Attachment 1

Meeting Transcript

Official Transcript of Proceedings

NUCLEAR REGULATORY COMMISSION

Title: Integration of Case Studies in the Use of Risk Information in the Nuclear Materials and Waste Regulatory Process - Public Meeting

Docket Number: (not applicable)

Location: Rockville, Maryland

Date: Thursday, October 25, 2001

Work Order No.: NRC-080 Pages 1-142

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NUCLEAR REGULATORY COMMISSION

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INTEGRATION OF CASE STUDIES IN THE USE OF RISK INFORMATION IN THE NUCLEAR MATERIALS AND WASTE REGULATORY PROCESS - PUBLIC MEETING

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THURSDAY, OCTOBER 25, 2001

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ROCKVILLE, MARYLAND

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The meeting commenced at 9:00 a.m., the Auditorium of 11545 White Flint North, Rockville, Maryland, Dr. Patricia Rathburn, Facilitator.

PANEL:

LAWRENCE KOKAJKO

DR. MARGARET FEDERLINE

MARISSA BAILEY

DENNIS DAMON

RAEANN SHANE

JAMES SMITH

DR. JAMES DANNA

DR. ROBERT BARI

VINOD MUBAYI

DR. PATRICIA RATHBUN, Facilitator

A-G-E-N-D-A

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

(9:10 a.m.)

MR. KOKAJKO: Good morning, and welcome to our meeting this morning on the Integration of our Case Studies. I see some new faces in the audience this morning, and I appreciate your being here today. I also see some of our old attendees, and I thank you for coming back. I would like to welcome you to this meeting and thank you for wanting to participate today.

Before I get to the specifics of today's meeting, let me provide some background of why we are here. The NRC is focused on safety, and we view the use of risk information assessment and management techniques and strategies as tools to help us achieve our goal of maintaining our focus on safety, and being an effective and efficient regulator.

The Risk Task Group is responsible for efforts related to risk informing materials and waste arena activities, and we report directly to the Deputy Director of the Office of Nuclear Material Safety and Safeguards.

As a result of our workshop in April 2000, it was suggested that we consider case studies as a way to determine which activities in the materials and

waste arenas would be both possible and beneficial to risk inform. The case studies were designed to cut across a spectrum of activities within the office.

We planned to do several things. We wanted to test the draft screening criteria that were developed to enable us to determine if a proposal was amenable to risk informing, to tease out any possible safety goals that were imbedded in the regulations or the staff actions, to determine the feasibility of developing broader safety goals, and to gain insights on risk-informing regulatory processes which include the identification of tools, data, methods and guidance that would be needed to support a risk-informed approach.

As the case studies were underway, we held public meetings for each case study area in order to get early stakeholder involvement into the process. At each of these public meetings, we stated we would hold a stakeholder meeting at the conclusion of all the case studies to discuss what we learned and to discuss our future direction. Today is that day.

Our meeting today has three primary objectives. We will summarize in an integrated fashion the results of the case studies as they applied to our case study action plan objectives. We

will make our presentation such that we will tell you our present plans for moving forward with risk information activities in the materials and waste arenas, and the third will be to solicit your comments and recommendations on what we have discussed here today.

Today's meeting will be somewhat different than our past meetings on the case studies. One of the differences which you might have already noticed is the use of posters to summarize the insights we gained during the case study process. Also, as we progress with the meeting, our agenda will be somewhat more fluid than in the past.

The morning session will be primarily devoted to the integration and lessons learned from the case study material, which we will cover in the first two hours of the meeting. This will include focusing on the final screening considerations, including its guidance and application, regulatory process improvements including tools, methods and data, and an introduction to the concept of safety goals and why we think they are important.

Later in the morning and in the afternoon, we will seek your input on these matters, particularly in regard to process improvement aspects and what we

should look at next, and your thoughts on developing safety goals that define what safety may mean in the materials and waste arenas.

At this time, we plan to synthesize all the individual case study reports and perhaps other risk-related information into one consolidated report and send it to the Commission sometime in January.

We had promised that we would put out our draft case study reports on the Website to allow for sufficient time to review before this meeting. However, due to the tragic events of September 11th, many things about how the NRC does business are in a state of change.

There is a renewed sense of caution about what information about our licensees and the products we regulate should be made public. Although the documents and references used for the case studies have been publicly available, we decided to err on the side of caution and not place the synthesized case studies on the NRC Website. The decision was reached in context with overall NRC policy in light of the September 11th tragedy. I apologize if this caused any undue problems.

I do think that we should be able to reach our meeting objectives today without the case study

reports. Furthermore, I hasten to point out that we will not directly discuss sabotage, security or safeguards issues at this meeting. However, I would like to note my personal view that risk assessment and management techniques and strategies can be especially useful in our work post-September 11th, in that risk and vulnerabilities can be identified and assessed so that we can marshal our resources to the most appropriate areas.

As before, I am grateful for Dr. Patricia Rathbun, who will be our Facilitator today and will coordinate our group discussion. In terms of our agenda, Dr. Margaret Federline, Deputy Director of our office, will provide an overview of the management philosophy on risk-informing NMSS regulatory activities. She will be followed by Ms. Marissa Bailey, who will present an overview of the case studies; Ms. Raeann Shane, who will go over the screening considerations in the proposed guidance and use; Dr. Dennis Damon and Dr. Robert Bari will make a presentation on our perspectives on safety goals; who will be then followed by Mr. James Smith, who will speak on process improvements. Finally, Mr. James Danna will tell you where we plan to go from here.

At the conclusion of the presentations,

there will be time for a group discussion and feedback session, and this will be continued after lunch. I expect to conclude this meeting around 4:30 this afternoon. I would also like to point out that we will have subject matter experts from each of the four divisions within NMSS, as well as from Brookhaven National Laboratory, who will support us today, and I thank them for their continuing assistance.

Also as before, let me say that this meeting is open to everyone, including NRC staff, licensees, applicants, Federal, State, tribal and local government organizations, non-government organizations, public citizens groups, manufacturers, users, industry and trade association representatives, and members of the general public. Everyone is invited to provide any thoughtful insights or commentary on this case study as applied to our objectives.

Finally, we will be seeking your feedback on what you thought about this meeting. One way of doing so is a feedback form you can mail into us, or you can provide any comments directly to one of us making a presentation today.

Before we begin with the actual case study presentations, let me introduce Ms. Margaret

Federline. As Deputy Director of the Office of Nuclear Material Safety and Safeguards of the U.S. Nuclear Regulatory Commission, Ms. Federline is responsible for regulatory programs to ensure that users of nuclear materials do so in a manner that protects public safety and the environment, safeguards special nuclear material and appropriately control the management and disposal of radioactive waste. Her broad experience has been recognized internationally, where she currently serves as the Chairman of the OECD, Nuclear Energy Agency, Radioactive Waste Management Committee.

Prior to assuming her current responsibilities in NMSS, she served in increasingly responsible Senior Executive Service positions, including Deputy Director of the Office of Nuclear Regulatory Research, Deputy Director of the Division of Waste Management, and Chief of the Performance Assessment and Hydrology Branch.

Ms. Federline also served as Senior Policy Advisor to Chairman Kenneth M. Carr, and Assistant to the Executive Director for Operations at the NRC. Before joining the Federal Government in 1979, she participated in life science research, including an experiment which flew on the MARS Viking Lander. In

addition, she developed and managed a commercial analytical chemistry and industrial hygiene laboratory. While serving at the National Institute of Standards and Technology, she led the development of a national system for accrediting laboratories. She joined the NRC in 1981, where she focused on development of occupational radiation protection standards.

She has been very supportive of our efforts to date, and I look forward to her continuing involvement and assistance.

DR. FEDERLINE: Thanks, Lawrence, I appreciate that introduction. I always say the only thing worse is having a boss who is really interested in what you are doing, and I have a life-long interest in risk assessment which will probably pick up in some of my remarks today.

We really appreciate you coming today. This is a very important meeting for us. We hope that you will participate actively in the dialogue. The staff that you see here today has put in a tremendous amount of effort, groundbreaking effort, I think, in the materials area, to pull together the case studies, and this is our opportunity to discuss them with you and get some feedback from you. So, I really

encourage you to participate in that dialogue.

As you are aware, this meeting is part of an ongoing process to develop methods for using risk information in NMSS. The objective of this effort is to improve the regulation of materials and waste, emphasizing a focus on safety.

The goal of NRC safety regulation is to prevent unintentional harm to the public, but as we have all seen with the tragic events that surrounded September 11th, it emphasizes that the public is also at risk from intentional harm.

It is the mission of the Agency as well as NMSS to protect the public from both kinds of harm, and in light of the current events the Commission has really taken immediate action both internally and with our licensees to protect the public from terrorist acts involving nuclear materials.

The NRC and its many regulated facilities have been placed in a higher state of alert and readiness, and the Chairman has directed the formation of a task force to re-examine all the assumptions underlying our safeguards and security regulations, and I am chairing that task force. I had hoped to spend the day with you today, but unfortunately I am going to be in and out as a result of some of those

responsibilities.

Now, one of the specific actions taken as a result of the terrorist acts was to remove much of the material, as Lawrence said, from the NRC Website. This was an extremely painful thing for us. The Agency has a history of being a very open agency, sharing all information, but we felt that it was a prudent measure and needed to be done to ensure that all the material on the Website had been reviewed for any items that could be beneficial to terrorists.

Now, this action, as Lawrence said, prevented us from posting some of the information for this meeting, and I regret any inconvenience that it caused you as participants in being able to prepare for this meeting, but you will see that my colleagues here have done an extra special effort to try and make sure that they discuss with you all the aspects of the case studies, to try and make up for some of the information that we couldn't put on the Web.

We are expediting our effort to review the materials that were taken off the Web, and we are trying to put back materials as rapidly as possible, and we are committed to putting back as many materials as possible onto the Website.

Now, risk information can have multiple

uses. Protection against the risks of deliberate harm shares many common elements with protection from accident risks. For example, the robustness of many containers for nuclear materials makes them difficult to damage, whether intentionally or by accident.

We expect that the information and risk insights that come out of this work will not only complement our safety mission, but will also help us in many of the activities that we are performing to make our regulations more effective against terrorist acts as well.

Now, as Lawrence explained, the purpose of the meeting is to continue the process of risk-informing appropriate areas of regulation within NMSS. Now, risk-informed for me means the use of risk information to gain insights, and to improve our regulatory process. And I see this as a win-win for everyone, all the stakeholders and the NRC staff to boot.

Our insights are going to be used to improve the focus of our regulatory efforts, and I am sure on the part of stakeholders there is a concern about whether we are going to throw everything out and start over again. That is certainly not the case.

We intend to use the benefits that we gain

from these risk insights to improve the focus of our programs. That means increasing our own effectiveness and efficiency internally by the information that we learn from these studies, as well as imposing more focused regulatory requirements, lessening burden in areas that are shown to have less significance to safety, and improving our focus to safety in other areas.

The results of this work may identify new vulnerabilities, or they can change the emphasis on ones that we already know about. It could also lead to more robust safety requirements. Such risk-informed reasoning augments traditional safety principles, it doesn't replace the things that we've relied on for so long to ensure the protection of public health and safety, ensuring that there are adequate margins in our regulation, using the best engineering standards, and emphasizing the use of defense in depth in our regulatory process.

Now, the Office of NMSS regulates many diverse areas. The nuclear facilities and devices involved have different risks and really different needs for protection. A number of issues arise in these areas. Risk information will provide varying insights in these different areas and, thus, the

appropriateness of using risk information is expected to vary across NMSS.

I just want to emphasize that one size doesn't fit all, and we are not attempting to make one size fit all. For this reason, the Risk Task Group selected eight very widely different areas in which to conduct case studies in order to gain risk insights on methods for the use of risk information. During this meeting, the Task Group will report to you what has been learned in each of these eight case studies.

Now, the insights from these case studies have resulted in plans for future action, and those we want to get your insights and get your feedback on those plans for further action. Among the future actions could possibly be the development of guidance on risk methods and the application of these methods in various areas across NMSS.

The overall goal, as I emphasized before, is to realize the benefits in improving our efficiency and effectiveness and improving our focus on safety, and reducing regulation in areas that are less significant to safety.

Now, for the remainder of the morning, the Risk Task Group will summarize the case studies. This afternoon, there will be a discussion facilitated by

Dr. Pat Rathbun to obtain feedback from you on these insights and on future plans, and I encourage you to participate actively in this process. This is your opportunity, including the NMSS staff that are in attendance today, to jump in and be part of the discussions and make sure that your feelings are known. In light of the current environment that we live in, we must learn how to be more effective and efficient in our mission.

Now I would like to turn it over to Marissa Bailey, of the NMSS Risk Task Group. Marissa is the Senior Project Manager for the case study project whose results will be presented today.

MS. BAILEY: Thank you, Margaret.

Good morning. My name is Marissa Bailey. I am the Senior Project Manager of the Risk Task Group. Over the last year, the Risk Task Group has been conducting case studies. These case studies are basically retrospective looks at a spectrum of activities in the materials and waste arenas. We started conducting these case studies so we could evaluate what has been done or what could be done in the materials and waste arenas with respect to the use of risk information, and also so that we could begin to establish a framework for using risk-informed

approaches in the materials and waste arenas.

The objectives of these case studies are to test the draft screening criteria and ultimately produce a final version, to determine the feasibility of safety goals and, if possible, to develop a first draft to gain insights on how the use of risk information has improved or could improve our regulatory processes, and to gain insights on the methods, data, guidance and tools needed to implement a risk-informed regulatory approach.

As Margaret mentioned, in our next presentations, we will be presenting to you what we have learned from the case studies. We would like to tell you where we are and where we are going with respect to those four objectives.

(Slide.)

I would like to begin the presentations by giving you an overview of the case studies. In my presentation, I will basically be giving you background information, and also summarizing some of the insights that we have gained from the case studies. The presentations that follow mine will be giving more detailed insights.

(Slide.)

In the last few years, NMSS has been in

the process of developing an approach for using risk information in the nuclear materials and waste arenas. This basically is part of an overall effort within the NRC that stems from the Commission's 1995 PRA Policy Statement to supplement our traditional deterministic regulatory approach with a risk-informed regulatory approach.

Basically, we see risk information as simply a way for us to keep our focus on safety, to improve our regulatory decisionmaking process, to make more effective use of our resources, to reduce unnecessary regulatory burden, and also to help us identify and address shortcomings in our current regulatory system.

The framework for risk-informed regulations in the materials and waste arena is detailed in a March 1999 Commission paper which is known as SECY-99-100. This Commission paper introduced a systematic five-step process for moving toward risk-informed regulations, and those five steps basically are to identify the candidate regulatory applications that are amenable to expanded use of risk assessment information, to make a decision on how to modify the current regulatory approach so that it is more risk-informed, to change the current regulatory

approach, to implement that risk-informed approach, and to develop or adapt existing tools and techniques of risk analysis to the regulation of nuclear materials and waste.

I would like to point out that steps 2 through 5 don't necessarily need to be taken in sequence. These steps could be interchanged or they could occur in parallel. I would also like to point out that at this point in time, we are basically in Step 1, although there are some areas in the materials and waste arenas that are further along in this five-step process but, in general, we are early in the process of identifying regulatory applications that are amenable to risk-informed regulation.

(Slide.)

In a June 1999 Staff Requirements Memorandum, or SRM, the Commission approved the proposed framework in SECY-99-100. In this SRM, the Commission also directed the staff to develop appropriate materials and waste safety goals analogous to reactor safety goals. In that SRM, the Commission also stated that these goals should guide the NRC staff and should define what "safety" means for the materials and waste program. The Commission also stated that in developing these goals, the staff

should include avoidance of property damage, consider whether critical groups can be defined for classes of material and use, and give due consideration to 10 CFR Part 20. So, SECY-99-100 and the associated SRM in the last year and a half have sort of been our guide as to what we've been doing in the Risk Task Group.

(Slide.)

To help us identify those candidate regulatory applications -- again, Step 1 of the five-step process -- we drafted screening criteria. Now, this screening criteria, once finalized, would be a decisionmaking tool. Basically, we are asking ourselves where in the regulation of materials and waste would risk insights provide a value. The intent of the screening criteria is to help us make those decisions in a consistent manner.

(Slide.)

The draft screening criteria basically consists of seven questions that we would ask to determine if an activity could be risk-informed. And I think one of your handouts include the screening criteria. The first four criteria basically ask whether a risk-informed approach would support the Agency's strategic goals of maintaining safety, improving efficiency and effectiveness, reducing

unnecessary regulatory burden, and enhancing public confidence.

A fifth criterion address the availability of quality data and models to support a risk-informed approach. A sixth criterion addresses the cost of implementing a risk-informed approach, and the seventh criterion addresses other precluding factors. Given that the activity passes the first six criteria, is there anything else that would or should prevent us from moving toward a risk-informed approach.

(Slide.)

A case study approach was adopted so that we could test the draft screening criteria, and also begin the process of examining the feasibility of safety goals. As I mentioned before, the case studies would be retrospective looks at the spectrum of activities in the materials and waste arenas and, individually and cumulatively, they should illustrate to us what has been done in the materials and waste arenas, were those activities risk-informed, and to what extent, and what lessons could be learned from them. Also, as I mentioned before, the objective of the case studies is to test the draft screening criteria and produce a final version, examine the feasibility of safety goals, and develop a first

draft, and also gain insights on process improvements and what tools we would need to implement the risk-informed approach.

I would like to point out that the intent of the case studies is not to reopen or reassess previous decisions made by the staff and the Commission.

(Slide.)

How we have conducted the case studies is outlined in a case study plan which we published in October 2000, and that case study plan has been made available in our previous stakeholder meetings.

(Slide.)

The case studies basically involve answering three sets of questions that are designed to meet the four case study objectives. These questions are screening criteria/risk analysis questions, safety goal analysis questions, and then questions that would be asked once we've developed draft safety goals.

(Slide.)

The case studies that were conducted are in the following areas: gas chromatographs, static eliminators, fixed gauges, uranium recovery, site decommissioning of the Trojan Nuclear Plant, transportation of the Trojan Reactor Vessel, dry-cask

storage of TMI-2 fuel debris at the DOE/INEEL facility, and specifically focusing on the seismic exemption for that licensing process, and the Paducah Gaseous Diffusion Plant seismic upgrades.

These activities were chosen because they had elements of risk-informed decisionmaking, or they were perceived to be activities that could benefit from risk-informed decisionmaking. And I hope that during our poster session earlier this morning, you were able to discuss these case studies with our Risk Task Group staff and also with our colleagues from Brookhaven National Laboratory.

What I'd like to do at this point is just summarize for you some of the main insights that we have gained from those case studies, and the presentations that follow mine will be going into more detail with those insights.

(Slide.)

With regard to the screening criteria, we basically found that they encompassed relevant considerations, and that they should be taken as considerations rather than as criteria, so at this point I am going to be referring now to the screening criteria as screening considerations instead. And this is just to basically reflect the fact that those

set of seven questions should be taken as a whole, and that it is one tool for decisionmaking.

We also found that the screening considerations is a useful decisionmaking tool, and the we are at a point now where we are ready to finalize them. However, we did find that the application of these considerations could be subjective and that guidance is needed.

(Slide.)

With regard to safety goals, our case studies indicated that the development of safety goals is feasible for the materials and waste arenas. We also found that a multi-tiered structure similar to the safety goal structure for power reactors would be one possible approach and, if we did take that approach, we would have to develop subsidiary objections for each program area within NMSS. There were also examples in the case studies that showed that decisionmaking could be facilitated if a clear set of safety goals existed.

(Slide.)

With respect to the value of using risk information or process improvements that could be made with risk information, we basically found that in those case studies the application of risk information

helped us to make decisions that were consistent with the Agency's current strategic goals. We also learned that the use of risk information could be useful in helping us identify shortcomings in our regulations or regulatory processes. And as far as tools, methods, data, guidance and information, we found that that's a mixed bag within NMSS, that in some areas tools and methods and guidance are developed to support a risk-informed approach. In some areas, there are tools available, but more would need to be developed, and that in some areas we need to develop some, that there are none available.

That basically concludes my presentation. As I've said before, the next presentations will give you more detailed insights from the case studies, beginning with Raeann Shane, who will be talking to you about the screening considerations. Thank you.

MS. SHANE: Thank you, Marissa. Good morning, everyone. My name is Raeann Shane, and I am a Health Physicist with the Risk Task Group, and I will be speaking this morning on the screening criteria.

(Slide.)

As Marissa just explained, we have been working on case studies in the materials and waste

arenas for the last year. One of the objectives of the case studies was to test a set of draft screening criteria, and to develop a set of final screening criteria with the help of public input.

(Slide.)

The screening criteria, taken as a group, provided a tool to help the NMSS staff decide whether risk-informing, particularly in the regulatory arena, would be possible and beneficial. In order to test the screening criteria, the staff applied them to the subject matter of the case study as if the decision to risk inform the subject were being made at that time. Through this process, the staff was able to determine the effectiveness of the draft criteria, and also to determine where additional guidance or changes might be necessary to the screening criteria.

(Slide.)

From comments received during the past public meetings and from insights gained during the completion of the eight case studies, it was decided that the term "screening criteria" should be replaced with "screening considerations", as Marissa mentioned earlier. This term reflects the idea that these seven factors are one tool in the management decision process to risk inform a particular regulatory

activity. The revised screening considerations are in one of your handouts. And when we were revising the screening considerations to try to achieve a final set, the staff of RTG believed that most of the changes needed were minor wording changes.

The most notable changes are that some of the considerations, such as No. 6, previously had parenthetical guidance statements which are now being incorporated into the screening considerations guidance document. This will enable us to present one consolidated guidance document which will be designed for the staff's use when applying the considerations to their work.

The need for guidance became evident during the process of completing the case studies. Many of the staff and stakeholders felt that the screening criteria were subjective in nature and could be used to produce a pre-determined outcome. The objective of the guidance will be to more fully explain what the staff should be thinking about when answering the seven questions, and we are open to your input today on additional aspects for guidance. We plan to have the guidance document issued concurrently with our final report on the case studies.

(Slide.)

I will now go over the revised screening considerations and what we were thinking about for rough ideas for guidance.

No. 1. Could a risk-informed regulatory approach help resolve a question with respect to maintaining or improving the activity's safety?

And what the staff should be thinking about when applying considerations is does the activity's safety level need improvement, or is the activity safe enough, but other aspects of the regulatory framework could use improvement while still maintaining safety, or would risk information be useful in assessing a new activity's safety level?

(Slide.)

The second screening consideration is could a risk-informed regulatory approach improve the effectiveness or efficiency of the NRC regulatory process?

And what the staff should be thinking about in this case is are there aspects of the regulatory framework which could be streamlined through the use of risk information, or could the use of risk information produce more consistent decisions among NRC staff?

(Slide.)

The third consideration is could a risk-informed regulatory approach reduce unnecessary regulatory burden for the applicant or licensee?

And for the staff guidance, we have: Could risk information be used to change regulations or policy so that the regulatory burden is more consistent with hazard, or could risk information be used to change NRC licensing or inspection policies to focus the most effort on those areas that have the biggest safety impact, while still maintaining overall safety?

(Slide.)

No. 4, would a risk-informed approach help to effectively communicate a regulatory decision?

And the staff guidance is, could risk information be used to provide a better understanding of the basis for a decision, or would risk information make staff decisions more clear and defensible, or provide greater transparency to our process?

(Slide.)

No. 5, do information such as data and/or analytical models exist that are of sufficient quality or could they be reasonably developed to support risk-informing a regulatory activity?

And the staff should be thinking about, in

this case, identifying what risk studies have been done and examining them to determine do they cover the relevant uses for the activity, the isotopes involved, the quantities of those isotopes, et cetera; are the studies complete, and are they up-to-date, do they reflect our current regulatory environment? And if computer codes are necessary, are those codes available, are they codes which could be modified, or would we have to start from square one?

(Slide.)

The sixth criteria, can startup and implementation of a risk-informed approach be realized at a reasonable cost to the NRC, applicant or licensee, and/or the public, and provide a net befit?

This is the consideration which I mentioned earlier that had the parenthetical reference, and the referenced introduced the concept of net benefit. The net benefit could be improvement to public health and safety, improve protection of the environment, improve communication or better regulatory efficiency at the same safety level, which would result in a cost-savings to the public.

(Slide.)

And, finally, No. 7, do other factors exist which would limit the utility of implementing a

risk-informed approach?

In this case, the staff should consider other precluding factors, which might be things such as legislative or judicial decisions which would limit the implementation of a risk-informed approach, long-standing Agency policy issues, or other social considerations.

(Slide.)

So, these are the considerations in revised form. We believe the considerations are a useful tool in the decisionmaking process, and later on today Jim Danna will be talking about where the screening considerations will be used. We also believe the screening considerations cover the relevant areas that should be considered when contemplating a regulatory change. And, as I stated earlier, we are seeking input into the guidance today, and we hope to have the guidance document finalized and issued with the final case study report.

That concludes my remarks, and I would like to introduce Dr. Dennis Damon, who will be giving you the safety goal presentation.

DR. DAMON: Thank you, Raeann. As Marissa Bailey discussed earlier, the case studies investigated several things. One of them were the

screening criteria that Raeann just went over. Another topic is safety goals, which I am going to address now.

The screening criteria tell you whether or not you should risk-inform an area -- in other words, should you do risk analysis to develop risk information. Safety goals address the question, what do you do with that risk information after you've gotten it.

What I'm going to do is just provide a few introductory remarks and then turn it over to Dr. Robert Bari, from Brookhaven National Lab. He and his colleagues at Brookhaven, including Vinod Mubayi, have been working on safety goals for many years, and they are supporting us in this effort, and they have brought a number of insights into safety goals drawn from these case studies, but to set the perspective on this, I'm going to try to make four points.

(Slide.)

The first point is one I've already mentioned, which is that the functions of the case studies was to evaluate whether safety goals made sense, was this something that would be useful in the context of NMSS as opposed to reactors? As Director Federline mentioned, NMSS covers a wide variety of

diverse things. It is not clear whether safety goals are feasible because of the magnitude and the scope of what NMSS does, or they may not be necessary because they know enough about them given where they are at. So, the question was, are safety goals feasible and useful in NMSS, and the case studies were looked at to answer that question.

The conclusion was that in several cases it was noted that quantitative measures of "what is safe enough" would have been useful.

(Slide.)

The second point I'm going to address is what is a safety goal because it is a subtle and complex concept, and Dr. Bari will get into some of the issues that come up.

The second point of what are safety goals, the simplest answer is "how safe is safe enough"? That is a subtle concept. It really is intended in this context -- there may be other contexts where these terms are used -- but in this context, what we are meaning by a safety goal is a level of risk that is very, very low. It is so low that when you've made something that safe and all you know is that it is that safe, then it is clear to you that is safe enough, as opposed to a case where you're trying --

you don't believe it's at the absolute level of safety that would be clearly safe enough, and you can't make it any safer, you are trying but you are not getting there, but you've reached a level that perhaps is as good as you can do. That is not what a safety goal -- a safety goal is not as good as you can do, a safety goal does not pay any attention to how good you can do, it is only the absolute level of safety -- is that safe enough?

There can be more than one type of safety goal. The reactor safety goals -- one reactor safety goal addresses risk to individuals. Another one addresses risk to society. And the difference there is, a risk to an individual means what is your chance of being harmed? Risk to society adds that up over the whole population, so it is a total picture of the risk from some thing, a facility or whatever.

The bottom line up there is safety goals are aspirations, not requirements. That conceptual mistake is often made, that's one of the reasons I included this in my introductory remarks. You have got to keep in mind that a safety goal is something that you would like to achieve, but you can't mandate it because it does not consider whether it is physically possible to do it. It doesn't consider

whether it is practicable to do, or reasonable to require it. It only considers it from an absolute point of view.

(Slide.)

Top level safety. Here is another concept about safety goals. They could be qualitative or quantitative. It is a simple concept. Those of you who are familiar with reactor safety goals will know what I'm talking about.

An example of a qualitative safety goal statement is given on this slide. Risks from nuclear accidents to individual members of the public near a facility should be an insignificant addition to other risks. It is not a quantifiable thing, but it is a concept, a qualitative concept of what level of safety is appropriate, namely, should be an insignificant level.

(Slide.)

A quantitative of a safety goal would be the frequency of accidental radiation exposures to the general public exceeding 100 mrem from a facility should be less than x, where x is some specific number. So, the idea of a quantitative safety goal is something very specific or quantitative to which the results from a risk analysis could be compared. A

quantitative risk analysis calculates a number, and this is a number to which it can be compared. So, that's the difference between qualitative and quantitative, and that gives you a feel for what we mean by safety goals.

(Slide.)

A third point I wanted to make is that the topic of this meeting and the goal of the effort the Risk Task Group has embarked on is not just safety goals, it is risk-informed regulation which is a much broader topic. Safety goals is one specific narrow area of that broader topic. Risk-informed regulation involves all beneficial uses of risk information, like evaluating the relative quantitative risk impact of various actions. You will learn from that something about which things are more important to the actual bottom line risk. What a safety goal is, remember, is simply a level of risk that when you have reached that you know you are safe enough, and that's just that one. It just addresses that one specific issue.

(Slide.)

The fourth point I wanted to make is why have safety goals. And you can sense from the screening criteria why you would want to have safety goals. That's what the screening criteria kind of

lead you toward, is the idea of what are you going to use risk information for? Safety goals are involved in that same reasoning process, but they are just one way you might reason using risk information. On the reactor side and in other countries, safety goals have proven useful in reducing burden and improving effectiveness, regulatory effectiveness. It allows you to identify when you've gone far enough and, therefore, not waste staff time or impose excessive burden.

It also tells you -- the second bullet up there says what risk metrics should you calculate? People tend to focus on safety goals and say you are really just focusing on what level of safety is safe enough. Actually, in a way, more importantly, you have to identify first what risks are you going to consider. There are more than one type of risk. There is risk to the public. There is risk to workers. There are different type forms of risk. There is risk of fatality and injury. There is chronic exposure. There is accident exposure. There is even terrorist exposure. There are different kinds of risks. It is very useful to risk-informing if you identify what all these kinds of risks are so that you are sure that your staff is considering all the things

that they should be considering.

After you have identified the areas they should consider, then the question comes up, what level of risk in that area is low enough? So, there's really two steps to safety goals -- identifying the risk metrics or the considerations that you are going to factor into your "how safe is safe enough", and then what level of them is safe enough.

So that concludes my presentation. I'm going to introduce now Dr. Robert Bari, from Brookhaven National Lab. Dr. Bari and his colleagues there have worked for many, many years on safety goals and use of risk information, and here is Dr. Bari.

DR. BARI: Thanks, Dennis. My name is Robert Bari. I work at Brookhaven Laboratory. Good morning.

(Slide.)

Just to recapitulate what Dennis just told you, the fundamental purpose of safety goals is to articulate the Agency's safety philosophy. Secondarily, it is really there to establish a level of insignificant risk, risks beyond which one would not really have to take further actions or consider improvements in a facility or process. This sometimes is colloquially referred to as "how safe is safe

enough". Importantly, the safety goals are very helpful in facilitating risk management. If you have safety goals, it provides aiming points to understand which activities require more attention, which require less attention. It's a very good approach to understanding how to manage a facility. And as Dennis emphasized and it cannot be overscored here, these are not requirements. There are requirements in the regulations, but these are aspirations of levels to be strove for but likely not to be met in general.

(Slide.)

Just in the way of background, work on safety goals started in the nuclear area in the U.K. back in the late '60s. Reginald Farmer developed what was called the "limit line", where he looked at probabilities and consequences, and developed a sense of what type of risks were acceptable, what type of risks would be unacceptable.

In the early 1980s, safety goals came to NRC, at least for the power reactors -- this was following the Three Mile Island accident. As some of you might recall, over about a six-year period, safety goals were put forth on a trial basis draft form, discussed with many stakeholders. Excellent input was obtained. And, finally, in 1986, safety goals were

approved by the Agency and stand today, and are, in fact, being used by the Commission on a routine basis.

There have also been parallel efforts in other countries on the safety goal efforts. For example, in some countries, safety goals are actually codified into law, other countries have not adopted safety goals, others practice and use them more informally.

The international agencies, as well, have developed safety philosophies and safety criteria, in particular the IAEA and the NEA have, after Chernobyl, gone forward and taken another hard look at what safety really means, particularly for our facilities.

In the early '90s, or leading up to the '90s, the Department of Energy considered draft safety goals and had actually put them forth for some comment, but did not finally approve them when the Administration changed in our government.

And, finally, and probably very important to this effort, is that following events in Japan over the last half a dozen years or so, the Ministry has tasked the nuclear agencies in Japan to develop safety goals, so this is a fresh look at safety goals across-the-board in Japan, not only for power reactors but for all types of facilities that come under regulation

in Japan -- nuclear facilities. So, this effort, as it moves forward here in the U.S., should stay in touch with what is being done by our Japanese colleagues.

(Slide.)

Just to also recapitulate some of the things Marissa said, in the materials use and waste areas, the guiding document here is really SECY-99-100, a framework for risk-informing this area and, in particular, in this document, the thought is to propose developing metrics and goals following the general structure of reactor safety goals as they exist and have been approved back in '86. Also, importantly, to recognize that it is not only the public at risk, but the workers at risk. The safety goals that were approved in 1986 were silent on worker risks.

Also, rather unique to this area, also consider, in addition to accidents, normal operations at the various facilities that come under the Office of NMSS. Further, to look at the roles of other agencies and organizations, notably the Environmental Protection Agency, OSHA, and also Agreement States, among others; to take a look at what are the actual capabilities of licensees to do risk assessments which

would be needed to compare with safety goals; and, very importantly, a part of why we are here, is to seek broad stakeholder input as the safety goals are being developed.

As Marissa mentioned, the Commission concurred in a Staff Requirements Memo in the middle of 1999, on the basic approach, with certain caveats and additional guidance as outlined in Marissa's Vu-graph.

Now, as we move forward in our consideration of safety goals, there are some specific issues that need to be considered in framing safety goals. Importantly, should they be focused on individual risk, and perhaps also risk to society? Dennis had mentioned that a few minutes ago. In this area, in the materials use and waste area, you really run the gamut from activities that more or less impose involuntary risk, such as operating large facilities for some national purpose or some commercial purpose to other types of activities that exemplified in some of the posters outside, where there is a gradation of voluntary risk that comes into play, notably with workers and perhaps co-located workers. And, in fact, the whole concept of looking at worker risk needs examination as SECY-99-100 underscored. This, again,

was an area that the earlier safety goal was silent on.

Some of the risk in these facilities, as our case studies have shown, not only involve the radiological hazard, but also non-radiological hazard -- for example, chemical hazards show up in various studies, particularly the ones in material use and production area.

Another important and different aspect of this area is that it is not only the operational phase of the facility or process that is of interest in regulation, but it is also longer-term risks, long after the facilities or processes have ceased that one needs to address.

So, in summary, the need here is to really recognize that these areas are qualitatively different from the issues that come from the reactor area. That is not to say that one should not take lessons learned and guidance from the reactor area, but one needs to fully recognize that there are many different issues that come up here in the non-reactor areas.

(Slide.)

So, in our case studies, we tried to glean implied safety goals or criteria that were perhaps used by the staff in some informal way -- we obviously

don't have any hard and fast safety goals at present.

(Slide.)

In the transportation risk study that was done, an accident probability of 10^{-6} was judged to be, formerly in a de facto way by NRC, to be acceptable for vessel shipment. This is the Trojan Vessel shipment case.

In the case of site decommissioning and the long-term license termination rule and long-term release of a site, the unrestricted release of a site was pinned to the annual dose that would be received, residual dose, from that facility, and this was into a small fraction of the annual public dose limit of 100 mrem per year.

In the uranium recovery, we found a more qualitative statement in the generic environmental impact statement that one should prevent significant adverse impacts of health and on the environment.

For the gaseous diffusion plant study that we did, health risks in particular, injuries to the public was determined to be sufficiently small to allow continued operation of the facility while the seismic upgrades were being made, as outlined on the poster that you saw outside.

(Slide.)

Other case studies on this Vu-graph, the one on gas chromatographs and fixed gauges, where a sense of safety goals also was given in various part of the Code of Federal Regulations. And for static eliminators, it was put forth that there should be zero release from sealed sources.

In the case of storage -- this is the DOE/INEEL exemption -- 10 CFR 72, in its statements of consideration, recognized that the dry cask risk is less than nuclear power plant risk.

(Slide.)

In this Vu-graph, we consider where safety goals might have helped. In the three studies where risks were dealt with in a very up-front way -- for example, certification of a gaseous diffusion plant -- the Trojan Reactor Vessel shipment exemption and, finally, the TMI-2 fuel debris storage activity at DOE/INEEL.

(Slide.)

Where they might help is, for example, the area of site decommissioning. It might be helpful particularly if one is looking at a facility where it is not clear whether to go for unrestricted release of the facility over the long-term, or restricted release. One might take an approach using a more

realistic assessment of the long-term scenarios. Right now, we look at a resident farmer scenario and going into the future 1,000 years, is that a realistic thing to do.

In the uranium recovery area, safety goals might be helpful in remediation alternatives with mill tailings, also might provide some helpful guidance in looking at weighing the non-radiological risks that some of these facilities pose.

In the transportation area, getting a better handle on worker and public risk connected with those activities. Dry cask storage, basically, to have a risk perspective would be very helpful. There are activities underway now within the Agency in that area.

And in the more broad area of byproduct materials, a consistent basis for licensing would be helpful to have here.

(Slide.)

The existing safety goal structure for power plants that was singled out in SECY-99-100 where it was recommended that one touch base with that or use that as a starting point for consideration, that approach is what is sometimes referred to as a three-tiered structure for safety goals. At the highest

level, one has a qualitative statement of the goals, and then a more quantitative one at a secondary level, and at the third level, which are objectives and not really hard and fast goals, one has what are called subsidiary objectives, and that is really where the rubber meets the road in risk management. Those have proven to be, in the case of power plants, the parameters that are most useful and most actively used in trying to determine the level of safety of a facility.

So, in the qualitative level, the items to consider are, again, the risks to the individual, both public and worker. Should they be considered a risk to society? Should one frame safety goal qualitative statements in that regard? And then, as also mentioned in the Staff Requirements Memo, the environmental and property damage risks, how should those be brought to the fore here.

At the quantitative level of objectives, there are items to consider as well. These are health objectives that would be spelled out in a very quantitative way and would give likelihood of health effects and, similarly, and what is not present in the current approved safety goals, is quantitative environmental objectives worthy of consideration.

In the area of subsidiary objectives, we have a situation for facilities and processes in the materials use and waste areas where it is not only accidents -- what I call here, episodic type events -- but also chronic exposure to a waste facility over the long-term. You are not having an accident or an event, there is a residual dose. And the question is, how does one recognize the risks there? How would one set safety goals which would recognize that?

(Slide.)

This Vu-graph puts this together in terms of a matrix for the three tiers. The left-hand side is what we currently have for reactor operations. On the qualitative level, we have risk to individuals and societal risks. And if we move over to the right, the analogs or the counterparts might be similar things -- risk to the individual and society, including public and workers as a possibility, and also environmental and property damage risk.

At the second level, we have a prompt fatality risk and a long-term cancer fatality risk. And, similarly, in the materials use and waste areas, we may consider again the quantitative health objectives which might have analogs to those, and also the development of quantitative environmental

objective.

At the third tier, the subsidiary objectives are core damage frequency -- that people in that business are all too familiar with -- and, also, a large early-release frequency. In the materials use and waste area, as I mentioned, there is a possibility of looking at chronic and episodic risks. In the chronic area, one might consider a subsidiary objective in terms of a dose rate. Dose rates tend to be very prominent in this area. We tend to see them in some of the criteria that are put forth. So, here one might consider a dose, let's say, in the millirem per year area, maybe ranging -- there might even be a range to consider somewhere between a single digit and a double-digit number in the millirem per year value.

(Slide.)

Episodic, what I've done here is tried to put together a sense of what the parameters might be for the various areas that are under consideration here. On the left-hand side -- and I'm not going to go through every one of these -- is the use or facility ranging from uranium milling, high level waste, spent fuel, and on the bottom I put the reactor operation area. And on the right-hand side, it would be the subsidiary objective parameter that might be

considered. So, clearly, for reactor operation, core damage and large early-release. But for, let's say, uranium milling, we might want to consider the likelihood of yellow cake release or chemical release. Pick another one, fuel fabrication could be a large radiological release, chemical releases again come in, and criticality, likelihood of criticality. Mill tailings, the likelihood of a release from an impoundment area.

So, these are some of the things, again, put up in the spirit of a strawman for consideration. We'd like to get your input on some of this.

(Slide.)

So, the next steps for us in the safety goal area is, first and foremost, to get your input on the value and need for safety goals in this area. We will be obtaining further insights from the case studies and other risk information, as we consolidate that and look forward to the second phase of this program, and part of that will be considering the development of draft safety goals.

Well, that concludes my talk. Thank you for your attention, and now I'm going to turn it over to Jim Smith.

MR. SMITH: Actually, before we start,

let's go ahead and take a 15-minute break.

(Whereupon, a short recess was taken.)

MR. SMITH: My name is James Smith. I work with the Risk Task Group. I'm a Health Physicist here at the NRC. I've been with the Task Group for about two years now, so I may be the longest surviving one here.

(Slide.)

I was asked to speak about process improvements, things that we've identified during the case studies where we need to have some work done in order to realize the benefits of risk-informed regulation.

One of the things that we really need to do is to train our staff to realize that a risk-informed approach works, also to realize that there is going to be a consistent process to doing this. We've had consistent processes in the past. We give our staff guidance on just about everything they do, so something that will surely come to pass is that we will have to inform our staff, as was mentioned earlier, in what is an acceptable level of risk, and what levels does the Agency endorse as far as safety goals when, and if, that comes about.

The other thing that we need to let our

staff know is that risk-informed approach will be the preferred option. The Commission has said that in the past, but we need to let them know that if you are looking at different options, you need to realize that a risk-informed approach is the best option, or at least the preferred option.

(Slide.)

As far as screening criteria/considerations, one of the ways that we can teach our staff is to introduce this as a common guidance document, such as how to deal with rulemaking issues, how to deal with licensing particular licensees where an increase or a decrease in risk might be associated with a certain special authorization. Also, our inspectors, we are in the process now of revising our inspector guidance to focus on areas where there is the greatest amount of risk, not necessarily compliance inspections but more to focus on areas that get you the biggest bang for your buck.

(Slide.)

We still have a problem. In order to tell our staff what is the accepted level of risk, or at least where they should shoot for, we don't have one of those yet, so it's going to be a learning process

as we go along.

One of the issues that NRR did not have to deal with, as Bob mentioned earlier, is we have both long-term effects such as latent cancers that are developed, and we also have in some cases the opportunity to have what we call "deterministic effects", such as injury, permanent injury, perhaps death.

We also have the added safety goal option of considering property loss, and also public perception. Sometimes there are risks that may result in someone being injured, but there often are risks associated with just loss of control of material, and we lose public confidence in our ability to regulate this material that may not really result in a health risk to anyone or any sort of property damage, but we need to take into account the tolerable level of risk.

Also, one of the things that we really need to recognize as an Agency and work towards teaching our staff is zero is not always possible in the real world. And what I mean by that is our strategic goals are generally set, as well as our regulations, where zero noncompliance is acceptable. In reality, there is always going to be a certain possibility that your regulations might fail, that

some event that you don't want to happen will occur.

(Slide.)

We've looked at a number of models that we have out there right now. One that I'm most familiar with is NUREG 6642, which is a byproduct materials study. There is another document out right now, NUREG 1717, that looks at a number of the types of materials that we have which we call "exempt", which, for those of you who don't know, those are generally the lowest level of control and generally no one who has one of these devices has to have any safety considerations. They just pick it up just like you would buying a computer. There are no instructions as to how to use it safely. Well, 1717 looked at those to see, well, what is the true risk associated with the distribution of these products.

(Slide.)

We also have ISA, the D&D codes. These are all models that we use. It helps to get a consistent approach to answering questions. We may not always be accurate, but at least we will be consistent.

We all have a problem in our regulations in the human factor. For the most part, if you could keep people away from material, then people don't get

exposed. Material doesn't get lost. But, generally, our licensees have to handle the material directly. There is an opportunity for someone to not follow procedure, or some other administrative detail, that may result in someone being exposed or material being lost.

One of the things that we have a problem with is people. It's awfully hard to predict what they are going to do in the future. They are just not very reliable sometimes. You can't always consider that a person is always going to push the right button.

(Slide.)

We have a number of options that we could do to address this weakness. We could start out by using NRR data and models for consistency, at least in generic cases. We have had a few specific cases that we've used where we built on the models that currently existed, and went out and collected more specific data according to that case-specific issue.

Some of these that I'd like to mention, one currently we have a petition for rulemaking regarding irradiators, and the issue at hand is a reduction in the amount of oversight by a trained operator.

So, instead of just relying upon the educated guesses of the people who developed the earlier models, we went out to look at several facilities to see how close were our engineering judgments to the real world. We collected specific data. And that's probably the approach we will take in other issues of this type.

Materials inspection program review. We used the information from NUREG 6642 to address issues of dose, worst possible consequence, other things that you can use 6642 with, but we used also a risk-informed approach. We didn't rely mainly on that information. We also had a number of seasoned individuals who knew the material well and could tell just from their experience whether or not the data really supported reality, or whether reality supported the data.

I'm not too familiar with the in-situ leach facility study, but I suppose that's the same issue. The Trojan Reactor Vessel shipment is one where not only did they look at the generic case, but they addressed specific weaknesses that existed for that type of shipment, such as controlling how high the canister or the reactor vessel could be raised above the ground on the road towards its ultimate

repository.

Those are cases where you take the generic to get sort of a field idea of how big is the issue, what are the things I need to consider, and then when you decide you want to tackle it, you can go in and get specific data.

(Slide.)

I guess what I'd like to say as far as -- it's kind of difficult to say that this is all process improvements because these are ideas that we gained from the case studies and some of our work that point us in the direction of where process improvements can be. I think Jim Danna will address these in just a minute. But we've learned that a single safety goal such as exists with NRR, not very possible here in this area. I mean, we could try to force it, but there are too many issues, too many considerations outside of chances of core melt that we have to worry about. The big one, again, is to recognize that zero is impossible in the real world. The only way to actually have a zero-probability of something occurring is to make sure that that activity never takes place where you preclude any accidents, any events that might lead you to the wrong path. But the fact is, we've been told by the Atomic Energy Act to

license these materials, so we have to take into consideration that there is a certain probability that a failure to follow administrative detail will occur, and we will have to deal with that consequence.

And, again, we need to address the human reliability issue, and it needs to be done in an approach that is consistent across-the-board, and also is credible, transparent, defensible -- I think is one of the words I heard earlier -- where we can put the numbers down and have some confidence that not only are they right, but won't have much opposition to them.

That's it for my set of slides. I'd like to introduce James Danna, who is going to tell us what we are going to do in the future to solve all these issues.

MR. DANNA: My name is Jim Danna. I'm a Systems Performance Analyst with the Risk Task Group. For the next few minutes I'll briefly discuss the next steps of NMSS to risk-informed regulatory activities. I'll refer to these next steps as Phase 2.

(Slide.)

We can consider our efforts and activities to develop a process to risk-inform in the materials and waste regulatory areas to date as Phase 1. Many of

you have been involved with Phase 1 activities. Phase 1 has included the development of the case study approach and plan, the conduct of the eight case studies, and the development of the screening considerations.

Phase 1 also included the development and implementation of a training program for NMSS staff that focused on risk, risk assessment, risk management, and risk communication.

Finally, Phase 1 also included the initial consideration of the feasibility and utility of safety goals for materials and waste regulation. The previous speakers have discussed most of these activities.

In Phase 2, we plan to apply what we have learned in Phase 1 to accomplish and to move forward with risk-informing materials and waste regulatory activities. In Phase 2, we will systematically review the regulatory applications for which NMSS is responsible, to apply the screening considerations, and initially identify those areas where risk-informing may be potentially beneficial and feasible.

(Slide.)

The basis for Phase 2 is provided in Commission paper SECY-99-100 titled Framework for

Risk-Informed Regulations in the Office of Nuclear Materials Safety and Safeguards. This is dated March 1999. Marissa mentioned this Commission paper earlier in her presentation. In SECY-99-100, the staff presented to the Commission, at its request, a framework for risk-informing materials and waste regulation similar to the framework developed earlier for reactor regulation. The staff also presented a process for implementing the framework.

As the first part of the framework, the staff proposed to define the regulatory areas where risk assessment methods could play a role in the regulatory decisionmaking process. These would be areas where a regulatory process might benefit from using risk insights and information.

To implement this first step of the framework, the staff proposed to identify candidate regulatory applications where risk insights and information could play a role in the regulatory process and where a benefit may be realized.

(Slide.)

Phase 1, the case studies, the development of screening considerations, the development of the staff training program, and the evaluation of the feasibility of safety goals was NMSS' initial effort

towards identifying regulatory areas and applications amenable to being risk-informed.

Phase 2 will be the NMSS effort to complete this initial identification. Here is the general approach we are proposing for Phase 2. The first step will be to develop a written plan for Phase 2 that describes the approach, the product, and the schedule for implementation. This will ensure that the scope and level of detail of Phase 2 is clearly defined and understood.

Next, the staff will systematically identify the general regulatory activities of NMSS. We will likely use the regulations as a starting point to define the NMSS regulatory universe, if you will. And we will use the current NMSS operating plans to describe what we actually do on a day-to-day basis.

Once this is initially completed, we will likely identify and set aside certain areas from further consideration at this time. These may be regulatory areas that have recently been revised or that are currently considered to be adequately risk-informed. Examples may be activities associated with fuel cycle facilities, medical applications, and the high-level waste program.

We will then categorize and bin the

remaining activities as appropriate for efficiency. And, finally, we will make a first attempt at applying the screening considerations. In applying the screening considerations, the staff will follow the guidance that will be developed as discussed earlier by Raeann. We will also rely on the experience and insights gained through the case studies and through the other risk initiatives and activities that NMSS has undertaken to date. And, of course, we will consult with NMSS management and the staff and other stakeholders throughout this process.

(Slide.)

The expected product of Phase 2 will be an initial set of potential NMSS risk initiatives. These initiatives would be the regulatory application areas defined in a general way, where a risk-informed approach or modification may further the Agency's strategic and performance goals.

In terms of safety, increased public confidence, increase regulatory effectiveness and efficiency, and reduce regulatory burden and, where we feel it would not be likely prohibited by technical feasibility, cost effectiveness, or other factors.

(Slide.)

We would document the Phase 2 effort and

results by presenting the potential NMSS risk initiatives and the basis for their identification. This would likely be expressed in terms of the screening considerations, and would describe the factors and issues reflected in the initial application of the screening considerations.

The documentation would also identify and provide the basis for the areas initially set aside or initially screened out. We feel that documenting the Phase 2 effort in this way will allow others to review the factors that were considered for each of the materials and waste regulatory areas in applying the screen considerations. This way, management, staff and other stakeholders will be able to review and revisit these considerations and determine whether or not they would hold up in the future, or they may be reconsidered.

(Slide.)

After Phase 2, potential risk initiatives identified through Phase 2 would be prioritized through the existing NRC planning, budgeting and performance management process, the PBPM process. The higher priority initiatives would be identified for further near-term consideration. Staff within the responsible NMSS divisions would continue to

investigate and develop the risk-informed approaches or modifications. This would be considered Phase 3, the actual modification and implementation process. It is expected that as the individual risk initiatives are explored, the screening considerations will be revisited and reconsidered.

(Slide.)

As many of you know, up to this point the staff has been risk-informing specific regulatory processes within the nuclear materials and waste safety arenas, in parallel with our efforts of Phase 1. The case studies and the development of the screening criteria are two examples.

The staff will continue with risk-informing specific regulatory processes on a case-by-case basis in parallel with the Phase 2 activities. Staff's experience to date with risk-informed initiatives and activities will be factored into the Phase 2 process. It is expected that the Phase 2 effort will benefit greatly from this experience.

Note that the identification of potential risk initiatives through the Phase 2 process will complement the existing avenues for identifying regulatory initiatives. As many of you know, these existing avenues include operating experience,

direction from the Commission, or proposals from stakeholders and staff.

Also note that safety goals for the materials and waste safety arenas, as discussed, and, finally, if found to be desired, will also be developed in parallel with the Phase 2 effort.

That concludes my comments on where we plan to go from here, and I thank you for your attention. I think Marissa has some concluding remarks, or Lawrence.

MR. KOKAJKO: Thank you, Jim. I'd like to thank everyone for their informative and succinct presentations today. Our purpose was to try to get as much information out in the shortest possible time, so that we can start having some interactions with the stakeholders.

We really do want your input today, and we want to hear from a variety of people and views. What we've presented today is what we think are appropriate things to do, what we derived from the case studies, and by no means are we set in concrete on many of these matters. We really do need your input on what we have done and what we should do further.

(Slide.)

Let me summarize where we briefly are.

Screening considerations seem to work well. They were tested in the case studies, and I have to tell you they have also been tested in some other applications, as I think Jim Smith mentioned, and they do seem to work. We would like to get your input on the application of them and what guidance might be useful to make them work even better.

Value-added process improvements can be made, but we would like your thoughts on this, particularly we would like to understand what you think we might do, what programs we might look at, what particular applications of the regulatory framework might be good to look at, and in what areas.

I would like to point out at this time, in case you have thought of this, that during the actual eight case studies work, we did not identify any areas within the current framework that would require an increase in regulatory requirements for that particular case study, although we did identify beneficial use of risk information and process improvements as a result of that. We didn't think that there would be any increase in regulatory requirements for that case study.

Finally, we think safety goals are feasible, and they could be helpful, but we would like

your stakeholder input on the value and utility of doing further work on safety goals. We would like your views on if you think that it's worthwhile and, if so, what can you tell us about what they might look like and what they might be used for.

This concludes the staff's portion of the presentation today. From now on, it will be a facilitated discussion with Dr. Rathbun to help us get your feedback and input. I would like to have this as an open exchange of conversation as possible. I would like to have some dialogue between members of the staff as well as our subject matter experts who are here, some of whom cannot be here and participate as fully as I would like today, due to the handling of events after September 11th.

With that in mind, Dr. Rathbun, would you please take over?

DR. RATHBUN: My name is Pat Rathbun, and my background is in social psychology and in statistics. And, basically, I'd like to work with you the rest of the day to kind of go over what the panel has discussed and get your specific ideas for input. I believe we have some questions on a slide.

These are the general areas. What are the factors that we should put into the guidance? What

should we think about as we develop that guidance for those screening criteria?

We came up with some ideas for process improvement but, frankly, we really need your help in that area. The value and need for safety goals. You've heard, I think, an outstanding discussion, but this is a very complex area, so we are looking to you for that. I see lots of people in the audience who have had many years of experience with safety goals.

And then, finally, after we have gone through that, we do want to take a hard look at the future direction of our program and where we are going. Okay.

All right. Under the guidance development -- let me say this. Before I take these questions, are there any general areas that you all would like to share with us before we go into specifically asking you things? Are there general comments or questions that you would like to give now? The only rule here is that you give your name before you speak, so that the Transcriber can get the right words with the right person.

QUESTION: My name is John Carter, and in a very general sense, I think the discussion of safety goals is commendable and very worthwhile, but I have

some concerns about the whole nature of the risk-based regulation discussion because, based on the last comment that was made, it appears that the risk-based regulation is really a way to go about deregulating certain areas that are already regulated. So, we are talking about a lessening of the regulation, not an increase in regulation, as is evidenced through the comment that none of the case study areas will result in greater regulation. And to me, that is fairly well known.

But I have a concern also as to, again, in a very general sense, the framework and the sphere within which this regulatory process will take place because I think the concern that I have is that there are a lot of areas of radiation and radioactive materials that are not regulated under current regulations, that perhaps the Commission and this group would want to consider, such as -- and there was a reference in the materials to the uneven regulatory scheme now in effect for byproduct materials. There is this area of pre-'78 non-11(e)2 material, not regulated. There is NORM material, some of which has greater radioactive dangers, health and safety and environmental risks in many regulated materials. There's the area of unimportant quantities of source

material, again, unregulated. And I don't see that this process is going to address any of those areas. And maybe that's completely outside the scope, but those are some of the concerns, some of the issues that I would like to see addressed. Thank you.

DR. RATHBUN: Thank you, John. Lawrence, did you want to address that?

MR. KOKAJKO: I think some of the things that you've mentioned I think a number of us may have to respond to. We are not saying our program is risk-based. We are not looking at making a risk-based program where you do calculations and come up with a number and you say that's the answer. We'd like to think that we're risk-informed. We're using different assessment techniques and strategies to help us arrive at a better conclusion.

Also, when I mentioned that the eight case studies did not identify any increase in regulatory requirements for these eight case studies, that is true. We thought the framework was sufficient in staff, the way they manipulated the information to arrive at their conclusions was adequate. That doesn't mean to say that there could not have been other areas where we think that it could be increased or maybe even decreased. In fact, we would anticipate

that.

You mentioned a byproduct material and perhaps the uneven framework for certain things. NUREG 1717 does talk about that, which Jim Smith, I think, mentioned earlier. There is a working group that has been formed to look at that right now. Also, there has been a materials review that has looked at some of the inconsistent treatment but not only in the licensing end, but also in the inspection end as well.

And that perhaps leads me to my final point, which is when we say we're changing the regulatory framework, we are looking at it very broadly. We are looking at it in terms of rulemaking, rules and regs, of course, but also in terms of licensing processes and guidance, inspection processes and guidance, enforcement, all of those four things are part of the framework, and all we think have the potential to be more risk-informed than they currently are. While we would like to say that we have enough information to risk-inform everything, I just don't think that's true. And that there is a double-edge to this. You could risk-inform and find out that maybe you're being too restrictive in some areas. In other areas, you may find out that you need to be more restrictive. And we are open to both possibilities.

DR. RATHBUN: Does anybody else want to address the whole idea of what's in and what's out, and what we do about those areas that we don't regulate now, such as NORM. Dennis?

DR. DAMON: This is Dennis Damon. I had a piece of information to pass on. I do not know what the Commission's reaction to the idea that the work that's being done here might lead to an expansion to the scope of what is regulated in general, beyond simply expanding the scope within the context of the existing Atomic Energy Act and regulations. However, there was an interesting study coming out of NCRP, which I can never remember the exact -- National Council on Radiation Protection -- and in that study it attempted to lay out a systematic way of identifying waste based purely on risk considerations, both chemical and radiological risk, and not on where that waste came from, which is the current -- if you look at the current Atomic Energy Act, this Agency is -- the scope of this Agency is based on where the material came from because it originated during the days when the Government had all the nuclear material for the purposes of making bombs, and it was trying to transition to using this material for civilian uses. And this new study backs off from that and takes a

more global view and says let's just look at waste, regardless of where it came from, but just look at what's dangerous about it and how you should manage it.

And so what I suspect is true is that if we investigate the rational structure behind safety goals, we will be creating a structure which will lead you to the same kind of conclusions, namely, it doesn't pay any attention to the current regulatory structure or the law, it is only looking at the risk. And so that conclusion will be implicit in the information structure that you create, just like the NCRP thing was. But whether the Commission or the staff, management of the Agency, is interested in addressing changes to that, to the scope of their work, is a broader question.

The risk information will be there for them to use, and that's what the difference is between risk-based and risk-informed.

DR. RATHBUN: Thank you, Dennis. Does that answer your question, John?

MR. CARTER: Yes.

DR. RATHBUN: Okay.

QUESTION: My name is Cal Ozaki, and I was really interested in your comment about the NCRP

because one of the questions I have regarding what the NRC is doing here is, it seems like this could be directly applicable also to other agencies' work, such as Department of Energy and how they regulate their materials and activities.

So, I was wondering what type of collaborative effort or communication you at the NRC are having with folks in the DOE that may be pursuing similar types of risk-informed regulations.

DR. RATHBUN: Lawrence?

MR. KOKAJKO: First, as you know, Bob Bari and Vinod Mubayi are from Brookhaven National Laboratory. They have a number of contacts, and I know they have been discussing things with others.

The other day I received a call from Argonne from someone who was interested in some of our information today, and I know we've had DOE participants at our stakeholder meetings. We try to get as widely attended gathering as possible to discuss what we are doing.

Specifically, we have not asked DOE to come in here just to meet with us on these topics. Perhaps as time goes on and as we move a little further along, we'll be able to maybe have some of those discussions, but hopefully this suffices for

that type of interaction and then on an as-needed basis.

DR. RATHBUN: I think there are a number of people from DOE here.

QUESTION: I'm Maggie Sturdivant, and I am from the Department of Energy. We have been working -- Bob can tell us how many years now on risk-informed approaches to doing work, particularly with waste management.

DR. RATHBUN: Okay. Any other questions or comments here?

QUESTION: Melanie Galloway. I was hoping you could explain in a little bit more detail the reason for the change from screening criteria to screening considerations, and whether or not there is any implication there for the rigor with which the staff should apply these now-called considerations, or the scope of the situations in which we should apply them?

MR. KOKAJKO: I will let Raeann take that, but before I do, one of the big reasons that we found was that people began to look at the screening criteria as yes/no, go/no-go type statements, and they are not. People began to think in terms of, well, if you said yes to everything, then you were to do it,

and that wasn't the case at all. It was meant to be just one tool in the management kit bag, if you will, that they could pull out and try to use, rather than if you came up to a yes, you had to do it. We felt it was confusing to the staff as well as to management about what the purpose was.

We also know that the performance-based paper that was approved by the Commission back in '98 or '99, they called the performance-based items "considerations" as well. So, in order to conform with that, we decided to call them considerations.

DR. RATHBUN: Did you want to add to that Raeann?

MS. SHANE: I think that was a pretty good summary.

DR. RATHBUN: Thank you. Melanie, does that answer your question?

MS. GALLOWAY: It answered the first part, but not the second. I was asking as a second part as to whether or not that means that there's any change in the way that we apply them.

MR. KOKAJKO: In terms of application, I don't think so because I still think you will tend to go about, you know, trying to look at the thing that you are interested in looking at, apply the criteria

as you see it, and then it is just now another input to management to make a decision on whether or not to proceed or not to proceed.

It comes down to a risk-management decision. If they want to continue with it, this appears to amenable for further work, that's okay. They may not want to do it, or the criteria itself may say, hey, this is not amenable, you ought to not pursue this particular approach anymore.

DR. DAMON: This is Dennis Damon. I'd just like to make a comment about this. I kind of have somewhat of an alternative, supplementary perspective on this, and that is, the screening criteria, in one sense, are a lot simpler than what they may appear to be. It looks like some complicated thing you go through.

All we're trying to do is get you to ask the question, what are you going to use the risk information for if you have somebody calculate it? In other words, don't hire somebody to do a study for you and calculate something before you figure out what you are going to use the information for. And then you have to add to that sort of the obvious thing. If there is some obvious -- if you don't have the money to do the study, then don't propose that it be done.

So, those type of things are imbedded in there, but they are kind of obvious things.

The idea is, figure out why you want a risk study done, what decision are you going to address, before you start, because if you just tell somebody, go do a risk study, they will do one, they'll come back and you say, gee, that wasn't what I wanted. That doesn't help me with the problem I have. So, you have to define your problem first.

I'll give you an example. The irradiator risk study, the question they wanted answered was -- it was a proposed petition that Jim Smith referred to. The petition came in and said the licensees would like to have the option of not having an operator present at the irradiator facility 24-hours-a-day whenever it was operating. Now, that means that it would have an irradiator running there for part of the day with no operator present.

So, the risk study was done, and they had to calculate two risk numbers. What is the risk of the irradiator, if it is operated with an operator, and then what is the risk if it is operated part of the time without an operator. So, if you don't define that question before you ask for the risk study, they won't calculate the information that you need to make

the regulatory decision.

So, that's all the screening criteria are about, is just common sense and do you have the money to do the study. Is there some law that would have to be changed, which you don't think anybody is going to change? It's really quite simple in that sense.

The other option, though, is it is actually more complicated because when you are applying the screening process, you don't know what the answer is going to be. You don't have the risk information. The risk -- it's hard to estimate the cost of risk studies very often. You haven't actually had somebody do a quantitative analysis to know what the cost savings are going to be, as to whether there is burden reduction or if the staff efficiency improvement and stuff like that. So, you are kind of making an a priori guess as to whether this is going to save staff time or reduce burden and stuff, and this risk information will help you make the decision.

DR. RATHBUN: Boby.

QUESTION: My name is Boby Eid. I have two questions, one question regarding ALARA, which is as low as reasonably achievable, and how it fits in the safety goals. That is my first question. Would you like to answer that?

DR. RATHBUN: Why don't you go ahead and say both questions, and then they know kind of who to field it.

MR. EID: The second question is specifically to Dr. Bari, about the quantifying environment of risk, and what is your approach for quantifying environmental risk?

DR. BARI: Those are two excellent questions, and we would very much like to get input from people here on how to go about those. With regard to ALARA, I think it's a very legitimate thing to consider in framing -- we are not yet at the point where we could propose something definitive. There are obviously benefits to invoking an ALARA scheme in this area. Of course, one does want to fully recognize the cost involved and the risks that are being mitigated.

Your other question was on the environmental -- we are in the very early stages of struggling with one, that is certainly an important one. I believe at an earlier stakeholder meeting, there was a comment, in fact, about decommissioning area in terms of moving dose-fixed contaminants and, in the process, scarring the earth and leaving behind environmental damage.

The question really comes down to, or maybe it could be framed in terms of what are the tradeoffs, what are the benefits to be gained, and what risks are being mitigated. This will be a difficult area of our discussion. It is our hope that we can get a better feel for that, going back and re-examining the case study and additional risk information, engaging folks in discussion of this issue, understanding the values of an environmental goal.

MR. MUBAYI: My name is Vinod Mubayi, from Brookhaven. Let me just add a couple of points to first safety. Safety goal is really a broader concept than ALARA. In ALARA, we look at a very specific process like, for example, how much shielding do we need to provide in some room consistent with the workers accomplishing their tasks, and then we can use some optimization principle to go as far as we think is reasonably achievable in that specific task. But the safety goal would encompass a number of -- you know, would encompass a large number of activities, like in reactor space, ALARA is usually done for workers with specific tasks inside the plant, and we look at specific processes. But the safety goal applies on a wider scale. It applies to accidents.

It applies to -- well, ALARA is in the context of normal operations mostly.

As regards your second question, I think it is a very interesting arena right now when you look at this environmental goal that one is thinking of, and what kind of metric will we actually use in terms of arriving at some quantitative environmental objective that is consonant or adds value like the quantitative health objectives in the regulatory process. And whether it is some sort of contamination level which then can be translated into a dose level with some procedure, or whether it is some sort of a dollar amount that may prove to be a more useful metric, I don't know right now, but I think we have to consider a variety of different metrics, apply them, and then try to understand their implications.

DR. RATHBUN: This is probably a good time to see if there is anybody in the audience who would like to add to this discussion. Now is your chance.

QUESTION: My name is Hugh Evans, AEA Technology. I believe my questions are going to be primarily directed towards Jim Smith. The perception that I have for three of the case studies that involve sealed radiation sources in gas chromatography, static eliminators and fixed gauges, is that the risk

analysis that has essentially been embodied into the licensing process by determining fitness for purpose via the ANSI and ISO tests has minimized risks to a very good degree. And my question, number one, is, is this also the conclusion that you have come to from the case studies to date?

And, secondly, you specifically mentioned the human element as a reference by "are you going to press the right button today". We are aware of shortcomings in licensees not carrying out necessary paperwork, et cetera. Do you believe that there is any easy way of improving on the human element?

MR. SMITH: That's a big question. I'm not sure that I can answer the second one, but I'll give it a try. The first one I can only answer for a gas chromatograph. The conclusion that I came to when I looked at the regulation as well as the licensing process and the other regulatory aspects of it, it greatly exceeds any safety requirement that may come up as far as a dose limit, either an accident or operations.

I don't believe I can say the same for the other two you mentioned, static eliminators as well as fixed gauges. I'd have to leave that to Mr. Danna on my left and Ms. Shane on my right.

The other issue with respect to reliability, I'm not sure at this point where to go with that. I just recognize that we have done several risk studies, and always the Achilles' heel for these types of studies are you are relying upon a guess as to how precise or how accurate or how reliable an individual will do a certain task because almost all of the materials areas rely upon human beings to do things. It's not a very engineered process to radiograph something, a source out of a shielded box and it sits there in front of a piece of gum for a period of time. Really and truly, a human being is controlling all the safety aspects.

I don't think that an engineer can come up with a prediction, they'd probably do some sort of study of past events and come up with what has happened before. I don't think you can predict what will happen in the future.

We do have a lot of licensees out there of these types, so I think that if you could mess it up, sometime in the past, most of our licensees have done that, but I'm not sure that they have done away with all the options for messing up. I'm sure that there are new and brighter ways to become exposed to radiation that they are going to come up with in the

future.

DR. RATHBUN: Okay. Anybody else?

MR. KOKAJKO: I think Raeann and Jim need to also respond.

MS. SHANE: If I remember your first question right, do we think the review standards have made these devices safe, and I would agree with that. I think major changes -- at least I'm talking about the fixed gauges study now -- perhaps it's our application of our licensing policy as far as which categories gauges would fall into that could benefit from some risk information. Currently, we have very similar devices regulated in very different ways, and I'd like to see that become more consistent some risk information.

MR. DANNA: With respect to static eliminators, I think in conducting the case study I found that your assertion is also correct, that -- think of it as a two-step process, it is actually the certification of the sealed source itself, which is the design which is held to the standards. That ensures the integrity and the containment of the byproduct material. The certification of the device ensures that the sealed source -- tampering with the sealed source is reduced, greatly reduced, or

prevented, and that is verified through the return of the device and verification that the device integrity has not been jeopardized. So, I think your assertion is correct.

DR. RATHBUN: Okay. Thank you. Dr. Pavlova, did you want to add to that?

QUESTION: Maria Pavlova, Department of Energy, Office of Health Status. What I would like to address is the important question about the human element. And I think going into that, we have to approach the whole process of risk assessment, risk management, and the risk communication that is a must. I don't know how many of you are familiar with our -- in 1997, there came a report from the congressional committee under the National Academy of Science that deals with the risk management process. And one of the most important principles there is that the stakeholders take a central part so that whether you identify a hazard or a problem or risk, and then you go through quantity or quality of this risk and what are the options to deal with this, and what is the evaluation on the effectiveness of what you have done. In all of those stages, one has to involve stakeholder.

I have been coming to those meetings of

the Commission for sometime, and myself, as a person that has been involved in risk communication for at least 15 years, I am very impressed with the progress that you have made, and the sincerity in what you do regardless of how difficult it is.

When we talk about the human factor, at DOE, as my colleagues you probably very well know, at the moment we have a chemical safety analysis. We technical people seem to talk more about analysis safety, and yet we do not think that this safety relates to worker or relates to community, relates to humans.

And I was fortunate to be involved in a health risk communication dealing safely with beryllium at the DOE sites, had three pilots with that, and find out how important it is that the human element, if they are occupational, in the workplace, are made aware, have been educated, have been motivated, and this is done only with the main purpose of making them involved.

So, it is not only regulation from the top and out or not, but how much they will participate in the whole process. And with this particular approach, we were able to have a task force of six people, but the driving source were the workers, the people

involved together with the managers and the technical people.

So, in this -- I don't want to be too long, I know you have --

DR. RATHBUN: That's okay, I was just moving toward my coffee.

DR. PAVLOVA: You always have it very close, that's good. And we have had discussions particularly with Lawrence and our colleagues from Brookhaven National Laboratory, and I talked with Marissa, you are trying to get to some practical guiding document. It is very important to do so.

So, I see at least two different type of audiences. One is your own, and then you can use a little more technical language as it has been today. As a physician, though, I have worked with EPA and now the DOE, sometimes have a hard time understanding what you mean by that. And I can imagine how the workers or how the community around, who are very concerned, understand that.

So, my suggestion will be that whatever you do, try to have at least two versions, one maybe for your managers and your stakeholders because you have quite a few stakeholders. I understand some are of the quality of the gentleman who sounded very

highly technically educated -- I forget your name -- but I am always very much impressed with people that communicate like the colleagues from Brookhaven, in a language that shows a lot of knowledge. So, you have these stakeholders.

But then within these stakeholders, you have their workers and you have the communities around. So, I find it very useful to have a smaller, perhaps, guiding document in which it is done with involvement of workers. Let them do it in the outline. Let them peer review it through their own, and make a focus group of the community so that the involvement of the people that are concerned will be there, and then they can sell either good sense to their peers what we are trying to do together because there is no question that their trust among them is much higher than the trust that we unfortunately have as government nucleus. Thank you.

DR. RATHBUN: Thank you. How about -- anybody else here?

(No response.)

Okay. As we move into this next stage, I'm going to be joined at the front of the room by Ms. Christiana Lui. She is one of the really long-standing members of the Risk Group, left for a while,

is now back, and she is going to help me by recording on the board items that we want to cull out for special attention.

All right. We will return to the more formal feedback session here, and our first question is on the guidance development, and just a basic question, and that is, what additional factors should we consider in developing our guidance for implementing the screening considerations? To recall Raeann's talk, at the bottom of each slide she put up the types of things that we were beginning to look at, and now we'd like to turn to you to see if you have any additional factors. We can even put our slides back up if you want memory jogging.

(No response.)

There's always time for later on. Let's move then to the process improvement area, and what we'd like to ask you is can you suggest additional areas for process improvements in the following three areas. One would be use of the screening considerations; two, using safety goals consistently, and in developing and using tools, data and methods. Do we have any feedback on that area?

(No response.)

Now, come on, we're not perfect here.

MR. KOKAJKO: I would be interested in knowing -- you saw the eight case studies out front. Those were our first pick, and that was based primarily on input from division directors which compose the NMSS Risk Subcommittee. And, clearly, we cannot take all of NMSS on at one time. We need some -- to see if you guys have some ideas about which would be a better -- there are some things in NMSS that need to be taken a look at now. I know that a couple of comments earlier were that there may be some inconsistent regulatory approaches in some of the byproduct material. Do people have a sense of some examples of that, and what it might be, what it might look like, and also if there's any proposed changes or processes that you would recommend. And I know we have staff here, and it would be a great time for staff to come up with some ideas as well. I know that they've been around here for a while, and I know that they've probably seen areas that could be improved upon.

QUESTION: My name is Paul Goranson. You were mentioning about the consistency of regulations on byproduct material. I think that one of the challenges I see ahead -- technical issues aside, the legal definition of what is byproduct material and

what isn't. Earlier somebody mentioned about the pre-1978 byproduct material and the current byproduct material which is regulated now by NRC. Those are the type of inconsistencies that occur which make it difficult for a licensee, who is either accepting byproduct material for disposal or has received in the past byproduct material for disposal that suddenly has come into question.

Secondly, there is quite a bit of material out there that's kind of in a licensing as to what the status is, it's still relatively questionable. So, if you're going to look at that type of direction would probably be a good place to look that may give the Commission better guidance on how they ought to regulate that material.

DR. BARI: I think that's a very good point. A risk-informed approach would be very helpful here. It will look at the hazards being posed by the byproduct materials, and also where they are going. Where they are going is already a fairly high hazard environment and contamination that's being added or introduced in very small increments.

MR. GORANSON: Well, I guess a follow-on to that is you have some material that's going to RCRA sites which have different criteria to material that's

going to a byproduct disposal site which falls under Part 40. There's two entirely different criteria, and the risks are the same, the materials are the same, they are the same but you have two different criteria all because of the legal definition.

DR. BARI: I believe that this is an opportunity to make the process more rational.

DR. RATHBUN: Did you want to add to that, Jim?

MR. DANNA: Yes. I believe that this issue sort of relates to question 7, screening considerations. There are issues that we can deal with as a regulatory body, and then there are issues that are outside of our realm, such as legislative issues. And the reason why those materials are treated differently is not based upon a risk analysis difference, more or less, because it was mandated to do that through law.

I mean, like Dennis said earlier, there are some laws that we may be able to impact to change, but they are not within our ability to -- we can't sidestep them to write our regulations.

DR. RATHBUN: I think we have a question from Joe Murphy.

QUESTION: I'm Joe Murphy, and I'm with

the Office of Research, and I've been playing in the area of safety goals and things like that for reactor space. Very complex issue.

As I sat and listened to your discussion, a couple of general thoughts came to mind that I'd like to share with you. One is that you have a big advantage that I don't think you realize, and that is that in the kind of things that are regulated by NMSS already have probably the best risk-informed, performance-based regulation known to the NRC. That is know as Part 20. Part 20 is definitely a performance-based regulation. It may be the only good performance-based regulation that we have. And it is definitely risk-informed, the way the numbers were picked.

So, you are starting from the standpoint of your basic regulation, one that is performance-based and risk-informed. You already have -- you are not shifting to a risk-informed approach, you already started with one. And now what you're trying to do is make it better.

One of the problems -- and this is true in reactor space -- more years ago than I like to remember, I stood before somebody and swore there was no undue risk to the health and safety of the public

in a public hearing. Our regulations back in the '60s were risk-informed, by our understanding of risk. What we did not necessarily do is update them as we got smarter.

And so some of them may not be risk-informed now, or they need to be updated, and I think you should think of it more in that kind of light.

It would help if I opened my notes to the page. The concept of ALARA is a risk-informed concept, as low as reasonably achievable. That's what "reasonably" means, to my way of thinking. Doesn't say as low as possible, as low as reasonably possible. You don't force things down to the point where you're spending billions to clean them up. You go as low as reasonably achievable.

So, the basic philosophy is there. Where I think safety goals will do you the most good is helping to realize the basic philosophy that you're operating under. That certainly isn't true in reactors. It is difficult for me to point to any rule that specifically has safety goals in it.

It is very easy for me to point to regulatory guidance in our regulatory analysis handbook or regulatory analysis guideline that are based on safety goal principles in the reactor end,

that tell us how to look at things, what's important, what isn't and, more important, where the dividing line is that says not "yes" on one side and "no" on the other, but you need to think more.

In the regulatory analysis guidelines, this is done by a box, like in a row of boxes that basically go down a line that says "management attention needed". It means you've got to think. There's no magic number. You can't rely on the numbers.

As you get into risk-based, you will get into exactly the problems I heard earlier. You're going to run into a complex, legal, technical battle because I know, I've been in some of the facilities that are licensed by NMSS. And as I walk around them, I look, and I say the radiological risk is small, the chemical risk is longest. That was a gut reaction, walking around. But if you're looking at the overall risk to the health and safety of the public, it seems obvious to me that in some of these facilities the risk to the public may well be chemical and not nuclear. Can you solve that problem? No. But you ought to know it. It affects how you regulate the radiation end of it if you know that the risk is

there. So, you have to understand the components of risk to really do it right.

I would call to your attention some work that has been done in the U.K. They are, I think, significantly ahead of us on how they use risk analysis and the regulation of their various activities. They have the advantage of having the Health and Safety Executive, which basically regulates the health and safety of all aspects of technology in the U.K., not just reactors. It starts with the kind of thing we do in NRC and goes down to the regulations that are put on the local butcher so that he doesn't cut his fingers off. It is the whole gamut of things.

There is a report that was issued within the last year, and I believe the title is Regulating Risk, Protecting People. I think it is available -- at least it was available -- from the Health and Safety Executive Home Page. I would call it to your attention. It's very good, and it uses a concept very similar to the safety goal principles that we use in the reactors, and it is well worth reading.

What they did is, about ten years ago they had a report called The Tolerability of Risk, which was put out by the NII, Nuclear Inspection Inspectorate -- I'm not sure what it is --

Installations Inspectorate -- and they broaden that now for everything that is regulated by HSE in this later report, and it basically takes the principles of the earlier report and has expanded all aspects of what's going on under HSE consideration. So, I would call that to your attention, and I hope I haven't rambled too much.

DR. RATHBUN: Thank you, Joe. Any other comments, either general or directed at improvements -- augmenting process improvements?

QUESTION: This is Mario Robles. I'd be interested in knowing where you see the program going. The case studies are retrospective in nature, looking at what might have been done or might have been applicable. Looking prospectively, how is it going to be applied? Are you thinking pilot programs to kind of have an example for staff to look at, what guidance is needed, or are you looking at establishing higher priorities for initiatives that are risk-informed and that way providing some benefit for licensees that are thinking of doing something but think it's not going to be put on the fast-track, but if it's a risk-informed initiative -- you know, you kind of get them to the fore? What are you thinking in that area?

One item of particular note, Dr. Bari's

presentation noted that risk-informed methods would have been useful in the certification of the GDPs, and I just wanted to point out that that's a process that is ongoing. The certificates are five years in nature, and the current certificates expire at the end of 2003, so there is a recertification effort. So, if the conclusion was that it would have been beneficial, then I would submit that it would be beneficial in a recertification activity.

DR. RATHBUN: Lawrence or Jim?

MR. DANNA: Apparently our plans are to lay out a framework, to identify the different regulatory areas, and then as folks like you point out specific areas to look at, we would plug those in. Once we identify those areas that may be amenable, where we could see a benefit and it would be feasible, then they would be pulled into the ongoing prioritization process. We wouldn't prioritize outside of that process. We would integrate that into the process that currently exists.

We hadn't anticipated a pilot program probably because, as I mentioned, there are, or there have been, ongoing risk-informed activities. So, it may not be necessary to begin again with pilot programs. We have enough experience to look at, a

number of activities to look at, and those case studies cover the different areas. We'll pull that information in to learn from those, and to move ahead with specific concrete areas where we can risk-inform.

DR. RATHBUN: Bob or Dennis, did you want to talk about GDP and safety goals, or not?

DR. DAMON: I have a thought. This is Dennis Damon. I had a thought. I guess Mr. Robles is from USEC. When it does come time for recertification, you might -- or you might now take a look at Reg Guide 1.174, which is the reactor regulatory guide that addresses how you use a risk analysis to justify making a change to your technical specifications or to your license, or certificate in your case, which is not clearly a reduction in risk.

So, if you are proposing a change to your license or certificate or to a TechSpec which is clearly a reduction in risk, there is no need to do a risk analysis. NRC would probably just simply approve it.

But if you are proposing something where it's not clear how this affects the risk of a plant, then Reg Guide 1.174 shows how, over in the reactor side, they consider risk information in evaluating whether that change would be acceptable or not. And so

that's kind of a prototype that might -- you might be able to exploit on the NMSS side.

DR. BARI: I think your comment is a very valuable one. I think given that we already have some of the risk-inform machinery in place for a gaseous diffusion plant and the seismic upgrade, it would be a very natural thing as you're going through recertification, to expand those tools and, in the first instance, use it to help prioritize your own efforts in the recertification, and then ultimately to engage NRC in that process. It's an excellent area, given the nature of the facility, aging issues that might come up, which are issues, of course, that you are very familiar with. I think that's a really great observation that you make.

DR. RATHBUN: I'd like to try for one more question before lunch.

(No response.)

All right. Let me consult with Lawrence and you all here on lunch. We had planned for a long period of lunch because we have to accommodate lots of people in the cafeteria. Do you want to shorten lunch and maybe dismiss the meeting earlier?

MR. KOKAJKO: Unfortunately, Pat, a number of people did come up to me and say that they would be

coming back this afternoon and could not attend all, but portions of today's meeting. So, I think we will have to reconvene at 1:30, at a minimum.

Also, I would like to go into the discussions a little more on process improvement and safety goals, if people have some comments on that. One of the things that we know we did want to talk about was, besides the process improvements of what you think we should be looking at next, in our next steps, but what is -- do people feel that safety goals are feasible, and what they might look like, if they would be useful, or should we not even consider that, the value of continuing the program, you know, what is the general sense of that. So, I'd like to capture some of that after lunch.

And given the fact that some people may be coming back, I'd like to have the opportunity for them to provide some comments at 1:30.

DR. RATHBUN: Okay. We will see you all then at 1:30. Thank you.

(Whereupon, at 11:55 a.m., the luncheon recess was taken.)

A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N

(1:35 p.m.)

MR. KOKAJKO: Welcome back, everyone. As anticipated, I see a number of people have not yet returned from lunch, and although this may make it a little more intimate setting, we would like to hear from everybody, if possible.

Pat is going to take over the facilitation again as we were doing before lunch, and I would like to, in anticipation that some people may have had some things they wanted to say beforehand but didn't, we will probably cover the four major objectives again so that we can try to get the input -- at least ask the questions one more time to solicit your feedback and input on what we've done so far, and where we might go, process improvements, the development if feasible of safety goals and what they might look like, and that sort of thing.

So, with that in mind, let's get started. Pat.

DR. RATHBUN: Just because I'm a psychologist, they believe I'm not mechanical. They are probably right.

All right. Just to go back to where we were, I'm going to revisit the question on guidance

development, the three areas of process improvement. For the first time, we will move on into safety goals, and then on into our view to the future.

There's also a couple of other things that Chris brought up that might be useful to take another look at, especially if we have new people. What would be an appropriate environmental safety goal? We thought we might go back and touch on that again. Are there ways of improving human reliability? We've mentioned that it is a very large problem, especially in materials. And, also, the difference between an ALARA and a safety goal, that they are not the same. And then two other issues perhaps to touch upon again, and that is that 10 CFR Part 20 is risk-informed and performance-based, and what are the implications of that for us as we go forward here. And then the whole picture of updating the regulations.

So, if you would bear those in mind, too, and if you have any additional comments on any of this, please feel free to speak up.

QUESTION: I'm Joe Tenhet, and I'm an RSO of a facility with about 200 gauges of mixed specific licenses and general. These are a couple of comments, so please don't feel obligation to respond.

One comment is with regard to general

license fixed gauges versus specific. In my very narrow experience, talking with a few number of manufacturers, it appears that often there's really no difference between the two, that it's an identical gauge, it just doesn't have a label on it. And the reason that they are offered in both modes is because smaller facilities, maybe facilities owned by very large companies but with only one or two gauges, don't want to go through the trouble of having a specific license, and are willing to pay somebody to come in on a rare occasion that a fixed gauge needs to be moved, but even fixed gauges need to be moved sometimes if they are tied into your production apparatus or assembly lines, other businesses need a response to go out there and move it in 15 minutes or 20 minutes, rather than have someone fly in from California.

So, under those circumstances, the facility will go through the extra effort of getting a specific license and training their people to take care of it, although as an approach it is a little odd if under some types of failures that have to be reported, if it is a specific gauge, it has to be phoned into NRC within 24 hours whereas the identical unit across the street under a general license it would have to be in writing to the manufacturer within

30 days.

The other comment I have is about the process, and there was a lot of discussion earlier about the laws and regulations, and it was sort of, in my opinion, an underlying assumption that once a regulation was written, that was sort of the end of the process.

I'd like to see some attention or emphasis placed on actual interpretations and policy as well. NRC does have its NUREGS and Guides for communicating policy and interpretations, but as an end-user -- perhaps this is not a fair comparison -- but I can go to the Websites of OSHA or DOT and I can look up letters and interpretation that other end-users around the country have written in -- this is my situation, this is the rule, how does it apply -- and there will be a copy of the agency's response. And as an end-user or licensee, I may, at my own peril, decide that my situation is the same or sufficiently different to call my Regional Office, but still there is a wealth of information out there. And so, it is not just enough to write the reg, how is it being implemented. In one region has this interpretation and practice, or perhaps in writing, how can folks find out about that? Thank you.

DR. RATHBUN: Jim, did you want to address that, some of the things you guys have that you have not been asked?

MR. SMITH: Are you asking this Jim, or that Jim?

DR. RATHBUN: Excuse me. Jim Smith.

MR. SMITH: Well, yes, we have identified the fact that there are some inconsistencies across the different regions in the way that they regulate materials. There's also a little bit of inconsistency across-the-board from Agreement States to the NRC. Trying to make sure that they are as consistent as possible, what they call the IMPEP process. We go out to make sure that everyone is reading from the same song sheet.

Unfortunately, there is always going to be some practice that is sort of a state-of-the-art, it's not someone that's following procedure, this is just the way they've always done it, so you may get some variation. We try to weed that out during the IMPEP process.

Additionally, those interpretations you are talking about -- we call them technical assistance -- you are not just asking for a special authorization, you are asking for a clarification of

regulations. Those are supposed to be provided to all of the Regions in generic fashion, get enough of the issue to put together -- they develop a guidance directive. Currently, 1556 is supposed to be that guidance, and you pick up the volume that applies to your program.

Again, lots of materials, very subjective. So it's going to be up to the individual licensee as to how they deal with it until more concrete guidance is developed for a particular item.

DR. RATHBUN: Does anybody else have anything more to add to that? Raeann? I don't want to put you on the spot, but you guys have a lot of knowledge in that area.

MS. SHANE: I think you've done a good job at capturing some of the quirks of our regulation that hopefully we can, as we go into Phase 2, maybe start to try to root those out. It's probably too soon to promise anything at this point.

DR. RATHBUN: Anybody else, any of our audience who knows of these things?

(No response.)

Any other general comments?

(No response.)

All right. Having eaten your lunch and

taken your nice walk, do we have anymore comments on what we might put into the guidance? It sounds like what you're telling us is to be consistent and look at how we could be more consistent and communicate that more effectively to the licensees.

Any other factors that have occurred to you that we might want to look at in the guidance development? Anybody on the panel want to say something they didn't get to say earlier on this?

(No response.)

All right. Well, we're going to work from Raeann's slides then, that will be in Phase 2, and we will go from there.

How about the process improvements? There were three areas we were looking for your advice on, and that was the use of the screening considerations, using safety goals consistently, and how would we get additional tools, data, methods, or what comments do we have on the adequacy of the existing ones? Do we have anything to add to that?

(No response.)

Okay. Now I guess we will move on into the fun stuff -- the safety goals. The first question Bob and Dennis had up on their slides, and it is just what are your general thoughts about the value of and

the need for safety goals? This is something that the Commission asked us to look at.

We are looking for feedback on whether we should or should not do it, and what is the value.

(No response.)

Where did you guys go for lunch?

MR. KOKAJKO: Pat, I notice that Felix Killar of NEI is here. He missed our morning program, and I think I see Dr. Judith Johnsrud here this afternoon. I'm not sure if you all have had a chance to look over the material yet or not.

It would be interesting to have your views on what you think might be appropriate in this area.

DR. RATHBUN: We can come back to you later, but if you want to speak now, that's fine. I'll give you my microphone.

QUESTION: I apologize for being unable to be here this morning. It's a very long trip and there were problems en route.

Judith Johnsrud, I am today representing Sierra Club and Pennsylvania Environmental Coalition on Nuclear Power.

I don't think it's possible to overemphasize the need for both safety goals and meeting those goals in every possible way. I found

myself thinking, as we all have, far more seriously in the past month and a half about safety needs with respect to risk assessment. Very frankly, although you have all been working on this issue now for at least a couple of years, I suspect that in the heart of hearts, each one of you is wondering if, in fact, we have thought seriously enough about what constitutes adequate risk assessment with respect to the management and control of radioactive materials and waste.

I recall attending a session sometime earlier this summer, I think it was, at which some of the discussion centered on the weight to be given to various incidents that are required to be reported to the Agency by its licensees and, as I recall, a private organization gave its approach which evidently, from the discussion, had been accepted by the Agency for the determination of the categories of significance for reported events upon which, in turn, to base risk analyses, among other uses.

And as I remember, those items that were reported most frequently were given a top category of concern whereas the infrequent events were to be given lesser consideration in regulatory control, and I think we all now have to consider much more seriously

the consequences of highly improbable events in making any kind of risk analysis.

I don't know if that really relates to your original question here or not.

DR. RATHBUN: Thank you. Felix, are you going to add to this conversation, or are you going to wait?

QUESTION: Unfortunately, I was in another meeting this morning, so I was not able to participate in this morning's session. So just kind of talking off-the-cuff from my general perspective on the aspect of safety goals, yes, we certainly value safety goals and think there should be safety goals established.

When you look at developing of safety goals, looking at the information here in your handout, giving an implicit answer that you're going to have safety goals that are going to be different between reactors, material licensees, and maybe even different between different types of material licensees, I'm not sure if that's the right thing to do or the wrong thing to do.

Safety goals are to protect a member of the public, the workers, the environment, and things along that line, and you should have a different level for this instance versus that instance. Now, what you

look at -- and maybe going to what Judith was just saying -- is look at the risk analysis and see what type of risks there are for that safety goal being exceeded by various different entities, and establish the parameters, safety requirements, to make sure you stay within that risk. And so a safety goal is a uniform safety rule across the Agency, but the application is based on the risk of that safety goal being exceeded based on the particular application.

So, when you're talking about safety goals, I think that's kind of my perspective, and that's just off-the-cuff.

Just looking at some of the insights of things that you have in here, I think there's probably some good stuff in here. I think that probably, after I get a chance to look at it some more, I may have some additional ideas or suggestions you may want to look at. I just gave it a quick scan in the last few minutes, and it looked reasonable.

DR. RATHBUN: Thank you. If you have more comments as you get a little more time to look through it, please step right up.

Dennis, is this something you want to respond to? Oh, I'm sorry -- Melanie. Excuse me.

QUESTION: Melanie Galloway. On the topic

of safety goals, I guess I have a question. I want to follow up on a statement that Dr. Bari had made on safety goals, stating in general that they would not likely be met. And I guess I'm wondering about the basis for that statement. I want to understand it a little bit further because I would think that while an individual facility or licensee might not be able to meet a given safety goal, that in the aggregate we would expect the licensees that fit the same category and apply to that safety goal, would indeed meet that safety goal.

And if I can recollect correctly -- it's been a few years since I've been in the reactor arena -- but I had thought that that was the consensus of the way reactors were meeting safety goals, that one individual reactor might not meet a given safety goal but, in the aggregate, the entire community of reactors would indeed be expected to meet the safety goal. And so I was wondering if there could be some expansion on that statement.

DR. BARI: Okay. The idea of a safety goal, as we mentioned, it really should be an aspiration, something that usually exceeds your reach, you would like to ideally make that goal, but in the regulations you would have limits that -- criteria

that licensees would be required to meet.

In the power reactor area, think of the core damage frequency -- of course, that's a subsidiary objective that people tend to be familiar with and relate to. The number there is 10^{-4} per year core damage, and some reactors meet that and other reactors do not, but the ones that do not meet them, are they unsafe? The answer is, I think not. But on the aggregate, you are probably right, that they tend to cluster around 10^{-4}, or perhaps a little bit lower than that.

MS. GALLOWAY: Am I to understand that when you made your statement, you were referring to individual licensees?

DR. BARI: That's correct.

MS. GALLOWAY: But that necessarily, in the aggregate, that indeed a safety goal would attempt to be met. That would be the goal of having a safety goal, that the industry or the category of licensees on the whole would meet the safety goal.

DR. BARI: Right.

MS. GALLOWAY: Okay. Thank you.

DR. RATHBUN: Dennis?

DR. DAMON: This is Dennis Damon. I would like to sort of concur with what Felix Killar said

about the -- you know, you raised the question or issue of should safety goals be the same, or should they be different in different areas, or what. And this is something that both Brookhaven, other people and I have thought about, and Dr. Bari pointed out in one of his slides, he said -- I believe the title of the slide was something like Issues to Consider, or something like that, and in that slide it starts to get into this process.

The general idea that I have absorbed from all this is you are not really focused on the source of the risk so much as you are focused on the characteristics of the persons at risk. I will give you an example of some of the things that come into defining different goals in different areas.

One is chronic exposure versus accident. It's not clear whether the risk that would be acceptable as a safety goal would be the same in both cases because a chronic exposure is incremental. It's much more under the control of the individual who is getting the exposure. He gets his badge read every month. He knows what he is getting. To a certain extent, he is in control of what he is exposed to whereas an accident often is something less under one's control. It happens to you. And some people

might be willing to accept more risk if it's chronic than if it was an accident.

Another one is the issue of voluntary or involuntary risk. The most obvious one is the general public in the vicinity of a facility. When the facility is put there, it is not voluntary, they are exposed to that risk. It is put there and they are exposed to it whereas if you choose to work at the facility, then at least to that degree you are voluntary, and maybe, therefore, the risk might -- one argument is that if you are a worker, you should be willing to accept more risk than the person who had no choice.

Then there is the issue that Dr. Johnsrud alluded to, which is should acceptability of risk -- should safety goals and the acceptable level of them -- should it be sort of flat with risk. In other words, the risk being the expected consequence or likelihood-x-consequence, that being -- say, we define a risk measure equal to likelihood integrated over consequences -- should that be the same if you're talking about high consequence events. In other words, I talk about two events. One is 10 times the consequences of the other, but it is 10 times less likely, so they have equal risk. Should the

acceptable level of risk for those two different situations be the same? Some people say no. They are what they call "risk averse". They say you should avoid the high-consequence event even more than the low one, even though the risk is the same.

My own view on that is that there are situations -- it depends upon the measure of risk you are using, but if the measure of risk is the same, my own personal view is I'm not risk-averse. I say it doesn't matter if you kill ten people one at a time, or ten people at one time -- you know, I am not risk-averse. I say it should be flat. But it is an issue. Some people think it should be tilted, and you should avoid the high-consequence thing more.

Another one is benefit. Some situations are such that the person exposed to the risk is also the person who benefits from the device or the thing that has it. For example, the smoke detector in your home has a radioactive material in it, but you benefit from having that smoke detector in there. And so, in that case, the tradeoff -- there is actually a tradeoff between risk and benefit. This happens in the medical field, but we don't regulate that tradeoff. But in other situations, there's actually a tradeoff there. You accept this risk and you get

this benefit. So the level of acceptable risk might be different in that situation.

So, there's all these factors like that so that it doesn't -- what I'm trying to say here is that it doesn't really depend on the device or the thing which is causing the risk but, rather, the person who is exposed and the characteristics of them, the degree to which they control the risk, the degree to which the benefit from it, and factors like that. Those are the ones we are thinking about influence what is acceptable to them or not, but not what the source of the risk was.

MR. MUBAYI: Just to amplify on a couple of things that Dennis just alluded to, one was in the question asked by the gentleman about the fact of having a uniform approach to safety goals across the Agency, or at least in specific parts. I think one can have a uniform approach, but as Dennis alluded to, the risk metric that you would use might be different because it is influenced by the kind of activity that occurs.

The risk metric that we have, for example, in the reactors where there are two safety goals that have been around for about 15 years, one relates to the likelihood of prompt fatality, which is a very

large release of radioactive material, and the other relates to likelihood of latent cancer fatalities with the linear, no-threshold dose response can occur, any level of exposure. So the risk metric for facilities where you have small amounts of material, you are not likely to benefit very much by a prompt or early fatality goal because you don't have -- that's a threshold-dependent exposure, and you are not ever likely to get -- or you are not going to get a level of exposure, so the metric may be different, but we would still strive to have a uniform goal.

The other was the issue raised about the high-consequence, low-probability releases or accidents. Just to remind us, in the reactor arena where risk has been calculated for a long time and the risk studies done later, NUREG 1150 and so on, most of the regulation is devoted towards precisely preventing accidents that have a very low likelihood or frequency of occurrence, but have high consequences. Those really dominate the risk and that's where most of our regulatory attention is directed.

DR. RATHBUN: Okay. I'd like to move a little bit further now into the safe goals, and see if you all can suggest, in addition to what you've just heard, any other applications of safety goals and/or

quantitative health objectives in regulating reactors that we might want to consider as we develop these for NMSS, if anything would come to your mind that we have not addressed in the reactor arena.

And I don't know how familiar you are with Reg Guide 1.174, but are there any insights from that document that you might want to bring to our attention, or anybody on the panel want to bring up anything about those. Vinod.

MR. MUBAYI: It's a big discussion. I don't want to enter that arena here, but Reg Guide 1.174 defines a process for doing risk-informed regulation, and I think one area that might be useful to look at is something that Joe Murphy alluded to in the morning, which is that when you come in for any kind of change to your current licensing basis, any kind of change that you want to make, and we do a risk evaluation and we evaluate the delta change in risk based on the proposal, then they have some suggested numbers for this delta change at which you will either accept it or you will reject it, or you will put it in a box for further re-examination, look at it more.

I think what might be useful here, if we move towards a risk-informed regulation, is to do some of these assessments where these delta changes to risk

would happen because of some action or the other, and see if the recommendations that are in Reg Guide 1.174 would also work in this arena and would more or less be a feasible way to go about doing business because it is a process, and that describes the process. And I think we would have to make a few tests to see how it worked here.

DR. RATHBUN: Thank you. The next question is for NRC licensees, but I think there is only one here, maybe two. But, nevertheless, for NRC licensees, have there been cases where regulatory requirement seems unnecessarily burdensome? Could qualitative safety goals or quantitative objectives help identify equally safe alternatives?

Do you want to give that a try, Felix? We know you, see, so that's the downside.

QUESTION: Felix Killar. What's interesting, we always ask our members are there regulatory guides or regulatory requirements that are a burden, and we can help the NRC reduce them. And they come back and say, well, we're working with it. We haven't identified any. And, also, to the second point, typically, the licensee has the obligation or ability to provide whatever method or process they use to demonstrate the safety of that facility. There's

nothing that dictates that you have to use this method, or what have you, to demonstrate that application, that process. So, right now the licensee does have the ability to come in with various alternatives and come up with what they think is best. Now, they have to defend that accordingly, and so right now I would say the process isn't broke, so we don't need to fix it. I don't know if Dennis will agree with me on that.

DR. RATHBUN: Did you want to add anything to that question, Dennis, that maybe I didn't pick up?

DR. DAMON: No, I think, you know, we're just looking for feedback. That's -- I don't know how to put this -- this is kind of an example of screening criteria. This is another way of saying what the screening criteria are about. One way to characterize it is that it's a way for you to clarify what you're going to use the risk information for. Another way of putting it is, if you come to an area and you run down the screening criteria, and the screening criteria talk about things like burden reduction and staff efficiency, and if your answer to the question is, well, staff seems pretty efficient to me, the licensee doesn't consider what's going on burdensome. We have very high confidence that the risk is low enough, even

though we don't have a number for it. Okay. Then the answer is, you don't need to do a risk assessment. There's no use for it. So, in other words, it's just like Felix said, this area is not broke so don't try to fix it, and that's what those screening criteria are all about, basically, is to do that. But if there had been a large audience, what we were fishing for here is where are some areas where people think they do have a burden, or that things could be improved.

DR. RATHBUN: All right. now let's shift to the other side of the equation and say, do you know of any materials or waste device, practice or facility where there is a question as to whether it is safe enough, or maybe too safe? So, let's take it from the other side now.

MR. KILLAR: Certainly, from the industry perspective, Revised Part 35 did not go far enough as far as reducing the burden. Certainly, for the diagnostic purposes, the risk to the patient has been minimal, and where the NRC -- I can't remember who mentioned this -- said that the NRC has no responsibility as far as the medical application. The NRC has extended itself into the medical application in Part 35, and they tried to back out with revision to Part 35. They have not accomplished that. So,

certainly from the perspective of the medical community, Part 35 still has not achieved the end result that they felt is reasonable.

I might want to pick up something else -- and, Dennis, help me out here a little bit -- going back to Reg Guide 1.174 and doing the risk analysis and stuff, we don't have the sophistication in our models and tools for our material licensees, in most cases, to do the type analysis that are done in 1.174 for the reactors. We don't have the risk analysis. We don't have the firm numbers.

Most of our stuff is more from physical characteristics, processing, handling and techniques rather than statistical type data and what have you. And so it's kind of hard for us to use 1.174 in our industry either from the aspect of a fuel site facility, a Part 70 license, or even from a Part 35 licensee. We don't have the baselines and risk analysis. Even for the Part 70 facilities, as we go through and do our integrated safety assessments, they are not going to give us those type PRAs that exist over on the reactor side. We're going to have what I would call qualitative type things rather than quantitative type numbers to demonstrate that we're comfortable with the safety of our facilities.

DR. RATHBUN: Thank you. That's really important feedback because I remember we were specifically directed by the Commission to take a look at that. Any other comments on this area -- too safe? Not safe enough?

QUESTION: Judith Johnsrud again. We have a continuing concern that there is insufficient attention given to combined impacts, if you will, particularly with respect to the impacts of low-dose, chronic low-dose irradiation upon the immune system. The subject remains in controversy in the radiation safety community. But in our view, there is public interest imperative to exercise what is generally know as the pre-cautionary principle which, in essence, says when in doubt, don't, and in this instance that would be, when in doubt, come down on the side of excessive safety and regulation as opposed to relaxed.

We are particularly concerned that the Agency still does not take into account the synergistic impacts between those doses attributable to a nuclear facility, and the relationship to other contaminants in the biosystem which, taken together, the multiple sources of potential hazard may be substantially greater for the individual recipient. These are not factored into standards, and we

certainly believe they should be, recognizing that these are very difficult studies to undertake and to ascertain with any exactitude.

DR. RATHBUN: Okay. This is a long question -- Dennis wrote it. Societal risk is typically measured a metric something like the population dose for a scenario times probability integrated over all possible scenarios for a facility, and that would be a measure of total risk.

What level of such societal risk for an application is clearly low enough?

The reactor safety goal compared the risk of reactors to the risk of other means of generating electricity. This model does not seem to be applicable to many cases in NMSS. What level of societal risk is clearly low enough? How low is low enough?

Dennis, did you want to tell them?

DR. DAMON: Well, I'm interested in what people may have thought about this. I mean, we do this thing in society -- that is, we have things out there like automobiles and all the other things that impose risks on other people, and you kind of have to look at the whole picture. In other words, what's the total risk from some facility, or allowing some type

of device or equipment to be used in society? The question then becomes, what level is appropriate?

It's obvious that there's kind of a risk-benefit tradeoff on a societal level going on there. We allow all kinds of things to go on in our society, but if you look at the total -- how do I put this -- if you look at total accident fatalities in our country -- let's not get into other things, but just accident fatalities, there are relatively few compared to total deaths. It's something like 90,000 accidental fatalities and, I don't know, 2.8 million people die every year. So, in a way, that's kind of a measure at the total level of how much risk our society accepts from all the stuff we do. But the question becomes, if you're talking about a particular thing, a facility or a benefit you're getting of some kind from something, and it has risk associated with it, is there some level at which the risk is clearly very, very low?

See, it's not like the -- the individual risk measure is easier to perceive there. What they do there is they compare it to your average risk of -- say, there's a risk of accidently being killed by the thing, then you can compare it to the risk of an individual being accidentally being killed in general,

which is a low number, and compare the risk that they are undergoing due to whatever the thing is. But when you're talking about societally, you're adding everything up, and then the question becomes, what do you compare that to? And one possible answer is you compare it somehow to the benefit society gets from whatever this thing is.

Another answer is, you compare it to the total -- actually, the reactor safety goal people do this, too, but only qualitatively. They say risks of a nuclear reactor should be a small fraction of total societal risk. Well, that's comparing total-to-total, but I'm not sure that's going to be that useful when you go to some of the things that are in NMSS. And so we are looking for what do you compare the total societal risk to for a facility, and then say is this too high, or is it low enough, remembering that there's always this individual risk goal. And the individual risk goal will have -- presumably, you will be trying to meet that already.

So, supposing -- I'll give an example. Is waste -- it comes up in decommissioning and waste disposal. You have material that has some hazard associated with it, and it's either out there or it's in a waste facility, but you've already made a

determination that the levels are low enough that no individual would ever get a significant dose out of it, they would all get very low dose, at the most. That's maybe true for that facility, but there's a difference between dumping that waste in Manhattan and dumping that waste in the desert in Utah. The difference is there's no people in the desert in Utah to get exposed to it. So, the societal risk would be very low whereas there are people in Manhattan, they will get the dose. So, even though in both cases the individual who gets the dose gets the same low dose, there's a big difference between those two situations. So, if we don't tell our regulatory agency that they need to reduce societal risk, then we're not following common sense here. So, I say there is a need to reduce societal risk. Then the question becomes, how far is far enough for societal risk? I'll ask it a different way. When do you think a societal risk is very low compared to what?

DR. RATHBUN: Felix?

MR. KILLAR: Basically, I think what you're talking here is philosophy versus actual technical numbers because there is no technical number that everybody will agree to. I could sit here and say that the risk of this operation, whether it be a

nuclear power plant, fuel cycle facility, or a hospital, has a certain amount of risk to me and I'm willing to accept that. Someone else will look at those same risks and say, no, they won't accept that.

And so, once again, for personal risk, different people have risk levels. Walt Schwenk's example, he thinks it's perfectly all right to jump out of a well-operating airplane and parachute down to the ground. I've never wanted to jump out of a perfectly-operating airplane, I'd rather ride that plane to the ground.

So, in the mind of the individual, it's what risk they are willing to accept and what risk they are not. But then when you start talking about societal risk, you are looking at society as a whole, and society is everybody in this room as well as everybody that's in this community, as well as everybody that's in this State, and then it goes to everybody across the country, and across the country, the perspective of the country provides what the societal risk will be. And they don't necessarily weigh one thing the same as everything else.

I know we've had a number of studies where we talked to people across the country about the risk of nuclear facilities versus the risk of an airplane,

or the risk of smoking, or things on that line, and when we've done numbers, like you suggested, and said, okay, this is the risk of crashing an airplane, this is the risk of dying from smoking, this is the risk of living next to a nuclear power plant, and you find that the risk of a nuclear power plant is the lowest amongst all those, they'll say, gee, I didn't realize the risk of flying was so hazardous, because it's something that they've done every day, that they were comfortable with, but if you look at the actual number and the risk value and stuff, you know, the numbers are considerably different. It's the perception of the individual of the risk, and it has nothing to do with the technical numbers of it. So, I don't think you can come up with a number for societal risk. Certainly, as an individual or as an organization, you can come up with a number you feel is supportive, and industry will come in and say, yeah, we agree with that, and Judith will come in and say that, well, it's a good number, maybe you need to add these things in to provide some additional levels of conservatism, and these are our perspectives, but it is up to the country as a whole to determine what they want to say is a societal risk.

I don't know if I've answered your

question or I've muddied up the waters more.

DR. JOHNSRUD: Your comments, Dennis, don't specifically list the difference between an area of low population and an area of high population density. From my training as a geographer, I would caution that there are many areas of low population that nonetheless are extremely dependent upon a scarce resource such as water, and the contamination of that very scarce resource is of perhaps a higher concern for the population within such an area.

And so there is a set of considerations there that I think all too often we tend to ignore, those of us who live in the humid East, you know, compared to those who live in a desert terrain, and we are quite happy to place undesirable objects for disposal in areas that are perceived to be low in population and therefore expendable.

There is one other factor. At a conference in Canada two or three years ago -- this was of nuclear waste regulators -- there was substantial discussion of the need for consideration of forms of life other than human beings. It is my understanding that DOE has undertaken substantial biota studies with respect to environmental management and cleanup, and perhaps they are occurring within the

NRC for consideration in your standard-setting. If so, I am not aware of it, and I would be delighted to hear that they are.

DR. RATHBUN: Okay. Do we have any other comments on this area? Those were good points.

(No response.)

I'm about to move on now to future plans, so at this point in time, I just want to make sure that everybody who has wanted to contribute to the material that we discussed earlier has had that chance.

(No response.)

All right. An issue of great importance to us as we move into Phase 2 is what are the areas that we should look at initially. Are there areas that come to your mind that we should immediately begin to work on or work on earliest?

DR. JOHNSRUD: Judith Johnsrud again. I think I've just named the ones that I believe the Agency very much needs to take into consideration, particularly the nonfatal, noncancer, low-dose impacts on human health. And the research is ongoing, and we are learning more and more about low-dose effects that have previously been able to be ignored.

The grand battle over the linear

hypothesis continues, but I really don't anticipate that it is likely to be abandoned in the near future. Is anybody nodding yes or shaking heads no up there? And, indeed, the time has come for examination of the synergies with other contaminants and the impacts. Until six or seven weeks ago, it didn't really seriously occur to many of us that we needed to consider the impacts upon the immune system from a radiation exposure with respect to the ability of a victim of, oh, anthrax or smallpox or plague, to be able to recover from that illness, but I rather doubt that we have very good data on such a matter which now is a reality among us.

DR. DAMON: Let me ask Dr. Johnsrud about the synergies thing. That does raise an interesting thing. I really do not, myself, know very much about chemical carcinogenesis, or whatever you call it, but is there an issue there of -- I mean, my impression is this, that there -- like, you take radiation, say, low linear energy transfer radiation, the effect of that is basically the same in -- how do I put it -- is basically -- produces one type of effect on the cells and produces oxygen radicals and so on and so forth, that you can determine the type of effects that those things have. But suppose you have two things, you

have a chemical which is different from the oxygen radicals that the radiation produces, and you have radiation. Are you saying that there's like the kind of mutations or other effects that the particular chemical might be synergistic with the ones that the radiation does, so that you get somehow -- you know what I mean -- that kind of -- is that what you're talking about?

DR. JOHNSRUD: You're asking "the" research question. Yes, indeed. And it's not easy to assess, there's no question about that. But, nonetheless, we do live in a sort of soup of a great variety of contaminants that are released into the biosystem that may, indeed, have variable impacts upon various sectors of the total exposed population, the very young as opposed to the healthy adult standard man, for instance.

I really don't believe that the Agency, or your brother agencies, have gone very far in such assessments, but the consequences to human health, or to the survival and the health of other flora and fauna upon which, incidentally, we may depend for our human survivability. All of these matters that are legitimately of need to be examined by the Agency and taken into consideration.

DR. DAMON: That reminds me of something, and don't quote me on this, but if I remember, the BEIR reports, when they were trying to estimate cancer caused by radon, I believe somebody asserted that actually what they were determining was the synergistic effect between smoking and radon exposure. It was actually most of the risk that was occurring were in the smokers, and it was some kind of synergism was going on there.

DR. JOHNSRUD: That relationship between cigarette smoking on the part of uranium miners and the radon from the mines, as I recall, was utilized in order to disallow compensations early on, and -- oh, gosh, this goes back to perhaps back in the Lyndon Johnson Administration -- when that concern was set aside as an excuse for not setting more restrictive standards for the workers.

Now, subsequently -- or about the same time, actually -- the work was done on cigarette smoking and polonium-210 by, as I recall, Ted Radford, who has died just this past week, who had chaired BEIR-3, and that relationship, I believe, has held in the literature since.

DR. RATHBUN: Do you have anymore questions for her, Dennis?

DR. DAMON: No.

DR. RATHBUN: All right. At this point --

MR. KILLAR: Could I just make one statement? There has been some work done, very much limited, but one of the issues that has come up is a question of hormesis (phonetic). Radiation as well as a damaging agent has been limited to and possibly synergistic effects, as Dr. Johnsrud has indicated, and also provide an enhancement to the immune system and improved the immune system, some aspects of it. This has been questioned, this has been challenged, and it continues to be questioned and challenged. So, it's not something that is greatly supported, but also at the same time there is enough peer evidence to indicate that there is certain advancements and improvements due to -- things along that line.

We have looked -- there have been some studies looking at the synergistics effects of various chemicals and radiation. The problem is that down in the levels that we're talking about, these low levels of radiation and also low levels of the chemicals, it's hard to trace something determined through epidemiology studies that the effects are there or there are sporaze, or whether they are true or false positives, things along that line. There just isn't

enough, and we don't have the techniques to necessarily demonstrate all the things that you need to demonstrate to say definitely one way or the other.

DR. JOHNSRUD: If I may follow through, the Department of Energy has undertaken a fairly substantial research project on low-dose impacts, which I assume that all of you are acquainted with, and my reading of the interim reports of their researchers mostly cellular and molecular studies are not epidemiological, are confirming that far more work on low-dose impacts is needed, but I haven't seen a great deal of confirmation in that research of hormesis. There may be some instances in which an irradiation is, indeed, beneficial as we consider it to be in medical practice certainly, but that takes us back to the fundamental of radiation protection, of the opportunity for choice, for decisionmaking such that the risk will be less than the benefit, and that is an individual choice in each instance.

DR. RATHBUN: Okay. If there are no other questions, I think I'm going to turn this thing back now to Lawrence, but I'll sit right here with you.

MR. KOKAJKO: I'd like to thank all of you for participating today. We view feedback from our stakeholders, both public and the NRC, to be a very

important component of implementing the case study plan. Your input regarding the case studies and development of safety goals is important to understanding where we are on-track and what areas we may need to give further thought. And I have appreciated your views in regard to the screening process, its guidance development, regulatory process improvements, including tools, methods and data, commentary, and your thoughts on safety goal development.

I don't think I have heard anyone negate or otherwise dismiss the idea of developing safety goals, that you think they could be feasible and that they may be worthwhile to pursue. And I did hear some things for process improvements that we may want to consider, and we will look into that in our next steps.

I also didn't hear today, this morning as well as this afternoon, that we should cease this activity, that there is some value to be gained from doing it, and that we should continue this effort.

Before I finish today, I want to note that we did start this back in April of 2000, and as we assess where we need to go in regard to this work toward the end of this year and next, we hope to have

future meetings as we progress.

If you signed the attendance sheet -- and I encourage you to do so if you have not -- we can contact you and invite you to any future meetings that we might hold.

We hope to issue a final case study report as an integrated report, as well as the screening considerations guidance document at the end of the calendar year. However, I should point out that recent events may mandate a more drawn-out schedule than what we originally thought, and we will have to adjust our activities and schedules as Agency priorities dictate, especially in light of September 11th.

As I mentioned in my opening remarks, we are interested in feedback on your views of how this meeting went and any feedback forms you fill out we would greatly appreciate hearing from you. They are in the lobby area, and you can either mail them in or provide them to a member of our Risk Task Group.

I'd also like to thank today those involved in coordinating and presenting this meeting today, especially our Deputy Director, Margaret Federline, our Facilitator, Dr. Patricia Rathbun. I'd also like to note that the administrative support

provided by Jessica Shin, who is a third-year chemical engineering student at the University of Maryland, has been outstanding, I might add. Without her help, we wouldn't have been able to put this on. Also, Marissa Bailey, Raeann Shane, James Danna, James Smith, Dr. Dennis Damon, and Dr. Robert Bari, and Dr. Vinod Mubayi, and our newest oldest member of the Risk Task Group, Christiana Lui.

I'd also like to thank our subject matter experts who have supported us throughout the past year: Jack Parrot, Andrew Persinko, Mike Layton, John Lusher, Brian Smith, Earl Easton, and Dr. Mahendra Shah, Michael Waters, and I hope I haven't forgotten anyone else. Your help was invaluable and we do thank you.

I'd like to seek your comments one more time.

(No response.)

Hearing none, hearing no further comments or questions, this meeting is adjourned. Thank you very much for your participation.

(Whereupon, at 2:40 p.m., the meeting was concluded.)