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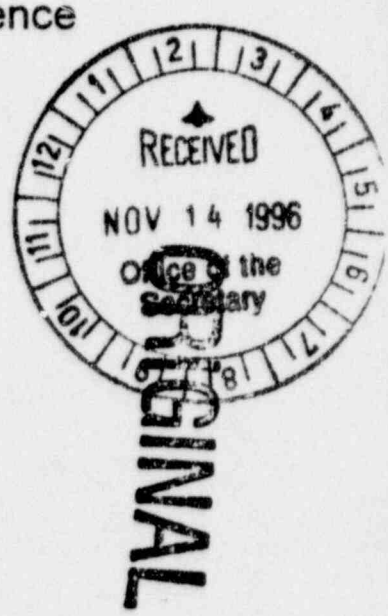
Building Public Trust and Confidence



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NUCLEAR REGULATORY COMMISSION

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STRATEGIC ASSESSMENT REBASELINING INITIATIVE

AND

STAKEHOLDERS PUBLIC MEETING

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BUILDING PUBLIC TRUST AND CONFIDENCE

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THURSDAY

NOVEMBER 7, 1996

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ROSEMONT, ILLINOIS

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The Building Public Trust and Confidence Session met at The Ramada Hotel-O'Hare, 6600 North Mannheim Road, at 8:00 a.m., Francis X. Cameron and Douglas Brookman, presiding.

PRESENT:

Kenneth Ainger, Commonwealth Edison
Kathy Allen, Illinois Dept. of Nuclear Safety
Gordon Appel, Illinois Dept. of Nuclear Safety
Douglas Beutel, Commonwealth Edison
Mark Burtschi, IBEX Engineering, Inc.
Mary Clarke, Washington University
Robin Colglazier, Commonwealth Edison, Byron
Stephen Collins, Ill. Dept. of Nuclear Safety/OAS
Mark Doruff, Amersham Corporation
Joseph Drago, Commonwealth Edison
Paul Eastvold, Illinois Dept. of Nuclear Safety
Ed Edgerton, NDTMA
Stephen England, Illinois Dept. of Nuclear Safety
Kristin Erickson, Michigan State University
Paul Farron, Wisconsin Electric Power Company
Stephen Floyd, Nuclear Energy Institute
Ronald Fraass, Kansas Dept. of Health
Linda Fraass, First Lutheran Church
Robert Goff, IBEX Engineering, Inc.
Peter Holland, Commonwealth Edison
Roger Houston, Nuclear Energy Institute

PRESENT: (CONTINUED)

Irene Johnson, Commonwealth Edison
Narinder Kaushal, Commonwealth Edison
William Litschgi, Monsanto
T. Derrick Mercurio, Southern California Edison
George Oliver, St. Luke's Hospital
Harold Pontious, Jr., Commonwealth Edison
Frank Popp, Univ. of Missouri/Kansas
Reginald Ronningen, Michigan State Univ., NSCL
Cheryl Schultz, William Beaumont Hospital
Victor Sgobba, USGAO
David Swank, Washington Public Power
Robert Sweeney, IBEX Engineering, Inc.
Tom Tipton, Nuclear Energy Institute
Mary Vincent, Commonwealth Edison
Robert Wagner, Loyola University Medical Center
Gerhard Wald, Commonwealth Edison
Heather Westra, Prairie Island Indian Community
James Williams, Ohio Emergency Management Agency
Ronald Wittschen, Detroit Edison

A-G-E-N-D-A

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

(8:26 a.m.)

MR. CAMERON: Good morning, everyone. My name is Chip Cameron and I'm the Special Counsel for public liaison at the Nuclear Regulatory Commission and my colleague and I, Doug Brookman, right over here, from Brookman, King Associates, are going to serve as your facilitators for the next few days and we'd like to welcome you to the third and final Stakeholders Meeting that the NRC is holding on the NRC Strategic Assessment and Rebaselining Process.

And the purpose of the meeting is for us to have an opportunity, first of all, describe the Strategic Assessment Process to all of you and to answer any questions that you might have on it. But, most importantly, to discuss your views on the Strategic Issues Papers that we're going to be presenting over the next two days.

And over the next two days, we're going to have a unique opportunity, I believe, to converse with each other on some of the most fundamental issues that are facing the Commission on the use of nuclear materials and I want to encourage as much interaction as possible between all of you, including the NRC staff, on the strategic issues.

The value of the public meeting is, of course, not only to hear your positions on the issues, your recommendations on the issues, but also to take advantage of the opportunity for all of us to talk with one another about the issues and, hopefully, for all of us to learn from on another.

One of the important values, another important value of the meetings and the discussion is this is really a good opportunity to take advantage of what you hear in formulating your written comments for the Commission later on in the process. Often, it's good to think about what people are saying and to try to anticipate those things in your written comments.

Now, Doug and I are going to endeavor to assist you in having an active and informative session, but ultimately this all depends on you and, again, I would encourage you to say what's on your mind and to participate in the discussion.

Now, the NRC staff looks forward to hearing your ideas and, as you will hear more about in a moment from our first panel, the staff is going to document all the comments that we receive here today, as well as the written comments, and they're going to present that to the Commission for the Commission's use in its decision making on some of the strategic issues.

This always reminds me of something that Woody Allen said that I think might put this in a little bit of perspective. He said that more than any other time in history mankind faces a crossroads, one path leads to despair and hopelessness, the other to total extinction. Let us pray that we have the wisdom to choose correctly. So I thought I'd put this in perspective for you, but it's not that bad.

I wanted to suggest a couple of guidelines for the meeting. One is after the NRC staff makes its presentation on a particular issue, I'll go out to all of you for comment and discussion. If you want to say something, please raise your hand and Doug or I will recognize you and please either go to one of the mikes over here or we do have a hand held mike that we'll be going through the audience with.

State your name and, if appropriate, your affiliation and this is particularly important for purposes of the transcription of the meeting. We are taking a transcript of the meeting and those transcripts will be available for people to look at.

We do want to hear everything that you have to say and, again, to make sure that we have everything on the record, I would just request that only one person speak at a time.

We don't have unlimited time. We do have, I think, a small enough audience and there will be some more people joining us, but I don't think we should have a time problem, but if we do in any particular session, I may have to ask you to quickly sum up your comment so that we can give another person the opportunity to speak.

Try to be constructive. I challenge you to not only give us your critique of the various issues papers, but also to suggest solutions and along these lines, keep in mind that one of the key factors here in the Strategic Assessment Process is how the Commission can perform effectively in times of diminishing resources.

So if you're talking about a particular option or if you have a suggestion, you might also want to keep that in mind, the diminishing resource concept and also another thing to pay attention to is that when you hear a strategic issues paper, there will be a number of options presented and what the staff and the Commission is doing is trying to select the best option and to look at the trade offs between those options on a particular strategic issue.

But another important point here is there are trade offs between each strategic issue area. So that's another thing that I would ask you to pay attention to. There may be something that you think should be done in

the reactor area that may have consequences in another area of the Commission's activities.

In terms of the agenda, I'll just briefly run over the agenda for you and we're going to start out with an opening session that will describe the Strategic Assessment Process for you and after that opening session, after we have comment and discussion from all of you, we're going to move into the second session of this morning, Looking at the Strategic Arena of Building Public Trust and Confidence and we'll go through each of the three papers in that session and we'll have comment after each of those papers.

We're going to break for lunch and then we're going to come back for two concurrent sessions, at least we're pretty sure we're going to have concurrent sessions at this point, but the first one is on the Strategic Arena of the Safe Use and Handling of Nuclear Materials and that will be in this room, I believe. The second concurrent session that's going to look at the Commission's Research Program and also the International Program is going to be next door.

And after we're through with those two concurrent sessions, that will end today. We will be back tomorrow at let's say 8:15 tomorrow. We're going to go into the first Strategic Arena, Assuring the Safe

Operation of Nuclear Reactors. Then we're going to break for lunch and then we'll go to two concurrent sessions again, one on Safe Management of Nuclear Waste and one on NRC Finances, the NRC Fee Program. After those two sessions, we'll come back here for a brief wrap-up.

And before we go to the first panel for today, does anybody have any questions on the process, the ground rules, the agenda?

Okay, good, well I look forward to a real good discussion with all of you and the first panel, we're going to have all three of these papers and then go to you for questions, but the first presenter is going to be Jim Milhoan who is Deputy Executive Director for Operations at the NRC and he's also the Co-Chair of the Commission's Strategic Assessment Steering Committee and he'll be describing the Strategic Assessment Process.

Next, we'll go to John Craig from our office of Nuclear Regulatory Research. John is the Manager of Phase Two of the Strategic Assessment Process and that's the phase that includes all of the public meetings and documentation of comments for the Commission.

Our final panelist will be Jesse Funches who is Deputy Director of the Controller's Office at the NRC. Jesse is going to talk about the outcome of all of this; Phase Three, the preparation of the Strategic Plan.

So let's hear from all of them and then we'll go back out to you for discussion.

Jim.

MR. MILHOAN: Thank you, Chip, and I do welcome you to the Chicago Meeting. As Chip said, this is the third meeting and the last in the series of public meetings we've had. We've had one in Washington, and last week we were in Colorado Springs. So we're here in Chicago and I do appreciate your attendance and certainly the value of the meeting will be dependent upon your participation. We've had excellent participation in the other meetings and I expect the same that we'll have these two days.

The environment in which the NRC conducts its activities is rapidly changing as a result of many influences. These include resource constraints, changes in the industry that the NRC regulates and the potential for new and revised mission requirements.

Also, in order to accomplish regulatory effectiveness, the agency must continually reassess changing technology, accumulated safety experience and improved assessment techniques for both the reactor and the materials program. Only by being prepared for the challenges of a changing environment will the agency continue to keep its health and safety mission in sharp

focus.

With these challenges in mind, Chairman Jackson established a Strategic Assessment and Rebaselining Initiative. To oversee this activity, a Strategic Assessment and Rebaselining Steering Committee of senior agency members was formed. Members of the committee, a large number of members of the committee are present today. The committee members were made up of Deputy or Office Directors of the major program offices in the agency.

Jim Shea, also the Director of the Division of Biolateral Cooperation Assistance in the Office of International Programs, also served as a sponsor for the International Activities Issue Paper and you will hear that paper in a session today.

The Steering Committee had a support group to help us in our carrying out our assessment and rebaselining activities and also was supported by a contractor, Public Strategies Group, Incorporated in conducting our work and I'll be discussing here the work that we had in the phases of the Strategic Assessment and Rebaselining Process.

The Steering Committee is analyzing where the NRC is today and developing options which the Commission can use to determine the agency's future path. The effort

is divided into four broad phases that will be carried out sequentially, with each of the phases building on the preceding phase.

The first phase, the Strategic Assessment Phase began in August of 1995. The Steering Committee began with the bottom up approach for assessing where the agency is today with the examination of current NRC functions and activities.

The Steering Committee requested the staff to provide at the lowest organizational level each activity presently being performed by the NRC, as well as its basis, in other words statute, regulations, Commission, guidance, what is the basis for the activity we're doing and also the request included the primary internal and external factors that are expected to affect the agency's performance of the activity in the future.

The staff assessment included approximately 4500 activities, which the Steering Committee reviewed to thoroughly understand what the agency is doing, why the agency is doing it, and what factors must need to be considered in providing options for change.

The Steering Committee organized the activities by major function and lines of business. This was done to consolidate similar activities and to render the data organizationally neutral.

Based on this information, the Steering Committee applied a top down strategic -- to define issues whose resolution will influence the future direction of the agency.

After identifying the strategic issues, the Steering Committee considered them in an integrated fashion. First, the individual strategic issues were arranged in logical groupings of related issues. The groupings were then examined to determine if a predominant issue existed within each group. These predominant issues are referred to as directional setting issues, or DSI's, because their resolution taken together would establish NRC's strategic direction for the future.

Resolution of the DSI's will provide a strategy for the agency to meet a strategic vision and goal. DSI's were developed into decision papers which are referred to as issue papers and which you have and were made publicly available.

The second phase builds on the strategic issues in the DSI's identified in Phase I. And as I indicated earlier, included the development of the issue papers. The issue papers are intended to provide broad direction from the Commission.

The issue papers include descriptions of the background of the issue and the external and internal

factors that the Commission may wish to be aware of when considering options to resolution of the issues. The issue papers also provide the Commission with policy options for the issues.

It should be noted that Chairman Jackson encouraged the Steering Committee to develop innovative options that are no constrained by existing practices or organizational structure. Additionally, in some issue papers certain options could be considered to be extraordinary.

While the Commission is unlikely to select such options, these options have been retained in the issue papers to illustrate to the NRC stakeholders the breadth of options that were considered.

It should also be noted that the Steering Committee was not requested to provide or recommend a preferred option, but we were responsible for assuring issue papers contained a rich set of options.

It is anticipated that final Commission decisions on the DSI's will result in a rebaselining or resetting of the agency's goals, assumptions and strategies. Final decisions on the issue papers will also influence the related issues identified as part of the assessment conducted during Phase I.

Feedback from the various NRC stakeholders

continues to be an important aspect of evaluating our regulatory programs. The primary goals in acquiring stakeholder comments are to obtain views for Commission consideration in reaching final decisions on the issue papers and to determine whether the agency has omitted any important considerations or issues.

In Phase III, the Strategic Plan will be developed from the agency's mission statement, its strategic vision, general goals and the Commission's decision on the issue papers. The development of the Strategic Plan will be guided by the requirements contained in the Government Performance and Results Act of 1993. The Strategic Plan will be the agency's tool for resetting priorities and allocating resources consistent with the vision and goals of the agency.

Phase IV is the Implementation Phase. The Implementation Phase includes implementing the Commission's decisions based on the issue papers generating Commission papers to resolve related strategic issues and complying with Commission guidance based on the Strategic Plan.

The Implementation Phase will also include developing a framework that allows for updating the Strategic Plan and for integrating the Strategic Plan into the budget process, performance monitoring and reporting

processes and the process for development of future Commission decisions.

At this time, John Craig, the Task Manager for the Phase II and the later phases of this effort, will be discussing in more detail Phase II of this particular project.

John.

MR. CRAIG: Good morning.

Phase II, as Jim mentioned, built upon the work that had been done in Phase I and in February of '96, writers and sponsors got together and we began to form think tanks to discuss options associated with each one of the issue papers. If you've had the opportunity to look at the issue papers or some of the slides for the subsequent discussions for the next two days, you'll see a number of options listed there.

We tried to identify options that we referred to as out of the box and by doing that you can discuss options that wouldn't constrain or limit the potential innovative approaches to the direction setting issues. Some of the options are a little extreme, some require legislation. The key was that the options were to be discussed and described to present a range of possible approaches to a direction setting issue without considerations for resources, schedules, et cetera. It

was to really focus on a broad range of good options.

And as Chip mentioned earlier, we're at the stage where that presents some interesting questions because the comments that we've gotten during the first two meetings, in general, are we should do more in a number of areas and only one or two areas where it was suggested, I think, that we do significantly less and in an era of reduced budgets and reduced staffing, that's going to be a real challenge to us.

The issue papers are available on the tables outside in the hall, all 16 of them. We started off with 24 direction setting issues, and we developed the issue papers and presented them to the Commission. Based upon their review, they made some preliminary views on a number of issue papers. They combined a few and a couple of others they thought weren't either at a broad strategic level or were more appropriately addressed after decisions had been made on the other issue papers, and I'll go over those in just a minute.

There are two other key documents associated with the Strategic Assessment Initiative. The Strategic Planning Framework Document, and there are copies of both the framework and the process paper out there also, contains the mission, vision and goals and it has broken up the issue papers in something called strategic arenas

and their related papers. So there's a strategic arena for operating reactors.

There are a number of issue papers that cut across strategic arenas, risk informed performance base, for example. So even though you'll see one issue paper and it will be discussed, and risk informed performance base is a good example, where it will be discussed in the Operating Reactor Program Strategic Arena, clearly risk informed performance based activities and decisions are going to affect the materials area also.

The Stakeholder Involvement Process Paper is just exactly what the title implies. It was intended to tell stakeholders, internal and external stakeholders, how to get copies of the documents and how to provide comments and I'll pause for a minute just to tell you, I heard some discussions about what a stakeholder is, and there are two kinds. People that are internal NRC staff are stakeholders and then everybody else, the public, the industry, Congress, Oversight Committees, et cetera. So the comment that I heard was that stakeholders somehow implied agreement with the views, et cetera, and that's not the case. Rather it was a term that's used just to describe people that could have an interest in the activities that are under way.

Jim's already mentioned the importance of the

stakeholder comments and I guess I would stress that this is sort of a unique process whereby the Commission has had the staff do a review, identify potential options. The Commission has indicated its preliminary views and now we're seeking comments from the regulated industry, the public at large and the NRC staff, about various aspects of those issues papers and the preliminary views.

There are four focus questions that you have seen in the meeting announcement to help you provide comments and help focus your comments and also, as Jim mentioned, the next stage of this will be a review of the comments by the Steering Committee and a review and consideration of the comments by the Commission as they make final decisions on the issue paper and then these decisions will be reflected in the Strategic Plan.

So in a very fundamental way, the comments that we're requesting are going to be used and incorporated to determine final decisions in the content of the Strategic Plan.

Following the Commission's review of 24 issue papers, as I said, we now have 16 issue papers that are part of the Strategic Assessment and Rebaselining Initiative. DSI No. 1, which was Regulating Areas of Little Public Risk, was combined with DSI 12, which is Risk-Informed Performance-Based Regulation. DSI 3, which

was Dual Regulation of Other Federal Agencies, was combined with DSI 7 and DSI 12. I'm not going to read the titles to you. We're going to discuss all 16 over the next two days.

DSI No. 8, which was Regulating a Small Number of Licensees was determined not to be at a strategic level. It affected just a small group of licensees.

On the next slide you'll see a gap between 14 and 20. These DSI's related to management philosophy, information resource management and planning, management and organization staffing and core capabilities and independent oversight. They are internal activities for the NRC and the thought is that a number of the decisions in these are more appropriately addressed after decisions are made on the other 16 and so that's how they're being addressed.

There's a summary that's part of the framework document that has the information I just presented and it's, as I said, also on the table outside.

We've gone to some significant lengths over the past few months to announce the availability of the issue papers, the framework document and the process paper to notify NRC staff and members of the public of the meetings. We issued press released beginning in September and in September and October we had individual mailings to

about 1650 organizations and individuals that covered a very broad spectrum of interests and we've had subsequent press releases in the month of October.

We've also held meetings with the internal meetings. We've had a series of meetings and meetings have also been held, which were public, with the Advisory Committee on Reactor Safety, the Advisory Committee on Nuclear Waste so that the oversight committees that look at NRC staff activities also have been briefed on the process.

And as Jim mentioned, this is the third of three meetings with external stakeholders and the other two meetings were in Washington and Colorado Springs.

What are we going to do with the comments? The comment period is scheduled to close November the 15th. We're keeping lists of the comments. We have indexes for each one of the comments that we've received. They're available in the Public Document Rooms so that if you wanted to know which comments had been received on a specific issue paper, there's a summary listing of those and all of those comments are also available.

The writers and the sponsors were going to review and collate the comments. The comments, in general, fall into two categories, the kind of comment that goes directly to the DSI or the factors that were

considered, the option that was chosen by the Commission or comments that are more at an implementation level that the staff should consider. We're going to try and sort those a little bit and present the ones to the Commission that are more central to the decision that they're about to make as part of the final decision making on the issue papers.

All of the comments are going to be incorporated into a Stakeholder Interaction Report. So both the broad comments and the implementation comments will be available to the Commission. The Stakeholder Interaction Report will be available to members of the public. It's going to be put on the Internet. It will also be available in the Public Document Rooms.

We've gone to some significant lengths to try and reach out and contact the various stakeholders who are interested in the process. We've gotten, I think, some outstanding comments and insights on some of the options and are being considered.

The next phase of the process, Jesse Funches is going to describe, where he takes the results of the hard work from Phase II and then I think the really hard part of the Strategic Assessment Initiative will begin to make the final decisions and then to actually implement it for the next three to five years.

Jesse.

MR. FUNCHES: One of the major outputs of the NRC Strategic Assessment and Rebaselining effort will be an NRC Strategic Plan. This is also referred to as Phase III of the Strategic Assessment and Rebaselining Initiative.

The activity that John has described for Phases I and II will provide the foundation for the NRC Strategic Plan. The identification of issues, the issue papers themselves, the Commission preliminary decisions, the identification of internal and external factors during Phase I will be used to develop the NRC Strategic Plan.

Your comments today on those issue papers and on those preliminary decisions by the Commission will also be important input to the development of the plan.

The primary purpose of the NRC Strategic Plan is to set the direction for the NRC for the next five to ten years. It's to respond to those external factors that Jim Milhoan mentioned as part of the introduction. In addition, the Strategic Plan will meet the requirements of the Government Performance and Results Act.

In summary, that Act requires us to do three things. First, we are to develop a Strategic Plan whose purpose is to guide the agency for the next five to ten years. In addition, we are to develop an Annual

Performance Plan. This Annual Performance Plan will set the annual goals and measures that we'll use for a particular year. This Annual Performance Plan will be an integral part of the budget in the future.

And, lastly, the Government Performance and Results Act requires us to develop a Performance Report that reports on the execution of the Performance Plan.

The Strategic Plan and the Performance Plan is to be completed no later than September of 1997 and it is to be used with the fiscal year 1999 budget. The Performance Plan will report on the execution of the fiscal year 1999 budget and, therefore, is required to be produced in March of the year 2000.

We see our Strategic Plan as not being static. We see it as being a quote living document. We will be updating the plan from time to time and we envision some type of review annually to make sure that the situation that we are responding to has not changed or that the strategies that we have developed are working and if they're not working we will adjust them.

The last phase of the Strategic Assessment and Rebaselining is implementation. One specific implementation action that we know we will have to take is to develop a budget that will be guided by the Strategic Plan. There will be other implementation activities.

Those will be specified as the Commission makes its decision on issue papers, utilizing the results from the stakeholders meetings.

I'd like to spend a few minutes talking about what we envision the Strategic Plan to be and what it will not be and I hope this will give you some additional guidelines to help you comment today on the issue papers.

We see the plan as being a relatively short document on the order of about 30 or so pages. It will be a guide for all levels of program decisions and resources decisions. We do not see it as specifying what those resources will be. It will specify important agency level goals and objectives. It will not provide individual organization goals and objectives, however we would expect it to guide those goals and objectives that specific organizations within the NRC might develop.

It would provide strategies for achieving the agency goals and objectives and I think the Commission preliminary decision and the issue papers plays a very important role in developing those strategies.

And, as I mentioned earlier, it would be updated periodically to reflect new information.

The budget will come later. Operating plans, performance plans also will come later and other details for implementation will follow the plan.

We have somewhat outlined what we envision the Strategic Plan to include. The five basic elements that we see in the plan would be a statement of NRC's mission, basically the purpose for the NRC's existence; a graphic picture of where NRC wants to be in the future, this will be our vision. We will also have a section on values and principles specifying those beliefs that will guide the NRC employees in their work. We will have goals and objectives and we will have the strategies that define how we will achieve the mission vision and goals.

To articulate the strategies based on the initial work that has been done, we have organized the plan around what we call Strategic Arenas and you will see those today as we discuss the issue papers. Based on what we have done so far, we have identified three broad categories. The first category is what will call Mission Critical, second category is Mission Enabling and the last category is simply called Core Resources.

Within the Mission Critical, we have arenas on reactor safety, material safety and waste. In Mission Enabling we will have building public trust and confidence, providing research expertise, supporting NRC domestic and national responsibility in the international arena and providing the necessary support to the Mission Critical areas.

We have three Core Resource strategic arenas. The first one would be Human Resources. Another one is Financial Resources and the last one would be Other Information Resources.

With that short introduction to our Strategic Plan, that's all I have and I turn it back over to Chip.

MR. CAMERON: Thanks, Jesse. Let's go out to the audience for comment. You know, I might note that the Strategic Assessment Rebaselining Process is not just unique to the Nuclear Regulatory Commission. As several of the panelists pointed out, all of the federal government agencies are going to be doing this. The NRC got a head start, but also private organizations, state government, local government organizations are also doing this.

So if there's anybody who's been through this type of process who wants to share any of their experiences that may enlighten our process, I would welcome you to do that and in this regard, I should introduce Steve Strothers in the back of the room, who's with the Public Strategies Group. PSG is what we affectionately call them, I guess, but they have an expertise in helping public organizations do this type of process. So Steve is with us today.

Any comments or questions for the panelists?

Kathy.

MS. ALLEN: I just have a question --

MR. CAMERON: Hold on a minute, let me get you this mike and because we are transcribing, if I could just have everybody just state your name, affiliation and just speak into the microphone.

MS. ALLEN: Kathy Allen from the Illinois Department of Nuclear Safety.

I have a question about stakeholder comments. I notice on your Internet Home Page or on your Internet Page that you have a place where you can click to review the comments and it's been about a week since I've been on and I haven't seen any. Are there any plans to get those on before the comment period ends?

MR. CRAIG: We're in the process of putting transcripts from the meetings we've held up on the Internet even as we speak. We hadn't planned to put the comments up on the Internet as they come in, rather we were going to put them up as part of the Stakeholder Interaction Report.

MS. ALLEN: Do you think that they will be available December 6th or will there be a lag time on the Internet?

MR. CRAIG: There will be a little bit of a lag time just because of the process of giving the

computer people the documents to get it up on the Internet. We're going to try to make it as short as possible.

MR. CAMERON: Thanks, John. Any other questions out here or comments on the Strategic Assessment Process or the public comment process?

Okay, it turns out that this usually is the clearest point of the two days. So let's take a little bit of a break to give Bob Perch time to, Bob is up here. He's Strategic Assessment Staff. He's going to get the handouts for the presentations in the next session, put them in the back of the room for you and we will have handouts for every session. If you need copies of the paper, they're outside, I believe, by the registration desk, all of the Strategic Assessment materials.

So let's take a quick break until 20 after 9:00. We'll start promptly then. That still puts us on schedule and we'll get the handouts for you.

(Whereupon, a short break was taken.)

MR. CAMERON: If everybody could begin to take their seats. We're going to get started here very shortly.

Okay, we're going to get started on the first Strategic Arena for discussion this morning, and that includes three issues papers. The first is Public

Communication Initiatives and we have Steve Crockett from our Office of General Counsel who is going to present that paper. We'll then have discussion on that.

Next, we have Stu Rubin who is from our Office of Analysis and Evaluation of Operational Data, who is going to present the Role of Industry Paper. We'll then have discussion.

Then we'll go to the final paper of the morning, Enhancing Regulatory Excellence, and Stu Rubin is also going to present that paper.

I'll ask Steve Crockett to come up now and present the Public Communications Paper.

MR. CROCKETT: Thank you, Chip. Can everybody hear me? If there's anybody out there who cannot hear me, please raise your hand. I see no hands, good.

I'm not either of the people named up there. Karen Cyr, our General Counsel, is headed for South Africa right now to participate in discussions on an International Treaty on Nuclear Waste and Roger Davis is in a Cor · ssicner's office at the moment and so I'm picking up where Roger left off and I'm very pleased to be able to do so. This is an extremely important subject.

I might add that although Karen is a lawyer, Roger is a lawyer and I'm a lawyer, this is not a legal subject. It's much broader than anything the law provides

for and the kinds of options that I'm going to present to you this morning, are not options that require any changes in the law.

The various issues papers have received some criticism for not being as clear as their readers would like. This was one of the papers that came in for such criticism. I will try to be as clear as I can this morning.

I will be covering the direction setting issue itself, why it arises, some of the key factors that will affect the Commission's decision on this issue, the options that the writer presented the Commissioners with and also the Commission's preliminary views.

Could I have the second slide, please? Oh, it's up there, good, thank you.

Here are the three key factors which will affect the Commission's decision. The NRC already has a very strong program of public communications and I'm going to outline that program for you later and give you some rather striking numbers. However, there are some factors, both legal and technological and social which suggest new opportunities. The third key factor is that the NRC has already undertaken in recent years several key initiatives in the area of communication with the public.

Let's look now at key factor number one. The

NRC has a policy which favors broad public disclosure of information and broad public involvement. Our principles of good regulation state that we should make our activities publicly known, that we should be candid about what we're doing and we should try to make our regulations as clear as possible.

We have two policies in place already dealing with public communication. Both of these came out last year. One is a policy on responsiveness to the public, the other is a policy on access to information about the agency's programs and activities.

Both of these policies are commitment, that is both of these policies are very amply demonstrated by several of the things that you see listed under the second bullet up there. We have a huge Public Document Room in Washington D.C. and over 80 Public Document Rooms around the country. The Public Document Room in D.C. has over two million documents and a few hundred are added every day to the list. We are making increasing use of the Internet. In fact, the bulletin board that we have at Fed World is second only to the IRS in the number of hits, and I hope somebody will explain that to me, why only the IRS comes ahead of us.

Much of our business is published in the Federal Register which, by the way, is becoming

increasingly available over the Internet. We have a very large office acting under the Freedom of Information Act which is sort of the grandparent of all our access to information activities.

The Office of Public Affairs is extraordinarily active in the area of public communications. They have 14 full time people. They have people out in the regions. They publish pamphlets. They have a very good Web site; I urge you to visit that Web site. They've received some 12,000 calls a year from representatives of the media. I did a little calculation; that turns out to be a call from a journalist about every ten minutes every working day of the year.

Congressional Affairs serves a similar function for Congress. We are under a statutory obligation to keep Congress fully informed and Congressional Affairs is very active in that area.

Finally, Chip Cameron operates OGC's public liaison function, a function which has been extraordinarily important in recent years, especially in our, what we call the enhanced participatory rule making on decommissioning and decontamination.

Let's look at key factor number two, the developments that are suggesting new opportunities.

In the last year or so, we've had legislation

and material coming out of the White House which promote new technologies and new standards to be applied in the use of that technology. We had a revision to the Paperwork Reduction Act. We have new circulars from the Office of Management and Budget. We are being told and sensibly told that we should try to make as much information available in as equitable a manner, in as timely a manner as possible and on a cost beneficial basis. I'll say more about cost and benefits later.

The second item under this key factor, there was also new super fund legislation this last year, which although it does not apply to us, will certainly make much more popular the idea of community resource boards in the area around sites which are covered by super fund. We can expect pressures to increase on us to devise similar techniques for communicating with the public.

Decommissioning is now on the horizon for several of our licensees. This will increase the need to communicate with the public whenever we have a major rule making, such as the decommissioning and decontamination rule making we need to get out there early and find out what the public concerns are.

The last item is developing very rapidly as we speak. There are all kinds of new economic challenges facing the industry. I recently attended an energy daily

conference on the increased competition in the industry. The industry faces those challenges. The NRC faces the challenge of figuring out how to regulate the industry in these new economic circumstances. And as we change policies, as we try to deal with this new situation, we need to be able to get out there and explain what we're doing.

Let's take a look at the third key factor. The NRC has been active in recent years inventing new ways to deal with old difficulties. As I mentioned before, we've had the enhanced participatory rule making on decommissioning and decontamination. We just finished up a pilot project conducting the activity preliminary to a rule making on the Internet.

We call it Rule Net. It allows for people to comment on the prospective issues in a rule making well before any proposed rule goes out. It also allows people, and I think this is extremely important, it allows commentors to talk to each other. Usually, the comments are, the way America On Line is wired, everything goes through a central location. It's not really a network, but Rule Net is really quite different and people were able to converse with each other, as well as with staff members. Staff members were able to converse with the commentors outside of the formal procedures of Federal

Register notices and the like.

For the last two or three years, we have been conducting open enforcement conferences; about one in four of our enforcement conferences has been open. This is a policy not without some controversy surrounding it, but it has been an effort that we're taking stock of now and we will see what course the Commission takes on it.

Finally, I'm going to skip over the NRC Citizen's Guide and mention something that's not up here. We took great pains to revise our, what we call the 2206 Petition Process. Under 10CFR Section 2206, any citizen can petition the agency for some enforcement action or other useful action involving a particular licensee. The process has had some revisions to it recently. We now provide a limited opportunity for a legislative style hearing. We make sure that there is one person on the staff who is assigned as the contact for the petitioner and we are much more regular in putting out status reports on these petitions.

Let's move now to the options that Karen Cyr and Roger Davis presented to the Commissioners.

There are fundamentally three options here, but they are not mutually exclusive and, indeed, you could say we are in some way or another pursuing all three options right now. Our decommissioning and

decontamination rule making, for instance, is certainly a case of putting a priority on early identification of public concerns and methods for public interaction. Anybody familiar with the work of the Office of Public Affairs knows how much effort they put in to general public outreach, making pamphlets available, making even such things as -- reports available at OPA's Web site, but we have separated these into three options, nonetheless, and we've put the emphasis here on priority.

It's not that if we adopted option one we would never set about seeking early identification of public concerns. It's not that we would not try to have good general public outreach, but if we were to adopt option two, we would place a priority on that. We would be more systematic about it. We would expand it. We would devote more resources to it.

I should say also that option one is by no means in status quo. It's a constantly changing activity, so it's not stable, it's not sitting still.

Let me begin now to describe these options in more detail very briefly. The existing approach consists mainly of dissemination of a huge amount of information and response to public comments and inquiries about that information. It's not a centrally organized approach. The results is then that there is a good deal of

inefficiency in it. It may be that one office is duplicating activities that another office is carrying out.

From the standpoint of an interested member of the public, that's not so bad, that inefficiency is not so bad because it means that you have many opportunities to find out a single piece of information. But in an era of declining budgets, I should have mentioned that as one of the key factors affecting the Commission's decision on this direction setting issue. In an era of declining budgets, efficiency is something that the Commission just must think more about.

Moreover under the existing approach, we may miss a good deal of information and ideas that we would get from members of the public. So it's good to think about other possibilities.

Now, there is a variation on this first option and that is to focus more systematically on maximizing effectiveness in economy. Now, this phrase, effectiveness in economy is a phrase borrowed from some of the new legislation that I spoke of earlier, some of the new material coming out of the Office of Management and Budget. It asks us to think more consistently and systematically about whether the methods of public communication we're using are really effective and,

moreover, whether they are the cheapest ways, the least expensive ways to achieve those same effects.

If we were to adopt this inset option, this focus on maximizing effectiveness in economy, we would set about a more wide ranging and systematic cost benefit analysis. We would develop a plan. We would then assess each of the elements in our public communications program to see whether it's the best possible.

As I've just described it, I think it's obvious that this would be a costly venture and for that reason, you'll see a slight variation on this option in the Commission's preliminary view.

The second main option, placing a priority on early identification of public concerns would have us put a priority on doing more things like we do in the decommissioning and decontamination rule making. We would train more people to carry out the kind of function that Chip carries out so well. We would work with our technical people to develop ways to communicate complicated technical subjects to the public. I think we have some reason to see from the so called popular science literature that that occasionally works and there are ways to do that and people can be trained to do that.

That, too, just like the focus on maximizing effectiveness in economy is going to carry some costs,

principally the costs of training, but we also know that there are many costs of not taking such efforts and those of you who lived through our difficulties with what we called our below regulatory concern policy statement back in the late eighties will know that our not getting out early on that to find out what the concerns of the public were cost us a great deal. In fact, the policy statement was simply wiped off the books by legislation in, I think, 1992.

The last option that was presented to the Commission was an option which would place priority on expanding the kind of thing that the Office of Public Affairs already does. The Office of Public Affairs would therefore have a much larger role. It would take an even more active role than it does already in describing the agency's program, the agency's philosophy. The Office would produce files, exhibits, say exhibits of things like waste containers, tutorials, say tutorials on radiation protection.

We would try to make sure that NRC professionals have a greater visibility at professional meetings and that kind of thing. That, too, would be a costly effort. There are two other possible down sides to this option also; one is that it might be viewed as promotional. People might suddenly think that we were out

trying to generate friends for the atom and to reproduce some of the booklets that the Atomic Energy Commission reproduced in its hay day.

There's also some concern that in the effort to explain technical questions to a larger public, we might simplify them and therefore lose some of the key, in the public discussion, some of the key technical details might be lost.

Let's move now to the Commission's preliminary views. For the time being, they are taking the middle path and with the memory of our difficulties with the below regulatory concern policy statement, they are thinking that we should set a priority on early identification of public concerns and methods for public interaction. They urge the staff to view the word public in its widest possible sense, to include all our licensees, all levels of government that these other federal agencies, the Congress, the Courts, state governments and our international partners. It means citizens who are interested for one reason or another in our activities.

Each one of these segments of the public have different needs, and the Commission urges the staff to take these different needs into account.

The Commission also urges us to look very

carefully at the role of technology. Many of us, myself included, are fascinated by the possibilities of the Internet and I spend a good deal of time almost every day on the Internet looking for material that's useful in my work, but there aren't all that many people attached to the Internet yet and if every member of the public were attached, it probably wouldn't work very well.

So the Commission urges us to remember that there are still many people that depend on paper and even for those of us who use the Net, paper is often very useful to us. So the Commission urges close attention to the appropriateness of technology.

The Commission also wants a more coordinated effort at public communication, but wants the implementation of our communication program to remain the responsibility of program offices. I may be reading between the lines here, because the Commission, in issuing some 16 sets of preliminary views on these issues, didn't have time to go into lengthy explanations, but I think what the Commissioners are aiming at here probably is to make sure that no one in the NRC thinks that public communication is someone else's business or is the exclusive business of the Office of Public Affairs or the Office of the General Counsel. It should be fully integrated into our activities, even though it has a

central focus.

The last item in the Commission's preliminary views is what I alerted you to earlier. It's a variation on the option to maximize or to focus on maximizing the effectiveness and economy. As I said before, that could be an expensive proposition if you were to draw up a plan of assessment and go about assessing each one of these things. So the Commission has taken a more cost effective approach here, one could argue, and it has essentially two parts. That is, if this becomes the final view of the Commission, the staff should focus on the highest cost activities and see if we're really getting what we want for our money and, moreover, each time some change is proposed, to look carefully at the costs and the benefits of that change.

That's a quick view of an extremely important subject. One could argue that it's somehow not right to be setting this off as a direction setting issue. That it's an issue which is always there. Failure in public communications is a very costly thing.

On the other hand, we just issued two policy statements and a report on public responsiveness last year and so one could wonder why this issue is suddenly coming up in this context. But, as I said, it's an extremely important one. You'll find this morning that it affects a

great many other direction setting issues and the time seems to be right to look at this closely.

So I'm through and I'll turn it over to Chip.

MR. CAMERON: Okay, thanks a lot, Steve.

As Steve noted, the Commission's preliminary view focused on early identification of issues and this preliminary view, as well as the entire paper, was based on an analysis of what's worked for us, what's not worked for us in the past and I would like to hear some comment on this issue. Not only on the Commission's preliminary views, but suggestions for how preliminary views could be implemented in terms of early identification of the issues.

Steve talked a lot about costs and benefits of various communications initiatives. Are there any suggestions about how the Commission might go about analyzing what it should do in this area and how do you evaluate costs and benefits in a public communications area? How do you define success in this particular area?

I'll go out to you. Do we have a lead off comment?

Yes?

MS. ERICKSON: Hello, my name is Kristin Erickson. I'm the Radiation Safety Officer at Michigan State University where we run a big broad licensed program

and of course have low radioactive waves, along with other issues to which the public has been sensitized.

In recent years, we also had a large incident involving off site release, which could have initiated a tremendous public outcry.

I believe that the NRC needs to not only take their preliminary identification of early issues, but in fact put option three and expand in large part what they're doing. I believe that the NRC needs to take the role of the tutorial with the public because I think we're all aware the public ignorance precipitates tremendous problems when we try to deal with an incident or even deal with some daily operations in our sites.

And if the NRC were to do this, it would be better even than our own licensees because the NRC is the watch dog, per se, in the eyes of the public. Their credibility is not that of fox looking after the chickens.

Now, to analyze the problem, I think that what the NRC could do and licensees, I'm sure, would cooperate, we would, would be to look at prior problem, prior incidents, cases where the public problems were high and then see what went wrong. How fast was this told to the public? How was it told to the public, if at all? And analyze those problems and then also look at places where they have similar incidents or difficulties and don't have

a public outcry and why did it work? That would be a good start.

I think the idea of the Web being increased, films, publications, little booklets could be a really good way to educate the public and then on top of that, reaching into the schools, the high schools, the grade schools would be a really fine option, too.

MR. CAMERON: Great, very thoughtful comment, Kristin. One of your comments, about looking at particular incidents and what worked and what didn't in terms of public reaction reminds me of some of the same problems that face a particular industry that runs into a problem.

For example, if you all remember the Tylenol scare back a few years ago, which I guess centered in Illinois or when AT&T lost its long distance line, how to react to that. What's the best way to react to those incidents? Do you just sort of go inside your shell and hide or do you become more proactive?

How about comments on Kristin's suggestions? Do we have any on that?

Yes?

MR. MERCURIO: I'm Derrick Mercurio with Southern California Edison.

I very much agree with Kristin's position. I

think that there's a general lack of any concerted or effective effort on educating the public. We've been ignoring that, especially like Kristin said, in our schools, starting with elementary through secondary and high school, colleges also.

If the NRC doesn't want to take this role because they feel that it's not in their regulatory interest, we need to work with the NRC and find a way to get this accomplished. Maybe the DOE is the right place to take the lead in this effort and like Kristin said, the industry would be seen as too self serving, if we're the only ones to do this. We need to do more within the industry, but it also needs to be a governmental program so we don't appear to be on our own band wagon.

If we don't do this, there won't be a nuclear industry, there won't be an NRC, either, if we don't start now. We may be too late now. We're a dying industry. We've got a lot of plants shutting down. No one is buying any new plants. We're not licensing any more. What we have, we're trying to hang on and we're not doing very well because what's going on in the whole industry and the economy.

In California we're already going into competition and will we survive? We don't know. We're doing everything we can, but we don't know where we're

going to be in three, five, seven years.

There's also something that doesn't make sense to me in this country, just a general perception, my own personal view is we have to be at least ten times safer than other countries in how we handle our nuclear power program. There's also the perception we're a hundred, my perception is we're a hundred times more dead as an industry as the rest of the world.

That doesn't make sense to me. Why are we there? We haven't been educating the public and not our legislatures, Congress, state legislators. We haven't been doing that education. We need to do that. We must combat the negative publicity that the press uses, the media and also the existing mind sets. Our children see things like Bart Simpson making a fool out of himself. We have to get back and educate people starting at that level. Otherwise we're not going to be here. It's takes a lot of education, effective education, not just technical, engineering types of education, to get through to the public.

We have to have this education or the judges and juries aren't going to understand what is the process of what's going on and they'll be coming out with judgements against the nuclear industry. We can't take very much of that. We're not going to survive if that's

what happens, if there's negative reaction to our technical approach to our industry.

Engineers are notorious for not understanding the big picture issues. We lose sight of the big pictures by getting lost in the details. Talking just to ourselves, not reaching out to the rest of the public. They're the people, they're the ones who are going to decide whether we exist or not.

The opening comment you had, the path we're on will lead either to despair or distinction. Unless we do something, and start now, we may be too late not, but surely if we don't start to do a lot more now, then those are the two paths we're on.

The NRC must look at their responsibility and contribution to the demise of the industry. We must both examine our roles and become part of the solution to creating a healthy nuclear industry in this country. The ship is sinking and good people are leaving it in droves now to go somewhere else so they'll have a career for the next 20 years instead of thinking they're not going to have a job in three to five or seven years being in this industry.

And if our hearts aren't in the right place, the message we put out to the country isn't going to work, if we just come from a pure technical viewpoint. If we

think that this is too big a task, if it's too much work to go out and do all this, then we've made our decision to whether we think nuclear power is safe, is worthwhile, it contributes to the health of this country or provides alternate energy supplies as a strategic balance against other energy supplies and the control other countries have over our energy supplies when we buy oil and all the other energy supplies.

MR. CAMERON: Thank you very much, Derek.

What we've just heard, I'd like to continue this thread. We've just heard a couple of suggestions along the educational front. One looking at particular incidents that might happen, the second looking at a more broader, generic public education approach to the use of nuclear materials.

Do we have some more comments on this public education aspect, the fear of crossing the line to being promotional that Steve brought up?

Steve, did you have anything to say?

MR. CROCKETT: Just one matter of fact and then perhaps a question.

The matter of fact is there are many people on the staff who year in and year out do communicate to the public about technical issues. They go into the schools under a voluntary program. As far as I know, a lot of

that has been pretty successful. So it's not that we haven't done some of this work. The question is whether we do it more systematically, whether we try to train ourselves to do it, whether we devote more resources to it. This is not a categorical question. It's a question of degree.

I say that as a matter of fact and I think some of the NRC staff people in the room here today have engaged in some of that, or at least they have been in many public meetings. That's a large part of their work and I admire them for it. All I've had to do is go into court, which is easy by comparison.

The question I have is how does one avoid crossing the promotional line? It would be a lot easier, for instance, if the Department of Energy were to take over some program, although it might be discounted as too promotional. Is there such a thing as a neutral presentation of the technical issues in an area like nuclear power and could, the minute the NRC stated a fact that seemed to lead toward the industry, would we be viewed as promotional or the minute we stated what we viewed as a technical fact that seemed to lead toward a public interest group's position on the matter, would we be seen as being in bed with the other side?

In many of these discussions, although the

technical presenter may start out in an uncommitted, unprejudicial way, the stakes are so high often, that it's almost impossible for the parties engaged in the subject to hear it as something other than an attempt to side with one party or another.

Now I suppose there's no perfect solution to that and we shouldn't pretend that we could avoid that, but maybe just consistency and dependable presentation of facts would eventually make a lot of people trust us. I don't know, but I'd like suggestions for that kind of thing.

MR. CAMERON: I think we have a comment here, Roger?

MR. HUSTON: Roger Huston from NEI.

I think that one word that you used there, Chip, is important, and that's facts. There is a concern, there always has been a concern about saying anything positive, crossing that line of being promotional. I think that concern is overblown within the staff, to the point where the staff tends to shy back from saying anything that is positive because it might be construed as promotional.

The public outreach aspects of the NRC don't shy back from saying things that are negative and so it becomes counter promotional. One objective way of looking

at that, it's been a few years since I did the analysis, but I went and looked at one year's worth of press releases from the headquarters Office of Public Affairs and when you weed out the administrative releases that talk about meeting announcements and what not, a very large portion of the substantive press releases reported the imposition of large civil penalties for the industry having done things wrong.

That's not balanced with a message of the results of research programs, for example, which tend to show that problems like direct containment heating aren't as important as we thought they were a few years ago when they were very publicly visible.

The think that needs to be kept in mind is that the NRC is viewed as the objective party in this. The industry needs to do more in terms of public relations and its own education function. It would be nice if DOE could do more of that, but we are viewed, not inappropriately, as having a bias in this and the NRC has been very effective in creating, in leaving itself visible as the unbiased observer.

But when the editors of papers in the neighborhood of nuclear power plants get press releases and those press releases continually paint the negative message from the unbiased observer, it can help tilt the

scales in a way that's not promotional, but also not completely accurate.

MR. CROCKETT: Noted.

MR. CAMERON: Thank you very much, Roger. I think Roger has just made a suggestion about how the NRC could avoid being regarded as promotional by keeping everything very fact oriented and I think that Derek would also probably support that type of idea.

What about the idea that Roger has about the press releases, the information coming out of the agency being negative? I think we can all understand why that might be so, but Roger, are you suggesting that perhaps the Commission could spend more time, in other words, talking about the positives about a plant like this plant was a particular good performer for a number of years, or things like that. Is that the type of thing you're suggesting? And I guess I would ask the rest of you whether there are some more comments along these lines.

MR. HUSTON: Well, I am suggesting there be some more attempt made to try to identify what the positive messages are and I think keeping them to facts, the results of programs, the conclusions that have been reached which are otherwise documented, but just not well available, is a way to avoid looking promotional.

The situation with the civil penalties is

probably something, it's not intentional, it's just easy. It's a crisp action and it's a crisp action of the agency which there's a good process to reach out and capture and say this is something that's important, this is something that we have to make publicly visible and so it happens. There's not such a program to capture some of the other aspects that might put forth a more positive message.

MR. CAMERON: Okay, thank you. We're going to go back to Kristin. Yeah, why don't you use that mike, that would be great.

MS. ERICKSON: I'd like to make one more comment and actually get to what I think is the nub of this problem and that is we don't have public trust, but how can we have public trust when we're continually talking with a forked tongue both at my level with my users, at the University level right on up to the federal NRC level. We give a mixed message.

We tell people, and it's our belief and our knowledge that numbers of doses such as ten -- or five -- occupation or tiny doses have little, if any, deleterious health effect and we know that this is true. There are lots of facts which could be shared with the public to prove this and convince them and I've done this, in fact, not only with users on the public, and also I've done this with media. It is possible, but the problem is we also go

and tell them well, this incident or this problem is no risk to public health and safety but yet the licensee is penalized or we tell our users well, don't worry, this is safe on our campus. We have numbers to show you haven't got any dose, but you've got 100 DPM contamination. You have to clean it up right now.

I mean, it goes right down to the tiny level and the public knows this. We tell the public the same kind of thing. We tell them there isn't a problem with radiation, that we're doing it perfectly safely. And, in fact, we're doing it so safely in this country that, as Derek said, we're just about doing ourselves out of the business.

One of our new draft guidances says that we must meet seven DPM in ash for monitoring of ash after incineration for Carbon 14. That's not possible. I've gotten lab 128 hours accounting time to even see it. Now, what's the point of this? Where are we going with these regulations, with these efforts?

The tremendous costs that the whole society pays for a program that goes beyond and beneath any known risk. In fact, beneath the levels of the airs, the variabilities of our genetic predisposition are the other factors we have to look at. I get these questions and I can't answer them.

So I believe that until the NRC establishes some kind of a threshold beneath which there are believed, to the best of our efforts, that there is no health effect. Until they establish, for example in security, that beneath a certain few minutes of time and a certain level of radiation, we don't have a problem, we will not be successful with the public because as long as we keep telling them two different things in the same message, they're not going to believe us and the trust is not there.

MR. CAMERON: Okay, thank you, Kristin. Kristin is going to what she believes is a fundamental root behind public trust, public credibility problem and it could cut a number of ways and I think that some of your comments are going to be addressed not only again, this issue is going to come up not only in the risk informed performance based paper, but it also will be in the materials paper for sure.

Do we have any follow up on Kristin's remarks on the, on what she termed the mixed message that we might be sending? While there's little risk here, but then why are our regulations so strict? You would say too stringent, I guess. Do we have some comment on that aspect of this?

Okay, how about the early identification of

issues? I would take it that there are probably, is there anyone out here who disagrees with the fact that that would be a good idea for the Commission to pursue? I mean, it's probably the better way to put it is that again, this is this prioritization business of where you spend your money to have the most effectiveness.

Any comment on this early identification of issues? Are there ways that we have suggested doing this that you think don't work? Are there other ways that we can do early identification of issues?

This is to give all of you, to give you the opportunity to tell the Commission this is a concern, this is an issue before the Commission sits down and makes a decision on a particular issue.

Any comments on that concept?

Okay, Mark?

MR. DORUFF: My name is Mark Doruff. I'm Director of Environment and Safety Regulatory Affairs with Amersham Corporation in Arlington Heights, Illinois.

Amersham is a major manufacturer and distributor of -- pharmaceuticals like science research radio chemicals and sealed sources for use in medicine and quality and safety assurance.

And I have a comment related to how NRC, once having identified an issue and an issue worthy of

communication to the regulated community or to the public, I would like to make one comment about the way that they're currently taking action on some of these issues. And this is regarding incidents that occur or issues that arise and subsequent information notices that are released.

I would like to recommend that NRC take a more active role with the particular companies or industries that are affected by the information notices. Allow them the opportunity to if not become, if not involved in the development of the notice, but at least be provided with the opportunity to review the information that is provided to ensure that, number one, the issues are correctly identified and number two, that the industry can be available to add any clarification and also to make sure that they are informed of the notice prior to the notice being released for review by the regulated community and by members of the public, including customers of some of the companies affected by the information notices.

Recently, a notice went out concerning the potential problems associated with heat sensitization of sealed sources. This notice went out without the knowledge of the manufacturers, such as Amersham, and the notice went. We received several calls from our customers questioning us about some of the information in the

information notice and we were not even aware that the notice had been released. So we were caught a bit by surprise and it was an awkward situation for us to deal with.

So we would like to recommend that in the development and subsequent promulgation of information notices, that the affected companies or licensees be involved in the process prior to release to avoid such problems in the future. Thank you.

MR. CAMERON: Okay, thanks, Mark. I think that's a suggestion that we haven't heard before in our travels. Thank you for that.

Other comments?

MR. BROOKMAN: Chip, this is Doug Brookman. I'm wondering if the question shouldn't be slightly recast. I'm wondering if the early identification methods could be improved; if there are other ways that the Commission should consider identifying those issues and if this group would like to comment on that.

MR. CAMERON: Okay, good.

Steve mentioned a couple of things that we're doing already. Anybody have any additional suggestions on what we could do?

I think Mark suggested a variation on that, at least involving the industry that may be affected by a

particular information notice.

Is there any more general, any ideas of a more general nature?

Okay, anybody have any other -- Stu, did you want to say something? Go ahead.

MR. RUBIN: Yeah, with regard to the lessons and the follow up from incident investigations and what we call augmented inspection teams, typically there are actions or action plans that are developed and those are issued by headquarters, Executive Director for Operations for IITs and by the Regional Administrator for AITs and quite often those action plans do allude to requesting the staff to look at the need for follow up feedback communications such as information notices and the like.

I do believe that at the present time, that kind of information is not necessarily placed in the public domain right away. It is eventually put into feedback documents such as the AEOD annual report, which does compile the lessons learned from the various incident investigation teams as well as citing the staff actions.

One of the things that AEOD is doing right now, as many of the offices are doing, is putting much of their documentation on to the Internet and we will be putting our AEOD annual report on to the Internet and so, for example, you will be able to see what are the staff

actions that have been assigned as a result of recent IITs for which the actions are yet to be resolved.

And so there may be an opportunity here to move up in time, putting that kind of information on the Internet. So public and the industry can see what our thoughts are in terms of developing feedback communication such as the information notice and thereby have an opportunity to make a call and get involved.

MR. CAMERON: Would that be helpful, Mark, that type of procedure, in terms of your specific issue?

MR. DORUFF: Yeah, I think any mechanism that can be employed to involve us in the process prior to publication of the notice would be much appreciated.

MR. CROCKETT: Could I cast a gray cloud over that? I mean this not by way of, I mean this not to dismiss your suggestion, but to challenge you a bit so that if you should, at some later point, reduce it to writing or want to further comment on it, you take this into account.

There have been incidents in the past when there has been close involvement between NRC staff and the licensee in the development of a rule or something of that sort, and there have been occasions where NRC people have been reassigned or even occasionally moved out of the agency as a result of that.

Things can become very unfriendly if the wrong kind of involvement takes place. You know, and I don't think you would disagree with me, that there needs, the agency and the licensees need to operate with each other at arm's length. The question, though, is what does that mean? What does that entail? And it may well be that we can do something of the sort you're talking about. I know the Federal Aviation Administration works with members of the industry in a way that the NRC never has. I know that the Occupational Safety and Health Administration now has a program which operates more or less in lieu of enforcement, which they provide assistance to regulated parties to help them be in compliance.

There are other things we could be doing, but when you propose things like this, and I welcome the proposal and I've made notes on it and I want to think about it more, please don't forget that I don't think anyone disagrees with the general abstract principle that we should remain at arm's length and an NRC staff member also somehow has to avoid conflict of interest.

MR. CAMERON: Okay, Tom, do you have a response?

MR. TIPTON: Tom Tipton, NEI.

The downside risk of not involving those affected by the action that you're going to take is one,

you're not going to get to the heart of the problem and, two, you're going to further confuse the public. There are many ways that you can make this accessible to those being affected by your information notice, bulletin, et cetera. You can put it in the PDR, notify the people it's going to be there for 30 days and then take action.

What we see is if you send something out final and it's wrong, that is totally confusing to the public and it affects the industry in terms of we're having to back pedal and trying to figure out what to do.

So there have to be ways where you can continue with this arm's length attitude, but you can involve it in a public form, and we have a policy at Nuclear Energy Institute. We do not receive any document unless it's in the PDR.

We have an obligation to the public to make sure what you're asking us to do is, one, accurate and two, doable, and three, needed for the health and safety of the public.

MR. CROCKETT: Well, now that's exactly the kind of argument I'm looking for. Two aspects of what you said that are the kind of thing I'm trying to challenge you to come up with. Number one, you're saying the whole process of involvement should be public, or at least that's what I understood you to say. That is it's in the

PDR for a while, giving you an opportunity to make some comments before it goes final and second, if we don't do this, we may end up provoking precisely the kind of reaction that we wanted to avoid.

MR. TIPTON: In my many years in Washington, I think the industry has always strongly supported a public type forum to get --

MR. CROCKETT: I'm not saying you haven't.

MR. TIPTON: But the problem I have is that if you go back and just look at most recent activity such as your bulletin that came out on heavy loads, there was a lot of confusion there and if it had come out for 30 days of public comment before we had to respond to that, it would have saved you a lot of headache in trying to figure out what we've responded to and it would have saved our industry a lot of headache in terms of spending money maybe unnecessarily, which is really public money.

MR. CAMERON: Okay, thanks, Tom. Stu, did you still want to comment before we go back to Frank Miraglia?

MR. RUBIN: Just one point, that there might be a difference here in quality of the interface between the commercial power reactor industry interfaced with NRC and the materials area. In the power reactor side, info. has been interfaced with the agency in terms of sharing operational data and feedback communications and we do, in

fact, have a memorandum of agreement with these two nuclear power operations to coordinate and ensure that there are not inconsistencies and conflicts in our various feedback documents.

I'm not sure that on the materials side we have a group that might be an industry wide organization that could serve in that same role. I understand for reasons of competition, there's not been a great impetus for that, but at least on the reactor side we have recognized and there have been lessons from the past that there can be inconsistencies put out there and that can compound safety issues as opposed to resolving them.

To the point about additional time to review bulletins, in terms of the issuance of some bulletins, some are viewed as of an urgent nature which would no allow or provide for the time that you would desire and that's a decision that's made internally. Whether or not the safety significance and importance of the particular action would entail not having enough time to get the industry's comments on it.

MR. CAMERON: Okay, I think we're going to have to wrap up here shortly.

Let's go to Frank Miraglia.

MR. MIRAGLIA: I'll just build off what Stu said. I was going to make the observation that in the

reactor area, we do publish a list. It's in the PDR provided to --, I believe also to NEI that talks about the generic issues that we have under consideration for the issuance and --, generic letters, bulletins of a less urgent nature and certainly --. So I'm confirming what Stu has already told you.

In addition, I think we've used a number of words in discussing this issue in this arena that I think are very important that perhaps have passed for resolution. Arm's length, the industry has a role and we have a role and I think we have to walk a fine line to make sure that that role is clearly understood by the public. If you do these things wrong, the public trust and the public confidence will be undermined and I think Kristin made that kind of reference.

So facts are important and the clear recognition of what each other's roles are so that the public confidence can be built and not eroded or seemed to be eroded as a cooperative kind of nature. It's a tough line, it's a tough issue. We've been trying to walk this line for a long time and any thoughts and ideas anyone has on how to do that better I think would certainly be appreciated.

MR. CAMERON: Good, thank you very much.

Okay, let's have one final comment from --

MR. STRUSMA: I'm Jan Strusma, I'm the Region Three Public Affairs Officer and I want to go all the way back to Kristin's original comment where she mentioned an incident they had with some off site contamination at the University of Michigan and it could have been a very serious problem from a public point of view, but the reason it wasn't was the way the licensee handled it. You put out press released promptly. They talked to the staff. They told everybody what was going on and, as a result, it wasn't a big deal. So I think you can't just look to the NRC to solve your problems with dealing with the public.

MR. CAMERON: Very nice wrap up, Jan, and I think that this is an interesting discussion because we focused, I think, mainly on the public educational aspect of the problem, both from a global, a macro point of view and a perhaps a micro point of view and we appreciate the discussion on that issue and I think we'll go to Stu Rubin now for the next paper, which is Role of Industry.

MR. RUBIN: Good morning, again, I'm Stu Rubin. I'm with the Office for Analysis and Evaluation of Operational Data. Edward Jordan, the Office Director, was not able to be here today. He was the sponsor of the issue. I worked very closely with Ed and I'll be presenting the DSI today.

The first DSI I'd like to talk about is DSI 13, which is the Role of Industry. Can I have the first slide, please?

As shown on the first slide, as simply stated, the issue asked the question in performing its regulatory responsibilities, what consideration should the NRC give to industry activities and so that really asks in what area and in what ways, if any, should the NRC pursue interaction with industry to increase the industry's participation and support for NRC's public health and safety mission.

It should be obvious that when we refer to the term industry, it really broadly cuts across all of the regulatory arenas, non-power reactors, materials, as well as the power reactors, of course.

And so if there is to be an effort that would increase the industry's participation and if we were to pursue a shift in the relative responsibilities between the NRC and the industry, then it's clear that the stakeholders, and especially the public, needs to be involved in looking closely at this and they need to know what will be the checks that the agency will have in place to assure that these new balances are working and we do need to hear from you today on this.

But having said that, it really needs to be

pointed out that this is not a particularly new issue that is being introduced for the first time. In fact, if you look back over the last ten years, you would see that there has, in fact, been a gradual shift toward increased participation for some time now, and it has evolved and has resulted in a gradual increase in NRC's reliance on the industry for self oversight activities with an attendant decrease in the NRC's oversight activities.

But this gradual increase, again as I indicated, has been evolutionary and it has, in fact, occurred in the absence of any specific NRC Commission policy or any strategic plan. Instead, it's really been driven by one of opportunity where the industry will make a specific proposal and the NRC would then look at that within its statutory limits and if the staff's review were positive on the proposal and based on good trial experience and with the appropriate level of continuing oversight and audit involved, then the agency has approved a number of these proposals over the years.

And this interaction with industry has involved a number of initiatives. They span many of our regulatory areas, including inspections, performance assessments and license examinations. And so the balance today between NRC oversight activities and the self regulation, you might say, efforts of industry has varied,

depending on the program area you're looking at and it has shifted in the past, as I had said, it will likely continue to evolve in the future.

So the opportunity and really the question we're asking today is should the NRC be more proactive and more structured and organized in actually seeking to expand industry's role or make their role better defined or should the agency keep the status quo that it has in place now, with the more passive and case by case posture in matters on increasing the industry's role and participation.

Next slide, please.

These next two slides provide several of the key factors, considerations that bear on these questions. First of all, as a general matter and from a legislative standpoint, the NRC is obligated to, not to fail to perform or for that matter to delegate to a private party any responsibility that the Congress has specifically mandated in the legislation and in the laws.

And so, for example, in the Atomic Energy Act, the Commission is not permitted to allow others to determine whether the Commission should grant a license. That is the Commission's responsibility in the legislation. Neither may the NRC entirely rely on industry standards. The legislation says that the agency

must establish its own regulatory standards, but it may choose to adopt standards that are developed by industry.

So there are restrictions that do apply based on the legislation and if we wanted to go outside that box, as we talked about, that we would require additional legislation to make that happen.

Another factor that comes to play here, obviously, is the conflict of interest or the potential for conflict of interest. Any time you have a situation where say a licensee or industry organization is placed in the position to check the adequacy of its own activities, then you create at least a perception that there's less objectivity, loss of impartiality in that oversight activity. And so we obviously need to be conscious of that. It really goes to the heart of the issue of public confidence and trust.

The public will also need to maintain its access to safety information in order to keep its confidence and trust in what we're doing. And so if there's going to be an increase in the industry's self oversight, really by our legal obligations and what will be necessary to keep that public trust, we will need to have agreements with the industry to ensure that there is sufficient safety information that is made available as a result of the activities that come out of the self

oversight area.

And the public will need this information in order to have confidence, first of all, that the self checking and self oversight process is working, but also to have confidence that safety is being maintained at an adequate level.

A fourth factor or question that we have for this issue is really address the commercial power reactor industry and that really is that there has, in fact, been a substantial overall improvement in performance within the industry for power reactors and, for example, the overall frequency of transients, safety system actuations and the extent of personnel over exposures has declined significantly over the years and those have been clear and measurable in the agency's own performance indicators as well as the industry's performance indicators and this is translated into a measurable or calculable decline in the overall plant risk.

So this performance improvement would suggest that there is a basis for expanding the industry's role and allowing for greater participation in the process. However, for the materials and non-power reactors area, we have a much more difficult time in measure performance and the trends not really as clear that performance has improved.

Now, on the other hand, there is, in fact, the issue that based on past performance, you need to consider the current context, I should say, and that is an increasingly competitive environment that most industries, including the nuclear industry, is finding themselves in today. For example, the economic deregulation that we all know about has added pressure on reactor licensees to reduce their costs, while increasing the availability of the units to produce power.

And so this economic stress, if you will, has created a period now of increased sensitivity on the part of the Commission and it's heightened the NRC's attention to the conservatism of the safety decisions that are being made by licensees. And so the economic stress factor really represents a caution flag for the agency today in the transfer of any additional responsibilities over to industry.

Next slide, please.

At the same time, the industry has continued to be concerned over the impact of even the current level of NRC oversight activities and has questioned the need for the level of inspection activities, for example, in light of the current high level or higher level of performance that we see. And so the agency must acknowledge that regulations and regulatory oversight

activities are an economic cost factor for licensees.

Codes and standards development, this is an area of particular interest and enthusiasm by the sponsor of the paper, Ed Jordan. He's a very strong advocate of this and he believes that it really should be strongly considered in the option on industry involvement and the Commission, if you would read the preliminary views, agrees with that as well.

Codes and standards development is an investment that the industry and the NRC must make in order to ensure that there's long term consistency and reliability in the NRC's safety framework and also to ensure that there is a clear understanding on both the side of the staff, as well as the industry, as to what is expected to meet an adequate level of safety. And there needs to be an increase in that investment, or certainly to maintain that investment.

Because, for example, as we move from a prescriptive regulatory framework more into one that's risk informed and performance based, it will be essential that we have in place the necessary comprehensive infrastructure of codes and standards and regulatory guides to allow both the staff and industry to have an efficiently viable basis to conduct safety review activities within this new framework.

So codes and standards are really an essential prerequisite for that successful transition.

And finally there's the fact that the industry, and this has been mentioned at least several times and will be over the next two days, is that we are in a period, the agency is in a period of declining resources. The NRC's budget is certainly getting tighter. Congress and the OMB continue to reduce our budget and so the agency's resources are continuing to be more constrained and the size of our workforce is going down with each passing year.

And it must be acknowledged that the industry is also tightening its belt, it's reducing its staff and making its operations more efficient. And so the declining resources clearly is a challenge for industry and NRC to allow us to develop these new frameworks that we will need as we move into this new environment.

But to reap the rewards in the later years, we really need to make that investment now, both sides.

Next slide, please.

Now, there are five options that are proposed in the issue paper, and they shouldn't be viewed as mutually exclusive, except perhaps for the first two.

The first option would simply continue on with the current program, which would be a deliberate and

evolutionary case by case review of proposals as they come up by industry. And so as opportunities were to arise and proposals are made to support NCR's responsibilities, they would be evaluated and negotiated with industry and the proper interface would be developed and the proper oversight and audit methodology would be put in place by the agency and approvals would come about.

The second option really is for the NRC to become much more proactive and active in seeking out new opportunities and initiatives for industry participation. To allow for more aggressive expansion of industry's role.

The third option would be to increase the use of accreditation and certification of licensee activities by qualified professional societies and industry groups and technical associations. In this particular case, the accreditation and certification criteria and standards would be subject, as they always have been, to NRC's review and acceptance and the accreditation process, once implemented, would also be subject to an ongoing audit level review by the NRC staff to ensure that it's working properly.

The fourth option would be to increase NRC's interaction with industry and professional groups in order to develop codes and standards and guidance documents, as I mentioned earlier.

And the last option would be to utilize what we call or is called a designated industry representative as a means of supplementing NRC's on sight inspection activities at selected facilities.

But before we go to the next slide, I'd like to talk a little more about each of those options so there's a little more clarity in in what we're saying here.

Again, as far as the first option, we continue the current program and it would be accurate to say that that current effort by both the NRC and the industry has been considerable and is likely to remain so. In fact, there are many ongoing reviews as we speak that would increase industry's participation in the oversight area.

An example of this would be the reactor operator license examination program. It's regulated by the NRC and that has seen an increase in industry participation and responsibility. And, again, this has allowed for a reduction of NRC's resource needs to ensure that that kind of activity is being conducted adequately.

The tech. spec. improvement program is another area for power reactors in which the agency and regulated industry have interacted and it has resulted in much more consistent and standardized tech. specs. The program has reduced the sheer volume in the number of technical

specifications and has resulted in certain material being placed in licensee control documents and where we are is that the agency is not put in the position of having to formally review many, many minor changes to the tech. specs. and this has been viewed as a beneficial successful effort on both sides.

Also, the ability of licensees to make minor changes to their QA plans and their emergency plans and security plans without NRC review is also beneficial to both sides.

There's also been good success recently in allowing licensees to conduct their own success with licensee qualifications to do that are clear and this has allowed the NRC to do an audit level review of the process that they conducted, as well as the results, and has been a successful alternative to what you might call the full scope NRC review, which is very resource intensive.

Now, as far as the implications of the current program, we believe that this, if we would implement, it would result in a slow decline in NRC's resource requirements while the industry's workload to carry out these additional self oversight activities would gradually increase, as would the NRC's reliance on industry.

We also think based on the experience and the evidence to date that implementing such or continuing such

a program, we wouldn't expect to see a significant decline or change in the NRC's credibility with the public and we also think that the current program could be pursued within the current legislative framework, but we do not expect the industry's safety performance, per se, to be affected either way by implementing the current program.

Now, with the second option, the agency again would be very proactive and aggressively seek out a broad expanded role of industry in the regulatory areas such as inspections and performance monitoring. But, again, in any event it would still be subject and any approvals would still be subject to a continuing ongoing audit level review by the agency for such activities.

Now, with respect to option two, we would expect that there would be a higher initial investment cost to the agency, as well as the industry, but we also would expect that there might, in fact, be a decline in NRC's credibility as an effective regulator in the eyes of the public if we were to implement this option.

There also could be areas that might involve requirements for further legislation to allow us to implement an expansion of industry's role.

The third option again would be to increase the accreditation and certification of licensee activities and this would involve NRC interacting with qualified

industry groups and professional societies who could develop and implement a qualified accreditation program. For option three, the considerations with respect to the initial costs and the public credibility and reliance on industry are about the same as I discussed in the second option.

Moving to the fourth option, the fourth option would be to increase the interaction with industry groups to increase our participation in developing national consensus codes and standards and various guides, which could be endorsed by NRC. This we believe is important. It would provide additional rigor and specificity to the regulatory framework and prove both the efficiency and the effectiveness of the conduct of safety activities.

Here again, there would be an increase in initial up front costs for both the NRC and the industry, but in the long haul, we do anticipate that this would lead to a decline in the overall resource requirements again due to the greater efficiency and effectiveness with which activities would be conducted on both sides. We wouldn't see a need for any legislation here for this option, but one of the important advantages we think is that we would see an improvement in licensee performance as a result of implementing this option, which we think is a real attractive feature of this particular option.

The last option, option five, the designated industry representative and the idea here would be to have an expert licensee employee or industry representative who would be designated or selected by the NRC and who would be authorized by the NRC to perform certain inspection and regulatory review activities at a specific site and the thought would be that this designated industry expert would supplement the current level of NRC's inspection activities and not be a replacement or a substitute for that current level of regulatory oversight.

And we think that this could have some, we believe this has some application where the particular activities that will be looked at are particularly complex and very specialized where the agency does not have the resources to maintain its own expertise within the Commission.

Again, as far as the considerations and implications, we do believe that there would be additional up front costs for both the NRC and industry in setting up the program. It would also involve a long term cost to the industry to provide people who would support the agency's mission. We also do believe that there could be a negative impact on the credibility of the agency if that individual was perceived as replacing NRC inspection activity as opposed to supplementing the NRC's inspection

activity.

But if, in fact, that was what we wanted as an alternate to NRC inspection activity, there certainly would be a legislative requirement to make that happen.

Next slide, please.

As far as the Commission's preliminary views are concerned, the Commission's preliminary views are that the staff should expeditiously pursue option one, which is really a vigorous implementation of the current program and to do that within our current budget considerations and the Commission has also indicated that we are to pursue option four, which is to increase our interaction on industry on standards and code development.

As far as option one is concerned, the Commission has indicated that staff should continue to evaluate industry initiatives on a case by case basis and they have further indicated that the staff should develop guidance and criteria for the use in guiding and evaluating industry proposals and to make the staff's reviews more efficient and consistent and again to have a consistent basis for approval.

Next slide, please.

As far as option four is concerned, the Commission again has expressed a preliminary view that the staff should increase its focus and emphasis on

interacting with industry in order to develop new codes and standards and guidance documents and they have also indicated that the initial development activities should be focused on PRA applications as well as the medical use program area.

The Commission has also requested that the staff identify and recommend areas where codes and standards and guides would be of special value. Areas for priority and emphasis and to feed back those suggestions to the Commission.

The last slide, please.

As seen on the last slide, with regard to option five, the Commission's preliminary review of that, although it's not a preferred option, the designated industry representative they believe might have potential for application to what I referred as large, broad scope material licensees, but if option five were ever implemented, it should be utilized, as I indicated before, to augment or supplement the current level of NRC inspection oversight and not as a substitute for NRC's oversight activities.

So that's kind of basically an overview of the paper and what I'd like to do now is just sit down and open it up for questions. Thank you.

MR. CAMERON: Good, thank you very much, Stu.

Just a couple of things before we go to you, keep in mind for this paper and all the papers, the four questions that the Commission flagged for particular attention at the beginning of the Strategic Assessment materials. One, are there any issues that we missed in considering the strategic areas. Two are the assumptions or the key factors that we have identified, are they correct. Third, specific comment on the Commission's preliminary views and the fourth question applies only to some papers, which I think we'll get into more this afternoon and tomorrow. There's some specific questions that the Commission had on some of the papers.

And just to sort of segway from our public communications paper, you can see that Stu has raised, does the reliance on industry raise any questions in terms of public trust, public credibility. Are there some cautionary things there that we should keep in mind? And too if we do go to more reliance on the industry, what's the role of the public? What's the access to information that the public gets if we move more to reliance on the industry?

And with that, I'll open it up for comment.

Roger?

MR. HUSTON: Roger Huston, NEI, and I apologize for going outside the bounds of those four

questions right after you've just so carefully laid them out, Chip, but I'm in a position where I've got to make a clarifying comment almost. We've been at the previous two meetings here and I've gotten some questions off to the side about how could we be opposed to option two, expanding the role of the industry and that's somewhat a function of the label, the title that's been applied to the individual options.

As Stu explained, but I'll got a little bit further, option two as described in the paper, would involve a significantly expanded role for the industry. As described, it would involve turning, shifting some NRC functions in a fairly large manner over to licensees or to some technically qualified group established by licensees to be done consistent with the current NRC process.

As an example, inspection has been talked about elsewhere here, but another example that's talked about in this option is a qualified industry group might conduct pre-evaluations or preassessments of licensing actions that the NRC could then come in and audit and they ultimately would take the licensing action, but the technical work might be done in the industry.

We do think that that kind of a shift is inappropriate and that it would indeed lead to the kinds of credibility problems that you just talked about, Chip.

We do believe that an expanded role for the industry is appropriate, but we prefer to reach that kind of additional role through option one, through continuation of the current program, much as the Commission has indicated in their previous views and the example of operator licensing and the increased involvement of the industry in the operator licensing program is significant. We can emulate that example, we can evaluate things on a case by case basis.

We can consider each of them in their individual context, both in terms of safety significance, the appropriateness of individual roles and the involvement of the public, the availability of information for the public.

So just as a matter of clarification, we're not opposed to expanding the role of industry, but we're not in favor of option two as described in the paper.

MR. CAMERON: Okay, thank you very much, Roger. That's a useful reminder for us, I think, and I don't mean to constrain anybody to be only within the bounds of the four questions. Those questions are more as a guide for all of us to think about the directed strategic issues, but that was a good clarification reminder on that.

How about other people out here on role of the

industry?

Mark?

MR. DORUFF: Again, my name is Mark Doruff. I'm with Amersham. I'm also here representing an industry group known as the Council on Radio -- and Radio Pharmaceuticals also known as CORAR. CORAR is an industry group that is an association of companies with common interests in radio --, specifically the manufacture and distribution of radio pharmaceuticals, sealed sources and radio chemicals for life science research.

I would like to make some comments on DSI 13 and I'll start out by saying that CORAR supports some elements of two, three and four and I would like to sort of piggy back on what Roger said about the fact that while we do support an expanded role of industry, we support option number two. We don't necessarily agree with all of the elements presented in that option and I think we're more supportive of some of the other elements of two, three and four and I'll expand on those briefly.

One comment on the assumption that's made on page six on the DSI and I guess somewhat in disagreement that Stu made earlier this morning on DSI 14 that materials licensees are often seen as competitors that tend to compete with each other and do not really reach a consensus on technical issues. I think CORAR is a good

example. Our industry has worked together and we have not only reached consensus in a number of technical areas, but we've been proactive in the rule making processes that have been made available to us and we appreciate the fact that NRC has been open to our participation and we would like to see that not only continue, but we'd also like to see that role expanded.

We support the concept of accreditation by industry groups and certification of industrial representatives included in option number three. We also support the concept in option two of increasing industry's role by allowing more self assessment in the regulatory process.

NRC points out that they are experiencing a decline in agency resources and we believe that increasing the role of self assessment in industry could provide an opportunity to lift the burden that is currently on NRC in this issue of lack of resources. One example where application of increasing the role of self assessment could help in this area would be the allowance of manufacturers of approved containers and registered sealed sources and devices to be able to evaluate design and manufacturing changes with regard to their QA programs. We don't believe that enough credit is given in the area of QA programs that are approved by NRC -- to allow

regulated licensees to make assessments with regard to their plans that certain minor changes are, these changes can be made without a formal review by the regulated, by the agencies regulating these containers and these devices.

We also support the use of industry groups for the development and endorsement of codes, standards and guidelines as included in option number four and we support the recognition of the Commission's preliminary view.

MR. CAMERON: Okay, thank you, Mark.

Mal Knapp?

MR. KNAPP: I'd like to respond briefly to the comment about the strength of industry groups and materials.

Your point is very well taken. In the original write up, one of the things we noted was that the materials licensees for the NRC cover a very broad range of licensees from large fuel cycle facilities through pharmaceutical manufacturers, hospitals down to individual radiographers and gauge users and in some cases you were quite correct, there are some strong groups.

In some aspects of the materials program, we don't find as many strong ones. I appreciate your correction.

MR. CAMERON: Okay, thanks, Mal.

Mark has, Bob, could we see the first preliminary view slide? Thanks, Bob.

I think the key word up here is initiatives. In other words, this case by case proposals for further reliance on the industry and I think Mark just gave us a good example of one of those initiatives that could be under taken.

Does anybody else have any other suggestions that might not have surfaced in the paper for specific initiatives where that the NRC might pursue along these lines in terms of increasing industry activities as an alternative for NRC regulation?

MR. FARRON: Yeah, Paul Farron from Wisconsin Electric.

Just as an example, I think that OSHA is probably in the same position that NRC is right now or NRC is going to be as far as manpower constraints and while I haven't looked at the paper in its entirety, I know that OSHA has used some mechanisms where for good performers, proven performers, they have reduced the level of on site, continuous on site review and come in on set frequencies to audit or look at the company's programs and I think that might be an area to look at.

Also, I don't know if the NRC has considered

it, but the insurance carriers, too, for the industry do look at a lot of the same things that the NRC looks at too for public health and safety. I know that NRC has informally asked various parts of the insurance groups for information about their inspection activities. Now, I don't know if there may be some problems with conflict of interest with this, but it may be an area to look at as well.

MR. CAMERON: Thank you very much, Paul. Those are useful suggestions.

Anybody else have anything along those lines? Kristin?

MS. ERICKSON: It would help me if we could put the other slide up with the options as I make a couple of comments on these.

It appears to me that with the current rules and programs as they exist for a broad scope licensee, such as Michigan State, that many of these are already incorporated. For example, the bottom one, designated industry representative, well that's myself, it's a Radiation Safety Officer. I view myself as a miniature NRC and even in teaching and training explain that yes, I do work for the University, but I truly report to the NRC and I truly work for them to implement these rules and keep things safe. So it seems that's already in existence

for any place that has an RSO.

The second option, expanding the role of industry, I think that's happening. At least in our institution and in the State of Michigan on somewhat of a performance basis, we are trying out with the NRC some new things, looking at our laboratories and our institution in a performance way. It's working very, very well and I think that this second option, in a more vigorous way, as is kind of stated in the NRC's preliminary view, is what needs to be done.

This is the perfect timing to have more cooperation, more dancing, if you would put it at arm's length, yes, not the up close dancing with the licensee, but to have it happen where there is some coordination and we don't have so much of this ready, fire, aim approach that then causes problems for everyone.

The business of the accreditation and certification, I think that's already in existence again, in the broad scope manner. We do a tremendously intensive audit of our own program, myself and my staff spend two or three months and then ongoing throughout the year looking at ourselves just ruthlessly and then we write a tremendously big report with details and charts and graphs, present it to the Radiation Safety Committee and, in fact now, we've been doing it for several years, that's

the first thing that I hand to the team inspectors and it helps them to focus because we self identify in complete honesty and talk about corrective action. Or if the corrective actions can't happen, we tell why can't they be that, that it's not reasonable or that it will never happen in any institution like ours.

The increased interaction with the industry and the professional groups, again I see that as already beginning. I don't know if it's going on throughout the country and from talking to other licensees, I think not, but at least in our region, I can comment that in Region Three between our university and the Region Three people, we have a tremendously fine cooperation that is not compromised by collusion of any sort, but I'm completely free to call them and discuss issues or, even as I said, dig into the lab to come up with some numbers when they don't have the time or perhaps the expertise on some issues. We have a fine cooperation but that is not destructive to credibility on the part of either institution.

And, in fact, what it does in the eyes of the public is it's increased our credibility with the public because the NRC does understand what we do and we do work together with them a lot and the public knows this, whether it be small numbers on campus or again in the

public outreach.

So I'm in favor of the expansion and I think it's happening, at least on a trial basis, and I would like to see it continue.

MR. CAMERON: Thank you very much, Kristin.

I want to follow up on a couple of your points. First, I'll go to George Pangburn.

MR. PANGBURN: George Pangburn from NRC.

You were talking about licensee performance and decreased inspection frequency and on time. At least with respect to materials licensees, we put into place about 15 months ago a program that would take into account inspection findings of materials licensees and the regions have flexibility now to decrease the frequency or increase the frequency, based on performance. That's one area where we have taken that particular factor into account.

MR. CAMERON: So I guess there may be more along those lines that we could at least consider or examples from other agencies, I guess is something I don't know if we've explored comprehensively.

Kristin brought up a couple of interesting ideas. I thought one is this, goes to this designated industry representative option and her view that the Radiation Safety Office already is functioning like that and I guess I would just ask for any comment, including

clarification from NRC, about potential distinctions between the designated rep. concept presented here and the Radiation Safety Officer. Is it a matter of degree or a difference in kind?

And also, is there any gold to be mined in this headquarters/regional dichotomy perhaps. Kristin was talking about the good relationship they have in Region Three. Is there anything more that can be done in regard to this paper in terms of increased regional interaction?

I would just open that up. Anybody have any comments on the designated rep. issue?

Mal?

MR. KNAPP: Malcom Knapp, NRC.

I think Kristin is correct in saying that the relationship which she has with the NRC is very similar to a designated industry representative. I would say the difference, in my mind, is that the designated representative might be more like the relationship that I believe the FAA has with certain of its, I believe they're called designated industry representatives in aircraft manufacturers and it's very similar in a number of ways to an RSO except that it's more formal. I believe the FAA uses a more formal approach in deciding what the qualifications of the representatives are and I believe there is a, perhaps even a sworn oath statement to the

FAA. I'm not real clear on the process, but you're correct that they're similar. I think it would simply be to take where you are right now and go a bit further.

MR. CAMERON: So that's a good comment then because it may not be such a stretch in this particular case.

Anything else on designated representative? Any comments from some of our state government representatives on how they view the relationship with the industry as they go about their regulatory activities as it relates to any of these options or this issues paper?

Okay, any final comments on this?

Kathy?

MS. ALLEN: Kathy Allen from the Illinois Department of Nuclear Safety.

I just wanted to raise a couple of points on option three, for increased accreditation and certification. The industrial radiographer certification program supported by the -- has been successfully implemented and that was also supported by the industry and I think you need to look at some of those other types of accreditation programs. Not necessarily as a direct cost savings measure, but as a way to improve safety and put the requirements for safety and training back on the licensees and let them have control of their programs.

An example would be accreditation requirements for nuclear medicine technologist. Illinois, as well as many other agreement states, have programs for accreditation. We believe that it enhances radiation safety by requiring the actual users, people handing the radioactive material, to be trained and maintain certification.

Contrary to the statements made on page 16 of this DSI, certification of personnel does not automatically reduce inspection frequencies or the level of oversight provided by the department. However, what we find is that accreditation requirements allows the licensee to demonstrate diligence in complying with the other department regulations and they may actually end up with reduced numbers of violations. They have better control of their programs.

So what you see is just a very good program. We don't automatically say well, since we have an accreditation program, we're never inspecting again. I just think you should look at other alternatives like that.

MR. CAMERON: Okay, thanks a lot, Kathy.

I know that we have one more paper to go here, but perhaps this would be a good idea to at least give you a short break to get some coffee and we are going to start

on the dot at 25 after and see if we can get done with this final paper by noon break for lunch.

(Whereupon, a short break was taken.)

MR. CAMERON: Okay, if everyone can take their seats. We're going to do the final paper for this morning and as you'll notice, this paper is on Regulatory Excellence and Stu Rubin is going to do this presentation for us and he's going to explain what this concept of Regulatory Excellence is all about.

Stu?

MR. RUBIN: Thank you, Chip.

Okay, the second DSI I'd like to talk about is DSI 23. As Chip indicated, the title is Enhancing Regulatory Excellence.

The concept of DSI 23 is perhaps somewhat unique among the set of DSI's because it is very much internally focused on the agency's processes and its people rather than externally directed, as most of the others are, toward the regulated community.

But even so, I think that it is important that we do obtain comments from external stakeholders. I'm sure there's a lot of good ideas and there's opportunities for participation by external stakeholders on how NRC does its internal oversight activities.

Can I have the first slide, please?

I showed on this slide the strategic issue that asks the question: How can the NRC enhance regulatory excellence through the maintenance of regulatory standards, rules, and requirements. But the issue I stated in this particular slide is perhaps somewhat too restricted. It really represents how the Steering Committee actually proposed it in the initial going, but the Commission and the Committee now would seek to apply this concept of regulatory excellence and its goal much more broadly than originally considered.

The Steering Committee, in conducting its reviews and trying to extract the strategic issues that we see here today, initially assumed that the staff's performance, as far as the staff's performance was concerned, it was kind of implicit and it was expected that excellence would be part of the staff's follow through on implementation of the selected options or there was a thought that the notion of the options themselves and the selection by the Commission had in it inherently the thought of excellence and how we were going to operate as we move into the future.

And so it seemed, at least in the beginning, that it was self evident that excellence was implicit in everything we were doing and in terms of the staff carrying out its regulatory activities. Well, despite

that view and that presumption, when you read the words in the DSI's and you take a look at other activities that are ongoing, some of the external factors and some of the internal factors that you'll see in these papers, you do come away with a very definite sense that an emphasis is on greater efficiency and economies in terms of how NRC is going to conduct its business to reduce its costs. These show up also as a byproduct of risk informed performance based approaches which still reduce burden on licensees, but they do have the potential for reducing costs.

And then there's also, as indicated in the previous issue paper, the thought that the agency would be looking at reducing its own regulatory oversight and putting in place greater industry roles in self oversight.

And when you looked at the words in the issue papers, there's really very little that you would see in the way of the notion of excellence, on how we might improve what we are doing currently and as we move forward into the new environment that we're finding ourselves.

So taken all together, there was a concern that when you read this body of work, that we might be putting out the wrong message to the staff. There might be a mistaken impression on the part of the staff that the priority for the agency had become one of regulatory efficiency and was superseding in some way or supplanting

in some way the pursuit of regulatory excellence in carrying out our work in the most exemplary way possible.

So based on this further review, we thought that it would be important to have a specific DSI that was focused in on our own internal processes, with a goal of enhancing regulatory excellence or achieving regulatory excellence as an explicit goal.

What I'd like to do is mention briefly what we do mean by the term regulatory excellence and what we don't mean by the term regulatory excellence. For purposes of this discussion, regulatory excellence is defined as a dedication to safety, a commitment to the principles of good regulation and the pursuit of superior staff performance.

And I would add that regulatory excellence, since it is internally focused, it is aimed at the NRC staff, its performance and its own processes, should be differentiated from what the industry, the nuclear power industry specifically would perceive that the NRC seeks to apply an ever higher level of excellence that's aimed at the performance of licensed facilities.

There is clearly a difference there. What we're talking about here is the internal excellence of the staff and the thought is that we would try to achieve, what we are seeking here is for the staff to do its job,

its own job in an exemplary way and it should not be construed as a quest for excellence for licensed facilities operation.

Next slide, please.

These next two slides identify the key factors that we see in pursuing or enhancing excellence in the staff's internal programs and internal performance.

First of all, I'd like to say that NRC views itself as what's called a learning organization and therefore rooted in our own organizational values is a culture which historically has sought to improve its own effectiveness in the way it conducts its own work and all of its regulatory activities, direct and indirect, on regulatory oversight.

And so the agency has and it does have in place a number of mechanisms that routinely assess its own internal performance. For example, there are many what we would call lessons learned reviews, self assessments and audits of our own regulatory oversight processes and cur procedures. We look at the adequacy of the qualification and training of our staff and its ability to effectively carry out their responsibilities.

I would also add the agency has been responsive to external stimuli and lessons. We do take advantage of the -- excuse me, let me back up a minute.

Going back to internal reviews, we also respond to things such as NRC Inspector General audits, as well as staff differing professional views on matters. We also would be responsive to any lessons on our processes that come about as a result of research findings. So we would seek to develop improvements from these other kinds of internal activities.

And so there are an extensive number of ongoing activities within the agency that have occurred and will continue to occur to improve our effectiveness regardless of DSI 13 and its options -- excuse me, 23 and its options.

Again, as I was to say, the agency is also responsive to lessons learned from external events and experiences, including those involving congressional as well as judicial and executive branch initiatives that have been directed over the years at improving NRC's regulatory framework.

But I would add that the processes that we have in place today do not have as a specific goal one of regulatory excellence nor would one be able to say that the improvement initiatives and activities, when taken together, that we are currently have in place would necessarily be sufficient to achieve the goals of excellence.

Another important consideration that I would mention or I mencioned earlier, was the apparent concern or the belief that the cost reduction tone of the DSI's and other recent initiatives might, when taken together, leave the staff with the mistaken impression that somehow we were backing away from the agency's top priority and commitment to a vigorous approach to safety, oversight and safety review and regulatory effectiveness and carrying our public health and safety mission.

And this consideration is a very important one. It cannot be over-emphasized and was perhaps the main stimuli in a way for initiating this particular DSI review.

Next slide, please.

Certainly the idea that changes that improve the efficiency of regulation for the NRC and the efficiency of compliance for licensees have been and will continue to be of interest to licensees and the industries that the NRC regulates, but at the same time, we don't think that industry has put any particular emphasis on changes that are specifically focused on enhancing NRC's regulatory program effectiveness.

And the last point, again, is in the declining NRC budget environment, it will become more and more difficult for the agency to make those added investments

necessary to achieve those improvements in our processes and our programs and our people that are needed to achieve a goal of regulatory excellence.

Next slide, please.

And again, as I mentioned earlier, the NRC's credibility as an effective regulator has declined as a result of lapses which have occurred in the staff's oversight processes and so this issue paper really provides certain options to address those regulatory process issues and the performance of the agency people and by doing so would help to restore the credibility that may have been lost with the public and with the regulated industry and with ourselves.

Next slide, please.

As far as the options are concerned, there really are only two that have been identified. In most of the other issue papers, there are a number of options that are identified, some that would do less than we're currently doing, some that would do the same and some that would do more than we're currently doing.

DSI 23 does not provide an option to do less than we're currently doing to improve the way we do business.

The first option we have sets as a minimum continue what we're currently doing to improve our

regulatory performance internally and, again, it would be fair to say that that activity level has been rather significant. It's been one of considerable dimension and involves a significant number of staff resources as we go on.

Again, the agency feels it is a learning organization and it does apply an extensive number of continuous improvement initiatives that do span virtually every activity area within the agency, every program and process within the agency.

With regard to that first option, continue the current approach, the NRC there would simply continue to conduct the periodic program self assessments from both reactors and materials and non-power reactors arenas and we would continue to see improvements as a result of those activities as we went along. These activities, these evaluations would be conducted by the responsible program office or staff office and it would be expected from this process that we would identify specific weaknesses in these programs and these activities.

And so it would be expected that specific improvements would be made as we move along into this changing environment that we now see ourselves in.

Also for option one, the staff would continue to respond to weaknesses that were identified by external

sources such as industry, allegers, the Congress and the like, and as well as from regulatory lessons identified from licensee, or excuse me, NRC incident investigations of operational events.

For this option, we believe that the agency's resource expenditures to identify problems and to respond to internal and external lessons would be expected to continue at about the same current level we are at now, but we don't believe that the current program would offer us any significant new opportunities for increasing the agency's pace with which it provides for proactive improvement versus being in a mode where the agency finds itself reacting to lessons that are identified.

Also, as I mentioned before, by simply continuing the current approach to improvement, there is the concern that the staff's efforts to improve the efficiency of our regulatory framework could lead to a staff misperception that we are somehow softening our safety vigilance and so I think that one of the principle reasons that the Committee felt that there needed to be a regulatory effectiveness issue, that this was an appropriate issue that needed to be considered very strongly and of course by continuing the current approach the rate of improvement in the public perception of NRC as an effective regulator, that pace of improvement would

really not change over what we're seeing today.

But there is a question of whether that would really be enough or whether we need to have a more overt and direct and accelerated effort at improvement and so a second option has been developed which would initiate what we would call a more proactive approach to improvement. I think it's fair to say that Ed Jordan, the sponsor of this DSI, that's where he comes out and if you read the Commission preliminary views, that's where they come out, as well.

And that would be to pursue the more proactive improvement approach. And so with option two, the NRC would have other additional measures built on top of the current level of or supplementing the existing base of improvement initiatives associated with option one. For this option, the paper proposes to add a senior management review group to periodically review the agency's internal processes and to identify regulatory program areas and staff performance issues for priority attention and improvement.

The key issues for the more proactive improvement approach would involve a substantial additional up front investment of agency resources and additional management attention to achieve these accelerated benefits. But option two would be expected to

have an important beneficial side effect, as I indicated, in assuring that the staff's regulatory effectiveness culture does not begin to erode.

And we also believe that with option two the agency would more rapidly regain its credibility with the public as an effective regulator as improvements were made at a more rapid pace.

Next slide, please.

As far as the Commission's preliminary views are concerned, their views were basically that the staff should go ahead and develop and implement strategies that would improve NRC's internal performance and, in fact, they did opt for option two which is to take the more proactive approach to improvement.

But as I mentioned, they did request that, or haven't yet mentioned, I should mention that they requested that the staff expand the scope that was originally proposed in the paper and the concept of regulatory excellence should be applied to all agency programs, not just to the regulatory framework, the dealing with codes and standards and guidance documents. They felt that whether activities were directly or indirectly involved with regulatory oversight, all should be included in a regulatory excellence initiative.

So you would have things such as accounting

and finance and information management which would also be included in the regulatory excellence initiative.

And the Commission also had the preliminary view that the staff should identify goals and mile stones and provide a means to fully engage the workforce, the staff at the grass roots level so as to better identify and achieve the improvements that would be needed to achieve excellence.

And so although for option two, the paper proposes to begin the more proactive approach for just the regulatory programs and expand it later based on success and suitable time in that arena, the Commission felt that the staff should start right off with the broadest possible proactive improvement campaign within the agency applied to all the agency's programs and activities.

The Commission also urged the staff to assign the necessary resources that would be needed to allow for the greatest possible benefits to be achieved at the earliest possible time.

And basically that's a summary of DSI 23 and I'd be willing to take any questions or comments on this particular issue paper at this time.

MR. CAMERON: Thanks a lot, Stu. Before we get into discussion on this issue, I have one important announcement to make.

When you have this microphone, it's not just like it's a --, I have the talking stick and this allows me to talk. There's also another function, which is so that it goes into the microphone system and I got a short course on this just a few minutes ago and this is wrong and also if you are talking this way, it goes over the mike. So when you are talking into it, try to direct your speech right into the microphone and I guess we'll go to regulatory excellence and how does the NRC build this into its operations and have we identified all the ways to build it in?

David, do you want to talk now?

MR. SWANK: Dave Swank, Supply System.

I guess I have a question to start with. Something I didn't see in this DSI or, in fact, in any of the DSI's was a discussion of any baselining that the NRC may have done against other federal agencies or, for that matter, foreign agencies performing the same function as the NRC. Was that part of the process and is it intended to be part of the process?

MR. CAMERON: NRC, any answers to that, Stu or anybody else here?

Jim Milhoan.

MR. MILHOAN: Jim Milhoan, NRC.

As part of our assessment of the individual

activity, one of the things that we did look at was the internal and external factors to the extent that it was described and it was not described in any great detail. If there was anything related to internal and external factors from foreign activities, we tried to capture that in our assessment in the first phase, but I think more direct to your question is with respect to the baseline against foreign practice, in the operating reactor paper, one of the preliminary views talks about us looking at foreign practice whenever we're looking at the operating reactor oversight issue.

And so to that extent, in the future when we do the implementation, it would certainly be looked at with respect to the foreign experience and the experience of others related to that.

Mal, in the materials area, did you have anything in the materials area that would cover the foreign experience?

MR. KNAPP: In materials, we really didn't do it explicitly. Within some areas we look at these things, waste management and other areas, but we did not cover this as heavily as we might have. I think that's a good comment.

MR. CAMERON: Okay, David, implied in your question is something that I would like to hear from the

rest of the group about is that are there things that other agencies, other organizations are doing in regard to regulatory excellence that the NRC might profitably pursue.

Do you have anything to offer us along those lines? Not right now, okay.

Steve?

MR. COLLINS: Steve Collins with the Illinois Department of Nuclear Safety representing the organization of Agreement States. There are 29 agreement states that regulate more than two-thirds of the licensees in this country, other than the nuclear power reactors, and we do have seven officers elected each year through either them or their designees come and speak at public forums like this to let you know what the majority of those states feel.

With regard to the question that was posed, basically we view that NRC in this Strategic Assessment and Rebaselining Study has decided how it can do or try to determine how it can do better what it's currently doing and after this process is done, we have suggested already that they need to go back and work with the agreement states and industry and everybody else, their stakeholders, to decide what should we really be doing, not how can we do what we're doing now better, but go back

and relook at the whole thing from the beginning again and say what should we really be doing and that will come out earlier -- do the high risk things and cut out some of the low risk things.

The Organization of Agreement States viewed on DSI 23 in general is that we concur with the Commission's initial views. The proactive approach to regulatory framework is desirable and with their new view that it should not be limited to just those initial items that were mentioned on the first slide. That the continual quality improvement in all areas and consultation with stakeholders should be sought and particularly with reviewing regulations, eliminating or changing those that are too restrictive, exempting those sources that pose no significant risk to the general public and concentrating efforts on radioactive material uses that have higher risk.

MR. CAMERON: Okay, thank you, Steve, for those Agreement State comments and one thing for people to keep in mind for further discussion is something, I think, was implied in what Steve said, that perhaps in addition to the institutional mechanism that the Commission is considering here, the senior management review team, but that there's also important sources of advice outside the Commission on this whole idea of regulatory excellence.

Would you agree with that?

MR. COLLINS: Yes.

MR. CAMERON: Okay. Derek?

MR. MERCURIO: Derek Mercurio with Southern California Edison.

We agree with the Commission's decision for more proactive approach. The issue paper focuses on regulatory effectiveness, which denotes a regulatory framework for ensuring public health and safety. That is clear, coherent, logical, consistent, reliable and technically sound.

It then provides a background in the appendix, a description of improvements that have been made over the years to that regulatory framework. However, when examined together, all these improvements fall far short of it being clear, coherent, logical, consistent, reliable and technically sound.

For the most part, we see the adoption of specific prescriptive regulatory approached and requirements, but no consistent or coherent level of safety significance supporting what was just said. The most notable exception is the performance based maintenance rule. However, the effectiveness of even that rule, the maintenance rule, will depend on how the NRC inspects through this rule. Whether their enforcement

practices will be they be based on performance instead of detailed compliance.

What isn't addressed in the issue paper is that there has never been a consistent underlying basis for the NRC's regulatory framework. It has been driven by the event of the day. Even though you need to respond to the event of the day, it still needs to be responded to in the context of an overall general, clear, consistent policy.

We object to the statement on page eight, that licensees have not emphasized changes specifically focused on enhancing regulatory effectiveness. On the contrary, in an attempt to provide a focused regulatory framework, the industry proposed NEI 9604 enhancing nuclear plant safety and reliability through risk based and performance based regulation. The goal of this initiative is to focus the NRC and the industry on more risk significant issues.

We're concerned to find the NRC's consideration of risk informed and performance based regulation relegated to a background discussion of recent initiatives as opposed to being the corner stone of a new regulatory framework.

The key to enhancing regulatory excellence is to establish this consistent, coherent, logical regulatory framework for all NRC actions, whether this be in rule

making, in review of a licensing action, performing inspections or in enforcement. Every action by a member of the NRC staff needs to be part of the overall regulatory picture.

It is important that the NRC establish an overall regulatory framework, such as that addressed in NEI 9604. If the best way to make this happen is to set up a proactive review group that's discussed in option two, that's the option we endorse. However, if that is not the intent of option two, then it would be better to go with option one.

MR. CAMERON: Okay, thank you, Derek. Let's get a clarification on your last point right now.

Is the review group an inherent part of option two, I guess is the question?

MR. RUBIN: Yes, it is. The process we have in place right now is very decentralized in a way. Each office works its own program areas, regulatory program areas and identifies activities for improvement would include many of the things that you have just mentioned.

What we're talking about here is building on that additional organization, if you will, that would establish top agency priorities for high priority initiatives that need to be undertaken by the agency to improve its framework and would set priorities and provide

oversight for those special areas that the agency would pursue.

The fact that the Commission has said that this program needs to be broadly scoped to include all functional areas does present a challenge to this particular group on which areas to go after first, but I would venture to say that the areas of concern that you have mentioned would, in my mind at least, be considered among the top priorities to be addressed within the agency.

MR. CAMERON: Thank you very much, Stu.

Do we have some other comments on the regulatory excellence issue?

Yes?

MR. FRAASS: Ron Fraass with the Radiation Control Program, State of Kansas.

I want to affirm Steve Collins' remarks on behalf of the Organization of Agreement States. Kansas was the ninth of the Agreement States. We are also trying to seek regulatory excellence with our own material licensees.

To that end, we view as our goal compliance. That's shared by our parent agency, which is Kansas Department of Health and Environment. We believe that a lot more can be done in partnership with those that we

regulate to lead them toward compliance. We seem to be getting a real good response in that area. Folks are coming to us saying, we have a problem. Can you lead us to other folks in similar industries that have the problem and have already solved it? We try to do that. That's one of the approaches we're taking towards regulatory excellence in Kansas.

MR. CAMERON: Thank you very much. That's something that we've heard before, I think, in other contexts, is the whole idea of compliance versus enforcement. Thank you.

Tom?

MR. TIPTON: Tom Tipton, NEI.

I agree with the comment of looking at other federal agencies and the international community.

Have you also looked at some of your internal reviews that have gone on and let me give an example.

The Office of Inspector General came out with a special evaluation report in May of 1995 entitled quote Now is the Opportune Time to Reexamine NRC's Organizational Structure, end of quote, and in there they discuss the fact that you need to focus on eliminating duplication, reducing program inconsistencies, et cetera.

There are other documents out of the Inspector General's office that focus on things like this. So have

you gone through and looked at those activities that you already have in hand?

MR. CAMERON: Good suggestion, Tom.

Jim Milhoan?

MR. MILHOAN: Tom, thank you for the comment.

With respect to the specifics of the IG reports, in fact we do look at each IG report and for those and most of them request a response, we review those and we provide a response back to the IG.

With respect, though, of looking at the activities that we have, I don't disagree with that and that's a good comment.

MR. TIPTON: Tom Tipton again. Thanks, Jim.

Stu, in your review of this, and this may be a little more detail that you went through, did you find any areas where the NRC feels that you no longer have to provide oversight review?

MR. RUBIN: Well, the paper was really not focused on specific program areas. I think that you would sooner see those in the specific DSI papers and evaluating whether or not additional oversight is warranted and I think it does come up as options in other papers.

That would be viewed perhaps more in terms of best possible utilization of resources or efficiency and that was not really the focus of the paper. It was really

one of consistency and rigor and reliability of how we do our jobs. And so we would do it in the most exemplary manner.

So that was really not the focus and I would suggest that that might be found in other papers.

MR. CAMERON: Thank you, Frank.

MR. MIRAGLIA: Yeah, Frank Miraglia, NRC.

I'd just like to add a little more context to what Stu has already said.

In terms of each of the papers, if you look at, lots of things have been discussed here, risk informed regulation. We do have a specific issue paper on how should we apply that across all of the regulatory processes.

The point to this paper is that if you look across most of the issue papers, we have one of regulating areas of low risk in terms of the material area. There's a question of that we need to get the regulatory base clearly defined so we are concentrating on the important things.

To build on the comment about compliance, to get the regulatory base and compliance as a circle of one and that we are paying attention to the right kinds of things and if there are rules out there that are not focused on the right kinds of things, then we ought to

change the rules and that's an element that flows through all of the issue papers.

This here paper is saying, is an internal look and saying that while we're talking about those kinds of efficiencies, we need to do something internal to make sure that the excellence of the staff's performance and meeting the agency's goals and missions is heightened and it's not that we're backing away from those safety goals and those safety missions and that kind of thing and so this was more of an internal structure. Regulatory excellence by the performance of the staff. Regulatory efficiency and effectiveness of each of the rules is built into all 16 papers and are ongoing activities. Maintenance rule has been mentioned as an area that we're proceeding in and we're looking to apply that in other areas, as well.

So I think Stu is right, is that some of those elements that you're talking about are embodied within all of the issue papers and the various options and many of those is how much, how fast, how deep, how broad and that goes back to the question that Chip raised in diminishing resources, each of these issue papers has priorities within the paper and then there's relationships between the issue papers. More attention to materials, more attention to high level --, more attention to reactors and

how will those trade offs be made? That's the goal and the objective that the Commission is trying to get a sense from the stakeholders. If you have views on those kinds of things, that's what it would like to hear in response to some of the comments on the issues you're hearing today and the rest of the day and tomorrow.

MR. CAMERON: Okay, thank you very much, Frank.

There was one suggestion in the paper, at least about an institutional mechanism for regulatory excellence, was with the senior management review team.

How about other types of strategies such as training or something like that?

MR. KELLY: My name is Glen Kelly. I'm with the staff at NRC and I have a little bit different perspective and I want to discuss, perhaps see what kind of comments people have about how the enhancing regulatory excellence is going to have an impact on the staff, which in turn is going to have an impact on the industry.

Many members of the staff are already significantly burdened working on the things that they're doing currently that management or they believe are the very important things to be doing.

If you look at what's in the various options, say for example option two here, the discussion might

imply that there would be many additional things coming on the plates of people in the staff, such as doing more work on 5059, more work on design basis, perhaps many more inspections coming out of headquarters. All of this additional work is going to take away from something and the question is where is that work, where is that coming away from? How does that affect people? Does that mean licensing actions are going to take a lot longer to perform than they were in the past? What do we give up in order to gain this additional work?

And I think that's probably one of the things that will come out of this, but I know the staff members are concerned about that because they want to make sure that urgent things don't push aside the important things. So I'd be interested in hearing what industry has to say about this.

MR. CAMERON: Okay, good point, Glen. I think that's an important point, is the more burden there is on the staff because of decreasing resources, the more potential there is for regulatory excellence to sort of decrease just because of that increased burden and that perhaps some sort of prioritization of importance would help maintain a level of regulatory excellence. That's a good question for all of us to consider.

Derrick?

MR. MERCURIO: Derrick Mercurio, Southern California Edison.

One minor response to Frank Miraglia. We're looking for a consistency and understanding from the regulation, from all of the levels of the regulators, right from the top management to the reviewers, programs managers, inspectors. So it's more where we're talking about this in alignment consistency through all the NRC, top down, side to side, that's what we're referencing. I think that's understood.

MR. CAMERON: Okay, thanks, Derrick.

Kristin?

MS. ERICKSON: Is this better?

I hope you'll all bear with me, because I'll tell you I'm going to probably comment all day long because I not only represent ourself, but something of an informal consortium of large university broad licensees.

I think our issue here goes right back to the other issues, and they're all intrinsicly entwined and I have a saying on my office door that says, If you don't like radioactivity, the earth is no place to live. And, in fact, that's what we've been doing. I tell the activists they need to find the universal radioactive waste site and ship the whole earth and everybody on it if they want to get rid of the danger of radiation.

I will take slight disagreement with Derrick in that the NRC, I believe, does have a baseline policy upon which everything goes back and that is, again, little or no threshold meaning that any radiation is assumed to have some danger and because of that, it goes back to what I said on my office door, that any radiation, anything that comes up can be a problem and triggers tremendous amounts of work and I know at the NRC level it's the same thing we do with our staff on campus.

And we have to spend horrendous amounts of energies on things that are no risk because of that policy. The NRC, likewise, has the same problem. The workload is horrible for the NRC employees and I know this. I have a lot of empathy for them and it's not going to get better until, again, we establish some threshold that's reasonable, that's based on fact, based on science. Something that's clear cut that we all know that beneath some reasonable dose, for example, we could choose ten millorem or 100 millorem, another number that's a reasonable number that is easy for us to use.

I had a real clear case a couple weeks ago. We had -- 51 users in lab and I had people who are all, something I call them, radiation cowboys because they use a lot of P32, a lot of isotopes. They have about 40 people in their lab, but we brought in this little tiny

chromium 52 use and they all went into a panic attack.

I had to have a meeting with up to 50 people from that department telling them why this is no danger and I ended up finally convincing them by calculating that to get their dose limit, they would have to eat 330 shipments of a -- each. Then they begin to realize, but there were people from all over the world who again had the same fear, based on our -- or no threshold and I think this is the underlying thing that in every one of these direction setting issues we have to look at before we can solve the rest. And I think that once we do that, we will then have a basis for going forward and saying okay, now, this is a risk, but this one is not. This program is necessary, another is not.

Now a way to do it, again, I will compare to our audits because that's exactly what has helped us on our campus. Our first two or three audits were just monsters, and we did it by dividing up tasks, each staff member took a part of our program and audited the dickens out of it.

Over two or three or four years, we then decided well, now, this last year now we don't have to audit certain things so thoroughly because we know we don't have problems there.

And over time, the NRC would find the same

thing to be true. It could enlist the help of licensees in these self assessments and these audits and establishing priorities. Then acting on the priorities. Thank you.

MR. CAMERON: Okay, thank you, Kristin, and we will be getting more to that fundamental point this afternoon, I think, and I would just say that no one has to be apologetic in any way about talking. We encourage people to say what's on their mind and we thank you for it.

And we do have to wrap up here. We have about two minutes or so. Tom, do you want to make a final comment?

MR. TIPTON: Tom Tipton, NEI.

In answer to the gentleman's question of a lot of work, not a lot of staff, et cetera, we're all in that. In a competitive environment, safety is paramount to our industry, obviously, so I want to put that right up front. It's paramount, but we do have to make sure we're doing things effectively and efficiently and cost effectively. And that's why the industry strongly supports risk based, performance based philosophy where we focus on results and we use risks to make sure that we're focusing on the right safety issues.

MR. CAMERON: Okay, thanks, Tom.

Paul?

MR. FARRON: Yeah, I'll take a crack at the last one here.

MR. CAMERON: Good.

MR. FARRON: I've heard the words consistency and inconsistency here quite a bit, and I know from past experience the NRC has always tried to maintain consistency within headquarters and between headquarters and the regions and between the regions.

If anything, I think we have seen more inconsistencies recently in the way that the NRC does business and that causes more work not only for the licensees, but also for the NRC, every time there's a --. And some of that may be due to some of the outside activities that people have been referring to, and I think you know what that is, and that goes from even the way generic communications have been issued recently. It's been inconsistent from what we've seen in the past and it generates more questions and takes more response from the licensees and like I said, from the staff as well.

MR. CAMERON: Okay, thanks. Well, that's a great final comment here because I think as Derrick and others have noted, consistency is one of the hallmarks of regulatory excellence and if you have specific examples of that, too, that when you follow up with written comments,

that would be very helpful for us.

Thank you. Let's be back at 1:15. That gives you slightly more than an hour and we'll start and remember we have concurrent sessions, one in this room, one in the next room.

(Whereupon, the morning session concluded at 12:15 p.m.)

A-F-T-E-R-N-O-O-N P-R-O-C-E-E-D-I-N-G-S

(1:21 p.m.)

MR. CAMERON: Good afternoon, everybody. We're going to start on the next strategic arena. And this strategic arena is the safe use and handling of nuclear materials. And I imagine that we'll have some more people join us in a few minutes.

But let's get started with the first paper. Dr. Malcolm Knapp is going to be the presenter. And he is the sponsor of these papers. And the first paper that Mal will present will be oversight of the Department of Energy. We'll then go into the Agreement States paper and into the Materials paper.

Mal is the Deputy Director of our Office of Nuclear Materials Safety and Safeguards. And I'll turn it over to him for this presentation. And if you're interested in the research or international papers, they are being done in the room next door.

DR. KNAPP: Thanks, Chip. I should begin by telling you two down sides about this paper. First is that Chip was my co-author. But despite that, the paper is still a very good one.

The other is that the lady running slides is Clare Defino. Clare has worked closely with me on all of the papers you'll hear this afternoon and the waste papers

tomorrow. We flipped a coin over who would talk. I wound up getting to do it. She won.

To move to this particular issue, our oversight over the Department Energy, the specific issue is, should the NRC seek to expand its regulatory authority and responsibilities to include DOE facilities. Let's emphasize the word "seek." How did this issue arise?

And I think probably most of you are pretty familiar with DOE. I suspect you're familiar with the size of the organization. They've got laboratories. They've got full-size nuclear reactors. They've got test reactors. They have all kinds of cleanup efforts. And for those of you that had a chance to look through the paper carefully, there a host of things that the DOE is involved in.

And DOE is now largely self-regulating. Now, there is some regulation, by the NRC actually. The high level waste facility that they're developing is one we're regulating. The remedial action they're taking on some milltailing sites is regulated by us. And they also have -- the EPA has generally applicable environmental standards which DOE must meet. But by and large, DOE regulates itself.

A couple of years ago, questions began to arise as to whether it would be wise to have an external

regulator of DOE to improve safety and to improve the credibility of that agency's efforts. These questions were being kicked around in Congress and in part, in response to this, I'd say the better part of two years ago, Secretary O'Leary put together an advisory committee on the external regulation of DOE nuclear safety.

That committee completed its activities in December of last year and reached a number of conclusions, basically that it would be appropriate if DOE were regulated externally, and that although they did not make a decision, they suggested that an existing agency would be appropriate. One alternative would be the NRC. Another would be the Defense Nuclear Facility Safety Board. That would have been a restructured board from what the current board is.

Given that this issue is present and that this could have a dramatic impact on the Nuclear Regulatory Commission, the question was raised, should we take a position on this. And with that question, there were a number of key factors that we identified.

First, we could wind up with broad oversight over the Department of Energy through congressional action. Simply change the law so we would be responsible for some, most or all of the current DOE activities. However, even without congressional action, the NRC's

oversight of DOE is increasing. There have been a number of DOE initiatives and some congressional initiatives which on an incremental basis have changed our oversight.

For example, the 1992 law which gave us responsibility for the U.S. Enrichment Corporation's gaseous diffusion plants. DOE's current activities in its Hanford tanks, where we are this year funded to give them assistance and may after several years, should DOE privatize, NRC would be the licensing organization.

There are a variety of other activities that as DOE shifts into privatization or different approaches, existing law could cause the NRC to get additional responsibilities. I think you're all aware that DOE is a pretty big outfit. They've got over 3,500 nuclear facilities in 13 states and tens of individual locations.

One of the concerns that we would have if we were to take on this work would be resources. As you know, I think, the NRC is a full fee recovery agency. That means that we recover our fees from our licensees. They're appropriated by Congress, but nonetheless, we are supposed to recover approximately 100 percent of our budget from licensees. If we were to take over DOE, the question comes, how would we be funded to do this. This could particularly be an interesting question if our incremental oversight of DOE increases and provision is

not made in Congress for how that work should be funded.

Finally, and perhaps most important, were we to regulate DOE, we would require considerable additional resources. The NRC today has a staff of a little under 3,000. We have a budget of around $475 million. Should we achieve broad responsibility for the Department of Energy, our best estimates are that it would take 1,100 to 1,600 additional staff and perhaps $150 to $200 million to be able to do this. That represents a 40 to a 60 percent increase in the NRC's current size, with corresponding workloads on staff, on the Commission itself, need to develop or modify a broad range of regulation. So it could have a tremendous impact should we wind up with this responsibility.

Given these factors, the Steering Committee brought four options to the Commission. We could support broad responsibility for NRC regulation of DOE. We could do this in several ways. If you've had a chance to look at this, you'll notice there are some suboptions. We could simply seek responsibility.

As the DOE Advisory Committee suggested, an external agency might do it. But those suggestions were a little different from the current structure that EPA has -- excuse me, the NRC has with EPA and with OSHA. Perhaps we should support responsibility but try to stick to the

current division of responsibility with the other agencies that are now involved in DOE and in commercial nuclear facilities.

Another alternative would be that we might try to take the best of both worlds. For example, for years we and EPA have been struggling with how best to deal with mixed wastes. While it might be a good idea to maintain our current commercial regulatory structure were we to oversee DOE, perhaps we should try to work something out with the other agencies to solve some of the existing problems.

Another alternative would be that we could take on broad responsibility for regulating DOE, but only for certain types of facilities. For example, we might say that we want to regulate non-defense facilities only.

The third alternative would be that we would just oppose taking on additional responsibility. We could argue that this broader responsibility would reduce the Commission's focus on safety of current commercial reactors and current nuclear materials users, and that we already have all the responsibility that we should take on.

Finally, as a fourth option, simply take no position. Now again, recognize these are positions that we would take. What may happen in the future will

obviously be directed by, among other things, congressional action. And should Congress give us part or an entire mandate to regulate DOE, we will do the best of our ability what we can. The question here is, what should the agency's policy position be on this issue.

Well, with these options in front of us, the Commission decided that they preferred the fourth alternative. They would not take a position on whether or not DOE should be regulated by the NRC. The Commission does feel that if we had adequate resources and a reasonable time table to develop a program, we could provide adequate regulation if we were asked.

Our view is that, therefore, if we were to be given this oversight, we would like to get it on an incremental basis, and we would seek some method of prioritization so that as we took on this responsibility, we could address first the areas which would have the most cost benefit from a safety perspective.

That's the issue and the Commission's preliminary view. And now, with Chip's help, I would like to hear what your views are on the topic.

MR. CAMERON: Okay. Thanks a lot, Mal. If you people in the back of the room are bothered by the noise from over there, please feel free to come up here to the front. And I think it would be less interference for

you, if you want to. Just move up if you have to.

As you can tell, this is a major issue for us, oversight of DOE, and I guess one place to start is, is it relevant to ask whether anybody believes that DOE does not need an external regulator? I won't take silence for an assent that they do. Perhaps no opinion on that.

How about this whole issue? Someone want to start us off with some discussion on external regulation of DOE? Steve?

MR. COLLINS: Stephen Collins with the Illinois Department of Nuclear Safety representing the organization Agreement States. With regard to your first question and followup, specifically on page 15, the second and fourth paragraphs on that page of this DSI, it indicates there's a recommendation that decontamination be excluded from the regulator's purview. And we disagree with that. Decontamination should not be excluded from the regulator's purview. And the following is from Chapter Five of the report issued by the ACER of DOE safety.

"We have listened to many days of testimony and have deliberated among ourselves for almost a year. We conclude that every major aspect of safety at DOE nuclear facilities, facility safety, worker protection, public and environmental protection all should be

externally regulated."

Agreement States agree with that.

MR. CAMERON: Okay. Thank you, Steve. One of the cautions and I don't think I'm stepping too far outside of my facilitator role here, but one of the cautions that I would give to everybody, myself included, when reading the external regulation of DOE Advisory Committee report, is that it can be a little bit tricky sometimes. And it's, to me at least, unclear about actually what they may have been recommending in some cases. And I won't turn to our resident expert yet on this. Okay? But that's a good point about whatever they said decommissioning should be included.

Mal, do you want to comment?

DR. KNAPP: Only that NRC was not intending to comment on whether any of these aspects should be externally regulated. I think the question might be, if they are, would decontamination fit best under the purview of the NRC or the NRC working with the EPA or perhaps the EPA alone.

My interpretation of the paper, and I'm perfectly willing to hear others, was that we would have had the role of what I think they called the facility safety regulator. And I was not clear on whether that role would include responsibility for decommissioning or

not. In any case, the question of whether they should be externally regulated with respect to decommissioning, and if so, would that be a better role for the NRC or someone else, certainly is an area where I'd be delighted to hear any comments.

MR. CAMERON: Steve?

MR. COLLINS: Stephen Collins. What we were trying to clearly say is that we thought out of all of the agencies available, the NRC was the agency that should provide that independent regulatory oversight for protection in all aspects of the decontamination, decommissioning effort.

DR. KNAPP: Thanks.

MR. CAMERON: How about comments on the options. Mal presented four options. And as he pointed out, at least their preliminary view is the fourth, take no position on broad NRC responsibility. Now, we've been hearing in other sessions, some people support the first option. In other words, a more aggressive approach on assuming regulatory authority.

Do we have any comments on the first option? In other words, should the Commission really go after this? Kristin?

MS. ERICKSON: My comment on this issue should be weighed according to the fact that I'm not a DOE

facility. But I do have a strong view on that because we have to interact with DOE facilities a lot. And in fact, our worst nightmares in regulatory and paper trails and working together with an agency is with DOE and EPA. I am very much -- our institution is very, very much against EPA being involved in any radiation things. And I do base that on experience.

Having had to work with them on the NISHAPS thing for two years, documenting that we were exempt when they already knew MSU was exempt from their own two studies, they refused to accept that. My staff and I spent literally hundreds of hours coming up with methods and documentation, methodology which wasn't reasonable, plus explaining basic radiation things to the EPA. And in the end, I also did a survey of about 15 broad licensings in our own region and determined that we all were told different answers to the exact same question. So we don't want EPA involved in any radiation thing if there's anything we have to say about it.

As far as the NRC taking over DOE, I think that's an excellent idea because of all the agencies that we are aware of, the NRC is doing the best job of trying to self-improve. It has a long history of regulations, a long history of experience with the public and the licensees, and I think they'd be best to do it. As far as

prioritizing, I think that's a good idea, too.

MR. CAMERON: Okay. Thank you, Kristin. Let me just ask one clarification. You would recommend that the Commission select option one, then?

MS. ERICKSON: I would recommend they select option one. And then within that framework, do the same thing we're talking about doing with all of our licensees, risk, analyze and then prioritize.

MR. CAMERON: Okay. And thank you. And there will be a special seminar in the Sports Bar tonight on subpart I. And it's sad that we're all laughing, because that's such an inside joke that hopefully no one would be. But I guess we all have experience with subpart I, don't we?

Yes?

MR. WILLIAMS: Jim Williams, the State Liaison Officer of the NRC from Ohio.

As a state that has a significant -- a series of significant problems and installations that DOE has been operating, particularly Fernaud and the Gaseous Diffusion Plant, which was mentioned earlier. We have seen a difference in the relationship and operation at the Gaseous Diffusion Plant since the NRC has been interacting with the United States Enrichment Corporation. And it would give us a basis to believe that NRC should interact

on a more broad basis in regulating the DOE facilities. And I agree with Kristin, because the EPA has functions for the Fernaud cleanup and there are differences of night and day between the relationships of those two facilities.

It would appear that we would favor some broad support and responsibility for regulating certain types of DOE facilities, and I agree that perhaps the defense facilities may be best left to DOE because of their long-standing relationship with that program. But certainly as we emerge from a defense-oriented production process, it would appear that some of those DOE facilities could best be regulated by an external source.

As far as some of the costs, DOE is self-regulating. And as it self-regulates, it doesn't do that for a zero sum. It has to spend some money in its self-regulation process. It would appear that consideration could be given to charging DOE the same type of fees that NRC charges other governmental agencies and other private industries to do the regulatory process. And that would offset some of the costs now to -- that you're discussing. Maybe not the $150 million worth, but a substantial portion of that that DOE might be paying now that they could use to offset the NRC's efforts.

MR. CAMERON: Thank you very much, Jim. Mal?

DR. KNAPP: Appreciate the comments. We have

a couple of budget folks who can speak better than I to the subject, but in the interest of brevity, I'd say that if we were to take broad responsibility for DOE, we would have to have a way to be compensated. The agency could not tolerate its current budget. Our interests -- there's a number of ways we could do it. Congress could just give us the money and say you don't have to get it back from DOE, or Congress could say you have the authority to take it from DOE, whatever.

Our principal interest would be in ensuring that we did not work a financial hardship on our existing commercial licensees and that we had enough growth that we could maintain the safety responsibility we now have while taking on the additional work.

Given that we were to be given broad responsibility, I would like to think Congress would help us work out a way that we could fund it in an equitable way.

MR. CAMERON: Thanks. That was a good observation on your experience in terms of the Gaseous Diffusion Plant there and it raised a couple of issues that Mal touched on in terms of key factors that the costs of regulating DOE, not only dollar cost but the number of staff, properly trained staff. You raised the defense facility issue. That was one of the things that I think

was flagged in the paper, is how would we deal with that national security type of issue.

And I guess I would ask the audience, and also, you, Jim, what about the role of the states in this whole scheme, if we were going to go to external regulation. And, Steve, I don't know if you wanted to address that at this point along with your other comments or what. But if you do, fine.

MR. COLLINS: Stephen Collins, representing the Illinois Department of Nuclear Safety and the organization of Agreement States. Don't let me leave that out when I get there, but I want to make a few short remarks first.

We believe the NRC's best approach might be characterized as a mix between options 1B and option four. The initial stance should be that defined in option four, but the NRC should go forward with option 1B. Illinois and the other agreement states may want to assume this authority, if that option is available. We know that there's a precedence under other EPA type regulation where states are in fact doing that. And Tennessee and Washington have in fact expressed a specific desire to do that already. And I think Colorado has also.

We also think that the NRC should actively participate with the Conference Race Control Program,

directors E5 Committee on Low Level Reactor Waste that has the task to evaluate various options available and to develop a regulatory strategy for the DOE facilities that does not create a new mess for the future.

That's partly specific about the fact that NRC does have representation on that committee, I believe, but they didn't show up for the last meeting. Maybe not the one before that, but certainly not the last meeting. That's all.

MR. CAMERON: Okay. I think it's worth -- one point of emphasis is that the view from the Agreement States is that, and for people to keep this in mind, if NRC assumed external regulatory authority over DOE, that the Agreement States would like to share that authority under some arrangement, although there is many ways to do that. But that was an important point.

And as a matter of clarification, I don't know if Mal or Steve knows, and Steve Crockett in the back, about our represent -- were you saying that we were on the external? E5, okay. Okay. And the E5 Committee basically deals with what?

MR. COLLINS: Low level waste.

MR. CAMERON: Okay. And is there also a Conference of Radiation Control Program Directors Committee that is specifically on the regulation of DOE

facilities?

MR. COLLINS: No. There's not a specific committee on it, but they do have a person authorized to speak for the conference on that. And that's the representative from Tennessee, Mike Mobley.

MR. CAMERON: Okay. Good. And Mike was also a member of the External Regulation Advisory Committee. Roger?

MR. HUSTON: Roger H.ston from NEI. The principal interest that the civilian nuclear industry, represented by our members, has in this arena is, as has been mentioned before, it's going to be expensive. And I'm happy to hear Mal talk about equitable ways that that funding needs to be provided rather than providing it through an increase in fees on existing licensees.

I do want to express one logical caution, though. It makes some sense that there are resources being expended at DOE in self-regulation, which, if they were externally regulated, could be moved over. But that may not be the end of the problem. At least one of the drivers for this -- look for external regulation of DOE, is a perception in at least some quarters that they're not doing enough. And if that perception is accurate, then what that means is a transfer of all of the resources that DOE is now using to regulate itself may not be enough to

cover the additional effort that has to be put in by NRC or someone else. So it's not just a zero sum gain.

DR. KNAPP: I might, in response I might note that in our estimates that you heard earlier, the 1,100 to 1,500 and so on, 1,100 to 1,600, our basis for those estimates was to look at DOE facilities that to the best of our knowledge closely resembled facilities which we now regulate. And our estimates were basically, this is what it would cost the NRC to do the job the way we now do it for commercial facilities. I would suspect those are probably higher than what DOE currently applies. So you're right. It will not be a zero sum gain.

MR. CAMERON: Anybody else wanted to express an opinion on any of these issues but to followup on Roger's point, the whole effect on the commercial side of NRC regulation? Roger gave an example that's an obvious point, which is don't have us pay for it. What about the quality of regulation issue? I think that's one of the factors flagged also in the paper, is that the NRC would just be so overwhelmed, possibly, by taking on responsibility that the quality of regulation of the commercial side would also go down. Any comments on that? Okay.

MR. FRAASS: Ron Fraass, Kansas Radiation Control. The general area of that one that I'd pulled out

was on page 17, where the DSI talked about the history and size of DOE nuclear facilities and programs may make it very difficult for that agency to provide sufficient resources and technical expertise to be able to maintain the same standards NRC sets for comparable commercial licensees. I think that was the point that was being made. That one concerned me as for option four to be the preliminary choice.

If the NRC's current standards are the appropriate minimum to ensure adequate protection of public health and safety, promote common defense security and protect the environment, NRC's goal statement, why should potentially less stringent standards apply to DOE. In an earlier life in the Air Force, I worked a lot with the DOE. And basically every contractor that they had set their own set of standards and then tried to maintain them. I did not see any real external set that applied broadly within the Department of Energy.

MR. CAMERON: That's also a good point that I think ties in with some of the down sides here, is that what would be the implications of having basically two different regulatory regimes, if that actually was the consequence. And I think that goes to Kristin's point also about one of the things referred to in this paper was the relationship between NRC and EPA in regard to any

future regulation of DOE. There is also issues of would the NRC take over regulation of NARM. And if you do it in a DOE sector, what are the implications of that for the commercial sector. And now we'll go to Gordon Appel.

MR. APPEL: I am Gordon Appel. I'm Deputy Director of the Department of Nuclear Safety. And I just want to clarify two things.

Chip walked around the issue of states and the authority relative to regulating DOE a little bit. I don't know about other states. I can only speak for Illinois. But in the perspective of Illinois, it's our view that we would want the authority to regulate the Department of Energy the same way we regulate other materials licensees.

And secondly, you mentioned in your last statement something that might have been a little bit confusing. Are you suggesting that one of the approaches to external regulation of DOE would be to somehow regulate them to a different set of standards than the current set of standards of materials licensees in the country?

MR. CAMERON: No. I'm not suggesting that that's what would happen, but it's been expressed that one of the fears was that NRC might, and picking up on Ron's comment, is that we might not be able to apply the same stringency of standards to them. And that would be one

thing that might prevent us from assuming regulatory authority or it might be one down side.

And Mal, do you want to amplify on that to perhaps clarify what I was trying to say? And then we'll go back to Gordon.

DR. KNAPP: I think the concern as expressed is that the NRC and its Agreement States hold their licensees to very high standards. For better or worse, partly because of the decade's long history of DOE, there are facilities which don't meet those standards, or at least the supposition is they wouldn't. And the supposition is it would take a great deal of resources to bring them up to those standards.

So if we were to take over regulation of DOE, it's been supposed that it would be difficult and time-consuming before we had Department of Energy facilities meeting the same standards that our commercial facilities meet today. And I think that's basically -- it's a recognition that we are not going to take over regulation of DOE tomorrow and the day after they meet every standard that the commercial facilities meet. It will take probably years. Excuse me, it will certainly take years. The question is, how many years.

MR. APPEL: Thank you for the clarification. That is different than what I heard. And I understand

that. I think anybody who looks at the history of that agency and your own agency would understand that.

DR. KNAPP: I think the challenge should be, and maybe I should go a little further. Given that that's going to be the case, how do we progress through these years? Is there some sort of a growth pattern that we would need to define as DOE comes closer and closer to achieving our existing standards? If we are given this responsibility, it will be quite a challenge.

MR. CAMERON: Yes?

MR. WITTSCHEN: Ron Wittschen. I'm with Detroit Edison. Also in a former life I worked at a DOE facility. And I believe that the resolution would be to meet the intent of the regulations. Having been at these 1950 facilities, there's no way in the world they're ever going to comply strictly to the letter that commercial plants meet. It would have to be a negotiated design basis that they would have to meet, you know. Based on where they are now and the best available, you know, improvements that they could make. That would have to be the final product.

MR. CAMERON: Are you suggesting that it's not just a question of timing, that it may actually be that there would be a difference in the regulatory regimes between commercial and defense or?

MR. WITTSCHEN: Not necessarily a difference in regimes. Probably not a whole lot different than applying a brand new regulation to a very old plant.

MR. CAMERON: Okay. Okay. Thank you. Thank you for that clarification.

Gordon, do you have anything else on this? Anybody want to say anything more on the Department of Energy issue?

I guess I would just ask Gordon one question. In terms of the state rule in regard to the DOE facilities, would it be to follow the Agreement States model where certain types of facilities are excluded with NRC setting some overall regulations, or are there different modes to follow? And I know that this is something that may be a little bit unfair because you haven't had much time to think about this. But I was really just curious about what your thoughts were on it?

MR. APPEL: Well, you're traditionally unfair. Chip and I have known each other for a long time, and we appreciate each other's unfairness. But we haven't put a great deal of thought into it. You have to understand, the State of Illinois is a whole lot different perhaps than some other Agreement States. I mean, we don't have a major weapons production facility in the State of Illinois for the DOE. And I think that makes a big difference.

From our perspective, however, with the exception of a few things that relate to safeguards and criticality type considerations, I think that we would apply the set of rules that we have for materials and accelerators and that sort of thing directly to DOE facilities in the State of Illinois.

MR. CAMERON: Okay. And I thought I saw an affirmation from Kansas. Kansas affirms that. And how about the State of Ohio? Do you have any views on that, Jim? I know you're not an Agreement State, at least not yet, but this doesn't necessarily need to fit into the Agreement State regime either. But if you have any comments, please feel free to add them.

MR. WILLIAMS: Well, I think the issue on safeguards versus nuclear safety, the safeguards in security issue versus the safety issue is one that needs to be dealt with if NRC were to exercise any of the options other than four, because the DOE has an established system that's worked for a number of years in the safeguards in the security process. And even at the Gaseous Diffusion Plants, they still have the security and safeguards program, although they do have a contract, USEEC, to work at the plant in Ohio.

And there I think they're looking at more in terms of what happens in the autoclaving process and on

the safety processes internally within the plant, which are totally different than the safeguards in security issue. So I think DOE's ability to do safeguards in security should be recognized on any of those three, first three, should they be adopted.

MR. CAMERON: Okay. Thank you. And I believe -- and Steve maybe would want to clarify on this. I believe that the External Advisory Committee did recommend that at least for the initial phase-in that DOE would keep its safeguards system and the NRC would not assume that. And Steve is shaking his head affirmatively on that one.

Do we have any other comments on the DOE issue before we move on? Okay. Mal, do you want to go to the next paper? Okay. We're going to go to the Agreement States paper.

DR. KNAPP: Okay. Direction setting issue number four is our relationship with Agreement States. I believe there may be some folks in the audience today that have an interest in this particular issue. The specific issue is, what should be our strategy regarding states becoming and remaining Agreement States.

I'd like to note in passing that two weeks ago yesterday, the NRC met with a number of Agreement States. We've got a lot of good comments. It was a very constructive meeting, and we were pleased to have it.

There are a number of factors that need to be thought about in our relationship. As has been mentioned earlier today, about 70 percent of the licensees, materials licensees, in this country reside in Agreement States. NRC's got about 6,500. The Agreement States have about 13,000 or so. It's also true, the general licensees, where we've got about 35,000, and the Agreement States have about 100,000. And right now we have four states which are not Agreement States which are either negotiating or very actively pursuing Agreement States status. If that happens, the number of NRC licensees, as I mentioned a moment ago at 6,500, would drop by about a third, to about 4,500.

This is of concern because of the Omnibus Budget Reconciliation Act, which requires us to recover all our fees. Excuse me, requires us to cover our budget from our licensees. And as the NRC's licensee numbers decrease and decrease and decrease, we begin to ask, what should be the budgetary arrangement with the Agreement States. And we see this as putting increased pressure on us to minimize our financial support to Agreement States.

And an area that has been, frankly, contentious over a couple of years is the extent of which NRC should provide the financial resources for Agreement State training and for travel to that training.

The last bone of consideration is the NRC's obligation to oversee the Agreement States Program. As most of you know, when we find an Agreement State to be adequate and compatible, we relinquish our authority to them, but we do retain a responsibility of oversight of the program. And the best way to do that is certainly a factor we need to consider in our relationship with Agreement States.

Given these factors, the Steering Committee brought five options to the Commission for consideration. One, turn the Agreement States Program over to the Environmental Protection Agency. Well, why would we want to do that? Well, EPA has an Authorized States Program right now. And arguably, some Agreement States might be most comfortable -- excuse me, some states might be comfortable dealing with a single federal agency rather than having to work with two. Of course, an adverse impact of that would be the EPA is principally concerned with the environment and would have to develop some sort of a material safety effort should they be given this responsibility.

Second option. Strongly encourage states to become Agreement States. Provide tangible incentives. Provide the money for training and for travel to that training. Provide seed money for states that might look

to become Agreement States. Provide intangible incentives. Strengthen the role of Agreement States in the development of NRC's regulatory decisions. Have commissioners actively pursue governors and legislatures of states to encourage them to become Agreement States.

Third alternative. Continue the current program, including adopting current initiatives. The Agreement States Program today is not static. It's in flux. We have initiated policies which the Commission has under consideration which hopefully would provide a better balance between flexibility and compatibility. We have an IMPEP Program, that's Integrated Materials Performance Evaluation Program, which was initiated not too long ago and which is still developing. So that to continue the current program, we would like to think, would result in improvements and a better relationship with the states than we might have had a few years ago.

Another alternative. Create the American States as co-regulators. We're all in this together. Everybody has an equal share. Everybody has an equal responsibility, including funding.

Last one. Evolve regulation of AEA Section 274 materials to the Agreement States. This would be the NRC gets out of the business. This might, depending on how we do it, it might involve seeking

legislation from Congress to do it.

Arguably, the states have the basic responsibility for the health and safety of their citizens. They do this well in a number of areas. Arguably, we should simply say 40 years ago, when we didn't understand nuclear materials, it made sense for the feds to have a major role. Now, we understand them pretty well. We have programs in place and the states might be a lot happier being allowed to do this as they see fit.

As we talk about these options, I would remind you that these are, as Jim Williams mentioned earlier today, out of the box thinking. One or two are probably provocative. We're interested in your comments. We're also interested in your comments on chunks of options. You may find part of one option good and another part intolerable. We'd be happy to hear how you might find a combination of options or pieces of options most attractive.

When we provided this to the Commission, their preliminary views were that they wanted to continue the current program, including the initiatives. They wanted to encourage more states to be Agreement States, but they wanted to use non-monetary incentives, although they were prepared to explore the idea of using seed money. They would try to provide training to states in a limited way

by giving them training without charge on a space available basis, but states would have to provide their own funding for travel.

The Commission has a number of questions with this issue paper, so it particularly seeks comment. Certainly, because of the interest in the issue, we'd like to hear from whether NRC should fund training, travel and technical assistance. And in this area, we particularly would like to hear from, obviously, Agreement States, but non-Agreement States, Agreement State licensees and non-Agreement State licensees. What we're trying to do here is strike the most equitable balance we can among everybody involved and so we'd particularly like your comments on this issue.

With that, I see Chip picking up his microphone, and I'd like to hear your thoughts.

MR. CAMERON: Okay. Thanks, Mal. And that last statement of Mal's was particularly important. Is that, when you take a look at these options, it may seem that they're within the province of an Agreement State to comment on, but keep in mind that there's a lot of issues that have the licensee community and the public wrapped up in here, including the burden, if that's what it could be called, on licensees for funding the Agreement States Program. Whether a particular licensee would rather be

under an -- in an NRC state or an Agreement State, the whole question about national uniformity, flexibility and regulation, all of those issues.

And I guess would cast it open here for an initial comment on the issues. And let's go to Steve Collins.

MR. COLLINS: Stephen Collins with the Illinois Department of Nuclear Safety and representing the Organization of Agreement States as well.

I'll try to hit every one of those in the next four or five minutes. Illinois and the other Agreement States should be treated as partners or co-regulators. That's an expression that comes in option four. In an effort to protect health and safety from radiation in the United States, the statute which created the Agreement States Program recognizes the growth of the states and their eventual assumption of a co-regulator status. Agreement States are fully capable of participating with the NRC in determining the shape of the program.

Only option four states that "the Commission would recognize the experience that lies within the Agreement States." This recognition should occur within the NRC regardless of the chosen strategy option. The NRC's ideas presented in option four are in direct contrast to the views recommended in the other DSI's where

cooperation with professional societies, international agencies and licensees is stressed.

We propose that the NRC transform its traditional view of the NRC-Agreement State relationship into strategic partnering. The relationship is less donor helping recipient. The relationship would be more equal and cooperative. And this idea is taken directly from the last paragraph on page 13 of the DSI 20, International Activities.

With the above in mind, we favor continuation of certain programs developed in partnership with the Agreement States and presented in option three, especially the IMPEP and the Adequacy and Compatibility Policy Statement as revised by the Agreement States on September 19, 1996.

Option three is the Commission's preliminary choice. In addition, NRC should recognize the many benefits that are received by the NRC and its licensees from the states and return to funding of training, travel and technical assistance. The use of intangible incentives to encourage more states to become Agreement States as well.

And with regard to your statement on equal responsibility for funding as stated in option four, the many benefits that the NRC and its licensees receive from

Illinois and the other Agreement States without reimbursement were conspicuously missing from this DSI. They include the Agreement States regulate all the commercial, low level waste disposal facilities. And the Agreement States are in the process of licensing all the new commercial low level waste disposal sites. And while this is going on, the open sites and Agreement States continue to receive waste from the NRC licensees as well as from the Agreement State licensees. That's a definite benefit and worth something in exchange.

Illinois and the other Agreement States respond to incidents involving transportation of NRC licensed material within their jurisdictions, particularly those involving interstate carriers. That's a benefit to the NRC and their licensees.

Many Agreement States provide salaries for their staff to participate in NRC IMPEP reviews and Agreement States and NRC regional offices. Illinois and other Agreement States staff are lecturers at NRC sponsored training courses without payment of their salary and for the Agreement States' staff time.

Illinois and other Agreement States develop many rules that benefit the NRC, industrial radar certification and draft changes to licensing requirements for licenses of broad scope that were developed at state

expense and provided to the NRC without any compensation.

Illinois and other Agreement States have conducted surveys and assisted in the removal of byproduct material from facilities at the request of NRC. Illinois and other Agreement States are currently investigating potentially contaminated sites for licenses that the NRC possibly terminated inappropriately. Illinois and other states monitor the environs of nuclear power plants and other nuclear fuel facilities licensed by the NRC in order to confirm the validity of NRC licensees' environmental monitoring programs and to confirm that releases is rare to the environment are in compliance with the limits, with only partial compensation. According to NRC staff, that's about 33 percent.

There are some other considerations that have been omitted from this DSI. The NRC did not acknowledge that it would do most of the work on regulation development even if there were no Agreement States. So the document's misleading in that aspect. There was missing an evaluation of the health and safety impact for each option. And that should definitely be included, as that's a primary reason for NRC's existence. So the health and safety considerations for each option should be included.

The NRC didn't even present an option of

reestablishing the historic Agreement States Program where NRC funding for all training courses for Agreement States staff that included course tuition, travel expenses and per diem. And that was the case up until a year -- well, prior to October 1st, actually. The advantage for NRC and the states with this method of training was that both Agreement States and NRC inspectors across the United States receive the same training, which helped assure uniform implementation of a uniform regulatory program, fairly uniform. The NRC new reg, 13-11, entitled Funding the NRC Training Program for States, recognizes the benefits of the historic program. On page two, it states, "The NRC Agreement States Program has been reviewed by the General Accounting Office, an internal NRC task force and the National Governors Association. In their reports, the NRC Training Program for States was consistently identified as a key to establishing states to prepare, and enabling states to prepare, for such agreements and to maintain Agreement States Programs that are adequate to protect public health and safety and compatible with the Commission program. Their reports also contained recommendations to expand the NRC training program."

I'll add that even if Illinois didn't do that -- I mean, even if NRC didn't provide that, Illinois would have no difficulty maintaining an adequate program. But

that's just for Illinois.

Continued funding would send a message that the NRC does recognize that the NRC and its licensees benefit from new states becoming Agreement States and the overall cost of such regulation on a national basis will be lowered with additional Agreement States. So the funding of annual training and travel is a small price to pay and in fact more states becoming Agreement States will save more than that cost. It is our firm belief.

With regard to option one, the Federal Government as a whole is looking for ways to save money. And that certainly would not result in any cost savings to the Federal Government. You'd have a huge transition cost and training cost for EPA.

With regard to option two, while we support the concept of all states becoming Agreement States, we're opposed to the proposal as it is described and presented in option two. We're in favor of continuing programs developed in partnership with the Agreement States as presented in option three. And that is the Commission's preliminary decision.

As a sign of its changed view, the Commission should immediately modify its policies and seek Agreement States' concurrence on all rules, practices and procedures which will become part of the program to which Illinois

and other Agreement States will be expected to be compatible. We recognize that NRC has an oversight role that the Agreement States don't have. With regard to developing new regulations and policies and things, we think we ought to be involved in the very front end in coming up with those policies, not to have NRC develop them and then say this is what it is, you have to be compatible.

We think NRC has misinterpreted the term co-regulator as it's presented in option four. Illinois does not support this option as it's presented. The term co-regulator should represent a shared vision of the NRC in the states. And that shared vision should have to do with the fact that we have the same health and safety goals.

With regard to option five, the NRC and the states, through the Conference of Raised Control Program Directors, should begin working on a long term goal of implementing option five, where regulation of byproduct material is vested with the states. So a long term goal and plan should be that all states become Agreement States essentially and NRC get out of most of that.

That's all I have.

MR. CAMERON: Okay, Steve. You gave us a lot to think about there, and I hope that it sparks a lot of

discussion. Let me ask you for -- let me try to restate something that you said and ask you if it's correct.

You were talking about all of the benefits that the NRC receives from Agreement States in the context of providing the travel, training, et cetera, et cetera, which we're not doing now, but we're struggling with that. Is it also true that some of those benefits really include benefits to NRC's regulatory program as a whole? In other words, to the regulatory program in NRC states and not just to Agreement States. In other words, it's not just a narrow quid pro quo, but that benefit that the Agreement States gives back is spread through the entire NRC program?

MR. COLLINS: Yes. Steve Collins. That was my point exactly. Some of the benefits are directly to NRC. Some of the benefits are directly to NRC licensees, whether they're located in Agreement States or in non-Agreement States. So it's not equally distributed, but there certainly, with regard to the equity issue, we believe that the NRC and its licensees receive back more value than the cost of NRC covering the expense of that training.

MR. CAMERON: Great. Thank you. I wanted to clarify that because I think that's an important point when we talk about the equity issue. It may not be a

determinative point, but it's an important point. And I wondered if anybody from the licensee community would like to say anything about the so-called equity issue at this point, which is the Commission's concern. Yes?

MS. SCHULTZ: Cheryl Culver Schultz, Radiation Safety Officer at William Beaumont Hospital in Michigan, broad scope license. NRC fee payer, and I strongly concur with your statement, Steve. I think we all get benefits from the Agreement States' contributions. And a lot of what you stated is consistent with our hospital's goal, which is to encourage the regulatory authority to be moved from NRC over to the state. And although Michigan is not one of the ones on the plate to come, you know, up to the plate, basically, at this point, it certainly is the hospital's goal that Michigan will do that. And we see the role of the Agreement States currently as very important in achieving that goal.

And so, we don't mind paying the fee. And we certainly feel we derive the benefit from the work that you do, California, New York.

MR. CAMERON: Okay. Thank you very much, Cheryl. Could we have other licensee viewpoints on that, because I think that's important to get this type of feedback on this issue. And you heard one view from -- it's Cheryl, right? From Cheryl. And Mark?

MR. DORUFF: Mark Doruff. I'm with Amersham Corporation, a NRC fee-paying licensee, Agreement State fee-paying license, and a non-Agreement State fee-paying licensee. And also on behalf of counsel on radionuclear and radiopharmaceuticals, whose members are also foreign to all three of the aforementioned categories.

We endorse a combination of options two and three and some aspects of option four. We strongly urge NRC not to consider options one and five. The objectives to be gained by continuing the Agreement States Program, while treating Agreement States as co-regulators, the NRC should strive for compatibility between the NRC and Agreement States as well as between the Agreement States themselves to enable our industry to continue to conduct interstate commerce. However, this compatibility should not come at the expense of adequacy with regard to essential radiation protection principles.

A major consideration to which relatively little attention was paid in the issues paper is a need for compatibility between the Agreement States and the NRC as well as between the states themselves. Another issue that was not addressed at all is reciprocity. The issues of NRC and Agreement State adequacy and compatibility have been addressed in detail by the recently revised and published NRC Agreement State Working Group Report and

Policy Statement on Compatibility and Adequacy. And CORAR and Amersham also agree, for the most part, with the policy statement and with the approach taken by the Working Group. And CORAR has provided comments on this report and the policy statement separately.

MR. CAMERON: Okay. Thank you, Mark. Do we have other comments out here? Yes, Kristin?

MS. ERICKSON: I'd like to say that I and our institution and other RSO's of this type predominantly agree with what's been said here today, but one thing that really rankles for a direct NRC licensee like ourselves is the fact that there's tremendous disparity from one Agreement State to the next and in fact, from some of those to the NRC standards. There are Agreement States I know of that have standards that are so far, I would say, beneath. Some licensees are permitted to do things that if NRC were to answer the question, it would be a completely different answer. And I think there needs to be a lot more uniformity amongst these Agreement States.

Now, to say that some are beneath the standard, there are also some that are far above it. And those do give us all some benefit. And we appreciate that. We agree that there should be some kind of recognition of their contributions, but we would like to see those few, what I would say, might be substandard

Agreement States brought up to at least the minimum NRC standards.

MR. CAMERON: Okay, Kristin. Let me ask you a clarification on that. Is it, on the states that are allegedly below the NRC standards, is it because of the regulation itself or is it because of the way it's enforced. In other words, implementation?

MS. ERICKSON: It's the implementation and the inspection and oversight, both.

MR. CAMERON: Okay. Thank you. Comments on that particular point from anybody?

DR. KNAPP: I'd like just to make one comment on that. One of the fundamental tenets of the NRC's program is that the Agreement States in fact achieve adequacy and compatibility, not just to the regulations, but the way in which they're implemented. I'm not looking for any comments in this forum, but any licensees or Agreement States or anyone who is aware of any Agreement State that is substantially below the NRC standard, we would very much like to hear about it. And we will deal with it constructively, but we do need to deal with it. So please, take an opportunity to share that with staff or whoever in the NRC you think would be appropriate.

MR. CAMERON: Okay. And I just want to try to put a finer point on some of the things we've been talking

about. Clare, could you put up the Commission's preliminary views slide? The first one? Thank you.

If you look at the fourth star, the one of the Commission's preliminary views is, provide training to the Agreement States, but funding for travel and technical assistance would be borne by Agreement States. Now, to just clarify one thing that Steve said earlier. Steve, you referred to the Commission's policy of about a year ago. And is it correct that that policy is different than the fourth star there? In other words, travel and technical assistance would be provided, or was provided?

MR. COLLINS: Steve Collins. Yes, up until around October 1st, not only was the training provided, but it wasn't on a space available basis. It was basically all of the funding for the travel and the tuition, if there was tuition, per diem and all of those expenses for the training of Agreement States staff was paid for by the NRC as they contracted for courses and they paid for the whole course at one time and also paid for the travel expenses for the state people to be there. And there were a whole lot of benefits, as I stated earlier, to the NRC and its licensees that they received from the NRC paying for that.

MR. CAMERON: Okay. Great. So the fourth bullet gives back some of what was suspended. And to go

to the Commission's, the slide where they particular seek comment on whether NRC should fund Agreement State training, travel, technical assistance, I think we've heard a good presentation from Steve on some of the things the Agreement States give back. I think we heard from Cheryl that at least from one licensee's point of view, that she agrees with that and they have no problem with the NRC funding travel, training, et cetera, for the Agreement States.

Kristin, I wasn't sure if that was the point you were trying to affirm or not. She's shaking her head affirmatively. Before we leave this issue, does anybody want to chime in from Kansas, Ron?

MR. FRAASS: Ron Fraass, State of Kansas. As Steve said, programs are seeming different. Our whole program in Kansas is about 14 people and $800,000. Just add some additional examples to what Steve said, that even small Agreement States add, I think, considerable benefit to the NRC and the rest of the nation's citizens. I'll give you a couple of our examples.

Just our own staff time and training. In the last year, we put about 250 hours personnel time into attending some of these courses. One of them was the five-week course. That's one of the ones that the NRC considers a requirement for our inspectors to really be

able to do compatible work. In addition to that, about two man months went into helping write some of these new standardized regulations. That was one of our senior staff who just retired. I put in personally eight weeks senior technical staff time in evaluating some courses that NRC attends and then helping to train some of the NRC staff. We got to do that in conjunction with the fermat courses.

If you take those and put them at NRC's rate, which I understand is an unusual way of doing rates, of $133 an hour, Kansas' expense was $100,000 plus. That's 10 percent, according to the paper, of their total expenses if they reinstituted the full training and travel of $1 million that was shown in the paper.

The question of interaction between NRC and the states. It looks pretty clear to me. Article G on 274 says that the Commission is authorized and directed, I emphasize directed, to cooperate with the states in the formulation of standards, to ensure that state and Commission programs will be coordinated and compatible. That compatibility program is the one that we would have to struggle with if these training fees and such are not reintroduced.

I think we'll still be able to provide safety for our citizens, but compatibility means, I need our

inspectors to go sit shoulder to shoulder with other state and other NRC inspectors and hear the same words.

Commissioner Betadikis, in her keynote speech to the All Agreement States meeting, provided several fine examples of that service by Agreement States, the NRC and the nation's citizens. I want to continue the excellent work in relation with the NRC that began in 1964 with Kansas becoming the ninth Agreement State. I trust the Commission will find a way to meet its own organizational goal to "meet our commitments, exceed expectations and do what is right." We in Kansas will do our part to help the Commission to protect all our nation's citizens from excessive radiation.

MR. CAMERON: Thank you very much. Any last comments before we -- Mal, did you want to say something before we go to Jim?

DR. KNAPP: Eventually I have a couple of questions that have surfaced from what I heard. But go ahead.

MR. CAMERON: Okay. Jim, would you speak, please?

MR. WILLIAMS: Jim Williams from State of Ohio. For a long long while, Ohio was not an Agreement State and has just entered into, has indicated its desire that we're investigating that process, primarily driven by

our position as a host state for a low level waste repository, which the state desires to license and regulate.

As a state from the Atomic Energy Act in 1954 forward, having over 1,200 byproduct material licensees, it was a significant chore to look at regulating and extending a bureaucratic setup to perform the Agreement State functions for all of that magnitude of a job.

Over the years, we've seen that number shrink from its 1,200 peak to about 750 licensees in terms of byproduct material that are licensed by the NRC. Notwithstanding the fact that the 450 that have gone down have left us a legacy of sites that have to be remediated and that are contaminated from the center of the City of Cleveland to slag piles in eastern Ohio.

There are a number of issues that now look favorable to Ohio to become such an Agreement State. However, when I look at the industry and Ohio just had a seminar yesterday with an update on where we are in terms of our efforts to meet the NRC's criteria for them to agree under 274 that, yes, Ohio could become an Agreement State, there's a tremendous amount of work that has to be done and presently vested with the State Department of Health, who will be submitting a written comment, Chip, to this particular DSI.

However, the Commission's feeling in saying, explore providing seed money or grants to encourage states to seek Agreement State status, it might be noted that in Ohio, users, the licensees, are paying dual fees now for a period of three years at about a 60 percent reduced rate. However, it's a double fee process for a period of three years to provide the state the ability to build up the capability and the staff within the Health Department to perform those functions of inspection and regulation that the NRC would expect an Agreement State to do.

Whether or not this process can go in three or four or five years as the time table expects, we're not really sure. But the lack of funding and the ability for a large state with multiple licensees that are almost a legacy from the NRC would certainly speak for an endorsement to have the NRC look at providing seed money or some type of incentive to the state rather than having the state have to appropriate that money or double fee the licensees.

MR. CAMERON: Okay. Thanks, Jim. That's a valuable input from a state that's considering becoming an Agreement State. And I think you were talking about star number two on the Commission's preliminary views, encourage more states to become Agreement States. But through non-monetary incentives. And what you're saying,

I take it, is that non-monetary incentives may not be sufficient or there should be some type of monetary incentive. Is that -- could you just clarify that for us?

MR. WILLIAMS: In the Commission's preliminary views, star number three, explore providing seed money and/or financial grants to encourage the states to seek Agreement State status is what I was addressing and which, you know, looks like a favorable position by the Commission to explore this. And it would certainly relieve a burden on the licensees in Ohio who are currently being double feed, and it would facilitate the state's advancement toward an Agreement State status in a more favorable time frame than three to five to six years.

MR. CAMERON: Okay. Thank you. I'm sorry about that. I guess that -- sorry for any confusion that I might have added to that. But I guess when I look at the second star, encourage more states to become through, primarily through non-monetary. And then the third star is, explore providing seed money. I guess that this could be looked at to be in conflict, I guess, unless you consider the fact that at least the Commission is saying, well, we'll explore the seed money concept. And you're supporting that.

And Mal, I don't know if you want to, in your points that you're going to make, I don't know if you want

to add any clarification for us on that second and third star. And then, we're going to go to Gordon Appel from the State of Illinois after you're done.

DR. KNAPP: I'm not sure that I necessarily can provide more clarification, but I can ask for comment, not necessarily here. Obviously, as you can see from the bullets, the Commission is looking for ways to encourage more states to become Agreement States. As you can see, they'd like to do it through non-monetary incentives, although they're considering seed money.

You mentioned a few minutes ago the difficulty that Ohio has in building up this body of regulation. When you make your final comments, if you have any suggestions in addition to seed money, where NRC could help. For example, there may be some sort of an assistance's role that we could take on working with you either in Ohio, or Washington. There may be things we could do that would make the job easier other than seed money.

MR. APPEL: When we got this DSI, we looked at that first option and said, well, they can't be serious. And then we said, well, I mean, they sent this out for review so they must be serious. So then we started to get insulted. And then we realized we shouldn't get insulted about things like this because they're asking us for our

comments. And we decided that what that really meant is that they were trying -- NRC was trying to tell Agreement States, we want you all to send your agreements back. We want to regulate all radioactive materials in the United States. And we realized that that probably wasn't the case either. And we finally figured it out, or at least I think I have.

And I think that was a message, you know, was kind of an inside NRC thing. And it was a message to Dick Banger, you know. Either get these guys under control or you're going over to the EPA. I don't think, I mean, the first option I don't think is a valid option for anybody. And I hope you take my comments in the sense in which they were offered. It just is not a productive option to consider.

But secondly, I wanted to -- earlier in the day you talked about public understanding of radioactive materials and things like that. And what NRC could do to improve the nation's understanding at a more fundamental, if not individual level, of radioactive materials and how helpful that would be to us all. And I'd like to just offer the suggestion that encouraging states to become Agreement States and supporting Agreement States is probably one of the most fundamentally constructive things the NRC can do in terms of bringing a base of knowledge

regarding radioactive materials down to a level that is accessible to the public in general.

We answer a lot of telephone calls on a daily basis from people who are obviously poorly informed about radioactive materials. We don't turn around and say, well, you know, that doesn't deal with one of our licensees so we recommend that you call the United State Nuclear Regulatory Commission. Here's the telephone number in Washington. We answer all those questions straightforwardly, and we, I think, provide a service to everyone in the nation. We, collectively, as Agreement States, because I'm not suggesting that Illinois is the only one who serves this function. There are lots of calls like that, and lots of issues that arise in state houses in Agreement States never get brought to the point of an issue that warrants legislative or congressional consideration, because there's someone in the governor's office who knows that they can call the Agreement State people over in the Radiation Protection Program and get an answer about whether or not the current, whatever the current hysteria is, whether it's medical or whether it's transportation or whether it's materials in general, they can get an answer from people who are knowledgeable, and the issue just kind of rests there then once the facts are known.

The third point I'd like to make about the Agreement States option is that we could all argue day-in and day-out, both NRC and the Agreement States, about who provides a greater service to whom. Being an Agreement State, of course, we believe that we provide the greater service. Okay? But all of us have examples of favors that we do for one another from time to time in an effort to regulate radioactive materials in this country in some sensible fashion.

The problem, and our particular problem, with the way the training and travel costs initiative was taken by NRC, and we understand the rationale that is given, how NRC's licensees don't want to be paying for us deadbeats in the Agreement States to do our job. We understand that. And we certainly would like to find another way. But the point is that we could have gone to Congress, NRC and the Agreement States, Illinois would have been happy to participate in that, I mean, if the problem is that the Omnibus Budget Reconciliation Act of whatever year it is that's the excuse prohibits you all somehow from funding Agreement States' training and travel, you could have come to Agreement States and said, look, we would like your assistance in going to Congress and explaining to them why it is necessary for them to perhaps fund some part of the Agreement State program. That could have been done

relatively easily. I'm not aware of any attempt on the part of NRC to develop an initiative like that with an Agreement States or more than one Agreement States. And now, you're going to find that, to a certain sense, we will end up in that position. This will end up being ultimately resolved if, for some reason, the previous policy on training and travel is not restored. I think ultimately we end up in Congress. Only in this case, the Agreement States won't necessarily be the allies that they could have been earlier on in this process.

MR. CAMERON: Thank you very much, Gordon. On that last point, that could still be an option, couldn't it? If the Commission wanted to consider that. So I think you -- okay. There is another option for us. And thank you for making that connection between public education discussion that we had this morning and a closer level of government on this. And I guess that I would say that Dick Banger, when you read this transcript, we hope you finally get the point. They haven't gotten it yet.

Do we have any further comments on this particular issue?

DR. KNAPP: I still had a question or two, actually.

MR. CAMERON: Okay. Good.

DR. KNAPP: Just areas where I'm not so much

seeking comments this afternoon, but I'd like to hear the comments eventually. With respect to funding, Agreement State training and travel to the training, I've heard at least informally that one of the biggest sources of difficulty in the Agreement States may not be so much the amount of money as the great difficulty that some Agreement States have in getting travel outside their state funded for any purpose. It's simply state law regulation or policy makes that extremely difficult.

I think if this is the situation, or the extent that is the situation, the Commission would very much like to hear about that. A recognition that this is not simply an equity issue but it's an actual doability issue for at least some of the Agreement States.

Another item I would be pleased to see addressed. We really haven't gotten to this afternoon, but it underlies some of the Commission's thinking. There is, of course, a close linkage between the Agreement States issue paper and the Materials issue paper. Specifically, if the Commission were to move strongly and actively to get as many states as possible to become Agreement States, then the Commission program would shrink a lot. Now, what we would do at that point is an area where we would be interested in your comment. I would suspect that we are not likely to see a day in the

foreseeable future when all states are Agreement States. The comments we've gotten from some folks on the IOM Report suggests that there are some states that will not become Agreement States, cannot, do not choose to do so, and have various small programs.

In the event that virtually all of the states are Agreement States yet there are a few left, then the question becomes, what is an effective and a cost effective way for NRC to deal with regulation of those. Any suggestions we have, such as ways in which Agreement States themselves might be able to assist in dealing with some of the non-Agreement States, if NRC were to go to a minimal program, because we had a minimal amount of licensees. Any suggestions like that would very much be appreciated.

At the moment, because we are not seeing all states becoming Agreement States, it isn't an immediate problem, but I know it's one that the Commission will think about down the road. So we'd appreciate your suggestions.

MR. CAMERON: Okay. Thank you very much, Mal. And thank you, everyone. Let's take a break. Come back at ten after three and we'll deal with the final paper.

(Whereupon a break was taken.)

MR. CAMERON: Okay, everybody, we're going to

get started with our last presentation of the day and this is the materials/medical oversight paper.

And we just remind you that tomorrow morning, when we start at 8:14, there are a couple of papers that deal with reactors. But there are two papers in that session tomorrow that are directly relevant to materials regulation and one is the Risk Informed Performance Base paper that Tom Hiltz, who is with us today, is going to be presenting.

And the second one that's a little bit further removed, but still relevant, is the Power Reactor Decommissioning paper. There may be things there that are relevant to material licensing, decomssioning.

So don't be discouraged just because it looks like reactors. It we do have some material, materials licensing relevancy there.

And Mal, I guess I would just ask you to do the last issues paper.

MR. KNAPP: The last issues paper. I feel like Johnny Carson and Ed McMahon.

Unfortunately, the last would really be tomorrow afternoon and that's when we will get the applause for wrapping it up.

MR. CAMERON: Unless you'd like to applaud now.

(Applause.)

MR. KNAPP: I will take that in the spirit that's intended, which is be brief so we can get to the discussion.

SPEAKER: No, get someplace else.

MR. KNAPP: Oh, somewhere else, okay, fine.

Okay. The issue here is what should be the future role and scope of our materials program and in particular, our regulation of the medical use of nuclear materials.

And the, obviously, any strategic assessment has a question like this in it. But in particular, this one was raised because of the controversy over exactly to what extent NRC should regulate nuclear materials and medicine and another of key factors.

The first one, which we always want to remember, is that the materials which we now regulate are those created or made radioactive by exposure to the radiation during the fission process. That is to say, we do not regulate NARM, we do not regulate x-ray, we do regulate linear accelerators.

The second bullet: There are opposing strongly held views of the regulated medical community and Congress and the media concerning the regulation of nuclear materials in medicine. There are and have been

people in medicine that believe that we are far too pervasive, far too prescriptive, that we interfere in the practice of nuclear medicine.

There are those in the media and in Congress who believe that we are not effective in providing the safety which is needed.

As a result of these differing views, among other things, some time ago, we asked the National Academy to take a look at our regulation of nuclear medicine and make some recommendations as to what should happen.

And they came back and in fact made the recommendations at least in part to Congress. That Congress should eliminate our medical use program. They would have us out of the business, they would have states regulate nuclear materials and medicine and they would provide, in their recommendation, through the Department of Health and Human Services, a sort of a leadership facilitator clearing house role on the part of the federal government, but not a formal regulatory role.

As we discussed in the last issue paper, a factor here is that as more states become agreement states, we will have fewer materials licensees and decisions that we make need to reflect those changes.

And finally, an ongoing process that we have called business process reengineering, an effort to try to

regulate more efficiently and effectively, is underway. Right now we are improving our licensing process. Once we've gotten further along with that, we'll be looking at our inspection process and others.

So these are the key factors that we think would, should be considered by the Commission and by you. With that in mind, the Steering Committee brought five alternatives, five options to the Commission.

One is to increase our regulatory responsibility. Take on the whole thing. Stick with what we have and then add to it NARM, x-ray, linear accelerators.

The second option: Continue the ongoing program, but again, as with the agreement state program, recognize that this is a program in change. We are doing the business process reengineering effort and we are examining our regulations to see how we can do better.

The third option: Decrease oversight of low risk activities, but continue to emphasize high risk activities. Now, I didn't say eliminate, I said decrease. We might look at such things as diagnostic nuclear medicine and perhaps no longer regulate it. We might do this with some gauges.

On the other hand, some gauges we might go from specific to general license or as we looked at low-

risk activities, we might find some that in fact were a higher risk than their current regulatory status might suggest and so, while we would pay less emphasis to low risk activities, we would do so with a careful check of exactly where the risk lies.

If we continue to emphasize high risk activities, these would be such things as fuel cycle facilities and large scale radiators.

The fourth option: Follow the recommendations of the National Academy of Science. We would discontinue our regulation of medical activities, with the exception of our oversight of device and pharmaceutical manufacturers.

Last: Discontinue the materials program. This is very much like the option that you saw as the last option in the agreement states issue paper. And it would follow a similar logic. That the states have the ability to do this kind of regulation and that it lies within the responsibilities the, the constitution generally provides to them.

As with the option, or with the other issue papers, these are broad options and they are in at least some cases provocative.

Given these options, the Commission expressed the preliminary view that they would like to continue with

the ongoing program, including the improvements the staff is now making. They would like to move in the direction of decreasing oversight of low risk activities and continue to emphasize high risk activities.

In making these decisions, they would use a risk informed to perform its based approach, to help decide which activities they would most like to emphasize and deemphasize.

Perhaps more than in any other issue paper, the Commission seeks comment from the public. We very much like to have the view of the affected organizations, particularly agreement states, CRCPD, and how we might best apply a risk informed performance based approach.

To elaborate that, on that briefly, a risk informed performance based might be a very good way to go in the case of perhaps fu l cycle facilities or broad scope licensees.

On the other hand, prescriptive regulation could very well be appropriate for licensees whose work is relatively simple and who may have limited means to comply, such as radiographers or perhaps some gauge users. They might they and we might be most comfortable with prescriptive regulation.

So we'd be looking for comments as, if we move towards risk informed performance based, where we might

most effectively do it across the spectrum of materials licensees.

On thought that was raised was without trying to get all states to become agreement states, perhaps we should strive to get states to become what amount to agreement states for medical use only. Interested in your comments on that idea.

Another question: Do you believe that a single agency should regulate radiation safety. Perhaps single federal agency might be a way to look at that question. Recognizing that now there is broad regulatory responsibility among a variety of agencies, including NRC, EPA, DHHS, DOT. Would it be better to have a single agency regulate safety.

And you could consider this question in two ways. You might have a single agency regulate safety, but perhaps not set standards. Or you might have a single agency do it all. For example, right now, EPA has the authority, responsibility, for setting generally applicable environmental standards. Perhaps all these responsibilities should be vested in a single agency.

Finally, we do have report in hand from the National Academy of Science Institute of Medicine. We put the information we have in terms of the conclusions that they reached in that report. Some concerns the NRC staff

has and the public comments that we had through about the end of August into an attachment to this paper.

We'd be very interested in your views as to whether that attachment reflects an accurate picture and in any case, whether you agree with the conclusions that were reached by the National Academy of Science.

That's the paper and the Commission's preliminary views and now with Chip's help, we'd like your's.

MR. CAMERON: Okay, thanks, Mal. Perhaps the best way to start this discussion and we can start it any way that you all want to. But how about the, the first star up there, applying a risk informed performance based approach to NRC's oversight of medical activities.

And keep in mind this doesn't have to be, your comments don't have to be exclusive to medical, but can be on materials regulation generally.

Who would like to start us off on this particular, particular issue?

Kathy? Okay.

MS. ALLEN: Kathy Allen from the Illinois Department of Nuclear Safety.

It's very difficult to argue with motherhood and apple pie up there. Yes, it sounds great to use a risk based approach for regulating radioactive materials.

Illinois strongly believes that you should not isolate out medical, that you need to approach this all across the board.

We're a little bit concerned that there is a pendulum affect that there are areas where the regulations are too stringent and too onerous. Maybe we've gone a little too far, regulating every nanicury and every, every atom out there.

But we don't want to see a knee-jerk reaction that brings the pendulum back and creates a bigger problem that five years, ten years down the road, we have a lot more work to do to get things back under, under some reasonable control.

The public is currently protected because there seem to be fairly reasonable regulations out there and radioactive material licensees generally try their best to comply with the regulations. We strongly agree with the ideas of eliminating duplicative or, especially contradictory regulations, creating some sort of uniform approach to regulations, updating the regulatory guidances, documents out there, BPR, the business process range nearing ideas and the information being presented through that group, about streamlining licensing processes.

We think these are fantastic ideas and this is

a good way to streamline the process and try and reduce cost associated with, with regulating materials licensees.

And also from the licensee standpoint, streamlining the process to get a license and maintain a good program. Gee, you know, where do you begin?

Is this, okay.

MR. CAMERON: Do you want to take a break?

MS. ALLEN: Yes. Does anybody else?

MR. CAMERON: I guess that if it's going to be, one of your points is that risk informed performance based approach is great, but it may be difficult to say any more about that until you know exactly what that, what that means. And I think Tom is going to be helping us with, with that concept tomorrow.

Do you want to say anything more about that?

MS. ALLEN: Sure. Sorry.

MR. CAMERON: This is, this is Tom Hiltz over here, for people who don't know him. From Nuclear Reactor Regulation Rights and he's going to presenting that, that paper.

MS. ALLEN: There's another aspect to the, this DSI. It talks about, when you're talking about risk based regulations and trying to cut back the regulations for some types of uses and gauges were mentioned in some discussions.

We want the Commission to look at option 3 very closely. A joint NRC/agreement state working group on devices recently made, reported that some of the problems associated with NRC's general license program had a lot to do with lack of oversight, inadequate control, poor accountability of devices and improper disposal of those devices.

A lot of that had to do with lack of oversight by the individuals using the devices, lack of oversight from the regulatory agencies and it recommends increased oversight of these devices, especially for certain categories of devices. Or possibly making a determination that there is a very low risk, move them to possibly an exempt-type status.

So we caution you to categorically say, well, there's other categories of users out there that we need to just drop the regulations off of and, and just treat them as general licensees. You need to take a look at the whole approach and role in some of the ideas from the working group concerning problems that have occurred when programs have been left alone and there's inadequate oversight.

MR. KNAPP: I think your point is very well taken. The Office Director, Carl Paparillo, and I share your concern about whether the current general licensee

program in fact fulfills what the NRC would like it to fulfill.

And we are pleased to have the working group results and your point is well taken.

MR. CAMERON: Okay. And let's continue on with this discussion. Keep in mind that we're not only talking about this first bullet where the Commission is asking for views of risk informed performance based approach, but if you go over to our options, the third option is decrease oversight of low risk activities with continued emphasis on, of high risk activities. And at least I read those, the option and the first question, as being a link together, even though they're not exactly stated that way.

Do we, Steve?

MR. COLLINS: Steve Collins with the Illinois Department of Nuclear Safety representing the Organization of Agreement States.

The Organization of Agreement States and the CRCPD both have already submitted comments that were virtually identical that Kathy Allen just presented, just so you're aware.

With regard to the decreasing of oversight on low risk activities and continued emphasis on high risk activities, some of the reasons that some of the low risk

activities are just that is because of some regulatory oversight. And Kathy has cautioned with regard to don't let the knee-jerk reaction go too far the other way is, is very carefully evaluate with your partners, the agreement states, in how you're going to deregulate any of these areas so that in fact we, we keep a few of the functions that are really needed, to keep them low risk.

So it's something that, the GL program and the working groups report, we think accurately, pointed out one area where you have a very low risk type of use of radioactive material that stays low risk until that safe or low risk source gets out of control and gets melted down at a scrap metal dealer. And all of a sudden something very low risk becomes something that's not low risk.

And due to the fact that it has been low risk for so long, NRC in particular, and some agreement states, have not tracked those devices well. And now the steel industry is paying for it and they're coming back and saying, this isn't right. You shouldn't be making us pay this cost.

And so the working group's recommendation that there is a need for some increased oversight, and particularly tracking by the regulatory agencies, needs to be brought home and this is one particular area where

there can be a lot of decrease in our regulatory activity. But that's going to have to be matched by an increase in certain other parts of it.

That increase can end up being a less time consuming and less costly thing after an initial year or two of getting the database in good shape.

MR. KNAPP: I think that's what we mean, or at least I hope that's what we mean by, when we say risk informed. We'd be looking not just say at the risk of gauges, but at where the risk of gauges occurs and then doing a performance based program so that we, we tackle the areas of risk.

Again, I think it's a good point and certainly would be our hope to consider these issues just that way.

MR. PANGBURN: George Pangburn, NRC.

When we were working on this particular paper and some others, we, and this maybe obvious to some of you, but Steve, Steve's comments and Kathy's are well taken because we recognized that if we made decisions, any decisions that we make regarding low risk have to be done very carefully. Because if we make decisions and remove controls from classes of devices or licensed activities, we have done just that. We have removed controls and we have to make sure that we're very comfortable with that. Because the consequences may not be ones that, that we

intended.

MR. CAMERON: Well, I was going to ask about the, I was going to move to the next star under the decrease oversight of low risk activities and see if anybody wanted to perhaps explore the relationship between those two stars or to just comment on the fourth star, period.

Yeah, Cheryl.

MS. SCHULTZ: Yeah.

MR. CAMERON: Wait until I give you the microphone here.

MS. SCHULTZ: I'd like to go ahead and comment again, as the RSO at Beaumont Hospital, which is the 6th largest hospital in the country right now.

And these comments represent the viewpoint of our hospital's administration, members of our radiation safety committee, our nursing staff, and the majority of our radiation workers.

And we support the IOM report and we also support the ACMUI recommendations that go ahead and address regulating all of radiation in medicine in a uniform fashion.

We believe this is in the best interests of our patients and we are very much interested in moving the whole process in that direction.

With that in mind, I'd like to address option 4, which is the option I'm here to say that we support. And that is to go ahead and discontinue NRC's regulatory authority over all medical use of byproduct material, to give the regulatory authority to the states, and to name another federal agency to provide a leadership role, as opposed to a regulatory role.

We also support that that federal agency be an authority on healthcare.

And on presenting this, I want you to know that we're also very aware of the impacts that were stated in the DSI, number 7 paper, related to unfunded federal mandates, the fact that the DHHS doesn't want to do it. And that we need to have some consistency of basic regulations.

So we see the problem with option 4 and yet we feel strongly that we need to stand up and say we are in favor of option 4.

Now, if you don't mind, I just want to finish saying the rest of my statement at this point. Which is, realistically speaking, if option 4 were not to come about, we would like to see, at a minimum, that the NRC would consider rescinding this fundamental 10th tenant that was included in the medical program policy statement of 1979, which states that the NRC has a commitment to

protect the patient from the use of radiation in medicine.

We feel this commitment is in conflict with the goal of the use of byproduct material by physicians in both nuclear medicine and radiation oncology where they're using the radiation to diagnose, treat, and cure our patients.

It is our belief that this commitment and this policy statement has led to regulations that are costly to comply with, burdensome, overly prescriptive, and intrusive into the practice of medicine.

We strongly believe that patients should not be regulated as members of the public and they should not be considered essentially as part of the regulatory group, if you will.

So that's, that's my take on option number 4 right now. I could go on and say the rest, but maybe I'll wait till later. Let somebody else say something.

MR. CAMERON: Thanks, Cheryl. And we will give you a chance to say the rest.

MR. KNAPP: I just, I would have two questions. You don't need to answer now, but in your final written comments. I think the Commission would be interested.

In view of the fact that DHHS does not appear to want the role, any comments you have on, for example,

well, they may not want it, but let's have them do it. Or if you have an alternative agency you would like in that role.

Second, your views are rather strongly opposed by a couple of non-agreement states who do not want the responsibility. Any suggestions you have as to what would be a good way to deal with those concerns would be very much appreciated.

MR. CAMERON: And I guess I would have one question for you, Cheryl. That if you could try to answer now, it might --

MR. KNAPP: You may need to give her 30 seconds on, we'll overwhelm her with questions.

MR. CAMERON: Okay.

MS. SCHULTZ: -- the second one --

MR. CAMERON: The second question is?

MR. KNAPP: The second question, one of the concerns that I have in looking at the overall issue of following the IOM recommendations, is that among the public comments we've received, there are one or two states who have been adamantly opposed on the view that they do not have, whether it's the money, the will, the competence, to take on that responsibility.

One of the things that I think the Commission will find very important is this concern about having a

few states or a few segments essentially unprotected. Now, I wouldn't suggest that they would be unprotected, but because of this concern, any views that you have that would alleviate that concern and yet still implement option 4 would be a help.

MR. CAMERON: I think she's going to try to give you some answers to the second question now.

MS. SCHULTZ: I think I'm in one of those states. Michigan, for example, does not have the will to become an agreement state.

But I believe that Michigan has the will to go ahead and regulate all medical use of radioactive material. Because they already have regulations in place and I think the problem with Michigan's reluctance is related to the fact, much of what the man from Ohio was describing, which is this process that the state has to go through to become an agreement state.

I think if you were going to consider the recommendation of the IOM, which is transferring that authority to the states and then allowing the states themselves to go ahead and come up with their own plan of regulating. And one of the incentives that was presented in that report was tieing this together with reimbursement for services.

I think you would see Michigan willing to take

up the moniker of regulating all of radiation in medicine in Michigan. Without the process of going through the agreement state.

MR. CAMERON: Okay. And let me ask you one last question and then we'll give you a break.

To try to get to the underlying rationale behind recommending the discontinue regulation star.

If the NRC in concert with the states perhaps undertook an activity to perhaps not rescind the commitment in the policy statement that you talked about, okay? But if they, if they undertook a look at the medical regulation area from the low risk standpoint and maybe that would sweep in the, the commitment.

If, if something was done in that area, would you still support star number 4 as your primary option?

MS. SCHULTZ: Very cleverly worded. And actually that is our fall-back position.

Absolutely. We would very much support, as opposed to option 4, the notion of a combination of option 2 and 3 under the following conditions.

That would be that the NRC rescinds the medical program policy statement of 1979, rescinds parts of 10CFR, part 35, specifically the quality management program and the definitions related to the word misadministration. And also, training qualifications for

the physicians.

MR. CAMERON: Okay, good. Thank you, Cheryl.

How about some other, other people on this issue? Mark?

MR. DORUFF: Mark Doruff with Amersham Corporation and counsel on radio -- and radio pharmaceuticals.

While we support the concept of decreasing regulatory oversight for low risk activities, as outlined in option 3, we also recognize the need, the needs of our customers in diagnostic and therapeutic medicine to get some relief from the, from the regulatory oversight of NRC and medical use.

However, we believe that the approach proposed in option 4 is, is a bit extreme and for a number of reasons, we don't necessarily, or we really don't support that the NRC regulation of medical use be totally deregulated.

We believe that that would result in a number of logistical, significant logistical problems for the manufacturers and distributors of these products. And I, I think what we would like to recommend at this time is an enhanced participatory rule-making be initiated to resolve the issue of regulation of medical use and involve all the affected parties in this rule-making process to try and

reach a reasonable, logical consensus on the issue.

MR. CAMERON: Okay. Thank you, Mark. We'll go to Kathy Allen.

MS. ALLEN: Kathy Allen from Illinois.

In addition to Mark's comments about the enhanced participatory rule-making, we would also like to see some sort of white paper or some sort of document describing the jurisdictional boundaries for NRC and FDA and what each entity is responsible for regulating and especially concerning where the practice of medicine falls.

When you look at a medical device, there are certain areas that NRC evaluates and FDA evaluates and it's not really clear, or that that there's a gray area between NRC and FDA as to who's looking out for what areas. And I think if it was very clear as to what FDA's role was and NRC's role and the jurisdictional boundaries regarding medical use of materials, I think that would be very helpful.

MR. CAMERON: Thank you, Kathy. Mal, do you have anything to say on that?

MR. KNAPP: I note that's a good point. I believe that our relationship, obviously NRC has relationships with a variety of agencies, including FDA. Some are a little rockier than others.

I think right now we've got a pretty good relationship with FDA and I'm trying to recall whether we have an MOU in place. Claire tells me yes, we do have an MOU in place.

I think that it would be worthwhile to make sure that if that's not available as publicly as it should be, it will. I'd like to think that information is there and we'll try to provide it.

MR. CAMERON: Okay. We're going to go over here.

MR. RONNIGEN: I'm Reg Ronnigen from Michigan State University, but I'm with the National Super -- Encycletron facility there.

I wanted to make a comment about accelerators. This is a, if the NRC goes in some of these directions, this will be quite an endeavor because, well, first of all, it impacts, if you regulate accelerators, there are DOE accelerators and we have a big one in this area here with Fermilab that would come under this particular topic.

And which I think in part that would be a good thing. Have that outside oversight say of a DOE facility. I'm kind of in favor of that.

For one thing, is, this would give us a common language in which to talk. Like our laboratory is quite a bit smaller than that, but laboratories have to constantly

evolve over time to exist and we're always in a constant state of construction, it seems. And we rely on external organizations and people from Fermilab in particular to provide us with some insight and expertise and how we should go on in the future. And it would be really nice if we could all talk the same language in talking over the issues and how to develop a safe program as we progress.

Also, I want to point out that accelerators in medicine is a whole different, that's a whole different ball game. There's more and more accelerators being used in medicine as, say direct therapy machines. And they carry with them all of the problems of that other research accelerators have. Doses to personnel, potential for contamination, activated parts either being, or neutron activated parts, and waste. And eventually decommissioning.

So there are a lot of issues that are involved. Especially one has to think about that and I think I agree with some of these comments, one has to carefully draw the line where medical stops and other things should be taking over.

MR. CAMERON: Thank you, Reg. Mal, do you have any comment on that?

MR. KNAPP: Only that I appreciate the comment very much.

The, you know, we have had a number of comments in the past that we should expand into the area of NARM. The possibility of looking at accelerators is one that I'm happy to get any public comments on because I have no idea where we'll head, but we'd like to get a sense of the public's view of accelerators. Or for that matter, x-ray machines.

So thank you.

MR. CAMERON: Reg, are you, who are you regulated by now?

MR. RONNIGEN: Well, it's the State of Michigan. But they are rewriting their particle accelerator regulations currently.

So, it's, it's an evolution process. We're, they're good, but right now they're based more on like turn-key accelerators. And for a large laboratory, it's a little bit more difficult to, how to really implement those regulations in terms of current state, state-of-the-art accelerators.

And then for, of course, the, for byproduct material sources and things like that, CNRC. And Kristin provides our oversight directly.

MR. CAMERON: Okay. Thank you. We're going to go to Kristin and I guess everybody, Reg just sort of moved us up to looking at the, the first option there.

And we'd like to get some viewpoints on that. Kristin?

MS. ERICKSON: I'd like to add some continued comment on accelerator-produced regulation.

As the radiation safety officer for the broad license and our large accelerator, which runs around the clock. 200 employees, 365 days a year. And we have some actual real radiation risk there.

As an RSO, it was a tremendous difficult challenge coming on-line and trying to implement a program because they kind of fell through the cracks. Although the State was the regulator, they don't really have the staff, or in some cases the expertise, to regulate this big, huge machine.

And in order to do it, what I basically did was I chose and convinced Reg and their, their uppers, to go along with this, is that we chose to use NRC law for the whole place because it was the most uniform, because those requirements and the way that they were written were able to be developed and modified and, and you know, in some cases fine tune to work for even that facility with all the varied things that go on there.

So even though most of it is not NRC regulated, we elected to do that and it's working very well.

So, I, my comment would be that I think we

should have the NRC overseeing accelerator-produced radioactive materials.

One other little fine thing that falls through the cracks, which was a funny little chuckle between region 3 and ourselves, is the isotope P33 is now common molecular biology isotope and at the time fell through the cracks because it was accelerator produced. And we again elected to use NRC requirements. Because you'd have one set of things for one isotope in the lab and all the others were another.

MR. CAMERON: Well, thank you. It seems there is some support here for, for option 1. And let's keep, Mark, do you want to comment, comment on that or comment on something else?

MR. DORUFF: Mark Doruff, Amersham and CORAR.

I would like to comment on the issue of NARM and regulation of NARM materials by NRC.

We believe that one federal agency should regulate both NARM and byproduct material and we believe this agency should be the NRC.

Amersham currently has five operating commercially producing cyclotrons in the U.S. Two, two of these are located in a, in a non-agreement state, New Jersey, three are located in Illinois. And again, we believe that NARM should fall under the purview of a

single federal agency, being the NRC

And we also would be in favor of a single standard-setting agency, an independent advisory group, to, to recommend standards of radiation protection and regulation for both NARM and byproduct material.

MR. CAMERON: Okay. Thanks, Mark.

Kathy, did you want to, George, do you have a clarification you want to put in on that first?

MR. PANGBURN: Mark, I was wondering, did you mean the same agency should be standard setting, or you wanted a separate agency that would be standard setting?

MR. CAMERON: Do you want to answer that for the record?

MR. DORUFF: A separate standard-setting agency, apart from NRC.

MR. CAMERON: I'm glad you gave the same answer. That's fine.

Kathy?

MS. ALLEN: Kathy Allen from the Illinois Department of Nuclear Safety.

We have, we have gone on record as, as also supporting NRC's idea, sorry, we agree with the idea of NRC expanding its regulatory authority under the AEA to cover all forms of ionizing radiation.

We recognize that this a major undertaking and

the DSI in fact mentions that it would take several hundred FTE's to regulate NARM. We take issue with that estimate of number of FTE's. I think if you ask the agreement states if we have used that many FTE's to regulate NARM and I think we can tell you, it doesn't take that many.

You have I125 and I123, they're fairly similar, it doesn't take much more effort to regulate the accelerator-produced I123 than it does the I125.

I think this also ties in with some of the other DSI's you have. There was the discussion about regulating DOE and other people have eluded to it also. I think if NRC were to actively look at the possibility of regulating, possibly beginning with discreet NARM, that puts you in a position so that if you are mandated to have oversight of DOE facilities, that's that much less effort you have to put in at that end. You'll, you'll be in a position to accept more responsibility for the other DOE activities.

I do have to put in a plug for agreement states, we do have areas of expertise. Almost all the other agreement states also regulate NARM and we have always been willing to offer our help in developing these types of regulations.

MR. CAMERON: Steve.

MR. COLLINS: Steve Collins with the Illinois Department of Nuclear Safety, also.

With regard to that one single federal agency having oversight over all forms of ionizing radiation, that does come with a qualifier that the NRC needs to recognize that the agreement states already have comprehensive radiation programs that cover all of those things and in the event that one single federal agency, the NRC or any other, in fact does achieve that responsibility, don't mess our programs up. We're in good shape, don't tinker with it.

Your authority would not interfere with what's already there in the states, but it would basically provide that same coverage for all federal facilities and in non-agreement states where that program does not necessarily exist.

MR. KNAPP: Thank you for the comment. I had two things I wanted to mention.

With respect to the concern about several hundred full-time equivalent FTE, you caught what should have been an editorial mistake in the paper. It was our intent to include the potential for x-ray and linear accelerators and somewhere along the line in the editorial process, those words got eliminated and it just dropped down to NARM.

So, that, we would agree with you. Based on the text of the paper as written, your comment is entirely correct and I'm sorry about the error.

I have a, I have one question for Mark and it may not be convenient for you to answer it here.

You would recommend that there be two separate agencies. One, I believe to set the standards and one to implement. Are you in a position to expand on the rationale for why that would be superior to have one agency do both?

MR. DORUFF: Well, it's our understanding that NRC cannot establish standards. I mean, it's generally the role of the scientific organization, such as NCRP and ICRP to recommend standards. However, their position is they can do, they really cannot take the role of, of moving those standards toward regulation. There seems to be a gap between the role of setting the standards and the role of regulating the licensees and the uses of radioactive materials in accordance with the recommendations of the scientific groups.

So, I don't know if that answers your question, but we, we believe there needs to be separation between the agency that is enforcing regulations and the agency that is establishing standards for the regulatory agencies.

MR. KNAPP: Let me pursue it just a bit.

Right now, for example, in some areas, we have a relationship with EPA. Where by law they set generally applicable environmental standards which the NRC then implements. And it sounds like you're endorsing that kind of an approach.

In other words, NRC would not be in a position to set standards. Another agency such as EPA or DHHS would set the standards and NRC would only implement.

I want to make sure that I clearly understand and that the record clearly shows, I see by your nod that is what you would intend.

MR. DORUFF: Yes. That is our intent; however, we do not intend at all to recommend that EPA be involved in this process. Either in a regulatory capacity or in an advisory capacity. I'm glad I had the opportunity to put that on record.

MR. CAMERON: Let me put one more nail on this.

You're going on the assumption that the NRC could not set the standards. If the NRC could set the standards, then would you support the NRC as a single agency to set the standards and implement?

I don't know whether your recommendation is based on what you perceive as a lack of legal authority on

the agents, on the NRC's part.

MR. DORUFF: I think you also have to consider the fact that the NRC would, is not the only regulatory agency in the States and that with the agreement states, I would assume that there would be a need to be an independent advisory authority, in addition to these regulatory agencies.

MR. CAMERON: Okay. So it's a larger issue.

Steve?

MR. COLLINS: Steve Collins for the Organization of Agreement States addressing that same question now.

What's been recommended and is being worked on by working groups of the concentration of controlled program directors, is that an independent body, through the conference of radiation controlled program directors, be established that would have as its, almost its sole role, developing model regulations, with the involvement of all the stakeholders and all that sort of thing.

So that all of the regulatory bodies that have to establish standards in fact work together with the stakeholders in developing a model rule that is basically agreed upon and then each state and the federal agencies that are appropriate, takes that model rule back and they all start with the same process to go through their rule-

making process.

So it is in fact, I'm not sure independent is the right word, but it is a separate body that has as its task for this shared working relationship and shared expense of developing the model regs and the policies and the guidance documents that all go along with that, as well as for the regulatory justification that's required.

And then since each state in the NRC right now has to go through its own rule-making process, it would do that as a separate part.

So that is some separate agency thing. But it would work more along the lines of the way the current U.S. Pharmacopeia works. Where they developed basically a model rule or something that's then adopted by their appropriate agencies for use.

MR. KNAPP: Thanks for the clarification.

MR. CAMERON: And does that clarify everything for you, Mal, on that issue?

MR. KNAPP: On that issue, yes. Thanks very much.

MR. CAMERON: Okay.

MR. KNAPP: I appreciate the responses.

MR. CAMERON: Jim, did you have something you wanted to add?

MR. WILLIAMS: Jim Williams from Ohio.

I, I would think that this discussion might harken back to pre-1974 concepts where NRC did it all. AEC did it all and it was determined that AEC couldn't regulate, develop, set standards, and do the whole package.

Therefore, the Nuclear Regulatory Commission was founded and the Energy, Research and Development Administration, and et cetera, et cetera, to down to the DOE, divisions were developed.

So I don't think you would want to go back to that concept where NRC was setting standards and enforcing and regulating, because it seems like that's a regressive step.

MR. CAMERON: Okay. I think before we turn to, well, George, why don't you make your statement and then I'm going to ask Steve Crockett of our office, a general counsel, to just clarify what the legal framework on this. Existing framework.

MR. OLIVER: George Oliver, a medical physicist working with the Unity Health System in St. Louis.

When Mark made his statement a while ago, I heard something different, I think, than what was expressed by several people.

I heard him reference the ICRU and the NCRP.

These, in my point of view, are standard-making bodies that use scientific fact, social relevance, ethics, and other factors. They are the kind of societies, technical organizations, perhaps, that make standards.

I would argue that agencies make standards. I think agencies regulate limits and I see a very distinct difference there.

MR. CAMERON: Thanks, George. You just made Steve's job a little bit tougher, I think.

Steve, do you want to try to give us a framework here?

MR. CROCKETT: I hope I don't confuse things further than, maybe all the confusion is in my mind.

But you do raise some very interesting questions here about the degree to which standard setting and enforcement authorities should be separated.

I should say right now that my own understanding of the law is, and I think Chip would probably agree with me here, the NRC and the AEC before it had the power to set standards and to enforce them. And when the NRC was, when the regulatory part of the AEC was split off and, and formed into the NRC.

The separation they were trying to achieve there was not between standard setting and enforcement, but between regulation and promotion.

Now, I'm not, I'm not trying to say that it wouldn't be a good idea, perhaps, to separate standard setting from enforcement. After all, the design of the federal government itself and the design of most state governments begins with the idea that the standards are set in the legislature and they're enforced by the executive branch.

But I wasn't sure that anybody here was proposing that radical notion of separation of powers.

The sum of what I've said so far is, we've got the regulatory authority to set the standards. But I think what you're proposing here is that when we go about that, or at least the message, the strongest message I'm coming away from this discussion is, when we go about setting those standards, we ought to be looking to a body, to bodies that have always been recognized as being, I don't want to say merely advisory, because they're really much more important than that.

But they are professional bodies that have continuity, they have the knowledge, and they have looked at these questions over and over again.

You saw in one of the earlier direction setting issue papers, a proposal that the NRC encourage even more such interaction with such standard-setting bodies and there's no reason that shouldn't be seriously

considered in the medical area, too.

I'm coming away with a sense not that you're proposing that our legal authority to set standards not be exercised, but rather that in the exercise of that authority, we look to the many sources of expertise that there are in the professional bodies and in the states.

Is that a fair rendition of at least what some of you are saying?

MR. CAMERON: Let the record note that two of the previous commenters are shaking their head affirmatively in response to, to Steve's characterization. Thank you, Steve.

Frank?

MR. MIRAGLIA: Frank Miraglia, NRC.

Primary out of the reactor area and I think we have an analogy that we could use in terms of codes and standards, we heavily rely on codes and standards by societies, the ASME, and those things.

I think the agency, NRC, traditionally in terms of radiation protection, has always looked toward the NCRP and ICRP as the technical and acceptable base to which to endorse standards. And I think that's what Steve was just eluding to and I was just going to point that analogy out, but Steve covered the territory very, very well. So I just wanted to add that as an observation.

MR. CAMERON: Thank you, Frank.

Since we've been really riding this horse of option 1 here on the NRC assuming regulatory authority for NARM, I guess I would like to ask you, first of all, whether anybody has a different perspective on whether the NRC should regulate NARM and for those of you who are recommending that we do that, since we don't by and large have authority for it now, and never had authority for it, how, what would be the mechanism for NRC to assume authority over NARM?

Is there any, any other perspectives on NARM and second of all, what would be the mechanism if we do try to go after it?

I won't take the silence as the fact that everybody thinks we should go after NARM. But, we're not hearing any other views, at least at this meeting. How about the mechanism?

Do we, Gordon, do you want to say something on this?

MR. APPEL: I sort of came in in the middle of this. I mean, if you want to be, if you would like to hear the opinion that, from someone, or a state that believes that you should not regulate NORM, Illinois clearly believes that you should not regulate NORM and NARM. That's the state's prerogative and it should be

left there.

That's all I have to offer.

MR. CAMERON: Okay. And I'm not, I wasn't trying to force any other perspectives out on this issue, but it sort of leaves us with an interesting dicophane.

But, I guess we're done with, I guess that, that's the end of the NARM discussion, unless someone else has something else to say on that.

Yeah, Kristin?

MS. ERICKSON: I have one quick thing to add to this. This is in addition to Kathy's comment that it was very simple and I maybe gleaned a little uncomplicated, to regulate these things and I'm going to disagree wholeheartedly. It is not simple to regulate an accelerator. There are far more than a couple of isotopes, there are far more risks and unpredictable situations of every type. Every type of radiation, alpha beta gama neutron.

Energies and isotopes which you've never heard of. When I do a wipe and put it on the gama spec, I see isotopes none of you have ever identified. We created something like 60 new ones a week or two ago.

And these issues, the hot parts, the hot equipment, the maintenance of these machines in particular, poses risks that I think most, most people who

don't deal with these machines are aware of. And can, and in fact, our State people are not aware of, they're learning together with us. We bring them out and work together to show them on site what happens.

So I think this is something that should be brought to the attention of the NRC that it isn't going to be a simple little thing, that it will take staff, but it certainly can be done and it can be done well within the framework of the NRC regulations.

So I still support that they would, that they would oversee and regulate. I think they're the best agency.

And finally, I want to comment on whether we have one agency for all things. I would be thinking I died and went to heaven if we didn't have five or six or seven different agencies regulating us with different rules. DOT now wants us to use international units and NRC, of course, is on old special units.

All the way across the board we have different agencies telling us different things and then they change them all the time. And that's tough. We'd like to see one agency or at least a complete consortium memo of understanding between all the agencies and they agree on how they're going to do it and do it the same way.

MR. CAMERON: Go ahead, Mal.

MR. KNAPP: Just as a little bit of a side bar, the federal agencies, with some help from the State Observer, Bill Dornsife, are trying to harmonize risk and harmonize in a number of ways the way we work.

Any comments, not necessarily on this DSI, but on the subject in general, such as difficulties or contradictions among agencies. Certainly if you would send them in and, because I'm a participant in that group, you can send them to me and we would try to, as we have resources available, consider them and try to make life easier.

MR. CAMERON: And I would just add on that either for now or when you submit a comment, if you do support the NRC assuming regulatory authority for NARM, if you could provide the rationale, whether it should be national uniformity or to fill gaps where some states are not regulating it now, or whatever the rationale is. That would be, that would be helpful for us.

Cheryl, you said that you had some other stuff that you wanted to, to say. I shouldn't characterize it as stuff, but do you, do you want to give us a few more comments?

MS. SCHULTZ: Not, I'm not completely satisfied with what I said and I was curious if anybody else in this room, I'm curious if anybody else in the room

appreciates the point of view that I presented about the regulation of radiation safety for patients.

MR. CAMERON: That's, that's a good, good question and it takes us back to some of these other options and the Commission's preliminary views.

Do we have, do we have some comment for Cheryl on, on that issue of, I don't know if I, do you want to quickly characterize that again? That patients shouldn't be treated as members of the, of the public. Why don't you continue?

MS. SCHULTZ: I just feel that from our hospital's point of view, that there is a conflict related to the fact that we have regulations out there that are specifically directed toward radiation safety of patients.

And the conflict comes in when you consider the fact that the patients are coming in specifically to be treated with radiation. And so all those regulations cause conflict between the practicing physicians, the healthcare workers at the hospital, and the NRC.

And I think we go a long way if we could resolve that issue because really, we've had a very excellent with the Nuclear Regulatory Commission over the years, we have a very good program. And I think the NRC does a tremendous job in what they're doing.

But I certainly appreciate the physician's

point of view as new modalities come up. It's very difficult for us to get approval for some of these procedures. The patients are lined up at the door, they're waiting for these things to be used.

And we need to work together to be more, if you're going to regulate the patient in radiation safety, you need to be more attune to the patient's needs.

And I do think there is a point you can make of separating medical use of radiation in the direct patient care environment from all these other issues. I think there's, you can make a very strong case for that.

And I think that's what the National Academy of Science recommendation was about. Was getting toward that. Achieving that goal. Of recognizing it's different when you're a patient.

Okay, now, as far as our workers in the hospital and as far as the rest of our program goes, we would of course want to continue to comply with the regulations.

But I guess that's just the point I was trying to make is, and get your opinion on this. What is the goal of regulating radiation safety for the patient?

MR. CAMERON: Okay. That's, I think, a question that goes to the root of this and does someone want to give an answer or their viewpoint on Cheryl's

question?

I don't know if Mal, if you want to jump into that right now or not. If you feel inclined, go ahead.

MR. KNAPP: I rush in where angels fear to tread.

I think our view in patient, taking care of the patient, is in the event that we would have a, you know, significant, I mean, let me back up.

Obviously we're not trying to limit the patient's dose to the dosage you have from an average member of the public. Obviously you're right, they're in there to be treated and we don't want to interfere with that at all.

I think the question arises as to when there is what we might call a gross misadministration. A physician prescribes 2000 RAD and maybe the physician has in mind, well anything greater than about 1400 or less than about 3000 is probably about right because of their understanding of the impact of the radiation. And then we have a patient that as a result of an error, gets 2000 RAD. Unfortunately, they give it to the wrong patient.

Is this other patient a member of the public? Because this person didn't come in to get radiation treatment at all, yet because they messed up the tags, that happened.

I think that's at least a part of the concern we have.

MS. SCHULTZ: That's a valid concern, but certainly, when you look at the use of radiation in a hospital setting in a direct patient care setting, there really isn't very much difference between that kind of an error or a chemotherapy error, or a pharmaceutical error, and all of these are handled much differently, without a Nuclear Regulatory Commission in, gaining access to patient charts that are patient privacy, and making sometimes decisions or recommendations that I believe, and the hospital believes, are inappropriate in that setting.

And certainly reporting a misadministration, first of all, the word misadministration is very disturbing. And it's, it's a very big problem when you have a patient that's being treated, for example, for cancer, and that patient inadvertently loses the source, whether they pull it out or it falls out by some process, this then has to be reported as a possible misadministration.

When you get into the whole process then, it becomes extremely difficult dealing with that patient, the patient's family, trying to describe to this patient, well, we're reporting this to you because an error was made and the error happens to be called this word,

misadministration. And this is very disturbing to the patient.

And it's a gray zone we're required to report, regardless of whether we know it was a patient-related incident or not. And I really question the need for this. And the word misadministration should definitely be thrown out and another word should be substituted. Because it is misleading and disturbing to the patients.

MR. CAMERON: Okay. Thank you, Cheryl.

MR. KNAPP: The problems you raised are ones that trouble us a great deal, too. And whether or not misadministration is an appropriate word is certainly a question we are asking ourselves.

I guess I would ask in the comments, you mentioned it was a gray area. Any particular place where you think it would be appropriate for the NRC to draw the line, we'd like to hear that. We know about the concerns of the various sub-parts of part 35 and what we're looking for is, where do we strike the right balance between appropriate protection and interference unnecessarily, interference which causes anxiety inappropriately.

So, yeah, we'll be very pleased to hear your comments.

MR. COLLINS: Steve Collins from the Illinois Department of Nuclear Safety.

Illinois agrees with her comment or concept that when the patient, particularly a therapy patient receives the wrong dose to patient's intervention by patient accidentally or on purpose removing the sources, and we do not classify that as a misadministration or the better term that we use, reportable event.

MR. CAMERON: Thank you, Steve.

Now, Kristin.

MS. ERICKSON: This comment is going to come from me as a citizen and a member of the public and a former patient.

I had malignant melanoma 18 years ago. At the time I was breastfeeding my daughter, who is now 18. I had the whole nuc med procedures afterwards. At that time the regulation wasn't as strict as it is now, there wasn't as much QAQC or training or anything else.

After the procedure, I knew a little bit about radiation, I said, well, now, I shouldn't breastfeed my daughter, should I? And they said, oh, go ahead. Don't worry about it.

Well, I didn't. Because I happened to be educated enough to know better. What shocked me, and this was a reputable, fine hospital in the Ann Arbor area, not U of M.

The thing was, I thought about all those

members of the public who don't know anything about radiation or about medicine or about any of those things, who went ahead and did feed their baby. You know, these are things that today now I look at this in retrospect and think, now, if we scale back, as a citizen and a member of the public in this comment, I'm saying this is something we really need to look at carefully.

There are still big issues and I hear a lot of RSO's complaining that the big broad licensed institutions about the M.D.'s who absolutely refuse to cooperate in any shape with radiation safety regulations as they exist. Whether they're the state or the federal regulations. They have trouble with these guys, some of them refuse to wear their badge. Some won't badge their students who are in the room. And they're battling these people a lot. They don't want to clean up a contamination.

They, they all believe that they're above the law and that isn't every doctor or every institution, but it is something of a problem and my concern, both as a citizen and now as the RSO, is to say that if we take away any regulation at all, then the institution, the safety managers, have no teeth whatsoever. No clout, no means other than please do this. It's a good thing to do or I want you to do this or it's the right thing to do.

So this is something that if it were to

happen, I would recommend that we continue to strive towards less regulation from looking again at the risk based approach. But not to completely remove the regulation from medical. Any more than we would from other radiation safety things.

If we're going to think about adding more regulation and oversight to things like NARM, contaminated sites, decommissioning, we're even looking at some natural things now. Why would we suddenly say that only one part of this shouldn't be regulated at all?

So that's the comment I have.

MR. CAMERON: Thank you very much, Kristin.

Steve?

MR. COLLINS: Steve Collins with Illinois Department of Nuclear Safety.

As a person interested in writing regulations that are appropriate to the need and the risk and all, I would be interested to know if she had any suggestions with regard to, does she think, as the former patient and concerned citizen, and a mother, that it's appropriate for a occupational radiation protection setting agency that's also interested in public health and safety standards being set. Is it appropriate for that agency to be the one that sets the standards that protect the patient and the unborn child? Or would that be better regulated by

someone else who regulates the rest of the practice of medicine?

My, my view is that comes under the practice of medicine area and they should have been more careful to be advising you properly. But it's not the radiation protection program for the state or the federal agency that's involved. Mostly in worker protection and in protection of the public from effluence basically.

And that, agencies with that expertise basically shouldn't be meddling into the board of medicine or board of pharmacy type areas that are more appropriately regulated there.

So if she wishes to make any comments with regard to what she feels is most appropriate there because of her technology expertise as well as the other experience, I'd like to know.

MR. CAMERON: I think you are going to get a response.

MS. ERICKSON: Your point is really well taken. And looking at it from, like I'm saying, many angles now, I do believe that the medical people should regulate these things. They should make these decisions. But so many times, there are M.D.'s and medical people who are so unfamiliar with radiation and its risks, its effects. I have the most ridiculous questions come to me

from even M.D.'s, veterinarians, patients who have been told something by an M.D. They are not getting good education in these things.

And until, I mean, that is, again, it isn't every M.D. or every veterinarian, or every medical practitioner. But until we have better education in these areas for these people in radiation protection, that I think that it should be done in tandem with some outside assistance, oversight, or spot-checking, something or another, so that we aren't just totally pulling out.

If we do that eventually, that's a good goal and I do think that the M.D.'s and the medical community should regulate these things. I think they can do it. But until things are in place, I think there's got to be a joint effort.

MR. CAMERON: Okay. Now, this has been an interesting discussion and I guess the last of the exchange between Kristin and Steve raises the issue of perhaps there's another way to try to, to regulate or guide the practice, rather than vary prescriptive regulations to try to ensure that the people who regulate every other aspect of medical care at the hospital are indeed knowledgeable about that.

I mean, there's other options besides prescriptive regulations.

Cheryl, you started this off, do you, do you have any final words on this? Or any last words?

MS. SCHULTZ: I just can't wait.

No, my final word is that I am very impressed with the radiation safety program we have at our hospital. As I said before, we're the sixth largest, but we actually have two hospitals and several off-site facilities.

And we have a very dedicated radiation safety committee and these members of this committee have made the commitment to have one unified radiation safety management program for our entire system. And this is working extraordinarily well and what this is means is we have uniform-type of rules, procedures, for all radiation workers, regardless of whether they're working in the radiology department, therapy, out in the research labs, what have you.

And the physicians are very cooperative. They are very knowledgeable, we have an excellent training program. And in our little cosmos, if you will, I see that we actually could serve as a little bit of a model for this idea of unifying, if you will, in medicine the regulation of all uses for the express purpose, which is the benefit of the patient.

And that's all I really wanted to say.

MR. CAMERON: Okay. Well, thank you very much

and thank all of you. That was a very thoughtful and constructive discussion on a number of complicated issues.

And Mal, unless you have any final things to say, I guess we can wrap up and be back here at 8:15 tomorrow. Mal? Go ahead.

MR. KNAPP: Only comment, I'm not sure whether it's the timing or the people but this is one the most effective discussions we've had. Thank you very much.

(Meeting adjourned at 4:32 P.M.)

C E R T I F I C A T E

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

Name of Proceeding: STAKEHOLDERS PUBLIC MEETINGS BUILDING PUBLIC TRUST AND CONFIDENCE

Docket Number: N/A

Place of Proceeding: ROSMONT, ILLINOIS

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

Ron LeGrand

RON LeGRAND
Official Reporter
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