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UNITED STATES OF AMERICA

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NUCLEAR REGULATORY COMMISSION

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OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS

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RISK TASK GROUP

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PUBLIC MEETING

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FRIDAY,

FEBRUARY 9, 2001

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ROCKVILLE, MARYLAND

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The meeting was held at 9:00 a.m. in the auditorium of the Nuclear Regulatory Commission, Two White Flint North, 11545 Rockville Pike, Lawrence E. Kokajko, Chief, presiding.

PRESENT:

LAWRENCE E. KOKAJKO	NMSS/RTG
MARISSA BAILEY	NMSS/RTG
DENNIS DAMON	NMSS/RTG
JAMES DANNA	NMSS/RTG
CANDICE DRUMMOND	NMSS/RTG
RAEANN SHANE	NMSS/RTG
JAMES SMITH	NMSS/RTG
TORRE TAYLOR	NMSS/IMNS

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1       ALSO PRESENT:  
 2           ROBERT A. BARI                   BNL  
 3           JOHN JANKOVICH                 NMSS  
 4           JOCELYN MITCHELL             NRC/RES  
 5           VINOD MUBAYI                 BNL  
 6           JOSIE PICCONE                 NRC/OEDO  
 7           G.E. POWERS                   NRC/RES  
 8           MARLA PAULOVA                 U.S. DOE  
 9           ALBERT WONG                   NMSS/RTG  
 10          T.F. YOUNG                    NMSS  
 11          RONALD ZELAC                 NMSS/IMNS

12  
 13       PUBLIC:  
 14           ROBERT BERNERO               NRC, Retired  
 15           GARY CAINE                    Honeywell  
 16           DIANE D'ARRIGO               NIRS  
 17           FRED ENTWISTLE               3M Co.  
 18           HUGH W. EVANS                AEA Technology  
 19           CLIFTON FARRELL             NEI  
 20           ROLAND FLETCHER             State of Maryland/DAS  
 21           JONATHAN FORTKAMP           ABB Automation  
 22           RALPH S. HEYER                Thermo Measureteck  
 23           JUDITH JOHNSRUD             Sierra Club/ECNP  
 24           FELIX KILLAR                 NEI  
 25           JOEL LUBENAU                 Consultant  
 26           JIM MEYER                    ISL  
 27           ELSA NIMMO                   Honeywell-Measurex  
 28           MARCUS PAGE                 Morgan Lewis &  
 29    Bockius  
 30           JACK RAMSEY                 Neles Automation  
 31           JOE TENHET                   PM-USA

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1		3
2		<u>PAGE</u>
3	Opening Remarks, Lawrence Kokajko	4
4	Background and General Information,	
5	Marissa Bailey	7
6	Present Status of Gas Chromatograph Case	
7	Study and Receive Feedback, James Smith	16
8	Present Status of Static Eliminator Case	
9	Study and Receive Feedback, James Danna	59
10	Present Status of Fixed Gauge Case Study	
11	and Receive Feedback, Raeann Shane	120
12	Receive General Comments and Feedback on Case	
13	Studies	144
14	Closing Remarks, Lawrence Kokajko	158
15		
16		
17		
18		
19		
20		
21		
22		
23		
24		

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

(9:15 a.m.)

MR. KOKAJKO: My name is Lawrence Kokajko, and I'm the section chief of the Risk Task Group in the NRC's Office of Nuclear Materials Safety and Safeguards. I'd like to welcome everyone to headquarters at the U.S. Nuclear Regulatory Commission this morning and thank you for wanting to participate in the first of several planned case study stakeholder meetings.

The Risk Task Group is responsible for efforts related to risk informing the materials and waste arena activities. As a result of our workshop last April, it was suggested that we consider a case study approach to determine what areas in materials and waste arenas could be amenable to risk informing. These case studies would cut across a spectrum of regulated activities within the materials and waste arena.

Furthermore, they could be used to test screening criteria that would enable us to determine if a proposal was amenable to risk informing and perhaps give us an idea of possible safety goals.

When the case study plan was rolled out last September, one comment that we received was that

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1 we should have early stakeholder involvement before we  
2 reached any conclusions regarding the case study area  
3 under consideration.

4 Today is your chance to provide your input  
5 on three case study areas, specifically, gas  
6 chromatographs, static eliminators and fixed gouges.

7 Marissa Bailey, behind me, will coordinate  
8 this discussion and at the beginning of her talk will  
9 discuss how we got where we are today and where we  
10 intend to go.

11 I hasten to point out that we do not  
12 intend to make or consider a regulatory decision or  
13 position today. We only intend to gather input on  
14 these three areas.

15 This meeting is open to everyone  
16 including, but not limited to, NRC staff, licensees,  
17 applicants, federal, state and local government  
18 organization, non-government organizations, public  
19 citizen's group, manufacturers, users, industry and  
20 trade association representatives and everyone in  
21 between.

22 Everyone is invited to provide thoughtful  
23 insight and commentary on these three case study  
24 areas.

25 While we will provide early information

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1 regarding our review to date, we are seeking your  
2 comments on what we have done but, more importantly,  
3 your thoughts on what we should do related to  
4 implementing the case study plan for these three  
5 topics.

6 As this is the first of many such  
7 meetings, we will be seeking feedback on what you  
8 thought about the meeting. One way of doing so is a  
9 feedback form that you can mail into us. I believe  
10 everything was provided at the entrance when you came  
11 in.

12 Also, at any break you can see a member of  
13 the Risk Task Group and provide your comments directly  
14 to one of us. In fact, if everyone from the Risk Task  
15 Group could just raise their hand to show where they  
16 are. These are the people that you can talk to.

17 Before I get to the agenda, let me cover  
18 some logistical information. The restrooms are located  
19 on the other side of the foyer, outside the auditorium  
20 doors. There's a cafeteria on the main floor, and an  
21 elevator can take you there.

22 We will be taking appropriate breaks  
23 during the day, if it goes for a long time. This  
24 meeting is being transcribed and we will put out a  
25 meeting summary afterwards, all of which will be a

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1 public record.

2 The agenda case study plan, feedback forms  
3 and any other information, as I noted, is out in the  
4 front. And please feel free to take as much as you  
5 want.

6 Our agenda today is noted on the slide.  
7 Marissa Bailey will provide an overview of what we are  
8 doing, followed by Jim Smith, who will discuss gas  
9 chromatographs, Jim Danna, who will discuss static  
10 eliminators and Raeann Shane, who will discuss fixed  
11 gauges.

12 Marissa and I will coordinate the general  
13 comments and closing remarks. And with that in mind,  
14 I'm going to turn it over to Marissa to provide an  
15 overview.

16 During the session -- this is meant to be  
17 interactive and we would like for you to provide  
18 comments. If you have questions, there are microphones  
19 to provide your comments, so please feel free to do  
20 so.

21 We will try to take everything into  
22 consideration as we move forward in the development of  
23 our conclusions of our case study areas. Thank you.  
24 Marissa.

25 MS. BAILEY: Again, I'm Marissa Bailey.

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1 And what I'd like to do first of all is, basically,  
2 give you an overview of why we're conducting the case  
3 studies.

4 Basically, the NRC is in the process of  
5 developing approaches for using risk information in  
6 nuclear materials and waste arenas.

7 This effort is simply a way for us to --  
8 well, first of all, it's to continue to maintain  
9 safety, but also to improve our regulatory decision-  
10 making process, make more effective use of our  
11 resources and to reduce unnecessary regulatory burden.

12 In SECY 99-100, which was a paper that was  
13 submitted to the Commission by the staff in March,  
14 1999, the staff proposed a framework for a risk-  
15 informed regulation in the materials and waste arenas.

16 As discussed in that paper, the framework  
17 would be implemented in a five-step process. First  
18 would be to identify areas that -- within the  
19 materials and waste arenas that would be amenable to  
20 risk-informed regulation.

21 The second step would then be to decide  
22 how to modify the regulatory approaches, change the  
23 regulatory approaches, implement risk-informed  
24 approaches and the develop or adapt risk-informed  
25 tools. Where we are at this point is, essentially,

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1 right there. We're, essentially, at this point. We're  
2 trying to -- we're in the process of identifying areas  
3 within NMSS that might need risk information.

4 I would like to point out, however, that  
5 these steps don't necessarily need to be taken in this  
6 sequence, and that they may be interchangeable and  
7 some of them may be taken in parallel.

8 The SECY 99-100 was reviewed by the  
9 Commission and in their staff requirements memo, which  
10 was issued around June, 1999, the Commission approved  
11 the staff's proposed framework. In that SRM, they also  
12 directed the staff to develop appropriate material and  
13 waste safety goals and to use an enhanced  
14 participatory process. Next slide, please.

15 In the spirit of using an enhanced  
16 participatory process, the staff held a workshop last  
17 April and the purpose of that workshop was to solicit  
18 recommendations and comments on how the NRC should  
19 proceed with incorporating risk information in our  
20 materials and waste regulatory programs.

21 In the workshop, we introduced the draft  
22 screening criteria, which would be the criteria that  
23 we would to identify activities that might be amenable  
24 to risk information. The draft screening criteria was  
25 further refined based on the comments that we received

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1 at that workshop.

2 Another thing that came out of that  
3 workshop was, basically, a general consensus that case  
4 studies would be a good way to test those draft  
5 screening criterias. The case studies would be a  
6 retrospective look at a spectrum of activities in the  
7 materials and waste arenas.

8 The purpose would be, basically, to  
9 illustrate what's been done before, whether what was  
10 done was risk informed or illustrate what could be  
11 done to more towards a more risk-informed approach.

12 Another purpose of the screening criteria  
13 is to test -- I'm sorry. Another purpose of the case  
14 studies is to test the draft screening criteria and  
15 also to determine whether there were any safety goals,  
16 whether explicit or implicit, imbedded in the staff's  
17 decisions in those activities and, ultimately, to  
18 determine whether those safety goals could be extended  
19 to other activities in NMSS or whether the safety  
20 goals could be applied across the board in the  
21 materials and waste arenas.

22 The purpose of the case studies, the  
23 objectives and just the overall structure of how we  
24 would be conducting the case studies are described in  
25 the case study plan and you should have a copy of

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1 that. That's one of your handouts.

2 The case study plan was developed by the  
3 Risk Task Group and also a group within NMSS called  
4 the NMSS Risk Steering Group. It was presented -- a  
5 draft version of it was presented to stakeholders last  
6 September and based on those comments that we received  
7 from stakeholders, we revised the case study plan and  
8 issued a final plan last October.

9 The case study plan includes the final  
10 form of our draft screening criteria, which we will be  
11 testing in these case studies. The draft -- the  
12 screening criteria are essentially a series of  
13 questions that we would be asking about an activity to  
14 determine if it could be risk informed.

15 The first set of -- the first four  
16 screening criteria has to do with -- basically, asks  
17 would a risk-informed approach resolve a question with  
18 respect to safety, would it improve efficiency or  
19 effectiveness?

20 Would it reduce unnecessary burden, would  
21 it help us more effectively communicate our decisions  
22 in that activity? If the answer to one of those is  
23 yes, then we would proceed with the next criteria.

24 The fifth screening criteria addresses the  
25 availability of data or information. Are they

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1 available or could they be developed reasonably? If  
2 the answer to that is yes, then we move onto the sixth  
3 screening criteria, which addresses the issue of  
4 cost.

5 Basically, it can start up an  
6 implementation of a risk-informed approach you realize  
7 at a reasonable cost. If the answer to that is yes,  
8 then we move onto the seventh criteria, and that  
9 criteria sort of addresses any other precluding  
10 factors, whether other factors exist, which would  
11 preclude changing the regulatory approach.

12 If the answer to that is no, then a risk-  
13 informed approach could be implemented. If the answer  
14 is yes, then I think we would have to step back and  
15 not necessarily say no, this can't be risk informed,  
16 but we would have to look at it and make a  
17 determination and make other considerations.

18 The case study plan also identifies the  
19 case study areas, the case studies that were  
20 conducted. There's a total of eight of them. The top  
21 four, gas chromatographs, static eliminators, fixed  
22 gougues and site decommissioning are what we have in  
23 progress right now. And today we're going to be  
24 talking about the first three.

25 Just going back on that slide, as you

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1 notice, there were eight case studies. For each one of  
2 them we do plan to hold stakeholder meetings. So this  
3 meeting right here is what -- intended to be one of a  
4 series of meetings that we will be holding with  
5 stakeholders.

6 The case studies, basically, involve  
7 answering three questions for each case study area.  
8 The types of questions are screening criteria analysis  
9 questions, safety goal analysis questions, and  
10 questions developed -- questions upon developing the  
11 draft safety goals.

12 Today what we are going to be presenting  
13 are preliminary answers to the screening criteria  
14 analysis questions, and in the case of the gas  
15 chromatographs some of our answers to the safety goal  
16 analysis questions.

17 I do want to emphasize that what we're  
18 presenting today, the answers that we're presenting  
19 today, are preliminary answers and that we have made  
20 no decisions at this point whether or not an activity  
21 can be risk informed. And also, that your feedback,  
22 the feedback that we receive today from you is very  
23 important to us.

24 I'd like to go ahead with the schedule for  
25 these three case studies for the gas chromatographs,

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1 static eliminators and fixed gauges.

2 In spring we plan to issue our draft  
3 report for comment and then in the summer hold a  
4 stakeholder meeting, and then based on any stakeholder  
5 input or comments, feedback, we would then issue a  
6 final case study report late this summer.

7 That pretty much concludes my  
8 presentation. I guess before I hand it over to the  
9 others, does anybody have any questions?

10 PARTICIPANT: Will it be one report or  
11 three separate ones?

12 MS. BAILEY: The intent is to have three  
13 separate reports.

14 MR. BERNERO: Do you want names for the  
15 record? Bob Bernero. Slide 14 has eight case studies  
16 and progress now on four of them. Is there a  
17 programmatic milestone or opportunity to reconsider  
18 the later ones as you get progress on the first four,  
19 to redirect program effort?

20 MS. BAILEY: Lawrence?

21 MR. KOKAJKO: If I understand your  
22 question, you're saying -- are we -- if, after we do  
23 these three and we come to some conclusions, would we  
24 then relook at resources through our planning budget?

25 MR. BERNERO: Yes, or outcome and, you,

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1 now, possibly going to some other case study or going  
2 into one of these case studies more deeply.

3 MR. KOKAJKO: I think so. I think that's  
4 the point of what we're trying to do as we go through  
5 here. I don't know what will happen, but let's say  
6 that we come to some conclusion that something can be  
7 risk informed and we may need to change the regulatory  
8 framework, we would make that recommendation to the  
9 appropriate division and then the division would have  
10 to put it in a PBPM process to decide if that's  
11 something that they want to go forward with.

12 On the other hand, if we come to a  
13 conclusion that more research needs to be done, we'll  
14 make that recommendation too. We don't have the  
15 implementing resources to do everything we say the  
16 divisions do. We can only make the recommendation.

17 However, I will tell you that elements of  
18 this are in every division's operating plan. So that  
19 whatever we give them, they do have to consider very  
20 formally and try to prioritize in accordance with the  
21 needs of the agency.

22 MR. BERNERO: Okay.

23 MS. BAILEY: Any more questions? Yes.

24 MS. JOHNSRUD: Judith Johnsrud. Unless I  
25 imagined what I read, you indicated that earlier

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1 decisions on the part of the staff will not be  
2 reconsidered. And I'm curious about the scope of what  
3 that entails. What will, therefore, be excluded from  
4 consideration?

5 MS. BAILEY: Well, the intent of the case  
6 studies isn't to go back on any earlier decisions that  
7 were made.

8 Basically, it's a retrospective look at  
9 that activity to see what was done and whether what  
10 was done, if it was done in a risk-informed manner,  
11 could be applied to some other activity in the future  
12 or could we improve upon our process in another future  
13 activity. Does that answer your question?

14 MS. JOHNSRUD: I think so.

15 MS. BAILEY: Any more questions? Okay. At  
16 this point, I'd like to go ahead and begin our  
17 presentations on the case studies. The format for the  
18 presentations are fairly simple.

19 Each of our presenters will discuss the  
20 case study and then we'll open it up to you for  
21 feedback. So our first presenter is James Smith, who  
22 will be talking about gas chromatographs.

23 MR. SMITH: Good morning, everyone. My name  
24 is James Smith. I'm on the Risk Task Group. I've  
25 worked with the Nuclear Regulatory Commission now for

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1 about 11 years. I've worked in health physics for  
2 about 15 total. So I know a little bit about this  
3 subject, but the area of gas chromatographs is one  
4 that I'm just fairly new to.

5 I was asked to take a look at the draft  
6 questions for the case studies developed back in April  
7 with respect to gas chromatographs. The first one,  
8 what risk information is currently available in this  
9 area?

10 Currently, to my knowledge -- and again,  
11 this is very subjective. This is my feeling and we  
12 didn't have any set criteria. So I came up with what  
13 I thought was risk information.

14 NUREG 6642 is the risk analysis and  
15 evaluation of regulatory options for nuclear by-  
16 product material systems. It was developed by  
17 Scientech, I think November of 1990. I'm not quite  
18 sure of the exact date it was sent out.

19 It looked at 40 different systems of by-  
20 product material use. One of those, System 37, looked  
21 at tritium and nickel-32 gas chromatographs. It took  
22 a hazard barrier analysis and looked at the approach  
23 as though you were having external exposure. You also  
24 might have a worst case of a fire where material would  
25 be released. They came up with fairly low doses,

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1 fairly low probabilities.

2 In addition to that, we recently had  
3 NUREG-1717 issued in draft. I believe it's going to be  
4 issued in final some time shortly. And that is the  
5 systematic radiological assessment of exemptions for  
6 source and byproduct materials.

7 It was mainly focused upon exempt licensed  
8 materials. But one of the -- it had four systems that  
9 are generally licensed that it looked at to see  
10 whether or not they could move into an exempt  
11 category.

12 Based on their worst case doses from that  
13 study, it came up with the recommendation that perhaps  
14 these gas chromatographs could be moved into an exempt  
15 licensing status.

16 In addition to these generic studies,  
17 there are also independent and specific reviews done  
18 for each type of device that's distributed in this  
19 country.

20 If it's a gas chromatograph that's going  
21 to be distributed under a general license, it must  
22 show compliance with Section 3251. One of those  
23 sections states the hazards that can be presented in  
24 an accident condition, as well as current normal use.

25 Some of the things are the device can be

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1 safely operated by persons not having training in  
2 radiological protection. So somewhere along the way,  
3 one of our staff members, or members of the Agreement  
4 States, have to make a decision if that statement is  
5 true.

6 Also, under ordinary conditions of  
7 handling, storage and use, the byproduct material  
8 contained in the device will not be released or  
9 inadvertently removed from the device.

10 Have you ever seen one of these devices?  
11 It's kind of hard to believe that material will get  
12 out of it.

13 In addition to that, it's unlikely that  
14 any person will receive a dose in excess of ten  
15 percent of the annual limit specified, Part 20, Sec.  
16 1201. And also, under accident conditions, such as  
17 fire and explosion, it is unlikely that any person  
18 will receive an external dose, or dose commitment in  
19 excess of the dose of the appropriate organ as  
20 specified in column 4, table 4, which lists a number  
21 of organ doses and whole-body doses. So in a way there  
22 have been radiological risk assessments done on these  
23 types of devices.

24 NUREG-6642, again, this is a -- what is  
25 the quality of the study? That's a very subjective

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1 question. When I looked at it, I didn't have a set of  
2 criteria saying it meets the following X's. The  
3 qualified of the study is sufficient.

4 When I looked at it, I said if I were  
5 asked to make a decision whether or not this was  
6 something I could make a risk-informed decision on I  
7 did it. So these are my answers. They're not bounded  
8 on the NRC in any way.

9 But I believe that NUREG-6642, draft  
10 NUREG-1717 and the individual source and device  
11 registration certificates could be used to support  
12 decision making.

13 Again, we could send that up -- that's a  
14 policy decision that would have to be put together in  
15 some sort of a paper and set before our policymakers  
16 in the other building and let them make that decision.

17 What additional studies would be needed to  
18 support decision making and at what cost? Since I  
19 don't think there's any more studies necessary, I  
20 don't believe we need to have any more studies. That  
21 could be turned around and sent back to us.

22 How is, was risk information used and  
23 considered by the NRC and the licensee in this area?  
24 Again, the seal source and device reviews have been  
25 used to determine that the sources and devices pose

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1 very little risk to the public. That's already been  
2 done. That's not something we're going to have to  
3 readdress. As long as we agree that those reviews were  
4 appropriate.

5 NUREG-1717 has some very good radiological  
6 assessments in it. But again, it's not finalized so it  
7 would be -- kind of has it to use that as a basis  
8 right now, although it's my understanding it should be  
9 finalized fairly shortly.

10 NUREG-6642 has not yet been used in  
11 decision making, although there are several approaches  
12 that we currently have using methodology, as well as  
13 the information from that, that we plan to use in  
14 decision making

15 One of the aspects of 6642 that's very,  
16 very nice is in addition to the paperwork there's a  
17 database that contains the systems, the probable  
18 accidents and the consequences and the probabilities  
19 associated with those.

20 This information, although not readily  
21 available to everyone, is a fine tool for us to use as  
22 we're trying to -- accident conditions and what are  
23 the possible outcomes and consequences.

24 What is the societal benefit of this  
25 regulated activity? Well, that's a tough one. I don't

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1 know whether or not there's necessarily a benefit.  
2 Some people find it necessary to have these in their  
3 jobs. So I guess you can call it a benefit.

4 In industrial and laboratory settings,  
5 they're used to detect small amounts of organic  
6 compounds. In the military, they have modified  
7 versions that they use as chemical agent monitors and  
8 explosive detectors. I think that's pretty important.

9 In forensics, they started designing a  
10 device that will assist them in detecting the  
11 chemicals that are given off by a dead body by a crime  
12 scene to determine the time and cause of death.

13 That's one thing that I thought about the  
14 other day that might lead me to want to exempt these  
15 devices. If you can imagine across the country  
16 medical examiners going out with a gas chromatographs  
17 on hand, they're going to be a lot of these. And to  
18 have to send the NRC inspector out to follow after  
19 this device with very little risk associated with it,  
20 it doesn't make sense. Not from my perspective at  
21 least.

22 What is the public perception of risk in  
23 this area? Who in here has heard of a gas  
24 chromatographs before today? Okay. I think it's safe  
25 to say none. No one knows about these devices.

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1 They're not widely used, they're not widely known. I  
2 don't think we're going to have too many people  
3 clamoring against them.

4 What was the outcome when this application  
5 was put through the draft screening criteria? Again,  
6 these are very subjective questions. So these are my  
7 approaches to it and my analysis.

8 But when I go through the screening  
9 criteria, the end result is that it passes all with  
10 the exception of Criterion 7. I'll go through them  
11 just to use up some time.

12 Does it resolve a question with respect to  
13 safety? Yes. I believe that when you look at the  
14 material that we have, the information, it says these  
15 devices do not cause a significant risk to society and  
16 probably can be moved into an exempt category without  
17 affecting public health and safety.

18 Would it improve efficiency and  
19 effectiveness? Yes, I think so, by not causing people  
20 to go through the licensing process, not sending our  
21 inspectors out to the field to look at these devices  
22 that were effectively zero risk, or in my perspective  
23 zero risk.

24 Would it reduce an unnecessary regulatory  
25 burden? Yes. Would it help to effectively communicate

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1 a decision? Yes, I think that if we could come forward  
2 and state emphatically that we've decided there's no  
3 risk associated with these or an acceptable level of  
4 risk, would could put a bench mark or a milestone  
5 saying this is an acceptable level and we can move the  
6 ball down the field accordingly, but that would be the  
7 first step. Because these are fairly innocuous  
8 devices.

9 There's information on analytical models  
10 that exist that are of sufficient quality or could be  
11 reasonably developed. Again, yes.

12 The device -- I just have to say yes. I  
13 believe there is. I think that 1717 and 6642, as well  
14 as all the sealed source device reviews have been and  
15 are of sufficient quality to make a decision.

16 Can start up of a risk-informed approach  
17 be realized at a reasonable cost? Again, since I  
18 think that most of the studies and data is already  
19 available to us, I don't believe it will cost us much  
20 of anything.

21 Do other factors exist? This is the  
22 question that I'm not sure about, I don't think  
23 anybody is sure about until you go out into the public  
24 domain and start questioning the way things have been.

25 There's quite a bit of inertia. A lot of

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1 xenophobia in the world. One of the reasons why we  
2 regulate these things is because we've regulated these  
3 things. It's not necessarily that they cause much  
4 risk, but we've always done it and so why are we going  
5 to change?

6 But it's unknown. I don't know what the  
7 members of the public or population are going to say  
8 when we get done with this, whether or not we have  
9 subjected them to undue risk.

10 I took a stab at the second set of  
11 questions under Section 7.22. I don't know if anybody  
12 else did. It was kind of difficult because these  
13 assume that you had developed a safety goal. But I  
14 thought I'd give it a try anyway.

15 What is the basis for the current  
16 regulations in this area? I think when you go back to  
17 the granddaddy of all the requirements, you go to the  
18 Atomic Energy Act, Section 81 under domestic  
19 distribution states "To exempt materials or to issue  
20 general licenses. Quantities and material must not  
21 constitute an unreasonable risk to the common defense  
22 and security, to the health and safety of the public."

23 That's -- again, it's a statement or a  
24 question you're going to have to answer in your own  
25 mind. It's fairly broad and it's left to

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1 interpretation.

2 When I look at it I say that's the basis  
3 and we have to make a decision whether or not it's an  
4 unreasonable risk. I believe it is. I mean I believe  
5 it's not an unreasonable risk.

6 Are there any explicit safety goals or  
7 implicit safety goals imbedded in the regulations?  
8 Yes, currently we have requirements under Section  
9 30.32, 32.10, 32.51, not necessarily in that order,  
10 and 32.5 Section 6.

11 Also under 32.23 there's safety criteria  
12 for accident conditions for these devices with  
13 possible consequences associated with it.

14 What was the basis for the development of  
15 safety goals? I put down here Section -- or Parts 10  
16 CFR 30.33(a)(2), which states that an application will  
17 be approved if the applicant's proposed equipment and  
18 facilities are adequate to protect health and to  
19 minimize danger and the life of property.

20 Section 10 CFR 20.1801 and 1802, which  
21 state that licensed materials stores in an  
22 unrestricted area must be secured from unauthorized  
23 removal. That's the notion that basically you have to  
24 maintain an oversight and surveillance of the devices  
25 so they don't go missing.

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1           Number four, are there any safety goals,  
2           limits or other criteria? I had a hard time  
3           differentiating this question from question 2. But I  
4           guess that if you look at it from a more generic  
5           basis, generically, Section 81, again, states our  
6           criteria and also the safety goal questions under  
7           question 2 should be reiterated.

8           Five, if safety goals are developed in  
9           this area would tools, data to be available for  
10          measurement?

11          Yes, we currently have the NMED database  
12          that lists the incidents of leaking sources over the  
13          past eight years. They may not be perfect, but I  
14          think it could give us a narrow window, maybe a  
15          sampling of what's out there.

16          Also with radiological hazards,  
17          information from these incidents and the methodologies  
18          on NUREG-6642 and the radiological assessments of  
19          draft NUREG-1717. I think the magnitude of the risk  
20          could be determined for a decision-making process.

21          Again, that's going to be a policy  
22          decision. We can crunch numbers all day long. Someone  
23          else has got to make a decision whether it's  
24          acceptable.

25          Who are, were the populations at risk?

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1 Well, in 1717 and 6642 they came up with approximately  
2 160 of these licensees out there right now. Of  
3 course, associated with those licenses you're going to  
4 have the manufacturers of the devices, you're going to  
5 have services of the source and the device,  
6 individuals involved in the transport of the device.  
7 That's UPS, me, you, anybody who carries them around.

8 And also the individuals involved in  
9 disposal of the device. That would be waste brokers,  
10 anyone else who might have to handle it along the way.

11 Question 7 -- I'm just about finished.  
12 What are or were, what could have been the various  
13 consequences to the populations at risk?

14 Well, NUREG-1717 -- again, it's a draft.  
15 But for accidents and misuse scenarios, it assumes a  
16 leakage rate from this device up to ten times the rate  
17 experienced. So if you go back and look at our data  
18 and multiply that by ten, I think that's a pretty  
19 conservative number.

20 From that, the highest dose to a user  
21 would be approximately 200 millirem from a tritium  
22 device and 300 millirem from a nickel 63 device.

23 But when you start looking at probable  
24 exposures and the possibility of someone actually  
25 getting all of that dose, the best estimate of a worse

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1 case dose would be about 100 millirem.

2 I think this is the root to a lot of our  
3 questions. What parameters should be considered for  
4 the safety goals? Of course, in this country we like  
5 to prevent deaths and illnesses associated in loss of  
6 property.

7 One of the issues that would need to be  
8 addressed here is the doses are fairly low. But if  
9 you assume a linear no threshold model, you're always  
10 going to have some probability of occurrence of some  
11 latent cancer in the future.

12 There's absolutely no possibility of  
13 getting an acute effect from one of these devices,  
14 other than maybe a blocked colon if you tried to eat  
15 it.

16 I have no other answers. The next two are  
17 blank, but I'll go through it anyway for the sake of  
18 your edification.

19 Nine. Assuming that you do develop an  
20 answer to those questions, would it be feasible to  
21 develop safety goals in this regulatory area? I guess  
22 so. Maybe.

23 Number ten, what methods, data result,  
24 safety goals or regulatory requirements would be  
25 necessary to make it possible to risk inform some of

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1 the cases?

2 I would imagine you'd need to do a  
3 somewhat analytical study although, generally, all the  
4 devices that we have out there have been through a  
5 source and review. So generally, this information  
6 regarding the individual specific risk associated with  
7 these devices has been developed and submitted to  
8 someone somewhere. So it exists, but I don't know if  
9 it would be sufficient.

10 Take, for instance, something like fixed  
11 gauge. There's a fairly broad spectrum of these  
12 devices out there. I don't think you can come with a  
13 generic fixed gauge. And that's about the end of my  
14 talk. Bob?

15 MR. BERNERO: Jim, I'd like to ask you a  
16 question, particularly about your question 7, where  
17 you identified for extrapolation of leakage from the  
18 source, a 50 percent greater postulated dose for  
19 nickel-63 than for tritium and it's probably related  
20 to the dilution transport of tritium.

21 MR. SMITH: I haven't looked at the reason  
22 why they came up with these numbers. I just looked at  
23 the raw data, the results and the recommendations. So  
24 I can't tell you how they came up.

25 MR. BERNERO: Well, the real question in

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1 my mind would be is there a possibility to discern a  
2 meaningful risk difference between these two low  
3 risks, such that NRC might say would could have an  
4 exempt distribution of tritium devices, but not of  
5 nickel-63?

6 MR. SMITH: With the order of magnitude  
7 differences? I mean, they're almost the same. 200  
8 milligram, and 300 milligram.

9 MR. BERNERO: Yeah, but their probability  
10 of release -- what's the form of the tritium and  
11 what's the form of the nickel-63?

12 MR. SMITH: I don't have any information  
13 on --

14 MR. BERNERO: My question really is in  
15 risk information of material licensing, is there the  
16 possibility of NRC evaluating one isotope versus the  
17 other for the same application --

18 MR. SMITH: I believe so.

19 MR. BERNERO: -- and discerning a  
20 meaningful risk difference?

21 MR. SMITH: I believe so. We have done  
22 that in the past. We've looked at brachytherapy, for  
23 instance. We've allowed people to use cesium and  
24 cobalt-60. And it took quite a while before we  
25 allowed iridium. Yes, we have looked at isotope-

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1 specific applications before. We changed the  
2 requirements associated with the risk associated.

3 MR. BERNERO: Okay.

4 MR. SMITH: Hi, Joel.

5 MR. LUBENAU: Joel Lubenau. Jim, just a  
6 couple of questions. First, the number of licensees  
7 which you estimated 160, that's NRC, right?

8 MR. SMITH: I believe, so, yes.

9 MR. LUBENAU: Do you have a figure for the  
10 U.S?

11 MR. SMITH: I don't know. I guess I'd  
12 multiply that by two and a half.

13 MR. LUBENAU: Okay. Two other questions,  
14 and I'll tip my hand because I'll be asking them again  
15 for the other two case studies where I think they may  
16 become more significant. What's the data on the  
17 thefts, losses and abandonments of gas chromatographs?

18 MR. SMITH: To be honest with you, I  
19 haven't looked at it, but I don't recall one ever  
20 being stolen.

21 MR. LUBENAU: And in your risk analysis,  
22 did you take into consideration -- and I seem to  
23 recall -- I should say his background -- and I recall  
24 under the Atomic Energy Act, protection of property is  
25 also in there.

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1 MR. SMITH: The NUREG-6642 did not look at  
2 property damage.

3 MR. LUBENAU: It did not.

4 MR. SMITH: That's one of the issues that  
5 we would have to address if the Commission determines  
6 that that's something appropriate.

7 MR. LUBENAU: Right. Because that was a  
8 point that was made in the NUREG that was put out  
9 jointly by the NRC and the Agreement States -- I  
10 looked at the old --

11 MR. SMITH: In 6642, the risks they were  
12 looking at were doses to a worker, doses to a member  
13 of the public in both off normal and normal  
14 conditions. It did not look at the cost associated  
15 with disbursal of the material and loss of property.  
16 That would be something we'd have to address separate.

17 MR. LUBENAU: Thank you.

18 MR. SMITH: Ron.

19 MR. ZELAC: Ronald Zelac, NRC. Jim, just  
20 a quick follow up on the Joel's question concerning  
21 the number of licensees. 160 sounds just kind of low.  
22 Would that number presumably include broad scope  
23 licensees who would also in many cases be likely to be  
24 using these devices?

25 MR. SMITH: I didn't actually go through

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1 the database of licensees to look at it. I just know  
2 that when 6642 and 1717 came up with the numbers that  
3 they did and the number they came up with, 160, I  
4 didn't have any reason to question that, but there may  
5 be more devices out there.

6 I'm not so sure that the total number of  
7 the devices is that important, unless you're worried  
8 about an accumulation of the material and landfills.  
9 I think from an individual standpoint, these things  
10 pose very little risk.

11 If you're talking about a risk to an  
12 individual, it's very slow. So if you protect the  
13 individual, you supposedly protect society.

14 MR. ZELAC: Okay.

15 MR. KILLAR: Felix Killar, Nuclear Energy  
16 Institute. Back on your slide -- I guess it's 18,  
17 where you talk about the various things that you  
18 looked at, you talked specifically about the criteria  
19 under 10 CFR 31.5 and 32.51. Did you go back and look  
20 at the regulatory analysis that was performed when  
21 31.5 and 31.51 was developed?

22 Because I think that would give you some  
23 additional insight as to how they came up with the  
24 basis behind what's in 31.5 or 32, and then that helps  
25 imply that information.

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1 MR. SMITH: I've looked at it in the past.  
2 I didn't specifically look at it this time though. I  
3 know that in the past, general license devices, it was  
4 thought that perhaps we could get rid of the  
5 requirements in bureaucracy of going through  
6 specifically-licensed, device-based on the fact that  
7 these pose very little risk or to be shown to have  
8 very little risk associated with them.

9 But I went straight to the horse's mouth.  
10 I went to one of the device reviewers, who happens to  
11 be hiding in the back right now, and asked them what  
12 is it you look at when you review a device, and what  
13 is your criteria?

14 MS. D'ARRIGO: On your slide no. 35 you're  
15 saying the best estimates of expected doses under such  
16 conditions are less than 100 millirems. When you keep  
17 talking about the low risk, are you talking about that  
18 number?

19 MR. SMITH: These numbers were very  
20 conservative. They were ten times what we've ever  
21 seen?

22 MS. D'ARRIGO: Can you talk a little  
23 closer to this?

24 MR. SMITH: Could I ask you -- could you  
25 mention your name?

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1 MS. D'ARRIGO: Diane D'arrigo, Nuclear  
2 Information.

3 MR. SMITH: That's what I'm talking about.  
4 There's not much of a chance of having an acute  
5 affect, so then you start looking at the doses that  
6 could cause cancer down the line. These numbers are  
7 fairly small. They're nearly equivalent to what we  
8 have for the public dose limits right now.

9 MS. D'ARRIGO: So you're saying then that  
10 each of these devices in a worst case scenario would  
11 be a hundred millirem dose. I'm trying to figure out  
12 -- when you talk about the low risks, what low risks  
13 you're talking about?

14 MR. SMITH: I'm talking about the dose  
15 that someone would receive from one of these devices  
16 if it -- I believe that the scenario they came up with  
17 was a fireman entering a laboratory that was on fire  
18 that caused this material to be released into the  
19 environment.

20 You get a dose of 200 millirem if they had  
21 a leakage rate ten times of what we've seen before.  
22 So a 200 millirem dose for somebody entering a fire to  
23 save a building.

24 So do you have a problem with the dose  
25 levels?

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1 MS. D'ARRIGO: Well, I have a problem with  
2 the assumption that the doses are low, but you don't  
3 say what those doses are. And so --

4 MR. SMITH: I think it's specific. Here it  
5 says 200 millirem for a tritium would be the worst  
6 case. 300 millirem for a nickel-63 device.

7 MS. D'ARRIGO: Okay.

8 MR. SMITH: I mean those are fairly low  
9 doses to start with, but they're under worse, worse  
10 conditions. I can't imagine that anything else would  
11 be much lower than that. There's no way you can get an  
12 external dose from one of these devices. You have to  
13 inhale it somehow. Somehow you'd have to get the  
14 material airborne.

15 And the only way we could figure that out  
16 is if you set the building on fire, the device catches  
17 on fire, the material is released and someone has to  
18 go into that area while the device is still on fire.

19 MS. D'ARRIGO: So you're saying there's no  
20 dose at all to workers as long as the thing is in a  
21 sealed forum.

22 MR. SMITH: I believe so. Physically --

23 MS. D'ARRIGO: And if the thing cracked  
24 open, like let's say it fell off the lab desk and  
25 opened up, is that a possible scenario?

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1 MR. SMITH: They're fairly robust. They're  
2 not going to fall over and release material to you.

3 MS. D'ARRIGO: No, no. I don't mean fall  
4 over. I mean in the situation where it did get dropped  
5 or something and cracked open.

6 MR. SMITH: Well, I guess I could always  
7 come with the worst case scenario. But I think the  
8 worst case would be if somebody had eaten one of these  
9 devices.

10 MS. D'ARRIGO: I'm sorry. The worst case  
11 would what?

12 MR. SMITH: I guess someone could eat one  
13 of these devices. But since the source is lodged  
14 inside of a metal container, it would be very painful  
15 to start with. But I don't think anyone would get a  
16 dose from radiation. They might die from a blocked  
17 colon.

18 MS. D'ARRIGO: I guess my only problem is  
19 that because of the specific situation, and this is  
20 going to be extrapolated to other materials. And I  
21 don't agree that a hundred, or 200, or 300 millirems  
22 is an acceptable negligible dose. That's an amount  
23 that we get -- that were are legally allowed to  
24 receive from licensed facilities.

25 And to say that there can be an unlimited

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1 number of sources -- and specifically for gas  
2 chromatographs, I may not care about chromatographs,  
3 I may not care about that particularly, but I see a  
4 larger thing that's going on here.

5           You're going to move on to decommissioning  
6 and other areas. And so I think that if you're going  
7 to make statements that the risk is acceptable or  
8 negligible, I'd like to know what specifically you're  
9 talking about so that you can't then go ahead and  
10 extrapolate to say that there can be a lot of these  
11 other things.

12           Earlier in your presentation you said at  
13 one point there could be a lot of these devices and it  
14 would be unrealistic or not feasible for NRC  
15 inspectors to go out and inspect them all. And,  
16 therefore, because there's so many, we shouldn't  
17 regulate them. To me that doesn't sound --

18           MR. SMITH: Well, we should regulate them,  
19 I think, A, because the dose is very low. I mean we  
20 don't regulate --

21           MS. D'ARRIGO: You think 200 or 300  
22 millirems is fairly low?

23           MR. SMITH: Well, you're taking it out of  
24 context?

25           MS. D'ARRIGO: No, I'm trying to find out

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1 what doses you're talking about when you say that.

2 MR. SMITH: I have a copy of 1717 right  
3 there, if you'd like to take a look at it. It has  
4 some analysis, it has a radiological assessment, it  
5 has a scenario. These are ten times what we've ever  
6 seen.

7 So if you want to look at what you would  
8 really expect in a realistic case of an fireman  
9 running into a building, it would be 20 millirem or 30  
10 millirem.

11 Again, that's a policy decision that I  
12 can't make at this point. It's not something I've  
13 been asked to do. I've been asked to look at the  
14 radiological assessments and risk information that's  
15 out there, and give what I think in a subjective view  
16 is the right answer. That's my opinion. It's not the  
17 opinion --

18 MS. D'ARRIGO: Well, I was asked to come  
19 as a member of the public and give my feedback, and  
20 I'm telling you that if you want us to -- I mean I  
21 asked for all the pre-documentation ahead of time. I  
22 printed out everything that was available on the web.  
23 I did not have 1717. You did not ever mention any  
24 numbers lower than a hundred, 200, 300.

25 And so I'm just responding that I don't

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1 accept, as a member of the public, and I know about  
2 gas chromatographs, I've used them. I don't think I'm  
3 especially scared to use one, but I don't think --  
4 what you're doing here is setting a precedent for  
5 deregulation of a lot materials and a lot of items in  
6 society. And so that's my comment.

7 MR. KOKAJKO: Okay. Maybe if I could  
8 comment on your remorse just for a moment. Jim, my  
9 name is Lawrence Kokajko. I spoke earlier this  
10 morning.

11 Jim, what is the normal doses for the  
12 normal uses of gas chromatographs? Do you know?

13 MR. SMITH: I think it's zero.

14 MR. KOKAJKO: Zero. You know, I don't know  
15 where this is going. I just know that the Commission  
16 has directed us to take a look at this, as well as  
17 Congress has asked us to use risk information so that  
18 we can focus our resources more effectively on where  
19 the real risk is. And I understand your concern. And  
20 I'm glad you're here to provide it to us.

21 I don't know that this is setting a  
22 precedent for anything yet. I mean, we're still in  
23 the early stages, and I view this as probably a multi-  
24 year effort to look at a variety of -- across a large  
25 spectrum of activities within the materials of waste

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1 area activities.

2 If we even came to a conclusion that this  
3 should move from general -- I think it's general now,  
4 Jim?

5 MR. SMITH: Specifically-licensed devices  
6 as well and generally-licensed devices. The only  
7 difference is the label in many cases.

8 MR. KOKAJKO: If it's -- just a label  
9 difference?

10 MR. SMITH: Yes, generally -- under a  
11 general license there has to be additional warning  
12 labels that are placed on it. Mechanically,  
13 generally, they're identical. There's no difference in  
14 the physical device.

15 MR. KOKAJKO: If this were to move to an  
16 exempt device, we would only be looking at it in terms  
17 of just this device. This particular thing. It would  
18 not be applied -- we could not make a determination  
19 that this applies to everything that we do.

20 MS. D'ARRIGO: I'm sorry. What we're  
21 trying to look at here is whether a specifically-  
22 licensed thing would be or -- I'm sorry. A generally-  
23 licensed --

24 MR. KOKAJKO: Gas chromatograph.

25 MS. D'ARRIGO: Yes -- item -- would be

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1 then exempt from even the general license  
2 requirements.

3 MR. KOKAJKO: I said that that is a  
4 possibility.

5 MS. D'ARRIGO: Okay.

6 MR. KOKAJKO: That could be an outcome.  
7 I don't know what the outcome is yet. I mean that's  
8 what we're still studying?

9 MS. D'ARRIGO: I would then point to the  
10 generally-licensed items that have been showing up in  
11 steel facilities and I know that there have been  
12 efforts to deal with the steel industry on those  
13 items.

14 But it seems like deregulating or letting  
15 more radioactive materials out with less notification  
16 or knowledge that they're out there is not a trend  
17 that would be publicly acceptable.

18 MR. KOKAJKO: Thank you.

19 MR. SMITH: Thank you.

20 MS. BAILEY: I believe the gentlemen to  
21 the left was next.

22 DR. JOHNSRUD: I believe I was, but go  
23 right ahead.

24 MS. BAILEY: No, he was --

25 DR. JOHNSRUD: No, I was already here.

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1 MS. BAILEY: Okay.

2 MR. HEYER: I'll defer to -- go right  
3 ahead.

4 DR. JOHNSRUD: To follow in from Ms.  
5 D'Arrigo's comments, my -- there's anyways a risk in  
6 inviting members of the public to these things, you  
7 know, but we appreciate the fact that the Commission  
8 did so.

9 My concern goes to the multiple sources of  
10 additive risks that each individual, whether a worker  
11 or a transporter, or potentially a member of the  
12 public who accidentally has an exposure of an  
13 additional 100, or 200, or 300 millirem.

14 How are you accounting for all of the  
15 additional low dose exposures, whether it's the one  
16 millirem from recycled materials that apparently is  
17 going to be adopted, or each of the additional  
18 sources, apart from the gas chromatographs?

19 Is the NRC in any manner taking account of  
20 multiple exposures which are additive to the  
21 individual and may indeed, as the Commission moves in  
22 this direction, add up substantially to significant  
23 doses?

24 So far as I can tell, you're not taking  
25 any account whatsoever. You're simply looking one by

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1 one and that does not protect public health and safety  
2 or worker health and safety. Either one.

3 MR. SMITH: I'm not sure I get your point,  
4 but --

5 DR. JOHNSRUD: You don't?

6 MR. SMITH: Well, I believe if you protect  
7 the individual -- if you have a device that you can't  
8 get a dose from unless you're running into a burning  
9 building, do you think that that's adding to the -- I  
10 mean --

11 DR. JOHNSRUD: How many other doses does  
12 that fireman receive in the course of a year?

13 MR. SMITH: I don't know.

14 DR. JOHNSRUD: You don't know. Have you  
15 looked?

16 MR. SMITH: No, but I can't imagine that  
17 anybody does.

18 DR. JOHNSRUD: And you are assuming a  
19 background dose of what? 300, 360 millirem per year,  
20 plus an additional one to 200 or more --

21 MR. SMITH: Yes.

22 DR. JOHNSRUD: From this, plus what  
23 amounts from other deregulated materials that are  
24 recycled into the consumer protects that this worker  
25 may encounter, unless the --

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1 MR. SMITH: This is my statement. This is  
2 -- when I look at it, these are my judgements.

3 DR. JOHNSRUD: May I ask -- I'm sorry.  
4 Larry, who is in charge, I believe, of this project.

5 MS. BAILEY: That would be Lawrence  
6 Kokajko.

7 DR. JOHNSRUD: There you are. Could you  
8 respond to how the Commission is looking at the  
9 totality of additive doses from multiple sources for  
10 either workers or individuals in the public?

11 MR. KOKAJKO: You know, I don't ever  
12 pretend to speak for the Commission. The Commission is  
13 composed of five people who are very independent  
14 thinkers.

15 The staff, as you know, and I hope that  
16 you think that by having this meeting today is we are  
17 seeking input across these activities and trying to  
18 get diverse opinions in here so that we can inform the  
19 Commission of what may be alternatives to do in this  
20 area.

21 I don't pretend to tell you what the  
22 answer is. I don't know the answer. In fact, we met  
23 with David Lochbaum of the Union of Concerned  
24 Scientists a few weeks ago and I told him the same  
25 thing. I don't have the answer of how the Commission

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1 is going to vote on this.

2 All I'm doing is gathering the input so  
3 that we can give them informed decisions, and  
4 including your opinion on your concern that -- about  
5 the additive dose.

6 DR. JOHNSRUD: That being the case, let me  
7 very strongly recommend that you recommend to the  
8 Commission that the time really has arrived to take  
9 into consideration all of the additive small doses,  
10 but incremental doses that both the workers at  
11 licensed facilities and members of the public are  
12 receiving from the multiplicity of sources as you --  
13 as Ms. D'Arrigo said, as you use the decision here as  
14 precedent setting for other decisions, each of which  
15 constitutes the additional dose.

16 This is an extremely serious issue from  
17 the perspective of members of the public who really  
18 aren't badged workers in the industry, who gain no  
19 benefit from the accidental exposures from the  
20 multiple sources.

21 MR. KOKAJKO: Thank you for your comment.

22 MR. HEYER: Good morning. My name is Ralph  
23 Heyer. I'm with Thermal Measure Tech. One item, no. 7  
24 there, Mr. Smith. A point of clarification that I'd  
25 like to have is your second bullet, where you make

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1 references to the mill run doses. Are those both  
2 committed effective dose and deep dose equivalents?

3 MR. SMITH: No, those are committed  
4 effected doses.

5 MR. HEYER: Okay. And then secondly, I  
6 think some of the confusion that's probably come up as  
7 you're bringing up the 10 CFR Part 2100 millirem, a  
8 member of the public dose, and perhaps some of the  
9 members here are not quite understanding that there's  
10 restricted, specific license.

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1           And just because you have an exempt  
2 quantity source, or a generally licensed source, that  
3 there are other conditions associated with minimizing  
4 exposure.

5           MR. SMITH: Well, if there are no other  
6 questions, I'll run away.

7           MS. BAILEY: One more.

8           MR. DAMON: My name is Dennis Damon. I'm a  
9 member of the same Risk Task Group that Mr. Smith is.  
10 And what I -- there may be a misperception about what  
11 he was saying about these dose levels of 200 millirem,  
12 and 300 millirem and so on.

13           The events that those doses are received  
14 in are extremely rare accidental occurrences. And  
15 there's -- what he's saying is in the context of being  
16 a rare accidental situation, that's not a high dose to  
17 see in an accident case.

18           And that the whole concept here of risk  
19 involves two things. Consequences and likelihood. And  
20 you have to consider the likelihood of those doses  
21 occurring. It certainly is not true that the  
22 Commission has made some determination that 200 or 300  
23 millirem is in some sense acceptable.

24           In fact, what they've said is that the  
25 hundred millirem dose to a member of the general

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1 public for routine release is something that one  
2 should always be under that value.

3 So no routine situation would ever be  
4 permitted to continue that exposed members of the  
5 general public routinely to any member over a hundred  
6 millirem.

7 So the 200 -- I'm saying -- the thing to  
8 keep in mind is this is a rare accident. Accidents do  
9 happen. And so the conclusion Mr. Smith was drawing is  
10 that the risk, the likelihood times consequences of  
11 the situation there appears to be low. But not that  
12 a 200 millirem dose in any sense is an acceptable  
13 dose.

14 MR. LUBENAU: Joel Lubenau, again. I go  
15 back to the first two questions I asked.

16 MR. SMITH: Okay.

17 MR. LUBENAU: How many of these sources  
18 are there? And you already told me you haven't looked  
19 at the NMED for the accidents. Now I'm also hearing  
20 that the accident rate is low. We have the same  
21 problem with the sources. Nobody's collecting data  
22 except for Jim --

23 MR. SMITH: I personally have not looked  
24 at it.

25 MR. LUBENAU: Who is going to look at it

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1 when the information goes to the Commission?

2 MR. SMITH: Sorry?

3 MR. LUBENAU: Is somebody going to look at  
4 it when the staff's recommendations go to the  
5 Commission? What I'm sensing here is some  
6 vulnerability.

7 You're saying gee, I've looked at this. I  
8 don't see a problem. And there are other people who  
9 are saying, but you haven't furnished the data, the  
10 objective data to show that there's no problem.

11 If there have been accidents, how many? What's  
12 the rate? What's the numerator? What's the  
13 denominator? What are the consequences? Has someone  
14 looked at the reports? Then we can have a more  
15 meaningful discussion.

16 And I'm saying this without agreeing or  
17 disagreeing with some of the views that have been  
18 expressed here. There's a lack of data and a lack of  
19 discussion of data thus far.

20 MR. KOKAJKO: Jim, let me answer that.  
21 Mr. Lubenau, that -- we are still in the early stages.  
22 I mean this is -- one of the comments that -- I'd like  
23 to restate what I said in my opening remarks, is that  
24 one of the comments that we received last September  
25 was the fact that we should have early involvement

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1 from people to say these are the things that would be  
2 of concern to look further into.

3 So if the comment is that we need to take  
4 a look at additional data, as far as the number of  
5 components out there, that's an item that we can take  
6 back with us to continue our review.

7 I believe some of that information already  
8 exists with IMNS. We're in our formative stages for  
9 completing the rest of that work activity as well, so  
10 we take your comment. Thank you.

11 MR. ENTWISTLE: Fred Entwistle. I'd just  
12 like to make a comment as a licensee who uses some of  
13 these devices. That I appreciate your looking at  
14 these from a risk-based approach.

15 If these are specifically-licensed, or  
16 generally-licensed, or exempt devices, I don't think  
17 that's going to make a significant difference in the  
18 actual hazard to the workers or to the public. There  
19 will be the same number of devices out there. They'll  
20 be used under pretty similar conditions.

21 The difference that it makes is that in  
22 our group we're responsible for the regulatory  
23 compliance. It will allow us to more accurately  
24 balance the use of our resources towards the actual  
25 risk present.

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1           If you look at the laboratories where  
2 these were are used, there are chemical hazards  
3 present, physical hazards, biological hazards, a  
4 variety of things.

5           And right now because of the licensing and  
6 the regulatory aspects, we put a lot more effort into  
7 regulating some of these very minor radiation sources  
8 than the risk really justifies, certainly, in  
9 comparison to the other hazards that are present.

10           So I think this risk-based approach, which  
11 tries to strike a reasonable balance among those  
12 things, is a very good -- good way to go. So I  
13 appreciate the effort.

14           MR. SMITH: Thank you.

15           MR. FLETCHER: Roland Fletcher, State of  
16 Maryland, representing the Agreement States. I want  
17 to comment on the early involvement that you're trying  
18 to get here, because the Agreement States have really  
19 been promoting that.

20           But I also want to tie in what Joel has  
21 said. We're not saying get us involved before you have  
22 data that you can defend. What we're saying is you  
23 get us involved before you draw conclusions from that  
24 data.

25           And I think as I look at just one bullet

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1 up here, where it says, "Assumes up to ten times the  
2 rate normally experienced in a leaking source, the  
3 expectation of an Agreement State representative would  
4 be you have data which shows what you're taking ten  
5 times of. And what I'm hearing is you don't.

6 MR. SMITH: I personally don't have it  
7 before me. The gentlemen who did 1717, as well as 6642  
8 did. They looked through NMED database, they looked at  
9 incidents that have occurred. They took that  
10 information in developing it. I didn't think it was  
11 necessary to bring all that data with me today.

12 MR. FLETCHER: I'm just saying that it's  
13 not so much that we want to get involved so early that  
14 we can't really know what you're doing. It's just  
15 before you draw a conclusion from that data is where  
16 we want to become involved.

17 MR. SMITH: Thank you.

18 MS. NIMMO: Elsa Nimmo. Just a very quick  
19 question. A number of us are interested in the NMED  
20 database, what that is and --

21 MR. SMITH: It's a nuclear materials event  
22 database, and it contains information about things  
23 that we think are noteworthy, preliminary  
24 notifications of occurrences, incident reports. I  
25 don't know exactly what all is put into NMED.

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1 MS. NIMMO: Is that a database NRC  
2 maintains based on reports to the NRC of leaking  
3 sealed sources?

4 MR. SMITH: I believe that not only do we  
5 maintain it, but we get information that's sent in  
6 from the Agreement States.

7 MS. NIMMO: As well.

8 MR. SMITH: So it should be -- I mean it  
9 hasn't always gotten the information from the  
10 Agreement States, but I believe in the last few years  
11 they've been feeding information from incidents. That  
12 was a bit of a touchy situation as to whether or not  
13 we were going to get the information.

14 But I believe now it's going fairly well.  
15 We're getting the information. A contractor puts it  
16 into the database, and they use that to analyze the  
17 number of events that have occurred.

18 MS. NIMMO: Are data from that available  
19 -- say you represent a manufacturer that uses seals  
20 sources and you're interested in the overall -- the  
21 leakage rate from a particular type of source that you  
22 might use, realizing there are different models.

23 MR. SMITH: I don't know, to be honest  
24 with you. Does anyone else in the audience know? I'm  
25 not familiar with the database that much. I don't use

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1 it on a daily basis.

2 MR. LUBENAU: Joel Lubenau, again. You'd  
3 better start putting me back on the payroll. The  
4 nuclear material event database has been in existence  
5 for a number of years.

6 The Agreement States have been providing  
7 information for many years, although only more  
8 recently has NRC been processing it.

9 I think it's available to the public, and  
10 you need to contact somebody in the NRC to get the  
11 information on how to do that. How somebody here can  
12 make that --

13 MR. SMITH: Sam Pettijohn, I think, is the  
14 manager for it.

15 MR. LUBENAU: All right. Well, there's a  
16 name and anybody who's interested in trying to get  
17 that information --

18 MR. SMITH: Sam Pettijohn is the manager  
19 for it, but I don't want to -- Pettijohn. P-E-T-T-I-J-  
20 O-H-N, I think, is his last name.

21 MR. LUBENAU: P-E-T-T-I-J-O-H-N.

22 MR. SMITH: Thank you.

23 MR. LUBENAU: Okay. A couple of caveats  
24 about the database. People who have events that meet  
25 criteria in the regulation have to report them to the

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1 NRC or the Agreement States, and then it's all pooled  
2 into this one databank.

3 Don't go forward assuming that that  
4 represents the entire picture. We've got an iceberg  
5 here. People, for example, with respect to lost and  
6 stolen sources, particularly the ones that are lost,  
7 we in the Agreement States will give that report.

8 If the licensee knows they have source,  
9 know they lost the source, know they have to report  
10 the loss and they make that report -- and in the  
11 general license population that's a big problem.

12 Secondly, we're not collecting information  
13 on findings of radioactive sources, such as by the  
14 scrap industry and the steel mills, because there are  
15 no requirements to make those reports.

16 So it's a very useful database. There's  
17 a lot of good information in there. Just keep in mind  
18 it's not a statistical representation and it's not a  
19 complete picture.

20 MR. SMITH: Okay. Now I get to run away.  
21 Thank you.

22 MS. BAILEY: If there are no more  
23 questions, I'd like to propose that at this point we  
24 take a 15-minute break and reconvene at 10:35. Thank  
25 you.

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1 (Whereupon, the foregoing matter went off  
2 the record at 10:21 a.m. and went back on  
3 the record at 10:44 a.m.)

4 MS. BAILEY: Excuse me. We'd like to go  
5 ahead and begin the next presentation. Before we  
6 begin the next presentation, there are three items  
7 that I'd like to bring up.

8 First of all, I'd like to emphasize,  
9 again, that the answers to the questions that we're  
10 presenting today are preliminary answers. They are  
11 not final and we are here for your input. So we  
12 encourage your input. And for those that have given  
13 input earlier, thank you very much.

14 Also, in relation to that, you do have  
15 feedback forms and we ask you to please fill those  
16 out. If there's something you don't like about what  
17 we've done, if there's something you like, please put  
18 that in the feedback form. That's something that we  
19 can take with us and use to improve what we do the  
20 next time around.

21 The third point is there was a question on  
22 the availability of NMED data. And Candice Drummond  
23 asked around for that, and she's got some information  
24 on how or where that may be available.

25 MS. DRUMMOND: Good morning, everyone.

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1 With NMED, it's currently not available to the public,  
2 but you can make a request through Samuel Pettijohn,  
3 and you can locate him at 301-415-7000, which his our  
4 general number. And we could do a small search.

5 If it happens to be larger, then we'd  
6 actually like you to make a FOIA request because of  
7 our resources as well. So again, that's Samuel  
8 Pettijohn at 301-415-7000.

9 MS. D'ARRIGO: But if it's not available  
10 to the public, then you're saying that maybe there  
11 could be an exception for a small search that we could  
12 arrange with him. Is that what you're saying?

13 MS. DRUMMOND: Yes, ma'am. And if it's  
14 larger, they would prefer you make a FOIA request,  
15 because of resources. But small ones you can go  
16 directly through Sam as well.

17 MS. BAILEY: By the way, the 7,000 number  
18 that Candice gave you is the NRC operator. At this  
19 point, I'd like to introduce Jim Danna, who will be  
20 doing the presentation on our case study in static  
21 eliminators.

22 MR. DANNA: Good morning, everyone. My  
23 name is Jim Danna. I'm a systems performance analyst  
24 in the Risk Task Group. And prior to being in the  
25 group, I spent my time doing performance assessment in

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1 the waste management area, waste management and waste  
2 disposal.

3 I've been assigned responsibility for  
4 conducting the case study on static eliminators and  
5 I'm happy to do this. This is giving me an opportunity  
6 to branch out a little bit, to learn about the  
7 regulations in other areas and also to become familiar  
8 with an area that I wasn't prior familiar with.

9 Also, I think it allows me to come in with  
10 an unbiased viewpoint. When I go through this process,  
11 when I go through the information and through the  
12 thought process and start to answer some of these  
13 questions, I feel I'm not coming in with preconceived  
14 opinions.

15 With that, as Marissa pointed out, I'll  
16 brief you on the status of the case study regarding  
17 static eliminators. I'll focus on the first set of  
18 case study questions. It's the same set that Jim went  
19 through. And in the same fashion I'll proceed through  
20 those one by one.

21 Before I do that, I'd like to briefly  
22 describe for those who aren't familiar with it, as I  
23 wasn't, just what a static eliminator is.

24 A static eliminator is a device, a small  
25 device that contains a sealed source, radioactive

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1 material. And the purpose of a static eliminator is  
2 to create an ionized environment to reduce a static  
3 charge build up on equipment and materials.

4 They may be hand held or mounted devices.  
5 They may be brushes or air guns. Or the sealed source  
6 may be contained in a -- in some sort of container  
7 that then is mounted into place.

8 Typically, or historically, polonium-210  
9 is used as the source material. Polonium-210 is an  
10 alpha emitter with a very weak gamma. It has a half  
11 life of 138 days. That's important to note. Figure in  
12 a couple of years it will be significantly decayed  
13 away. Also, americium-241 is used in static  
14 eliminators.

15 However, the studies that I've looked at  
16 haven't evaluated americium 241. And as I get to that  
17 point, I'll note that that's one thing that I would  
18 suggest that we look into.

19 With respect to what they're used for, the  
20 applications, there's generally two categories.  
21 Consumer devices and commercial devices. And that  
22 categorization is based primarily on the source  
23 quantity.

24 Commercial devices are used in printing  
25 shops, electronic applications and photograph

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1 applications, paint shops, anywhere where you'd want  
2 the static on surfaces reduced for quality.

3 Also, it's used, I found out, in the  
4 aeronautic industry to reduce static on laser steering  
5 systems. I think that's right.

6 With respect to consumer application, they  
7 have been used in photograph and phonographic  
8 applications. But again, as you will see, this is  
9 based on historical evidence.

10 One of the things I would propose is  
11 looking into current consumer uses. I think most would  
12 agree probably the phonographic applications might be  
13 somewhat outdated. Ask my daughter. Next slide,  
14 please.

15 Jim went over a little about the  
16 regulation of generally-licensed devices. Static  
17 eliminators falls under that same category. The  
18 manufacture and distribution of static eliminators is  
19 regulated in Part 32.

20 The use and disposal of static eliminators  
21 is licensed -- regulated under Part 31, specifically  
22 31.3, addresses static eliminators with sources of  
23 less than 500 microcuries of polonium-210, and 31.5  
24 addresses static eliminators with sources greater or  
25 other than polonium-210 or greater than 500

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1 microcuries.

2 I'd like to emphasize at this point that  
3 the focus of this case study is somewhat hypothetical.  
4 It's whether or not static eliminators could be moved  
5 from being a generally-licensed device to categorized  
6 as an exempt device.

7 Now we're not charged with formally doing  
8 this evaluation, putting together a package and  
9 putting this forth as a regulatory option.

10 We're looking at this in a hypothetical  
11 sense. It's not necessarily on the table. It's not  
12 pending. Our goal is to look at how such an analysis  
13 might be done. What sort of information might be  
14 needed and how a risk-informed approach might be used  
15 in this application.

16 We're testing our approach to finding what  
17 areas risk information is useful. We're not actually  
18 putting together the package that supports this  
19 particular regulatory issue. So I wanted to make that  
20 clear. This in some sense is a hypothetical issue to  
21 test the screening criteria, as Marissa pointed out.

22 In the case study plan, Marissa identified  
23 the three sets of screening -- three sets of case  
24 study questions, and today I'm going to focus on the  
25 first set, which are those related to application of

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1 the screening criteria.

2 Do we have a Plan B?

3 MR. KOKAJKO: Jim, why don't you continue  
4 with your presentation and just note the number --  
5 slide number that you're discussing.

6 MR. DANNA: Sure. Actually, I'll note the  
7 question number. My slides are numbered a little bit  
8 differently.

9 MR. BERNERO: Larry, perhaps I could ask  
10 a question regarding the last slide?

11 MR. KOKAJKO: Feel free.

12 MR. BERNERO: Bernero. The question -- on  
13 your last slide you seem to confine the risk-informed  
14 application to the single question could these devices  
15 that are generally licensed be classified as exempt  
16 devices? Is there not, or should you not, also  
17 consider a second risk information use, and that is is  
18 there anything with regard to Part 31.5 for generally-  
19 licensed devices that could be changed?

20 For instance, should americium-241 be used  
21 in lieu of polonium-210? Because polonium-210 has the  
22 inherent protection of the shorter half life.

23 MR. DANNA: I would say yes. Envisioning  
24 what might happen down the road, I can see taking --  
25 and we'll see this as I review the available

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1 information and looking at what I would consider to be  
2 lacking, what additional information would be  
3 necessary.

4 At the conclusion, we might reach that  
5 point, that this type of analysis might lead us to the  
6 position that we might have to regulate on a nuclide  
7 by nuclide basis.

8 And, in addition, in looking at static  
9 eliminator case study and putting it next to the gas  
10 chromatographs graph case study, both regulated under  
11 the same set of regulations, however, the result may  
12 be very different.

13 We might find that for in the case of  
14 static eliminators with polonium-210 it might risk --  
15 the risk information -- the risk-informed approached  
16 might be very appropriate.

17 In other areas, we might find that risk  
18 information may not be useful to support moving a  
19 device from generally exempt to -- or generally  
20 licensed to exempt, but instead may actually support  
21 a refinement of the actual regulations that are  
22 applicable.

23 I think that once we -- these case studies  
24 -- and we look at the results and put them side by  
25 side, then started to ask some questions, why gas

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1 chromatographs came up with different answer than  
2 static eliminators, what are the similarities, what  
3 are the differences, it may lead us off into a  
4 different direction.

5 And I think that's what the second and  
6 third set of questions will do when we get into safety  
7 goals and the other -- that there are follow on  
8 questions.

9 It's as if this were the end point of the  
10 case study, and once we finish this first set we're  
11 finished. We give you a thumbs up or a thumbs down.  
12 Hopefully, we'll gain insight that will lead us to the  
13 next steps.

14 All right. I guess we're going to do this  
15 --

16 MS. D'ARRIGO: Can I ask one more quick  
17 question?

18 MR. DANNA: Sure.

19 MS. D'ARRIGO: Diane D'Arrigo. Is there  
20 a place where there's a listing or a compilation of  
21 all of the generally-licensed -- all the general  
22 licenses?

23 MR. DANNA: Is someone from IMNS here that  
24 might be able to answer that question better than I?

25 MR. KOKAJKO: Excuse me. Diane? There is

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1 a program that the NRC has started. It started a  
2 couple of years ago to register generally-licensed  
3 devices. I believe the Commission decided that back in  
4 1998 some time and we are coming up with a database to  
5 register generally licensed devices now.

6 That program has not gotten fully started  
7 yet. They're still working on the computer system to  
8 make that happen. And that's about the best I can  
9 provide you right now.

10 MS. D'ARRIGO: I guess the categories of  
11 them. Like there are gas chromatographs, and there  
12 americium smoke detectors. Is there somewhere that  
13 lists all the categories?

14 MR. DANNA: The regulation 31.5 does a  
15 pretty good job of walking through those, but it's not  
16 -- I wouldn't say it's definitive. It gives generally  
17 classifications.

18 With respect to sealed sources and  
19 devices, where a static eliminator -- the sealed  
20 source and device registry identify those that have  
21 been certified, if I have the terminology right.

22 And that's available on the internet under  
23 the material's web page. I can't tell exactly where it  
24 is. And that's something that's searchable.

25 But as far as all generally-licensed devices, I

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1 couldn't answer that question.

2 All right. So what we'll do is we'll start  
3 with question no. 1 and we'll just walk through and,  
4 hopefully, we'll all stay together on this.

5 And forgive me for looking back. You know,  
6 the last time I gave a presentation, the same thing  
7 happened and I did this for the first couple of  
8 minutes.

9 Question no. 1. What risk information is  
10 currently available in this area? Have any specific  
11 risk studies been done?

12 In looking at the area of static  
13 eliminators, I identified four studies that seem to be  
14 focused on dose assessment or risk assessment. Jim  
15 discussed two of them, the two more recent. It's  
16 NUREG-1717 and NUREG/CR6642. In addition, I found two  
17 earlier studies, NUREG/CR1775 and CRP Report No. 95.

18 What I'll do is I'll briefly go through  
19 each of those four, trying to hit the high points, the  
20 focus or the purpose of the particular study or report  
21 and then how static eliminators were considered and in  
22 a summary fashion what the results were. And if  
23 anybody needs more information on any of these four  
24 reports, I can provide you with that.

25 The first one, NUREG/CR-1775 is titled

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1 "Environmental Assessment of Consumer Products  
2 Containing Radioactive Material," and that was  
3 released in October of 1980.

4 This study assessed the impacts -- and I  
5 apologize. I'm going to read a lot of this because I  
6 don't have it all within my head and I want to make  
7 sure I get it right.

8 The study assessed the impacts of various  
9 consumer products which contain radioactive material  
10 and the impacts of those products on people and the  
11 environment. The study was focused on the benefits and  
12 risks associated with the distributed consumer  
13 products at that time. This is 1980.

14 Consumer products were considered to be  
15 those available in the marketplace, to the general  
16 public as off the shelf. Just a point to note, this  
17 study did not look at commercial devices. And within  
18 this set, static eliminators intended for consumer use  
19 were considered.

20 At the time, again, 1980, static  
21 eliminators were used by consumers primarily in the  
22 photographic and hi-fidelity applications. At that  
23 time, the report indicates that only one line of  
24 static eliminators containing radioactive material was  
25 manufactured in the United States for consumer use.

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1           There were two sizes available. One with  
2 a nominal source of 200 microcuries of polonium-210  
3 and another with a nominal source of 500 microcuries  
4 of polonium-210.

5           In these particular sources, the polonium-  
6 210 was absorbed onto ceramic microspheres which were  
7 then resin-bounded to an aluminum backing and the  
8 report -- it was estimated that 50,000 of the 200  
9 microcurie devices, and 20,000 of the 500 microcurie  
10 devices were distributed each year. And again, these  
11 were a polonium-210 with a half life of 138 days.

12           The report considered the radiological  
13 health impacts in terms of committed organ doses that  
14 would result through the -- that possibly could result  
15 through normal manufacturing, distribution, use and  
16 disposal and during accident conditions, specifically  
17 fire, and also, misuse.

18           The next report, NRC Report No. 95 is  
19 titled "Radiation Exposure of the U.S. Population for  
20 Consumer Products and Miscellaneous Sources." This  
21 was released in 1987.

22           It includes static eliminators and it was  
23 -- with respect to static eliminators it was based  
24 almost entirely on the proceeding report, on the 1980  
25 NUREG-1775.

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1           In NCRP Report No. 95, they took those  
2 organ doses for static eliminators and converted them  
3 to effected dose equivalents.

4           Therefore, I won't go over the source  
5 again. The source is the same, polonium-210 in ceramic  
6 microspheres. The scenarios were the same. The source  
7 sizes were the same.

8           The NCRP report assumed 37 -- roughly  
9 37,000 units were distributed annually of the 5,000  
10 microcurie size device. That's up from 20,000.

11           Based on the assumptions that were in  
12 NUREG-1775 -- and again, I risk taking this out of  
13 context, however. The NCRP report provided very little  
14 background of the context of these numbers.

15           However, during normal use, it was  
16 expected an individual might receive 320 millirem.  
17 However, during a fire in a warehouse, the dose to a  
18 firefighter without respiratory protection was  
19 estimated to be 32 REM. SO you have quite a range  
20 there.

21           Again, the report did not provide any of  
22 the background and it was based on a device that is no  
23 longer -- I believe is no longer in use, the ceramic  
24 microspheres.           I provide that information  
25 mostly for historical background.

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1           The NCRP report though, however, does rank  
2           these consumer devices and applications and static  
3           eliminators comes out very near the bottom, meaning  
4           that in the realm of consumer materials and devices  
5           applications that involved radioactive material,  
6           including those that are exempt, the risk associated  
7           with static eliminators is very low.

8           So I think we can take -- even though the  
9           numbers may be off from current applications, the  
10          relative risk is useful.

11          The next report is NUREG-1717 and Jim went  
12          over that. I'll just summarize, again, that that  
13          report -- titled "The Systematic Radiological  
14          Assessment of Exemptions for Source and Byproduct  
15          Materials."

16          It documented an assessment of potential  
17          radiological impacts on the public associated with the  
18          present regulatory exemptions for source and byproduct  
19          material.

20          In addition to evaluating current  
21          exemptions, it also looked at -- I think there were  
22          five devices or applications that are generally  
23          licensed under Part 31, one of which was gas  
24          chromatographs. Another is static eliminators.

25          NUREG-1717 evaluated individual collective

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1 doses associated with distribution, routine use,  
2 disposal as ordinary trash and a misuse, including  
3 accidents, of both commercial and consumer static  
4 eliminator devices.

5           You may recall that the earlier two  
6 studies didn't look at commercial devices. The source  
7 in a commercial device is much greater than in a  
8 consumer device.

9           NUREG-1717 looks at the source as being a  
10 -- I'm sorry. NUREG-1717 was released in December of  
11 1999. So it's fairly recent. The source that was  
12 considered was a composite foil of gold and polonium-  
13 210, pressure welded onto a silver backing plate and  
14 then gold plated to encapsulate the source.

15           Again, this is different from the earlier  
16 studies which looked at the polonium-210 absorbed onto  
17 the ceramic microspheres.

18           For the consumer units, it was assumed  
19 that 30,000 units are distributed annually, each with  
20 an initial polonium source of 500 microcuries. So it's  
21 comparable to what the other two studies estimated.

22           For the commercial units, a source of 200  
23 millicuries was assumed and 10,000 units were assumed  
24 to be distributed annually.

25           And again, I know this is a lot of

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1 numbers, I can provide detailed information. All of  
2 this will be in the case study report.

3 The study estimated doses resulting from  
4 normal distribution, consumer and commercial use and  
5 disposal. The study also considered misuse in accident  
6 scenarios.

7 With respect to results, one scenario that  
8 was considered was the driver that -- essentially, the  
9 study assumed that all the devices produced annually,  
10 all were produced by the same manufacturer, a total of  
11 40,000 units, 30,000 consumer units and 10,000  
12 commercial units.

13 That over the course of year, all of those  
14 devices were picked up by the same driver and  
15 transported to whatever the distribution location was.  
16 So you have a single driver transporting all 40,000  
17 units in a given year.

18 It is estimated -- the report estimates  
19 doses to that individual, the driver, being  
20 approximately 2 millirem. Again, I think we could  
21 agree that as far as the driver goes, that's a worse  
22 case -- those are worse case assumptions.

23 Individual doses received during normal  
24 consumer and commercial use and disposal through  
25 landfill and incineration, were all estimated to be

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1 much less than 1 millirem.

2 I'll jump in here right now and say that  
3 the report itself doesn't provide the details of the  
4 analysis or all the assumptions. And n a couple of  
5 slides further, I'll note that as one of the areas  
6 which I consider to be necessary for additional study.

7 To go back and look at the details of  
8 these assessments, what the assumptions were made and  
9 what scenarios were developed, and what the  
10 likelihoods are so that these numbers are put into  
11 context, rather than working straight one millirem  
12 number or the two millirem number.

13 And I think in listening to some of the  
14 questions I made heard this morning, that would  
15 address some of those concerns that we're just  
16 marching forth with a number. We're not looking at the  
17 details of how that number was developed.

18 For misuse, the 1717 study assumed that a  
19 unit -- a static eliminator unit was carried in an  
20 individual's pocket for 2,000 years -- 2,000 hours  
21 during the course of one year. The worse case  
22 assumption.

23 For the consumer unit, this resulted in an  
24 estimated annual effective dose equivalent of .2  
25 millirem to the whole body and a dose equivalent of 20

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1 millirem to a small area of the skin.

2 For the commercial unit, this resulted in  
3 an estimated annual effective dose equivalent of 80  
4 millirem to the whole body and a dose equivalent of 8  
5 rem to a small area of the skin.

6 Again, this is a misuse scenario where the  
7 static eliminator is carried in the individual's  
8 pocket for 2,000 hours during the course of a year.

9 Accidents that were evaluated involved  
10 fire, both a truck fire and a warehouse fire. Doses to  
11 a firefighter with respiratory protection were on the  
12 order of -- let me get this straight. 20 millirem.

13 The doses to an individual coming in and  
14 cleaning up after the fire were in the order to 200  
15 millirem for a truck fire and a hundred millirem for  
16 a warehouse fire.

17 Again, that's somebody coming in, cleaning  
18 up after one of these fires without any respiratory  
19 protection, and the report didn't describe the  
20 assumptions that were made, just how many of these  
21 devices were involved in a fire.

22 I would venture a guess to say that they  
23 assume that all 40,000 eliminators were in one truck  
24 or one warehouse. But again, this something I think  
25 we would want to verify if we're going to use these

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1 numbers or basing these sort of decisions on such  
2 numbers.

3 The fourth report that I'll describe is  
4 NUREG/CR-6642. It's titled the "Risk Analysis and  
5 Evaluation of Regulatory Options for Nuclear Byproduct  
6 Material Systems." And again, this is one and that  
7 Jim described and included gas chromatographs.

8 This report documents a project directed  
9 by the NRC staff to identify regulatory options for  
10 byproduct material, including static eliminators, that  
11 -- regulatory options that are risk informed.

12 That's defined as options that are  
13 formulated in light of insights obtained from risk  
14 analysis comparable to what I think we're doing here.

15 The licensee's activities and devices were  
16 organized into 40 systems. Static eliminators were  
17 grouped into system 29, along with other small sealed  
18 sources, including check sources, calibration sources,  
19 scintillation detectors.

20 So static eliminators weren't in a system  
21 by themselves. They were grouped with other small  
22 sealed sources.

23 A radiation risk assessment was performed  
24 for each of the 40 byproduct material systems to  
25 determine both normal operation in an accident to the

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1 worker and the public.

2 The study -- this study, 6642, considered  
3 static eliminating units intended for both consumer  
4 and commercial use and it referred -- it directly  
5 referenced NUREG-1717 for characteristics,  
6 radiological and physical characteristics of those  
7 commercial and consumer devices. So there's a link  
8 between 1717 and 6642 with respect to static  
9 eliminators.

10 The study -- the assessment of static  
11 eliminators was bounded by the commercial unit with a  
12 source of 500 millicuries. Again, this referenced  
13 NUREG-1717.

14 The number of commercial units in use  
15 ranged from 10,000 units, which is the number assumed  
16 in 1717, up to 150,000 units. And that was based on  
17 tabulated data on the number of sources produced and  
18 multiplied by a factor of three to account for  
19 Agreement States.

20 So we've got quite a range there. 10,000  
21 to 150,000 for the number of units. For the analysis,  
22 they assumed the midpoints of 75,000.

23 The study provides the results in various  
24 summary fashion. It indicates that with respect to  
25 static eliminators the risks are -- and it's called

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1 very low and qualified as being much less than 1  
2 millirem per year on a per unit basis, under normal  
3 conditions.

4 For a fire with failure to follow good  
5 radiation practices, that dose to a worker was higher,  
6 but it was considered -- it was stated to be well  
7 under 500 millirem and the dose under those conditions  
8 of fire -- the maximum dose to the public, the report  
9 is less than 500 millirem.

10 And again, the study does -- the  
11 particular report doesn't provide details of those  
12 numbers. However, the next step would be to go back  
13 and look at the assumptions that were made and how  
14 those numbers were calculated. That was a long slide.

15 Number 2. What is the quality of the  
16 study? Is it of sufficient quality to support  
17 decisionmaking?

18 Basically, I went back over those four  
19 studies and I assessed how useful that information  
20 would be to developing a risk-informed basis for the  
21 case of moving static eliminators from generally-  
22 licensed devices to exempt.

23 I've touched upon these points as I  
24 described the reports, but I'll summarize them  
25 briefly. NUREG/CR-1775, the 1980 report, I considered

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1 to be outdated from a quantitative standpoint.

2 Basically, the source described the  
3 polonium-210 absorbed onto ceramic microspheres.  
4 Again, I believe that's no longer in use and that it's  
5 -- the study also assumes consumer applications that  
6 may no longer be relevant, the high fidelity  
7 application, the phonograph application.

8 The study -- the 1980 study was based on  
9 disseminating models that are no longer current.  
10 Basically, it reported organ doses, and the study did  
11 not consider commercial devices or applications.

12 However, that study did lay the groundwork  
13 for future studies, notably, NCRP Report 95. NCRP  
14 Report 95, as I mentioned, took those organ doses for  
15 static eliminators and converted those to effective  
16 dose equivalents.

17 And although it has the same shortcomings  
18 as 1775, I mentioned that it did provide that ranking  
19 of consumer products, both exempt and general license,  
20 and I think it provides useful qualitative insight of  
21 relative risks.

22 The two more recent studies, 1717 and 6642  
23 -- 1717 being released in 19 -- as drafted in 1999,  
24 December of 1999, and 6642 released in January of  
25 2000.1717 provided good general information.

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1           However, the detail was not presented in the  
2 report and I think that detail and information would  
3 be very useful and probably critical to determine the  
4 basis for some of these numbers.

5           I think it should also be compared to the  
6 current uses of static eliminators with respect to the  
7 types of devices and the number of devices.

8           I mentioned, I think, on my first slide  
9 that the static eliminators are currently manufactured  
10 with americium-241 as a source. However, americium-241  
11 was not evaluated in the 1717 study, or the 6642  
12 study. So it's somewhat lacking in that respect.

13           Also, I think I mentioned that the  
14 scenarios and the assumptions appear to be worse case  
15 assumptions and may not be -- as far as a risk-  
16 informed approach goes, I think we'd want to insert  
17 more realism into the numbers.

18           Therefore, take some of this worse case  
19 analysis and maybe adopt some of the methodology, but  
20 validate some of the numbers, maybe provide some more  
21 realistic assumptions. Also, I don't believe that  
22 study looked at the likelihood of these scenarios.

23           And Dennis Danna pointed this out, that  
24 some of these numbers look bad, but you need to get  
25 the risk insight.

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1           To get the risk insight you need to weigh  
2           those consequence numbers against the likelihood of  
3           these scenarios occurring, such as an individual  
4           worker carrying a device in his pocket for 2,000 hours  
5           during the course of a year or an individual driver  
6           transporting all 40,000 units during the course of a  
7           year. I think you agree that those are probably worse  
8           case assumptions.

9           6642, again, the same situation. I think  
10          that that's -- you could take the detailed  
11          calculations in that study, but then expand them to  
12          incorporate americium-241.

13          Also, that report states that the risks --  
14          these risk numbers have large uncertainties, generally  
15          because on an order of magnitude, which as you can see  
16          by some of these numbers, that significant -- and that  
17          the uncertainties generally arise from a lack of data.

18          So, again, I would suggest we go back and  
19          look at some of the numbers, pull out those associated  
20          with static eliminators and see what we could do with  
21          some of the data and how we could update some of those  
22          numbers.

23          The next slide. What additional studies  
24          would be needed to support decision making.  
25          Succinctly, I would suggest that a detailed dose

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1 calculation that underpen the results reported in  
2 NUREG-1717 and 6642 would be useful.

3 They should be reviewed. The assumptions  
4 reviewed and the methodologies reviewed. That the more  
5 definitive information regarding the physical and  
6 radiological characteristics of static eliminators  
7 would be needed.

8 That would involve probably going through  
9 and identifying current manufacturers, specifically  
10 identifying the characteristics of the devices that  
11 are being manufactured at this time, and try to get a  
12 feel for the numbers distributed and who the users are  
13 and what the current applications are.

14 Basically, take all the information we've  
15 had in these proceeding reports and bring it all up to  
16 date and, hopefully, validate some of it. Again,  
17 impart some realism.

18 And thirdly, I would propose that this  
19 information be compiled to support a realistic,  
20 probablistic calculation.

21 Realistic in terms of moving away from  
22 some of the worst case analysis and applying some of  
23 the -- the likelihood of some these scenarios  
24 occurring, and probablistic in that we would represent  
25 some of these numbers, such as the quantity

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1 distributed, and giving it by distributions, if at all  
2 possible, to get a feel for what the uncertainties  
3 are, to try to quantify some of the uncertainties  
4 associated with these numbers.

5 Presumably, it would lead to -- would  
6 allow us to compile the doses potentially received  
7 under normal conditions, with those under accident  
8 conditions and put those in some of -- in a  
9 perspective of what -- over the course of a year, what  
10 other true risks incorporated and the likelihood of  
11 occurrence and the uncertainties.

12 Question no. 4. I think Jim mentioned  
13 that these devices -- when these devices are submitted  
14 for registration, risk information is provided by the  
15 manufacturer and when the certificates are given --  
16 and I hope I get this right -- that the safety  
17 assessments are performed. With that respect, risk  
18 information is incorporated into the certification  
19 process.

20 As far as risk information being incorporated  
21 into the decision of whether or not they should be --  
22 or static eliminators or other devices should be  
23 generally licensed or exempt, I think a lot of that is  
24 based on historical perspective and probably less on  
25 risk perspective.

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1           And that's supported by the analysis in  
2           the NCRP report where we show -- where it shows the  
3           range of consumer applications, both exempt and  
4           licensed and the relative risks.

5           And we'll see that some of the generally  
6           licensed -- the risks of some of the generally-  
7           licensed devices and applications are lower than the  
8           ones that are currently exempt.

9           And I think that type of risk can be  
10          imparted into that decision to put these things into  
11          perspective and support a decision of whether or not  
12          something should be generally licensed or exempt.

13          As far as societal benefits go, I won't go  
14          into this too much -- in too much detail. At the  
15          beginning, I mentioned some of the applications of  
16          static eliminators.

17          I would note, however, that static  
18          eliminators are used in applications where other --  
19          static eliminators with a radioactive source are used  
20          in applications where other types of static  
21          eliminators could not be used in hazardous conditions,  
22          such as a paint shop, where you risk explosion.

23          So there is a direct societal benefit.  
24          There is a direct need for these devices.

25          Public perception. I didn't have any

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1 strong basis for this preliminary answer, but my  
2 feeling is that because the number distributed in  
3 let's say fairly limited, the application is fairly  
4 limited.

5 And at least with polonium-210, the half  
6 life is relative short, that I would say that public  
7 awareness of static eliminators as a radioactive  
8 devise is probably low.

9 And based on minimal public awareness, I  
10 would take the next step to say that probably public  
11 perception is also low, figuring that if the public is  
12 not aware, then the public would not be too aware of  
13 the risk either.

14 Finally, the last question, "How does this  
15 fare with the draft screening criteria?" Stop for a  
16 moment and indicate that these answers to the  
17 preceding six questions are preliminary.

18 This is based on my review of the existing  
19 data and I hope I left you with the feeling that I  
20 think that additional study is necessary to look into  
21 some of these numbers and see how they can be used,  
22 how they can be updated.

23 Question no. 7, application of the draft  
24 screening criteria. These also are my first gut  
25 feelings on how these questions may be answered.

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1           Again, if the additional studies indicate or  
2 provide us different information, we would revisit  
3 these questions. We would revisit these questions no  
4 matter what we do. These are preliminary answers.

5           The idea is that given the information  
6 given through such a case study, would we have enough  
7 information to answer these questions and determine  
8 whether or not risk information is useful in this  
9 particular application.

10           The first question, "Would a risk-  
11 informed regulatory approach help to resolve a  
12 question with respect to maintaining or improving the  
13 activity's safety?"

14           My answer to that was no, in that I --  
15 nothing seemed to indicate that currently there is a  
16 risk that needs to be minimized at this point. I  
17 didn't identify a problem.

18           And so, therefore, I didn't think that a  
19 risk-informed approach would help resolve a question  
20 regarding safety.

21           Question no. 2, "Could a risk-informed  
22 regulatory approach improve the efficiency or  
23 effectiveness of the regulatory process?"

24           My answer to that initially was yes. I  
25 think someone mentioned this point before, that if we

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1 look at activities on a risk basis, or from a risk-  
2 informed perspective, it may allow us to direct  
3 resources to those areas that pose more risk to  
4 workers or the members of the public, not that it's  
5 not necessary to -- not necessary to consider these  
6 applications, but that it may be more useful with  
7 limited resources to apply those to an area that  
8 requires more attention.

9 Question no. 3, "Could a risk-informed  
10 regulatory approach reduce unnecessary regulatory  
11 burden for the applicant or licensee?"

12 On the surface I would say yes, in that my  
13 feeling was if you move from a generally-licensed  
14 device subject to 31.5 to an exempt device, there most  
15 likely would be some reduction in a regulatory burden.

16 However, it's not clear at this point just  
17 how much burden those requirements of 31.5 are placing  
18 on the licensees or the users. And that's where,  
19 again, feedback would be useful to validate or to  
20 change this answer.

21 Maybe the answer is no, that there really  
22 wouldn't -- you would think there would be some  
23 reduction, but in the true sense, there really  
24 wouldn't be a significant reduction and, therefore,  
25 it's not worth moving forward.

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1           Question no. 4, "Would a risk-informed  
2 approach help to effectually communicate a regulatory  
3 decision or situation?"

4           And I think Marissa pointed out that the  
5 answer to that was yes, and that in any type of  
6 situation like this, where we're putting out numbers  
7 of less than a millirem or 200 millirem, a risk-  
8 informed approach puts those numbers into perspective.

9           It factors in the likelihood that these  
10 scenarios may occur and it also allows us to quantify,  
11 to some degree, uncertainties associated with those  
12 numbers.

13           I think you mentioned -- someone mentioned  
14 -- it may have been you, Bob, that is there really a  
15 difference between 200 millirem and 300 millirem?

16           It may be that such differences are mashed  
17 by the uncertainties and those uncertainties can't be  
18 reduced.

19           And in that respect, just from the dose  
20 number standpoint, that there is no difference. ~~It~~  
21 that 300 is not greater than 200, but factoring in the  
22 risk it may not be significant.

23           So I would think that, yes, a risk --  
24 initially, yes. A risk-informed approach would help  
25 to effectively communicate or support such a decision.

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1           Question no. 5. I never thought that I  
2 would take this much time to go through these slides.  
3 Question no. 5, "Do information and models of  
4 sufficient quality exist?"

5           My first reaction was yes, that the  
6 information exists. It just needs to be collected.  
7 That the information that's imported, 6642 and 1717  
8 needs to be compiled and also, some of the information  
9 from the sealed source and device registry needs to be  
10 pulled together and some surveying of the  
11 manufacturers needs to be done.

12           But I think that the information is  
13 relatively readily available and could be pulled  
14 together at minimal cost.

15           No. 6, "Could start up and invitation of  
16 a risk-informed approach be realized at a reasonable  
17 cost?"

18           I think with this particular issue, I  
19 don't see a significant cost associated with a  
20 reclassification of such a device, other than the --  
21 I would -- I venture to say the routine costs  
22 associated with any regulatory action.

23           Finally, Question No. 7. "Do other factors  
24 exist which would preclude changing the regulatory  
25 approach in this area and, therefore, limit the

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1 utility of implementing a risk-informed approach?"

2 I said that it's unknown, because we're  
3 not sure how this will proceed. However, I do see two  
4 potential blocks.

5 One would be whether or not the regulatory  
6 framework or process exists to use risk-informed  
7 information to move a device from being generally  
8 licensed to exempt.

9 I think we're not quite sure how that  
10 would be done if we were to present risk-informed,  
11 probabilistic information with the associated  
12 uncertainties, how that information would be digested.

13 I think part of the discussion we saw this  
14 morning, earlier this morning, was that it's not clear  
15 whether or not 200 millirem is significant or not  
16 significant.

17 And so in presenting these numbers, I'm  
18 not sure that a threshold is available to say if it's  
19 less than such a number with certain certainty then  
20 yes, it is -- it can be moved to exempt. I don't think  
21 that framework exists.

22 And also, I think that in any type of  
23 action like this, there will always be some -- most  
24 likely, there will always be some adverse public  
25 reaction.

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1           It's just a matter of whether or not  
2 through communication opportunities and the risk-  
3 informed information that could be -- what's the word  
4 I'm looking for? I need one word and then I'm done.  
5 That could be minimized.

6           With that, thank you for your attention.  
7 I welcome questions.

8           MR. BERNERO: Jim, I'm going to go back in  
9 concept to your slide 43. I got a whole body of  
10 question and comment.

11           First of all, the information base that  
12 you've used, NUREG/CR1775, NCRP Report 95, et cetera,  
13 I don't think is an adequate information base, in  
14 light of the agency's experience.

15           In 1988, there was a very serious trauma  
16 in this agency, with the recall of an enormous number  
17 of static eliminators and they were commercial static  
18 eliminators.

19           They were static eliminators used in the  
20 food and beverage packaging industry, as well as in  
21 these little photo shops in malls and all sorts of  
22 places.

23           And it included the possibility of the  
24 scenario of somebody sticking a static eliminator in  
25 his pocket for 2,000 hours and carrying it regularly.

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1           A key to it is if you go back and get that  
2 information, when my recollection is there were just  
3 two manufacturers in the U.S. for virtually all the  
4 commercial static eliminators using polonium-210, that  
5 the doses that you quoted are puzzling to me, because  
6 the whole procedure is to get a ceramic particle to  
7 absorb polonium-210, which has a protectively short  
8 half life, and is an alpha emitter and, therefore has  
9 not range. You can shield it with a piece of paper or  
10 something.

11           So I think that database, for separate  
12 reasons -- I've been trying to track down the  
13 experience data and I've already gotten an internal  
14 memorandum that was sent to me to Brookhaven,  
15 NUREG/CR's and so forth.

16           All of this stuff is 1988/89 and not long  
17 thereafter. So you really have a lot more information  
18 to look at before you make an appraisal.

19           I would just point out, once again -- here  
20 is a question. Is there an alterative to the  
21 regulatory process that might be justified based on a  
22 risk-informed approach?

23           And the risk-informed approach, I think,  
24 might conclude that where a household smoke detector  
25 uses americium-241 tightly encapsulated in an

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1 extremely small quantity, that that can be distributed  
2 exempt from regulation.

3 But where a static eliminator, in  
4 industrial or commercial use, has a very large  
5 quantity -- and I don't remember how many microcuries  
6 they had when distributed -- but where you get into  
7 high microcurie quantities or even millicurie  
8 quantities, then there's a serious question about  
9 whether the regulatory process should tolerate a 500  
10 year half life americium-241, or instead reserve  
11 approvals to 138 day half life material, like  
12 polonium-210.

13 So here, again, it's not a question of  
14 whether or not you can go exempt distribution. It  
15 should be in there a risk-informed insight on control,  
16 generally-licensed or specifically-licensed  
17 regulation.

18 MR. DANNA: Great. Thanks for those  
19 comments. I'm appreciative of the first comment  
20 regarding that particular recall, and I'll look into  
21 that. I may contact you directly for the information.

22 But also, the second point, I think that's  
23 important to note that these studies -- that the  
24 studies that I've seen did not consider americium-241  
25 and there is a significant difference.

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1 I mean if you're dealing with 138 day half  
2 life, you might reach one conclusion. Americium-241  
3 might be a completely different animal, you might  
4 find, and that's where building on what's already  
5 available, I think, would be useful.

6 MR. KOKAJKO: Could I add one more thing?  
7 The event that you were talking about back in the late  
8 '80's, we -- at least, for this part of the study, we  
9 confined ourself just to what studies had been done  
10 rather than looking at event-based items.

11 We are going to expand that in the future  
12 and that's -- we had a limited time to get there and  
13 this what we looked at first.

14 MR. BERNERO: Lawrence, I'm just going  
15 back to that. I was personally involved in it. But it  
16 did lead to a study, and I haven't found it yet, but  
17 there was a Commission paper to say what lessons do we  
18 learn from all of this?

19 And it contained a very large element of  
20 risk other than radiological risk. The economic risk  
21 was enormous. My recollection is there were 20,000  
22 general licensees holding 50,000 devices under lease  
23 from that one company.

24 And from a regulatory, administrative  
25 burden and the commercial impact on these companies

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1 was just enormous and unquantified, to my knowledge.  
2 And that's real risk.

3 MR. KOKAJKO: Thank you for your comment.

4 MR. DANNA: Just to note, I think that's  
5 important also because it lends us to consider other  
6 scenarios that aren't -- when you aren't necessarily  
7 conceived when sitting at a desk. But the real  
8 experience would lead -- lead you to develop these  
9 other scenarios and put on likelihoods. Some of these  
10 things may not be as unlikely as we would think. Yes.

11 MS. NIMMO: Elsa Nimmo. I have a generic  
12 question just on exempt devices versus generally-  
13 licensed devices.

14 For exempt devices, is there something  
15 equivalent to the sealed source and device evaluation  
16 and registry?

17 MR. DANNA: Maybe someone else can answer  
18 that question, again. Maybe someone from IMNS on what  
19 the registry for exempt devices would be?

20 MS. TAYLOR: All devices that are  
21 considered a sealed source device usually goes through  
22 a sealed source device registry evaluation and they  
23 would be on file under that situation.

24 And then it depends on how the  
25 manufacturer wants to distribute that. They will come

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1 in and ask for it to come out under exempt  
2 distribution license, under the provision of the  
3 regulation and they cite that whatever -- whatever  
4 that material.

5 Like smoke detector licensees come in and  
6 say we want to distribute this under an exempt  
7 distribution license, so that these things are  
8 evaluated and it is in the sealed source device  
9 registry.

10 MS. NIMMO: Currently, if you have a device  
11 that is approved as a generally-licensed device, on  
12 the registry sheet it will say G.

13 Or if you're going to be distributing to both specific  
14 licensees and general licensees it will say B, for  
15 both.

16 Are the SS&D's that are for exempt  
17 devices, would they have some similar notation?

18 MR. FLETCHER: Roland Fletcher, State of  
19 Maryland and the Agreement States. I was going to make  
20 the same point that Bob made about the actual event.

21 Because you've outlined probabilities and  
22 assumptions, but there is a body of data that you've  
23 apparently not looked at.

24 And I've found that no matter what you  
25 usually come up with in studies, real events are

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1 always full of surprises, and that's where you need to  
2 be looking.

3 Secondly, you need to incorporate, to my  
4 thinking, a lot more contact with the Agreement  
5 States. You seem to be basing a lot of information on  
6 what might be available through studies and there's a  
7 lot of experience in the 32 Agreement States, after  
8 all, we regulate 70 percent of all radioactive  
9 material licensees.

10 So I think before you start to make that  
11 -- any consideration of what should be considered as  
12 a general licensee and what should be considered for  
13 being made exempt, you need to hear some of the  
14 experiences.

15 Because I anticipate that this will be  
16 something that the Agreement States will probably not  
17 be for. I can anticipate that even now.

18 MR. DANNA: I agree. Thank you. I think  
19 that would be addressed under the need for additional  
20 studies. I think I'm concluding that additional work  
21 is done. So I've noted that. Something that I need to  
22 do is contact the Agreement States.

23 MR. KOKAJKO: By the way, we have -- we  
24 participated -- I know I participated in a telecon  
25 with the Agreement States programs just a few weeks

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1 ago.

2 And one of the comments, besides the fact  
3 that we were talking about this upcoming meeting, we  
4 were seeking Agreement State input.

5 We are not going to do anything -- first  
6 of all, we don't have the authority to change any of  
7 the regulatory framework. We're just doing the  
8 studies at the moment.

9 But I can tell the NRC is not going to  
10 make wholesale changes without at least doing the  
11 proper ruling making procedure and the notifications  
12 and working with the Agreement States. So I'd like to  
13 put that to rest. If you think that we're going to do  
14 this without Agreement States input, you're way  
15 mistaken.

16 MR. LUBENAU: Joel Lubenau. First of all,  
17 I would like to thank you for your presentation. I'd  
18 like to underscore something that Bob Benero said, and  
19 he used a very catchy term, and maybe that's what we  
20 need here, and that's economic risk.

21 I mentioned damage to property or  
22 protection of property. He's right on the mark there.  
23 Most of the discussions thus far this morning have  
24 focused on dose, and that's not surprising. I think  
25 that's one of the lessons to learn here.

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1           There are other impacts. There are other  
2       -- you can even call health effects, except they're  
3       not biological. They're financial.

4           Bob mentioned the impact it had on the  
5       company that manufactured those devices, as well as a  
6       number of users who had them and had to go through  
7       decontamination procedures.

8           And I would also mention the economic  
9       impact, the economic risk when these devices become  
10      lost or stolen and they end up in the public domain  
11      and are recovered by the scrap metal industries.

12          Static eliminators have been showing up in  
13      metal scrap, and when they do, the finder -- it's  
14      losers, weepers, finders weepers. Because the finder  
15      is responsible for recovering that source, storing it  
16      and dispositioning it. That's an economic risk and we  
17      haven't had much discussion on that.

18          And I can tell you, just as Roland told  
19      you, the states are going to be concerned about  
20      shifting some of this to except from general license.  
21      Do you want to make a guess on what the reaction is  
22      going to be of the steel industry and the scrap metal  
23      industry to that?

24          So I would very much urge you, start  
25      thinking about economic risk. It's a very good term.

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1 Bob, I thank you.

2 MR. DANNA: Great. Thanks for that  
3 comment. That's a very good comment.

4 DR. JOHNSRUD: I liked your presentation  
5 too. Thank you for it. Two points, one of which goes  
6 to recognized and unrecognized hazards. And the other  
7 to a follow from Joel's comment about the economic  
8 impacts.

9 First, I was troubled by your responses to  
10 question no. 6 with respect to public perception and  
11 acceptance of risk.

12 And as I jotted down, you indicated that  
13 -- well, first off, you described limited uses  
14 nationwide for static eliminators. Gosh, I don't  
15 think of photography shops and paint shops as being  
16 limited nationwide. They're everywhere, aren't they?

17 So that, in fact, there is a wide  
18 distribution of whatever risk may be associated with  
19 the distribution of the equipment.

20 Secondly, though, is the comment with  
21 regard to public awareness. You said it was very low,  
22 perception is very low, so it wouldn't worry people  
23 about the risk.

24 And I don't know, are you old enough to  
25 remember kids following the DDT truck down the street?

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1 Nobody thought there was a risk.

2 We could describe any number of consumer  
3 products that were thought to be harmless, may I  
4 whisper tobacco, among them, that have resulted in  
5 enormous economic consequences for the producers and  
6 health consequences of financial concern to those who  
7 receive the doses and subsequently suffered illnesses.

8 The assurances that seem to accompany  
9 these assessments, that low-dose radiation is, in  
10 fact, risk free, I think has come under very serious  
11 question, certainly, internationally, even if not  
12 among many of the people in the United States  
13 associated with the industry.

14 Therefore, I would strongly recommend that  
15 there be a reconsideration of the assumptions that  
16 you're making that the risks are low and that are made  
17 in those prior studies.

18 MR. DANNA: Sure. And I've noted those and  
19 I can see from their presence today that public  
20 awareness is not necessarily low, so I would agree.

21 DR. JOHNSRUD: Public awareness -- when  
22 the NRC published its below regulatory concern -- I  
23 guess we're not supposed to use that term -- BRC  
24 policy statement, rose very rapidly.

25 And, certainly, we're finding, for

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1 instance, the landfill operators are very much  
2 concerned about radioactive materials that appear.

3 And simply exempting them from regulatory  
4 control really doesn't solve the problem of the  
5 concern, for there we get perhaps many sources coming  
6 together in a single location.

7 MR. DANNA: Yes, sir?

8 MR. EVANS: Good morning. My name is Hugh  
9 Evans. I'm from AEA Technology, a sealed source  
10 manufacturing company that manufactures static  
11 eliminators.

12 Earlier on it was referred to the fact  
13 that you may heavily depend on the 1988 results on the  
14 3M debacle using the microsphere data, that was  
15 basically a flypaper type of source with the  
16 microspheres stuck onto a background.

17 That type of technology has ceased and the  
18 type of technology that is used in static eliminator  
19 production these days is essentially identical to that  
20 used in the smoke detectors.

21 So I would question the relevance of  
22 depending heavily on the technical information that  
23 was put together in that very excellent report of the  
24 1988 incident.

25 Secondly, it was mentioned that americium-

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1 241 might be looked at. And I would question the  
2 relevance of that also in terms of the statistical  
3 population of americium-241 in static eliminators.

4 You could almost count the number of  
5 locations on one hand, in comparison to static  
6 eliminators in general utilizing polonium-210.

7 So, again, I would seriously question the  
8 relevance of background history for americium-241  
9 either.

10 MR. DANNA: With respect to the first  
11 comment, I think that's good. I think that  
12 demonstrates why it's important to look at these  
13 numbers, but also look at what went into these  
14 numbers.

15 For instance, a review of that particular  
16 recall, we might be able to pull out that information,  
17 that it is a different form.

18 And I think that's one of the things I  
19 noted that somewhere along the line, a line might be  
20 drawn between the forms that were previously used and  
21 contrasted to the forms that are currently used, so  
22 that when questions like that come up, have you looked  
23 at that particular situation, the response -- instead  
24 of saying we didn't consider it, or we decided it  
25 wasn't important, the answer should be yes, we

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1 considered it and this is what we found and this is  
2 why it is or is not relevant.

3 So I wouldn't throw it out. I would  
4 evaluate why it's important and what we can learn from  
5 it.

6 As far as our second point goes, again,  
7 the same answer there. Rather than be faced with the  
8 question you only looked at polonium-210, you didn't  
9 consider americium-241, rather than give the answer  
10 that it's not widely used, I'd feel more comfortable  
11 saying that we did look at it, we looked at who the  
12 manufacturers are, and who the users are, and the  
13 numbers distributed. And based on those numbers, this  
14 is what we found, and then evaluate.

15 I think in my mind a useful -- a use of a  
16 risk assessment is in its completeness and it being  
17 comprehensive. So that it lays out the thought process  
18 and allows individuals to see what was considered and  
19 what was not considered and what assumptions were  
20 there so that these other points can be factored in as  
21 necessary.

22 If they're not relevant, they'll likely  
23 fall out. If they are relevant, they'll included.  
24 But in my mind, I always think completeness is  
25 important, not to throw out anything on the surface.

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1 MR. EVANS: Thank you very much. I agree.

2 MR. FLETCHER: Rolan Fletcher. I'd like to  
3 put a follow on on that, and that is the fact that one  
4 of the things that maybe you also should consider is  
5 the fact that perception of risk also depends upon the  
6 location and the resolution of the problem.

7 I recall in 1988 it took some time for the  
8 NRC to disseminate the information through their  
9 lists, if you will, of general licensees so that these  
10 facilities could be monitored and any contamination  
11 located.

12 Now as time passes, the ability to let  
13 anyone know that you're in control or we're in control  
14 dwindles. And this was from static eliminators that  
15 were under general license.

16 So just project, if you will -- maybe it  
17 won't happen again --but it won't happen again, but  
18 just project, if you will, how much more difficult  
19 that might be if now they're exempt.

20 MR. DANNA: Thanks for that comment.  
21 Thank you.

22 MR. BERNERO: I'd like to just add one  
23 other point about alterations to the regulatory  
24 process. The gentlemen who referred to the 3M static  
25 eliminator design as a flypaper design is exactly on

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1 the mark.

2 The difference between that design and the  
3 other approved design was the difference between an  
4 epoxy holding microsphere's like flypaper, and the  
5 other was a metal encapsulation of the microspheres,  
6 albeit very thin, so as not to stifle the alpha  
7 emission.

8 And it is in risk-informed evaluation of  
9 those designs that one can decide whether or not to  
10 approve a design, albeit a generally-licensed device.  
11 And it makes the point very well.

12 And that's why that background experience  
13 is useful. It's for modification or lessons learned  
14 of the regulatory process itself.

15 MR. DANNA: Thanks, Bob.

16 MR. KOKAJKO: Jim, can I make one more  
17 comment? You had mentioned the 3M static eliminator.  
18 If you recall from our earlier comments, and we're  
19 looking at the very beginning, is that we're looking  
20 at what may be explicit or implicit safety goals based  
21 upon past decisions.

22 This would clearly -- the staff and the  
23 Commission came to some conclusion about the event.  
24 What we're trying to do is was there some type of  
25 safety goal that was embedded, that they may not have

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1 stated, but was somehow embedded there. And we  
2 wanted to find out what that is.

3 I don't know that answer, once again. I'm  
4 open to whatever that might be. We're getting to that  
5 point. We will further research -- I mean we are going  
6 to further research it.

7 We were aware of it and your comment  
8 regarding, essentially, the difference in technology  
9 is well taken. And thank you both.

10 MR. DANNA: Yes.

11 MS. D'ARRIGO: I'd like to ask whether  
12 what's being envisioned for exemption -- and I realize  
13 nothing's finalized, but in moving from a general  
14 license to exempt status, are you talking about a  
15 specific amount of each isotope, or are you talking  
16 about the design of the instrument or the equipment  
17 that's being exempted.

18 And the reason I ask is if there's a set  
19 amount of americium-241 that was on the fly paper and  
20 that's the same amount that's now being handled in a  
21 much more protective way, is there anything within the  
22 exemption that prevents future changes in design that  
23 might go back to something less protective? What is  
24 it that's getting exempted?

25 MR. DANNA: Well, again, I'm glad you

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1 noted at the beginning of your question that it is --  
2 it's not something that's pending. It is a  
3 hypothetical action, this moving from a generally-  
4 licensed device to an exempt device.

5 And I would answer again with my vision of  
6 what a good risk assessment is. A good risk  
7 assessment is detailed and it also supports not only  
8 an uncertainty analysis, but also a sensitivity  
9 analysis.

10 And through a -- I think a well-conducted  
11 sensitivity analysis, we would be able to identify  
12 those elements that were incorporated into the risk  
13 assessment that are significant or that contribute --  
14 that are significant factors to the result.

15 So that if we were to find at the  
16 conclusion of such a risk assessment and sensitivity  
17 analysis that the form or the calculated risk is not  
18 sensitive, or does not vary significantly with  
19 different forms, then we might say that regulation of  
20 a particular form is not critical.

21 However, if we find if the risk results --  
22 sensitivity results indicate that the nuclide is  
23 significant, then maybe we would regulate based on  
24 that.

25 It's hard to say now what the answer would

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1 be. Well, it's impossible to say now what the answer  
2 would be, but presumably, a well thought out risk  
3 assessment would lead us to identification of those  
4 elements of, let's say in this case static  
5 eliminators, that are actually significant to the  
6 result and risk. And presumably, those would be the  
7 areas we would focus on.

8 MS. D'ARRIGO: I guess another way of  
9 asking what I'm asking is -- let's see. How much  
10 information and analysis and staff time and resources  
11 will be expended on exempting various devices, or  
12 isotopes at given levels versus the amount that is  
13 currently expended to give a general license, versus  
14 a specific license.

15 MR. DANNA: That's a very good point. I  
16 think that plays right into the question of reducing  
17 unnecessary regulatory burden. As -- who pointed out  
18 that --

19 MS. D'ARRIGO: Well, it sounds like maybe  
20 there's a chance that reducing the -- that putting all  
21 this resource into all the studies that you're going  
22 to go through, it might be better to just keep control  
23 over this stuff.

24 MR. DANNA: That may be right. It may be  
25 that the reduction in burden is not commensurate with

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1 the costs of the risk-informed demonstration that is  
2 warranted.

3 You might find that it's very costly to  
4 make the argument, when really the regulatory burden  
5 or the reduction in regulatory burden would be  
6 insignificant from an economic standpoint. And that  
7 may be what comes out of that question.

8 My preliminary guess was there would be  
9 some reduced regulatory burden, but in contacting some  
10 of the users or manufacturers they may say well, no,  
11 really it's -- we're happy with the way things are and  
12 we really wouldn't realize any great significant  
13 regulatory relief from an economic standpoint. So that  
14 may play right into your answer.

15 And I think this is the value of doing  
16 these type of case studies. We can presume what we  
17 think we know, but when we actually get the  
18 information and process and the information, and put  
19 it through these questions, we might come up with a  
20 completely different answer, something along the lines  
21 of what you're indicating. And I think several people  
22 have pointed out that the economic risk is important  
23 to consider.

24 MS. D'ARRIGO: And I guess I'll just throw  
25 into the pot then that the concept of taking things

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1 that are currently -- having general licenses and  
2 requiring better regulatory control and specific  
3 licenses is parallel to what the steel industry has  
4 expressed is a concern with materials getting into the  
5 facilities.

6 And that it's true, there's not a lot of  
7 general public knowledge of the various different  
8 radioactive materials and products that are out there.

9 But I don't think that the NRC should take  
10 advantage of that to justify further deregulating or  
11 moving to even a less -- to less of a licensing  
12 status.

13 I'll bet you the public doesn't know that  
14 general licenses even exist, generally. I mean that  
15 probably people assume that if something's radioactive  
16 that somebody's regulating it and taking care of it,  
17 and taking care of them.

18 And so I would put into the pot -- I don't  
19 know also what portion of the NRC budget is going  
20 toward doing these case studies and whether taxpayers  
21 are paying for all the people to do all these analyses  
22 and risks that are based on studies that that person  
23 -- does not have a full understanding of the risks --  
24 the documents upon which their numbers are based.

25 In other words, there are serious

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1 questions about ICRP, NCRP and those kinds of  
2 assumptions. Now always, but I don't think that the  
3 agency could automatically assume that we know  
4 everything about radiation and what the risks are.

5 And so in making decisions that are going  
6 to disperse this stuff into commerce and into the  
7 environment in a completely unregulated, unrecorded,  
8 unretrievable way can't assume that the very well  
9 meaning, highly-educated staff people at the NRC that  
10 are evaluating these risks even know what the  
11 practical reality is of what they're saying, which is  
12 evidenced by the practical results in the field, and  
13 that the states have to deal with, and that the public  
14 has to deal with.

15 I've covered a lot of different concerns  
16 that I have in that one spiel, but I think that that's  
17 the message that I want to give, is that look at doing  
18 a more responsible regulatory job.

19 MR. DANNA: Right. Two points on that,  
20 and one this woman mentioned that I took note that --  
21 and again, my feeling is this is the purpose of having  
22 this early stakeholder involvement. These are just  
23 preliminary answers to promote such discussion.

24 But I think what this woman said early, if  
25 I can paraphrase, is that just because people aren't

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1 aware that something's going on doesn't mean that  
2 their perceived risk is minimal. And I noted that.

3 Also, earlier on I said that even those  
4 the issue may be the -- the hypothetical issue may be  
5 -- does a risk -- would a risk-informed approach  
6 support our regulatory action of moving a device from  
7 generally licensed to exempt?

8 When it's all said and done you might put  
9 some of these case studies side by side -- well, I  
10 assume we would -- put them side by side and start to  
11 contrast why do we reach certain conclusions in this  
12 particular study, and other conclusions in this study,  
13 when both are covered by the same regulatory  
14 framework, in the gas of chromatographs and static  
15 eliminators.

16 And in that case we might identify areas  
17 of the regulations that need to be revisited, rather  
18 than our original issue was moving something from  
19 general license to exempt.

20 So I don't think we're narrowly focused on  
21 what we want to evaluate as an outcome. I think we're  
22 willing to look at all the available information and  
23 look at our results, and see what we came up with case  
24 studies.

25 And, again, I think when we get to the

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1 second and third set of questions, when we start to  
2 address issues like over arching safety goals, that  
3 might become apparent. Thanks for your comment.

4 MR. KOKAJKO: I'd like to point out that  
5 -- and I hope -- if the impression was left that we're  
6 trying to take advantage of the public's non-knowledge  
7 of something, we are not trying to do that.

8 I hope that it's -- the fact that we  
9 called -- I mean we called people to come here today.  
10 We're not trying to take advantage of anything. We're  
11 trying to get the information out so that we can  
12 understand the concerns out there.

13 And Jim is right on target. And I think  
14 you'll see a little of that when we talk about fixed  
15 gauges this afternoon. It could be that we are  
16 thinking about at least proposing increases in  
17 regulatory requirements.

18 We don't know everything about certain  
19 things yet, and perhaps we need to begin to reassess  
20 some things or at least put some questions on the  
21 table.

22 And where this ultimately goes is still  
23 unclear to us, and we are open to any outcome that  
24 relates to this. Dr. Johnsrud.

25 DR. JOHNSRUD: That was the nicest comment

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1 I could have hoped for today. Thank you. As a matter  
2 of fact, as some of us have dealt with this issue of  
3 release, recycle, reuse for a long time, there have  
4 been those, even within some of the regulatory  
5 agencies, who are concerned about the need to recover  
6 certain materials that have been lost, stolen,  
7 otherwise unaccounted for.

8 And I think in terms of the calming  
9 concern for looking at the impact -- the totality of  
10 impacts of the variety of contaminants to which an  
11 individual is exposed to, that this approach of  
12 concern for minimizing the distribution of hazardous  
13 materials will increase on the part of the public.

14 But what I wanted to add here, and then I  
15 guess we all need lunch, is I am concerned about the  
16 dismissiveness that continues within this agency with  
17 respect to low probability events.

18 Oh, the dose is very low, the likelihood  
19 of something getting lost, the likelihood of somebody  
20 getting multiple exposures.

21 Oh, those are all very low probabilities,  
22 according to our analyses, allows us to ignore low  
23 probability events that do indeed have consequences,  
24 whether they are high for the individual or high for  
25 society or high from the economic interest concerns of

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1 many of us.

2 The -- what was it? A 7.9 earthquake in  
3 India? That's a low-probability event. Most of us  
4 live our lives assuming low-probability events. I  
5 guess if I lived on the San Andreas fault I'd be  
6 pretty nervous.

7 But there's a general applicability that  
8 this agency over the years, going back to the  
9 Rasmussen Reactor Safety Report, simply dismisses the  
10 likelihood of consequences as low probability and,  
11 therefore, it's safe to ignore them.

12 And that is particular significant when,  
13 as here, the agency is proposing to relinquish any  
14 regulatory control over materials that do pose a risk.

15 And a risk, whether it is low or high, that  
16 remains still unknown with respect to the recipient of  
17 the additive doses.

18 So I would -- I do ask you to incorporate  
19 that kind of concern in your comments that will go the  
20 Commission.

21 MR. DANNA: Just two points that you made.  
22 One is that -- again, I'll reiterate that we're not  
23 looking at or evaluating an agency proposal on a  
24 particular regulatory action. This is not something  
25 that's pending and that we've been tasked to defend of

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1 support.

2 We're doing the case studies to evaluate  
3 a methodology that could be used to see where risk  
4 information would be useful.

5 And the second point, with regard to low  
6 probability, high consequence events, my feeling on  
7 that is that, again, I've said it a couple of times,  
8 a well thought out risk assessment incorporates all of  
9 that information and it allows the reviewer -- or the  
10 -- questions -- results to see how the such decision  
11 were made.

12 Presumably, it would be included in the  
13 analysis and I think the other half of that is that  
14 the agency is moving to a risk-informed approach, but  
15 not a risk-based approach, meaning that the risk  
16 information is taken into the account if decisions  
17 aren't made solely on the quantified risk that these  
18 other aspects are taking into consideration, such as  
19 economic risks and societal risks. And it's a big  
20 picture.

21 But the idea is in moving to a risk-  
22 informed approach is to look at some of these  
23 calculations, impart realism in the calculations to  
24 quantify uncertainties, to perform sensitivity  
25 analysis, to identify what's significant from a risk

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1 perspective and what's not, and then to see how that  
2 information can be factored in with other information,  
3 as you mentioned, to make a decision.

4 I don't know if that captured your  
5 concern, but it was my attempt.

6 MR. KOKAJKO: Let me put it a little more  
7 succinctly. We want to focus where the risk is.

8 DR. JOHNSRUD: Who defines it?

9 MR. KOKAJKO: Well, part of it is being  
10 defined, hopefully, with input from you today.

11 DR. JOHNSRUD: As is the question of risk  
12 tolerance?

13 MR. KOKAJKO: I understand that. I can  
14 only say that what we're trying to do today is to try  
15 to understand where you, the public, and others who  
16 are concerned citizens -- and we're trying to find out  
17 where the risk is. And as I said, we're open, if it's  
18 necessary, to increase regulatory requirements.

19 Raeann, you had a comment and Diane, you  
20 would like to make a comment? If we're interested in  
21 eating lunch --

22 MS. D'ARRIGO: I have one question and I  
23 doubt you're going to be able to answer it now, but I  
24 really would like the answer.

25 I'd like to know how much of the NRC's

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1 resources in hours, and money, and however else you  
2 define them, have been put toward this risk-informed  
3 approach, not just on NMSS stuff, but also on  
4 reactors.

5 And you can't try to tell me in a very  
6 polite way that the NRC is not moving in this  
7 direction, it has not made decisions to proceed in  
8 this way.

9 I just want to know how much has been  
10 expended on exploring this option?

11 MR. DANNA: As far as the NRR goes, I  
12 don't have that information. Someone from NRR could  
13 probably tell you that.

14 As far as what NMSS is doing, I can tell  
15 you that my task group -- counting myself, there are  
16 eight people associated with it and we have a small  
17 contract budge associated with those people. Raeann?

18 MS. SHANE: Raeann Shane, also from the  
19 Risk Task Group. I wanted to, hopefully, try to clear  
20 up some of the mystery about exempt products and how  
21 they're evaluated.

22 And with respect to the sealed source and  
23 device review, exempt products that contained a sealed  
24 source do undergo a similar type of review, as would  
25 be for a generally-licensed product or a specifically-

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1 licensed product.

2 And in many cases, it would be more  
3 astringent because we do recognize that once the  
4 product is out there, it's in the hands of someone who  
5 has no training or control over them.

6 The product -- the user is exempt from  
7 licensing, but the product is not. And -- what else?  
8 You know, they have to be property labelled and tamper  
9 resistant.

10 And I guess I wanted to address your  
11 question about what would prevent someone from going  
12 back to the old type of unsafe source design would --  
13 our review of that product.

14 Even if this all came out and it said  
15 okay, it's okay for these products to be exempt, they  
16 would still have to undergo a review and make sure  
17 that they meet the requirements for exempt products.

18 MS. BAILEY: Thank you, Raeann. I guess  
19 I'd like to point out that later on this afternoon  
20 there will be more opportunities for comments. So I  
21 guess what I'd like to do is just take one last  
22 comment and then let's break for lunch.

23 MR. EVANS: Thank you very much. Hugh  
24 Evans from AEA Technology following on Raeann's  
25 comment. She took the number one -- that's what - the

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1 very point I was going to make.

2 But secondly, there was a comment made  
3 regarding the dissemination of isotopes or radioactive  
4 material in an unreported manner.

5 I'd like to remind people here that  
6 manufacturers do have the responsibility of reporting  
7 on a regular basis to the USNRC the quantities of  
8 exempt sources that go to these exempt applications.  
9 So it is reported.

10 MS. BAILEY: Thank you. At this point,  
11 let's break for lunch and reconvene at 1 o'clock.

12 (Whereupon, the foregoing matter went off  
13 the record at 12:16 p.m. and went back on  
14 the record at 1:10 p.m.)

15 MR. KOKAJKO: Good afternoon and welcome  
16 back. It looks like a few people are still at lunch,  
17 but I'm going to have to go ahead and start if I want  
18 to maintain any hope of keeping to the schedule.

19 This afternoon, the remaining item that we  
20 would like to discuss is fixed gauges. The topic will  
21 be presented by Raeann Shane and we'll cover -- do the  
22 same type of -- as we did this morning.

23 She'll go over and present our assessment thus far,  
24 based upon the screening criteria and the like, and  
25 then we'll move on to questions and answers.

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1           We'll open it up toward the end to some  
2 general comments across the entire area if people  
3 would like to provide comments, and we will also --  
4 I'll have a few closing remarks toward the end of that  
5 period of time.

6           I understand that there's been several  
7 people who have expressed that -- I guess have flights  
8 that are out of here. We will try to keep to the  
9 schedule as much as we can so that you can have the  
10 entire discussion without people feeling rushed for  
11 their flights.

12           With that in mind, I'd like to introduce  
13 Raeann Shane and she will begin her presentation on  
14 fixed gauges.

15           MS. SHANE: Well, as Lawrence said, I'm  
16 Raeann Shane, for those of you who haven't met me yet.  
17 And we're here to talk about fixed gauges.

18           First, I'll go over a little bit of  
19 background on fixed gauges. Fixed gauges are most  
20 often used as a way of monitoring a production process  
21 or insuring quality control.

22           The types of fixed gauges that we're  
23 considering our case study would be primarily  
24 thickness gauges, density gauges, level gauges,  
25 insertion gauges and volumetric flow gauges, which

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1 contain either gamma or beta sources.

2 Fixed gauges are commonly used in all  
3 types of processing environments and be located in  
4 harsh environments, including hazardous environments,  
5 such as vibration, poor air quality, corrosive  
6 atmosphere, possible impact conditions and fire and  
7 explosion.

8 The most common byproduct materials used  
9 in fixed gamma gauges are cobalt-60, cesium-137 and  
10 americium-241. For beta gauges we see mostly krypton-  
11 85, strontium-90, promethium-147 and thallium-204.

12 The problem this case study hopes to  
13 address is that very similar devices can be controlled  
14 under different regulatory schemes. Our question is  
15 can risk information be used to make this structure  
16 more uniform for gauges that present similar hazards?

17 Use of fixed gauges can be conducted --  
18 the authority of either a specific license, under 10  
19 CFR Part 30, or under a general license, in accordance  
20 with 10 CFR 31.5.

21 Whether a device is authorized for use  
22 under a general license or under a specific license  
23 depends on number one, whether or not the manufacturer  
24 requests to be able to distribute the device to  
25 general licensees, and two, whether the device meets

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1 the manufacturing and dose criteria that we have in 10  
2 CFR 32.51.

3 Briefly, 32.51 requires that the device  
4 can be safely operated by persons not having training  
5 in radiological protection and that under ordinary  
6 conditions of handling, storage and use of the device,  
7 it is unlikely that any person would receive in one  
8 year a dose in excess of ten percent of the annual  
9 limit specified in 10 CFR 20.1201(a), which is  
10 currently five rems. So the general licensee would be  
11 allowed to receive 500 millirem.

12 Thirdly, under accident conditions, it  
13 must be unlikely that any person would receive an  
14 external radiation dose or dose commitment in excess  
15 of the dose to the appropriate organ, as specified in  
16 Table 32.24, which -- those doses are 15 rem to the  
17 whole body, 200 rem to a localized portion of the  
18 skin, 50 rem to an organ.

19 And the last requirement would be that  
20 each device must bear a durable, legible, clearly  
21 visible label that is approved by the Commission.

22 But there are pros and cons to each type  
23 of licensing structure. A general licensee is usually  
24 not allowed to performance maintenance on the device  
25 or to relocate the device within their facility.

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1           In addition, in accordance with a recent  
2 rulemaking, some generally-licensed devices are  
3 required to be registered with the NRC and the license  
4 is required to appoint a responsible individual for  
5 the device and to pay a registration fee.

6           The registration requirements are that the  
7 device contains at the time of manufacturing any one  
8 of the following: 10 millicuries of cesium-137, 1  
9 millicurie of cobalt-60, .1 millicurie of strontium-90  
10 or 1 millicurie of americium-241 or any other  
11 transuranic.

12           These requirements were added to the  
13 general license in an effort to increase licensee's  
14 accountability and control over their devices.

15           On the other hand, a specific licensee is  
16 required to have a radiation safety officer operating  
17 in emergency procedures, dosimetry and training in  
18 radiological protection if the user is likely to  
19 receive more than 100 millirem exposure annually.

20           So what risk studies have been done for  
21 fixed gauges? Well, the four that I will address  
22 today -- the first is the NUREG/CR-6642 risk analysis  
23 and evaluation of regulatory options for nuclear  
24 byproduct material systems.

25           Now we've heard a lot about this one

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1 already, and it does also pertain to fixed gauges.  
2 Systems 22 and 23 pertain to fixed gauges and the  
3 study contains generic risk information about the  
4 receipt, storage, maintenance, operation and disposal  
5 of fix gauges which contain gamma or beta sources.

6 The next study would be NUREG-1669, which  
7 is titled "Risk Analysis of Fixed Nuclear Gauges."  
8 This study focuses on gauges containing cobalt,  
9 cesium, or americium in the scrap or and recycling  
10 stream only. It does not address users of the device  
11 and normal use conditions.

12 NUREG-1551, which is the final report of  
13 the NRC Agreement State working group to evaluate  
14 control and accountability of licensed devices.

15 This study is not specifically a risk  
16 study. The report contains information on proposed  
17 solutions to improve licensee control and  
18 accountability for fixed gauges and other types of  
19 devices. This report also formed the basis for our  
20 registration program.

21 And lastly, we have PNNL-11905, which is  
22 the peer review of improper transfer and disposal  
23 scenarios for generally-licensed devices.

24 This report details the author's opinions  
25 as to what would be necessary to create a risk study

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1 of sufficient quality to support decision making.

2 So what are the quality of these studies  
3 and does it support decision making? Looking at  
4 NUREG-1669, the risk analysis of fixed gauges, the  
5 study states that an accurate assessment of risk was  
6 precluded by a lack of data for the elements of risk.

7 To quantify risk, information from surveys  
8 about licensees and the steel industry is needed. The  
9 survey forms were completed for this effort, but were  
10 never sent to licensees.

11 This study does not address the aspect of  
12 risk to the worker and the public at facilities where  
13 gauges are used. So this study on its own would not  
14 support decision making.

15 The second study, NUREG-6642 -- this study  
16 calculates doses to workers and the public for both  
17 specifically-licensed and generally-licensed fixed  
18 gauges.

19 For fixed gamma gauges, they considered  
20 the isotopes, americium 241, cobalt-60 and cesium-137.  
21 They calculated doses based on an average source  
22 strength.

23 The study concludes that while normal  
24 risks are larger than accident risk, the accident risk  
25 for the americium-241 device for both specifically and

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1 generally-licensed devices could yield a maximum dose,  
2 such that significant adverse health effects would be  
3 expected.

4 The study further states, however, that  
5 that evaluation of these events is based on extremely  
6 limited data. There is at least an order of magnitude,  
7 overall uncertainty in the accident results. The risk  
8 to the public probably have an uncertainty of two  
9 orders of magnitude.

10 For fixed beta gauges the study considered  
11 krypton-85, strontium-90, promethium-147 and thallium-  
12 204 and calculated doses based, again, on an average  
13 source strength.

14 The risk to workers and members of the  
15 public from fixed beta gauges were seen to be small.  
16 The doses are below those for which a significant  
17 adverse health effect would be expected to either the  
18 worker or the public.

19 However, again, the overall uncertainty in  
20 the accident risk is at least an order of magnitude.

21 Neither NUREG-6642 or 1669 addresses the  
22 issue of which types of fixed gauges are suitable for  
23 distribution under a general license and which should  
24 be specifically licensed.

25 Additionally, neither of these two studies

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1 addresses the discrepancy that exists between the dose  
2 requirements in 10 CFR 20 and those in 10 CFR  
3 32.51(a)(2)(2).

4 The dose criteria in 32.51 were not  
5 updated when 10 CFR 20 was revised to reflect ICRP 20  
6 guidelines. General licensees using their devices  
7 under ordinary conditions of handling storage and use  
8 are allowed to receive radiation doses up to ten  
9 percent of the annual limits specified in Part 20,  
10 which is currently a total effective dose equivalent  
11 of 5 rems. So again, general licensees are allowed to  
12 get 500 millirem a year.

13 However, general licensees are not  
14 required to receive training in radiological  
15 protection to receive this exposure, as would be  
16 required of a specific licensee under 10 CFR 19.2,  
17 "Instructions to Workers."

18 Without such training, workers at a  
19 specific licensee's facility are limited to 100  
20 millirem annually, which is the public dose limit.

21 The PNNL-11905 report. The report is a  
22 review of another study which is insufficient to  
23 support decision making. However, the report does  
24 include criterion for a useful study.

25 The study states that there is a need for

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1 detailed data on numbers or devices by source type,  
2 isotope, dated placed in service, source activity and  
3 design type.

4 So that brings us to what additional  
5 studies are needed and at what cost. The first thing  
6 that comes to my mind is that we need to examine the  
7 dose criteria of 32.51 and have come up with a  
8 definition for the term unlikely.

9 As previously stated, the design dose  
10 criteria for generally-licensed devices has not been  
11 definitively addressed with respect to the 500  
12 millirem dose limit or the accident dose criteria.

13 Generally-licensed devices are required to  
14 meet 10 CFR 32.51(a)(2)(3), which states that under  
15 accident conditions, such as fire and explosion, it  
16 must be unlikely that a person would receive an  
17 external radiation dose or dose commitment in excess  
18 of the dose to the appropriate organ, which is, again,  
19 the 15 rem whole body, 200 rem to a localized area of  
20 the skin and 50 rem organ dose.

21 However, the probability for failure that  
22 should be assigned to unlikely is not clear. I also  
23 feel that we need to complete the surveys that were  
24 proposed in NUREG-1669 to further quantify the risks  
25 from devices that find their way into the scrap and

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1 recycling stream.

2 And along with that, we need to examine  
3 the current device population, as mentioned in the  
4 pacific northwest lab report.

5 If the dose criterium were lowered in  
6 32.51 to 100 millirem a year, it would be necessary to  
7 determine how many fixed gauges, which are currently  
8 generally-licensed, would exceed this limit.

9 Devices subject to registration would be  
10 the most likely to exceed this limit and information  
11 on the number of fixed gauges which meet the  
12 registration criteria will be available once the  
13 general license tracking system is in operation.

14 Radiation exposure data for devices is  
15 contained with the individual sealed source and device  
16 registration sheets and could be used to determine the  
17 devices which are likely to exceed the 100 millirem  
18 limit in some cases.

19 Additional data, however, may be needed  
20 and that information may be obtained from case files  
21 that we have or it might have to be obtained from  
22 manufacturers in the case where the SS&D registration  
23 file is not sufficiently complete to make this  
24 determination.

25 We also need to reexamine the approach

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1 used in NUREG-6642 to see if their methodology could  
2 be applied to produce a more realistic set of doses.

3 Right now I mention that they did their  
4 calculations based on a average source strength. They  
5 looked at all the devices for gamma fixed gauges, the  
6 microcurie range to the curie range and they picked  
7 the middle and did calculations based on that.

8 We can't use that to make decisions, but  
9 we might be able to use their methodology using a more  
10 representative set of doses. And right now the cost  
11 to develop this additional information is unclear.

12 How has risk information been used in  
13 general? Risk information is just beginning to be  
14 used by the NRC for fixed gauges. The new  
15 registration requirements in 10 CFR 32, which are  
16 based on recommendations of the GL working group, were  
17 developed used consequence-based information and  
18 professional judgement, and these are a beginning in  
19 the use of risk information for these devices.

20 Additionally, devices must pass the sealed  
21 source and device review, so they are looked at  
22 individually. And again, they have to pass the dose  
23 criteria. It has to be unlikely that they would cause  
24 a significant dose as defined in 32.24.

25 What is the societal benefit of this

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1 regulated activity? I touched on this a little bit  
2 earlier, but gauges are used in many industries to  
3 improve quality control and lower the costs of  
4 products.

5 They are used in areas which would be  
6 inhospitable to humans, such as in tanks or other  
7 dangerous locations and the use of gauges in these  
8 hazardous locations may reduce the immediate safety  
9 risk to workers at the facility.

10 And to the public perception of this risk,  
11 it's my feeling that the general public is generally  
12 unaware of these devices and the fact that they  
13 contain radioactive material.

14 However, the public concern over  
15 radioactive material in recycled metals is increasing.

16 So when we look at the draft screening  
17 criteria, with regard to the first four, would this  
18 resolve -- would risk information resolve a question  
19 with respect to safety?

20 Yes, I believe it would. It would use risk  
21 information to identify higher risk devices and we  
22 could determine how they should be regulated more  
23 appropriately or lower risk devices, which may be fine  
24 as they are.

25 Would this improve our efficiency of

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1 effectiveness? Yes. A risk-informed approach in this  
2 area would improve effectiveness of NRC regulatory  
3 process by providing a greater degree of consistency  
4 as to how fixed gauges are licensed.

5           Would it reduce unnecessary burden? Yes  
6 and no, depending on what you define unnecessary as.  
7 A risk-informed approach may reduce burden for some  
8 licensees but, in fact, it may increase requirements  
9 for more hazardous devices.

10           Would it help to communicate a decision?  
11 Initially, I had no on this, but after listening to  
12 some of the other presentations we had this morning,  
13 I'm saying maybe it would, if we could -- give us a  
14 more clear basis to explain our decisions.

15           Now for the big questions. Do information  
16 and analytical models exist that are of sufficient  
17 quality and could they be reasonably developed?

18           Well, data is lacking in many areas for  
19 fixed gauges. We need more data on the number of  
20 devices that are out there, how licensees are using  
21 these devices at their facilities and how the devices  
22 behave in the scrap system.

23           Could start up of a risk-informed approach  
24 be realized at a reasonable cost? That is very unclear  
25 at this point.

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1           And do other factors exist which would  
2 preclude changing the regulatory approach? Again, I'm  
3 not sure. So that concludes what I have to say. I'm  
4 open up for comments.

5           DR. JOHNSRUD: I'm curious to know if the  
6 difference in your concluding remarks of being unsure  
7 reflect the difference in the kinds of equipment that  
8 were considered in the other two presentations or  
9 differences in the way that the staff evaluated them?

10           MS. SHANE: I think mostly the difference  
11 would be the kinds of equipment because fixed gauges  
12 cover such a broad spectrum of devices. We have some,  
13 like I said, that us millicuries sources and some that  
14 use curie sources.

15           And it's a lot of work to do to really  
16 quantify what's out there and what kind of risks they  
17 pose.

18           DR. JOHNSRUD: Okay.

19           MS. SHANE: So it's not just dealing with  
20 one type of device where we could look at it easily.

21           MR. FORTKAMP: Just kind of a quick  
22 question, maybe clarification. On your item 6 you say  
23 or -- I'm sorry. Not item 6, but where you're talking  
24 about the data, item 5. You say it may be lacking in  
25 some areas?

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1 I don't think it's lacking. I just don't  
2 think it's compiled yet. Because you've got your  
3 database of events from worst case scenarios, looking  
4 at those.

5 You've got your SS&D registrations, which  
6 have comprehensive information on the dose from these  
7 devices, as well as you've got a significant history  
8 with most of these devices, or very similar devices of  
9 50 years of field experience.

10 The data is there. It's just not compiled  
11 and I just to make sure that that's not a --

12 MS. SHANE: Yes, that may be more --

13 MR. FORTKAMP: -- a stopping point --

14 MS. SHANE: That may be a more accurate  
15 way to say it.

16 MR. FORTKAMP: -- for continuing looking  
17 at this.

18 MR. LUBENAU: Joel Lubenau.  
19 Unfortunately, I didn't catch the beginning of your  
20 presentation. What I heard was very interesting. I  
21 would like to offer another thought for you, to be  
22 considered by the staff.

23 And that concerns the principal of  
24 justification. It's an integral part of the ICRP. It's  
25 one of the cornerstones of the ICRP system of

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1 radiation protection.

2 Basically, what it says is that any  
3 application of radiation shall be justified, there  
4 should be a reason for doing it and one can imply that  
5 there are not alternatives.

6 Unfortunately, in the United States we  
7 haven't incorporated that into our National Radiation  
8 Protection Policy. But it does exist.

9 I have seen -- and I'll give you a  
10 practical example -- I have seen isotope gauges used  
11 in facilities that are filling beverage containers,  
12 breweries, for example, but use americium-241.

13 And we've had cases where those types of  
14 gauges have shown up in the scrap recycling. In fact,  
15 we had one incidence where one of those gauges was  
16 actually shredded and the source itself was breached,  
17 and it came from a brewery.

18 I've also been to breweries where they use  
19 xray machines for that same purpose. Now there may be  
20 technical reasons, depending on bottling speed and all  
21 that kind of stuff. And I think there are people here  
22 than can probably speak to that.

23 But I do wonder is that is not something  
24 that ought to be looked at from a National Radiation  
25 Policy point of view of our regulatory agencies?

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1 I'm not trying to discourage the use of  
2 radio isotopes. All I'm trying to say is if we use  
3 them, let's be sure that it's an application that, in  
4 fact, the isotope is needed as a radiation source.

5 The neat thing about the xray machine is  
6 that you pull the plug on it, and if you'll forgive me  
7 for drifting back to my native Brooklynese, it ain't  
8 a radiation source no more. And that's a very  
9 important factor for a lot of people. So think about  
10 that. Thank you.

11 MR. TENHET: Thank you very much for doing  
12 this and for giving us the opportunity to learn from  
13 you and perhaps express some of our views.

14 My name is Joe Tenhet and I'm an RSO at a  
15 factory. We have maybe 250 gauges and about 400  
16 sources. However, my experience in radiological  
17 matters is very narrow, nowhere near what most of you  
18 know and deal with.

19 I've got a couple of comments, and if I  
20 express them in the form of questions, please take  
21 them as rhetorical. There's no need to give a response  
22 today.

23 But I would hope that eventually this will  
24 lead to if not changing the regulations, perhaps some  
25 clarification of the regulations as they exist today

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1 with regard to fixed gauges.

2 Frankly, my problem is occasionally I have  
3 to deal with a regulation that seems that it was  
4 written for a nuclear power plant or a bomb factory,  
5 and I just have fixed gauges with 25 millicuries of  
6 strontium-90 in it.

7 And two specific examples, one to Section  
8 3050, and I'm just checking with my manufacturer  
9 friends, there's a requirement for a 24-hour telephone  
10 notification for an equipment failure if the equipment  
11 if required to prevent exposures exceeding regulatory  
12 limits or mitigate the consequences of an accident.

13 Now most every gauge I've ever seen has  
14 got a shutter and a shutter indicator, a red light and  
15 little green light. If that red light burns out, do I  
16 have to make a 24-hour phone call?

17 MS. SHANE: No comment.

18 MR. TENHET: I've talked to a few agency  
19 personnel and they've all sort of said I don't want to  
20 get the call, but nobody will go on record as saying  
21 no, you don't.

22 And the other example is you had mentioned  
23 the part 32, the issue of defining unlikely. I'd like  
24 to continue with that idea. If you go back to part 20,  
25 our requirements to provide annual training, and

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1 indeed for personal dosimetry, are based on a criteria  
2 of is likely to exceed.

3 Now is likely to defined as being 51  
4 percent probability, 95 percent probability or ten  
5 percent probability?

6 And when you're dealing with 3,000 people  
7 in a factory, who might have to be paid overtime for  
8 annual training, that's an issue.

9 So I would hope that the concept of risk  
10 analysis would be applied there as well and help us  
11 define -- in the case of a gauge it might depend on  
12 whether somebody stands in one place for eight hours  
13 a day or three feet away, and how much overtime they  
14 work.

15 And, of course, we can train people not to  
16 stand closer. But the fact that a person can stand  
17 there, does that mean it's likely? So thank you again.

18 MS. SHANE: Thank you.

19 MS. BAILEY: Are there any more comments?

20 MS. SHANE: I thought this was going to be  
21 more provocative.

22 MR. KOKAJKO: You couldn't have eaten that  
23 much lunch that --

24 MS. SHANE: Thank you.

25 MS. NIMMO: Elsa Nimmo. You know, I think

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1 a lot of us who represent manufacturers really like  
2 the idea of there being more attention paid to the  
3 risk.

4 Because it's been obvious that some of the  
5 problems that we see are because things have been put  
6 in categories and it doesn't necessarily relate to  
7 risk.

8 I think one of the frustrations a lot of  
9 us have is that we end up putting in a ton of time  
10 that we can see is not really productive towards  
11 safety, and we can see other things that look more  
12 productive to us.

13 But because the way the regulations were  
14 forced into activities that to us, as people concerned  
15 about safety, doesn't seem like the most productive.

16 And I've often thought that some of the  
17 requirements that have come down is because there are  
18 some devices, perhaps that have been put in the  
19 general license category that never belonged there in  
20 the first place.

21 And it's sort of like it's tainted the  
22 license category and made things stricter when it  
23 would have been better just to remove that group of  
24 things, put them in a different category and let the  
25 items that really are lower risk sail along.

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1           And I'm not going to get into trying to  
2 define lower risk and probability of risk, but my  
3 comment is I think I speak for a lot of us that we  
4 kind of welcome this, more let's take a step back,  
5 let's look at the risk, let's sort this out. I think  
6 that's a very good approach.

7           MS. SHANE: Good. Thank you.

8           MR. KOKAJKO: Any other comments?

9           MS. SHANE: Any input's welcome.

10          MR. FORTKAMP: Jonathan Fortkamp. It's  
11 kind of a generic question. Maybe you're going to get  
12 into it in these closing slides here, but my question  
13 is are these questions that are being posed here by  
14 both the NRC staff and the public going to be  
15 addressed in the final draft that comes out?

16                 I mean is there going to be firm NRC this  
17 is what we're saying type statements, or is it -- I  
18 mean, everything seems very loosey-goosey right now.

19                 Is there going to be firmer statements  
20 from the NRC on what they believe, you know, yes, you  
21 know, fixed gauges definitely meets the criteria and  
22 we're going to move forward with implementing a risk-  
23 based review?

24           MS. SHANE: Yes, we will, eventually.

25           MR. KOKAJKO: Let me -- first of all,

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1 risk-informed, not risk based. Risk based has some  
2 real negative connotations and I think it implies a  
3 degree of certainty to things that I suspect that we  
4 just don't have, and particularly in the materials  
5 areas where, to be quite honest, the breath of stuff  
6 that is regulated is just rather broad. I mean, that's  
7 the first thing.

8 I'd also like to mention something that I  
9 probably should have said earlier today and I failed  
10 to do that. And that we're assessors of risk, we're  
11 not the risk managers. We're here to try to take a  
12 look at where risk may be and to make recommendations  
13 and, hopefully, these case studies will help  
14 illuminate some of those things.

15 The risk managers -- we will provide our  
16 input to risk managers who will take our input, among  
17 other things, and try to make sense out of it.

18 This was identified in a National Academy  
19 of Science report done back -- I think it was in 1990.  
20 I think it's called the Redbook. And they essentially  
21 said the same thing, that once you assess the risk,  
22 it's only one data point that you go into the  
23 management of risk.

24 And this I view as an early start in  
25 trying to assess where the risk is, apply our

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1 resources in a very effective manner. We are in the  
2 materials and waste arena, at least in the stuff that  
3 we're doing right now, we're sort of in our infancy.

4 Because as the studies pointed out, that  
5 some of the information that we have leaves something  
6 to be desired as far as the quality of what we have  
7 done thus far.

8 One of the commenters earlier asked about  
9 what we did toward nuclear reactors. This agency  
10 spends a lot of resources in regulation nuclear  
11 reactors.

12 We are trying to take some of the tools  
13 and benefits of risk insights that have been through  
14 the application of those tools and try to apply them  
15 in areas, in some cases, for the first time and,  
16 hopefully, will be successful.

17 And that's why we're seeking input today,  
18 to see how we might go about doing that.  
19 I don't know if that answers your question, but that's  
20 sort of the best answer I can provide you.

21 We are not going to make a -- and I think  
22 I said earlier too, that we're not making a regulatory  
23 decision today. We're getting input so that we will be  
24 able to provide input to regulatory decisions  
25 tomorrow. And tomorrow, by the way, is a long way

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1 away, perhaps.

2 MR. FORTKAMP: Real quick, is that then --  
3 when you say tomorrow -- the next report that comes  
4 out, is that going to be pretty firm or is that going  
5 to be what you gathered through this -- formally  
6 submit that to the Commission?

7 MR. KOKAJKO: Marissa was going to cover  
8 that. Why don't you cover that slide now?

9 Because this is a long-term project. This  
10 is not going to be done -- and the overall results  
11 will be done -- will not be done at least until the  
12 end of the year. Thank you, Raeann, I appreciate it.

13 MS. SHANE: Is that a question for me or  
14 is that --

15 MR. EVANS: No, in fact, if I may -- Hugh  
16 Evans from AEA Technology, again. To respond to a  
17 comment made by Joel a little bit earlier.

18 Within the industry we have somewhat of  
19 a facetious saying that nucleonic gauging is as  
20 technique of last resort.

21 Why would anybody resort to all the rigors  
22 of the licensing process and the onerous demands of  
23 owning radiation sources and devices containing them  
24 if there was an alternative technique that could do  
25 the job just as well?

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1           And I think we find in the industry that,  
2 generally speaking, the devices are installed that are  
3 fit for the intended purpose, both in terms of safety  
4 criteria and the accuracy of the measurement with  
5 respect to the speed of the product, et cetera.

6           I think only recently are we now beginning to  
7 see xray systems sufficiently miniaturized and with  
8 sufficiently stable electronic circuitry such that the  
9 -- certainly, in the case mentioned by Joel of  
10 americium-241, within the industry I would declare  
11 that there is a definite trend now of the exit from  
12 americium-241 for that particular application as the  
13 competing technologies have actually come up and can  
14 do an as good or slightly better job than the  
15 nucleonic gauging device with an isotope.

16           MR. KOKAJKO: Thank you.

17           MS. BAILEY: Let me just briefly go over  
18 the schedule. Currently, this is our schedule, and  
19 that's to issue a draft report in the Spring of 2000  
20 and issue that for comment.

21           And then in the summertime hold another  
22 stakeholder meeting and then following the stakeholder  
23 meeting and taking stakeholder feedback into account,  
24 issuing the final report.

25           Now this schedule is tentative. And based

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1 on the many comments that we received today, that we  
2 need to look at more data, that we need to talk to  
3 more people, that we need to talk Agreement States and  
4 take their experience into consideration. That  
5 schedule is something that we may need to revisit.

6 As far as what's going to be in the  
7 report, currently, what we have planned for the report  
8 -- and this includes a draft report also, would be the  
9 answer to the three types of questions, the results of  
10 our testing of the screening criteria, any safety  
11 goals that we may have been able to pull out from the  
12 case studies and recommendations. Those are  
13 recommendations that would then be forwarded, as  
14 Lawrence mentioned, to the risk managers, to the  
15 different program offices in the materials and waste  
16 arena and then it would be their decision to decide  
17 how they would dispose of those recommendations.

18 Before I hand it over to Lawrence, I do  
19 want to go back and go over the purpose of the case  
20 studies again.

21 The purpose of the case studies is to help  
22 us identify areas in the materials and waste arenas  
23 that could be risk informed, to allow us to examine  
24 what was done in the past, was it done in a risk-  
25 informed manager?

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1           If it was done in a risk-informed manner,  
2           what would happen? Would we be able to conduct our  
3           business better? Would we be able to maintain safety  
4           better? Increase in effectiveness, reduce burden,  
5           communicate our decisions better.

6           So it's really a way for us to determine  
7           what can be risk informed and if we did risk inform  
8           it, would things be better?

9           The other purpose of the case studies is  
10          to test the screening criteria and then to pull out  
11          safety goals.

12          Today we are not proposing anything. We  
13          are just giving you information and we are trying to  
14          get feedback from you on how we are going about doing  
15          this.

16          And I guess before I do hand it to  
17          Lawrence, I'd like to open it up one last time for  
18          comments, general comments across the board about the  
19          three case studies or about what we're doing here.

20          MR. KOKAJKO: By the way, while you're  
21          going to the microphone, I'd like to point out that  
22          the schedule that she has here are just for these  
23          three case studies. The other case studies will have  
24          a different schedule associated with them.

25          I don't want you think we're going to get

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1 all eight done by the summer. We're not. Three have  
2 not started and two are in various other formative  
3 states.

4 DR. JOHNSRUD: That was exactly my  
5 question. Thank you.

6 MR. FLETCHER: Roland Fletcher, Agreement  
7 States. I do, first of all, appreciate what you've  
8 done. And from an Agreement State perspective, I see  
9 many opportunities that we need to be involved now and  
10 I will pass that word along.

11 In particular, your next subject is  
12 probably of more interest to Agreement States than any  
13 other, and I would encourage you very strongly that  
14 before you even embark upon what areas you're going to  
15 look at and get the Agreement States involved very  
16 heavily, because site decommissioning is something  
17 that's very heavy on any of the Agreement States right  
18 now.

19 MS. BAILEY: Let me ask you a question.  
20 For the decommissioning case study, when we do hold  
21 our stakeholder meeting, how much time, advance time,  
22 advance notification would you need to get you to --  
23 or the Agreement States in general?

24 MR. FLETCHER: I wish I could give you a  
25 specific -- I would just say as much as possible. I

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1 mean when you start sitting down and deciding what  
2 things you're going to look at, please have the Office  
3 of State Programs involved at that time because they  
4 have direct communications into the Agreement States  
5 and can probably -- there's a monthly communication,  
6 which I think some of you participate in, as early as  
7 possible.

8 I can't give you a date and time, but  
9 availability of individuals depends upon lead time.

10 MS. BAILEY: I think I can tell you this  
11 much. It's that at this point, we're looking at a  
12 stakeholder meeting in the springtime, probably mid-  
13 spring.

14 MR. FLETCHER: Okay. It's time to get the  
15 word out now then.

16 DR. JOHNSRUD: With regard to the  
17 stakeholder meeting, I really want to urge you to  
18 arrange meetings throughout the nation.

19 Quite clearly, there is a distribution of  
20 the equipment that's being discussed today nationwide.  
21 And I hear a complaint from the agency that members of  
22 the public aren't aware, don't know and, therefore,  
23 don't care. If they had an opportunity to know, they  
24 might care quite a lot.

25 And certainly, there will be, I think,

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1 probably much greater interest in the decommissioning  
2 issues, and those certainly have concerned people in  
3 the public realm, as well as others nationwide. And  
4 they deserve to have an opportunity. It's tough to get  
5 to D.C. for most folks in the U.S.

6 MS. BAILEY: Thank you.

7 MR. KOKAJKO: If I may comment on Dr.  
8 Johnrud's comment -- remark. I think that for this  
9 early go around, unfortunately, we're going to be  
10 having most of our meetings here in D.C.

11 I do think that as we begin to move into  
12 development of safety goals, we will be expanding out  
13 to the nation to not only have them in our regional  
14 offices or -- excuse me.

15 Not the regional offices, but where the  
16 regional offices are located, which is outside of  
17 Philadelphia, outside of, I think, Atlanta, outside of  
18 Chicago and between Dallas and Fort Worth.

19 We are interested in other participation  
20 from other areas as we move beyond this, but you  
21 understand that these early meetings are -- as you  
22 see, we're still in a very formative state and I'm not  
23 sure that going out to every -- moving out to multiple  
24 locations would be cost effective to us because we  
25 have a limited budget as well.

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1           We are going to have a decommissioning  
2 meeting, I think, mid-Spring sometime. And it will  
3 focus on one particular case study and application.  
4 It's going to be the Trojan LTP under the new license  
5 termination rule. And that's the case study we've  
6 selected.

7           That will be done -- hopefully, it will be  
8 roughly around the same state of knowledge by the time  
9 that -- well, we will be.

10           And we will be inviting the Agreement  
11 State of Oregon to that and Adam Bless, who is the  
12 Oregon Department of Energy Representative, and others  
13 who may be able to attend as well.

14           MR. PAGE: My name is Marcus Page. I'm  
15 with Morgan, Lewis and Bockius. One of the things I  
16 wanted to bring up, and it follows on this comment,  
17 which we might be able to consider. I know the  
18 Commission is now holding conferences that are videoed  
19 and we can see on ADAMS.

20           And what this -- what I would propose --  
21 because the first think I looked at this meeting was  
22 to see was there going to be a live webcast.

23           Now as far as exposing it, you make a  
24 large audience for yourself. And on that system it  
25 has, people won't be able to ask a direct question and

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1 interrupt the conference, but they will have the  
2 ability to send an e-mail on what they heard.

3 And that would tend to allow you to get  
4 maximum use of touching the public all over Agreement  
5 States. So you already have that system set up.

6 And maybe on some of these critical  
7 issues, like decommissioning, somebody might say well,  
8 it might not be cost effective for the gauges, but on  
9 decommissioning where it's going to touch so many, you  
10 all might look at going to that procedure.

11 And it's just -- it's a really reliable --  
12 I've monitored a couple of the briefings lately. So  
13 that might be something you want to consider that  
14 would help reaching out to the Agreement States, other  
15 stakeholders, the industry to provide. And that's just  
16 a suggestion.

17 MR. KOKAJKO: That's an excellent idea.  
18 The unfortunate thing about that is that there's only  
19 one -- I believe there's only one room in the agency  
20 that is allowed to do that and the Commission probably  
21 would not like it if I tried to take over their room.

22 But we will look at -- that's a great  
23 idea. I mean I didn't think of that. I'm glad you  
24 brought it up.

25 MR. PAGE: And that's why I said on

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1 decommissioning we might express an issue that is such  
2 a major concern to the public and industry that there  
3 might be enough public pressure and industry pressure  
4 to say can't we just hold this meeting in this room  
5 where it could be webcast live? That's all.

6 MR. KOKAJKO: That's an excellent idea.  
7 Thank you very much.

8 MR. FLETCHER: Roland Fletcher again. Did  
9 you say that you're decommissioning case study is  
10 going to be based upon just one decommissioning and  
11 that's Trojan?

12 MR. KOKAJKO: Yes, sir.

13 MR. FLETCHER: Is it possible for you to  
14 incorporate others? And the reason I'm saying that,  
15 when you talk about decommissioning power plants,  
16 essentially, that's an area of experience that won't  
17 be directly related in the Agreement States, even  
18 though they may get involved from a public  
19 perspective.

20 But decommissioning a facility where there  
21 are radioactive materials, if you want to get a  
22 complete site decommissioning picture, I think needs  
23 to be included in that argument.

24 MR. KOKAJKO: I understand your comment.  
25 We were -- the decommissioning board at the NRC was

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1 the one that wanted us to do this particular project,  
2 and decommissioning of power plants is part of the  
3 NMSS program area.

4 And Adam -- excuse me. The State of Oregon  
5 is also an Agreement State and they do have a -- would  
6 have a particular interest in this.

7 We recognize that there's limited  
8 applicability to most of what the Agreement States  
9 regulate. We recognized that at the beginning, but we  
10 take recommendations from the other groups within the  
11 staff.

12 MR. FLETCHER: Well, I guess the point I'm  
13 making is from a decommissioning of a power plant, the  
14 Agreement States are aware, are informed, but are not  
15 directly involved.

16 But a facility that's within a state that  
17 is -- has to be decommissioned, that's licensed by  
18 that state, that means that Agreement States needs to  
19 be directly involved.

20 And if we're looking at the whole picture  
21 of site decommissioning, we've got to take those  
22 aspects into account.

23 MR. KOKAJKO: I understand your comment.  
24 Right now the case studies are focusing -- they're  
25 much more limited applicability, at least in

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1 decommissioning.

2 We may be able to expand that for a future  
3 case study, but right now that's what the game plan  
4 calls for.

5 MR. KILLAR: Felix Killar with NEI. I  
6 want to echo what Roland has said as well. The  
7 decommissioning for nuclear facilities, for reactors,  
8 I think are actually fairly well standard and there  
9 isn't that much of an issue with those.

10 You run into more of the issues when you  
11 talk about a facility that's handled natural uranium  
12 or depleted uranium, where you have questions about  
13 determining differential between background and what  
14 the facility handles or processed, and in some of the  
15 facilities as well.

16 And I think you need to look at some of  
17 these, because a lot of the risk analyses that go into  
18 what is clean and is clean enough, was right up the  
19 alley, I think, of some of the work you guys need to  
20 do. So I think you certainly need to expand this beyond  
21 just reactor.

22 MR. KOKAJKO: Thank you.

23 MR. FARRELL: I'm Clifton Farrell with NEI  
24 as well. I had a follow up question on your schedule  
25 of activities, and that pertains to the four case

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1 studies that I guess are pending, uranium recovery  
2 being one of them.

3 Are those remaining case studies going to  
4 be developed probably in 2002, after all of the --  
5 after you've worked through these first three or four  
6 examples?

7 MR. KOKAJKO: It's still undetermined. We  
8 are trying to embark with a contractor support to get  
9 everything done before the end of the calendar year,  
10 and then we want to work with research on trying to  
11 establish some means of developing a safety goal  
12 program. Any other questions?

13 Now I get to say what I planned to say.  
14 I'm glad to have met all of you today, and I look  
15 forward to meeting you in the future.

16 I do recognize the need for early input as  
17 we test the screening criteria and look at the  
18 possibility of developing safety goals in the  
19 materials and waste arenas.

20 I hope you appreciate the point we are at,  
21 in that we are seeing input at this time and trying,  
22 over the long term, to focus our resources where  
23 significant risk is across the spectrum of materials  
24 applications. Your help is essential to that end.

25 I'd like to thank you for participating

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1 today in this meeting, and I'd like to thank you --  
2 those who were involved in coordinating and presenting  
3 this meeting, especially Candice Drummond, Marissa  
4 Bailey, Jim Smith, Jim Danna and Raeann Shane.

5 As I mentioned in my opening remarks, and  
6 I think it was mentioned throughout the day in some  
7 comments, that we are interested in feedback on the  
8 case studies themselves, as well as on how this  
9 meeting went, and I would like for you to provide your  
10 feedback form to us, and I believe there was some  
11 outside on the table.

12 You can either provide it directly to us  
13 or you can mail it in. I believe all you have to do is  
14 fold it and send it in.

15 With that in mind, I'd like to seek your  
16 comments and questions one more time. And hearing  
17 none, I'd like to adjourn the meeting and, once again,  
18 say thank you very much.

19 (Whereupon, the meeting was adjourned at  
20 2:01 p.m.)  
21  
22  
23  
24  
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