# Official Transcript of Proceedings

DSI 03
2

# NUCLEAR REGULATORY COMMISSION

Title: Stakeholders Public Meetings
Handling of Nuclear Materials

Docket Number: (not applicable)

Location: Washington, D.C.

Date: Thursday, October 24, 1996

Work Order No.: NRC-890 Pages 1-119

NEAL R. GROSS AND CO., INC.
Court Reporters and Transcribers
1323 Rhode Island Avenue, N.W.
Washington, D.C. 20005
(202) 234-4433

070014

0/1

9611070152 961024
PDR NRCSA I
GEN PDR

Disk Located in Central Files

DS13

# D I S C L A I M E R

PUBLIC NOTICE
BY THE
UNITED STATES NUCLEAR REGULATORY COMMISSION'S

STAKEHOLDERS PUBLIC MEETINGS

OCTOBER 24, 1996

The contents of this transcript of the proceedings of the United States Nuclear Regulatory Commission's Advisory Committee of the Stakeholders Conference on October 24, 1996, as reported herein, is a record of the discussions recorded at the meeting held on the above date.

This transcript has not been reviewed, corrected and edited and it may contain inaccuracies.

UNITED STATES OF AMERICA

+ + + + +

NUCLEAR REGULATORY COMMISSION

+ + + + +

STRATEGIC ASSESSMENT AND REBASELINING

STAKEHOLDERS PUBLIC MEETINGS

+ + + + +

ASSURING THE SAFE USE AND

HANDLING OF NUCLEAR MATERIALS SESSION

+ + + + +

THURSDAY

OCTOBER 24, 1996

+ + + + +

WASHINGTON, D.C.

The Assuring the Safe Use and Handling of Nuclear Materials Session was held in the Lincoln Ballroom of the Washington Hilton and Towers at 1919 Connecticut Avenue, Northwest, at 1:00 p.m., Malcolm R. Knapp, Deputy Director, NMSS, NRC, presiding.

PRESENT:

MALCOLM R. KNAPP

CLARE DEFINO

CHIP CAMERON

RUTH MCBERNY

EDWARD RHINGHE

PRESENT: (cont'd)

BOB CRITES

RICHARD RATLIFF

JUDITH JOHNSRUD

LYNNE FAIROBENT

LISA JARRIEL

ROB MCDOUGAL

LAWRENCE J. CHANDLER

STEVE COLLINS

CARDELIA MAUPIN

ROY BROWN

DICK BANGART

TONY THOMPSON

DARRELL McINDOE

TOM HILL

A-G-E-N-D-A


| Agenda Item | Page |
|---|---|
| Oversight of the Department of Energy | 5 |
| Agreement States | 38 |
| Medical Materials Oversight | 77 |

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

(1:10 p.m.)

MR. CAMERON: Okay. Good afternoon. We're ready to start. And, for those of you who are interested in the international arena, or the research arena, it is next door. And this session is going to be on nuclear materials.

A couple of announcements. First, if you need the handouts from this morning's session, they're all going to be in the Georgetown West room, along with copies of any of the full papers that you would, you would like to have.

And remember that you can go down to the Georgetown West room, and have your comments videotaped, or just, you know, if you want to do a song and dance, or some comedy routine, I guess you can go down there. And, speaking of -- no.

(Laughter.)

We have three papers for discussion this afternoon. And what we're going to do is we're going to go through each one, and then have audience participation, and then go to the, the next one.

And the first one that we're going to be looking at is oversight of DOE. And then, I believe, we're going to move to agreement states, or -- right?

(No audible response.)

Okay. And then we're going to talk about materials medical oversight.

And Mal Knapp, who's Deputy Director of our Office of Nuclear Materials Safety and Safeguards, was the sponsor for all three of these papers, and Mal is going to be doing a presentation on each of them. So, as laid out in the agenda, we're going to go with oversight of DOE first.

DEPUTY DIRECTOR KNAPP: Thank you, Chip. I am pleased to work with Chip, not just here but, as you can see from the first paper, he is the principal writer of this particular issue paper.

The question is whether this introduces a conflict of interest, but we don't think so. I've been -- I've worked with Chip for a number of years, ever since we were in the same work release program back in the seventies, and.

(Laughter.)

I think he has a very good product here for us to discuss. The issue at hand is should the NRC seek to expand its regulatory authority and responsibilities to include DOE facilities.

A moment or two of background. DOE is largely self-regulated. NRC does have a role, as probably most of

you know, in some aspects of DOE operations. Should DOE apply for license application at Yucca Mountain, the NRC will receive and make decisions on that application.

DOE has been engaged in over 15 years of work on remediation of certain uranium mill tailing sites. The NRC has regulatory authority over those.

We are also involved in DOE in other areas that are not strictly licensing, with equal rigor. But, with certification, we've been involved in certifying the USEC gaseous distribution plants which were previously operated by DOE.

And we have a, if you like, a collegial role, in DOE's clean-up of West Valley, where we give them certain advice. So, we are involved with the Department of Energy in a number of areas.

But about, my recollection, the better part of two years ago, a little more, questions began to arise as to whether DOE should be externally regulated broadly. Questions were raised in the Congress.

As a result of some of these interests, the DOE created their Advisory Committee on External Regulation of DOE Nuclear Safety.

They considered the merits of external regulation, and provided a report in about December of last year, and concluded that external regulation would,

in fact, be appropriate. The detailed reasons appear in the issue paper, or they are summarized in the issue paper.

Among the alternative regulators that the committee considered were the Defense Nuclear Facilities Safety Board, which already has a role at the DOE, and the Nuclear Regulatory Commission.

Recognizing that this was an issue, recognizing the possibility that, at some point, Congress might act to give us this kind of responsibility, or a portion of it, it seemed very appropriate, as a part of our strategic assessment process, to examine whether or not NRC would wish to regulate DOE, given the opportunity, would wish not to, or would wish for something else.

Among the factors that we have considered in this decision process would be two alternatives, and I think we are going to have one alternative or the other. In fact, I'm going to argue one alternative we have right now.

One would be that Congress could approve broad regulation of DOE by the Nuclear Regulatory Commission. The other would be that we would regulate DOE increasingly, on an incremental basis. And this is happening.

Within the last few years, as I mentioned

earlier, we have been given responsibility for the gaseous distribution plants.

We are currently working with DOE to provide them with advice on their clean-up of the Hanford tanks. And, in a variety of other areas, we are considering whether or not we would be more actively involved with DOE.

So, it would be my expectation that, even if Congress were not to legislate broad responsibility, that we will be given opportunities, perhaps direction, on an incremental basis, to take on additional responsibility over DOE facilities.

That, if we were to take on the whole job, would be big. DOE has over 3,500 nuclear facilities, depending on how you define them.

If we were to take them on, our best estimates in the paper, should we take on all of the external work that the DOE committee would have an external agency take on. Not necessarily the NRC.

But, should we do that, our best estimate is that it would take somewhere between 1,100 and 1,600 additional staff to regulate DOE in the way in which we now regulate commercial reactors and materials. Our budget would have to increase by something like 150 to 200 million dollars.

Now, to offer perspective on that, right now, we have about 3,000 people working for the NRC. Our current budget is about 475 million dollars. So, you can see what a dramatic increase this would be, to the Agency, were it to occur.

And that raises a lot of questions. How would we divvy up the work? How would we avoid being spread too thin? These are considered, again, in the issue paper.

Another question that we would want to deal with, if we were to regulate DOE broadly, or, perhaps more importantly, if we were to regulate DOE on an incremental basis, is that I think, as most of you know, we are required to cover, recover our budget.

We are a full fee recovery agency, so we recover the budget by fees for licensing, by fees for inspection. How would we best go about doing that?

Because, if we were to do it incrementally, there is the possibility we would get additional work, but it might be more complex to recover the resources, with the possibility that the NRC might find itself stressed to take the existing resources, and add, incrementally, responsibility for DOE.

So these are some of the concerns that we had, some of the key factors. And, with that in mind, the committee considered a variety of options.

Now, you see four options on the slide. I would note that we, in fact, have sub-options to many of those. And I'll sketch over them.

The first option, support broad responsibility for NRC regulation of DOE has several sub-options. One, we could simply support that responsibility as described by the DOE external committee -- excuse me. The Advisory Committee on External Regulation.

That particular method of regulating DOE would be somewhat different than the version that NRC now has, dealing with commercial facilities.

Our relationships with other agencies is somewhat different. The External Advisory Committee would have us regulate such things as NARM, which we do not now regulate.

So that suggests, as a possibility, a sub-option, taking on broad responsibility, where we would take on the responsibility, but use the same responsibilities which we now have through the commercial industry.

If -- one advantage, if no other, is that there would at least be consistency between NRC's regulation and its relationship with other agencies, across the spectrum of its responsibilities under that option.

A third alternative under that option would be to try to improve a bit on where we are now. For example, many of you in this room are probably aware of some of the frustrations that the public, the licensees, and the agencies have had, in dealing with the subject of mixed waste, with EPA.

If we were to take on these responsibilities, it might be good to regulate DOE in such a way that we and the EPA come up with a more workable division of responsibility than what we now have for commercial facilities.

Another alternative would be that we could take on broad responsibility for regulating DOE, but only regulate certain types of facilities.

For example, the NRC could limit its regulation to non-defense facilities. This could have the advantage of avoiding our injecting comparisons of national defense and public health and safety in some of our regulatory decisions.

Another alternative would be we could regulate those things which are very similar to those which we regulate right now.

As we -- as you can see in the issue paper, there are descriptions of DOE facilities. Many of those are the same things that we regulate commercially, or very

close to them. But there are some, such as NARM, which we do not now regulate.

Another possibility would be that we would take on all responsibilities, with the exception of environmental restoration. One question to be asked is, given that DOE is doing environmental restoration for a number of its sites, what should the NRC role be?

Should we be active in that, or should we recognize that it would be a better responsibility for EPA? Would it be a good use of our resources and DOE's time?

The third alternative is we could simply oppose being given the additional responsibility. I recognize any of these decisions would be positions for the Agency to take. Obviously, whatever decision Congress might make, we will certainly carry out to the best of our ability.

But we could decide we not want the additional responsibility. We could argue that, for us to properly protect public health and safety from commercial nuclear facilities, be they reactors or materials facilities, we need to focus our management attention and our resources on those alone, and it would be inappropriate for us to expand our responsibility.

We could even say that we don't want any

additional responsibility. That what we have now is enough, and that we should not expand, even on an incremental basis, what our current responsibilities for DOE facilities are.

Finally, we could take no position on broad NRC responsibility. We could note that DOE is continuing to wrestle with the idea. We could note that Congress is going to make the final decision.

We can position ourselves to speak to it, if asked, but not take a position at this time. That it would simply be better for the Agency to be prepared to discuss the subject when asked.

Those options were provided to the Commission. As you've seen with other sets of options today, they were intended to provide a broad range of alternatives for the Commission to consider.

And, as you can see on the next slide, the Commission's preliminary view is that it would not take a position. We would neither encourage nor oppose legislation that would give us broader authority over DOE facilities.

The Commission did note one or two things in their preliminary review. They believe that, if we were given adequate resources and a reasonable timetable to develop them, that we could provide adequate regulatory

oversight over DOE, if asked.

And, in the next viewgraph, we note that, were we given that kind of oversight, so that we could have the time to develop proper programs, we'd very much like to have it, it given to us on an incremental basis, and that we'd have some methodology or type of prioritization available, so that we could best decide what would be the most important thing to do, as we take on regulatory responsibility.

What should we deal with first? Where could we be most cost effective? Where we could, could we most constructively help health and safety?

That's the issue paper, very briefly, and the Commission's preliminary views. And I'd like now to turn it back over to Chip, to hear what you think.

MR. CAMERON: Okay. Thank you very much, Mal. There's a lot of things to consider, as you can see from, from Mal's presentation on this particular issue. Not only in terms of the options, but also in terms of the sub-options on this particular paper.

And I guess I would just open it up to, to anyone who wants to make a lead-off comment here, either on the reasonableness of the preliminary option, are there any downsides to that, or, or anything. Ruth, do you want to, to make a statement?

MS. MCBURNEY: I'm Ruth McBurney, from Texas Department of Health. I'm here representing the Board of Directors of the Conference of Radiation Control Program Director.

The CRCPD is a national organization dedicated to raciation protection that is made up of personnel from state, district, and territorial radiation control program throughout the country. That is, non-agreement states and agreement states. So, we're pretty comprehensive in, in the, the collective voice of all the state and local programs.

We have established, within the Conference of Radiation Control Program Directors, a committee that is made up of state radiation control personnel in the states in which the Department of Energy sites are located, and they are working to develop some positions on how DOE oversight is to, could be accomplished, working with the Department of Energy and some of the other federal agencies as well.

As far as our comments on this issue, we noted that there are several aspects of the issue that were not, that we felt were not adequately addressed in the document.

The first of which was that the description of the Department of Energy facilities or programs omits

nuclear weapons assembly and disassembly facilities. And we felt that they should at least be described there.

The concept of a waiver of sovereign immunity for federal facilities, and what impact that would have on the workload of the NRC versus that which states could assume.

This is really clear in the discussion, especially like accelerators, where the states have all the regulatory expertise, and NRC has much less.

Regarding a funding mechanism of how this might could be accomplished, the NRC must find a way to assure that the costs associated with the regulation of DOE are not treated as overhead, and distributed among its other licensees.

We recommend that NRC seek amendment of the Atomic Energy Act, to allow for a funding process similar to that used for U.S. Enrichment, or to be able to charge fees to the federal agencies it regulates.

DOE must -- should be regulated just as other licensees, including the payment of fees. This would also help remove the idea that NRC would have to develop some new and different program for the regulation of DOE.

The CRCPD Board of Directors supports the inclusion of decontamination as a regulated activity. If NRC intends to not regulate decontamination, there needs

to be a clear justification for that.

Supporters of the concept of the NRC regulation of, of DOE point to NRC's high standards as an advantage, rather than an obstacle. If NRC standards were not high, we doubt that there would be much incentive to initiate the oversight process.

In addition, allowing development of different standards for the DOE facilities would only dilute the process, and cause frustration among other NRC licensees being held to different standards.

Regarding the option, based on the record of past omissions, the Department of Energy should not regulate itself.

The options and the direction-setting issues include regulation by the Defense Nuclear Facility Safety Board, or the NRC.

Of the two agencies, only NRC has the experience and resources necessary to enable a transfer and implementation of regulatory responsibility to an outside organization.

We believe NRC should pursue adoption of the advisory committee recommendation. That's the Advisory Committee on External Regulation.

Incorporation with agencies with adjacent responsibilities. NRC should work with the state

radiation control programs to develop a model proposal, per sub-option 1B.

A plan for the NRC to subsume the Defense Nuclear Facilities Safety Board into its operation, during the transition from self-regulation to NRC regulation, could be developed, along with a determination of which facilities and operations were going to be regulated by NRC or by the states.

And this could be done by focussing on main concepts developed by the committee. That is, that DOE should be regulated like other nuclear facilities.

DOE has signified its commitment to external oversight, Congress has indicated in providing legislation, host states are supportive of external oversight, and affected stakeholders have petitioned the federal government to resolve this issue. Thank you.

MR. CAMERON: Thank you, Ruth. Mal, do you have follow-up questions for, for Ruth on that?

DEPUTY DIRECTOR KNAPP: I don't think I do, at this time. I'd just like to note for the record that there was a meeting yesterday where a number of agreement state representatives joined us.

We got their suggestions, and we had a very constructive discussion. And a summary of that meeting and the written comments will be part of the public

record.

MR. CAMERON: Okay. That's a, that's a good point. That will be part of the public record, that session. Okay.

DEPUTY DIRECTOR KNAPP: Okay. So, given that, I believe I understand Ruth's comments. Thank you very much, and we will consider them.

MR. CAMERON: And I guess I would just ask Ruth, if you -- if I could ask you to clarify the one point. In terms of -- you talked about the waiver of sovereign immunity.

In terms of the conference position, is it advocating that, if the NRC was given authority for a broad scope of DOE facilities, that we should, should operate our regulatory framework in the same way that we operate the regulatory framework for commercial facilities?

In other words, the agreement states should be allowed to regulate the DOE facilities that might fit, might correspond to the present types of facilities that we have the states regulate?

MS. MCBURNEY: I believe that part of that is right. Part of it would be to allow those states that have facilities like accelerators, like the, the DOE labs, to regulate those. And not so much for the states to

assume, agreement states, oversight on those.

MR. CAMERON: So we wouldn't necessarily have to follow the agreement state model?

MS. MCBURNEY: No.

MR. CAMERON: Okay. And I guess that what, what the Conference is recommending is that the Commission aggressively pursue taking over the regulation of DOE facilities?

MS. MCBURNEY: Right.

MR. CAMERON: In other words, 1B, rather than just sort of sitting back and waiting to, to see what happens?

MS. MCBURNEY: That's correct.

MR. CAMERON: Okay. Thank you. Do we have some comments on, on the Commission pursuing option 1B? Yes?

MR. CRITES: That's the takeover option?

MR. CAMERON: Yes, I hate to say. Takeover. I don't know. I don't know if that sounds right. But yes.

MR. CRITES: Bob Crites, Gaithersburg, Maryland. Yes. I would support option 1, for NRC to assume the responsibility for regulation of DOE.

And, although it was pointed out that there are 3,500 DOE facilities, that's only about a tenth of the

licensed facilities NRC now oversees.

It was pointed out in the option paper that these facilities are located in 13 states. However, the NRC has a national presence, and, in 21 of the states, provides all the regulation. So I believe that NRC has capability, has presence there, and can manage this effort.

As to the resources, the ability to staff this. There are currently about 100, 120 full-time employees in the Defense Nuclear Facilities Safety Board, and DOE has its own staff, NEH, that has been providing regulatory oversight, within the agency.

These staff would not be necessary, if the NRC were to take over that responsibility, and could be transferred to helping out this effort.

The final point that I would like to, to make addresses the issue, or the concern about the priorities of nuclear, or of national defense versus public safety.

And, if universities and medical installations can meet NRC requirements, it's inconceivable to me that DOE, with its resources and scientific backing, could not do likewise.

MR. CAMERON: Okay. Thank you. How do other people feel about the NRC assuming responsibility for external regulation of DOE facilities?

And a related question to think about is what are the downsides if the Commission pursues option four? In other words, the more or less wait and see posture. Is there, are there dangers there? Richard?

MR. RATLIFF: Richard Ratliff, to clarify. With the State of Texas, Texas State Department of Health, but representing the organizational agreement states.

We've also submitted detailed comments at the meeting yesterday, and will have follow-up comments. But we really believe that it's time for the DOE to not have self-regulation, but have oversight.

Multiple of the agreement states, for the last five years, have had cooperative agreements in place with the Department of Energy, where we do enhanced environmental monitoring off-site, sometimes on-site, and we do emergency response planning.

I think one thing that, that may be lost at the federal level many times is that, when you get to the agreement state level, the states are responsible, whether it be an NRC-licensed reactor or a DOE facility, for the protection of public health and safety of the citizens of that state.

And so we do have emergency response capabilities and environmental monitoring responsibilities. And so we do feel that NRC should move

into this arena.

We agree with the fact that, that the states have been working in this area for years, that there should be a program similar to the way EPA has worked the hazardous waste program, where they have delegated authority to states, and the state regulatory program actually does the inspection of hazardous waste at DOE sites, including, in Texas, the PANTEX site, and the mixed waste that would be associated with nuclear weapons production or disassembly.

And we really do feel that the, the production and assembly facilities should be included, if NRC has oversight.

As we all know, the, our President has entered into treaties with the Russians to disarm, and, because of this disarming, there are multiple warheads that are being disassembled, with an increasing number of, of what they call pits, the center of the nuclear weapon, being store at PANTEX.

And I, and I think it's a successful program, but we need to make sure that there is adequate oversight, and the states have the resources to assist NRC, and that this could really be a joint partnership, where we really do work together for the, the good of not only the whole nation, but the states and the people in the adjoining

areas.

Ruth basically covered all the other common areas, but we, we also agree, if the NRC waits the problem just gets more and more unwieldy, and I think that, with the expertise of all of the people concerned, we can bring this to a better, satisfactory conclusion.

MR. CAMERON: Thank you, Richard. Again, the suggestion is, is that the NRC would be well-served, everyone would be well-served by being more pro-active on this. I mean, assuming that the NRC was the best organization to, to take over external oversight.

Is the committee that, that Ruth mentioned -- that's a standing committee now, that the NRC, we would be able to work you on, on these issues?

(No audible response.)

She's shaking her head yes. Okay. Is, is, would -- you know, there's the question of should DOE be externally regulated, and there's the question of who should do it.

Does, does anybody believe that DOE should, should not be externally regulated? Just to get that off the table.

(No response.)

Okay. No one stepped forward on, on that one. Mal, do you have any things that you would specifically

like to, to find out from people?

DEPUTY DIRECTOR KNAPP: I'd be interested in views on one particular subject. This is, this relates not only to this issue paper, but to others that are being discussed. It has to do with the regulation of mixed waste.

As I mentioned earlier, a number of us have some frustrations with the overlapping responsibilities of NRC and DOE -- excuse me, and EPA. Sorry about that. I don't which of those two agencies I would aggravate by saying that.

(Laughter.)

But one of the alternatives, one of the sub-options here is that, if NRC and EPA were to have responsibility for DOE, and if we were to regulate DOE's mixed waste, that a very simple solution would be to determine if we have chemical -- let's talk about what mixed waste is, for those of you that may not be familiar with it.

It's waste which is, has hazards both because it's radioactive and because it's chemically toxic. Now, one of the proposals made by the issue paper would be that, given that both hazards are present, we would attempt to determine which was the controlling hazard.

In many of these cases, the chemical toxicity

could far outweigh the radioactive toxicity, or the other way around.

Once we had determined which hazard was controlling in mixed waste, we would then simply have the agency that has the lead for that hazard deal with disposal of that waste.

Thus, for radioactive, it would fall to NRC. If it were principally chemically toxic, it would fall to EPA. It's a simple way of making life a lot simpler. We have worked for years to try to resolve the mixed waste issue in other ways.

I would be interested whether anyone has any comments on whether that particular aspect of the issue paper is good, bad, or indifferent. I did hear a comment yesterday from the states, that they think that that could be workable. I'd like to hear any other ones.

MR. CAMERON: Good. Do we have a response for Mal on that issue, from anyone, the mixed waste issue? Judy?

MS. JOHNSRUD: I have a question. I have a question. Can we anticipate a substantial increase in the quantities of mixed waste, resulting from decommissioning clean-up activities? DOE's activities, not to mention the commercial realm.

DEPUTY DIRECTOR KNAPP: I don't know that I'm

real comfortable answering that question. I'd have to deal with, with hearsay. I understand there is a fair amount of mixed waste that DOE has responsibility for, but I honestly don't know how much.

If there are any NRC staff in the audience who can give some sort of a quantitative, or somewhat quantitative answer to the question, I'd be happy to hear form them.

MR. CAMERON: Anybody else have a response or information on the mixed waste issue, for Dr. Johnsrud? Yes? And please state your name, Ed, and affiliation.

MR. RHINGHE: Edward Rhinghe, from the Department of Energy. Even though that's not my particular area of expertise, I feel confident in giving you a one word answer. Yes. There will be a large increase in the amount of mixed waste generated as a result of all our clean-up activities.

MR. CAMERON: And can you tell us why that would be?

MR. RHINGHE: Well, for example, if you look at the, the Hanford tank problems, and the problems there. There are many areas where there is contamination in the soil that is both radioactive and chemical, and there will be -- and also, in disassembling a lot of our plants, they have the same thing there currently.

The buildings are sitting there. They're contaminated with both hazardous and radioactive material. As those are torn down and cleaned up, they will generate waste to be disposed of.

MR. CAMERON: Okay. Thank you, Ed. Yes?

MS. FAIROBENT: Lynne Fairobent. Chip, I think one think one thing that bothers me, as I sit and listen to all of this discussion, is the fact that we continue to try and differentiate and make a difference out of the risk associated with DOE type of activities and the risk associated with commercial type of activities.

The amount of mixed waste that may be generated, whether DOE is externally regulated or continues under its current regulatory scheme, is no different. Okay.

That amount of waste, quantity-wise, hazard-wise is still going to be the same. The only thing that will change on that is the technologies employed during D & D and remediation activity.

I think, in answer to Mal's question on the mixed waste, I guess my concern stems from the fact, again, that, when you take a look at the risk, and you take a look at the hazards involved to the public around any of these facilities, be it a commercial site or a DOE facility, because of the split with the Atomic Energy

Commission, and DOE's self-regulation over the nuclear aspects of their program.

Remember, EPA regulates the environmental. DOE is not self-regulated in that sense. And DOE, about four years ago, made the commitment to go to external regulation for OSHA, for non-nuclear safety hazards.

So we're talking about, really, who continues, or who should be regulating the nuclear aspects of it. To the public, I think, that differentiation is not very clear, especially if you're in the state where you're co-located to a commercial facility and a DOE reservation.

The off-site releases are not differentiated if they come from a DOE facility or a commercial facility. They don't look different out there. And we continue, or we have been continuing to perpetuate this split in, in approach and philosophy.

And I think somebody earlier asked should we, you know, what happens if we don't expedite taking on responsibility. I think we continue to propagate the continuation of dual regulatory paths, let's say, in the radiation area, and different philosophies.

A key example is 40 C.F.R. 193, which EPA's been trying to promulgate for years, that is a low-level waste standard.

If you go back and look at it now, I believe

the current draft would not apply to commercial facilities, but continues to apply to DOE facilities. The hazards are basically the same.

So we continue, within DOE, as we revamp its regulatory pro ess, either in the transitioning from DOE orders and responses to DNFSB recommendations, or Price Anderson Amendment rules.

We're just continuing another set of regulations. If one set is good enough on the commercial side, and the material is the same, why is that set not good across the board?

MR. CAMERON: Okay. Thank you, Lynne. I think that's a, a good point on what may be one of the downsides of option four.

It also brings up another issue, which is we tried to identify a number of factors in the paper about why it might be -- what are some of the difficulties of NRC taking over, assuming regulatory authority over DOE, and Mal mentioned staff, cost, there's type of staff that might be needed.

I think your comment shows that there may be no differences, in terms of regulating DOE facilities, in some respects, from commercial facilities.

But I guess I would like to ask all of you have we identified all of the factors that should be

considered in external regulation of, of DOE? National security, whatever.

And, among those factors, are there, is there any factor that would influence the decision of who should be the external regulator of DOE? Yes?

MS. JERRILL: Thank you. My name is Lisa Jerrill, and I work for the United States Enrichment Corporation, and we operate the gaseous diffusion plants. And we're just going through this process, where NRC is taking over regulatory authority from DOE.

And we're in a transition phase right now, and that's one thing you haven't mentioned, that there is going to be a phase where the facility is going to be dually regulated.

And that has been very problematic for the company, and for the plants themselves that are continuing operation.

So that's something, I think, that should be factored in as a, something you should plan for, this transition phase, and how the plants have to go to two regulators, and get them to agree on a tech spec change, or NKTSR. It's very problematic.

Secondly, the point about holding these facilities to the same standards as the utilities you now regulate.

I also think the Agency has to take into consideration that these are facilities that have operated for 40, or odd years, or however many odd years, under DOE. And, in many cases, design criteria doesn't exist, let alone can't be found, somewhere in Oak Ridge.

So, I mean, that has to be taken under consideration. That there are standards that should be set, and goals that should be set for these facilities to meet, but that, the minute they are under NRC jurisdiction, they're, they can't, they can't possibly meet the same standards that a facility that has started with the NRC, and gotten their license from the NRC is held to.

MR. CAMERON: Thank you. That's a good point. I believe that point is something that, that we haven't -- have given some though to.

DEPUTY DIRECTOR KNAPP: We have given some nought to it, but I'm pleased it come up again. I agree with you on both your points.

MR. CAMERON: Okay. Anybody else out there want to make a comment on this particular issues paper? Did you want to make a comment, sir? Oh, good. Come on out, or up here, if I can make it a little easier.

(Asides.)

MR. MCDOUGAL: My name is Rob McDougal, and I

work for SAIC, which is a contractor for DOE, and their environmental management program.

One of the things that struck me was, from reading the legislation that died in the recently concluded session of Congress, to create an interim spent fuel storage program.

There was a provision there clarifying that NRC regulatory jurisdiction would continue after DOE is required to take possession of the spent fuel from the utilities, under the provisions of the Nuclear Waste Policy Act, January 31st, 1998 deadline.

I was wondering if anybody at NRC has thought about what the statutory basis is, for the survival of NRC regulatory jurisdiction, after DOE takes possession, as it is now required to by the federal appeals court ruling?

MR. CAMERON: Does Larry want to handle that?

(Laughter.)

MR. CHANDLER: I understand. It's -- I'm not sure the premise of your question is completely accurate. I believe the court was speaking to the take title provision that requires that the Department would take title.

: You need a mike.

MR. CHANDLER: I said I'm not sure the premise for the question is correct. My understanding is the

Court of Appeals was addressing the take title provision, which requires the Department of Energy to take title to the spent fuel, but not actually possession of it.

So, it's unclear to me where possession would remain. It might actually remain in the possession, I suppose, of the licensed, currently licensed facility, which is subject to NRC licensing.

And, in that context, I could more readily understand, understand the question. We would have authority over the facilities, and continue -- over the fuel, to the extent it's being possessed by the current licensee. But I, I don't know. I'm not that familiar with it.

MR. MCDOUGAL: If you assume that a utility executive would probably want DOE to take possession and title to the fuel, under the, under the provisions of the Act, which I think they would probably have a financial interest in doing, what -- I was just curious about what the basis is for NRC regulating DOE, absent some legislative clarification of its authority.

Under the, as you know, under the Energy Reorganization Act, the NRC has authority to regulate DOE only with respect to certain facilities that are considered exceptions to the general structural feature of the Reorganization Act. But NRC would not be regulating

DOE's Atomic Energy Defense activities, certainly.

MR. CHANDLER: That's clear. And part of the premise of the, of the issue paper was the need for legislative authority to do a lot of what we're speaking of.

Clearly, under the Energy Reorganization Act, I think there are four specific categories of facilities. There's the High Level Waste Act, which gives you Yucca Mountain. Beyond that, you would need specific legislation to deal with it.

But I think the first part of your question is right. I'm sure the utilities would love DOE to take both title and possession, in the way that you're saying.

MR. MCDOUGAL: So, do I understand correctly that it's your view that, without, absent congressional action to clarify its statutory authority, that you, the NRC corporately, is presuming that there is a significant jurisdictional question about the continuation of its regulatory jurisdiction over what started out as licensed material?

MR. CHANDLER: You're, you're asking a very large question over there. I'm not prepared to answer it that broadly.

MR. CAMERON: Would you like to sign a statement?

(Laughter.)

MR. CHANDLER: I've lost my voice again.

MR. CAMERON: That issue, I think, is also relevant to the high level waste spent fuel storage paper that's going to be discussed tomorrow, and perhaps we'll be better prepared to, to discuss that particular issue.

Before we end, we heard a number of people support a more planned, pro-active, whatever you want to call it, approach to, to this particular issue.

Is there anybody else -- does anybody out there who wants to speak to the Commission's preliminary choice of option, about take no position? Yes?

MS. JERRILL: I'm not sure on the timing on what, when you said take no position. Do you mean take no position now, or take no position even after Congress says go ahead and do it?

(Laughter.)

For instance, I mean, there are a lot of people out there taking positions, and I would just think it would be, it behooves the industry for the regulatory body to take a position. I know somebody successfully now has passed, through one of the houses, a change to the Act, to mandate that the Paducah guards have guns.

My God, they're changing the Act so that one set of guards has guns, and where -- I wonder where the

NRC was there, let alone something like this. I just can't believe you wouldn't take a position.

MR. CAMERON: Mal?

(Laughter.)

DEPUTY DIRECTOR KNAPP: Without, without going into detail, in a number of measures, including security, the NRC is aware of pending legislation, and does take positions. That does not necessarily mean that our views carry the day with Congress.

With respect to whether we should take a position, on overall regulation of DOE, if you like, that's, that's what's on the floor right now.

There are arguments that would be that perhaps we would be muddying the waters, and that the better thing to do, from a national perspective, is to take no position, which is certainly one possibility, and obviously that's -- the Commission's preliminary view is that they would not take a position.

But I'm, what I'm hearing today is that the comments we've received are that we should take a position, that we should seek broad responsibility for regulating DOE, and I think, listening to Chip's queries, did not hear people commenting in favor of the present preliminary view.

MR. CAMERON: Yes. It seems that we've heard

a number of comments on the downsides of option four, and a number of comments in support of, of option one.

Now, of course, there are plenty of opportunities, by the November comment close date, for people to offer comments contra to this in writing, or e-mail, and we would encourage you to, not to do, file comments contra to this, but to, to comment on it.

But anybody else, before we go on, who wants to state a position on, on the option issue?

(No response.)

Okay. Well, good. Mal, are you ready to, to discuss the agreement state issue?

DEPUTY DIRECTOR KNAPP: All right. The second issue paper for this afternoon's session is direction setting issue number four that deals with our relationship with agreement states, and the particular issue is what should be our strategy regarding states becoming and remaining agreement states.

And I'd like to go right ahead to some of the key factors that we think, we have in the paper as items of concern.

There are many agreement state representatives in the audience, but, for those of you that are not, you might like to know that agreement states are responsible for approximately 70 percent of the

materials licensees in the country today.

The NRC licenses about 6,500 material users with specific licenses. The agreement states have around 15,000. The NRC has about 35,000 general licensees. The agreement states handle about 100,000.

Of the 50 states, 29 are presently agreement states, and four states are in the process of seeking, or becoming agreement states. Others may continue to do so.

With these things in mind, it's fairly clear what the first bullet is. The number of our licensees is expected to decline as more states become agreement states.

And here I'm going to give a little bit into the overlap between this issue paper and the next one, which is the NRC's materials program. I would expect some of the comments we receive on this paper will overlap with the next, and please feel free to do so. These papers are closely linked.

Clearly, as the number of agreements states increases, the number of materials licensees with the NRC will decrease. This will have an impact on our materials program, and the direction it should take.

One of the concerns that we have is the NRC's method of funding. The Omnibus Budget Reconciliation Action of 1990. That may be Act.

OBRA, as we frequently refer to it, makes us a full fee recovery agency. This means that our licensees pay for the things that we do, although, in some cases, the licensees may not receive the direct benefit for our actions.

A question to be asked is what should be our relationship with agreement states? Recognizing agreement states licensees, in general, would not pay money to the NRC. When I say in general, there are certain circumstances in which they do.

We also recognize that, as we've said in a couple of other issue papers today, we are coming under pressure to decrease the Agency's budget, and this would mean that we should reduce the amount of financial support that we provide to agreement states.

To be a little more specific, right now, we spend in the neighborhood of about a million dollars a year to pay for the training that agreement state staff receive, and the travel that they take to get to that training.

One could argue on both sides of whether that sort of funding should be continued, and it's a significant issue to the Agency and to the states, so we look for comments in that area.

Finally, we recognize that, as was mentioned

earlier, when the state becomes an agreement states, we relinquish our regulatory authority to that state, but we still have a remaining responsibility to oversee an agreement state program, and oversee agreement states through, currently, the IMPEP process.

With these factors in mind, we came up with a number of options. This is what I think a couple of folks in the agreement states refer to as an extremely broad set of options.

(Laughter.)

Turn the agreement states program over to the Environmental Protection Agency. Why would we want to do that? Well -- oh, I'm sorry. I didn't mean to quote you directly, Ruth, but.

(Laughter.)

The fact is that EPA has an authorized states program, which, in some ways, resembles the NRC's agreement states program.

Now, while EPA focusses on the environment, and does not necessarily focus on public health and safety, or worker health and safety, the fact is, there is an existing program in place at the federal level.

And one can argue that, in the interest of effective and efficient regulation, that perhaps states would prefer to be dealing with one federal agency at a

time, in an agreement authorized status, rather than two.

Another option would be to strongly encourage states to become agreement states. This is simply a recognition that the process does appear to be going in that direction. More states are becoming agreement states.

Perhaps we should try to come up with a way to get as many states to be agreement states as possible, and couple this with appropriate change in out materials program, which might somehow phase it out, or limit it, or change the NRC's entire role from being in materials as much as a regulator, as it might a guide, a leader, a coordinator of the agreement state programs.

Another alternative would be to continue the current agreement states program, including adopting the current initiatives.

We could also, as another alternative, treat the agreement states more as co-regulators. Another way of looking at that would be that we would have a less, shall we say, paternalistic role of the NRC, and we would treat the agreement states much more as equals.

Again, for those of you that are not familiar with the process, we do have an oversight responsibility, yet, at the same time, we recognize that agreement states have a principal role, they are regulators.

Certain agreement states have very large programs. That a partnership is certainly a very reasonable way to proceed. This option has, as a part of the partnership, that our funding of agreement state programming would not continue.

And I'd like to digress a second. In all of the options that you see, in the materials papers and all of the issue papers, they are not meant to be cast in concrete.

We drew these things broadly, to give folks a chance to see what they look like. An option, by itself, is not necessarily an only option, and variations on options are being considered.

So, as you talk to us today, particularly on this paper, there may be aspects of an option, such as having co-regulators or partners among the agreement states, that some will favor, but another facet of that option, such as not paying for agreement state training and travel, could be a part that you would not like.

And these are certainly not intended to be an irrevocable package, and comments, that you may like part of an option but not the whole option will be very welcome.

Last but not least, we could go, if you like, all the way. Devolve regulation of AEA materials to the

states. Arguably, when we began to learn about nuclear materials, a half a century ago, we had a great deal to learn.

Now, we know a lot more. We have a pretty good idea of what the hazards are that are associated with many materials.

States are already doing a good job of regulating a number of aspects of safety. They regulate NARM today. Is it possible that we should consider that current AEA nuclear materials could also be turned over to the states? Would that be a reasonable solution?

So, those are some of the options that we considered. As I said, it is a very broad set, and intended to provoke thinking.

The Commission's preliminary views are that they would continue the current program, including adopting the current initiatives. They would encourage more states to become agreement states, but they would not use tangible or monetary incentives.

Instead, they would use intangible incentives, trying to strengthen our co-regulator partnership role. They are considering providing seed money to states about to become agreement states.

The idea here is that a state considering becoming an agreement state needs to develop programs,

needs to develop regulations, procedures. Perhaps seed money could be of an asset to some of these states, to become agreement states.

And, as a possible compromise with respect to training, provide training to agreement states, without charge, on a space available basis, and funding and travel -- funding for travel would be borne by the agreement states.

This is an area where the Commission particularly seeks comment, and as -- I think we have one more slide to go. No?

(No audible response.)

Well, if we had one more slide, here's what it would say, and I think it's in your handouts. We particularly want comment on whether we should fund agreement state travel, training, and technical assistance.

And we particularly want comment from agreement states, non-agreement states, keeping licensees, keeping licensees to the NRC and keeping licensees to the agreement states.

A lot of what you've just heard is a result of the constraints we are under with OBRA, the Budget Reconciliation Act.

We would like very much to come up with a way

of dealing with this situation that is as fair as it can be to licensees in both agreement states and non-agreement states, and the agreement states themselves.

With that summary, I would like now, again, to return it to Chip, and ask for your comments.

MR. CAMERON: Thank you, Mal. Steve?

MR. COLLINS: You've already heard my comments on option one.

MR. CAMERON: Steve, can you repeat those in public?

(Laughter.)

MR. COLLINS: You heard them. The agreement states should be treated as partners or co-regulators, in the effort to protect the health and safety from radiation in the United States.

The statute which created the agreement states program recognized the growth of the states, and their eventual assumption of a co-regulator status. The majority of the states are now agreement states, and are fully capable of participating with the NRC in determining the shape of the program.

By the way, I'm Steve Collins, with Illinois Department of Nuclear Safety, representing the Organization of Agreement States.

In your options, only option four states that,

quote, "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 assertion, under option four, that, as a part of this recognition, agreement states should be self-sustaining, and should require minimal support, in the form of subsidized training, amounts to saying that the agreement states must pay the NRC to recognize the contributions made by the agreement states that support the NRC and its licensees. The contributions are identified in the specific comment section below.

Option four has taken the spirit of cooperation between agreement states and NRC, and reduced it to a destructive game of tit for tat.

NRC's ideas presented in option four are in direct contrast to the views recommended in other DSI's, where cooperation with professional societies, international agencies, and licensees is stressed.

The term co-regulators, as described under option four, appears inconsistent with the states' views of the NRC-agreement state relationship.

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.

This idea is taken directly from the last paragraph on page 13 of DSI 20, international activities. Yet the NRC is willing to foster such healthy relationships overseas. They should also want to foster equally healthy relationships with regulatory agencies in the United States.

Something that's in answer to your question of what is missing from the DSI, from the discussions, is an evaluation of the health and safety impacts for each option should be included, as these impacts are the primary reason for NRC's existence.

With the above in mind, the agreement states favor continuation of certain programs developed in partnership with the agreement states, and presented in option three, especially the adequacy and capability policy statement, as revised by the agreement states in September, 1996, and the IMPEP.

This is the Commissioner, the Commission's preliminary decision. In addition, we recommend the NRC recognize the many benefits received by the NRC and its licensees from the states, and return the funding of training, travel, and technical assistance.

To use intangible incentives, to encourage

more states to become agreement states, to recognize the fact that the agreement states are regulatory partners with the NRC, and seek appropriations for the functions involving agreement states with assistance in the form or testimony before congressional committees provided by agreement states.

I have some specific comments now, that I referred to earlier. The many benefits the NRC and its licensees receive from the agreement states, without reimbursement, were conspicuously missing from this DSI, resulting in an inaccurate representation of the benefits-cost situation.

In September of 1996, the Organization of Agreement States passed a resolution, pertaining to training and funding, that summarizes the services and benefits provided to the NRC and its licensees by the agreement states.

The benefits include the agreement states regulate all commercial, low level radioactive waste disposal facilities, and are in the process of licensing all the new commercial, low level radioactive waste disposal sites.

Although the NRC charges a supplemental fee for waste disposal, and these revenues are not provided to the agreement states, low level radioactive waste

facilities in agreement states continue to receive waste from NRC licensees, as well as agreement state licensees.

The second one. The agreement states respond to incidents involving transportation of NRC-licensed material within their jurisdictions, particularly those involving interstate carriers.

The third one. Many agreement states provide salaries for their staff participating in NRC IMPEP reviews of agreement states, and NRC regional offices.

The fourth. The NRC has requested and received agreement state staff lecturers at NRC-sponsored training courses, without payment of salary for agreement state staff time.

Five. Agreement states develop many rules that benefit the NRC, such as well logging and industrial radiographer certification, without compensation from the NRC.

Six. The agreement states have conducted surveys, and assisted in the removal of by-product material from facilities at the request of NRC.

Seven. The agreement states are currently investigating potentially contaminated sites for licensees that the NRC possibly terminated inappropriately.

And the last one. The 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 of radioactive materials to the environment are in compliance with effluent limits, with only partial compensation. Now, that's estimated to be about one third of the cost.

In addition, other considerations that have been omitted from this DSI include the following three. The NRC states that it requires a minimum of 500 to 1,000 licensees to have a viable NRC program.

Most agreement states have less than 500 licensees, and would remain viable programs even if NRC's by-product material program ceased altogether. The NRC would do the same amount of work on the regulations if there were no agreement states, or if there were 49.

An evaluation of the health and safety impacts for each option should be included, as these impacts are the primary reason for NRC's existence, as I said earlier.

There is no evidence that so-called tangible incentives, or seed money, without continued support from NRC, would result in any new agreement states. Funds would be better spent on training, travel, and technical assistance to the existing agreement states.

While the Commission wants to encourage more states to become agreement states through intangible

incentives, charging them for assistance is a tangible disincentive.

Continued funding would send a message that the NRC recognizes 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.

The NRC should look more closely at program areas such as low level waste research, detailed data collection, and analysis of operational data and events, and support of international students for spending cuts which would not likely reduced level of safety for the public and workers.

We have specific comments on each option, if those are desired later.

MR. CAMERON: Thank you very much, Steve. Mal, would you like to follow up with Steve on any of that?

DEPUTY DIRECTOR KNAPP: I did have two points, and I think I understood them from yesterday, but I think it might be worthwhile so that others interested in the discussion could be aware of them.

I believe, when we talked about international students, you were referring to international attendees at our training classes, where states presently participate.

Am I correct in that?

MR. COLLINS: Yes.

DEPUTY DIRECTOR KNAPP: Thank you. Second, you mentioned yesterday what the states said was an advantage to having the training programs that did not arise in the comments you just made, and, if you are in a position to sort of summarize it again, it might be worthwhile.

This was the point, I think, that was made. That the advantage of having a program run by the NRC to provide training would be the uniformity and perhaps the independence associated with having all of the regulators, NRC and agreement state, trained in approximately the same way.

Perhaps you, or one of the other agreement state representatives might like to elaborate on that, the basis -- or, for the benefit of the rest of the folks here.

MR. COLLINS: Yes. One way of assuring that the same level of protection is provided across the United States, from the same types of uses of radioactive material, is to ensure that, regardless of who the employer is, that the people out there, at the grass roots level, you know, face on face contact with the licensees, actually receive their training and instruction from the

same people, in an environment where the students are learning together, and sharing the benefits of their experiences.

So that basically, when they come across situations that are similar, they're handled similarly, and the applicable regulations get applied similarly. And, basically, the real spirit of what's compatible, that is, comparable application ends up coming through with that.

And one of the other things is I referred several times to benefits and the services NRC and its licensees receive. Typically, if there's a transportation incident, something in interstate commerce is under NRC jurisdiction, not the states.

But, if it occurs in the states, we're not going to wait for NRC to fly somebody in, and it's really good for NRC to have state people there that they know, because those students were in their classes with their own employees, that the level of training is something they feel comfortable with, when we go out and handle incidents that involve material that are technically under NRC jurisdiction, or under another federal agency jurisdiction that NRC has an MOU with, to provide assistance.

DEPUTY DIRECTOR KNAPP: Thanks for the

additional comments.

MR. CAMERON: And I guess I'd have one question, or clarification for you, Steve. You were talking about the fourth option, which is, treats agreement states as co-regulators.

And, at a minimum, I think you're saying that it's, it's really overstated, in the sense that it implies that the agreement states are not, are not co-regulators now.

Given that, is there anything within that option that, if you take it out of this context of the implication that agreement states are not co-regulators now, are there, is there anything in there that could profitably be applied to, to any of the options that, that you're supporting? Or, should it just be scrapped entirely?

MR. COLLINS: Well, as I stated, basically, we are already your co-regulators or your partners, whether you like to recognize it or not. We do recognize that NRC has a role, under the Atomic Energy Act, that is not provided to the agreement states. That is, the oversight of the agreement states.

But that difference in our roles should not result in our failure to recognize that, in most other respects, the agreement states have equal responsibilities

and functions, and an even larger scope of sources of radiation to regulate.

So, with that stated, most everything else in option four is basically pretty good stuff.

MR. CAMERON: Okay.

MR. COLLINS: We don't have a problem with the rest of it.

MR. CAMERON: Okay. Thank you.

MR. COLLINS: The -- we made very clear that the training and stuff, and the funding of that is not really ties to recognition of the partners that we are. That we are, have been sharing with you our resources, and services, and stuff from the beginning.

We specifically think that our agreement, between our governor of these states and their commissioners, in fact, pledges our best efforts to cooperate and provide those services and things, without getting into this tit for tat, who pays for what kind of thing.

And we think that the benefits you receive are worth well over the one million dollars, or 1.1 million dollars per year that's spent. We think the states' efforts on low level waste licensing alone are worth more than that.

MR. CAMERON: Okay. Good. Good. Thank you.

Thank you, Steve. Let me ask Mal. Is it -- it seems like it's a fair characterization to say that the Commission's preliminary option combines elements of options two, three, and four. Is that, is that correct?

(No response.)

I guess the point I'm trying to get to is it seems like this option, about giving the agreement state program to another federal agency, or the fifth option, about just basically giving the programs, program completely to the states, are pretty much off the board, at this point.

DEPUTY DIRECTOR KNAPP: You're correct in that. I think I would -- my interpretation of the Commission's words, and those of you that have them right in front of you can do this just as well as I can, would be that the real, the real focus of the Commission at this point, a preliminary view, os to continue the current program.

But -- and then they would encourage, with intangible incentives, additional states to become agreement states.

So, I -- yes. I think it could be reasonable to say it contains elements of the three in the middle, but I think the principal focus is that they're.

MR. CAMERON: Okay. Well, given that, is

there anyone out there who would like to comment on either option one or option five? I'd just like to make sure that we're not ignoring someone who, who feels that those, those options might be the best way to go.

DEPUTY DIRECTOR KNAPP: Chip, could I add just another thought, as you look at these. Someone that is strongly opposed to one of the options, we want to hear that two. You don't necessarily have to favor.

MR. CAMERON: Oh, that's right.

(Laughter.)

I think we heard, earlier, some, some opposition to, to option one, at least, and I think we have a reluctant comment, or perhaps, over here, on those. But we're not, I'm not trying to -- I'm not looking for people who just want to support those options, but I just want to make sure that we have a discussion on this. Judy?

MS. JOHNSRUD: Yes. When the SECY-95, was it 201, came out, years ago, a year ago, proposing to abolish the low level waste division, I found myself in the rather awkward position of supporting the NRC, around the low level waste division of the NRC. I gasped at the thought that you might be wiped out.

But, with regard to the fifth option, I, I fully appreciate and concur that we need some baseline of

standards that are uniform, throughout the nation. But I think, increasingly, the states are seeing that they may have clusters of pollutants of various kinds, that impact upon their citizenry.

And the, the synergisms and the multiple source problems devolve back to the states, to deal with those who may suffer health impact from a variety of environmental pollutants.

And it's for that reason that many of us in the environmental community are urging that the states be authorized and permitted to set standards, radiation standards, that may be more restrictive, but not less so, than those of the NRC.

And this is in order to deal with the real world problem of health damage that may result not only from the radiation, but from that, or perhaps from several sources of radiation, within a given portion of a state.

It's a, in a sense, it's a very difficult problem, and yet -- and I know some states want to go down to the other end, and simply let go, but there, there appear to be some needs for the ability to be more restrictive than the baseline federal standards.

It would give us uniformity, but would also permit the particularity on the part of a state that wished to protect its citizens better.

MR. CAMERON: Okay. Thank you. Mal, do you have a, any comment on that?

DEPUTY DIRECTOR KNAPP: I just want to make sure. I think I interpret your comment well, but I just want to restate it. With respect to the general concern of regulation, it's your view that states should have an opportunity to be more restrictive than federal standards, but not less.

To translate that into an application of option five here, you would not favor devolving this to the states, because that would essentially eliminate a federal presence in this material?

MS., JOHNSRUD: That's right. And I think it is, I think the situation is compounded by some states, where administrations and legislatures are even more determined to cut the budgets and the existence of regulation. So, it's -- we're in a difficult era.

DEPUTY DIRECTOR KNAPP: Thank you.

MR. CAMERON: Okay. Thank you, Judy, and thanks, Mal. Cardelia?

MS. MAUPIN: Hi. Cardelia Maupin, Office of State Programs, NRC. Hi, Judith. I remember you from our compatibility workshop, back in 1994. We just sent out revisions on our compatibility and adequacy policy that we're looking at, and we did send you a copy.

And, in looking at that, you should see that the states would be given, or we're envisioning to, in that proposed finding, to give the states more flexibility in dealing with the issues that you just mentioned.

On the other hand, in looking at those states who want to use other legally binding measures to implement requirements, we're also looking at using what we call the IMPEP program to make sure that the overall protection of -- that the state is doing an overall adequate job of protecting public health and safety, which is the primary mission.

So, I would just encourage you to look at that package. I know it's very extensive, but that's what we hope to get with those revisions, and that new policy statement.

MR. CAMERON: Okay. Thank you for that information, Cardelia. Roy?

MR. BROWN: Roy Brown, with the Counsel on Radionuclides and Radiopharmaceuticals. CORAR member companies have fixed facilities, nuclear pharmacies, distribution facilities in all 50 states.

We obviously sell to hospitals and physicians in all 50 states. So, we deal quite a bit with NRC licenses. We have agreement states licenses. We are selling NARM products in NRC states. We have a whole

variety of regulatory authorities, in doing really everything in all 50 states.

One thing that we're disappointed that was not addressed in this DSI was the issue of compatibility. We see there are quite a few problems with compatibility now, between the NRC and the agreement states. But there's also a problem with compatibility between agreement states.

Even though the CRCPD has done a very good job developing standards for states, the states that have adopted them, they work very well, but the states that have not adopted them create some problems for us.

We have problems everyday in transporting radiopharmaceuticals in all 50 states. We have problems with the regulations I'm talking about. We also have problems with licensing.

When we go to license a new radiopharmaceutical that contains a NARM radioisotope, it's very, very difficult. In some cases, we have to deal with many different states that want many different types of licensing requirements.

So, we would like to see the issue of compatibility between the NRC and agreement states handled, and also the, the problem of compatibility between agreement states handled.

Also, just to quickly address the options. CORAR is a group that can strongly disagree with one and five. Chip, you're looking for someone -- you're looking for strong disagreement. You have it with CORAR.

MR. CAMERON: Okay. Thank you, Roy. I'm not looking for it, but.

(Laughter.)

MR. BROWN: Issues, options two, three and four, we can go with, but, in particular, three and four, we, we like aspects of that. We're not sure we agree with the words strongly encourage in option number two.

MR. CAMERON: Okay. Thank you very much, Roy. I guess I would ask Mal, and perhaps Dick Bangart, who's head of our Office of State Programs, or any of the, the steering committee.

We're in the midst of developing a new compatibility policy. Can, can someone explain why the strategic issue focussed on these issues, and did not focus on, on compatibility? I think there probably is a good reason for that.

DEPUTY DIRECTOR KNAPP: Dick may wish to say something about it.* But from our perspective at the time, as I think you recognize, many of the issues and the options are very broadly written. They're written at a very high level.

And I think I might say that we are more interested in if you like the underlying way in which we relate in this case to agreement states. Given that that has been pretty well settled, then the issue of compatibility would be if you like an implementation or a furthering of it. That would be my view, but Dick is standing so perhaps he can correct me.

MR. BANGART: I'd agree with your comment. This is Dick Bangart.

Certainly, there is a relationship between the broader direction-setting issues captured in this issue paper and other ongoing activities that we have in dealing with the agreement states in setting up policies and programs. And over the last three-year period, there has been a significant number of changes to the agreement state program that have resulted from both Commission direction and input from the agreement statement community that are in various stages of being put into place right now.

And the compatibility issue is one where the Commission a year ago did give preliminary approval to a new policy statement on that issue, but it was commissioned by a statement also from the Commission that it would not go into effect until implementing procedures were developed and finalized and approved by the

Commission.

What Cardelia mentioned was the fact that those implementing procedures, together with at least a slightly revised policy statement, are now out for public comment. I believe it's the middle of November that -- November 8th. We've asked for public comment by November 8th. There is still opportunity to further influence the Commission as we go forward with developing our final policy statement and implementing procedures on the compatibility issue.

MR. CAMERON: Okay. Thanks for that clarification, Dick, and I see we have someone over there at the mike.

MR. THOMPSON: I'm Tony Thompson on behalf of the National Binding Association.

And with respect to stricter state standards as they relate to the regulation of radioactive materials, you have some preemption questions that raise legal questions, it seems to me, particularly since the Atomic Energy Act has been interpreted to provide NRC and the Federal Government with preemptive authority. EPA for that matter, too, is with respect to setting health and safety standards regarding radiation exposures.

At the same time, the Commission has the position on certain aspects of 11(e)(2) byproduct

material, wherein non-agreement states are authorized to regulate without making the same kinds of commitments that the agreement states have. So it seems to me there are a number of very dicey legal issues tied up in the discussion that was related to evolving authority, more authority, to the states on the regulation of health and safety.

MR. CAMERON: Which would make it even more difficult. Thank you, Tony.

Steve?

MR. COLLINS: Steve Collins, Organization of Agreement States.

In a moment when you hear from Ruth McBurney of the Conference of Radiation Control Program Directors you will hear a couple of specific sentences to option 5. But before that, with regard to the comments from the gentleman representing the radiopharmaceutical distribution industry, and for that matter any other manufacturing and distribution that is more than one state, that the states, in fact, agree with your comment with regard to what you're calling a lack of compatibility from states to NRC and state to state.

What we intended to convey in our comments that maybe wasn't clear enough is that as a part of this DSI, and the implementing procedures for adequacy and

compatibility policy statement, our proposal is -- and that partnership concept that we explained -- is that the states and the NRC work together on deciding what regulations are needed, what policies are needed, and the exact wording of the model rule or regulation that will be used by each state and the NRC in its promulgation process.

The process that we have right now that the agreement states become at times so frustrated with is that the NRC develop ones and then says, "Here it is. Take it or leave it. This is the way you're going to do it. And oh, by the way, there's a few where you can be a little more restrictive if you want to." We don't like that. We don't think that's the way to go.

In the beginning states 25 years ago in the infancy of agreement states program, that was an okay way to start. And our statements where the Atomic Energy Act recognized that the agreement states would mature and one day become co-regulators or equal partners, with the exception of the oversight role, we are there now. We want to be recognized there, and we want to start working as partners in this early stage of developing those rules. And we think that the compatibility issues will almost disappear if, in fact, we work together in the beginning to come up with what are we going to regulate, and what

are the words of those draft rules going to be?

And we also have proposed through the Conference a new organization to help make that happen, and under that new organization it would -- basically, the states and the NRC are not supplanting each other's roles. We each have to go through our Administrative Procedures Act process for promulgating a rule. But the model rule that everybody starts with would be co-developed or developed by all of us, the partners in the process, as opposed to just one and then the one being the big butter from Washington saying, "Do it this way."

MR. CAMERON: And is that going to be Brought out in your comments to the partnering idea?

MR. COLLINS: In the written comments, yes.

MR. CAMERON: Good. Thank you.

Rob?

MR. McDOUGAL: Rob McDougal from SAIC.

I arrived a few minutes late for the beginning of the DOE regulation session, but I wanted to find out if there was a discussion of the connection between the two issues -- the agreement state issue and the external regulation issue. As I'm sure most of you know, the Advisory Committee on External Regulation of DOE Nuclear Safety recommended that, quote, "Essentially all DOE facilities and activities, nuclear facilities and

activities, be externally regulated." And the Secretary accepted that recommendation and appointed a task force to implement it.

And last I checked, which was some months ago, the task force appeared to be favoring NRC as the principal candidate to be recommended as an external regulator.

And my question really I guess goes to: regardless of whether NRC takes a position on external regulation, does its preliminary position here on the future of the agreement states program, which I take to be pretty much option 3 -- continuing that program with adopting current initiatives -- does that contemplate some sort of help to prepare agreement states for the assumption of regulatory responsibility for all of the DOE nuclear materials that would come to be regulated under NRC in the agreement state program?

MR. CAMERON: Go ahead.

MR. KNAPP: I was going to ask Steve if he wanted to answer the question. It was discussed briefly yesterday. And then I think I might have a comment, Steve, after you.

MR. COLLINS: Well, after my comment, I'm sure you will.

(Laughter.)

I think we made the statement fairly clearly yesterday, if not today already, that the states that currently have these DOE facilities in them think that in those particular areas we've got more expertise than NRC does and we're going to be advising them, if they'll listen.

MR. CAMERON: Okay. Thanks, Steve.

And I believe Ruth McBurney from the Conference, in her statement at the beginning of the session that you missed, Rob, did speak to the relationship between the NRC and the agreement states in regard to the regulation of DOE.

And you may want to repeat that, Ruth.

MS. McBURNEY: Yes. I think -- and correct me if I'm wrong, because I was not at all of the meeting yesterday -- but since those are federal facilities the materials maybe still continue to be regulated by NRC with the assistance of the states. But what we are seeking is the exemption from sovereign immunity for the other sources of radiation in those facilities where the states do have more expertise, those being the accelerators, the X-ray machines, and so forth, the other sources. Not just the agreement states, but all of the states -- state programs.

On behalf of the Conference of Radiation

Control Program Directors, I had some other comments on this issue as well. We concur with the comments made by the Organization of Agreement States but have a few additional remarks.

The mission of the Nuclear Regulatory Commission is partly to ensure adequate protection of the public health and safety, and that is one of the primary missions. One important way that this mission is accomplished efficiently is through the agreement states program, and we support the concept of states as partners in the effort to provide effective regulation of radioactive materials.

We would like to add to the list of benefits that states as a whole provide. Both agreement states and non-agreement state programs respond to incidents. Steve mentioned transportation of radioactive material, reciprocity issues where NRC-regulated material is brought into the state.

We also respond to incidents at landfills and scrap yards that may involve the improper disposal of radioactive materials, some of which may involve NRC license material. These incidents can take up a significant amount of staff time with no reimbursement for those resources.

And as Mal mentioned earlier, training should

be provided. Aside from the funding issue, it's necessary to keep training uniform throughout the country in order to know that when anywhere we have to deal with these regulatory issues that there is somebody close by that can respond and that the training is consistent in agreement states as well as the NRC staff.

Just from a personal experience, I found that having the NRC courses and having the regulators from both the states and the NRC attending these together you not only hear the same thing, but you share experiences among yourselves and come out a little more than just being inbred in an NRC-only course or a states-only course. There is a sharing of information.

Along with the partnership issue on the standards, we are trying to develop -- the CRCPD is working with creating an organization or a group to develop national consensus standards, model regulations that the federal agencies can use, that the states can use. And Steve touched on it, but it would be in parallel -- the NRC and the states on materials issues, FDA and the states on X-ray issues, and so forth -- to develop consensus standards. Not that each one would not have to go through its own rulemaking process, but just to keep the level of uniformity going across the country and that you would not have the bifurcation of all of the state

programs.

MR. CAMERON: Okay. Thank you, Ruth, and thank you, the Conference and the Organization of Agreement States for coordinating your presentations.

MS. McBURNEY: Steve mentioned that both the Organization of Agreement States and the CRCPD had some comments about 1 and 5. And as we mentioned earlier, you know, concerning EPA, why would NRC want to do that. Again, there would be reciprocity issues involved. If EPA is regulating states and NRC is regulating the other materials licensees, that would be a problem.

And also, it would not make any difference in the cost. I mean, it would increase the cost on a transition level to put it over in another federal agency.

On option 5, the position of both groups was that the NRC and the states, through the CRCPD, should begin working on the long-term goal of as more and more states become agreement states -- not that it would be encouraged -- toward implementing option 5. In addition, NRC should never consider walking away from regulating licensees in a state where there is no agreement state program.

MR. CAMERON: Okay. Thank you very much for those comments, Ruth.

Richard, do you have some comments?

MR. RATLIFF: Yes. Richard Ratliff, Chief of the Texas Department of Health, Bureau of Radiation Control, not Organization of Agreement States this time.

I think that NRC did in their options miss one real specific option that just occurred to me while everybody was talking. Whereas NRC did not consider the historic relationship with agreement states, where the NRC paid for the agreement states' travel and per diem to the agreement states courses and to the annual all agreement states meeting, which has historically been an exchange of information to benefit NRC and the states, and this really -- option 3 talks about continuing the program with those caveats, which is not funding the travel. And so this other option just I think was not considered and should be considered.

Steve had mentioned that NRC receives a lot of free money from states, from state licensees, because it has been several times mentioned that it's an equity issue that the NRC licensees shouldn't be paying for agreement state activities.

But when you look at it, in Texas alone we have major U.S. manufacturers of well logging instruments and actually doing services -- Slumber J, Western Atlas, Dresser Atlas, Tan Technologies -- and they pay NRC fees because they have national operations that are much higher

fees. So they really are paying, and we do the major inspections at their facilities as well as our nuclear reactor facilities which we do the emergency response at and they pay NRC fees.

Also, in NRC NUREG-1311, funding of NRC training program for states, which was published in June 1988, on page 2, paragraph 3, it states, and I quote, "The NRC agreement state program has been reviewed by the General Accounting Office, an internal NRC task force, and the National Governor's Association."

In their reports, the NRC training program for states was consistently identified as the key to enabling states to prepare for such agreements and to make agreement state programs that are adequate to protect public health and safety and compatible with the Commission's program. Their reports also contain recommendations to expand the state training program.

So, in conclusion, I think that NRC should continue the agreement states program with the reinstatement of NRC paying for agreement state training courses, which is tuition, travel, and per diem, as well as travel and per diem for the annual all agreement states meeting that benefits both the states and the NRC and all of the people we regulate.

And the NRC should continue to advise Congress

that some areas, such as international programs, the agreement states program, and maybe even the research program, should be exempted from 100 percent fee recovery, not be charged to NRC licensees but should be directly appropriated by Congress.

MR. CAMERON: Okay. Thank you, Richard. And you would add those into the Commission's preliminary option.

MR. RATLIFF: Correct.

MR. CAMERON: Okay. Why don't we take a break and come back and talk about the materials program, unless -- does anybody have any final comments on this issue? Okay. How about 10 after 3?

(Whereupon, the proceedings in the foregoing matter went off the record at 2:55 p.m. and went back on the record at 3:23 p.m.)

MR. CAMERON: Okay. If everybody could take their seats, we're going to get started on the last topic for this afternoon.

And I have one announcement. There has been a message on the board for Rod Krich, K-R-I-C-H. Okay. Well, if anybody knows Rod, you might tell him that. I don't know if he has picked it up, but -- so any message in anybody's hand --

(Laughter.)

Okay. The last topic of discussion in the nuclear materials area is materials oversight, which includes the medical program, and Mal is going to discuss some specifics on that.

MR. KNAPP: I'm going to presume that the size of the audience means that it's late in the day and not a lack of interest in whether the NRC should retain its materials program. But in my view, the important people are here, so I'm perfectly happy. It always works.

Okay. DSI number 7: what should be the future role and scope of NRC's nuclear materials program? And in particular, the NRC's regulation of the medical use of nuclear materials?

I'm going to skim these, because I suspect that most of you in the audience are pretty familiar with this. But in a few of the key factors -- this we might want to remind ourselves of -- we regulate AEA materials, those created or made radioactive by exposure to radiation during the fission process. It means we don't regulate NARM, we don't regulate linear accelerators, we do not regulate X-ray machines.

I think we are all pretty aware that there are opposing strongly-held views on the part of the regulated medical community and Congress and the media concerning the regulation of nuclear materials in medicine.

In part because of these differing views the NRC instituted a study by the National Academy of Sciences some time ago. Last winter the Academy's Institute of Medicine provided a report which recommended that NRC eliminate its regulation. Actually, recommended to Congress that they pass legislation which eliminates NRC's regulation of its medical use program.

Earlier this afternoon we talked about agreement states, the increase in the number of agreement states. This is a factor, as I said earlier, on the materials program. As the number of NRC licensees decreases, we begin to have a smaller and smaller program, and eventually there is a concern that our materials program will drop below a critical mass and require that the program be changed or that it can no longer be self-sustaining.

And finally, the NRC is conducting business process reengineering of its materials licensing program and anticipates expanding business process reengineering in time to other aspects of its materials program. For those of you that are not quite familiar with this topic, basically it constitutes standing back, asking how and why what we do -- in this case in licensing -- and asking if there is not a better way to do it. It comes from the concept that if you've got a process and you start to

automate, you can make the mistake of automating a process which is inefficient to begin with.

So if you're going to do that, look at the process, make it efficient, and then take advantage of the information technology tools we have today to make that as workable as possible. We are seeing some success in that. We anticipate reducing the number of staff that we will need as a result of the efficiencies, and we expect to expand that to other areas.

Given these key factors, the staff provided the Commission with a variety of options. The first option would be to increase our regulatory responsibility. We would add X-rays, accelerators, NARM, and NORM, naturally-occurring as well as accelerator-produced radioactive materials. It would be expanded to cover essentially all forms of ionizing radiation.

The second alternative would be to continue our ongoing program. "With improvements" means improvements such as the business process reengineering I spoke about just a moment ago.

The third option would be to continue the program but to decrease the oversight of low-risk activities but continue to emphasize high-risk activities. In talking about our materials program, at this point sometimes it's important to remember that we look at a lot

of things in the materials program, from things as small and as numerous as gauges to things as large and as few as fuel cycle facilities.

And so this option would be one in which we consider some aspects of the regulation of nuclear materials and ask whether we should deemphasize those which have a lower risk. I did not say deregulate; I said deemphasize. And what we would do there is something we would consider as we look at those applications. Possibilities might consider such things as diagnostic medicine or certain gauges which have very small sources.

At the same time, if we were to look at that and base it on low risk/high risk, we might find that there are some things which right now we regulate under a general license, or which are exempt, and we might decide the risks are sufficient that maybe we should consider specific licenses.

So this would not be a deregulation. It would be a reconsideration of that which is low risk and that which is high risk and getting comfortable with the fact that our regulations are consistent with the risks we now believe are available.

Another alternative would be to accept the recommendations of the National Academy of Sciences, which in essence would be to discontinue our regulation of all

medical activities, with the exception of our oversight of devices and manufacturers on devices such as -- or, excuse me, manufacturers such as radiopharmaceuticals.

And then the last option would be to discontinue the materials program. And although there are various ways to do that, this would not be unlike option 5 in the agreement states paper which you saw in the last presentation. Given these options, the Commission gave us a number of preliminary views and asked a number of questions.

First, their preliminary view would be that they favor option 2, continuing the ongoing program with improvements such as the business process reengineering. But they would also like us to at least add some elem... of option 3 -- that is, to consider the low-risk and high-risk activities, decrease our emphasis on low-risk activities, our oversight, but continue emphasis on high-risk activities.

In implementing option 3, we would use the Commission's risk-informed performance-based approach to regulation to decide how we might best approach it. Specifically, the Commission would ask us to look in the medical area at which are low-risk activities.

Given these views and the issue paper in general, the Commission has asked a number of questions to

which it particularly seeks comment. And here, unfortunately, the last slide left the meeting early, so I'm going to have to ask you to look at your handouts. Or, if you're close enough, just at least to help us focus, the last slide appears on the flip chart.

There are four particular areas in which the Commission would specifically like comment. They'd be interested in the views of other affected organizations, such as the Organization of Agreement States, Conference of Radiation Control Program Directors, on applying a risk-informed performance-based approach to NRC's oversight of medical activities.

One suggestion which was made where the Commission would particularly like comments would be: should the agency strive to have the remaining non-agreement states acquire agreement state authority for medical use only? Recognizing that states regulate many aspects of medicine which are not based on radioactive materials already.

The Commission would particularly like comments in this area on whether a single agency should regulate radiation safety. This question is broader than simply the concern about materials in medical. It arose from some of the comments which we had received earlier. And you've heard today some of the concerns we have with

multiple agencies being involved. Comments as to whether a single agency should regulate radiation safety are sought.

And finally, as a feed to your understanding of the issues, particularly those involving nuclear medicine, this particular paper had about a 30-page appendix added to it, which we hope reasonably accurately summarized the views of the Institute of Medicine, and summarized the comments which we have received so far or which we had received through about the end of August on those views. Any comments on whether or not we accurately reported their views, or the views of others, any comments on whether you agree or disagree with those views, would certainly be well received.

That's a quick snapshot of where we are, and I would now again like to give it to Chip and ask for your comments.

MR. CAMERON: Could you just clarify what we mean, just generally I guess, by "risk-informed performance-based"? And also, in terms of the fourth -- or the third specific question -- single agency -- are we talking about single agency at the federal level that would exclude state regulation, or are we talking about single agency within a state? I think it might help people if we clarified both of those.

MR. KNAPP: All right. Let me begin with the risk-informed performance-based and mention a little bit about it, particularly as it applies to materials regulation.

Risk-informed regulation, more broadly than simply PRA -- Probabilistic Risk Assessment -- is something that the NRC is moving toward. As you may have heard earlier today, a number of our regulations are very prescriptive. The question can be asked: should we go to regulations which are less prescriptive, "Do this and this and this," and more performance based, "Achieve this result and use what you think is the best way to do it. Provide us a plan for how you're going to get there."

The question is: should the successes and the insights -- or could the successes and the insights gained in risk-informed performance-based regulation of nuclear reactors enhance, perhaps make more efficient, more effective, NRC's regulation of its materials program?

Now, I misspoke just a second ago. I don't want to give you the impression we're asking whither. The Commission has issued a policy statement on risk-informed performance-based regulation, which says, "This is the direction we will go." Some questions to be asked about the materials program are: how fast and how far?

And with respect to how far, one can argue

that a broad scope licensee with considerable talent and an ability to tap its health physicists could rather easily handle risk-informed performance-based regulation by achieving levels of performance using their understanding of radiological matters.

On the other hand, some of NRC's licensees, such as radiographers, have limited training, they use the devices as a tool, and they might be best served -- we all might be best served -- by a relatively prescriptive program which does not necessarily emphasize performance-based approaches.

So as we look at the materials program as a whole, we need to look at moving towards risk-informed performance-based regulation and asking: where is this applicable and where are there places where it is perhaps not that good an idea? That's risk-informed performance-based.

Your second question was: what do we mean by a single agency? We have a host of federal agencies these days involved in nuclear regulation. Certainly, we have EPA that sets generally applicable environmental standards. We have NRC, with the responsibilities you've heard about today. There are certain transportation regulations which are created and implemented by the Department of Transportation. FDA has certain regulations

which it implements in the medical area.

In some cases, we find that we work smoothly with other agencies and things don't seem to cause very many problems. On the other hand, in some areas we do have disagreements. Those of you that are students of the NRC/EPA relationship would know that although we are working hard at it there are fundamental differences in the legislation, and occasionally in the philosophies, of the two agencies.

And we have developed this outfit called the Interagency Steering Committee on Radiation Standards, and we are trying to come up with consistent ways of doing risk assessment and risk management. But it's a long process.

The question could be asked: given all of this, would a single agency's regulation be the most effective way to go in nuclear materials or for radiation safety in general? And given that the issue had surfaced, the Commission would be very interested in comments about it.

MR. CAMERON: Okay. Thanks, Mal.

MR. KNAPP: Excuse me. I didn't finally finish your question. I'm sorry.

We were thinking principally at the federal level. Your question said: are we thinking about federal

and state? We'd be happy to entertain comments in both directions. But I think what we had in mind: would licensees, states, others, be best served by a single federal agency?

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

With that, who would like to start out with a comment? Right there in the back.

MR. McINDOE: Allow me to introduce myself. My name is Darrell W. McIndoe. I am a full-time nuclear medicine physician. I represent the American College of Nuclear Physicians and the Society of Nuclear Medicine.

I wish to thank you for the opportunity to present oral comments at this time.

Both organizations, and I will concur as an editorial comment, think that what you're doing now has been long overdue, and we appreciate the effort that is being expended to take a relook at medical oversight. We hope that you will take our comments and utilize them in your final decisionmaking. Rapid action in this area would be greatly appreciated by professionals in these organizations.

The last 20 years there has been a steady increase in regulation of nuclear medicine activities, and these tend to be prescriptive type changes and not

performance based. We do 10 million diagnostic nuclear medicine procedures each year. We do approximately 60- to 70,000 therapeutic nuclear medicine procedures.

The amount of regulatory effort required to document, monitor, undergo, and fulfill the prescriptions is an exceptional financial burden, and I might parenthetically add, as a practicing clinician, non-reimbursable. We cannot add this as our overhead.

And when you spend 45 minutes to an hour of your day filling out papers to fulfill requirements and not get reimbursed for it, this is a very expensive proposition when you multiply it over the national spectrum. And we feel that the NRC needs to assume some form of fiscal responsibility in terms of trying to reduce this cost to the national medical effort.

Today we would like to comment specifically on three areas, and that's diagnostic nuclear medicine, therapeutic nuclear medicine, and nuclear pharmacy regulations.

As I mentioned before, we do 10 million procedures a year, and these are tracer elements. We cannot afford to have our diagnostic tool interfering with the body's physiology, so they have to be extremely low level. There is no injury. There is no morbidity or mortality from these procedures. It has a superb safety

record; nobody has ever died of a diagnostic nuclear medicine procedure in the last 20 years.

These things are accomplished in every hospital. And as a matter of fact, for a hospital to gain accreditation it must have access to nuclear medicine technology.

Because of its common usage, and because of its very safe nature, we feel it imperative that the NRC reevaluate its attitude regarding regulation of diagnostic procedures. We feel that basically a general license would cover diagnostic nuclear medicine. That we would be licensed to received these materials, carry out our professional duties, and on an annual basis to inform the NRC that we are still in business, or we have gone out of business. This would remove many of the prescriptive requirements in 10 CFR 35, which we find somewhat onerous at times.

In the field of therapeutic nuclear medicine, we are increasing the dose and activity which we inject or have the patient ingest many magnitudes in terms of activity. But let me emphasize that the amount of activity that we are using, even though it is therapeutic, is not lethal. And by prescription we cannot give a lethal amount of a therapeutic radionuclide.

We think you really need to review the

classification of this as a high-risk activity. Again, we have a superb safety record. Nobody has ever died in the last 20 years of an overdose of a radionuclide used therapeutically.

Now, in terms of the fact that we anticipate increasing growth and prescriptions in the area of therapeutic nuclear medicine, we feel that the mix of options in 2 and 3 could be applicable. And one of the things that we would like to encourage is that there be a participatory-type workshop with the organizations who utilize these therapeutic radionuclides, and that you sit down and hammer out what the risks are, what procedures need to be accomplished in terms of their regulation.

And it, I'm sure, is our attitude at the present time -- but there is always room for other comment -- that we'll find that there is very little risk in this area, and that, again, the prescriptive-type approach which is being accomplished at the present time can be reduced and put on a performance-based status.

We also have sent a rather lengthy model for regulation of the therapeutic nuclear medicine to Chairman Jackson regarding revisions which have been suggested for 10 CFR 35. And this, with other significant detailed written comments, will be forwarded before the closeout date.

Finally, I'd like to talk a little bit about nuclear pharmacy, and this differs from radionuclide pharmacy manufacturing. We're talking about the actual pharmacy application which occurs in hospitals or in free-standing -- what we call unit dose organizations that give us our activity to use on patients.

And we would ask you to strongly consider separating out the regulation of the pharmacy versus the manufacturer. The pharmacy fits into our hospital category as part of our armamentarium and the risk again is at the level that we deal with with patients. It is not in the risk of manufacturing.

These practices of nuclear medicine, nuclear pharmacy, are state functions. And we are feeling that the NRC should regulate their activities in a similar manner that the state would.

In conclusion, we hope to make it clear that our 12,000-member Society of Nuclear Medicine and 1,500-member American College of Nuclear Physicians favor a low-risk approach for evaluating and restructuring the regulations regarding diagnostic nuclear medicine, and hopefully come to a meeting of the minds on therapeutic nuclear medicine.

We are happy to engage in any participatory-type forum that you would wish to set up in order to

establish a performance-based risk analysis and hope we can assist you in moving forward with the changes that we are recommending. But this does not preclude most of the stuff that we have said. It is basically with options 2 and 3, but I think we also need to look very strongly at the possibility of requiring congressional legislative activity to perform some of the goals that we hope to reach.

Thank you for allowing me to testify.

MR. CAMERON: Okay. Thank you for the suggestion. Is it Dr. McAdoo?

MR. McINDOE: McIndoe.

MR. CAMERON: McIndoe. If you could just bear with me for a minute --

MR. McINDOE: Sure.

MR. CAMERON: -- I did have a clarifying question for you.

Clare, could you put the options back up for us?

Basically, what I heard you say is that the Society and the College would endorse options 2 and 3 -- in other words, look at apply a risk-based, risk-informed, performance-based approach under 3, and that that theoretically would take care of most of the problems that you see with the Part 35 regulations. Is that correct?

MR. McINDOE: Well, let me just put it this way: there are things which we feel that you have the capability of doing very rapidly and allowing us to get on with our business that can be done without legislative affect.

But when you take the entire problem of the materials and the nuclear medicine radiopharmacy, etcetera, etcetera, it may be necessary in the future -- which typical of any legislative action takes a lot longer time than a 90-day comment period in the Code of Federal Regulations. So what we are asking for is a sort of "step briskly forward" and do the recommendations which are within your authority to do and, if necessary, also fall back when necessary for legislative action.

But to answer your question: yes, a lot of it could be solved by taking diagnostic nuclear medicine, making it nothing more than a general license, and that would remove 10 million procedures out of the pipeline in terms of paperwork on them. And we're still going to have to keep accurate records, but it's one of those things that it just doesn't have the same onerous time-consuming properties that you go through when you're fulfilling all of the regulations of CFR 35, and cross the Ts, dot the Is, and make sure this is done and that is done and something else. And what we're really after is: hey, are

we doing a good job and we're doing it safely?

MR. CAMERON: Okay. And I take it that you're not endorsing -- you're not necessarily not endorsing -- but you're not endorsing at this time option 4, which ties into the Institute of Medicine report. That's what I really wanted to clarify.

MR. McINDOE: Right. And I think the Institute of Medicine report -- quite honestly, I think most of us sort of look at it and say, "Wouldn't that be wonderful?" But there is reality also. And I think we would like to get things done that we can get done now, and if it comes out to the fact that -- sometime later on that there is an omnibus medical nationwide concept in terms of regulation, and so on, that requires congressional action, so be it.

What we're trying to do is give the best service that we can for our patients at the least cost.

MR. CAMERON: Okay. So that implementing options 2 and 3 would not only be a big first step, but maybe the only step necessary to avoid implementation of option 4, I guess is what you're saying.

MR. McINDOE: I would say that that is, you know, a reason -- at this stage in the game, we don't know what the future holds. And it may be that going through changes in 2 and 3 may suddenly bring to the surface

something that we haven't thought about that would take congressional action to do. I don't know. I think the --

MR. CAMERON: Okay.

MR. McINDOE: -- just one of those things, though, that come in and say, "Let's t..e the Institute of Medicine report and institute it tomorrow." It isn't going to happen tomorrow. And I think what we're really after is something we've been after for the last 10 or 15 years, and that is pull down on the noose a little bit and give us some breathing room. And that is to cut out diagnostic nuclear medicine and understand the very low risk that's associated with therapeutic nuclear medicine, as well as nuclear pharmacy.

MR. CAMERON: Okay. Thank you very much, Dr. McIndoe. That's enlightening, at least to me.

Do we have some further comments on the options or on some of the points that Dr. McIndoe raised in terms of the risk-informed approach to medicine or the suggestion that we do an enhanced participatory process on potential revisions to Part 35?

Tom?

MR. HILL: Tom Hill with Georgia Department of Natural Resources speaking on behalf of the Organization of Agreement States.

I think in my comments that I have here we'll

address some of those. I think we have added maybe one additional step to what the previous commenter made, so let me make these and we'll get to those points I think.

The Organization of Agreement States supports the concept of a consistent, unified, national program for the regulation of all sources of ionizing radiation. It makes little sense to continue to divide radiation programs according to historical distinctions.

However, NRC's strategic assessment and rebaselining initiative, stakeholder involvement process paper, falls shorts in addressing all radiation safety issues and doesn't provide a complete perspective on this issue. Little mention is made that the majority of radiation exposure is from non-AEA sources, and thus gives the impression that only minor changes to NRC's program are needed.

Further, it appears to provide questionable information to support its conclusions -- for example, the statement that it would take several hundred FTEs to regulate discrete NARM.

OAS supports efforts to identify regulations that are unnecessarily burdensome, duplicative, or too prescriptive. This is especially needed for Part 35.

The option of using a risk-based approach is supported by most of the states. However, such criteria

must be uniformly applied to both existing and proposed regulations. Identification and classification of low-risk activities should be done in conjunction with the agreement states, and we ask that it be done in conjunction with them.

NRC must not abandon regulatory control over low-risk activities solely to reduce its regulatory burden. Such an action would result in additional problems faced by all radiation control programs, such as the problem of poorly controlled, generally licensed devices.

Although this paper purports to address all materials oversight, the vast majority of the paper focuses only on the medical area. The Organization of Agreement States is in support of NRC's initiatives to streamline the licensing process, eliminate duplicative or contradictory regulations, update regulatory guidance for all categories of licensees, not just the medical licensees.

We would caution the NRC not to abandon the regulation of radioactive material altogether. The use of radioactive material in this country is safe for workers, because there are established requirements for users of radioactive material. The public is protected because of the regulatory community's diligence in ensuring that

individuals using radioactive material do so safely.

In some cases, it is necessary to modify the regulations to be less prescriptive. But it is not necessary to relinquish all control over the safe use of radioactive material. In fact, it is appropriate for NRC to consider expanding its regulatory authority to establish uniform safety standards for all forms of ionizing radiation.

Some specific comments on the options. Option number 1 -- the increased regulatory responsibility with addition of X-ray accelerators, naturally occurring material. As indicated on page 15 of DSI 7, agreement states are in support of establishing one federal agency to work with the states to establish basic standards for all uses of radioactive material.

We recognize that this is a major departure from the current federal approach. However, we believe that it makes sense to treat all ionizing radiation equally. A rem to an individual is still a rem, whether it comes from AEA material, NARM material, or an accelerator.

Although this report states that it would be difficult to support legislation to address all sources of ionizing radiation in the absence of a compelling safety problem, we find that to be a little short-sided. As

indicated through this DSI, and DSI 2 and 4, many state regulatory agencies already have established programs to address all uses of ionizing radiation in their respective states.

States did not wait for an incident to develop a program but have been proactive in ensuring the safety of workers and the public. In fact, it may be that the states are in a better position to oversee certain DOE operations because the state programs are more encompassing, and that refers back to the earlier paper this afternoon.

We do not understand the report's estimate of several hundred FTEs to regulate discrete NARM possessed by persons in non-agreements states and by federal agencies. However, if NRC was referring to adding -- needing those people for accelerators, for X-rays, etcetera, then it may be a more reasonable estimate. But for discrete NARM only, we do not think so.

Looking at several -- the several hundred statement would mean that the effort to be applied to discrete NARM is vastly larger than resources now devoted to agreement material. So I think those were probably referring to X-rays, accelerators, etcetera.

Option number 2 -- continue the ongoing program of improvement. As stated above, we support the

NRC's effort to identify regulations that are obsolete, unnecessarily burdensome, duplicative, or too prescriptive, in the NRC's work to modify or delete these regulations.

We also support the NRC's effort to streamline the licensing process. The modifications made to date through the business process reengineering should benefit up to at least a third of NRC's licensees. We agree that this option should continue to be pursued.

Option number 3 -- decrease the oversight of low-risk activities with continued emphasis on high-risk activities. We strongly urge the Commission to reconsider its support for this option.

A joint NRC-agreement state working group on devices recently reported that problems associated with the NRC's general license program included inadequate regulatory oversight, inadequate control and accountability of devices, and improper disposal of devices. The working group developed straw man solutions and recommendations aimed at regaining control of the use of both generally licensed and specifically licensed devices.

These recommendations include requirements for users, distributors, and regulatory agencies. Option 3 of this paper, however, recommends minimal regulatory

oversight, minimal licensing requirements, and the possible elimination of inspections. As written, it appears that option 3 is advocating regulation of only high-risk activities. We agree that some streamlining commensurate with risk is warranted. However, we are firmly opposed to abandoning requirements for all low-risk activities.

In evaluating the risk, there are some things now that probably should be regulated a little more stringently than they currently are, such as some generally licensed devices that carry sources of cesium. There are some specitically licensed devices that maybe shouldn't be regulated quite as stringently as they are. So we think that looking at the risk is an appropriate way to go.

The regulations are written to minimize risk to workers and the public. Proper training and use of radioactive material will result in lowering any risk associated with using radioactive material. To remove the regulations designed to limit risk, if you remove the regulations designed to limit risk, you can no longer ensure that low-risk activity will remain such.

Option 4 -- discontinue regulation of medical activities except for NRC oversight of the licensing manufacturers. The NRC should not discontinue the

regulation of all medical activities, just as it should not discontinue the regulation of all other uses of radioactive material. It is vital that the NRC recognize the professional views of the agreement states, physicians, physicists, pharmacists, hospitals, and professional organizations regarding the unnecessarily burdensome and detailed and prescriptive requirements of Part 35, and make modifications.

To assist in determining the proper course of action, the NRC, FDA, and representatives from applicable boards of medicine and pharmacy should jointly develop a paper describing the jurisdictional boundaries of each entity relative to regulated use of radioactive material and the practice of medicine. Such a document would be a great reference point to begin recalibration of existing regulations.

Under some circumstances, it may be appropriate for states to regulate federal facilities. This also gets back to the previous comment on sovereign immunity. It may be appropriate, and we oppose self-regulation of medical uses by federal facilities. NRC got out of the business that would have the possibility, then, of self-regulation by federal medical facilities, and we oppose that.

Number 5 -- discontinue the radioactive

materials program. As indicated in our comments on option 3, the NRC must not simply discontinue its oversight of the use of material. It is reasonable to assume that individual states and federal agencies would self -- unreasonable.

(Laughter.)

I thought that was coming out wrong.

It's unreasonable to assume that individual states and federal agencies would self-regulate to the same degree. This would cause problems for facilities doing business across state borders. Deregulation of radioactive materials sends the message that the material is inherently safe -- a sentiment that Congress and most of the citizens of the country are unlikely to agree with.

Regarding the Commission's preliminary views, we agree with the Commission's preliminary views regarding option 2 and caution the Commission to consider possible problems encountered with deregulation of low-risk uses of radioactive material. We do not believe there should be encouragement for non-agreement states to develop programs to regulate only medical use.

Thank you.

MR. CAMERON: Thank you very much, Tom.

Mal, do you have --

MR. HILL: Let me make one other comment.

MR. CAMERON: Sure. Go ahead.

MR. HILL: I'm sorry. I forgot this. There are 29 agreement states, and these views are a consensus of those. I'm not saying that it's unanimous, because we do have at least one agreement state that strongly recommends the adoption of option 5. So I'll put that in.

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

I think Mal might have some questions for you, and I also have some clarifications to ask you about.

Mal?

MR. KNAPP: Actually, I only had one very limited clarification. The question you raised about our estimates for NRC staff needed to regulate discrete NARM -- thank you for the catch. That was an error in our paper. We meant the resources associated with X-rays, linear accelerators, and discrete NARM, and we appreciate your catching the oversight.

MR. CAMERON: Okay. Tom, in relation to option 1, the NRC option of regulatory authority for NARM, I take it that the agreement states would support the NRC seeking legislation to assume that authority, assuming that it would be under the same sort of agreement state framework if we assumed that authority.

This has been suggested by the Conference and

others a number of times in the past, and I just wanted to clarify: is that what you're recommending?

MR. HILL: Yes.

MR. CAMERON: Yes, it is. Okay.

And going back to the point that Dr. McIndoe raised, it seems like we focus on the Institute of Medicine report. But it seems like you're also saying that the initial focus may be on -- may be more properly placed on Part 35. And after that process, then you could see whether there is any viability left to the Institute of Medicine report. Is that a correct characterization, or -- in other words, look at the Part 35 in terms of the low risk -- from the low-risk perspective.

MR. HILL: Yes. And I think the IOM report kind of is the driving force for that.

MR. CAMERON: Okay. Okay. Thank you.

How about some other comments on some of the points raised? Option 1 -- well, Roy, go ahead.

MR. BROWN: Roy Brown with the Council on Radionuclides and Radiopharmaceuticals.

Let me start off by commending NRC for their ongoing activities that are addressed in item number 2, option number 2, the BPR activities of Part 35 revisions, identifying regulations that are obsolete and unnecessary or too prescriptive. That's a very good process NRC is

going through right now, and by all means that should be continued regardless of what other options are incorporated.

Section 81 of the Atomic Energy Act never envisioned the development of cyclotron-produced isotopes and NARM-produced or NARM radiopharmaceuticals. There are many of these NARM radiopharmaceuticals and radioisotopes in use today being regulated by a variety of different agencies. CORAR believes one federal agency should regulate these NARM materials and believes it should be the NRC, as outlined in option 1.

I'll withdraw my comment about the several hundred FTEs.

(Laughter.)

CORAR feels very strongly in support of the deemphasizing regulatory oversight for very low-risk activities as outlined in option 3. We believe this is a much more sensible approach than option 4 with the IOM report.

As Dr. McIndoe indicated, diagnostic nuclear medicine and nuclear pharmacy is a very, very safe activity with very little risk to the public. And we do believe -- CORAR believes that this activity could be safety deemphasized. However, we recognize that therapeutic nuclear medicine with slightly higher amounts

of radioactive material presents a slightly higher risk.

We also suggest that the NRC undertake an enhanced participatory rulemaking to resolve the best way to regulate this therapeutic nuclear medicine. We also recognize that the manufacturing of radiopharmaceuticals and medical radioisotopes presents a slightly higher risk, even though it's a very safe activity, and we fully recognize that we will continue to be regulated by the NRC.

Let me point out at this point CORAR had previously supported the IOM recommendations. However, with the NRC looking at this, considering low-risk activities, and possibly deemphasizing these low-risk activities, we are now withdrawing our support for the IOM recommendations and getting behind option 3. So this is a change in policy, a very dramatic change in policy, for CORAR if this goes through as postulated.

A specific response to question E -- I mentioned this earlier. CORAR feels one federal agency should regulate radiation safety, and we feel that agency should be the NRC. However, CORAR also advocates that a different independent advisory group set the standards that NRC and the states enforce.

Lastly, let me thank NRC for the opportunity to present these comments and let you know that CORAR is

very interested and very willing to work with the NRC in the further development of this activity.

Thank you.

MR. CAMERON: Thank you very much, Roy.

Mal, do you have any questions?

MR. KNAPP: I'd like to explore, Roy, one of your comments a little further, if I may, and you may not have developed it enough. I don't want to put you on the spot.

The concept of a single agency having regulatory jurisdiction, but having an external body develop the standards -- if you could elaborate on that at all -- for example, who the external body might be or what that relationship would be -- that would be very helpful.

MR. BROWN: We will go into greater detail in our written comments when we submit those next month, but we are thinking along the lines of an NCRP or a group like that, an independent group, not an NRC or an EPA.

MR. KNAPP: Thank you.

MR. CAMERON: Okay. I think it's interesting what we're hearing, at least from people here today. There seems to have been -- to be a lot of support for option 1, and also option 2, and option 3. It seems like there is consistency among a number of different people on that.

Is there anybody out there who doesn't think -- outside of the NRC staff -- that doesn't think that --

(Laughter.)

-- we should try to assume regulatory authority for NARM? I am just looking for any other views on that particular option, since we have heard support from a couple of people at least.

Go ahead, Ruth.

MS. McBURNEY: Ruth McBurney, Conference of Radiation Control Program Directors, Board of Directors.

Just to clarify on option 1, that we are in support of establishing a federal agency to work with the states to establish basic standards for all sources of radiation but not particularly to take on the task of regulating all sources of radiation. So we're not purporting that NRC take on X-ray and accelerators, and so forth.

MR. CAMERON: Okay. That's an important distinction.

MS. McBURNEY: Right. If every state other than Wyoming has an established program for X-ray machines -- and it's unlikely that any state would choose to relinquish control of X-ray services -- for X-ray sources, federal agency should work with all of the states to establish basic standards and minimal requirements. But

the active oversight and inspections should remain the state authority and control, except for maybe federal facilities.

MR. CAMERON: Okay. Thank you.

Mal, did you have any questions on that?

MR. KNAPP: One. If we were to take that approach -- as you're well aware NRC has an oversight responsibility over the agreement states. I didn't clearly understand whether you would see that sort of an oversight responsibility over states that regulated -- over regulation of X-ray equipment.

For example, let's say that we follow the option, we reach agreement that we work appropriately to set standards for safety and for use of X-ray equipment, and that the states use their existing programs to implement those standards. In the event that a state did not do that, chose not to do it, or did it badly, would you see that the NRC would have any role at that point, or would you leave that at the, say, discretion of the state legislature?

MS. McBURNEY: Our first option would be to work together for consensus standards, that there would be a consensus standard-setting group made up of the federal agency -- whether that's NRC or whatever -- and the states to set model regulations, and so forth.

I guess our fallback position, then, would be the second option as an agreement statement type regulation.

MR. KNAPP: Right. But in your first choice, the single agency would set standards --

MS. McBURNEY: Right.

MR. KNAPP: -- but would not have the oversight authority.

MS. McBURNEY: That's correct.

MR. KNAPP: Thank you very much.

MR. CAMERON: Roy?

MR. BROWN: Roy Brown with CORAR. I wanted to clarify CORAR's position here. CORAR is only recommending the adoption of NARM and the use of medical isotopes and radiopharmaceuticals in option 1. The concern we have right now -- if we're selling a NARM radiopharmaceutical, if we're selling it to an agreement state, or a state that's following CRCPD guidelines, it's a very well-addressed program, a very well put together program, that they have a license and we sell to them and check the position limits, just like an NRC license.

However, if we try to sell a NARM radiopharmaceutical or a NARM medical isotope to a non-agreement state, in some cases they have a license, and in some cases they have a registration. And as Ruth

indicated, in some cases like the State of Wyoming there is nothing. And that goes back to our comment earlier about consistency as well.

MR. CAMERON: Okay. Thanks for that clarification, Roy.

Dr. McIndoe?

MR. McINDOE: Just a question here on using option 1. Where we have accelerator-produced radionuclides for diagnosis and therapy, I would hope that if this option comes about that it would still tie into option 3, that the regulation and categorization of safety, etcetera, would fit in with that.

I think the idea of CORAR's having an independent organization be the lead for establishing standards that professional organizations, states, etcetera, can agree with and say, "This is what we think is the national standard for all forms of ionizing radiation," and then also we previously have mentioned have some participatory type of forum where we can establish a degree of risk with each of these things that we are utilizing.

Then, NRC as a regulating agency can see whether we are in compliance, and in those places where the standard has been established and you review and find that there is non-compliance, then you have the statutory

authority to give sanctions. Or what would be better probably is reeducation, to make sure that these standards are complied with.

But I think if you're going to lump things together you've still got to have risk stratification, you've still got to keep the same comments in your options 2 and 3. And I think everybody feels that it's more efficient to have one compact place where you can deal with rather than four or five like we have to have at the present time. But I still think there has to be the concept of options 2 and 3 that have to be applied to 1.

MR. CAMERON: Okay. Thanks.

And I believe Mal wanted to comment on that.

MR. KNAPP: I just have a question. I would like to make sure that I clearly understand the positions of several of the recent speakers. I look ur the definition of NARM -- naturally occurring and accelerator produced.

Okay. Let's go a little further; let's talk about discrete NARM versus diffused NARM. And I'd be interested -- I want to make sure I understand -- diffused NARM, for those of you that may not be experienced with it, would be naturally-occurring radiation in large quantities, such as in piles of tailings but tailings which are of other ores, not necessarily regulated by the

Nuclear Regulatory Commission.

My question to the various speakers is: when you talk about NARM, do you refer to all forms, or do you refer to what we might just call "discrete NARM"? Any help would be appreciated.

MS. McBURNEY: I think in our comments we are referring to discrete NARM only, naturally-occurring and accelerator-produced radioactive material. That would be, for example, radium sources, radiopharmaceuticals that are cyclotron or accelerator produced, waste that is either accelerator produced or some of these discrete, naturally-occurring sources, such as uranium.

We're not referring to the types of naturally-occurring radioactive material that a lot of the states are having to deal with, such as phosphogypsum piles, and oil and gas, NORM, and so forth.

MR. BROWN: Roy Brown, CORAR. CORAR's comments were limited to discrete NARM.

MR. KNAPP: Thank you.

MR. CAMERON: Okay. Does that clarify it for you, Mal?

How about anybody else on this particular issue? Does anybody have any other viewpoints that they want to put on the floor at this time?

Ruth?

MS. McBURNEY: Ruth McBurney, CRCPD, Board of Directors.

Just a few additional comments. Basically, we concurred with the comments made by the Organization of Agreement States that there is a definite need for regulatory reform in the materials area. Current regulatory schemes should be assessed for effectiveness, including appropriate risk reduction, comprehensiveness, cost, including both cost to the regulated community and the cost to the regulators, and responsiveness to rapid advances in technology, both in medicine and industry.

The public is protected because of the regulatory community's diligence in ensuring that individuals using radioactive materials do so safely. In some cases, it is necessary to modify the regulations to be less prescriptive, but it is not necessary to relinquish all controls over the safe use of radioactive material.

Just as a matter of discussion, considerable consultation with the state programs must be utilized in implementing any of the options under this issue. Significant risk exists that either, one, further fragmentation of radiation and safety regulations would occur with some of the options, or that the NRC will continue to mandate regulatory requirements that have no

health and safety basis.

The important conclusion one must draw from the IOM report is not that medical regulation should be deregulated but that NRC implementation of the prescriptive regulations was inappropriate and heavy-handed.

Under option 1, we too are in support of establishing that one federal agency to establish -- work with the states to establish the basic standards. And I think on the other options we were in agreement with what was mentioned by OAS, except under option 3 we have some additional comments. Hand in hand with the proposals from option 2, under option 3 a risk-based approach should also identify areas of low risk in which NRC and the agreement states should reduce the type and degree of regulation, and other areas in which the degree and type of regulation should be increased.

As mentioned, some of the high-curie, generally-licensed gauges probably should be specifically licensed, and some gas chromatograph sources, which are now specifically licensed, could go to general license.

We are opposed to an across-the-board ramping down of all so-called low-risk sources, just for sake of expediency, or whatever.

As contained in the -- regarding option 4, as

contained in the position passed by the CRCPD on May 8, 1996, we are concerned that the adoption of this option, as well as option 5, would be considered an unfunded mandate for some states. The elimination of the entire program could have a detrimental impact on the uses of radioactive material on the citizens of non-agreement states which are unable to develop a state program that is not consistent with the national model.

Separating medical uses of radioactive materials would add to the confusion over jurisdictional issues among federal and state agencies at a time when we need to be moving toward greater consistency. In-house sources of radiation are regulated. And we will be attaching our entire position on the IOM report as an attachment with our written comment.

MR. CAMERON: Ruth, one clarification. But you would not be in support of option 4, at least given the possibility of moving forward with option 3.

MS. McBURNEY: Correct.

MR. CAMERON: Okay. Thank you. I always feel like I'm trying to trick you.

(Laughter.)

And I am. No.

(Laughter.)

Wait 'til you see how this looks on the

transcript.

Does anybody else have anything to say? Any other comments on this?

Okay. Well, just let's close up. Mal, do you have --

MR. KNAPP: I have a final closing comment. Go ahead, though.

MR. CAMERON: I just wanted to say that we are going to get started at 8:00 tomorrow, and the focus tomorrow morning is going to be on reactors. But for those people who are in the materials area, keep in mind that there will be a paper on risk-informed performance-based.

And Jim, correct me if I'm wrong -- I mean, that's broader -- it's more broadly focused than just reactor regulation, so that it might be useful for people to be there, because I know you have a lot of good ideas on this.

We're not going to do a wrap-up session today, but we will do a wrap-up session tomorrow to give you one final chance to revisit things that we have done during the two days.

Mal?

MR. KNAPP: Very briefly. These are not easy issues. The fact that they are on the table indicates

their complexity and their difficulty of resolution. In addressing these things, feelings can run high. It can become difficult to be constructive. I was very, very pleased today with the constructive comments, with the spirit of cooperation I heard from the commenters. You have made our jobs over the next six weeks much easier.

Thank you.

MR. CAMERON: Thank you very much. See you tomorrow.

(Whereupon, at 4:29 p.m., the proceedings in the foregoing matter went off the record.)

# 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
HANDLING OF NUCLEAR MATERIALS

Docket Number: N/A

Place of Proceeding: WASHINGTON, D.C.

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.

Corbett Riner

CORBETT RINER
Official Reporter
Neal R. Gross and Co., Inc.

# *Direction Setting Issue No. 2 Oversite of the Department of Energy*

October 24-25, 1996

Sponsor: Malcolm R. Knapp, NMSS
Writer: Francis X. Cameron, OGC

# *DSI 2*

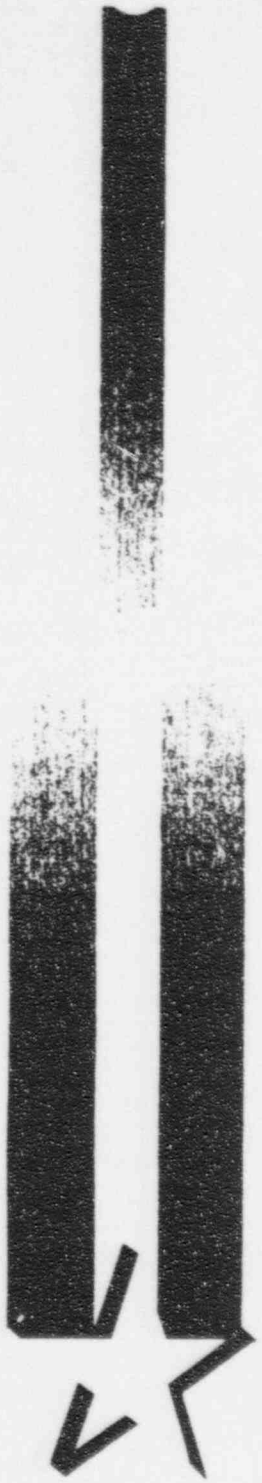
- ★ Should the NRC Seek to Expand its Regulatory Authority and Responsibilities to Include DOE Facilities?

# *Key Factors*

- ★ The Commission Could Be Required to Assume Jursidiction over DOE Facilities and Activities in Two Ways:
  - Congress Could Approve the Recommendations of DOE's Advisory Committee on External Regulation of the Department of Energy Nuclear Safety
  - NRC Jurisdiction Could Increase Incrementally as a Result of DOE Initiatives Such as Privatization of Specific Facilities
- ★ DOE Owns & Operates ~3500 Nuclear Facilities
- ★ NRC Is Required to Recover its Budget by Assessing Fees to NRC Applicants and Licensees
- ★ NRC Would Need Considerable Additional Resources

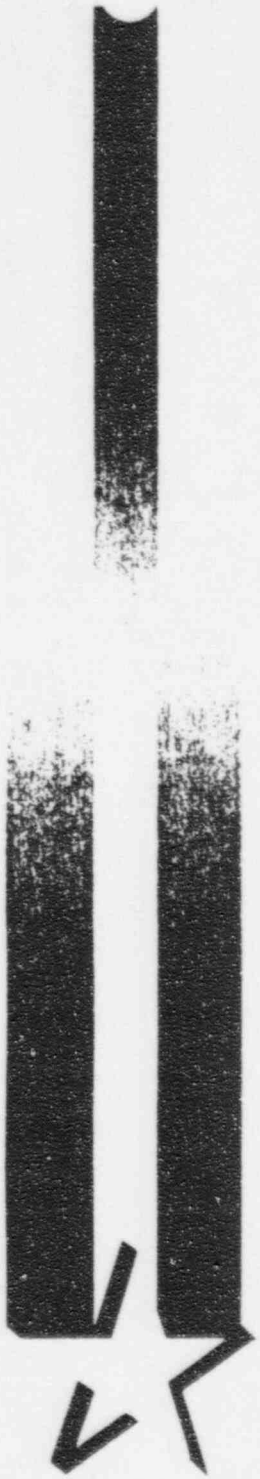
# *Options*

- ★ Support Broad Responsibility for NRC Regulation of DOE
- ★ Support Broad Responsibility for Regulating Certain Types of DOE Facilities
- ★ Oppose Broad NRC Responsibility for Regulating DOE Facilities
- ★ Take No Position on Broad NRC Responsibility for DOE Facilities



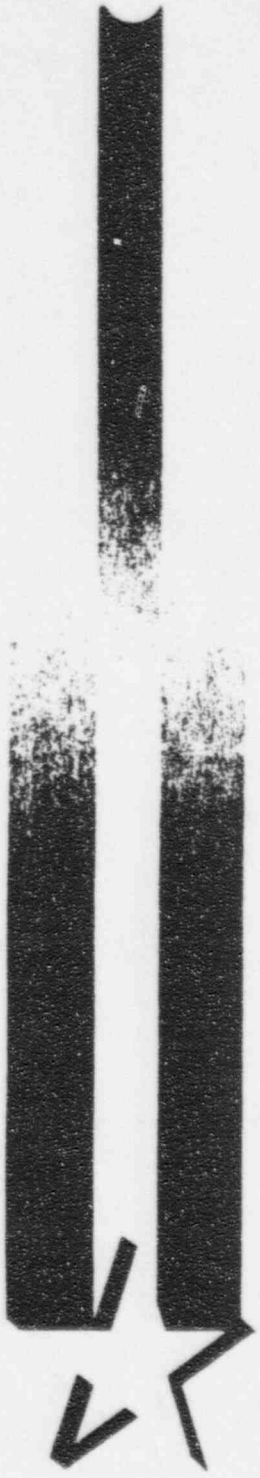
## *Commission's Preliminary Views*

- ★ The NRC Would Not Take a Position on Accepting Broad Responsibility for DOE Facilities (Option 4). NRC Would Neither Encourage Nor Oppose New Legislation Giving it Broader Authority over DOE Nuclear Facilities.
- ★ Given Adequate Resources and a Reasonable Time Schedule to Develop and Initiate a Regulatory Program, the NRC Could Provide Adequate Regulatory Oversight of DOE, If Asked.



## *Commission's Preliminary Views (cont)*

- If NRC Were to Be Given Added Regulatory Oversight of DOE Facilities, the Commission Would Prefer That the Regulatory Responsibilities Be Placed on the NRC on an Incremental Basis and That Some Type of Prioritization Methodology Be Used to Determine the Types of DOE Facilities That, If Subject to NRC Oversight, Would Provide the Greatest Potential Benefit to Public Health and Safety.



## *The Commission Particularly Seeks*

★ Comment on Whether NRC Should Fund Agreement State Training, Travel, and Technical Assistance.

Comments Are Especially Sought from Agreement States, Non-Agreement States, Fee-Paying NRC Licensees and Agreement State Licensees.

# *Direction Setting Issue No. 4*
# *NRC's Relationship With Agreement States*

October 24-25, 1996

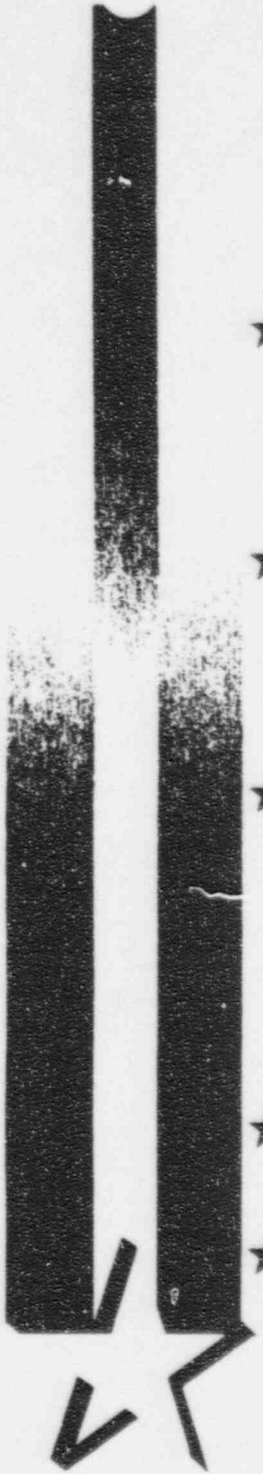
Sponsor: Malcolm R. Knapp, NMSS

# *DSI 4*

- What Should Be NRC's Strategy Regarding States Becoming and Remaining Agreement States?

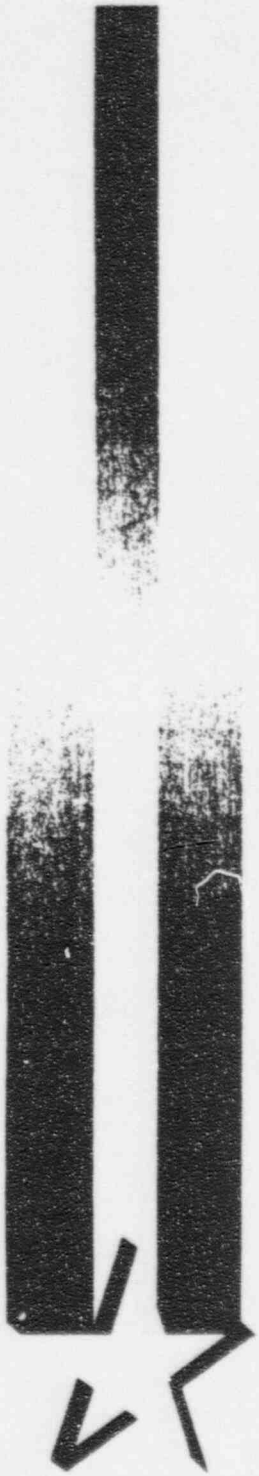
# *Key Factors*

- ★ The Number of NRC Licensees Is Expected to Decline as More States Become Agreement States
- ★ The Omnibus Budget Reconciliation Action of 1990 Requires NRC Programs to Be Funded by its Licensees
- ★ NRC's Decreasing Budget May Increase Pressure on the Agency to Minimize its Financial Support to Agreement States
- ★ NRC Is Obligated to Oversee the Agreement State Program



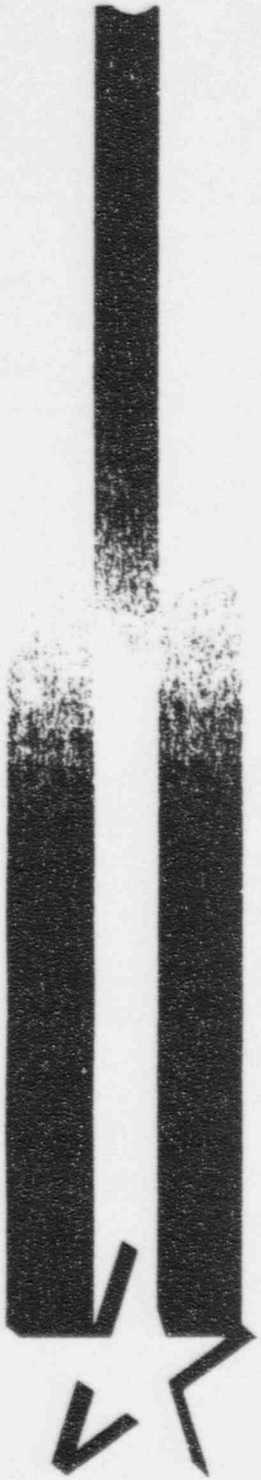
# *Options*

- ★ Turn the Agreement States Program over to the Environmental Protection Agency
- ★ Strongly Encourage States to Become Agreement States
- ★ Continue the Current Agreement States Program, Including Adopting Current Initiatives
- ★ Treat Agreement States as Co-Regulators
- ★ Devolve Regulation of Atomic Energy Act Section 274 Materials to the States



## *Commission's Preliminary Views*

- ★ Continue the Current Program, Including Adopting Current Initiatives
- ★ Encourage More States to Become and Remain Agreement States Primarily Through Non-Monetary Incentives
- ★ Explore Providing "Seed Money" and/or Financial Grants to Encourage States to Seek Agreement State Status
- ★ Provide Training to Agreement States Without Charge on a "Space Available" Basis. Funding for Travel and Technical Assistance Would be Borne by the Agreement States



# *Direction Setting Issue No. 7*
# *Materials/Medical Oversight*

October 24-25, 1996

Sponsor: Malcolm R. Knapp, NMSS
Writer: Josephine M. Piccone, NMSS

# *DSI 7*

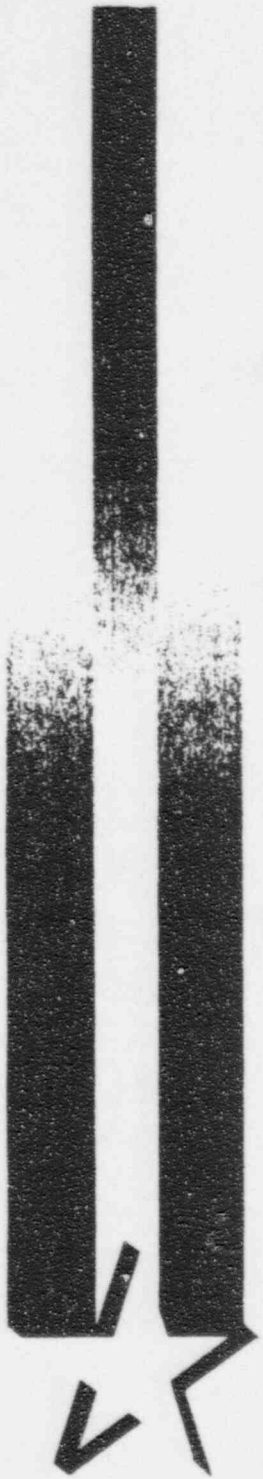
- ★ What Should Be the Future Role and Scope of NRC's Nuclear Materials Program, and in Particular, NRC's Regulation of the Medical Use of Nuclear Materials?

# *Key Factors*

- ★ NRC Regulates Nuclear Material Created or Made Radioactive by Exposure to the Radiation During the Fission Process in Reactor
- ★ There Are Opposing, Strongly Held Views of the Regulated Medical Community and Congress and the Media Concerning the Regulation of Nuclear Materials in Medicine
- ★ The National Academy of Science Has Recommended That Congress Eliminate the NRC's Medical Use Program
- ★ The Number of NRC Licensees Is Expected to Decline as States Pursue Agreement State Status
- ★ NRC is Conducting "Business Process Reengineering" of its Materials Licensing Program

# *Options*

- ★ Increase Regulatory Responsibility with Addition of X-ray, Accelerators, and Naturally Occurring and Accelerator Produced Radioactive Materials (NARM)
- ★ Continue Ongoing Program (With Improvements)
- ★ Decrease Oversight of Low-Risk Activities with Continued Emphasis of High-Risk Activities
- ★ Discontinue Regulation of All Medical Activities Except NRC Oversight of Devices and Manufacturers (National Academy of Sciences Recommendation)
- ★ Discontinue Materials Program



## ★*Commission's Preliminary Views*

- ★ Continue the Ongoing Program with Improvements (Option 2) and;
- ★ Decrease Oversight of Low-Risk Activities with Continued Emphasis of High-Risk Activities (Option 3).
- ★ In Implementing Option 3, the NRC Would Utilize the Risk-Informed Performance Based Approach to Determine Which Activities in the Materials Area, and Specifically in the Medical Area, Are Low-Risk Activities.

# *Direction Setting Issue No. 7*
# *Materials/Medical Oversight*

October 24-25, 1996

Sponsor: Malcolm R. Knapp, NMSS
Writer: Josephine M. Piccone, NMSS