

UNITED STATES OF AMERICA NUCLEAR REGULATORY COMMISSION

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HIGH-LEVEL WASTE PROGRAM

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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**

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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

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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?

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1 MR. KNAPP: Thank you.

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

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

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

17 MR. KNAPP: I think that's good.

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

23 CHAIRMAN SELIN: Good.

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

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

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

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

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

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1 the High-Level Program to two areas.

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

10 COMMISSIONER REMICK: Mal, to make sure I
11 understand, you're applying it to the existing Part
12 60, so you're not really using it to develop
13 regulation, right? Aren't you taking it, in this case
14 where we have a regulation, going through and
15 systematically saying what does this regulation
16 require and trying to follow that through, then, the
17 process? Is that right?

18 MR. KNAPP: I'll get to that more in a
19 moment, but the quick answer is we applied it to Part
20 60 after the regulation was complete. We used it in
21 the past to ask some questions such as sufficiency and
22 clarity of the regulation. We've answered those
23 questions and we're now doing things like moving to a
24 rulemaking, in fact one which we proposed last July
25 which I'll also speak about as a product. So we are

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

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

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

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

25 MR. KNAPP: To answer your question, yes,

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

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

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

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

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

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

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

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

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

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

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

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

5 (Slide) SRA has five principal
6 attributes.

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

11 Through these activities, it helps us
12 prioritize the work.

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

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

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

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

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

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

11 We've already developed program policies.

12 We've evaluated Part 60 for clarity and
13 sufficiency.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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1 97, we've identified five kinds of review and each of
2 the plans would fall under one of the five. They go
3 from something as simple as an acceptance review to
4 something as complex as a detailed review that would
5 have to be supported by independent investigations.

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

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

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

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

7 One way to look at it is we found 12 where
8 we need research. Another way to look at it, of the
9 97 review plans, we found that 85 we did not need
10 independent research. So, we brought our research
11 program into considerably more focus through this
12 process.

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

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

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

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

11 COMMISSIONER REMICK: That's good to hear.

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

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

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

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

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

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

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

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1 multiple barriers and permit retrieval.

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

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

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

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1 operation and post-closure operation.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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1 after the fact, there's a few things in there that if
2 I'd had it to do over, I would have done differently.
3 More than once I've said to myself, "You know, if we
4 had just started from first principles." Not that we
5 didn't. The staff did that, but not with the
6 discipline that SRA has provided. I think if we'd
7 done that, there are a couple things in Part 60 we
8 would have done differently. Also, on behalf of Part
9 60, we have not focused on a single site and we were
10 looking at saturated media. Some of the concerns I
11 had with Part 60 result from that.

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

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

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

12 CHAIRMAN SELIN: Commissioner Rogers?

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

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

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

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

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

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

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

18 That's all I have to say.

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

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

25 I can see this approach somewhat. It's a

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

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

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

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

3 CHAIRMAN SELIN: Commissioner?

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

7 Thank you.

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

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

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1 most concerned about in terms of major areas in Part
2 60 that could stand attention.

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

6 MR. KNAPP: Sorry about that.

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

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

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

25 Thank you very much. Thank you,

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1 gentlemen.

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

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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**



RELEASED TO THE PDR

4/29/94

date

initials

POLICY ISSUE

April 20, 1994

(Information)

SECY-94-106

FOR: The Commissioners

FROM: James M. Taylor
Executive Director for Operations

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

PURPOSE:

To provide the Commission with a discussion of how the staff is using Systematic Regulatory Analysis (SRA) to undertake its responsibilities in the high-level waste (HLW) repository program.

EXECUTIVE SUMMARY:

SRA is a management process applied to the Nuclear Regulatory Commission's HLW repository program. This paper explains what SRA is, why it is needed, its attributes, activities, accomplishments, and how the staff has implemented the SRA process.

DISCUSSION:

1. What is SRA?

SRA is a management process applied to the regulations and development of guidance and the license review capability for NRC's HLW repository program. It supports the management of both the complex interactions of the components of a deep geological repository and the interdependent requirements of the HLW

NOTE: TO BE MADE PUBLICLY AVAILABLE
AT COMMISSION MEETING ON
APRIL 26, 1994

Contacts: Joseph J. Holonich, NMSS
504-3387
Robert L. Johnson, NMSS
504-2409

regulation, 10 CFR Part 60. In practice, SRA has defined the approach for planning, organizing, conducting, and documenting the staff's work. SRA was derived from systems engineering for this purpose by the NRC staff and the Center for Nuclear Waste Regulatory Analyses (CNWRA).

2. Why is SRA Needed?

There are two reasons the staff has chosen to use SRA in its HLW repository program. First, unlike the many reactor and material licenses issued by NRC, the HLW geologic repository is a unique system for which no prototype or precisely comparable NRC licensing experience exists. Thus, the Commission's regulation for the disposal of HLW, 10 CFR Part 60, has never been applied. Therefore, the staff requires a technical and programmatic framework for implementing its HLW program that is sufficiently flexible to accommodate the evolutionary nature of the project.

A second reason why SRA is needed is that the geologic repository will have too many complex interactions to be handled by conventional problem simplification methods. Generally, problems can be solved either by reducing them to a manageable number of dominant parameters or by decomposing them into a number of relatively independent units, each of which may be solved separately. Unfortunately, the regulation of geologic disposal of HLW is not amenable to either of these approaches because of the extensive coupling of the component processes and their high degree of non-linearity.

For example, placement of waste packages in the geologic environment will raise temperature profiles near the packages. These increased temperatures may alter the flow of nearby water or water vapor, will probably cause expansion of nearby rock, and could cause nearby minerals to dehydrate. Any of these phenomena could affect the thermal response of the rock, thereby altering temperature profiles. Such coupled thermal-hydrological-mechanical-chemical (TMHC) interactions could affect the degradation of waste packages, groundwater flow, and radionuclide retardation. These interactions are not yet well enough understood to attempt to decouple them, particularly in view of the regulatory need to predict repository performance for 10,000 years.

In addition to the above technical challenges, NRC's regulation itself is internally coupled in ways that encourage a systems approach to its implementation. For example, the natural system performance objective is a 1000-year groundwater travel time; a favorable condition for disposal in the unsaturated zone is a host rock that provides free drainage; and a potentially adverse condition is the potential for changes in hydrologic conditions. Guidance on how to meet these and other hydrologic criteria must be consistent and reflect each criterion's contribution to confidence in meeting with reasonable assurance the overall system performance objective.

SRA provides the structure and the process to address the above technical and regulatory challenges in a prospective manner before licensing.

3. What Are the Attributes of SRA?

A. Defines a Well-Organized, Systematic Set of Specified Activities

SRA defines six activities that the staff should undertake to conduct its technical work (see Section 4(A)). These activities are done in a manner that results in work being completed on higher-order program activities first, to help ensure that work undertaken in the subsequent steps is based on a sound foundation. In its analyses, the staff uniformly applies a set of procedures and criteria across all technical disciplines, which contributes to the completeness, consistency, and integration of the staff's work.

B. Assists the Staff in Identifying and Prioritizing Work and in Allocating Resources

The SRA process helps the staff identify significant regulatory issues related to repository performance and the associated work it should undertake to address these issues. This identification, along with DOE schedules for site characterization work and other NRC program needs, such as the development of necessary licensing documents, is used by the staff to prioritize its work. Prioritizing work in this manner also helps to determine the amount of staff resources that should be allocated to various activities.

C. Facilitates Program Integration

SRA facilitates integration in two different ways. One is the integration of staff technical work, to ensure that all requirements for the site design and for performance are addressed, and that the interrelationships among the different repository systems are evaluated. The second is integration of NRC program activities to ensure that work is coordinated to eliminate duplication of effort and to support overall program objectives.

D. Permits Consideration of Results and Feedback in the Program

SRA's flexibility permits results from ongoing staff work to be considered in all program activities. This helps the staff either confirm that work should continue, or determine when it is appropriate to terminate work in certain areas.

E. Provides Documentation of Results

Finally, SRA is designed to document NRC program decisions and technical results that support the staff's published regulatory documents. Because of the long-term nature of the repository program, many staff members working on the program today may not be conducting the review at the time of a license application submittal. Therefore, documenting the results of program work in a computer database (referred to as the Repository Program Database) will facilitate the staff's licensing review and decision-making process.

4. How has the Staff Used SRA?

A. Description of SRA Activities and Accomplishments

This section describes the six SRA activities and related accomplishments. Specific products are listed in the Enclosure. Because of the evolving nature of the SRA process, the six activities were not conducted in the sequence listed below. Rather, some of the activities have been conducted concurrently.

i. Developed Program Policies

The purpose of this activity was to develop internal staff policy documents that define the program's goals, objectives, and strategies to guide the staff's work in a systematic and consistent way. These policies also established, at a top level, a system for prioritizing and integrating the staff's work.

The staff completed three Commission papers that describe the staff's Regulatory Strategy for the program (see the Enclosure). The Regulatory Strategy primarily establishes the staff's policies for evaluating 10 CFR Part 60 for clarity and sufficiency. For example, policies establish how the staff will identify regulatory and institutional uncertainties as well as how rulemaking and guidance will be used to resolve these uncertainties.

The staff has also completed the Overall Review Strategy (ORS), which complements the Regulatory Strategy. The ORS defines a set of objectives and strategies for pre-licensing reviews, license application reviews, and development of review capability (i.e., License Application Review Plan (LARP), performance assessment, analysis methods, and research). The strategies provide a framework for prioritizing and integrating pre-licensing reviews and development of review capability with the staff's eventual license application review. For example, strategies in ORS are given for the staff to prepare the review strategies for the individual review plans of LARP, which identify five potential levels of review for the license application and the corresponding types of work it needs to complete today to support that review effort. Highest review priority is given to the greatest uncertainty and some research and independent modeling is used to support these reviews. ORS also includes the staff's initial Performance Assessment Strategy.

Finally objectives and strategies from both the Regulatory Strategy and the ORS have been incorporated into the staff's 1994 Management Plan.

ii. Evaluated 10 CFR Part 60 for Sufficiency and Clarity

The purpose of this activity was to evaluate 10 CFR Part 60 for sufficiency and clarity, such that the regulation could either be amended or guidance provided to resolve concerns (i.e., regulatory and institutional uncertainties) identified in the evaluation. Resolution of these concerns will help ensure a clear and complete regulation, thus minimizing the potential for time-consuming disputes about the meaning of the regulation during licensing.

The staff and the CNWRA conducted a functional analysis of a HLW repository independent of 10 CFR Part 60. The resulting functions determined to be related to radiological health and safety were then compared with 10 CFR Part 60, to determine whether they could be adequately regulated by this part. Additional analyses supporting this effort included studies of repository operational and post-closure phase activities, to ensure that they could also be adequately regulated under 10 CFR Part 60.

In addition to analyzing 10 CFR Part 60 for sufficiency, at staff direction, the CNWRA examined 10 CFR Part 60 in detail to identify any potential regulatory or institutional uncertainties. The results included the identification of 43 such uncertainties. Follow-on work by the staff defined an additional 11 uncertainties for a total of 54. These uncertainties were further evaluated by the staff, to examine the best methods for reducing them. This effort determined that 24 can be addressed in regulatory guidance, 10 through major rulemaking, and 3 in minor rulemaking. One institutional uncertainty, related to the implementation of the Resource Conservation and Recovery Act (RCRA), was resolved (as reported in SECY 89-298 and SECY-90-051) by determining that NRC's role does not include independently evaluating DOE's demonstration of compliance with the requirements of RCRA, since this responsibility falls within the jurisdiction of the U.S. Environmental Protection Agency. The remaining 16, such as the definition of "substantially complete containment," were determined to require further analysis, which is a staff activity nearing completion. The conclusions were, in general, that 10 CFR Part 60 is a sound rule. By doing this work early on, the staff was able to ensure that the regulation with which it would be conducting its program could be used with confidence.

The activities discussed above were all performed using procedures and criteria concurred in by the staff, and they yielded a number of regulatory products (see the Enclosure). The functional analyses and comparisons with 10 CFR Part 60 resulted in these CNWRA reports. Uncertainty identification was documented in a CNWRA report and subsequently in a Commission paper that included the recommended resolution methods and their status. This systematic uncertainty identification activity enabled the staff to determine that 10 of the 54 regulatory and institutional uncertainties mentioned above will need major rulemaking. Furthermore, the staff has addressed three of the ten regulatory uncertainties in its July 1993 proposed rulemaking, for clarification of assessment requirements for the siting criteria and performance objectives. This rulemaking would clarify the standard for "adequacy" of investigation and evaluation of potentially adverse conditions. It would also explain that evaluations should consider the interaction of conditions.

iii. Defined Organizational Structure

The purpose of this activity was to define an organizational structure, for the staff's program and regulatory documents, that is based on the requirements in 10 CFR Part 60 that the staff must address.

The staff has defined a two-part organizational structure. First, a general structure has been developed based on the repository system and subsystems

defined in 10 CFR Part 60 and other similar subject areas (see Table 1). Second, the staff has grouped the regulatory requirements of 10 CFR Part 60 into 97 topics, which are organized within the general repository system structure. This organizational structure forms the outline of the LARP and the 97 individual review plans comprising it. It is also similar, at a general level, with the outline for the 1990 draft Format and Content Regulatory Guide (FCRG) for the License Application, the structure of which will be revised to achieve complete consistency with the draft LARP. Since DOE is developing its License Application Annotated Outline following the draft FCRG structure, a common organizational structure is evolving that will significantly contribute to the integration of the primary NRC and DOE licensing documents.

iv. Developing the Staff's LARP

The purpose of this activity is to prepare the LARP, which will ultimately provide the staff with guidance to review DOE's license application. It will also be used by the staff in focusing its pre-licensing reviews of DOE's repository program on licensing needs. As noted above, ORS describes the strategy for developing a draft LARP during the pre-licensing phase as a series of annual revisions, which add the individual review plans completed each year until the LARP is finalized in FY01. The general organizational structure and the 97 topics described in Section 4(A)(iii), above, have been translated into the table of contents including 97 individual review plans. Each individual review plan will consist of a standard set of sections: applicable regulatory requirements; review strategy; review procedures and acceptance criteria; responsibilities and interfaces (information inputs and outputs); and example evaluation findings.

The initial step in preparing individual review strategies is to identify key technical uncertainties, which are technical issues judged by the staff at this time to be most important to the staff's regulatory review and evaluation of repository performance (i.e., they might pose a risk of noncompliance with the performance objectives of 10 CFR Part 60). These key technical uncertainties not only identify the most important technical issues for the NRC staff, but also what review capability (e.g., modeling and research) the staff must develop to be prepared to review how DOE will address them. The staff has used key technical uncertainties as a method of prioritizing its technical work, as well as for integrating all the work needed to review them in DOE's license application.

Once the identification of key technical uncertainties was complete, the staff was able to prepare the review strategies for 93 of 97 review plan sections. By developing the review strategies, the staff was able to identify what type of review was appropriate for each of the 97 individual review plans (see Table 2). With this information, the staff has identified that for those 91 review strategies completed, only 12 review plans will need some amount of independent modeling or research support. This information has helped the staff prioritize its technical work and better integrate it with the review plans in LARP that it supports.

The draft LARP, Revision 0 is currently in press and is planned to be published in May 1994. It consists of the applicable regulatory requirements for all 97 individual review plans, 93 review strategies, and 2 complete review plans ("Potentially Adverse Condition: Evidence of Igneous Activity" and "Quality Assurance"). The review strategy sections define the scope, level, and type of review, including any key technical uncertainties. The two completed review plans provide examples of review procedures and acceptance criteria, interfaces, review responsibilities, and example evaluation findings. Appendix C of LARP, Revision 0 identifies the technical skills needed to implement each review plan, by identifying lead and supporting review responsibilities. Such assignments are used to identify the multidisciplinary teams needed to review DOE's on-going site characterization program. Appendix E of LARP, Revision 0 describes 58 key technical uncertainties identified by the staff in its work to date.

Lastly, the staff has started to use the draft LARP for pre-licensing reviews of DOE's site characterization activities related to erosion and volcanism.

v. Identified Technical Assessment and Staff Research Needs

The purpose of this activity was to identify the specific NRC technical assistance work (such as development of performance assessment models and other analytical methods) and research needed to support the LARP.

The staff's development of review strategies in LARP, Revision 0 has resulted in identifying 12 out of 97 individual review plans that need some research and independent modeling to support the staff's detailed reviews. The staff plans on evaluating the draft LARP review strategies and key technical uncertainties to systematically identify specific needs. This will result in an update to the existing 1992 Research User Needs. The completion of this activity will result in a fully integrated program that links all research and technical assessment work and resulting products to the LARP. Such work should support development of review procedures, methods, and acceptance criteria in the individual review plans.

vi. Revising License Application FCRG

The draft FCRG, issued in 1990, provides guidance to DOE on the format and content of its license application. Although this regulatory guide was prepared before the SRA process was fully developed, it is the staff's intent to prepare its final FCRG in FY95, using the SRA process to achieve consistency with the draft LARP, Revision 0 described below. In addition, the staff will use experience gained from: (1) development of the draft LARP, Revision 0; (2) review of DOE's License Application Annotated Outline; and (3) submission of comments on the draft guide by DOE.

B. How SRA Activities Have Been Conducted

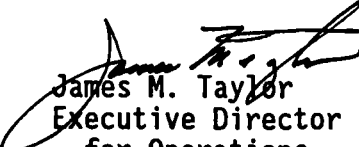
The staff has conducted SRA activities within the requirements of the CNWRA's 10 CFR Part 50, Appendix B, quality assurance program. This program requires that SRA activity use approved procedures. The procedures specify criteria, analysis methods, content and format of products, and requirements for review

and record keeping. The procedures must receive concurrence from NRC and CNWRA management, and staff training in their use must be conducted and documented. These procedures therefore ensure consistency of analysis and product quality across the many staff elements and disciplines. This is an important integrating force. Since the quality assurance program also requires formal reviews, comment resolution, and approval of products, staff management is enabled to maintain appropriate oversight of SRA efforts. The technical staff contribute to procedure development, and the procedures are allowed to evolve in response to regulatory program needs.

The SRA procedural requirements for consistent analysis criteria and product reviews have stimulated an extremely productive working relationship with CNWRA staff. Typically, NRC staff and CNWRA management jointly designate multidisciplinary teams with all appropriate technical disciplines represented to conduct the analyses and document the results. Consequently, staff regulatory and technical expertise is thoroughly integrated with the more focused capabilities of the CNWRA. Both staffs enhance their programmatic and technical knowledge, and the CNWRA has come to better understand the regulatory aspects of its work.

COORDINATION:

The Office of the General Counsel has reviewed this paper and has no legal objection.


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Executive Director
for Operations

Enclosures: Products Produced
Using the SRA Process

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Table 1
General Organizational Structure

- General Information
- The Natural Systems of the Geologic Repository
- Geologic Repository Operations Area
- Engineered Barrier Systems
- Overall System Performance Assessment
- Conduct of Repository Operations
- Performance Confirmation Program
- Land Ownership and Control
- Quality Assurance
- Emergency Planning

Table 2
Distribution of Review Types in the LARP

<i>Review Type</i>	<i>Number of Review Plans</i>
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 Tests, Analyses, or Other Investigations (Type 5)	12
REVIEW TYPE TO BE DETERMINED	6

Products Produced Using the SRA Process

4Ai. Developed Program Policies

SECY-88-285, "Regulatory Strategy and Schedules for the High-Level Waste Repository Program," October 5, 1988.

SECY-90-207, "First Update of the Regulatory Strategy and Schedules for the High-Level Waste Repository Program," June 7, 1990.

SECY-91-225, "Second Update of the Regulatory Strategy and Schedules for the High-Level Waste Repository," July 29, 1991.

Memorandum from B.J. Youngblood to HLWM Staff, "Subject: Overall review Strategy for the Nuclear Regulatory Commission's High-Level Waste Repository Program," February 19, 1993.

Memorandum from B.J. Youngblood to HLWM Staff, "Division of High-Level Waste Management Repository Program Management Plan (January 1994)," January 31, 1994.

NUREG-1495, "Overall Review Strategy for the Nuclear Regulatory Commission's High-Level Waste," 1994 (in press).

4Aii. Evaluate 10 CFR Part 60 for Clarity and Sufficiency

CNWRA 90-003, "Identification and Evaluation of Regulatory and Institutional Uncertainties in 10 CFR Part 60," February 1990.

CNWRA 91-001, "High-Level Radioactive Waste Repository Functional Analysis," March 1992.

CNWRA 92-007, "Repository Operational Criteria Comparative Analysis," September 1992.

CNWRA 93-001, "Repository Isolation Criteria Study Recommendations Report," January 1993.

SECY-89-339, "Regulatory Strategy for the High-Level Waste Repository Program Description of Uncertainties Being Addressed by the U.S. Nuclear Regulatory Commission Staff," October 31, 1989.

Memorandum from J. Holonich, J. Bunting, and R. Ballard, to B.J. Youngblood, Subject: "Report on Uncertainty Reduction," April 1, 1991.

"Proposed Rulemaking on Clarification of Assessment Requirements for the Siting Criteria and Performance Objectives," July 9, 1992.

4Aiii. Defined Organizational Structure

Memorandum from M. Delligatti to B.J. Youngblood, Subject: "Report of the Joint U.S. Nuclear Regulatory Commission-Center for Nuclear Waste Regulatory Analyses Structural Task Force on the Compatibility of the Structures of DG-3003, "Format and Content of the License Application for the High-Level Waste Repository" and Regulatory Requirements and Regulatory Elements of Proof of the Systematic Regulatory Analysis," January 13, 1992.

NUREG-1323, "Draft License Application Review Plan for a High-Level Waste Repository," Revision 0, in publication.

Aiv. Developing the LARP

NUREG-1323, "Draft License Application Review Plan for the Review of a License Application for a Geologic Repository for Spent Nuclear Fuel and High-Level Radioactive Waste, Yucca Mountain, Nevada (Revision 0)," 1994 (in press).

Other

CNWRA 92-027, "Review and Analyses of PASS/PADB System for Systematic Regulatory Analysis," December 22, 1992 (letter report).

CNWRA 93-011, "Development Plan for PASS/PADB System Design (version 3.0)," May 11, 1993.

CNWRA 93-009, "Open Item Tracking System (OITS), Version 1.0 User's Guide," November 1993.

CNWRA unnumbered, "User's Guide for Regulatory Program Database (RPD) (version 1.0)," November 1993.