## OFFICIAL TRANSCRIPT OF PROCEEDINGS

## NUCLEAR REGULATORY COMMISSION

Title: National Materials Program Stakeholders' Meeting

Docket Number: (not applicable)

Location: Rockville, Maryland

Date: Wednesday, March 31, 2004

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Pages 1-254

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| 1  | UNITED STATES OF AMERICA                               |
| 2  | NUCLEAR REGULATORY COMMISSION                          |
| 3  | + + + + +  |
| 4  | NATIONAL MATERIALS PROGRAM STAKEHOLDERS' MEETING       |
| 5  | + + + + +  |
| 6  | WEDNESDAY,   |
| 7  | MARCH 31, 2004   |
| 8  | + + + + +  |
| 9  | ROCKVILLE, MARYLAND                                    |
| 10 | + + + + +  |
| 11 | The Stakeholders met at the Nuclear Regulatory         |
| 12 | Commission, Two White Flint North, Room T2B3, 11545    |
| 13 | Rockville Pike, at 8:20 a.m., Lance Rakovan,           |
| 14 | Facilitator, presiding.                                |
| 15 | ROUND TABLE PARTICIPANTS:                              |
| 16 | RALPH L. ANDERSON, Health Physics Society              |
| 17 | CINDY CARDWELL, Texas Department of Health, Conference |
| 18 | of Radiation Control Program Directors                 |
| 19 | DIANE D'ARRIGO, Nuclear Information and Resource       |
| 20 | Service  |
| 21 | R.D. "DONNY" DICHARRY, Source Production & Equipment   |
| 22 | Co., Inc., NDTMA/ASNT                                  |
| 23 | LYNNE FAIROBENT, American College of Radiology         |
| 24 | MARGARET FEDERLINE, NRC Office of Nuclear Material &   |
| 25 | Safeguards   |
|    |  |

|    | 2   |
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| 1  | STAN FITCH, New Mexico Environment Department,        |
| 2  | Organization of Agreement States                      |
| 3  | PAUL GENOA, Nuclear Energy Institute                  |
| 4  | JUDITH JOHNSRUD, Sierra Club (Waste Committee)        |
| 5  | PAUL LOHAUS, NRC Office of State and Tribal Programs  |
| 6  | GEORGE PANGBURN, NRC Region I                         |
| 7  | CARL PAPERIELLO, NRC Office of the Executive Director |
| 8  | of Operations   |
| 9  | KATE ROUGHAN, AEA Technology QSA, Inc.                |
| 10 | LEONARD SMITH, Perkins Elmer Life Science/CORAR       |
| 11 | SHAWN SMITH, NRC Office of State and Tribal Programs  |
| 12 | KATIE SWEENEY, National Mining Association            |
| 13 | JARED THOMPSON, Arkansas Department of Health         |
| 14 | KEN WAGNER, North Dakota Department of Health         |
| 15 |   |
| 16 | OTHER ATTENDEES:                                      |
| 17 | JAN ENDAHL  |
| 18 | ROBERT GALLAGHAR                                      |
| 19 | MARCIA HOWARD   |
| 20 | KEVIN HSUEH   |
| 21 | MICHAEL MARKLEY                                       |
| 22 | RUTH MCBURNEY   |
| 23 | JIM MYERS   |
| 24 | THOMAS YOUNG  |
| 25 |   |
| •  |   |

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| 1  | P-R-O-C-E-E-D-I-N-G-S                                  |
| 2  | 8:21 a.m.  |
| 3  | FACILITATOR RAKOVAN: Good morning. If                  |
| 4  | everyone could take their seats, we're going to get    |
| 5  | underway in a few minutes. Thank you. To kick things   |
| 6  | off this morning, we're going to have Carl Paperiello, |
| 7  | Deputy EDO, come up and say a few words. Carl, if you  |
| 8  | would.   |
| 9  | MR. PAPERIELLO: Good morning. I would                  |
| 10 | like to welcome everyone to this workshop to discuss   |
| 11 | the National Materials Program. I think this is a      |
| 12 | workshop. Is that what you are billing it as? Okay.    |
| 13 | We have meetings and workshops. What is the National   |
| 14 | Materials Program? It's a term or word that was        |
| 15 | developed to define the broad framework in which the   |
| 16 | NRC and the Agreement States function in carrying out  |
| 17 | their roles in regulating radioactive material.        |
| 18 | Although the term appears to be new, the               |
| 19 | program is not. It began with Section 274 of the       |
| 20 | Atomic Energy Act. I have said all along we will       |
| 21 | always have a National Materials Program because it's  |
| 22 | what we do in the United States. The question is,      |
| 23 | what are the roles or the players or the various       |
| 24 | parties? What has changed and evolved over the years   |
| 25 | is what I will call the existential situation.         |

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| 1  | Over 40 years ago, the AEC had most of the             |
| 2  | licensees. Man-made radioactive isotopes were rare at  |
| 3  | least in the sense of being out in commerce. The       |
| 4  | industry, technical, and educational infrastructures   |
| 5  | to support the use of commercial isotopes was just     |
| 6  | beginning. In fact, I'm old enough to remember in the  |
| 7  | fifties - that really makes me old - that one who      |
| 8  | wanted to show some kid being really smart was reading |
| 9  | a book that said "Nuclear Theory" which of course is   |
| 10 | funny because "Nuclear Theory" never gave right        |
| 11 | answers in the sixties when I was in graduate school   |
| 12 | and from the latest readings I have done on the web,   |
| 13 | it doesn't give right answers now anyway even though   |
| 14 | it's tremendously complicated primarily because we     |
| 15 | don't know the nuclear force.                          |
| 16 | Today, Agreement States have most of the               |
| 17 | material licensees. Man-made radio isotopes are        |
| 18 | widely used. In many areas, there's an extensive       |
| 19 | support system for commercial activities including     |
| 20 | professional societies, professional certification,    |
| 21 | and consensus standards, things that we did not have   |
| 22 | 40 years ago. But this all gives us new challenges.    |
| 23 | In the past, since the federal government              |
| 24 | was the dominant user and regulator of radioactive     |
| 25 | material, it provided as a service and frequently a    |

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1 free service things like training, equipment, and 2 procedures that the states could make use of. My 3 Ph.D. was paid for by a combination of NASA and the 4 Atomic Energy Commission.

5 Those programs don't exist anymore. In fact, my field is dead. In fact, I was told by a 6 7 retired nuclear physicist from the University of Columbia on Sunday - we were having dinner together -8 9 who still had a few graduate students finishing up that he had to send his students to a radio chemistry 10 course because low energy nuclear physics, which was 11 my field, is no longer taught. 12 So there's things like that that don't exist. 13

14 And the government provided a lot of 15 stuff. With the change in the environment and what 16 we're in, we have to make changes. As a complication, 17 many aspects of radiation protection have grown far more complicated. When I got involved in health 18 19 physics in 1970, I taught myself health physics. Ι never took a course before I got certified. 20 I did it out of the NCRP and ICRP standards. 21

I can derive all of the ICRP-2 maximum permissible concentrations using that book and a slide rule. Today, you need computers and you have to get your hands on computer codes. I cannot personally

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derive ICRP-66, ICRP-67 dose conversion coefficients. And the standards have come down.

So therefore, what we used to do 30 years 3 4 ago, which was bounding calculations which you could 5 do with a slide rule and paper, you can't do it 6 anymore. You have to use computer models to show compliance because you are dealing with much lower 7 Instrumentation has grown more complicated. 8 levels. 9 Our job and part of this meeting is how to structure 10 the regulatory program in the U.S. within the framework of existing legislation so that both the NRC 11 and the states can most efficiently and effectively 12 meet their responsibilities. 13

14 Now, I'm going to add something because I 15 think it's important and relevant. Last week, I was at the RASC meeting which is the Radiation Advisory 16 Committee for IAEA. 17 Standard I'm the U.S. representative on there. ICRP made a presentation. 18 19 The fact of the matter is, before the end of the decade, we are likely to iterate radiation protection 20 standards again in the United States. 21

A couple of things are going on. The EPA is reexamining a public dose limit. It still officially sits at 500 millirem per year. We've been kicking things around with them, even going out to the

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people and asking them, what should we do or how should we change it? Part of the issue is, should there be the NRC as a limit of 100? Should the EPA set a national limit of 100?

5 Of course, as we all know, the EPA has the The risk standard is down in the order 6 risk standard. 7 of a few tens of millirems. The problem is, as you lower the standard, problems or issues that could fit 8 9 quite nicely under a 500 millirem umbrella become a 10 real problem. For example, TE-NORM. You have a lot of stress and strain with TE-NORM at 100 millirem per 11 year let alone if you want to put a constraint of 30 12 millirem which is what ICRP is likely to come out 13 14 with.

15 A practical matter is, even here in the 16 NRC, we've had to be loosy goosy. We have had to 17 write some exceptions. In particular, the medical community wanted visitors to patients to be allowed to 18 19 qet up to 500 millirem on a one time basis or let patients go home and maybe family members get 500 20 millirem on a one time basis. In the European 21 standard, that's written in. In fact, what they just 22 do is call it medical dose. So we don't call it 23 24 public dose anymore.

So there's a lot of issues when you do

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1 that: homeland security, emergency worker dose, 2 cleanup, PAG criteria for the long-term - what will 3 that come under - and lastly, ICRP. ICRP is going to 4 roll out in May at the ERPA Conference its new 2005 5 recommendations. Although, they said last week they will probably not get published until 2006. After 6 7 they roll it out at the ERPA Conference in May, it 8 will go on their website in June for a six month 9 comment period.

10 Internal dosimetry coefficients will change again because they are going to change the 11 organ waiting factors. They said they almost have to 12 because the thyroid is clearly wrong. One of the 13 14 things we know now is that the adult thyroid is not 15 very sensitive to radiation in terms of carcinogenic. The child thyroid is different. I almost wonder if 16 17 they are going to need waiting factors for children that are different than they are for adults. 18

19 So I don't know. I don't know what they are going to look like. I am just summing up what 20 they said. Public dose. They are going to come out 21 with a public dose not being a limit but a constraint. 22 Why? For all the reasons I told you. When you go 23 24 from 500 millirem a year and you bring it down, the We don't have to regulate it. 25 NRC is lucky.

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| 1  | But the Europeans and in countries where              |
| 2  | there is a comprehensive radiation program, you do.   |
| 3  | In Europe, health spa workers are radiation workers   |
| 4  | because radon and stuff like that are running around  |
| 5  | all the European health spas. So that's going to      |
| 6  | happen. The occupational limit will probably stay     |
| 7  | where it is in ICRP which is essentially five rem a   |
| 8  | year but ten rem averaged over a five year period.    |
| 9  | Then with all that going on, the United               |
| 10 | States is going to have to decide what to do. And I   |
| 11 | say the United States. I don't just say the NRC. I    |
| 12 | say the United States because the EPA has a           |
| 13 | responsibility in here and the President's Science    |
| 14 | Advisor by law has a responsibility. We are all going |
| 15 | to be in this.  |
| 16 | I have made this remark to the Commission.            |
| 17 | Even if we stay put and make no changes, we are going |
| 18 | to have to justify doing what we do. From my view     |
| 19 | point, I'm going to be looking at putting more        |
| 20 | resources in the basic radiation protection standards |
| 21 | in this agency over the next several years just so we |
| 22 | can engage.   |
| 23 | Anyway, that's the brave new world that's             |
| 24 | in front of us. You have a number of topics that you  |
| 25 | are going to discuss today. I hope you have a good    |

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| 1  | meeting. As I started out, when we got into this       |
| 2  | business about maybe 1999 and made up the term         |
| 3  | "National Materials Program," I have tried to point    |
| 4  | out to the Commission we have a National Materials     |
| 5  | Program. We have always had one at least since 274.    |
| 6  | We will keep on having one. The question is, what are  |
| 7  | the respective roles and responsibilities of all the   |
| 8  | parties involved? Thank you.                           |
| 9  | (Applause.)  |
| 10 | FACILITATOR RAKOVAN: Thank you, Carl.                  |
| 11 | Can everyone hear me all right with this on? Again,    |
| 12 | my name is Lance Rakovan. I'm going to be acting as    |
| 13 | facilitator for today's meeting. Before we get things  |
| 14 | kicked off with the presentations and such, I just     |
| 15 | wanted to take a moment or two to go over the agenda,  |
| 16 | go over some groundrules, talk about objectives and    |
| 17 | these kinds of things.                                 |
| 18 | I'd like to go around and have everybody               |
| 19 | at the table introduce themselves, if that's possible, |
| 20 | to start out with. Jared, since you got first          |
| 21 | position, would you like to start? Just tell us your   |
| 22 | name and who you are representing if you would.        |
| 23 | MR. THOMPSON: Jared Thompson. I'm with                 |
| 24 | the Arkansas Department of Health.                     |
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| 1  | Dakota Department of Health.                          |
| 2  | MS. CARDWELL: Cindy Cardwell with the                 |
| 3  | Texas Department of Health here representing the      |
| 4  | Conference of Radiation Control Program Directors.    |
| 5  | MR. FITCH: Stanley Fitch, Organization of             |
| 6  | Agreement States. I'm a health physicist with the New |
| 7  | Mexico Environment Department.                        |
| 8  | MS. ROUGHAN: Kate Roughan, AEA                        |
| 9  | Technology. We manufacture sources for industrial     |
| 10 | radiography equipment and medical uses.               |
| 11 | MR. DICHARRY: Donny Dicharry. I                       |
| 12 | represent Source Production and Equipment Company. We |
| 13 | also are an industrial radiography equipment and      |
| 14 | source manufacturer. I'm also representing the Non-   |
| 15 | Destructive Testing Management Association.           |
| 16 | MS. FAIROBENT: I'm Lynne Fairobent. I'm               |
| 17 | representing the American College of Radiology.       |
| 18 | MR. ANDERSON: I'm Ralph Anderson. I'm                 |
| 19 | representing the Health Physics Society.              |
| 20 | MS. SWEENEY: Katie Sweeney, National                  |
| 21 | Mining Association.                                   |
| 22 | MR. SMITH: Leonard Smith representing the             |
| 23 | Council on Radionuclides and Radiopharmaceuticals     |
| 24 | whose members are the major manufacturers and         |
| 25 | distributors of radionuclides in North America for    |

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| 1  | medical therapy diagnosis, biomedical, and             |
| 2  | environmental research, safety, and quality            |
| 3  | applications.  |
| 4  | MR. PANGBURN: I'm George Pangburn. I'm                 |
| 5  | representing NRC's Region I. I'm the Director of       |
| 6  | their Division of Nuclear Material Safety.             |
| 7  | MS. FEDERLINE: I'm Margaret Federline.                 |
| 8  | I'm representing the Office of Nuclear Material Safety |
| 9  | and Safeguards. I'm here for Marty Virgilio.           |
| 10 | FACILITATOR RAKOVAN: Thank you. Paul,                  |
| 11 | would you like to continue?                            |
| 12 | MR. LOHAUS: Sure, I'm Paul Lohaus,                     |
| 13 | Director of NRC's Office of Tribal and State Programs. |
| 14 | MR. PAPERIELLO: I'm Carl Paperiello.                   |
| 15 | Most people know me. I'm Deputy Executive Director     |
| 16 | for Materials, Research, and State Programs.           |
| 17 | FACILITATOR RAKOVAN: I know we have the                |
| 18 | chairs of the various pilot groups sitting over here.  |
| 19 | They will be introducing themselves when they get up   |
| 20 | to do their presentations. With that, I would like to  |
| 21 | go to the agenda just to give a quick run through of   |
| 22 | that.  |
| 23 | For the morning session, essentially what              |
| 24 | we're going to be doing is giving some updates on the  |
| 25 | pilot programs and having presentations. For the       |

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15 1 afternoon session, we're going to be having more of a 2 roundtable discussion. Primarily the roundtable 3 discussion will be between the members at the table, 4 but we'll definitely allow times for the audience to 5 participate. We have one mic that is set up for that if 6 7 people want to get up. Please use the mics when you 8 can. If you are going to speak, please identify 9 organization yourself and the that you are 10 representing if that's appropriate. That way, our stenographer can make sure that she has you down as 11 12 speaking. Also, you will notice that we don't have 13 14 any chairs in the front row here for the morning 15 That's primarily because we're going to be session. 16 using the overhead screen for the presentations, and 17 we didn't want anybody to get in the way. Once we're done with the presentations, we'll probably have some 18 19 chairs here and have Paul, Carl, and whoever else wants to come and sit at the table to close things in 20 and have a roundtable discussion that's a little more 21 22 intimate so to speak. For those of you who don't have copies of 23 24 materials, everything that you need should be on the table in the back. There's focus questions for this 25

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| 1  | afternoon's session. There's copies of the            |
| 2  | presentations that are going to be given by all the   |
| 3  | presenters. There's also a copy of the agenda.        |
| 4  | If you are a member of the public, please             |
| 5  | pick up a form that you can send back. It's an        |
| 6  | evaluation form to let us know how we did today and   |
| 7  | give us some hints on how we might be able to improve |
| 8  | things in the future. And those are on the table as   |
| 9  | well.   |
| 10 | In terms of groundrules, again, if you are            |
| 11 | going to speak, make sure that you use the            |
| 12 | microphones, identify who you are and what group you  |
| 13 | are with. For the roundtable discussions, we're going |
| 14 | to use the same old trick that's normally used at     |
| 15 | these things. If you have something that you want to  |
| 16 | say, put your tent up. I'll try to get to you         |
| 17 | eventually. I might not get to you in the order that  |
| 18 | you put the tent up. But I promise you that we will   |
| 19 | get to you, and we'll try to keep the discussions     |
| 20 | going.  |
| 21 | The transcript is going to be publicly                |
| 22 | available. So check back in with us or look back to   |
| 23 | the website. We'll have information on how you can    |
| 24 | get a hold of that after the meeting. Other than      |
| 25 | that, we have a white board here to use as a parking  |

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If there are issues that come up that we want to put off until the roundtable discussions, I can write it down up there and we'll make sure we get to those. There will be time for question and answer and clarification periods in the morning with the presentations. But we ask that you let the presenter get through their entire presentation and save your questions until the end of their presentations if you have anything that needs to be clarified.

Are there any other questions? I'm going to ask Paul to come up. Paul is the Director of the Office of State and Tribal Programs. He's going to be talking this morning about the National Materials Program in terms of the genesis and the background of the program.

Good morning. 17 MR. LOHAUS: I wanted to also welcome you and express our appreciation for your 18 19 willingness to come here and participate with us. 20 Although Lance indicated that he would like to see us hold questions to the end, at least during 21 my discussion, I would like this to be interactive. 22 So 23 if there are questions that you have as I'm going 24 through, please stop me and I'll answer those.

But what I wanted to do was provide some

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1 background information and maybe a grounding in terms of how did we get to where we are today and maybe move 2 on to the first slide. Carl really covered this. 3 But 4 an important aspect that we always need to keep in 5 mind is there is a National Materials Program today. In many cases, we talk about this as a 6 7 future activity or future state in terms of the 8 interactions of the NRC and the Agreement States. But 9 we have an existing program today. What is that 10 program made up of? It's basically the collective programs that NRC and the Agreement States carried out 11 in the materials program area. 12 As Carl indicated, that program was really 13 14 started with Section 274 of the Atomic Energy Act. set the framework for federal and state 15 That 16 cooperation, for the assumption of authority by the 17 states in the materials program area, and the relinquishment of that authority by NRC. If you look 18 19 at the program today, there's 33 Agreement States. The important aspect here is that they regulate about 20 the national total of materials 21 80 percent of licensees. 22 Also see that the relationship between NRC 23 24 and the Agreement States has been evolving and is 25 continuing to evolve. If you look at where the

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| 1  | program was ten years ago, what you would have seen is |
| 2  | NRC would really have had lead responsibility for      |
| 3  | almost all of the materials program activities. A lot  |
| 4  | of the developmental work was done. Then it was        |
| 5  | shared with the states for review and comment.         |
| 6  | Today, what we have is a collective,                   |
| 7  | cooperative program where states and NRC work together |
| 8  | on common problems, where the Organization of          |
| 9  | Agreement States has taken the lead for certain of the |
| 10 | activities. For example, they have the lead for the    |
| 11 | annual meeting of the Agreement States. In the past,   |
| 12 | that meeting was done by NRC. The agenda was           |
| 13 | developed by NRC. Today, it's handled by the states    |
| 14 | through their Organization of Agreement States.        |
| 15 | Another area where there's a lot of                    |
| 16 | evolution going on today is the area of security.      |
| 17 | This is a tough area for the states. The activities    |
| 18 | that are being carried out to further enhance security |
| 19 | relate to common defense and security. As such, they   |
| 20 | are a reserved function to the NRC. So this is an      |
| 21 | evolving area. It's a new area where there's a         |
| 22 | different relationship. There's a different            |
| 23 | interaction with licensees.                            |
| 24 | There's a direct contact by NRC to                     |
| 25 | annorment state lisensons. On itle a different and     |

25 agreement state licensees. So it's a different and

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evolving area. There's a continuing evolution that's going on in the program. As I mentioned, there is a greater need and role and responsibility for the states. I want to come back and talk more about that in a minute.

In recognition of the growth in the number 6 7 of Agreement States and the shrinking licensee base that NRC has given that, the Commission chartered an 8 9 NRC and agreement state working group to look at 10 options that should be considered for a National Materials Program. This working group examined a 11 range of options which ranged from NRC basically 12 taking back all authority and having a central program 13 14 within NRC to an option where all of the authority 15 with the exception of maybe a few categories of 16 licensees, for example federal facilities, were transferred to the state. 17

So you basically had all states being 18 19 Agreement States carrying out all the programs. There were also a number of options that were within those 20 Two of those options that you are going 21 two extremes. to hear about during the discussion from the pilot 22 chairs and during the meeting today, one is the 23 24 current program and the other is the alliance option. If you look at the working group report 25

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program and some of the current evolution where there are working groups where NRC and the states worked together to address common problems.

7 The alliance option also reflects somewhat 8 where we are today. It's a collaborative, cooperative 9 structure where the states and NRC work cooperatively 10 together to identify priorities that need to be addressed in the materials program, to identify how 11 those priorities would be addressed, in other words, 12 whether they be done by NRC, by a state, by the 13 14 Conference of Radiation Control Program Directors, by a working group, how that would be carried out. 15 But the idea is that it's a further evolution of where we 16 17 are today.

It's really a coalition, if you will, of 18 19 NRC and the states that work together to ensure that the envelope of national infrastructure needs, the 20 regulations, the guidance, the supporting implementing 21 procedures are in place and are known and developed on 22 a schedule to meet the needs in the program. 23 The 24 working group identified that they had been able to go so far in looking at where the National Materials 25

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| 1  | Program should go.                                    |
| 2  | They discussed a need for additional                  |
| 3  | information. They talked about a need for some pilot  |
| 4  | projects to really demonstrate how this relationship  |
| 5  | could work. The Commission provided direction in a    |
| 6  | staff requirements memo in August 2002. Basically     |
| 7  | what they approved was a blending of the current      |
| 8  | program and the alliance options to carry out five    |
| 9  | pilot projects. The pilot projects have a specific    |
| 10 | design. I'm just going to touch on each one. You're   |
| 11 | going to hear more about these as we go through.      |
| 12 | The first pilot project was to provide a              |
| 13 | demonstration and to gain some experience in terms of |
| 14 | NRC and the states working together to identify       |
| 15 | priorities and areas within the national program that |
| 16 | need to be addressed and to look to how those         |
| 17 | priorities could be addressed. Could they be          |
| 18 | addressed by a state? Could they be addressed by a    |
| 19 | group of states? Could they be addressed by the       |
| 20 | Conference of Radiation Control Program Directors?    |
| 21 | Would it be NRC that would do it? Would it be a       |
| 22 | combination of NRC and the states working together to |
| 23 | carry that out?                                       |
| 24 | The second pilot project was directed at              |
| 25 | using an existing committee within the Conference of  |
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Radiation Control Program Directors to demonstrate the ability of the states through that organization to take on an area that would serve the nation. This is the National Industrial Radiography Certification Program. So that group was focused on demonstration in that area.

The third pilot project was to demonstrate 7 8 the ability of NRC and the states to work together to 9 assess the national suite of operational information, 10 events, incidents that occur. What's the significance of those? How should they be folded back into the 11 regulatory program and to share across the NRC and the 12 states the review of those and the actions that would 13 14 come out of that as opposed to having NRC, if you 15 will, take the lead in that area.

The fourth pilot was designed to provide 16 17 a demonstration that a state or the Organization of Agreement States would take on the responsibility for 18 19 developing the licensing and inspection guidance for a new use of material or a new modality. 20 The idea here was to provide a demonstration that the states, 21 individually within 22 either working а state or collectively together, could establish guidance that 23 24 could serve the nation, serve both NRC's needs in its material program as well as individual agreement state 25

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program needs.

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2 The final pilot was really an existing 3 working group that was developing inspection guidance 4 that was focused on risk informing NRC's inspection 5 program. The thought here was to use an existing working group to further demonstrate the collaborative 6 7 process and the cooperative interactions and the effectiveness of those interactions in the alliance 8 9 framework.

Commission indicated 10 The that their consideration and future direction relative to how we 11 should proceed would be guided by information coming 12 out of the pilot projects. They also noted the 13 14 importance of having stakeholder involvement. We have 15 tried to operate and work in a very open framework. 16 The meeting here is part of that to provide an 17 opportunity for us to talk about what we've done and to hear from you in terms of what you see as issues, 18 19 where you see the challenges are, where you see the program going, and to have the benefit of your 20 expertise and thinking. 21

We developed this to try and provide some clarity to what we're talking about again with respect to the National Materials Program. If you look on the left side, it talks about individual program

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25 1 activities. These are activities that each program that the Agreement States and NRC are going to carry 2 3 out regardless. 4 We're going to be doing the licensing. We 5 have inspection responsibilities. We need to respond to incidents. We need to make sure our staff is 6 7 trained and qualified. We need to work our 8 enforcement and investigation programs. They are 9 really activities that cannot be shared, if you will. 10 They are really individual program activities that each program carries out. 11 You can maybe argue that there can be some 12 sharing in terms of staffing and training. 13 You'll see 14 that we do quite a bit there. On the other side 15 though, that's really the focus of the National 16 Materials Program. It's really the shared program 17 activities. It's really the infrastructure that is necessary for each of the programs to carry out the 18 19 individual program activities. This is the area of key focus of the National Materials Program. 20 What talking 21 we're about here are development of a supporting base of rules, development 22 the guidance, evaluating programs so there's 23 of 24 consistency and adequacy across the nation among all the programs of NRC and Agreement States, our in PEP 25

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(PH) or integrated performance evaluation program, and the policies that would be applied in those programs. It's hard to see, but you'll see a dotted line in the box below there between NRC and the Agreement States.

5 Right now, the focus of the program is given the greater proportional share of licensees that 6 7 the states have, should the program begin to move that 8 line a little bit to the left and maybe more to the 9 left proportional such that the share of 10 responsibility in the work to maintain the infrastructure is proportionally shared within the 11 larger agreement state program. If you think about 12 it, the expertise that the states have, the larger 13 14 share of licensees, their programs, the staffing, et 15 cetera, that is a resource that, coupled with NRC's 16 resources, can help ensure that there's an effective 17 program.

As Carl mentioned, that's part of the key 18 19 How do we look at the roles and here. responsibilities? How do we ensure that there's an 20 effective program and an efficient program that 21 effectively utilizes the suite of resources that are 22 within the program across the nation, the states and 23 24 the NRC to meet the licensing needs and inspection needs and other needs of the program? 25 That completes

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| 1  | what I wanted to talk through. I will be pleased to    |
| 2  | answer any questions at this time. George.             |
| 3  | MR. PANGBURN: Just an observation. I                   |
| 4  | would note under the individual program activities,    |
| 5  | one of the areas where we interact a lot with states   |
| 6  | in the regions are response to incidents and           |
| 7  | enforcement investigations because frequently we have  |
| 8  | events that cross jurisdictional boundaries or that    |
| 9  | have implications that affect states as well as NRC    |
| 10 | regions.   |
| 11 | It is an area where we do share and work               |
| 12 | very closely. That's not necessarily true for          |
| 13 | individual licensing and inspection decisions and      |
| 14 | inspection and training. Those areas are key areas     |
| 15 | where under this current National Materials Program we |
| 16 | do, in effect, work very closely. Just an              |
| 17 | observation.   |
| 18 | MR. LOHAUS: Thank you very much. That's                |
| 19 | a very good observation. There's many cases where      |
| 20 | there's just excellent coordination and cooperation    |
| 21 | between the states and the NRC in the response to      |
| 22 | incidents.   |
| 23 | MS. FEDERLINE: Paul, if I could just add               |
| 24 | one point. One area that I think the states and NRC    |
| 25 | are beginning to work very effectively in is the       |

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1 planning process. Looking ahead and trying to 2 understand what assumptions or what new events are coming down the pike helps us plan our resources. 3 The 4 better we do in joint planning, the better off we're 5 going to be in the future. MR. LOHAUS: Yes, thank you. Any others? 6 7 MR. ANDERSON: Ralph Anderson, Health 8 Physics Society. I noted in the Commission's response 9 in providing some quidance for this effort that they had called out the initiatives within the security 10 areas as almost a virtual sixth pilot program. 11 12 MR. LOHAUS: Yes. Is that actively being 13 MR. ANDERSON: 14 integrated into this process at this point? 15 Yes, we are. We can maybe MR. LOHAUS: 16 talk about that more later. We're very fortunate. 17 Stan Fitch is co-chair of a materials security working group that was set up. It's a joint effort on the 18 19 part of the states and NRC to develop additional security measures and look at the overall framework 20 for the program in terms of how that program would be 21 implemented and the kinds of measures that would be 22 adopted and in terms of a graded approach within that 23 24 program. So yes, that information is being considered and folded in as a part of the evaluative process. 25 We

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| 1  | can talk a little more about that.                     |
| 2  | MR. ANDERSON: In particular, I would be                |
| 3  | interested in hearing about how lessons learned coming |
| 4  | out of the process might be generically applicable to  |
| 5  | the overall consideration of roles and                 |
| 6  | responsibilities. So if we get to that, I would        |
| 7  | appreciate it.   |
| 8  | MR. LOHAUS: Good. Thank you very much.                 |
| 9  | That's good, yes. Thank you. Others? Stan.             |
| 10 | MR. FITCH: I would like to expand a                    |
| 11 | little bit on what George mentioned a while ago. The   |
| 12 | states and the NRC currently interact a great deal on  |
| 13 | sharing information on different program activities.   |
| 14 | It's more common between the states to share ideas and |
| 15 | topics. To be really effective, the states that agree  |
| 16 | have to start pushing more of it up out of their own   |
| 17 | ranks up into the NRC as well. But we do currently do  |
| 18 | that.  |
| 19 | MR. LOHAUS: Thank you, Stan. Lynne?                    |
| 20 | MS. FAIROBENT: Yes, thank you, Paul. One               |
| 21 | of the things hits me when I look at this overall      |
| 22 | program system and stuff. One of the pieces that I     |
| 23 | don't see or I have not heard anybody talk to either   |
| 24 | from the states or from the NRC side is perhaps an     |
| 25 | earlier on - and Margaret touched on it with the       |

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planning process - discussion piece as federal legislation may be being developed that would then flow down and impact the regulatory system for materials use whether it's NRC or within the states. I have never heard any discussion on any involvement in looking at the legislative process as it's being developed.

8 MR. LOHAUS: Thank you. That's a very good comment. I think we should come back and talk 9 10 about that later in the program. But that is one of the areas that the OAS executive board and the CRCPD 11 board has identified. Just quickly, as a part of our 12 routine conference calls, we do 13 trv and share 14 legislative initiatives that we're aware of with the 15 states to help ensure that there's good grounding and opportunity for input into that process. 16 That's a 17 very good thought and part of the program too. I'm going to stop at this point. Again, thank you very 18 19 I will turn this back to Lance and we'll much. 20 proceed.

FACILITATOR RAKOVAN: Thanks, Paul. Lynne and Ralph, if you could give me a brief synopsis of those points you just made so I can put them in the parking lot to make sure we get them covered later. Mr. Anderson, if you would go first please.

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| 1MR. ANDERSON: Okay, yes, an interest a2understanding how lessons learned from the process a3implementing enhanced security requirements will b4utilized in the next iteration of the National5Materials Program.6MS. FAIROBENT: Yes, basically Lance, b7early on look and discussion of legislation8development and flow down to the regulatory scheme9FACILITATOR RAKOVAN: Is that okay the | of<br>be<br>the<br>on |
|---|-----------------------|
| implementing enhanced security requirements will in the next iteration of the National Materials Program. Ms. FAIROBENT: Yes, basically Lance, the early on look and discussion of legislation development and flow down to the regulatory scheme   | be<br>the<br>on       |
| <ul> <li>4 utilized in the next iteration of the National</li> <li>5 Materials Program.</li> <li>6 MS. FAIROBENT: Yes, basically Lance, to</li> <li>7 early on look and discussion of legislation</li> <li>8 development and flow down to the regulatory scheme</li> </ul>  | the<br>on             |
| <ul> <li>5 Materials Program.</li> <li>6 MS. FAIROBENT: Yes, basically Lance, to</li> <li>7 early on look and discussion of legislation</li> <li>8 development and flow down to the regulatory scheme</li> </ul>  | on<br>•               |
| 6 MS. FAIROBENT: Yes, basically Lance, t<br>7 early on look and discussion of legislation<br>8 development and flow down to the regulatory scheme   | on<br>•               |
| 7 early on look and discussion of legislation<br>8 development and flow down to the regulatory scheme   | on<br>•               |
| 8 development and flow down to the regulatory scheme  | •                     |
|   |                       |
| 9 FACILITATOR RAKOVAN: Is that okay the   |                       |
|   | way                   |
| 10 that I have it characterized? Okay, it's awkward w   | ith                   |
| 11 only having one mic. So it leaves me to have to fi   | ind                   |
| 12 a mic to go to but that's okay. Thank you, Paul  | •                     |
| 13 Next up is going to be Shawn Smith. Shawn is   |                       |
| 14 currently coordinating all of the pilot projects. S  | he                    |
| 15 is also the co-chair of pilot project number one.  |                       |
| 16 Shawn actually has quite a lot to say the  | is                    |
| 17 morning so I'm going to be brief. Something that I   | 'm                    |
| 18 going to try to do - and I hope it's not going to I  | be                    |
| 19 very disruptive - is try to patch into the phone line  | e.                    |
| 20 We established a listen-only phone line for the othe   | er                    |
| 21 members of the pilot project to listen in. We have   | 7e                    |
| 22 been having trouble getting through, so hopefully  | I                     |
| 23 won't be disruptive in attempting to do that. Shaw   | n.                    |
| 24 MS. SMITH: Is this on? Good morning.   | As                    |
| 25 Lance said, I'm going to give a brief overview of the  | he                    |

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pilot project activities to date before hearing from each of the pilot project chairs as they give a progress report to date of the activities related specifically to their pilot projects.

5 Some of the major pilot project 6 milestones. As Paul stated in August 2002, the 7 Commission approved the implementation of a blending 8 of the current program and the alliance option through the initiation of five pilot projects. In October 9 10 2002, pilot project chairs were selected. For pilot project one, that's myself, Shawn Smith, and Ruth 11 McBurney of Texas. 12

Pilot project two is Jane Endahl of Texas. Pilot project three is Mike Markley of NRC and NMSS, Nuclear Material Safety and Safeguards, and Marcia Howard of Ohio as co-chairs. Pilot four is Bob Gallaghar of Massachusetts. Pilot five is Thomas Young of NMSS, Nuclear Material Safety and Safeguards.

19 Charters were developed for each of the pilot projects in 2002 as well. Subsequent working 20 established for each of 21 groups were the pilot In December 2002, NRC and agreement state 22 projects. staff jointly developed a National Materials Pilot 23 24 Project Implementation Plan which includes milestones and schedule for each of the pilot projects to meet. 25

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The plan provides a step-to-step guide for implementing the pilot projects leading to the submission of the final report of all the pilot projects to the NRC Commission in November 2004. Once established, each working group then developed a pilot project specific work product plan, pretty much a schedule, to meet the milestones identified in the implementation plan.

9 Overall project management of the pilot 10 project activities. The lead responsibility to carry out the overall project management of the National 11 Materials Pilot Project has been with NRC's Office of 12 State and Tribal Program Director Paul Lohaus. 13 STP 14 also provides administrative support for the pilot 15 projects.

This includes helping to coordinate the 16 17 logistics of working group meetings. We act as a centralized point of contact for the pilot projects 18 19 including maintaining documentation of the assignments that the pilot project working groups develop. 20 We accomplish this mainly through our monthly pilot 21 project chair calls that we have with the pilot 22 project chairs. 23

We also provide a centralized point for a collection of information, reports, and products to be

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1 disseminated to the leadership of OAS, CRCPD, and NRC management. We also provide funding for state working 2 3 group members to attend the working group meetings. 4 Paul went through each of the pilot 5 projects, so I'll go through them briefly. The lead organization for pilot project one is the Office of 6 7 State and Tribal Programs. As Paul stated, the goal 8 is to have the Agreement States involved in 9 establishing materials priorities for and the 10 development of a materials policy and rulemaking guidance products. 11 The lead organization for pilot project 12 two is the Conference of Radiation Control Program 13 14 Directors. The goal of this one is to have the 15 Agreement States, CRCPD, take the lead responsibility for the administration of a national radiographer 16 17 safety certification program. For pilot project three, the lead organization is NRC's Office of 18 19 Nuclear Materials Safety and Safequards. The goal here is to develop and test a structured process for 20 evaluating cumulative licensing data and perform it. 21 22 For pilot project four, the lead organization is the Organization of Agreement States. 23 24 The qoal here is to have an agreement state assume the lead responsibility for the development of licensing 25

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1 and inspection quidance for new use of material or a new modality not previously reviewed or approved. 2 Finally, for pilot five, the lead organization is 3 4 NRC's Office of Nuclear Material Safety and 5 Safequards. The goal of this one is to revise 6 Inspection Manual Chapter 2800 and this associated 7 non-medical inspection procedures and temporary instructions. 8 That completes the brief overview of the 9 10 pilot project activities. You will now hear from each individual pilot project chair to give you more 11 information related specifically to their pilot 12 If I can have Ruth McBurney, the co-chair, 13 projects. 14 come up as well. 15 Good morning. MS. MCBURNEY: As it's been 16 discussed several times this morning, the pilot 17 projects were set up to test the process. The pilot number one has early on gotten the nickname as the 18 19 monster project because of the high expectations of what might come out of this because it gets to the 20 essence of the alliance concept on can NRC and the 21 states work together to establish the priorities for 22 what are we going to work on collaboratively and also 23 24 then make the assignments to working groups or whatever entities might be working on those high 25

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| 1  | priority items such as rules, guidance, and so forth.  |
| 2  | The make up of the working group. We                   |
| 3  | wanted input from several different aspect of both NRC |
| 4  | and the state process. We have Shawn Smith who is      |
| 5  | from the NRC State and Tribal Programs and myself, a   |
| 6  | state person, as the co-chairs for this group. We      |
| 7  | have representation from NRC's Office of the Chief     |
| 8  | Financial Officer to provide budget input. I see Kim   |
| 9  | back there. We have several of our committee members   |
| 10 | here.  |
| 11 | Jane Halvorsen from NMSS provides valuable             |
| 12 | input on financial management. Anita Turner is from    |
| 13 | NMSS who provides input on the technical aspects of    |
| 14 | this. We also have a regional Agreement States         |
| 15 | officer, Jim Lynch, from Region III and another state  |
| 16 | director, Bob Walker, from the State of Massachusetts. |
| 17 | So it was a good blend of folks to discuss the co-     |
| 18 | establishment of priorities and then how that might    |
| 19 | work.  |
| 20 | The alliance concept has been mentioned by             |
| 21 | several of our speakers this morning. It came out of   |
| 22 | the recommendation of the national materials working   |
| 23 | group that an alliance concept be used in the          |
| 24 | development of the National Materials Program. Just    |
| 25 | for a definition, this is a collaborative process      |

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between the Agreement States and NRC that identifies radiation safety regulatory priorities and the means to address those priorities. Basically this is what our pilot project was set up to test.

5 The current programs in each of the jurisdictions would still continue. But state and 6 7 federal agencies would work together in а 8 collaborative process and, as Margaret mentioned, 9 joint planning for the future to optimize resources -10 we're all being hit with budget cuts - and to promote consensus between the regulatory agencies and work 11 together to produce standards, rules, and guidance and 12 to look at other options such as consensus standards 13 14 for achieving those work products.

15 The purpose of pilot one was to develop a process whereby we could identify and prioritize the 16 17 regulatory needs of both NRC and the Agreement States and also to ensure that both the Agreement States and 18 19 NRC had input on those regulatory needs and that all in establishing 20 were considered those national Then the third purpose was to demonstrate 21 priorities. a shared decision-making process between the NRC and 22 23 the Agreement States.

24 The expectations for the work products to 25 come out of this Committee were a national priority

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list that could be agreed upon by both the NRC and the Agreement States and a framework and process whereby we could go into the future and continue updating and having a clearinghouse for new needs that come along that could be used to prioritize the regulatory needs and the National Materials Program under that alliance option.

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Our first work product is we did develop 8 9 a national priority list. Step-wise the way we 10 accomplished this was to obtain and analyze input. We just had everybody send in lists of their regulatory 11 needs as it affected their regulatory jurisdiction 12 both from the states and the NRC offices. 13 Then we 14 developed what we call a prioritization package.

We took that long list and analyzed it. 15 16 There were a lot of duplicates, a lot of overlap. 17 There were items that were not done by NRC or they might not be in the purview of the states. So we took 18 out those and we made a list of those items that were 19 shared by both the Agreement States and the NRC. 20 We also developed an evaluation strategy to look at how 21 do we go about ranking these as to high priority, 22 medium, or low priority? Then we analyzed the results 23 24 and produced a list of needs.

So we collected the list of regulatory

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| 1  | needs from the NRC headquarters and the regional       |
| 2  | offices and from the Agreement States. From that, we   |
| 3  | developed the list for prioritization. The worksheet   |
| 4  | that we sent out then, in order for NRC offices and    |
| 5  | regions and the states to go about the prioritization  |
| 6  | process, were based on actual performance goals.       |
| 7  | They weren't just say rank them one, two,              |
| 8  | three, four, five. We wanted you to rank them based    |
| 9  | on a list of performance goals. Those were protection  |
| 10 | of public health and safety, the security of           |
| 11 | radioactive materials, and then efficiency and         |
| 12 | effectiveness and to rank those as high, medium, and   |
| 13 | low under each of those performance goals. So what we  |
| 14 | wound up with was a matrix to do that ranking.         |
| 15 | So then the NRC offices and the agreement              |
| 16 | state program directors completed the prioritization   |
| 17 | worksheets. We got those back in and did a             |
| 18 | statistical analysis on that to come up with what was  |
| 19 | truly a priority matrix of the high priority needs.    |
| 20 | So we had one list that was just based on overall      |
| 21 | level of priority and then another list that was based |
| 22 | on the performance goals. We chose to use the one      |
| 23 | based on performance goals to actually roll out what   |
| 24 | the high priority needs were.                          |
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and the Agreement States to see where there were differences. There were only a few differences. There were a couple of items that were of high interest to the states such as the role of the states in homeland security type operations. Of course, that would not be a high priority for NRC but would be of interest to the states.

8 And likewise there were a couple of things 9 that were of higher priority to NRC than to the 10 states. But overall, the top ten of each group were pretty much the same. So we now have a list. 11 The next part of that would be to test the framework and 12 how to get the decision-makers involved in actually 13 14 making a decision on accepting some of those lists and 15 assigning the resources those them to to qet 16 accomplished.

17 The other work product that was to come out of this pilot was to set up the framework for 18 19 continuing prioritization and assignment of work products to be accomplished because priorities are 20 going to change from year to year. Carl mentioned 21 this morning that sometime in the future we may need 22 to relook at basic radiation protection standards. 23 So 24 that may rise to a high priority item for both NRC and the states in the next few years. That might be a 25

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| 1  | project then for some joint group to work on.          |
| 2  | In the National Materials Program report               |
| 3  | from the earlier committee, there had been suggested   |
| 4  | a basic framework for how the alliance might work that |
| 5  | there would be some sort of prioritization group and   |
| 6  | then some level of decision-makers that would be made  |
| 7  | up of both Agreement States and NRC and then some sort |
| 8  | of administrative core to handle the administrative    |
| 9  | duties. So in setting up our framework and process,    |
| 10 | we identified what groups in the alliance would be     |
| 11 | involved in this process.                              |
| 12 | We are developing a process for                        |
| 13 | prioritization of the regulatory needs and             |
| 14 | establishing the regulatory agenda and defining the    |
| 15 | specific work products. The groups within the          |
| 16 | alliance, as I mentioned earlier, would be a           |
| 17 | priorities committee, a steering committee - that      |
| 18 | would be the decision-makers - and then an             |
| 19 | administrative core.                                   |
| 20 | Under the pilot, the pilot one working                 |
| 21 | group actually worked as the priorities committee in   |
| 22 | the continuing framework. The priorities committee     |
| 23 | would be composed of NRC and agreement state           |
| 24 | representatives. We're recommending that it be almost  |
| 25 | an equal representation in the future that would       |

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| 1  | develop and provide recommendations to a steering      |
| 2  | committee, to the decision-makers on what are the      |
| 3  | priorities that both NRC and the Agreement States are  |
| 4  | needing in the way of regulations, guidance documents, |
| 5  | standards, and maybe inspection guidance, licensing    |
| 6  | guidance, whatever that need might be?                 |
| 7  | Also then we would look at each of the                 |
| 8  | high priority items, figure out, define what work      |
| 9  | products need to come out of that, what resources are  |
| 10 | going to be needed, where the centers of expertise     |
| 11 | are. There might be an existing working group in       |
| 12 | CRCPD as in what pilot two is doing. The NRC might     |
| 13 | have a lot of expertise in a certain area.             |
| 14 | If we combine that with some expertise                 |
| 15 | from the states, for example in the area of financial  |
| 16 | assurance, then there might be other options that we   |
| 17 | can look at such as if an ANSI standard is being       |
| 18 | developed in that area, if HPS has worked on a         |
| 19 | standard that could be used, just other resources that |
| 20 | we can pull in and buy into that will optimize the     |
| 21 | resources that we have available and then also to      |
| 22 | assess the level of commitment from, for example, the  |
| 23 | Organization of Agreement States, NRC, CRCPD, or an    |
| 24 | individual state if an individual state has already    |
| 25 | come up with a solution that could be used without     |

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43 1 these other groups having to reinvent the wheel. 2 The priorities committee would also act as a clearinghouse for new ideas, new priorities that 3 4 spring up, for example, the security issue that came 5 up last year. That would then rise to a top priority It would then go through the 6 and be identified. 7 process of making those recommendations to a steering 8 committee. 9 We would foresee this group actually 10 meeting at least twice annually to do a prioritization of items that have come in to that committee and have 11 been identified. We might go through a similar 12 evaluating amonq 13 process of those the program 14 directors as well as the NRC offices in order to make 15 that everybody has input onto where these sure 16 priorities fall because we can't do everything every

17 year. But as things come to the top, then they can be 18 addressed. Shawn will take us through the rest of the 19 framework by discussing how the steering committee 20 would then act as well as the administrative core.

MS. SMITH: Pretty much Ruth talked you through the priorities committee. Members serve for staggered terms and convenes twice annually for a prioritization process meeting. The other group identified is the steering committee. The steering

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committee will be composed of NRC management and the chairs pretty much of OAS and CRCPD or their designees. This group will provide the management oversight of the alliance process and make decisions on cooperative agreement state and NRC regulatory efforts.

7 The administrative core is the third group that we identified in the alliance. 8 This group will 9 provide the administrative and logistical support for 10 the alliance products and priorities committee recommendations and work products to be developed by 11 12 individual working groups NRC or state or This group also tracks assignments and 13 organization. 14 products and maintains an information infrastructure, 15 pretty much the collection of work product data and information and work products. 16

17 As I spoke earlier to what the pilot projects overview overall activities are and similar 18 19 recommending, our process that we're the to administrative core currently is state and trial 20 programs, the pilot projects. We pretty much provide 21 the administrative and logistical support for all the 22 pilot projects and track assignments, projects and 23 maintain an information infrastructure. 24 So it's similar to what we're operating under the pilot 25

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project initiative.

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2 The prioritization process that we're 3 proposing. Ruth talked you through some of it. I'11 4 just highlight some of the major points. Step one 5 would be to identify regulatory needs by the Agreement States and NRC and communicate those to the priorities 6 7 committee. Pilot project one, under a process that we completed under the pilot project, acted as this 8 9 priorities committee.

10 As Ruth said, we collected regulatory needs from NRC and the Agreement States. This is step 11 12 one of our process. For licensees, public, and other stakeholders, NRC and the Agreement 13 States will 14 consider their input and it's fed up through your 15 regulatory agency. So either through the Agreement States or NRC is how your input is considered into 16 17 what regulatory needs are identified.

For step two, the priorities committee 18 19 then analyzes the regulatory needs and develops and maintains a database of regulatory needs. 20 As you see again for what we're proposing and what we did very 21 much similarly, we collected the needs, analyzed, and 22 identified them. We currently have a list of 23 24 prioritized regulatory needs from both NRC and the Agreement States. We're maintaining that currently. 25

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1 Like Ruth said and as we mentioned 2 earlier, the priorities committee will meet twice a 3 If an issue is deemed to be urgent such as a vear. 4 security matter and other issues, the priorities 5 committee will then research that issue immediately and make a recommendation to the steering committee 6 7 regarding its priority and disposition. We meet twice a year for the prioritization process and then once 8 9 with the steering committee. For step three, the priorities committee 10 then seeks input annually from the NRC and Agreement 11 First, we receive regulatory needs. 12 States. Then we need to prioritize them so that we can have a 13 14 prioritized list of regulatory needs. The level of 15 priority for each identified regulatory need will be addressed during our prioritization process meetings. 16 Mechanisms for providing input can include surveys, 17 worksheets like we use, or focus discussion at the 18 19 annual OAS, CRCPD, or other special called meetings such as the HBS meeting and others. 20 Step four of the process. The priorities 21

22 committee then numerically evaluates the input on 23 priorities for regulatory needs and makes 24 recommendations to the steering committee. Ruth 25 pointed out pilot project one did this. We haven't

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went to the point where we make recommendations to the steering committee, but we have evaluated the input and developed a prioritized list of regulatory needs. Another thing I wanted to point out on step four is when we evaluate and the committee does our research, we're going to research the top ten priorities.

7 This is our proposed process. We'll top 8 research the ten NRC and agreement state 9 priorities and based on those top ten, make 10 recommendations on those top ten to the steering committee. Like Ruth said, we're going to define 11 specifically what the regulatory need is, identify 12 where the expertise is to develop the regulatory need 13 14 or alternate resources, identify the specific work 15 products that need to be developed because the 16 regulatory need isn't necessarily the work product that needs to be developed of course, and other 17 recommendations as appropriate. 18

19 Step five. Once we make recommendations 20 to the steering committee, based upon our recommendations, the steering committee will establish 21 the regulatory agenda pretty much based on the top ten 22 items and all of the information that the priorities 23 24 committee gives to the steering committee. The steering committee pretty much says we have resources 25

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| 1  | to do this, defines the specific work products, and    |
| 2  | commit appropriate NRC and/or agreement state          |
| 3  | resources to get the work product developed.           |
| 4  | The steering committee also uses input                 |
| 5  | from the administrative core, who are tracking the     |
| 6  | alliance assignments and products throughout this      |
| 7  | process, to evaluate progress on the assignments.      |
| 8  | Like I said before, they provide the overall           |
| 9  | management and oversight of the work products and      |
| 10 | assignments, but the administrative core are tracking  |
| 11 | them. So those two groups are working together.        |
| 12 | The next steps for pilot project one.                  |
| 13 | Like I said before, we have gotten to the point where  |
| 14 | we have identified regulatory needs and prioritized    |
| 15 | them. Now we have a list. What we're going to do is    |
| 16 | constitute a steering committee because we don't       |
| 17 | currently have an official steering committee. We are  |
| 18 | calling them the regulatory decision-makers but we all |
| 19 | know who that is composed of, pretty much NRC          |
| 20 | management and the chairs of OAS and CRCPD, and also   |
| 21 | constitute an administrative core so that when we run  |
| 22 | through the rest of our proposed process, in the       |
| 23 | components, the other two groups are there and         |
| 24 | constituted so we have an official group to work from. |
| 25 | Instead of ten, like I said earlier in my              |

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earlier discussion, the report on all of the pilot projects are due to the Commission in November 2004. So instead of researching top ten, because that's going to take a little bit of time, we're going to research two regulatory needs identified in our prioritized list.

7 Since this is just a pilot, we figured two 8 should be enough to at least get an idea. The 9 steering committee will have an idea of what the recommendations look like and what information it will 10 be composed of. And then there's complete a test of 11 12 our proposed prioritization process that I talked you through and issue our final report in September of 13 14 this year. Any questions on this process? CARDWELL: Consider mine after 15 MS. 16 George's. I just can't reach it. 17 MS. SMITH: Okay, go ahead, George. MR. PANGBURN: Just two questions. 18 You 19 mentioned that the steering committee is not yet composed or comprised. What parts of NRC management 20 organizations do you envision being 21 on the or committee? 22 MS. SMITH: We recommended the steering 23

24 committee be composed of the Director of State and 25 Tribal Programs, Paul Lohaus, or their designee,

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1 Director of NMSS, Marty Virgilio, Director of NSIR, Roy Zimmerman, or their designees so it could be 2 3 someone else, and an NRC Regional Division Director 4 such as yourself or Mark Depas, and then the chairs of 5 OAS and CRCPD or their designees of course. Okay, and one other process 6 MR. PANGBURN: 7 question, maybe you haven't gotten there yet. But once you have developed your list of regulatory needs 8 9 and made recommendations to the steering committee, 10 have you thought ahead to how that might be incorporated into the budget process? Assume for the 11 12 sake of argument that you have ten products that you identify regulatory needs, three or four of which 13 14 might be NRCs to have the lead, have you thought about 15 how you would factor that into the budget development 16 process? 17 MS. SMITH: We have. We're currently thinking about that. As you saw the make up, we have 18 19 a representative from PMBA and CFO. So we are considering how to structure the process and to budget 20 so that the resources will be identified before and 21 will be available at the time for work products to be 22 developed and resources committed. So we're looking 23 24 at this as a timing issue maybe of when we work the Just thinking, this isn't finalized. 25 process.

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| 1  | MR. PANGBURN: I understand.                           |
| 2  | MS. SMITH: Just thinking from the working             |
| 3  | group, we were thinking that the process will have to |
| 4  | be run through when it's time for the budget. So      |
| 5  | that's our thinking.                                  |
| 6  | MR. PANGBURN: Thank you.                              |
| 7  | MS. SMITH: It's more of a timing that                 |
| 8  | we're looking at initially. But we are considering    |
| 9  | that as we look further to our report.                |
| 10 | MR. PANGBURN: Thank you.                              |
| 11 | MS. McBURNEY: Also on that, a lot of                  |
| 12 | times that will come up as high priority for the      |
| 13 | combined groups will already be on a high priority    |
| 14 | item that has gone into NRC's budget. So there are    |
| 15 | already planning on working on that issue. What this  |
| 16 | would propose is how to do that most efficiently. It  |
| 17 | might be that NRC could do it even less expensively   |
| 18 | than they had planned for in their original budget by |
| 19 | incorporating some expertise from the states as well  |
| 20 | rather than just having all staff from NRC working on |
| 21 | that particular issue.                                |
| 22 | MR. PANGBURN: Thanks.                                 |
| 23 | MS. SMITH: Cindy?                                     |
| 24 | MS. CARDWELL: Two questions actually.                 |
| 25 | One was the fact that stakeholder input was a vital   |

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1part of what was envisioned in the alliance concept2and was addressed in the National Materials Program3working report. I wondered if the committee discussed4that or if the committee saw that stakeholder input as5a part of this process or the next step which is the6product development once the regulatory agenda is7established and resources are committed.

8 MS. SMITH: Actually both. Considering 9 input, when we go to the NRC and Agreement States to 10 obtain regulatory needs for the upcoming year, we think that since those are the groups that are hands 11 on with the licensees and other stakeholders that as 12 those issues are communicated through your licensees 13 14 and your stakeholders and industry and professional 15 groups within your state or NRC jurisdiction then those are filtered through the regulatory agency being 16 the state or NRC region and then are brought into the 17 process at that point. 18

19 So it's not necessarily the priorities going directly to the industry and stakeholders but 20 their input 21 filtered through the regulatory jurisdiction or agency. And then for the second part 22 of your question, as far as work products being 23 24 developed, we did consider that also. That's what we call our alternate resources. 25

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53 1 So not only could there be an NRC or 2 agreement state working group. There may be a group 3 within HBS that's working on a specific guidance 4 document or has some expertise so we can pull in that 5 professional input as well or other groups. Like, if there is something dealing with a radiographer, we can 6 7 go to radiographer licensees and they provide input. For example, pilot two, Donny Dicharry is on that 8 9 pilot so he's been providing input. That's another In the front end, it's filtered through. 10 way too. Then when work products are developed, it's filtered 11 through at the end as well. 12 MS. CARDWELL: So it's going to be clear 13 14 in the report then so that stakeholders can see 15 clearly where they have opportunities for input. 16 MS. SMITH: Yes. 17 MS. CARDWELL: Like to the organizations or as they do currently. 18 19 MS. SMITH: Yes, it will be identified in 20 our process. MS. CARDWELL: The second one had to do 21 with the establishment of priorities. You said early 22 on that there were priorities that were priorities 23 24 that were specific to states and specific to NRC. That's because of the regulatory scheme or regulatory 25

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1 framework. 2 Not that you don't care, but NORM is not 3 an issue for the NRC. It is for the states. So those 4 priorities are there. It was also part of the 5 alliance concept within the original national materials working group report that those still be 6 7 readily identified so that you get to the point when 8 you are at what you are calling the steering committee 9 looking to make decisions on not only the combined ones but then commit resources, that there's an 10 awareness already that there are other competing 11 priorities and resources may be dedicated to those 12 other priorities that are individual to one or the 13 14 other groups so that when you commit resources you are 15 not over-committing or over-extending those resource 16 commitments. 17 MS. SMITH: Yes, and we're looking at that issue as well. Early on in our process, we only asked 18 19 regulatory needs that for were shared program activities so not including fuel cycle for NRC and not 20

including NORM and X-ray for the states. We only
wanted those items that fell under both NRC and
Agreement States. It gets back to the budget.

24 What you are saying is, how does NRC deal 25 with - I forgot what Paul called it - but the

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| 1  | regulatory licensing inspection and all the other      |
| 2  | stuff you have to do as a part of your day-to-day      |
| 3  | activities? The working group is taking that into      |
| 4  | consideration. As far as how far, we'll get to that.   |
| 5  | But we are looking at that issue as well.              |
| 6  | MS. CARDWELL: Because that was a major                 |
| 7  | point that we made in the National Materials Program   |
| 8  | report that that be certainly addressed and recognized |
| 9  | certainly with the understanding that resources,       |
| 10 | regulatory, jurisdictions don't always permit one      |
| 11 | group to work on one or visa versa. But that needs to  |
| 12 | be out there for resources issues.                     |
| 13 | As Carl pointed out earlier, if we're                  |
| 14 | going to change public dose, it involves X-ray in the  |
| 15 | states as well. It's an issue we have to consider as   |
| 16 | well. So those kinds of things need to be out there    |
| 17 | as identified as high priorities individually and then |
| 18 | the combined priorities.                               |
| 19 | MS. SMITH: Yes, Paul.                                  |
| 20 | MR. LOHAUS: Thank you, Shawn. I wanted                 |
| 21 | to comment on the issue that George raised. To me,     |
| 22 | that's one of the real challenges that the National    |
| 23 | Materials Program will face. That is as soon as we go  |
| 24 | through a process, we come up with a list of           |
| 25 | priorities. How do the individual programs then        |

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decide yes this is one that I can do, and will there be assurance that that program can budget the resources for it and have the resources survive that agency's budget process?

5 I don't know what the answer to that is, 6 but to me, that's one of the challenges. Just to 7 think about NRC's budget process, there's different steps in that process that we go through in terms of 8 9 review and approval including commission. There's 10 OMB, President, Congress, et cetera. So exactly how together is one of the 11 that is qoing to come Maybe you all can think about that. challenges. 12 Maybe there's some thoughts that you will have too 13 14 that you can offer on that.

15 discussion But the has very clearly 16 identified that as a part of that process it will have to be a shared decision by both the states and NRC. 17 The states will need to be prepared to come away from 18 19 that discussion and say yes we can do these activities and we'll be able to budget that. I think the same 20 would need to apply for NRC. 21

22 Otherwise, you end at a point where you 23 don't really have any assurance that this cooperative 24 program will in fact be effective and be able to 25 produce products on time to meet agency needs. Just

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57 1 thinking through this, to me, that's one of the 2 challenges in the program. 3 MS. McBURNEY: Just to comment on that. 4 For the most part, most of these items that are going 5 to float to the top probably have already been identified and earmarked. Somebody is going to be 6 7 throwing some resources to that. It's not very often that you will have a priority need coming to the top 8 that nobody has done anything about or thought about 9 or even started some sort of development on. 10 So folding that into an existing budgeting 11 process I don't think will be as difficult as one 12 In fact, what we're trying to do is 13 might think. 14 optimize the resources of all the groups, all the regulatory agencies, and trying to cut down on those 15 16 individual costs rather than putting all the 17 requirements on one group to do or one particular state program or so forth. 18 19 MR. LOHAUS: Thank you, Ruth. That's very 20 helpful. Thank you. FACILITATOR RAKOVAN: If we could go to 21 Lynne, she's had her hand up for a while now. 22 23 I can't reach my sign MS. FAIROBENT: either. 24 These tables are made for non-vertically challenged individuals. 25

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| 1  | FACILITATOR RAKOVAN: We'll have to move                |
| 2  | those back.  |
| 3  | MS. FAIROBENT: Two points. One, I wanted               |
| 4  | to follow up on the budget questions too because the   |
| 5  | initial response focused on how NRC would deal with it |
| 6  | within their budget process. But I have a little more  |
| 7  | concern with how either CRCPD as an organization would |
| 8  | handle it if it should be a priority item that comes   |
| 9  | back to them for the lead and also knowing the great   |
| 10 | concern and constraints on state budgets today, how    |
| 11 | that falls or would be looked at to be handled within  |
| 12 | the state.   |
| 13 | I feel a little bit better having heard                |
| 14 | the follow up discussion as a result of it. But I do   |
| 15 | think that those are two absolutely critical issues    |
| 16 | that need to be looked at. The federal budget is also  |
| 17 | being extremely constrained as each fiscal year cycle  |
| 18 | comes up and there are more and more competing         |
| 19 | priorities. So I do think that's probably going to be  |
| 20 | one of the key stumbling blocks overall.               |
| 21 | But I do think that in moving to the                   |
| 22 | National Materials Program it will help to better      |
| 23 | everyone if we can share resources. Then that leads    |
| 24 | to me following up on Cindy's comment on stakeholder   |
| 25 | involvement because listening to your process and      |

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| 1  | stuff I'm very much concerned that there is not as     |
| 2  | much up front incorporation as stakeholder input as    |
| 3  | perhaps was initially envisioned in the initial        |
| 4  | working group report that went forward.                |
| 5  | I don't believe that it will benefit the               |
| 6  | entire community by relying on stakeholder input to be |
| 7  | a very informal catch as catch can process which is    |
| 8  | what I was hearing the response to be. Yes, we at      |
| 9  | ACRD work very closely with CRCPD as an organization.  |
| 10 | We provide a lot of resources and stuff. But it still  |
| 11 | needs to be a formal thought through process on        |
| 12 | getting early input from the stakeholders into the     |
| 13 | development of the regulatory agenda.                  |
| 14 | For example, I know we haven't talked                  |
| 15 | about working group four. But you had mentioned that   |
| 16 | Donny was on working group two for the radiographers.  |
| 17 | But when I look at working group four, there is no     |
| 18 | stakeholder on working group four. That is very much   |
| 19 | a very focused medical issue or new use, I would       |
| 20 | assume you are terming it. There is no stakeholder     |
| 21 | member on that.  |
| 22 | As far as I know, there has not been any               |
| 23 | request to the stakeholder community for any input in  |
| 24 | your development of the work going on in that area.    |
| 25 | So that does give me some concern. The other question  |

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| 1  | I have is, can you tell us what the two regulatory     |
| 2  | needs are that are going to be researched in the next  |
| 3  | several months to fall into your September `04 report? |
| 4  | Are those publicly available?                          |
| 5  | MS. SMITH: We do have the regulatory                   |
| 6  | needs, the top ten of those. We haven't specifically   |
| 7  | chosen which ones to identify. I can tell you what     |
| 8  | the top ten are that we're going to choose from if you |
| 9  | want. The first one was develop licensing and          |
| 10 | inspection guidance for new medical technologies       |
| 11 | including medical devices and procedures.              |
| 12 | Number two was to identify the roles of                |
| 13 | state radiation control programs and homeland          |
| 14 | security. Three was financial assurance for            |
| 15 | decommissioning, funding of accidents, disposition of  |
| 16 | orphan material in small industries going bankrupt.    |
| 17 | Number four was the resolution to the                  |
| 18 | collection of disposal and storage of orphan sources.  |
| 19 | Five is security review of general license device      |
| 20 | programs. Six is rulemaking on americium neutron       |
| 21 | sources and large activity source disposal. Seven was  |
| 22 | to identify or develop subject matter experts and      |
| 23 | technical assistance personnel that would be useful in |
| 24 | cases of emergencies.                                  |
| 25 | Eight was guidance for first responders                |

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| 1  | who will be equipped with radiation monitors. Nine is  |
| 2  | codify estimates not overly conservative of doses to   |
| 3  | be received by the public during performance           |
| 4  | assessments. Ten was develop guidance for              |
| 5  | veterinarian medicine treatments involving radioactive |
| 6  | material in release of animals.                        |
| 7  | MS. FAIROBENT: But for example, is that                |
| 8  | list on the website somewhere that it's publicly       |
| 9  | available?   |
| 10 | MS. SMITH: No, the list is not on the                  |
| 11 | website where it's publicly available.                 |
| 12 | MS. McBURNEY: It will be a part of our                 |
| 13 | final report. What we thought we would do is take one  |
| 14 | public health and safety item and one security of      |
| 15 | radioactive materials item to further develop and      |
| 16 | figure out what are the resources that are available   |
| 17 | on that and how could it best be optimally carried out |
| 18 | to get the work product?                               |
| 19 | For example, number one, the development               |
| 20 | of the licensing and guidance for new medical          |
| 21 | modalities is really what pilot four is already taking |
| 22 | on. It's to develop some sort of guidance for a new    |
| 23 | medical modality. So then we would make                |
| 24 | recommendations to the steering committee on a couple  |
| 25 | of those for the purposes of the pilot and work with   |

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| 1  | them on how best to do that to accomplish those.       |
| 2  | MS. FAIROBENT: Then the other thing,                   |
| 3  | Ruth, you had made a comment that in the future you    |
| 4  | were going to look at the priorities committee         |
| 5  | membership to be more equally distributed between      |
| 6  | states and feds. A similar question comes to mind in   |
| 7  | looking at the steering committee being constituted.   |
| 8  | It's four feds to two state representatives.           |
| 9  | Again, what is the equal voice? Is that                |
| 10 | the optimum representation in order to ensure that     |
| 11 | there is a balance on determining the collective       |
| 12 | priorities if you are going to have a fully integrated |
| 13 | program? It may be. It's just something to consider.   |
| 14 | MS. McBURNEY: For the purpose of the                   |
| 15 | pilot, that's the way we're going to set it up. Since  |
| 16 | we haven't really constituted that group and had       |
| 17 | discussions with them, that might be something that    |
| 18 | comes up during the steering committee discussions.    |
| 19 | Back to your earlier comment on having early input     |
| 20 | from the stakeholders on establishing priorities, how  |
| 21 | would you think that would be best accomplished?       |
| 22 | Should there be something that goes out to the         |
| 23 | professional societies early on to get their           |
| 24 | FACILITATOR RAKOVAN: If I could, is this               |
| 25 | something that we could put in the parking lot for     |

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| 1       later?         2       MS. MCBURNEY: Yes.         3       MS. FAIROBENT: Yes, I think it's a         4       discussion topic.         5       FACILITATOR RAKOVAN: We're talking         6       getting the priority list out to stakeholders.         7       MS. FAIROBENT: We're talking about         8       priority lists out and publicly available but more         9       importantly, Lance, is the incorporation of         10       stakeholder input in the early development of what         11       becomes the regulatory agenda.         12       MR. MARKLEY: Lance, I think the budget         13       process should also be part of the parking lot here.         14       FACILITATOR RAKOVAN: Okay.         15       MS. FEDERLINE: Yes, two things I wanted         16       MS. FEDERLINE: Yes, two things I wanted         17       to raise probably for the parking lot. We're dealing         18       with the `06 budget now. One thing we're finding is         19       that there are so many emerging issues that come upon         20       the scene even in the year that we're working in that         21       So I think we're going to have to have a |    | 63   |
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| 22 So I think we're going to have to have a   | 20 | the scene even in the year that we're working in that  |
|   | 21 | we're continually doing add/shed.                      |
|   | 22 | So I think we're going to have to have a               |
| 23 very open communication process between the states and   | 23 | very open communication process between the states and |
| 24 NRC and with the stakeholders to understand the  | 24 | NRC and with the stakeholders to understand the        |
| 25 emerging issues and look at priorities so we all have  | 25 | emerging issues and look at priorities so we all have  |

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a common understanding there. I know George
 understands that we go through this add/shed process
 on the budget. Keeping open communication will help
 on that.

5 The other issue I wanted to raise is my first comment relates to planning assumptions. 6 One 7 thing I think would be particularly important is to have an earlier stage before the prioritization where 8 9 we talk about planning assumptions and perhaps look 10 out two to three to four years and have the stakeholders involved in that discussion and perhaps 11 once a year have a meeting like this and talk about 12 what we should assume for the next three to five years 13 14 and plug that into our planning process. Thank you.

16 MR. SMITH: This is Leonard Smith. I have 17 a question. Is there a provision for involving other 18 federal agencies in this process like EPA and DOT and 19 Homeland Security?

MS. SMITH:

Thank you.

Leonard Smith.

MS. McBURNEY: Certainly they are stakeholders in a lot of this particularly some of the homeland security issues and transportation issues and disposition of orphan sources. So yes, we will be needing to involve those other agencies.

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MS. CARDWELL: As a clarification point on

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| 1  | that, that was part of the original National Materials |
| 2  | Program report. The other federal agencies are         |
| 3  | considered stakeholders in the report, but they are    |
| 4  | indeed involved early in the process. The report was   |
| 5  | done prior to 9/11. So I think Homeland Security has   |
| 6  | put a whole new twist on a lot of what the             |
| 7  | recommendations were and interactions that need to     |
| 8  | happen.  |
| 9  | MS. McBURNEY: Yes, and if there is early               |
| 10 | planning, they need to be involved with that as well   |
| 11 | on the planning assumptions as Margaret mentioned.     |
| 12 | MR. MARKLEY: On that issue of the other                |
| 13 | federal agencies                                       |
| 14 | FACILITATOR RAKOVAN: Could you please                  |
| 15 | identify yourself?                                     |
| 16 | MR. MARKLEY: Yes, I'm Mike Markley with                |
| 17 | NMSS. There are two pieces of that with Homeland       |
| 18 | Security that typically impact us. One is the          |
| 19 | security thing which you are most familiar with now.   |
| 20 | But the other is the emergency planning and response   |
| 21 | because a lot of the interagency exercises we're       |
| 22 | dealing with now were not things we budgeted a few     |
| 23 | years ago. Of course, we're all spending resources on  |
| 24 | it. So to me, this also fits into the budget piece as  |
| 25 | well.  |

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| 1  | MS. SMITH: Thank you.                                  |
| 2  | FACILITATOR RAKOVAN: Okay, I see two more              |
| 3  | tents up. Stan, we'll go to you first.                 |
| 4  | MR. FITCH: I have one comment to Lynne                 |
| 5  | about pilot four. Actually our new modality wasn't     |
| 6  | identified until just very recently. When we put       |
| 7  | together the working group, the intent was to research |
| 8  | all options about which would be the best way to go.   |
| 9  | The feedback we got from the most recent OAS meeting   |
| 10 | was that the membership for that pursued something on  |
| 11 | homeland security.                                     |
| 12 | In our discussions with NRC, we went back              |
| 13 | to the point that we really need to focus on a new     |
| 14 | modality. Just recently, a week or so ago, a new       |
| 15 | modality was settled on. As part of that research      |
| 16 | process, the pilot group worked with several           |
| 17 | stakeholders in identifying this and receiving         |
| 18 | feedback. Mr. Gallaghar will identify that later. I    |
| 19 | think there are three or four people from the medical  |
| 20 | community that they involved. So we definitely did a   |
| 21 | stakeholder feedback early on in the process.          |
| 22 | One comment, and I know we're going to be              |
| 23 | talking about budget later. But if you are looking at  |
| 24 | 50 states and 50 states full of legislators, you will  |
| 25 | get a very small percentage who actually are going to  |

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| <ol> <li>commit to the National Materials Program. They</li> <li>going to look at it. They are going to have thei</li> <li>budgets and their figures. They are not going t</li> <li>commit themselves to NMP. There are alternatives</li> <li>participation. We can discuss that later.</li> </ol> | r     |
|--|-------|
| <ul> <li>3 budgets and their figures. They are not going t</li> <li>4 commit themselves to NMP. There are alternatives</li> </ul>  |       |
| 4 commit themselves to NMP. There are alternatives   | 0     |
|  |       |
| 5 participation. We can discuss that later.  | for   |
|  |       |
| 6 FACILITATOR RAKOVAN: Would you like  | that  |
| 7 on the board?  |       |
| 8 MR. FITCH: Just with the budget port   | ion.  |
| 9 FACILITATOR RAKOVAN: Lynne?  |       |
| 10 MS. FAIROBENT: Yes, Lance, one othe   | r     |
| 11 parking lot item needs to probably be brought up la   | ıter  |
| 12 and thought about. That's the impact of petition  | for   |
| 13 rulemakings and how do they fit into this wh  | ole   |
| 14 overall process and switch your priorities?   |       |
| 15 MR. WANGLER: Lance, do you have stee  | ring  |
| 16 committee membership as a parking lot item?   |       |
| 17 FACILITATOR RAKOVAN: I do now.  |       |
| 18 MS. McBURNEY: Okay, is there anythin  | ng    |
| 19 else?   |       |
| 20 MS. SMITH: I think it's time for a b  | reak. |
| 21 Thank you for your attention.   |       |
| 22 FACILITATOR RAKOVAN: We're going to   | take  |
| a 20 minute break I believe. Be back here and re   | ady   |
| 24 for the next round of presentations starting wit  | h     |
| 25 pilot project two at 10:20 a.m. Off the record.   |       |

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| 1  | (Whereupon, the foregoing matter went off              |
| 2  | the record at 9:59 a.m. and went back on               |
| 3  | the record at 10:21 a.m.)                              |
| 4  | FACILITATOR RAKOVAN: On the record.                    |
| 5  | We're going to reconvene. For the next session, we're  |
| 6  | going to have the various chairs of pilot projects two |
| 7  | through five giving short presentations on their pilot |
| 8  | projects. The way we'll probably work this is have     |
| 9  | short clarification, Q and A after each individual     |
| 10 | presentation so that way it doesn't get all mixed up.  |
| 11 | So if you have any specific questions on pilot project |
| 12 | two, we can handle them right after pilot project two. |
| 13 | With that, I will turn it over to Jan Endahl.          |
| 14 | MS. ENDAHL: Thank you. It made me                      |
| 15 | nervous when you all got so quiet. I'm Jan Endahl.     |
| 16 | I'm with the Texas Program and Industrial Radiographer |
| 17 | Certification. We do testing of the industrial         |
| 18 | radiographers. I'm also the chair of G-34 Committee    |
| 19 | with CRCPD, the Conference of Radiation Control        |
| 20 | Program Directors and as such ended up as the chair of |
| 21 | pilot project number two.                              |
| 22 | What were we charged to do? We were                    |
| 23 | charged with serving as the lead organization to       |
| 24 | oversee a National Industrial Radiographer Safety      |
| 25 | Certification Program. We were the logical choice for  |

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this particular project because we are a ready-made working group within CRCPD.

3 We have representatives from NRC, Jim 4 Myers from STP, Bruce Carrico from NMSS. We also have 5 an industry representative here today, Donny Dicharry, who has already been noticed. He has for years served 6 7 double duty on our committee serving as a 8 representative from ASNT and also from NDTMA. The 9 other two members of our project were Lauren Palmer from Georgia and David Turberville from Alabama. 10

The oversight activities that we were 11 12 directed to take а look at were reviewing and initial applications 13 approving from states and 14 independent organizations, such as the American 15 Society for Non-destructive Testing, to be recognized as certifying entities, also to review changes to 16 17 existing programs, and to develop recommendations for the follow up evaluations of the program status which 18 19 would include such activities as test administration, program maintenance activities, and data collection, 20 document review, et cetera. 21

The question might arise in some of your minds as to why we think that a national program is important. Let me just take a couple of minutes to give you some information regarding that. Consider

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that currently there are ten states and the American Society for Non-destructive Testing that are recognized as certifying entities.

4 In addition to Texas, there's Louisiana, 5 Oklahoma, Iowa, Illinois, North Dakota, Georgia, Alabama, South Carolina, and Maine. These states and 6 7 ASNT offer certifications anywhere from radioactive 8 materials only certification to X-ray only 9 certification to a combination certification that 10 involves both X-ray and radioactive materials. Currently only ASNT has ever submitted applications to 11 have their programs requested recognition of 12 as programs. No follow up evaluations of any of the 13 14 existing certification programs has been conducted.

We believe that centralized certification 15 16 concept promotes the efficient use of resources and 17 expertise. Essentially the individual states don't have to do independent reviews of new applications in 18 19 order to determine whether states or independent organizations should be recognized as certifying 20 entities, nor do the states or NRC have to keep up 21 22 with program changes.

We believe that a centralized concept ensures comparable programs nationwide, that they all have the same program components which facilitates the

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1 uniform acceptance of certification cards and what 2 We know that the industry is very mobile. they mean. Being able to move from job to job is very important. 3 4 Essentially then centralized certification ensures the 5 integrity of the centralized certification programs. So what did we do and how did we do it? 6 7 Well, we created flow charts that define the 8 application review and the evaluation process for the 9 independent states and for the certifying 10 organizations, associations. These were first outlined during this process. We didn't actually 11 They were previously discussed and put 12 create them. on paper in May 2000 during a G-34 committee meeting 13 14 when we were discussing an industrial radiographer 15 certification center of expertise. From the flow charts, we went to documents 16 that formalized the review criteria which are based on 17 nationally accepted standards and good practices. 18 We 19 used 10 CFR Part 34 for radioactive materials and CRCPD's suggested regulations Part E for the X-ray and 20 combination certification programs. Originally an NRC 21 state and federal 22 working group made up of representatives developed the criteria in 1997 for 23 24 evaluating ASNT's request to have its radioactive material program recognized. 25

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| 1  | Once that happened, ASNT turned around and             |
| 2  | said now that we're recognized for radioactive         |
| 3  | material, we would like to be recognized for our X-ray |
| 4  | programs and for our combination programs. So the G-   |
| 5  | 34 committee at that time then took that criteria that |
| 6  | was developed by the NRC working group, expanded the   |
| 7  | application to include X-ray machines, and in 2001     |
| 8  | completed the evaluation of ASNT's request for         |
| 9  | recognition of its X-ray and combination programs.     |
| 10 | Once we had the flow charts and the                    |
| 11 | process established, we needed a volunteer for testing |
| 12 | the criteria. We sent out letters to ten states along  |
| 13 | with ASNT and the Canadian Nuclear Safety Commission   |
| 14 | and invited them to be our test case. We chose         |
| 15 | Louisiana. Of the people we polled, eight              |
| 16 | organizations said yes, choose us, and four of them    |
| 17 | declined participation in the actual criteria testing. |
| 18 | We also solicited comments on the criteria             |
| 19 | and the process from the people we had sent the        |
| 20 | letters to the current certifying states, ASNT, and    |
| 21 | Canada. We also added one more state to our list of    |
| 22 | people we invited and solicited comments from. That    |
| 23 | would be the State of California since they are in the |
| 24 | process of developing a certification program and      |
| 25 | could potentially be the first group to actually go    |

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through this process if we go forward with this concept.

3 So what did we learn? We learned that 4 early communication between a prospective certifying 5 entity and an oversight committee is really important 6 and should be encouraged. For Louisiana, we 7 deliberately fabricated a false situation in that we 8 didn't allow them to ask us questions like what do you 9 send us this or what do you mean in the mean, 10 criteria? We as a group had decided before soliciting information from Louisiana that we wanted to see how 11 the criteria stood on its own. 12

If there were gaps in how it was written, 13 14 how it should be conveyed that we could better improve 15 on, then it would be incumbent on us to do that. So 16 we didn't let them ask questions. But we did think in 17 the response that we got back from Louisiana that any gaps in the information that we received could very 18 19 well have been minimized by allowing that back and forth dialogue between the oversight committee and the 20 21 program.

We learned that the present criteria is adequate for reviewing a proposed state certification program as well as that of an independent certifying organization. We have sensible criteria that focuses

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| 1  | on the key elements necessary for sound certification. |
| 2  | We have an outline of a process that we believe is     |
| 3  | necessary for a successful program.                    |
| 4  | Together, these provide a solid basis for              |
| 5  | future certification program reviewers for assessing   |
| 6  | the minimum requirements for an effective              |
| 7  | certification program. They also provide the basis     |
| 8  | for reviewing existing certification programs to       |
| 9  | ensure uniformity and continued credibility.           |
| 10 | Naturally we had to make some                          |
| 11 | recommendations. The group decided that there were     |
| 12 | certain rulemaking, administrative, and procedural     |
| 13 | improvements that could be made to the current and     |
| 14 | envisioned future certification system. These would    |
| 15 | include parallel rulemaking activities by NRC in its   |
| 16 | Part 34 and CRCPD in its SR Part E to facilitate the   |
| 17 | criteria changes that are necessary.                   |
| 18 | We also recommend that there be a                      |
| 19 | promotion of sharing of information concerning the     |
| 20 | individual radiographer's radiation safety             |
| 21 | certification status and history, performance, and     |
| 22 | safety and that there be included provisions that make |
| 23 | individuals on the job site responsible for their      |
| 24 | actions. Additionally, some other actions we           |
| 25 | identified that need to occur is the formal            |

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75 1 establishment of an oversight committee of qualified 2 individuals with specific responsibilities and 3 authorities to administer a national program. 4 Also there's the establishment of 5 protocols for a systematic and uniform sharing of information regarding enforcement actions, final 6 7 actions, and orders and sanctions and that they be in 8 sufficient detail to give opportunity for other 9 certifying states to reciprocally recognize those 10 sanctions. And finally that there be formal evaluations of independent certifying organizations 11 and state certification programs at regular intervals. 12 So what's next for this group? After 39 13 14 conference calls and 1,160 hours spent on the project, 15 I wish I could say we're going to Disney World. But 16 don't think that's even on the screen of the 17 prioritization project. We do appreciate the opportunity to focus again on refining the building 18 19 blocks for a national certification program. It seems like in the past when we have had 20 the opportunity or been forced into the opportunity of 21 taking a look at the process and the criteria that 22 we've always had an application waiting in the wings. 23 24 So we have always felt rushed to get through the

criteria and make sure that we were working together

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1 to review the application. That was not the case this 2 time. So we had some extra time to really ask 3 ourselves, why are we asking that question and why are 4 we requiring that?

5 For some of us, going back to `97 to the 6 original criteria was a mental exercise that was 7 somewhat challenging as to why we made those 8 recommendations back then. Essentially this was 9 another day at the office for this group. You got a 10 group who has been working on certification issues for well over a decade through CRCPD. Because this 11 project was an extension of these activities, we will 12 continue to be proactive on the issues that involve 13 14 industrial radiographer safety certification.

15 We anticipate refining the criteria that 16 presented to Louisiana and to the we states 17 incorporating the information and feedback that we got from ASNT and from the states. Additionally, CRCPD 18 19 has recently established an industrial radiographer certification page to share information with states 20 and with others regarding this particular project and 21 certification issues. You can visit that at their 22 website at www.crcpd.org. I'll take any questions. 23 24 MS. FAIROBENT: This might sound a little 25 strange but as you went back and looked at your

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process and stuff, did you look at other types of 1 equivalent programs? What comes to mind is the 2 National Mammography Program. 3 In that case, ACR is 4 the only national entity that accredits or certifies facilities and stuff. But then there are five states 5 that do it and you have FDA oversight on it. 6 I just 7 wondered if in looking at how your process maybe 8 should be refined or adequate or needs to change, et 9 cetera, did you look at any other types of similar 10 programs that are addressing the same type of elements? 11 No, we did not. 12 MS. ENDAHL: MR. WANGLER: Hasn't the IR process been 13 14 around longer than mammography? 15 MS. FAIROBENT: Yes. 16 MR. WANGLER: Quite a bit longer. 17 MS. FAIROBENT: Yes, and one of the major differences - and I know you just used that as an 18 19 example - is that there's not the image reviews that It's not a patient dose industrial use. 20 are required. FACILITATOR RAKOVAN: 21 Paul? I wanted to offer two items 22 MR. GENOA: for the parking lot. Really they deal with what's 23 24 next. The first is in going back and looking at the earlier material, in particular the commission paper 25

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that laid out each of the pilots, one of the things that you can see within the description of this pilot is that to the extent possible this should be a demonstration that the conference could take the lead for the nation, if you will, for the states and NRC in implementing a radiography certification program.

7 I quess the thought is whether the working 8 group can do additional work to actually identify --9 other words, they talk about the oversight In 10 committee or review committee. But to me, that committee could very well be the CRCPD. If the states 11 are willing to accept it and NRC is willing to accept 12 it, that could serve as the mechanism for basically 13 14 running the nation's program. So I guess my thought it whether that should be explored further by the 15 16 working group and either a recommendation or a 17 proposal developed along those lines.

The second part of it relates to the 18 19 evaluation piece. That's a very important piece that I guess the thought the working group has identified. 20 is, could there be some consideration relative to 21 whether the current integrated materials performance 22 evaluation program could be expanded, if you will, or 23 24 a new non-common performance indicator identified or prepared, drafted that would serve as the mechanism 25

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| 1  | for doing the evaluation? I don't know but these may   |
| 2  | be two areas we can talk about further this afternoon. |
| 3  | FACILITATOR RAKOVAN: Thank you Paul. Any               |
| 4  | other clarifying questions or discussion on this topic |
| 5  | before we move on to the next pilot project? Thank     |
| 6  | you, Jan. While we are switching presenters, we have   |
| 7  | had another member of our roundtable discussion join   |
| 8  | us. Ms. Johnsrud, if you could grab a mic and          |
| 9  | introduce yourself please.                             |
| 10 | MS. JOHNSRUD: My name is Judith Johnsrud.              |
| 11 | I represent Sierra Club's National Waste Committee.    |
| 12 | I do chair the club's nuclear waste subcommittee as    |
| 13 | well as directing a Pennsylvania-based environmental   |
| 14 | coalition on nuclear power among others. So it's       |
| 15 | public interest representation.                        |
| 16 | FACILITATOR RAKOVAN: Thank you, Ms.                    |
| 17 | Johnsrud. Next on pilot project number three, we have  |
| 18 | Mike Markley.  |
| 19 | MR. MARKLEY: I'm with the Office of                    |
| 20 | Nuclear Material Safety and Safeguards. My co-chair    |
| 21 | is Marcia Howard with the State of Ohio. Our other     |
| 22 | members were Debbie Gilley from Florida and Duncan     |
| 23 | White from Region I. We did not have a big team. We    |
| 24 | did have equal representation between states and NRC.  |
| 25 | We had an outstanding team. I couldn't ask for more    |

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1 enthusiastic participants than what we had. Just to tell you a little bit about how we 2 3 qot started on this, it was initially chartered to 4 look at events and how generic implications were 5 reviewed. Along the same time that we were getting started, the Davis Besse event occurred. There was 6 7 a well logging event in a particular state and a 8 medical event in another state. So there was a huge effort at the NRC -9 10 and I think it was shared by many people among the Agreement States and state and tribal programs - that 11 we couldn't really look at the events. We had to look 12 more at the operating experience program. 13 At that 14 time, the NRC created an action plan and ultimately 15 had a task force looking at operating experience evaluation. 16 17 That did create a few problems for us because of the vocabulary and dialogue between us and 18 19 That became rather apparent during our the states. meetings with CRCPD and OAS. But nevertheless, we 20 proceeded and we modified our mission to the great 21 extent early on to focus on operating experience 22 evaluation. Our mission was really to increase the 23 24 partnering of that kind of an activity with the 25 Agreement States.

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1 We met with ACMUI twice. So we have had 2 public meetings on this where others had the opportunity to participate. 3 We have had to go through 4 this process of describing what do we mean by 5 operating experience? It's really domestic and foreign event data, special studies, generic issues, 6 7 reviews that we might do, risk studies, whatever they may be, industry issues and studies that may exist. 8 9 The material there doesn't really have an NEI like the 10 reactor program does. It's out there doing things and leading initiatives on the part of the industry. 11 But that would normally be what we would 12 consider part of that process too, and of course, the 13 14 feedback process for regulatory action. I really would suggest that this probably could have been a 15 little bit different too because ultimately what we're 16 affect licensee behavior and 17 trying to do is performance. So that is really a major part of what 18 19 operating experience is all about. So what did we do? We tried to address 20 three basic questions. How can we better communicate 21 between the NRC and Agreement States on operating 22 experience information? How can this information be 23 24 used to better trend and optimize our resource How can we better use risk insights in 25 utilization?

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| 1  | our decision-making? I emphasize integrated decision-  |
| 2  | making, that it's looking at things collectively and   |
| 3  | not just looking at a particular event in isolation.   |
| 4  | We looked back over history. We looked at              |
| 5  | some of the major events and inspection activities and |
| 6  | some of the NUREG reports that summarized those over   |
| 7  | time to try to examine some of the lessons learned and |
| 8  | delineate common threads across those. We conducted    |
| 9  | interviews and questionnaires both with NRC and        |
| 10 | agreement state participants.                          |
| 11 | We issued surveys, as I think probably                 |
| 12 | every pilot did. We got some feedback from OAS that    |
| 13 | surveys are probably not always a good thing to do     |
| 14 | because everybody is doing it and it does have a       |
| 15 | burden associated with it. So we definitely want to    |
| 16 | fold that into our forward look. We had two test       |
| 17 | cases. One was intervascular brachytherapy. The        |
| 18 | other was portable gauges.                             |
| 19 | What I'm going to talk to you about here               |
| 20 | today mostly is about issues and options. In the       |
| 21 | issues that we came up with essentially communication  |
| 22 | was the big thing. We all do things well. The NRC      |
| 23 | does a lot of things well. They come up with good      |
| 24 | evaluations and studies. But they are not necessarily  |
| 25 | shared or disseminated in a timely manner. Likewise,   |

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| 1  | we don't necessarily                                   |
| 2  | MR. PANGBURN: Before you go on, could you              |
| 3  | just clarify what you mean by the test cases? I'm a    |
| 4  | little confused on that point as to how it factored    |
| 5  | into what you were doing.                              |
| 6  | MR. MARKLEY: What we looked at in the                  |
| 7  | test cases was we had a survey to address what are you |
| 8  | doing currently to evaluate these areas, what has      |
| 9  | worked, what hasn't worked, and what can we do         |
| 10 | differently or do better in each of these cases? The   |
| 11 | common thread we had a hard time getting off of        |
| 12 | initially. As I said, it was a vocabulary thing of     |
| 13 | operating experience evaluation.                       |
| 14 | But really the states do many things well.             |
| 15 | We realize that and so does the NRC. But it's how we   |
| 16 | communicate with each other and share things to work   |
| 17 | collectively and to partner on common things. One      |
| 18 | thing I would say about this pilot which was probably  |
| 19 | unique - and this is a lesson learned for the          |
| 20 | materials program itself - we did this entire pilot    |
| 21 | via teleconference. We did not travel for a single     |
| 22 | meeting.   |
| 23 | So in terms of the efficiency and the                  |
| 24 | limitations of constraints for travel and so forth,    |
| 25 | which both the NRC and states have now, there are ways |

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to work around it and to try to accomplish things. One of the primary options and really recommendations that we're probably going to be carrying forward here - and we're looking for feedback from you on all of these options that we're talking about - is a clearinghouse on operating experience information.

7 It was discussed in the context of the 8 Davis Besse task force report. We looked at that. We 9 also participated in the meetings of NMSS and in an office-wide committee that was evaluating the Davis 10 Besse lessons learned on an office-wide basis. 11 We participated in those via teleconference. I was the 12 chair of that as well. But we made sure that these 13 14 two things were going on in parallel and were 15 communicating with each other and that the ball wasn't 16 dropped.

But the central clearinghouse is where you 17 could go and find studies, issues, events, lots of 18 19 different kinds of information. Now, what we're talking about here is not necessarily telling the NRC 20 or Agreement States how to do these things or what 21 should be in a clearinghouse exactly but that a 22 clearinghouse, from what we delineated from feedback 23 24 and the agreement state participants, was that would be something that would benefit everyone. 25 Right now,

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| 1  | if you look at even our websites, the NMSS has one,    |
| 2  | the SDP has one, it would be really nice to have one   |
| 3  | stop shopping to be able to go and look for the things |
| 4  | that you are trying to find and to be able to spin off |
| 5  | into NMED and other things from that.                  |
| 6  | The other thing is ready to use products.              |
| 7  | If the NRC is doing risk studies or something, it's    |
| 8  | not going to do us any good to drop a three inch       |
| 9  | document on someone's desk, whether it's an inspector, |
| 10 | a reviewer, or a manager, that you don't have the time |
| 11 | to read or use. What inspectors, reviewers, and        |
| 12 | managers need for the most part, that we deliniated    |
| 13 | back, was a user friendly product that provided the    |
| 14 | insights and the vulnerabilities.                      |
| 15 | Participation. One of the downsides,                   |
| 16 | unfortunately, of working groups - and that's          |
| 17 | something I would like to carry back - is that these   |
| 18 | things are typically conducted with existing           |
| 19 | resources. There's no extra FTE being allocated due    |
| 20 | to these working groups. That does to some extent      |
| 21 | constrain the participation. We had a small group.     |
| 22 | We were very fortunate. They were all really good      |
| 23 | people. But it's very difficult to put together a      |
| 24 | group when people are not being given up some of their |
| 25 | other responsibilities to do these things. That's      |

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| 1  | part of it.  |
| 2  | The other point that we would like to make             |
| 3  | here as far as participation is we think that in       |
| 4  | addition to working groups - and maybe working groups  |
| 5  | should be done more selectively - that the real value  |
| 6  | added activities that could occur and would provide    |
| 7  | more timely opportunities for sharing are really       |
| 8  | decision-oriented activities where you would come      |
| 9  | together. These are just a few examples of things.     |
| 10 | If you like them, tell us. If there are                |
| 11 | other things that we haven't considered here, tell us, |
| 12 | something like an NRC/OAS roundtable or the NRC        |
| 13 | typically on a quarterly basis has counterpart         |
| 14 | meetings with the regional managers and the            |
| 15 | headquarters management here. It seems to us that      |
| 16 | would be an ideal opportunity for state issues to be   |
| 17 | brought to the table and for some partnering and       |

The agency action review meeting, 19 the annual report is in development right now. 20 That 21 process of nominating licensees or areas of concern for consideration by the Commission and by the senior 22 executives of the agency and to disseminate that kind 23 of information more broadly, it seems that's another 24 opportunity where state participation would be of 25

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mutual sharing of issues to occur.

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| 1  | benefit.   |
| 2  | And lots of routine meetings and things                |
| 3  | that we're all focusing on or issues that may be       |
| 4  | coming up in the states, lots can be done by a         |
| 5  | teleconference. It doesn't have to be that you travel  |
| 6  | for a meeting. There are lots of things that we're     |
| 7  | not doing in terms of outreach, not just to the states |
| 8  | themselves but deriving licensee input on these types  |
| 9  | of activities. If you look at the risk informed arena  |
| 10 | in particular, the majority of those, even on the      |
| 11 | reactor side of the house, have come from licensees    |
| 12 | who see the burden that we don't necessarily.          |
| 13 | Data evaluation and trending. Although                 |
| 14 | NMED and the SSDR are not perfect and probably never   |
| 15 | will be perfect in everyone's eyes, they're the best   |
| 16 | thing we have right now. That's the conclusion we      |
| 17 | came up with looking at the information that was       |
| 18 | available. It is a tool that's there. It can be        |
| 19 | enhanced. It is currently under development for more   |
| 20 | changes.   |
| 21 | It's a place where the opportunity to look             |
| 22 | at precursor events and so forth can be built into it. |
| 23 | The next generations are where we need to be thinking. |
| 24 | How can we use this information? We don't have         |
| 25 | another alternative right now that we can say, we      |

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| 1  | could do this or that. It's an ideal product and it    |
| 2  | may even be part of the clearinghouse that we were     |
| 3  | suggesting to work towards some of these things.       |
| 4  | So we would like to enhance the usefulness             |
| 5  | of these tools. You were talking about the pilot       |
| 6  | cases. One of the things that we got feedback on, in   |
| 7  | particular the intervascular brachytherapy, was that   |
| 8  | they would like to have seen more information on       |
| 9  | malfunctions and failures and to be able to understand |
| 10 | that within the population of the tools that we have   |
| 11 | so that quicker discussion and response can be dealt   |
| 12 | with.  |
| 13 | We just issued an information notice last              |
| 14 | year on intervascular brachytherapy. But there was an  |
| 15 | ongoing discussion. ACMUI was involved in looking at   |
| 16 | things. But our tools aren't really necessarily that   |
| 17 | well suited for picking up some of those things just   |
| 18 | yet. So the failures and malfunctions were one of the  |
| 19 | primary recommendations of some of our participants    |
| 20 | and some of the survey results.                        |
| 21 | Again, incorporating the use of risk                   |
| 22 | guidelines. Right now, the NUREG 66.42 risk byproduct  |
| 23 | study and tool that exists is not really being used    |
| 24 | very much. It may be used in some places. We are       |
| 25 | encouraging that it be used further. There's also an   |

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89 1 ongoing activity with Brookhaven National Laboratory risk task group is doing to 2 that the develop 3 guidelines for developing tools. 4 Their focus right now is in many ways 5 toward revising regulations. The recommendations that we would have along those lines is pick something 6 7 easier to do than rulemaking. It's easier to do licensing, inspection guidance, and other things and 8 9 have quick impact and to to make changes to 10 accommodate your risk insights. If you know where the vulnerabilities are, 11 you can focus your time and your resources better. 12 Those are the quick paybacks that we see. Rulemaking 13 14 is going to take longer. Quick rulemaking is 15 Generic communications, NRC sometimes two years. 16 bulletins, bulletins and generic letters are fairly 17 rare in this area. We mostly issue information notices and regulatory issue summaries. 18 19 The NMSS newsletter, the NMED newsletter are fairly good at capturing some of those things. 20 But again, if you had a one stop shopping place where 21 you go say here's the newsletter and here are some of 22 the things that are there, it would be a very useful 23 24 tool. The one thing in looking at some of the events and some of these incidents that we examined is that 25

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| 1  | we probably need to look at how we're evaluating      |
| 2  | bulletin genetic letters right now.                   |
| 3  | We went away from the GAP or generic                  |
| 4  | assessment panel at least as far as the NRC is        |
| 5  | concerned. So we haven't issued a generic letter or   |
| 6  | bulletin over time and in quite some while. There are |
| 7  | a couple of incidents that we thought may actually    |
| 8  | have warranted it. So that process probably needs to  |
| 9  | be looked at a little bit more.                       |
| 10 | So what we're suggesting is a self-                   |
| 11 | assessment. Here's the process. Look at your          |
| 12 | procedures. Let's see how it's working. Go back and   |
| 13 | look at them a little bit more. That's our            |
| 14 | recommendation, a self-assessment. I would mention    |
| 15 | that that has already begun.                          |
| 16 | NMSS and IMNS are already looking at the              |
| 17 | quarterly report to see, do we have things that are   |
| 18 | being issued as information notices that probably     |
| 19 | could have been bulletins or generic letters? There   |
| 20 | is a burden associated with those documents and       |
| 21 | issuing them. But at the same time, there are safety  |
| 22 | issues that need to be addressed as well.             |
| 23 | As I mentioned before, there's quite a bit            |
| 24 | of risk guidance development and process right now.   |
| 25 | It would certainly be helpful if the Agreement States |

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were up to speed with what the risk task group is doing. Maybe that's something that we could advertise a little bit more. Resource utilization and so forth. It really does have a potential payback, but again, it has to be in a product that's user friendly for people that don't have much time like inspectors and reviewers and managers. If you can't get the insights quickly and

9 you can't understand the vulnerabilities, it's not 10 going to really get you very far. I looked at a document the other day. It was three inches thick. 11 You get to page six and it's onerous. 12 So that's what we prefer that it be and that it be procedural to help 13 14 you get there rather than tutorial. A tutorial is not 15 going to help an inspector go out and do something 16 better.

17 Communication plans. This is generic across all of these areas. If you had something 18 19 substantial that occurred, even if it's an AIT that, 20 inspection or something like it's very advantageous to have a communication plan to lay out 21 we developed this or we have this result, how are we 22 going to notify the various stakeholders? When are we 23 24 going to notify the Agreement States? When are we going to notify Congressional Affairs, if needed? 25 How

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| 1  | is the Commission going to be notified?                |
| 2  | There's a lot of stakeholders involved                 |
| 3  | that if you just sat down and created a one page to do |
| 4  | list and laid out the sequences, it's really not that  |
| 5  | difficult. It worked rather well for a few things.     |
| 6  | I understand they did it with the Honeywell AIT        |
| 7  | recently. So again, there are common threads that we   |
| 8  | can learn from here. Really, when you get down to it   |
| 9  | for risk information, the ultimate point is that you   |
| 10 | really want the licensees to address the               |
| 11 | vulnerabilities, not just that we use our resources    |
| 12 | better. That's the end point that really matters.      |
| 13 | Consistency. We do have four regions and               |
| 14 | 33 Agreement States. There is going to be a certain    |
| 15 | amount of variability. We would like to think that     |
| 16 | the clearinghouse could create an opportunity for      |
| 17 | people to be looking at a lot of the same information  |
| 18 | to the extent that we can, that the Agreement States   |
| 19 | and others could volunteer things that would go into   |
| 20 | that location, and that quality assessments still need |
| 21 | to occur.  |
| 22 | Right now, the MPEP (PH) is getting a lot              |
| 23 | of accolation (PH) (PH) because of the success that    |
| 24 | it's having as compared with other agencies and their  |
| 25 | programs. But there were issues that were raised in    |

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| 1  | some of our discussions about we have to make sure     |
| 2  | we're not glossing over things here. So it's not as    |
| 3  | though you can walk away from the table and say we're  |
| 4  | being successful. It's a continuous process.           |
| 5  | You have to have timely closure. The one               |
| 6  | thing about bulletins and generic letters which are    |
| 7  | problematic for us as regulators, whether it's the NRC |
| 8  | or Agreement States, is that they typically require    |
| 9  | some degree of follow up. We're all resource           |
| 10 | constrained. They have to be done judiciously, but in  |
| 11 | some cases, they may be warranted.                     |
| 12 | The other point that we would like to make             |
| 13 | is that budgeting for relationship building            |
| 14 | participation is really what the outcome should be for |
| 15 | operating experience. It's more of an ongoing          |
| 16 | activity as opposed to something where you would have  |
| 17 | a working group come up with a product. Those kinds    |
| 18 | of meetings that we talked about earlier would be very |
| 19 | useful.  |
| 20 | Let me back up just a little bit because               |
| 21 | there are things that if you don't put it in a budget  |
| 22 | it isn't going to happen. That's the bottom line.      |
| 23 | Whether it's in the state or NRC, it has to be         |
| 24 | budgeted and allocated for and accounted for somehow.  |
| 25 | That's just the groundrule. I did want to go back to   |

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94 1 the clearinghouse issue one time here because I failed to mention something that we were tossing around the 2 3 other day. The Agreement States don't really have 4 5 access to our technical assistance requests, TARs. 6 The regions, George's group among the others, send us 7 TARs to do evaluations and so forth. Typically, we'll 8 share that information with an agreement state if they 9 know it exists and they call. But that's not the kind 10 of relationship that we really want to build. Some of those things that are resolved 11 within the context of a TAR, one of the thoughts that 12 we had is that it might be something that could be 13 14 converted into a branch technical position or 15 something like that that could be disseminated more 16 openly than what we have. So these are the kinds of 17 things that we've been tossing around. None of these things are all decisions right now. We're really 18 19 process of converting options still in the to recommendations. So if you have suggestions and 20 feedback, we would like to have it. 21 Getting back to issue three 22 MR. DICHARRY: and the sharing of data evaluation and better use of 23 24 tools that currently exist, was there a recommendation to make the NMED available to the public? 25

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| 1  | MR. MARKLEY: That certainly constrains                 |
| 2  | some things. That's something we have debated a bit.   |
| 3  | That is feedback we need. It certainly is not          |
| 4  | available right now. If you are talking about          |
| 5  | safeguards, security, and proprietary information,     |
| 6  | right now we don't have to go through and redact       |
| 7  | anything from it to share it with the Agreement States |
| 8  | in that regard.  |
| 9  | If we were to make it publicly available,              |
| 10 | it would probably send us through a major activity.    |
| 11 | That doesn't say that it's not worthwhile, but again,  |
| 12 | there's a balance of how that would fit. So I don't    |
| 13 | have an answer for you right now. We're still forming  |
| 14 | recommendations.                                       |
| 15 | MS. ROUGHAN: In relation to issue three,               |
| 16 | you made a comment on data evaluation trending in      |
| 17 | reference to the SSDRs. What was the recommendation    |
| 18 | or the thought process there?                          |
| 19 | MR. MARKLEY: Well, right now the feeling               |
| 20 | and the feedback that we've received is that the       |
| 21 | things we're missing that we would like to see are     |
| 22 | information failure data and malfunctions and that     |
| 23 | even one recommendation was along the lines that it    |
| 24 | would be worthwhile to have an expiration date on the  |
| 25 | SSD so they have to be updated periodically.           |

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MS. ROUGHAN: So the proposal of the recommendation is to include malfunctions and failures 2 within each device or source SSDR during the review process.

That's possible. 5 MR. MARKLEY: That's a 6 suggestion that we received from one individual, yes. 7 Like I said before, we haven't made decisions on these These are some of the issues that are out 8 things. 9 there. How we would incorporate issues such as 10 malfunctions and failures we could even consider within the context of the inspection process. 11 So there are tools, but we're not really at a point of 12 saying what the recommendation is. We're still trying 13 14 to see how it would all fit. You are shaking your 15 head.

Well, because we manufacture 16 MS. ROUGHAN: 17 sources and devices. It would be very difficult to update each SSDR with a history of failures and 18 19 malfunctions. AEA has about 120 SSDRs through the State of Massachusetts. We rely more on NRC 20 information notices or bulletins if there's something 21 out in the industry for a particular product and how 22 it's used to communicate that information. 23 I just 24 have a very hard time understanding how we would implement that from an SSDR standpoint. 25

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| 1  | MR. MARKLEY: I'm not answering your                    |
| 2  | question. I'm just taking it in at this point.         |
| 3  | MS. ROUGHAN: That's fine.                              |
| 4  | MR. MARKLEY: I appreciate it.                          |
| 5  | FACILITATOR RAKOVAN: If we could go to                 |
| 6  | Ralph Anderson from HPS. I'll remind all of you, even  |
| 7  | those sitting at the table, if you could identify      |
| 8  | yourself because our stenographer can't see a lot of   |
| 9  | people on this side of the room because of the pillars |
| 10 | especially.  |
| 11 | MR. ANDERSON: Ralph Anderson, HPS.                     |
| 12 | Within this, is there in place already or was there    |
| 13 | consideration of a common system for classifying and   |
| 14 | prioritizing incoming information to make sure that    |
| 15 | the important stuff is recognized early, evaluated,    |
| 16 | and communicated more promptly?                        |
| 17 | MR. MARKLEY: We were looking at the NRC                |
| 18 | management directive 6.4 and the inspection manual     |
| 19 | chapter as well as the PPNLs, the policy and planning  |
| 20 | procedures. Those were the primary documents we        |
| 21 | looked at. The Agreement States did not really bring   |
| 22 | to the table their methods, if you want to call it.    |
| 23 | If I look at what we got back from our survey, what    |
| 24 | are you evaluating? I mean, everybody is looking at    |
| 25 | the same stuff for the most part, the Agreement States |

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| 1  | as well as the NRC. And most of that stuff goes into   |
| 2  | NMED.  |
| 3  | MR. ANDERSON: I was just thinking that                 |
| 4  | because so many of these things are resource dependent |
| 5  | and the attention that they get, resources that are    |
| 6  | available right at that time. I just wondered if       |
| 7  | there was a thought toward lending itself towards a    |
| 8  | common prioritization scheme to assure that things     |
| 9  | don't get lost on the cracks for a while and then      |
| 10 | surface at a very inopportune time.                    |
| 11 | MR. MARKLEY: We're asking for self-                    |
| 12 | assessment because we have a little bit of concern     |
| 13 | that some of the things aren't necessarily always      |
| 14 | being done.  |
| 15 | MR. ANDERSON: I might suggest that as a                |
| 16 | parking lot issue, a common scheme of the              |
| 17 | classification prioritization especially for incident  |
| 18 | and event analysis. That would be my largest concern   |
| 19 | including things like failures and malfunctions.       |
| 20 | FACILITATOR RAKOVAN: Can you clarify that              |
| 21 | for me please, Ralph?                                  |
| 22 | MR. ANDERSON: Yes, consideration of a                  |
| 23 | common system for classification prioritization of     |
| 24 | incident and event analysis and communication. You     |
| 25 | hate to read two weeks after you have had something    |

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| 1  | happen the answer to how to make it not happen.        |
| 2  | FACILITATOR RAKOVAN: Thanks, Ralph. I'm                |
| 3  | going to go to Paul Lohaus next because I saw his flag |
| 4  | first.   |
| 5  | MR. LOHAUS: Paul Lohaus, State and Tribal              |
| 6  | Programs. My comment - and really it's a parking lot   |
| 7  | issue - is very similar. I think a key issue within    |
| 8  | this pilot is the role of the Agreement States - and   |
| 9  | I'll use the term "clearinghouse" - in the             |
| 10 | clearinghouse. Again, looking at the fact that the     |
| 11 | states have responsibility for 80 percent of the       |
| 12 | licensees, what's their role and what's the process    |
| 13 | for reviewing the operational experience and event     |
| 14 | information for generic implications and then folding  |
| 15 | that information into some type of regulatory action   |
| 16 | at the national level?                                 |
| 17 | What's identified here is that NRC may                 |
| 18 | issue an information notice. But there have been       |
| 19 | cases where states have also issued information        |
| 20 | notices and got them all promptly. To me, that's part  |
| 21 | of the spirit here is in terms of doing the review,    |
| 22 | looking for generic implications, and then getting the |
| 23 | information out and sharing it with the other          |
| 24 | regulatory agencies and the licensees.                 |
| 25 | MR. MARKLEY: Well, that's the notion of                |

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| 1  | the clearinghouse, Paul, is that they would have the   |
| 2  | opportunity to provide that kind of input to it.       |
| 3  | MR. LOHAUS: But in terms of really                     |
| 4  | identifying the role and the expectation, if you will, |
| 5  | from the national materials standpoint. What's the     |
| 6  | role of the states? What's the expectation that's      |
| 7  | held there? And having that understood, if you will.   |
| 8  | To me, it's a parking lot issue to come back and talk  |
| 9  | about more maybe.                                      |
| 10 | FACILITATOR RAKOVAN: Okay, I see one more              |
| 11 | tent, Ken Wangler, North Dakota.                       |
| 12 | MR. WANGLER: Ken Wangler from North                    |
| 13 | Dakota. I guess I would even expand on Kate's          |
| 14 | concern. I don't think the SSND is necessarily a good  |
| 15 | place to be putting incident issues because oftentimes |
| 16 | those are corrected. One thing that comes to mind is   |
| 17 | an incident that we just had involved an improper      |
| 18 | source placement for a high dose rate remote after-    |
| 19 | loader.  |
| 20 | It's a software problem. As soon as that               |
| 21 | software gets updated, that problem shouldn't exist    |
| 22 | anymore. To put it in the SSND seems like a permanent  |
| 23 | record of something that's not going to be all that    |
| 24 | permanent. But I also agree with Paul. I think the     |
| 25 | information notice route is a good route.              |

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| 1  | This incident is real close to home right             |
| 2  | here because we investigated that incident involving  |
| 3  | the HDR. I quite frankly don't know how to get the    |
| 4  | information out to the states. I think the            |
| 5  | information notices are good. I don't think it would  |
| 6  | take that much to make that accessible to the states  |
| 7  | even in the near future.                              |
| 8  | MR. MARKLEY: How do you address issues                |
| 9  | like Part 21? Do you consider it within that context? |
| 10 | MR. WANGLER: Part 21?                                 |
| 11 | MR. MARKLEY: Reporting defects and                    |
| 12 | noncompliance.  |
| 13 | MR. WANGLER: It is an NMED issue. But                 |
| 14 | quite frankly, NMED is a good idea for the right      |
| 15 | reasons. But it's not something that people go and    |
| 16 | spend time perusing to look for issues that might be  |
| 17 | out there. Information notices are proactive. They    |
| 18 | end up on the director's desk. Then action can be     |
| 19 | taken as far as spreading that information. I have    |
| 20 | never gone to the NMED to see some issues that might  |
| 21 | be there that I should be doing something about. So   |
| 22 | the information notices are much more proactive and   |
| 23 | demand a response.                                    |
| 24 | MR. MARKLEY: We're not in any way                     |
| 25 | criticizing information notices.                      |

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| 1  | MR. WANGLER: No, but Paul just said, how              |
| 2  | do the states participate nationally with the         |
| 3  | information notice? And I don't know how. Can I send  |
| 4  | it to you? Can I send this information to you?        |
| 5  | MR. MARKLEY: That's where they would                  |
| 6  | come, yes. That's our division's responsibility.      |
| 7  | PARTICIPANT: So it's a communication                  |
| 8  | issue.  |
| 9  | MR. MARKLEY: Yes, probably.                           |
| 10 | FACILITATOR RAKOVAN: Okay, I see a lot of             |
| 11 | tents coming up here. Let's try to get through some   |
| 12 | of these comments briefly so we can move on to the    |
| 13 | next pilot. I saw Lynne's first. Jim, I'll get to     |
| 14 | you second and then Stan.                             |
| 15 | MS. FAIROBENT: Lynne Fairobent, ACR. I                |
| 16 | would just like to follow up on what Ken was just     |
| 17 | addressing. I think a key thing goes back to Don's    |
| 18 | question on the availability of NMED being publicly   |
| 19 | accessible and it isn't. One of the concerns in fact  |
| 20 | from the user community is sometimes also being able  |
| 21 | to share when somebody has a software problem because |
| 22 | there's somebody else who has that same software      |
| 23 | program.  |
| 24 | If it's simply put into NMED or into                  |
| 25 | another secure database that only the state and the   |

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| 1  | federal regulators can have, sometimes that is not     |
| 2  | disseminated. Also, we have communications problems    |
| 3  | on the other side of the house. So in the parking lot  |
| 4  | issue for this pilot, Lance, I would also suggest that |
| 5  | in any establishment of anything to better             |
| 6  | communication there is also consideration for public   |
| 7  | accessability of that information.                     |
| 8  | MR. MARKLEY: Well, information notices                 |
| 9  | and regulatory information.                            |
| 10 | MS. FAIROBENT: Exactly, and those are.                 |
| 11 | MR. MARKLEY: So good tools for                         |
| 12 | communicating things especially risks and getting the  |
| 13 | word out quickly.                                      |
| 14 | FACILITATOR RAKOVAN: Thanks, Lynne. I'm                |
| 15 | going to go to Jim Myers from the Office of State and  |
| 16 | Tribal Programs, NRC.                                  |
| 17 | MR. MYERS: Good morning everybody. I'm                 |
| 18 | Jim Myers if you haven't met me. I'm with State and    |
| 19 | Tribal Programs. I guess I'm one of those evil people  |
| 20 | who brought this National Material Program thing       |
| 21 | because I was on that working group. On this           |
| 22 | particular project, there's a couple of things that    |
| 23 | struck a chord with me because I have worked with      |
| 24 | SSNDs. I have touched NMED a little bit. I do the      |
| 25 | website and I do all those kinds of things that are    |

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1 communicative I quess. And I hope I do them okay. 2 But one thing that just hit me is that you 3 always have to look at the SSNDs as just a tool for 4 licensing. That's what they are. When you start 5 encumbering them with all kinds of other information about defects and stuff like that, I don't think 6 7 that's appropriate because what you want to do is have 8 the people who issued that SSND review the device and 9 amend the sheet for the conditions of use to prevent 10 а future event and not use it as a vehicle to publicize some generic issue. 11 That's my opinion. But I think that's how 12 most people use these, as strictly licensing tools. 13 14 That's what they are. Kate's point is very good 15 because for a big company like that you have lots of It's really expensive to do all of them. 16 sheets. 17 Maybe you are not going to do them all. But you might have a group of them to do. So again, that's another 18 19 process that really doesn't really get to the heart of the matter. 20 I had the good fortune or bad fortune to 21 work with Jan again which is always good for her. 22 It's a good relationship that we have. But we've been 23 24 working on this two person crew thing for quite some We have looked at NMED data. We really cut it 25 time.

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| 1  | to see what two person crew does in terms of safety    |
| 2  | things.  |
| 3  | I have to tell you, that database is just              |
| 4  | what it is. The data is what it is. You really can't   |
| 5  | interpret too much out of it because it's the way it's |
| 6  | entered. Everybody enters everything differently.      |
| 7  | There's no consistency. The questions you ask today    |
| 8  | or tomorrow, nobody had a crystal ball to put that     |
| 9  | information in NMED.                                   |
| 10 | MR. MARKLEY: What would you have us use?               |
| 11 | MR. MYERS: Okay, I'll tell you what I                  |
| 12 | would do. I'll base this on about 32 years of          |
| 13 | military experience. I grew up as an Air Force brat.   |
| 14 | I was surrounded by safety stuff. The Air Force        |
| 15 | publishes a magazine on safety. They have an active    |
| 16 | safety culture. The Army has an active safety          |
| 17 | culture.   |
| 18 | We had a brachytherapy event. I think it               |
| 19 | was Omnitron, not to mention a name, but it was in     |
| 20 | Pennsylvania someplace. I think that was it. There     |
| 21 | was a fatality. It was a really bad thing. We made     |
| 22 | a hoo-rah about that. Oddly enough, does anybody       |
| 23 | remember the second event? There was a second event.   |
| 24 | Yes, ma'am, you are going to get the award today for   |
| 25 | remembering.   |

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106 1 There was a second event. It occurred 2 about a month or month and a half later. It was in The guys did all the right 3 Pittsburgh, if I remember. 4 stuff. They had a kit together. They did their 5 surveys. They got the source back. They put it safe. Did we say anything about that? Not one word was 6 7 mentioned about doing it right. Those guys should 8 have been poster guys. That's the kind of information that you 9 10 have to put out so that users know what to do which goes back to Ken's point. What do I do right here, 11 right now? Or maybe it was Mr. Anderson's point about 12 I don't want to find out how to fix something a week 13 14 after I had the event. That's a proactive safety 15 So I'll leave it at that. concept. MR. MARKLEY: I think we're really on the 16 17 same page. All we're really after is being able to identify precursor events and be able to get that 18 19 information out in a timely manner and communicate it better. 20 MR. MYERS: That I think I would agree 21 That's where you maybe want to go. 22 with. FACILITATOR RAKOVAN: Stan, one last 23 24 comment. MR. FITCH: Well, actually I was thinking 25

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| about it, Jim, before I get ready for this comment.    |
| How do you get the information out? Well, having come  |
| from the world of Department of Energy, they have a    |
| weekly operating summary with health and safety        |
| concerns.  |
| I am not necessarily advocating that NRC               |
| and the states adopt something DOE does, but there's   |
| something to be learned from this. It's a simple       |
| digest of an occurrence. This is what happened. It     |
| doesn't go into the root analysis or anything else     |
| like that. That would provide interested stakeholders  |
| like HPS or licensees to say this is what happened.    |
| Now, the NRC and states may be doing an analysis later |
| on but at least they find out right away. So I would   |
| recommend the NRC and the states consider a weekly     |
| operating summary.                                     |
| FACILITATOR RAKOVAN: Thank you. All of                 |
| these have been very good comments and good input.     |
| We're going to move on to pilot project four which is  |
| chaired currently by Robert Gallaghar from the State   |
| of Massachusetts.                                      |

22 MR. GALLAGHAR: Good morning and thank 23 you. Again, my name is Bob Gallaghar. I'm with the 24 Commonwealth of Massachusetts. What Lance is 25 referring to, as I'll mention later on, I am recently

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named the chair of this group. I wanted to start this morning, as others have, with what is our charge?

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3 For this pilot project, а qroup of 4 Agreement States assumes responsibility for 5 development of licensing and inspection guidance for a new use of material or a new modality not previously 6 7 reviewed and approved. The pilot would demonstrate that the regulatory agency, having jurisdiction over 8 9 the new use of material or a new product or a device, would develop in coordination with other Agreement 10 States and the NRC the licensing and inspection 11 quidance which reviewers should apply in reviewing 12 applications, issuinq licenses, and 13 conducting 14 inspections for the new use, product, or technology.

15 This will better define pilot the 16 feasibility and viability of the alliance option 17 recommendation by the National Materials Program The pilot, as has been said earlier, working group. 18 19 implemented by the Organization of Agreement is Why is this important? 20 States.

The development of licensing inspection 21 quidance along with the associated sealed sources and 22 products for modalities, if 23 reviews for new 24 applicable, by a single regulatory program would 25 provide efficiency gains for all programs and

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eliminating the need for each program to independently develop the supporting implementing guidance. The regulatory products resulting from this effort would be a set of licensing and inspection guidance which all programs could use in the review of applications, for the use of the new procedure, product, or device, and the revised inspection guidance.

8 Who are we? In December 2003, I was asked 9 by Stan Fitch, Chair of the Organization of Agreement 10 States, to replace Kathy Allen as chair of the pilot four working group. My first goal was to assemble a 11 team of agreement state personnel who are actively 12 involved with licensing new medical technologies. I 13 14 was very fortunate to find what I think is the ideal 15 group to develop the quidance information in the short time remaining. 16

The members of my working group are Debbie 17 Gilley of the Florida Department of Health, Bureau of 18 19 Radiation Control, who is also sharing duty on pilot three I understand, Eric Jameson of the Georgia 20 Department of Natural Resources, Radioactive Materials 21 Gibb Vinson of the Illinois 22 Program, Emergency Management Agency, Division of Nuclear Safety, and 23 24 Cassandra Frazier of NRC Region III.

How did we choose the new use or medical

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use of material? The pilot four working group held 1 2 its first meeting during the week of February 15, 3 2004. During this meeting, we reviewed the 4 prioritized list of regulatory needs analyzed by pilot 5 project one, which you heard earlier about. This list identified the development of licensing and inspection 6 7 quidance for a new medical modality ranked among the 8 top third in the protection of public health and 9 safety. 10 We then took a look at what emerging technologies exist on the radar screen for the 11 development of our licensing inspection guidance. 12 То accomplish this, we reviewed what quidance has been 13 14 developed for such new emerging technologies as the GliaSite radiation therapy system involving Iodine 125 15 balloon catheters, the Yttrium 90 microspheres such as 16 17 the TheraSpheres, the Nucletron seed selected

18 brachytherapy device for use with Iodine 125 sealed 19 sources, and Iodine 125 seed localization for non-20 palpable breast lesions.

We also surveyed the Agreement States and the NRC regions utilizing the rad\_rap server and contacted major medical institutions and manufacturers and distributors throughout the United States. What we learned was that the states and the NRC have

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already developed guidance for the GliaSite balloon catheders, the Yttrium microspheres, and the Nucletron seed selected device. However, no regulatory program has yet to develop licensing inspection guidance for the use of Iodine 125 seeds for localization of nonpalpable breast lesions.

7 What medical use have we chosen and why? 8 After determining that no regulatory approach to 9 license the use of Iodine 125 for the localization of non-palpable breast lesions has been performed, 10 we began to look closely at this new procedure. 11 We contacted the institutions directly involved with the 12 clinical trials and learned that the procedure is not 13 14 only a significant improvement over existing surgical 15 techniques but it is beneficial for the patient in that the surgeon can more precisely locate the area of 16 interest with minimum surgical intervention. 17

The technique involves the implantation of 18 19 an Iodine seed or several seeds, the same type of seed is currently used and approved for use 20 that in permanent prostrate implants, around the edges of the 21 The seed or seeds are then identified by the 22 lesion. surgeon using a common hand-held gamma probe and 23 24 surgically removed with the lesion. The lesion is then brought to the pathology department. 25 At what

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1 stage the Iodine seed is removed is one of the issues 2 identified by working our group as requiring 3 clarification. 4 Why have we chosen this procedure? First, 5 Iodine 125 is a radioactive material and is therefore

regulated by both the NRC and the Agreement States.
Second, this particular application of Iodine sealed
sources does not fit into brachytherapy because they
are not being used to deliver a dose to any tissue,
nor does it fit into the use of sealed sources for
diagnosis because they are being used to localize a
lesion.

Therefore, this application falls into the newly created category in 10 CFR 35.1000, other medical uses of byproduct material or radiation from biproduct material. Finally, we chose this application because no regulatory program has reviewed the procedure and developed licensing and inspection quidance information.

Where do we go from here? The working group is currently working on various elements of the licensing guidance. These will be submitted to the chair by April 16, 2004 for inclusion in the draft guidance document. The chair will prepare the draft work product document and submit it to the NRC, the

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Organization of Agreement States, and the Conference of Radiation Control Program Directors on May 14, 2004.

4 This will begin the process which will 5 ultimately lead to the final document for presentation to the Commission in November. The working group will 6 7 also prepare our draft, pilot project report, for 8 submission to the NRC, the OAS, and the CRCPD in 9 The members of the working group are September 2004. 10 in agreement that the process we have begun in the partnership between the Agreement States and the NRC 11 is an important step in the development of a workable 12 National Materials Program. 13

14 We would like to see this partnership 15 continue with a further development by the centers of 16 expertise, be they the Agreement States or non-17 Agreement States, of licensing and inspection guidance for use by all regulatory programs. For example, I 18 19 learned just yesterday of a manufacturing agreement between a Massachusetts manufacturing distribution 20 licensee who is sitting at our table today and a 21 nanotechnology company interested in the development 22 of a silicon-based P-32 product called BrachySil which 23 24 is for the intratumoral (PH) injection into liver tumors. Could this be our next project? Thank you. 25

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| 1  | FACILITATOR RAKOVAN: Thank you, Bob. Any               |
| 2  | clarifying questions or comments?                      |
| 3  | MR. ANDERSON: Ralph Anderson, HPS. Bob,                |
| 4  | in terms of developing the draft work product, are you |
| 5  | doing that as a group or are you simulating how this   |
| 6  | might occur in the future by having one of the         |
| 7  | individuals take it on through their state agency?     |
| 8  | How is the product itself being developed?             |
| 9  | MR. GALLAGHAR: The product itself is                   |
| 10 | being developed by the entire group. Each of us sat    |
| 11 | down and took a look at what we consider to be the     |
| 12 | core elements of that action, what we as license       |
| 13 | reviewers need to look at to effectively approve a     |
| 14 | request to use this material, issues like training,    |
| 15 | issues like security, issues like training for all     |
| 16 | those people who are involved be it the radiologists,  |
| 17 | be it the surgery staff, be it the pathology           |
| 18 | department.  |
| 19 | All of us have selected two or three                   |
| 20 | elements to work on our guidance under some templates  |
| 21 | that we're using now, similar to a TAR that's been     |
| 22 | talked about earlier. These will then be coordinated.  |
| 23 | They will all come in to me. I'll be working with the  |
| 24 | other members of the NMSS to format it into an         |
| 25 | existing format which will then lead to the            |

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| 1  | development of the work product.                       |
| 2  | MR. ANDERSON: Thank you.                               |
| 3  | MR. GALLAGHAR: And we have been                        |
| 4  | soliciting input from the stakeholders.                |
| 5  | FACILITATOR RAKOVAN: I'm going to go to                |
| 6  | Ms. Johnsrud first.                                    |
| 7  | MS. JOHNSRUD: Judith Johnsrud, Sierra                  |
| 8  | Club. I'm a bit curious about whether you intend any   |
| 9  | opportunity for other outside parties that may have an |
| 10 | interest above and beyond submission of your draft     |
| 11 | work to NRC, CRCPD, and the Agreement States. Is       |
| 12 | there any consultation with the medical community      |
| 13 | apart from any representatives that may be part of     |
| 14 | your working group, any opportunity for review by      |
| 15 | scientists working in relevant areas, and any review   |
| 16 | by the public prior to a final submission to the       |
| 17 | Commission?  |
| 18 | MR. GALLAGHAR: In a partial answer to                  |
| 19 | your question, I have talked with the people who first |
| 20 | came up with this procedure in Florida and at the Mayo |
| 21 | Clinic in terms of technical input so I understand     |
| 22 | exactly what the procedure involves. They are          |
| 23 | involved at the early stage.                           |
| 24 | To answer your second question, I have                 |
| 25 | asked that same question since I am new to this        |

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| 1  | process myself of Shawn and Lance and others. Where    |
| 2  | does the public get involved in this? Where do I       |
| 3  | solicit input from stakeholders for an advisory        |
| 4  | position on the committee? So we are working on that   |
| 5  | internally.  |
| 6  | MS. JOHNSRUD: If I may, I would strongly               |
| 7  | recommend and urge that you do so. Certainly           |
| 8  | treatments of breast cancer are a matter of individual |
| 9  | concern. My sense is that there are rapid changes      |
| 10 | going on in attitudes and decision by the affected     |
| 11 | people. So the greater the access to the information   |
| 12 | early I think would be beneficial to everyone.         |
| 13 | MR. GALLAGHAR: I understand and we are                 |
| 14 | working towards that.                                  |
| 15 | MS. JOHNSRUD: Good.                                    |
| 16 | FACILITATOR RAKOVAN: We're going to go to              |
| 17 | Margaret Federline next.                               |
| 18 | MS. FEDERLINE: Yes, it's an excellent                  |
| 19 | process. It's very fertile for licensing guidance to   |
| 20 | be a very cooperative effort. I'm just wondering if    |
| 21 | we can look out several years through a planning       |
| 22 | process which involves the industry, stakeholders, and |
| 23 | the public to try and identify what might be coming    |
| 24 | down the pike three to five years so that we could     |
| 25 | plan the resources.                                    |

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I know for folks like you and your team time is very valuable. If we could get people planned ahead of time that they are going to be working on something, do you think that's possible or are these products coming up so quickly that we can't anticipate them?

7 MR. GALLAGHAR: Well, to answer your 8 question, what we chose to do as a working group was 9 we took a look at some existing technologies that had 10 already been submitted to the NRC or states. In addition, all of us sat in my hotel room actually and 11 got on the cell phones and got on the computers and 12 started to call people we knew. I called Mass. 13 14 General Hospital in Boston to solicit their input on 15 we know what currently exists in terms of approved 16 modalities and procedures. What are you thinking of 17 next?

So we solicited that input from the people 18 19 who are actually doing that, the medical community, hospitals in Florida, hospitals in Arizona, hospitals 20 in Illinois. When we started to focus on a medical 21 technology, we certainly went out and called the 22 people that all of us collectively knew in that 23 24 industry and said, what do you see on your radar What do you see coming up that shows promise? 25 screen?

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1 I will say that a number of cases came up with boron neutron capture therapy. It's going to 2 3 come back again. It's an old technology that's been 4 around for 20 or 30 years, but there's a renewed 5 interest in that. So that's something that it's not quite ready for us to develop yet in terms of 6 7 licensing and inspection guidance but it's out there 8 still and it's going to come back. 9 So yes, we did solicit the participation. 10 We did take a look at, what do you see that's coming up on the radar screen? That's why I was informed by 11 the gentleman from AEA technology to let me know that 12 yes we can now tell you that in about a year's time 13 14 you are going to see this on your desk to help us to 15 license this particular technique using the 16 nanotechnology. 17 MS. FEDERLINE: That's why I feel if we had a list of planning assumptions in addition to a 18 19 prioritized list of activities we could capture those future looking items. Thank you. 20 FACILITATOR RAKOVAN: We have time for two 21 22 more quick comments. Lynne. Margaret, to follow up 23 MS. FAIROBENT: 24 just a little bit in answer to that, one of the things that we do at the college and with our sister 25

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organizations is obviously many of our members are involved in the early stages of clinical trials. We certainly probably have the best insight collectively as to what might be coming down the pike via our members who are out there doing the phase one, phase two clinical trial work along with the manufacturers who are developing it.

8 That is why my concern was raised. It's 9 fine to go out and call those you might know, but they may not be the ones with the information or have an 10 appreciation of the information collectively from the 11 community-at-large. So I do think that is something 12 that needs to be factored in a little bit different. 13 14 In the reactor world, it's nice and simple because we 15 It's not as clear cut as one entity in the have NEI. 16 medical community. However, there is workmanship to 17 integrate what we're all doing in the professional societies. 18

I just had a question on one of the things that I heard when you were discussing who the draft work product will go to. Since I know this, one group will not be publicly available initially if it follows the suit with the others. I did not hear mention of this being shared with the Advisory Committee on Medical Use of Isotopes.

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| 1  | MR. GALLAGHAR: Again, I'm new to this                |
| 2  | process.   |
| 3  | MS. FAIROBENT: Right.                                |
| 4  | MR. GALLAGHAR: That was a recommendation             |
| 5  | that actually NRC staff made to me to share it not   |
| 6  | only with the group that participated in the Part 35 |
| 7  | rulemaking changes but also the ACMUI group.         |
| 8  | MS. FAIROBENT: Yes, and in particular                |
| 9  | since ACMUI has an emerging technology subcommittee  |
| 10 | now that Ruth is currently chair of.                 |
| 11 | FACILITATOR RAKOVAN: Okay, we're going to            |
| 12 | do to Ken Wangler from North Dakota.                 |
| 13 | MR. WANGLER: Ken Wangler from North                  |
| 14 | Dakota. I would ditto Margaret's and Judith's        |
| 15 | comments regarding fast track on this. In North      |
| 16 | Dakota, fast track is different than it is for some  |
| 17 | other states.  |
| 18 | (Laughter.)  |
| 19 | MR. WANGLER: We're just licensing our                |
| 20 | first PET cyclotron here in the next week or so. We  |
| 21 | rely heavily on guidance that's been developed by    |
| 22 | other states. Certainly other states have more       |
| 23 | resources in a lot of cases than we do. But the      |
| 24 | medical use of radionuclides is expanding rapidly.   |
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| 1  | we even had an idea of who had licensed some of these  |
| 2  | uses of radioisotopes, it would help us in knowing who |
| 3  | to contact. What we do when there's no licensing       |
| 4  | guidance available is we begin to poll the states or   |
| 5  | the NRC regions to see who has something. Then we      |
| 6  | pull in several of these guidance documents and piece  |
| 7  | together one for ourselves. So if we knew who had      |
| 8  | these, that in itself would be beneficial yesterday    |
| 9  | already for us.  |
| 10 | FACILITATOR RAKOVAN: Thanks, Ken. You                  |
| 11 | got your tent up just before the wire.                 |
| 12 | MS. ROUGHAN: I'll be quick. From the                   |
| 13 | manufacturing standpoint, a lot of the background work |
| 14 | and the R & D is going on for quite a while. Until     |
| 15 | the product gets to a state where we know we want to   |
| 16 | issue it to people, at that point, we start looking at |
| 17 | the regulatory issues. That's why we have talked to    |
| 18 | the State of Massachusetts saying, this is a new type  |
| 19 | of usage of this material, and we'll start getting     |
| 20 | involvement there. So this is a great effort to get    |
| 21 | these things out to the market quickly and safely.     |
| 22 | MR. GALLAGHAR: Thank you.                              |
| 23 | FACILITATOR RAKOVAN: Thank you. We're                  |
| 24 | going to finish up with the last pilot project,        |
| 25 | project five, which is chaired by Tom Young from NRC   |

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| 2 | MR. YOUNG: Good morning. I wanted to                   |
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| 3 | tell you about the revisions to Inspection Manual 2800 |
| 4 | which is the materials inspection program. It's        |
| 5 | posted in the NRC Inspection Manual which is publicly  |
| 6 | available on the NRC website. Just to let you know     |
| 7 | that we started our work in February 2002. We had our  |
| 8 | work products developed and were already testing them  |
| 9 | by April 2002.   |

10 We sent Bob Gallaghar. He was our OAS rep on our working group and CRCPD because he participated 11 in the CRCPD meeting in Minnesota in 2002 and then 12 Then he visited again in again at the OAS annual. 13 14 Anaheim in 2003. Then we had a little bit of a 15 presentation at OAS annual in 2003 to try to keep the states informed. We also had opportunities for the 16 states to provide comments to the NMP pilot project 17 webpage during last summer 2003. 18

So we were a working group developing 19 20 revisions to the inspection program that came out. We 21 were tagged or identified as pilot five in the spring 22 Then we changed our milestones to fit the of 2002. 23 implementation plan which was then developed February 24 2003 or so. We have completed our testing period. We have completed our analysis. So we just have a few 25

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123 more details to complete for this pilot project. 1 2 had about six meetings where We the 3 working group came for a full week here to Rockville. 4 We worked together on developing our products, doing 5 our analysis, and also developing the inspection procedures for non-medical routine inspections. 6 There 7 were seven of those. There was a separate writing 8 team that worked on the medical types of use 9 inspection procedures. So that lets you know how we 10 were working. We also had an oversight committee that was comprised and included an OAS representative from 11 South Carolina. 12 So this is the basis for the IMC 2800 13 14 There were some high or elevated extremity changes. 15 exposures at manufacturing plant and also at some nuclear pharmacies. That working group developed 16 their set of recommendations which then went to a 17 phase two working group which was a high level broad 18 19 review of the materials of the program to try to identify targets for effectiveness and efficiency and 20 empowerment. 21 We also consulted the national materials 22 working group final report during this review period. 23 24 George Pangburn was the chairperson for our working That was available in August 2001. 25 group. The

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recommendations from phase two included this set of
 quick hits that could be used to enhance effectiveness
 and efficiency. They were incorporated into
 Inspection Manual Chapter 2800.

5 The audiences that we had, we assume we were writing to qualified inspectors, inspectors who 6 7 were in the qualification process, and NMSS interns. 8 So we kept that in mind as we were writing. Now, to 9 revise the inspection priorities, we changed the 10 inspection intervals on the routine inspections. Ιf they were ones, they became twos. We were relaxing 11 inspection intervals because we found on the 12 the routine inspections we were extending good performance 13 14 about 80 percent of the time.

15 So ones became twos, twos became threes, threes became fives, and sevens became fives. 16 We brought them back to a five year routine inspection 17 Like I said, fives remained fives. After interval. 18 analysis, we 19 left industrial radiography at our temporary job sites at a priority one. We have also 20 adjusted medical uses that involve written directives. 21 We've adjusted those back to threes so they are back 22 where they were before the pilot period started. 23

Then we empowered inspectors. Actually flexibility remained with the supervisors and the

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1 managers had discretion. Then we streamlined the 2 inspection preparation. This was important because 3 supervisors could take experienced inspectors and 4 expect that they would just look at previous 5 enforcement and the previous inspection and the recent amendments, look at NMED, and they would be ready to 6 7 go out to the field and do the inspection.

8 They wouldn't necessarily have to look at 9 all the back-up material that was in the license and 10 the applications. If they had a question on that, they could ask the licensee for it while they were 11 Then we also revised the initial inspections 12 onsite. to make them more flexible and more simplified. 13 They 14 just need to be completed within 12 months of the issuance of the license. 15

10 CFR 35.1000, emerging technology, those 16 types of amendments are included in the initial 17 inspection adjustment. Then we made field office 18 19 inspections more flexible. The Form 591 that you see here is a short form that's introduced at the end of 20 the inspections during the exit interview where the 21 inspector can document that there were no violations, 22 they closed out violations, or there were violations 23 24 that they were citing and then there were non-cited violations. 25

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Then I wanted to tell you that we used 2 these focus elements to risk inform the inspection 3 procedures. Inspectors were already working to look these focus elements. at But we revised the to reflect what inspection procedures then the approach was that was already being used in the field 6 by the inspectors.

8 I'm just going to move quickly. The 9 impact that we want to tell you about is that it 10 remains a performance-based approach which means the inspector observes the work in progress, interviews 11 and talks to the people that are on the site and 12 involved with the work, the cognoscente people. 13 They 14 take independent measurements. They compare radiation measurements with the licensee. 15

16 They review records as a secondary need. 17 There are some records that they need to look at like those records to workers and members of the public, 18 19 that type of thing, but it's a limited records review. 20 Then the changes in preparation of documentation of the inspections were significant because we used the 21 591 short form to just do a brief narrative of the 22 inspection findings where they would just document the 23 24 scope of use, the people they contacted.

They would have to support the violations

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that were recorded on page one of the form. Then the inspectors were empowered to sign that out, actually 2 in the docket file without further 3 it to post management review according to instructions from their 5 supervisor.

For that last bullet there, I wanted to 6 7 tell you that we did see a reduction in the labor 8 rate, 14 percent FTE, full time equivalent, reduction 9 overall for the materials inspection program. The 10 value for just documentation alone was a 25 percent reduction. That helped a lot. 11

On the last slide here, again, this is 12 just a schedule on what we did. For 2004, we're going 13 14 to go out to the states and ask them to what extent 15 they have implemented the revised IMC 2800 and the 12 16 inspection procedures for routine inspection. Have 17 they implemented all of that or none of it or part of it and let us know are they using the revised 18 19 inspection procedures? And did they find them to be helpful? 20

The lessons learned. Early communication 21 is necessary and essential for the Agreement States to 22 be full partners in what we do. That's for sure. 23 24 Communication with State and Tribal Programs Office, 25 we have to be very consistent in the way that we

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include them as well because they were keeping up with us even though we weren't really talking to them as much as we should have.

4 Then the method of working with our 5 working group was an advantage for implementation because our senior HPs from the regions were on our 6 7 working group. They were involved in the training 8 initially and the refresher training in the regions. 9 They could handle questions from individual inspectors 10 during that implementation as they came back from the field. Of course, they were the writers on the 11 changes in the revision process. 12

Bob Gallaghar was giving us the state 13 14 perspectives on whether this could be adopted by an 15 agreement state. So he influenced in that way and 16 then helped us with our meetings. He did poster 17 sessions. He did plenary sessions. He did break out sessions at all of the meetings that he attended for 18 19 So that's what I needed to tell you so thank you. us. FACILITATOR RAKOVAN: 20 Thank you, Tom. Are there any clarifying questions? I see Lynne has her 21 22 tent up. Tom, just to follow up, it 23 MS. FAIROBENT: 24 peaked my interest that you said you were going to go

out with a survey to the states to see how many have

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| 1  | implemented it. Cindy and Stan from CRCPD and OAS,    |
| 2  | since the states haven't yet fully implemented the    |
| 3  | comparable Part 35 changes, should we expect to see   |
| 4  | that states have implemented the changes to the       |
| 5  | inspection process?                                   |
| 6  | MS. CARDWELL: I can tell you they                     |
| 7  | haven't. I think there was a run of - was it last     |
| 8  | year, or help me out, Tom, the year before that - run |
| 9  | of training that was done that the states attended?   |
| 10 | MS. FAIROBENT: Right, in `02.                         |
| 11 | MS. CARDWELL: I can't tell you how many               |
| 12 | of them right now have adopted that. Bob may be       |
| 13 | better able to do that. I can speak for one who       |
| 14 | hasn't. One, two, three that haven't.                 |
| 15 | (Laughter.)   |
| 16 | MS. FAIROBENT: I'm just curious. You may              |
| 17 | not get any valuable data if they haven't implemented |
| 18 | the comparable Part 35 changes yet. So the timing of  |
| 19 | the survey to come into change your philosophy on the |
| 20 | inspection process may have to wait until they        |
| 21 | implement the regs. I don't know.                     |
| 22 | MR. YOUNG: Well, one anecdotal comment we             |
| 23 | had was that the states were in some ways already     |
| 24 | performance-based in their approach. So we're hoping  |
| 25 | to see that they will say yes we are in-sync with the |

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| 1  | changes in the routine inspection procedures.          |
| 2  | MR. FITCH: This process moves very                     |
| 3  | slowly. It is performance-based. This performance is   |
| 4  | really based on whether or not management sees it      |
| 5  | important to implement it as quickly as it is coming   |
| 6  | forth. They may see it as not being necessary. So it   |
| 7  | could be a little bit behind. I wouldn't hook the      |
| 8  | Part 35 adoption promulgation to that. It's probably   |
| 9  | not a good comparison.                                 |
| 10 | FACILITATOR RAKOVAN: Ken Wangler, please.              |
| 11 | MR. WANGLER: Yes, Ken Wangler from North               |
| 12 | Dakota. I raised my hand. We have adopted Part 35.     |
| 13 | We do try to do performance-based inspections. I       |
| 14 | don't think IMC 2800 would change. We're now trying    |
| 15 | to look at the new criteria in Part 35 even as we try  |
| 16 | to understand it.                                      |
| 17 | But my question for Tom is, did you speak              |
| 18 | in general terms that you think the states have        |
| 19 | adopted IMC 2800, the new version that you say is out  |
| 20 | as of fall of last year? I hate to sound uninformed.   |
| 21 | We know there were changes in the works. Some of       |
| 22 | those we've even implemented like the priority changes |
| 23 | and things like that. But is this a formal thing       |
| 24 | that's been  |
| 25 | MR. YOUNG: Right, when something goes to               |

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| 1  | the inspection manual on the web, the change notices |
| 2  | are distributed to the Agreement States.             |
| 3  | MR. WANGLER: Right, so it's come out.                |
| 4  | MR. YOUNG: Right, so the final one of                |
| 5  | those was distributed to the Agreement States I      |
| 6  | believe in November 2003. It's on the web now. We    |
| 7  | weren't sure that the states were going to implement |
| 8  | the changes in the priority. So that's one of the    |
| 9  | reasons why we want to query them now to see to what |
| 10 | extent they have implemented the changes.            |
| 11 | MS. CARDWELL: And you are going to do                |
| 12 | that this summer.                                    |
| 13 | MR. YOUNG: We want to be done by                     |
| 14 | September. We're just now getting that out, so there |
| 15 | should be time to analyze it.                        |
| 16 | FACILITATOR RAKOVAN: I see a couple more             |
| 17 | tents up. Ms. Johnsrud.                              |
| 18 | MS. JOHNSRUD: Yes, I'm in one of those               |
| 19 | still non-Agreement States, I think, more or less. I |
| 20 | am curious. Is there a difference in your priority   |
| 21 | establishment sharing cooperation with or discussion |
| 22 | with the non-Agreement States as opposed to the      |
| 23 | Agreement States?                                    |
| 24 | MR. YOUNG: No.                                       |
| 25 | MS. JOHNSRUD: How are you handling that              |

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| 1  | relationship which is a bit different from the         |
| 2  | Agreement States?                                      |
| 3  | MR. YOUNG: Well, we didn't specifically                |
| 4  | talk to the non-Agreement States during the            |
| 5  | development of this. They are within our               |
| 6  | jurisdiction, and we're dealing primarily with the     |
| 7  | regional offices that have to implement these changes. |
| 8  | If you are asking, did we talk specifically with       |
| 9  | Pennsylvania, no, we did not.                          |
| 10 | MS. JOHNSRUD: That may be good or bad.                 |
| 11 | FACILITATOR RAKOVAN: Okay, one last                    |
| 12 | comment, George.                                       |
| 13 | MR. PANGBURN: George Pangburn, Region I.               |
| 14 | Just to clarify things, as Tom mentioned, I led the    |
| 15 | phase two effort here. Phase two was really intended   |
| 16 | to focus broadly on the entire byproduct materials     |
| 17 | program and not specifically linked to Part 35. The    |
| 18 | changes we made to inspection priorities were across   |
| 19 | the board.   |
| 20 | The 2800 revisions were made. We                       |
| 21 | presented this phase two report to Marty Virgilio, the |
| 22 | Director of NMSS. There were some recommendations      |
| 23 | that were taken fairly near-term and found their way   |
| 24 | into 2800. Others that involved the process changes    |
| 25 | to the specific inspection procedures happened at a    |

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| 1  | later time.  |
| 2  | That's what Tom was talking about in terms             |
| 3  | of going out and looking and doing the inspections     |
| 4  | differently and focusing on these seven focus          |
| 5  | elements. But the most immediate change and the one    |
| 6  | that we saw the greatest benefit from were the         |
| 7  | priority changes and the revisions to how the          |
| 8  | inspectors prepared and documented their inspection    |
| 9  | findings. I just wanted to try and clarify that        |
| 10 | because it is sequential. It happened over a several   |
| 11 | year period.   |
| 12 | FACILITATOR RAKOVAN: Thanks, George. I                 |
| 13 | saw somebody got their tent up as I was trying to move |
| 14 | on to the next one. That's all right. We'll go to      |
| 15 | Cindy.   |
| 16 | MS. CARDWELL: Just a quick suggestion,                 |
| 17 | Tom. You mentioned earlier that some of the states     |
| 18 | you think may have implemented some of this maybe      |
| 19 | without knowing so. It's just due to the variations    |
| 20 | and how we do inspection processes. Maybe those        |
| 21 | variations are truly indeed part of the risk informed  |
| 22 | process. If you go out with your survey, you might     |
| 23 | try to capture that somehow in the survey. If you      |
| 24 | just say, if you implemented INC 2800, they may say no |
| 25 | and not realize that you are looking at it that way.   |

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| 1  | MR. YOUNG: Thanks.                                    |
| 2  | FACILITATOR RAKOVAN: Ms. Johnsrud, did                |
| 3  | you have a follow up?                                 |
| 4  | MS. JOHNSRUD: No, I'm sorry.                          |
| 5  | FACILITATOR RAKOVAN: That's okay. I just              |
| 6  | wanted to make sure. That concludes the presentations |
| 7  | on the pilot projects. Before we go to lunch, we have |
| 8  | a short session that will involve just some general   |
| 9  | comments on the National Materials Program. First up  |
| 10 | is Paul Lohaus from the Office of State and Tribal    |
| 11 | Programs.   |
| 12 | MR. LOHAUS: Thank you, Lance. I have one              |
| 13 | slide I want to talk from. What I have tried to do    |
| 14 | here is to identify what to me are maybe five key     |
| 15 | issues or key areas or key challenges relative to     |
| 16 | looking to the future on the National Materials       |
| 17 | Program. I think one of these is, as several said     |
| 18 | starting with Carl and others, there's an evolving    |
| 19 | environment that we're dealing with.                  |
| 20 | Security is one that I mentioned. There               |
| 21 | are others that people have mentioned. That's going   |
| 22 | to continue. We're going to continue to have an       |
| 23 | evolving environment. There's going to be issues.     |
| 24 | For example, there's been issues relative to fiscal   |
| 25 | constraints that states face. So there's a lot of     |

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135 1 issues like this that are going to have to be taken into consideration in looking to the future. 2 3 The second key area - and this really goes 4 to the heart of pilot number one and also to the item 5 that Margaret raised in terms of the planning process and looking at identifying things that are coming down 6 7 the pike when you put that together - that's our ability to share with the states identification of 8 9 what the planning assumptions are and establishment of 10 the priorities and sharing in that process. That to me is a key ingredient and necessary part of looking 11 to the future. 12 The third - and we have talked about this 13 14 - is the ability of states to assume and carry out 15 responsibility for the development qreater and maintenance of the products that are necessary to 16 maintain the infrastructure for the National Materials 17 Program. As you can see, each of the pilots touched 18 19 on aspects of that. But that's a key item. Although it's not stated there, along with 20 that goes the ability of NRC to accept and use 21 products that are prepared by the state without 22 putting a lot of additional effort into putting those 23 24 products into a form that may fit within NRC's

structure. That's two aspects of that challenge

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| 1  | there.   |
| 2  | The fourth - and we have talked about this             |
| 3  | as well - is the ability of states to commit           |
| 4  | resources. You could certainly add NRC to that. But    |
| 5  | the idea is you have 33 separate programs. How is      |
| 6  | that going to work? Are certain states going to put    |
| 7  | a lot of effort in at one time and then others at      |
| 8  | another? Is there going to be a blending among the     |
| 9  | programs that would provide the resources necessary to |
| 10 | do that? How is that going to work?                    |
| 11 | Finally - and Carl touched on this right               |
| 12 | at the front - what are the respective roles of NRC,   |
| 13 | of the Agreement States, of CRCPD, of the Organization |
| 14 | of Agreement States? How will we continue to work      |
| 15 | together to improve the effectiveness and efficiency   |
| 16 | of the materials program? But that to me is five key   |
| 17 | items to keep in mind during the discussion this       |
| 18 | afternoon and to me are important for both the success |
| 19 | and future direction of the National Materials         |
| 20 | Program. Thank you.                                    |
| 21 | FACILITATOR RAKOVAN: Thank you, Paul.                  |
| 22 | Seeing no one looking like they would like to comment  |
| 23 | at this point, we'll move on to Stan Fitch.            |
| 24 | MR. FITCH: Having reached old age or                   |
| 25 | nearby, I decided to put on my glasses so I could at   |

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least read what's on the piece of paper. If I have a presentation that's about five or six minutes and it's funny. I was sitting the hotel last night and kept writing more stuff on there because you continue to think about more things and usually I just speak off the cuff. I looked at my own bullets, but it kind of grew.

You may be asking what is OAS? For those 8 9 of you who are not familiar with the OAS, the 10 Organization of Agreement States or AOS for short is a nonprofit, voluntary, scientific and professional 11 society incorporated in the District of Columbia. 12 Our membership consists of staff from states that have 13 14 entered into a effective agreement with the NRC under 15 Section 274(b) of the Atomic Energy Act. These states 16 I'll refer to as "Agreement States."

cooperation 17 The OAS promotes and communication among Agreement States, NRC and those 18 19 states that are seeking to become Agreement States. We support our members by preparing, disseminating and 20 promoting the exchange of information on matters 21 affecting Agreement States' programs. 22

23 Since the earliest history of the National 24 Materials Program, the OAS has represented the 25 concerns of its membership by working for an NMP

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138 1 framework that accounts for the very perspectives and resources of the Agreement States. Now with the pilot 2 3 projects drawing to a close in a few months, the OAS 4 commits itself to representing its membership in a 5 permanent NMP framework. What is the future of the NMP alliance? 6 7 I use that word alliance because for people who are 8 outside of the state/NRC domain where we have 9 interactions, we currently have an NMP alliance. What is the future of that alliance? It looks like it's 10 going to be much more formalized. 11 The OAS believes that the pilot projects 12 are successfully demonstrating the suitability and 13 14 viability of the NMP. Many of the challenges are However, the specifics of integration 15 being resolved. The NMP has significant effort primarily 16 lie ahead. 17 because separate organizations must be meshed into a single coordinated program. 18 19 It successfully developing means а of 20 structure autonomous organizations working collectively to develop effective quidances, policies, 21 procedures, and regulations. 22 The OAS encourages NRC prioritization of 23 toward equal need and equal 24 regulatory stature with the states. 25 The have long sought states greater

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opportunity for affecting materials regulation. In the states are frequently the sources of 2 fact, 3 expertise on a number of radiation regulatory issues. With the Commission's decision to share materials program responsibilities with the states, the focus is shifting closer to the public because the public is 6 closely represented by their respective state 8 radiation control programs.

9 The result will be a greater say outside the federal domain on how materials and radiation 10 usage will impact business and the health and safety 11 of the public. As stated before, America already has 12 the National Materials 13 semblance of Program. 14 However, now more than ever is the time to optimize our collective resources and harmonize the national 15 16 regulatory process.

17 Alonq this line of the discussion, efficacy of NRC state cooperation is being tested in 18 19 the realm of material security. It must be noted that NRC's actions in Syria caused many states to question 20 its willingness to accurately release authority to 21 make the NMP a reality. Nevertheless, because of my 22 involvement as co-chair of the material security 23 24 working group, I see material security to be an excellent springboard capable of proving the NMP 25

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| 1  | concept through NRC and state cooperation.             |
| 2  | Many productive strides have been made                 |
| 3  | through that working group. Even though our            |
| 4  | representation has not been equal, the states have     |
| 5  | surely been equal partners with the NRC. To make the   |
| 6  | National Materials Program a success, the NRC and      |
| 7  | states must commit the resources necessary to create   |
| 8  | products that are attractive and appropriate for the   |
| 9  | NMP alliance as a whole.                               |
| 10 | The OAS endorses the vision of the NMP                 |
| 11 | that embraces the collective diversity of our          |
| 12 | membership and the NRC. A challenge for OAS is to      |
| 13 | better identify personnel, resources, and broaden      |
| 14 | participation. Centers of expertise are frequently     |
| 15 | staff members, not a state as a whole. Working in an   |
| 16 | alliance framework means that supporting organizations |
| 17 | like OAS must act intrinsically to facilitate the      |
| 18 | participation of its membership. We, the OAS, commit   |
| 19 | ourselves and our resources to this cause. Thank you.  |
| 20 | FACILITATOR RAKOVAN: Thank you, Stan.                  |
| 21 | Last up we have Cindy Cardwell. I believe your proper  |
| 22 | title is chair.  |
| 23 | MS. CARDWELL: Actually I am the current                |
| 24 | past chair of CRCPD here in place of Richard Ratliff,  |
| 25 | also from Texas, who is the current chair.             |

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FACILITATOR RAKOVAN: Thank you for the clarification.

3 MS. CARDWELL: Just in case you think 4 Texas is trying to do any kind of take over thing, I 5 want to assure you that our chair elect does not current live in Texas. Remember, I'm the only thing 6 7 between you and lunch right now so listen carefully. 8 The comments I have represent the views of the CRCPD 9 Board of Directors. So for those of you who have seen 10 me talk before know I ad lib quite a lot. I'm going to try not to do that. I'm going to try to read this 11 more because they have been reviewed by the rest of 12 the board members and do represent their viewpoints. 13

14 CRCPD firmly believes in the alliance 15 concept that was developed by the National Materials 16 Program working group several years ago. It's a 17 cooperative consensus process. It provides a flexible structure that permits task organization of national 18 19 resources and expertise. These are some of the concepts that CRCPD has embraced for many years now. 20 In fact, the main purpose of our organization is to 21 serve as a common forum for the many governmental 22 radiation protection agencies to communicate with one 23 24 another and to promote uniform radiation protection regulations and activities. 25

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| 1  | Here's where I'll ad lib some. Stan                   |
| 2  | explained that OAS, for those of you who may not be   |
| 3  | familiar with either organization, is also made up of |
| 4  | state members and deals primarily with issues         |
| 5  | associated with the agreements between the Agreement  |
| 6  | States and NRC. CRCPD's purview is a little bit       |
| 7  | broader in that we also concern ourselves with issues |
| 8  | that the states regulate on a broader basis, meaning  |
| 9  | essentially non-AEA materials and X-ray machines and  |
| 10 | non-ionizing sources of radiation. So there's a       |
| 11 | little bit of difference between the two there.       |
| 12 | CRCPD products such as the adjusted state             |
| 13 | regulations for control of radiation, guidance        |
| 14 | documents, and other technical reports that have been |
| 15 | developed are done so using the same cooperative      |
| 16 | consensus process among the state agencies that's     |
| 17 | envisioned with the alliance concept that we've heard |
| 18 | about today. We think it's a process that works.      |
| 19 | However, there are challenges to the alliance that we |
| 20 | see, some of which Stan and Paul have already         |
| 21 | mentioned both in conjunction with the pilots that    |
| 22 | have been done and even possibly outside of the       |
| 23 | pilots.   |
| 24 | The first challenge we're going to call               |
| 25 | cultural baggage. The alliance will not work if any   |

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one of the pertinent parties involved is unwilling to drop their mindset that doesn't allow things to be done differently and to accept that. The outdated idea that it's always been done this way and therefore it will be done this way is something that we all have to take care with.

7 It can easily become attendant of any kind 8 of organization, especially regulatory programs 9 because we're so tied to prescriptive regulations and 10 procedures. It has to be done this way. So we must be very careful about that. When it is ingrained in 11 an agency's overall mindset and decision-making, it 12 becomes part of that agency's culture. That's why we 13 14 call it that cultural baggage.

15 I'm going to throw out an example of that. Bob's pilot group, pilot four, was working on the 16 17 development of licensing and inspection guidance for a new modality or a new use of materials. However, we 18 19 learned at a recent symposium just a few months ago that NRC is in the process of developing guidance on 20 some of the very uses and modalities that that group 21 explored in the beginning. 22

The disturbing thing was we found out that there was no state involvement in that. There's not been any state involvement in the developing of that

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| 1  | kind of guidance. So this is the status quo that       |
| 2  | we're seeing carried forward as cultural baggage that  |
| 3  | we need to do something about.                         |
| 4  | Along with that, probably the thing that               |
| 5  | was most disturbing was that some of those very        |
| 6  | modalities were first licensed in the Agreement States |
| 7  | and used in the Agreement States. In fact, the SSND    |
| 8  | sheets were done in the Agreement States. So it needs  |
| 9  | to be a cooperative process. That's something we have  |
| 10 | to be careful about.                                   |
| 11 | We think one of the second challenges for              |
| 12 | all of us in the alliance is the challenge not to lose |
| 13 | the forest for the trees. I have had the opportunity   |
| 14 | to talk with several of the pilot chairs. My office    |
| 15 | happens to be right in the middle of two of them.      |
| 16 | It's not just those two. But I have observed that      |
| 17 | there appears to be a substantial amount of reporting  |
| 18 | requirements that were required of the pilot project   |
| 19 | chairs and the members of the pilots themselves.       |
| 20 | Just as a reminder, in our current                     |
| 21 | economic state - and I mean both federal and state     |
| 22 | agencies - we're facing more limited resources. As     |
| 23 | such, we have to accomplish what we need to accomplish |
| 24 | more effectively and more efficiently. In hindsight,   |
| 25 | we believe it was probably unnecessary to have         |

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required an interim progress report in addition to monthly updates of the progress of each one of the pilot projects.

4 It appears to be especially true since the 5 final interim progress report is due to the Commission only two weeks before the final pilot project reports 6 7 are due to NRC, OAS, and CRCPD for review. It's a detailed example I'm giving you, but it's just a way 8 9 to point out that we have to be careful not to try to 10 mold this into busy paperwork that we're used to doing because we're regulatory agencies and not lose sight 11 of the bigger picture. We have to try to resist our 12 tendencies to mold what we're doing into any one of 13 14 our existing processes.

The final challenge is broader in nature. 15 It's really outside of the pilot projects themselves 16 17 I believe. It involves the question of whether all parties are truly committed to a cooperative consensus 18 19 Recent material security issues and the way process. in which they have been handled - and this is from the 20 initial onset of them - helped to raise this question. 21 NRC has chosen to evoke common defense and 22 security as a means of ordering and ensuring that 23 24 certain security measures are implemented for NRC and The Agreement States 25 for Agreement State licenses.

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have been very vocal in stating they play a vital role in this security effort. Many states maintain that these security measures are also a component of public health and safety and as such are more appropriately implemented through the current Agreement State structure and the NRC-Agreement State partnership as we now know it.

Implementation of security issues under 8 9 the common defense and security clause of AEA seems to be moving us toward a hybrid, more limited partnership 10 than what we're envisioning in this alliance. 11 While many of us are striving to ensure that security 12 developed 13 measures are and implemented in а 14 cooperative process, there were early concerns raised 15 - and I believe they are still held out there in many 16 places - that efforts in the security arena represent the antithesis of this alliance concept. 17

I will add on a personal note and will 18 19 mimic what Stan has said from this time a year ago coordination and cooperation has tremendously improved 20 in this area. So we're moving forward and more 21 22 towards this alliance. Again, to state, the alliance concept has worked for CRCPD for many years. 23 The 24 cooperative consensus process has been modified numerous times in our organization in order to make 25

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| 1  | them more efficient and our organization more dynamic. |
| 2  | I anticipate that that will continue to                |
| 3  | happen over the years and hope that it will. We        |
| 4  | believe that it will work for both federal and state   |
| 5  | radiation control programs in developing and           |
| 6  | maintaining what is a true National Materials Program. |
| 7  | It's a two way street that involves commitment on all  |
| 8  | sides. For the alliance to succeed, it takes the       |
| 9  | willingness of both NRC and state radiation control    |
| 10 | programs to drop that cultural baggage and be willing  |
| 11 | to practice the alliance concept until that becomes    |
| 12 | our cultural. That's the end of my comments.           |
| 13 | FACILITATOR RAKOVAN: Thank you, Cindy.                 |
| 14 | Comments? Diane, if you could please introduce         |
| 15 | yourself as well since you joined the table.           |
| 16 | MS. D'ARRIGO: Yes, I'm Diane D'Arrigo                  |
| 17 | with Nuclear Information and Resource Service. I       |
| 18 | really can only stay until lunch and apologize for     |
| 19 | only coming for a short piece of the workshop today.   |
| 20 | I think Stan mentioned that the state regulatory       |
| 21 | agencies are closer to the general public and would    |
| 22 | represent the public perspective.                      |
| 23 | My question is really, how does the public             |
| 24 | intersect with the CRCPD and the Organization of       |
| 25 | Agreement States? It seems like the public kind of     |

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| 1  | knows that the NRC is the regulator. Then when you    |
| 2  | are in an Agreement State, you deal with your state   |
| 3  | agency on certain issues.                             |
| 4  | But now if we have an alliance or                     |
| 5  | something else forming or if CRCPD or OAS is having a |
| 6  | more formal role in either doing a rulemaking or      |
| 7  | making policies both on AEA and non-AEA materials,    |
| 8  | this is something that those of us in the general     |
| 9  | public need to figure out how to interact with.       |
| 10 | MS. CARDWELL: To answer question                      |
| 11 | FACILITATOR RAKOVAN: If you could                     |
| 12 | identify yourself please.                             |
| 13 | MS. CARDWELL: Cindy Cardwell from Texas               |
| 14 | CRCPD.  |
| 15 | FACILITATOR RAKOVAN: Thank you.                       |
| 16 | MS. CARDWELL: That is one of the ways                 |
| 17 | that our organization has started to change.          |
| 18 | MS. D'ARRIGO: Which organization?                     |
| 19 | MS. CARDWELL: CRCPD. One of the things                |
| 20 | that we did a couple of years ago was look at the way |
| 21 | we developed suggested state regs. One of the         |
| 22 | recommendations from the working group was that that  |
| 23 | process needed to be more like what each individual   |
| 24 | state does and what the federal agencies do in terms  |
| 25 | of soliciting more public input.                      |

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149 1 We currently have and have had for some 2 time advisors to all of our committees that develop those regulations that are a part of industry. 3 Donny 4 has been on it. Kate's been on it. Lynne's been 5 there. I can name people who are around the table. But we realized that we were lacking in terms of 6 7 getting some of the public input. 8 An example of how we're trying to change 9 that most recently was our suggested state regs for 10 TE-NORM. We solicited comments from the public. Sierra Club I believe was one of the ones for sure 11 that solicited comments from. 12 So we're making an effort to improve in that such that the SSRs can 13 14 include the public component as well. 15 MS. D'ARRIGO: SSR is what? 16 MS. CARDWELL: It's the suggested state 17 regulations for radiation. I hate to throw acronyms The organization has been developing those 18 here. 19 almost since its inception in 1968. They are model regulations that states can then use to adopt their 20 own without having to do all of the leg work over 21 22 again. MS. D'ARRIGO: It sounds like so far that 23 that 24 vou knew Dr. Johnsrud was potentially 25 knowledgeable on that one issue. But although she

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| 1  | represents a large organization, it doesn't mean that  |
| 2  | the members of that whole group know that that issue   |
| 3  | is now out for some public comment.                    |
| 4  | People that may have some expertise in                 |
| 5  | that area or interest in that area wouldn't know say   |
| 6  | in Louisiana or somewhere. I guess they would deal     |
| 7  | with their own agency. I'm just trying to figure out   |
| 8  | if there's going to be some kind of Federal Register   |
| 9  | announcements, not that everybody reads that.          |
| 10 | MS. CARDWELL: Well, it's part of our                   |
| 11 | long-term initiative. Part of the process of this      |
| 12 | alliance coming forward is if we can be assured that   |
| 13 | NRC is going to have buy off on some of that. In fact  |
| 14 | some of our SSRs, that's happened in the past. The     |
| 15 | states were the first ones to do radiography           |
| 16 | regulations. NRC followed.                             |
| 17 | The states were the first ones to do well              |
| 18 | logging regulations. NRC followed. But that's old      |
| 19 | history now. One of our things that we have pegged as  |
| 20 | something we have to look at is how to identify the    |
| 21 | public interest groups that would have interest in     |
| 22 | these specific SSRs, for instance, the medical ones or |
| 23 | the X-ray ones or some of the ones that are more       |
| 24 | environmental in nature. Again, we'll point to our     |
| 25 | latest effort which is Part N. That had a long list    |

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| 1  | of stakeholders when we first promulgated that rule,  |
| 2  | Sierra Club being one of them.                        |
| 3  | MS. D'ARRIGO: Because the CRCPD does have             |
| 4  | an SSR - I'm not sure what it is - but you have a     |
| 5  | position on what used to be below regulatory concern. |
| 6  | I don't know what you call it now, an exemption level |
| 7  | or something like that.                               |
| 8  | PARTICIPANT: Name of the month.                       |
| 9  | MR. FITCH: Somebody had to say BRC.                   |
| 10 | (Laughter.)   |
| 11 | MS. D'ARRIGO: Well, people have been                  |
| 12 | writing into the EPA, the NRC, the DOE, the DOT, the  |
| 13 | IAEA, various places. But a lot of people didn't even |
| 14 | know that there was a CRCPD to give input into. That  |
| 15 | was done back a long time ago. So I'm just trying to  |
| 16 | see if there are other things that are going to be    |
| 17 | coming down the pike that we may or may not know      |
| 18 | about. You may have routine relationships with        |
| 19 | certain people.                                       |
| 20 | If the National Material Program is going             |
| 21 | to proceed and have states, which we have             |
| 22 | traditionally very much supported state authority on  |
| 23 | these issues, so I don't think it's necessarily       |
| 24 | adversarial. It's just how are we going to know that  |
| 25 | there's something happening if we're not part of the  |

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| 1  | radiation community or whatever?                       |
| 2  | MS. JOHNSRUD: Or even being, I guess in                |
| 3  | a way, part of the community. I found myself           |
| 4  | wondering, having submitted my comments, where am I    |
| 5  | going to find them? Since they are model regs that     |
| 6  | are being proposed for NORM, where are they going to   |
| 7  | be? Are they going to be in the Federal Register?      |
| 8  | Will each state, all states publish the CRCPD final    |
| 9  | version?   |
| 10 | Will it become available to any members of             |
| 11 | the public only when there is an actual model reg      |
| 12 | being adopted having gone through some process without |
| 13 | members of the public or other states either knowing   |
| 14 | what the history and the background has been which     |
| 15 | would be very beneficial to them? Then I guess I have  |
| 16 | one other related question. I'm curious about the      |
| 17 | statutory origins of CRCPD, OAS, and who am I missing? |
| 18 | I know about the Agreement States obviously and the    |
| 19 | AEA. But what is the statutory authority of each? I    |
| 20 | don't know whether that's yours, Cindy, or Paul's.     |
| 21 | MS. CARDWELL: Do you want me to respond?               |
| 22 | Let me make sure I give you all the answers.           |
| 23 | MS. JOHNSRUD: Sorry.                                   |
| 24 | MS. CARDWELL: Well, some of it I don't                 |
| 25 | have it insofar as good feedback. Obviously the        |

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| 1  | organizations don't have a Federal Register. There's   |
| 2  | not a Federal Register.                                |
| 3  | MS. JOHNSRUD: That's right.                            |
| 4  | MS. CARDWELL: There's not a Texas                      |
| 5  | Register or New Mexico Register, whatever else, to put |
| 6  | that kind of thing forward. So that's one of our       |
| 7  | challenges to do. In answer to your question, Ms.      |
| 8  | Johnsrud, about comments to the questions that were    |
| 9  | submitted on Part N, this is also one of the first     |
| 10 | ones where the board has actually directed that all    |
| 11 | those responses be made part of the rationale that     |
| 12 | goes along with the rule and will be made available on |
| 13 | our website.   |
| 14 | MS. JOHNSRUD: You mean all of the                      |
| 15 | comments that are submitted including those from other |
| 16 | governmental agencies.                                 |
| 17 | MS. CARDWELL: That's correct. They will                |
| 18 | go on the website when that's finally approved. There  |
| 19 | was another question on statutory jurisdiction.        |
| 20 | Neither one of the organizations have any kind of      |
| 21 | jurisdiction in order to promulgate rules that are     |
| 22 | enforceable. But for years what CRCPD has done is      |
| 23 | develop these model regulations - and again call it    |
| 24 | the pre-alliance movement - in trying to utilize the   |
| 25 | most effectively all the state resources.              |

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154 1 Rather than each one of us doing our own rules and doing our own thing, there's a model out 2 To answer your question do 3 there that states can use. 4 states have to adopt them verbatim, no, there's no 5 requirement for that. Do states do that? Yes, and implement their own specific wording where they need 6 7 to in terms of their statutory requirements. But each 8 state has to go through its own statutory obligations 9 in order to promulgate the rule meaning it will go 10 back through the process. MS. JOHNSRUD: So an Agreement State would 11 have to conform with NRC's requirements with respect 12 to the agreement. 13 14 MS. CARDWELL: If there were any. It's 15 for the compatibility rules. But there is a whole 16 series of suggested state regs that NRC doesn't have 17 statutory jurisdiction for. MS. JOHNSRUD: Well, are you going to be 18 19 seeking a statutory status? 20 MS. CARDWELL: No, there's no plan for that. 21 No plan at all. 22 MS. JOHNSRUD: So this really has no legal significance in terms of --23 24 MR. FITCH: What you are really seeing here is more at OAS than CRCPD. CRCPD does work with 25

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| 1       this with the SSR, suggested state regulations. We're         2       almost like a union representing our membership         3       conversely to another party.         4       MS. JOHNSRUD: The OAS you mean.         5       MR. FITCH: Yes, the OAS is conversely to         6       the NRC. So that was a lot of the reason for it.         7       However, the OAS and CRCPD - and we're both members of         8       both         9       MS. JOHNSRUD: Interlocking directorate.         10       (Laughter.)         11       MR. FITCH: We have committed ourselves in         12       our organization to facilitating Agreement State         13       action. So we're attempting the best we can to         14       compliment the NRC and to improve upon the process.         15       Eventually National Materials Program, the best way to         16       look at it is we represent a membership but we can't         17       speak for them legally. I cannot represent the New         18       York Department of Labor as a certain person has         19       minded me.         20       (Laughter.)         21       MR. FITCH: So I can't represent a given |    | 155  |
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| 20 (Laughter.)  | 18 | York Department of Labor as a certain person has       |
|   | 19 | reminded me.   |
| 21 MR. FITCH: So I can't represent a given  | 20 | (Laughter.)  |
|   | 21 | MR. FITCH: So I can't represent a given                |
| 22 state. However, I can represent the concerns of the  | 22 | state. However, I can represent the concerns of the    |
| 23 membership as stated to the board. So we work to   | 23 | membership as stated to the board. So we work to       |
| 24 facilitate the concerns and represent them.  | 24 | facilitate the concerns and represent them.            |
| 25 MS. JOHNSRUD: Now, let me ask, if I may,   | 25 | MS. JOHNSRUD: Now, let me ask, if I may,               |

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| 1  | one final question. Sorry, it's going to be a late     |
| 2  | lunch. How can we, I, as a member of a public          |
| 3  | interest organization which is national in scope,      |
| 4  | assist members of the public in knowing, understanding |
| 5  | the roles of these two state level semi-official, non- |
| 6  | official organizations to have a better understanding  |
| 7  | of how all those rules and regulations really come     |
| 8  | about and where, when, how members of the public can   |
| 9  | have an active and I might add effective role in the   |
| 10 | decision-making? I was quite concerned. Apparently     |
| 11 | there were very few members of the public interest     |
| 12 | realm who were involved in the commenting on the NORM. |
| 13 | MS. CARDWELL: There were quite a few                   |
| 14 | asked to comment and very few that actually did.       |
| 15 | That's probably the more accurate way to assess that.  |
| 16 | MS. JOHNSRUD: I don't think I ever knew                |
| 17 | who it was.  |
| 18 | MS. CARDWELL: I can't tell you off the                 |
| 19 | top of my head, but I can get you the list. I would    |
| 20 | have the same question for you. How best can we get    |
| 21 | the information out to the public? We do have a        |
| 22 | website. The information is there.                     |
| 23 | MS. JOHNSRUD: You have to get people to                |
| 24 | know about it.   |
| 25 | MS. CARDWELL: But if we could somehow                  |

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1 modify it to explain the role of the suggested state They fill a void, not necessarily on the 2 reqs. materials side where we try to work in cooperation 3 4 with NRC when rules are being developed but most definitely on the machine produced radiation side, 5 non-ionizing radiation, and of course the non-AEA 6 material regulation where there is no federal agency 7 8 that sets use requirements. 9 There may be a standard set, but there are 10 no specific use requirements. So it most definitely fills a void for those particular areas. 11 The states can use those as a model. I'll reiterate that it in 12 no way alleviates the state from having to go through 13 14 its own statutory requirements for development or 15 rulemaking. 16 So there's yet another venue for comments. 17 I know many states have gone back and used the CRCPD rationale when they developed the SSRs to use as their 18 19 basis for their rule development. But we do need more It needs to be more open. 20 public input. So I'm open to any suggestions that we can take back to the board 21 and membership on how to make that happen. 22 MR. FITCH: One other comment on the SSRs. 23 24 Just because a state adopts them does not mean they are compatible with the requirements of the NRC. 25 The

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| 1  | NRC will remind us of that. You have to make sure you |
| 2  | are compatible with our requirements. Yes, and you do |
| 3  | have to go through the statutory process.             |
| 4  | In my state, we go through a hearing                  |
| 5  | process. The first one was with our radiation         |
| 6  | technical advisory council. They have to look at      |
| 7  | everything we propose to promulgate. Then we work     |
| 8  | with them. We work on the wording. We demonstrate     |
| 9  | the compatibility requirements because sometimes we   |
| 10 | have to go with what the NRC says and that's conveyed |
| 11 | to them.  |
| 12 | Otherwise, they are a board council                   |
| 13 | appointed by the governor. They are there for         |
| 14 | staggered terms. They will review that. We'll go      |
| 15 | back and tweak it. If appropriate, they will approve  |
| 16 | it. Then it goes before our environmental approvement |
| 17 | board. The environmental approvement board will hear  |
| 18 | that. They will analyze the language. So we have      |
| 19 | this formalized process within our state where the    |
| 20 | public has the opportunity to get involved and make   |
| 21 | comment and to make an appeal before bodies of people |
| 22 | who are appointed by the governor so they are not     |
| 23 | government employees.                                 |
| 24 | CRCPD has SSRs. Just because those don't              |
| 25 | necessarily at all times involve the public during    |

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promulgation, the public can get involved within other areas. The CRCPD is not into itself. It's just simply a tool to help the states develop and meet certain regulatory needs.

5 MS. JOHNSRUD: May I then suggest that I have a little trouble with this? When finally a state 6 7 decides to adopt a model or to alter the model to suit 8 its own needs, it's as if it becomes the starting 9 Members of the public and other point given. 10 organizations with an interest will perhaps have had opportunity to be involved in the 11 no original formulation of the draft finalized model. 12 They may have some problems with that. 13

14 MR. WANGLER: Can I? That's a real good 15 point because Cindy mentioned it just briefly but we 16 oftentimes that SSR, the suggested use state the 17 regulation, in defense of regulation we're This brings me back to why I first put my proposing. 18 19 tent up in the beginning.

I think the private sector has really made 20 good point here today about their level 21 of а in all of this, 22 participation not only in the rulemaking that goes on with the SSR, the suggested 23 24 state regulations, but even in if we're going to have an alliance, what's their level of participation in 25

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receiving things like information notices, putting out guidance documents for licensing? It's one thing to write out a regulation, but it's a whole other thing to license a material.

5 I can tell you that the regulation is a big framework whereas the guidance documents are very 6 7 detailed. There is virtually, to my knowledge, little 8 or no public input from the private industry, the 9 health physics society, or the ACR when we do those 10 licensing guidance documents. That's really where the rubber meets the road is when we issue the license and 11 all the conditions that go in there and those kinds of 12 So you have done a good job of telling us 13 things. 14 that you are not being heard very well in some of 15 those areas.

FACILITATOR RAKOVAN: Ruth, I will get to you in a second. Paul Lohaus has had his tent up for far too long and has sat there so I'm going to give him an opportunity to speak.

20 MR. LOHAUS: Thank you, Lance. Paul 21 Lohaus with State and Tribal Programs. I wanted to 22 ask that we capture this discussion and add this to 23 our parking lot. The discussion has several aspects 24 to it. I did want to comment on a couple of these. 25 One, this to me is what I would call a pure or true

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| 1  | National Materials Program issue.                      |
| 2  | I'll just use the suggested state                      |
| 3  | regulations as an example. Generally in the past, the  |
| 4  | suggested state regulations would be based on NRC's    |
| 5  | rule with respect to Atomic Energy Act material.       |
| 6  | There are exceptions because in some cases CRCPD has   |
| 7  | taken the lead and developed the rule where NRC did    |
| 8  | not have an equivalent rule. Basically NRC eventually  |
| 9  | adopted that rule and it was more in the reverse.      |
| 10 | But normally the route is that the                     |
| 11 | conference develops a rule based on NRC's rule. More   |
| 12 | recently what we have tried to do - and there's a      |
| 13 | commitment on the part of CRCPD and the NRC staff - is |
| 14 | to try and work in parallel so that the process of     |
| 15 | developing the NRC rule and the CRCPD rule are done in |
| 16 | parallel. It's not done in all cases but that's part   |
| 17 | of it.   |
| 18 | The third part of it is that we do review              |
| 19 | each of the suggested state regulations for            |
| 20 | compatibility. Our goal - and I think the goal of the  |
| 21 | conference would be - is that the SSR is compatible    |
| 22 | with NRC's rule so that when each state uses that rule |
| 23 | to go through its internal process of adoption -       |
| 24 | obviously there's going to be individual preferences   |
| 25 | and there's going to be public input as a part of that |

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| 1  | process that may result in changes in the rule - but   |
| 2  | the end product hopefully is within the bounds of      |
| 3  | compatibility similar to as NRC goes through its       |
| 4  | rulemaking process and considers all of the input.     |
| 5  | Our rule is also going to be within those              |
| 6  | bounds of consistency and compatibility across the     |
| 7  | nation. But as you pointed out, in looking to the      |
| 8  | future under a National Materials Program that's been  |
| 9  | pushed out here today in terms of what this could be,  |
| 10 | you may have cases where CRCPD may take the lead or    |
| 11 | the states may take the lead and develop a rule.       |
| 12 | At the same time though even though they               |
| 13 | put all that work into it and they are going to save   |
| 14 | a lot of resources, NRC and each state will need to go |
| 15 | through its own administrative process and provide     |
| 16 | opportunity for public comment, input, consideration   |
| 17 | as a part of that process as is normally done. But     |
| 18 | the challenge for the National Materials Program, as   |
| 19 | you point out - and we need to capture this - is, how  |
| 20 | do you gain that input early when the model, if you    |
| 21 | will, or the basis for what's going to be carried      |
| 22 | forward is being developed? That's the challenge I     |
| 23 | think. Thank you.                                      |
| 24 | FACILITATOR RAKOVAN: Thanks, Paul. Ruth,               |
| 25 | one last comment before we break for lunch, please.    |

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1 MS. McBURNEY: Wearing another hat, I also 2 chair one of the suggested state regulations working 3 groups. It's the one developing regulations for 4 financial securities for decommissioning. We have on 5 that committee two members of the public as advisors. One represents a manufacturing firm who would have to 6 7 comply with such regulations on developing а 8 decommissioning funding plan. 9 The other is an attorney who is a member 10 of the health physics society who has had a lot of experience in dealing with financial matters and on 11 funding of decommissioning funding plans 12 and the working out those for a uranium firm. We do assign 13 14 people who have an interest in a particular suggested state rule that's being worked on as advisors. 15 I do value all the other opinions that people work with on 16 17 that. So that's a good point. FACILITATOR RAKOVAN: Thank you, Ruth. 18 19 Barring any other further comment, I would like to take this opportunity to break for lunch. 20 I would like to thank all the presenters from this morning. 21 I would like to thank everyone who added to the 22 comments and discussion. It was a very productive 23 24 session. I'm expecting that the afternoon will be as productive if not more so. 25

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| 1I'm going to ask the group at large a2question. We're ending about ten minutes late. Is3everyone okay with starting back on time at 1:20 p.m.4to begin the roundtable discussions? Is that all5right with everyone? Okay, then by this clock, we're6going to start at 1:20 p.m. Have a good lunch. Off7the record.8(Whereupon, at 12:29 p.m., the above-9entitled matter recessed to reconvene at101:27 p.m. the same day.)1112131415161718192021232425   |    | 164   |
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| 12         13         14         15         16         17         18         19         20         21         22         23         24   | 10 | 1:27 p.m. the same day.)                              |
| 13         14         15         16         17         18         19         20         21         22         23         24  | 11 |   |
| 14         15         16         17         18         19         20         21         22         23         24   | 12 |   |
| 15         16         17         18         19         20         21         22         23         24  | 13 |   |
| 16         17         18         19         20         21         22         23         24   | 14 |   |
| 17         18         19         20         21         22         23         24  | 15 |   |
| 18         19         20         21         22         23         24   | 16 |   |
| 19         20         21         22         23         24  | 17 |   |
| 20<br>21<br>22<br>23<br>24   | 18 |   |
| 21<br>22<br>23<br>24   | 19 |   |
| 22<br>23<br>24   | 20 |   |
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| A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N                       |
| 1:27 p.m.   |
| MR. RAKOVAN: On the record. Okay. If                  |
| everyone will take their seats. I think we're ready   |
| to get started for the afternoon session and the      |
| roundtable discussion. Before we get started, I just  |
| wanted to go through few ground rules again just to   |
| make sure that everybody's on the same page.          |
| What we are trying to do is make sure that            |
| there is only person speaking at a time. The putting  |
| the tents up on the side is a good way to do that. In |
| a lot of discussions that we've had today so far, it  |
| really hasn't been a problem. Everybody seems to be   |
| respecting each other quite well and it seems to be   |
| working out. But do your best to make sure that only  |
| person is talking at a time. That way everybody can   |
| follow along and more specifically we can make sure   |
| that we get it all on the transcript.                 |
| We've had a recommendation from those on              |
| the phone line to make sure that you do use your      |
| speakers. It's a small room so a lot of us, even the  |
| transcriber, can probably hear you even if you don't  |
| speak directly into your mike. But if you could try   |
| to use them, it definitely helps keep everything at a |

to use them, it definitely helps keep everything at a louder level so that the people on the phone can hear. 

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166 1 And one more time, I'm going to ask you if 2 at least initially you could introduce yourself again. 3 I know we've been through this a number of times. Ι 4 know most of us know who each other are at this point 5 of the day. But especially like the people kind of over here on this side of the room, it's difficult for 6 7 her to see you when you start talking. So it's 8 especially important to make sure that our transcriber 9 knows who you are. Having said that, I want to make sure that 10 everybody has a copy of the focus questions that were 11 on the back table when you walked in. 12 If you don't, we'll make sure that we run and get you a set right 13 14 The focus questions are in four different groups now. 15 and what I'm just going to do is go group by group, throw it out there for discussion. 16 17 The first group primarily is just to make sure that people are on the same page. Everybody 18 19 understands what we've discussed. Everybody understands what the current state is and we can move 20 on from there. What I wanted to know before we 21 started though if there are any left questions or 22 anything else that we wanted to throw into the parking 23 24 lot before we started into the focus questions. Having said that, the first set of 25 Okay.

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| 1  | focus questions focuses on Structure and              |
| 2  | Responsibilities? The first questions are "Is the     |
| 3  | National Materials Program Clear? If not, please      |
| 4  | offer suggestions on ways to improve the information  |
| 5  | being communicated?" Anyone? Paul.                    |
| 6  | MR. LOHAUS: Thank you. I wanted to offer              |
| 7  | a comment on the question. This question came from me |
| 8  | and there is maybe an aspect to it that's not clearly |
| 9  | identified here. What I'd like is feedback. Given     |
| 10 | our discussion this morning when we talk about the    |
| 11 | National Materials Program, when we're communicating  |
| 12 | about the National Materials Programs, is our         |
| 13 | communication clear? Is it understood what we are     |
| 14 | talking about? What the aspects are?                  |
| 15 | That's what I wanted to get. Because in               |
| 16 | some of the discussions I've had, I'm not certain in  |
| 17 | all cases that we are in fact clearly communicating   |
| 18 | and some feedback on that I think would be very       |
| 19 | helpful for all this in terms of we interact, how we  |
| 20 | communicate, how we share information in the future.  |
| 21 | Thanks.   |
| 22 | MR. RAKOVAN: Thank you, Paul. I saw,                  |
| 23 | Jared, your tent first.                               |
| 24 | MR. WANGLER: Excuse me. Can I just                    |
| 25 | respond to Paul?                                      |

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| 1  | MR. RAKOVAN: Please.                                   |
| 2  | MR. WANGLER: I would say I was not clear               |
| 3  | on it until this morning. So I suspect that there are  |
| 4  | probably other regulators out there with some of the   |
| 5  | same questions. In fact, I told Jared that's one of    |
| 6  | the reasons when he asked that I agreed to come for    |
| 7  | this was because I thought it would help clear it up   |
| 8  | and it did.  |
| 9  | Carl's discussion made it very clear that              |
| 10 | this is nothing new and for some reason, it seems like |
| 11 | we have a brand new title here and where does it fit?  |
| 12 | I think perhaps just for other regulators, other       |
| 13 | states, just saying that this is nothing new, this is  |
| 14 | just trying to redefine how we do things. I know it's  |
| 15 | been said before but it cleared it up for me.          |
| 16 | MR. LOHAUS: Thank you.                                 |
| 17 | MR. RAKOVAN: Jared.                                    |
| 18 | MR. THOMPSON: Jared Thompson, Arkansas.                |
| 19 | To follow up on Paul's comment there, feedback from    |
| 20 | last year's OAS meeting seemed to indicate that        |
| 21 | there's some membership of OAS that's unclear on the   |
| 22 | National Materials Program much as Ken just spoke. A   |
| 23 | lot of that is due to the fact that there has been     |
| 24 | some turnover particularly on the upper management     |
| 25 | side of radiation control programs and you're having   |

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| 1  | influx of new people who have been out of the loop.    |
| 2  | We have to somehow reeducate and get people to rethink |
| 3  | about the National Materials Program.                  |
| 4  | MR. RAKOVAN: Thank you, Jared. I saw Dr.               |
| 5  | Johnsrud's tent first.                                 |
| 6  | DR. JOHNSRUD: Yes. I thought I had                     |
| 7  | participated in some sessions related to this program  |
| 8  | much earlier with regard to materials management and   |
| 9  | the non-AEC materials or AEC, AEA materials. I was     |
| 10 | quite puzzled by what was described in and not         |
| 11 | described perhaps because I had to unfortunately be    |
| 12 | late this morning.                                     |
| 13 | I was thinking over lunch how on earth do              |
| 14 | I describe this relationship if I understand it now    |
| 15 | and I don't think I really do to other members of the  |
| 16 | public, to groups of people with concerns about some   |
| 17 | of the materials that are not necessarily either       |
| 18 | associated with the industry or with public interests  |
| 19 | organizations. I think it is not clear. So it needs    |
| 20 | very definitive explanation for the public             |
| 21 | particularly.  |
| 22 | MR. LOHAUS: If I could just interject, if              |
| 23 | I could. If you have some suggestions, write them      |
| 24 | down, pass them on to us. Any of the members of the    |
| 25 | group, please do that because I think that will help   |

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| 1  | all of us. I'm looking at this collectively in terms   |
| 2  | of the NRC staff and the agreement states and the      |
| 3  | working groups. The extent that we can clearly         |
| 4  | communicate and impart understanding.                  |
| 5  | It also reflects a degree of understanding             |
| 6  | on our part as well. Because if we're not clear, then  |
| 7  | it may indicate that we don't fully understand this.   |
| 8  | And you're seeing as people talk work in progress.     |
| 9  | There are not clear answers to a lot of this so that's |
| 10 | part of it. Any suggestions, please pass them on to    |
| 11 | us.  |
| 12 | DR. JOHNSRUD: Yes. As a communications                 |
| 13 | start, it would have been nice to have emails to get   |
| 14 | in touch with you on the participant list.             |
| 15 | MR. LOHAUS: Okay. Thank you.                           |
| 16 | MS. CARDWELL: It may be helpful. I heard               |
| 17 | several comments today that could be put into bullets  |
| 18 | and a lot of them had to do with the why and one that  |
| 19 | Ken just said. Unfortunately, I think, Dr. Johnsrud,   |
| 20 | that you may have missed some of that this morning in  |
| 21 | talking about some of the whys. It's about 80 percent  |
| 22 | of the materials licenses are now regulated by the     |
| 23 | states. So it gets to the why.                         |
| 24 | DR. JOHNSRUD: Yes.                                     |
| 25 | MS. CARDWELL: Those can be bullets. Yes,               |

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| 1  | it has a name, but it's not new. It's redefining      |
| 2  | responsibilities based upon that allocation of        |
| 3  | regulation. So maybe bullets like, maybe we could put |
| 4  | on an NMP site on the website to try to get that      |
| 5  | summary out so somebody could quickly go and say "Oh, |
| 6  | okay." Some of our new managers like Jared said that  |
| 7  | have not been a part of the process or not have been  |
| 8  | steeped in this over the last several years, they are |
| 9  | clueless and rightly so.                              |
| 10 | MR. RAKOVAN: I'll get to you in a second.             |
| 11 | Smith.  |
| 12 | MR. SMITH: This is Leonard Smith, CORAR.              |
| 13 | I want to say similar things about what Ken mentioned |
| 14 | earlier. When I first came to the meeting, I didn't   |
| 15 | really have a full understanding of what materials    |
| 16 | program was. I think if you go into your website and  |
| 17 | look at the information on the website, there doesn't |
| 18 | seem to be a clear definition of the program or the   |
| 19 | scope of the program. I think that's probably what    |
| 20 | you really need to have.                              |
| 21 | MR. RAKOVAN: Thank you. I'm going to go               |
| 22 | to Mike Markley from the NRC really quick.            |
| 23 | MR. MARKLEY: I was going to say the same              |
| 24 | thing, Paul. You know your SECY 0112 actually had a   |
| 25 | pretty good description in there of what the program  |

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| 1  | is about, but updating with Carl's concept of things   |
| 2  | would be really worthwhile if there was a single       |
| 3  | mission statement type page or something there to      |
| 4  | describe it. The previous suggestion is actually very  |
| 5  | good.  |
| 6  | MS. CARDWELL: We need a primer.                        |
| 7  | MR. RAKOVAN: Mr. Anderson.                             |
| 8  | MR. ANDERSON: I guess I'll just second                 |
| 9  | the motion a little bit. I already know how to go to   |
| 10 | SECY. I suspect most members of the public really      |
| 11 | don't know what a SECY is.                             |
| 12 | DR. JOHNSRUD: That's right.                            |
| 13 | MR. ANDERSON: But at the same time, I                  |
| 14 | just went through your standard website stuff and I    |
| 15 | did manage to find after a great search through all of |
| 16 | NMSS, you do use the words "National Materials         |
| 17 | Program" in a paragraph that talks about how you       |
| 18 | regulate it. But aside from that, the only other       |
| 19 | information I could really get was to know where to go |
| 20 | to look for documents. I think if you're going to      |
| 21 | pursue this that you might want a keyword something on |
| 22 | the NMSS portion of the website so somebody can        |
| 23 | immediately can put "National Materials Program" and   |
| 24 | then get that perspective. But right now, it ain't     |
| 25 | there. It was very hard to get it over.                |

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| 1  | MR. RAKOVAN: I'm going to stick to the                 |
| 2  | table and then I'll go to the audience. Ms.            |
| 3  | Fairobent.   |
| 4  | MS. FAIROBENT: I'm going to say something              |
| 5  | totally different because I don't think it matters a   |
| 6  | hill of beans to the average licensee that there's a   |
| 7  | National Materials Program. I think that the fact      |
| 8  | that there is a slight transition in who may be taking |
| 9  | a leadership role to the average licensee isn't going  |
| 10 | to matter.   |
| 11 | I think that what matters is that the                  |
| 12 | regulatory process and in particular the guidance that |
| 13 | is out there is actually accurate and implementable.   |
| 14 | I think that for those of us who have been in the      |
| 15 | field for many years - and I started with NRC in 1977  |
| 16 | so I go back a long way - this definitely is no        |
| 17 | different than how we've done business. The            |
| 18 | difference is whether or not the lead responsibility   |
| 19 | is going to be in Texas or the lead responsibility is  |
| 20 | going to be sitting here in Rockville. So from the     |
| 21 | average licensee standpoint, I don't think it matters. |
| 22 | However I do think what matters is that                |
| 23 | whatever we transition the program and the emphasis to |
| 24 | needs to be sure that the third member party which are |
| 25 | truly the stakeholders that was envisioned in the      |

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1 original alliance concept is not lost in the early on I think the concern the licensees have and 2 process. 3 it's more so from those who are left in the 17 NRC 4 states is carrying a bigger burden dollar wise to have 5 NRC remain the overall lead for everything and to continue to be able to support or fund the activities 6 7 out in the states as the agreement state numbers have 8 grown or perhaps to have to be carrying the burden to 9 have a more comprehensive regulatory infrastructure remaining at NRC as your level of responsibility have 10 decreased due to the lower number of licensees that 11 12 you have the authority for. But I think for the average licensee, all 13 14 they care about is that they send a license request. 15 The license request gets approved. They can do their 16 They can function and we're all protecting work. 17 public health and safety. So I don't know how I wouldn't spend a lot of time important this is. 18 19 reemphasizing the definition of what the program is. I do think that there are things that can 20 be done to beef up the website area or to bring 21 together the concept of the bullets and stuff 22 SO somebody could have a one-pager. But that's not where 23 24 should be spending our time, our money, we our emphasis on as we move forward with this program being 25

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| 1  | redefined and refashioned.                             |
| 2  | MR. RAKOVAN: Okay. Mr. Dicharry.                       |
| 3  | MR. DICHARRY: Donny Dicharry, NDTMA/ASNT.              |
| 4  | I think that the program is quite clear, but I've been |
| 5  | involved with it for quite some time now. The only     |
| 6  | think that maybe I'm not clear on is whether or not in |
| 7  | fact it is established program that is going to stay   |
| 8  | or is this still a concept that is under               |
| 9  | consideration?   |
| 10 | As far the radiography segment of the                  |
| 11 | industry goes, I am quite certain that it is not clear |
| 12 | to them despite the fact that there have been a couple |
| 13 | of presentations at national conferences by NRC        |
| 14 | personnel simply because at this point, the            |
| 15 | radiography licensees do not perceive either an impact |
| 16 | or an opportunity on them. I think that to the extent  |
| 17 | that licensees perceive an opportunity to participate  |
| 18 | in the process you will find their interest and        |
| 19 | enthusiasm for the program to increase.                |
| 20 | MR. RAKOVAN: Thank you. Mr. Pangburn.                  |
| 21 | MR. PANGBURN: Yes. George Pangburn,                    |
| 22 | Region 1. I think I would agree with Lynne on the      |
| 23 | point that she made and that is while licensees may    |
| 24 | not have a strong interest at this point in time to    |
| 25 | the extent that the program moves towards that         |

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alliance concept and that results in a realization of lower user fees, there may not be a ground swell support for it. But you will certainly find in licensees' interests.

5 I would also agree that licensees do appreciate having a clear and implementable guidance 6 7 and an expectation that they'll receive a license in a reasonable degree of time from when they submit. 8 9 Although we still have our fair share of licensees who say "Guidance? What guidance?" 10 But that's another matter. Thank you. 11

MR. RAKOVAN: Ruth McBurney.

MS. McBURNEY: If there could be some 13 14 bulleted or some sort of article written about the 15 basics of the National Materials Program and what this 16 means to licensees, what this means to the public and 17 what sort of opportunities for stakeholder input, if something like that could be written up, it could be 18 19 communicated through professional newsletters and through the newsletters of the public stakeholder 20 organizations. It's just another way of communicating 21 it. 22

I know there have been articles about the program since Joan did one, I believe, for the Health/Physics newsletter because she provides

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| 1  | articles from what's going on at NRC and so forth. So  |
| 2  | that would be one way of communicating that other than |
| 3  | having something at the website. Or people could have  |
| 4  | clickable links to that website for more information   |
| 5  | if it were put there as well.                          |
| 6  | MR. LOHAUS: Just to mention quickly, we                |
| 7  | are planning to do a poster at the Health/Physics      |
| 8  | Society Meeting this year too. That's a good thought.  |
| 9  | MS. McBURNEY: That's a good opportunity                |
| 10 | because that's going to be here in Washington this     |
| 11 | year.  |
| 12 | MR. RAKOVAN: Okay. I'm going to go with                |
| 13 | the tents in the order that I saw them. Ms. Roughan.   |
| 14 | MS. ROUGHAN: Kate Roughan, AEA                         |
| 15 | Technology. When I started back in 1999, I thought I   |
| 16 | understood the concept and it was going to be NRC      |
| 17 | agreement states and key stakeholders to participate   |
| 18 | in making rulemaking that would be effective,          |
| 19 | efficient and the people that actually had to          |
| 20 | implement the regs on a day to day basis could         |
| 21 | implement them as Lynne has already said. I see that   |
| 22 | we've gone away from that a little bit and now it's    |
| 23 | more saving of resources which is a good thing. But    |
| 24 | we're missing a little bit from the original concept   |
| 25 | that I thought we were going towards on this.          |

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| 1MR. RAKOVAN:Mr. Anderson.2MR. ANDERSON:That's really a comment3that I was going to make.I'll just build onto the4Part of the difficulty I've had as I've seen the5surface over time including articles we've had earl6is I've haven't been able to pin down just how7reaching is this project. | nat.<br>his<br>ier |
|---|--------------------|
| 3 that I was going to make. I'll just build onto th<br>4 Part of the difficulty I've had as I've seen th<br>5 surface over time including articles we've had earl<br>6 is I've haven't been able to pin down just how   | nat.<br>his<br>ier |
| <ul> <li>4 Part of the difficulty I've had as I've seen t</li> <li>5 surface over time including articles we've had earl</li> <li>6 is I've haven't been able to pin down just how</li> </ul>   | his<br>ier         |
| 5 surface over time including articles we've had earl<br>6 is I've haven't been able to pin down just how   | ier                |
| 6 is I've haven't been able to pin down just how  |                    |
|   | far                |
| 7 reaching is this project Now that might be becau  | Lal                |
|   | use                |
| 8 that's not known.   |                    |
| 9 For instances, when I look down thro  | ugh                |
| 10 your questions, suddenly you're talking about "  | Gee                |
| 11 should we throw norm and other things under this   | as                 |
| 12 well?" That's about 15 times as large of another   |                    |
| 13 understanding of what it is which is to find the m   | ost                |
| 14 efficient way to use resources within the existin  | ng                 |
| 15 program. So somehow nailing down how an end of t   | his                |
| 16 is probably creates a direct function of interest  | of                 |
| 17 stakeholders.  |                    |
| 18 Because if we're rearranging the d   | eck                |
| 19 chairs, I think we'll all put a certain amount   | of                 |
| 20 effort into that. As Lynne said, most people fram  | nkly               |
| 21 won't care. But if we're doing something more  |                    |
| 22 profound than that, that's what needs to be  |                    |
| 23 communicated. That's the opportunity and impact  | issue              |
| 24 that Don was referring to. It has to be relevant   | and                |
| 25 clearly you're thinking that way or you wouldn't   | be                 |

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| 1  | asking these kinds of questions.                       |
| 2  | MR. LOHAUS: Just quickly, it has aspects               |
| 3  | of both. I mean we're really looking to improve the    |
| 4  | effectiveness and the efficiency of the overall        |
| 5  | program. But at the same time, I'll steal some         |
| 6  | thoughts that Cindy talked about at one of your        |
| 7  | earlier meetings and that is that it's going to take   |
| 8  | place in steps and some of the steps are going to be   |
| 9  | small steps. Others may be larger steps, but it's      |
| 10 | hard to characterize that because it's an evolution in |
| 11 | a sense.   |
| 12 | There are a number of steps going on, but              |
| 13 | at the same time, the goal is effectively utilize the  |
| 14 | suite of resources that the states and the NRC staff   |
| 15 | represent to meet the needs in the Materials Program.  |
| 16 | How do we do this most effectively, most efficiently,  |
| 17 | and meet the needs of everybody, all the stakeholders, |
| 18 | the licensees, the public as well as the regulatory    |
| 19 | agencies that implement the program?                   |
| 20 | I have to agree. It's very difficult to                |
| 21 | get your hands around this. You have to get steeped    |
| 22 | in it if you will. But the idea that Cindy had in      |
| 23 | terms of this is some of this is going to be small     |
| 24 | steps that you may not really see a big change. But    |
| 25 | when you put all those steps together, you will see an |

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| 1  | increment in change that occurs.                       |
| 2  | MR. RAKOVAN: Margaret Federline.                       |
| 3  | MS. FEDERLINE: Margaret Federline, NMSS.               |
| 4  | My perception is that we will all understand this      |
| 5  | program when we all work together to define success    |
| 6  | measures because I think we're each sitting with our   |
| 7  | own idea of what success would be for us and I think   |
| 8  | this group or a similar representative group of        |
| 9  | stakeholders, if we could work to define some success  |
| 10 | measures then it would probably be clear to all of us  |
| 11 | what the outcome should be.                            |
| 12 | MR. RAKOVAN: And that's part of the                    |
| 13 | further questions. So we'll get to that later. We'll   |
| 14 | put that on the parking lot that's already there so to |
| 15 | speak. Mr. Fitch.                                      |
| 16 | MR. FITCH: Yes, just one comment. I                    |
| 17 | would like to quote Kathy Allen who was on the         |
| 18 | original working group, not verbatim, but she talked   |
| 19 | about the fact that well the whole concept was to      |
| 20 | somehow make the most of the resources of the          |
| 21 | agreement states in conjunction with the NRC because   |
| 22 | the NRC's fee base is shrinking more and more over     |
| 23 | time. There has to be a way to get the states          |
| 24 | involved and the states are looking for the            |
| 25 | opportunity to get involved.                           |

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So the idea is we'll sit down and we'll talk about how we're going to start merging this tomorrow. But then as typical when you redevelop a process is you ask yourself who are our stakeholders. To quote Kathy, well we considered the public and our licensees to be stakeholders. So we identified them and that was the right idea.

That is the correct idea, but now we see 8 9 a challenge where the states and NRC have to go back 10 and assess the primary challenge of merging resources How are we going to make this work? 11 together. I'm confident that as they try to get their ducks in a row 12 if you will they will start bringing the stakeholders 13 14 into this more and more to where they can better 15 address stakeholders. Because until the framework is 16 best defined or best salvaged, it's going to be 17 difficult for them to do that satisfactorily. Dr. Johnsrud. 18

19 DR. JOHNSRUD: Yes. Judith Johnsrud. Ι have a feeling that my governor is going to want 20 21 something а little stronger than an aspirin From the sound of what I'm hearing 22 financially. today, the NRC is concerned about its financial 23 24 resources as well it might be. But the states are in 25 a lot of financial trouble. It appears to me that

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| 1  | this program while there would be an NRC control, at   |
| 2  | the same, will involve substantial increases in the    |
| 3  | responsibilities of the states. They are in trouble    |
| 4  | as well as the Federal Government. That's point one.   |
| 5  | My second question is how will this affect             |
| 6  | the preemptive authority under the AEA currently held  |
| 7  | by the NRC or will it? Will it be increased? Will it   |
| 8  | be lessened? Will the states take over, be permitted   |
| 9  | to take over greater authority?                        |
| 10 | MR. FITCH: It think we should take over.               |
| 11 | DR. JOHNSRUD: Well.                                    |
| 12 | MR. RAKOVAN: I think the points that                   |
| 13 | you're making leads good into the next set of          |
| 14 | questions, but I do want to stop one moment just to    |
| 15 | see. I see Margaret Federline's tent is up before we   |
| 16 | move on to the next set. All right. Great.             |
| 17 | Excellent segue. Thank you, Dr. Johnsrud. The next     |
| 18 | set of questions is "Are the roles and                 |
| 19 | responsibilities of all stakeholders clear? What       |
| 20 | should be the respective roles and responsibilities of |
| 21 | the NRC? Agreement states? The Conference of           |
| 22 | Radiation Control Directors (CRCPD)? The Organization  |
| 23 | of Agreement States (OAS)? Licensees? Then Licensee,   |
| 24 | medical and industry associations?" I think like I     |
| 25 | said the points that you made kind of lead directly    |

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| 1into that. Cindy.2MS. CARDWELL: I guess to answer maybe3some of your questions or to help out with that I'm4going to give the vision of the National Materials5Working Group in response to some of those questions6when we put the program together in the first place7and yes, there was great stakeholder input in the8beginning. But we didn't envision any change9statutorily on the Federal level or on the state10level.11We said it at lunch. We've essentially12done this all along. We're doing a shifting the13amount of contribution the states are making and I'm14not talking monetarily. We've done this for years and15years and it's the work effort. Realistically, no16state is going to put a line item in their budget that17says we're going to support the National Materials18Program because they are not just going to.19But the states have budgets that are not20that specific. There is a budget out there for21radiation control and it covers certain activities22that happen under that. Our regulatory concerns that23were addressed in some of the working groups, the24Pilot 1, where we had combined, those are still our25priorities if we chose not to participate at all and |    | 183  |
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|  | 23 | were addressed in some of the working groups, the      |
| 25 priorities if we chose not to participate at all and  | 24 | Pilot 1, where we had combined, those are still our    |
|  | 25 | priorities if we chose not to participate at all and   |

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we would have to put the effort into developing the products that are necessary whether it be rule or guidance documents or anything else that we can come up with.

5 So it's to our benefit to cooperate, the states' benefit to cooperate, in a process that could 6 7 qet it done potentially more quickly, with more resources and ideally with a better product. 8 That was 9 the vision behind the initial working group report. 10 It was that we didn't see a big change in any of the agreements or statutory responsibility, but it was a 11 shifting of that responsibility towards where what 12 we're calling the centers of expertise are. 13

14 With 80 percent of the licensees there are 15 that regulate that have a some states lot of experience regulating certain kinds of licenses. 16 Over time, it just makes logical sense that they will then 17 have the experience in not only what the industry has 18 19 but what the public's response to that industry is and then the regulatory responsibilities associated with 20 It therefore is the next logical step to say 21 that. 22 "Well that should be the group that leads in developing the documents with the input of everyone 23 24 else." So it's a shifting. We're not trying to reinvent a whole lot of statutory obligations here. 25

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| 1  | DR. JOHNSRUD: May I ask a follow-up?                   |
| 2  | MS. CARDWELL: Go ahead.                                |
| 3  | DR. JOHNSRUD: How are you going to                     |
| 4  | balance the variations among the states in terms of    |
| 5  | the extent and the types of their responsibility and   |
| 6  | the amounts that are variable from one state to        |
| 7  | another while retaining a cohesion of these proposals? |
| 8  | MR. FITCH: I'm sorry. Two years ago,                   |
| 9  | Pallo House (PH) was with us sat in a board meeting of |
| 10 | the OAS out in Salt Lake City and one of the           |
| 11 | challenges that came up was the fact that any given    |
| 12 | state cannot contribute the same amount any given      |
| 13 | year. In fact, there are going to be some states due   |
| 14 | to budget restrictions or changes of personnel or      |
| 15 | other effecting factors that might cause their         |
| 16 | participation to be diminished or increased.           |
| 17 | So one thing that the OAS insisted upon is             |
| 18 | that sufficient latitude be understood in this because |
| 19 | the states cannot be bound by that. While they might   |
| 20 | be willing, they are going to be able to have the      |
| 21 | latitude and the flexibility to contribute on what     |
| 22 | they see to be their priorities. I am confident.       |
| 23 | Besides being confident, that's the reasons why the    |
| 24 | NRC is relying on the CRCPD and the OAS to help        |
| 25 | facilitate this because we're going to have to remain  |

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| 1  | a driving force to keep prompting our members to keep  |
| 2  | participating. That's the reason why the NRC needs to  |
| 3  | see the level of commitment from the two organizations |
| 4  | to ensure that this perpetuates.                       |
| 5  | MR. RAKOVAN: I saw Ms. Fairobent's tent                |
| 6  | up.  |
| 7  | MS. FAIROBENT: Yes, Lynne Fairobent, ACR.              |
| 8  | From my perspective as one who has been in the field   |
| 9  | for a number of years on all sides of the table, I     |
| 10 | guess the only side of the table I haven't been on is  |
| 11 | I have not worked for a state agency. I've worked for  |
| 12 | licensees. I've worked for the NRC. I've worked for    |
| 13 | other Federal agencies that may or may not come into   |
| 14 | play because of some broader issues. I've worked for   |
| 15 | associations across the board.                         |
| 16 | I'm in total agreement with Cindy. I                   |
| 17 | don't see the vision that the original working group   |
| 18 | had. I see no change to statutory authority as far as  |
| 19 | what falls under the 274 type agreements today. I      |
| 20 | think when we get down the mission and scope and the   |
| 21 | second question there some of that could change, but   |
| 22 | that has nothing to do with the vision of the National |
| 23 | Materials Program per se.                              |
| 24 | I think that all we're talking about is if             |
| 25 | we go back historically - and they were brought up     |
|    |  |

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1 earlier and look at that original industrial 2 radiography licensing requirements and we look at the initial well-logging requirements, they were developed 3 4 because those materials were being used in a certain 5 state and the state kept seeing more and more our They had to come up with a 6 increased interest in it. 7 regulatory process to deal with it.

8 NRC at the time wasn't dealing with that. 9 Their licensees weren't coming into that fold. So it 10 made sense that the state develop the first set of requlations. I see no difference. The only think 11 we're looking at now is a broader definition to use 12 Cindy's term of where does that center of excellence 13 14 exist. For example, well-logging, industrial 15 radiography, there is a handful of states where it's 16 really prevalent.

17 Well-logging I don't ever see prevalent in the Northeast. It just is not going to lend itself to 18 19 So I would not expect Massachusetts to become that. the center of excellence for well-logging. 20 However there's an awful lot of medical developments that are 21 done in the Commonwealth of Massachusetts either be it 22 because of the industries that are there 23 that 24 supporting the development of new devices and new modalities or because of the high concentration of 25

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| 1  | Ford medical research centers that are in essence in   |
| 2  | the medical communities centers of excellence so they  |
| 3  | are moving forward in the medical technology.          |
| 4  | Massachusetts could become a center of                 |
| 5  | excellence in some part of the licensing arena.        |
| 6  | Collectively none of us can afford to duplicate the    |
| 7  | effort of somebody else. We should be working          |
| 8  | together to just development and establish if you want |
| 9  | an initial protocol or guidance package that then      |
| 10 | could be utilized while incorporating the concepts of  |
| 11 | everybody else as far as they then can take it and fit |
| 12 | it into their legislative and regulatory structure     |
| 13 | within the state themselves.                           |
| 14 | MR. RAKOVAN: Thank you. Paul Lohaus.                   |
| 15 | MR. LOHAUS: Thank you. I just want to                  |
| 16 | stop for some thoughts to stimulate a different view   |
| 17 | if you will. Lynne really touched on this and Judith   |
| 18 | Johnsrud did too. The thought is if you look at the    |
| 19 | program and given how Cindy and Pierce have            |
| 20 | characterized it that there would be confidence that   |
| 21 | the states would provide resources. In some cases, it  |
| 22 | may be three states. In other cases, it could be ten   |
| 23 | states, but it may not be all the states at any one    |
| 24 | particular point in time.                              |
| 25 | But the other side of that is should the               |

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expectation though be that there be a more formal establishment of a commitment and maybe even a commitment with respect to either a portion of the fees or a line item that's included in the budget within a state program that really is directed at the resources necessary to help contribute to the overall National Materials Program. It's just a different way of looking at it.

9 If you think about it, it would be 10 extremely difficult to accomplish. But at the same time, it goes to the heart of the issue of would the 11 nation have confidence that the informal grouping in 12 cooperative, collaborative process is going to be 13 14 effective in meeting the needs of the nation or does it have to be done in a more certain and hard sense in 15 16 terms of how we normally handle the commitments that 17 are made to provide the resources to do the work that's necessary to carry on our respective programs? 18 19 I don't know the answer to that, but I just wanted to throw that out as a different way of 20

20 Just wanted to throw that out as a different way of 21 looking at it. It's an issue I think that we'll 22 continue to wrestle with for a long time. There is no 23 clear answer today to me, but I just wanted to throw 24 that out for thinking.

MR. RAKOVAN: Mr. Smith.

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| 1  | MR. SMITH: Leonard Smith from CORAR.                   |
| 2  | Answering the question of roles of responsibilities    |
| 3  | for industries, associations and licensees, I think    |
| 4  | first of all there needs to be an understanding that   |
| 5  | licensees especially in the manufacturing distribution |
| 6  | arena need a comprehensive framework of regulations.   |
| 7  | We need uniform regulations. We need uniform Federal,  |
| 8  | state, local and international regulations. If we      |
| 9  | don't have that kind of framework, it makes our        |
| 10 | business very difficult.                               |
| 11 | One thing you should be aware of is that               |
| 12 | virtually all the licensees in the country are being   |
| 13 | supplied by these suppliers and distributors. We take  |
| 14 | a very active role in helping those licensees develop  |
| 15 | their safety programs. So we're not just sending       |
| 16 | material off to people that we don't have any          |
| 17 | relationship with. If we find that our customers have  |
| 18 | different regulations that apply to them, we're less   |
| 19 | likely to be able to help them. Frankly we would tend  |
| 20 | to not do that because it becomes too expensive and    |
| 21 | too difficult for us.                                  |
| 22 | So we're really a very supportive kind of              |
| 23 | program because we see that what you're trying to do   |
| 24 | is to come up with more uniform regulations. I think   |
| 25 | our role is probably reflecting back to you the        |

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| 1  | current condition of the regulations how they impact   |
| 2  | on our operations and we should stay engaged. I see    |
| 3  | that as a role and responsibility in this process.     |
| 4  | MS. FAIROBENT: Yeah, Lynne Fairobent.                  |
| 5  | Paul, to answer your question a little bit, I'm going  |
| 6  | to flip the table on you. Does the National Materials  |
| 7  | Program show up as a line item in NRC's budget. I      |
| 8  | think that gets to Donny's issue. We've talked about   |
| 9  | the formal concept of this now for a number of years   |
| 10 | and we're still in pilot programs. Is there truly the  |
| 11 | commitment on the Federal side to use an earlier term  |
| 12 | to embrace a cultural change and recognize that NRC    |
| 13 | does not have to be the lead in all of these areas?    |
| 14 | So I'm not so sure for the agreement                   |
| 15 | states in particular. I think that the commitment on   |
| 16 | the part of the state is the governor's signature on   |
| 17 | the agreement to undertake 274 material and to commit  |
| 18 | to having their state program for it. So I don't know  |
| 19 | that adding a line item entitled "National Materials   |
| 20 | Program" in the state budget would give me much more   |
| 21 | of a warm fuzzy than the fact knowing the governor had |
| 22 | signed the initial agreement and committed to having   |
| 23 | the totality of the program and concept anyhow.        |
| 24 | But I throw it back because I think it has             |
| 25 | to be whatever sort of visible burden in essence you   |

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| 1  | put on the states. I think it has to be an equivalent  |
| 2  | visible commitment within the NRC structure, whether   |
| 3  | it is a line item in the budget or how one would       |
| 4  | define it.   |
| 5  | MR. LOHAUS: Right. Well, I'll ask for                  |
| 6  | some help from Margaret here too. But to answer your   |
| 7  | question, you won't find a line item in our budget.    |
| 8  | MS. FAIROBENT: I know.                                 |
| 9  | MR. LOHAUS: But you will find that                     |
| 10 | there's resources identified to support working groups |
| 11 | and interface and interaction with the states in terms |
| 12 | of the cooperative, collaborative process that we've   |
| 13 | evolved to and we're continuing to further evolve in   |
| 14 | that area. So you'll find that it's budgeted. So in    |
| 15 | a sense, it's there from that standpoint, but,         |
| 16 | Margaret, you may want to comment as well.             |
| 17 | MS. FEDERLINE: Yeah, if I could just add.              |
| 18 | We've gone to outcome oriented budgets. So the         |
| 19 | outcome. That's why to me the planning assumptions     |
| 20 | are so important and the success measures. Because if  |
| 21 | we can define what we're going to do together, we can  |
| 22 | put line items in our budgets for the outcomes. Can    |
| 23 | I?   |
| 24 | MR. RAKOVAN: Yes, I was going to say. I                |
| 25 | noticed your tent was up before being requested to     |

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| 1  | speak.   |
| 2  | MS. FEDERLINE: I was just wondering.                   |
| 3  | We're talking about taking advantage of the expertise  |
| 4  | in NRC and the states. Is there a way we can take      |
| 5  | better advantage of the expertise that's in the        |
| 6  | industry and the professional societies and how would  |
| 7  | you recommend that we go about that in a fair and      |
| 8  | equitable public process?                              |
| 9  | MR. RAKOVAN: That was a good lead-in.                  |
| 10 | Mr. Anderson, would you like to comment on that lead-  |
| 11 | in?  |
| 12 | MR. ANDERSON: That's why I raised my                   |
| 13 | card. Actually I was reflecting off some comments      |
| 14 | that Lynne Smith made. Ralph Anderson, Health Physics  |
| 15 | Society. You know obviously one of the things that     |
| 16 | the Society encourages very strongly is a single       |
| 17 | coherent framework for radiation health and safety in  |
| 18 | this country. And as that leads to this involvement    |
| 19 | by other parties, it just continually strikes me that  |
| 20 | the differences in implementation of standard          |
| 21 | frameworks most often arises because of new issues     |
| 22 | that emerge that just weren't visible at the time that |
| 23 | the standard framework was put together.               |
| 24 | In my own observation given the role that              |
| 25 | I have for one segment of the industry is when you get |

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| 1  | a broad base of stakeholders involved on the front end |
| 2  | you surface 95 percent of the issues. When you don't,  |
| 3  | you always miss two or three key issues that show up   |
| 4  | at the most inopportune times.                         |
| 5  | So I would suggest to you that it's not                |
| 6  | just the industry and the professional societies. It   |
| 7  | really goes more to the National Materials Program     |
| 8  | helping facilitate a process to get broader based,     |
| 9  | earlier input so that you have a more coherent         |
| 10 | framework that is implemented more uniformly. That's   |
| 11 | an huge opportunity that I see in the process and      |
| 12 | that's a role that I think all those organizations     |
| 13 | play in the process.                                   |
| 14 | MS. FEDERLINE: Can I just follow up and                |
| 15 | ask you?   |
| 16 | MR. ANDERSON: Yes.                                     |
| 17 | MS. FEDERLINE: How can we ensure that                  |
| 18 | people have the right level of information and are     |
| 19 | able to participate because it's an investment in      |
| 20 | time. I know when NEI on the reactor side presents     |
| 21 | proposals that takes quite a bit of time to develop    |
| 22 | those. How do we go in Materials Program about asking  |
| 23 | people to make those investments because there clearly |
| 24 | are centers of expertise out there?                    |
| 25 | MR. ANDERSON: Well, I think there's                    |

1 probably two ways to do that. One way is if you started with the notion that NRC is the broad umbrella 2 3 under which this activity is taking place then it 4 seems to me that the NRC website becomes a very 5 effective nexus for distribution of information. 6 Whether or not it makes the Federal 7 Register, whether or not it's beinq done in а 8 particular state or among three or four states, there 9 is no reason that it can't be advertised through the 10 NRC. You're allowed to put things on your website that aren't Federal Register notices. You do it all 11 And if you had a central location to go to the time. 12 look for that thing, that would be fairly simple to 13 14 do, fairly low cost and fairly easy for people to 15 access.

16 I think also as a part of the process that 17 you probably need to find a mechanism for over communication to groups that have participated in some 18 19 of the various initiatives you've undertaken over the last three or four years. My colleague, Judy and I, 20 21 for instance would represent the issue of NRC rulemaking on disposition of materials. 22 Well, that probably surfaced a whole range of interested groups 23 24 that are interested most of the time. So if you pick up the NUREG on those public comments, you have a list 25

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| 1  | of organizations.                                      |
| 2  | If you look to some of the major                       |
| 3  | initiatives you'd undertaken when you feel that you    |
| 4  | have an appropriate description of the program, it     |
| 5  | would seem to me that you can communicate that to      |
| 6  | those organizations and direct them to where           |
| 7  | information is going to be conveyed in the future and  |
| 8  | invite them to participate in the process as it goes.  |
| 9  | So I don't think it's difficult to do these things.    |
| 10 | That struck me when I looked in that                   |
| 11 | NUREG, Margaret, on the disposition of materials for   |
| 12 | comments. I opened that one section and it listed all  |
| 13 | the organizations that provided input. I thought       |
| 14 | "Well that's probably 90 percent of the usual          |
| 15 | suspects." So I don't think it would be that hard to   |
| 16 | develop a generic list to inform people where they can |
| 17 | go and then it's up to them after that if you give     |
| 18 | them an easy access location to track what's going on. |
| 19 | Anyway, that would be my input.                        |
| 20 | MR. RAKOVAN: Okay. I'm going to go to                  |
| 21 | Mr. Dicharry next.                                     |
| 22 | MR. DICHARRY: Donny Dicharry. Yes, this                |
| 23 | also is in response to Margaret's question regarding   |
| 24 | what sort of communications could be most effective at |
| 25 | getting the involvement of industry and industry       |

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groups. My response is not so much focused on means of communications but rather what should be in the communication.

4 Ι think that as lonq as licensees 5 recognize an opportunity to participate in a process that can result potentially in reducing the cost of 6 7 the implementation of a rule I think that you won't 8 have to struggle to obtain their participation. 9 Licensees and those groups that represent licensees 10 all share in that one same motive of trying to implement rules in a way that is most cost effective. 11

The question that Lynne posed earlier 12 today is whether or not industry participation would 13 14 be on a catch-as-catch-can basis. Well, I fear that 15 in fact it will be catch-as-catch-can unless industry 16 has a proper incentive to be involved. The incentive 17 qoes far beyond in my opinion simply gaining some benefit by reducing the overhead of the NRC and the 18 19 states and enjoying reductions in fees and such that are passed onto the licensing community. 20

I think that the greatest opportunity to offer an incentive to the licensees is to suggest that in fact this new concept will provide opportunity to participate at all ends of the program. From a resource sharing standpoint, it is important to

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1 recognize that there are most probably more experts in 2 health physics and regulatory compliance matters in 3 the halls of private industry than there are in the 4 halls of government especially since most of them have 5 come from government at one time or another. All we need is the proper incentive to participate and we 6 7 will be there. 8 MS. FEDERLINE: I have another guick 9 follow-up. How do we make it into a manageable 10 process? I can see perhaps putting these products on the web and getting 400,000 comments, all which 11 disagree with one another. How do we deal with a 12 process like that? 13 14 MR. DICHARRY: If I may follow up, I would 15 suggest that the example that has already been created 16 by CRCPD is a very workable model. Industry advisors 17 have been participating in working groups of CRCPD successfully for years and I would think that it would 18 19 be a good model to build upon. 20 Okay. Ms. Fairobent. MR. RAKOVAN: Margaret, a couple of 21 MS. FAIROBENT: I think with both of us having 22 perspective points. come out of the reactor industry at one point in our 23 24 lives, it's really nice that there is truly one voice that you can go to and it makes it much simpler. 25 Ιf

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| 1  | we take a look just at the medical piece of the        |
| 2  | Materials Program, I think you can accomplish the same |
| 3  | thing and we've seen it. In the past three years,      |
| 4  | you've seen some movement in this in that if you go to |
| 5  | the key associations of which there's four to six      |
| 6  | depending on how you cut the issue that are going to   |
| 7  | deal with NRC regulatory issues. If the initial        |
| 8  | communications on all of this is to those groups, you  |
| 9  | will get the technical experts you need to either      |
| 10 | serve as an industry advisor or resource on the group. |
| 11 | Or in fact, let's flip it a little bit.                |
| 12 | There is nothing to say that if a request came out to  |
| 13 | us to say "Collectively it gets to your planning       |
| 14 | process. Collectively we've identified the following   |
| 15 | things coming down the pike. Can you all fit this      |
| 16 | into your schematic for either technical guidelines or |
| 17 | standards and come up with a guidance document?"       |
| 18 | There is no reason why industry would not embrace that |
| 19 | sort of a request in my mind.                          |
| 20 | I think the other thing on the medical                 |
| 21 | side that I do not believe NRC does utilize            |
| 22 | effectively enough is the Advisory Committee on        |
| 23 | Medical Use (ACMUI). I truly believe that the ACMUI    |
| 24 | is not utilized in the same fashion as the ACRS and    |
| 25 | ACNW are in their areas of expertise. I really think   |

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1 that process is something that is totally under 2 utilized and I don't think is as effective as it could 3 possibly be for the NRC in either helping to develop 4 guidance or identify how to solve potential problems 5 that are surfacing through either failures or inspection findings. That is something that as a tool 6 7 that certainly is your in-house panel experts for the 8 medical use. 9 Okay. I'm going to go in MR. RAKOVAN: 10 the order that I saw the tents go up starting with Dr. Johnsrud. 11 Ralph referred a little 12 DR. JOHNSRUD: earlier to having the usual suspects involved. 13 I'm 14 looking beyond the involvement of the industry with regulators at the state level as well as at the 15 16 Federal level to the segments of the public who are 17 ultimately the ones effected by whatever ruling-making quidance may be developed in this process. But by the 18 19 time it gets to them at particular locations in which they have a personal, perceptual interest, there 20 really is no mechanism, no opportunity, no opening for 21 them to have any impact on the decisions that have 22 been made if you will above or outside the realm of 23 24 their opportunities for involvement.

It may be said that they should create the

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opportunities for involvement, but most members of the public are already holding two or three or four jobs per family and really don't read the <u>Federal Register</u> online or off all that often. So I don't see or hear from everything thus far how this program is going to manage to open to those who ultimately are the most effected by your decision making.

B Diane said earlier "Gosh, we're going to have to deal with not only the NRC and DOE and EPA and the states, but some super coalescence of several of these." That's yet another step, another impediment to what I think many of us in the public realm would consider to be good, effective and accepted, trusted regulation.

MR. RAKOVAN: Okay. Ms. Roughan.

16 MS. ROUGHAN: This goes back to the 17 original request of Margaret. In many cases there is depending on the segment of the industry an industry 18 19 group representing that. Where there isn't, most of the larger manufacturers and distributors will solicit 20 comments from their end users. So instead of the NRC 21 getting tens of thousands of comments, we'll feed them 22 We'll in some cases do a template to our end 23 in. 24 users saying this is how it will affect you. You need 25 comment and get that into the NRC. So that to

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| 1  | consolidates all of the information. You still get     |
| 2  | the feedback to the NRC and that's a key piece of      |
| 3  | information. You have to go back to get it from the    |
| 4  | end user, but they sometimes don't see the larger      |
| 5  | picture. So it helps to get fed up through the larger  |
| 6  | company. Thank you.                                    |
| 7  | MR. RAKOVAN: Mr. Anderson.                             |
| 8  | MR. ANDERSON: Seconding that motion, I                 |
| 9  | think that's part of the answer to the 400,000         |
| 10 | comments is that by making sure everyone sees it       |
| 11 | people will take advantage of organizations that are   |
| 12 | already in place to have those interactions. So        |
| 13 | although you may get 700 copies of the same comment,   |
| 14 | it's still the same comment.                           |
| 15 | Alternatively, I think the more                        |
| 16 | fundamental question is if you really had 400,000      |
| 17 | substantive differences and I'm just using that as a   |
| 18 | figure of speech that's even more important to get     |
| 19 | that on the front end of the process because it should |
| 20 | tell you that you perhaps haven't properly evaluated   |
| 21 | the issue before starting forward. I mean if they      |
| 22 | really were substantive in nature. Whenever I've       |
| 23 | thought about that kind of question when it comes up   |
| 24 | and I know the Commission likes to raise that question |
| 25 | a number of times, to me it's the backwards way of     |
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| 1  | looking at it. You should welcome hearing that         |
| 2  | there's a large diversity of use on the front end and  |
| 3  | deal with it rather than get two-thirds of the way     |
| 4  | through the process and then find out that you're      |
| 5  | going to have to do all over again. I think it         |
| 6  | corrects itself.                                       |
| 7  | MR. RAKOVAN: Before I go to Mr. Fitch, I               |
| 8  | want to try to refocus. We've been having a lot of     |
| 9  | good discussions on getting public involvement,        |
| 10 | stakeholder involvement and these kinds of things, but |
| 11 | in terms of the first set of focus questions on        |
| 12 | structure and responsibilities, there's a lot of areas |
| 13 | that we haven't addressed yet and we're stuck a little |
| 14 | bit if I may on one set.                               |
| 15 | What I wanted to make sure is that we're               |
| 16 | focused on these. It's coming up on 2:30 p.m. I know   |
| 17 | a lot of you have other things that you need to scoot  |
| 18 | off to. I just want to make sure that everybody is     |
| 19 | okay with the way that we're moving through these and  |
| 20 | is bringing up the topics that they want to make sure  |
| 21 | are discussed. Stan.                                   |
| 22 | MR. FITCH: Probably the one group of                   |
| 23 | people that are the most able to comment on radiation  |
| 24 | protection and how it affects your license or the      |
| 25 | licensing process are licensees or license applicants. |

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| 1  | This is certainly the opportunity for them to work     |
| 2  | with the licensing agency.                             |
| 3  | To be able to speak for my own state, I                |
| 4  | can tell you that many times we go back to the license |
| 5  | applicant or the licensee and ask for clarification on |
| 6  | several issues. This is certainly an opportunity for   |
| 7  | them to express themselves to express what they see to |
| 8  | be their program and anything they might have so we    |
| 9  | can suit the license to meet their needs. I would      |
| 10 | really encourage people to do that.                    |
| 11 | Recently, I reviewed a lengthy application             |
| 12 | for a fuel enrichment facility proposed for New        |
| 13 | Mexico. Looking at the application, I realized that    |
| 14 | it was technically speaking left a lot of be desired.  |
| 15 | It's probably 20 percent of what I've been looking for |
| 16 | in a way of somebody processing a licensing            |
| 17 | application.   |
| 18 | So if the stakeholders, the licensees,                 |
| 19 | especially need to express themselves better to the    |
| 20 | regulatory bodies in what they're looking for. Tell    |
| 21 | us what you see to be the health and safety issues or  |
| 22 | tell us what you see be your operational challenges.   |
| 23 | We can't anticipate those. We really have to be told   |
| 24 | what they are.   |
| 25 | MR. RAKOVAN: Thank you, Stan. Wow, I                   |

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don't see any tents up. If that's the case, then I'm going to push on. Ruth, what are you going to do to me? Ruth.

4 MS. McBURNEY: Well, just coming from the 5 Pilot 1 project standpoint, I was just going to try to address on some of these roles and responsibilities 6 7 and the budget issue just make a couple of comments. As has been mentioned, there probably is no line item 8 9 in the state budget or in NRC's budget that would 10 specifically address the National Materials Program. However, as Paul mentioned, there is support of 11 working groups in NRC's basis and also what will come 12 out as some high priorities as we mention in our 13 report, a lot of these were already on NRC's top list 14 15 anyway.

Likewise, there are lines items -- Of 16 17 course, OAS doesn't have a real budget yet, but CRCPD certainly has a budget and the support of the 18 19 Suggested State Regs Working Groups and other working groups as part of their budget. Based on that, I 20 think how this will work into the budgets of both the 21 organizations and NRC will be more important than what 22 an individual state is bringing to the table in the 23 24 form of money. What they are bringing is they are paying the salaries of those people who are working on 25

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| 1  | these working groups and the time that's involved.     |
| 2  | The other thing is we've been tasked with              |
| 3  | working as the Priorities Committee in establishing    |
| 4  | not only what the priorities are but for those top     |
| 5  | ones, how most effectively to get those done. We'll    |
| 6  | probably be based on the topic specific thing going to |
| 7  | some of these organizations and saying what sort of    |
| 8  | expertise can you bring to this particular issue.      |
| 9  | For example, one of them may be the safety             |
| 10 | review of the General License Program. We will         |
| 11 | probably be going to some of the manufacturers. Or if  |
| 12 | there is a group of manufacturers that can bring some  |
| 13 | expertise to that as well as to the regulatory         |
| 14 | agencies.  |
| 15 | MR. RAKOVAN: Okay. Thank you. I'm going                |
| 16 | to push on to the next set of topics, Mission and      |
| 17 | Scope. "Is the current National Materials Program      |
| 18 | meeting national needs? If not, how could it be        |
| 19 | changed? How would you define a successful National    |
| 20 | Materials Program" which I believe is something that   |
| 21 | popped up earlier that we said was on the list and     |
| 22 | that we'd get to. So I guess now is the time.          |
| 23 | I'm going to throw in the second question              |
| 24 | that's in there too. That's something that's popped    |
| 25 | up a few times too. Should the National Materials      |

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| 1  | Program include regulatory authority over all          |
| 2  | radioactive materials such as AEA materials, NORM,     |
| 3  | NARM? I see tents all ready. Mr. Anderson.             |
| 4  | MR. ANDERSON: Ralph Anderson, Health                   |
| 5  | Physics Society.                                       |
| 6  | MR. RAKOVAN: Could you speak more into                 |
| 7  | your mike please?                                      |
| 8  | MR. ANDERSON: Sure. Ralph Anderson,                    |
| 9  | Health Physics Society. It would be the most           |
| 10 | appropriate opportunity for me to provide an input     |
| 11 | that is very important to the Society. That goes to    |
| 12 | both questions really so I'll start with the second    |
| 13 | question. Yes, the reasoning is that we think one of   |
| 14 | the key success measures ought to go to the issue of   |
| 15 | reducing the extent of and ultimately preventing       |
| 16 | orphan sources.  |
| 17 | We have a position on that subject and we              |
| 18 | spread that around enough. I'm sure the agencies have  |
| 19 | seen that a number of times. CRCPD has positions on    |
| 20 | that. But we think that among other things that a      |
| 21 | plan to enhance the National Materials Program ought   |
| 22 | to have integrated into that how that will improve the |
| 23 | situation with orphan sources. Again that's what       |
| 24 | leads to a yes answer on number 2. A source is a       |
| 25 | source is a source.                                    |

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| 1  | MS. FAIROBENT: Number 2 being "If not,                 |
| 2  | how could it be changed?"                              |
| 3  | MR. ANDERSON: No, number 2 "Should the                 |
| 4  | National Materials Program include regulatory          |
| 5  | authority over all radioactive materials?" A simple    |
| 6  | answer. Yes.   |
| 7  | MR. RAKOVAN: Okay. Ms. Fairobent.                      |
| 8  | MS. FAIROBENT: Yes. First off in                       |
| 9  | answering, we do have a National Materials Program     |
| 10 | now. It does in the broadest sense include regulatory  |
| 11 | authority over everything if you take all of the       |
| 12 | entities collectively together. What we don't have is  |
| 13 | we do not have a Federal agency that has single        |
| 14 | authority over all of the materials. But collectively  |
| 15 | between the states and NRC, we do have an integrated   |
| 16 | program that has it.                                   |
| 17 | I'm not going to give it a yes or no                   |
| 18 | answer as far as from the College's perspective on     |
| 19 | whether or not NRC's authority should be broadened to  |
| 20 | include non-AEA material. But from a health physicist  |
| 21 | standpoint, my personal view is much of what we're     |
| 22 | discussing today we're in the dilemma based on the way |
| 23 | in which the original legislation was enabled because  |
| 24 | it had nothing to do with risk. It had nothing to do   |
| 25 | with source of origin or did have to do with source of |

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| 1  | origin. It had no other basis in that, but that was    |
| 2  | the way in which everything was structured before      |
| 3  | then.  |
| 4  | If we are going to proceed to a risk-based             |
| 5  | system however, it does make sense that the elements   |
| 6  | of the program are all the same. Because whether       |
| 7  | iodine is processed from a reactor or whether iodine   |
| 8  | comes from an accelerator, the health and safety risk  |
| 9  | and the implications to the patient or the environment |
| 10 | or to the public or even to the workers are all the    |
| 11 | same. So there are some pros and cons for broadening   |
| 12 | authority and integrating everything together.         |
| 13 | I think defining a successful National                 |
| 14 | Materials Program would come about when we stop asking |
| 15 | what it is because I think that would be the first     |
| 16 | step of success. I think it becomes then transparent   |
| 17 | because I do think it's just a title for how we do     |
| 18 | business and how the process works.                    |
| 19 | The pieces of the program that we're                   |
| 20 | trying to redefine into something under a uniform      |
| 21 | title are in fact meeting national needs. One could    |
| 22 | say though how successfully and that's a very          |
| 23 | different question and you're going to get a very      |
| 24 | different answer depending on what part of the         |
| 25 | industry you're in. But I don't think we are missing   |

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1 anything in the true broad, collective sense of how we all carry out our jobs and functions. 2 3 I mean overall we do provide adequate 4 protection to public health and safety and the 5 environment. I think that should not be lost. As we move forward to change whatever it is we're doing, 6 we're not changing because we haven't been doing 7 8 everything else to the best of our ability to date. 9 We're not changing because something is drastically 10 wrong and needs fixing. We're trying to make a better wheel, but we're not trying to make a new wheel. 11 MR. RAKOVAN: Mr. Smith. 12 This is Leonard Smith with 13 MR. SMITH: 14 I agree very much with what Ralph and Lynne CORAR. 15 have been saying. I would just like to add a 16 practical recommendation. If NRC was to take on the regulation of NARM, I think the cut point should be 17 the accelerator facility should be left where it is 18 19 with the states. But if you take material out of that facility, then it should come under NRC jurisdiction. 20 That's actually rather similar to the way that you cut 21 things between the agreement states when you look at 22 power reactor versus radioactive materials that's 23 24 generated in the reactor that could be removed from the facility. 25

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| 1  | Another thought. One of the problems of                |
| 2  | course is yes, we are trying to differentiate between  |
| 3  | accelerator and the material from the point of view of |
| 4  | regulatory compliance. Another definition that really  |
| 5  | could be improved is the definition of waste. That     |
| 6  | has provided a lot of problems with both the public    |
| 7  | and the licensees and everybody.                       |
| 8  | MR. RAKOVAN: If we can go to Margaret                  |
| 9  | Federline please.                                      |
| 10 | MS. FEDERLINE: Yes, Lance, I want to make              |
| 11 | sure. Can we also talk about what makes the program    |
| 12 | a success?   |
| 13 | MR. RAKOVAN: Certainly. That's all part                |
| 14 | of this.   |
| 15 | MS. FEDERLINE: Okay. I see three main                  |
| 16 | challenges that I think are going to define success of |
| 17 | the program at least in my view. The first is to       |
| 18 | define outcomes early, to see stakeholders, the states |
| 19 | and NRC working together to define the outcomes early. |
| 20 | That will help us in defining adequate resources. I    |
| 21 | think adequate resources are the other key point that  |
| 22 | I see.   |
| 23 | I see it a little differently. I don't                 |
| 24 | necessary see that we need to get a commitment in      |
| 25 | state budgets or our budgets, but budgets are going to |

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| 1  | shrink. I think we need to bring more parties into     |
| 2  | the pool. If the state doesn't have a resource and we  |
| 3  | don't have a resource, then perhaps we need to bring   |
| 4  | in the professional societies or others who do have    |
| 5  | available resources. So we're going to have to make    |
| 6  | the existing resources that we have work.              |
| 7  | I think the third element of success is                |
| 8  | stakeholder acceptance of the product. I think if the  |
| 9  | National Materials Program doesn't develop products    |
| 10 | that are acceptable to the stakeholders and that means |
| 11 | both the public and the licensees that's going to be   |
| 12 | a key criteria. From what Ralph says, it means early   |
| 13 | involvement of those people to make sure that we       |
| 14 | understand the problems up front. Thank you.           |
| 15 | MR. RAKOVAN: Ken.                                      |
| 16 | MR. WANGLER: I guess I would on that                   |
| 17 | second part of that question state yes. It should      |
| 18 | include all radioactive material. Then Lynne, you say  |
| 19 | that we're covering all the fields now. I won't        |
| 20 | challenge that but who covers PET in non-agreement     |
| 21 | states? Are all the states covering that? Do we        |
| 22 | know?  |
| 23 | MS. FAIROBENT: I wouldn't say that.                    |
| 24 | Lynne Fairobent. In answer to that, I wouldn't say     |
| 25 | all the states are covering it to the same extent or   |

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| 1  | perhaps to the same quality.                           |
| 2  | MR. WANGLER: Are they covering it at all?              |
| 3  | I mean are there any states that don't have any        |
| 4  | regulation on cyclotron generated material right now?  |
| 5  | MS. FAIROBENT: I can think of one right                |
| 6  | now off the top of my head that I don't think does.    |
| 7  | And that is part of the problem with there not being   |
| 8  | any overall or overarching vehicle. But I did want to  |
| 9  | follow up. One concern I would have is if NRC          |
| 10 | authority gets broadened over to the areas that have   |
| 11 | historically have been the jurisdiction of the states. |
| 12 | I would be very concerned or I would issue             |
| 13 | the caution that that expertise that's in the states   |
| 14 | not be overlooked or diminished because I think that's |
| 15 | where the expertise in those areas definitely has      |
| 16 | resided. Margaret, that gets a little bit to your      |
| 17 | statement on having adequate resources.                |
| 18 | Along with that, it's not simply the                   |
| 19 | number of resources, but it's the right mix of talents |
| 20 | and is becoming more and more challenging for many of  |
| 21 | the regulatory agencies. Both Federal and at the       |
| 22 | state levels, as pardon the expression those of us who |
| 23 | have been in the field are getting older and nearly    |
| 24 | retirement, three is not so much new bloodline coming  |
| 25 | in many of these areas because there's not been new    |

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1 opportunity for growth in many of them. I think that that is one of the biggest collective challenges that 2 3 we have is ensuring that there is continuity and 4 understanding that there remains a sound technical and 5 scientific basis in the resources that are working on the technical issues as they confront us all. 6 7 MR. RAKOVAN: George. 8 MR. PANGBURN: George Pangburn, Region 1. 9 Going back to the first question, is the program 10 meeting national needs? I think it met national needs ten years ago if we define national needs as being 11 assuring that we were adequate protection public 12 health and safety. I don't think that was ever the 13 14 question. The question is really if we weren't, we'd all be in big trouble, states and the NRC. 15 I think we first saw this term evolve if 16 17 memory serves me correctly as I near retirement that increasingly is less frequently was in one of the 18 19 Integrated Commission papers on the Materials Performance Evaluation Program. We talked about the 20 concept of the National Materials Program by getting 21 agreement states on the teams that were doing the 22 actual reviews and in the Management Review Board. 23 24 We've moved a long ways since then to where working groups as Paul and Carl mentioned this 25

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| 1  | morning were routinely staffed. The question is is    |
| 2  | that sufficient to define success. Have we come far   |
| 3  | enough to say we've done it and this is as good as we |
| 4  | can get? Or is there another increment to go?         |
| 5  | I think defining success in that sense                |
| 6  | means that we do have a little bit further to go.     |
| 7  | It's the task of these working groups and ultimately  |
| 8  | the paper that goes on up to the Commission may help  |
| 9  | to define what an ultimate, if you will, National     |
| 10 | Materials Program might look like. I think we always  |
| 11 | need to keep in mind just how far we've come from a   |
| 12 | point where rules came out and went to states in very |
| 13 | short notice with very little time frame for comment  |
| 14 | to where states are intimately involved in the        |
| 15 | development of those rules and guidance documents     |
| 16 | before they are issued.                               |
| 17 | MR. RAKOVAN: Margaret.                                |
| 18 | MS. FEDERLINE: I keep forgetting.                     |
| 19 | MR. RAKOVAN: Sorry.                                   |
| 20 | MS. FEDERLINE: Thank you for waking me                |
| 21 | up.   |
| 22 | MR. RAKOVAN: Ken.                                     |
| 23 | MR. WANGLER: You know, George, I'm not                |
| 24 | sure that I agree that we're adequately covering all  |
| 25 | the bases. I look at North Dakota. We have the        |

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| 1western part of the state which has a fairly prolific2oil industry. A lot of NORM generated. We do very3little with it. We're on a reactionary basis only4because it's not a priority on our plate.5One of the things I said about IMPEP was6that it conditions the states to respond to the things7that we all think are important. I said this at a8previous meeting. That's true. So IMPEP has improved9us in the areas that get reviews, but it's done10nothing to move us towards NORM regulation. One state11does nothing with cyclotron material. That's becoming12fairly common. Cyclotron material is a pretty13significant radiation hazard or can be. I don't know14that I'd necessarily agree that we're covering all the15bases. I wouldn't go that far.16MR. RAKOVAN: Mr. Anderson.17MR. ANDERSON: Ralph Anderson, Health18Physics Society. Margaret, you triggered my thinking19in another arena as well. You made the observation20which I think is a very good one that to offset the21predictable reductions in available resources in terms |    | 216  |
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|   | 19 | in another arena as well. You made the observation     |
| 21 predictable reductions in available resources in terms   | 20 | which I think is a very good one that to offset the    |
|   | 21 | predictable reductions in available resources in terms |
| of budget, one good strategy is to broaden the pool in  | 22 | of budget, one good strategy is to broaden the pool in |
| 23 terms of available resources. I would add to that and  | 23 | terms of available resources. I would add to that and  |
| 24 suggest that a feature you might want to look at   | 24 | suggest that a feature you might want to look at       |
|   | 25 | actively integrating into the goals and objectives of  |

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| 1  | the program is the continued development of resources  |
| 2  | to provide and an adequate number of resources to      |
| 3  | assure that protection of health and safety.           |
| 4  | All of the studies that are coming really              |
| 5  | predict really grim news in the five to 15 year time   |
| 6  | frame in the field of radiation safety. Health         |
| 7  | Physics Society will be putting its report out a       |
| 8  | little later this year. My day job at NEI, we're       |
| 9  | already fully understanding that information among the |
| 10 | whole fuel cycle complex. For the program in my mind   |
| 11 | to be successful, one element of it needs to be to     |
| 12 | provide for that. You mentioned before what are key    |
| 13 | assumptions that are being made. I think that one      |
| 14 | needs to be pivotal in the process.                    |
| 15 | What I would like to add to that is                    |
| 16 | looking at Pilot Project No. 2 I think. Is that the    |
| 17 | training qualifications of radiographers? Industrial   |
| 18 | radiographers, that becomes in my mind a good model    |
| 19 | for another issue which is if we're going to           |
| 20 | potentially have fuel resources available, there needs |
| 21 | to be an effective process for assuring that those     |
| 22 | people charged with radiation safety under the license |
| 23 | have the adequate expertise to do so.                  |
| 24 | I look at that program and it just screams             |
| 25 | out to me "Boy, that's analogous to what we probably   |

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| 1  | need in a number of areas with direct radiation safety |
| 2  | responsibility." Our countries have already            |
| 3  | recognized that because they are farther along on the  |
| 4  | resource curve than we are and they have created       |
| 5  | standardized certification testing and requirements    |
| 6  | for key radiation safety positions that if you want to |
| 7  | have a license you have to have somebody that meets    |
| 8  | these requirements. So those kinds of issues should    |
| 9  | be well integrated into this process as an extension   |
| 10 | of Pilot Program No. 2.                                |
| 11 | MR. RAKOVAN: Okay. Stan Fitch.                         |
| 12 | MR. FITCH: I think you have to answer the              |
| 13 | question, is the current national geo-sporger (PH)     |
| 14 | meeting national needs? I would say yes, not as        |
| 15 | efficiently or as effectively as possible. However     |
| 16 | having dose-based standards insures that licensees and |
| 17 | registrants in the states for instance use non-AA      |
| 18 | material are required to meet the most basic standards |
| 19 | which are for whole body dose or for organ dose, that  |
| 20 | sort of thing. So in that sense, it is.                |
| 21 | If we go and amend the Act, the Congress               |
| 22 | is going to put in there that it's incumbent upon the  |
| 23 | NRC to do this. The response is going to be on the     |
| 24 | NRC to do it when the centers of expertise are in the  |
| 25 | states for non-AA material. So the states for some     |

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1 time have been screaming that if this happens we want to make sure that the NRC comes to us for this to be 2 3 done because the work's already there. The 4 infrastructure is already in place and we can make a huge difference. However at the Congressional level, 5 they're not necessarily going to recognize that. 6 7 You have to careful what you ask for for 8 the states will scream long and hard especially at 9 things like the NORM regulations, like the NORM 10 regulations in my state. I don't know if anybody in the NRC had a piece in that. Yet we did something. 11 We sat down with the stakeholders. We sat down with 12 industry and with the environmental groups and with 13 14 our own radiation advisory council and we came up with 15 that were workable and obtainable for centers 16 everybody and met the cost. So things like that are 17 in place. MR. RAKOVAN: Seeing as there is no tents 18 19 up, we have a comment from the audience. James Myers, NRC. 20 Oh, James, it is this 21 MR. MYERS: afternoon. I'm Jim Myers. I'm with the Office of 22 State and Travel Programs. I worked on the National 23 24 Materials Program Working Group. From what I'm hearing here, I thought I'd just hopefully add a 25

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| 1  | little bit of perspective in this.                     |
| 2  | The working group that looked at National              |
| 3  | Materials Program thought about all of this stuff. We  |
| 4  | really did. Cindy can probably tell you that. Yes,     |
| 5  | she's shaking her head now. We probably spent - what   |
| 6  | do you think, Cindy - maybe about three meetings       |
| 7  | looking at different scenarios of how to make a        |
| 8  | national materials program. We went through every      |
| 9  | iteration that we could think of. We went looked at    |
| 10 | things.  |
| 11 | We got wild and crazy and said "Well you               |
| 12 | know actually the National Materials Program is        |
| 13 | actually what we're doing today." That's what we're    |
| 14 | doing today and that's what we continue to do. We're   |
| 15 | still doing this process of sharing of working groups, |
| 16 | of bringing people in and trying to get better advance |
| 17 | participation let's say in all those kind of things    |
| 18 | that you all are talking about. That is the program.   |
| 19 | So it shouldn't be any big surprise except             |
| 20 | that gosh, oh gee, we're already there. I think        |
| 21 | that's what Lynne was trying to say which was maybe to |
| 22 | move on. But you can agonize over it. I will say       |
| 23 | save yourself a lot of time because we did that for    |
| 24 | you and that was what we came up with. It was a        |
| 25 | program that really integrates all of the best things  |

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| 1  | and amplifies the best things that we saw in the      |
| 2  | existing program. That's National Materials.          |
| 3  | MR. RAKOVAN: Okay. We'll go to one more               |
| 4  | comment. Mr. Gallaghar from Massachusetts.            |
| 5  | MR. GALLAGHER: Bob Gallagher,                         |
| 6  | Massachusetts. I just wanted to point out for those   |
| 7  | of you who may not know the Serocipity (PH) does have |
| 8  | an active working group looking at standardizing the  |
| 9  | NARM/NORM regulations throughout the agreement states |
| 10 | and non-agreement states overall. So there's a        |
| 11 | national effort to bring all that into some semblance |
| 12 | of commonality.                                       |
| 13 | MR. RAKOVAN: Thank you.                               |
| 14 | MR. GALLAGHER: That will include doing an             |
| 15 | in-path like review of those programs.                |
| 16 | MR. RAKOVAN: Okay. What I'm going to do               |
| 17 | at this point since we haven't formally put them on   |
| 18 | the table even though there has been some discussions |
| 19 | on the challenges. I'm just going to go through the   |
| 20 | Challenges questions. "What challenges must be        |
| 21 | overcome to make the program a success? What are the  |
| 22 | key issues or areas that need to be addressed by a    |
| 23 | National Materials Program? What are the potential    |
| 24 | burdens on licensees and applicants?" I think in the  |
| 25 | flow of conversation we've touched on a few of these  |

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things, but I wanted to use the focus questions to focus our discussion. At this point, we can look at any of the questions besides the Future Direction. Essentially if there's a topic that you think needs discussion and an opinion that you want to interject, now would be a good time to do it. I'm going with Mr. Pangburn because I saw his tent go up first.

8 MR. PANGBURN: George Pangburn, Region 1. 9 Being a regional guy, I tend to focus on process and 10 implementation. So one of the questions I have and challenge I see is in those instances where products 11 would be developed by let's say a state's group as in 12 OAS working group. How would those products be taken 13 14 by NRC and somehow be implemented into something whether it's a rule or some other product that would 15 16 be used by NRC licensees.

I'm not sure I know the answer to that 17 I see that's a challenge that we as an question. 18 19 agency have to be in the role of recipient as opposed to the person that's taking the lead in putting 20 together the effort that we have to come up with. 21 Maybe that comes under the cultural baggage kind of 22 23 thing. 24 MR. RAKOVAN: Thank you, George. Mr.

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25 Dicharry.

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| 1  | MR. DICHARRY: Donnie Dicharry,                         |
| 2  | NDTMA/ASNT. To the extent that the alliance concept    |
| 3  | will need to involve numerous ad hoc working groups    |
| 4  | and standing committees at centers of expertise        |
| 5  | throughout the country and to the extent that they     |
| 6  | will also need to engage the participation of industry |
| 7  | and other private sector experts, it occurs to me that |
| 8  | one of the problems that might need to be overcome is  |
| 9  | to have non-governmental participation that does not   |
| 10 | automatically trigger all of the public notice         |
| 11 | requirements that otherwise might be involved. I       |
| 12 | notice that I'm the only industry participant in any   |
| 13 | of these working groups.                               |
| 14 | Yet I should explain that I am here by                 |
| 15 | virtue of my participation on the G-34 Committee of    |
| 16 | CRCPD. Otherwise, I'm just wondering whether or not    |
| 17 | we would have had to have posted a public notice in    |
| 18 | advance of everyone of the 39 telephone conferences    |
| 19 | that we had. That's just one issue that perhaps        |
| 20 | should go in the parking lot.                          |
| 21 | MR. LOHAUS: Let me comment on that                     |
| 22 | because that is a very important aspect and it was     |
| 23 | mentioned this morning and I thought I'd wait until    |
| 24 | this afternoon to talk about this. But the conference  |
| 25 | committee process as Ruth and Cindy discussed includes |

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| 1  | opportunity to have advisors that are outside of NRC   |
| 2  | or agreement state government if you will.             |
| 3  | If you actually even look at NRC                       |
| 4  | participation, NRC participation is really identified  |
| 5  | as a resource representative. It's really a            |
| 6  | conference committee and it has advisors that may be   |
| 7  | licensee, industrial, medical, educational that serve  |
| 8  | and there are also NRC resource reps that serve on at  |
| 9  | least some of those committees as well. But as Donnie  |
| 10 | points out, when you move into the NRC/agreement state |
| 11 | working group process which is under Federal law, we   |
| 12 | have the ability to operate in that as a working group |
| 13 | with states and Federal representatives.               |
| 14 | But once you bring in other stakeholder                |
| 15 | interest, there's a formality to the process, the      |
| 16 | Federal Advisory Committee Act, that comes into play   |
| 17 | and it does carry with it specific requirements in     |
| 18 | terms of appointment of individuals, noticing of       |
| 19 | meetings and how meetings are conducted and a whole    |
| 20 | series of pretty formal requirements that go with      |
| 21 | that. Under the working group process, we follow the   |
| 22 | guidelines that are set out in the Federal Advisory    |
| 23 | Committee Act, but there's not a binding requirement   |
| 24 | if you will that all of those be followed.             |
| 25 | That's the reason that there's a                       |

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1 difference in one of the working groups. The reason is that we use the existing conference committee which 2 has advisors and we did not want to disturb that. 3 But 4 at the same time, we did not want to violate if you 5 will or affect the fact that we cannot have as a direct member of the working group, if you will, a 6 7 party outside of the Federal or state government. So it's a little bit of a fine line. 8 We 9 are using an existing conference committee. We did 10 not want to effect that because that was part of the intent of the pilot. It was to use the conference 11 committee as the group that would demonstrate that 12 yes, the conference can take on the job of having a 13 14 National Radiography Certification Program for the If that's how that committee functions 15 nation. including advisors, we did not want to force a change 16 17 to that process. So I hope that's clear. Maybe Cindy or 18 19 others may want to comment further on that. But that's the reason for that. At the same time, we've 20 heard and it's on the list that we need to look at how 21 we involve stakeholders in the public early in the 22 That's an area for further consideration and 23 process. 24 part of the working groups in looking at the program. But I don't know if others may want to comment on this 25

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| 1  | aspect. Cindy or others? That's the genesis and        |
| 2  | reason.  |
| 3  | MR. RAKOVAN: I'm going to go table                     |
| 4  | members first. Dr. Johnsrud.                           |
| 5  | DR. JOHNSRUD: Judith Johnsrud. I have to               |
| 6  | say, Paul, I'm troubled by what you just said because  |
| 7  | that sounds to me as though you're skating on a pretty |
| 8  | thin layer of ice with regard to FACA. Really it       |
| 9  | almost reverses everything that has been said          |
| 10 | previously about wanting input of the public of those  |
| 11 | who are ultimately affected by the regulatory          |
| 12 | decisions as well as violating the spirit of FACA.     |
| 13 | Thus all of this work that has gone on has             |
| 14 | been without any opportunity for input for access to   |
| 15 | the discussions by the public at large or even         |
| 16 | representatives through public interest organizations. |
| 17 | That seems to me very contrary to the spirit of what   |
| 18 | I thought you were doing.                              |
| 19 | MR. LOHAUS: If that's how you interpret                |
| 20 | it, that's not what I intended if you look at the      |
| 21 | process that we've tried to follow going back to the   |
| 22 | initial <u>Federal Register</u> notice.                |
| 23 | DR. JOHNSRUD: Which would have been when?              |
| 24 | MR. LOHAUS: I'll have to rely on my staff              |
| 25 | to give me the dates, but this goes back to probably   |

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| 1  | when we started these would be in the late 2002 time    |
| 2  | frame. But what we tried to do was we tried to follow   |
| 3  | a similar process that what we had used for the         |
| 4  | earlier working group where we set a place up on our    |
| 5  | website. We published a <u>Federal Register</u> notice. |
| 6  | The meeting announcements for the working               |
| 7  | group meetings were published and made available. The   |
| 8  | meetings were open meetings if you will. There was      |
| 9  | opportunity to provide feedback and comment based on    |
| 10 | information that was posted at the website. So I        |
| 11 | think the intent - and part of the spirit is having     |
| 12 | this meeting as well - was to provide additional        |
| 13 | opportunity for stakeholder input and to seek views.    |
| 14 | But what I was trying to respond to though              |
| 15 | was the specific question on why there was a            |
| 16 | representative that participated on to the G-34         |
| 17 | committee as a part of that process. But there was no   |
| 18 | intent to not provide for full opportunity in terms of  |
| 19 | both knowledge as well as opportunity for input into    |
| 20 | the process.  |
| 21 | DR. JOHNSRUD: And was that person then a                |
| 22 | formal invitee if you will and participant and were     |
| 23 | there comparable invitations then issued to             |
| 24 | representatives of other stakeholders if you will?      |
| 25 | MR. LOHAUS: I guess what I will do is                   |

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| 1  | maybe defer to the working group, but my sense is that |
| 2  | the committee was used as the "working group" if you   |
| 3  | will. That committee included the advisor, but I'll    |
| 4  | defer to the chairs of the working group for a more    |
| 5  | direct answer on that question.                        |
| 6  | MR. RAKOVAN: Jan.                                      |
| 7  | MS. ENDAHL: Jan Endahl. Yes, Paul, you                 |
| 8  | are correct. The committee was the group elected for   |
| 9  | use and the committee members as they were intact were |
| 10 | the ones who participated. Like I mentioned earlier,   |
| 11 | Donny was a double representative both for ASNT and    |
| 12 | NDTMA. During the process, ASNT has requested that     |
| 13 | another individual be their representative and he has  |
| 14 | since joined CRCPD and has joined G-34 as an advisor.  |
| 15 | Because we were in the middle of our project, he did   |
| 16 | not join us in the activities. Donnie remained as the  |
| 17 | representative for both ASNT and NDTMA during the      |
| 18 | duration of the project.                               |
| 19 | MR. RAKOVAN: Okay.                                     |
| 20 | MS. CARDWELL: Jan makes an excellent                   |
| 21 | point that Ken just whispered in my ear as well. The   |
| 22 | advisors on the CRCPD committees are members of the    |
| 23 | CRCPD. They are affiliate members and both qualify in  |
| 24 | terms of that category of membership.                  |
| 25 | MR. RAKOVAN: Donnie, did you have a                    |

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| 1  | comment this context?                                  |
| 2  | MR. DICHARRY: Yes, I just wanted to point              |
| 3  | out that as a stakeholder I had no more rights or      |
| 4  | opportunities to join CRCPD and volunteer my           |
| 5  | participation to them than you or anyone else or any   |
| 6  | member of the public would have.                       |
| 7  | MR. RAKOVAN: We're going to go to outside              |
| 8  | real quick and then, Mike, I promise I will get to     |
| 9  | you. Jim, very briefly please.                         |
| 10 | MR. MYERS: Very quickly, I would also say              |
| 11 | that in terms of the G-34 committee the actual members |
| 12 | of the committee - and correct me if I'm wrong - are   |
| 13 | Jan Endahl, David Turberville and Lauren Palmer from   |
| 14 | Georgia. They are the actual members of the            |
| 15 | committee. Even my participation is under an advisory  |
| 16 | capacity because I'm not a member of the committee.    |
| 17 | I'm just there to help. So there are lots of advisors  |
| 18 | and few members.                                       |
| 19 | MR. RAKOVAN: Mike Markley.                             |
| 20 | MR. MARKLEY: Mike Markley, NMSS. Pilot                 |
| 21 | 3 made a very deliberate effort to try to interact and |
| 22 | seek early feedback in a public meeting with the       |
| 23 | ACMUI. We came back middle stage in a public meeting   |
| 24 | with the ACMUI. We also had a public notice and        |
| 25 | published telecon bridge number for public meeting on  |

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| 1  | an interview we held with Bob Emory at the University  |
| 2  | of Texas who had done work relevant to our project.    |
| 3  | So we've really tried very hard in soliciting and      |
| 4  | getting public participation at each stage of the      |
| 5  | process to the extent that we can. Thank you.          |
| 6  | DR. JOHNSRUD: It was not clear from what               |
| 7  | you said, Paul.  |
| 8  | MR. LOHAUS: Okay. Thank you.                           |
| 9  | MR. RAKOVAN: Cindy.                                    |
| 10 | MS. CARDWELL: I think what Dr. Johnsrud                |
| 11 | brings up is a communication issue. We ran into this   |
| 12 | problem with the initial National Materials Program    |
| 13 | every single meeting and we met every six weeks. It    |
| 14 | was noticed, but we had someone - I believe it was the |
| 15 | lady sitting right next to you this morning - show up  |
| 16 | the very first time and not again because it was such  |
| 17 | ethereal idea at the time. There wasn't a lot to be    |
| 18 | able to comment on.                                    |
| 19 | This appears to be some of the same kind               |
| 20 | of thing with people who are new to what we've been    |
| 21 | working on. But it's a matter of the opportunities     |
| 22 | are there. How do we communicate better obviously      |
| 23 | than what we're doing that those opportunities are     |
| 24 | there? It's a good point.                              |
| 25 | DR. JOHNSRUD: I think this does exemplify              |

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| 1  | the nature of the problem.                             |
| 2  | MR. RAKOVAN: Before we move on to Future               |
| 3  | Direction, are there any other Focus questions that    |
| 4  | anyone has something that they would like to comment   |
| 5  | on, bring up one last time? Wow, we're doing better    |
| 6  | than I thought. Okay. Moving on to Future Direction.   |
| 7  | Given everything that we've discussed and everything   |
| 8  | that we've gone over today, "How should the work of    |
| 9  | the Pilot Projects be incorporated into the National   |
| 10 | Materials Program? Should there be additional work?    |
| 11 | If so, what are the next steps?" Paul.                 |
| 12 | MR. LOHAUS: I'll start here and I think                |
| 13 | this point has already been covered, but it's sort of  |
| 14 | the question of if you take the results of the pilots  |
| 15 | and you take where the program is today and we were to |
| 16 | continue to function along those lines, have we gone   |
| 17 | far enough or are there additional things that are     |
| 18 | critical to incorporate into the program? I think to   |
| 19 | me that's one of the key questions or may be the key   |
| 20 | question here.   |
| 21 | I think what I've heard is there are some              |
| 22 | additional things that we need to think about and      |
| 23 | factor into the program. That's sort of the key issue  |
| 24 | which is given where we are, given what we've done     |
| 25 | with the pilots if we were to bring that to an         |

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| 1  | operating framework, is that sufficient? Or what       |
| 2  | additional things do we need to make sure are covered  |
| 3  | in there?  |
| 4  | One of the items I want to come back to                |
| 5  | which we didn't really touch on - and I think Leonard  |
| 6  | Smith and many others touched on this, but I remember  |
| 7  | you mentioning this too and it's covered in one of the |
| 8  | potential burdens on licensees and applicants - is the |
| 9  | degree to which it's essential to have national        |
| 10 | coherence.   |
| 11 | I don't want to use the word uniformity                |
| 12 | but there's a degree of coherence and consistency      |
| 13 | across the nation, if you will, so that the            |
| 14 | requirements are known. There is predictability.       |
| 15 | There is understanding. If you cross multiple          |
| 16 | jurisdictions, there aren't wide variation. But        |
| 17 | that's sort of a question I think too that's a         |
| 18 | challenge for the program particularly when you look   |
| 19 | at 33 states in NRC. I think that may be too many.     |
| 20 | I'd like to put that in as part of this as well.       |
| 21 | MR. RAKOVAN: I'm going to go in the order              |
| 22 | that I saw the tents go up starting with Mr. Anderson. |
| 23 | MR. ANDERSON: I'll just keep it short.                 |
| 24 | One thing I think you need to look at is how to more   |
| 25 | explicitly integrate the sixth pilot program.          |

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| 1  | Security is an integral part of being licensed these   |
| 2  | days and regulating licensees. Without that, you're    |
| 3  | just ignoring it as part of the progress.              |
| 4  | MR. RAKOVAN: Cindy.                                    |
| 5  | MS. CARDWELL: I would say, Paul, our next              |
| 6  | step - I don't think we've gone quite far enough, but  |
| 7  | we're still at the baby steps stage. My steps are the  |
| 8  | baby steps first. I think we have to integrate the     |
| 9  | processes that have all been created and piloted here. |
| 10 | Along with the suggestions, we still have to address   |
| 11 | the stakeholder issue. I don't think we've adequately  |
| 12 | addressed that at all from all standpoints, from the   |
| 13 | organizations, the states as well as NRC.              |
| 14 | Then after that, I think we look around                |
| 15 | and the next step after integrating that is the        |
| 16 | acceptance phase. We've all talked about the cultural  |
| 17 | baggage thing. Can we accept, can everybody accept,    |
| 18 | what some of these products come out of here? If we    |
| 19 | integrate them, is there an acceptance of that? Then   |
| 20 | after that, we stop and assess. Now where do we go?    |
| 21 | So we're still in the baby step stage, but we're a lot |
| 22 | closer. But we're taking those steps down the same     |
| 23 | path this time instead of different paths.             |
| 24 | MR. RAKOVAN: Ms. Roughan.                              |
| 25 | MS. ROUGHAN: Kate Roughan, AEA                         |

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| 1  | Technology. In terms of the question of consistency,   |
| 2  | I believe in the original working group one of the     |
| 3  | objectives was to have uniformity among all the states |
| 4  | so licensing would be uniform. Again uniformity is     |
| 5  | not the right word, but consistent and compatible to   |
| 6  | make it easier for all licensees to comply as they     |
| 7  | cross state boundaries and also for the manufacturers  |
| 8  | and distributors to supply the appropriate license     |
| 9  | product to the various states.                         |
| 10 | MR. RAKOVAN: Dr. Johnsrud.                             |
| 11 | DR. JOHNSRUD: Judith Johnsrud. I                       |
| 12 | continue to see the likelihood that there are          |
| 13 | differences in the degree of control between and among |
| 14 | states depending upon their industrial nature and      |
| 15 | various contaminants in the biosystem and therefore,   |
| 16 | differing states may have greater needs for greater    |
| 17 | restrictions than other. At the same time, the idea    |
| 18 | of some degree of national uniformity certainly at the |
| 19 | base is very important. But always, there needs to be  |
| 20 | a mechanism for those that need to go beyond those     |
| 21 | basic requirements to be more protective of their      |
| 22 | populations and environments.                          |
| 23 | MR. RAKOVAN: Ms. Federline.                            |
| 24 | MS. FEDERLINE: Yes, I would just like to               |
| 25 | urge us as part of our process to have an annual       |

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| 1  | meeting where we sit down with the key stakeholders    |
| 2  | and look ahead, look three to five years ahead, and    |
| 3  | ask ourselves what's coming down the pike. I think it  |
| 4  | would be an important input to the prioritization      |
| 5  | process that we define to take a long term look.       |
| 6  | MR. RAKOVAN: Mr. Fitch.                                |
| 7  | MR. FITCH: When we approach the idea of                |
| 8  | the materials security when the Commission authorized  |
| 9  | the creation of Material Security Working Group and    |
| 10 | their steering committee, it was said at that time     |
| 11 | that it would probably be the greatest test of         |
| 12 | something similar to the National Materials Program.   |
| 13 | In that case, it has probably been a pilot. Virtually  |
| 14 | all of our considerations constitute safeguards in the |
| 15 | atomic hearing so they can't be discussed here and     |
| 16 | obviously we can't always get public members involved  |
| 17 | like industry because of the fact that it does         |
| 18 | constitute safeguards.                                 |
| 19 | Nevertheless what we did and what will be              |
| 20 | done in the future was to see areas where impression   |
| 21 | stood out in our minds about whether or not we're      |
| 22 | actually hitting the nail on the head. Do we need to   |
| 23 | go out to industry? Do we have stakeholder meetings?   |
| 24 | That has been the case to date with the larger         |
| 25 | manufacturers and distributors where we have           |

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stakeholder meetings. It will be so in the future for whatever decisions are made to try to gain additional understanding.

4 But you have to understand about Material 5 Security Working Group is the fact that we're working under the constraints of terrorism of trying to act as 6 7 quickly as possible and a lot of people want to say 8 "Well gee, it's not real quick." But when you 9 consider the breadth and the scope of everything 10 that's involved, it takes some time to do. So you sit down and you sit in the back of the room and find ways 11 of working with each other. 12

For the states in the beginning, there 13 14 were some issues because we felt like it was more 15 focused on the NRC position and not so much on the So what we learned to do was we learned to 16 states. 17 scream and yell and make lots of noise and kick, fight, scratch, whatever. There were some changes on 18 19 the working group and along the way, it became a very 20 receptive process where we could actually have significant input towards something good. 21

I would say that in light of National Materials Program, this was an unabashed success. This is fantastic and it continues to be a fantastic success just simply because of the fact that the NRC

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recognized that they within themselves cannot be it, the sole voice within Materials Security. They had to 2 3 have other people involved. When you have something of national importance such as terrorism, you have to broaden your base of talent as far as you can. The state and the NRC would have lack the support of the 6 states. By getting the states involved, that means 8 that you not only have greater expertise behind you, 9 but you also had a greater support mechanism to help you out.

I would hesitate to go much further on 11 that currently because of the state - in fact, we have 12 information - except to say that we 13 safequards 14 probably have resembled very much the original 15 National Materials Program working group in the fact 16 that we've spent countless hours behind closed doors 17 choking each other and the stress at times gets very But at the same time, you learn to trust each 18 hiqh. 19 other. We cut somebody from the NRC and they bleed just like the people from the states and you get to 20 learn who people are and you learn to trust them. 21 Out of that, come significantly productive outcomes. 22

MR. RAKOVAN: I'm not going to ask about 23 24 that whole cutting and bleeding thing. Mr. Anderson. Yeah. Actually you almost 25 MR. ANDERSON:

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made my point. Obviously in the reactor world we've in safeguards for a number of years. 9/11 was a step up in the process. My comment is in listening to what you said it just reinforces it. What you've precisely done is dealt with all the cultural baggage issues on an expedited fashion and you've cut through the crap to put it simple.

That means there's probably a lot of 8 9 insights and lessons about process and framework that nothing to do with safeguards that are 10 have transferrable to use in moving forward with the 11 National Materials Program. That's my point. 12 I don't mean that you should take all the substantive data 13 14 that is in fact safeguards and put it on the table. 15 mean the processes that you had to invent Ι to 16 effectively integrate a large number of organizations 17 well beyond just state rad health.

You probably have a wealth of process knowledge there and that's where I see the value. It's to capture that and transfer that. I think that's what the Commission is looking for. First of all, you have an IOU from the Commission to say something on that, but that where I suspect that there's value.

MR. FITCH: Obviously I'm a co-chair. I

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have another co-chair that I work with. We do interacting in the background. You see what the challenge is and you get a vision. You talk with each other about what the vision should be and what needs to be accomplished.

Now you're not purposing yourself that 6 7 everything going to be exactly how you want it. But 8 you have a vision of what needs to be accomplished and 9 you'd be amazed what the talented people who are 10 behind are able to conceive behind your vision. So you say this is the golden light in the sky and we 11 have to reach for the golden light. Then they start 12 telling you "Well this is how we're going to reach for 13 14 that golden light." So you are able to direct your efforts. That's been a chief success in the efforts 15 16 of the working group. 17

MR. RAKOVAN: Dr. Johnsrud, do you haveyour tent up?

DR. JOHNSRUD: Oh, I beg your pardon.

20 MR. RAKOVAN: That's okay. I just wanted 21 to make sure. Any other comments? Questions? I'll 22 put this to the mercy of the group. Okay. Hold on. 23 MS. Fairobent.

24 MS. FAIROBENT: Well, a process question 25 of where we're going from this meeting. We have a lot

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| 1  | of items on the parking lot.                           |
| 2  | MR. RAKOVAN: That's where I was just                   |
| 3  | headed now.  |
| 4  | MS. FAIROBENT: It's already after 3:00                 |
| 5  | p.m.   |
| 6  | MR. RAKOVAN: Do people want to go and do               |
| 7  | a quick run-through of the issues that we put on the   |
| 8  | parking lot before we convene today?                   |
| 9  | MS. FAIROBENT: Yes.                                    |
| 10 | MR. LOHAUS: I think we should. Depending               |
| 11 | on interests, we can talk about each one. But I think  |
| 12 | we should review the list and make sure there's no     |
| 13 | areas that may have been raised that we may not have   |
| 14 | picked up on the list. I want to make sure we've       |
| 15 | captured everything. So I think let's do that, Lance.  |
| 16 | MR. RAKOVAN: And also please remember                  |
| 17 | that we are having this whole meeting transcribed so   |
| 18 | everything that's been said will be written down. We   |
| 19 | will be going through the transcript. I believe we'll  |
| 20 | try to get the transcript up on the National Materials |
| 21 | Program site so that if you were here or if you        |
| 22 | weren't here, everyone can take a look at what the     |
| 23 | discussions were. Lynne, you had a further point.      |
| 24 | MS. FAIROBENT: That's goes to my next                  |
| 25 | question because some transcripts go up within 48      |

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hours of the meeting occurring from NRC and others are four to six months. What sort of time frame would the 2 availability of the transcript from this meeting as well the slides that were handed out and Stan's slides from OAS being available on the website that could be shared with our members?

7 MR. RAKOVAN: The presentations, we can 8 get those up probably tomorrow. The transcription I 9 believe we asked for within a week. Hopefully we'll 10 have that up by the end of next week. So we're looking by the end of next week to have everything up. 11

This is Paul Lohaus. MR. LOHAUS: Yeah. 12 We have a contractor that we use to help us post our 13 14 information on the web and we have electronic copies 15 of everything. We could provide it to the contractor 16 and it's very quick. So I think within a week, not 17 more than two weeks, the information should be available there. 18

19 FAIROBENT: My real concern was MS. because of the discrepancy in the length of time it 20 takes to make some transcripts from NRC meetings 21 available publicly is really from the Commissioners' 22 meetings being up within 24 to 48 hours to some other 23 24 meetings not going up for six months to nine months. 25 I was hoping we weren't in the latter range for this

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| 1  | meeting.  |
| 2  | MR. LOHAUS: Right. We're not.                         |
| 3  | MR. RAKOVAN: Lynne, if you don't see it               |
| 4  | up within the next week, call me. Mr. Smith.          |
| 5  | MR. SMITH: Are you looking for further                |
| 6  | input after this meeting from the participants?       |
| 7  | MR. RAKOVAN: Always.                                  |
| 8  | MR. LOHAUS: Yes. As you reflect if you                |
| 9  | have additional thoughts and comments, please pass    |
| 10 | them on. You can send them directly to me in writing  |
| 11 | or you can send them by email if you'd like. What I   |
| 12 | think we should do is before we leave, we'll write    |
| 13 | down on the flip charts here my email address and     |
| 14 | Lance's and Shawn's. If you want to send it to any or |
| 15 | all of us, we welcome the feedback. I was just going  |
| 16 | to ask, Stan, whether OAS or CRCPD would want to      |
| 17 | receive a copy as well. We can share that after we    |
| 18 | receive it, but if you want to receive a copy         |
| 19 | directly, you can put your emails up there as well.   |
| 20 | MR. FITCH: Yes.                                       |
| 21 | MR. LOHAUS: Yes.                                      |
| 22 | MR. RAKOVAN: Okay. Then if I understood               |
| 23 | the general consensus is that we'd like to go through |
| 24 | the parking lot just to make sure of the issues if    |
| 25 | there is no more discussion on them.                  |

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| 1  | MS. FEDERLINE: I have one question.                    |
| 2  | MR. RAKOVAN: Margaret.                                 |
| 3  | MS. FEDERLINE: One of the things we                    |
| 4  | learned in our interactions with the states is that    |
| 5  | trust is built if the stakeholders get feedback on     |
| 6  | what you do with their comments. How is this group     |
| 7  | going to give feedback on what we're doing with the    |
| 8  | comments?  |
| 9  | MR. LOHAUS: The comments and feedback                  |
| 10 | would be taken by each of the working group pilot      |
| 11 | chairs and the working groups themselves and they will |
| 12 | factor that in those that are specific to the working  |
| 13 | groups. Those that are more generic relative to the    |
| 14 | National Materials Program as a part of our preparing  |
| 15 | the - I use the term - evaluation report for the       |
| 16 | pilots which will be going to the Commission in the    |
| 17 | November time frame, they will be identified in that   |
| 18 | paper.   |
| 19 | I guess I'm trying to think in terms of                |
| 20 | whether there's another mechanism we consider. But I   |
| 21 | think that's probably the place that they would        |
| 22 | addressed is in the Staff's report where we would      |
| 23 | evaluate the pilots. We would include input and        |
| 24 | feedback from the stakeholders meeting. Some of the    |
| 25 | items we'll be able to address as a part of that.      |

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Some of the others we're may need to identify those as areas for further consideration or further work. But I think we'll need to work through that and sort those out as we go through this. But let me ask Shawn and maybe Kevin Hsueh who's had overall project manager responsibility and Lance whether there's anything additional that you all see.

8 MS. SMITH: I didn't have any anything 9 I just was going to say what Paul said additional. 10 that it would be incorporated in the final report and the issues that we have addressed today, seeing as 11 though we have the five pilot projects and they are 12 working specifically to address certain issues and 13 14 develop specific work products, go to the overall 15 National Materials Program development. Given that there's a working group looking specifically looking 16 at the overall issues, some of the issues we'll try to 17 But we'll at least account them in the final address. 18 19 report to the Commission in November.

20 MR. RAKOVAN: Kevin, did you have anything
21 you wanted to add?
22 MR. HSUEH: No.
23 MR. RAKOVAN: Easy enough. Okay. Should

24 we go through the parking lot real quick? Hopefully 25 my notation here will allow us to remember what we

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| 1  | were talking about. Lessons learned from the various   |
| 2  | security dealings, how would those effect or be        |
| 3  | incorporated to the National Materials Program? Does   |
| 4  | anyone have any discussion on that?                    |
| 5  | MR. FITCH: A comment has been provided in              |
| 6  | the past. Early on, we provided comments, insights,    |
| 7  | into process and provided that last fall. I would      |
| 8  | imagine that additional comments would be provided in  |
| 9  | the future.  |
| 10 | MR. RAKOVAN: Okay. Early development of                |
| 11 | legislation and flow into the regulatory process. How  |
| 12 | is the National Materials Program going to handle      |
| 13 | that?  |
| 14 | MR. WANGLER: Does NMP really involve                   |
| 15 | legislation development? Is that a part that National  |
| 16 | Materials Program? I don't think it is, is it?         |
| 17 | MS. FAIROBENT: Let me clarify. That's my               |
| 18 | point. My point is though we can have something come   |
| 19 | up on the Hill and be hidden in a bill. I'm not sure   |
| 20 | how many of you all spend a major portion of your life |
| 21 | reading Congressional legislation and drafted bills,   |
| 22 | but it's a major part of my business.                  |
| 23 | For example, in the Energy Policy Act                  |
| 24 | that's pending, there is a couple of provisions that   |
| 25 | had we not been watching them would not have come to   |

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1 the forefront for our members. One is the availability of isotopes and potential export of HEU 2 3 ensure availability of isotopes. It's verv to 4 important in nuclear medicine in their radio-5 pharmaceutical industry. There's also some language in earlier versions of the Energy Policy Bill that 6 7 deals with materials safety/security issues that based on the way the wording is if that is what is passed 8 9 could mandate extensive FBI background clearances for anybody in a medical or hospital institution that uses 10 radioisotopes from the RSO office down to the 11 department of radiology. 12 I don't believe that necessarily that was 13 14 the intent of the person on the Congressional staff 15 that wrote that legislation. But the impact of then 16 how that is interpreted into the regulatory world can 17 be very different. My only concern is as we're looking at a National Materials Program I do think 18 19 that we need to be sensitive to stuff that appears in legislation, be it Federal or state, that ultimately 20 ends up being direct guidance to the regulatory 21 authority to then develop the regulation and the 22 guidance to implement and live under it. That's why 23 24 Ι brought it up. I did not hear that it was considered a thought into the process. 25

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| 1  | MR. LOHAUS: I'm going to maybe restate                 |
| 2  | this in a little bit different way and see if this     |
| 3  | captures it, Lynne. We started to do this with the     |
| 4  | states at their request. I think this is very          |
| 5  | important.   |
| 6  | As we become aware of legislative                      |
| 7  | proposals, we share those so that they're known.       |
| 8  | Folks have an opportunity to reflect on them. If they  |
| 9  | want to provide feedback through whatever mechanism,   |
| 10 | they're in a position to do that. But if we were to    |
| 11 | ensure that there was a flow of information on         |
| 12 | legislative proposals into the community, if you will, |
| 13 | for knowledge base and thinking. Maybe we need to      |
| 14 | identify that more clearly.                            |
| 15 | MR. RAKOVAN: I'm going to try to keep it               |
| 16 | at the table to finish. Mr. Smith.                     |
| 17 | MR. SMITH: You might be aware that                     |
| 18 | there's quite a bit of legislative action coming       |
| 19 | forward in the past years promulgating new regulations |
| 20 | on decommissioning and waste disposal and so forth     |
| 21 | which are in direct conflict with NRC based, agreement |
| 22 | state regulation. It seems to me that this program     |
| 23 | should be at least aware of that kind of process       |
| 24 | happening and there should be also some mechanism for  |
| 25 | NRC being involved in getting that corrected I would   |

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| 1  | think.   |
| 2  | MR. RAKOVAN: Okay.                                     |
| 3  | MR. LOHAUS: I'm going to interject here.               |
| 4  | I need to step out. I'll tell you why. There's an      |
| 5  | individual that's retired from NRC and I asked to      |
| 6  | speak on their behalf. So if I could, I would like to  |
| 7  | take ten minutes and I'll ask Shawn to fill in for me. |
| 8  | But I'll be right back if you'll bear with me. Thank   |
| 9  | you.   |
| 10 | MR. RAKOVAN: Thanks, Paul. Okay. Moving                |
| 11 | along the lot, so to speak, we talked about getting    |
| 12 | the priority list from the National Materials Program  |
| 13 | Pilot 1. I think we can pass that along to the chair   |
| 14 | of Pilot 1 and either get that up on the website.      |
| 15 | MS. SMITH: I don't think that as a                     |
| 16 | working group we'll have an issue with getting it out  |
| 17 | to the stakeholders. As a mechanism, we'll use the     |
| 18 | National Materials Program website. The address was    |
| 19 | listed in the front register. We'll get that up        |
| 20 | within the next two weeks also.                        |
| 21 | MR. RAKOVAN: Okay. Thank you, Shawn.                   |
| 22 | Stakeholder input into the regulatory agenda. Unless   |
| 23 | there is something else that anybody wants to discuss  |
| 24 | on this, that seemed to be one of the main points of   |
| 25 | the meeting that we talked about. I think that         |

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actually crops up a couple more times. Budget issues. 1 2 That's something that we really didn't touch on. Did 3 anyone have a specific point that they wanted to make 4 in terms of budget issues in the National Materials 5 Program? Okay. Impact of petitions for rulemaking. 6 I'm 7 just going to throw these out here and if anybody has 8 anything else that they want to make a point on, get 9 my attention somehow. Steering committee membership 10 for various steering committees in the National Materials Program. 11 12 MS. SMITH: The person that made that, 13 what's the key? Clarify. 14 MS. FAIROBENT: That was me. Lynne 15 I just simply brought up the point Fairobent. Yeah. that in what was being proposed for the steering 16 committee membership it appeared to be for NRC 17 managers and two state reps. 18 19 MS. SMITH: Okay. 20 MS. FAIROBENT: My only question was on the quality of that based on the fact that there had 21 been a previous comment made that what is - I forget 22 what you called it. 23 Priorities Committee. 24 MS. SMITH: Pardon? 25 MS. FAIROBENT:

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| 1  | MS. SMITH: The Priorities Committee.                   |
| 2  | MS. FAIROBENT: Right. Would be                         |
| 3  | reconstituted to be more equitably shared between both |
| 4  | organizations. That was all.                           |
| 5  | MS. CARDWELL: And we, the states, kind of              |
| 6  | talked amongst ourselves. There is a solution to that  |
| 7  | that would kill two birds with one stone. It's to      |
| 8  | increase on the steering committee the state           |
| 9  | membership, but the steering committee is a decision   |
| 10 | maker group.   |
| 11 | MS. SMITH: Yes.  |
| 12 | MS. CARDWELL: And if you were to get for               |
| 13 | instance in OAS the chair and the chair-elect, you     |
| 14 | also establish a continuity there. And if you were to  |
| 15 | get on CRCPD site either the same thing or the chair   |
| 16 | and our executive director which gives you a           |
| 17 | continuity on going then.                              |
| 18 | MS. FAIROBENT: Cindy, exactly that's what              |
| 19 | had come to my mind when I heard it because again,     |
| 20 | it's the continuity. You don't want someone brand new  |
| 21 | coming into the process each year.                     |
| 22 | MR. RAKOVAN: Stan.                                     |
| 23 | MR. FITCH: I was told to say this.                     |
| 24 | MR. RAKOVAN: I won't ask by who.                       |
| 25 | MR. FITCH: Mostly because I was brain                  |

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1 dead about that time. For the OAS if we only have our chair on there, then that person has one year to 2 3 effect change or to be involved or to come up to speed 4 and that's really not enough. If they have an 5 additional person besides the chair like the chairelect or even one of our other board members, but I 6 7 would prefer chair-elect, that would certainly be 8 preferable. It would work better. 9 MR. RAKOVAN: Okay. Can you move on to 10 the next one? The next one, radio-photography Who is in the lead and should this be added 11 program. to Pilot Project 2 in their scope? Mr. Myers. 12 MR. MYERS: And a point of clarification, 13 14 we really would like to see some written guidance on 15 that, not just talk about that. We want to see how 16 that would work so that we know what to do. 17 MR. RAKOVAN: Okay. Should there be a non-common performance indicator in the Integrated 18 19 Materials Performance Evaluation Program? For Radiography Certification Programs? Cindy. 20 MS. CARDWELL: I think speaking on behalf 21 of some of the certifying entities, we've been asking 22 for that for years. 23 24 MR. RAKOVAN: So that would be a yes? 25 Common prioritization of instant event analysis and

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| 1  | communication I believe that's supposed to be. I      |
| 2  | can't read my own writing. Role or expectation of     |
| 3  | states in terms of clearinghouse which I believe was  |
| 4  | discussed as part of Pilot Project 3. Communication.  |
| 5  | Public accessed information. I think we've discussed  |
| 6  | that. Stakeholder involvement in working groups. I    |
| 7  | think we touched on that a few times as well. Public  |
| 8  | input. This was Paul's last point that he brought up  |
| 9  | on consistency of regulation across the nation.       |
| 10 | Anyone have any other input that they would like to   |
| 11 | put in any of that? Speak now. Kevin Hsueh.           |
| 12 | MR. HSUEH: This is Kevin Hsueh. I'm from              |
| 13 | Office of State and Tribal Programs. I just want to   |
| 14 | mention that after this stakeholders meeting we are   |
| 15 | going to make a presentation, a poster presentation,  |
| 16 | as Paul mentioned. One is in-house Society annual     |
| 17 | meeting and the other one is in the CRCPD annual      |
| 18 | meeting. One is in May and the other one is in July.  |
| 19 | At those meetings we will have post the presentation  |
| 20 | and then we will receive feedback from you all if you |
| 21 | attend.   |
| 22 | MR. RAKOVAN: Thank you, Kevin. If there               |
| 23 | aren't any other comments, I'm going to turn things   |
| 24 | over to Paul for a quick closeout.                    |
| 25 | MR. LOHAUS: First, I wanted to thank each             |

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1 of you for taking time to join us today and participate with the expertise and the views, the 2 3 comments, the input, that you've given us today. It's 4 very valuable. I think we've had some very good 5 discussion, a lot of good ideas and a lot of things for us to think about and to fold into the future 6 7 work. I very much appreciate this. I want to thank 8 each of you that came and participated. I want to 9 thank the working group chairs for their help in 10 developing presentations and also the NRC and state staff that helped make this a success. 11 I want to just again comment on what would 12 we do with the feedback that we've received because 13 14 this is a common comment that we hear from the states 15 and others that we hold meetings or we publish 16 materials for comment and it's not always clear what 17 we do with the comments, how those comments are considered, how they are folded into further work and 18 19 I want to think some more about this. Sometimes what we do is we prepare what I 20 call an analysis of comments which basically takes 21 each comments and then provides a statement in terms 22 of how that comment has been dispositioned. I'm not 23 24 certain that dialogue, the discussion, the feedback today, may lend itself for that. That's where in my 25

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| 1  | thinking I see this as areas we'll address as part of  |
| 2  | the assessment as a part of the stakeholder feedback   |
| 3  | that we've on the process and pursue the items that    |
| 4  | maybe these are items that are going to need some      |
| 5  | further work and some further thinking and some        |
| 6  | further help from all of us in terms of how we address |
| 7  | those and make sure they are reflected in the program. |
| 8  | Again I want to thank each of you very much. Have a    |
| 9  | good and safe travel back home. Thank you.             |
| 10 | MR. RAKOVAN: Thank you, Paul. With that,               |
| 11 | I believe we're convened. Thank you. Off the record.   |
| 12 | (Whereupon, the above-entitled matter was              |
| 13 | concluded at 3:30 p.m.)                                |
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