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NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON NUCLEAR WASTE

144th MEETING

(ACNW)

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THURSDAY,

JULY 31, 2003

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ROCKVILLE, MARYLAND

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The Advisory Committee on Nuclear Waste met at the Nuclear Regulatory Commission, Two White Flint North, Room T2B3, 11545 Rockville Pike, at 8:30 a.m., Dr. B. John Garrick, Chairman, presiding.

COMMITTEE MEMBERS PRESENT:

DR. B. JOHN GARRICK, Vice Chairman

DR. MICHAEL T. RYAN, Vice Chairman

DR. GEORGE W. HORNBERGER, Member

DR. MILTON N. LEVENSON, Member

ACNW STAFF PRESENT:

SHER BADAHUR	Associate Director, ACRS/ACNW
HOWARD J. LARSON	Special Assistant, ACRS/ACNW
NEIL COLEMAN	ACNW Staff
MICHAEL LEE	ACRS Staff
RICHARD K. MAJOR	ACNW Staff
JOHN T. LARKINS	Executive Director, ACRS/ACNW

ALSO PRESENT:

DR. RUTH F. WEINER	Invited Expert

A G E N D A

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

(8:30 a.m.)

CHAIRMAN GARRICK: Good morning. Our meeting will come to order. This is the third day of the 144th meeting of the Advisory Committee on Nuclear Waste. My name is John Garrick, Chairman of the ACNW. The other members of the committee are Mike Ryan, Vice Chairman, George Hornberger, and Milt Levenson. Ruth Weiner is also with us at the meeting as an invited expert, at least she is supposed to be.

Today the committee will do a number of things. We will discuss risk-informed regulations for NMSS, with representatives of the NMSS Risk Task Group. We are going to receive an update from the ACNW Summer Intern on her project, discuss the ACNW September Retreat which is scheduled during the 145th meeting, and the committee visit in November to Yucca Mountain.

We are also going to discuss proposed topics for the new ACNW meeting with the NRC Commissioners, which is presently scheduled for October 23rd. And we are going to discuss proposed ACNW reports on various issues.

Howard Larson is the Designated Federal Official for today's initial session,a nd the meeting

is being conducted in accordance with the provisions of the Federal Advisory Committee Act. The committee has received no written comments or requests for time to make oral statements from members of the public regarding today's session, and should anyone wish to address the committee, please make your wishes known to one of the committee staff.

It is requested that the speakers use one of the microphones, identify themselves, and speak clearly and loudly so we can hear you.

I have a few announcements I want to make, a few items of interest.

On July 14, 2003, Dr. Bhagwat Jain and Mr. Marvin Sykes joined the ACRS/ACNW staff as senior staff engineers. They will both be working principally on ACRS issues.

Dr. Jain has been with the NRC for five years. Currently he is a Project Manager in Research, Division of Engineering Technology. Prior to joining NRC, Dr. Jain worked at Carolina Power & Light Company, AES Corporation, and Sargent & Lundy Engineers.

Mr. Sykes has been with the NRC 12 years. He is currently working in NRR, Division of Inspection Program Management. Prior to joining NRC Headquarters

staff, he worked in Region II and in Alabama Power.

Ms. Sonary Chey has been selected as ACRS/ACNW staff secretary, replacing Barbara Whitaker. You'll get to know her very well. Ms. Chey has 13 years experience with the NRC, having last supported the activities in the NRR Directorate of License Renewal and Environmental Impacts. She reported yesterday to the ACNW staff.

Ms. Gilena Monroe joined the ACRS staff on June 16th as a summer intern. Currently, Gilena is a full-time Graduate student attending North Carolina A&T State University. She has a B.S. degree in Computer Science and is presently majoring in Industrial and Systems Engineering with a concentration in Human-Machine Systems/Human Factors. She is working with the ACRS as a Student Engineer on topics of Human Factors Engineering and Human Reliability.

Members may be interested to know that the Office of Nuclear Security and Incident Response, NSIR, announced the selection of Dr. Cynthia G. Jones as the Senior Technical Advisor for Nuclear Security. She will be advising NSIR on a comprehensive range of radiation protection and nuclear safety issues related to homeland protection and incident response.

On July 18, the White House announced that the President intends to nominate John Joseph Grossenbacher of Illinois, to be a Member of the Nuclear Regulatory Commission, for the remainder of a five-year term expiring June 30, 2004. Upon confirmation, the President intends to designate him to be Chairman of the Nuclear Regulatory Commission. Vice Admiral Grossenbacher has served in the U.S. Navy since 1970 and currently serves as Commander of the U.S. Submarine Forces in the Atlantic.

Which brings us to our agenda for this morning. This topic is Risk-Informed Regulation for NMSS: Status Report and Plans for Future Work, and this must be our rookies' week because the lead member on this is Mike Ryan. Mike is looking forward to the next member of the committee so that he is no longer referred to as the rookie but, Mike, this is your time, so would you lead our discussion on this.

DR. RYAN: Yes, indeed. Thank you very much, Mr. Chairman. I will still be the tallest member.

We are going to be informed this morning on risk-informed regulation for NMSS. We have a team of three folks who are going to be presenting. Christiana Lui will be introducing her colleagues,

Raeann Shane and Alan Rubin, and will lead us off with their presentation. Good morning, all, welcome, and thank you for being with us this morning. I think everybody has a set of the handouts.

MS. LUI: Good morning. My name is Christiana Lui, Section Chief of the NMSS Risk Task Group. I have with me at the table today Raeann Shane, on my right, a Health Physicist on the NMSS Risk Task Group, and Alan Rubin, on my left, a Section Chief in the PRA Branch in Research. Dennis Damon (phonetic), the Senior Level Advisor for Assessment in NMSS, over there, and Ed Chow, a Senior Project Manager in PRA Branch in Research, on the right hand side of Dennis. Together, we would like to provide you a briefing on the status and future plans for risk-informed materials in the waste arena, and answer any questions you might have.

Before we start, let me just give you some introductory remarks and valuable information.

As you are aware, NMSS has been working on implementing SECY 99-100 and the Commission directions in associated SRM. Because the wealth of knowledge and experience that Research has been developing risk-informed approaches for the reactor arena, and NMSS has requested the assistance of Research in our risk-

informing effort.

The ongoing work is challenging because the diversity of NMSS' licensee, the broad spectrum of NMSS-regulated activities, and the need to develop realistic guidelines and risk metrics for the wide spectrum of application and licensees. We want to take advantage of the risk-informed approaches taken in the actual arena, but we also recognize that those approaches may not be directly applicable to the materials and waste application. Therefore, Research and NMSS are working together to ensure that the tools, data and guidance developed will meet NMSS needs and be applicable to NMSS' situation.

In addition to case-by-case applications of the risk-informed approach, we have also been working on incorporating the lessons learned and developing guidance to assist the staff in consistently and effectively applying the risk-informed approach, where appropriate. In particular, we are focusing on using the risk-informed approach to help us address resource issues and issue prioritization.

NMSS has seen the benefit of the risk-informed approach on a case-by-case basis, and expect to continue to realize benefits by developing a

systematic and transparent approach to risk-informed NMSS regulatory activities.

We have been coordinating with NRR, OSTP, OGC and Regions, various staff working groups and steering committees such as the PRA Steering Committee and NMSS Risk Steering Group. Although this is a work in progress, because the committee's views are very valuable to us, we would like to take this opportunity to provide you a status report and the path forward, and receive any feedback you may have regarding our work. A SECY paper on the same subject has recently been submitted to the Commission.

If you view our work favorably, the committee's letter of endorsement to the Commission will certainly have a very positive effect on the staff effort.

Unless there are any questions for me at this time, I would like to turn the presentation to Ms. Raeann Shane. Raeann is the NMSS Project Manager for the risk-informing guidance development work, and she will provide the detail on the status and our future plans.

MS. SHANE: Good morning. My name is Raeann Shane, as Chris said, and I am a member of the Risk Task Group.

(Slide)

The purpose of our briefing today, as Chris mentioned, is to provide the status and the path forward for using risk-informing in the materials and waste arenas, and to do that we are going to talk about the status of the NMSS risk-informing initiatives, the value of risk-informing NMSS, our plan for future work and, as Chris said, we'd also like to request the committee's view of our approach.

(Slide)

The rest of the slides I'll go over this morning will provide you with an overview of the information contained in the SECY paper that was sent to the Commission on July 24th. The first slide covers the risk-informed decisionmaking process. To give you some background, one of the first things that NMSS realized when developing its risk-informing approach is that the ways in which risk information would be used in NMSS would vary widely across NMSS' diverse program areas. NMSS also recognized that it would not always be cost-beneficial for either the NRC or licensees to perform a risk assessment in certain areas. So, in light of this, we developed a systematic process to determine when risk-informing an activity a regulatory decision would be worthwhile.

This process consists of four steps, which are listed here and depicted graphically in the next slide, and on our poster.

(Slide)

So I'll take you through that process briefly now. The first thing is we start out with identifying regulatory issues or action alternative, the top block labeled No. 1.

Then we move on to Step 2 and apply our screening considerations. The screening considerations consider both the benefit and the feasibility of using a risk-informed approach. To assess the benefit of using a risk-informed approach, the screening considerations test whether the use of risk information would enhance safety, improve efficiency and effectiveness, reduce unnecessary regulatory burden, or help to communicate a risk-informed decision.

To assess the feasibility aspects, the screening considerations test whether risk-informing could be accomplished in a cost-beneficial way, and examine whether other factors such as legislative or judicial issues would preclude the use of risk information. We have developed a guidance document for the staff use when applying the screening

considerations, and I will talk more about that guidance document later in the presentation.

So, if the activity is screened in, we go on to Step 3, and risk information is evaluated and, if necessary, additional risk information could be developed. We have also developed a guidance document for this step.

So then as we move on to Step 4, the final step is the decisionmaking step. We are currently developing guidance for this step as well and, in a companion document, we are developing risk guidelines for use in this final step. The guidelines are currently a work-in-progress and, as shown in the diagram, the risk guidelines would be considered in conjunction with defense-in-depth, adequate safety margins, other competing risks, and cost-benefit analysis in making the risk-informed decision.

In developing the risk guidelines for NMSS, we have recognized that there are many challenging issues due in large part to the diversity of NMSS-regulated activities and to the potential uses of the guidelines. We are looking at applicable international standards and guides, relevant domestic experience including the safety goals for the reactor program, and the relationship to the principle as

considerations for development of these guidelines. So that is the risk-informed process.

(Slide)

In addition to developing the risk-informed decisionmaking process and the associated guidance documents, the NMSS divisions have also been actively using risk insights to focus resources commensurately within activity safety significance. Some examples of this include in the fuel cycle arena we have ISA reviews. NMSS has sharpened its focus on safety and reduced labor rate for ISA reviews under 10 CFR Part 70, by using risk insights.

In the materials inspection area, we have refocused the inspection effort to address the highest risk activities while maintaining overall safety and saving resources.

In the high-level waste area, staff has used, and continues to use, risk insights to resolve issues. The details are described in the staff's Risk Insights Report which you have previously reviewed.

In the decommissioning area, staff is completing a project to consolidate, update and risk-inform the policies and guidance of its decommissioning program. The project involves review, consolidation and revision of all existing NMSS

decommissioning guidance documents, decommissioning technical assistance requests, decommissioning license conditions, and all decommissioning generic communications issued over the past several years.

In the spent fuel project area, staff has used quantitative risk insights and reduced unnecessary conservatism with better data and analysis on the issues associated with the storage and transportation of high burn-up fuels.

So, in addition to the previous examples that illustrate how the staff has successfully applied risk insight, more comprehensive efforts are currently underway in NMSS. For example, spent fuel storage is an area where NMSS believes there is potential to reduce unnecessary regulatory burden while maintaining safety.

Accordingly, the staff has initiated an effort to risk-inform standard review plan guidance for certifying casks for the dry storage of spent fuel. In this effort, NMSS has been reviewing the draft pilot PRA of a dry-cask storage system performed by the Office of Research, to identify risk insights that may have applicability to current licensing and certification requirements in inspection program. NMSS will give a presentation to you on the PRA in

October.

In a similar effort in the fuel cycle area, NMSS expects that risk insights gained from ISA reviews will assist the staff in conducting the fuel cycle oversight program. NMSS' long-term objective is to have the licensing, inspection, assessment and enforcement programs involved, to become more risk-informed and performance-based through application of risk information contained in the ISAs.

The third example is in the area of control of sources, where the primary consideration of the ongoing activities is security. In fact, NMSS has considered risk insights and, in working with the Department of Energy and Agreement States, has defined radionuclides and thresholds of concern based on relative hazard and attractiveness for malevolent use. This information will be used as a basis for proposing compensatory measures in the materials arena. This study will provide insights into the broader question of how risk information might be used to re-evaluate the sealed source and device review process, or to refine categories of exempt general and specific byproduct licensees under 10 CFR 30, 31 and 32.

The efficiency and effectiveness initiative will examine the licensing and

certification programs across the office, to identify opportunities for efficiency and effectiveness improvement.

(Slide)

As I mentioned earlier in going over the risk-informing process, we are developing a system of guidance document to help the staff apply the risk-informed process consistently and effectively. The first in the series is the screening considerations guidance document. This guidance will help the staff use the screening considerations to determine whether a regulatory issue is amenable to a risk-informed approach.

The next document is the risk assessment guidance document. It will provide guidance on such areas as how to determine the appropriate depth and scope of an analysis, how to determine who the recipient of risk is, and treatment of uncertainties.

The risk guidelines document is intended to be a companion to the risk-informed decisionmaking document and will provide the technical background and basis used in the development of these guidelines. The guidelines are intended to provide a measure or benchmark which will serve to facilitate consistent risk-informed decisionmaking and greater coherence

across NMSS.

And, finally, we have the risk-informed decisionmaking guidance document, which will be used in the final step of our risk-informing process. The document will focus on the unique aspects of NMSS-regulated activities, while leveraging the experience gained from risk-informed regulation in the reactor arena. Principles from Reg Guide 1.174 and NUREG BR0058, the Regulatory Analysis Guidelines, will be considered, as appropriate, to support NMSS decisionmaking needs for its very diverse licensee base.

DR. RYAN: Excuse me for interrupting, but this might be a good time to ask this one. Do you have a rough schedule for these guidance documents and when they will be coming out?

MS. SHANE: Yes, I think that's the last thing we're going to do here.

DR. RYAN: All right. Thanks.

MS. SHANE: And, lastly, we are conducting pilot studies to test the concepts and methodologies laid out in the risk-informed decisionmaking guidance document. One example of a pilot study that we are conducting from the materials arena is the evaluation of chemical agent detectors owned by the U.S. Armed

Services. These chemical agent detectors use small quantities of radioactive material in sealed sources to detect the presence of hazardous chemicals. These devices are subject to loss because of their use in field training and combat situations. The pilot study will evaluate the control and accountability of these devices using risk insights, and will look for any possible holes in the guidance document methodology.

Pilot studies will also be conducted for issues in the fuel cycle area and spent fuel area. Use of the concept laid out in this system of guidance document will result in targeting case-by-case improvements to the regulatory activity being addressed rather than wholesale reform, and will facilitate consistent transparent well-documented risk-informed management decisions in NMSS.

(Slide)

Implementation of the risk-informed approach to-date has led to an improved focus on safety, effectiveness and efficiency, and reduction of unnecessary regulatory burden on a case-by-case basis. Continuation of this work will further realize these benefits, and will ultimately lead to improvements in communication, greater transparency, and greater consistency and coherence for NMSS activities.

Experience has shown that a risk-informed approach can improve both safety and efficiency at the same time by focusing resources on areas where they are most needed.

(Slide)

So, as I have just discussed, NMSS has seen benefits from risk-informing its regulatory activities, and we intend to continue this work in the following way: We will identify NMSS regulatory activities amenable to a risk-informed approach. We will develop the necessary risk metrics, methods, data, guidelines, and guidance documents. We will assess the implications for the public, NRC staff, licensees, and Agreement States, and the divisions will determine the priority, plan, and schedule for implementation of the risk-informed approaches. We will also develop and conduct staff training in risk assessment techniques and risk-informing methodology, as necessary.

(Slide)

The proposed schedule for our near-term activity is, in January we will issue the risk-informed guidance document for internal comment, and this will include updating the guidance document based on the results of the pilot studies that I described

earlier.

In the spring, we will brief the ACRS/ACNW Joint Subcommittee regarding our progress, and also in the spring of '04 we will prepare a second paper to the Commission to detail our technical progress, policy issues, options for proceeding, and our recommendations. We will also hold public workshops after receiving Commission direction in these areas.

(Slide)

So, to summarize, we have provided the status and path forward for risk-informing materials and waste arenas. We have shown how risk-informing has benefitted NMSS on a case-by-case basis, and how more can be realized by developing and implementing a systematic and transparent process. We have indicated that we will engage the committee and subcommittee at appropriate times as we go forward, and we would like to request a letter from the committee to the Commission regarding your views of our work.

That concludes our formal presentation.

(Slide)

We have included a few backup slides, and this one discusses the policy issues. We are not really going to go over these, I guess.

MS. LUI: No. We have included backup

slides, we have included three backup slides to give you more information regarding the screening considerations that we have developed, as Raeann briefly spoke of, and also highlight the differences between the characteristics of the NMSS applications and reactor applications. That is where we have to consider the existing approach from the reactor arena, whether they are applicable to our considerations. And, also, we have provided you some indication about the issues that we are currently working on, at least the areas that we are tackling right now.

DR. RYAN: Thank you very much.

MS. LUI: This is the end of our formal presentation.

DR. RYAN: One thought that struck me, how much of NMSS' licensees or generally or specific licensed activities will ultimately be changed by this assessment in terms of how you regulate, and what the risk-informing process might do? Do you have any kind of forecast or idea in your head on how this might end up? Will things change a lot, or a little? I know I'm asking you to predict the future and that's maybe not fair.

MS. LUI: I don't know to what extent other briefings from the other presentations

previously, from the other staff in NMSS, have given you some indications about the path we are on. Because of the post-9/11 activities, certainly we are looking at the different byproduct materials of how we regulate them from a security standpoint. But at the same time, because we take risk insights into consideration, that will also have implications from the safety standpoint, and ultimately we have to decide whether it will be cost-beneficial to really alter the existing regulatory framework for the exempt, general license or specific license in Part 30, 31, and 32, and basically in Part 30 we are looking at. So we are on a path to utilizing risk insights, but in terms of the impact we will have to assess what will be the benefit gain from the overall safety and security standpoint, but we have started working that area.

DR. RYAN: Thanks. Questions from members? George?

DR. HORNBERGER: Can you perhaps amplify a little bit, somebody, whoever is appropriate, on exactly what the screening criteria are, give me some examples of how you would screen something out? Is that a backup slide?

(Slide)

MS. SHANE: Yes, the last slide in the package lists the screening consideration questions themselves.

DR. HORNBERGER: And who answers these questions?

MS. LUI: These questions will be answered by the staff because whatever -- as depicted in the box diagram there, first, we would look at what would be a particular action or particular regulatory issue or action alternative, and then we have to develop what would be the best way to address those decisions. Maybe the risk-informed way is not the best way, and there will be the combination way of looking at the issue. These screening considerations are formulated to help us to make that judgment on whether the risk-informed way is the appropriate way to address the issues that have been identified, and mainly we are looking at staff applying these screening considerations.

Raeann, do you want to go through a little bit more detail what issues of those we try to address?

(Slide)

MS. SHANE: The benefit questions, which are in the left column, are really focused on the

Agency's goals as far as what question. Would using risk information help resolve a question with respect to maintaining safety, or efficiency or effectiveness, reducing unnecessary regulatory burden, or communicate a regulatory decision. As Chris said, using risk information might now really be an improvement, so these questions are designed to hopefully determine that.

And the feasibility questions really are do we have the data, or could we get it? Would it cost more to actually do the risk-informing than we would save in efficiency? And then there is, of course, No. 7, which catches a lot of things, and that's the other factors question. And some of our activities are just hampered by legislative requirements, so that would screen out things in that area.

MS. LUI: One of the examples I can think of in the most recent past is in the area of uranium recovery. I think we have been regulating that area using Appendix A in Part 40. And everybody thought it would make more sense, based on the information and the performance to actually form a new part to regulate that particular industry. But because the industry is relatively depressed and the cost-benefits

they employ, it just did not make sense for us to go forward, so that particular proposal was dropped. And you can see that the screening considerations certainly take that into consideration.

And, also, one thing Raeann mentioned, we are conducting a pilot study to test the draft guidance that we have developed, and the two pilot studies that we are looking certainly are going through the screening considerations to help document why certain actions were taken, and we hope that through those pilot studies it will help us to modify or confirm the validity of the screening considerations.

DR. HORNBERGER: And then after something is screened in, your box up there, the No. 3 box says perform risk assessment, and that ties in with some of the questions you have on feasibility. So when you say conduct a risk assessment, is this a PRA, or do you have various levels?

MS. SHANE: Yes, I think it could be a hazard barrier type analysis, it could be just whatever fits the particular situation. It might be a PRA in come cases, but I think for most of NMSS applications it would be some less rigorous kind of risk assessment.

MS. LUI: Well, the goal is to use as much existing information as possible. In fact, in a lot of different areas in NMSS, we already have some baseline in the study. For example, in the byproduct material, we have NUREG 66.42, which is studying about 40 different systems that we regulate the byproduct material. So that does form some baseline risk estimates for us. And in terms of doing new analysis, we will have to look at what is the particular issue and what are the actual alternatives that we are looking at to make sure that whatever we need to develop will help us address the issue and bridge the gap, rather than just do a PRA without any good reason.

DR. HORNBERGER: And just a couple other questions. How about your risk measures here, are these doses to workers, to the public? I guess it depends upon the application?

MS. LUI: I suppose that you are asking the risk guidelines, regarding the risk guidelines area. In other words, what kind of outputs that we are trying --

DR. HORNBERGER: What is your risk measure, what is your measure of risk that you are looking at?

MS. LUI: The NMSS arena, in addition to consideration to exposure to the general public, a lot of the activities really involve risk to the worker. And some of the events that we have seen in the past not only do we need to be concerned for latent health effects, you have acute and also injury effect. So we are taking all that into consideration and looking at developing the proper measures possibly for public and worker, and looking at latent, acute, and also injury. So that is because we want to produce indicators that would be useful to NMSS to help NMSS' regulatory activities. So we are considering risk measures in those areas.

DR. HORNBERGER: And just one final one. So in considering risk to public in the cases where you do that, how do you handle the different transport pathways? Do you have transport models and dose models?

MS. LUI: Transport in the sense of --

DR. HORNBERGER: Atmospheric, water, soil -- pathways to humans, if you are going to consider risk to the public.

MS. LUI: Okay. You brought up another good point, population at-risk certainly depends on the particular NMSS activities that we are looking at.

A lot of the byproduct applications such as fixed gauges, the transport model that Dr. Hornberger mentioned may not come into play at all because it is really kind of direct exposure type of situation. But in cases such as dry-cask storage, that transport model does come into consideration and play, and in that sense we are utilizing whatever existing tools that we have available to us. For example, in the reactor arena they have consequence models, they have transport models, and that will be our preferred path to be on. However, those models may need to be modified in order to produce the results that would be relevant to the particular NMSS applications that we are looking at.

In terms of transportation, we have modal studies that have been done, and those will be the starting point for us to look at risk measures and the existing risk baseline.

DR. HORNBERGER: Thank you.

DR. RYAN: Thank you, George. Milt?

DR. LEVENSON: I think this is a very good initiative, and I think you know from previous things that the committee generally supports such activities. I have one rather basic sort of concern.

Our experience is that whenever you try to

change the normal way that an organization does business, unless there are very unusual actions taken or what have you, no matter how good is the intention of the management, it really doesn't happen, is an incredible inertia in the system. And two things sort of bother me a little bit about the presentation. One is the fact that the determination whether it's going to be done or not has been delegated pretty far down in the organization -- that is, the setting of priorities, plans and schedule for implementation has been delegated down to managers. The list of questions you had on the board for any individual case is being left to the staff member involved, and I think I have a little concern whether under those conditions, no matter how good your intentions are, whether it will really be implemented because there's tremendous inertia for any person who is doing something to not rock his boat, let somebody else undertake the burden.

So the question that I sort of have is how are you going to really make sure that what your intentions and plans are come into being -- you know, the "have you stopped beating your wife" question.

MS. LUI: I'm glad you raised that particular question and issue. We ask ourselves that

question from time to time to time. One of the reasons why we are doing the pilot studies is that we want to introduce to the NMSS staff all the tools that we have already developed, and work with them to apply the tools, and hear from their standpoint what would be most helpful to them.

One of the things that we are working on is to make sure that the process we are developing is transparent so people understand what we are trying to do. Based on our experience working on the pilot studies, I have to say that most of the staff are very, very cooperative in looking at the potentially different way of doing business.

As I have alluded to in my introductory remarks, NMSS is facing resource challenges. We have a lot of work that we would like to get done, however, we need to find some way to prioritize the work for ourselves. And the risk-informed way to the staff is a tool to help the staff to prioritize the work. And, also, the message that has come from the very top management in the office is that we want staff to work on this to figure out -- to use the available tools and to figure out priorities for themselves. Of course, the management will be available for consultation, but it is really both a management and

staff initiative at this point in time.

So, I understand your concern that this is a potentially major change to the way we are conducting our business, but we are doing incremental improvements and progress, and we want to pass that by you on the way so it will not be viewed as something that is being mandated on the staff to make sure that we are working towards this in a collaborative way.

DR. LEVENSON: I understand what you are saying, but seldom is the individual worker or staff in a position to set priorities because they don't have the total picture, and the setting priorities, my personal view, really is a management responsibility to provide help and guidance to the individuals. And if you delegate that too far down, they just don't -- no matter how competent they are, they don't have the background and the information. So, that's one of the things I just --

MS. LUI: Well, I understand, but, Mr. Levenson, you have also mentioned that the management's role is to assist and provide the necessary resources, and that is exactly what NMSS is doing.

DR. RYAN: John.

CHAIRMAN GARRICK: I want to talk a little

bit about the management issue as well. As a long-time practitioner of risk assessment, I'm very aware of the challenges that are involved and the surprising fact that no everybody buys into the religion of risk assessment. And I'm sure that your program has some bumps along the road as to whether or not it makes sense and whether or not it should be implemented at any level at all.

You just said that as far as the staff is concerned, that you feel you've gotten considerable cooperation and support. I think what we're very interested in is at the higher level, what kind of support and challenges you are facing, and we know you are facing some, and what the impact has been on what you are trying to do.

So, my first question is, are you satisfied that what you're doing here and the path forward that you've laid out for the future has the full support of let's say the senior management of the NRC, including the Commission. And you don't have to name names and places, but I think it is important for us to have that kind of feedback as to whether or not this is a concept, this is a program that is being supported and, as I say, I wouldn't be at all surprised if you weren't able to share with us, that

there are some definite challenges in that regard.

MS. LUI: Thanks for the question.

CHAIRMAN GARRICK: That's all right, I know you, Christiana.

MS. LUI: Well, at least I can share with you my personal experience in this regard. Let me start with the NMSS management. NMSS' management, from the very top level, sees the risk-informed approach is a very essential part of how we can evaluate the way we conduct our business and to focus on the important issues, and addressing the resource challenge at the same time. That is the reason why they have dedicated this particular group -- I'm talking about the Risk Task Group -- to really look at developing the guidance and to work with the divisions in finding by the way, if there are opportunities to conduct our business.

So, I will say that in terms of NMSS management, we have buying. And as we have mentioned, the SECY paper that we have sent forward has been reviewed by all the managers, and also whoever they have delegated to, with our concurrence, in a relatively short time, after of course a couple of months of planning and rewriting, the final product was concurrence very quickly. So, from NMSS'

standpoint, I think we have general buying.

From an ideo level, Carl has been a supporter of our work, and we have had numerous interaction with him regarding the progress and status of our work. And over and over again he always told us "You don't have to convince me, I am a believer, but I also know that you have a lot of challenges in front of you". For example, the population at-risk that I mentioned earlier, Carl said that he had found that issue many, many, many times, but does not have the quick answer or a very direct answer is not really available. So he believes that the work that we are doing is valuable, and he is a supporter.

The SECY paper that we are sending up to the Commission is a consent paper. In a way, we are trying to get some reconfirmation from the Commission to make sure that the Commission -- even though in SECY 99-100 they have told us to do this particular work, we want to get reconfirmation that they still view this work as valuable and we should be on the path as we have laid out. However, if there is any concern, that would be a vehicle for us to get your viewpoint. Rather than getting viewpoint from one or several or a selected few Commissioners, we want to get the Commission's direction overall so that we

don't get agitated one way or the other. We want to make sure that we are doing the right work for the Commission, and we are value-added to the work that we are doing.

I think we also have the support from the Research management, too, and, Alan, you may want to speak to that.

MR. RUBIN: There is no question that Research wants to make -- does support the work. Obviously, have been working a lot with the reactors on risk-informed activities across-the-board, and with the initiative to be more as informed across the Agency for NMSS, Research is supporting the technical work on developing guidelines, risk metrics to support the risk-informed decisionmaking process.

There are a lot of questions, lot of issues, you'll see one of the backup slides looking at the differences between the reactors and the waste and materials arenas. There's a vast difference if you just took reactors -- you've got different plants, but certainly in concept you've got power plants generating electricity. In materials arenas, you have across-the-board from small radiographers to large fuel cycle facilities, and whether or not all the risk guidelines will apply across-the-board in NMSS is a

real question. It's one of the issues that we're looking at. It's one of the challenges that we have. But, yes, the Research management does very definitely support this activity.

CHAIRMAN GARRICK: You talked quite a bit about risk guidelines and that you have a schedule for those. What about the impact and influence you're having on more fundamental documents such as new rules and regulations? You recall that when we were in the development days of Part 63, the comment was often made that this is one regulation that is being crafted from the ground up in the environment of risk-informed regulatory practice.

Is there anything going on, or anything you're doing right now that is having a direct impact not so much just on NUREGs and guidance documents, but on rulemaking and the formulation of regulations that have the principle of risk-informed emphatically embedded in their makeup?

MS. LUI: In terms of rulemaking -- direct impact on rulemaking right at this time, I will have to say no, we are not doing that right now. But as Dr. Ryan's question earlier that in the work that we are doing for the security area in combination with safety concerns, it could lead to a change in the way

we regulate the exempt, specific and general licensing material, so that could be on the horizon.

And, also, the work that we are doing with Spent Fuel Project Office, even if the starting point is to look at the standard review plan, but ultimately it may lead to changes to the regulation.

In terms of impacting formulation of new regulations and rules, we also have to have opportunities to do that. For Part 63, we were given the opportunity that you can start from ground up, you know, design something that would really, really make sense by using the risk insights. And in the work that we are doing now, we will be looking for opportunities to make such improvements.

Rules and regulations are always on the horizon, but it may take us a little bit of time to get to that place. Like you, Dr. Garrick, and Mr. Levenson have pointed out, we are really trying to implement a different way of doing our business, as appropriate, and a lot of good work has been done in the area. And when those rules and regulations were put into place, they were risk-informed at that particular point in time. Even though we have new information now, it may take us a little bit of time to convince people that based on new information we

need to go back and look at the existing rules and regulations and how we do a review, how we do a certification, to make sure that we can incorporate the lessons learned and operating experiences into the current way of doing business.

CHAIRMAN GARRICK: In the past, of course, this committee has been a little concerned about the reactor way of thinking about risk assessment on the materials side and on the fuel cycle side and what have you. As we have gained more experience, especially in the high-level waste arena with respect to performance assessment, the closest thing to risk assessment in the waste field, there's been a tremendous evolution of the performance assessments from being somewhat purely deterministic to at least risk-informed. In my opinion, they are still very much compliance-oriented with respect to risk more than they are fundamentally risk, but there's still a lot of progress. A lot of very creative algorithms and ideas and concepts have been developed as a result of the performance assessment work.

Has the performance assessment work had any influence on your thinking with respect to the more detailed activities of developing guidance documents and methods of analysis and what have you?

MS. LUI: Recognizing that performance assessment is definitely a pretty major activity within NMSS, high-level waste is, again, as we pointed out, one component of the entire energy process. So in terms of how performance assessment has influenced the thinking or the methodology in the other areas, I will have to say that that systematic thinking certainly has influenced how we think about doing the assessments for the other areas but, in turn, that exact methodology may not be applicable to these other areas.

One of the reasons why we have the Risk Task Group is that we have expertise from all the different disciplines within NMSS, and we have through this cross-fertilization learned from each other in developing guidance that division over the guidance documents that would be generally applicable to all the different NMSS activities. But as we apply the approach in the guidance document, we intend to really append those experiences to a guidance document to give us exact examples of how exactly the guidance document could be applied in their areas. So, at a high level we will have examples that can apply across-the-board, but on the detail level we will have examples that can really show the staff how to apply

the risk-informed approach in their specific areas.

CHAIRMAN GARRICK: How do you see your business in terms of what's different now as a result of your activities? And I know you are just getting started, but what's different -- and you've said some things about that in your presentation, but in the way you conduct your day-to-day business as you transition into a risk-informed regulatory practice, what are some of the things that you do now that you didn't do in the past, or that when you move this thing along, looking to the future a little bit, that you see will be taking place that were not taking place when you ran the businesses as it's been in the past. What are a few key activities? I know George was trying to get to this with the screening questions and the performance assessment question in the risk-informed decisionmaking diagram. But could you identify a couple of specific things that are different in the way you conduct NMSS business now than in the past, that have been a direct result of this transitioning to risk-informed regulatory practice?

MS. LUI: As you have pointed out, this is a work-in-progress. Well, one of the most vivid examples, of course, is in the high-level waste area. Of course, high-level waste, they have their own

expert risk assessments, so they are probably ahead of the rest of NMSS at this point.

But one of the examples I can think of is the byproduct material we are studying, NUREG 66-42. We are really -- every time there are questions come up regarding byproduct material uses, then we always look at the applicability of the results from 66-42 to at least help us get started.

You may or may not be aware that there was an effort in NMSS about two or three years ago, that we are looking at the way we are conducting byproduct material inspection program, and they really utilize the information in 66-42 to help them devise a different scheme of conducting byproduct material inspection. Based on the most recent result we have seen, there has been a saving on the order of 25 percent of just the paperwork preparation area. So as the program becomes more and more mature, we can expect to see more and more efficiency be gained.

In the fuel cycle area, during the ISA review, the staff has been coming to RTG to ask for assistance in using the risk insights to help them conduct the ISA review. So that certainly has been a positive development, too. And I would like to emphasize in the Spent Fuel Project Office area that

has been working with the Risk Task Group folks and really trying to pass out a guidance document and really trying to figure out where they can possibly reduce unnecessary regulatory burden while maintaining safety. So those are some specific examples.

CHAIRMAN GARRICK: A final comment and question. The committee, as a result of the joint Advisory Committees, is on record as having some concerns about the integrated safety analysis process. We were pleased to see that that process has some of the elements of risk thinking in it with respect to the structuring of scenarios and the addressing of issues in the way in which it is done in the front end of the risk assessment. We were a little critical of the fact that why not go all the way, particularly for fuel cycle facilities, and carry it through to the quantification process.

Is there any intentions to revisit the integrated safety analysis approach and take the next step, if you wish, towards making it more resembling a risk assessment?

MS. LUI: I have to say that we knew that you were going to ask this question, so hopefully our answer will be satisfactory to you. The integrated safety analysis is one of our first attempts to really

ask the fuel cycle licensees to use a systematic approach to look at the potential vulnerabilities within their own system, and also identify what are the components of the system that they rely on for safety.

So, like anything that we do, we have to start from someplace. And, also, it has been very well highlighted by you and Mr. Levenson that not only within NMSS we are looking at the potential of cultural change or big change in terms of doing business from licensee community is same situation. So we see the ISA is a very good first step forward, and it will be -- it could be an intermediate step for going to where ultimately that everybody would like to be.

Based on my limited knowledge about the ISA review, I believe that most of the licensees have elected to use semi-quantitative methods so it is not just purely qualitative. And as we accumulate better and better information, potentially it could become a more quantitative analysis.

CHAIRMAN GARRICK: I think that Raeann said earlier, and this is a point that I would want to emphasize, that the risk assessment ought to be commensurate with the complexity of the problem. And

I think that that's an arena where the NRC has not done a very good and creative job of analyzing. I think that there is often the expression that we don't want to do a risk assessment in every case because they are too complex. They don't have to be complex.

The fundamental thought process is what we are talking about. We want to answer the question what is the risk in the best reasonable way, and we don't want to answer it in anymore detail than necessary.

I think that one area that requires maybe a little more creative thought and investigation would be how do you do risk assessments for varying complexities of systems, and you don't have to do a volume library of faultries for every system. And I think that was one of the reasons the Joint Committee was a little critical of the integrated safety analysis process, because the arguments that seemed to becoming forward were that a risk assessment is too complicated. And I think that this is an arena I would hope that your task force would take a look at and, in the future guidelines and in the future training, begin to think of terms of applications that can be matched up with the process in such a way that

convinces people that you can do limited scope PRAs.

MS. LUI: Yes. A lot of times, at least I have found through my own experience, the only way to convince people that it can be done is through examples. So as we move forward, as you have pointed out, Dr. Garrick, that we will certainly want to gather lessons learned and examples so that there can be illustrative examples to people that this can be done and it is not that complicated. But we have to make progress as time and the environment permits.

CHAIRMAN GARRICK: Thank you.

DR. RYAN: Thank you, John. Ruth? Just a note on time -- we're running a few minutes over, and I would like to do that, which is fine because I have a few questions myself, so, Ruth, go ahead and take it away.

DR. WEINER: Thank you. First of all, I defer to our Chairman, as risk analyst he is certainly far senior to me in risk analysis experience.

CHAIRMAN GARRICK: Be careful how you use that word.

DR. WEINER: And he asked high-level questions, and I have low-level ones and low-level comments. But I would first like to make a comment and a suggestion. The NRC invented risk analysis for

the transportation of radioactive materials, with NUREG 01-70. This was a real breakthrough, and I suggest that you look at the approach that was taken, especially to incident-free transportation. This is one of the most unique and really creative ways of looking at risks from radioactive -- due to any kind of radioactive emissions.

You talk about pilot studies, Raeann mentioned pilot studies. NUREG 01-70 was issued in 1977. Both the code used, RADTRAN, has been through a large number of refinements and improvements, and we have 30 years of experience of doing these risk assessments. And I would suggest that you take a look at this history and see how the approach has changed, and what is valuable about the approach, and what is not so valuable about the approach, especially if you look at it in the light of the two more recent documents, the Modal Study that was done by Lawrence Livermore and NUREG CR66-72, looking at both the approach to transportation accidents and incident-free transportation.

There have been -- we've had a lot of experience in this area. The world has had a lot of experience in this area. So I notice you look at pilot studies. Some of these pilot studies have

already been done for you, and I'd suggest you take a look at them.

I did have a couple of questions -- one more comment. On your screening considerations, you talk about the benefits and the feasibility questions. It's been my experience teaching risk analysis and doing them, that communicating risk is far more difficult than communicating consequences, and that as a rule a risk-informed approach doesn't help you communicate -- people don't understand it, and they particularly don't understand the sort of risk that you get from using event-frees and then multiplying probabilities times consequences or probabilities times something else. And this in communication, this devolves into separately communicating the consequence and the probability, which is exactly what you didn't want in the first place. This is a real challenge, and I commend you for taking it on, I really do. I think that's a wonderful thing.

It's also going to be the case that the risk assessments are going to cost money but, again, I think that Dr. Garrick's comment that there are varying complexities and that the complexity should fit the problem. If it is not a complex problem, you don't need to do a complex risk assessment.

There are a number of codes available. One of them, RADTRAN, was developed by NRC. It is an NRC code. And I would suggest that you look at the field of available risk assessment codes. Most of these codes, in one way or another, multiply things, that's all they do.

Finally, I have a question about one of your backup slides, and maybe you can enlighten me. The comparison of reactor and materials in the waste arenas. I don't understand -- this is probably just my lack of understanding -- I look for transportation in these things. Under radioactive materials location, you have under reactor area, "fixed" and, under material and waste area, "fixed to moving". I really don't understand that that means. Does it mean that the radioactive material is in one place and sometimes it gets moved around?

MS. LUI: I think Alan will be able to answer your question.

MR. RUBIN: This table was not meant to go into too much detail, but to answer your question, yes, at a reactor site, you generally have the source either in the cooler or in storage, sometimes you are moving it between storage to an independent fuel storage bed, but in materials and waste you have

transportation. Either by train or by truck, you are transporting spent fuel from a reactor site to a storage facility, long-time storage.

DR. WEINER: Well, how does putting fixed and fixed to moving compare to the other entries in those columns, like "large" and "small to large", and "high" and "low to high"? What do those mean?

MR. RUBIN: One of the issues that I think Raeann or Christiana mentioned earlier, what is the population at-risk, and that's one of the factors that really needs to be determined when you are looking at something that is a moving source, as in transportation. You know, you have population that is exposed to the risk for only a short period of time.

DR. WEINER: Well, I guess it is the table that is confusing me. I don't mean to dwell on this, but if I start at the top and it says "The characteristic is the frequency of an event", "Reactor arena is low", this means low frequency of events?

MR. RUBIN: Of actual events and accidents.

DR. WEINER: And the material and waste arenas are "low to high", there is a range of event frequencies?

MR. RUBIN: Depending on the activity, the

range of event frequency.

DR. WEINER: I don't want to go through this point-by-point, but it is rather confusing -- at least it confuses me -- maybe it doesn't confuse anyone else. You sort of read it as low to high risk and things like that. It's difficult to make the connection, and I'd encourage you to look at it from the point of view of somebody who didn't produce it, but is reading it without understanding it very well. That's all I have. Thank you.

DR. RYAN: I'll pick up on the same chart with the opposite view -- I found it helpful. Being an NMSS licensee for part of my life, I really understand what low to high means in some of these arenas. And that brings me to a point.

I commend you on recognizing that NMSS -- of course, you clearly know this much more than I do -- that there is a wide range of regulated activities in terms of amount of material and potential risks, whether it's too a worker, to a member of the public, in transportation or whatever, you happen to find it. And trying to put together a coherent system of risk assessment that meets those broad spectrum of activities is a formidable challenge, but I think one that is very important.

If I take just something simple like a low-level waste facility, which I know a bit about, you have everything from check sources in a laboratory on up to Class C irradiated hardware shipments where the contact dose rate on the waste material is 10,000 r/per hour, so it is a very broad range of licensed activities for which risk assessment can be very simple, as Dr. Garrick points out, up to rather complicated and can address worker, environmental or transport issues, again, there's a complexity to it that is certainly formidable. I don't think any one chart could capture all that, but I think that's the idea you're trying to present here, is that you've got a much broader range of things to consider on the NMSS than perhaps the reactor side. There's a little bit more focus on the reactor side.

With that in mind, I turn to that previous question asked about schedule, and let me ask you to think about something on that slide. How about Slide 9.

(Slide)

As you move things forward, I think, somehow conveying this range of need for risk assessment, something very, very simple, a small source that's handled in a specific way, in a specific

use, may not need the same kind of retention as a byproduct, broad-scope licensee for some activity, conveying your perception or knowledge or ranking in some way of what's the most important subset of all NMSS activities to focus on would be helpful to those that really don't appreciate in the depth you do that broad spectrum of issues. So implementing or informing the readership of where you think the priorities ought to be, I think that would serve your case well. I think we all agree that it's good to do what you're doing, but we're trying to say of the 1,000 things we face, these top 100 are the really important ones, or whatever the numbers are, that would really add to your case to be explicit about that.

I would certainly try and add that to your list of things for the 2004 spring paper to the Commission that you want to try and get that idea of priorities into that report as well. That would help, I think, have people see the top level of value. And we can all agree that for some licensees or licensed activities it is much more important to do this than perhaps someone else. So you presenting your view of that priority would be, I think, a helpful part of your case.

MR. RUBIN: Priority to mean which area, which activity --

DR. RYAN: You're going to focus on for us because it is the most important, and it has the best return on enhanced protection, efficiency, and all your operational goals, so being real explicit and detailed about that I think helps your case.

Too, I think it's important to do what my junior high school English teacher, Bob Moyna (phonetic), of compare and contrast, and compare and contrast to the security and safeguards questions. You know, since 9/11 we've sort of been overpowered by a whole new set of questions on gauges, instruments and articles that contain curie or multiple curie quantities of radioactive material. And to me there is a fundamental question there about, on the one side of the NMSS material question, you're thinking about when something sort of goes unintentionally wrong versus something that's intentionally done with material. I think distinguishing how assessing outcomes or risks from intentional versus unintentional kinds of acts would be an interesting way to maybe address that. I think you need to somehow deal with security and safeguards questions as either how it integrates with what you are doing or

how it's separate from what you're doing, again, in an explicit way so you can show the added value to your activities and risk assessment. I think that would be helpful.

You know, you could make a snap comment, which I wouldn't say or agree to, that, you know, we're dealing with all these things because we've got safeguards and security issues. We're kind of subsuming risk assessment into that question. Well, that may not be exactly right for all things, and it is clearly not as perhaps systematic -- could be, I guess -- but the risk assessment approach you are taking I think has a lot of systematic value that can, in fact, enhance some of the safeguards and security questions as well. So I just offer you that couple of points to think about in terms of how you communicate what it is you are about.

Milt, you had an additional comment?

DR. LEVENSON: Yes. I really have two comments applied to the same thing, and that is I want to warn you that we're now in the year 2003, and so what you do and what you write and what you publish is not technical person-to-technical person, it goes into the public arena and, if you don't do it right, it's going to come back and bite you. And I'd like to

comment on the three documents that our expert mentioned -- 01-70, the Modal Study, and 66-72. The concept might have been okay in those reports. They are incredibly bad and unrealistic in estimating consequences. And I hope that nothing you do will use the model from any of those. In fact, one of those is now involved in a lawsuit against the Commission, quoting its own documents.

And with that thought in mind, I go to the table which has been blessed and condemned --

DR. HORNBERGER: I like that.

DR. LEVENSON: Well, I'm just going to point out that if I take this literally, I have to come to the conclusion that the material thing is considerably more dangerous than reactors because they both have the potential for high consequences, they both have the potential for large population at-risk, they both have radioactive source material that's large -- you're using the same words -- but the reactor frequency is only low, and the waste and material area can go high. And taken literally, that means that the potential in that certainly is not correct, and I don't think any of us believe it, and it's why we say "don't carry over the reactor thinking into the materials area". But you just have to be very

-- completely reorient your thinking about using words. "Large" in connection with waste is a different number than the "large" in connection with reactors. You just have to be sensitive to that.

DR. RYAN: Milt, let me react because, again, coming from the material side of the house, I think I can offer you a different perspective. While it's true that a big event in a reactor can have a significant loss of economic value and production capability, if you will look across the history, I think -- and please correct me if I'm wrong -- that worker exposure and potential exposure to members of the general public and, in fact, worker overexposure, have occurred more often in the material area than in the reactor area.

MS. LUI: Somebody has actually died from those events in the past, too.

DR. LEVENSON: But that's a small population at risk. There's not a large population at risk compared to a reactor accident. How about people in medical applications, isn't that a large population? I bet more people have died from misapplications of medical radiation than have from reactors.

DR. RYAN: I get a couple of the

newsletters, and medical misadministrations and gauge issues tend to dominate that arena. So the fact that it's not as individually catastrophic might not mean that the cumulative risk isn't different. I don't want to debate that to some endpoint, but the point is I agree that this chart is qualitative --

DR. LEVENSON: These are a lot, but the others are --

DR. HORNBERGER: As you can see, we all agree.

DR. RYAN: But nonetheless, I think the point here is that effectively communicating about this is probably the collective advice we can agree on that we're giving you, that figuring this out in a better way and to communicate it would be helpful to your effort.

Right, you had a question?

DR. WEINER: I had a very brief question, again, on this table, and I was not condemning it, I just didn't understand it. You have for dominant risk contributors, radiation and chemical. That's true, but a little bit misleading. There are cases where the chemical contribution to risk enormously dominates the radiation contribution. UF6 comes immediately to mind, and I believe that that is an area where your

communications can be very, very helpful, especially to the general public.

The other thing is that if you have the time and the access, I would encourage you to look up William Ruckleshouse's 1982 presentation of risk in EPA standard-setting. He was EPA Administrator at the time, and he basically introduced the concept to risk. And I believe that the way it was communicated -- it was a speech to the public, and I believe that the way it was communicated might give you some insights into risk communication.

CHAIRMAN GARRICK: It was a speech to SRA, as I recall.

DR. WEINER: Yes, that's correct, it was a speech to SRA.

MR. RUBIN: Thank you all very much. I just want to say I appreciate very much the comments the discussion at this table has generated. Lesson learned from this for me is that to try to put something that's very complicated in a simplified table is risky.

CHAIRMAN GARRICK: Chronic problem with the risk sciences. And I think you now have seen why we ask you to save half of the time for discussion.

MS. LUI: Well, we certainly have tried to

do our part.

CHAIRMAN GARRICK: You did. You did.

MS. LUI: Well, I walk away with two messages. We need to do the right thing, and we need to communicate effectively both internally and externally, to a various audience. And we certainly appreciate all of your comments.

MR. BAHADUR: May I ask for a clarification?

CHAIRMAN GARRICK: Yes.

MR. BAHADUR: On your Slide 9, you talk about the schedule, and you talking about coming to the Joint Committee in Spring of 2004. The NMSS, as I understand, has to deal with Agreement States as well, and in your schedule in which you are saying you are going to develop a risk-informed decisionmaking document in January, would it have gone to the Agreement States before it would come to us, or would you send it to them after?

MS. LUI: Well, in the SECY paper, we have explicitly asked the Commission that we share that particular SECY paper with the Agreement States two weeks after the SECY has gone to the Commission, so that will be our first step in terms of sharing any actual documentation with the Agreement States. In

the past, we have been communicating with them informally, and we are going to participate in the Organization of Agreement States conference in October, and to start a dialogue. We are not envisioning the formal working group as some of the other agency's efforts, but we will be asking Agreement States through OSTP about helping us to review the documents as they are generated internally.

MR. BAHADUR: Okay.

DR. RYAN: Back to you, Mr. Chairman.

CHAIRMAN GARRICK: Thank you very much. We are running a little behind. A couple of us have to exit at about 10:20 to have a meeting. I would hope that, however, if Tina hasn't finished, she would just continue with her --

MR. LARKINS: Yes. I think you'll probably have a number of questions. We've been going back and forth -- she's made several iterations since the last time she presented to the committee, and if there's something you don't like, you can blame it on me.

CHAIRMAN GARRICK: Well, that we will especially do.

DR. RYAN: Tell us something new.

CHAIRMAN GARRICK: Tina, will you

introduce yourself. We know you, of course, but maybe some of the members of the audience do not, and why you are here.

MS. GHOSH: Why am I here? That's an excellent question.

(Slide)

My name is Tina Ghosh. I am a Ph.D. candidate in the Nuclear Engineering Department at MIT. I'm working with Professor Postolakis (phonetic), and for probably the past six years I've been thinking about various model uncertainty issues in performance assessments. And from what I understand, Dr. Larkin at some point told my advisor that the ACNW could maybe use somebody to look at these issues, and so I guess that's why I'm here, and I hope to answer some of those questions. Is that enough of an introduction?

CHAIRMAN GARRICK: That's fine.

MS. GHOSH: And so I presented what I wanted to do for the summer I guess about five weeks ago, and I was really hoping I would have some answers by now, but I knew starting out there was a very low probability of that, and I can confirm that. I don't have any answers yet, but what I am working on is basically an approach to deal with how to assess the

uncertainties in the models that are used in the PAs, and my title is a little bit misleading because I'm not just looking at how to assess the uncertainty, but also what to do about it. And my focus from the start has always been how the PA and the uncertainties fit into the risk-informed integrated decisionmaking framework that the NRC is trying to use across-the-board, and I guess this is a great time to talk about it because we just had a talk about risk-informed initiatives in the NMSS, and the Yucca Mountain program is a very specific example of how risk information can be used because you clearly already have a PA to start working with, you don't have the issue of whether it's worthwhile to have a risk assessment and so on.

(Slide)

Probably most of you -- I'm sorry, Dr. Weiner, I guess you don't have my prospectus from what I had planned to do, but I think it will be obvious as I go along.

So my main questions were basically what would constitute an adequate assessment of model uncertainty in the PAs, how to deal with issues of incompleteness, and how to prioritize research and other important activities given the uncertainty.

(Slide)

So the first thing I wanted to start out saying is that the performance assessment is basically, as it stands now, is really a projection of the repository behavior over time, and it's a little bit different than the focus of risk assessment as it was invented because risk assessment originally, for example, for a reactor, you are looking at just those scenarios that can actually fail your system criterion and whatever you define that to be.

So, I think the first bullet is basically what's happening now, and the second is you might want a different mode for the PA, which is basically doing more detailed sensitivity and uncertainty analyses. And what I'm saying is that these should concentrate just on those scenarios that might actually fail your system criterion, and once you find those scenarios you can identify what sets of assumptions and parameter values actually affect those scenarios, and so ultimately affect your decisions. And then just focus on evaluating the uncertainty in these factors, and this should give you a better way to estimate the safety margins. And I just wanted to point out that in practice, often a simpler version of your overall model is used for the sensitivity and uncertainty

analyses, and I think a very good example of that is basically the NRC's version of the TSPA, which is a much simpler model than the DOE's version for obvious reasons. I mean, they have different purposes for the PA, but theirs is more flexible to do the types of sensitivity analyses quickly whereas the current DOE model is much more cumbersome and it's much harder to look at combined effects of different uncertainty. So that's just something to keep in mind.

(Slide)

So the first question, what constitutes an adequate assessment of model uncertainty, and I just wanted to pick up on a few things. You want to make sure that the uncertainty from the sub-models is propagated to your system-level performance. You want to make sure risk is not diluted, and what I mean by that is that you haven't screened things out that might actually be the risk scenarios.

The effects of incompleteness should be considered. And I think one thing that may be missing in current PAs is that the synergistic effects from the uncertainties of the sub-model level should be uncovered, and this is difficult to do when you do your sensitivity analyses looking at one uncertainty at a time because you are not looking at the combined

effects. And I understand that DOE is planning to do a lot of these combined effects analyses, but I don't know yet what that is going to be.

And you want to be able to estimate your level of conservatism in the model, which is also related to how you think of your safety margin in your repository system. And the treatment for the sub-model should be commensurate with their importance with respect to your top level systems.

(Slide)

And just some examples of model uncertainty -- I'll just go through this quickly because everybody here knows -- you might have alternate models to represent the same physical process, and their effects could be different for your system level performance.

There may only be one model available, but you know that it's weak, and so what do you do about that?

There might be dependencies among the variables, and this is sort of the synergistic effect that I was talking about in the previous slide, or coupled processes that are decoupled in your model, and you might end up underestimating your scenario probabilities because you haven't considered these

dependencies.

And in some cases, we see that there are inconsistencies in terms of how they are sampled in the PA with other variables. So one example, if you use a group of experts and you have elicited probability distribution for a particular sample, they may give you reasons why they think the parameter ranges in a higher range versus a lower range, but the PA doesn't take that into consideration in the sampling process, and you end up sampling a parameter range that is inconsistent with the conditions that you are sampling in another part of the PA, and you end up underestimating the variance in your system-level performance if you do this.

And, last, I think the hardest part is we just don't know what we don't know, and historically we've seen many examples of surprises, and this is the incompleteness in our assessment, and how do we deal with that?

(Slide)

So I guess what I'm proposing and what I want to do in this talk is just basically propose to dealing with how to assess the uncertainty and what to do about it. And I'm saying instead of starting with the tough integrated PA, let's focus in on just those

parts of the PA that give us a possible failure of the decision criteria. So what we are looking for -- and this is based on sort of the risk triplet idea of risk from 1981. All we care about are just those scenarios that actually fail our system criterion.

So somebody might come back and say, well, that's the point of the TSPA. I mean, you have these nice curves and you can sort of assess the probability that different scenarios are going to happen, because the Latin Hypercube sampling and the Monte Carlo Simulation give you a very nice theoretical basis for the probabilities that are associated with different evolutions for the repository. But the problem with that is that this theoretical grounding is lost because you have a potential of -- you have a mixture of potential conservatisms that you are sampling, and some parts are realistic, you have some bounding analyses, and I think most importantly, not all of the important uncertainties are propagated together so that you can see the combined effect. So I don't think we have this as the PA stands right now anyway.

(Slide)

So this is what I propose should be the assessment, uncertainty assessment and the decision process, and it has to be an iterative process

because, obviously, as you go along, you reassess what's happening in the other boxes. You want to identify the important uncertainties and the repository attributes, and based on those you can identify failure scenarios.

Once you have those scenarios, you can assess the probabilities, which is very difficult. Once you have the probabilities, you can prioritize them in terms of which ones are the dominant ones relative to each other, which ones are more likely to happen than others. Once you do that, you may want to reassess which ones are the important uncertainties in the repository attributes.

And after you do all this, what is ultimately important is that the risk information is just one element that feeds into your integrated decisionmaking process. So once you have the dominant scenarios and the relative probabilities, the DOE chooses how to allocate its performance and identifies what they are going to do in the performance confirmation program. And we had a lot of discussion about this in the last couple of days, and also the quality assurance and QC requirements. And I think I'm talking about QA/QC a little differently than what's there in the regulations, and I'll bring that

out a little bit later.

(Slide)

And I think a really nice place to start in terms of the integrated decisionmaking is the Reg Guide 1.174, which is basically -- I know this is for the reactor arena. It's a totally different application, but the high-level concepts are very good. So I think this could be adopted for the Yucca Mountain Program.

So, basically, you have the risk information from PA, and you have a graded approach in terms of how you use the different elements in your integrated decisionmaking, depending on the level of risk and uncertainty that you have uncovered through the PA.

So, our major source of information is the PA, and then how are we going to use the defense-in-depth and safety margins, quality assurance and the performance confirmation in order to deal with the uncertainty in the PA.

And just to start with, as it stands now, there's plenty of defense-in-depth already built into the system because you can say the regulations have some pretty conservative criterion -- for example, the dose criterion some people would say is prescriptive

and conservative. The structure of the repository itself in terms of the design incorporates defense-in-depth because you have the multi-barrier criterion and people use it. So some of that is already there. And I think that's like the structural with defense-in-depth approach at the high level. And what I'd like to deal with is how to use the rational with defense-in-depth approach at the lower level once you have the information from the PAs and so on.

(Slide)

So what I hope to do -- well, what I hope will be my final outcome -- is to demonstrate how this assessment and decision process could be implemented, and to use two examples of the hypothetical dominant scenarios. And here I wanted to use ones that the NMSS has developed. And given those scenarios, assessing the probability bounds for those occurring, and that's a very difficult part.

And then given those scenarios, the associated probabilities, the residual uncertainties, basically how to implement this integrated decisionmaking process in terms of the implications for the performance confirmation and the QA and QC requirements. And I would keep the current DOE assumption of having allocated a large part of the

performance on the waste package. I think in the current case, they want to say about 60 percent of the safety case is based on the waste package durability.

(Slide)

Okay. So, first, how do we find the scenarios of interest? One way is to look at the current performance assessment and pick out any of the runs that might fail your decision criterion. Now, in the PA, as it stands, this almost never happens because the dose criterion is 10,000 years at about 15 mrem. It might be lower for the groundwater protection requirement, but it is always at least an order of magnitude or even lower. But if we look at -- this is just one example of the PA. This was done for the EIS in 2001.

And what they did was in addition to the normal spent fuel and the defense waste, they said what would happen if we include the greater than Class C waste and the SPAR waste, which is special performance assessment required, and this is the run that they got. And you see that the majority of runs, nothing is happening until about 100,000 years. But what's interesting is that you have a couple of runs where you have some funny behavior where you get a dose starting at around 1100 years or something.

Now, given that most of your PA -- you're not getting anything at all, wouldn't it make sense just to figure out what is going on in those particular realizations to make that? I mean, it might be something as simple as a couple of waste package failures. But even if that is the case, you want to know why that's happening. So, that's one way to pick out the scenarios. But as I said, it's been very difficult to do that just because nothing ever fails in a given criteria.

(Slide)

I think another way, I think the NMSS staff has suggested a way through their tracing studies for looking at particular radionuclide release and how it travels through the system. They identified the Np-237 as an important radionuclide because of its contribution to dose. And given that it's important, they looked at just the processes that lead to release of Np-237 and its travel through the repository, and identified important attributes. And I think they started out by partitioning the realizations based on criterion and looking at the overall sensitivity analyses, and looking at which parameters CDFs were sensitive to this partitioning, and then focusing sort of combined sensitivity

analyses on these parameters.

So, what I've done is basically just very crudely constructed some scenarios based on their findings, and I want to talk a little bit about the implications for assessing the probabilities of these scenarios and other integrated decisionmaking activities.

(Slide)

So, one example was what if we have a high influx and flow into the waste package, and we assumed we need 40 waste packages to breach at 1,000 years, a very conservative assumption, but just to start with to give you a scenario where you actually see a dose. And then, in addition, we have very low retardation factor in the Calico Hills nonvitric unit in the unsaturated zone. And if we have that, then it takes about 9,000 years for the Np-237 to get through the unsaturated zone. You've seen all this in Tim McCartin's March presentation, so maybe this looks familiar.

In addition, if we have low diffusion and low retardation factor in the alluvium in the saturated zone, it takes another 700 years to travel to the point where the calculation was done, which was 1 km from the repository, and you end up with about 15

mrem at about 11,000 years. Now, clearly, there is a series of conservative assumptions that were made in order to get this scenario, but at least you have some type of failure scenario. You can go back and look at possible model uncertainties in the PA, as it stands now.

And just another example of a possible scenario is if you have a 110 waste packages that are breached at 1,000 years, and you have high Np-237 possibility with all other factors being the same, you end up with --

CHAIRMAN GARRICK: Tina, the reason that I'm interrupting is that a couple of us have to leave. You weren't here when we announced it, but a couple of us have to leave in a couple of minutes, and you can continue, but I wanted to make a comment or two.

Now, are these conditional? Are these scenarios conditional -- conditional on these initiating conditions, initial conditions?

MS. GHOSH: Yes.

CHAIRMAN GARRICK: So you haven't factored likelihood into --

MS. GHOSH: No, no, no, no, and that's what I'm getting to. First, I'm saying it's so hard to find those failure scenarios in the first place.

This is one way to find them. But then you have to assess the likelihood of these things happening together. As a first cut, the probability is going to be extremely low. Maybe I should just get to that.

(Slide)

So the point is how do you assess the probabilities of these scenarios happening? As a first cut, you can just take the probabilities from the existing PA, and you're going to get an extremely low number, but what we really care about are the uncertainties that might have been left out of the PA that might have had this scenario happening together.

So you can look for the potential common cause or the synergistic effects among the elements in this scenario, to see if you might want to revise the probability assessment.

Another thing is if you do scrutinize the possible failure scenarios to this degree, you might find out that the probabilities are actually highly overestimated in the PA, and it might be also a revelation of extreme conservatism in the PA. But, basically, this is a way to get a better assessment of the probabilities for those things that might matter to the system performance.

CHAIRMAN GARRICK: Now, one thing that's

very different here is that in the reactor side, of course, we think of scenarios in the context of an event tree, and each initial condition, each initiating event will have emanating from it hundreds of scenarios, maybe thousands, maybe millions, and each pathway through the event tree could be considered as a scenario.

And, in general, the approach to scenario structuring is very different between performance assessment modeling and in reactor modeling. But all I'm pointing out is that when you postulate an initial condition like a high flux rate, you are postulating a condition that could go in any one of hundreds or thousands of different directions. And, in principle, therefore, you would have hundreds or thousands of different pathways which could be interpreted as hundreds or thousands of different scenarios for each initial condition, each initiating event. That's one thing that's very different.

The other thing I was very happy that you pointed out, that what you get from Monte Carlo is not the probabilities, you get the process by which you do sampling and by which you do the probability arithmetic. The actual probabilities have to come from somewhere else. But it's important to look at

these differences between the two types of modeling.

MS. GHOSH: Okay.

(Slide)

In terms of incompleteness, there could be scenarios that were willfully screened out, which may not have been appropriate to be screened out, or unimagined ones. And probabilities for various features, events, and processes could be over- or underestimated. And, historically, we see many instances of both of these in past risk analyses.

So the question is, how can we account for this incompleteness, and I think one of the nice things about focusing on just the failure scenarios is that you don't have infinite resources to scrutinize visually everything that you have, and if you find those scenarios where you actually might get a failure, you can focus your resources on looking at the supporting information for those scenarios to help you better quantify the uncertainties and review any incompleteness and, ultimately, get better probability estimates.

(Slide)

So, I wanted to just give an example of how you might further scrutinize the available information. So this is an example from the DOE's

experts' elicitation for their UZ flux model, and this is basically water coming down above the repository which they used to ultimately determine the percolation flux into the repository drift.

So they did an expert elicitation, and they had seven experts, and this is basically the representation of the probability density functions from each of the experts and their aggregate estimate, which is shown on top. And in this case, they just did a simple equal weighting for each expert to get the aggregate pdf's on the top. But the thing is, if you look at their actual study, there's really a wealth of information in the elicitation report that is not captured in the summary of the pdf.

(Slide)

So one thing I did is try to decompose what each of the experts considered when they assessed the various ranges for the percolation flux. At the top we have the seven experts. I know the writing is small, but the numbers aren't important, it is just to show you.

And they discussed in a series of workshops the range of factors that might affect the percolation flux coming into the repository, but not all of the experts thought all of the factors were

equally important, and some just disregarded some factors all together in terms of their effects.

So, here I tried to map which factors were considered by which experts, and just the size of the arrow is a rough idea of the strength of how much that particular expert considered the various factors, so you get a better idea of who considered what. And one of the reasons this is important is that, especially with the performance confirmation activity, you are collecting more and more information. So it might be worthwhile to reassess the distribution for the percolation flux, for example, as you get more information.

(Slide)

And the benefits of decomposition is once you can see who considered what, as you get more information you can update your sort of aggregate probability. One thing to consider would be to change the nature of the information that you sort of keep from the expert elicitation.

So, it's not just which factors were considered by which experts, but you want to know how they interpreted those factors in order to arrive at their estimates so that as new information comes in you may have a better idea about how to update their

relative distribution. You can get an estimate of incompleteness perhaps, based on the disagreement among the experts -- anyway, you get the idea.

(Slide)

So in terms of the incompleteness in the collective state of knowledge for a particular issue, you can look at the level of disagreement among the experts. You can look at historical data on how the relevant expert community performed in terms of affecting issues in a particular subject area. And you can also use performance data on the experts themselves, if it is available. And this is a little bit controversial, but it is an interesting idea.

And in terms of confidence studies for those areas where you still have a lot of incompleteness, this is where your other elements come in. You have your performance confirmation activities. You have model validation activities. And the NRC has some guidance on how to do this in terms of distinguishing between different models and so on. And you have your natural analogs and experiments you might not have considered as relevant to your assessment in the first place, and an example of this is the recent fuel cask experiments that were presented at the last committee meeting, which were

not done for Yucca Mountain but which may end up being useful for the Yucca Mountain project.

(Slide)

So I just want to end with an example of maybe what I'd like to do in terms of the decisions that one could make in order to deal with the uncertainties in the assessment.

So, once you have those, the scenarios and the associated probabilities and uncertainties, what you want is only for those that are actually important, you want to come up with some compensation activities so that you feel comfortable with it.

So, just as an example, in the 2001 TSPA, they assume that 20 percent chance of one early failure in the waste package; 3 percent of two early failures; and probability goes to almost zero when you go above two early failures, and this is, from what I understand, I think it's more than 10,000 packages. But the thing is, what do you need to do in order to be confident that your waste package really is going to last that long.

And the other thing is you want to see that even if you are wrong about the number of waste packages, maybe you still don't fail your decision criteria, so it might not be important that the

assumption is that there's almost zero chance of more than two failings. And so you have to consider your entire scenario in order to be able to assess particular aspects of the safety case, and once you find that, maybe you find that actually what you really care about is to make sure that it's not more than 20 that fail in your repository. And then when you're manufacturing the waste packages, you have to have adequate sort of quality control requirements to make sure that you can prove that you're not going to have more than 20 failures. For example, like welding, I guess, is historically a touchy issue. Can you show that your welds are going to be durable enough to have less than 10 waste package failures over 50,000 years or something.

And, of course, with all of this, you might still have limitations in terms of the uncertainty on what you can show, and you can have your ongoing performance confirmation activities in order to increase your confidence about the technical basis for the assumptions that are necessary.

So that's just an example. I haven't finished going through this yet, but I plan to do so in the next few weeks. I mean, I guess maybe my end message is basically there should really be a graded

approach. First, it's hard to identify those things that are important, but once you have identified those important things, you want different levels of confidence based on the uncertainty and the scenarios that you've uncovered. And I guess that's about it.

(Slide)

Well, we don't have to talk about this. This is just an example of what I think that the defense-in-depth that's already there now, and how the NMSS is using risk information combined with defense-in-depth in their prioritization activities, but I don't want to talk about that today.

(Slide)

I just want to thank all the people who really helped me. It's been great being here and, well, just thank you.

(Slide)

At the end, the last page I have a number of selected references. The things that I numbered in the presentation match the numbers of the references. I also threw in some of the other key references that I've looked at.

DR. HORNBERGER: Thanks very much, Tina. We have time for some questions or comments. Ruth?

DR. WEINER: The first comment I'd make is

that maybe you can reprint your reference list in a type font that I can read with my glasses because I sure can't do it -- I can barely read it up there.

MS. GHOSH: I'm sorry. I'll put it on more than one page so it's bigger.

DR. WEINER: Thank you very much. My comment is, as you know, Latin Hypercube sampling ensures that you're going to sample the tails of the distribution. Could you put up that slide of the PA results -- it was an early slide.

(Slide)

Okay. Yes, that one. So the reason for looking at the mean and the 95th percentile and so on is precisely because you use Latin Hypercube sampling, and what you have done in picking your scenario is to take a scenario from the tail, and this is done in all of the arguments about Yucca Mountain, but is there an implicit suggestion in what you are saying, that we shouldn't make the tail so long that perhaps these very extreme scenarios should not be part of the PA at all?

MS. GHOSH: I think what I was trying to bring out is that I think people are uncomfortable with maybe the quality of the PA in terms of representing the whole picture right now. So one of

the things we might care about is -- of course, I picked out a tail, and if you believe this picture, that tail has an extremely low probability of occurring, but the point is do you believe that that is the accurate probability given that you have all of these uncertainties in the performance assessment that you may not have considered the synergistic effects among the models or parameters that you've screened out, and so on. So that is sort of the motivation behind this, because I think, as it stands now, if we believe the TSPA, there's nothing to do, just let everything go as it is, but the thing is people are uncomfortable with whether we've accurately portrayed the probability of that tail scenario happening.

DR. HORNBERGER: Milt?

DR. LEVENSON: Can you put up Slide 5?

(Slide)

If I believe what you are telling me, that 300 realizations means that each one has 1 in 300 probability of occurring, I can determine absolutely what is going to occur by only doing one realization because that will have a probability of 1.

MS. GHOSH: I'm sorry. Obviously, I don't believe that. And the more realizations you do, the more comfortable you can feel, but isn't that -- this

is an argument I've seen -- you know, when people talk about the sampling process, that's how they represent it. So there is a second issue, which is you have this guesstimate of the probability and then how much confidence you place on it because, really, there's the bounds that you have to place on these probability estimates. And the more realizations you do, maybe you can be more comfortable about the balance. But I take your point.

DR. LEVENSON: Okay. The next slide, Slide 6.

(Slide)

From my basic hang-up, I have to ask, how -- I get uneasy when people rank dominant scenarios based on probability only, and haven't included consideration of consequences.

MS. GHOSH: Right. So I guess that's why I brought up the point of the desideratum -- I mean, what do you actually care about. And I guess the typical approach has been to pick some threshold consequence and look at just that. But one might want a more graded approach. It's just that in the regulations right now, the criterion is the 15 mrem at 10,000 years, so you might want to construct your whole case around that.

DR. HORNBERGER: Ruth, did you have a follow-up?

DR. WEINER: If you go back to the 1-300 that -- the previous slide, Slide 5.

(Slide)

I was just going to say that in making this presentation, a better way to -- perhaps improved way to look at that question because this statement -- Milt is absolutely correct -- when you have only one realization, then it is completely random what your scenario is going to be. If you have 4 realizations, then you've stratified. And if you have the same number of realizations as your stratification, then it's random within those strata. But the more you take, the more likely you are to sample over the entire curve, and I think that's the point, the 300 realizations as compared to, say, 100 realizations gives you a better sampling of everything that you have considered. That's one point I wanted to make.

And the question -- if you go to the next slide --

(Slide)

When you were making your presentation, I was mentally filling in, and when you said dominant, in my mind I included consequence along with

probability. I think that should be explicit. And I commend you for walking through each scenario in a PA. That is extremely instructive, if you look at where each parameter was -- the way in which each parameter was sampled.

You also might look at something else, which is there are a certain number of parameters that -- the parameters have, as you know, different distributions, they are not all Galcean (phonetic) or whatever, and there are a certain number of parameters that are constant values, like the half-life of Np-237, that's a constant. So you might look at where the fixed value or a known value dominates the scenario, and where some kind of distribution determined by expert elicitation dominates a value.

DR. HORNBERGER: Tina, in listening to your presentation today, it strikes me that -- let's see if this is a correct interpretation -- that to a certain extent what you are aiming at is identifying the potential weak spots of a performance assessment almost independent of the low estimated probability of that sequence of events because, after all, probing the weak parts of a case may be a useful way to look at things, such as the example you gave, how many waste packages would have to fail to reach this

extreme scenario, and then what kind of quality assurance/quality control program do you have to have in place to make sure that your welds will meet that criterion. Is that a fair assessment?

MS. GHOSH: Yes, that's a fair assessment. I mean, that's exactly the point, you want to find the weak spots because, as I said, you don't care about all the ways that your repository is wonderful and everything works -- I mean, that's great -- but what are the things that could defeat the system. And once you find that, you have to get an idea about at least the relative likelihood of those things happening.

DR. HORNBERGER: You had made a comment somewhere in your presentation -- actually, on Slide 7 -- about bringing in defense-in-depth. So that was your slide where you said this was from a reactor arena, and I've had some, let's say, interesting conversations with George Apothtolokis (phonetic) on how defense-in-depth, as used in reactors, may or may not carry over to repositories. Can you amplify a little bit on your views on what you mean here? You go through your procedure of identifying the weak spots. How are you going to contribute to decisions on defense-in-depth?

(Slide)

MS. GHOSH: Okay. You know the two views of the defense-in-depth, one is like what's embodied in the structure, the structuralist approach where you look at what's already embodied in the structure of the regulations and the structure of your design and so on. I think that structural part is already there because the regulatory requirements -- I mean, they are not all risk-based. You have the multi-barrier requirements. You have the performance conservation requirement and so on, so a very high level. That's one defense-in-depth strategy.

I think what I was concentrating on is how to use it at the low level -- how to use a rational approach. I think what I'm looking at is how to employ the rationalist approach to defense-in-depth at the low level, which is basically you have the information from the PA and the uncertainties and hopefully important. And what are the things that you can do in order to build confidence that those uncertainties are as low as they are, and so on. So, I hope that makes sense.

Now, the thing is, obviously, the repository system is very different than a reactor. The multi-barrier thing, for example, with reactors, at least they assume some independence of some of the

barriers. You don't have that much in the repository system just because there area lot of coupled processes and one thing leads to another. So the structural multi-barrier defense-in-depth means something different for the repository system than the reactor. I don't think I'll be dealing that, I guess, so much in what I'm trying to do.

What I'm trying to do is to -- I think all the activities that you do to build confidence in your PA results, and whatever decisions you've made, sort of fall into the defense-in-depth in terms of whatever you do to convince a rational person that you have -- that you are comfortable with your decision. Does that make sense? I don't know if I answered your question.

DR. HORNBERGER: Yes, more or less. Jack Sorenson still comes in once in a while, doesn't he? You should have a chat with Jack.

We have some experts in the audience, and I'll invite them, if they have any questions or comments?

MR. McCARTIN: Tim McCartin, NRC staff. I just wanted to offer for the committee, we appreciate the opportunity to interact with Tina on this, and it's a two-way street, and it's always good

to get new ideas into the program. She went over it real quick, but her Slide 20, which you don't necessarily have to look at it now, but in terms of -- as you know, we are constantly trying to find better ways to explain and communicate risk. And on Slide 20, she came up with this, and I've talked a little bit with her, but as an example there, if you look at the bottom box on corrosion where there's arrows going both to the waste packages affected and cumulative release, we've talked about the synergistic effect and the kinds of things that affect multiple things. Graphically, this is a nice way to communicate. So right there is an idea that I think when we go forward with our -- as we update our risk baseline report, here's a way that -- you'll probably see it again in that report -- and there is at least one example I'll give you of a way that's a useful way to present the information. So we know -- Tina will be gone by the next time you guys meet, but I think NMSS is happy with the opportunity to help out on this effort.

DR. HORNBERGER: I'm very glad to hear that. Any other -- Dick?

MR. CODELL: Dick Codell, NRC staff. I did have one question. Looking at the worst scenarios bothers me a little bit because the rule is based on

risk, and I think maybe Dr. Weiner touched on this, too, but I'd be more concerned with how the extremes of the realizations affect the mean, which is really basis of the risk and not the extremes themselves.

MS. GHOSH: Okay. I guess my path on this is that we want to be able to reassess the probabilities of those extreme events happening. So in the end, I guess you end up doing the same thing because what I didn't show is, ultimately, after you scrutinize sort of the tail scenarios, you want to feed back to your overall integrated PA, so you should be able to see the effect in your mean dose once you do that. I don't know if that's a satisfactory answer.

MR. CODELL: That's a good answer.

MS. GHOSH: But the motivation of this is basically let's make sure we got those probabilities right for the tail scenarios because we don't have infinite resources to scrutinize everything.

DR. HORNBERGER: Questions from staff? Neil?

MR. COLEMAN: I just wanted to mention that I saw a really good point all through your talk, but one about metals fabrication which came up in the performance confirmation meeting, about you asked the

question is it possible to actually manufacture at the extremely low failure rates that are being claimed, a key point and one that the committee has expressed interest in following.

I just wanted to mention one other thing. I'd be interested in any suggestions you might have about how to systematically root out the synergistic effects that you were talking about, anything that would be helpful?

DR. HORNBERGER: That's a challenge, and it's now on the record. Other questions or comments? Sher?

MR. BAHADUR: George, I just wanted to place on record the fact that Tina came here as a summer intern. She had shown great insights into the issues that we are dealing with in the waste, and her contribution has been very valuable. This is just her progress report. By the time she completes her work, her term will be expiring at NRC. But in your next meeting, which is perhaps in September, we would invite Tina to come here and present her final results on this particular activity that she is doing. thank you.

DR. HORNBERGER: That's great, and we'll look forward to that. And I will also express for the

whole ACNW, the committee, our pleasure in having had you to work here with us. We've all enjoyed it.

MS. GHOSH: Thank you so much. I've really enjoyed it, too. It's like the first time I've actually had a full committee of advisors.

DR. HORNBERGER: Well, this isn't MIT.

MS. GHOSH: It's been a pleasure.

DR. LEVENSON: Tina, I want to ask you a question that's completely outside of the study, but you may be in a unique position. There recently has been some concern about expert solicitation, and one viewpoint saying that what you should do is get from the experts their knowledge and information and not necessarily the final decision, as many people are expert in a field, but they don't necessarily know how to translate it into, say, a probability.

Since you are unfolding or taking apart the pieces of the expert solicitation, do you have any comment on the approach to just letting an expert give you his answer, as opposed to his being an information source?

MS. GHOSH: I think that's an excellent point, and probably an area of major study.

DR. LEVENSON: But I just wanted your opinion from what little unfolding you've done.

MS. GHOSH: Sure, absolutely. I've looked at a lot of different expert elicitation techniques as well as how you summarize the information and so on and, as you know, there's a whole body of literature on how to do it right and what you get and what it means, and so on. That was one of my points of showing the decomposition of the expert solicitation because I think you're absolutely right, you don't just want the final number that you're going to plug into the PA, you want to know why they think a particular range of maybe which model they think are applicable. There's a lot of aleatory uncertainty about what's actually in the geologic formation, so you want their sort of ideas about what's going on down there, and how it affects things. And so you may choose to elicit the information at a different level and compile it to the end number. Of course, you still want to go back and make sure that once you've done that, they agree with what you've done. But, yes, I think it's a really interesting point, especially with the Bayesian framework. As you do collect more information, you want to be able to take the elicitation and update the distributions and, if all you have is the distribution, you can't do that.

DR. LEVENSON: I want to thank you for

having undertaken to take that apart because I think that's a very valuable insight.

DR. HORNBERGER: Mike, one last quick question.

MR. LEE: Tina and I had a conversation previously about the staff position that was written a number of years ago about the use of expert judgment, and one of the things that the staff noted on the strengths of any particular elicitation was the ability to document the assumptions that went into a particular issue that was being addressed. So if you're interested in particular distribution or range of values or things like that, the more you can do up front in terms of free elicitation training to tell the particular expert that you want to understand why he came up with the distribution that he came up with is valuable.

DR. HORNBERGER: Okay. I believe that we will not need the Recorder any further, so this will end the recorded part of the session. We are now going to take at least -- at least -- a 20-minute break and, in fact, I'll say 10 past 11:00.

(Whereupon, at 10:45 a.m., the recorded portion of the meeting was concluded.)

CERTIFICATE

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

Name of Proceeding: Advisory Committee on Nuclear Waste 144th Meeting

Docket Number: n/a

Location: Rockville, MD

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

Phyllis Young
Official Reporter
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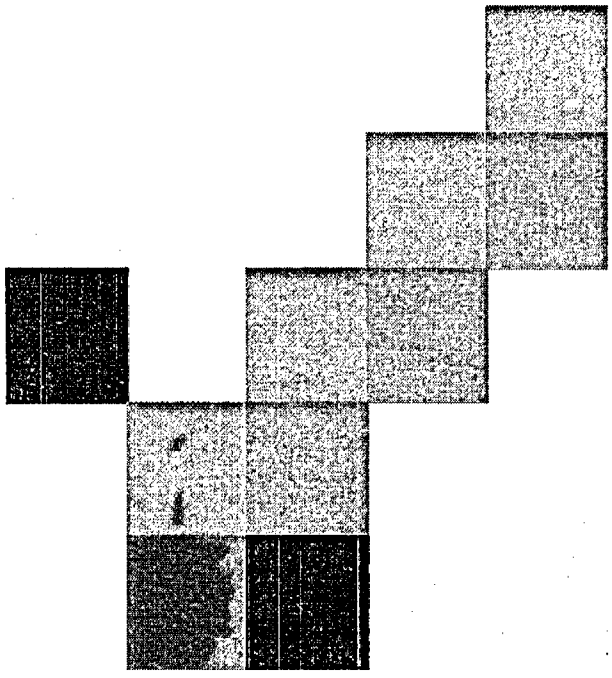

Risk-Informed Regulation for NMSS: Status Report and Plans for Future Work

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July 31, 2003

Purpose Of Briefing

- To provide the status and path forward for risk-informing the materials and waste arenas
  - Status of NMSS risk-informing initiatives
  - Value of risk-informing NMSS
  - Plan for future work
- To request the Committee's view of our approach

Risk-Informed Decision-Making Process

- Identify regulatory issue
- Apply screening considerations
- Evaluate available risk information
- Consider risk information, risk guidelines, other factors, and uncertainty to make a risk-informed decision

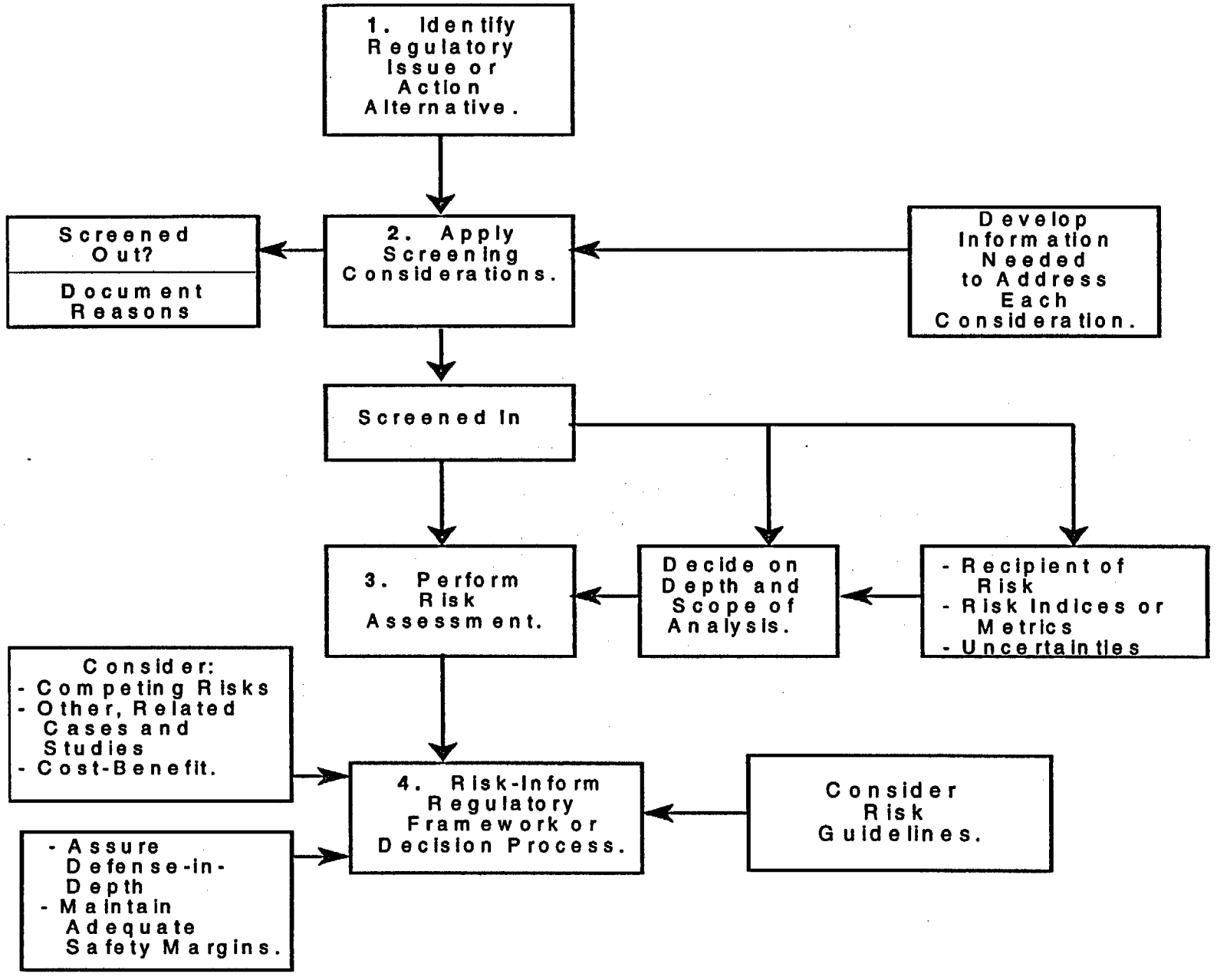


Figure 1. Risk-informed decision-making process.

Successful Uses of Risk-Informing Approach

- Integrated Safety Analysis reviews
- Byproduct materials inspection
- High-level waste
- Decommissioning
- Spent fuel transportation and storage

Ongoing and Planned Risk-Informing Efforts

- Risk-inform standard review plan for certification of casks for the dry storage of spent fuel
- Fuel cycle oversight program
- Control of sources
- Refine licensing of devices containing byproduct material
- Efficiency and Effectiveness Initiative

Guidance Development

- Screening Considerations guidance document
- Risk Assessment guidance document
- Risk Guidelines
- Risk-Informed Decision-making guidance document
  - Pilot studies to test guidance

Benefits of a Risk-Informed Approach

- Improvements in safety focus
- Improvements in efficiency and effectiveness
- Reduction of unnecessary regulatory burden
- Improvements in communication
- Greater transparency
- Greater consistency and coherence

Plans for Future Work

- Identify NMSS regulatory activities amenable to risk-informed approach
- Develop necessary risk metrics, methods, data, guidelines, and guidance documents
- Assess implications for the public, NRC staff, licensees, and Agreement States
- Determine priority, plan, and schedule for implementation
- Conduct staff training

Proposed Schedule

- January 2004, issue RIDM guidance for internal comment
- Spring 2004, brief ACRS/ACNW joint subcommittee
- Spring 2004, provide 2nd paper to Commission to detail our technical progress, policy issues, recommendations, and options
- Hold public workshops after receiving Commission direction

Summary and Conclusion

- Provided the status and path forward for risk-informing the materials and waste arenas
- Risk-informing has benefited NMSS on a case-by-case basis and more can be realized by developing and implementing a systematic and transparent process
- Will engage the Committee/Subcommittee as we go forward
- Request a letter from Committee to Commission

Back Up - Issues

Currently working on:

- Developing appropriate risk guidelines and applications
  - identification of population at risk
  - considerations of safeguards and security issues
  - consideration of consistency and coherence of risk-informed approaches in the materials and waste and reactor arenas
- Implications for staff, licensees, applicants and Agreement States from the use of risk guidelines

Back Up

Comparison of Reactor and Materials and Waste Arenas

Characteristic	Reactor arena	Materials and waste arenas
Event frequency	Low	Low to high
Accident experience	Few actual events	None to significant number of actual events
Potential consequences	High	Low to high
Population at risk	Large	Small to large
Area impacted	Large (1 to 10 mile radius)	Small to large
Radioactive material (source term)	Large	Small to large
Radioactive material (location)	Fixed	Fixed to moving (i.e., transportation)
Dominant risk to:	Public	Workers
Dominant risk contributors	Radiation	Radiation & chemical
PRA available	Available	Some to limited availability
Number of facilities	100+	Few to 1,000s
Size of companies	Large	Small to large

Screening Considerations

- Benefit Questions:
  - Could a risk-informed approach:
    - Resolve a question with respect to maintaining safety?
    - Improve the effectiveness or efficiency of the NRC regulatory process?
    - Reduce unnecessary regulatory burden?
    - Help to communicate a regulatory decision?
- Feasibility Questions:
  - Do information (data sources) and/or analytical models exist, or could they be reasonably developed?
  - Can startup and implementation be realized at a reasonable cost to NRC, applicant or licensee, and or the public and provide a net benefit?
  - Do other factors exist which would limit the utility of implementing a risk-informed approach?

Evaluating Model Uncertainty in Performance Assessments

7/31/03

Tina Ghosh
ACNW Summer Intern
M.I.T. Nuclear Engineering Department

Purpose of PAs – Risk-Inform Decisions in YMP

Two modes for PAs:

- Create most realistic integrated TSPA – project repository evolution
- Risk assessment targeted to demonstrate decision sensitivity; Sensitivity/Uncertainty Analyses (SA/UA)
  - Should concentrate on scenarios that could defeat the repository system, and their associated probabilities
  - Identify what sets of assumptions and parameters affect decision; these are the important model issues
  - Evaluate uncertainty in these factors
  - Can estimate safety margins
  - In practice, SA/UA often uses a simpler version of PA model[1]

What Constitutes an "Adequate" Assessment of Model Uncertainty?

From uncertainty at the level of sub-models:

- Uncertainty is propagated to system-level performance, the top desideratum
- Risk is not diluted
- Effects of incompleteness are considered
- Synergistic effects among sub-models are uncovered
- Level of conservatism and "safety margins" can be estimated
- Treatment for a given sub-model (or set of sub-models) is commensurate with importance

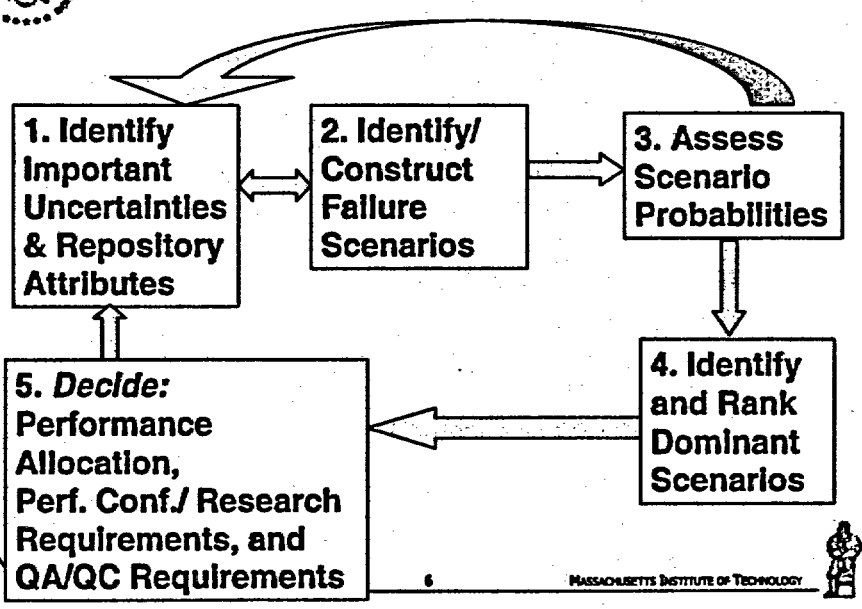
Examples of Model Uncertainty

- Alternate models available to represent a physical process
- One model is available, but it is known to be weak
- Dependencies among variables and/or coupling between processes not considered or omitted, hence underestimating scenario probabilities
- Inconsistencies – e.g., use of parameter sample ranges that don't fit with the conditions in mind when experts provided distributions; can underestimate system-level variance
- We don't know what we don't know

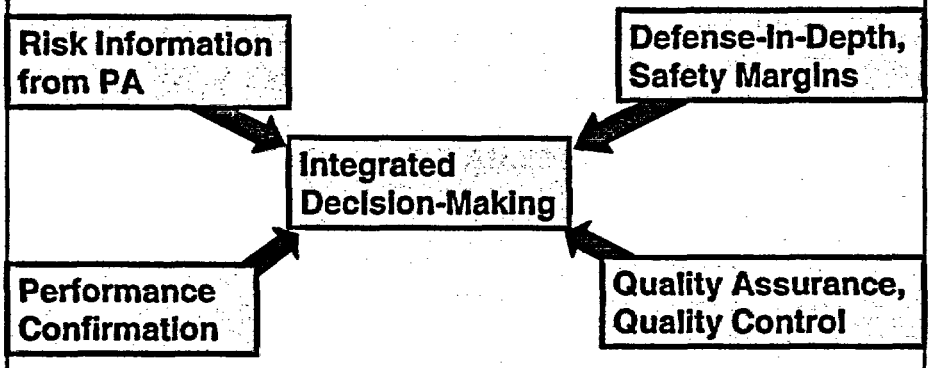
Focus on Failure Scenarios (Risk^2)

- What we care about are those scenarios that can fail the system performance criteria
- All the different ways that the system works is not important, EXCEPT to help establish probabilities associated with different failure scenarios
  - ➢ LHS/MC simulation provides theoretical basis for establishing these probabilities – i.e., 300 realizations means each one has 1/300 probability of occurring
  - ➢ But this theoretical grounding is lost anyway when mixture of (potential) conservatism and realism is employed and all important uncertainties are not propagated

Assessment/Decision Process



Risk-Informed Integrated Decision-Making Framework (adapted from RG 1.174[3])



My Anticipated Final Product

- Demonstrate of how this assessment/decision process could be implemented
- Use two example scenarios (the TPA ones below tracing Np-237) as the hypothetical dominant scenarios
- Assess probability bounds, using TPA-based SA and DOE information base
- Given dominant scenarios, associated probabilities, residual uncertainties, and performance allocation, formulate hypothetical strategy/requirements for license application and performance confirmation
  - ➢ Requirements for performance confirmation research activities, and QA/QC
  - ➢ Assume the DOE retains current performance allocation – i.e., large emphasis (~60%) placed on WP durability

Example of DOE Realizations of Interest[4]

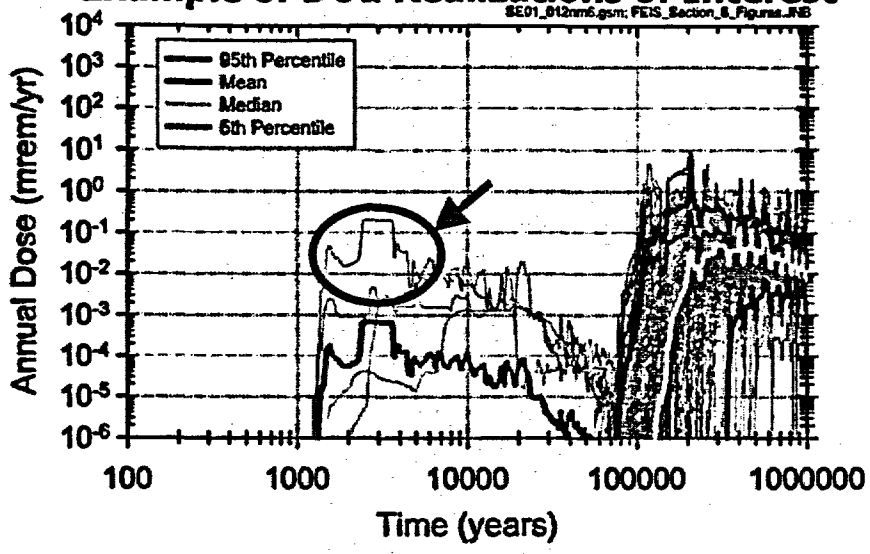
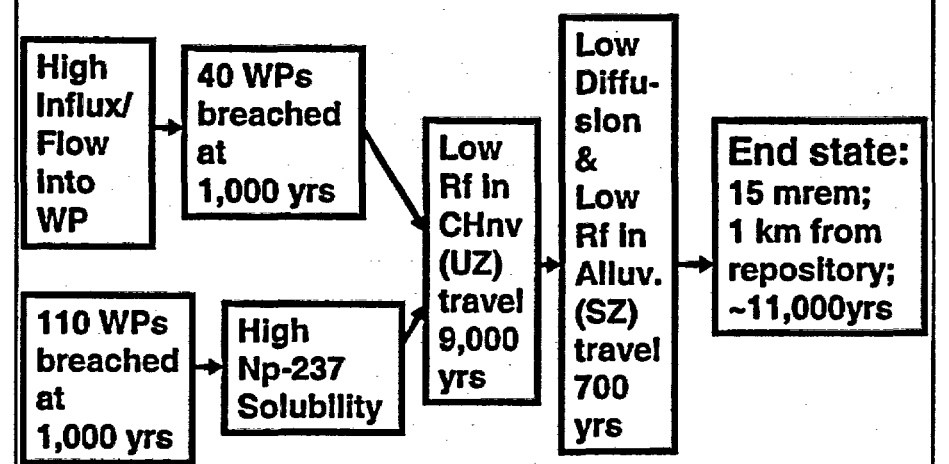


Figure 6-8 Annual Dose versus Time for 300 Probabilistic Simulations of the Module 2 Expanded Inventory for the HTOM at the RMEI Location Downgradient from a Repository. The Figure Displays the Results for Each Simulation and the 5th and 95th Percentiles, and the Mean and Median of these Simulations

2. Constructing Failure Scenarios

- NMSS staff traced radionuclide release and transport through system[5]
  - ➢ Np-237 is an important radionuclide because of its contribution to dose (long half-life)
- Important attributes (sensitivities) identified, e.g., by partitioning realizations based on decision criterion[6]; then focused SA (Step 1)
- Construction of scenarios based on these preliminary studies (Step 2)
- Implications for 3. assessing probabilities, 4. ranking scenarios, 5. research priorities?

Example of Scenarios



1. Important Sensitivities

- Tracing studies[5] revealed following important sensitivities/uncertainties for Np-237:
  - Solubility limit
  - Water flow into WP
  - Waste form degradation rate
  - Sorption in Calico Hills vitric unit
  - Retardation (variation) in SZ
- In terms of ranking scenarios, e.g., we see that high solubility requires 110 breached WPs whereas high flow into WP requires 40 breached WPs, other factors being equal

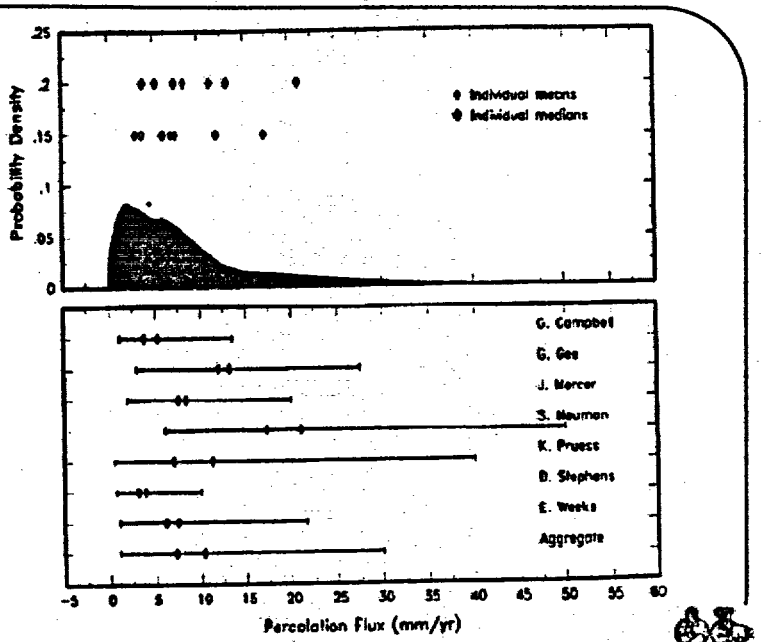
3. Assessing Probabilities

- Analysis focused on just failure scenarios
- What set of assumptions and parameter values led to these realizations of interest?
- As first-order estimate, can use existing TSPA modules to assess probability of given event/process – e.g., Pr(40 WPs failed at 1,000 years)
- Are there potential common-cause or synergistic effects for the important elements in this set? e.g., high infiltration also increases WP degradation/failure rate?
- Are there conceptual uncertainties in related sub-models that could affect the probability of this scenario?
- Considering these factors, should the probability (or probability bounds) for this scenario be revised?
- How should formal expert judgment elicitation be used to answer these questions and then 4. rank the scenarios?

Incompleteness

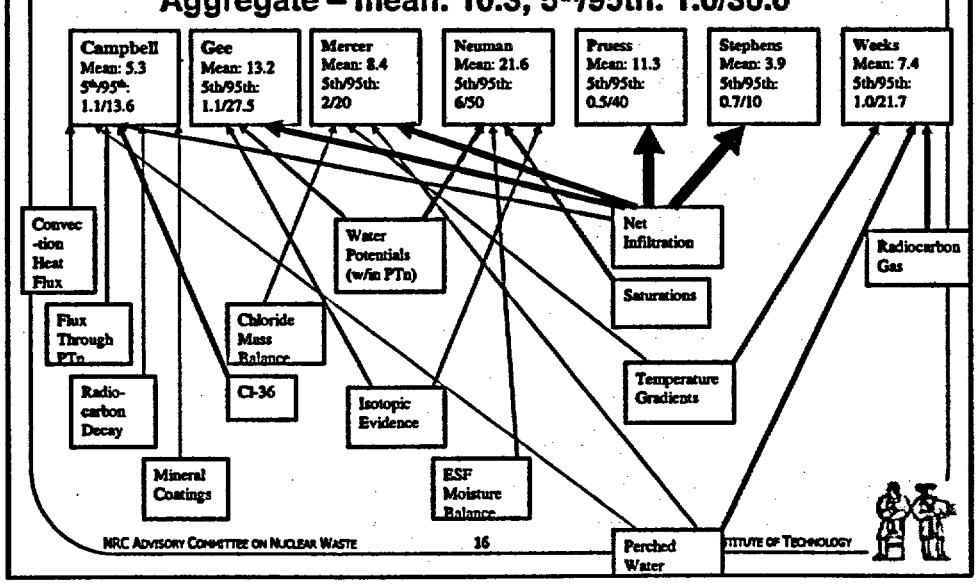
- Types of incompleteness:
  - ➢Scenarios willfully (but improperly) screened out, or unimagined
  - ➢Probabilities under- or over-estimated because of unknown FEPs
- Historically, many instances of both of these
- How can we account for incompleteness?
- Focusing study on failure scenarios of interest may improve use of available information, help reveal common-cause and synergistic effects, and produce better estimates of associated probabilities

UZFM Experts' pdf's for Percolation Flux (mm/yr)[7]



Decomposition of UZFM Experts' Estimation of Percolation Flux (mm/yr)

Aggregate – mean: 10.3; 5th/95th: 1.0/30.0



Benefits of Decomposition

- Identify the underlying factors[8] supporting each expert's (or model's) analysis (results)
- Understand how different experts interpreted the same data, in terms of its relevance to estimating the quantity of interest
- Can estimate incompleteness
- Understand how new information, and uncertainty in information sources, affect individual and aggregate estimates
- Assist formulating a Bayesian framework (e.g., GLUE[9]) for on-going re-assessment of probabilities

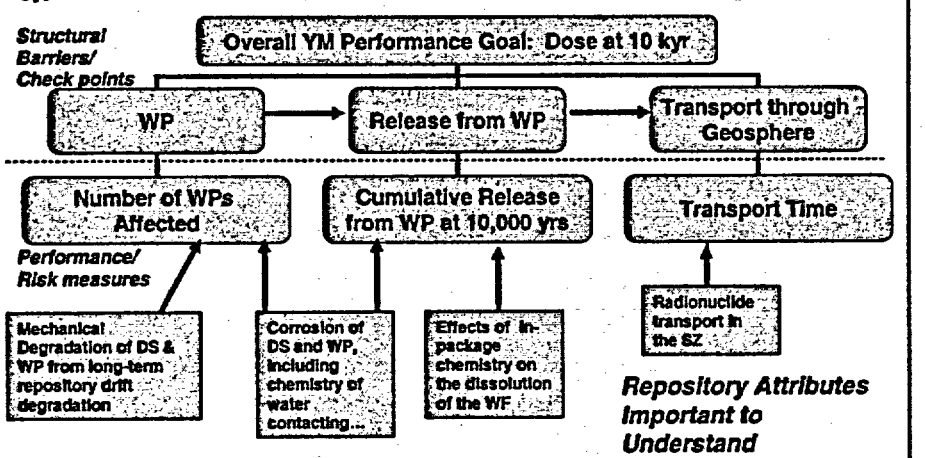
Dealing with Incompleteness

- Ways of estimating incompleteness in collective state of knowledge, based on:
  - Level of disagreement among experts
  - Historical data on expert community's performance in subject matter area
  - Performance data on experts[10] (e.g., through seed variables), if available
- Confidence studies and estimating completeness in the TSPA
  - Performance confirmation activities to build confidence
  - Model "validation"[11]
  - Natural analogs, experiments outside YMP – e.g., recent fuel cask experiments

5. Integrated Decisions (example)

- Compensation activities for the different scenarios depends on how close they come to desideratum
- 2001 TSPA[4] assumes 20% chance of 1 early WP failure; 3% chance of 2 early failures; 0.2% chance of 3 early failures; almost 0% chance >3 early failures, out of >10,000 packages
- What are the bounds on acceptable number of early failures (i.e., would still meet regulatory requirement)?
  - ➢ Entire scenario must be considered to assess this
- What would be the operational testing and QC requirements (manufacturing) to ensure this level of WP integrity, particularly in weld areas? Is it attainable?
- What on-going research activities (PCP) are necessary to ensure technical basis of assumptions?

Integration of Defense-in-Depth and Risk Information in Prioritization of KTI Agreements



Cross-cutting meta-issue: Development of *confidence in the model abstractions* used in the PA

Disruptive events that have the potential to affect all barriers: Volcanic activity

Acknowledgements

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- Tim McCartin and Chris Grossman (NMSS)
- George Apostolakis (MIT), thesis supervisor

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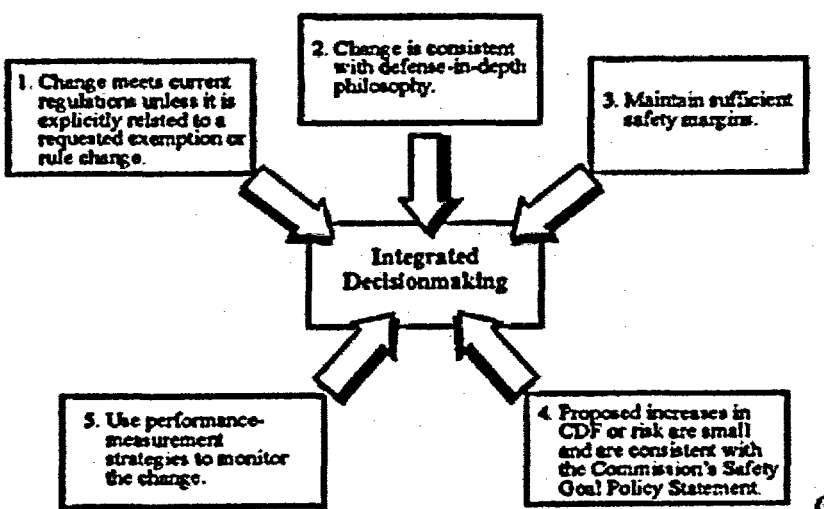
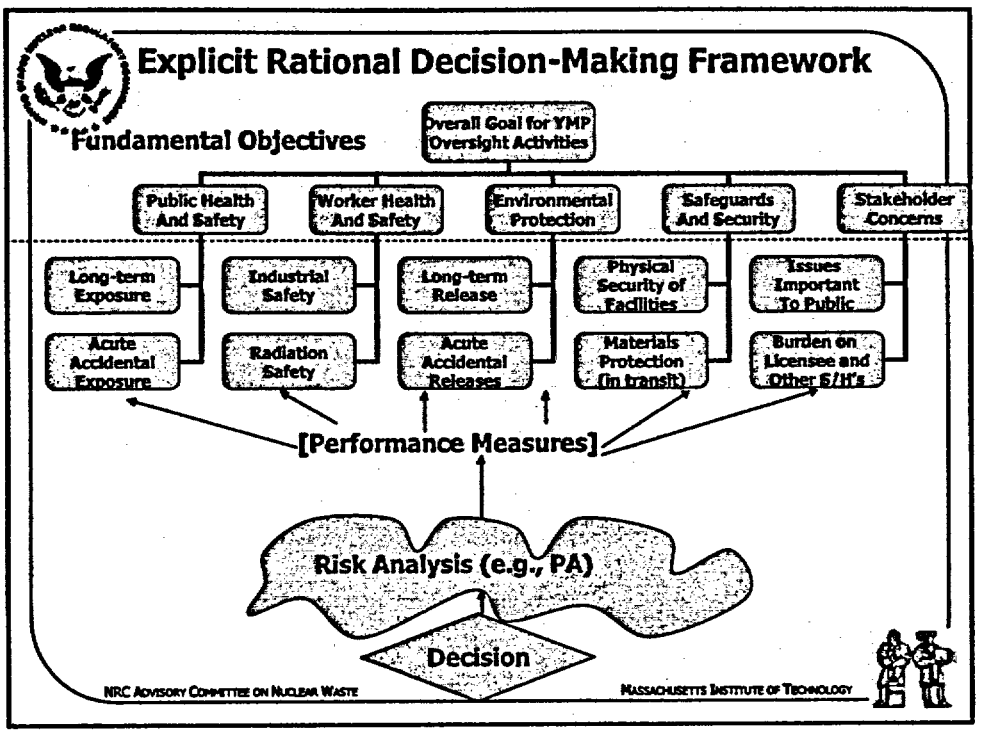
Back-up Slides

NRC's Principles of Risk-Informed Integrated Decision-Making (from RG 1.174[3])




Explicit Rational Decision-Making Framework
Fundamental Objectives
Overall Goal for YMP Oversight Activities
Public Health And Safety
Worker Health And Safety
Environmental Protection
Safeguards And Security
Stakeholder Concerns
Long-term Exposure
Industrial Safety
Long-term Release
Physical Security of Facilities
Issues Important To Public
Acute Accidental Exposure
Radiation Safety
Acute Accidental Releases
Materials Protection (in transit)
Burden on Licensee and Other S/H's
[Performance Measures]
Risk Analysis (e.g., PA)
Decision
NRC Advisory Committee on Nuclear Waste
Massachusetts Institute of Technology