UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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PUBLIC WORKSHOP - PRIORITIZING NUCLEAR

MATERIALS REGULATORY APPLICATIONS FOR

RISK-INFORMED APPROACHES

Embassy Suites Hotel

Chevy Chase Rooms 1 and 2

4300 Military Road, NW

Washington, DC 20015

Tuesday, April 25, 2000

The above-entitled workshop commenced, pursuant to notice, at 9:15 a.m.

P R O C E E D I N G S

[9:15 a.m.]

MR. CAMERON: Good morning everybody. My name is Chip Cameron. I'm the Special Counsel for Public Liaison at the Nuclear Regulatory Commission and I'd like to welcome you to the NRC's public workshop on risk assessment in the NRC nuclear materials program. I briefly wanted to cover three topics with you before we started and one is the objectives of the workshop; the second is the format and, also, the ground rules for the workshop; and, thirdly, I'd like to just go over the agenda and do an agenda check with you before we begin.

In terms of the objectives, the NRC wants to inform you of the NRC efforts to use risk assessment methods in the regulation of nuclear materials and waste disposal, but most importantly the NRC wants to solicit your recommendations and comments on how the NRC should proceed in the future with incorporating risk information into our regulatory program; and, also, in addressing risk management issues, such as safety goal issues.

And in terms of our format for today, we've invited a group of knowledgeable participants that represent the broad spectrum of interest that might be affected by the NRC program or concerned about the NRC program to use risk assessment in its regulatory efforts. And some of you around the table represent specific regulated activities in industries; others of you are from federal agencies that have experience in risk assessment or that regulate various

activities of concern, also, to the NRC. We have representatives from the citizen and environmental group community with us today, as well as a representative from the Agreement States and Organization of Agreement States with us, and we have experts on risk from the consultant world and, also, from the professional societies. And in a few minutes, we'll give you an opportunity to introduce yourselves.

There are NRC staff here today, both around the table and, also, in the audience from all of our major programs areas in the materials world, and they'll be speaking from time to time. They are here to provide you with information, to listen to what you have to say, and to explore your recommendations with you.

We're using a round table discussion, so that we cannot only listen to what each one of you has to say on these issues, but, also, to get the reaction and have a discussion of your colleagues around the table on your comments.

The ground rules are very simple. If you want to speak, please take -- these are called name tents, which I probably right this moment figured out why, but I've always accepted it, as a matter of faith, the name tent. If you want to talk, just turn it up like this and that will allow me to keep track of who wants to speak; and it, also, saves you the trouble of always having to try to raise your hand, to get my attention; and it helps to contribute to this one person at a time speaking and that will allow our stenographer, Mike over there, to get a clean copy of the transcript for us. And at least at the beginning of our session,

just state your name before you talk and I think Mike will be able to keep track of where you are at the table, so we should be able to dispense with that after the first session.

And we do have a lot to cover and we have a lot of expertise and knowledge around the table. I would just ask you to use a certain amount of economy, so to speak, in your remarks, so that we can make sure that we do here from everybody today. I may not take the cards -- the name tents in order that they are raised, so that we can try to follow a discussion thread on a particular topic, rather than just jumping from topic to topic.

The focus of the discussion is going to be around the table, but we, also, want to hear from those of you in the audience. So, after each major discussion -- agenda item, we will go out to you for your comment.

In terms of the agenda, we want to start by giving you a context on what the NRC efforts are, in regard to use of risk assessment and risk information. And Marty Virgilio, who is the Deputy Director of Office of Nuclear Materials Safety and Safeguards, is going to give us an overview presentation at 9:15 and then we'll have the question and answer session for Marty, to make sure that what the NRC is doing, what the NRC needs, in terms of input, is clear to everybody.

The 9:45 session today is our first real discussion period and we're going to ask for all of your perspectives on the wisdom and feasibility of using risk information. And Stacy Rosenberg, who is over here to my left, will be

introducing that particular sessions with a few remarks, as well as other sessions that we do today. You might have noticed from the so-called SECY paper on this subject, the NRC stated what its objectives were in trying to use risk information. You may or may not agree with those objectives and during this perspective session, we'd like to hear your comment on issues like that.

After that, we'll take a break. When we come back from the break, NRC has three proposed screening criteria on how to select the areas to be more risk informed. We would like to hear your comments on those criteria, as well as additional criteria that you may think might be useful here.

We'll then break for lunch. One-fifteen, we're going to come back to a continuation of the screening criteria discussion; but, in that session, we want to be more focused on how those criteria might apply to particular areas of regulation that are covered in the materials and waste disposal program. And Marty is going to lay a lot of this out for you. But, you'll notice again in the SECY paper on this subject, that there were four categories of activities that were identified and we'll go through those in further detail.

The last topic under this, what we've been calling session one, use of risk assessment methodologies, use of risk information, is to see if -- going to be to see if we can develop some recommendations on how the NRC should proceed from this point forward.

We'll then take a break and move into our second major discussion topic for this workshop, which is the whole idea of safety goals. And, again, we

will have a member of the NRC staff, Gary Holahan will set the framework for you and talk about lessons learned from the development of the reactor safety, though it may be instructive for the materials world.

We'll then close off today with a discussion of what is a safety goal; do we need them; how should they be used in NRC regulation and we'll do some agenda setting for tomorrow's session. And tomorrow, we're going to go through various safety goal topics.

I just would remind you that there were questions set out in the Federal Register notice, that you all should have, about these topics. And we're not going to go through those question by question, because we think that the answers to those questions will develop through the discussion of the agenda items; but, we will check back in specifically on each of those questions, to see if we've covered them sufficiently.

Are there any questions on the agenda, at this point?

[No response.]

MR. CAMERON: Okay. There may be issues that we haven't anticipated, that I will keep track of over here on the parking lot. There may be issues that come up during the discussion of a particular agenda item that don't really fit squarely within that agenda item, and we'll defer those to a future agenda item in this workshop. And we'll, also, note those over there. I will, also, use the flip charts, to keep track of any action items or recommendations that the group develops.

And what I'd like to do now is to go around and have everybody introduce themselves. So, if you could just tell us your name, your affiliation, and what your -- just sort of brief few sentences of your interest or concern in this particular topic. And I will start with Barabara to my right. Barabara?

MS. HAMRICK: I'm Barabara Hamrick. I work for the California Radiologic Health Branch. I'm a health physicist there. I'm here actually in place of Ed Bailey, chief of our program, representing the Organization of Agreement States. And our interest, of course, in any changes to the NRC's regulatory scheme is the impact it would have on our programs and how we would be required to adjust to any new philosophical structure.

MR. CAMERON: These microphones may be directional, so that we'll have to test them out to see how well they pickup from a distance. But, go ahead, Andy.

MR. WALLO: I'm Andy Wallo. I'm with the U.S. Department of Energy. I'm Director of Air, Water and Radiation Division. We develop environmental policy and DOE's standards for protection of the public and environment in the radiation areas. And our interests are fairly broad in this assessment. We have used and developed various tools, in fact, needs for doing various forms of uncertainties analysis and try to use them generally in our application of our requirements, to the extent possible. And we've worked on a number of interagency efforts with EPA, DOD, in the area of risk analysis.

MR. FLACK: My name is John Flack. I'm from the Nuclear

Regulatory Commission, the Office of Nuclear Materials Safety and Safeguards. I'm head of a risk group within the office and primarily support a workshop, in the sense of striking whatever insights we can gather from today and tomorrow's meeting; walk through those insights, ideas, as we try to develop and use risk in the office, to provide value to our decision-making process. Next week, we will go before the ACRS-ACNW, ACNW, to discuss these workshop results and so we're very much interested hearing from everyone. And I do have everything transcribed, so please feel free to jump in and put in your thoughts on the matter.

DR. LULL: I'm Robert Lull. I'm a practicing nuclear medicine physician at San Francisco General Hospital, part of the University of California, San Francisco, so I have an interest in the medical impacts -- the impacts on our medical programs. As a physician, we, also, have a great deal of concern about health impacts of radiation. We deal with risk benefit, cost ratios all the time in medicine and it's becoming more important all the time. I, also, have a background in -- in my days when I was in the Army medical department, where I consulted with the U.S. Service, the Weapons School, dealing with and lecturing on the medical effects of nuclear weapons accidents and cleaning up and all that sort of issues, very much related to risk benefit, also.

I'm currently a California Commissioner with Southwestern Radioactive Waste Compact and so we, also, have a lot of interest in some of the outcome of this, with regard to disposal of low-level radioactive waste. Thank you.

MR. FORTKAMP: My name is Jonathan Fortkamp. I'm the corporate radiation safety officer for ABB Automation. I'm here to represent one segment of materials licensees, namely manufacturers, distributors. We manufacture and distribute industrial paging devices.

MR. EISENBERG: My name is Norman Eisenberg. I'm with the NRC Staff through the beginning of February, at which time I retired. I'm currently pursuing a career in consulting and teaching. I'm currently teaching a course in environmental risk assessment at the University of Maryland. I have about 25 years experience in materials risk and I have a continuing interest in the subject.

MR. BROWN: My name is Roy Brown. I'm Director of Regulatory Compliance for Mallinckrodt. Mallinckrodt is a radiopharmaceutical manufacturer, based in St. Louis. I'm, also, here today representing the Council on Radio nuclides and Radiopharmaceutical, CORAR. I'm currently the chairman of CORAR. CORAR is a trade association for radiopharmaceutical manufacturers and manufacturers of medical radioisotopes. Obviously, my interest here today is to see if risk informed process apply to the materials facility. It's been used on the reactor side with some success and I'm anxious to see it applied to the materials side.

MR. WANGLER: My name is Michael Wangler. I'm the Director of the Package Safety Approval Program within the Department of Energy. That program includes the internal certifying authority for Type B package of

radioactive materials. As you well know, the transportation presents a unique challenge to regulation and to risk. To put it in terms that some of my fixed facility colleagues understand, I refer to transportation as a rolling facility. And my interest, our interest primarily in a forum such as this is the application -- or a greater approach toward the application of compliance assurance and quality assurance programs, to ensure that we're making the maximum effective use of the limited resources that we have, in ensuring compliance with internal and external --

MR. BERNERO: My name is Bob Bernero. I worked at the U.S. NRC for many years, culminating in my last six years as Director of the Office of Computer Materials Safety Safeguards. I retired from that position five years ago and I have been engaged in consulting with nuclear fuel cycle facilities and the Department of Energy, with regard to waste management.

MR. KARHNAK: John Karhnak with the Environmental Protection Agency. I've worked in a number of different areas with EPA dealing with radiation and working with the Department of Energy, as well as the Nuclear Regulatory Commission. Personally, I'm interested in this subject of risk from several perspectives. One is that we look at risk assessment, we look at risk policy, and then we all have to pull it all together in our risk management approach for each different agencies, and sometimes those are a little bit different. One of the things that, also, fascinates me is a perception of risk and how people perceive it, as compared to some of the science and some of the

data that is associated with it.

MR. KILLAR: Good morning, I'm Felix Killar with the Nuclear Energy Institute. I'm the Director of Material Licensees and Nuclear Insurance. In this position, I have responsibilities for all the non-reactor programs at NEI. Risk is -- risk informed is one of our top priorities, as most of you are aware in the industry, and very active with the NRC on the reactor side for our 50 states, in putting risk informed regulations into that effect. We're the team that developed that. We sort of like to see the same type of thing apply on the materials licensee side.

I guess one of the concerns, too, that we have is the understanding of this and the paradigm shift that has to go through NRC's mind, in order to implement these. And two examples of this is the Part 35 rulemaking, while we derive a lot of good information from the staff on the risk involved with therapeutic versus diagnostic medication, what we found is that the staff still did not go forward and truly implement what we considered a risk informed rule. It was more of a consequence to the rule.

And we have a similar experience in Part 70 rulemaking, where we're moving to a risk informed rule for Part 70 facilities; yet in a recent workshop we had with the staff last week, they are more concerned about the total consequence of adverse consequences, rather than the risk involved. So, where you may have a large consequence of minimal frequency, the risk is small; so, again, look at the total package. We're not sure that the staff are

really attuned with getting into risk informed, if you're still geared to the consequence -- that's one of our concerns.

The second concern is that we frequently applaud the NRC putting together an office of risk informed or risk regulation on the materials side and John Flack taking over. I understand John is not going to be here much longer. John succeeded Charlie Hahn, who originally started the office, himself, and less than six months we're going to go through a second person, moving on to the third, and this doesn't give signals to the industry that the NRC is really serious about moving this thing forward.

DR. PAVLOVA: Good morning. My name is Maria Pavlova. I apologize that I put my back towards you, but my grandmother used to say that women are like flowers, they have no backs. I came originally from Bulgaria and got my medical education and physician from the -- and my Ph.D. in drugs. So, the issues regarding risk assessment, particularly risk communication and perception, as John said, and involvement of communities is very close to my heart, coming from a place that right now the information is -- was not existing.

I was in the National Laboratory, doing research in the medical department -- I joined EPA, worked with John at research and development, and it was very interesting here, developing of the risk assessment as a science, although to me, I think it's still kind of voodoo for us. I think we all know it exists. And I had the opportunity to chair an interagency committee on environmental -- so this way we early addressed the risk assessment and the risk communication

as a way to get into the evolvement into the risk management.

I had a lot of publications and workshops on the role of government and non-government organizations in the risk assessment and communication. How do we do? Do most people think in the direction of effectiveness of what we do? Probably the first case, that is the -- so, I really did it the hard way, how people -- what terribly surprised me in the risk -- don't trust the government. And I'll never forget my first lesson when I went to go to a community, introduced myself, my position, and is there coming from the other world, behind the Iron Curtain. And the moment I said I worked for EPA, my real estate value dropped 50 percent. And it took a long time, as you know, and it has to be an early, sustained relationship, an honest relationship with stakeholders, as we call them.

So, this is my school for risk assessment and risk communication and five yeras ago, I joined the Department of Energy. I am at the Office of Health Studies, so we -- I'm particularly with the Office of Occupational Medicine and Medical Surveillance. But, we do have projects with Russia, Chernobyl, Japan, North Carolina, and so now the issue of comprehensive health risk communication, using the risk as a science, will help these scenarios.

And I, also, am a member of the interagency subcommittee on risk assessment and risk communication. We did have four years ago some -- communicating risk communication and we are in the process of a new symposium in November, here in Bethesday, on international risk communication. So, if you don't mind, I will call your names and we'll invite you

to come and join us. Thank you.

MR. VIRGILIO: Good morning. My name is Marty Virgilio and I am currently serving as the Deputy Director of NRC's Office of Nuclear Materials Safety and Safeguards. I've been in this position now for about a year-and-a-half and I look at where we're going, in terms of risk informing our programs as an exciting opportunity and challenge.

I come out of NMSS, although new to the program area, with -- on the reactor side. I've been with NRC for about 23 years now and the last 12 years before I came to work in the materials side, I worked primarily in the system safety and safeguards area, where we were moving the risk forward on the reactor side. It was our division responsible for basically risk informing through the NRR programs, working very closely with research, to make what we have today, in terms of risk informed approach, the reactor regulation for radiology.

I'm here today to share with you some ideas about what we have got ongoing in NMSS today, where I think we would likely go in the future, but mostly to hear back from you, given some thoughts and ideas that I have, as to where you think we ought to be going and on what basis should we be moving in any particular direction. Thank you.

MR. JOHNSON: Good morning. I'm Ray Johnson. I'm currently President of Health Physics Society. With me this morning is Dr. Bill Mills, who is in the audience, also to represent the Health Physics Society. Bill Mills is the

scientific consultant and agency liaison for the Health Physics Society. My interest is, also, related to work that I've been doing. Over the last 12 years, I've been managing a contract with the National Institutes of Health in the radiation safety program, and so further my interest in the session today has to do with applications of a risk informed approach at a medical research facility.

In addition, I, also, operate a training center in Gaithersburg, where I train people, who qualify as radiation safety officers. Part of that is to help them understand what the regulatory compliance requirements are for carrying out their roles as RSOs. And in addition to that, my special interest is in the area of risk perception and risk communication, and would like to consider how much of what I've learned in the name of radiation safety is being driven by what people believe are the risks, what I would call perceptions, versus what we, the technical, deem the risks to be.

MR. CHEN: Chia Chen from OSHA. I work as an industrial hygienist in the Office of Health Standards Program. Basically, we change -- into public policy.

DR. JOHNSRUD: Judith Johnsrud, representing an organization, the Environmental Coalition on Nuclear Power. My background represented here with geography -- specializing in the geography of nuclear energy and I have been -- I don't think I'll have to use the term "the loyal opposition," as it is used politically, but I have deep concerns about the nuclear -- radiation on human health, as well as the environment, particularly in conjunction with other

potentially synergistic interactive sources of contamination from the environment. I'm a member of Pennsylvania's advisory committee on low-level radioactive waste, though I'm not representing it here today, and I have been heading the Sierra Club's national nuclear waste group, and sort of, also, with a number other citizens organizations. And I will take a strong citizen hand in environmental perspective.

I would like to add for the record that I am more than quite concerned that there are so few at your table to represent the entire mental community and the public interest citizens concerns with public health. It's not just a matter of perception; it's matters of reality for citizens.

MS. SHOLLENBERGER: My name is Amy Shollenberger and I'm a senior policy analyst with Public Citizen's Critical Mass Energy Project, which is a consumer governmental watchdog organization, founded by Ralph Nader in 1979. We represent over 150,000 members and I guess I'm one of the few with Judith here, who are presenting citizen viewpoints. And Public Citizen, also, is deeply concerned about this, moving towards risk informed regulation. We feel that there -- as you said, the public perception is more than just perception. When you're there and you're the one exposed to the risk, it's a lot different from being in an office doing a mathematical equation about what the risk is. And so, I hope to ask some questions that will help to bring those issues to light.

MR. KING: My name is Tom King. I'm with NRC's Office of Research, Director of the Division of Risk Analysis and Applications, responsible

for developing basic tools and data that NRC uses for risk assessment; also, working on standards for quality. We provide support to both the reactor and the NMSS side of the house, in the risk informed area.

MR. CAMERON: All right, thank you, very much, Tom and all of you and congratulations on not knocking any glasses of water off. The microphones around are sort of awkward, but I think that they do pick up pretty well, even if you're not close to them. So, we may not have to move them as much. But, one of the personal pleasures for me, in doing workshops like this, is to bring such a experienced group of people together for a discussion. And I think as Maria alluded to, this relationship is something that can build over time, not just this workshop; but the people you meet here may be good to interact with in the future, in other types of venues.

We can see that there were already a number of issues raised: the risk benefit issue -- in other words, where costs come into this; different ways of applying risk, not only, for example, in the development of regulations, but in terms of compliance, quality assurance. John brought up the whole idea of there is risk assessment and risk policy, how does that translate into risk management. A number of people, who have addressed the issue of risk perception, from various sides of that particular issue, and that ties in with the whole societal values issue, for example, in setting safety goals. And I think we'll have some discussion of that later on today.

Felix brought up the issue of paradigm shift and he got us into what

I think will be important for us to at least clear up, at least from my reading of the documents. The terminology that is used can be all over the board. For example, when we talk about risk assessment methodologies, I'm not exactly sure what that suite of risk assessment methodologies are. When we use the term, as you've seen in the Commission paper, of PA, performance assessment, I take it, does that -- is that equivalent to PRA or is it PRA used in PA? The acronym ISA, integrated safety analysis, how is that different than KPA or PRA? And I'm hoping that after Marty gets done, perhaps through some discussion, we may have a better idea of that terminology.

But, Felix talked about the use of risk versus the use of consequence driven regulatory approaches and it might be worthwhile to try to put a finer point on what that means. The whole issue of what is different in moving to a risk informed approach, how is that different than what we're doing now? What are we doing now?

The lack of NRC staff stability was, also, mentioned. If you look through some of the material that the NRC has prepared on this, one of the factors in how feasible it is to use risk information in particular areas was the extent of NRC resources and training. That's an organizational stability is, also, an issue there.

Maria referred to -- I like to call PRA, referred to it as either hoodoo or voodoo. Either term may be applicable. There's that whole issue.

And the last thing is greater involvement of citizen groups in these

processes and in these processes, as the NRC moves forward in the future, to refine its approach here. And I try to characterize Amy's point about -- often when we talk about perception, we juxtapose that to "science." Well, perceptions can be reality, in a sense.

But, I think we're going to be addressing all of these issues. And I would just wish Bob Bernero a belated birthday. His birthday was yesterday.

[Laughter.]

MR. CAMERON: Perception versus reality, I won't talk about his exact age, but it's hard to believe what someone in their 30s can look like, and it must have been a pretty hard act to follow. But, happy birthday. But, it's really sort of doubled. Any rate, Marty, are you ready to do your presentation?

MR. VIRGILIO: Yes.

MR. CAMERON: All right.

MR. VIRGILIO: And what I'll try to do is follow your advice and exercise economy. So, I'm going to move quickly through a little bit of history. But, if you have questions, if you want to put your tent up or if you want to wait until the end, we can do that.

If you go to the first slide, what I want to do is sort of lay out a sort of sense of what are the scope of activities that we're talking about here today and by the representation at the table, you get a good sense of who is involved in this process. But, if I look across NMSS, I would like things in two arenas: one is waste and one is materials. But, that's further subdivided into a high-level

waste and low-level waste and uranium recovery and decommissioning and transportation issues -- that's the waste side of it; and on the materials side of it, I think about our medical, industrial applications, as well as the fuel cycle facilities. So, I see seven program areas and that's further subdivided, and those are the areas that we're going to be talking about today, is how do we move forward within these areas to risk inform our activities.

We've talked about risk assessment a little bit. But one of the things that Norman and I used to kick around a lot, when he and I worked together, was, you know, what is a risk assessment. And very simply, it's a trickle of questions that you ask yourself: what can happen, how likely is it, and what are the consequences if it does happen. And any kind of risk assessment that we talk about today, be it a performance assessment or a PRA or a PSA or ISA, I think comes back to those three questions. And so that simply stated: what is a risk assessment, what can happen, how likely is it, and what are the consequences.

Then, there's the other half of this and that's risk management; how do you manage risk. From our perspective, we encourage or we would require programs that address the risk issues, that bring the risk levels down. And when I talk about bringing the risk level down, I think about both the workers and the members of the public. So, we're involved in protecting both public health and safety. In that broad envelope, I, also, include workers that are handling the materials or working at the facilities. And from our perspective, I think about --

and how do you management risk? What you do is you either encourage or you require the development of programs, procedures; you foster training programs, so you're increasing the knowledge and skill of the people that are working with these materials; or you require some hardware that will provide some sense of barrier, some additional measures of safety.

NRC's responsibility in all of this is that, again, encourage, require, and then oversee, to ensure that we require is effective.

If you go the next slide, the application of risk assessment and risk management technology at the NRC is I don't think a new program at all. We've been doing -- we've been using risk in a number of various activities throughout the years, and I go back to the early reactor experiences I have. But, I know looking across at the materials and waste arenas, there have been a number of risk applications that we can point to.

One example that Stacy and I were talking about the other night involved some -- where she was involved in, the transportation of a reactor vessel. Some of you may remember, because it got a lot of national news, Trojan Nuclear Power Plant, as part of their decommissioning process, moved the reactor vessel. Part of what we did, at the time that we looked at that, was we looked at it from the probabilistic point of view. The licensee submitted a risk assessment and we took a look at that risk assessment, as part of the approval process. Based on its own risk assessment, what the licensee identified were some vulnerabilities in the transportation, in the tie downs, associated with how

that reactor was going to be secured to the barge. And on their own initiative, having done this systematic look across the reactor and the transportation of that reactor vessel, they decided that they needed to increase the strength of certain fasteners. They made those modifications and we continued our review and we eventually approved the transportation of that reactor vessel, which was done safely, and then from that point of view it was a success. But, here was a case where a licensee used risk assessment techniques in our high-level waste disposal activities and it actually led to identification of issues and improvement of safety.

If you go to the next slide, I think a major milestone, a watershed event in NRC's application of risk technology came back in August of 1985, when we promulgated a PRA policy statement. The impetus here was a desire to advance the use of risk. And there were a number of us involved in that project. Norm was there, as well as Gary Holahan -- you'll meet Gary later this afternoon -- myself, and several other people worked for months, literally, to just sort of hammer out what are we trying to do; what are our objectives. And we laid out these three objectives in formulating that policy statement that the Commission accepted and promulgated. And I think it became a guiding light for us for the next several years. And it's simply to improve our regulatory decisionmaking, make more efficient use of our resources, and reduce regulatory burden.

Those of you that are familiar with the strategic plan that we're working on today will recognize some of those elements within our strategic plan.

So, we've evolved, but yet we've held on, I think, to these basic tenements, as we move forward to advance the use of risk thinking in the NRC's activities.

If you go to the next slide, the question comes up as to why is NMSS developing its own approach. Why can't you just use what the reactors have developed? Why can't you apply those techniques? And we've looked at it very carefully and realized that there is such dissimilarities in the nature and the consequences of the use of nuclear materials and the reactors; and then if we look at it from the industrial and medical perspective, that a single approach just didn't make sense to us. And, again, that led us to thinking about what is it we're going to be doing and, again, that led up, I think, to this workshop that we're having today, to help formulate why -- not so much why we're working on our own approach, but what is our approach going to be; what is it that we're going to risk inform and how we're going to go about doing that?

So, it's really going to be important to get your feedback today, because I think we're just on the edge. We haven't gone very far. We've done some initial thinking. And it's a real opportune time for you to come in and help guide the way our program is going to develop.

The next slide just gives you a little bit of background and history of the paper that we wrote a couple of years ago. There's out on the shelf, it's SECY 99-100. It was a paper that the staff wrote to the Commission, laying out what we thought we ought to be doing, in terms of risk informing our approaches. And that paper went to the Commission in March of '99 and then the

Commission responded to us in June of '99. And subsequent to that, one of the first things we did with that response was to establish a task force. That task force as evolved; not only have we changed in membership already, as we've gone through the program, but we've changed the location. And a number of the task force members are here with us today and you'll be interacting with them: John Flack, who is here at the table with us; Stacy Rosenberg, here at the table with us; and Dennis Damon, Christie Lew, and Jim Smith, who I believe are in the audience with us today. You'll have an opportunity to interact with them, as well, and influence their thinking about where we're going to be going in the near future.

The next page, what I wanted to do is just lay out some of what we recommended in that Commission paper. And I'll talk a little bit more about the five-step process that we outlined in that paper and what the staff's approach is going to be to implementing risk management issues.

One of the other things John mentioned is he introduced himself as we'll be meeting with the ACRS-ACNW in the near future, an idea that we had that the Commission accepted, as a matter of fact, and we're real pleased that they did, was the formulation of an ACRS-ACNW subcommittee. They stand as a technical sounding board for what we do. In addition to competing groups like this to get ideas, we will, also, have another group that we can call on to bounce ideas off of, and that's the ACRS-ACNW. They've been tremendously helpful in the reactor arena, in shaping the programs that we have there and providing, I

think, third-party feedback on what we're proposing to do. And I look forward to the relationship that we're going to establish with them, as well, for the same reasons, critical feedback on what we're proposing to do in our programs.

In the next slide, I just want to give you a sense of what the Commission's reaction was to our proposal. And the Commission in June directed us to move forward. They amplified and modified some of what we proposed. One of the things they said was that they thought we should develop materials safety goals, analogous to what the reactor safety goals are today. They encouraged us to use an enhanced participatory process to develop these goals and, hence, we're here today to work consistent with the Commission guidance, to work in a participatory way, to get your ideas on the sense of where we should be going on the safety goals.

And then they asked us to consider whether critical groups could be defined for classes of material of use. For those of you that are not familiar with some of our program areas, we're looking at critical groups, as we evaluate a high-level waste repository, and it's basically a hypothetical group, who would live close to the repository. And we assess what the consequence or what the risk would be to those people living close to the facility. So, basically, the Commission is asking us to think about whether those kinds of concepts could be applied to some of our other activities, as well.

The next slide, continuing with what the Commission asked us to do, they asked us to consider Part 20, our existing regulations, also consider

some of the other guidance that we have in place associated with license termination, as guidance on what is an acceptable level of risk. And they asked us to work closely with the Agreement States, to make sure that what we did in our programs was -- we're able to transfer that information in programs to the Agreement State activities, as well.

I talked about the five-step process, which was sort of the backbone of the Commission paper, as to what we were proposing, and, basically, it was to identify the applications, where we can move forward and risk inform our approaches; then decided how we were going to modify our regulatory programs to implement our risk assessment and risk management techniques; then the third bullet was actually to make those changes; fourth, as well, to implement these approaches; and then last is to look at what tools that we have out there, to help us with risk assessment in answering those questions and see if we could develop additional tools or modify or adapt tools.

We're here today, just sort of as an aside, on that first bullet, to identify those candidate regulatory activities for which risk assessment and risk management approaches are most appropriate.

Just taking the insight that you derive from the risk assessments and use it in combination with traditional engineering approaches to focus our attention and the NRC's attention and those that we regulate's attention on what's most important from a safety perspective.

And from our perspective, you know, you see the examples up

there of what we hope to risk-inform of our regulations, our guidance documents, risk-informing our decisions more fundamental to that than the paper that we produce -- use it to help allocate resources and use it to approach inspection, assessment and enforcement activities.

Just by way of current activities, I mentioned that we had a risk group, so we formulated a working group. That group was at one time located in one of our divisions, but in order to give it a little bit more visibility and to advance the ball a little bit further down the field maybe a little bit more quickly, we've moved that group up so that it reports directly to Bill Cananon. So it's got a lot of visibility in the front office.

And we've also established a steering group. This is, I thought, was a real important move on our part because what we've done is we've taken the division directors and senior representatives from other offices and put them on a steering organization to guide our activities as well so that we don't become disconnected from the program areas. You have in the audience Don Cool today; you also Mike Weber next to him. These are our division directors; these are the folks that are responsible for implementing the programs, and it's really important to me, and I think to this effort that I think that they are closely connected, that they agree with what we're doing, because it's one thing to move it up to the front office and give it laudability. But if it's not, there's not a strong sense of ownership there by the divisions that have to implement it, it's not gonna work.

And so the steering group idea came about, and so we put, put out four principal division directors as members of that steering group -- Don Cool, John Greaves, Mike Weber, and John Lanihan -- are NMSS employees. Then we looked across and said, how can we also advance the knowledge base and strength of that group, and so Gary Holahan will be here later today.

There's also a member of that steering group -- Joe Gray from OGC is also a member of that steering group. Tom King, who's at the end of the table with us today, is a member of that steering group. And we brought a regional component, Bruce Mallet, who's the deputy director from our Region 2 office to also be part of our steering group to keep us, keep us guided and keep us on track.

Other things that we're doing on the next line is, again, increasing our interactions with the stakeholders. I talked a little bit earlier about this CRGR, about the ACRS/ACNW. We've also been interacting with the CRGR, another organization within our, in our NRC family responsible for helping us ensure that when we add new requirements, they're justified on a cost-beneficial basis.

We're continuing to interact with the Commission. We briefed them back in March on our programs and our activities. We have today's workshop. And so it's continued interactions with the stakeholders.

The last thing I want us to do is see us get into an ivory-tower kind of approach that is meaningless to you and will eventually not help us make us

more risk-informed or our activities more risk-informed.

Then I think another important component of this -- is a near-term activity on our part -- is to get training for our staff. Training -- there's three tiers of training to ensure that everybody that's working in the materials and waste program areas have a basic understanding of what we're doing and risk-informing our programs. That's, that's one level. Another level is all of the managers in the program are going to be exposed to the training program so they understand what our objectives and vision is for the future in risk-informing our activities. And then a third level for the experts that'll be out there conducting the risk assessments and developing the risk management techniques will get a higher level of training.

The last area I wanted to touch on was today's workshop. And that's, that's what we're here -- I talked about the five-step process. And so we're really focused on step one of that five-step process, to develop a criteria, a methodology for identifying what are the activities that would most benefit from being risk-informed, and solicit input on the development of safety bills is the second part of discussions that we'll have today.

So that's, that's pretty much a summary of where we've been, a quick history, but if you have any questions, I'd be happy to entertain them now or as we get involved in the process. You know, I'd be a resource to answer questions.

MR. CAMERON: And thank you, Marty. That was a great

overview and I think that what we can do is move into cost trends and also just perhaps blow into the perspectives on risk since we're running a little bit behind. But we have flexibility to make up that time.

But first of all, I was remiss. I apologize to Stacy for cutting off the introduction right before we got to her, and I would just ask her to introduce herself at this point.

MS. ROSENBERG: Hi, I'm Stacy Rosenberg. I work for the Nuclear Regulatory Commission. For a number of years, I worked in risk assessment for the nuclear reactor program, and now I am working in nuclear materials in the risk task group. And that's where I am.

[Applause.]

MS. ROSENBERG: And should we just go right into the --

MR. CAMERON: Let's, just let me make one other comment, and that's -- we referred to several of the people in the audience. We do have our cordless mic, which we'll install after the break. And since we don't have a whole lot of people out here, at some point we'll give you a chance to introduce yourself out here. But why don't we -- I think that there's probably questions at this point. Why don't we just move to, to going to, to Ray Johnson, and we'll just move into questions and perspectives. Ray.

DR. JOHNSON: Thank you. One of the areas that I'd be interested in -- and this goes back to my work at NIH. And I've just been told today that there's an inspection team on the campus at NIH, which I didn't know

about that yet.

What I'd be interested in is, when inspectors come into a facility, they work from a regulatory compliance checklist of things that they normally would inspect for. But the question I'd raise is, at what point is someone asked the question what is the risk connection to the compliance requirements? And I could understand, for example, limiting dose limitations. There's a clear risk connection there. But I wonder about risk connection with other regulatory requirements as simple, for example, as has your survey meter been calibrated in the last year? If it's not, that's a compliance violation, but what's the risk of that? And you can go on with a long list. I mention that as a fairly simple one.

So the question I'd like to have us be considering for compliance requirements is, what is the risk connection?

MR. CAMERON: Okay, we're gonna note that for an agenda item. Which is the connection between compliance particularly for survey meters and other instruments like that, and risk --

DR. JOHNSON: Well, I only offered that as an example. I'm really thinking of all compliance requirements, and particularly at medical research facilities.

MR. CAMERON: Okay. Let's go to CHIA Chen.

MR. CHEN: Yeah, CHIA Chen. I have one question and one comment. My question is maybe I'm new here, so if answer the question can be read in some document, that's fine. My question is this: What are the basic

difference between April 1997 Commission direction and the March 1999 SECY 99-100.

My comment is this: in this member in this steering group, I would like to suggest maybe you involve some people outside the NRC, such as people from state and also people from the environmental group. Thank you.

MR. CAMERON: And let me just make a note that that's an excellent suggestion for consideration. And when we get to the process part of the agenda on Session 1 about where should the NRC go from here, let's come back to that concept of some type of external hearing group or advisory group. And so we'll make sure we'll come back to that.

And does someone -- Marty, did you touch on Chia Chen's question, his first question, and do we have an answer for that?

MR. VIRGILIO: I would say that there's a lot more specificity. When I look back to where we were in '97, we put out some general concepts to the Commission, but what's different I think, the tangible difference was the five-step approach that I think put more focus on what we were gonna do in the near-term activities. So it was from '97 an evolution, I think, and a maturing on our part, as to what direction we wanted to go. The Commission telling us, go out and provide additional information as to what you were thinking, and then our paper 99-100, I think we laid out that more mature thought on direction.

MR. CHEN: I think basically you move on the nuclear reactor to nuclear materials.

MR. VIRGILIO: I think in '97 we were already headed toward materials, but I think there was a lot more specificity when you got to the '99 time frame.

MR. CAMERON: Okay, thank you. Let's go to Bob Bernaro, and then we'll come to Barb and we'll go down this way and go over to Amy.

MR. BERNARO: Bob, you mention the Commission's desire for safety goals analogous to reactors. The long experience with reactor safety goals, that they are accidental risk to the public was in parallel with the experience of worker safety problems, period or occasional injuries and even fatalities from steamline breaks or things like that. And the NRC never applied the safety goals to the workers' safety.

In NMSS, the SECY even acknowledges that worker risk is the dominant risk, that it's very difficult to have an off-site public risk. And it suggests that the worker risk, accidental risk to the worker, would be the arena for the safety goal and for, in some cases, extension of NRC jurisdiction. Is the NRC considering the use of risk information to evaluate and perhaps propose extension of its regulatory authority?

MR. VIRGILIO: Some of the initial scoping studies that we've done -- and these are publicly available -- one recently published on transportation risk and another one that we published probably about six months ago on material by-product risk, is providing us some insights on the workers and risk to public, and the comparisons that we see.

The most recent one on transportation risk I think is telling us that if there's -- the risk there is to the, to the people that are handling the materials, moreso than the public. It's also telling us I think that that the risk is less than what we had seen in some earlier studies. But again, there's still scoping studies. There's still large uncertainties. But I think that we do need to think about worker risk in the materials and waste arena, I think maybe even moreso than what we have done in the reactor site.

MR. BERNARO: But the question is, is the NRC considering the application of that information to change its regulatory authority. For instance, in transport risk, would NRC seek to regulate shippers? Transport companies, rather than work with the existing system?

MR. VIRGILIO: We could, but it's way premature. You know, at this point, I don't see us heading down that, having enough information or, you know, an issue there that we would. Conceivably, you know, it could happen, but we're nowhere near a level of information, knowledge, or concern that we would want to do that.

MR. CAMERON: And Bob, let's go back to that issue when we go down to application of some of the criteria because, you know -- I mean, you've framed it in the form of a question, but I think the implication is that there's a recommendation there that perhaps we might want to go down that road, and what is necessary to go down that road. So we'll make sure we come back to that. Barbara?

MS. HAMBRICK: Marty, you talked about ownership by the NRC staff of the concept of risk-informed regulation, and that's gonna be critical for the agreement states as well. The training resources are very limited for agreement states, and if we don't have appropriate ownership by the program managers, the program supervisors, and the, and the first-line staff, the license reviewers and the inspectors, the programs will not be effective.

It's easy to see where prescriptive regulation is very easy to apply, and as Dr. Johnson pointed out, there's a checklist, and you go out and you say, did you calibrate? And there's no risk information.

In order to really change that paradigm, there will have to be a lot of resources that the NRC will need to make available to the agreement states or that the agreement states will have to be willing to provide in order to really get that shift to work because a risk-informed -- and I don't want to discourage risk-informed regulation.

I personally support the idea and I believe that philosophically the agreement states support the idea, but it takes a particular -- it takes a lot of training to understand how to really apply that on a day-to-day basis. And without that, you may end up sacrificing some safety, if there's not appropriate training given.

MR. VIRGILIO: That's a good reminder. Just this past week, John and I were working with our training organization, human resources and folks from the training center in Chattanooga trying to lay out an approach for training

and the specific details. And what we're hoping to do is have the first pilot training course run off sometime this summer. And one of the discussions that we have was about agreement states because we had agreement state participation in the reactor PRA fundamental training courses. So we are thinking about it, and you're right -- we need to do that in order to foster the cultural changes that it's going to take to implement risk-informed approaches.

MR. CAMERON: Okay. And I think that we'll need to specifically go back and look at that, discuss that training issue later on today.

Let's go to Roy, and we'll come over to this side and get the mic going. Roy?

MR. BROWN: Marty, when I read the SECY paper, I noticed that NRC had set up a joint committee between ACRS and ACNW. I'm just curious why ACMUI wasn't included. That seemed to be a logical group to incorporate a series of medical licensees, and it seemed like that would be a likely player in a joint task force or joint subcommittee like this.

MR. VIRGILIO: We thought about all the stakeholders and at this time what we wanted to do was just start at a certain level and build. I mean, it wasn't, it wasn't consideration and a deliberate decision -- "let's start small and work outward." If there's interest, that's something we could come back and revisit.

MR. BROWN: Well, I can't really speak to the ACNUI, but I would just hate to a segment of the NMSS just cut out of the process because they

weren't in on this, is my concern.

MR. VIRGILIO: Good point.

MR. CAMERON: Another good point for discussion. In the process we go to this internal advisory committee. I'm sorry -- Andy. Why don't you --

MR. WALLO: I wanted to kind of focus us on the fact that your risk-informed probabilistic risk assessment, these are decision tools, part of making a whole decision. And we seem to be focusing on the health risk or the probability of an accident. But indeed, to make the decision it may be risk-informed, but there's a lot more than risk that goes into the decision. There are other factors that have to be looked at and maybe that's why regulations cover other things besides just a risk calculation. When you're deciding on establishing a waste site, you may go through and do your probabilistic risk assessment, but the question is what are your alternatives? Much like an ALARA analysis, you do your cost, your benefit. But the benefits are more than just the health risk in one area. It may be broader than that. In addition, an action you take -- we're doing a lot of clean-ups and when you do a risk assessment, you have to consider the ecological damage or the ecological benefits that your decisions may make.

And more than just risk again, there's multiple factors. Just the simple thing of taking a clean piece of property and saying, well, gee, let's reindustrialize it or release it. The Department releases it. What are the other

factors you have to consider? Was that essential to a buffer zone for a waste management area? Was it essential to a buffer zone for an operating facility?

Or what other impacts would reindustrialization of this property have? Will it meet conformity needs for the Clean Air Act, or would we violate or cause increased pollution by actually allowing other uses of this property? Would there be increases to water pollution because of the loss of watershed controls?

So I guess I see us focusing this discussion a lot on risk, and I just want to get that the decision-making process for regulating or for taking an action -- while risk-informed is important, there are other things that need to be considered. And if you want to call them part of the risk, that's fine. But if you're just saying risk informed, means health risk or accidental risk, there's more to a decision than that.

MR. VIRGILIO: On one level, you know, when I think about the risk information, the sophistication that we have today, we have to be very careful that we don't overstep and make decisions without the right knowledge base. So we would use traditional engineering approaches to supplement the risk information we have. That's at one level.

Then I step way back, and I think at another level about our decision-making today, and I think about four factors that we're trying to work through in all our decision, one being, maintaining public health and safety; another being public confidence. Another being public confidence. Another

being efficiency and effectiveness of our activities, and then finally, the burden associated with the activities that we do or don't do. And so you've got those four factors as well that play into any decision that we're gonna make. So yeah, risk is just one piece, at one level.

Now when you step back and look at the big picture, there's so many other things that have to go into the regulatory decision-making.

MR. BROWN: A context.

MR. VIRGILIO: Yeah, putting it into context, you're absolutely right.

MR. CAMERON: I think it's another issue for further exploration today. Let's go to Amy, and then we'll go to Mike, then we'll go to Judith and Maria.

MS. SCHOLENBERGER: Amy Scholenberger. I have a comment and a question. I have a lot of comments, but I'm only gonna use one. All right, on your slide 8, it's titled "SRM on SECY 99-100." And my comment goes to the last bullet on that slide, which says "consider whether critical groups can be defined for classes of materials use.

And what you said about the critical group while you were describing that point was that it would be a hypothetical group who would live next to the repository, or where -- I assume next to other facilities or other transportation routes.

And that really struck me, because my comment earlier about perception being reality, and the difference between being a person who is at

risk and being a person who is determining risk, I think just really was synthesized on that comment, because a critical group is not a hypothetical group. It's a group of real people who live in a real place next to a real facility, with real risks. And you know, when you say "repository," of course I think of your high-level waste repository that may happen at Yucca Mountain. And I traveled out there in January and I went to the mountains and I met people who lived right next to the Mountain. And they're not hypothetical people. I shook their hands; I talked to them. They're real.

And I think that's something that really gets missed in risk assessment. We talked about hypothetical people. We talked about hypothetical risk. We talk about potential consequences. And it never gets based in reality. And it just really reminds me of my son playing video games. You know, it's like virtual reality, for nuclear people. So that's my comment.

My question goes to the bullet above that, on slide 8, where you mention that the Commission directed the staff to include as a goal the avoidance of property damage. My question is whether "included in property damage" is property devaluation? I've been doing quite a bit of research lately on how property gets almost instantly devalued just by the idea that someday nuclear waste might travel near that property. It could be decreased by as much as ten percent. And I just am wondering whether you all are including that in your assessment?

MR. VIRGILIO: As part of what we're gonna be doing later today,

and then tomorrow, we're gonna be talking about the safety goals, so we really haven't formulated anything yet. We have an opportunity now to think about those things as we move forward, but there isn't really one -- you know, I can't hold up anything to say yeah, we have or we haven't. I -- you know, in the reactor area I would say that by-and-large, we haven't. You know, we've looked at loss of use, but not necessarily of devaluation of the property.

MR. CAMERON: Is this question also the tie-in sort of related to Andy's point about what's included in a risk assessment, and I think that we still need to put a finer point on what do we mean by a risk assessment? What are the various forms of risk assessment methodologies? And what gets considered when you do a risk assessment. It may be that other information has to be integrated into the total decision-making process after you do the risk assessment, but it may be that there's other , some of these factors are directly involved in risk assessment.

MR. WANGLER: I was speaking partially in jest awhile ago when I referred to transportation as a moving facility.

As I also mentioned, it presents a very challenging aspect. Unlike fixed facilities where you can control the boundaries, the perimeters, the radiation zones, the carriers, the conveyers of the materials, have to control that, and that is pretty much limited to the perimeter of the trucks or rail cars or SeaLand containers or cargo holds or what have you that they can control.

In the transportation arena -- excuse me, give me a cup of caffeine

and I begin to get a little hyper here -- in the transportation arena -- and will just mention those classes of hazardous materials, not Class 7, not radioactive materials -- there is a risk, a kind of quasi-risk-informed approach that has a socioeconomic value attached to it.

That is, for example, in the case of flammables such as gasoline, we have lots of tankers out on the highways. The tankers are vulnerable to accidents.

Those of us who have been here for awhile know that 270 and 495 Interchange was closed down a few years back when a tanker exploded and killed some people, and just almost destroyed the bridge.

But society doesn't make those containers accident-proof, because there is a need in the society to transport gasoline so that we have gasoline for our automobiles and other devices that depend on it.

So, society in a sense has looked at the packaging and the need for the commodity, and while it may have some comments and may have some fears, it's pretty much accepted the type of packaging that we have accepted for those materials.

And the same thing could be said for other non-radioactive materials packages. But even in the arena of radioactive materials packages, we have kind of a risk-informed approach.

That is, we have a number of levels of integrity of packaging, depending on the hazard of the materials; that is, on the risk of materials. Spent

fuel, for example, has to be shipped in a very, very robust package that has to meet certain performance requirements, because we don't want any releases of materials to the environment.

On the other hand, some of our lesser quantities of radiopharmaceuticals can be put into lesser quality packages. If they were to get out into the environment, they don't cause the same amount of risk.

They are easier to clean up, the radiation levels around smaller quantities aren't the same as for the larger quantities.

Now, as soon as I say that, in the Department of Energy -- and I guess this is a bit of a caution with going straight to relying 100 percent on a risk-informed approach -- is that in the Department of Energy, which adopts the DOT approach to packaging and the NRC approach to Type-E packaging, we have concentrated almost exclusively on the performance of the packages for our spent fuel and our high quantity materials, and to a lesser extent on the boxes and things that we ship our lesser quantities in.

But we haven't done such a good job for even the lower risk materials such as the low-level wastes in trash from some of our cleanup activities. We've had a couple of incidents recently where the packages transporting very, very low quantities of materials, which actually represent extremely low risk from exposure and hazard to the public, we've had those materials get out of the package and create a much greater public relations risk than we would have expected.

What we have found or what we think we have found is that in addition to using a risk approach to packaging -- and I mentioned this earlier -- is that we need to develop an approach toward quality assurance in the systems that we use to transport the materials.

That is, just because a material may be of relatively low risk in my mind or in the minds of some of the other people, it doesn't mean that we can scale back on the quality assurance of any of the packaging that we use to transport the materials.

So, even with low-risk materials, you still have to worry about quality assurance. I just want to emphasize that even in a risk approach, we need to make sure that we adequately consider, even the low-risk materials; we can't ignore them, and we need to factor in quality assurance in the equation.

Marty had mentioned that they have done some risk assessments or some studies in transportation. I'm glad to hear that.

I have seen some of the stuff, some of the materials. Not all of them are completed yet.

I guess I'd just like to ensure that when you look at, when you do these studies in any depth, that you make sure that you go beyond the walls, back up, make sure you think beyond the usual fixed facility terms that one oftentimes sees within a facility.

Even DOE oftentimes has fixed facility people looking at transportation, and they don't really have as good a perspective on what's going

on in the outside world, compared with what's going on within their walls.

MR. CAMERON: Thank you, Mike, for that. I think you raised an issue that's going to come up when we discuss the screening criteria. One of the issues here is reduction of unnecessary regulatory burden.

I think one of the things that you were saying is that even though there is an area that's extremely low risk, that you might need to still focus regulatory requirements on that for various reasons. I think we need to have a discussion about how you make those types of decisions.

Let's take the rest of the cards that are up, and I think Stacey is going to have a question for the group, and then go on to the audience and then take a break, and we'll set up the cordless mike.

We're not following any of these threads; we're sort of waiting to do that, and getting your individual perspectives now.

Let's go to Judy.

MS. JOHNSRUD: Bits and pieces. My principals concerns in response to you, Marty, yes, have been mentioned.

First off, I find myself very deeply distressed at the imbalance within the Agency making risk determinations between, on the one hand, engineers of a certain kind of technical background, and the lack of representation of the fields of academic endeavor and practical application that are pertinent to those who receive the risk, as Amy mentioned.

We don't have a Nuclear Regulatory Commission peopled by

expertise in areas of environmental and ecological maintenance, sustainability, protection.

We don't have biologists heading the offices of the NRC and making these determinations. We don't have a whole battery of first-rate physicians with concerns for exploring impacts, in particular, of low-dose radiation on human beings.

I think some years ago I think I recall writing a comment that said the best thing the NRC could do would be to fire the Commissioners and then fire the staff and start over, so, please, all of you, forgive me for what was more or less seriously meant.

But in all seriousness, whose risk is of primary concern? The risk to the companies that produce radioactive materials and wastes? To their shareholders? Or to the public, who not only in current generation, but also in future, will receive the impacts of whatever risk assessments and decisions result?

And that raises the second point: I'm not hearing any indication of concern in that longer realm of those who follow our immediate time period. That critical group, after all, is a very significant group of those who will receive the primary exposure.

However, as we look at the move on the part of the Agency and other agencies toward greater deregulation and recycle, release and recycling of radioactive materials, the critical group of those exposed or potentially exposed

will be total populations.

How do you define a critical group when it's actually the whole population, rather than some within a reasonable distance of punctiform.

Once the materials are disseminated, then multiple sources become of great significance in the realm of reuse, recycle.

And that takes us, in turn, into an addition realm of the relationship between the radiation exposure, whether it's a high dose or a very low dose, but a repetitive set of sources, and the relationship also with other contaminants in the biosystem and their impacts on human health and upon the environment.

I hear you speak of public health and safety, confidence, efficiency, burden, but I don't hear that burden defined, even in economic terms of the health costs to those members of the public who actually receive exposures.

And I do speak from a position that adheres to the, at minimum, the linear hypothesis, and actually probably lower doses than are considered with linear hypothesis.

I think there were several other points, but that covers it sufficiently for now.

MR. CAMERON: Okay, thank you, Judy. I think that that sounds like the topic for discussion of specific criteria. But what else needs to be added.

MS. JOHNSRUD: Not just specific criteria, but approach.

MR. CAMERON: Okay, we'll go there next. Let's go to the

positions at the table. Maria?

MS. PAVLOVA: Well, have in mind that I wanted to be an opera singer. My grandmother -- I come from the old country -- she said, you want to --

Anyway, I want to continue what Judy was saying that there are a couple of important points. In terms of risk assessment and anything, it's very important to have a definition, so that when we all talk about something, we all have some kind consensus as to what we understand, and particularly in risk assessment since we all know that it has a lot of uncertainties.

And it's very difficult for the public to accept that there are too many uncertainties.

From my personal practice working for two years in the community, when you try to explain the risk assessment, that's why I used the word voodoo.

There are so many uncertainties in terms of extrapolation from animal to human data, particularly for radiation from high dose to low dose, to which we are, so you get so many of those.

And if you over-talk about those, then you can over do it. And it has happened to me that the public will say, so why do you waste our money to do some risk assessment or whatever you call it, that it's really no good, because if you compare a risk assessment done by different groups, you come with different numbers?

And it's very natural for people to say somebody must lie, must be lying. So who is the one to trust?

So what we're coming to is also perceptions. And there is a perception in the general public, in all of us, that science is a very exact thing, and the answers are yes or no.

And there is no such thing. Those of us who do science know this. You have to have peer review journals, a couple of different articles in the same issue, and even then, methods and all of that.

So, in terms of risk assessment, it is a technical thing, and I think that generally we have to somehow make sure that what is risk? First you have to say that.

In the risk, if you take the classical process of risk assessment as it is done by the National Academy of Sciences and the new Presidential Committee on Risk Assessment, you do have a hazard identification.

We have a lot of hazards -- physical, chemical, biological, and then we have to know how toxic they are. Most of them, let's face it, most of the questions that people have are health questions. What is it doing to me? Is that why I got the cancer? Or my daughter has an abnormal baby?

So, you do have to address hazard in terms of how toxic it is, what it is. But then another thing that is very important -- and I don't believe that we have done a good education in this sense is the question of exposure.

Unless you have exposure of human beings to a hazard, you do not have a risk. You can have in Nevada a million tons of things, and if nobody lives around that is not exposed, then you cannot expect a risk.

But this is a very sensitive issue to explain. And then you get to the health effects. I speak as a physician of the health effects.

Then you to see what is the end point. Is it cancer, or what is it? So you go into characterization.

And there was a point when a risk assessment was considered as a very technical thing done only by technical people and expressed in technical language. If you talk about, for example, four times ten to minus six, and if you go to talk like that to people, then you will be thrown out and rightly so.

And even if you are capable to say that four additional people get cancer, if one million people are exposed in the worst scenario to the maximum amount, the most hazardous element, still we have to know -- put things in perspective.

One of every four people gets cancer. One person of a million, in addition, is not too much. But if you go there and talk to the people, and come to me, and say, Maria, can you tell you me that I'm not going to be this one person?

So, it's -- when you go to risk management, in this process between risk assessment, we'll come to some kind of a statement, number or qualitative, then it's so important to include the people, the stakeholders, public workers, whatever you want to call them, the real people, as you were saying --

And we usually say we inform. Well, information alone is not enough. I hear very nice things like ownership.

So you inform, then you call to involvement, and when you come to

participation, and when the participation is real, and these people really have to say something about the solutions when you go to risk management, so that their work means something, as the people around Long Island had to say something, and the Shoreham plant was closed.

I work in Brookhaven National Lab. I felt bad, because really the risk were not so bad. But you have to involve the people early enough, and we have all kinds of rules when were in EPA. We have the seven rules of risk communication.

Communication has to be two ways. You cannot just go and give a lecture. You have to listen first.

As a physician, I'm very disappointed with the medical practice, I'm sorry to call it. I hope that you will agree with me.

It's too commercial. You go to a physician. It could be the best professor and so.

But if this person keeps me 45 minutes almost naked in the room, comes inside and just knocks a little bit here and there, and starts talking to the tape recorder, this is a patient, female, dah-dah-dah, and doesn't listen to me, and after all does not explain to me, and does not show some kind of empathy, understanding that I care and I'm upset and I'm afraid, then no matter what expert you can get to that, if you don't work with these people and respect what they have to say, and listen, not just listen, but hear and respond and work with them, it may be, as we say, perception, it may be absolutely very, very small risk

comparing to what it is.

But it has to be done properly. Now, what I am going to say is what -- a magic word you said, and talking about culture. Now, I have a lot of colleagues here form DOE. I'm new to DOE.

And what it is that is the worst thing is that we have lost trust. I don't know how much trust NRC has. But I'm surprised and very saddened to find out that DOE, ten plus years after the Cold War, and we had the good reason to have classified things and not be open, but it's too long after that.

And yet culture doesn't change. We don't change fast. So what -- I know that we have to go to the break. Maybe later on in the afternoon, I would like to share with you what we are doing in DOE who have started, and I initiated it, because my heart is in it. I come from a country -- and as a physician, with a task force in one place as a pilot in Oak Ridge.

We're doing it with the workers. We very often say we have to train and communicate with workers, and separately communicate with the community.

There is no such a differentiation. These workers live in the community. Their families are there, so we have to -- what we have to do -- and I see, and in my colleagues in DOE can probably say so, maybe because it's such a huge -- it's an empire in a way.

And even people do assessment or communication or what it is, it's so fragmented. We don't have communication, even within, and unless we get

to some kind of an agreement, and we get with the message, and this is now -- I would like to stress with three points into it: DOE is suffering and is losing more trust and it's kind of a Catch-22.

DOE is not trusted, so we give money to NIOSH, to CDC, to ATSDR, and all this to do studies for us. And then these people go with something like half an hour of public meeting, talking in technical language, very unclear. This is the communication.

And so the message is not consistent, is not sound, is not clear, and then we, what we gain back, is increased distrust and low credibility.

Bulgarians talk a lot, I have to warn you. I'll stop here, but later on I would like to share what we tried to do.

MR. CAMERON: Thank you, Maria. We'll look forward to that. I think you're making a strong point about the risk management process that has to include listening to real people with empathy and issue like that.

I think we'll get to that. Before that, we'll have to break at some point here. Stacey, did you have a question?

MR. ROSENBERG: I think that we agree that communication is very important, and one of the things that we wanted to accomplish this morning was to get the view of everybody here as to your perspective on using a risk-informed approach in the radioactive materials area. So, we just wanted to comment that we're trying to collect this from you to communicate to us.

MR. CAMERON: Thank you, Stacy. This is a first step in the

communication process, and when we get to recommendations, at various times today, as to where the NRC could go, I think a strong part of those recommendations are going to be how can we continue this communication effort. Let's go to Bob Lull, and we haven't heard from Norman Eisenberg. And then I think I'm going to ask the audience for comments, then we'll take a break. And we're going to come back and focus more in on these issues. Bob?

DR. LULL: Thanks. Well, all the comments have been so germane, and I think fairly appropriately touching on important aspects I think. The concept of perception is reality I think is very important. One's perception of a doctor is he just looks at you as a scientific object, and doesn't treat you as a human being is like an analogy for the NRC looking at scientific risk assessment without looking at people's perception who are involved in -- people who perceive themselves as being at risk. I would hope that Amy and Judith don't feel that they're the only people, you know, representing the public and the environment because all of us live in the world, and we all have a stake in it. And I think it would be foolhardy for anyone, even an engineer in the NRC, to be thinking that he shouldn't -- he should be scornful of the environment. Yet, we all know that corporate profits and greed often times shifts the cost-benefit equation to towards the other side, and slightly more risk, and I think that's why there needs to be an important balance.

But the concept about perception being reality -- I'd like you to think for a moment about what you perceive -- look around the room and perceive the

people here. You perceive what is. What's important in this issue that we're discussing today is to perceive what isn't, but what could have been had we directed resources that are better utilized for extremely low-risk activities towards solving real problems that aren't getting solved because we're wasting our resources doing things that are spinning wheels and catering and dealing with people's perceptions of risk instead of going out and educating the public and the media and the regulators and the politicians about what the risks really are. What we need to do is, and what we do is we just keep throwing money after things. And I think, like Judith talked about people looking at assessing low-level risks on people, and her concern that there wasn't enough explanation in the NRC on that.

You know, and she talked about she -- she believes in a linear hypothesis theory or worse than that concept on low-level radiation effects. But I do happen to know that there is a medical fellow at the NRC who is devoting a great deal of energy and time looking at low-level risk. He doesn't agree with that theory. That's why he's currently pursuing -- you know, polycove, probably, and, but, you know, you know, because someone doesn't agree doesn't mean that it's not being studied, and I know this man who's an emeritus professor at my university, the University of California, San Francisco, and believed that where the data took him is where he would go.

And the point was made that scientific risk is not -- it's a moving target. It's not fixed; that scientific methods demands that it be open to new data

and new interactions between radiation and other environmental pollutants that have been pointed by Judith earlier. I think these are, again -- you, we need to make -- know that this is not something that's fixed and can be boxed. It's something that's always open with regard to discussion and to new data and new information. If we don't have that kind of open attitude, then you're not really applying the true scientific method to this approach.

And part of that is looking at the real perception people have. In other words, that's something that absolutely has to be taken into account when you're trying to create something really works in our democratic environment. That has to meet the perception of the people. Now you've got very -- widely varied perceptions, and the only way to deal with that probably is through a strong educational effort.

We've already talked about educating -- the difficulty in having resources to educate people like inspectors. I know I've been looking at what California bureau -- on this issue and, for instance, we've taken inspectors and actually bring them through our university to give them experience with the year-old operating program, to try and get them from being prescriptive with a checklist to being programmatic and risk-based so they can evaluate the program.

That takes the highest level of knowledge to be able to go in and say well, you're doing this in a way that's very effective for your circumstances, and this works really great. Most of the inspectors don't have that kind of

experience, because it's an input, entry-point job rather than a higher level job. Even the highest level person wouldn't be able to do that kind of careful assessment in an inspection kind of thing. So these are all very, very important points that have already been made. I'm just reiterating giving my viewpoints on those. But I think that we have to look at these. We have to remember that you can never prove a negative. You know, that's one of the problems that we deal with is that you can never guarantee that there's no risk whatsoever. That's an impossibility that cannot be accomplished.

And we get stuck in a real big problem because we can measure things down to very, very low quantities, and you can just say that the very low amount of some toxin is going to create, you know, tremendous impacts, which we often times don't gather data to be able to make that assessment. And yet, we're spending huge amounts of money trying to control this low-level that we're able to measure based on theoretical risks. And yet, we have very real risks that are not getting handled because we don't have the resources, because we're squandering our resources in areas that aren't making a difference.

MR. CAMERON: Okay, thank you very much, Bob. And I think that that's something that we also need to discuss when we get into the criteria. I think one of the NRC's objectives here is to direct its resources most efficiently towards areas of greatest risk. And you're also suggesting that education be used to try to align perception perhaps with science.

DR. LULL: Or science with perception.

MR. CAMERON: Or science with perception, okay.

Let's go for a final comment from Norman, and then check in with the audience, and then we'll take a break. Norman.

MR. EISENBERG: Okay, well, Chip provoked me.

MR. CAMERON: Well, at least I had some use today.

MR. EISENBERG: With his question about what is risk. I thought Marty did an admirable job in defining risk in terms of the, not that it get too technical, but in terms of the Kaplan Garrick risk triple, but in everyday terms. What can happen -- what's the likelihood and what are the consequences.

The point I want to make is that the consequences are not a single scalar quantity. The consequences, in mathematical terms, is the vector. It has many components. You have public exposure potentially and workers exposure, and they can be from normal operations or they can be from accidents. And this kind of transplantation of the consequence part of the equation or the analysis has been around for a long time.

Also, as we've heard you have property contamination, which can include -- and maybe this may be a very important factor about it -- denial of use of the property. If you have an transportation accident in a very busy artery, even though the release of radioactivity may be zero, you may still have the artery closed down for a long period of time until it can be cleared.

And another possible component of the consequences is public response. And I think people that have done risk analysis for a while understand

that you need to make sure that the consequence part of the analysis includes all the various factors that might influence the decision.

And so I think we have a definition of risk assessment. It's whatever determines these three factors relating to risk. But the consequence part, there needs to be clarification and this needs to include everything that might be important.

So that was the part that Chip provoked me to say.

I'd like to make one other comment, and I think it's a thread that's running through the discussion, and many people have spoken to this from different perspectives. But one of the key questions for the management of risk in the materials area or even in the assessment of risk in a material area is that when you are looking at regulatory compliance, and regulatory compliance has a -- more or less of a binary nature -- you either comply or you don't. If you're looking at regulatory compliance, and you're talking about activities that pose small risks or risks that might involve very small consequences, should you have more flexibility in how do you judge whether there is compliance. And I think this is a -- really is a policy question that probably should be directed to the Commission. But it's I think a question that is interwoven in many of the considerations that were described this morning by Marty as things that the staff was going to look at. And it really is a question I think that needs to be answered.

MR. CAMERON: Okay, thank you very much, Norman. And when

you see opportunities to highlight that in our discussion, please do. And your point about the consequence part of the risk assessment is -- it should include all the factors that influence the decision. It might be a nice way to wrap up some of the disparate, perhaps disparate, types of impacts that people have been talking about.

So I'm glad I provoked you on that. Let's go the audience. You've heard the discussion and I'm sorry we don't have our cordless mike now, but does anybody want to offer any perspectives of their own on the discussion they heard around the table today? Yes, sir, please. And identify yourself and affiliation as appropriate.

MR. DAVIS: Jack Davis, technical assistant to Mike Webber at NRC. I think all along what Maria said about defining what risk is you also need to consider defining what is reasonable and acceptable risk. And I know it's kind of varied from the public prone the NRC and from a few other folks. But outlays are on the table, and get that common understanding what you all think is reasonable and acceptable, it's not going to work.

MR. CAMERON: Okay. Thank you. And I guess the challenge is how do you determine what is reasonable and acceptable. What is the process for determining that.

Thank you. Anybody else right now before we take a break? Okay. Why don't we come back at 11:30 a.m., and we'll go from 11:30 a.m. to 12:30, next session, and then we'll take a 12:30 p.m. to 1:30 p.m. lunch. Okay?

Thank you very much.

[Recess.]

MR. CAMERON: If everybody could take their seats.

Regulation in the materials arena should be selected for a risk-informed approach. And there are three criteria, and Stacey in a minute is going to talk a little bit about this. But some of the questions -- and I would like to do a better job of trying to follow some of these threads, and we'll suggest how we might move through this discussion. But there are three criteria. I guess the issue is should there be other criteria. What do you think of these criteria? What's included under each criterion? What are the relationships between the criterion? Are some more important than others, for example? And I'm just going to leave a little footnote or maybe it's a header so that you can see it in your mind.

I am just little worried that we're not all on the same wavelength about what taking a risk-informed approach means, and that sort of was triggered by Felix Killar's comment about the fact that our Part 70 efforts are not risk informed or we're not doing as good a job as we could there; that we're still taking what Felix termed the consequence approach. And if the NRC thinks Part 70 is the risk-informed approach, and the industry, and I'm not putting any special emphasis on the fact that it's the industry, but if any particular interest thinks diametrically -- is diametrically opposed in their opinion about whether we're being risk-informed, then it indicates that we need to -- that there's a

difference in the definition of risk informed that people are using.

So keep that in your mind, and we may have to address that issue. But right now, we're going to go specific criteria. And I'd like to ask Stacey Rosenberg to sort of tee that up for us. Stacey?

MS. ROSENBERG: Thank you, Chip. What we'd like to do is we want to know where risk insights are going to provide value in regulation of radioactive materials and waste disposal. So, in order to do that, we've proposed draft screening criteria to help us make these decisions in a consistent manner.

And ideally, at this -- during this session, we would like to come up with -- come to a consensus on these screening criteria, and we would like your input on these criteria, and also if you have any additional criteria that you think will be important as well.

So these are -- these are the three screening criteria that we have proposed. The first is a risk-informed regulatory approach to an activity. We'll solve a question with respect to maintaining or improving the activity. State B, we'll improve efficiency or the effectiveness of the NRC. Or it will reduce unnecessary regulatory burden for the licensee.

The second one is that sufficient information and analytical methods exist or it could be developed to support risk-informing or regulatory activity.

And the third that we propose that implementation can be realized

at a reasonable cost to the NRC and our licensees and that providing that benefit.

So we would like your input on these as well as any others.

MR. CAMERON: Okay, let's -- I have a suggestion to make as perhaps we look at the first criterion, okay, and talk about that, and then move to second, third, additional criteria, and they may flow out of our discussion of this one. And I guess -- the balancing aspect that I mentioned, I wasn't clear on that. I wasn't so much concerned about balancing between each separate criterion, but certainly there's three items -- three parameters in this first criterion -- what types of balancing goes on between them? I don't know or should there be any balancing. But, Bob, let's go to you, and then we're going to try to follow up on Bob's comment, and we're going to look at this criterion.

MR. BERNERO: Yeah, the first comment I would make is on the first criterion, and I am basing the comment on my experience of at least 25 years ago in developing risk-informed regulatory approach in reactors. And the key thing in that criterion that bothers me is will it -- fourth line -- will improve efficiency or the effectiveness of NRC process. And I think that is a misdirected test of improvement. The safety review or risk review responsibility is the licensee's. And what you're looking for is improvement of the efficiency or effectiveness of the safety control process; and, thereby, perhaps, reducing unnecessary regulatory burden.

Thereby -- but the important thing is to get this regulatory approach

out into the arena so that it is understandable and useable and makes the self-control process more effective.

And I think this very much like NRC saying NRC would be gathering the risk information. NRC would be gathering the ideas or concepts that would be useful. And NRC would be improving its regulatory process.

MR. CAMERON: Bob, is the problem the use of this term effectiveness of NRC process rather than effectiveness of the regulatory process?

MR. BERNERO: Of the process -- of the regulatory process -- the safety process. You're, you're, you're -- what you're trying to do is manage risk. And this makes it unduly focused on NRC gathering of risk information, making judgements, and making what is risk-based regulation rather than having the licensee.

Back in the reactor days, the biggest problem was, aside from a few pioneering contractors, John Garrick, to name one, and the NRC and its contract to the National Laboratories staff, the use -- the reactor owners didn't understand risk assessment. They didn't have a grasp of the terminology.

And all they could do was hire someone like Garrick to do a PRA, and that was a big white book of multi volumes, and it didn't mean anything. And there was a great deal of effort to get risk-informed analysis, and where the regulated community understands it then, the regulated community can take advantage of it, and say, hey, here's a better way to control this process. And

the NRC can gear its regulatory oversight accordingly.

MR. CAMERON: Okay.

MR. BERNERO: It's just that flagrant.

MR. CAMERON: Let me first ask -- might ask Felix, what would -- what do you think about Bob's comment, and also I'd like the NRC staff, if they could to, offer any clarification on what they thought that meant and also on Bob's comment.

Felix?

MR. KILLAR: Well, I'd -- first, I'd like to agree with Bob 100 percent. And a lot of the reason we had the problems in the early on was because well, we thought this is a good process. We didn't really have the end objective. And I think that's part of what the gentleman in the audience spoke of is you have to establish what is the line you're going to. Where is acceptable risk defined. And everybody has their own definition of acceptable risk.

And so, when people are out there and we get a number and say, okay, this is what the risk is, there would be very little meaning if people didn't know how to use that number. What's the -- the importance of that number was or significance of that number. So I think right along with what Bob was saying is that we could do some very nice problem risk assessments, but without having any context or a meaning to that gives very value to it.

And I agree with Bob as far as improving the effectiveness of the NRC's processes -- it's really the effectiveness of the regulatory process. And

it's not limited to the NRC. Risk assessment apply in other industries. FAA uses them all the time as well.

So, when we look at using risk assessment, if you have both the tools, but it's more of the application and the putting into the perspective of what those numbers, or what that significance really means.

MR. CAMERON: Okay, so you're agreeing with Bob, but you're also raising another point, which goes to the relationship between this risk information, risk assessment process and the risk management/safety goal issue. Is that -- unless you have a goal or a standard to aim for, you really are just spitting out these studies with really no place to go. Is that?

MR. KILLAR: Yes, that's correct. In fact, that's a part of what my comment was on early on is that one of the things that's happened at Omentero as at Seaside is that the goals have always been more on the line of, you know, zero consequences and minimal consequences, so trying to move from a consequence base to a risk base is hard for the staff to understand the difference between a risk-based and consciousness-based.

MR. CAMERON: I see. So that's what you're -- that puts a finer point on what you were saying before. Looking at too much emphasis on the consequence aspect of the triplet. Alright. Further comments on Bob's point? Roy?

MR. BROWN: Yeah, I had a follow up to what Bob said. I disagree to some degree because where I saw the NRC getting involved in the process

was setting up the original regulatory framework; that the NRC would go in, do a risk assessment, say this is very low-risk activity. We're getting ready to license. The consequences are minimal. They would set up a regulatory framework, using that risk assessment. It would be a risk-informed rule -- regulatory framework they would develop.

So to set up the initial regulatory framework, I think it is NRC's responsibility. I think a good example of this or a good opportunity that NRC could have used -- what Felix brought up before Part 35. I mean, NRC said diagnostic nuclear medicine under Part 35. It's a very low-risk activity, going back to the baseline from a couple of years ago, DSI-12. They said they were going to go in and look at the low-risk activity of nuclear medicine, and, in some cases, make it less prescriptive. Why the NRC had the opportunity to do that and didn't -- so I think that's where NRC can do risk assessment and make a new rule, do a new regulatory framework and make it risk informed.

So I think to that degree that statement's right.

MR. CAMERON: Okay, Bob, let me check in with you on Roy's comment on that, and get your perspective on what he just said.

MR. BERNERO: You know, I agree with Roy on that. And that's why one of my closing remarks I referred to risk-based regulation as against risk-informed regulation. In some of the literature since I retired, I've seen that distinction being made in the NRC. And that's where, in fact, you can go in past history where we were -- the NRC -- developed regulatory changes, regulation

changes. The ATWS rule, years ago, was a good example, based on comparative risk assessment. And it wasn't consequence-based, that is, finding the quantity derived from the assessment and then saying is that too high or is it low enough. No, it was a comparative. It's a, you know, sort of a judgement of risk. And that's fine, but I was thinking when I commented on this kind of NRC bias criteria, I was thinking actually of the fuel cycle.

I had the pleasure of promoting integrated safety analysis some years ago, when I was at the NRC, and I remember in Commission meetings trying to explain to the Commission that this is not to discover a population of risks or threats that were previously undiscovered and we had reason to believe there were all kinds of risks. No, it was to enhance our management of risk, and to get an integrated understanding of how all of them come together and being sure of potential synergisms and everything else.

And it appears that it's working out that way. It's working out to be the operating facility is getting a very great enhanced understanding, and I think a good simplification of the regulatory process.

MR. CAMERON: And that understanding would not necessarily -- that understanding would be valuable regardless of what the risk management goal would be, to just go back to a point Felix was making. I mean, it has a value in and of itself.

Further comments? Who has a comment on Bob's original point? Bob Lull?

DR. LULL: Yes, I just say that I have a tendency to disagree with the viewpoint that the NRC has no obligation or risk assessment and as it promulgates regulations. I think any new regulation ought to be taking this into account as to whether it should be regulated at all, and, if so, exactly how it should be regulated. And it shouldn't be the responsibility of the people that the NRC is intending to regulate to come up with the risk assessment.

I think in terms of regulations already in place, when they come up for some sort of renewal, that risk assessment ought to be taken into account by the agency. I'm not saying that the agency needs to go and do everything, change everything by -- and by risk assessment that everything's already in place. That would be a huge task, and obviously you're trying to select things that more bigger candidates for that as part of the goals here, as I understand it.

But I think that the NRC does have an obligation to utilize risk assessment, and they do. I mean, it's part of the whole natural process, even if it's not formalized. But I think there needs to be a formalized approach to that for any new regulation or any changes to regulations that occur.

MR. CAMERON: Okay. Thank you. Further comments on Bob's or -- if there's none other, we'll start with new comments on this first bullet.

Judy, did you have something?

DR. JOHNSRUD: I sense that Bob, and perhaps some others, find the term risk-informed questionable. And I would like to suggest to you that I think the NRC could not have chosen a terminology better designed to create

further mistrust on the part of the public.

People really don't like being talked down to, you know. And what -- but certainly what I'm hearing around the table, in part, is, well, we'll just inform the public. We'll let them know that we've taken everything into consideration, and there's nothing to worry about, folks. The risks are low. I don't think that that's an appropriate approach to what I had assumed the agency intended to do.

MR. CAMERON: Now, you're reading into risk informed certain perhaps -- and I'm not saying you're wrong about this -- but to you, that -- there's a loaded -- it's sort of a loaded terminology?

DR. JOHNSRUD: I'm suggesting that I think that if it is presented to the public in this form that that would be the response.

MR. CAMERON: Can we get some -- I'm going to go to Maria on this. Can we get some perceptions, some perspectives on what Judy just said about the basic use of that term, risk informed? Maria?

DR. PAVLOVA: Well, I was going to ask the same thing that Bob mentioned. As I know, all other agencies use risk-based, and everybody understands that it is based on a some semi-scientific, whatever, we don't have anything better. So we use risk assessment, but it is based.

Now, and I was going to ask why did you pick informed? It kind of brings the question, are we only going to inform or are we going to base on the risk, scientific risk assessment, our regulation? And may I say something that

bugs me a little bit. Because we're talking about risk-based regulation. The regulation by itself is already risk management. So what we are talking about is not risk assessment. It's just a method that we come to the management, but before we come to the regulation, management, then we have to involve the stakeholders -- the public and everybody else.

And so together, having in mind all the political, economic, emotional, cultural, whatever -- are the values are, then we'll come to regulation which is management.

Could I just show something which will take only a minute? This is the last presidential congressional commission on risk management and risk assessment in 1997, which was a blue-ribbon panel that NAS put together, and this is the last report. And it changes the whole risk assessment management view, put not so much on the technical part of the risk assessment as to including CODIS values so that the thrust is on the stakeholders in risk management. If not now, later. It will be only a minute.

MR. CAMERON: No, Maria, let's -- I very much would like everybody to see that. And I think it ties in your last part of your comment -- ties into the risk management aspect of this. And I -- it's sort of a chicken or egg thing, but we have our agenda, it seems, divided up into discussion of risk assessment, and then this second session on safety goal is really the risk management portion of it. And maybe that would be the appropriate time to put this information up.

DR. PAVLOVA: I agree. The only thing that I suggest is stake informed and good based.

MR. CAMERON: Okay, and let me -- let's explore that aspect of it. I want to go to Marty who can fill us in on what the NRC was thinking in the use of these two terms, and I want Judy to keep in mind would you feel less put off, so to speak, if the term used was risk-based rather than risk-informed? Marty, why don't you go ahead?

MR. VIRGILIO: Well, I think it's a little more than semantics. I want to give you little history on this. It was about five years ago, where I recall we were constantly using the term risk-based regulation, when the Commission said, no, wait a minute. What you're really doing is something quite different. In their minds, risk-based regulation was very numerically driven. It was a presumption that we had the data and the tools to make decisions based on numbers alone.

And the Commission said, first of all, you don't have the tools and the data to make those kinds of decisions. Furthermore, we really don't want to make those kinds of decisions on the numbers alone. It's something we've talked about a little bit earlier, but I don't think we got into a lot of depth.

Risk-informed decision making is just using risk information and risk tools as part of the equation for the decision that you're going to make. Other things that have to factor into that decision, then, include public confidence -- include things like the efficiency and effectiveness of what that decision is going to do to you processes. And it includes burden. And it includes broadly

burden I think not only on those we regulate, but the public at large.

So the Commission made this deliberate shift to say we are not in the business of risk-based regulation. We're not going to base our decisions solely on the numbers. That's too narrowly focused.

What we're going to do is think about all these factors, and use risk information to supplement and inform the decision making. So that's the way it was meant. And it was not well communicated I don't think at the time because not only people outside the agency are still confused, but many of our staff still have problems understanding the difference between these concepts.

MR. CAMERON: And on that -- and I don't know how much more do we want to get a couple other comments on this, and then look at some of the other aspects of this first criterion, because I see other people have their cards up, but I guess that I would ask Judy, hearing that explanation does that make you feel more sanguine about the use of the term risk-informed when you see that it's actually a broader concept that just number crunching, and it has room for consideration of a number of different factors.

DR. JOHNSRUD: The short answer is no, but let me add, as I looked at the last phrase about criterion one, I think that the public will be even more distressed by this approach.

To be honest, a great many people in the public really don't care about the burden for the applicant or the licensee. They care about safety. And they care about any forms of regulation that enhance safety for them.

MR. CAMERON: Let's go to the issue of -- at the very minimum, how are these three different -- there are "ors" used here. How are these three different aspects balanced? How are they prioritized? Any views on that? Any views on the legitimacy of including reduced, unnecessary regulatory burden? Okay, Amy.

MS. SHOLLENBERGER: I think, first of all, it's really important to see that the first thing in that list is to maintain or improve safety. But the other two things are not an either or. They improve efficiency of NRC, and reduce burden.

It's not prioritizing safety at all, to say either maintain or improve. It's prioritizing safety to say improve no matter what. Maintaining safety at the level that it's at is certainly not going to inspire a vote of confidence.

MR. CAMERON: Okay.

MS. SHOLLENBERGER: I have a few more comments, and I'd like to make them because I think that one that really frustrates me, and Judy brought this point up before, going back to a comment -- I forget who said it -- Mr. Lull -- saying that the public is represented by each of us. I think it's truly inaccurate. Because it's true that you all live in the world, but you're here to represent whatever specific interests you're getting paid to be here to represent just like I am, when Judy's not paid at all. She just cares. Because she cares, and you know to say that someone from NEI is going to come in and say something that's going to go against that industry perspective is -- you would be

doing your job if you do that.

So I just want to make that point. And I think that it goes to something Judy said earlier is that we, you know, every time Judy or I makes a comment, eight or nine of you could make another comment. So we're really outnumbered here. So I'm going to talk for a while, because I may not get another chance.

MR. CAMERON: Should we stay? Go ahead.

MS. SHOLLENBERGER: So first of all, I'd like to go -- just really highlight that I don't think we can ever reach consensus on these criteria, because they do not at all represent the interests of the public. That's number one.

Number two, I'd like to go back to some of the things that were said earlier, which I think relate to the question that's on the table right now. And I think that one key thing that was brought up by Dr. Pavlova -- I'm just sort of amazed that you think DoE has lost trust. I just don't think there's anything that DoE could ever do to gain trust, but that's just my opinion.

Anyway, you also said that communication is the key and that agencies must listen with empathy to what the public has to say. And I think that, you know, someone reading the transcripts probably thinks, oh, well, hey, that's a pretty good point. That's what we wanted the agencies to do. That's what we want DoE to do. That's what we want NRC to do.

But the truth is, is that it's impossible for you to listen with empathy.

It's impossible for you, with your hypothetical critical group and your unrealistic scenarios and your inability to believe that a member of the public can understand what you're talking about could ever listen to us with empathy. And by us, I mean both non-profit groups, non-scientists, members of the public, people at risk, workers at the plants or wherever they are. There's just no way that you can do that; that you -- you can't accomplish that.

And so I think that what happens is instead you focus on trying to make us understand that there's nothing to worry about. And it's just not true. There's lots to worry about for us, and whether you want to admit that or not is, you know, is your own decision, I guess. But whether you think that it's a big deal for four people in a million to get cancer or not, and whether I think that's a big deal are probably never going to be the same. Because I think it's a huge deal. Because I don't believe you're telling me the truth that only four people in a million are going to get cancer, number one.

And I'll never believe that. And, also, I know that when somebody gets cancer, it affects more than that one person. It affects probably at least 10 if not 20 or 25 people in their family and at their work -- and -- you know, in their church--everywhere. It's not just four in a million.

And I think, you know, I'm glad that Mr. Bernero brought up Mr. Garrick's name, because I think Chairman Garrick is the master at risk communication. And I think that he really works hard to help you all understand how to tell the public that it's okay. And he's -- we've had several conversations

about that, Chairman Garrick and I. And I think that if you all really want to learn, you should go and talk to him because he's really good at it.

So that's one point there. And I'd also like to go back to something Mr. Lull said, and he said that -- when he was talking about perceptions -- he said it's important to perceive what isn't but could have been if we hadn't wasted resources dealing with people's perceptions of risk, and that's probably not exactly a perfect quote, but I think it's pretty close. And I just think it's really key to see how your -- how your perspective is different from the public's perspective. Because you look at it as throwing money down a hole to find out whether what people are afraid of is really something they should --

DR. LULL: But I think that your viewpoint is very important because if we're going to get something that works, we're going to have to deal with your distrust and your viewpoints, and be able to convince you that something that is happening is actually okay and that you trust them to do it. You know, and that's going to be a really big, big hurdle.

I would point out, however, though that, you know, reemphasizing that while you formally feel you represent to us the people and the people at risk, the fact is that all of us really are part of that. When I talk about resources being wasted, I'm talking about the patients that I see in my hospital, who, I can't -- they can't get the drugs and the care that they need, because there isn't money. You know, the fact is that people, you know, want to end up spending money on the things that they're afraid of and they're concerned about. And also real risk.

I mean, I'm not talking about just only made-up, perceptual risk. Their perception of risk is a real risk, and it's a real issue. But you have to put some things in perspective. I see there are women who are not getting mammograms because they're afraid that they're going to cause breast cancer by the low-level radiations they get exposed to from the x-ray and mammography technique, and so they -- I see people who avoided that, and they're dying of breast cancer that could have been detected at a curable state. Risk perception is very complicated, but the fact is that when we are -- there isn't enough money for all the things that we'd like to do and all the issues that need to be done, in spite of the tax rates that all of us have just recently experienced.

And we need to prioritize where the money's going to go. And while your viewpoint -- and every one of us has a viewpoint about where the money should be spent -- the fact is it's important for us to be open to other viewpoints about where there's need and where there isn't enough money and look at areas where we're spending money now, and say is that worthwhile when we could be putting money into vaccination programs that have tremendous impact. And we're using huge amounts of money on regulation of radioactivity, for instance, is one of the examples, but there are a number of other examples, that produce very, very little impact and change in our society, and yet we have very major problems, like cancer that aren't getting handled properly, and like infectious diseases that aren't getting handled properly.

I get to see those every day, so that's the public I'm kind of

representing in a sense, too. So there are different public "us" being represented by each of us, and I think it's important that we look at the totality of everybody, including the "us" that you guys represent.

MR. CAMERON: Okay, thank you, Bob. Any further comments for Amy before we go on to another issue. Let's go to Chia Chen, and then over to Barbara. Chia?

MR. CHEN: Yeah, Chia Chen. In my judgment, so-called first criterion actually is the purpose of this new approach. And I think the three elements you have -- let's start with second first -- is the data -- what the data or information need and then what's the risk assessment method to assess those data or information.

And then the second is this we have to have what is so-called reasonable and acceptable risk. This is very controversial, but this have -- decides on where first. And then, but you have a how to judge the benefit and cost that you have some kind of benefit-cost analyzed, yeah.

MR. CAMERON: Okay. Thank you, Chia. Let's get to Barbara, and then to Roy and Jonathan and Norman and get some other reactions to some of Amy's suggestions. Barbara.

MS. HAMRICK: I'd just like to address the criticism of the last sentence in the first criterion. And this kind of goes with what Bob was saying as well, reducing the unnecessary regulatory burden isn't just a means of making things easier for a licensee, but the people who end up paying for the increased

regulatory burden is the public. And it's Bob's patients, and patients in other medical centers. And what will happen is when you're trying to reduce the risk on one end of the spectrum, the theoretical, critical group on this end, there's a theoretical, critical group on the other end that is now being burdened by the risk, and that's the people who are not getting the medical exams or not receiving the treatment that they could -- that they should be able to receive, because the regulatory burden is so high, there's no place to dispose of waste. There's no way to generate, manufacture the sources that are needed for treatment or diagnosis. So the balance of the regulatory burden is not just to ease -- it's not something to make it easy for industry. Those costs are passed on to the public as real monetary costs and as real risk costs as well. So I'd make that point.

I also wanted to make the point that even though it -- some people are a little disturbed by the idea of a cost-benefit analysis when we're talking about real people with cancer. In fact, every day of our lives is filled with risks that we make the decision to accept. When we go out on the highway -- no matter what activity we partake in, there is risk, and we have to look at the real benefits from the activities that we're talking about today and balance that. And it is a cost-benefit analysis. And it's just -- that's the practicalities of your life.

MR. CAMERON: Okay. Thank you, Barbara. I guess that you would say that this phrase should be in there, but perhaps another point that you're making is that there could be a better elaboration by the NRC of why these phrases are in here.

MS. HAMRICK: Yeah, I just think that it needs to be clear that that burden is not just a burden to an individual industry member or an individual industry; that the burden is borne by the public and recipients of the industry's services.

MR. CAMERON: Okay. Let's go to Roy and then Jonathan and then Norman.

MR. BROWN: Amy, let me start off by saying, you know, we're real glad you and Judith are here. You guys represent a very important opinion and the opinion of all the people you represent. So we're very glad you're here. It's very good you're a stakeholder. I'm glad to see you at the table. I wish you weren't so outnumbered.

I did want to -- I'm sorry?

MS. SHOLLENBERGER: You can change that.

MR. BROWN: Well, I don't want to get into that, but I would like to say you guys are an important stakeholder, but -- so you need to be here.

I want to go back to Judith's comments a few minutes ago, talking about -- Marty brought up the social factors involved from getting a risk-based to risk-informed, and from a licensee standpoint I always saw -- I mean if we looked strictly at risk-based, I could see us possibly, our industry possibly, getting out of some of the specific licenses and getting into general licenses. For example, for the practice of nuclear pharmacy. I mean, that is low -- a low risk enough activity where that could be possibly be handled under a general license if you do it

strictly risk-based.

But if we looked at the social factors -- well, how will people react to not licensing the pharmacies and when you look at those social factors, you tend to go conservative. You don't tend to go negative. So, from an industry standpoint, I feel like we lose something by going from risk-based to risk-informed, not going the other way. So I see those social factors as being more conservative, not being more liberal, Judith. Not -- moving us toward more regulation, not away from regulation.

DR. JOHNSRUD: I think you just totally lost me.

MR. BROWN: Okay.

DR. JOHNSRUD: The feeling was just reversed my position, but okay.

MR. BROWN: Well, what one -- I guess that's what I'm trying to do. When we look at just risk -- I'm sorry?

DR. JOHNSRUD: I think you know.

MR. BROWN: What I consider is just risk-based, as Marty said he looked just at the numbers, some of the things that we do in the medical industry I think are low-risk enough activities where if you looked at just the risk numbers involved, they could be done under a general license or essentially no specific license.

DR. JOHNSRUD: Well, that assumes that the NRC would continue to allow the kind of general license that it has. And there are many of us who feel

that that is not anywhere close to adequate regulation.

MR. BROWN: Okay, well that's a whole other--

DR. JOHNSRUD: For the protection of public health and safety and the environment.

MR. BROWN: Sure. That's a whole other subject, but I guess what I'm saying is the social factors, once you bring risk-informed in -- the social factors tend to make you more conservative. You're saying, no, you guys can't operate under a general license. You have to have a specific license.

MR. CAMERON: Okay, for the -- and I would note that the general license regime is being changed right now, probably in response to risk information.

MR. BROWN: I guess -- what my point was I would think that -- I would think you would prefer risk-informed over risk-based I guess is what the bottom line is, but maybe we can talk at a break or something.

But the other comment I had real quickly -- on the last comment there was -- the other comment I wanted to make was on the unnecessary regulatory burden.

Let me give you a specific example, and this may help us understand this. When I read that unnecessary regulatory burden, I liked the idea of that, because I look at, from a practical standpoint, what we do a day-to-day basis. I'm going to give you an example.

Air effluent releases now are controlled very tightly by NRC. We

have a certain concentration. We have to read -- there's certain release criteria that we can meet or what those regulatory limits. Not to pick on EPA, but several years ago, EPA came out with a radionuclide standard that put another layer of air concentrations on there. You had to do a whole separate set of calculations, use all different software to essentially analyze the same thing--your air point releases.

Once again, we met those numbers. There was no problem with that. The way we see this is this is -- I mean, we've already made the numbers. We're spending hundreds of thousands of dollars a year just to demonstrate compliance. We already have compliance. We can show compliance through NRC, but we have to throw out all the EPA forms. We have to run all the EPA software. We consider that an unnecessary burden. We would much rather say, well, we're already showing compliance through NRC, and not have to fill out those duplicate forms and spend the money actually reducing those releases, but spend the money, you know, with radiation safety or nuclear safety rather than filling out forms that we consider are not necessary.

So that's what I think of when I see the unnecessary regulatory burden. I'd like to see a statement on that.

MR. CAMERON: Okay, there's an example of that particular phrase. I think what we're going to do is we're going to run through these cards quickly on this first bullet, and then we need to see -- I think the other two may be less problematic -- get your opinions on those, see if there's anything else and

check in with the audience. And, again, this is a subject that is very broad, very important, and I'm sorry that we don't have more time now to address it, but will in the future. Jonathan?

MR. FORTKAMP: Yeah, I want to say again -- My name is Jonathan Fortkamp with ABB Automation. I think this is a good approach, looking at it from this perspective. I hear a lot of talk here about public perception and what have you, but there's a lot of materials licensees that are not in or not well known by the public. And I think if too much emphasis is given to only public perception, those licensees can get kind of lost in the shuffle, such as manufacturer and distributor of industrial gauges, paper machines, for example. Paper mills everywhere have nuclear devices in their -- as part of their processes. Very little public knowledge of that, very low risk out of these, granted. Very minimal risk out of these, but if too much is given to only public perception of risk, then regulatory controls on those types of processes are not analyzed thoroughly enough.

As well, talking about unnecessary burden, again, looking at these types of licensees, I think that's important to look at because a lot of these licensees are smaller licensees. If the burden -- if there's a lot of burden on the licensees, naturally their costs are going to go up. They're not going to eat the cost. They're going to rotate those costs off to their customers, and it eventually it gets out into the public realm. It also takes away time from those licensees that if there's an unnecessary burden on them for paper work, not doing

inspections or what have that are not really risk-based, that they're just regulatory based, that takes time away from other activities that would be more beneficial on reducing true risk to the members of the public and the workers of that licensee.

So I -- you know, I think this is a good first step for screening criteria. I think the public's perceptions and public's concerns are addressed in the first line of that or the -- you know, with respect to maintaining or approving the activity's safety basis.

MR. CAMERON: Okay. Thank you, Jonathan. Norman?

MR. EISENBERG: Well, I have one thing to follow up on this discussion that was a follow-up on Bob Bernero's comment. It seems to me that there are probably two poles at which risk informed regulation will take place.

One is with large licensees that have lots of resources -- that do technical analyses in a risk context. The other pole is for ubiquitous, small licensees where the NRC staff may do risk analyses to modify the regulation to either make them safer or make them more efficient. I think that needs to be kept in mind because I think sometimes the discussion focuses on the first kind of activity where you would do a lot of analysis or the licensees who do a lot of analyses, and I think there's this other part that may be just as important. And I think it would be probably not feasible to have these large number of small licensees do this kind of technical analysis. So I think that needs to be borne in mind.

But I had a comment on the first criterion, and I -- actually, it's a question. Maybe you can clarify it. I thought that the first step in this five-step process was to identify areas where risk-informed regulation might be profitable to explore, to look -- to try to identify where these kinds of method and approaches might yield some benefit to all the pitfalls. And the way it's phrased is it's talking about a specific regulatory approach, and it almost reminds of some of the regulations on the reactor side where licensees propose particular methods of compliance with the regulation, and they have to show certain risk analyses to justify the change that they want.

And so my questions are getting out of all of these policy issues down to very practical things or operational thing -- does everything need to go through this process, or will everything go through this process, and can't individual staff and inspectors propose risk-informed approaches without going through a central clearinghouse. And I wonder if this level of command and control is consistent with good regulatory practice.

And I -- it would seem to me that you'd want to articulate the policy very clearly, train the staff, develop methods for feedback and evaluation, and then reward the successes.

And the other thing that is a little confusing about this to me, anyway, is what about those areas where risk-informed regulation is already the dominant mode of regulation, as in the waste business?

MR. CAMERON: That's not -- those are -- that's a good question.

In other words, these criteria are here, but it doesn't tell you anything about how they're going to be used I guess. Is it something that the staff would, for example, go through -- part of it we're going to try to do here -- is try to, in the next session, apply these criteria. But is it something that all of the NRC regulatory efforts will now be put through this screening. What about existing efforts, and I don't know, Marty, if you want to make any comment about that at this point.

MR. EISENBERG: And very specifically, is it regulatory approaches or different areas of regulation that will be put through these criteria?

MR. CAMERON: And I got the impression that it would not only be all of the different categories, but within those categories there are specific activities, but for each of those activities, you could use this to develop a rule. You could use this to assess compliance. You could use it in a number of different ways. So it's sort of anything is possible, is that correct, Marty, at least at this stage?

MR. VIRGILIO: Yes, I think -- you know, as we developed this, what we weren't trying to do was chill an individual's use of risk thinking, you know -- and the triplet. And asking themselves that question. You know, every time that they go conduct an activity, you want them eventually to be thinking along those lines of what can happen, how likely is it, and what are the consequences.

I had in mind -- you know, and I'm sure everybody had a different

thought as they read this -- but I had in mind a certain level of effort is that we would start up a new program or, you know, change an approach to inspection at a fairly high level, like, say, Bob, today we are -- say, we would approach medical inspections. Just to clearly revamp the inspection procedures that we would use to do that. That level of effort I would see that we would run through this before we would start.

So, but I think -- I don't think we're settled on that. I think that there's an opportunity for some shaping of thoughts here. And then -- I think we ought to. I think we ought to discuss it.

But I had in mind the threshold.

MR. CAMERON: Okay, let's go quickly to Ray, Judith, and Amy, and then see if we can get some further comments on the other criteria, and go to the audience. Ray?

MR. JOHNSON: I wanted to speak briefly on behalf of the people who are responsible for implementing regulatory requirements for radiation safety. Licensees is what I'm referring to.

Over the past year, I have been asking members of the Health Physics Society to consider what's happening to our profession, especially as we're coming into a new century, a new millennium, and what I would offer is that the profession of health physics had its origins among people with training in science and biology and physics in terms of understanding radiation risks.

And they applied their understanding of science to make judgments

about radiation safety for implementing good practices for radiation safety.

Now, what I would observe is happening, though, over the last 50 years is that more and more, requirements for radiation safety have become very prescriptive, where what's happening today is that people can qualify to be the responsible person on a radioactive materials license for implementing a safety program with only 40 hours of training.

Now, do these people have a good understanding of radiation risks or even an understanding of safety? And I would suggest that they do not and, in fact, I would ask is it even required that they have an understanding of safety or risks.

One thing that people know today in terms of compliance, under the requirements of their license, what's the biggest risk they have to face; that is, violations of the regulations. So what are they trained in? They're trained to understand what the regulatory requirements are and how to implement those in such a manner that they're not cited for violations.

So what's happening to the profession of radiation safety? We're losing the science because it's no longer a requirement. I think we're even losing the focus on safety.

So as far as the people understanding risks, I would say that, well, first of all, I think for their to be risk information, there has to be a risk basis. So I'm not quite sure I would distinguish is there a risk base versus risk-informed. Now, can you inform about risks without knowing what they are?

But I think it would be a big step forward in what's happening on this evolution of radiation safety programs if we would begin to go beyond the very prescriptive requirements that do not require an understanding of safety or risks into the level where people would actually implement a knowledge of radiation safety and risks in the process of carrying out good radiation safety programs.

MR. CAMERON: One of the things I guess you're saying is that using a risk-based/informed approach may enhance a better development, a better understanding of safety rather than sort of go through the checklist type of compliance requirements.

MR. JOHNSON: I think it would require a much better understanding of safety and I believe that would be an improvement in radiation safety programs. It would involve a lot of training, training of licensees, training of inspectors.

I think that that could become quite a big challenge on how to implement this. But right now, there's very little need for understanding either risk or safety. To be successful as an RSO, you just need to know how to implement the very prescriptive requirements.

MR. CAMERON: So perhaps that's something for the NRC to think about in terms of explaining what the objectives or benefits of using a risk-based approach might be. Thanks, Ray.

Let's go quickly to Judy, and then Amy, and then see if we can deal

with these other issues.

MS. JOHNSRUD: First, a comment concerning the prior comment with regard to costs. I don't want to be repetitive, but what really appears to many of us to be needed is an internalizing of what are now ignored as externalities, that are not included in standard and cost-benefit analysis.

And I think we've heard some comments earlier about the need for breadth in whatever kind of analysis is to be done. That goes to totalities of impact of risk of the action, of the activity.

Secondly, I would respectfully disagree with regard to the need to move away from prescriptive regulation. Back in Bob Bernero's day, the primacy of redundancy of safeguards and defense-in-depth was a description, as it were, of indeed a prescriptive, careful, conservative approach to regulation.

And I find, by comparison, that the performance-based risk-informed approach moves us away from emphasis on the regulators taking the responsibility indeed to be prescriptive and indeed to do so on a very conservative basis. There are far more facilities, there are far more licensees than there were 20, 30, 40 years ago, and hence there are far more radioactive materials and far more of them either now or in the future as deregulation expands and radioactive materials more and more are recycled into the consumer realm.

Individuals in the public have reason to expect that the regulator is going to regulate, not turn over risk analyses to the licensees. That's self-serving

with, again, regard to the licensees. It is indeed where there are interests that are not the interests of those who receive the risk.

That takes me to my third point, and I appreciate Amy's comment about our feeling rather embattled about time available for commenting in response to so much.

I haven't heard a word here -- well, let me say, first, I'm not a gambler and as I watched NASDAQ tanking, I was so glad I'm not a gambler, financially or otherwise, with health or with the environment. And I would be far more comfortable to hear the word risk used in association with the term avoidance of risks and reduction of risks and prevention of risks to the public, and I'm not hearing the slightest recognition that that's something important.

It certainly is to the public.

MR. CAMERON: Judy, how would you -- and I know that you may not have a suggestion or specific language, but how would you change that first criterion to reflect what you're saying?

MS. JOHNSRUD: Well, Chip, I would throw out the use of risk assessment in the forms that have been developed and certainly in this notion of risk-informed regulatory approach. I would return to doing the job.

Now, there are elements of what go into risk analyses that are very significant, very important, indeed, and need to be taken into consideration by both licensees and the regulators. But to move away from doing the regulatory job and doing it in the toughest manner, including enforcement, I think, is a

dereliction of duty on the part of the agency.

MR. CAMERON: Although conceivably, I at least think it's in the NCR's mind that using risk information could lead to a more stringent regulatory regime. In other words, risk-informed does not mean performance-based. You could use risk information to set very prescriptive requirements in a particular area.

And, Marty, let me turn to you, or Stacy, for a clarification on that. Was that correct?

MR. VIRGILIO: Yes. And I don't recall who brought up the point earlier, but particularly when we think about the smaller licensees that we regulate, we may, in fact, wind up using the insights and information to increase requirements.

I think as we watch -- hopefully, I don't offend any radiographers in the room, but I think if we watch that segment of the industry we regulate, we do a risk analysis and we realize that there may be areas where we need to increase requirements.

So we wouldn't turn this over to them. Again, somebody made the point earlier that there may be two polls. I think Norm brought up the issue of you've got large licensees that maybe it would be beneficial to have them do risk assessments, and then you have another category of the smaller licensees, like the radiographers, where we would do our own assessment, identify some vulnerability, if there was one, and require additional action to be taken on the

part of the radiographer.

We recently did that in terms of training qualification requirements. So there was a rule promulgated within, I think, the last two years that increased the training and qualification requirements. We required the radiographers to get independently certified, because we believed that that would, in fact, decrease the number of events we were seeing and increase public health and safety.

In that case, the public was the radiographers themselves and the people in the immediate vicinity of where the radiography was being taken place.

MR. CAMERON: Thanks, Marty. We really do have to move on here, but I want to give Amy one last -- not last, but an additional opportunity here. Amy?

MS. SHOLLENBERGER: I wanted to go back to something that Barbara said, I think, in response to my comments earlier. It really struck me, because you said that we make choices every day and we make those choices pretty much based on cost-benefit analysis, and I totally agree with that. I think it's really true.

If my son falls down, I might choose to expose him to an X-ray machine to find out if his bone is broken, even though I fear the side effects of x-rays. However, I think especially in the materials side of regulation, when you're talking about the public making choices, it's just really not at all true, and it's also really important to see that the people who pay the costs are not necessarily the people who get whatever benefit is derived from the use of these

materials.

For instance, people living near a nuclear waste dump in a state that has no nuclear reactors are not getting any benefit. They're only paying costs. People who live along transportation routes and are having their property values go down by ten percent never chose to have nuclear waste roll along the road where they live and maybe even when they bought the house, they didn't even have the idea that nuclear waste might go on there.

So they didn't even make the choice knowing that this cost was going to be a problem, and I think that's something that's really different from the reactor side. I think that although I don't agree with it, I could see how someone could make the argument that people who live next door to a reactor take a risk and they get a benefit by getting energy.

I disagree with that, but I could see how someone could say that. But when you live next to a waste dump or along a transportation route, it's an entirely different story. You're not making the choice, you're not getting the benefit, and you're only paying the costs.

MR. CAMERON: Thank you. Barbara, real quick, and then Stacy has a question for Amy, and then we're going to look at the second bullet. Go ahead.

MS. HAMRICK: I quickly want to respond that in the same way that they don't realize that they're expending this cost by unknowingly living on this transportation route, they're probably unknowingly receiving the benefit, too.

Medical research that uses radioisotopes, down the line, they may be the recipient, and that's kind of -- you balance the hypothetical people who benefit with the hypothetical people who pay the cost, and maybe they will be the same person and maybe they won't, but really you have to balance both sides, is all I'm saying.

There will be people who will receive the benefit, who won't know, who won't realize the benefit they got from it.

MS. ROSENBERG: I would just like to ask you a question. In terms of the first bullet, if it were worded in a different way, something like including the use of risk assessment techniques in a regulatory application will solve a question with respect to improving an activity's safety.

Would that be something that -- would that be a criteria that --

MS. HAMRICK: Would you read that over?

MS. ROSENBERG: Including the use of risk assessment techniques in a regulatory application will solve a question with respect to improving the activity's safety.

MS. JOHNSRUD: If there is an existing question about an activity, about the safety of an activity, it may, but it may not, and to rely upon it adds risk.

MS. ROSENBERG: What I'm saying is not relying on it, including it, just including --

MS. JOHNSRUD: But you said will, will solve the problem.

MS. SHOLLENBERGER: This is in the form of a question, though.

What you're saying is when you're trying to decide whether or not to use risk-informed, your first question is will it solve a question to include. I think your phrasing is really confusing. I think the criteria should be in the form of questions all the time. You guys never put them in the form of questions. You make them statements like they're truth.

So maybe if you rephrase it. I think it's better than that. I'm not sure that I agree with it totally.

MR. CAMERON: Okay. Well, I think we've probably milked this for as much as we can right now. I'd just like to get a couple of quick reactions from you on these other bullets, and I'll probably retreat real quickly, too, because they probably won't be quick reactions, nor should they be.

But this one seems pretty straightforward, although there is a lot going on underneath it. Sufficient information can be developed. Well, that's true, but what does that mean? Any comments on that from around the table? Judy?

MS. JOHNSRUD: Based upon all experience that I'm aware of, with the use of PRA, I really do not believe that sufficient information or data or analytical methods, for that matter, either exist or can be developed to support the utilization that apparently is being proposed by the agency of, quote, risk-informing.

MR. CAMERON: Let me go to Norman on that issue. Norman?

MR. EISENBERG: I guess I'd disagree. I think you could always

get the data and the methods. The question is at what cost, and this is partially addressed in the next question.

So I'm not sure, by itself, that that's a useful criterion, because maybe the real question is what is the possible improvement in regulation that might occur versus the possible cost that it will take to get the methods and the data to go to a risk-informed approach.

MR. CAMERON: Which is more, I guess, maybe sort of wrapped up, although not articulated in the third bullet. You would get rid of the second bullet and talk about is the benefit of improving safety or if you had these other things in there, is it worth the cost to get the data. That would be your specific comment.

Anybody else on that particular issue? Maria?

MS. PAVLOVA: I think that probably it will be a little more -- how to say -- it's better if we just state the state-of-the-art data and methods should be used in the risk-informing or risk-based regulation, because we have to realize that everything changes and we're getting better and better in that, but we can wish and will try to use what is peer reviewed and existing state-of-the-art and as they change, we will follow with them.

MR. CAMERON: Okay. Something on state-of-the-art related to the second bullet. Does anybody disagree? Rob and then Andy, I wondered what people thought about what Norman said?

MR. LULL: I actually don't disagree, but the fact is that you're

never going to have really perfect data. In life, we're always operating on the best data available that we can collect at the time and then oftentimes you have to make a decision. If you're doing something, you're doing it, you should use the data that's available.

I think I also wanted to comment, and I don't want to break the string of thought here, but risk is in the eye of the beholder and I want to sort of support something that you mentioned, Amy, and that is the public doesn't get to decide really and they feel like it's getting done to them by the agency and when people feel that they are subject to involuntary risk -- that is, they don't get the -- you drive your car someplace, you take an airplane flight, you volunteer to do that. When she has her son x-rayed, she volunteers to do that.

When it's something that's involuntary that you're getting exposed to as a risk by some other outside force, you really are very unwilling to take any risk, and no matter how you -- you can define it as a very, very small risk, but basically what you get is the concept that we heard earlier, eliminate the risk completely. Don't do whatever it is that's going to make a risk, even if -- no matter how small it is, if it's involuntary. If it's voluntary, it's different.

There are some communities who have actually volunteered to take waste sites and they make money for their community out of that and the people there are willing to do that. There have been a few volunteers. They haven't actually put something in there. But that does happen and it's really about perception and whether or not it's being done to you or you're part of the

process.

MR. CAMERON: Thank you, Bob. Andy?

MR. WALLO: I think this is very useful and I would agree with those statements. The question you really need to be asking is does it help with the decision and help explain the situation. We look at the sufficiency for data. Nearly a decade ago, we had a bunch of data on the repositories.

Some people said that, gee, that was a good site, some said it's a bad site. A decade later and, I don't know, it must be about three or four billion dollars more of data, we end up with some people thinking it's a good site and some people thinking it's a bad site.

You really need to move toward trying to cohesively, everyone involved, identify your data quality objectives and see if the criteria should be will the analysis help you; if it won't, then do some other approach, because you could go on forever trying to decide if it's sufficient data unless you set some groundless early on.

MR. CAMERON: Okay. Well, thank you for those suggestions. I think that the NRC will find that very helpful. Quickly, and we're going to -- we can -- as we talk about these other areas, as we go further into this afternoon after lunch, we will have a chance to test these out. So there will be time to address these again.

The third criterion, startup and implementation are reasonable cost. Well, that's sort of -- again, that sounds like a truism. I don't know what

reasonable is. Cost to NRC and the applicant or licensee to provide a net benefit, net benefit will be considered to apply to the public, the applicant, the licensee or the NRC staff.

Doesn't this get us back into some of the things that we were concerned or some people were concerned about here? Is this trying to be too many things to too many people or what are perspectives on this? Judy?

MS. JOHNSRUD: We're right back to cost-benefit to whom and you state it clearly here, reasonable cost to the NRC and the applicant or licensee. How about the costs that are not internalized to the public? I don't see that those costs are under consideration and, therefore, one has to conclude that cost to the NRC and the applicant or licensee do not constitute a reasonable cost to the society as a whole, not to mention to the environment.

MR. CAMERON: Thank you. Felix?

MR. KILLAR: I think the way it's worded is fairly good. In fact, going back to the first one, it's worded very good, because we have finite costs in this country. We don't have infinite resources to do everything that we want to do.

So you've got to do a balancing between all the various things and if you're going to spend a lot of money on this little gnat down here, that means that money isn't available, those resources aren't available to address these issues over here.

So you have to look at the total cost and the whole societal benefit

of that program and the benefit to the applicant, to the public, and to the NRC. The NRC doesn't have infinite resources. They have I forget how many people now, but if you double that number of people, does that mean we'll actually be safer? Not necessarily. It means we may have higher costs.

So I think you have to look at the total aspect and the total societal benefits and stuff. So I think by including the public, the NRC and the applicant and licensee does cover the gauntlet and is appropriate.

MR. CAMERON: So, Felix, you look on this as sort of a broad, maybe broad is not the right word, but a balancing of the many factors involved. Judy, at a minimum, was saying that the externalities to the public should be specifically recognized in here, whatever those externalities might be.

Norman.

MR. EISENBERG: I just have a minor clarification. It's a small point, but NRC is a full fee recovery agency. So I don't see how you can separate the cost to the NRC and the cost to the applicants or licensees. Maybe what you're really driving at is that there are the direct regulatory costs in terms of license fees and then there are the indirect costs in terms of burdens on operations or actually doing analyses in order to demonstrate compliance.

MR. CAMERON: Maybe that needs to be articulated better in the explanation for this. Okay. Anybody out here in the audience that wants to make a comment on any of these points on criteria that we were discussing, before we break for lunch? That's a risk-benefit equation for you, I guess.

Anybody? Matt?

MR. QUINT: My name is Matt Quint. I work for the Australian Nuclear Science and Technology Organization at the Embassy here in D.C., although that's where my knowledge of the nuclear field comes from. These comments I make are going to be mine as a U.S. citizen and stakeholder as a part of this system, not as anything to do with ANSTO's concerns.

I would just like to point out, as a member of the public, I really like Barbara's point and trying to get through the distinctions between public interest group and industry and regulators of -- what the NRC seems to be attempting to do is say what we want to do is reduce areas of exactly excess paperwork, costs spent in areas where there isn't an improvement in safety, to better spend that money to improve safety, unlike the attitude of the public interest groups, the, quote-unquote, unnecessary burden, if you're eliminating those, it's eliminating, completely eliminating safety criteria.

And I don't think that's the case and I'd like to see a better concert or an agreement of some sort of -- going after the same goal or some realization that you really are going, should be going after the same goal.

And while I like -- part of -- I also am -- a little of the involuntary risk factor also gets me a little bit. Again, Barbara's point here, sometimes what you think is an involuntary risk you're actually getting a benefit from that you don't realize or how often risks are -- or where cost-benefit considerations -- they're sort of -- it's not always win-win.

I go to the bathroom, so afterwards, I should wash my hands to prevent bacteria spreading and improve public health and safety, but at the same time, I'm using energy to heat the water, I'm using soap that's contaminating the environment and waste paper to wash my hands.

So clearly somewhere there needs to be an analysis of -- I mean, that's what the risk-informed idea is about, is looking at that, looking at the fact you want to both benefit public safety, and protect the environment, and sometimes those two things -- you know, you've just got to make a judgment call.

And the reality is that that is going to have to occur and not everything we do can't be completely stopped because of some concern that a member of the public somewhere down the line is going to get harmed by an activity.

And like I just came across a Gloria Steinham quote recently, which I'm going to paraphrase, but I thought was really well put and I wish I had it exactly, but it was along the lines of the dangers of everything are so great that I don't fear anything.

MR. CAMERON: Thank you very much, Matt. Let's break for a well deserved lunch right now and we will come back and we'll try to pick up Amy's comment at that time.

What I propose to do is -- there's two sessions left, two discussion segments left on the issue of these criteria, and one is we were going to start talking about, well, how do these criteria apply to part areas. Roy has already

sort of given us an example, many examples like that perhaps.

I think that we might be able to take that discussion and perhaps combine it with -- it leads naturally into these recommendations about where we might go for a -- the use of risk information in a particular application.

So let's combine all those when we come back, 2:00. Thank you.

[Whereupon, at 1:00 p.m., the workshop was recessed, to reconvene at 2:00 p.m., this same day.]

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

[2:10 p.m.]

MR. CAMERON: My apologies. We are running late, but I think we're having a good discussion and we are going to try to do some combinations of sessions here. But Felix Killar from NEI recommended that people probably want to get a room here overnight, we probably won't get out of here till late, but we will get out of here at the point in time.

I wanted to mention something for the NRC staff, which is if this wasn't a workshop where we were trying to cover sort of the tip of the iceberg, a lot of issues here, is that we would take the recommendations on how these might be changed and then we would work that through to see if there was any sort of consensus or a majority or minority, whatever.

The NRC staff is going to take those comments into account in revising this. The reason I say this now is that we're going into the next topic, which is how would you apply these criteria to some specific instances, and the fact that we're staying with these criteria as written in terms of looking at specific examples doesn't mean that we haven't been listening to what you've been saying about possible changes to this.

But I think we can also consider some of the changes that we've heard, eliminating these phrases, coming up with something different here as suggested by Norman, for one, and Andy, for another.

Let's talk about some examples of how these criteria could be

applied during this next hour, to either -- to a specific activity or a specific example that someone might offer, to see how they might work out in reality.

I'd like to end up the session with some suggestions as to how the NRC should proceed from here with finalizing these criteria, choosing a particular area where we could use them.

Should we have more workshops with, for example, revised criteria that we would talk about? Should we do it category by category? In other words, what process should be used? Is it possible to have a pilot program I a particular area? What are the implications of doing a pilot for some of the ongoing efforts that we have that we call risk-informed?

Chia Chen brought up the point of perhaps an external advisory committee. Could you use these criteria to look at the proposed rules that are on the NRC's regulatory agenda that we don't have resources to work on now? Could you use these to test out which ones we should take off the shelf and start working on?

Ideas like that, I'd like to see if we could give the staff some concrete recommendations along those lines.

At its simplest form, I think that the idea that the NRC is trying to do here is how to bring better information to bear on the activities that we regulate. There's a lot of things that go with that, but I think -- and, Marty, I think you may want to chime in on this, I think the basic objective here is how do we get better information to improve our regulatory products.

MR. VIRGILIO: And I would say our decision-making.

MR. CAMERON: And our decision-making.

MR. VIRGILIO: Products aside, just on everyday decisions on what we do, how we expend our resources. That's the use of this risk information.

MR. CAMERON: Thank you. Let's go to potential applications of these criteria to specific categories of regulation. There were four categories mentioned in the SECY paper. Category one was high level waste, low level waste, decommissioning.

Category two -- let me go to category three, until someone can tell me what category two is. Category four, sealed and unsealed sources. Fuel cycle. Well, people seem to be familiar with that.

Stacy?

MS. ROSENBERG: As a possible suggestion, we could look at inspection allocations of byproduct materials. Sorry. As a suggestion, we could look at inspection resource allocation of byproduct material.

MR. CAMERON: Okay. Let me get some ideas down here. Inspection resource allocation for byproduct material. And when you -- what types of activities or facilities would be involved in this when you talk about byproduct? Are we basically talking category four or are there other areas?

MS. ROSENBERG: Yes. No. Just the industrial uses and the medical uses.

MR. CAMERON: Okay. Any other examples that might be worthwhile discussing at this point? Roy, you mentioned specific versus general license before.

MR. BROWN: Yes. That's one. Another one I will mention, I'm sure it'll stir some controversy, and that's prescriptive versus performance-based regulations. A lot of times we have some concern over prescriptive regulations. In some cases, we've had situations where, if we followed the prescriptive regulations, all our numbers would be zero.

And once again, I hate to pick on EPA, as I seem to be doing that today, but when the radionuclide NESHAPs first came out, there was a methodology for sampling I-125 in the source term, and if we followed the prescriptive regulations of EPA, all our numbers would be zero because we wouldn't be able to detect I-125.

That dealt with the specifics of the detector we were supposed to use that would have shielded the I-125 gammas.

So I guess we have a concern about just across-the-board prescriptive regulation, telling us how to do things. In some cases, we're just told the wrong way to do it. In other cases, we're told a way to do it that's not the best way.

What we end up happening is we're much better if it's performance-based. We figure out the best way we can do it rather than being told how to do it with prescriptive regulations.

MR. CAMERON: Would risk information somehow be brought to bear about whether there should be prescriptive regulation versus performance-based? I guess this is a question for all of you, including the NRC staff, is that would the use of risk information be helpful in some cases to decide whether you should have a prescriptive regulatory framework versus a performance-based framework.

MR. BROWN: I guess the assumption is if we go with either risk-based or risk-informed, if the risk is low enough, that could yield a possibility of having performance-based standards rather than prescriptive. So that's kind of where the risk comes into play.

On something that's a higher risk, prescriptive regulations may be appropriate.

MR. CAMERON: Okay. Thank you. Bob?

MR. BERNERO: I was going to suggest that really if one took the four categories and NRC developed a case study in each of the four categories, limited scope, but a case study that could illustrate what was done or what could be done to alter the regulatory approach in a risk-informed manner and not implement those things unless they already were implemented and let the Commission see what that spectrum of case studies would display, because I really think this would be very helpful to go forward.

And then there is a matter of terminology, I'd just like to make the observation. Eight or ten years ago, there was a concerted effort to distinguish

the terminology of engineering risk assessment, such as a reactor PRA, or a dam PRA or a safety of airbags in automobiles, which is an engineering risk assessment, from health risk assessment.

And in the comments this morning, I heard people using terms that suggest they're thinking of health risk assessment, which is usually Health and Human Services, EPA and others. When you hear exposure, that, to me, is a trigger. There is a difference in the terminology and NRC's jurisdiction in materials involves both.

MR. CAMERON: Okay. Is that -- did everybody pick up on the distinction that Bob was making on that one? And, Bob, this -- I think this is the type of recommendation that the staff is looking for in terms of moving forward. In other words, do this case study in each category.

MR. BERNERO: Yes.

MR. CAMERON: And show how the application of risk information would affect that particular area of regulation.

MR. BERNERO: Yes. And by limited case study, for instance, the transition from specific licenses to general licenses is so broad a scope that it would be difficult to come at it practically.

But gas chromatographs, which, to my knowledge, are still half in specific licenses and half in general licenses, would be a very good case study of what might be done to simplify, effectively control, but simplify the regulatory process in that field. It's not biting off all of them, just a case study of one type.

MR. CAMERON: Okay. We're going to come back to more process suggestions, too. Barbara, did you have another suggestion in terms of what we might talk about today?

MS. HAMRICK: I just wanted to bring up an example that we implemented in California, working actually with the UC system, to -- at the universities where they have a wide variety of uses, the research applications, medical applications, things of that nature, and there is a lot of prescriptive regulation included in their procedures.

What we did was we worked with the university to develop kind of indicators, as it were, performance indicators, where we wouldn't cite, for example, necessarily, if there was a meter that was out of calibration for over 30 days, but rather we would look for trends in their program, trends in the calibration program, in the survey program, in areas where we didn't see a lot of risk.

In the very low level laboratories, for example, where even a fairly large contamination event would not have a great impact, those types of areas we would look at really -- we would be looking more at the forest than at each individual tree and we set up some criteria for our inspectors to use to make judgments about whether or not there was a failure in the program, per se, versus one individual event that really might not have any significance.

There are people out there trying things like that already.

MR. CAMERON: Stacy, would that be the type of example that

would be grist for the mill about this resource allocation for byproduct materials? I mean, we will talk more about that, but is that the type of thing that you're thinking of about how risk information might be used to allocate resources? And, Barbara, is that -- do you think that that has an application?

MS. HAMRICK: Yes, I think it does. I think that one of our -- again, one of our problems, we have a large number of licensees, a great, vast percentage of those are extremely low risk activities and prescriptive regulation for us means allocating a huge percentage of our resources to very low risk activities, which I don't think results in any net benefit.

If you're doing prescriptive regulation across the board, regardless of actual risk associated with an activity, you end up expending a lot of energy and really not getting a lot of regulatory benefit out of it.

MR. CAMERON: Okay. Thank you. Any other examples that we should explore? Chia?

MR. CHEN: I think here there is a division of the description for the inspection. Your criterion is prescriptive and for the people who confirm, then it should be he performance. And since you have, as I have heard what she described, I think we need to monitor the process.

I think for people to confirm, it should be performance, and for the regulator to monitor that would be prescriptive.

MR. CAMERON: And does OSHA use any sort of risk information in terms of the inspections that you do?

MR. CHEN: Well, OSHA is different. Here you don't do the risk assessment, but we do the risk assessment. Our risk assessment is dictated. You need to have a regulation or you need to modify the regulation and then you set those criteria, those regulations, and these regulations are somewhat like she described, that you have certain criteria.

MR. CAMERON: So what I think I hear you saying is that OSHA already has a process in place where it uses risk information to decide how it will regulate a particular activity.

MR. CHEN: That's right.

MR. CAMERON: So that's consistent with what the NRC is trying to do with the objective the NRC has, I guess.

MR. CHEN: A little bit different. If I understand correctly, you have a case study and you think you need those information and then if they provide those information and you look into those information, I think you're making a judgment.

MR. CAMERON: Okay. But it sounds like at least you're taking a look at various regulatory areas using risk information in deciding how you want to regulate in that particular area.

MR. CHEN: We have to send to the public that when you perform the promulgation or modification, there exists significant risk.

MR. CAMERON: Maybe this would be a good time to ask the other agencies around the table if they have examples that they use, in their

experience, that would be instructive for the NRC in following this approach.

In other words, it sounds like OSHA is pursuing some sort of a risk-informed process and the person, the entity that gets informed is the agency, when we talk about risk-informed.

John, anything to offer on EPA's use of risk information, risk assessments in terms of developing regulations or deciding how you're going to do your enforcement, allocate your inspection or enforcement resources?

MR. KARHNAK: Yes. I don't know exactly where to start on this thing. One of the things that I had looked at before getting ready to come here was looking at probability, probabilistic analysis and how it's used in the agency, and I found that we do have a couple of guidances on how it's being used in our pesticide program, as well as in the Superfund area.

I guess the one message that came from both of those was that they were tools to be used as part of an overall approach, and I think that's an idea that came out here as well today, that these are not the know all and end all, they're not going to solve all of your problems, but rather will give you some more information by which to look for an answer.

And I guess the other thing about the risk is, one of the points on the differences between the way that it was described to me that NRC does some of its regulation versus the way that we do, is that the differences in the cleanup standard, the 25 millirem standard that you have versus the Superfund standard, where we do look at a risk range and we're actually looking at a

broader perspective and applying different criteria, looking at criteria depending how we would modify that.

So I'm not sure how much that's adding to our discussion right now, but there are some differences here in looking at the way we -- that risk isn't a unique number that one needs to look at, but rather it's one thing that's balanced with the other criteria, something along the lines of some of the other discussions that came out, that nothing is done in a vacuum.

MR. CAMERON: Thank you. Andy, do you have anything that you want to offer on that?

MR. WALLO: I think John's comments were pretty much along the lines with ours. We've done several efforts jointly with EPA, looking at probabilistic risk assessment and how it might be used and we worked on joint DOD and EPA projects trying to apply it.

I guess one of the things we find is not so much applying the regs, but when we're trying to apply it out in the field to make decisions on what kind of actions to take, the fact is we might give guidance and the scientists might understand how to do it, but then many times the regulators don't understand what to do with it or the folks that are looking at it to try to assess does it help in the decision.

So I guess the one thing I'd say is that as you start through the process and doing this, make sure that it's going to be of benefit to the decision-making process, that it's going to come out with something that will give

you some information.

And that's along the lines, the same thing we find with performance-based and prescriptive. The general tone is that performance-based is better. That's not always true. We do performance-based for our low level waste sites and other sites and do performance analysis and actually it does all right, but on the outside, if you look at trying to get low level waste sites opened, you don't see a whole lot of success.

On the other hand, EPA, wisely, put prescriptive design base standards under their RCRA program. You see a lot more RCRA sites open than you do low level waste sites, and by and large, the waste materials are very much the same hazard and same risks.

So I'd say sometimes you have to decide what's better, a prescriptive regulation that everybody understands or a performance-based regulation that you end up explaining all the time and not having much success at it.

MR. CAMERON: And that choice of performance versus prescriptive is -- in that situation, the risk -- there's no difference. In other words, the risk doesn't drive you one way or the other towards prescriptive or towards performance.

MR. WALLO: I think it's the input and the understanding. It's those other things besides the risk that you have to address, understanding of concern through what is it they like to see, what is it they need to see to understand the

process.

So I think it's those other factors that lead you to choose whether you want prescriptive, performance-based or some combination. One might look at the UMTRACA standards, which have been fairly successful, as a combination of performance and prescriptive design base standards and they seem to generally be supported and well understood and accepted out in the public.

MR. CHEN: OSHA standards actually are performance standards, because we don't care how you achieve it, you can do it any way you want to.

MR. CAMERON: Okay.

MR. CHEN: That's why Barbara described it. You have regulations, we have regulations, and she said that they have prescriptive monitoring criteria there. So it's for the regulator to monitor.

MR. CAMERON: Thank you. All right. Thank you, Chia. Let's go to Amy and Judith and then see where we are here.

MS. SHOLLENBERGER: Thanks, Chip. First of all, I would just like to take a quick minute to apologize to everyone, I'm going to have to leave in a few minutes and I don't want anyone to take it personally, in case anybody in particular is talking at the time when I walk out.

Anyway, I have a leftover comment from the first session that I didn't get to give, but it's related to your question. So I'd like to just give it quickly and then sort of ease into the question that's on the table right now.

My comment goes to the third bullet and the net benefit question, and I think what really -- what my concern with that bullet is, is that even though that sentence implies that the NRC would not apply a risk-informed regulatory approach unless there was a net benefit to all of those things listed, the public, the licensee and the NRC, I think what scares me is who is calculating the net benefit and also who is defining what benefit means and what it means to whom. And I'd like to go back to my video game analogy that I used earlier this morning, because my son has a -- it's not exactly a video game. It's a PC educational game and I forget the name of it, but I like to call it the NRC training game, because the idea is to build this civilization and what you do is you get all these different resources and you have to put the resources in different places in order to make the civilization grow.

And often what happens when my son, who is 12, plays the game is that large portions of the civilization just die because he has a goal and his goal is to build a big building over here. So he puts all his resources over there and all those people benefit and all his scores go up really high and the economy goes up really high, but all the people who live over here are starving because there's no resources put into anything that they need.

And then there's also -- you can have slaves in this game, so they don't get calculated into the picture at all. So he wins the game every time and his civilization grows and it's a great civilization. That would be a net benefit, right? Based on the calculation parameters that the game has.

And so that's my concern with that bullet, is that the NRC has a definition of benefit that I think great numbers of the public do not agree with, and that's my concern there. And that transitions into your current question of how can we look at these four activity groups, I think that's what you call them, and apply these criteria to these activities and it goes back to the question of choice. My choice here is to participate or to not participate.

My choice is even though I disagree with the whole premise, my choice is whether I give you suggestions that make it less fat or whether I walk away from the table and don't say anything.

So when I do my cost-benefit analysis and I think about, well, how can I reduce my risk, my only choice is to give you suggestions. But even in doing that, I increase my risk, because I am totally opposed to this whole scenario.

It's like there is no choice here.

MR. CAMERON: Let me ask you a very fundamental question. What represents the whole premise to you, because very simply put, at least one way to look at the basic idea is how do we get better information to be applied to our regulatory decision-making? I mean, someone might argue that, well, that's a real fundamental premise here.

But when you look at what the NRC is proposing, what comes across to you as the whole premise? Maybe we should -- if you don't mind, it might be useful to test that out a little bit to see. Why don't you tell us what that

is, if you would, or you can think about it and we'll go down to Maria, who has something to offer on that.

MS. SHOLLENBERGER: I think, for me, when I read your SECY papers and your other papers that I have accumulated, to me, the question is how can we save money, how can we make people think we're doing the right thing, how can we cause less of a public relations problem for ourselves and for the industry. To me, that's the premise here. That's the fundamental goal.

And I think I can never agree with that.

MR. CAMERON: But is that something that -- in other words, is there something that the NRC could do to better state what its objective is or to change these criteria that would -- that would reassure you or is your belief that this is all just about saving money, something tied to your belief about the NRC or the government in general?

MS. SHOLLENBERGER: I don't know if I can answer that question.

MR. CAMERON: All right. Let's go down to Maria.

MS. PAVLOVA: What it is is -- and I think that I have the right to speak, because I come from a place where there is no right to ask, there is no democracy. Whatever we say or not, this is the best, it is this, believe me.

I have been going, in the last couple of years, to the newly developed democracy in eastern Europe, where I came from. And what we have -- what we are doing there are using what EPA is doing, which includes the

public in the real sense.

For example, with the new privatization, they use the environmental impact statement otherwise if they don't -- if some company comes and wants to buy a factory that has belonged to the state, they have to do the risk assessment, they have to prove that in ten years, the things will get better, not worse.

I don't know how I -- well, let me put it another way. I worked for ten years in EPA and I work in Superfund and I went to the small town of 70,000, something like where Judy is and I found people like you, very suspicious, but on the other side, I'm a civil servant and all the people that I worked in EPA, particularly in the original agency, are young people, the whole EPA is a new agency.

So there are a lot -- most of the people are very sincere and very much committed to health and to environment for improvement of that. So my concern, and I heard, when I hear the cynicism in your voice, and I am sure that you have your right to do so, but you represent the younger generation and the future is in you, not in us. We're already going to retirement.

What I would like to tell you is -- that's the truth -- in Tom's River, I went to psychotherapy for a couple weeks because people were so angry. I thought I was doing something wrong.

What was it? It was outrage because nobody went to tell them and to involve them. And with two years work, they trusted me and I am starting

something now in DOE, which is not easy, and I am -- you are getting trust if you are sincere and if you involve the people early enough.

Now, I complement you because I don't believe that you can make any good decision unless you use some sound scientific method. It's not the best method, but I don't know, tell me, John, do you know of any other method except risk assessment that is more scientific and more will give us something? And John was right when he said that we work with range.

Usually, when you do a cleanup, it's a long process with the Superfund. It may take ten years, and people are angry because nobody goes to tell them and to involve them from the very beginning to say what are the pollutants, what are the plume, I didn't know what the plume is with the pollutants, and ground water, what it is.

And throughout the whole process, to involve the people and hear them, until you get to the final number or something. Now, you have a range of ten-to-the-minus-three versus ten-to-the-minus-six, which means one in -- I don't have to tell you, I can see already you know better than I do. I never was good in mathematics.

So what it is is it depends on the community, on the size of the population, what other risks are there. So we ended up in Tom's River with Ciba Geigy that there were three different options. Throughout the whole process, we had a community of leaders and they participated at every single step and we developed together a fact sheet, that's true, what are the health effects and what

is the exposure, what is the good of this and what means risk assessment and how it's being done.

I just got a letter yesterday from somebody from Ethiopia, this is 15 years later, they still want those fact sheets, not because I did it, but because we did it with the communities of the people and they did it in question and answer type of style.

But believe me, and I hope that we can do it as -- I'm sure that Andrew is doing this in the environmental side. But on the health side, what DOE needs, and I complement you again that you are going to use something that is a little more sound.

Now, I understand your concerns here and I agree that probably maybe you can break it and put as the number one concern will be safety, as the number one concern will be health. You go and make a survey in the country. This is what people are interested in.

So I think that you are in the right -- I'm not going to climb down, but I think -- well, my name is Pavlova and very often people ask whether I am related to the Anna Pavlov, the ballerina. But I'd rather be related to Anna Pavlov than to Rich Pavlov and his salivating dogs. I'm not trying to be entertaining. It's after lunch.

I like the passion and I like what Judy is saying, because you have to put your heart, you care, that's the most important thing. Now, this came from the last Congressional and Presidential commission about the risk assessment

and what they talk about is not just only risk assessment, although they cited the risk assessment, but management.

Now, you have a team of geologists and toxicologists and physicians that will engineer air, geography, if you want, and will come with some kind of a statement of what the range of risk is and then you have to decide what you're going to do.

So it is the risk management, but now with the new policy, you do not look so much strictly into this number, but you try to put in the center the stakeholders. So what you do is from the very beginning, you have all this six stages.

You define the problem, put it in context, you analyze the risks. It can be qualitative, it will be quantitative. You examine the options and all this, like the Superfund, we give 10,000, 50,000 grants to the community so they can hire their own toxicologists, because they don't trust us.

That's fine. As long as they can be involved. And then you make a decision and take an action and conduct evaluation. Unless you evaluate, you never know whether you have done it right or not. Now, I know that this is too small and it means that I do not --

MR. CAMERON: Let me ask you one question. That process that you put up.

MS. PAVLOVA: Yes.

MR. CAMERON: Would you say that that could be a

recommendation for the NRC when it applies the criteria, whatever criteria we come up with, that the stakeholders should be in this type of process recommended by the Presidential commission?

MS. PAVLOVA: I think so, and I can give you the whole report, if you want. What I'm doing at the moment is what Bob suggested. You do a case study. Or somebody else suggested. You do a pilot. You cannot take the whole universe.

I was very naïve when I went to EPA and I learned that you just have to work with the people and let them scream at you and when they get it out of their system, then you sit together and you prove that you want to work with them.

At the moment, we have a model for how do we work with the beryllium workers in DOE sites and nuclear sites, like White Well and Oak Ridge, that's where I'm going to be tomorrow there, and we put together a task force. So you have worker, a sick worker, a physician, industrial hygienist, all the specialists and the public, but the main focus will be the worker or whoever is affected.

This is what makes him or her stakeholders and together we put together a manual as to what is the agent, what is the toxicity, how -- so it's training, in a way, but it's a two-way of doing things.

So that if you take a case study, take a pilot, put all the involved people into it, put them in small groups -- we had a workshop. I put industry

people next to the workers. They didn't want to talk to them. But then my grandmother said to share food with people and then when they eat your food, they cannot hate you. Somehow you already develop a little better relationship.

And so after two of those workshops and working in small groups on small problems to come to suggestions, at the end, we do have then the standing and we're not a family. Now, tomorrow, it's not my birthday, but one of the workers baked his cheese pie, stay till midnight and made -- not cheese pie -- cheesecake -- and he brought it and we sat and now wherever we go, I never have on the panel -- don't go without a worker or a line manager.

So what I'm trying to tell you, this is how we have to do it. The world is not perfect. In Tom's River, we had three options. One, it was ground water pollution. One was to dilute it in the ocean and the other was to dilute it through the river and the third was to put it back into the soil, which may go to their private wells.

And the safest was to go into the ocean, but this is a small town, where people get three million people from crazy New York to come there to the ocean. So the ocean is holy. And so they decided although it was the safest, they didn't want it. So they went into the river and now the community above the river is not happy.

Now, this is '85. We're already 2000. It's continuous. It doesn't matter. The people are involved and they'll come to it. We all have to make a little give and a little take, as long as the main purpose is safety and health and --

but within the limit of the budgets that we all have, because we're not --

MR. CAMERON: Thank you very much for telling us about that.

MS. SHOLLENBERGER: Chip, can I just respond to that?

MR. CAMERON: Yes. And let me ask some of your colleagues around the table, Maria, now that they've seen that model, and let me ask Bob first, and then go to Amy.

Bob, when you think about a case study in each of these areas, would that be a case -- would the Commission -- would the staff be -- should they do it in sort of this same framework in terms of involving all of the stakeholders in doing the case study? I'm trying to think about if we do a case study or a pilot, what should be the fundamental elements of that.

MR. BERNERO: I think you would have a spectrum of possibilities. I mentioned in my earlier remarks a possible example for a case study, the gas chromatograph. Now, recall that this -- all of these case studies would be iterations of previously done regulatory assessments, because there are existing regulatory practices, and in the case of the gas chromatograph, the staff could take the present criteria for specifically licensed gas chromatographs, the changes in such criteria for generally licensed gas chromatographs.

One that I recall is the screws that hold the source in are non-reversing screws. And look at the differences and the real question would be not can I regulate future gas chromatographs with general licenses, but should I just grandfather the existing ones. Is the increment of risk associated

with shifting those gas chromatographs that are specifically licensed at substantial cost for very little safety benefit, does that make sense.

And I would think that the public, well, the stakeholders or licensees could add some information, but the public could participate through the process of informing the Commission and saying here is the sort of risk-informed judgment we might make.

That's a very simple answer, but I would see an involvement of stakeholders or other parties as appropriate to the case study in question.

MR. CAMERON: And I know, Amy, you have to go at some point, but I know you had something to say. Let me ask you, from your point of view of being skeptical of what is happening here.

If you were involved in a case study, and it sort of ties in with what Maria was saying about being involved and getting to know people, not exactly breaking bread together, but do you think that that would be something that would be useful for you to participate in, to see how this might work in reality? And I don't mean to pick on you. I'll pick on Judith, too.

MS. JOHNSRUD: I'll be happy when I see you picking on those guys over there.

MS. SHOLLENBERGER: I think I might take a roundabout way to answer your question. I think I'd like to just respond to some of the things that Dr. Pavlova said.

First of all, I think, number one, the EPA is not the NRC and vice

versa. Those are two totally different agencies with really different ways of dealing with the public. So I think -- I mean, I appreciate what you're doing and I appreciate your comments, but telling me that the EPA has been successful in involving the public at Superfund sites does not at all inspire confidence in me for the NRC.

And besides that, I know what the Superfund sites are like. I worked in Cincinnati on an environmental project there and I talked with people who were involved in fresh and in the Fernauld site there and I would not say that they had confidence in the EPA.

I think they felt like they were doing the best they could with the opportunities they had, but I would not say that they had confidence. So it's all a matter of your perspective.

Sure, it's maybe better than it would have been if EPA hadn't been willing to listen, but it certainly isn't at the level of confidence.

Secondly, I would like to say that as far as I'm concerned, you say this is good because it's based on a sound scientific method. As far as I am concerned, science is a perception just like anything else, anything that the public says is a perception.

I think that -- you know, I've been in a room with five different kinds of scientists and asking the same question and they give me five different answers, because there is no one way to answer any question. And there's no way to say, well, this answer is based on the best possible scientific analysis,

because best is a relative term and it depends on who is deciding what's best.

And so it doesn't inspire any confidence in me to say, well, we're using the best scientific method available because I don't think there is any such thing and I don't think a lot of the public thinks there's any such thing, and I think even some scientists would say there is no such thing, because there are different ways to look at different problems and the only way to come up with a complete answer is to get all of the different perspectives, or as many as possible, into the equation.

I think that's what you're trying to do and I think as an individual within the DOE, you're probably doing your best and I appreciate that, but that doesn't mean that I think the DOE is open to the public in an interchange or whatever.

MR. CAMERON: Stacy, did you have a comment? I guess at some point, we need to get back to process suggestions and also looking at these criteria. For example, the third criteria, if you use the gas chromatograph example or if you use the inspection resource allocation, how would you -- how would the third criteria of net benefit apply to those? I might ask you that, Stacy, at the same time. You have a comment, though. Go ahead.

MS. ROSENBERG: I just had a comment for Amy in the sense that using scientific methods. If you were to go to a doctor because you had a bad back, if you went to five different doctors, you might get five different answers as to what was wrong with your back.

But you would still seek out professional help. You wouldn't go to your brother or your sister. So these are -- the scientific methods are what we have available. It's the best that we have available and what we're asking is should we be using them or not.

So I was just trying to clarify that.

MR. CAMERON: Okay. Thank you. Judith, do you want to say something at this point? Then I'm going to go back to ask Stacy something.

MS. JOHNSRUD: Yes, and it follows from, it's associated with some of the points that Amy has just made.

I heard the comment earlier, you'll get trust if you involve people early enough and explain to them that there is going to be a long process involved in whatever you're doing.

I have some friends who have been dealing with DOE, forgive me, Andy and Maria, and they say every time the public rejects the latest proposal, whatever it is, they change their process. First, it was -- gosh, I can't remember all the buzz words, but transparency last year, what is it this year.

New approaches are tried to incorporate the public, but never, they tell me, does DOE ever act upon what the public actually proposes, what its representative say, they have been empowered to propose.

They are listened to, but they're not heard, or else they're heard, but they're not listened to. They are not acted upon. And that occurs repeatedly with all the agencies.

Perhaps it's simply an artifact of government, but surely, surely, if there is anything approaching a democratic process, it can be done better.

That takes me back to where we began here, Chip. Too often, it sounds as though the outcome has been pre-determined, that nothing but lip service is given to public involvement, and that actually what we're dealing with is a situation in which the desired outcome is decided in advance and the data then selected in order to sustain that pre-determined outcome.

It's sort of like the wonderful character, the Red Queen -- no, the Queen of Hearts -- Alice in Wonderland, yes? Sentence first, verdict later. That's how the public views the kinds of approaches that are being taken and, in turn, that takes us back to fundamental, the most fundamental questions of the underlying assumptions that go into the decision-making process in risk analysis.

We're all -- the best scientist is subjective and can't help it. I hark back to Rosak's, the Myth of Objectivity, for instance, or as Amy said, Thomas Koonz, and I don't know whether the agency can overcome this all too human failing.

MR. CAMERON: Let me see if I can get us -- I mean, we've been talking about the need for the process, but the -- I think that Bob Bernero and others around the table can offer examples of where risk assessments were used to demonstrate that the particular regulatory approach was not the regulatory approach that should be taken to protect public health and safety.

I guess, Bob, your suggestion about the case studies is you would

run these criteria, you would apply these criteria to the case study and that there might be certain results that you would come out with.

MR. BERNERO: Yes. And I would recommend that the NRC, in choosing a range of case studies, would seek to find somewhere the finding would be negative in the sense that there is not enough information to proceed on further risk information, where the existing approach is the best we have so far, and you would need further research.

I would just like to observe that risk informed regulatory approach, looking to improve the process or alter the process, you're really looking at yesterday's risk-informed approach. You go back to the design basis accident, the deterministic reactor licensing, that was widely believed to be the right way to do it, a risk-informed approach, and that the design basis, therefore, bounded risk.

It took further studies, risk assessments, PRAs, to show that that was a myopic approach. It was weak and it was risk-informed to supplement that process.

And so I think it would be useful, if there's going to be some progress here, to have a series of case studies that would find ripe fruit, ripe for the picking, and, again, that simple example of a gas chromatograph might be useful, and to find unripe proof and lay that out and get the reasonable public comment on it, because that would be the general process of risk-informing the regulatory approach.

MR. CAMERON: Thank you, Bob. Let me get some views. Let me ask Marty, John Flack, Stacy and the rest of the people around the table.

MR. CHEN: Excuse me. I have to say something. I'm very objective to what my neighbors say. What he say is not applied to OSHA, because we have involved the public in every step on the way. That's why we can get somewhere. So I just suggest maybe what I heard here, maybe DOE or NRC does not involve the public much.

And what I just heard, I think that's a very good step. When you do the case study, just involve the public from the very beginning.

MR. CAMERON: Okay. Thank you.

MR. FLACK: I tend to agree with Judith. I think there is a lot to be said from experience. I think when we decide to take an action, experience seems to indicate that an action is warranted. What the risk assessment tends to do is lay out the justification for what action is to be taken.

I think people misconceive the risk assessment as being some answer that pops up, yes or no, but that's clearly not the case. When we go through these assessments, we try and understand why it is what it is, and I think that's the insight you gain from doing the assessment, and many cases that are brought forth based on experience and history indicate that some change may be warranted.

It's not unusual that experts in the field feel that way. I mean, they're around it every day. So we get cases in where we do the assessment,

we gain the insights, what happens if we change this or what happens if we change that, what kind of defense-in-depth do we maintain.

This is what the assessment is all about. It's not the answer yes or no. It's what's the insight that you gain from doing it. And once it's done, it becomes clear the justification of why you're to take the action. In many cases, the experts bring forth things that are successful, but it's not true that they're all successful.

We have had case. I mean, we could go around with examples where things were not substantiated because the assessment pointed out something that we weren't aware of how significant it was and, therefore, we couldn't go along with it.

So to say that we are pre-determined once the problem comes on the table I think is a misconception.

MR. CAMERON: Okay. But from the NRC point of view, from the point of view of our NRC staff up at the table and the rest of you around the table, we've already heard from Chia Chen, does Bob's suggestion of the case study sound like a reasonable way to proceed on this?

Are there other process steps that should be used? Should there be more workshops? Would the case studies be a good way to involve the public through many workshops, to sit in and discuss this? Case studies, I guess, would bring in different aspects of the regulated industry, so they could all be involved.

Marty, what are your thoughts on this?

MR. VIRGILIO: Maybe a slight twist on what Bob has suggested. We have a number of activities ongoing today, where we're actually making risk-informed decisions within NMSS, and maybe looking at those objectively, as sort of a slightly different way of what Bob is proposing.

Not just do the case study, but look at what we're actually doing. Let me go through a quick list so that people are informed about what we're doing today.

We're piloting what I would consider a risk-informed approach to how we're going to be inspecting our medical facilities. The results of that pilot I think could feed back into this criteria and let us know whether it's the right criteria. I think we started on that pilot based on, I guess, at least our view, that it met the criteria. Another area that we're working on today is the fuel cycle facilities inspection and assessment process.

We are moving forward to risk-inform that entire program. We believe it meets this criteria and that's why we've started on it. The list goes on. In transportation, we're doing a major study today on transportation package performance. We believe it meets this criteria and this is the right criteria to proceed. But the list goes on.

We're looking at it as far as our independent spent fuel storage facilities. We're doing a risk assessment there. Again, we believe it meets this criteria, we believe it's the right criteria, but we're proceeding forward.

Now, I think what we can do is look at the results of these as case studies and see how it informs the criteria. But I think there's -- maybe there's a little confusion on some people's part that we're not using risk-informed regulatory approaches or moving forward today.

That's not true. We are. We're making significant progress in a number of areas. And what I hope to do out of this segment is to identify what other areas should we be probing, given this criteria or some other criteria, based on what we discussed this morning of how best to modify the criteria, where should we going next.

MR. BROWN: Marty, I'd be curious to have you give just a quick summary of how it went with the gamma steriotactic effort on doing risk-informed. Would that be worth going over that?

MR. VIRGILIO: It was before my time, so I can't speak with authority on how that really went. I don't know if there are other people here in the room that were involved in that process at the time.

I thought the bottom line for that was the human error was the major risk contributor; therefore, a very mechanistic treatment of the risk was not very useful because the risks generated somewhere else.

MR. BROWN: And it was dropped with that?

MR. VIRGILIO: Well, it wasn't dropped, but it didn't look like a fruitful area to really push a risk approach.

MR. BERNERO: Early on, I raised the question about jurisdiction,

looking at risk information and jurisdiction, and my recollection of the gamma steriotactic issue and of the Indiana-Pennsylvania incident in 1992, I think, there is a serious question of how and when NRC can risk-inform its regulatory process when it does not have jurisdiction over patient safety. And that's a very serious question for the regulator.

The safety and efficacy of radio pharmaceuticals was changed from the Atomic Energy Commission to the Food and Drug Administration, Health and Human Services, 25 years ago and the Indiana-Pennsylvania incident, which was really tragic, horrible thing, did not involve significant hazard to the radiation workers, to the doctor or the technician.

Of course, it involved death for that poor woman that had the source left in her and that's a very serious question, because if you conclude -- in that case, Carl Paperiello led that investigation team and was terribly frustrated because you get to the end, you have the answer, and you don't have jurisdiction over it.

You don't have the jurisdiction to act. Now, that would have been an enforcement action, but it's a very serious question in doing risk information in the NMSS arena, because there are many areas that are outside the jurisdiction. Worker safety is one where there is a very delicate balance between OSHA authority and NRC authority. Off-site chemical release, which is a dominant hazard at some facilities.

MR. CAMERON: Should that be a criterion up there, about don't

do it in areas where jurisdiction isn't clear?

MR. BERNERO: I'm not sure what NRC should do on that.

MR. BROWN: But in the past, NRC made an effort to go in and join with OSHA and look at chemical and radiological hazards, and it should have been done.

MR. BERNERO: I know. Yes, I was heavily involved in that.

MR. CHEN: We need to create another group.

MR. BERNERO: But keep in mind that now you have a regulatory process in NMSS that is setting explicit safety goals for the workers. I happen to disagree with some of the ones I've seen, but it is setting a quantitative objective of protection for the worker and it's getting perilously close to ten-to-the-minus-four per year probability of death for a worker in a reasonable industry, and that's not NRC's safety goal. That's OSHA's safety goal.

MR. CHEN: But when you have that, that's for the performance of that agency. If NRC set that, it means the Commission has used that for performance of the NRC.

MR. BERNERO: But what I'm saying is the control of the risk to the worker is an interesting mixture of agency jurisdiction and NRC, for instance, in a fuel cycle facility that handles fissile material, clearly has the authority to protect the workers from criticality, because that is a worker risk, virtually no off-site risk. It's a worker risk.

But at the same time, there is a steam line or a process vessel full

of acid and if it breaks, it can kill the worker just as dead as a criticality could, but it is a worker hazard, an occupational work hazard. It's not a radiation hazard. And that makes it very difficult to have a clear line of regulation and that's the only point I'm making.

It baffled me when I was there and I'm glad it baffles you now.

MR. CAMERON: Let's take -- we need to get to the next segment, and Gary Holahan is with us, but let me hear from Bob Lull. I'm going to go out in the audience and then I want to see if we have any -- if anybody wants to respond to Marty's question about -- are there any suggestions of specific areas that might benefit from the application of this criteria.

So what I'd like to do is go around and poll you or anybody who has a suggestion, before we bring up Gary Holahan. Bob?

MR. LULL: I just want to quickly respond to Bob's comments. I'm not sure exactly what the details of this Pennsylvania incident were. It sounds like someone got over-exposed from source left in used medically and killed as a result of the exposure.

The fact is that the NRC doesn't have total control of everything, but there are other organizations and bodies that do have control over that, and any regulatory changes are not going to bring that person back. What you want to do is prevent that from happening in the future, and there are multiple medical and state regulatory groups, as well as the legal system, that provides pressures to make that not happen.

These things, unfortunately, will probably happen occasionally anyway.

One point I'd like to make, and it's kind of contrary to where I'd like to be coming from, but when we look at assessment of risk in activities that the NRC is already doing in a prescriptive manner and we think that there are low risks because we look at the outcomes and nobody has gotten hurt and there haven't been any problems, realize that's occurred within the environment of the prescriptive world that was created around that, and that may or may not be true when you remove the prescriptive approach, which I think many things can have that removed, like medical inspections and that sort of thing.

So I think that when you do make a change, you ought to end up evaluating against your history how things do in a non-prescriptive environment and make sure that it's really keeping the risk the same or not increasing it, and that all the measurable concerns aren't increasing in some fashion.

So I think that it's very important, when you make these changes, that you actually have some evaluation time afterwards and make sure it's cool and then I think you're okay.

MR. CAMERON: Thank you, Bob. Anybody out here in the audience who has a comment on the discussion that you've just heard? Cindy?

MS. FOLKERS: I have to say that there was a lot of talk about workers and worker exposure. I just kind of want to know where the unions are in this, transportation union, Teamsters, Pace, metal workers, if you're going to

release this stuff, release the metal into consumer metal streams.

I think that they should be another party to this, from the beginning, and I don't see any of them here. And when we say public, we are not speaking for the workers. We regard them as another important entity. So that was my comment.

MR. CAMERON: And thank you, it was a good comment and we did -- we did not have success in getting the unions here for this meeting, but they have to be a fundamental component of it.

Barbara, do you have any suggestions for Marty and in terms of from the agreement state perspective about areas that -- where it might be profitable to explore this risk-informed approach?

MS. HAMRICK: Well, as I mentioned, we have looked at kind of doing something like that with the broad scope programs and it may seem like, gee, that's a big place to start, but, in fact, there's a lot of resources in the licensee domain that can be pulled together to work on something like that.

That is, when you've got RSOs and the researchers at those large facilities, you can get a lot of assistance from -- and input from them that help make informed decisions.

MR. CAMERON: Does NRC understand what Barbara means when she's talking about the broad scope program? Okay. That's one possible suggestion.

Ray, let me ask you, before you talk about the -- you were talking

about compliance and specific devices. Do you have a suggestion of an area where the NRC might profitably use the risk-informed approach?

MR. JOHNSON: I think the area I suggested is the same one Barbara is talking about. I would think in terms of research and medical application.

MS. HAMRICK: That's what I was thinking of, too. Looking at the research laboratory programs specifically.

MR. CAMERON: Okay.

MR. JOHNSON: There is also another category that might be somewhat easier to deal with and this also affects a lot of isotope uses, and that would be sealed sources and gauges, for example, for density and film gauges, process gauges.

MR. FORTKAMP: For example, in those types of systems, and Ray and I were talking about this earlier, leaking sealed sources are very rare, very rare, yet that's one of the dominant regulatory burdens on licensees is for six month inspections of these.

Where the risk that's coming out now is actually control of these devices, a risk-informed approach to regulations might take less emphasis on the inspection for leak testing of these sources and more on the control of the devices throughout their lifetime, as one example.

MR. CAMERON: Okay.

MR. FORTKAMP: I don't see any programs or any areas that

would not be applicable to this type of approach, a risk-informed approach. I think every regulation that comes up for review and every material licensee out there, to some extent, could benefit from this type of approach in the regulations.

MR. CAMERON: Let's go to Roy, who might have a follow-up on that.

MR. BROWN: Chip, also, from a consistency standpoint, from a licensee standpoint, who deals with all 50 states, there is a terrible inconsistency between agreement states, between non-agreement states. Like if you're within the state of California, it's very, very uniform, but if you compare the risk and the importance that the California people put on certain things and you go across the border to Nevada or Oregon or Washington, it's much different. It's much, much different.

Even from a licensing standpoint, you would think that the risk of licensing a new radio pharmaceutical would be the same in one state to another, but it's dramatically different, especially when you get into machine produced isotopes, which I realize is not your jurisdiction.

But I would like to include something on trying to get consistency between agreement states, non-agreement states and even within one region to another region of NRC, as well.

MR. CAMERON: This is sort of a different take, but it's an agreement state/NRC sort of a consistent risk approach to, in this case, radio pharmaceutical regulation.

MR. BROWN: In both inspection and licensing both.

MR. CAMERON: Marty, did you want to comment on that?

MR. VIRGILIO: Yes. Just another way to frame that is to call it the national materials program, which is something that we've started a working group with the states on, but I hadn't thought about how to bring risk insights and risk information to bear on that activity. So that's really good. It's something that you will be hearing more about. We've briefed the Commission on and we've got a pilot program underway now for our scoping studies.

MR. BROWN: I guess the example would be what was brought up earlier on inspection work for the state of California. An inspector goes in and looks at calibration and source term and things like that, the things they should be looking at, that's great. But if you have a -- what state should we pick on -- Idaho. You know, if you have an Idaho inspector come out and all he does is sit at a desk and clicks through surveys to make sure a survey was done everyday, that's not very risk-informed, that's not really a very good inspection.

So I think some kind of uniformity would be very helpful.

MR. VIRGILIO: Good suggestion.

MR. CAMERON: Great. We're going to get to Chia. We're going to Mike Wangler and Felix Killar.

MR. WANGLER: Just one other -- a couple things to add to the sealed sources. Radiography devices are always a favorite topic of mine to -- I'd like to see them subject to -- see a risk-informed approach applied to regulation

of radiography sources.

The other area is a subset of these, and I can give you examples in transportation. I can probably create one in facilities, as well, is whether things that have a low probability, high consequence aspect to them, evaluating a high consequence, low probability situation would benefit from a risk-informed approach.

And then conversely, a very low consequence, high probability incident. The Department of Energy is getting a lot of the latter, where we have, at least in transportation, where we have a lot of boxes containing very, very little levels of activity are found to be leaking or contaminated, what have you.

MR. CAMERON: An example of the low probability, high consequence.

MR. WANGLER: Example, in a transportation incident is a box containing very, very low levels of waste, radioactive material waste, but they're not packaged properly to keep the contents in. So you find them leaking during transportation and potentially crap up the conveyance or even the environment.

MR. CAMERON: Thank you. Let's go to Felix, and then Chia Chen, and, Norman, I didn't know whether you had your card up from before or have it up now.

Felix?

MR. KILLAR: I spent some time talking to our reactor people and how they're using the risk-informed aspect over there on the Part 50 side, and

the one thing that no one has touched on yet that's one thing that they're looking at is the administrative aspects. And what I mean by the administrative aspects is you're looking at the reporting requirements.

There are a lot of reporting requirements that the industry has to do to various agencies, particularly the NRC, and as a result of doing this reporting requirement, we spend a lot of resources filling out forms and reports and what have you, and let's look at the risk significance of these things. What's the value of them and what's really the importance of it, and so let's kind of do away with the ones that there is minimal value or minimal risk involved and that's just paperwork.

MR. CAMERON: Thank you. Good suggestion. Let's go to Chia, and then Norman.

MR. CHEN: Ray mentioned about the sealed source and I was thinking that to add to the group, my suggestion could be right. You talk about it leaking. Leaking is a very serious problem, but it could be very well prevented. I think we just put that in the implementation. You have a certain monitoring criteria.

MR. CAMERON: Okay. Thank you, Chia. Norman? Or maybe we should stop now. No, go ahead.

MR. EISENBERG: I just wanted to not elaborate, but try to place an addendum on a couple of Bob Bernero's comments. If you're going to do case studies, it might be wise to have a mix of prospective and retrospective

studies to look at how successful a transition to risk-informed regulation has been, as well as whether a current activity could benefit from such a transition.

The other comment also expands on Bob's comment about jurisdiction, but in the context of Dr. Pavlova's risk hexagon from the national study, with the stakeholders in the middle, and I think something that the NRC staff probably needs to think about is the fact that if they focus only on what NRC regulates and only on what they might change in their regulations, without at least taking some step back and looking at the entire problem, and all the other actors that might enter into it, because it's really the entire process that produces the risk, then I think the studies might not be as effective as they could be.

I think a broader look, without spending a whole lot of resources on things that NRC can't do anything about, but at least the NRC should be sensitive to arenas where maybe they can't do a whole lot and, therefore, that's not a good candidate for this kind of activity.

MR. CAMERON: So you might either make it a criterion that it was self-contained or that other agencies, however it would need to be done, that it would have to be a complete comprehensive look at the issue rather than just the partial.

MR. EISENBERG: Yes. You know, that circle of looking at the different elements of assessing risk, you have to recognize that the NRC track is just one band on there and that there's a lot of other actors that may have regulatory authority or that certainly the licensees themselves have a lot to do

with what the actual risk experience is, and the NRC may not have authority always to be concerned with those other aspects.

Another just -- and maybe I'm just too much into the technical details, but if you want to move to a risk-informed approach in the radiological aspects that NRC regulates and it results in a higher risk from common cause accidents, that may not be a good idea. You kind of have to look at the entire problem.

MR. CAMERON: Okay. Thank you. Marty, a comment?

MR. VIRGILIO: I just want to clarify something with Norm. Could it possibly also be the situation where you have other influences, like economic influences, that regardless of what NRC does, that ultimately behavior will continue in the same pattern that it is today, that you could change your regulatory requirements, but because of other forces, that the licensee, the applicant will continue to do business just the way they have in the past, and, therefore, we've wasted your time and you've wasted your money going after this and trying to make it risk-informed.

So maybe that even contributes to the criteria that if you're going to make a change, it really will make a difference.

MR. CAMERON: I will list the types of factors here, just under cautions. I have a question for the group. We have a real interesting presentation coming up by Gary Holahan to kick off the safety goal part of this, and I think that our final discussion will come right out of Gary's presentation in

terms of the questions and answers.

So basically we have one more segment to go. Do you need to take -- do you want to take a short break now and then come back and start with Gary fresh or do you want to go right into it?

MR. VIRGILIO: We need to set up the equipment, so we need to take a break, Chip.

MR. CAMERON: That's right. That does it. Okay. Let's take a break and come back in 15 minutes. Thank you.

[Recess.]

MR. CAMERON: We're going to go into the second component of this workshop, which is the whole issue of safety goals. We are fortunate to have Gary Holahan with us to talk about the potential use of safety goals in materials and waste regulation and talk about lessons learned from the development of the reactor safety goal.

And as you see, Gary is the Director of the Division of Systems Safety and Analysis, Office of Nuclear Reactor Regulation, and one of the foremost practitioners of the dark art of PRA. He did not wear his robe, but I'm sure he has some of the amulets and powders with him.

But I would also say that he is one of our foremost thinkers on the philosophy and policy, conceptual framework for developing safety goals.

So let's listen to Gary and then we'll have a discussion out of that, and we'll break no later than 5:15.

MR. HOLAHAN: Thanks. I think I'd rather stand up. May I stand up? Do you want me to stand up?

MR. CAMERON: Do you want to use this?

MR. HOLAHAN: That would be good. I don't know if I want to admit to any of the things that Chip said. I think he's set me up for high expectations anyway.

I'm glad to be here. I was asked to say some things that at least relate to the reactor safety program and how it develops safety goals and how it's using them. I think I'll say a lot more about the reactor programs than I will about any of the materials programs, but I think the intent is to sort of provide some historical perspective and if there's things you can learn for the materials program, great; if there are things that don't fit, that's okay, too.

Since Chip asked me to be a little bit philosophical, I chose a philosopher or at least an author who is at least French, and I thought he looked a little more like Chip than he looked like me.

But there is an interesting quote that I pulled out of the literature and it's translated from the French. I've actually seen it translated in slightly different ways. But basically the thought is there is one thing that's stronger than all the armies in the world, and that is an idea whose time has come.

Well, the trick seems to be to figure out whether the idea you've got on the table is one of those ideas or not. I think in a democracy, one of those ideas is not one of those great things until people actually accept it as a part of

their society.

So I'm going to give you some thoughts about how the reactor program has used risk information, how it's used safety goals, and what I'm going to leave you with is, is this one of these great ideas, is this such a great idea that it belongs in a materials program and in OSHA and in lots of other places. So history will be whatever it is. So a slight history lesson.

PRA technology, at least as we talk about it in the reactor program, which is quantitative analysis, using probabilities and consequences, was really developed in the mid 1970s, but it wasn't until the mid 1980s that an actual safety goal was developed.

So the tool was developed first. The ability to calculate risk in the context of probability times consequences, before we knew exactly how we wanted to use it.

The safety goal development took a long time, I think, and, in fact, Tom King, who was here, I think, spent more of his hours on it certainly than I did and I think we usually say it took about six years, but that was like 14 years ago and I sort of have the feeling that the 14 years after 1986 were sort of having it sink in in some way. So it was not a one-time thought. It's really an evolutionary process.

Reactor licensees were asked to use probabilistic risk assessment and do studies in the mid 1980s. We asked them in 1988 to do something called the individual plant examination, to take probabilistic risk assessment, apply it to

their plants and see what lessons they can learn to find areas where there may be some safety matters that were not well covered by the existing regulations. What does that mean?

In about late 1993, the staff decided that if it was going to make more serious progress in terms of the use of risk information, that it needed kind of a kick-start. It needed to have a common understanding of what we were trying to achieve. It needed to send a message to the staff, it needed to send a message to our licensees, it needed to send a message to the public as to what this new tool was and how it might be used.

And we thought it was important to have that message come from the Commission itself. So we developed a policy statement, which, in fact, went out for public comment. It actually two years to develop what is a relatively simple statement that says there should be more use of PRA in all regulatory matters, and it has some additional detail.

But the message is PRA technology is a good idea and ought to be used where it fits, where it supports good safety program, more extensively.

It took something like a year to go through the public comment process. It took something like a year for it to sink in and to be adopted by the Commission. We thought that was an important step in this process.

The Commission then told us now that you've got something of a technology and you've got something of a policy statement, that's not enough; it doesn't really tell you how to use it. You've got to go out and develop guidelines

so that our licensees and our own staff know how to deal with these things.

And we wrote basically five pairs of documents. We wrote a general document on how to use risk information in the reactor licensing process and we wrote a corresponding document for the NRC staff that says here is how you ought to view those applications by licensees when they come in, and then we wrote four specific guidance documents and four specific review guidance documents for the staff.

And these were joint efforts between the Office of Nuclear Reactor Regulation, which regulates the reactor licensees, and the Office of Research, which I think spent a lot of time and effort developing the technology.

So it was both a technology and an implementation effort. And then we found that you can't just decide that everyone ought to do these things, they really need technical training and what does this mean. And we made a commitment that every technical member of the Office of Nuclear Reactor Regulation technical reviewers, project managers, all needed to take a course on probabilistic risk assessment. And we, in fact, developed a course for all our managers to take and we developed another course for all our inspectors to take.

So there have been probably something between 500 and 1,000 training courses given to people to help make probabilistic risk assessment, and I will show you a little later how the safety goal and the risk assessment technology work together. You can't just decide you want to do this. When you

decide you want to use risk information, you have to figure out what you want, you have to figure out if the technology exists, you have to train people, it has to become part of the culture.

In 1998, we moved from using risk information in the licensing context to saying we are ready to consider the basic regulatory requirements that are in the regulations to consider how risk information can be used to write better regulations, and that's an ongoing activity.

So you will see from the beginning, from the development of the technology to where it has serious impact on the regulatory requirements and on the everyday activities of the staff, is three decades. So this is an evolutionary process. It's not just something you decide to do overnight.

Recently we've had a pilot activity and we're just about to start a formal program in which our inspection program, our oversight and inspection of licensees at the nuclear power plants is being done with a risk-informed program. So we've restructured our inspection program. We've at least offered an alternative to use risk information in the licensing process and we're looking at our basic regulations. So it's a comprehensive program in the reactor area.

What have we learned from doing this? I don't know, let's see. Well, number one is it didn't happen all at once. The program evolved with the technology and so in the 1970s, you couldn't just decide you were going to use risk information, because the technology didn't exist.

And in the '80s, there was a stage at which the NRC staff and its

contractors and national laboratories had some experience, but the licensees didn't understand the technology and weren't involved and it didn't make sense to jump into a regulatory program in which one of the basic components was something that people didn't understand well enough.

I think it's really important that the licensees and the public and the regulators have a good and common understanding of the technology. Otherwise, people get left out of the process and that's a real difficult problem for public confidence or even from a confidence on the part of the staff or any of the licensed entities.

When safety goals were developed, it's important that they were developed not as a separate thought, but in the context of a whole regulatory program, and I think that's an important element, too, and maybe that will come out a little bit as I go along.

Safety goals are not regulations. In the reactor area, there is a safety goal, in fact, there are two safety goals and they have to do with the level of risk that members of the public ought to be exposed to, but they're not regulations. In fact, they don't replace the regulations, they don't displace the regulations.

So when you talk about having safety goals, I think it's important to figure out what you want them for and how they will work in a regulatory scheme.

You can't have every regulator and every regulated entity walking around being philosophical all the time. There as to be some real concrete

understandings of what are the rules of the game, what are the expectations that exist on both sides. Otherwise, you're going to have chaos.

So what are the safety goals? Well, they are thoughts that are used to enlighten the regulations. They provide clarification of what it is that you're trying to achieve.

The PRA, big R, big A, sometimes PSA, sometimes PA, sometimes other things, the analysis is just a tool for figuring out whether you're meeting your objectives or not. The hardest thoughts are not in the PRA. They're not in what numbers should I use for human reliability, what's the likelihood of something failing, how often does lightning strike.

That's not the difficult part. The difficult part is figuring out what it is that you're trying to achieve. And I didn't have the benefit of today's whole meeting, but I did sit in the back for the last hour or so, and it's clear that different people have different expectations.

And it's only when you have at least clarity and hopefully consensus on what you're trying to achieve that you understand what your safety goals mean.

What's next? How have the safety goals been used in the reactor program? If they're not regulations, what are they? What do they do? Well, the first thing that happened was the safety goals basically said how safe is safe enough for people who live near nuclear power plants.

So one thing we did was we wrote basically a backfit rule and the

backfit rule test is whether nuclear power plants should have additional requirements.

So the test of how safe is safe enough was basically converted into the underlying technical analysis that goes into a backfit analysis.

The safety goals influence our rule-making through something called regulatory analysis guidelines, which are quantitative guidelines on -- they're a way of testing to see whether a new proposed rule provides some substantial amount of additional protection and the guidelines are built upon achieving the safety goals.

Now, the safety goals are kind of philosophical things and there's not a one-to-one numerical relationship between the safety goal, which is a qualitative expression, and the numbers that go into an analysis.

But it is -- the safety goals probably provide the most insight into whether a new rule should be written or not or whether an old rule should be rewritten. And all the NRC rules in the reactor area that have been rewritten since the 1980s have basically been tested against the safety goal and the regulatory analysis guidelines.

What you see is in the '70s, rules were added because people felt that, well, it was important to have this, that or the other thing. But in the '80s and the '90s, rules were added or changed because there was an analysis, quantitative or qualitative, to say we think we are doing a better job of achieving the safety goals by having these regulations, and so it is a real clarifying and

unifying concept for the regulations.

I said before that we developed guidance on how to do licensing reviews and, in fact, those guidelines are contained in something called Regulatory Guide 1.174, which is about 30 pages of discussion of how to use probabilistic risk assessment and other concepts, like defense-in-depth and engineering safety margins in the regulatory process.

The guidelines chosen in those documents are derived from the safety goals and so what we're doing is we're using insights from the safety goals to establish what the regulations ought to be and how we ought to do our licensing reviews on an individual basis.

The reactor oversight process, which is our way of doing inspections and enforcement to assure that licensees, reactor licensees are complying with the regulations, is being influenced by the safety goals and probabilistic risk assessment.

I've put on the back, for everyone who hasn't cheated yet, I can see there are cheaters already who are looking on the back, this chart, which is a little complicated and is probably imperfect in a number of ways, what it does is it lists, across the top, a number of different reactor programs and for people who are not familiar with the reactor program nomenclature, I'll just sort of run across.

Regulatory Guide 1.174 is guidance on amending licenses for reactors. Those first two columns refer to how -- the guidance to the staff and to the industry on how to deal with applications where the licensee has a relatively

high core damage frequency or large early release, and think of large early release as a core damaging accident with a failure or bypass of the containment building. So it's a very, very serious type event, how to deal with those in terms of core damage frequency on the left-hand side and in terms of large early release frequency on the right-hand side, and the numbers are simply different by a factor of ten.

EPRI, which is an industry organization, the Electric Power Research Institute, put out a guidance document in the mid to late 1990s giving advice as to how probabilistic safety assessment could be used in the licensing process and you will see in each of these programs, people developed terminology about whether things were acceptable or not acceptable or marginally acceptable.

A little further over there is something called OL, which is Office of Nuclear Reactor Regulation, Office Letter 803, which is guidance to the staff on how to deal with the process for dealing with license amendments. The oversight process is our inspection of reactor licensees. Regulatory analysis guidelines, as I mentioned before, is the guidance on how to change the regulations themselves.

And when I mentioned that licensees were asked in the late 1980s and spent part of the 1990s doing studies to determine what level of safety they had achieved, NEI, at the time I think it was probably NUMARC, put out guidance on what should you do if you find what looks like a potential

vulnerability to a severe accident or maybe you find that your analysis shows that you could have a severe accident, but it's a very low probability, how do I judge what I ought to do for it.

And you see there is a gradation from you should fix things down to you should simply include them in some of your guidelines and there's a certain point at which you don't do anything.

And one reason I lay this out is because in one way or another, having a safety goal has influenced every one of these programs and it's put into perspective that core damage frequencies less than one in a million per year are not so important and although the terminology changes a little bit, sometimes it's called green, which is good, or maybe not so bad, or the risks could be called very small or not significant, what we see is there is relative consistency in all of these programs.

It's not identical, but there is a relative commonality of thinking between a relatively diverse group of people putting together programs to deal with regulation or an inspection or a license amendment or a number of different issues.

What we can see is almost uniformly across the top of the chart, you will see core damage frequency or an issue that relates to core damage frequency is ten-to-the-minus-four or higher, these things are generally considered not acceptable.

You see the word unacceptable shows up in a couple of places. Or

these are things that we should proceed immediately to doing rulemaking to make sure that we're dealing with them.

So on the low end, there is relative consistency that things are not so important. On the high end, they're generally consistent, and in the middle, you see there are some cautionary words to say management attention is required or this is something that needs to be studied more carefully or that you may grant this license amendment, but be careful about how you do it because these are no longer negligible type issues.

The reason I put this up is it wouldn't be possible to have a whole set of programs doing different things, to have any level of consistency, unless there was some sort of safety goal involved. Now, the safety goal didn't lay out all these words, but it influenced every one of them.

Having a safety goal influences the regulatory program and I think when the safety goal was written, it's not even clear that everyone understood how it would be used. It was a general philosophical statement of how safe was safe enough, what level of safety ought to be searched out and achieved, and then individual programs, sometimes in various ways, sometimes by the industry itself and sometimes by the regulator, picked up that thought and used it. And what we see is the safety goal, although it's not in the regulations, has been a very influential, almost a central concept over the last ten or 15 years in helping people understand what does it mean to say something is safe, what does it mean to say something is not safe enough and needs to be dealt with right away.

So I think I've talked too much and listened too little, so I think I'm going to be quiet a while and see if people have comments on the subject. I might even be willing to give Chip back his microphone.

MR. CAMERON: Thanks, Gary. Let's go to questions for Gary and get into discussion, too. I think that this quote may be a watch word for us in terms of is a safety goal or goals for the materials program an idea whose time has come.

Questions for Gary, Marty?

MR. VIRGILIO: Gary, could you see maybe us either -- maybe as an evolutionary process, that in the materials area, that we might want to do something non-quantitative; that is, define our goal in some other way, qualitatively?

MR. HOLAHAN: Even in the reactor area, the goal is really expressed qualitatively and Tom could probably quote it better than I can, but basically there should be no substantial additional risk to public health and safety because you live near a nuclear power plant.

And the NRC and the industry are not achieving that safety goal of people who live near nuclear power plants are having noticeable, measurable, calculable increase in risk over the other things that society accepts.

So I think yes, I would say you always start out with a qualitative, sort of philosophical expression of what your safety goals are and I think you start out with a large number of them and then maybe you can combine them in

some way, but I wouldn't try -- I would discourage people from picking a number and saying our safety goal is 25 millirem. I think that's not a good idea.

I think you pick a philosophical thought and then you try to cover all of the real social values that are encompassed in both the regulatory program and the use of materials.

So you might start out with a do no harm or you might start out with an optimize safety and test whether that's really the kind of goal that you want.

MR. CAMERON: Let's go to Ray and then we'll go to Jonathan and Bob. Ray?

MR. JOHNSON: I just wanted to ask, how does a safety goal and the practice of ALARA relate?

MR. HOLAHAN: Well, they can. For example, in the reactor program, I think that in effect, ALARA is almost a separate safety goal. So you establish -- because ALARA basically says continue to make things safe, if it's practical to do so.

And I think that in itself is an expression, it's a safety goal expression. It's something that you decided that you wanted to achieve. So a safety goal, in my mind, doesn't have to be a single value. It can be a concept of as low as reasonably achievable. It is a safety goal itself. Then you've got to test whether that's a goal that you really want to strive for.

MR. FORTKAMP: That was going to kind of my comment. It seems that there is already that regulatory requirement for ALARA, at least with

respect to safety of program management.

So I guess I'm not quite sure beyond that what the -- if a single or even two single safety goals beyond ALARA could be applicable to all materials licensees. I would think it would have to get pretty specific getting much beyond that, I mean industry specific.

MR. CAMERON: Indeed that is a possibility, isn't it? To have more than one goal because of the reasons that you stated, Jonathan.

Bob?

MR. BERNERO: I was about to make a comment on something else, but the last two comments have prompted me to change entirely.

There is a very important difference in ALARA and what Gary was referring to as make it as safe as you can within reason or something like that. I used to refer to that as ASARA, as safe as reasonably achievable.

And ALARA, in the radiation protection context, does not apply to the reactor safety goal and reactor risks because it is an accidental release. It's a risk of accident or risk associated with accidental release.

The reactors, of course, have Appendix I and their 10 CFR 20 radiation protection programs that cover ALARA in the health physics sense.

In the materials side, the whole arena of waste management has been dogged for years by the question of ALARA in the inability to apply it. Radiation protection ALARA for the public, because the releases from waste are chronic exposures. The stuff is there. It's just a matter of predicting what will

leak out and how far it will leak and who will get it up in their food chain.

So there has been a great deal of concern about is ALARA even a meaningful concept. And I suggested some time ago that as isolated as reasonably achievable might be more appropriate for the waste management area.

And when you go to the material regulation of the fuel cycle or of the commercial or academic use, medical use of isotopes, there, you have ALARA truly in the chronic exposures and should have it there, but at the same time, you have to have an accident goal.

And I think what this risk-informed direction is looking for is a meaningful way to evaluate accident releases, in particular for the workers. And that's where you -- for instance, in a fuel cycle facility, you get a worker, if that facility handles fissile material, there is an ALARA program for the day-to-day service the worker provides and radiation exposure that the worker receives over the course of the year, and there is an accident goal for criticality, which would harm or even kill the worker by radiation.

And I think it's very important to keep the material area focused on that idea that it is a management of accident risk and, in particular, accident risk toward the worker rather than the public.

MR. CAMERON: Gary?

MR. HOLAHAN: I just want to follow up on something that Bob has reminded me of. That is, in the reactor area, when we talk about safety goal, the

truth is that the reactor safety goals are really incomplete in that what they really address is, as Bob said, they really address accident risks. We don't have a specific safety goal for workers and there are a number of additional areas.

So the safety goals are important, but they're not a complete expression of what you really think of as your really underlying safety program.

I think one of the things that we discovered between when the safety goal was written the mid 1980s and when we actually tried to apply it in the mid to later 1990s was that if you just took the safety goal or just took numbers derived from the safety goal, you could up and make a bunch of decisions that you really didn't believe were right.

What we discovered was that there were some hidden values that we have. For example, in the reactor program, we have a defense-in-depth philosophy and I know it's used in other places, as well. But the safety goals don't say anything about defense-in-depth. They just say the end point of the analysis ought to show a low risk.

And what we discovered was in some way, your safety goals express only one of your values. So, in fact, in order to develop a way of doing risk-informed regulation, we found that we had to draw out what are our other hidden safety values.

We think that good engineering is important. We don't want reactors that are run, that shut down every other day or have leakage, and just because they have systems to capture that and prevent events turning into

public health and safety issues, we don't want the plants to run in an awful way.

It's like saying you design a car that is reasonably crash-proof and then you crash it all over the place. That's a terrible safety program.

So one of the things you have to do if you want a real useable safety goal program is to draw out, not only from the regulators and the regulated, but what it is that society expects from you, what are the real hidden values.

So you have to worry about the doses to worker, health effects to workers, you have to worry about the public from accident doses, you have to worry about low level chronic doses, what is acceptable. Then you have to start -- I heard earlier talk about doing case studies.

You have to do some mental sort of case studies and say, gee, if these were my safety goals, what sort of decisions would I make. And when you come across one that says, well, I don't like that decision, that's a wrong decision, how did I lead myself to make such a decision, you will find out you have some hidden values and say, well, I don't like that decision.

Well, what is it that was making you think that, and that becomes one of your underlying values that you have to respect in the process.

MR. CAMERON: That may be a good way to get at those hidden values, is to test them out. Tom?

MR. KING: Just to add to what Gary said. What Gary said was the reactor safety goals are really directed toward the protection of the public under

reactor accident conditions. They don't address the worker safety.

They also are written for early and latent fatalities. They are not written for cancer incidents. They're written for cancer and early fatalities. They also do not address land contamination or other environmental impacts. They do not address economic impacts, property damage, which the Commission has asked, in the materials side, that that do be addressed in your safety goal.

So there's a number of things to think about when you're thinking about safety goals and what's important to the materials community and how would you address that in some sort of safety goal fashion.

For the reactor side, it was just people off-site and fatalities.

MR. CAMERON: Thanks, Tom. John?

MR. FLACK: I think one of the turning points here is what we mean by the goal in terms of relative risk. We're sort of talking about risk in an absolute sense, what's low enough.

But I think what the safety goal bears out is you have to look at risks in general and then try to capture a certain fraction of that risk and say that's acceptable.

So it's not -- I mean, that's the turning point. That's where the transition is made where you're no longer in an ALARA space, where you're trying to minimize things, but you're looking at what risks are we normally exposed to and then a certain fraction of that we would find to be acceptable.

Now, whether that's the same as what the reactors use or it's

different in materials is really a question and is it going to be different between public and is it going to be different for the worker, for example, and what fraction should that be.

I think that's the thing that we'd have to come to grips with.

MR. CAMERON: Gary?

MR. HOLAHAN: I think one of the complicating features is that you just can't pick a value, because one of the underlying values is people take risks, people take risks in their lives all the time and they do it for a reason, because there is some benefit involved.

People are willing to drive in cars because they find that that's really important to their lives. But risks from driving an automobile are very high. If you calculate any of the risks we're talking about, none of them compare to the risk of having automobiles in society.

So you have to think not only of what's a high value and what's a low value, you have to think about what society thinks about those values. People are willing to take risks under certain circumstances. People are willing to accept risks when they have some control over the situation, when they see a social benefit.

One of the things you have to ask is -- there was a time in history when society thought that nuclear reactors would produce electricity very cheaply and that was seen as a social value. I think some of that has been eroded.

If you ask people what they think the value of waste in their

community is, they probably don't think it has a very high value, so their willingness to accept a certain level of risk is influenced by that.

How much control they have over the situation and what is the social value of that activity? So sometimes I sort of discourage people from trying to find the right number, because I don't think there is a right number. This isn't a science question. This is a social question.

What does society want us to pick as the appropriate level of risk for the kind of activity that's involved? That's why governments don't pick these numbers. It's societies that ultimately tell you what's acceptable to them.

MR. CAMERON: Andy?

MR. WALLO: Actually, I think I was going to comment a little bit about ALARA, some of Bob's comments, stating that ALARA is really just another decision-making tool, whatever name you give it. It may not be a quantitative monetary equivalent with dose type analysis, like you classically do with workers, and the environment. You deal with many attributes and dose, as a matter of fact, may be the least important of the attributes in evaluating your options for waste disposal.

But I think the point I want to make is it's just the fact that you're going to go through a decision-making process that however you use the term optimizes comes out with the best practical decision for -- of your options. It helps you decide on which of the options optimizes the costs and the benefits.

MR. CAMERON: Jonathan.

MR. FORTKAMP: I'd like of like to ask a little more general question of the NRC. I guess, first off, kind of what's coming first here, the safety goals or the risk analysis development safety goals.

They kind of play off of each other and kind of along those same lines, do you see, at least on the materials side, a requirement for safety goals or some similar type of parameter to define in the development of regulation.

MR. CAMERON: Gary?

MR. HOLAHAN: Let me tackle the first one first, which is I think the answer is yes, you need -- it's no sense having safety goals for things that you can't calculate or things that you can't judge.

So I think there is an interplay between the technology and the safety goal. You pick your goal so that it's something that you can measure or something that you can calculate and if you don't have the technology for doing that, then you don't tend to pick those things. So there is a practicality element to it.

The second part, I think, is a highly philosophical question about whether you need safety goals. My answer is I think you've got them. Everybody has them. They're the values that you bring to the activity.

In my mind, the -- what we call safety goals is merely writing down what people think is safe enough and if you don't write them down, then you have 260 million versions of the same -- of what people think are safe enough.

If you write them down, then you've got something you can argue

about, what is a reasonable goal or what is an official goal of an agency or what is an acceptable goal of an industry or whatever.

But the fact that you don't write them down doesn't mean that you don't have them. Everybody's got safety goals. That's why they fight over things. That's why people say it's not safe enough, it's because they've got at least some concept that this isn't acceptable.

I think you're always better off when you write them down. First you write them in words and then you figure out whether you can calculate such things or measure them and then you put them in numbers.

MR. CAMERON: Following upon this most recent colloquy. One of the things that you said, Gary, is that the development of the tool preceded the development of the goal. Is there anything that we can say from the materials area, do we have the tools? Marty?

MR. VIRGILIO: I would say that ideally you would like to have the goals developed in advance of the tools, but where, like in the reactor arena, you have the tools today, we are performing risk assessments, and we don't have the goals.

What we're doing with those risk assessments are things like identifying where we have uncertainties. Take a system, study the system using risk assessment techniques, and you can get a lot out of it beyond just the bottom line number, is it safe or unsafe.

You get information about where you have large uncertainties, you

get information about where you have large conservatisms. It helps focus you so that you know where to apply your engineering efforts.

So I think even without having safety goals, we are today using these tools in a number of ways to help improve safety and make decisions. We use them today to help prioritize activities.

We know we're going to conduct inspections at a number of facilities. We know we're going to inspect a number of different things. How does one go about prioritizing that, given that you've got some constraints of a program you're trying to administer? Well, you can use some risk techniques to tell you what's important and what's not important and some that bin things into high, medium and low risk significance, and then apply your programs.

So I think, as I said earlier, I think ideally it would be nice to have the goals before you start using this, but I think there's an awful lot you can do, just like in the reactor arena. I think we had -- we were using risk for years before we had the safety goals. Or maybe you haven't expressed your safety goals, but you sort of know that minimizing dose to the public is in there somewhere.

MR. CAMERON: Marty raised the point about the goals or the tools may be valuable in and of themselves, but Gary is raising the issue of how do you know if you have the right tools if you don't know where your goal is.

I'll go to Bob perhaps for comment on that or something else.

MR. BERNERO: I'd like to stick to that. If I recall the statement

Gary made early on, I think it was just shorthand words, where he said we wrote a backfit rule 50.109 and 50.109 existed for years and years before that version that Gary participated in re-writing, and it was applied.

I can recall an example where I was personally involved, where it is really an exercise in systematic judgment. Here is an apparent shortcoming in a design or in construction and it appears that if you required one additional feature, you would achieve this much safety, is that worth requiring.

People never called them backfits. It was an unwritten rule. You never used the word backfit in the regulatory paper.

But it was done and actually the safety goal was implicitly developed with the reactor safety study. In 1972 to 1975, when the reactor safety study was developed, it had an analysis of collateral or related societal risks, accident risks, cancer risks and so forth, and the difficulty was that the executive summary of the reactor safety study seriously under-estimated the uncertainties and it was presented as here is a picture of societal risks and here is a picture or an estimate of reactor risks and it is substantially lower or it's small, it's acceptable, and really what the safety goal development by the Commission was preceded -- the Commission made a policy statement disavowing the executive summary of the reactor safety study, but it had the de facto effect of disavowing PRA on many people, including the NRC staff itself.

I used to be called constantly, you're doing something against the Commission's will by developing PRA. But when the Commission developed the

safety goal, they developed a statement that would be valuable to NMSS now. It really was a statement of objectives that the risk goes to the public from accident measured by both prompt fatality and latent cancer fatality, should be very much lower than the background risk for the average American, one-tenth of one percent, and then, of course, all the arm-waving about whether you use a ten-mile radius or a 50-mile radius. Those are mechanics.

But it's the statement of objective that the risk posed should be negligible or very small, however you describe that. In NMSS, that's one of the reasons why I raised the point of jurisdiction. In the regulatory area, let's take nuclear medicine, what is the Commission's regulatory objective, not in quantitative terms, not a safety goal. I agree with Gary, don't pick ten-to-the-minus something, but try to state it in direct qualitative terms. The objective is that the radiation worker or the doctor or the technician or the patient shall suffer or be exposed to whatever.

That's what I really think would be helpful in any regulatory area that NMSS has. It's a very broad spectrum and a very broad spectrum of jurisdictions and risk exposures.

MR. CAMERON: Are you suggesting, Bob, that there could be one goal that would cover the whole spectrum of categories and activities in materials regulation?

MR. BERNERO: I don't think so. An area maybe, but I think in a case study, for instance, if NMSS, in preparing a case study, said this case study

is on this narrow piece of the regulatory area, gas chromatographs, and the fundamental objective of this body of regulation, 10 CFR 30 or 32 or whatever is involved, the fundamental objective is that the public or the user of this device will suffer no more than some qualitative statement of risk.

And that would go with products for exempt distribution. What was the objective of regulating smoke detectors that a licensee can make them, but they're exempt from further regulation, and millions of them were sold and they end up in landfills and so forth. And what is the underlying objective in that particular arena of regulation?

I don't think it's a single objective, like you can enjoy with a reactor. I think it may be unique to each of the areas, in medicine, in consumer products, in gauges -- well, gauges may be quite similar to radiography sources or things like that.

MR. CAMERON: Gary mentioned the fact that we already have a lot of values in the material regulatory framework already and, Bob, you're suggesting that there would be a useful function of having a safety goal for a particular area that would take those values that are in the regulatory framework now and integrate them or test them to see what you wanted.

This goes to the question on the agenda at this point, what would be the role, what would be the function of safety goals in the materials program.

MR. BERNERO: A safety goal is a statement, in this case, by the Commission, of the objective, the regulatory purpose of its system of controls.

One might say, and I'm not speaking out of school, I made this comment publicly on Part 63 for Yucca Mountain, that is that the performance assessment objective of Part 63 is really a safety goal that can be put in terms of it is the Commission's objective that no person in the future will suffer a radiation exposure we would not find licensable or acceptable today.

That's a safety goal. Now, whether you can ever demonstrate that by some calculation over 10,000 years or 100,000 years is a matter of do you have the tool.

But what is the underlying objective? The objective is that waste will be disposed with sufficient isolation or sufficient selectivity of location that no person in future will suffer an exposure we would not find acceptable today.

MR. CAMERON: Gary, a comment on what Bob just said?

MR. HOLAHAN: I think that is exactly what a safety goal is. What I find is most of the disagreement on technology issues are not arguments about the numbers, they're arguments about values. They are arguments about, well, you can do the best calculation you like, but I'm not trying -- I think I heard it in the earlier meeting.

No matter what you achieve and you think your program is doing a great job, you're not achieving something that corresponds to my values and you're doomed to have those arguments and those discussions over and over and over again, unless there is some clear expression of safety goals.

You at least then have the opportunity for at least some

convergence on what you're trying to achieve. I think Bob is exactly right that his expression, and I don't know whether that's what exactly corresponds to Part 63 or not, but his articulation of future risk is exactly a safety goal.

I think his example with smoke detectors goes to the point that the reason you minimize regulation on smoke detectors is because they have a huge social benefit to allow the proliferation of smoke detectors, low cost, reliable smoke detectors for houses. There is some judgment that the net effect of lowering the requirements for dealing with americium-241, whatever it is, has a net positive effect on society.

So we're sort of regulating in the public interest and what the public interest is is different depending upon what the circumstance is, and sometimes it involves what does it mean to be a worker and sometimes it means what does it mean to protect people from fires versus from radiation.

And when you pick your safety goals, you have to consider those things. If you didn't consider the social value of smoke detectors and said I'm just going to pick a number, you could very well have shut down the smoke detector industry, at least the type we have now.

I think that would be a tragedy.

MR. CAMERON: Let's go to Felix and then Bob Lull and John.

MR. KILLAR: I'd like to go back and build a little bit on what Bob was saying, also what Gary was saying, in that right now the NRC already has safety goals. They just haven't written them down for material licensees.

Because if you look at materials licensees, materials licensees are for the possession of material and when the NRC issues a license to that licensee to handle and possess that material, you're saying we believe you can safely handle that material.

So we've arbitrarily established a level that we think is safe enough and we think you're going to meet that level. Therefore, we have established a safety goal for you and we believe you're going to meet that safety goal. And it's a goal in the fact that the NRC cannot guarantee that that licensee will ever go above that level or below the level, whichever you want to say, and go into non-compliance space, violation space, but to the best of their ability, they believe they won't.

So it's a goal, not a fact of life, so to speak.

MR. CAMERON: Do you see a value in writing -- not writing the goal, of specifically calling out what the goal is? I mean, do you think that they're there? Do you think there is a value to doing more than that?

MR. KILLAR: I think there is some value to writing the goal down and I think it goes to the point that Gary made earlier. As soon as you write the goal down, you can be arguing whether that's the right goal or not, whether it should be higher, it should be lower, where is the bar, things along that line, but there is some value to it, because that way it does provide an indication of what is the relevant significance of that goal. How does it compare to other facts of life, other things in life, things along that line.

So that the NRC can then provide a justification for whatever number or whatever way they phrase this safety goal to compare it to other risks that the public is involved with that the -- that other Federal agencies license or allow facilities to use hazardous materials.

MR. CAMERON: Gary, any comment on what Felix just said?

MR. HOLAHAN: I guess I agree with a number of his comments. I think there is a little bit of a danger of saying because we wrote a regulation, that is our safety goal, in a sense.

I think you ought to step back and test those, because if you write down all your regulations, you'll find they don't provide a uniform level of safety. Some of them are stricter than others. That may be for good reasons or it may be just for historical reasons, as to who was making what decisions at what time.

I think there is a value in comparing sort of the level of safety and the value of the activity that the various regulations currently require, because there is always the danger of doing too much or too little and you would like to have a rational set of regulations that are derived from a set of commonly understood values.

Yes, I think what I heard you say was some of our values are expressed in requirements, but I think it's still valuable to go through and sort of write them down in a little more philosophical way, because it helps you test why you made that requirement there in the first place and if you don't remember, it's a good thing to go back and think about anyway.

MR. CAMERON: Okay. Bob?

MR. LULL: I think it's a very important thing to have safety goals outlined. They shouldn't just be that all the regulations be followed and that all the checklists on the inspections be checked off positively and that's your goal. I mean, the goal should be why you're doing it, like why are you doing all the detailed things in a medical inspection that usually amount to -- many of them amount to useless information, prescriptive stuff that should probably be looked at carefully and many of them done away with.

But I think you have to realize in all the discussion about safety goals, that there is an overriding unspoken goal and it is true for every bureaucratic organization and it's equally true for the NRC and that's to avoid embarrassing consequences and events.

That even though they may be insignificant, they get media attention, because radioactive, and it becomes blown out and becomes a really big deal. I think that that's always in the back, lurking in the background as we don't discuss them, maybe, but it's there, because management -- their jobs are on the line.

Even though nobody gets hurt, even though it's not a big deal and in terms of real safety, it becomes a very big problem for management if things blow up and get blown into a big media event or something that happens, like a truck accident or so.

We see that happening a lot and that's kind of what's always

balancing out the -- how much of the risk analysis actually gets informed into the regulation. So you may do a lot of risk analysis and make sure it's all low risk, and yet since the consequences could be pretty severe and embarrassing, you get a lot of prescriptive regulations anyway.

I think somehow dealing with that and recognizing that fact, and I don't have a good solution for it.

MR. CAMERON: Gary, is that type of concern one of the hidden values you talked about or is that something else?

MR. HOLAHAN: Well, this is a really important topic and it's not a nuclear radiation topic. It applies to a lot of other things, as well. It's a very difficult question because we're basically in the business of giving society what it wants. I mean, society makes the laws, we just try to figure out what it is that they want.

Some of the things that society wants, they want because these are reasonable values and some of the things society wants don't make sense, because some people are not well educated or because they have what we might call irrational fear of X, and it becomes very difficult for a regulatory agency to decide which of the things that society doesn't want, society doesn't want that truck to do whatever that -- would show up on the front page of the paper.

Does society not want that and we should decide that no, they're wrong, it's really not that bad, they shouldn't be worried.

Education is very important, because what you -- you can't have

rational decision-making in a country in which the citizens don't participate in that rational dialogue.

But it's a very difficult topic. It's very hard to say that a public agency, and whether it's for the self-protection of the individual manager or whether it's the agency trying to be responsive to the public, how do you deal with situations in which, let's say, the scientific rational analysis is different from the public perception of the importance of an issue.

You can't ignore the fact that the public takes things -- takes some things seriously. How do you deal with the fact that the public finds an airplane crash that kills 150 people much less acceptable than 150 automobile accidents on the same day? Should we just tell the public don't worry about it, you haven't thought about this deeply enough, or should we say, no, there's some underlying social value about maybe a whole family is involved or things that involve more people in one place.

Why is it that society finds that unacceptable? Is it because it's not a rational value and we should ignore it or because there is something in it and we should take it seriously? So it's really hard to deal with those situations.

Personally, we really try, I try not to overreact to things in which our reaction to them makes them look important when, in fact, we think they are not, because it decalibrates people more. It makes them less rational in their decision-making.

I don't know any other tool better than education and that means

education for the public as to what the risks are and education with respect to the government as to what people really value.

If people find that cancer risks are less acceptable to them that automobile risks, even when the numbers might say it's the other way around, then maybe you have to live with what the public wants.

MR. CAMERON: Thank you.

MR. FLACK: I can live without numbers, but numbers do mean something. It does expose people, exposes positions and it says this is what your expectations are, just like you put down ten-to-the-minus-three for a pump or a valve or something like that.

It tells you that that's what you expect and it's very difficult to write down a number in this sense of what expectations you have with respect to safety or risk to an individual.

Putting that aside, and the goal should certainly be higher than just numbers and we all know the problems you get with numbers, the question remains should we develop goals relative to risk.

That's the fundamental question, I think, we're trying to face ourselves with. If it could be worker, public and so on, do we need to make decisions based on what risk they're already exposed to and that we have to compare what we're doing to that risk or do we just compare it in isolation or develop goals in isolation of that risk.

That's a more difficult question, because one has to understand

what risk is all about and then how much more are we imposing and what will be acceptable.

I mean, putting the numbers aside, it's difficult to imagine that we couldn't -- we're doing what we're now in reactor space without .1 percent. That's pretty fundamental to what we do.

But the goal is higher than that. It has more fundamental meaning than that, I think, when you talk about what risks people are exposed to from day to day and what is the nature and what is the benefit of what we're doing and what fraction of that risk do we need to accept in order to do what we're doing.

It brings you always back to that question and I think that's the guideline. Instead of just minimizing things and using words like what's reasonable, when we really don't define it. We just try to practice it, to whether or not we're actually going to write it down and say this is our goal, let's see if people -- how acceptable is that and is it acceptable.

And certainly not everybody is going to agree with it, but that's just exposing it. It's just PRAs expose uncertainties, they're there, we're just exposing it through the mathematics and the modeling.

So I see purpose in it all. I see it as the whole package serving a purpose.

MR. CAMERON: Barbara, did you have a similar comment to that? Do you want to express it?

MS. HAMRICK: One of the things I wanted to add on about the

importance of explicitly expressing the safety goals is to always keep in mind, and that's the reason I'm here, that there are 31 agreement states out there and the NRC often has a tendency to be developing things with the idea of the internal application of that.

But when you go to the states, you've got -- you not only have 31 different states, but there's 31 really completely different programs at completely different scales, and the more guidance that's available, the more consistency we'll get throughout the United States.

I really can't express enough how different these individual programs play out, because of the difference in size. Look at us and look at Rhode Island and you can kind of get an idea of how the researchers are going to be completely different and the more guidance that's available that's out there, the more explicitly it's expressed, the more consistency you'll get throughout the country.

MR. CAMERON: Gary?

MR. HOLAHAN: How different are the goals and objectives of the programs?

MS. HAMRICK: You know, I don't think that I'm prepared to speak to that. I think the ultimate kind of ivory tower goals would be relatively similar, but in practical application, you get vast differences in the programs.

MR. CAMERON: So the implication, if the goal is a reflection of a social value, do you have a different social value in a state versus national.

MR. HOLAHAN: Last time I picked on Montana, somebody told me they had just been in Montana and they complained. There are some states in which the speed limits are higher than others and it's not just because the highways are better than others. It's because they have different values. That's real.

MS. HAMRICK: Again, I guess that comes down the political question of is this the values that should be imposed, is that something in the radiation arena that should be a national value that's imposed or local value.

MR. CAMERON: I think that's interesting to look at the agreement state adequacy and compatibility policy from the perspective of this discussion, because it seems that the criteria in there where certain aspects of regulations should be uniform reflect a national social value, so to speak.

MR. HOLAHAN: I'm allowed to be philosophical today. When I actually go back to the office, I have to do the budget and all that sort of stuff. But today I'm philosophical.

I think the values are not imposed on people. The values are exposed in the sense that if you're doing this right, you're figuring out what -- you know, the people of Montana want the speed limit to be 85. The people in New York City don't want it to be 85.

And so if you're doing -- if you're governing right, you're making the speed limit in Montana what they want it to be in Montana and you're making it in New York City what they want it to be in New York City.

Now, I'm not sure that we want 31 or 50 or whatever different radiation protection sets of values. Maybe we do want a common set of values, but then you've got to search the populous to figure out what that value is, and I don't think you impose that value on them. They impose it on us.

MR. CAMERON: That's a good point. Let's go to Norm, and then to Jonathan, and then see if we have some comments from the audience. Norman?

MR. EISENBERG: I just wanted to try to respond to a question that Gary Holahan asked quite some time ago, which was do we have the tools. I believe we have a wide range of tools. There is almost a toolbox that we have that we could apply to materials risk.

There may be some areas where data are not as forthcoming as we'd like them to be. We may need to get more detailed data.

The other question was asked, what -- how can you develop the tools if you don't know what the goals are, but I think there is some benefit in looking at what the risks are and you were not here this morning, but I pointed out that if you look at risk as this risk triplet and consequences, consequences are really a vector and that there are many components to it, worker normal risk, worker accident risk, public risk, contamination of property, and even the public reaction might be included in that.

Perhaps one of the things that, again, the NRC staff needs to think about is just that set of consequences might be and whether it would include

some of these things that are perhaps not quantifiable as physical quantities, but may be more of a public reaction.

But I think the idea that you could go through several different examples and look at where the risks are could help formulate useful safety goals.

MR. CAMERON: So you're suggesting, Norman, that if you really took a broad look at the consequences prior to the triplet, that that may expose some social values that would underlie a safety goal. So you're making a tie-in there.

MR. EISENBERG: But that's likely to be a very controversial thing for a government agency to do. But I think that's where NRC lives.

MR. CAMERON: Let's got to Jonathan.

MR. FORTKAMP: I just wanted to expand on some things Barbara said and got into as well. When I asked the question if the NRC thinks safety goals are necessary, I kind of expected the answer I got, that they are, and I agree with Felix in that they are already there. It's just a matter of defining them specifically.

I guess my thoughts are that I think they need to be defined specifically, especially in the materials section for the very reason Barbara brought up, that the agreement states.

And at least in my field, I'm seeing it already, is there is becoming gross inconsistencies across states in how the NRC's regulations or NRC's general

guidelines are being interpreted and rewritten and with respect to general license devices.

For example, the State of New York has all but gotten rid of the generally licensed device. NRC perceives certain devices to be relatively safe or safe enough that untrained individuals can be using those. The State of New York has gone and said that there are no such devices or almost no such devices.

I think what needs -- there needs to be some consistency, more consistency than is happening with agreement states. As more and more states are becoming agreement states, the differences are going to become broader and broader. As agreement states that are already agreement states become more comfortable with their situation, become more developed and have more experienced personnel on staff, they're going to start making regulations that go off on tangents that they feel are appropriate.

I think the safety goals need to be defined, I think, and they need to be of the highest level compatibility across all agreement states to maintain consistency of the regulations.

MR. CAMERON: I guess you're making the assumption that the development of a safety goal would somehow promote consistency, and I don't know that that's true.

MR. FORTKAMP: As Bob mentioned, safety goals are kind of the objectives for the regulations and, to some extent, and certainly these safety

goals are going to be argued substantially.

But being the objectives to the regulations, I think therein lies the consistency, if that is applicable to all regulatory bodies.

MR. CAMERON: Okay. Thank you, Jonathan. Let's see if anybody in the audience from NRC staff or outside NRC has a comment. Mike Weber.

MR. WEBER: Mike Weber, from NRC. I think this afternoon's discussion on safety goals has been especially illuminating and it sounds like there is a fair bit of interest in pursuing that. So I'm looking forward to tomorrow morning's session, including comments from Judith and other folks who might represent some of the public interest groups.

One thing I would point out is NRC and EPA, in the area of risk harmonization, pursued the topic of what are our current programs accomplishing several years ago, and that might be a good point to start with in terms of looking at what do the NRC programs accomplish and then compare that in the broader perspective.

MR. CAMERON: Thank you, Mike. In that regard, we do have some agenda items set for tomorrow, but I think what I would like to do and ask you to do is in light of our discussion here today, is to think about some broad topics that we might want to proceed with tomorrow.

I think that hopefully, Gary, you're going to be -- are you going to be able to be with us tomorrow?

MR. HOLAHAN: Yes.

MR. CAMERON: Good. Gary will be here tomorrow, but think about some of the things that were said and I'll do that also and suggest we'll have an agenda planning discussion tomorrow morning perhaps so that we can figure out the best topics to try to get us the furthest down the line.

But anybody else in the audience that would like to make a comment about the safety goal? Dennis?

MR. DAMON: My name is Dennis Damon. I'm in the Risk Task Force in NMSS. I would just like to hear from people tomorrow about -- on the subject of safety goals, to address the fact that there is this variation in who the target of the risk is among the different divisions in NMSS and how different that is from the reactor.

The reactor was focused on persons in the vicinity of a nuclear power plant. What I characterize these people as is semi-voluntary -- they're exposing themselves semi-voluntarily to risk.

In NMSS, I just made -- I tabulated -- you've got fuel cycle facility and health facility workers who are exposed to what you would call voluntary risks, because they're working in that plant. They presumably know, understand the risk to a certain extent.

You have people exposed to -- you have the analog to the nuclear power plant situation, people exposed to risk due to a facility cited in their vicinity, and then you have the transportation risk public, who are what I would

say is totally involuntary exposure. They didn't choose to be exposed at all.

And I would like people to talk about whether, when you start talking about -- even whether it's qualitative or quantitative expressions of how much risk these people should be exposed to, the question will come up should it vary depending on the degree of voluntarism here.

MR. CAMERON: Good issue, Dennis. Then we'll put that on the agenda for tomorrow. Anybody else? Okay. Well, I'd just thank all of you and I'd particularly like to thank Gary for an excellent presentation and some illuminating comments on some of the discussion, and thank all of you. We will be starting at 8:30 tomorrow.

[Whereupon, at 5:22 p.m., the workshop was recessed, to reconvene at 8:30 a.m., Wednesday, April 26, 2000.]