas where we want independent research, we then went to what our technical assistance and research needs were. We identified, as I mentioned, 12 areas.

One way to look at it is we found 12 where we need research. Another way to look at it, of the 97 review plans, we found that 85 we did not need independent research. So, we brought our research program into considerably more focus through this process.

You can see some of the ones mentioned here, such as past temporal and spatial patterns of igneous activity. What we can do is to talk about that particular subject. That falls under the review plan on igneous activity. We have key technical uncertainties associated with it, such as whether or not we're able to sample igneous features and whether or not we can use tectonic models, not only as I mentioned a moment ago for seismicity, but also to predict igneous activity.

And I can go further and tell you that right now the Office of Research has two projects going on that address that area, volcanic systems of

the basin and range, and field volcanism. So in short, we have gone from a review plan to identifying the biggest uncertainties in the review plan to actually looking at something which correlates with what the Office of Research is doing.

One of the advantages of this process, then, has been that I consider and tell you in confidence that the research program is very well coordinated with our needs here and that we believe the products are going to be useful to us.

COMMISSIONER REMICK: That's good to hear.

MR. KNAPP: Although, I will also note in the last bullet that as we proceed through the license application review plan we will be updating our user needs at the end of this year. At this point, I don't expect dramatic changes.

(Slide) The 14th slide shows a product of the license application review plan. That is, we're simply going to go back to the existing format and content guide. The overall organization of the two documents is similar and the detail at this point of the format and content guide does not match. We will be updating the format and content guide late this year and we will reflect not only the review plan but comments we've received from the public on the plan

and comments we've already received on the format and content guide.

That goes through a number of the activities we've undertaken under SRA.

(Slide) I'd now like to talk about some of the specific products that we have created. There are four I'm going to highlight this afternoon: the functional analysis and evaluation of 10 CFR Part 60, and this is Joe's clue to put that one on the table; our proposed rulemaking to clarify siting criteria; our overall review strategy; and the draft version of the license application review plan which is going to be published shortly.

Let me go back and talk about them in a little more detail.

The functional analysis is the one which speaks to your earlier questions, Commissioner Remick, and I thought it was a very nice piece of work. They started out and asked what are the functions that a deep geologic repository should accomplish, asked questions-- or they came up with four principal functions such as the obvious: dispose of high-level waste and spent fuel in a mine geologic repository; protect public health and safety, worker health and safety, and the environment; and two others, employ

multiple barriers and permit retrieval.

From these basic functions, they went into more detail until they had created what amounted to a tree that had as many as five tiers in it. This got to the level of detail at which we would write a regulation. At that level, they identified not only functions but also constraints and system elements. For example, a function might be to receive waste or to emplace waste. A constraint might be to limit personnel radiation exposure during that process. And a system element could be the equipment necessary to off-load a waste package from an off-site transportation vehicle.

When they had broken the functions of the repository down into that level of detail, they then assigned a safety category to each of these functions. Category 1 was directly affects post-closure isolation, down through category 5 which was not safety-related. So they broke all these repository functions into these categories.

When they had done that, they then compared 10 CFR Part 60 to the functional analysis. We did that in a total of three documents, the functional analysis by the Center, and then an examination by the staff and Center of the pre-closure

operation and post-closure operation.

One of the things that I think was rather gratifying about that analysis was that they found only one area which they felt required rulemaking. This was one which coincidentally has also been identified in the previous investigation, which is the one that focused on uncertainty as opposed to sufficiency, and that area was a rulemaking on design basis events which I think you will all recall we had interactions on earlier this year. And I believe we owe you a proposed rule on July 29th, so that is being addressed.

Another proposed rulemaking, and this is one that Joe brought out a moment ago, is one on siting criteria. This would resolve three regulatory uncertainties. This was identified in the earlier process as uncertainty. It's fairly straightforward, although we've had I believe around 20 public comments on it.

One question was, what do we mean by adequacy of investigations? What do we mean by adequacy of evaluations? It's a very simple concern, but it could cause problems in the hearing process.

We did not in the original rule link adequacy of investigations to a demonstration that the

performance objectives had been met. Therefore, depending on your view, you could infer that an adequate investigation could require more, less, or the same amount of information to comply with the performance objective. It's a simple clarification. What we have in mind is adequate is enough to determine whether the performance objective has been met, creates a linkage between the two.

Those were two areas. Adequately evaluated was used at some locations in the rule, adequately investigated in another location.

Another clarification that we brought forward was the concept of evaluations. There was an indication in the rule that adverse conditions might be evaluated separately. We did not necessarily intend that. Adverse conditions which would be likely to occur at about the same time we felt should be evaluated in combination. For example, we would expect that if dissolutioning were considered to be a potential process, as well as say hydrologic changes due to climate change, we would expect that dissolution and hydrologic changes would be considered as they interact. They would not be considered independently. Simple clarifications, but these are things that would potentially have caused confusion

with DOE and with the public at the time of licensing.

(Slide) The 19th slide talks about the overall review strategy. That does a number of things. It documents the major assumptions that we had for that strategy and some of the objectives and strategies that we have based on those assumptions. A couple of the assumptions are that we will be able to review much of the DOE license application in advance in preliminary form. So, if we can look at those issues and get early resolution, that will enable us to move a lot faster when we get the final application.

We also made the assumption that Nevada and other interested parties will participate technically in the early years so that we'll be able to consider their concerns as we proceed with our pre-licensing activities.

With those things in mind, a couple of the strategies we have are that we will [illegible] the results of DOE's reports. We will review DOE's reports in the pre-licensing phase. We will use those in the licensing phase. If we have reviewed a DOE report, if we believe the issues raised in that report have been resolved, then we will say that's fine and we will not need to review it again until the license application

comes in. If no new information has been identified, our review at that point may stand.

We also made the decision that our reviews will be a vertical slice review. This is consistent with what I mentioned earlier with areas of uncertainty. The areas where there is the greatest uncertainty will be the areas where we will take the deepest vertical slice.

Among our strategies for review are a couple I think you'll be interested in. For example, quality assurance. One of the focal points of our pre-licensing interactions with DOE has been and will continue to be QA because we want to be darned sure that when the application comes in we do not have questions over the quality of the data that they have taken or the models they're bringing forward. Again, part of our pre-application strategy will be to involve Nevada and other interested parties so that we can consider their views as we review the DOE products.

A last strategy is development of review capabilities. Among other things, develop our performance capability early so that we can have the iterative performance assessment. As we collect data from DOE, we can upgrade the performance assessment

and we can use the results of that performance assessment to help us decide what's important both in our review plan and, of course, to guide DOE as they develop further data.

(Slide) The final product is the review plan which is about to be published. The review plan is provided in draft form. It's not complete, but it's reached a point where it's certainly ready to be shown to the public and ask for comment. Of the 97 review plans, we have review strategies for 91. There is a typo in the slide. As a result of developing the strategies, we have found, as I mentioned earlier, the key technical uncertainties. We had a total of 54, 18 of those required work from Research. As I mentioned earlier, we compared these to the research program and we are satisfied at this point that they are being addressed. We have more work to do because this document has been completed recently and the question of whether they are being fully addressed or being addressed on the time table that we may need to meet still remains to be answered. But they are being addressed.

(Slide) That brings me to the summary page. In summary, the SRA process has been developed and we are now applying it. We used it to prepare

some of the regulatory documents that we have and we're using it to prepare other ones. I think it's a useful tool because it helps us work with the complexity of this operation and it also helps us to be flexible to respond to changes. There's one thing I believe is going to happen in the program the next two or three years. I expect to see substantial change and this will help us respond to it.

I'll be happy to answer any questions that I can.

CHAIRMAN SELIN: I'll turn it over to Commissioner Rogers in a second, but I'd like to know where your epiphany occurred. Which page did you decide that this was -- I mean seriously, what happened that convinced you that this was a real tool as opposed to a paperwork exercise?

MR. KNAPP: I think it was when I was reading the functional analysis. You mentioned earlier credit or blame. One or the other, I deserve a certain amount of credit and blame for having written Part 60 in the first place.

COMMISSIONER REMICK: Are you sure you want to admit that?

MR. KNAPP: I'm not sure. You know, this is a public meeting. I can tell you, 10 to 15 years

after the fact, there's a few things in there that if I'd had it to do over, I would have done differently. More than once I've said to myself, "You know, if we had just started from first principles." Not that we didn't. The staff did that, but not with the discipline that SRA has provided. I think if we'd done that, there are a couple things in Part 60 we would have done differently. Also, on behalf of Part 60, we have not focused on a single site and we were looking at saturated media. Some of the concerns I had with Part 60 result from that.

But the bottom line is having written a couple regulations and struggled through them, the idea of starting with philosophically what's the function this thing is supposed to do, let's break it down into more and detail and ask what's important I think is a good one. So, if you like, the epiphany occurred principally when I was reading that document. It also occurred when I got a sense of how these things interact.

(Slide) If you like, if Mike can throw up a backup viewgraph, which would be B6, I don't know whether we're going to be able to get that up or not. But if he does, I felt initially that a number of the products I've described were something of a loose

collection of parts. I wasn't sure how they fitted together. Seeing how they fitted together, seeing how we first got a philosophy, then we did a functional analysis, we then did an organizational structure, we used that to figure out what we should put in the LARP. We then used that or we are using that to decide what our research ought to be, and then we had feedback as appropriate among those. I saw this thing as a coherent whole and I think that's when I began to develop the enthusiasm. I saw this as something we could use to guide and drive the project.

CHAIRMAN SELIN: Commissioner Rogers?

COMMISSIONER ROGERS: Well, I think this general approach is one that many of us, I think, have felt was appropriate for all of NRC. It wasn't necessarily called SRA, but starting with a systems engineering approach. I think that there's more and more recognition that this is an approach that has to be taken not only in our affairs but I think the whole reinventing government, reengineering the corporation philosophy is very much along these lines. The notion that one has to look at the entire process as a whole, that the great success of fragmenting and solving problems by breaking them down into smaller and smaller parts and then individually solving these and

then trying to put them back together again, while it has been extremely successful, does run into difficulties in highly interactive systems that just fail.

There's no doubt in my mind that this general philosophy not only applies to -- could not only be applied here, but could be applied to everything that NRC does. That's a big order, but I think it's very clearly in my mind the way we ought to be thinking about our activities.

Along those lines, yesterday we heard a staff presentation on Part 70 and it seems to me that while the rewrite of Part 70 is in progress, that the approach here, the functional analysis approach that you've taken here could be very useful in the rewrite of Part 70 and perhaps there's some way that that can be brought in before the rewrite is totally completed. I'd like to ask the staff to take a look at that because I think this general approach is one that has great power and great utility in producing a tightly knit result that we ought to try to use wherever we can.

I was particularly struck with the Appendix C of the LARP identifying the technical skills needed to implement each review plan. That's

a very powerful way to go, I think. As we look at our future, the entire Agency's future, it seems to me that we need to have a very strong grip on what our technical skills are for the future. This kind of an analytic approach can be of great help to us, it seems to me, in ultimately coming down to what I would call the core of the Agency's needs for technical skills in the future.

So, I'm really sold on the philosophy and it seems to me that not only is it a point of view, but you're beginning to start to produce products and that's the ultimate test of a utility, not of an approach, can it ultimately produce something that's useful. It looks to me as if it's starting to do that. I'd like to just personally applaud the work so far and wish you good success in continuing to turn out useful products here for the future.

That's all I have to say.

COMMISSIONER REMICK: I think the first that I became aware of this project was an early visit to the Center for Nuclear Waste Regulatory Analysis. If I recall, didn't this have a different name at one time, a little more complex name? I'm not sure. Anyhow, as I better understood it from that presentation, likewise I was very impressed with it as

a powerful tool. I remember coming back and making a comment which I think caused Mr. Taylor to groan. I suggested we ought to apply it to Part 50. I still think that ultimately might be a good idea, but I could see a similarity because of the systematic approach to training where basically you look at the jobs that people have to do, the tasks of the jobs that they have to do and then you ask, "Well, what knowledge, skills and abilities must they have to carry out those tasks?" Then you ask yourself, "Where, where do you expect the people to get those? Do you expect to have it already from previous education or training? Is it something that you expect them to learn on-the-job training or is it something you must learn in the classroom or in the laboratory and so forth?" Then you develop a program along those lines and you make sure the learning programs or whatever technique that you're using is consistent with the overall goal of the tasks that they have to perform. Then you evaluate the people and see if they learned it and then you ask yourself which of these should we retrain them from time to time because they might lose that skill because they haven't done it recently.

I can see this approach somewhat. It's a

systematic approach of looking at basically what are the risks, how are we going to address them and so forth and trying to follow this through the whole process. I also see a relationship kind of between ITAAC and DAC in the design review where ITAAC are designed to later on be sure that we test that the equipment and the systems function as they were intended to when we approved the design. So, once again it's following through the whole process with some kind of consistency and I strongly agree with what Commissioner Rogers suggested, that if it could apply it to the Part 70 that we heard about yesterday, I think it could be very, very helpful.

I hope our Division of Rulemaking which is being formed or has been formed or will be formed is aware of this process and look at it from the standpoint of the benefits that might accrue to that division in the future. When Mr. Taylor comes to us in a month and says, "Commissioners, we've accomplished everything that you've given us to do and all your SRMs. What would you like us to do?" I'd say, "Well, why don't we look at Part 50?"

But I also compliment you on a good job. I think it's an extremely powerful tool. I'm enthusiastic about it. I'm pleased with the products

you've already produced and I compliment you on a very good presentation.

CHAIRMAN SELIN: Commissioner?

COMMISSIONER de PLANQUE: I have nothing in addition to ask. I would offer the same compliments.

Thank you.

CHAIRMAN SELIN: Mr. Knapp, do you have some observations on Part 60 based on this review, parts that will be hard to carry out, parts that you know are going to -- not so much that you might have done them over for questions of elegance or congruency, but parts that are going to be a serious problem in the implementation of the licensing function?

MR. KNAPP: I'm not ready to name anything as a serious problem. I'm troubled by groundwater travel time. When that was written in Part 60, we did not contemplate a repository in the unsaturated zone. That applied to the general geologic systems. It has been identified as a concern, it remains one and I'm going to be looking at that pretty hard in about the next -- well, I'm looking at it hard now. It's possible we may need to go to rulemaking or something else to fix it. Right now in my mind, that's what I'm

most concerned about in terms of major areas in Part 60 that could stand attention.

CHAIRMAN SELIN: What about interaction between Part 60 and the EPA standards to which it's adopted?

MR. KNAPP: Sorry about that.

CHAIRMAN SELIN: You knew you weren't going to get out of the afternoon without that.

MR. KNAPP: Oh, no, of course not. Well, the reason that that didn't immediately come to mind is because candidly I believe that's pretty well under control. As a result of the things that I mentioned earlier, that functional analysis does tell us what the repository ought to do. That expands beyond meeting the initial EPA standard that we received some years ago and it gives us the capacity not only to interact with the National Academy of Science, but to alter Part 60 as needed. When the EPA standard comes out, should it come out in revised version? I guess the reason that that doesn't come to my mind as a major area is that I believe we're going to be able to respond to that using this process.

CHAIRMAN SELIN: Commissioners, do you have anything else? Fine.

Thank you very much. Thank you,

gentlemen.

(Whereupon, at 2:44 p.m., the above-entitled matter was concluded.)

CERTIFICATE OF TRANSCRIBER

This is to certify that the attached events of a meeting of the United States Nuclear Regulatory Commission entitled:

TITLE OF MEETING: BRIEFING ON SYSTEMATIC REGULATORY ANALYSIS OF HIGH-LEVEL WASTE PROGRAM

PLACE OF MEETING: ROCKVILLE, MARYLAND

DATE OF MEETING: APRIL 26, 1994

were transcribed by me. I further certify that said transcription is accurate and complete, to the best of my ability, and that the transcript is a true and accurate record of the foregoing events.

Carol Lynch

Reporter's name: Peter Lynch

USE OF SYSTEMATIC REGULATORY ANALYSIS IN THE HIGH-LEVEL WASTE PROGRAM

April 26, 1994

Malcolm R. Knapp

OVERVIEW

- What is SRA?
- Why is SRA Needed?
- What are the Attributes of SRA?
- What is the Staff Doing with SRA?
- What Specific Products Has SRA Produced?

WHAT IS SRA?

- Management process
- Applied to regulations and development of license review capability
- Directs planning, organizing, conducting, and documenting
- Derived from systems engineering

WHY IS SRA NEEDED?

- First-of-a-Kind Endeavor
- Complexities of HLW Geologic Repository
- Interactions Among 10 CFR Part 60 Criteria
- Need for Prospective Pre-Licensing Program

WHAT ARE THE ATTRIBUTES OF SRA?

- Defines a well-organized, systematic set of activities
- Assists in identifying and prioritizing work
- Facilitates program integration
- Permits consideration of results and feedback
- Provides documentation of results

WHAT IS THE STAFF DOING WITH SRA?

- Developed Program Policies
- Evaluated 10 CFR Part 60 for Clarity and Sufficiency
- Defined Organizational Structure
- Developing Staff's License Application Review Plan (LARP)
- Identified Technical Assessment and Staff Research Needs
- Revising License Application Format and Content Regulatory Guide (FCRG)

DEVELOPED PROGRAM POLICIES

- Regulatory Strategy and Overall Review Strategy
  - Focus Pre-Licensing on Licensing Issues
  - Use Some Research and Independent Modeling
  - Integrate Regulation with a System/Subject Structure
  - Use 5 Types of Review
  - Highest Review Priority to Greatest Uncertainty

EVALUATED 10 CFR PART 60 FOR CLARITY AND SUFFICIENCY

- Identified 54 Regulatory and Institutional Uncertainties
- Resolve 13 Through Major and Minor Rulemakings
  - e.g., July 1993 Proposed Rulemaking on Clarification of Siting Criteria
- Resolve 24 with Regulatory Guidance
  - e.g., Definition of Quaternary Period

EVALUATED 10 CFR PART 60 FOR CLARITY AND SUFFICIENCY (Continued)

- Resolved 1 Administratively with two Commission Papers

- Further Analysis of 16 to Select Resolution Method
  - e.g., Meaning of Substantially Complete Containment Subsystem Performance Objective

DEFINED ORGANIZATIONAL STRUCTURE

- Common Organizational Structure of NRC Regulatory Documents
  - Draft FCRG
  - Draft LARP
- DOE Agreed to Follow Guidance for License Application Annotated Outline
- Have Achieved Integration of NRC and DOE Regulatory Documents

DEFINED ORGANIZATIONAL STRUCTURE (CONTINUED)

- GENERAL INFORMATION
- THE NATURAL SYSTEMS OF THE GEOLOGIC SETTING
- GEOLOGIC REPOSITORY OPERATIONS AREA
- ENGINEERED BARRIER SYSTEMS
- OVERALL SYSTEM PERFORMANCE ASSESSMENT
- CONDUCT OF REPOSITORY OPERATIONS AND PERFORMANCE CONFIRMATION PROGRAM
- LAND OWNERSHIP AND CONTROL, QUALITY ASSURANCE, AND EMERGENCY PLANNING

DEVELOPING THE STAFF'S LICENSE APPLICATION REVIEW PLAN

- 97 INDIVIDUAL REVIEW PLANS
- ACCEPTANCE REVIEWS (Type 1) 97
- COMPLIANCE REVIEWS (Types 2 - 5) (77)
  - GENERAL INFORMATION REVIEW (Type 2) 10
  - SAFETY REVIEW (Type 3) 47
  - DETAILED SAFETY REVIEW SUPPORTED BY ANALYSES (Type 4) 8
  - DETAILED SAFETY REVIEW SUPPORTED BY INDEPENDENT INVESTIGATIONS (Type 5) 12
- TO BE DETERMINED 6

IDENTIFIED TECHNICAL ASSESSMENT AND STAFF RESEARCH NEEDS

- 12 out of 97 Review Plans May Include Research
- Examples of Supporting Research:
  - Past Temporal and Spatial Patterns of Igneous Activity
  - Effects of Regional Hydrogeology
  - Effects of Corrosion Mechanisms on Waste Package Materials
- Use LARP/Key Technical Uncertainties to Update 1992 Research User Needs Letter by December 1994

REVISING LICENSE APPLICATION FORMAT AND CONTENT REGULATORY GUIDE

- Draft FCRG Issued November 1990

- Staff Plans to Revise and Issue Final Guide in FY95 Using the SRA Process
  - Consistency with Draft LARP
  - DOE comments on Draft FCRG

WHAT SPECIFIC PRODUCTS HAS SRA PRODUCED?

- Repository Functional Analysis and Evaluations of 10 CFR Part 60
  - Functional Analysis (CNWRA 91-001)
  - Operational Criteria Comparative Analysis (CNWRA 92-007)
  - Repository Isolation Criteria Recommendations Report (CNWRA 93-001)

WHAT SPECIFIC PRODUCTS HAS SRA PRODUCED (Cont'd)

- Proposed Rulemaking for Clarification of Siting Criteria (July 1993)

- Overall Review Strategy (NUREG-1495)

- Draft LARP, Revision O (NUREG-1323)

REPOSITORY FUNCTIONAL ANALYSIS AND EVALUATIONS OF 10 CFR PART 60

- Identified Repository Functions Independent of Rule
- Compared Safety-Related Functions to Rule for Sufficient Coverage
- Compared Operational and Post-Closure Activities to Rule for Sufficient Coverage
- Results: Rule is Generally Sound

PROPOSED RULEMAKING FOR CLARIFICATION OF SITING CRITERIA

- Would Resolve 3 Regulatory Uncertainties Regarding Potentially Adverse Conditions

- Would Clarify Standard for "Adequacy" of Investigations and Evaluations

- Would Clarify that "Evaluations" Should Consider Interactions of Conditions

OVERALL REVIEW STRATEGY (NUREG-1495)

- Documents Major Assumptions

- Defines Objectives and Strategies for:
  - License Application Reviews
  - Pre-Licensing Reviews
  - Developing of Review Capabilities

LICENSE APPLICATION REVIEW PLAN
REVISION 0, (NUREG-1323)

- Publish Draft LARP, Revision 0 as NUREG-1323 (July 1994)
- Draft LARP, Revision 0 Includes:
  - Applicable Regulatory Requirements for all 97 Review Plans
  - Review Strategies for 92 Review Plans
  - Review Responsibilities for all 97 Review Plans
  - All Sections for 2 Review Plans
  - 54 Key Technical Uncertainties

SUMMARY

- Development of SRA Process Complete

- Implementation of SRA Process is Ongoing
  - Prepared Regulatory Documents
  - Further Preparation Ongoing

- Structured Program and Flexible Process
  - Helps with Complexity
  - Helps adjust to Changes