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UNITED STATES OF AMERICA  
NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

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OPEN MEETING

+ + + + +

THURSDAY,

October 21, 2010

+ + + + +

The meeting was convened in room T-03B2 of  
Two White Flint North, 11545 Rockville Pike,  
Rockville, Maryland, at 11:00 a.m., Bruce Thomadsen,  
Ph.D., ACMUI Acting Chairman, presiding.

MEMBERS PRESENT:

BRUCE THOMADSEN, Ph.D, Acting Chairman

DARRELL FISHER, Ph.D, Patients' Rights Advocate

DEBBIE GILLEY, State Government Representative

MILTON GUIBERTEAU, M.D., Diagnostic Radiologist

SUE LANGHORST, Ph.D, Radiation Safety Chair

STEVE MATTMULLER, Nuclear Pharmacist

CHRISTOPHER PALESTRO, M.D., Nuclear Medicine

Physician

JOHN SUH, M.D., Radiation Oncologist

ORHAN SULEIMAN, Ph.D., FDA Representative

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MEMBERS PRESENT (CONT'D)

WILLIAM VAN DECKER, M.D., Nuclear Cardiologist

JAMES WELSH, M.D., Radiation Oncologist

PAT ZANZONICO, Ph.D, Nuclear Medicine Physicist

NRC STAFF PRESENT:

ROB LEWIS, Director, Division of Materials  
Safety and State Agreements

CHRIS EINBERG, Designated Federal Official

MICHAEL FULLER, Alternate Designated Federal  
Official

MARK L. BANKS, OIG/AIGI

NEELAM BHALLA, FSME/DILR/RB-B

KIMYATA MORGAN BUTLER, Ph.D, FSME/DILR/RB-A

ASHLEY COCKERHAM, FSME/DMSSA/LISD/RMSB

MARC FERDAS, R-I/DNMS/MB

JAMES FIRTH, FSME/DILR/RB-B

PATRICIA HOLAHAN, Ph.D, NSIR/DSO

VINCENT HOLAHAN, Ph.D, FSME/DMSSA/LISD

SOPHIE HOLIDAY, FSME/DMSSA/LISD/RMSB

DONNA-BETH HOWE, Ph.D, FSME/DMSSA/LISD/RMSB

JOSE IBARRA, OE

JOHN JANKOVICH, Ph.D, FSME/DMSSA/LISD/LB

ANDREA KOCK, COMM/OCMWO

VARUGHESE KURIAN, FSME/DWMEP/DURLD

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NRC STAFF PRESENT (CONT'D)

ED LOHR, FSME/DIILR/RB-B

PATRICIA PELKE, R-III/DNMS/MLB

MICHAEL RODRIGUEZ, ADM/DFS/FSB

MARIA SCHWARTZ, OE/CRB

JOHN SZABO, OGC/GCLR/LCLSP

CATHERINE THOMPSON, Ph.D, OE/CRB

RON ZELAC, Ph.D, FSME/DMSSA/LISD/RMSB

ALSO PRESENT:

DAVE ADLER, ASTRO

PETER CRANE

JAMES A. DEYE, NIH

JESSICA LLOYD, SNM

MICHAEL PETERS, ACR

GLORIA ROMANELLI, ACR

ERIC SOLTYCKI, AEHN

ANN WARBICK-CERONE, MDS NORDION

JENNA WILKES, ASNC

GARY E. WILLIAMS, VA NHPP

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

(11:09 a.m.)

ACTING CHAIRMAN THOMADSEN: We'll get started with the late morning session. And there's a change in order in the presentations. We are going to be starting with an overview of the NRC's Initiatives on the Use of Cesium-137 Chloride Radiation Sources, item number 19 in your binders. And with that, I will turn the program over to Dr. Jankovich.

DR. JANKOVICH: Good morning.

MEMBER LANGHORST: Good morning.

DR. JANKOVICH: I represent the NRC to provide you an overview of the NRC's Initiatives regarding cesium chloride sources. I have been with this project since it started four and a half years ago, and I would like to give you a little bit of historical perspective: how it came about that cesium is a focus of attention, where we are now, and where we are going.

As you know, NRC is responsible for the safety and security of all radioactive materials. Lately, security takes the forefront of our attention. Out of all of the radioactive materials, cesium chloride came to the foreground lately, for a few reasons, which I will show you in a moment.

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1 But this presentation is, thankfully,  
2 about not safety issues, not about health and safety.  
3 It is all about security. So let's go and consider  
4 why cesium chloride is a focus of attention.

5 It has three primary areas of use. It is  
6 used extensively in blood irradiation. It is used in  
7 biomedical and pharmaceutical research, extensively,  
8 and in calibration.

9 Overall, to give you an idea, cesium  
10 chloride only makes up about two percent of all the  
11 curie content that is used in civilian use. However,  
12 for particular reasons, we focus on cesium chloride.

13 As you may know, blood irradiation is an  
14 important area for disease prevention. Fifty years of  
15 biomedical research is based on using irradiators with  
16 cesium chloride. And the national and international  
17 systems of measurements are based on cesium chloride  
18 irradiation.

19 Why? That's the second bullet there. We  
20 have an ideal energy spectrum at 670  
21 kiloelectronvolts. That is right in the middle of the  
22 energy spectrum that we want to measure, so every  
23 survey meter is calibrated to cesium, all film badges  
24 are compared to cesium.

25 Cesium has a long half life, 30.2 years,

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1 so these irradiators don't need to be charged for a  
2 long period of time. And it is readily available, a  
3 byproduct of the reactors. It's very cheap. And it  
4 needs relatively short, small shielding, because of  
5 the energy spectrum.

6 But why is it important for security?  
7 That's the third bullet there, the meritorious  
8 properties of cesium chloride as it is used today. It  
9 is in a compressed powder form, doubly encapsulated in  
10 old irradiators. It is comparable to Tic-Tac candies.

11 So it is a compressed powder. And being a  
12 chloride, it is highly soluble in water, just like  
13 sodium chloride, table salt. And in solid form, if  
14 somebody pulverizes it, it is highly dispersible in  
15 air. It spreads like cigarette smoke.

16 Consequently, it is a security  
17 consideration if it is subjected to malicious use, to  
18 create panic or a so-called radiation dispersal  
19 device, a dirty bomb. Cesium chloride could be a  
20 candidate for such consideration. Therefore, security  
21 is important.

22 To bring everybody to a common  
23 denominator, I'll give a few examples of how these  
24 irradiators look. That's two steps. Here is one.  
25 This has two sources, one above -- maybe I will show

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1 it quickly. Here is a door, which flips out. They  
2 put the specimen, either a blot or a petri dish, that  
3 kind of thing.

4 They flip it back, and then there is a  
5 source above it, in a shield, which when the exposure  
6 plug comes out of the shield, there is another source  
7 underneath. The curie content of these machines  
8 varies from 5,000 to 15,000 curies per box.

9 Here is another one, also used for blood  
10 irradiation. These are secured in obscure places, in  
11 hospitals, research institutions that are protected.  
12 Here is another manufacturer of this product, a  
13 similar irradiator.

14 Now I will show you two calibrators. This  
15 is an old one, manually used. They put the survey  
16 meter into the middle, into the door, and then the  
17 source is shielded here. There is a toggle, manually  
18 operated, that pulls the source out of the shielded  
19 position and they calibrate the survey meter.

20 There is a newer model with all the  
21 computer gimmicks. It performs the same calibration  
22 of survey meters. You should see the manual for this,  
23 with all the multicolored screen printouts. Probably  
24 the manufacturer's teenage boy wrote that book, or  
25 something. The calibrators only use about 440 curies,

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1 while the others may go up to 15,000 curies.

2 Now, let's go to the history. I think  
3 this is important, for the Committee to see how we  
4 came to today's situation. We start back in 2005,  
5 with the Energy Policy Act. As far as we are  
6 concerned in this presentation, it did two things. It  
7 established a task force for the protection of all  
8 radioactive sources in us.

9 But that, of course, includes those gamma  
10 gauges used at petrochemical plants, those moisture  
11 density gauges they use for road building, and the  
12 irradiators. And then, also, this act told something  
13 else to the NRC. "Please fund a study by the National  
14 Academy of Sciences about source security."

15 Again, this is broader. Not just cesium.  
16 But we will focus on cesium right away. In 2006, the  
17 task force would give its first report. I will talk  
18 about this quickly, and you will see why these  
19 milestones are important.

20 Then, in 2008, the Academy wrote their  
21 study. Then the task force established a subgroup.  
22 That was the Cesium Chloride Working Group, to address  
23 cesium chloride. And then we had a public workshop to  
24 call for stakeholder input in 2008. The task force  
25 produced a second report in 2010, and we are coming

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1 close to the present time.

2 This summer, we published a draft policy  
3 statement on cesium chloride. Up until 2010, the  
4 Commission was in the information-gathering mode, what  
5 to do about cesium chloride irradiators. Now the  
6 Commission is about to make a final decision. That's  
7 why we published a draft policy statment.

8 Then, two weeks from now, we will have a  
9 public meeting on the draft policy statement to get  
10 stakeholder input. As you know, the NRC is an open  
11 agency. Everything that we do is open to the public.  
12 So the policy statement is not a declaration by the  
13 Commission, "This is what we think."

14 It is the result of input from the  
15 stakeholders. How it comes about, just like our  
16 rulemaking process. We publish a draft, we ask for  
17 input. We summarize the input, and based on that  
18 comes out the final.

19 So we are right before the final. I am  
20 going now to pass through here quickly, just for the  
21 summary, to give a few words about the task force and  
22 the following issues down here on this chart.

23 The objective of the task force that  
24 Congress told the NRC to lead is to address security  
25 on all radioactive sources. This group has been very

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1 active, meeting three or four times a year. The  
2 members include 12 government agencies, and the  
3 Agreement States.

4 The other objective was to identify gaps,  
5 missing links in the security system, and then  
6 periodically provide recommendations to the President  
7 and Congress, how do we stand about security for all  
8 radioactive materials.

9 And the act in 2005 said to please write a  
10 report in one year from 2005, and following every four  
11 years. That's how we came to the first task force  
12 report in 2006. And then the present task force  
13 report that you have copies of around here is 2010,  
14 four years later.

15 What was the conclusion of the first  
16 report? Thank God, no significant gaps in security,  
17 the current framework is sufficient. But they had a  
18 lot of recommendations and actions, that they  
19 identified as what to do next.

20 One of them is cesium chloride.  
21 Important, because they said "could be a subject of  
22 misuse." And then, the NRC should consider a study to  
23 rule out the use -- discontinue the use of cesium  
24 chloride.

25 Think back to my earlier slides. It has

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1 three important fields of application. If we say "no  
2 more," what comes to substitute? That's why cesium  
3 chloride is the focus of our attention, what to do.  
4 The task force established a subgroup, and that was  
5 the Cesium Chloride Working Group, worked on it here  
6 and there, and came up with their conclusions. This  
7 was an interim step to that hard copy 2010 report.

8 And the subgroup was the first, actually,  
9 who identified and really made the distinction between  
10 the three fields of applications. Then, their charter  
11 was clearly as I said. Determine the feasibility, if  
12 cesium chloride can be ruled out.

13 And here are the answers, what the  
14 subgroup said. Immediate phase-out would not be  
15 feasible right now. The three fields of application  
16 are so important, we cannot just stop using it.  
17 What's the next thing? A step-wise phase-out of those  
18 irradiators.

19 And the working group said it would be  
20 feasible. And they said challenges would have to come  
21 over -- would have to be overcome. Challenges is  
22 another word for preconditions. That's what I like to  
23 use.

24 And what are those preconditions? That's  
25 this fourth bullet, here. That viable replacement

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1 technologies must be available, and there must be a  
2 disposal pathway available. Think of both of these.  
3 Viable alternatives, which we may have, may not have;  
4 and disposal.

5 Disposal is a big issue, because there is  
6 nowhere to put commercial sources at the moment, at  
7 this activity level, up to 15,000 curies. So if we  
8 have to rule out the use of these irradiators,  
9 effective any day, what do we do with it? We put them  
10 into storage at the same sites where they are being  
11 used now. So what do we gain on the security issue,  
12 versus security for storage?

13 So these are challenges as they are called  
14 there, but these are really the preconditions, viable  
15 technology and disposal, for bringing in new  
16 technology. And then the subgroup goes further, that  
17 you should have sufficient time, and do it in a proper  
18 time sequence. And then interim security measures, to  
19 secure what we have at the moment are also important.

20 We come to the next step in the process,  
21 that is, the task force report in 2010. Well, this is  
22 shorter than the previous one, and much more concise.  
23 But it also includes cesium chloride. But before I go  
24 there, I'll tell you quickly, to give you an idea of  
25 what's in your book, it talks about four major subject

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1 areas.

2 One is that communication, coordination  
3 with the public for security of radioactive materials  
4 is important. The bottom line in plain English, is  
5 that there should be proper communication from the  
6 government to prevent any misinformation if there is  
7 any radioactive material threat.

8 The report sums up advances in security  
9 and control of radioactive sources, and then it says  
10 that disposal of sources is -- solution to the  
11 disposal is imperative. And then it talks about  
12 alternative technologies.

13 And to give you a little bit of an  
14 overview of what's going on about radioactive  
15 materials, it covers about seven subject areas where  
16 radioactive materials could be replaced with  
17 alternative technologies.

18 What are those alternative technologies?  
19 They address other isotopes, that's one way to do it.  
20 Or they talked about completely new technologies  
21 replacing radioactive materials. What are these  
22 subject areas, fields of use they talked about? Blood  
23 irradiation, calibration, research irradiators,  
24 industrial radiography, industrial irradiation, et  
25 cetera.

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1 And for each of these areas, the task  
2 force talked about the viability of the alternatives.  
3 Is it ready? It could be viable, but some  
4 technological development may be needed. And then  
5 they talked about other alternatives, where completely  
6 new research is needed, which is not feasible at the  
7 moment.

8 So that's the overall content of that  
9 report. They have developed recommendations. Four of  
10 them concern cesium chloride. I will run through  
11 those quickly. One of them is indirectly related to  
12 cesium chloride.

13 So, recommendation three. That is, if  
14 there is an initiative within the U.S. that we do  
15 discontinue the use of cesium chloride, then we should  
16 also address export. Because the used machines then  
17 could be sold overseas, and we just transfer the  
18 security risk from the U.S. to somewhere else. So  
19 they say make sure there is not such a situation  
20 developed if we were to discontinue the cesium  
21 chloride within the U.S.

22 And then recommendation four. Disposal  
23 options should be addressed, including cesium  
24 chloride. I already told you that there is not such a  
25 system at the moment.

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1           Then we come to recommendation ten. And  
2 this is important because this is a stepping stone  
3 towards the policy statement. The report says that  
4 they encourage one third use of alternative  
5 technologies, and the government's role should be to  
6 build incentives for use of alternatives.

7           And, of course, the report says that  
8 everything depends on the disposal options. We should  
9 not make hasty decisions and quick steps until we know  
10 what to do with the disused sources.

11           Recommendation 11. That's related to the  
12 first report, because the first report says "Look at  
13 stopping licensing the use of cesium chloride." So  
14 now the second report addresses that issue, and says  
15 "contingent on alternatives." Actually, "contingent  
16 on viable technologies."

17           Also, NRC should secure the threat  
18 environment. Rarely does it make sense that we  
19 interfere with existing processes, technologies, and  
20 benefits that these devices provide to society, unless  
21 there is sufficient threat to make that change.

22           And then recommendation 9, which is just  
23 in here because it is related to cesium chloride. It  
24 says the government should support research for  
25 alternative technologies into everything, including

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1 cesium chloride.

2 I'd like to give you here an overview of  
3 an important document that the NRC received from this  
4 committee that was an important input into the draft  
5 policy statement. ACMUI, in 2008, wrote a report for  
6 the NRC, and now, when I read it again, I find it very  
7 important, and almost prophetic in a number of ways  
8 that we received it at that point.

9 So I put this on the top for you. And of  
10 course there is the reference number, the ML number  
11 here for the NRC records system. So the purpose was  
12 to provide the staff an overview to help to form the  
13 NRC's policy.

14 And the title of this report had a very  
15 succinct summary. It said quickly, and very clearly,  
16 "Irradiators are needed. They have important medical  
17 and research functions." The security requirements at  
18 that time were quite extensive. They addressed  
19 individuals who were at the facilities, the sites  
20 themselves, and then the devices themselves.

21 So the conclusion was that the security  
22 measures in place are sufficient. Then, the report  
23 goes into discussing a number of technical issues.  
24 Those are listed in the third bullet, with the dashes  
25 down there. And to those who haven't seen this

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1 report, I'd like to note that this was very important  
2 for us.

3 The first issue was the practicality of  
4 alternatives. In plain English, cesium irradiators  
5 versus X-ray, because that's the only alternative we  
6 have at the moment. And then, the report discussed  
7 the biological effects, the cost -- of course, X-rays  
8 are much more expensive to operate. The power  
9 supplies need to be replaced every four years, they  
10 need big cooling from the public water system, and  
11 then goes down the drain. That huge electrical power  
12 need. Those of you who don't know how these devices  
13 work, huge X-ray machine.

14 And while the cesium irradiators work  
15 without maintenance, you know, initial purchase price  
16 compared to an X-ray machine, and then it runs for --  
17 they are still running. We haven't seen them  
18 discontinued. So the costs are discussed. And even  
19 on those, the report goes into further details, like  
20 rating the various X-ray machines: are they FDA  
21 approved? Are they approved for biological research?  
22 And what are the potential upcoming models?

23 So very good survey of the entire  
24 industry. In addition, the committee at that time  
25 conducted other surveys. They contacted the American

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1 Association of Physicists in Medicine, AAPM, and they  
2 provided data that 85 percent of them used cesium  
3 irradiators. They talked shortly about another  
4 alternative, the linear accelerators, and they said  
5 that the machine costs two million dollars, versus  
6 less than 200 for the traditional method, plus the  
7 annual operating costs are 200 thousand dollars.

8 So their conclusion was that for the  
9 present blood irradiation industry, those were not an  
10 answer. They looked at alternative nuclides. What's  
11 an alternative? Cobalt. Cobalt is different. There  
12 are no irradiators on the market that could substitute  
13 for the cesium machines.

14 In addition, cobalt has a short half life,  
15 four or five years, so the sources need to be  
16 replaced. That means transportation, source exchange  
17 at the site, additional expenses. In addition,  
18 because of the energy spectrum of the cobalt, these  
19 machines need much more shielding. They are three or  
20 four times heavier than the existing machines, so they  
21 cannot be used on upper floors at institutions. They  
22 have to be down in the basement with special  
23 foundations.

24 Why I'm telling you these details is so  
25 you can see how important information the committee

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1 provided to the NRC at that time. And it is not  
2 enough that they wrote this down at that time. They  
3 provided references, and they surveyed, as I started  
4 saying, the users.

5 When we go to the next subject they  
6 discussed, further considerations, they presented the  
7 result of another survey. They surveyed hematologists  
8 and oncologists, who are using irradiated blood, and  
9 they provide quantitative numbers. How much  
10 percentage of the blood would they describe as being  
11 irradiated, and what would be the impact if it was not  
12 irradiated.

13 They went to a research institution here,  
14 and they saw how big traffic was around the cesium  
15 machine. They have 250 people to use it. Those are  
16 researchers. They do 40 or so irradiations a day, and  
17 200 research projects involve just that one place with  
18 the present machine.

19 So to establish equivalency between the  
20 irradiation provided by cesium on that single  
21 frequency with something like X-ray, which has a broad  
22 energy spectrum, would take years. And they provided  
23 us this information. They also discussed irradiator  
24 security: what are the measures? The committee at  
25 that time went out to a research facility, and then --

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1 who are using it, how are they classified, how is the  
2 site secured? They provided all that information to  
3 us.

4 Then they went to the last issue, which is  
5 still open: alternative forms of cesium chloride.  
6 What is an alternative? As I told you, at the moment  
7 it is compressed powder. Cesium can be used in other  
8 chemical forms, in ceramic or in glass, vitrified  
9 form.

10 Cesium-137 is present in different  
11 molecular compositions, and supposedly these are other  
12 solid materials. At that time they said and concluded  
13 that there is no evidence to show that these  
14 alternative forms would provide further security. Now  
15 we are two years after this study, and the further  
16 study supports this conclusion. Very interesting. At  
17 that time, nobody knew.

18 I am going quickly to the present time.  
19 We published a draft policy statement, and this is  
20 where we are at the moment. The Commission is about  
21 to come to a final position, what to say about cesium  
22 sources. But as I told you, the process is open. We  
23 are collecting input.

24 That's what this draft policy statement is  
25 about. And it was published for that purpose in June,

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1 and in November we will have -- two weeks from now --  
2 this public meeting to collect, orally, input from the  
3 stakeholders. And then we keep the written comment  
4 period open well after the public meeting, so that if  
5 somebody wants to send us more information, we will  
6 have the opportunity. So the comment period for  
7 written submissions ends on December 17.

8 What does the policy statement say? It is  
9 in the style of a proclamation. Think of the  
10 Declaration of Independence. That set principles that  
11 we adhere to. So our policy statement makes sense --  
12 it makes a statement about principles.

13 So I will recap these principles for you,  
14 quickly. And it used the big words, you know. "NRC  
15 believes." "NRC encourages", and so on. Number one.  
16 "NRC's mission is the protection of public health and  
17 security." Number two. "Licensees are the primary  
18 responsible party at their sites for maintaining  
19 security."

20 And the policy statement says "If the  
21 current safety requirements are met, then the sites  
22 are secure. NRC encourages design improvements. NRC  
23 recognizes the important role that cesium chloride  
24 plays in the present socioeconomic situation. These  
25 are the three areas of use. NRC recognizes that there

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1 is no disposal facility at the moment, and the NRC  
2 monitors the threat environment and is ready to issue  
3 further security requirements if warranted."

4 In addition to these seven declarations,  
5 the draft policy statement discusses in detail four  
6 subject areas, technical subject areas. That is, the  
7 security of control of the sources, the areas of use,  
8 the three fields, how imperative it is to have a  
9 disposal facility, and the NRC's perspective on  
10 further security requirements.

11 And the NRC, in this last item here on the  
12 page, says that we encourage stakeholders to take an  
13 active role in further enhancing security. And then,  
14 also, we explain and state that we recognize that it's  
15 prudent to maintain an awareness about future research  
16 on a voluntary basis.

17 Okay. I present you here six technical  
18 sessions that we will have at this meeting to read  
19 from now. I don't want you to read all this, but I'd  
20 like to highlight, really, what we expect in each  
21 session.

22 The first one is about the NRC's mission  
23 and the licensee's responsibilities. We will present  
24 the history, what has happened so far, but we would  
25 like to keep the users', the license-holders'

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1 experience. And then NRC will also present the  
2 inspection results. As you may also know, the  
3 security requirements are implemented at the sites,  
4 and then NRC inspectors will go out and inspect how  
5 well those requirements are met. So those inspection  
6 results will be summed up.

7 Of course, the second technical subject  
8 will be how NRC monitors the threat environment, and  
9 what additional security requirements may be issued in  
10 the future. So we will describe how NRC monitors  
11 security issues. We will present how the new Part 37  
12 was formed, and what it will contain; that is, the new  
13 requirements in our Code of Regulations Part 37, about  
14 solidifying all of the previous requirements into one  
15 place.

16 And then we want to discuss here, in the  
17 second technical session, if cesium chloride deserves  
18 special attention. Don't forget, it's not just  
19 presentations. It is input from the stakeholders.  
20 That's what we want to hear.

21 Maybe I'll add here how these technical  
22 sessions will be conducted. We have alternate  
23 panelists to give five, ten minute presentations of  
24 their own views, and then we open the floor to  
25 discussion from anybody from the floor. It will be

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1 transcribed, and whatever is said and heard at that  
2 open meeting will be folded into the final analysis  
3 stage.

4 Technical session number three. Hardware  
5 improvement. That is a discussion of the irradiators.  
6 So we will hear from the manufacturers, we will hear  
7 from the users, and the alternative industry. The X-  
8 ray industry expressed strong interest that they want  
9 to come. And they will come, and they will present  
10 lots of information. And we will, of course, consider  
11 whatever they present to us.

12 Session number four. Alternative forms of  
13 cesium-137. This is about sources. Again, about the  
14 ceramics and the vitrified forms of cesium. We will  
15 hear from the source manufacturer -- there is, at the  
16 moment, only one manufacturer of cesium chloride, so  
17 they will come present their views, and the results of  
18 their R&D efforts.

19 The want to hear -- something important.  
20 Why do we talk about changing cesium chloride? So  
21 that it would be less soluble, less dispersable. But  
22 how do we measure something less? We, as physical  
23 scientists, know that we need quantitative measures,  
24 guidelines. "This is soluble at this point, not  
25 soluble afterwards." And we need a test protocol, how

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1 to test for it.

2            Luckily, for solubility, we have an  
3 international standard, ISO, on the source  
4 classifications. That has a section, how to measure  
5 solubility. Put the material in water, hold it there  
6 for four hours, measure how many parts per million is  
7 soluble. We can use that measure. We still have to  
8 determine what is acceptable and what is not.

9            But when it comes to dispersability in air  
10 of solid particles, we don't have such a test  
11 protocol. And of course, even if the physical  
12 scientists come up with "so many microns is  
13 dispersible with certain impact forces," is it  
14 acceptable to the security community, as far as risk  
15 is concerned? So there is a lot to discuss about  
16 alternative forms before the NRC, or anybody, comes to  
17 a conclusion.

18            Technical session five. This is the wide  
19 open area to discuss the present use of the present  
20 technology in the three fields of applications.  
21 Technical session six is on the disposal situation.  
22 We will have presentations from the Department of  
23 Energy. They will provide the status of the current  
24 environment of intent statement, and the pathway to  
25 how we may reach a final disposal site. And we will

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1 have presentations from licensees who have sources  
2 that they don't use, how do they handle it?

3 And we will have a presentation,  
4 interesting, from New York State. As you may be aware  
5 of it, last November, one of the cesium irradiators, a  
6 Gammacell 40, which was the first of my picture  
7 slides, was found leaking. Now, what to do with it?  
8 It has, I think, 1,500 curies in it. It still sits  
9 there locked up.

10 But ever since, the Department of Energy,  
11 NNSA, National Nuclear Security Administration is  
12 busy, promised that they would take it away. And they  
13 are in the process of taking it away. We don't have  
14 any transportation containers to take it away. So it  
15 is a big, expensive issue. But that will be discussed  
16 here.

17 Okay, I will sum it up now. So then we  
18 will have the meeting. The location will be two exits  
19 up on I-270 from here, at the University of Maryland  
20 Conference Center. We will have panelists, we will  
21 have participations, and there is a website where  
22 every document is posted.

23 If you want to reach us, send us any  
24 comments, you can send it to the docket, which is  
25 listed in the Federal Register. You can send it to

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1 our dedicated email address,  
2 CesiumDraftPolicy@NRC.gov. You can call Dr. Cynthia  
3 Jones or myself. Everything will be entered into the  
4 record.

5 Bottom line: we, as scientists, are  
6 citizens -- are concerned about security. Are we  
7 secure and safe? And if we look at the present  
8 requirements, we are secure. And we have a number of  
9 initiatives in place which make it possible. And then  
10 NRC is in continual interaction with our domestic and  
11 international partners to maintain this situation.

12 Finally, the NRC is planning -- the  
13 Commission is planning to come up with a final policy  
14 statement. As I said, the comment period is open  
15 until December 17th. We will sum up all the comments,  
16 then the Commission will come up next year with a  
17 final policy statement.

18 ACTING CHAIRMAN THOMADSEN: Thank you very  
19 much, Dr. Jankovich, for the very nice summary of the  
20 situation. Let's open the discussion to the committee  
21 for questions or comments.

22 Dr. Zanzonico?

23 MEMBER ZANZONICO: It just seems that they  
24 really have thoroughly looked into this. Obviously,  
25 you've got comments from stakeholders already. You've

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1 got hospital sites, and so forth, which are really  
2 unhappy about this, as I hear often when I tell them  
3 I'm going to an ACMUI meeting.

4 "Don't forget to remind them how unhappy  
5 we are about the potential for discontinued use of  
6 cesium irradiators." But I gather, until this final  
7 meeting is held, and all the comments are collected  
8 and so forth, a final decision remains to be made as  
9 to what will happen to cesium irradiators.

10 DR. JANKOVICH: Well, as the draft stands,  
11 as I pointed out those seven proclamations should give  
12 you an indication of what the Commission was thinking  
13 when they published it in June. And that's different  
14 than it was two and four years ago.

15 And input from the stakeholders, the Red  
16 Cross, the American Association of Blood Banks, coming  
17 to our meeting, they give us written comments too.  
18 University researchers will be coming, and they  
19 already gave us input.

20 ACTING CHAIRMAN THOMADSEN: Dr. Suleiman.

21 MEMBER SULEIMAN: I attended your first  
22 public meeting, and what I took away, which was  
23 troubling to me, was that -- I understand that it was  
24 only the powder form of the cesium chloride that was  
25 the real issue, if you could somehow put it in a

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1 ceramic, some sort of a chemical form that wouldn't  
2 allow it to be dispersed, that would solve some of the  
3 major concerns.

4 Then I found out that most of this is  
5 purchased from a foreign reactor site, because we in  
6 the United States just don't manufacture this. And  
7 they had some occupational issues about vaporization  
8 during production. And they would get to addressing  
9 our concerns if they found time.

10 This goes back to the source of molybdenum  
11 in this country, where we're getting it from outside.  
12 I just find a complete lack of policy in terms of  
13 radioactive materials and production capability in the  
14 country. I know we all have our little -- we're  
15 employed by certain people. We have our restrictions.  
16 We can't stray into other areas.

17 But somewhere, in some of these  
18 interactions, that case has got to be presented, that  
19 if we had more domestic production of some of these  
20 things -- putting this powder in ceramic form, talking  
21 with some chemists, I don't think that's a big  
22 technological challenge. We've done an awful lot of  
23 more fascinating things.

24 But for us to be economically dependent on  
25 getting this source from outside, and having them

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1 solve our problem for us, was troubling to me. So my  
2 question is a much larger one. I think the resources  
3 exist in this country to solve this problem, but who's  
4 going to solve it? You know, the NRC is a regulatory  
5 agency. You're not supposed to solve this problem.

6 DR. JANKOVICH: Exactly. That was going  
7 to be my answer. NRC is not supposed to promote the  
8 use of radioactive materials. We are just regulating.  
9 Our sister agency, the Department of Energy, is the  
10 agency who should be thinking about it.

11 MEMBER SULEIMAN: I just see this as  
12 symptomatic of a bigger lack of cohesive policy in  
13 terms of radiation safety and radiation products.

14 ACTING CHAIRMAN THOMADSEN: Thank you for  
15 those comments. Dr. Fisher?

16 MEMBER FISHER: Thank you for a very  
17 comprehensive, well thought out presentation. It  
18 shows that the agencies involved have really worked  
19 hard on this analysis. I appreciate the fact that  
20 your underlying assumptions are that cesium chloride  
21 sources are very valuable in the practices of medicine  
22 and health care.

23 And the question that I raise in my mind  
24 is -- I keep wondering, with all this expertise from  
25 many agencies, all the hundreds of scientists who have

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1 participated in many different ways, that the basic  
2 premise, or the underlying assumptions in the Energy  
3 Policy Act, as of 2005, isn't being challenged.

4 That we need to penalize the use of cesium  
5 chloride in this country to such a degree that we  
6 would develop policy to eliminate its use, without  
7 recognizing that, perhaps, the security of existing  
8 sources will, essentially, solve the problem.  
9 Penalizing the users of these materials in this  
10 country will not eliminate the international sources  
11 of cesium-137.

12 It doesn't control the manufacturing uses  
13 of cesium-137 beyond our borders. It really doesn't  
14 inhibit terrorist activities using materials coming  
15 from foreign sources, but it does severely jeopardize  
16 the legitimate use of these materials within our own  
17 borders, and that's my concern.

18 I can see that the thinking behind your  
19 presentation has already taken most of those thoughts  
20 into consideration, but what I don't understand is  
21 that the expertise involved does not challenge the  
22 legislatures who wrote the original legislation in the  
23 first place, to let them know that there are some  
24 errors in that logic.

25 ACTING CHAIRMAN THOMADSEN: Thank you very

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1 much, Dr. Fisher. Ms. Gilley?

2 MEMBER GILLEY: John, are we going to get  
3 an update on the voluntary participation in the  
4 irradiator enhancement projects that DOE has been  
5 supporting?

6 DR. JANKOVICH: Yes. We will talk about  
7 it. But I think you will not get a quantitative set  
8 of data, because that's security-related information.

9 MEMBER GILLEY: I simply wanted to know  
10 how successful it was, and if there was a reason to do  
11 some additional promotion or outreach within the  
12 states, for the facilities that have not had the  
13 enhancements, based on the information that we would  
14 receive at this meeting.

15 MR. LEWIS: And NRC would ask for  
16 additional outreach. And we've done some of that  
17 within NRC, with some of our states. But we have to  
18 work with them about where they're going to be at a  
19 certain time, because we can't advertise to everybody,  
20 and then they won't come to Arizona for five more  
21 years, you know? So we can work with the agreement  
22 states on that.

23 MEMBER GILLEY: Some of the licensees have  
24 been hesitant to take free enhancements until some of  
25 the other people had taken it and shown it to be

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1 successful. Or not successful. Whichever one it  
2 would be.

3 DR. JANKOVICH: You know, if you look at  
4 the process, how this enhancement goes -- I saw it at  
5 several sites, you know. Two technicians come out in  
6 the morning, and by mid-afternoon they are done with  
7 it. The environment is clean. We went to great  
8 expense to make sure that the process doesn't  
9 interfere with the ventilation system, and everything.

10 And cleaning up, they have to scrape off  
11 paint and things like that. So it's all cleaned up.  
12 So that's the impact, physically, at a facility.  
13 About three quarters of a day where the machine is not  
14 in service.

15 ACTING CHAIRMAN THOMADSEN: Okay. Dr.  
16 Welsh?

17 MEMBER WELSH: I would like to also thank  
18 you for the very well thought out and presented  
19 overview. A couple of years ago, when the  
20 subcommittee was contemplating this matter, we came to  
21 a few conclusions that you included on one of your  
22 slides.

23 Cesium-137 seems to be radiobiologically  
24 valuable. It may be ideal in its biological,  
25 radiobiological properties. Alternatives may be

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1 available, but have not been proven to be as  
2 biologically equivalent, and they were certainly going  
3 to be much more expensive, and have less longevity.

4 And alternative chemical forms of cesium-  
5 137 might be less vulnerable, and alternative  
6 chemical/physical forms such as vitrification or  
7 ceramic forms might be a solution to some of the  
8 problems. Yet, it was likely to be exorbitant. And  
9 the question was who would pay for the conversion from  
10 the powdered form to the vitrified form.

11 And forgive me for not having the details,  
12 but I thought there was some discussion about it not  
13 being the burden of the owner, and that there would be  
14 a source of funding to make that conversion. Is there  
15 any such discussion at this point, or am I  
16 misunderstanding something?

17 MR. LEWIS: We have tried to -- it would  
18 not be the regulator's role to develop a new chemical  
19 form for industry to use. That's what we were saying  
20 earlier. But we have, through this task force, and I  
21 think this report covers it, tried to work with other  
22 agencies to try to interest them to support  
23 alternative forms or alternative technologies.

24 And we have had limited success to get a  
25 government effort to do that. But, you know, the

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1 private sector ultimately would have to have a role.  
2 As John said, there is only one current manufacturer  
3 of cesium in large curie quantities. That's in  
4 another country, and it's only cesium chloride. And  
5 that's the world's supplier.

6 So there needs to be a business case to  
7 develop a different form. And as part of that, all  
8 those other countries would have to sign on to that  
9 business case, whether there would be the capacity to  
10 continue producing chloride and a ceramic form at the  
11 same time, or -- you know, all those questions are  
12 beyond the ability of a regulator to tackle.

13 It's very similar, in fact, to the Moly  
14 situation in that regard. But we will have the vendor  
15 for the sources at the workshop, so those kinds of  
16 questions can be posed to them.

17 DR. JANKOVICH: Yes, they are coming.  
18 They are also United States licensees, so they have  
19 representation here, in Illinois. So they will come  
20 from that facility, and their distribution center in  
21 England, so we will have somebody from England, too.

22 ACTING CHAIRMAN THOMADSEN: Dr. Langhorst?

23 MEMBER LANGHORST: Just a quick question.  
24 I understand that the only way to participate in that  
25 meeting is to be there. And so my question is, how

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1 soon will transcripts of that meeting be out? And  
2 will they be out soon enough to help us who want to  
3 comment on this by December 17th?

4 DR. JANKOVICH: Well, I'll tell you what  
5 happened two years ago. The technical staff at NRC  
6 got the transcript within two days from the  
7 transcriber. And then we proofread it, and it was  
8 finalized very quickly.

9 MEMBER LANGHORST: Okay.

10 DR. JANKOVICH: So within days, I think --  
11 and don't commit me to it, but within a week or two it  
12 will be on our website.

13 MEMBER LANGHORST: Okay. Thank you.

14 ACTING CHAIRMAN THOMADSEN: Good. Any  
15 other comments from the committee? In that case, I'll  
16 thank you once again, and we'll be moving on to item  
17 number 18 in your book, which is 10 CFR Part 37  
18 Rulemaking and Guidance.

19 MR. O'SULLIVAN: Good afternoon. I'm  
20 Kevin O'Sullivan. I'm a branch chief in rulemaking  
21 here at the NRC, and I took the call from Merri Horn  
22 this morning, who is sick. That's going around,  
23 especially with the flu shots just being administered  
24 over the last few days.

25 I'm giving an update on the Part 37

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1 Proposed Rule. I'm sure you're familiar with it  
2 following the excellent presentation yesterday. You  
3 all know that the proposed rule was published in June,  
4 that the workshops were held in the end of August, and  
5 then in September. They were very successful.

6 Very recently, now, I think last week or  
7 the week before, there was an extension published in  
8 the Federal Register extending the public comment  
9 period to, actually, January 18th. And that rule is  
10 going to be due in the spring of 2012 as a final rule.

11 Currently it's scheduled for the end of  
12 this year, but because of the extra ninety days in the  
13 public comment period, it will be extended. Probably  
14 the Commission will approve an extension to sometime  
15 in the spring of 2012. That's all I have for this  
16 update.

17 ACTING CHAIRMAN THOMADSEN: Thank you very  
18 much. Any questions by the committee, or from the  
19 committee?

20 MS. COCKERHAM: I have a comment, if there  
21 aren't any. This is something that -- well, since the  
22 proposed rule is out, we wanted to give the ACMUI the  
23 opportunity to discuss this, and since it's not on the  
24 agenda for full discussion at this meeting, and  
25 waiting until the next meeting would be after the

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1 comment period, Debbie and I had talked about having a  
2 teleconference for the ACMUI to discuss this during  
3 this open public comment period.

4 So if everyone -- we don't have to set the  
5 date right now, but during the lunch break I want  
6 everyone to look at their calendars for the week of  
7 December 6th, so it will be the 6th, 7th, 8th or the  
8 13th, 14th, 15th, or 16th. So look at those first two  
9 full weeks in December.

10 And typically our teleconference would be  
11 two hours, and since we have people on both the west  
12 coast and the east coast we wouldn't start before  
13 11:00 a.m., and we wouldn't go any later than 2:00 to  
14 4:00 p.m. So look between 11:00 and 4:00 east coast  
15 time.

16 MR. LEWIS: And the purpose would be for  
17 the committee to decide if they're going to submit a  
18 comment on the record as part of the public comment?

19 MS. COCKERHAM: I think so.

20 ACTING CHAIRMAN THOMADSEN: Sounds like  
21 it.

22 MS. COCKERHAM: And as he was just saying,  
23 you can certainly comment individually. But as you  
24 know, having a good opinion from the ACMUI always  
25 holds weight, so we would appreciate any input that

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1 you could provide. And I'll be sure to send you the  
2 Federal Register notice, and some specific  
3 instructions so you're prepared for that  
4 teleconference.

5 MEMBER GILLEY: Do I have the floor?

6 ACTING CHAIRMAN THOMADSEN: I'm sorry.  
7 Ms. Gilley?

8 MEMBER GILLEY: I would like some help, so  
9 I would like to make a motion that we put a small  
10 subcommittee together to help flesh this out, and they  
11 have something, at least a draft, before December, so  
12 that we'll have a working document to work off of at  
13 that meeting.

14 ACTING CHAIRMAN THOMADSEN: So I'll take  
15 it that that's in the form of a motion. Do we have a  
16 second?

17 MS. COCKERHAM: Actually, the Chair just  
18 creates a subcommittee, and -- yes, actually. So you  
19 can just create a subcommittee, and --

20 ACTING CHAIRMAN THOMADSEN: I think that's  
21 a wonderful idea, and we will make a subcommittee to  
22 provide -- as a steering committee for this, to  
23 provide documents to guide the discussion for the full  
24 committee. And I would like, if you would, to serve  
25 as the chair of that. Can I get about two other --

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1 Dr. Fisher?

2 MEMBER LANGHORST: So I have to be? I  
3 don't want to be, but I have to be.

4 ACTING CHAIRMAN THOMADSEN: And Dr.  
5 Langhorst. Good. Any other volunteers who really  
6 feel moved to act on it? Not that those are the only  
7 people who will have input. The entire committee, I  
8 expect, will have input on this very important topic.  
9 In that case, I guess -- so we don't need a vote?

10 MS. COCKERHAM: No, you don't need to  
11 vote. And what we'll do during the closing  
12 administrative session today, when we're setting up  
13 the April/May meeting, I'll pulse you on these  
14 December dates as well, and we'll lock in a two hour  
15 time slot, an alternate, and just pick a time, pick a  
16 day.

17 ACTING CHAIRMAN THOMADSEN: Very fine.  
18 With that, I will thank you very much for the update.  
19 We're running behind schedule. We were supposed to  
20 have been back from lunch at 12:45, which is a half  
21 hour. That might be a little tight, but we should be  
22 able to make it within forty minutes. So please come  
23 back from lunch, and we'll resume again at five  
24 minutes to one.

25 (Whereupon, the proceedings went off the

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1 record at 12:11 p.m., to resume at 12:55 p.m.)

2 ACTING CHAIRMAN THOMADSEN: Why don't we  
3 get started? We will be moving into Patient Release  
4 Subcommittee report. Dr. Langhorst?

5 MEMBER LANGHORST: Thank you very much.

6 20. PATIENT RELEASE SUBCOMMITTEE REPORT

7 MEMBER LANGHORST: In today's slides, I  
8 wanted to put up front the fabulous group that helped  
9 with this report that we will be discussing this  
10 afternoon: Dr. Fisher, Ms. Gilley, Mr. Mattmuller --  
11 Dr. Suleiman is here someplace -- Dr. Thomadsen, Dr.  
12 Welsh, and Dr. Zanzonico.

13 I thought today I would go ahead and go  
14 through my presentation I gave yesterday at the  
15 Commission briefing in case there are those who maybe  
16 did not see that yesterday. And you'll notice that  
17 I've added a few extra slides at the end of my talk to  
18 kind of guide our discussion of our report with the  
19 Committee and with the NRC staff.

20 And if that is okay with you, Mr.  
21 Chairman, I will get started.

22 ACTING CHAIRMAN THOMADSEN: Please.

23 MEMBER LANGHORST: Okay. Our Subcommittee  
24 was formed in May 2010 to review and analyze issues  
25 associated with patient release, including review of

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1 the current international recommendations.

2 We were also asked to provide statements  
3 on patient release to locations other than private  
4 residence, per-release limit versus annual limit for  
5 other individuals exposed to the released patient, and  
6 to recommend needed changes or improvements.

7 The Subcommittee concluded that dose to  
8 other individuals is safely and cost-effectively  
9 controlled by the current patient release criteria,  
10 supported by scientifically developed, dose-based  
11 release calculation methods and physician assessment  
12 of patient release suitability and with patients and  
13 their caregivers understanding of and adherence to  
14 release instructions on maintaining dose to others as  
15 low as reasonably achievable.

16 Use of the radioactive materials in  
17 medicine is the example I often use when giving public  
18 talks explaining the three fundamental principles for  
19 use of radioactive materials. First, there must be a  
20 justification of use, an overall benefit from that  
21 use. Medical diagnosis and treatment are benefits  
22 that are readily recognized.

23 Second, the principle of maintaining dose  
24 as low as reasonably achievable is applied, taking  
25 into account economic, societal, and medical factors.

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1           And third is the application of  
2 appropriate dose limits. In the case of patients,  
3 there is no dose limit. Instead, we rely on the  
4 physicians' medical judgment of benefit versus risk  
5 for that patient and the application of ALARA  
6 precautions.

7           Based on these three fundamental  
8 principles, the Subcommittee considers the current NRC  
9 patient release criteria appropriately balances public  
10 safety, patients' access to treatment, and cost. We  
11 believe the criteria are consistent with NCRP and ICRP  
12 and IAEA recommendations, both in principle and in  
13 practice; that is, the limit of 5 millisieverts, or  
14 500 millirem, per release for family or caregivers and  
15 the addition of written ALARA instructions if dose to  
16 others is likely to exceed 1 millisievert without  
17 them.

18           These instructions are needed most often  
19 when therapy doses involve I-131 radiopharmaceuticals.  
20 These administrations are typically given once a year  
21 but in some cases may involve two or more treatments  
22 in one year.

23           The Subcommittee considers the ALARA  
24 precautions provided to patients give reasonable  
25 assurance that doses to children, pregnant women, and

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1 general public are below one millisievert, even in the  
2 cases of multiple therapies.

3 And so the current limit on per-release is  
4 more applicable than annual limit. And we recommend  
5 that the focus should be on the reasonable development  
6 and effective communication of these precautions.

7 NRC has been petitioned to return to the  
8 old release criteria known as the 30-millicurie rule.  
9 The release is based on less than 30 millicuries of  
10 activity remaining in the patient or a dose rate of  
11 less than 5 millirem per hour at one meter.

12 The Subcommittee rejects the suggestion.  
13 There is no scientific basis for returning to this old  
14 criteria, which is not based on risk or on patient  
15 actions. The ICRP and IAEA specifically state that  
16 they do not recommend this type of release criterion.  
17 We, therefore, believe return to the 30-millicurie  
18 rule is inappropriate for today's NRC regulations.

19 Instead, the Subcommittee advises NRC to  
20 update and improve guidance for update and improve  
21 guidance for release dose calculations using current  
22 knowledge of biokinetic models and patient dose rate  
23 data. We recommend NRC support the development of  
24 computer-based calculation tools with realistic  
25 assumptions for use by licensees.

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1           While the Subcommittee believes patient  
2 release to a private residence is preferred, we also  
3 recognize that circumstances may warrant different  
4 living or release situations. And we recommend NRC  
5 guidance be developed to address various release  
6 situations.

7           The IAEA states that the success of a  
8 patient release program is critically dependent on the  
9 quality and specificity of the information provided to  
10 the patient, the skill with which it's communicated,  
11 and whether or not the patient believes the  
12 information provided.

13           Again, the Subcommittee believes the NRC  
14 should enhance its support of this aspect of patient  
15 release, such as development of scientifically based  
16 communication tools that are readily available to  
17 physicians and patients in support of research efforts  
18 to gather scientific data to better understand patient  
19 behavior, and effective communication for patient  
20 comprehension, both circumstances that impact release  
21 decisions, instructions, and perceptions.

22           To summarize today's presentation, medical  
23 use of radioactive materials benefits millions of  
24 patient and their families each year. The  
25 Subcommittee advises the current patient release

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1 criteria not be changed. We recommend that NRC focus  
2 on providing appropriate/realistic guidance for  
3 licensees and patients and focus on providing research  
4 support for understanding and communication of the  
5 real world issues impacting patient care and public  
6 safety.

7 So let's skip the next slide or -- sorry.  
8 Go back. Yes. So I thought we would open up  
9 discussion. And I certainly want to encourage the  
10 Subcommittee members to participate in some of our  
11 considerations and so on in developing our proposed  
12 report. And I thought we would start with the three  
13 fundamental principles.

14 You know, this is medical use of  
15 radioactive material is so obviously of benefit. And  
16 I know those of us in the medical realm, we're in this  
17 a lot because of this whole fact. But patients, I  
18 know I ask my audiences, "Would you take your child or  
19 your mother or your brother to a hospital that had  
20 absolutely no X-ray machines?"

21 And they say, "No.

22 We want the best that there is." And so I  
23 always say, "Well, then you understand the benefit of  
24 using radiation."

25 So let's discuss this a little bit. One

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1 of the things that patient release means is that  
2 licensees give the control of this radioactive  
3 material to our patients. And licensees can educate  
4 them and give them the knowledge and assess if they  
5 know the knowledge, but we ultimately release it to  
6 our patients. Those people are not licensed by the  
7 NRC.

8 This is part of what is the justification,  
9 what is ALARA, including economic, societal, and  
10 medical factors. I think one of the things that  
11 emphasizes this point of the importance of medical use  
12 of radioactive material is the section in part 20 that  
13 allows release of radioactive material through the  
14 sanitary sewer from humans. That is judged to be an  
15 acceptable societal condition and allow us to use  
16 radioactive materials.

17 My Subcommittee members have nothing to  
18 add?

19 ACTING CHAIRMAN THOMADSEN: I didn't think  
20 you have any argument in this group.

21 MEMBER LANGHORST: Okay. I guess I would  
22 ask --

23 MEMBER SULEIMAN: I can now or later.

24 MEMBER LANGHORST: Go ahead.

25 MEMBER SULEIMAN: I think the low as

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1 reasonably achievable. The doses we're talking about,  
2 I think we all assumed it, but one milliGray or five  
3 milliGray dose limits are less than natural background  
4 levels or less than the amount of radiation the  
5 average person in the United States receives.

6 So these are not toxic levels. These are  
7 as extremely safe as anything you could get. So I  
8 think these limits are extremely low. And I think,  
9 even in cases where somebody could be exposed to that  
10 level, it is nothing to be concerned about.

11 I think we need to sort of remind people  
12 of that. So we're dealing with a very, very low bar  
13 in the first place.

14 ACTING CHAIRMAN THOMADSEN: Pat? Dr.  
15 Zanzonico?

16 MEMBER ZANZONICO: Well, the first thing I  
17 would like to do is just commend Dr. Langhorst for her  
18 chairing the Subcommittee. She really did an  
19 outstanding job and made an heroic effort to  
20 consolidate a lot of information and generate this  
21 report.

22 And I know I am going to be redundant from  
23 what I said the last time, but if one reads  
24 Congressman Markey's report or his most recent letter,  
25 it simply ignores the peer-reviewed scientific data

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1 that are in the literature. It cites facts and  
2 figures which are no doubt accurate but don't bear on  
3 that hazard or either the lack of hazard of the  
4 exposure of the public, family members, et cetera,  
5 from radionuclide therapy patients who are treated on  
6 an outpatient basis.

7 There have been at least a dozen and now  
8 more peer-reviewed scientific papers where a patient  
9 or family member doses have been measured, including  
10 assay of their thyroid burdens of iodine. So that  
11 directly addresses the issue of contamination of the  
12 home environment and possibly internalization.

13 And the preponderance, really the  
14 unanimity of those data, indicate that there is a  
15 remarkable lack of hazard, a lack of dose, even at the  
16 subhazardous dose limits that we are discussing.

17 Those are the scientific facts. I mean,  
18 one can offer opinions, and one can try and dispute  
19 them. But these are peer reviewed scientific data in  
20 journals, such as Health Physics Journal, Nuclear  
21 Medicine, and so forth.

22 The other point I want to emphasize -- and  
23 it shouldn't need stating, but apparently it does --  
24 detectability of radiation does not mean hazard. The  
25 tremendous benefits of nuclear medicine in the use of

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1 radioactivity and radiation, one of their tremendous  
2 benefits is how sensitively it can be detected.

3 So the fact that a patient or source of  
4 radiation triggers an alarm, alarms that are set at  
5 very low trigger levels to interdict illicit  
6 radioactivity does not mean that the person or the  
7 source triggering that alarm is in any way hazardous.  
8 And it's really disingenuous to imply that triggering  
9 of societal alarms means a hazard. It just does not.

10 The other point I would like to make is  
11 the data on patients who have received both diagnostic  
12 as well as therapeutic amounts of I-131, those data  
13 clearly indicate a lack of hazard. The latest data  
14 indicate that patients who have had no prior NECA  
15 radiation, external beam radiation, and who when  
16 referred for an I-131 procedure, diagnostic procedure,  
17 for therapy exhibited no increased risk of any cancer,  
18 including leukemia, at doses below 100, tissue doses  
19 below 100, Rad. So to apply those, doses of the order  
20 of one Rad -- and we're talking even about doses on  
21 the orders of magnitude below that -- are in any way  
22 hazardous just doesn't jibe with the scientific data.

23 So I'm really at a loss to understand why  
24 there is this tremendous concern about release of  
25 radionuclide therapy patients. Both the radiation

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1 safety data, the clinical data, et cetera, et cetera,  
2 indicate a clear lack of hazard.

3 And the final point I would like to make  
4 is you really are doing these patients a disservice if  
5 you require that they be hospitalized. Hospitals are  
6 not safe places to be, frankly. There are all sorts  
7 of hospital-borne infections and so forth that you are  
8 exposing these patients to. So it is in their medical  
9 benefit to be released. Now, that's not to say that  
10 they shouldn't be given a written, understandable  
11 written and oral, instructions. And I think all  
12 responsible practitioners do so to minimize their  
13 dose.

14 But to say that it's preferable to restore  
15 the 30-millicurie rule really ignores both the  
16 clinical and radiation safety data and, really, the  
17 well-being of patients.

18 ACTING CHAIRMAN THOMADSEN: Thank you very  
19 much.

20 Dr. Fisher?

21 MEMBER FISHER: I have a question for Dr.  
22 Zanzonico, if I might pose it. And it's based on a  
23 paragraph in the Markey letter that was provided to us  
24 today and released yesterday. The paragraph is this,  
25 "NRC's weaker current regulations depend on the

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1 ability of medical professionals to assess the living  
2 conditions of patients and use the results of these  
3 assessments to calculate the likely radiation dose to  
4 those people the patient might come into contact with.  
5 It is unclear whether such a calculation could be  
6 accurately performed for a patient choosing to recover  
7 from treatment of radioactive iodine in a hotel since  
8 it would be impossible to characterize every hotel's  
9 layout or know whether hotel occupants or employees  
10 included the most vulnerable populations, such as  
11 pregnant women or children."

12 Pat, did you do a detailed dose assessment  
13 of the risk to members of the public in a hotel  
14 situation where the hotel resident was a recovering  
15 patient from an iodine-131 procedure? And what were  
16 the results of that calculation?

17 MEMBER ZANZONICO: Well, that was part of  
18 the analysis that we performed as part of the  
19 Subcommittee's work. And, as always in such  
20 calculations, we made conservative assumptions. We  
21 assumed, for example, that a patient would excrete up  
22 to 50 percent of an administration of I-131, 175  
23 millicuries, into bed linens and that a hotel worker  
24 would usually pick them up and hold them for a  
25 half-hour.

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1 And we also made assumptions about doses  
2 to patients, to guests in adjoining rooms, assuming an  
3 11 by 11 square foot room and that the headboards were  
4 back to back, et cetera, et cetera. The largest doses  
5 we found, which were, predictably, to the housekeeping  
6 staff, were less than 100 millirems, so below even the  
7 dose limit for "sensitive" populations.

8 And I should point out that the National  
9 Council on Radiation Protection Measurement, the NCRP,  
10 published report 155, which generated an Excel-based  
11 dose calculation algorithm, which basically all one  
12 needs is to measure the dose from the patient with a  
13 Geiger counter at .3 meters and 1 meter immediately  
14 post-administration and enter those data into the  
15 spreadsheet. And it will generate the durations of  
16 post-release radiation precautions in terms of, for  
17 example, you have to sleep with a sleeping partner, if  
18 that sleeping partner were pregnant or not, how long  
19 to not hold the child, et cetera, et cetera.

20 So the calculational tools are in place.  
21 It doesn't require very sophisticated analysis or very  
22 probing questioning of patients to deduce the  
23 information. So it's a practically doable task. And  
24 the bit of time and effort it takes is well worth the  
25 benefit of outpatient radionuclide therapy, not only

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1 to the patients themselves but to society generally.

2 ACTING CHAIRMAN THOMADSEN: Thank you.

3 MR. LEWIS: I have a question for the  
4 subgroup.

5 ACTING CHAIRMAN THOMADSEN: Yes, Dr.  
6 Lewis, please?

7 MR. LEWIS: In what's been said about  
8 justification, it seems like the focus was only upon  
9 the patient and how, if at all, did the Subcommittee  
10 consider justification in terms of individuals other  
11 than the patient who are getting a small increase of  
12 risk from some exposure.

13 ACTING CHAIRMAN THOMADSEN: If I may  
14 reinterpret the last part of your question to people  
15 other than the patient who are receiving a small  
16 increase in exposure? I don't think we can talk about  
17 a small increase in risk at the moment.

18 MEMBER LANGHORST: But I think the  
19 benefit, I mean, the benefit, is not only to the  
20 patient. Benefit is also to the family. There's  
21 access to, more ready access to, this type of  
22 diagnosis or therapy procedures. It's a lot easier to  
23 go home and rest than it is to have your family member  
24 in the hospital.

25 And does anyone else want to add to that?

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1           ACTING CHAIRMAN THOMADSEN: Yes. I mean,  
2 if you were to hospitalize these people, about 8 to 12  
3 percent, I believe, would pick up an acquired  
4 infection, most likely MRSA, of whom a good number of  
5 those will become carriers. And that certainly is not  
6 of benefit to the family or to society as a whole.

7           MR. LEWIS: And I think those are  
8 arguments that can be made in the report. I think my  
9 point was mainly that the report didn't -- it had a  
10 section about others, but it didn't talk about the  
11 justification in their context. I didn't see that in  
12 there.

13           MEMBER LANGHORST: Okay.

14           ACTING CHAIRMAN THOMADSEN: Point very  
15 well-taken. Thank you.

16           MEMBER LANGHORST: Thank you.

17           I think one of the things that is  
18 different, especially from an RSO point of view, is  
19 the amount of activity that we let a person walk out  
20 with. And that activity does decay away quickly.  
21 There are affected methods to minimize the dose to  
22 those around them and those around them who gain  
23 benefit, mostly their family members. It is a good  
24 balance. And so we think that NRC got it right in the  
25 late '90s in establishing this patient release

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1 criteria.

2 MEMBER ZANZONICO: Can I just --

3 ACTING CHAIRMAN THOMADSEN: Yes, Dr.  
4 Zanzonico?

5 MEMBER ZANZONICO: The other point that I  
6 think is worth noting is that activity-based release  
7 criteria in and of themselves not only are not most  
8 protective of public safety but in some instances may  
9 be less protective. I mean, it can be shown by  
10 calculations and measurements very easily; for  
11 example, that a hyperthyroid patient treated with less  
12 than 30 millicuries, perhaps as few as 10 to 12  
13 millicuries, will deliver a significantly higher dose  
14 to individuals around them than would a thyroid cancer  
15 patient treated with of the order of 100 millicuries  
16 because the hypothyroid patients retained their  
17 activity for a far longer period of time. So the  
18 integration period sort of speaks of the dose around  
19 them will be greater.

20 And so that is the scientific fallacy of  
21 activity-based release criteria, that they're most  
22 proximal to the "radiation risk" or "radiation  
23 hazard." It's dose that's the most proximal physical  
24 quantity.

25 So it just makes sense logically and

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1 scientifically that release should be based on dose,  
2 not on activity, because activity-based release  
3 criteria, for example, the illustration I just gave,  
4 could result in higher doses and more "hazardous  
5 doses" than that which would be intended.

6 ACTING CHAIRMAN THOMADSEN: I think that  
7 is an excellent point that I don't believe is in the  
8 Subcommittee's report either, which we should --

9 MEMBER GUIBERTEAU: I just think I would  
10 like to add to that that these patients with  
11 hyperthyroidism are treated as outpatients. And the  
12 reason for that is because the dose, as you said, can  
13 be higher than that with patients with no thyroid, but  
14 they're still well within the limits that we're  
15 talking about.

16 ACTING CHAIRMAN THOMADSEN: Thank you.

17 Mr. Mattmuller?

18 MEMBER MATTMULLER: Sure. Mister will  
19 work. First, those of you who aren't at this table  
20 probably don't realize the incredible effort that our  
21 Committee put into this. Congratulate her on her  
22 fabulous effort.

23 Two, Pat spent a lot of time in developing  
24 the charts that are in our book on exposures to  
25 housekeepers, laundry workers. And, to emphasize the

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1 point that he just made, he did one chart with green  
2 colors if you have color of 175 millicuries in a  
3 cancer patient versus on the next page 29.9  
4 millicuries per patient staying the exact same  
5 conditions.

6 And if you look at the numbers for dose  
7 to housekeepers, laundry workers, et cetera, they are  
8 not that significantly different. They're very, very  
9 close. But it reflects the biological handling of the  
10 iodine within the two different types of patients, the  
11 cancer patient being excreted much, much more rapidly.

12 ACTING CHAIRMAN THOMADSEN: Thank you.

13 Dr. Suleiman?

14 MEMBER SULEIMAN: Yes. I want to add on  
15 what Pat was saying. First off, I think the NRC got  
16 it right in 1996. And they should be complimented for  
17 making the right decision at that time because to  
18 readdress the old rule is in my opinion a step  
19 backward.

20 You can give 30 millicuries to a small  
21 patient and give the same amount to a much larger  
22 patient or even give them more activity. Dosimetry  
23 also depends on the size of the patient and all the  
24 biokinetics we're talking about.

25 So for somebody to go backward and talk

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1 about activity-based limits I think would actually  
2 expose the public to more hazardous environments.

3 And we discussed this, but I want to  
4 emphasize I think Dr. Wahl mentioned it yesterday. He  
5 implied that the old activity-based limits also I  
6 think impacted on the practice of medicine because  
7 patients were -- I was at an IAEA conference earlier  
8 this year where I had individuals from countries where  
9 they still had the activity-based limits. And they  
10 said patients are denied therapy until a hospital bed  
11 is available so they can spend the night as long as a  
12 year. All right? This is not my imagination. This  
13 is something somebody was pleading with me in terms of  
14 what needs to be done for some of these other  
15 countries.

16 The second thing I heard, when I came  
17 back, I shared this with a colleague at the agency who  
18 is a nuclear medicine technologist. And she said,  
19 "Oh, we used to do that all the time. We would limit  
20 patients to 30 millicuries so they could be released  
21 immediately."

22 Now, I raised the question, "Does that  
23 impact on the effect of the medical treatment of the  
24 patient?" I think the NRC is clearly on the record  
25 that their regulation is not to inhibit the practice

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1 of medicine. And I think the old activity-based  
2 criteria, in fact, may have compromised efficacy in  
3 iodine therapy treatment.

4 So I think to go backward would be the  
5 wrong thing. I think, if nothing else, this is a lot  
6 of solipsious issue again, but the strong consensus  
7 was going on a risk-based approach was far the  
8 smarter, the better approach.

9 ACTING CHAIRMAN THOMADSEN: Okay. Mr.  
10 Lewis?

11 MR. LEWIS: It was a reaction to that.

12 MEMBER WELSH: I do have a follow-up  
13 point.

14 ACTING CHAIRMAN THOMADSEN: Dr. Welsh?

15 MEMBER WELSH: It's a follow-up point to  
16 what Dr. Thomadsen has said and Dr. Suleiman has just  
17 mentioned, that going back to the old policy could be  
18 a step backwards in many ways.

19 Dr. Thomadsen has pointed out that being  
20 in the hospital is dangerous for patients. There is a  
21 risk of nosocomial infections. And if one quantitates  
22 that risk and compares it to the risk to family  
23 members and others from the radiation exposure due to  
24 release of the patient, I think there is no  
25 comparison.

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1           Additionally, Dr. Suleiman has pointed out  
2           that in some ways, this could be a step backwards.  
3           NRC got it right, but it's critically important to  
4           keep in mind a practical point, which is that  
5           insurance may no longer cover hospital stays.

6           As an authorized user, I really don't have  
7           tremendous opposition to keeping my patients in the  
8           hospital, but I have to tell them that "You've got to  
9           pay \$10,000 cash for that if you want to stay in the  
10          hospital for 3 days. Are you willing to do that or  
11          you could go home?"

12          And this is something that seems to be  
13          forgotten and cannot be dismissed because if the  
14          insurance will not cover the patient's stay, that  
15          means that it's incumbent upon the patient to come up  
16          with the many thousands of dollars for the hospital  
17          stay.

18          And since there is no medical or  
19          scientific justification for it, it's hard for a  
20          patient to then say, "Well, I'd be happy to spend  
21          5,000-10,000 dollars for those few days in the  
22          hospital." Nobody does that.

23          And, therefore, we look for ways to  
24          accommodate patients that are realistic. Since their  
25          insurance won't cover it, there are shortcuts like Dr.

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1 Suleiman has mentioned, which are medically  
2 inappropriate, such as giving 30 millicuries and doing  
3 it again and again. That is not the best way of  
4 managing the patient.

5 So, in effect, policy could wind up  
6 hurting patients and interfering with appropriate  
7 medical care because of the realities imposed by the  
8 insurance matters.

9 ACTING CHAIRMAN THOMADSEN: Now Mr. Lewis.

10 MR. LEWIS: It's been mentioned twice.  
11 And I just wanted to mention for the record of the  
12 meeting that we did supply at lunch a letter that the  
13 Chairman of the NRC received yesterday, October 20th,  
14 from Congressman Markey, which compiled the results of  
15 a survey and some outreach to agreement states that  
16 the Congressman's office had done over the last  
17 several months.

18 And because of the relevance of the letter  
19 and its content to this discussion, we have provided  
20 it to all of the Committee members. And I do believe  
21 copies are in the back as well.

22 And I know you have already started to  
23 read it because several people have mentioned it in  
24 their comments. And so we are just entering it for  
25 the record. I realize there is not a lot of time to

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1 digest the findings here, but as we move forward, we  
2 will have to do that together. And there in the  
3 letter, it does specifically ask for this meeting to  
4 consider some of these issues.

5 On a separate matter in reaction to some  
6 of the comments, I am hesitant. We need to be mindful  
7 of the overall risk, you know, the risk of infections  
8 and the radiation-type risks when we justify a  
9 practice.

10 But I think in terms of setting the  
11 radiation safety standard, we need to focus only on  
12 the radiation risk. And I think the NRC regulations  
13 do that. But I think that's a general principle. It  
14 always tends to be speculative about the overall risk  
15 in societal benefits.

16 And when we justify a practice, we can get  
17 into that discussion. But when we start to set what  
18 is the safe level of radiation, we try as much as we  
19 can to limit ourselves to radiation safety principles.

20 MEMBER LANGHORST: Let's go ahead and go  
21 to the next slide because it talks about limits. That  
22 is a good segue, Rob. Thank you.

23 MR. EINBERG: Ashley, can we get the  
24 slides from --

25 MS. COCKERHAM: Yes.

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1           MEMBER LANGHORST: On this slide, I put a  
2 couple of topics: per release versus an annual limit.  
3 I wanted to really also have a discussion of I-131  
4 versus other radiopharmaceuticals and recommendations  
5 of these advisory groups: NCRP, ICRP, IAEA.

6           Discussion yesterday at the Commission  
7 meeting, that was the first time I had been able to  
8 present at a Commission meeting. And it's very hard  
9 not to want to stand up when other panels are talking  
10 and say, "Hey, can I say something about that?"

11           But the aspect of whether NRC meant to  
12 have this be per year or per release and also that it  
13 seems an easy thing just to make it, "Oh, well, let's  
14 just make it per year" I do not believe -- I think the  
15 rest of the Subcommittee would agree that NRC got it  
16 wrong, that they were looking at a per release.

17           I know there was discussion of per  
18 year/per release, but some of the discussion has been,  
19 well, we have felt like patients would only have  
20 therapy. And when they mean therapy, they generally  
21 talk I-131 once a year.

22           If you go to an annual dose limit, we're  
23 not just talking I-131 there. You have to keep track  
24 of all the Tech-99m scans. You have to keep count of  
25 all the stress tests. How do we do that? If one

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1 parent, if the other has that and the father has that  
2 in the same year, how do we keep track of that? And  
3 is it worth that effort?

4 When we talk about dose to others, we  
5 generally are talking I-131. So do we just have a  
6 limit on I-131? That doesn't seem very risk-based.  
7 And, again, is it worth that effort? So I offer those  
8 discussion points.

9 ACTING CHAIRMAN THOMADSEN: Dr. Gilley?  
10 Ms. Gilley?

11 MEMBER GILLEY: Thank you. Not yet.

12 I think regulatorily there are issues with  
13 that. And the issue is how does the licensee know  
14 whether or not the person or family members have had  
15 other therapies that would contribute to an annual  
16 dose?

17 So I'm thinking that the system might be  
18 very difficult to comply with if it becomes annual  
19 limit versus a per-procedure/episode issue.

20 ACTING CHAIRMAN THOMADSEN: Dr. Suleiman?

21 MEMBER SULEIMAN: I clearly dissented  
22 during the discussions on the Subcommittee. From a  
23 regulatory point of view to not have it over a period  
24 of a time makes it meaningless. I mean, that was my  
25 argument.

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1           So we have a regulation, FDA does, that  
2           basically has an annual and a per-administration, but  
3           we have always wondered. The per-administration is  
4           useless because basically the annual constraint limits  
5           the amount and their equipment.

6           I would argue that most patients  
7           undergoing this type of treatment are probably going  
8           to get it once a year. The diagnostic doses are going  
9           to be a fraction of what you could get from therapy.  
10          So that would be pocket change compared to the --  
11          there would be doses you could get from therapy.

12          I would also be concerned if -- let's call  
13          it a caregiver who is treating multiple members in  
14          their home and you're allowing them to get three  
15          milliGray each time. Where does it stop?

16          So how do you protect that individual?  
17          There are mechanisms to address that. But to  
18          basically allow carte blanche no annual limit and  
19          allow the per-administration, you basically ensued  
20          that there is no way to protect that.

21          I could see when a patient is going to get  
22          therapy, you ask, have you been treated, has anybody  
23          in your family been treated, previously, which would  
24          raise a flag? I don't think you'd have to keep track  
25          of each and every member of the public or the family

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1 or whatever. So --

2 MEMBER LANGHORST: Do you make that a  
3 regulation? I mean, how do you make that a  
4 regulation, then?

5 MEMBER SULEIMAN: No. How do you make  
6 sure you comply with that regulation? You know, there  
7 are many ways to approach that.

8 MEMBER LANGHORST: Well, maybe they get,  
9 you know, 490 millirem. And then that diagnostic  
10 stress test puts them over 500. Do we have to go -- I  
11 mean, it seems like an onerous task that in reality  
12 there are very few people who get multiple therapies  
13 in a year. And there are added precautions when a  
14 licensee is treating a therapy patient multiple times  
15 in a year that there are added precautions they can  
16 provide the patient to again minimize dose to their  
17 family members.

18 ACTING CHAIRMAN THOMADSEN: If you do base  
19 limits on a linear no-threshold model, it doesn't  
20 really make any difference if you're going to be  
21 giving the patient the treatments. Whether they're in  
22 different years or whether they're all together, the  
23 risk to the family members is going to be integrated  
24 the same.

25 I mean, it doesn't make any difference in

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1 that respect, just different from an occupational  
2 dose, where you're assuming the people are going to be  
3 working continually at that level as long as they're  
4 working and then quitting.

5 Here you're going to be giving a therapy,  
6 whether it's this year or next year. And the risk,  
7 the radiation risk, to the family is going to be  
8 exactly the same.

9 MEMBER LANGHORST: So are you saying,  
10 then, Dr. Thomadsen, that annual dose is not  
11 appropriate for this?

12 ACTING CHAIRMAN THOMADSEN: It doesn't  
13 make any difference, right.

14 MEMBER ZANZONICO: I think another point,  
15 you know, one of the cardinal principles of radiation  
16 biology is the dose rate effect and the dose  
17 fractionation effect. And I can see it's very  
18 difficult to quantify, especially for stochastic  
19 effects like cancer induction. But it's shown  
20 certainly in animal models that protracting the dose  
21 and if we're ultimately interested in risk-based  
22 evaluations reduces dramatically the carcinogenic  
23 effect of radiation, as I said, by dose fractionation.

24 So even if a patient were treated twice in  
25 the same year, presumably it would at least be months

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1 apart. One could argue that the risks associated with  
2 an exposure several months ago or six months ago has  
3 no bearing on a risk from a current exposure. I mean,  
4 I think there are some data that support that.

5 And when you factor in the practical  
6 difficulty of trying to track all these doses,  
7 diagnostic and otherwise, you know, I think you can  
8 make a case that it could be a per-episode dose limit.

9 I think your point is very well-taken.  
10 It's how does one implement that in practice, an  
11 annualized dose limit in this kind of context.

12 MEMBER LANGHORST: Let's look at it from  
13 another perspective, too, since we're already talking  
14 about release to hotels, patient release to hotels,  
15 where you may have hotel workers who are exposed to  
16 many different people that I know we had discussions  
17 on that and exactly how NRC should handle that or how  
18 guidance should be given to licensees on how to handle  
19 that.

20 MEMBER SULEIMAN: When I went to school,  
21 we were told to make estimates and if the estimates  
22 fall below a certain level, you don't have to worry  
23 about making actual direct measurements.

24 And we're assuming right now that we're  
25 going to have to go and document what each and every

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1 person gets. If you make some reasonable assumptions,  
2 occupancy factors, you know, exposure and whatever,  
3 you're going to find out that the vast majority of  
4 these people are going to fall below a very safe  
5 level. You don't even warrant doing dosimetry.

6 So where do we almost always jump and say  
7 we have to do this for everybody? Most diagnostic  
8 procedures, you're going to find out the doses are  
9 very, very low. You're not going to worry about it.  
10 You're not going to need to keep track of it.

11 What I'm concerned about is if this is, in  
12 fact, a regulatory limit to protect members of the  
13 public and you're dealing with somebody who is going  
14 to be getting close to five millisieverts. What is to  
15 prevent that person from taking care of another  
16 friend?

17 Oh, I just did it for this person. I'll  
18 come over and do that. At that point, if this becomes  
19 a business, she can become or he can become an  
20 occupational workers. And we can change the scenario.

21 But this is a big hole. I think it's  
22 easily addressed, but I think when the commissioner  
23 yesterday made that statement, I mean, I agreed with  
24 him completely. I didn't understand why you had a  
25 dose limit that had no period of time associated with

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1 it.

2 As I've said before, that is my opinion.

3 ACTING CHAIRMAN THOMADSEN: We have a  
4 member of the public to make a statement. Please give  
5 your name.

6 MR. CRANE: Yes. My name is Peter Crane.  
7 And I really didn't intend -- I might have some  
8 thoughts later on. I didn't intend to interrupt, but  
9 I have studied that 1997 rulemaking final statement  
10 pretty closely.

11 And I believe there is a discussion in  
12 there. And the Commission's or the staff's  
13 understanding at the time was that there was no  
14 practical difference between an annual and a  
15 per-episode standard because they thought it was going  
16 to be a once-a-year occurrence and most likely a  
17 once-in-a-lifetime occurrence.

18 ACTING CHAIRMAN THOMADSEN: Thank you very  
19 much.

20 MR. CRANE: Thank you.

21 MEMBER LANGHORST: Let me ask a question  
22 about I-131 versus other isotopes. I mean, as we  
23 discussed, should that be different? And if it is  
24 different, how do we justify that difference?

25 ACTING CHAIRMAN THOMADSEN: Dr. Zanzonico?

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1                   MEMBER ZANZONICO:   Again, I hate keeping  
2   to push NCRP report 155.   I was one of the authors.  
3   But that was a completely general document.   It was  
4   for radionuclide therapy applicable to all  
5   radionuclides or I should say it was independent of  
6   the radionuclides.   And, again, the proximal physical  
7   quantity to risk is absorbed dose or dose equivalent.

8                   And I don't see any scientific basis for  
9   not extending these dose limits and practices to all  
10   radionuclides.   The releasability should be based on a  
11   dose rate measurement from the patient.   And a  
12   properly calibrated survey would give you a reasonably  
13   reliable estimate of whatever X-radiation or gamma  
14   radiation is coming from the patient.   And that should  
15   be the key physical quantity in determining  
16   releasability.   And that should be independent of the  
17   radiation, the patient or the radioactivity, the type  
18   of radioactivity the patient received.

19                   One can argue that there is different  
20   relative biological effectiveness, et cetera, from the  
21   particulate radiations, but that's of no concern  
22   whatsoever in terms of exposure to individuals.   It's  
23   the XM gamma radiation.   So that's reliably evaluated  
24   with a survey meter as well for I-131 as any other  
25   radionuclide.   And the projected dose is the

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1       releasability of the patients can be just as reliably  
2       determined for other radionuclides.

3               ACTING CHAIRMAN THOMADSEN: Thank you.

4               MEMBER LANGHORST: Let's talk a little bit  
5       about our international or our national and  
6       international recommendations. The Subcommittee  
7       looked at NCRP commentary 11, ICRP report number 94,  
8       and IAEA report 63.

9               And the ICRP and IAEA recommend a  
10      per-episode, as they call it, a per-release limit for  
11      the caregivers and family members but recommended a  
12      one millisievert per year for general public and  
13      children and pregnant women.

14              And our Subcommittee feels that the  
15      current release criteria based on the physician's  
16      assessment of the patient's ability to follow  
17      precautions and the precautions given meet those  
18      intended recommendations.

19              ACTING CHAIRMAN THOMADSEN: Okay.

20              MEMBER LANGHORST: Can I have the next  
21      slide?

22              MR. EINBERG: Ashley, can we get the  
23      slides again? A/V, can we get the slides up?

24              MEMBER LANGHORST: Use of realistic  
25      assumptions to assess patient release. We have talked

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1 a little bit about that. Different release scenarios.  
2 Actual data on exposures to others. I know we have  
3 already touched on some of these. I wanted to kind of  
4 open it up for any other comments in regard to that.

5 MEMBER FISHER: What is the next slide?

6 MEMBER LANGHORST: It is number 13. Is  
7 that? No. Sorry. My numbers are different. I'm  
8 sorry. It's "Use of Realistic Assumptions to Assess  
9 Patient Release." Sorry.

10 We feel that, again, the use of  
11 precautions by patients can adequately address  
12 different release scenarios. And we would like to see  
13 the development of more guidance in regard to  
14 different types of release scenarios.

15 ACTING CHAIRMAN THOMADSEN: Dr. Zanzonico?

16 MEMBER ZANZONICO: I think a point worth  
17 making -- and this is a point that Congressman Markey  
18 made in his letter and in other documents -- was that  
19 the current release criteria we're imposing on the  
20 licensee this onerous task of assessing the living  
21 conditions and so forth of the release patients. And  
22 that's true, but one can base the calculations on a  
23 combination of reasonably conservative assumptions  
24 plus the patient's living conditions.

25 In other words, a practitioner doesn't

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1 have to parse the living conditions of a patient that  
2 final, that one can do this in a conservative manner  
3 that would adequately address and integrate an  
4 individual's living conditions into the calculations.

5 So assessing the patient's living  
6 conditions has to be an essential component of  
7 assessing the releasability, but it doesn't have to be  
8 done in such a detailed manner that it obviates the  
9 safety and effectiveness of the approach.

10 ACTING CHAIRMAN THOMADSEN: Thank you.

11 MEMBER LANGHORST: What about need for  
12 additional data on exposure? Dr. Welsh?

13 MEMBER WELSH: I have a few comments on  
14 that point. I think that it is critically important  
15 to eventually get actual data and obtain that data in  
16 a rigorous, scientifically acceptable method.

17 And, just as an aside, I see the survey  
18 that we have been handed out. As much as we have to  
19 rely on such surveys, we have to accept that these are  
20 not necessarily scientifically validated tools. And,  
21 for example, in question 1, the most recent treatment,  
22 please check all that are appropriate.

23 For example, the fourth box there is "Your  
24 insurance company wouldn't authorize payment." It's  
25 unlikely that a patient would actually have acquired

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1 that if the decision has already been made about  
2 whether this is going to be an outpatient or a  
3 procedure. And, therefore, this box would perhaps not  
4 be checked in a good number of individuals. So there  
5 are some caveats with this as an example for the  
6 scientifically maybe not validated tool.

7 Similarly, we heard yesterday that maybe a  
8 sizeable fraction of patients vomit, which to me  
9 personally as an authorized user and someone who has  
10 treated many patients comes as a bit of a surprise  
11 because statistically I should have encountered this  
12 by now.

13 And none of my patients have ever reported  
14 this, despite the fact that I give my patients a bag  
15 and tell them if they are going to vomit, "Please use  
16 this. We would have to do some further investigation  
17 to find out how much dose was absorbed, do we need to  
18 compensate for that."

19 And, therefore, there should be accurate  
20 records on the amount of vomiting that occurs, but we  
21 are dependent upon some scientifically questionable  
22 anecdotal information except that I acknowledge that  
23 my discussion here is, similarly, anecdotal.

24 As far as actual data about exposure, I  
25 think this is critically important. Our assumptions I

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1 believe have been quite realistic. The paper by Dr.  
2 Grigsby published in JAMA in 2000 supports that. The  
3 abstract that was available last week from Japan  
4 supports the idea that our assumptions are correct.  
5 But both of those studies have been, perhaps  
6 appropriately, criticized, one being a different  
7 country, one being a small sample at a single  
8 institution.

9 And, therefore, I encourage the NRC to  
10 consider funding a study that would provide actual  
11 data and answer this question in a scientifically  
12 rigorous fashion so that we get the numbers and  
13 corroborate or refute the Subcommittee's findings.

14 And the way I would propose doing this is  
15 just giving out film badges -- they may or may not be  
16 done easily -- real film badges so the individuals  
17 wouldn't know. And we would have that data in very  
18 short order. And I suspect strongly that we would  
19 find that the actual exposure to caregivers, members  
20 of the public who are interacting with this released  
21 individual, are consistent with our estimates.

22 ACTING CHAIRMAN THOMADSEN: Thank you, Dr.  
23 Welsh.

24 Yes, Dr. Palestro?

25 MEMBER PALESTRO: I have a question. I

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1 agree that it would be useful to obtain actual data,  
2 but the question that comes to my mind is, how can you  
3 reliably obtain actual hard data?

4 Giving someone a film badge doesn't  
5 automatically mean that they're going to use it or if  
6 they take it off in the wrong location, you're going  
7 to get an overestimate of the amount of exposure to be  
8 far greater than anything that might have been  
9 obtained.

10 I think in a sense, when you have this  
11 sort of setting in an individual's home, you wind up  
12 once again with very much of a survey and maybe a  
13 suggestion of what goes on, rather than what really  
14 goes on.

15 In addition to that, I think the  
16 individuals who are most conscientious about complying  
17 with the survey are going to be most conscientious  
18 about complying with the safety rules that we have  
19 given them to follow. And the people who don't comply  
20 with the survey may be less rigorous in their  
21 following of the safety guidelines. I just don't know  
22 how you go about doing it.

23 ACTING CHAIRMAN THOMADSEN: Thank you.

24 Do you want to reply or --

25 MEMBER WELSH: I could reply that those

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1 points are well-taken. And I've given this a fair  
2 amount of thought. But I do have some suggestions or  
3 solutions to those, but perhaps it's not relevant to  
4 this immediate discussion.

5 ACTING CHAIRMAN THOMADSEN: We have  
6 another comment from the public.

7 MR. CRANE: If I may? My name, again, is  
8 Peter Crane. If I could just toss out a few thoughts.  
9 I wanted to say that I thought that Dr. Zanzonico's  
10 NCRP 155 was a very valuable effort to make the  
11 present rule as workable as possible. It's got very  
12 clear sample guidance toward the end of it.

13 I wish that the NRC and licensees were  
14 using guidance like that. As it is, what we have is  
15 guidance based on an SNM/NRC pamphlet from 1987 dating  
16 from the days of the 30-millicurie rule, which is  
17 really quite obsolete. And I think patients and  
18 providers would be much better off if we had guidance  
19 on the order of what is contained in NCRP 155.

20 I wanted to say I thought that part of the  
21 Committee's charge was to look at international  
22 practice. And, although it's said that there is no  
23 basis for an activity standard, we do have the  
24 international basic safety standards, which say 1,100  
25 megabecquerels or 33 millicuries. And it's been there

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1 since 1996.

2 I didn't see any reference to the guidance  
3 of ICRP 94 or 103. All of these reports take a very  
4 conservative concern view of the risk that patients  
5 pose to family members. You do have ICRP 94 talking  
6 about how a kiss that gives one milliliter of saliva,  
7 transfers one milliliter of saliva, from parent to  
8 child can double a child's risk of developing thyroid  
9 cancer. You may disagree with that, but that's in  
10 ICRP 94. And it does seem like a valuable data point.

11 The example of the hotel housekeeper, I am  
12 interested to hear about the dose reconstruction. But  
13 if you're a hotel close to Mayo and Mayo treats I-131  
14 patients on an outpatient basis, that housekeeper may  
15 clean a lot of rooms from a lot of patients. You  
16 won't know because the data isn't there.

17 Now, it was said that I asked for a return  
18 to the 30-millicurie rule. That is true, but I  
19 amended that several months later and said, "I'm not  
20 fixed with that. What I would like to see, that might  
21 be appropriate. It might be inappropriate. There may  
22 be situations in which outpatient treatment is  
23 appropriate."

24 But the 1997 rule was based on the  
25 assumption that international contamination was

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1 negligible, and we know that that is incorrect. And  
2 it seems to me that a lot of water has passed under  
3 the bridge. There is information, for example, about  
4 the hazard posed by simply being in a hotel.

5 I think all of these things are useful for  
6 the mix and that what is needed is a comprehensive  
7 look that isn't intended to reach some particular  
8 pre-ordained point but that says that what makes  
9 sense, what is good for patients, what is good for the  
10 public.

11 The question is, did the NRC get it right?  
12 You probably know that Health Physics in 2007 has an  
13 article by Dr. Marcus and others saying that the NRC's  
14 guidance is way off, that it's three times more  
15 conservative than it should be. They're talking about  
16 release limits of 457 millicuries, I believe.

17 And it's not that long ago that Dr. Marcus  
18 was saying that -- and I quote here -- "1992, the  
19 concept of sending patients home with 400 millicuries  
20 of NAI I-31 was ludicrous. Although I could  
21 theoretically concoct a situation where it could  
22 possibly be justified, there are not too many patients  
23 who would qualify as hermits in isolated areas."

24 Well, I'm not a doctor. She is. And I  
25 think these are all concerns that need to be looked at

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1       anew in a comprehensive way.

2                   Thank you.

3                   ACTING CHAIRMAN THOMADSEN:   Thank you.

4                   MEMBER LANGHORST:   I would mention that we  
5       did use ICRP 94.   That was one of our main things.  
6       You indicated we did not.   So we did look at that.

7                   ACTING CHAIRMAN THOMADSEN:   Did you also  
8       use IAEA?

9                   MEMBER LANGHORST:   IAEA report 63, yes,  
10       and their following letter.   I can't remember exactly  
11       what that was termed but their clarification letter,  
12       too.

13                   ACTING CHAIRMAN THOMADSEN:   Dr. Zanzonico?

14                   MEMBER ZANZONICO:   Also, there is a lot of  
15       data in the peer-reviewed literature where family  
16       members, including children of I-131 therapy patients  
17       who returned home, had thyroid assays done.   And  
18       thyroid radioassays are extraordinarily sensitive for  
19       contamination with radioiodine.   We just had an  
20       episode recently where an animal technologist who was  
21       injecting animals with minuscule amounts of  
22       radioiodine got a positive thyroid assay.   So it's a  
23       very sensitive assay.

24                   And in these published data -- I'm  
25       thinking particularly of the paper by Plato.   I think

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1 it was in the American Journal of Public Health.  
2 There really was no significant thyroidal version of  
3 I-131 above the background among family members. I  
4 think that was limited to perhaps a half a dozen  
5 patients and close to two dozen family members,  
6 including young children.

7 So there are data. I mean, I think we all  
8 agree. I think one thing we all agree on is that more  
9 and more systematic data are badly needed. But the  
10 data that exists not only point to the low doses from  
11 the external exposure, the ambient radiation exposure,  
12 but also from contamination.

13 ACTING CHAIRMAN THOMADSEN: Thank you.

14 MEMBER LANGHORST: As I tell my research  
15 fellows, if the research was easy, it would have  
16 already been done. So just because it's difficult  
17 doesn't mean we should not try it. I mean, we would  
18 encourage NRC to look at what they can do to support  
19 this kind of research effort.

20 Let's talk a little about instructions.  
21 We talked, it was discussed, yesterday about  
22 written/oral instructions, when they're given, at what  
23 level, talk about determination of suitability of  
24 patient to follow these instructions, development of  
25 communication tools.

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1                   ACTING     CHAIRMAN     THOMADSEN:     Dr.  
2     Guiberteau?

3                   MEMBER    GUIBERTEAU:     As   a   matter   of  
4     disclosure, I have an interest in this because I have  
5     treated quite a number of these patients.

6                   I think there's no substitution in terms  
7     of putting things in writing as the assessment of the  
8     patient's treating physician of the ability of the  
9     patient to understand.   And, even then, it can be  
10    difficult.

11                  I also think that explaining to the  
12    patient and their caregivers in one room again is the  
13    primary way that this information should be given.

14                  Following it up with written instructions  
15    I think is a very nice thing because people have  
16    various states of mind, including the caregivers, when  
17    they are listening to what you say.

18                  But I do want to emphasize that just  
19    giving something, no matter what language it is in, in  
20    writing doesn't guarantee anything.   And the  
21    instructions, no matter if they're too detailed, they  
22    get to be burdensome.   And people get overly  
23    concerned, for one.   And, two, they can't remember  
24    what they are supposed to do.   And so there is a  
25    balance there.

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1 I think the ideal is to actually give it  
2 to them in writing to read before. And this is what  
3 we do at our institution. And a number of  
4 institutions have instituted this.

5 You speak with the family and go over it  
6 and make certain that they understand it, then make  
7 your decision as to whether the treatment should be  
8 administered. And before they leave the facility,  
9 this is gone over with them one more time because by  
10 then, you know, they have had their treatment. They  
11 have sat outside. They have had a chance to think  
12 about it. They come back in. And they relate to us.

13 I also think that something has come up  
14 here that is an issue. And that is of the caregivers  
15 who have had exposures to radiation outside of this  
16 episode; that is, whether it was a risk-benefit  
17 treatment for themselves or whether they have cared  
18 for other persons who have received radioactive,  
19 radioisotopic doses.

20 And I think in developing these new  
21 communications that we are talking about, that it  
22 would really be a prudent idea to include these sorts  
23 of pieces of information to communicate to caregivers  
24 or the patient to give to their families of our  
25 concerns that if people are intimately involved in

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1 their care, that they understand that they shouldn't  
2 really be doing this again.

3 And I think this reevaluation has helped  
4 to uncover some of these concerns.

5 ACTING CHAIRMAN THOMADSEN: Mr. Lewis?

6 MR. LEWIS: My question may be a question  
7 for Dr. Guiberteau or others. I am going to put a lot  
8 of words in your mouth, but I think the message I got  
9 out of that was you don't see a lot of value if like a  
10 regulator were to set up a standard set of written  
11 instructions for everyone to use, that you would much  
12 prefer that the physician and the patient have that  
13 discussion and develop tailor-made written  
14 instructions.

15 MEMBER GUIBERTEAU: Well, you know, one  
16 set of instructions doesn't fit everybody. And, in  
17 fact, some of the instructions that we have in writing  
18 and are given in writing will not apply to certain  
19 patients for certain reasons. And there are ways to  
20 get around those instructions to do other things.

21 And so having an intimate understanding of  
22 the patient's living circumstances, the individuals  
23 who live with them or around them, it is exceedingly  
24 important to tailor those.

25 I think a model set of instructions if you

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1 take out the written, it's not a bad things. I know  
2 there are numerous organizations that have it. But I  
3 also think that this involves intimately the practice  
4 of medicine between the doctor and the patient and the  
5 patients' families.

6 And there are times when I feel a need to  
7 modify those instructions, in which case we actually  
8 -- after talking to them, we will take the information  
9 back and change it to modify it to their particular  
10 circumstances.

11 ACTING CHAIRMAN THOMADSEN: Thank you.

12 MEMBER LANGHORST: I think also that the  
13 Subcommittee believed that in the current regulations,  
14 35.75(c), a licensee shall maintain a record of the  
15 basis for authorizing the release of an individual in  
16 accordance with 35.2075(a).

17 So I think the regulations are there.  
18 And, as licensees, we have to document for our  
19 regulatory inspections what is the basis for our  
20 release and meeting the criteria.

21 But it is helpful to have some models out  
22 there for physicians to assist physicians and to  
23 assist patient understanding and that can be out there  
24 for both to see because I know as a major caregiver  
25 for my mom last year, it is very difficult to follow

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1 everything that you have to do in a medical situation  
2 for a family member. And those written instructions  
3 and the talk with the doctors, those are just  
4 essential in any medical situation.

5 ACTING CHAIRMAN THOMADSEN: Another  
6 comment from a member of the public?

7 MR. CRANE: This will be very brief. I  
8 recently saw on the Web instructions from a British  
9 hospital in Bradford. It was a video. It was simple.  
10 It was clear. It was from a nuclear medicine  
11 department explaining what we were doing and why.

12 If the medical community and the NRC could  
13 get together on, for example, a ten-minute video that  
14 would lay it all out in simple terms, it could be  
15 supplemented as need be for a particular person. But  
16 then your documented record could be we showed them  
17 the video, we told them if they had any problems, they  
18 could see it again. And then you'd be in the clear.

19 ACTING CHAIRMAN THOMADSEN: Thank you.

20 Dr. Welsh?

21 MEMBER WELSH: I think Mr. Crane's point  
22 was very well-taken. I agree with Dr. Guiberteau that  
23 for any individual patient, we might need to tailor  
24 the discussion, but I do agree with Mr. Lewis that  
25 perhaps an approved set of written guidelines from an

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1 official regulatory agency would be of some benefit as  
2 a bare minimum, as would a video.

3 I use videos regularly for other  
4 procedures, genetic testing as an example. And it  
5 makes the discussion that I have with the patients far  
6 easier for I-131.

7 I do have the discussion with the  
8 patients. I provide them with written directions.  
9 And recently I have been asking them to sign a form  
10 saying that "I have had this oral conversation with  
11 the physician, I have asked all the questions, I do  
12 understand, and I do agree that I would be able to  
13 comply with the requests for time, distance, hygiene  
14 that will minimize risk to others." And then they  
15 sign that. So I have that as documentation, but I  
16 like the idea of having a video also to further  
17 enhance the education of the patients to make this go  
18 a little bit further.

19 It raises the question, however, that came  
20 to me for the first time yesterday when I was at the  
21 Commission briefing. And it was the first time that I  
22 ever got the feeling that the patients would prefer to  
23 be in the hospital than to be treated as outpatients.

24 And this was the feeling I got from the  
25 Commission briefing, from the representative from FICA

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1 after the discussion about the vomiting, that those  
2 numbers seemed much higher than in my personal  
3 experience. But if those are the real numbers, so be  
4 it.

5 These things were surprising to me. And  
6 it got me to asking, what do my patients really want?  
7 As a physician, as an authorized user, somebody who  
8 cares about these people, I would like to cure them of  
9 their cancer, treat them of their hyperthyroidism, rid  
10 them of the disease, but not make enemies with them.

11 I want them to be happy and continue to  
12 have confidence that I'm trying to do what is  
13 appropriate and best for them. If I'm learning that  
14 my patients are in general opposed to my  
15 recommendation that this be done as an outpatient, I  
16 am surprised.

17 And so I have had conversations with  
18 several patients, but not all of them, about whether  
19 or not inpatient versus outpatient treatment would be  
20 preferred. And every one of them preferred the  
21 outpatient that I did discuss this with.

22 But I am very curious. And I would ask  
23 anybody in the room, members of NRC or members of the  
24 public, if anybody could educate me on what patients  
25 actually want.

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1           And I got up and walked away from the  
2 discussion yesterday with the impression that patients  
3 want to be hospitalized, which to me was a bit of a  
4 shock. So I am just looking for some feedback or  
5 guidance from anybody any time, not necessarily right  
6 now.

7           ACTING     CHAIRMAN     THOMADSEN:         Dr.  
8 Guiberteau?

9           MEMBER GUIBERTEAU: I just want to -- I  
10 understand your question. And I'll be happy to speak  
11 to that in a moment, but I want to get back to the  
12 written instructions because I think this is a very  
13 important issue. And I didn't want to give the  
14 impression that I am opposed to model instructions or  
15 model as long as this is offered as guidance.

16           And, as an exercise, I frequently have my  
17 residents do this and go to the Web on an issue that  
18 is controversial and just put it in and see what is  
19 out there.

20           If you put in I-131 therapy, written  
21 instructions or something similar to that, you will  
22 get a myriad of models, not all of them good.  
23 Whichever one you pick may or may not fit the patient  
24 or the situation that you were talking about. I do  
25 think that if such guidance is provided by the NRC,

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1 that it should be very carefully considered and that  
2 it should be used as an educational tool and not just  
3 a list of things without some significant  
4 understanding of the reasoning behind certain  
5 instructions because there are instructions out there  
6 that basically isolate the patient completely, which  
7 is not necessary. There are instructions out there  
8 that leave out significant factors.

9 But I think the idea here would be to  
10 educate the public, to educate physicians, to educate  
11 not the treating physician but referring physicians,  
12 who sometimes give them different instructions. So, I  
13 mean, I think an educational tool could be very, very  
14 useful.

15 ACTING CHAIRMAN THOMADSEN: Thank you.

16 Dr. Suleiman?

17 MEMBER SULEIMAN: There has been an awful  
18 lot of effort in terms of patient advocacy, in terms  
19 of patient information, communication. And there is  
20 little doubt in my mind that we probably have  
21 excellent examples of communication with patients on  
22 what to do and what not to do.

23 It is obvious to me, however, that there  
24 may be a segment of facilities out there and a segment  
25 of patients that may not be getting the best

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1 communication on what to do.

2 So I think clearly one of the messages I  
3 have gotten is maybe we need to sure up that because  
4 I've said before most of the people at this table are  
5 not from the bottom tier of the professional  
6 societies. They're up to date. You have a very  
7 biased perspective on what goes on out there. There's  
8 a lot of going-on out there that you don't know about  
9 except for maybe the state regulators who get to see  
10 them all.

11 So I think addressing that is probably a  
12 valid point. I think there are probably things that  
13 could be improved in terms of communication. It's not  
14 just other language. We don't do a good job in  
15 English.

16 So I think whether the professional  
17 societies would be better suited to do that, you know,  
18 the different societies, or whether it's something  
19 that falls on the NRC, I'm not sure.

20 I know at FDA, we have groups that are  
21 involved with patient communication for a variety of  
22 issues. But I think that is an area that needs to be  
23 maybe addressed more.

24 ACTING CHAIRMAN THOMADSEN: Thank you.

25 MEMBER LANGHORST: I provided each of you

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1 a copy of this book of radiation answers. And this  
2 book comes from the website also known as  
3 www.radiationanswers. What is it?

4 MEMBER GILLEY: C-o-m.

5 MEMBER LANGHORST: Okay. .com. It's  
6 health physics. It's NEI, DOE, the initial support.  
7 And I want to recognize Kelly Classic and the whole  
8 Health Physics Society for providing me with these.

9 This is another route of a very  
10 scientifically based reasonable I think very useable  
11 website that I send our pregnant workers, our  
12 patients, and so on to.

13 And I do want to mention inside the front  
14 cover are the organizations that helped them as they  
15 developed, first developed, this website and now this  
16 booklet.

17 I talked with Kelly about future additions  
18 to the website and so on. And they would be willing  
19 to work with organizations that are involved with  
20 hotels, organizations that may be impacted with some  
21 of the topics that we have been discussing that could  
22 get some very scientifically based information out  
23 there for public access. So I just wanted to mention  
24 that and thank Kelly again.

25 ACTING CHAIRMAN THOMADSEN: And thank you

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1 for the books --

2 MEMBER LANGHORST: You're very welcome.

3 ACTING CHAIRMAN THOMADSEN: -- on behalf  
4 of the Committee.

5 MEMBER LANGHORST: I know we're kind of at  
6 the end, aren't we?

7 ACTING CHAIRMAN THOMADSEN: Oh, we're  
8 past, but go ahead.

9 MEMBER LANGHORST: Sorry.

10 ACTING CHAIRMAN THOMADSEN: You're getting  
11 near the end, too.

12 MEMBER LANGHORST: There were a couple of  
13 things brought up yesterday at the Commission  
14 briefing. And I thought I would bring those up. We  
15 touched upon some of them already about patient  
16 release or patient waste.

17 One thing was licensee's responsibility in  
18 regard to the death of a released patient, patients  
19 self-discharging, leaving without medical approval.  
20 And I think I was a little shocked about potential of  
21 the state imposing quarantine authority on those types  
22 of patients and documentation of patient housing  
23 arrangements. We touched on that, I think, pretty  
24 well.

25 So I offer this up in case we wanted to --

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1           ACTING CHAIRMAN THOMADSEN:   Some of that  
2 was not in the Subcommittee's charge --

3           MEMBER LANGHORST:   No.

4           ACTING CHAIRMAN THOMADSEN:   -- to deal  
5 with.

6           MEMBER LANGHORST:   I think one of the  
7 issues in regard to patient waste -- and I think Pat  
8 may have touched upon this -- we have detectors that  
9 detect very low amounts of radiation.   And I  
10 understand in some states the regulatory authorities  
11 between radiation and landfill responsibilities don't  
12 work well together.   And there are regulations out  
13 there that even prevent one atom of radioactive  
14 material to be buried, which I'm not sure that they  
15 get any waste that has no radioactive material in it.

16           So that is an issue that is being faced by  
17 many of our RSOs out there and patients or patient  
18 caregivers in having to deal with waste that then  
19 comes back to them.

20           I think that we have talked a lot about  
21 the 30-millicurie rule.   So I think the final slide  
22 that I have here was need for scientific data on  
23 patient behavior and effectiveness of communication.  
24 I think we have talked about that, too.

25           ACTING CHAIRMAN THOMADSEN:   Yes, we have.

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1 Thank you very much.

2 Dr. Welsh? I'm sorry. All these people  
3 on this side of the table just look alike.

4 (Laughter.)

5 MEMBER LANGHORST: Insert foot in mouth.

6 ACTING CHAIRMAN THOMADSEN: Dr. Fisher?

7 MEMBER FISHER: It's important to me from  
8 a patient advocacy and a patient's right standpoint to  
9 just briefly mention two items that I think move  
10 toward violating patient rights and would not be good  
11 for patients. And those two items are found in two of  
12 the four recommendations near the end of the letter to  
13 the Chairman from Congressman Markey.

14 Specifically, they are number 2. They are  
15 both in recommendation number 2. And I just briefly  
16 would like to mention these on the record, that as a  
17 patient rights advocate, I would object to the NRC  
18 taking these seriously.

19 This states -- and I quote -- "The new  
20 regulations should ensure that patients who are  
21 released from the hospital after treatment are  
22 prohibited from recovering from such treatments in  
23 hotels or taking taxis or public transportation in the  
24 days that immediately follow treatment." I would  
25 object to that as a patients' rights advocate.

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1           Secondly, I would object to the final  
2 sentence in number 2, "In cases where the patients  
3 cannot identify a suitable outpatient facility in  
4 which to recover, NRC regulations should mandate  
5 inpatient stays in the hospital." And I think from an  
6 inconvenience and a cost standpoint to the patient,  
7 that this would go against the principles that we  
8 discussed yesterday in the patient rights section.

9           Thanks.

10          ACTING CHAIRMAN THOMADSEN: Thank you.

11          Dr. Guiberteau?

12          MEMBER GUIBERTEAU: I know we're  
13 belaboring this a little bit, but I think this is a  
14 very important issue. I don't want to minimize at all  
15 the comments that have been made from Drs. Welsh,  
16 Fisher, and others on the access of care to patients  
17 in terms of not being able to afford hospitalization,  
18 especially when insurance companies are reluctant to  
19 pay.

20               I understand that safety is not dependent  
21 on the costs of things. However, there are patients I  
22 have had at least one patient in the past before this  
23 rule who actually forewent therapy because they could  
24 not afford the hospitalization, they had no insurance.  
25 Ultimately they found a charity to back therapy, but

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1 access to care I think is one of the things we should  
2 really have in our forethoughts.

3 And, finally, just a thought. As  
4 frustrating as it is, in terms of the public and the  
5 interests of Congressman Markey in public safety, I  
6 mean, that is what we are here for. And I think this  
7 has been an excellent opportunity to let our  
8 Subcommittee here do a very, very superb job of laying  
9 out the issues and stating in terms of the newest data  
10 in terms of the most current regulations by national  
11 and international organizations and in terms of  
12 reassessing and looking again at activity base and  
13 dose risk-based determinations of patient release have  
14 really been an opportunity.

15 I think this letter from October the 20th,  
16 which was yesterday, needs to be given a little bit of  
17 slack because it possibly did not have the benefit of  
18 reading this excellent report from our Subcommittee.

19 Thank you.

20 ACTING CHAIRMAN THOMADSEN: Thank you very  
21 much.

22 I would normally at this point ask for the  
23 Committee to endorse the report. There were a couple  
24 of items that we thought should go back into the  
25 report.

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1           What I would like to do if it is  
2 compatible with the timing for the NRC staff is to ask  
3 the Chair of the Subcommittee to incorporate the  
4 suggestions and comments that came from this, run this  
5 back to the Committee. We will have an electronic  
6 vote and send that back to the NRC staff.

7           I would like to keep that on a fairly  
8 short time schedule. Would the Chair be able within  
9 two weeks to get a copy out to the Subcommittee for  
10 approval and then to the --

11           MEMBER LANGHORST: Yes. I will probably  
12 touch on --

13           ACTING CHAIRMAN THOMADSEN: Yes.

14           MEMBER LANGHORST: -- the folks who have  
15 made those comments to make sure I get them.

16           ACTING CHAIRMAN THOMADSEN: Very good.

17           Is that amenable to the rest of the  
18 Committee?

19           (No response.)

20           ACTING CHAIRMAN THOMADSEN: Hearing no  
21 objections, that is what we will do with the time.

22           MEMBER LANGHORST: Thank you.

23           ACTING CHAIRMAN THOMADSEN: Since the  
24 letter from Congressman Markey has been raised during  
25 this discussion, I would ask that -- there was a

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1 subgroup of the Subcommittee which was addressing  
2 issues raised in the report from Congressman Markey.  
3 And I would ask that that subgroup also include  
4 addressing issues raised by this letter that can be  
5 used in developing a response from the NRC. I believe  
6 that chair was Mr. Mattmuller.

7 MEMBER MATTMULLER: I don't know if I was  
8 a chair, but I was active.

9 ACTING CHAIRMAN THOMADSEN: You were  
10 active. And could I ask you to chair a subpanel again  
11 to extend that work? Very good. And we'll check to  
12 see who is on that panel with you and extend that. If  
13 there are people who do not wish to sit on that panel,  
14 please let me know.

15 Dr. Welsh, are you volunteering or are you  
16 commenting?

17 MEMBER WELSH: No. When you are finished,  
18 I have one final comment.

19 ACTING CHAIRMAN THOMADSEN: Okay. I  
20 believe that we are finished. Dr. Welsh?

21 MEMBER WELSH: I wanted to ask if it might  
22 be possible to add an addendum to this Subcommittee  
23 report, similar to what I did for the Permanent  
24 Implant Subcommittee report, to record any potential  
25 dissenting views or votes that might not have been

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1 unanimous.

2 And the reason I would like to is I am  
3 going to say that I fully support the Subcommittee  
4 report in general. I find no scientific or medically  
5 valid basis for what I am about to say, but I am  
6 ambivalent about releasing patients to hotels.

7 And the reason for my ambivalence is that  
8 as a physician, I always ask for informed consent with  
9 regards to any procedure that I am about to perform.  
10 And I am not sure that the individuals at a hotel are  
11 getting the information; whereas, the individuals who  
12 are the immediate caregivers for the patient are asked  
13 by me to agree verbally that they are willing to have  
14 this patient in their household. And they also  
15 participate in the discussion about the time,  
16 distance, and hygiene. And they are informed.

17 So it's not because of scientific or  
18 medical reasons. It's because of the lack of informed  
19 consent for certain members of the public, such as  
20 hotel workers. And I have a little bit of ambivalence  
21 on this one.

22 ACTING CHAIRMAN THOMADSEN: Thank you very  
23 much, Dr. Welsh. I think that using as a model the  
24 Subcommittee report you had, we should probably have  
25 that be part and parcel of every Subcommittee report

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1 that comes out so that we do record minority opinions  
2 and things like that.

3 That is I assume agreeable with the Chair.

4 MEMBER LANGHORST: Absolutely.

5 ACTING CHAIRMAN THOMADSEN: Thank you.  
6 And thank you for bringing that up.

7 Before we break, I think we should  
8 probably address the December meeting or the  
9 conference call. Have people looked at their  
10 calendars?

11 MS. COCKERHAM: Does anyone have a  
12 preference as far as Monday, Tuesday, Wednesday,  
13 Thursday? Dr. Fisher?

14 MEMBER FISHER: Preference against  
15 Thursdays.

16 MS. COCKERHAM: Okay. So that takes the  
17 9th and the 16th off.

18 MEMBER SUH: The week of the 6th is bad  
19 for me.

20 MS. COCKERHAM: The week of the 6th is bad  
21 for Dr. Suh. Okay. So let's look at the 13th, 14th,  
22 and 15th, Monday, Tuesday, Wednesday. Any preferences  
23 for one day over the other?

24 MEMBER GILLEY: Tuesday or Wednesday.

25 MS. COCKERHAM: Tuesday or Wednesday?

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1 ACTING CHAIRMAN THOMADSEN: Wednesday.

2 MS. COCKERHAM: Wednesday? Okay. Let's  
3 look at Wednesday, the 15th.

4 ACTING CHAIRMAN THOMADSEN: Wednesday, the  
5 15th is good with me.

6 MS. COCKERHAM: Okay. For the West Coast  
7 people, -- I think that's Dr. Fisher -- is 8:00 a.m.  
8 okay for you if we start at 11:00 East Coast time?

9 MEMBER FISHER: Sure.

10 MS. COCKERHAM: Okay.

11 ACTING CHAIRMAN THOMADSEN: 11:00 o'clock?

12 MS. COCKERHAM: 11:00 to 1:00 East Coast  
13 time? Is that a good time for everyone?

14 (No response.)

15 MS. COCKERHAM: All right. And then as an  
16 alternate time, would you rather pick like a 2:00 to  
17 4:00 that is more afternoon type in case there is an  
18 overlap? No?

19 MEMBER SULEIMAN: I have a conflict that  
20 afternoon.

21 MS. COCKERHAM: Okay.

22 MEMBER LANGHORST: The 15th is not the  
23 greatest for me. And I'm sorry. I was trying to get  
24 to my calendar as quickly as possible.

25 MS. COCKERHAM: Okay.

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1           ACTING CHAIRMAN THOMADSEN: Would you want  
2 to look at -- how is Tuesday afternoon?

3           MS. COCKERHAM: Can we look at the 14th?

4           ACTING CHAIRMAN THOMADSEN: On the 14th?  
5 Not good?

6           MS. COCKERHAM: Not good for Dr. Van  
7 Decker and Dr. Zanzonico.

8           MEMBER VAN DECKER: No. Tuesday, the 14th  
9 is fine with me.

10          MS. COCKERHAM: Tuesday is fine with you?

11          ACTING CHAIRMAN THOMADSEN: I thought it  
12 wasn't for Dr. Van Decker.

13          MEMBER SULEIMAN: The 15th works for me.

14          MS. COCKERHAM: Sue, is --

15          ACTING CHAIRMAN THOMADSEN: Is there a  
16 time on the 15th that would work for you?

17          MEMBER FISHER: How about December 13th?

18          MS. COCKERHAM: That's a possibility.

19          MEMBER LANGHORST: December 13th is great  
20 for me.

21          ACTING CHAIRMAN THOMADSEN: That works for  
22 me.

23          MEMBER SULEIMAN: I'm okay with that.

24          MS. COCKERHAM: Does anybody have a  
25 problem with Monday, December 13th?

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1 MEMBER ZANZONICO: At what time?

2 MS. COCKERHAM: We can do 11:00 to 1:00  
3 again. Debbie?

4 MEMBER GILLEY: I will make arrangements.  
5 I'm Chair of the Committee. I've got to.

6 (Laughter.)

7 MEMBER SUH: I won't be available until  
8 after 12:00.

9 MS. COCKERHAM: So Dr. Suh is not  
10 available until after 12:00.

11 MEMBER SUH: No, no. Between 8:00 to  
12 12:00.

13 MS. COCKERHAM: 8:00 to 12:00 you're not  
14 available on the 13th.

15 MEMBER FISHER: How about 12:00 noon,  
16 then?

17 MEMBER GILLEY: What time is --

18 MEMBER SUH: I have a scheduled meeting.  
19 I won't be back until 1:00.

20 ACTING CHAIRMAN THOMADSEN: Eastern?

21 MEMBER SUH: Easter.

22 MS. COCKERHAM: So 1:00 to 3:00 Eastern?  
23 1:00 to 3:00, Monday, December 13th. Anyone that has  
24 a problem with that raise your hand. So that is going  
25 to be our first choice, Monday, December 13th from

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1 1:00 to 3:00.

2 And do you want me to still leave  
3 Wednesday, the 15th from 11:00 to 1:00 as a backup?

4 ACTING CHAIRMAN THOMADSEN: Yes.

5 MS. COCKERHAM: Okay.

6 ACTING CHAIRMAN THOMADSEN: What was the  
7 backup?

8 MS. COCKERHAM: Backup is Wednesday,  
9 December 15th from 11:00 to 1:00 East Coast time.

10 ACTING CHAIRMAN THOMADSEN: While we're  
11 going on break, are we going to be looking for dates  
12 for our spring meeting and people could --

13 MS. COCKERHAM: If you want to look behind  
14 tab -- say it again, Sophie --

15 MS. HOLIDAY: Twenty-three.

16 MS. COCKERHAM: Twenty-three. Look at tab  
17 23. If you will notice, there are lots of days that  
18 have writing on them. If there's writing on it, it  
19 means it's not available for whatever the reason is  
20 that's listed there.

21 There are also some X's based on Dr.  
22 Malmud's schedule.

23 ACTING CHAIRMAN THOMADSEN: On the 22  
24 through 25th, that's the ABR.

25 MS. COCKERHAM: I'll do all of this in the

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1 closed session. We'll go through all of it to pick  
2 dates.

3 ACTING CHAIRMAN THOMADSEN: Very fine.

4 MS. COCKERHAM: But just if you want to  
5 look at this in advance and be ready for it, that's  
6 what this is for.

7 ACTING CHAIRMAN THOMADSEN: Very fine.  
8 Okay. We were scheduled for a break. We will do  
9 that. The break was going to be over at 2:45. Let's  
10 try and be back here as close to that as possible. We  
11 would like to try to start at 10 to 3:00.

12 (Whereupon, the foregoing matter went off  
13 the record at 2:34 p.m. and went back on the record at  
14 2:52 p.m.)

15 21. MEDICAL RELATED EVENTS

16 DR. HOWE: This is essentially the annual  
17 October preliminary talk that gives you the data which  
18 you can go back and look at and talk about in terms of  
19 things that interest you in trends in medical events.

20 And what I have done is once again I have  
21 taken all of the medical events that were reported in  
22 2010. And I got those that are reported because they  
23 may have happened prior to 2010. And if I just went  
24 for those that happened in 2010, they would be lost  
25 forever to the system.

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1           So if I say, "just reported in 2010,"  
2 we're assured of capturing all of the medical events  
3 over a period of time. And we do have a number of  
4 events in here that happened prior to 2010 that were  
5 reported in F.Y. 2010.

6           In my first slide, I like to give kind of  
7 an overview of where we are in the past fiscal year as  
8 to where we were the fiscal year before. We are  
9 tending to have at least one 35.200 medical event.  
10 And, as I get into it, you will see that most of our  
11 35.200 events are really I-131 events, where the  
12 initial treatment was not supposed to be in excess of  
13 30 microcuries of I-131 or was supposed to be I-123.

14           In 300, we fluctuate a little bit on the  
15 therapies. We are down one from where we were last  
16 year. 35.400, it looks like we have a marked  
17 increase. I would venture that part of that marked  
18 increase is that we have one licensee that had about  
19 nine medical events that were reported independently.  
20 So each one of those counted as a separate medical  
21 event, where normally if we have a licensee, we will  
22 have one report with multiple examples. So that may  
23 make the number look a little high in that case.

24           In 600, we're about where we were last  
25 year. This would be HDR, the traditional gamma knife.

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1 And we didn't have any teletherapies issue; in  
2 35.1000, which are the emerging technologies,  
3 basically microspheres, intravascular brachytherapy,  
4 and the Perfexion.

5 Okay. 35.200. This was really a series  
6 of communication errors. The patient went to the  
7 referring physician. The referring physician wanted  
8 an I-123 procedure. The referring physician wrote an  
9 I-123 prescription and gave it to the patient. The  
10 referring physician's office faxed an I-131 whole body  
11 scan request to the hospital.

12 The patient shows up at the hospital, has  
13 the written prescription for I-123. The hospital  
14 says, "No. We're not taking that. We believe we have  
15 the right procedure that was sent over to us. And  
16 you're getting I-131." And, of course, the medical  
17 event is not determined to be a medical event until  
18 they go to image the patient and find out that they  
19 have got a thyroid.

20 We see this all the time. In this one, it  
21 would be probably a little difficult to have prevented  
22 since there really was a document that went over to  
23 the hospital that asked for an I-131 procedure.

24 ACTING CHAIRMAN THOMADSEN: Well, if they  
25 had the procedures to question if somebody questions,

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1 then --

2 DR. HOWE: If they had had the culture to  
3 question when somebody comes in with a piece of paper  
4 that is different, they might have been able to  
5 prevent it.

6 The 35.300 medical events, we had four of  
7 those. Three of them were oral sodium iodide I-131.  
8 One of them was an MIBG. In one case, we had the  
9 wrong patient.

10 With all three of them, they were issues  
11 associated with receiving material in packages. The  
12 first one, the package came. And it had two vials for  
13 two separate patients. The techs were expecting one  
14 patient, one vial. They pulled out a vial. And they  
15 gave that to the patient that came in. And then when  
16 the second patient arrived, all of a sudden, they  
17 realized they had given the wrong dose to the wrong  
18 person.

19 Now, in the other two events, we had  
20 multiple capsules sent by the pharmacy. And in one  
21 case, there were two capsules. They believed that  
22 there was only one capsule because the paperwork said  
23 there was one capsule. They gave the one capsule.  
24 It's not clear why they didn't discover that they had  
25 another capsule in there when they were preparing to

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1 ship it back.

2 So there were procedures that probably  
3 were not done correctly on the shipping. And when it  
4 got back to the pharmacy, they said, "Wait a minute.  
5 There's still a capsule in here." So that's how they  
6 discovered that medical event.

7 The next one was really a series of  
8 comedies, of missteps in places where you could have  
9 caught things. There were three capsules. It was  
10 supposed to be 100 millicuries total given to the  
11 patient. The paperwork said, one capsule, but it said  
12 304 millicuries. So if the facility had been paying  
13 attention to what came in on the paperwork, they would  
14 have immediately questioned, why do they have 300  
15 millicuries for one patient?

16 So there would have been a question. They  
17 would have been "We've got to resolve this." They  
18 expected one capsule. They gave one capsule, even  
19 though the paperwork said that they had an activity  
20 that was nowhere near what they were supposed to be  
21 giving to this patient.

22 And then they sent the package back to the  
23 pharmacy without -- they measured the package before  
24 they sent it out, before they put the empty, the  
25 supposedly empty, vial in it. Okay? So they did not

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1 discover that they had an extra capsule in before they  
2 sent it back to the pharmacy. The pharmacy had to  
3 discover.

4 So we've got two cases where the medical  
5 licensee is sending the materials back to the  
6 pharmacy, is not doing adequate surveys. And they  
7 would have had an opportunity to pick up their errors  
8 quicker.

9 We have a case, one of those cases, where  
10 if they had been paying attention to the paperwork,  
11 they should have picked up and questioned things much  
12 earlier. And they would have found that there were  
13 some other areas associated. It was more than one  
14 capsule. So those are our 300.

15 Our MIBG case is an interesting one. In  
16 this case, the MIBG is given by infusion, infusion  
17 pump. The material at that particular facility is  
18 normally made up in a 50 mL quantity. Instead, it was  
19 made up in a 40. The infusion pump was supposed to  
20 trigger it 45 milliliters. It didn't have 45  
21 milliliters. Oxygen, air bubbles, started showing up  
22 in the tube early on. And so not all of the MIBG was  
23 given because of the air bubbles and the lack of  
24 volume that was needed to infuse it into the patient.

25 In 35.400, we had 25 medical events. As

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1 usual, most of our medical events are in the area of  
2 prostate treatment. We did have three gynecological  
3 ones. We had an unusual one in that we had a medical  
4 event based on a tumor to the anus.

5 If we look at the gynecological ones, the  
6 first one that we had where the applicator came out in  
7 20 minutes. Most of these were poor placement of the  
8 applicator or poor placement of the seeds inside the  
9 applicator.

10 In the first case, the applicator came out  
11 in 20 minutes. And when they went to check on it,  
12 there was probably a 75-rem dose to the thigh. So you  
13 have an overexposure to an unintended area.

14 And on the last one, where they failed to  
15 put the sources in place correctly, one fell out of  
16 the buttocks. And I believe they had some skin  
17 erythema there. And then the other source was found  
18 in the trash.

19 And then we had one applicator that  
20 dislodged about halfway through a procedure. So we  
21 had poor applicator positioning and poor positioning  
22 of seeds within applicators.

23 The one to the anus is not that different  
24 from the type of medical events we see with prostate  
25 brachytherapy. There was a tumor. The tumor was

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1 larger than they had expected. When they went to give  
2 the procedure, they modified the procedure to go for  
3 the extended volume. But they also seemed to make a  
4 mistake on thinking that the ten-centimeter mark was  
5 the five-centimeter mark. So all of the seeds were  
6 placed pretty much outside of the tumor area.

7 For prostate, we had 21 events. That  
8 included 40 patients. This first slide, I've got four  
9 licensees, but it's really five licensees had multiple  
10 medical events.

11 And not in all cases but at least in some  
12 cases, the description indicated that the licensees  
13 were not reviewing their results of the brachytherapy  
14 treatment but had some medical event criteria. When  
15 they started to go back and review them against the  
16 medical criteria, then they discovered that they had  
17 medical events.

18 Most of these cases were underexposures.  
19 There were some overexposures. A number of them were  
20 poor placement of seeds. And we'll see that later.

21 So these multiple events per sites because  
22 many of our prostate brachytherapies are a single  
23 event per licensee. The VA had 11 new medical events  
24 at a location that had ten previous medical events.  
25 And that was part of a follow-up on the previous ten

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1 that were identified.

2 Mercy St. Vincent was discovered to have  
3 one medical event. They asked them to go back because  
4 they had poor seed placement. They asked them to go  
5 back and look at their preceding ones. And they ended  
6 up identifying to date eight, seven more. And then  
7 there's an affiliate facility that also had a medical  
8 event based on, I believe, poor seed placement.

9 Marshfield Clinic identified nine in one  
10 report. And then they found another one later. And I  
11 believe they were one of those that had not been  
12 evaluating their administrations.

13 Jewish Hospital had two events on one  
14 report. It appears that they identified one medical  
15 event based on 30-day images. And the other event  
16 they identified within a day. So I think they  
17 realized they had a couple of problems there.

18 And Bristol Hospital had two events also.  
19 So it was kind of unusual for us to have this many  
20 licensees with multiple patients involved in the  
21 reporting.

22 Now, what were the root causes or how did  
23 these split out? We had 20 that were underdoses to  
24 the prostate, but there really was no reason given.  
25 Perhaps if I go back in and look more closely at the

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1 reports from the regulator, I might find more reasons  
2 provided.

3 Three were overdoses to the prostate with  
4 no reason given. Two were multiple seeds eliminated  
5 from the bladder or the urethra. One of those cases,  
6 the seeds came out. But then they went and they  
7 looked. And most of the other seeds were not near the  
8 prostate at all. So it was a lot of misplacement of  
9 seeds.

10 We had one where the tumor volume  
11 increased due to edema. We had 11 that gave  
12 descriptions of either suboptimal dose distribution,  
13 poor placement, poor visualization in ultrasound,  
14 incorrect identification of the prostate.

15 One of the incorrect identifications of  
16 the prostate was a real-time prostate brachytherapy,  
17 where they were using ultrasound. When they finished,  
18 they believed they had a very good procedure. Then  
19 they because the ultrasound indicated they got all the  
20 seeds in the right geometric formation, then when they  
21 went and did an X-ray of it, they discovered that the  
22 cloud was correct. HS wasn't near the prostate. It  
23 was down near the penile bulb.

24 And we also had three overdoses to other  
25 organs. And one of the organs listed was the urethra.

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1 35.600 events. We had 12. Most of them  
2 were HDRs. I always look at the HDRs. And if I have  
3 MammoSite medical events, I split those out from the  
4 HDRs because they are generally subordinate with  
5 specific issues with the MammoSite versus issues with  
6 the HDR device itself.

7 We had three medical events with a  
8 traditional gamma knife.

9 Okay. For the HDR, we had a software  
10 failure. There really wasn't a good description of  
11 that, but there was a software failure that affected  
12 the dose to the patient.

13 We had two human errors. One, the  
14 technician/technologist, he had an auto-radiograph and  
15 gave ten times the dose to the patient.

16 We had the treatment site was entered  
17 incorrectly. So they treated the wrong treatment  
18 site.

19 We had three issues where the catheter  
20 either a tight bend or there may have been catheter  
21 movement between placement and insertion of the seeds.  
22 And then we had one in which no reason was given, but  
23 in this particular case -- and you can see that this  
24 is kind of unusual for us. We had HDRs where we had  
25 more patients than reporting locations. So once of

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1 the locations reported five patients were involved.  
2 They didn't give a reason, but there seemed to be  
3 uniform problem that they were underdosing the  
4 patients to 50 percent. But they didn't provide us  
5 with the reason yet.

6 For the MammoSite, we had two cases, but  
7 we had three patients. And in one case, there was a  
8 source positioning error. And the source positioning  
9 error was not identified until one of the patients was  
10 almost all the way through and the other patient was  
11 all the way through the treatments. And once they  
12 identified that the source was not where it was  
13 supposed to be and it was outside of the breast  
14 tissue.

15 In some cases, they had erythema. And in  
16 one case, the patient came in with erythema. The  
17 physician didn't recognize it until they came back for  
18 another treatment.

19 In the second one, there was an incorrect  
20 distance measurement that was blamed on a damaged  
21 source positioning simulator tube that wasn't  
22 discovered until they did another procedure and  
23 realized that the distance was not correct.

24 For the gamma knife, we had three cases.  
25 If you look at the first one and the last one, you'll

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1 see that there were problems with immobilizing the  
2 patient.

3 In the first one, instead of using the  
4 four-pin, one of the pins was going to interfere with  
5 the frame. So they took it out. We know from past  
6 experience that three pins are not as secure as four.  
7 And so the frame moved and the treatment was given two  
8 centimeters from where it was supposed to be.

9 In the third one, the patient felt pain.  
10 They stopped the procedure. And they looked and found  
11 that the head immobilization bracket wasn't fully  
12 secured. So we had two problems with pinning down the  
13 head.

14 The middle one, this was another human  
15 error when they gave half of their fractions and they  
16 put in the wrong coordinates. They used the x  
17 coordinate as the number for both the x coordinate and  
18 the z coordinate. And they didn't discover it until  
19 they went to give the next five and they had to change  
20 the coordinates on the position.

21 So now let's look at 35.1000, our emerging  
22 technologies. We have got seven medical events there.  
23 We have got our first medical events for the  
24 Perfexion. We always seem to have medical events for  
25 the microspheres. And we've got another medical event

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1 for the intravascular brachytherapy. And we don't  
2 have that many intravascular brachytherapy procedures  
3 done, but we have had a number of those recently.

4 For the Perfexion, first, they intended to  
5 give it to the left side. They gave it to the right  
6 side. And they did discover the error fairly soon  
7 into the procedure, but they gave it to the wrong  
8 site.

9 In the second example, there was a failed  
10 computer disk error. And the machine froze. And the  
11 treatment was automatically stopped. And the patient  
12 came out.

13 And we have got another software error  
14 problem with the gamma knife. I think it is with the  
15 Perfexion. It probably came right after this one and,  
16 therefore, went into this fiscal year. And so we're  
17 going to be following up on that.

18 For the TheraSpheres, I always break them  
19 down into the TheraSpheres versus the SirSpheres  
20 because there is a slight difference in them.

21 We had a case where they were supposed to  
22 be delivering two doses: one to the left lobe, one to  
23 the right lobe. They put the material into the left  
24 lobe. They wanted to put it into the left lobe. They  
25 got it into the right lobe. So the got the wrong

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1 amount of material into the wrong lobe. And it ended  
2 up that that particular part was supposed to get a  
3 dose, but it wasn't supposed to get that dose. And so  
4 there was a medical event based on the amount that it  
5 should have gotten, the amount it did get.

6 We also had one where they believe they  
7 gave a good treatment. They were pretty confident.  
8 And then they went back afterwards and they found out  
9 that they had 25 percent of the material was still in  
10 the waste container. They thought that the  
11 possibility that they had an iodine contrast media in  
12 the catheter may have contributed to impeding or  
13 causing the aggregate to go into the waste, don't  
14 know.

15 For SirSpheres, we had leakage around the  
16 stopper. They confirmed the leakage but thought maybe  
17 it was the licensee's problem. We have had problems  
18 in the past with the septa for these vials with  
19 SirSpheres and TheraSpheres. We are receiving a lot  
20 of radiation during shipment and, therefore, being  
21 less elastic than it should be.

22 I don't know if that's part of the issue  
23 here so that when you put the needle in, instead of  
24 having a nice, tight elastic hold on the needle, you  
25 put the needle in and it tends to -- it's more brittle

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1 than it's supposed to be.

2 Another one thought they -- and this is  
3 SirSpheres -- had given the complete dose without any  
4 complications. And they were surprised to find out  
5 that they still had four millicuries of the dose in  
6 the tubing in the vial. So one cannot always tell by  
7 visualization as to whether all the material went in.

8 For intravascular brachytherapy, they gave  
9 the wrong treatment time. They were supposed to have  
10 the authorized user review the written directive and  
11 sign it before they gave the treatment. They wrong  
12 treatment time was in this directive. And the  
13 authorized user did not review it. They did not sign  
14 it before they gave it.

15 So there is a possibility that if they  
16 were following their procedures and if they were  
17 following the requirements to have the authorized user  
18 date and sign prior to administration, that they could  
19 have caught this error in confusion in treatment times  
20 before the administration.

21 So that is kind of a quick overview of the  
22 medical events that we saw reported in F.Y. 2010. Any  
23 questions? Yes, Sue?

24 MEMBER LANGHORST: When you say that there  
25 is no reason given, does that mean no reason given in

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1 the NMED database? Is that what you mean?

2 DR. HOWE: No reason given in the  
3 paragraph summary.

4 MEMBER LANGHORST: Okay.

5 DR. HOWE: That doesn't mean that there  
6 won't be documents that are provided later in the  
7 reference documents that might provide more of a  
8 reason. And that's a little more research.

9 In some cases, we don't get very much  
10 information from the final inspection report or  
11 licensee's report.

12 ACTING CHAIRMAN THOMADSEN: Dr. Welsh?

13 MEMBER WELSH: One question about the  
14 TheraSphere case that you described that had more than  
15 anticipated activity in the tubing.

16 ACTING CHAIRMAN THOMADSEN: The  
17 TheraSpheres?

18 MEMBER WELSH: Was it SirSphere or  
19 TheraSpheres?

20 ACTING CHAIRMAN THOMADSEN: TheraSpheres.

21 MEMBER WELSH: If it was in the tubing and  
22 the hypothesis is that the viscosity of the iodine  
23 contrast material contributed --

24 ACTING CHAIRMAN THOMADSEN: That's the  
25 other one. I'm sorry. That was TheraSpheres I was

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1 thinking about. It was the other.

2 MEMBER WELSH: But it's the same concept  
3 here. I guess my question is, how was that assayed?  
4 And the reason I ask is because it is well-known that  
5 iodine contrast material would interact with the beta  
6 particulates from the Y-90 to increase the  
7 bremsstrahlung and potentially give you an increased  
8 reading, depending on how you're assaying this. I'm  
9 just wondering if there's any information on that.

10 So could there possibly have been less  
11 activity than was calculated because of the  
12 artifactual increased bremsstrahlung?

13 DR. HOWE: Let's see. They believed about  
14 a third, slightly less than a third of the activity  
15 was in the waste or they had expected to give 1.74  
16 gigabecquerels. They had .58 gigabecquerels left in  
17 the waste. My arithmetic at the front of the room is  
18 maybe about a third.

19 I don't know. Bremsstrahlung could have  
20 been a factor in giving a higher reading. They  
21 believe that the viscosity was such that it impeded or  
22 trapped the microspheres. We could go back and --

23 MEMBER WELSH: Dr. Zanzonico may have an  
24 answer.

25 MEMBER ZANZONICO: It's unlikely that

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1 bremsstrahlung at that energy and in iodine -- that  
2 there would be that much bremsstrahlung produced to  
3 account for that large a discrepancy in the activity.

4 I mean, if there's even ten percent of the  
5 data energy dissipated, bremsstrahlung is probably an  
6 overestimate. I would be surprised. I don't think it  
7 would account for that discrepancy.

8 ACTING CHAIRMAN THOMADSEN: Comments?

9 Yes, Dr. Suh?

10 MEMBER SUH: So do we have any records of  
11 how many cases are done in each of these events? I  
12 mean, do you have like a denominator at all or is that  
13 possible?

14 DR. HOWE: In some cases, there is an  
15 inspection report but not in all cases. And in some  
16 cases, if you go into an inspection report, there may  
17 be a general statement about how many patients are  
18 treated per year. But that's generally not the  
19 information that we have.

20 We might be able to get it for a site but  
21 certainly not across the board. And Ashley has her  
22 hand raised.

23 ACTING CHAIRMAN THOMADSEN: Ms. Cockerham?

24 MS. COCKERHAM: This was a request from  
25 the last meeting, when Dr. Welsh was the Chair of the

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1 Subcommittee. That was a recommendation that came out  
2 of the Subcommittee. They actually suggested specific  
3 reports that the NRC should look at purchasing.

4 We did purchase those reports. I have one  
5 of the two. One is for nuclear medicine. The other  
6 one is for radiation oncology. I have the nuclear  
7 medicine one. So I will provide that to the  
8 Subcommittee. As they start to do the fiscal year  
9 2010 analysis, they will have numbers for that  
10 denominator.

11 And then the radiation oncology report  
12 will be available later this month. So you will have  
13 hopefully what you need to get a better grasp of that  
14 denominator.

15 MEMBER WELSH: So, then, Dr. Suh asks a  
16 great question. And I'm glad that we have an answer  
17 for it.

18 MS. COCKERHAM: Yes.

19 DR. HOWE: I also think that his question  
20 may have been facility-specific. In other words, if  
21 you had so many events, how many procedures did you do  
22 at that facility? Was that your question or --

23 MEMBER SUH: That was going to be the  
24 second part of my question. It is like as a gamma  
25 knife user, I might see some of these issues that

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1 occurred. I see the more experience you have, some of  
2 these events can be -- if you have proper standard  
3 operating procedures. And it is very robotic in terms  
4 of how you do things. Time out. Is it the right  
5 patient? Is it the right site?

6 We move the right fraction. If not, you  
7 press the stop button. Because I would suspect some  
8 of these sites may be -- they may only do a very few  
9 number of cases a year, which may lead to a pretty  
10 high percentage of these.

11 DR. HOWE: And that kind of information  
12 probably with the gamma knife could be obtained per  
13 site location if you went into -- if it was available  
14 in an inspection report.

15 ACTING CHAIRMAN THOMADSEN: Dr. Fisher?

16 MEMBER FISHER: Dr. Howe, in some of the  
17 cases, were there patient-specific factors? The  
18 definition of medical event does not apply. That's  
19 why I wondered on slide number 6, you've got an  
20 applicator on the cesium-137 source dislodging after  
21 vigorous coughing after being in place 20 hours. The  
22 prescription was for 45 hours of exposure.

23 That leads me to ask a question, why isn't  
24 the source simply put back in place to continue the  
25 treatment? And why is this classified as a medical

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1 event?

2 DR. HOWE: It wasn't patient intervention.  
3 We consider normal patient bodily function not to be  
4 intervention. And the licensee does not indicate why  
5 they didn't put the sources back in to continue the  
6 treatment.

7 So because they stopped the treatment,  
8 which may have been the best thing for that patient,  
9 so we are not getting into an evaluation, they stopped  
10 the treatment and did not continue. So it's a medical  
11 event because they did not give the amount of activity  
12 they originally intended to give. They may have made  
13 the very best decision not to continue, but it wasn't  
14 patient intervention.

15 And the other case where the applicator  
16 came out in 20 minutes, that patient was heavily  
17 sedated. So the implication is that they took steps  
18 to make sure that the applicator would be in, but it  
19 still came out in 20 minutes. So that patient  
20 intervention --

21 MEMBER FISHER: Yes. I understand the  
22 first one. It was the second one I had a question  
23 about.

24 DR. HOWE: Yes.

25 MEMBER FISHER: Thanks.

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1                   ACTING CHAIRMAN THOMADSEN: Other comments  
2 from the Committee?

3                   (No response.)

4                   ACTING CHAIRMAN THOMADSEN: Well, thank  
5 you very much, Dr. Howe. And I believe Ms. Gilley is  
6 the chair of the -- I'm sorry. Dr. Welsh, you're the  
7 chair of the subcommittee that is going to be looking  
8 at that, medical events?

9                   MEMBER WELSH: Yes.

10                  ACTING CHAIRMAN THOMADSEN: Right, he  
11 says. Okay. Good. We look forward to a report from  
12 your subcommittee at the next meeting.

13                  DR. HOWE: And keep in mind if you believe  
14 you need additional information for any one of these  
15 cases, there are references there. And by the time  
16 you get ready to do your study, there may be  
17 additional references. And we can ask for those  
18 references to be pulled so that there may be  
19 additional information available to you other than  
20 just a paragraph.

21                  ACTING CHAIRMAN THOMADSEN: Very fine.  
22 Thank you again.

23                  DR. HOWE: Yes, sir.

24                  ACTING CHAIRMAN THOMADSEN: Okay. We are  
25 moving on to item number 22, "Further Considerations

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1 on Options to Revise Radiation Protection Regulations  
2 and Guidance." And filling in for Dr. Cool will be  
3 Morgan Butler. Welcome.

4 DR. BUTLER: Thank you.

5 So your eyes are not playing tricks on  
6 you. I am Morgan Butler. I work with Dr. Cool. And  
7 he was unable to join us this afternoon because he had  
8 a family medical issue that he had to attend to.

9 And so he sends his regrets. And he  
10 wanted me to make sure to let you know that he looks  
11 forward to talking to you in the future and meeting  
12 with you in the future on this issue.

13 ACTING CHAIRMAN THOMADSEN: And I'm sure  
14 we send him our concern.

15 DR. BUTLER: Thank you.

16 22. FURTHER CONSIDERATIONS ON OPTIONS TO REVISE  
17 RADIATION PROTECTION REGULATIONS AND GUIDANCE

18 DR. BUTLER: As on the slide, the topic of  
19 today is "Options to Revise NRC's Radiation Protection  
20 Regulations and Guidance."

21 Dr. Cool addressed ACMUI maybe two or  
22 three times before in the past on this subject. And  
23 he gave you an extensive overview of the background  
24 and some of the issues that we are looking at. And I  
25 am here to further some of those considerations, just

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1 to give you basically a status report, a little  
2 background, and some of the things that we are doing  
3 now.

4 In December of 2007, the International  
5 Commission on Radiological Protection, or the ICRP, as  
6 we call it, completed revised recommendations. And in  
7 these recommendations, there are a number of technical  
8 considerations. And the NRC staff was tasked with  
9 evaluating these considerations and to let the  
10 Commission know whether we should move forward with  
11 aligning our radiation protection standards with the  
12 recommendations contained in ICRP publication 103,  
13 which was published in '07.

14 And so the Commission asked us to move  
15 forward with that effort. They did take the  
16 staff-recommended option or they sent us in the  
17 direction of the staff-recommended option to engage in  
18 stakeholder conversations to solicit feedback and also  
19 to begin to develop a technical basis.

20 So over the last year from that point, we  
21 did a series of interactions with other federal  
22 agencies, with state agencies or with the states, with  
23 a number of professional communities, including  
24 professional societies, including SNM and AAPM. We  
25 interacted some with ASTRO; of course, with our state

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1 organizations, OAS and CRCPD. And we just went out  
2 and explained that the NRC had received the  
3 recommendations and that we are considering making  
4 changes to our recommendations.

5 So that what we consider a phase one  
6 interaction. We have moved on to our phase two  
7 interactions, which are more detailed interactions.  
8 So in April at the CRCPD meeting, we did a mini  
9 facilitated roundtable workshop. And we solicited  
10 detailed comments at that time.

11 We are moving forward with this type of  
12 facilitated workshop on a larger level. And the first  
13 workshop is in the Washington, D.C. area. Actually,  
14 it's this coming Monday. And it's at the Crowne Plaza  
15 in Silver Spring. And it will last from October 25th  
16 through 27th.

17 The first two days are dedicated to just  
18 general uses of radioactive material. And the third  
19 day is dedicated to the power reactor industry.

20 For the Los Angeles, California meeting  
21 from November 3rd through 4th, that meeting is more  
22 focused on the medical sector. And when I say,  
23 "focused," I mean at the roundtable, there will be a  
24 greater percentage of panelists from the medical  
25 sector.

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1 And in the Houston, Texas meeting, which  
2 is November 8th through 9th, we will have the  
3 industrial application sector, so industrial  
4 radiographers; well-loggers; and, indeed, some of the  
5 industrial uses and applications of people  
6 representing the industrial uses and application of  
7 radioactive material. So we are moving forward.

8 We didn't specifically ask ACMUI to send  
9 any representatives, although because some of your  
10 representatives are also members of professional  
11 societies, they may or may not be seated at one of our  
12 roundtables, we wanted to use this forum through the  
13 ACMUI meetings, where the full Committee is gathered,  
14 to solicit your detailed comments.

15 And when I say "detailed comments," I am  
16 going to get into the technical issues and options a  
17 little later. And I am not asking necessarily for  
18 that information today, but we are looking to you to  
19 give us information on how many individuals may be  
20 affected by a certain practice or in one year. Will  
21 that year be the same as the next year and along those  
22 lines?

23 So we are doing all of this in hopes of  
24 and are planning to submit a paper to the Commission  
25 with rulemaking options in Fall of 2011. We're

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1 targeting October of 2011.

2 In that Commission paper, we will look at  
3 both 10 CFR part 20 and 10 CFR part 50, appendix I,  
4 more related to the reactor sector, in tandem  
5 together.

6 And, actually, I just want to point out  
7 that we're not in rulemaking. So it may be a little  
8 different than some of our rulemaking processes.  
9 We're not at the proposed rule stage. We're before  
10 that stage. So the Commission hasn't given us  
11 direction yet on whether they want us to move forward  
12 with the formal rulemaking or not.

13 And in the package, you say advanced  
14 notice of proposed rulemaking to move forward, but in  
15 this case, we thought that if we put forward through  
16 the Commission direction, that would give us a little  
17 more flexibilities, where we wouldn't have to stick to  
18 a script. We could select from staff, identify  
19 issues, and then allow people to also introduce more  
20 issues as we move forward. And so it's open.

21 If some of the issues that we are covering  
22 are not complete or they don't cover some areas of  
23 concern, then you do have that opportunity to submit  
24 additional topics.

25 What have we heard thus far? Well, we

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1 have heard a wide range of views on the major topics,  
2 which I will go over in a few minutes. There is  
3 general support for increasing alignment with  
4 international recommendations. And there is general  
5 agreement that the scientific information should be  
6 updated.

7 This comes back for the most part from  
8 what I hear when I talk with people the fact that our  
9 recommendations are based on science from the '70s,  
10 1979, for occupational dose limits and other things.  
11 And for some parts of the regulations, when we made  
12 the last update, if a regulation was based on explicit  
13 dose criteria, we didn't do that update either.

14 So some people think that we should update  
15 it to just catch up with the state of the science.  
16 And then there are also trans-boundary issues with  
17 people who may work in the United States and work  
18 abroad. And they may have two different exposure  
19 limits that they are bound to.

20 So the issues, there are four issues that  
21 are on the table as of now. There is the effective  
22 dose and numerical values, the occupational dose  
23 limits, the dose limits for special populations, and  
24 as low as reasonably achievable planning. And that  
25 goes into dose constraints, which I will touch on in a

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1 future slide.

2 In terms of the effective dose, in general  
3 people have been supportive of this update. There are  
4 questions about the application of the current rule.  
5 The current rule allows the use of effective dose for  
6 external exposures. And that was a change that was  
7 made a few years ago. So we are still spreading word  
8 that that change has been made.

9 And there is a recognition that the  
10 schedule is an extended schedule for the dose  
11 conversion factors and the weighting factors. Some of  
12 the widely used dose conversion factors are  
13 radiological weighting factors -- well, some of the  
14 most widely used radionuclides weighting factors will  
15 be available in December or November of 2011. But for  
16 some of the transuranics, it won't be until 2014.

17 In terms of the occupational dose limit,  
18 the United States is currently the only country that  
19 has a 50 millisievert per year dose limit. And so  
20 there has been concern there by some groups, but  
21 certain groups of licensees continue to have  
22 individuals above 20 millisieverts per year. We have  
23 heard that from the medical community in terms of  
24 interventionalists and maybe radiopharmacies and  
25 others. And we have heard those comments also at the

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1 Commission briefing yesterday.

2 Many want us to stay at the 50  
3 millisieverts per year limit. And there is also  
4 another suggestion that is on the table, that we keep  
5 the higher dose limit but increase the ALARA  
6 requirements with mandatory constraints. And so I  
7 will go a little bit more into detail with that. And  
8 that will go over maybe some flexibilities.

9 The next topic is the limits for special  
10 populations. The occupational dose limit for the  
11 embryo/fetus of a declared pregnant person in the  
12 United States is currently five millisieverts per  
13 year. And internationally, the recommendation is for  
14 one milliSievert per year.

15 There is really mixed feedback on the way  
16 we should proceed forward. The United States, the  
17 five millisieverts per year is over the entire  
18 gestation period; whereas, internationally, the  
19 recommendation which has been adopted by most other  
20 countries is one milliSievert from the point of  
21 declaration. So there is a little difference there.

22 And we really do have a lack of data on  
23 this issue. We are working with our Office of Nuclear  
24 Regulatory Research to attempt to reach out to states  
25 to solicit certain information that they may or may

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1 not have on occupational dose exposures, but in  
2 general the NRC has limited data on this issue.

3 There is also an issue of the public  
4 exposure. In 20.1301, there are special provisions  
5 for a greater dose than the public dose limit of one  
6 millisievert per year. And this is for  
7 embryos/fetuses, children, pregnant females, and  
8 nursing mothers.

9 And I just want to point out for the part  
10 20 regulations, it excludes things such as background  
11 radiation, the public dose limit, excludes the  
12 calculation of the public dose limit, excludes the  
13 background radiation and also medical exposures and  
14 anything that's covered under 35.75. So things are  
15 excluded from this 100 millirem per year because there  
16 are levels set in other places of the regulation.

17 And so we are not looking to change any of  
18 those other organizations. We are just looking to see  
19 if maybe the language should change or maybe we should  
20 send some of these issues to our guidance to match how  
21 it was presented in other parts of our regulatory  
22 framework.

23 In terms of ALARA planning, these are the  
24 constraints that I mentioned before. Constraints are  
25 a tool in the optimization of protection. The ICRP

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1 has been very strong in stating over and over again  
2 that constraints are not to be used as limits.  
3 They're mostly -- well, they're actually supposed to  
4 be used as planning values.

5 So if a licensee were to exceed a certain  
6 planning value, they just would have to report to the  
7 NRC how they would bring their numbers back into  
8 compliance in the future. And there this may be  
9 looked upon as having a severe impact to licensees or  
10 maybe not so severe. We really don't know yet. And  
11 that is why we are looking for details on whether this  
12 will have an impact.

13 And there is the alternative, just keeping  
14 the dose limit the way it is, at 50 millisieverts per  
15 year, and then imposing a numerical value as a  
16 constraint; so, for example, imposing the 2 mSv, 20  
17 millisieverts per year, as the constraint.

18 And, as I stated, you would just have to  
19 have a special approval to go over the constraint,  
20 which from situation to situation, there may be  
21 certain instances where if you receive pre-approval to  
22 exceed that constraint, it won't be a major regulatory  
23 issue. But constraints are still not to be looked at  
24 as limits.

25 And, with that, I will ask for any

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1 questions that you may have. This is just part of our  
2 own ongoing outreach. So if you have any general  
3 comments that you want to make and if you have any  
4 detailed comments that you want to make?

5 I do want to be clear that we have heard  
6 from you at different points and that we have heard  
7 some of the comments on some of the impact to some of  
8 your licensees, but we are still looking for that  
9 information but with details also. That would be  
10 great if you can.

11 ACTING CHAIRMAN THOMADSEN: Thank you very  
12 much.

13 Dr. Van Decker?

14 MEMBER VAN DECKER: I have three short  
15 comments and then I have a question. Comment number  
16 one is when you are talking about reaching out to  
17 medical stakeholders. I heard you mention a whole  
18 bunch of societies, but the three I didn't hear you  
19 mention were ACC; SCAI, which is the interventional  
20 cardiology group; and then ASNC, which is the nuclear  
21 cardiology group. All three of those should be  
22 involved. There is more than enough information here  
23 that they need to have a feel for.

24 Number two comment, which I guess is half  
25 a question, is you talk about going to rulemaking

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1 within the next couple of years. I think we heard  
2 yesterday that you can't do two rules simultaneously  
3 between prostate brachytherapy and the 28 things on  
4 the table.

5 You can't do two, but you can do three or  
6 they're in a separate section of the organization.  
7 And, therefore, as long as they're in a separate  
8 section, it's okay. So now we'll just change where  
9 the other one sits to a third section. Then we can do  
10 all three or -- okay. Just trying.

11 MR. LEWIS: Are you talking about a new  
12 part for prostate?

13 MEMBER VAN DECKER: I'd call it 1,000 from  
14 my viewpoint but okay.

15 The third comment I would just make is I  
16 would just point out I guess since I was a little  
17 surprised he took this approach yesterday that Dr.  
18 Wahl was a stakeholder at the commissioners' meeting  
19 so that SNM supported the keeping occupational dose  
20 limits at 50 millisieverts per year. I suspect there  
21 are many other societies that would kind of have that  
22 feel, but if you want to bring back the Don Cool  
23 effect that that was mentioned yesterday. It got lost  
24 in the midst of a lot of other stuff that would be  
25 useful.

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1 DR. BUTLER: Yes. We took note of his  
2 comments because we heard his comment from -- I forget  
3 who it was -- last year on this Board that sometimes  
4 the more talented interventionalists are the ones who  
5 receive the highest doses.

6 MEMBER VAN DECKER: That is definitely  
7 true in cardiology.

8 DR. BUTLER: And those people may be  
9 isolated geographically. So if you're given a limit  
10 that's lower than 50 millisieverts, then it may be  
11 hard to maintain that dose limit from year to year.

12 MEMBER VAN DECKER: I think my point is if  
13 SNM is also supporting it, you are going to find a  
14 variety of the societies nervous about changing the  
15 legal limits. It's going to be more than just one or  
16 two.

17 I guess my last thing is just a question  
18 because I am a concrete kind of person. Can you give  
19 me a medical example of a constraint that is not a  
20 legal limit? I mean, give me a hard example. What do  
21 you mean when you say that? How is that going to  
22 work?

23 DR. BUTLER: Yes. So if an individual, an  
24 occupational worker, were to -- if we maintained the  
25 50-millisievert dose limit but we said that an

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1 occupational worker was under a 20-millisievert  
2 constraint per year, if that individual were to exceed  
3 that exposure, then a notice would have to be sent to  
4 the NRC or some type of communication explaining why  
5 the 20-millisievert constraint was exceeded. And then  
6 we would also need an explanation on how you would  
7 lower your future exposures.

8 Now, nothing has been concrete, now. That  
9 is just one way that the staff is looking at it. Now,  
10 even internationally there is still debate on exactly  
11 how to implement a dose constraint. So we're flexible  
12 at this point. And it's important that you hear.

13 MEMBER VAN DECKER: So I'll give you some  
14 feedback on that concept as a concrete concept from a  
15 guy who, unfortunately, chaired a university radiation  
16 safety committee for many too many years, where  
17 obviously internal ALARA constraints are the common  
18 way we do things, right?

19 There's a ten percent ALARA, and there's a  
20 30 percent ALARA, road bump 1, a road bump 2. You  
21 send out a letter. You wait for it to come back, try  
22 to figure out whether someone is put in the circular  
23 barrel, you know, and trying to absolutely because to  
24 the worker who has been in this environment forever,  
25 there will be some obviously influx of new workers,

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1 the old workers have been there forever, and they know  
2 that they're going to get, you know, percentage hits  
3 on a legal limit, then, you know, they'll respond once  
4 in a while or if it's way out of line, they may  
5 respond. But they may not -- you know, an  
6 interventional fluoro is probably going to break  
7 constraints frequently. And so they see the things  
8 all the time. And so they say, well, it's no  
9 different than what it usually is.

10 So it either has teeth or it doesn't have  
11 teeth. You know, if it's way out of whack, then you  
12 get an internal and external reporting system. What  
13 does that really mean when you're reporting externally  
14 versus internally?

15 MR. LEWIS: So a constraint is kind of --  
16 the example is a good one. And I think that's a  
17 constraint. All a constraint is it's mainly the  
18 state-of-the-art thinking in health physics. And ICRP  
19 and IAEA, it's a trigger. A level at which licensee  
20 or user action is warranted, a regulatory action isn't  
21 necessarily warranted. So it's another way to think  
22 about it.

23 MEMBER GILLEY: You already have them with  
24 investigational levels.

25 MR. LEWIS: Yes.

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1 MEMBER GILLEY: It's a constraint.

2 DR. BUTLER: I don't think we're thinking  
3 in the enforcement bit. In fact, we don't fail for  
4 this. There won't be an enforcement action. You just  
5 have to let us know how you would optimize the  
6 exposures.

7 ACTING CHAIRMAN THOMADSEN: Dr. Suleiman?

8 MEMBER SULEIMAN: I consider it  
9 investigation level. ICRP 26 actually introduced that  
10 concept back in 1977. It's basically a level where if  
11 you go over, you say, "What's going on here?"

12 It's intended not to penalize, but the  
13 issue that I get concerned with all the time is how do  
14 you know how high or low. I think the flippant  
15 attitude that you're bothered by these regulatory  
16 limits I think leads to poor radiation safety  
17 practice.

18 And I think people who take it seriously  
19 and get an idea of what the doses are they're being  
20 exposed to will factor that into their behavior. So I  
21 firmly believe that professionals will, in fact,  
22 practice ALARA if they take it seriously.

23 And I think the constraint is a concession  
24 to the practicing community that we don't want to come  
25 down on you. And the limit can have adverse effects,

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1 you know, if it forces you to stop a procedure or  
2 whatever.

3 So it gets back to what we discussed in  
4 previous meetings, safety culture. How do you instill  
5 people to take this seriously? So I think the  
6 constraints or investigational level or whatever I  
7 think should be taken seriously.

8 And if people administer them and follow  
9 up on them in a serious environment, I think they will  
10 have the effect they are. But if they just took that  
11 as another regulatory limit to sort of avoid by doing  
12 all sorts of tricks, it defeats the purpose.

13 ACTING CHAIRMAN THOMADSEN: Thank you.

14 Dr. Fisher?

15 MEMBER FISHER: It seems that I recall  
16 that Dr. Don Cool mentioned on a previous presentation  
17 that the current limits, the current 10 CFR 20, has  
18 served us quite well for over 20 years and has  
19 adequately protected workers, --

20 DR. BUTLER: Yes.

21 MEMBER FISHER: -- done a pretty good job.  
22 There are some relatively minor updates in biokinetic  
23 modeling for certain radionuclides.

24 The question I have concerns what is the  
25 NRC philosophy on the following issue, that if a

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1 worker is limited to 20 millisieverts per year and to  
2 do a certain job, like protein labeling, with  
3 iodine-131, it requires work.

4 Let's say it requires work that will  
5 expose the worker to 60 millisieverts per year. So  
6 they have to go through three workers. Is it better  
7 for one worker to have 60 millisieverts per year or 3  
8 workers to have 20 millisieverts per year, which is  
9 the same, same total exposure?

10 MR. LEWIS: So we regulate on that  
11 individual's dose and we rarely look at collective  
12 dose in our regulatory approach. And along those  
13 lines, I did want to make a point because a lot of  
14 people comment on the two rem versus five rem. And we  
15 hear a lot from users of the regulations that we can't  
16 do it, you know, or it would cost too much to go down  
17 to two rem.

18 And that's not the question we need to  
19 answer. The question we need to answer is, are five  
20 rem safe or are two rem safe? What is adequate  
21 safety, not what is feasible?

22 So I think when we have, what licensee had  
23 on the feasibility question is very legitimate  
24 feedback in NRC needs, but in terms of how the  
25 Committee looks at it is what is safe.

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1 And we hear a lot of comments already that  
2 five rem is safe, continue to use it. You know, that  
3 is a valid view. And then we've got to answer why as  
4 part of this rulemaking effort.

5 DR. BUTLER: Yes.

6 ACTING CHAIRMAN THOMADSEN: Dr. Langhorst?

7 MEMBER LANGHORST: I wanted to make a  
8 comment on Rob's comment there. I agree I believe  
9 five rem is safe and with ALARA. And essentially we  
10 get to what the recommendation is, which is o more  
11 than five rem in one year and no more than ten rem in  
12 five years.

13 And NRC does not regulate on a five-year  
14 basis. They regulate on an annual basis. And so I  
15 think our current system fits that model. And there  
16 is additional cost to NRC in having to follow up  
17 constraints and so on.

18 So you're looking at a lot more either  
19 approvals, which I guess the approval we would have to  
20 get approval from NRC. Is that the approval or not  
21 that a license would self-approve?

22 DR. BUTLER: Approval from NRC.

23 MEMBER LANGHORST: And so how long would  
24 that take? And would that stop the individual from  
25 doing any work and --

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1 DR. BUTLER: Well, actually, let me  
2 back-pedal on that.

3 MEMBER LANGHORST: Okay.

4 DR. BUTLER: We haven't decided yet.

5 MEMBER LANGHORST: Right, right.

6 DR. BUTLER: So we don't have a -- we  
7 would want to hear comments from you.

8 MEMBER LANGHORST: Okay.

9 DR. BUTLER: If the general consensus is  
10 if we have to wait for the NRC and it's going to take  
11 too long, then we would consider imposing to the  
12 licensee to do a self-regulation.

13 MEMBER LANGHORST: So I think the NRC has  
14 to look at what resources will it take to implement  
15 these kinds of regulations, too. And so I think you  
16 have to look at little bit at the cost also and is it  
17 a worthwhile cost or does it take away from other  
18 aspects of radiation safety that you all asked to  
19 regulate.

20 So I agree with that that is not your main  
21 concern as far as cost to licensees, but it does  
22 impose additional requirements on here.

23 DR. BUTLER: And we are looking at the  
24 cost through our Office of Nuclear Regulatory  
25 Research. They have a few grants and contracts with

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1 some international agencies to gather international  
2 data because other countries are already using an  
3 average of 20 millisieverts per year.

4 And, actually, if we set our dose limit,  
5 it may end up being an average in the same way. We  
6 may have a rolling average or just a set average. We  
7 haven't figured that out either.

8 MEMBER LANGHORST: Okay.

9 DR. BUTLER: It may not be a straight 20  
10 millisieverts per year, which is the case for most  
11 countries there, 20 millisieverts over a 5-year, 10  
12 over --

13 MEMBER LANGHORST: Got you.

14 MR. LEWIS: And I wasn't trying to say  
15 that we don't need to consider cost.

16 DR. BUTLER: Right.

17 MR. LEWIS: It's just the argument we  
18 shouldn't go from five to two because it will cost too  
19 much --

20 DR. BUTLER: Right.

21 MR. LEWIS: -- is another question for the  
22 regulatory agencies. What is the proper level of  
23 safety? What is adequate safety? That is the  
24 overriding question.

25 MEMBER LANGHORST: Can I just --

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1 ACTING CHAIRMAN THOMADSEN: A follow-up?

2 MEMBER LANGHORST: One more question. I  
3 really commend you and Dr. Cool on the outreach. For  
4 the Los Angeles meeting, if you're not able to attend,  
5 how can you participate?

6 DR. BUTLER: Well, we are going to have  
7 transcripts of each meeting. So there will be a  
8 written version of all the comments. And for the D.C.  
9 meeting, which is next week, we are going to have a  
10 webinar.

11 MEMBER LANGHORST: It would be very nice  
12 to have something that the medical community can  
13 participate in when we can't all get to Los Angeles.

14 DR. BUTLER: Well, there will be  
15 participants from the medical community at each of the  
16 meetings.

17 MEMBER LANGHORST: Right.

18 DR. BUTLER: The focus is just different  
19 at each of the meetings. So next week we will have an  
20 interventionalist. We are go have a technologist.

21 MEMBER LANGHORST: Okay.

22 DR. BUTLER: We are going to have a  
23 radiopharmacist. So for the Washington, D.C. meeting,  
24 it is just more general. We are going to have  
25 representatives for all of the uses of radioactive

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1 materials versus having a greater percentage of the  
2 medical --

3 MEMBER LANGHORST: Okay.

4 ACTING CHAIRMAN THOMADSEN: Dr. Zanzonico?

5 MEMBER ZANZONICO: I just wanted to  
6 address this issue of safety, which obviously is the  
7 most important issue in terms of considering reduction  
8 in the occupational dose limit.

9 And you mentioned bringing this, you know,  
10 making consistent with the up-to-date science. But my  
11 understanding is that the dose limits are based on  
12 some acceptable risk of mortality, the so-called safe  
13 industry, which I believe is 1 in 10,000.

14 And the BEIR V and then the BEIR VII  
15 mortality risk factors for cancer were basically .5  
16 percent per sievert. And that has a change from BEIR  
17 V to BEIR VII. And that's consistent I think with the  
18 1 in 10,000 mortality.

19 So I don't quite understand the rationale,  
20 therefore, of reducing the risk unless the criteria  
21 for "safe" industry is being reduced to some like 1 in  
22 2,500. Otherwise it then just seems arbitrary.

23 MR. LEWIS: I think the basis is if you  
24 look at -- I am no ICRP expert, but if you look at  
25 between ICRP 60 and ICRP 103, they had epidemiological

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1 data that said the risk was higher than they  
2 originally expected. And that's why they lowered from  
3 five to two.

4 DR. BUTLER: On the fake industry model to  
5 more of a --

6 MEMBER ZANZONICO: So it is no longer the  
7 same occupation --

8 DR. BUTLER: Not exclusively.

9 MR. LEWIS: Well, yes. They wouldn't say  
10 it's not safe to be five but that they would probably  
11 conclude that if you get five rem each and every  
12 single year through your entire career, you would have  
13 a risk of latent cancer that is higher than they would  
14 recommend.

15 MEMBER ZANZONICO: Are they basing that on  
16 the Cardis data or --

17 MR. LEWIS: Hiroshima survivors was the  
18 big one.

19 MEMBER ZANZONICO: Well, again, the NCRP  
20 -- there are obviously authoritative groups that  
21 disagree with that, you know, like the NCRP, the BEIR  
22 Committee, et cetera, et cetera. I mean, I think it's  
23 nice to be consistent with the international  
24 standards, but, you know, I don't feel constrained by  
25 that. I mean, they also have waste holding tanks,

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1 which I want to follow up with patients in hospitals.  
2 That is beside the point.

3 The other point I wanted to make was just  
4 to point out there was a recent publication, PLOS,  
5 from the Canadian study on pregnant women who  
6 underwent diagnostic radiology studies. I believe it  
7 was a case-controlled study. So it was statistically  
8 a very robust study showing the absence of any  
9 stochastic effects in children exposed to a variety of  
10 diagnostic radiology procedures in pregnancy.

11 So I think that that study should really  
12 be factored into the thinking when considering  
13 increasing the dose limits to the pregnant workers.

14 ACTING CHAIRMAN THOMADSEN: Dr. Welsh?

15 MEMBER WELSH: A quick follow-up point in  
16 regard to what Dr. Zanzonico said. If some of the  
17 recommendations are still being based on  
18 extrapolations from the atomic bombs in World War II,  
19 it should perhaps be tempered or balanced by some of  
20 the long-term epidemiological data from Caralla,  
21 Ramsar, and other high-radiation environments that  
22 suggest otherwise.

23 The point is that just because one  
24 authoritative agency has a particular perspective, I  
25 think we have discussed in our Subcommittee that NRC

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1 is just as reputable and authoritative as any of the  
2 organizations. And perhaps they should be taking our  
3 lead, rather than vice versa.

4 And I think that our Subcommittee has  
5 considered this extensively in the patient release  
6 matter that was considered a little bit too much of a  
7 side issue to focus heavily on. It wasn't considered  
8 in a good deal of depth. And our conclusion is that  
9 maybe ICRP should follow NRC, rather than vice versa.

10 MEMBER ZANZONICO: Can I make one final  
11 point? You know, even the prevailing BFI/NCRP risk  
12 factors are age and gender average. And the greatest  
13 number of cancers by far among the A bomb survivors  
14 were those under 18 years old who would not be exposed  
15 in an occupational setting. So even the five rem per  
16 year limit has a built-in safety factor in that  
17 respect.

18 ACTING CHAIRMAN THOMADSEN: Dr. Suleiman?

19 MEMBER SULEIMAN: This is my perception.  
20 I thought NCRP 160 showed that the vast majority of  
21 occupational doses are low, like easily under 20  
22 milligray.

23 MR. LEWIS: Except for one industry.

24 MEMBER SULEIMAN: Okay. That's fine.  
25 That's fine. I mean, I think one of the comments

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1 somebody made earlier was that generally speaking  
2 we're okay, but it could require some tweaking.

3 The other thing, in respect to other  
4 standards groups, we sometimes have to respect all  
5 these other experts who pull together because they  
6 have different levels of expertise. And sometimes if  
7 you don't accept some sort of standard, you're going  
8 to have a multitude of different numbers and limits,  
9 which just adds to the confusion.

10 But I think the BEIR reports, I think the  
11 ICRPs, I sort of buy into most of the concepts. My  
12 biggest personal issue is the general public. You  
13 know, when you get down to natural background levels  
14 in terms of limits, it bothers me. And I have noticed  
15 that some of my colleagues at work, it raises  
16 questions.

17 I think maybe for the occupational, we may  
18 be in the right ballpark. You may need some tweaking  
19 or whatever.

20 MR. LEWIS: Yes. These are all the  
21 discussions we have to have. I misspoke earlier. I  
22 said going from ICRP 160 to 103 is that delta. It's  
23 actually from ICRP 26 and 30 to ICRP 60 is that delta.  
24 So our current regs are based on ICRP 26 and ICRP 30.  
25 Some of them are based on ICRP 2, not part 20. And

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1 those come from BEIR IV.

2 DR. BUTLER: IV.

3 MR. LEWIS: So ICRP has considered BEIR V  
4 and BEIR VI now in what they have developed.

5 DR. BUTLER: And NCRP report 7, as you  
6 mentioned, showed that 600 or so workers exceeded the  
7 5-rem per year dose limit.

8 MR. LEWIS: So the hurdle we have if we  
9 want to continue to vary -- well, they have considered  
10 dose reports. We are the ones who haven't. So I'm  
11 kind of --

12 MEMBER ZANZONICO: It still seems to --  
13 again, it sounds like the criterion is different.  
14 It's no longer the 1 in 10,000 mortality per safe  
15 occupation because the prevailing Asian gender match  
16 risk factor in both BEIR V and BEIR VII is consistent  
17 with 5 rem per year.

18 MEMBER GILLEY: Will there still be  
19 opportunity for planned special exposure? Is that  
20 still on the table or would that be something that  
21 would be removed from the occupational standards?

22 DR. BUTLER: Well, for planned special  
23 exposure, that's for the NRC dose limit? If it's a  
24 constraint, then these are planning values that you  
25 have. So it adds a cushion there.

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1           For the planned special exposure, I think  
2           that for the NRC in general, I think maybe one company  
3           applied for a planned special exposure and they didn't  
4           go through with it at the end because there are so  
5           many requirements that are needed, you have to finish  
6           --

7           MEMBER GILLEY:     But those requirements  
8           could change for planned special exposure if --

9           MR. LEWIS:    If we open up all of part 20,  
10          why not?   I mean, that's a regulation that had a good  
11          purpose but has never really been practical.

12          MEMBER GILLEY:   Right, right.   Well, I  
13          think the constraints on planned special exposure are  
14          probably why it has never been used institutionally by  
15          anyone.

16          DR. BUTLER:   And the constraints may be a  
17          way -- I think I heard this at the briefing yesterday.  
18          And it may be a little stretch, but I think  
19          constraints may be a way to self-report to have that  
20          buffer where you're not -- and I think this was the --  
21          the airline industry does it where there are no  
22          enforcement issues.  If people report within a certain  
23          amount of time.  And the constraint may work actually  
24          in the same way.

25          ACTING CHAIRMAN THOMADSEN:   Any other

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1 comments from the Committee?

2 (No response.)

3 ACTING CHAIRMAN THOMADSEN: Well, thank  
4 you for the update.

5 DR. BUTLER: Thank you.

6 ACTING CHAIRMAN THOMADSEN: We next have  
7 the discussion of the safety culture policy statement.

8 23. SAFETY CULTURE POLICY STATEMENT

9 MS. THOMPSON: My name is Katherine  
10 Thompson. I am a safety culture specialist in the  
11 Office of Enforcement. Thank you for giving us this  
12 opportunity slide into your agenda and talk about our  
13 safety culture policy statement for a few minutes.

14 The purpose of this briefing is for  
15 information purposes and to provide you with an  
16 opportunity to discuss the revised draft policy  
17 statement.

18 Looking forward, we will be providing  
19 ACMUI and the ACRS with a copy of the draft final  
20 policy statement and hope to get an endorsement and/or  
21 comments before we provide it to the Commission for  
22 their consideration. And that's in January.

23 We want to spend most of the time today  
24 talking about the policy statement itself. So I am  
25 just going to go over just some highlights of where we

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1 have been for the last few months to give you a  
2 reminder of some of the highlights.

3 In November 2009, we issued the draft  
4 safety culture policy statement. And in February  
5 2010, we had a workshop. At this workshop, we had 16  
6 stakeholders from various affiliations. And they  
7 reached alignment on common definitions and traits of  
8 the safety culture, policy safety culture.

9 In May, Debbie Gilley introduced a  
10 discussion of the draft policy statement and talked a  
11 little bit about the outcomes of the February  
12 workshop. I wasn't at that meeting, but I was told.

13 So then, between May and June, we reviewed  
14 the public comments that we received on the 2009  
15 policy statement. We received 66 comments. And we  
16 evaluated them. Most of the comments focused on three  
17 issues: how the policy statement would be  
18 implemented, how security was going to be addressed,  
19 and on why this was being a policy and not a  
20 regulation.

21 During the summer, we also participated in  
22 many outreach activities, including American  
23 Association of Physicists in Medicine, Health Physics  
24 Society, and so on. So the staff really did go out to  
25 various conferences and meetings and talked about the

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1 safety culture policy statement.

2 We also had three public meetings over the  
3 summer into September. Two of these were conference  
4 calls with panelists and stakeholders. And the third  
5 was a public meeting in Las Vegas. And that was just  
6 recently, September 28th, where we talked about the  
7 policy statement again and invited comments and  
8 discussion.

9 So that brings us up to the September  
10 17th, 2010 draft policy statement. And that is where  
11 we really want to talk the most and tell you what is  
12 in it and for your comments and thoughts.

13 MS. SCHWARTZ: Hi. My name is Maria  
14 Schwartz. And I also work in the Office of  
15 Enforcement. And I work with Kitty. What she didn't  
16 mention was at the July 28th meeting, prior to that --  
17 excuse me -- the September 28th meeting. We had  
18 published a revised draft statement of policy. And  
19 that is what we used as a basis for our discussions at  
20 that meeting.

21 What I would like to talk to you  
22 predominantly today is about why we made the changes  
23 that we made to the draft to get to the revised draft  
24 so that we can go forward with a final statement of  
25 policy to the Commission.

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1           We, as Kitty mentioned, have done a lot of  
2 research. And that is because this is a policy  
3 statement, not a regulation. We feel it is extremely  
4 important to engage our stakeholders. We want to  
5 impress upon stockholders the importance the  
6 Commission places on this, but we also want to hear  
7 from the stakeholders to find out what role they  
8 believe safety culture plays in their activities so  
9 that we can develop a policy statement that really  
10 works over a really diverse group of entities.

11           So, as Kitty mentioned, three of the  
12 greatest comments that were expressed on the draft  
13 policy statement were concerns about the way security  
14 was addressed. The other was about how implementation  
15 would be conducted. And the final one was, you know,  
16 how are you going to enforce a policy statement, which  
17 indicated to us that a lot of people really didn't  
18 understand the way that a policy statement is used.

19           So in our September 17th revised draft, we  
20 did some other things to the policy statement to  
21 revise it, but those are three areas that we really  
22 focused on.

23           And when we looked at security first in  
24 the draft policy statement, we were told by the  
25 Commission to make sure to address the unique aspects

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1 of security in the policy statement. And so the way  
2 that was developed, it was incorporated into the  
3 definition of safety culture, and it was also  
4 incorporated into the characteristics of what is a  
5 positive safety culture.

6 And when the February workshop met, the  
7 panelists aligned around a different definition of  
8 safety culture and different traits. And the  
9 definition that they aligned around and the traits did  
10 not include the word "security." And they did this  
11 deliberately.

12 So, first of all, we wanted to find out  
13 whether this was something that resonated stronger  
14 with the regulated community or whether we should  
15 continue to use the draft definition and draft traits  
16 that we had already published.

17 As it turns out, in our outreach  
18 activities, there has been a lot of support and in the  
19 comments that we received on the draft policy, a lot  
20 of support for the February workshop definition and  
21 traits. And so we wanted to look at how we could best  
22 accomplish what we wanted to accomplish, which is to  
23 make sure that we stress the importance of security  
24 and at the same time to recognize the concerns that  
25 our stakeholders were having with putting the term

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1 "security" in the definition and in the traits.

2 Most of the individuals that commented on  
3 taking security out of the definition and the traits  
4 did so because they felt that, first, safety culture  
5 is an over-arching concept. It includes safety, and  
6 it includes security. And by calling out security  
7 specifically, it might not confuse nuclear power plant  
8 operators, but it would probably be confusing to a lot  
9 of other stakeholders. And so it was not a useful way  
10 to approach things.

11 We still had to recognize the fact that  
12 security is an important part of what the NRC does.  
13 It's one of our pillars. It is important for us to  
14 ensure that when people are looking at how they are  
15 addressing safety culture, they recognize the  
16 interface of safety and security.

17 So what we did in the revised draft was to  
18 ensure that we would continue a robust discussion of  
19 the importance of security; the importance of  
20 considering the interface of safety and security; and  
21 then, though it was not in the definition and the  
22 traits that we adopted, which were from the February  
23 workshop, we did add a preamble to the traits and  
24 indicated that although security is not specifically  
25 called out in the traits, it is important to remember

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1 that the importance of considering both safety and  
2 security issues commensurate with their significance  
3 as an underlying principle of the statement of policy.

4 The next thing that we looked at which was  
5 of great concern to people was implementation. And  
6 that is probably the biggest issues that people have,  
7 and it is understandable. Now, of course, this is the  
8 policy statement. It's at high level.

9 If you look at it in tiers, you have your  
10 definition, which is your highest tier. The second  
11 tier would be your traits, which describe in a very  
12 generic sort of way what we believe are included in a  
13 positive safety culture.

14 And then you have the next layer, which is  
15 the implementation layer. And, of course, that is  
16 where the rubber meets the road. And that is where  
17 people have to spend resources. And that is where  
18 they have to decide how they need to incorporate this  
19 policy statement into what they're doing.

20 So implementation is very important, but,  
21 as I said, since this is a policy statement at this  
22 point, we haven't gotten to that third tier.

23 We intend to continue having the same kind  
24 of dialogue with stakeholders as we get to that level,  
25 but first, of course, the Commission has to look at

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1 what we have done with the policy statement and  
2 determine that they want to improve it. And then they  
3 have to also come back to the staff and tell us what  
4 they would like to see us do with it. And before  
5 anybody can do anything, we have to get that  
6 direction.

7 So the program offices will then look at  
8 what the Commission tells them they would like to see  
9 happen. And then they will need to work with their  
10 stakeholders to see how that works.

11 We want to continue this dialogue. We  
12 have found that the outreach that we have had has  
13 really paid off in a big way. People really want to  
14 talk about this with us. We feel it has been very  
15 open and transparent all throughout the process. And  
16 we want to continue that approach as we go into the  
17 implementation phase.

18 We do recognize, even at this stage, that  
19 it is going to be very different for a gauge user, who  
20 may not have even known, even if they use their  
21 materials safely, what safety culture is; whereas,  
22 nuclear power plants are testing pilots and to see how  
23 some of the traits that they think are important in a  
24 positive safety culture lay out.

25 So it will be very different for the

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1 various stakeholders. And that is addressed in the  
2 revised statement, in the revised policy discussion,  
3 but it isn't actually included in the actual statement  
4 of policy because, as I said, as a third tier, that  
5 will be the next phase. And that is really where the  
6 most work is going to go.

7 I mean, this is a lot of work getting  
8 here. It's been two years because we have wanted to  
9 have stakeholder input. But, actually, when we  
10 proceed with implementation, that's where there will  
11 be the greatest amount of effort.

12 The third thing was about, as I mentioned,  
13 you know, using a policy statement to enforce  
14 something. And when we went back in this revised --  
15 in the FR, we revised the policy statement, we did  
16 explain the difference between a policy statement,  
17 that it is not enforceable, that it is not a matter of  
18 compatibilities, that it reflects an area that is of  
19 extreme importance to the Commission over which they  
20 have jurisdiction, but it is not like a regulation  
21 where they can enforce it and they can use it in that  
22 manner.

23 And after we did that, actually, the  
24 comments that have come in have reflected the fact  
25 that people now are more aware of what we are doing

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1 and why we are doing it. And they have for the most  
2 part still continued to say that they think that a  
3 policy statement is the right way to go.

4 Now, there are a few people that still  
5 believe that it has to be a regulation because that is  
6 the only way they can dedicate resources, but a  
7 predominant view is that this is a policy statement,  
8 this is the right way to go, and we should continue to  
9 do it that way.

10 The final thing that was a really big  
11 difference is that the Commission asked us to consider  
12 whether we should incorporate vendors and suppliers of  
13 safety-related components. And I guess most people  
14 responded that they thought that was a very good idea.

15 Why would you isolate this entity and say  
16 that they shouldn't be subject to considering the  
17 importance of safety culture in their activities? I  
18 mean, of course, the problem is that a lot of these  
19 are entities that are not under NRC's jurisdiction,  
20 but in the agreement states, although we have this  
21 strong relationship, they also have a different kind  
22 of an approach to this.

23 And we're not telling them they have to do  
24 it. We're trying to I guess lead by trying to develop  
25 this together. And so there will be no reason why you

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1 would not want to include vendors and suppliers. But  
2 there will be implementation issues that will be very  
3 difficult that will have to be worked out in that  
4 implementation phase.

5 So that is pretty much how things have  
6 evolved. And before we go to brief the Commission on  
7 January 24th, there are other things that we will have  
8 to do. We have to evaluate the comments that have  
9 come in.

10 And there actually have been really some  
11 meaty comments that have come in this time. Before  
12 they were sort of general comments. These have gotten  
13 really much more to it. To me that indicates that  
14 people are really getting into this and they really  
15 want to make sure that we understand that as we are  
16 getting to this point of getting to a final policy  
17 statement, we understand where they are coming from  
18 and what is important to them. So I think that is  
19 going to be a very important part of this.

20 We are making presentations to you. And  
21 we are making a presentation at the ACRS because we  
22 are hoping to seek your endorsement on this. And then  
23 we are developing a SECY paper right now, which will  
24 contain the FRM, will have the policy statement. And  
25 that will be going to the Commission around January

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1 18th.

2 And so that is pretty much where this is.  
3 It is still ongoing, but it is getting to the point  
4 where we are getting down to the final nitty-gritty we  
5 are going to be sending up to the Commission.

6 ACTING CHAIRMAN THOMADSEN: Thank you very  
7 much.

8 Comments from the Committee, questions?  
9 Dr. Zanzonico?

10 MEMBER ZANZONICO: I had sent in some  
11 written comments to the Committee.

12 ACTING CHAIRMAN THOMADSEN: Yes.

13 MEMBER ZANZONICO: So I will just express  
14 them here. One trait I thought would be useful to  
15 include explicitly is redundancy. I mean, I think  
16 that most people would agree that is a component of a  
17 safety program in any operation, checks, double  
18 checks, et cetera. And I think the value of including  
19 that explicitly as a trait is that, even though you  
20 said this is not a regulation, you did allude to the  
21 fact that regulations give you some leverage in your  
22 home institutions, where you have to expend funds to  
23 comply. And redundancy is just such a case.

24 I mean, if you buy an additional piece of  
25 equipment in the nuclear medicine setting, if you need

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1 to buy a dose calibrator close to where you are going  
2 to do the injections and not just in a radiopharmacy,  
3 so that someone can now recheck an administered  
4 activity, I think having that trait explicitly  
5 included would be helpful in that regard. And I think  
6 that it is legitimately part of a safety culture.

7 The other comment I had with regard to the  
8 definition, where you allude to safety I think over  
9 other competing goals of the organization. And I  
10 think somehow that needs to be couched to allow for  
11 those competing goals that are safety.

12 I mean, the extreme example would be a  
13 firefighter. The last thing that is safe is to run  
14 into a burning building. But their goal is to safe  
15 life and property by running into a burning building.

16 There is not nearly as dramatic examples  
17 in a health care setting, but potentially there are.  
18 The demonstration or the example I cited was someone  
19 gets radionuclide therapy and they have some acute  
20 event and they require emergency surgery. Well,  
21 you're not going to not do the emergency surgery  
22 because the surgeon and the surgical staff are going  
23 to get a relatively large radiation dose from the  
24 procedure.

25 So I think somehow that should be

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1 reflected, you know, in the unlikely event that  
2 someone would say, "Well, but the NRC says, you know,  
3 we should have a prevailing safety culture," et  
4 cetera, et cetera. So maybe you could be competing  
5 non-safety goals of an organization.

6 So those are my comments.

7 MS. SCHWARTZ: Thank you.

8 ACTING CHAIRMAN THOMADSEN: Thank you.

9 Dr. Fisher?

10 MEMBER FISHER: I think it's a good thing  
11 that the NRC has put this in as policy, rather than  
12 regulation, because the question I always have is, how  
13 do you measure it? What are quantitative measures of  
14 a safety policy? How do you know that one  
15 organization has it and another organization doesn't?  
16 And are there any definable quantities that help us  
17 better understand this concept?

18 MS. SCHWARTZ: Of course, that's a part of  
19 the reason that we developed the traits, because they  
20 are indicators. But I agree with you that, at this  
21 point at least, we haven't developed into a  
22 connotative.

23 I mean, one of the traits that we  
24 concluded was a environment where people trust each  
25 other. That would be very difficult to measure,

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1 although if you walk into an environment where you  
2 know people don't trust each other, it becomes very  
3 obvious very quickly.

4 But if you were an inspector, you were  
5 doing that, how would you write that down? So I agree  
6 with this.

7 ACTING CHAIRMAN THOMADSEN: Dr.  
8 Guiberteau?

9 MEMBER GUIBERTEAU: I just have a question  
10 that sort of intrigued me in the Federal Register.  
11 And that was you listed the traits and then you sort  
12 of focused for a moment on what I guess I would call  
13 an anti-trait. And that was addressing the issue of  
14 complacency.

15 And it seemed to be, although it wasn't  
16 raised to any significant level, it seemed to appear a  
17 few times and seemed to be bothersome to those of you  
18 involved in this. And I'm just wondering how since  
19 that is a huge issue, sort of the elephant in the  
20 room, because if you're doing well, what else do you  
21 need to do? So I'm just wondering.

22 I think you asked the question, should  
23 this be addressed? Personally I think it does in some  
24 way, but I am just wondering how you are dealing with  
25 that.

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1 MS. SCHWARTZ: I think that that was  
2 raised when the staff itself especially was reviewing  
3 literature. And a lot of the literature reviews point  
4 to complacency as a real problem because when you are  
5 doing really well, it is so easy to say, you know,  
6 "Why mess things up? We're going great. We have  
7 great reviews. Everybody loves us."

8 I think that one of the ways that may  
9 address this is by adding a ninth trait, called  
10 questioning attitude, which we feel would then address  
11 because if you have a questioning attitude, it sort of  
12 combats the idea that everything is going great, so  
13 never ask any more questions.

14 I agree with you that it is sort of the  
15 flip of the other traits. So it was added as a  
16 thought because we do feel some kind of complacency  
17 needs to be addressed somehow in the policy.

18 MEMBER GUIBERTEAU: I guess I am casting  
19 my comment that I think it needs to be addressed.

20 MS. THOMPSON: Public comments?

21 ACTING CHAIRMAN THOMADSEN: Dr.  
22 Mattmuller?

23 MEMBER MATTMULLER: I did attend remotely  
24 the February workshop. And I caution to you, ma'am,  
25 that be careful what you ask for because this is a

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1 difficult process. With the time delay, it makes it  
2 very hard to actually participate in their time.

3 MS. SCHWARTZ: Do you mean the September  
4 one when you were --

5 MEMBER MATTMULLER: No. The February.

6 MS. SCHWARTZ: Oh, okay. Because you're  
7 in a different time zone.

8 MEMBER MATTMULLER: Yes. Or she's  
9 thinking ahead or -- I'm sorry. Not a safety culture  
10 but a different workshop.

11 I know that in the February workshop,  
12 there was a representative from the Joint Commission.  
13 And from a medical perspective, this was heavily  
14 represented by -- the Joint Commission I know has  
15 worked on this issue diligently over many, many years,  
16 20 years or so. I can remember some of the first  
17 attempts. And so I think they have really got it down  
18 pretty good for health care facilities.

19 So I guess my only question would be for  
20 you is not to design something that mucks up their  
21 efforts because I think we are in pretty good shape.  
22 And it was my impression from everything I have read  
23 and participate in that it's the nuclear power plants  
24 that need a little bit more help and guidance, which I  
25 would agree with.

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1 But in terms of health care, medical care,  
2 in terms of safety culture, I think we are in pretty  
3 good shape.

4 MS. SCHWARTZ: I mean, I think that that  
5 is a good point. We don't want to be mucking up what  
6 other people have already started. We wouldn't even  
7 want to muck up what we have been starting internally  
8 because we have been working very hard towards a  
9 safety culture internally as well.

10 And I think that any organization that  
11 started to focus on it and started to work towards it,  
12 we certainly don't want to impede those efforts  
13 because they are important and they come from the  
14 organization itself. So they do reflect what that  
15 organization really holds dear.

16 Luckily, as you said, there was a  
17 representative from the Joint Commission. So the  
18 definition that we developed did take -- you know,  
19 there was an alignment of all of -- and there was  
20 given and take on the part of all of the members.

21 And it was very impressive to me. I had  
22 never seen -- I mean, INPO, which had developed these  
23 principles, was willing to stand back and say, "You  
24 know what? If this is what the group really thinks is  
25 important, you know that is what resonates with them,

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1 then we need to step back and look at that."

2 I was very impressed with that. There was  
3 no ego involved. And it was a really amazing process.  
4 And so in that spirit, going forward, we still want to  
5 keep that in mind.

6 ACTING CHAIRMAN THOMADSEN: Any other  
7 comments? Yes?

8 MR. LEWIS: NRC, the staff?

9 MR. FIRTH: If I could add something?  
10 James Firth, NRC staff.

11 We did get three comments from ACMUI  
12 members. So we appreciate those. We just wanted to  
13 come in here with a copy of the revised draft policy  
14 statement. As Kitty and Maria mentioned earlier, once  
15 we get to a final, draft final, policy statement, we  
16 will be providing it to both of the advisory  
17 committees in terms of the ACRS and ACMUI.

18 We wanted to meet here in this meeting  
19 because of the way the timing is working, that by the  
20 time that is complete, we are not, the Committee is  
21 not, going to be meeting, but I understand there is a  
22 chance the Committee may be either meeting by  
23 teleconference or might otherwise be able to look at  
24 the draft final policy statement.

25 So we would be interested in either

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1 comments or an endorsement on the policy statement.

2 ACTING CHAIRMAN THOMADSEN: And we  
3 certainly can, yes.

4 Further comments? Yes?

5 MEMBER ZANZONICO: So do you ultimately  
6 want a formal endorsement from the Committee?

7 MS. SCHWARTZ: That would be very nice.

8 ACTING CHAIRMAN THOMADSEN: Ms. Cockerham?

9 MS. COCKERHAM: To kind of address that,  
10 what I talked to James Firth and people within our  
11 office about was adding this to that December  
12 teleconference that we have already planned so that  
13 you have some time to look at the draft that they have  
14 provided us so far.

15 And I think the timing works out about the  
16 time that this is going to ACRS. You guys could be  
17 looking at this in very early December and they could  
18 still meet their January deadline. So you will have  
19 more time to look over this and review it. And we  
20 would expect that you can endorse it at the December  
21 teleconference if that --

22 MEMBER ZANZONICO: If we get it in time.

23 MS. COCKERHAM: Well, yes. It's out.

24 ACTING CHAIRMAN THOMADSEN: Is it? I  
25 thought you were coming up with another draft.

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1 MS. SCHWARTZ: Well, there is going to be  
2 a final.

3 MS. COCKERHAM: There will be a final, but  
4 you have the draft already.

5 MS. SCHWARTZ: If you have the revised,  
6 that's the --

7 MS. COCKERHAM: Which is what you  
8 commented on. I had comments from three of the  
9 members.

10 MEMBER LANGHORST: It's in our book?

11 MS. COCKERHAM: It's not in your book.

12 ACTING CHAIRMAN THOMADSEN: No. We got it  
13 electronically.

14 MS. COCKERHAM: Yes. It was sent  
15 electronically.

16 MS. THOMPSON: We have additional copies  
17 if anybody --

18 MS. COCKERHAM: Sure. Yes. Pass those  
19 around.

20 MR. LEWIS: I guess just for Dr.  
21 Zanzonico's comment about endorsement, you know, we  
22 would certainly love to have endorsement, but what  
23 we're asking, I think we can only ask for the  
24 Committee to do is advise us on any policy or  
25 technical implications you see for the medical

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1 industry.

2 ACTING CHAIRMAN THOMADSEN: Thank you very  
3 much.

4 MS. SCHWARTZ: Thank you.

5 ACTING CHAIRMAN THOMADSEN: And, Ashley,  
6 you're up.

7 24. ADMINISTRATIVE CLOSING

8 MS. COCKERHAM: What is coming around  
9 right now are the recommendations that you made at  
10 this meeting. So we'll go over all of those as soon  
11 as everybody has a copy.

12 And while you are waiting for that, I know  
13 most of you have met Sophie Holiday. And she is going  
14 to be more involved in ACMUI stuff and is definitely  
15 going to be helping. So if you see e-mails from her,  
16 consider them from me. I'll probably be on cc.

17 MEMBER LANGHORST: I don't know. Those  
18 are big shoes.

19 MS. COCKERHAM: So we'll be working  
20 together a lot in the next few months to handle all of  
21 the Committee activities. Chris, could you grab those  
22 copies so they don't stop? And there should be one  
23 for you as well. And there should be several for the  
24 public.

25 Okay. So if everybody has one, we will

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1 start with item number 9. And it was ACMUI endorses  
2 the Permanent Implant Brachytherapy Subcommittee  
3 report with the caveat that this is an interim report  
4 that may be revised in the future to consider  
5 additional input, such as that received from  
6 stakeholders at public workshops.

7 I don't think that is verbatim what you  
8 said during the meeting, but does that capture what  
9 you wanted? Yes? I'm seeing nods. Okay. Then we'll  
10 use that as the recommendation.

11 For item 10, ACMUI endorses the draft  
12 version of FSME policy and procedures 2-5, revision 0  
13 presented at the meeting. Any issues there?

14 (No response.)

15 MS. COCKERHAM: Okay. Move on to item 11.  
16 Dr. Thomadsen created a subcommittee to prepare a  
17 document --

18 ACTING CHAIRMAN THOMADSEN: I'm sorry?

19 MEMBER GILLEY: No. Go ahead. I'm going  
20 to just say something when you get through.

21 MS. COCKERHAM: Okay. Dr. Thomadsen  
22 created a subcommittee to prepare a document to guide  
23 the December discussion on 10 CFR part 35. That  
24 should actually read part 37.

25 Is that what your comment is? Okay. I'm

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1 with you. Can you hand me that pen right next to you?

2 MEMBER GUIBERTEAU: You won't take that  
3 on, too?

4 (Laughter.)

5 MS. COCKERHAM: No thank you. Okay. So  
6 part 35 will read part 37.

7 MEMBER GILLEY: That would be a full-time  
8 job.

9 MS. COCKERHAM: All right. So that will  
10 be 37. So Debbie is the chair. Sue Langhorst and  
11 Darrell Fisher will also be helping out with that  
12 document.

13 ACMUI will incorporate -- this is item 12.  
14 ACMUI will incorporate the comments made during the  
15 meeting to revise the Patient Release Subcommittee  
16 report. The Committee will vote to finalize the  
17 report via e-mail and will resubmit it to NRC in the  
18 near future. All right.

19 Next slide on number 13. You may have to  
20 correct me on this one, but I think that Steve  
21 Mattmuller and Bruce Thomadsen offered to provide  
22 support to respond to the letter dated October 20th,  
23 2010 to Chairman Jaczko from Congressman Markey  
24 regarding patient release.

25 MEMBER MATTMULLER: We were able to

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1 recruit another eager volunteer, --

2 MS. COCKERHAM: Okay.

3 MEMBER MATTMULLER: -- Susan Langhorst.

4 MS. COCKERHAM: Sue, you are in on that,  
5 too?

6 MEMBER LANGHORST: Yes.

7 MS. COCKERHAM: Are you waving the white  
8 flag?

9 MEMBER MATTMULLER: I did say eager.

10 MS. COCKERHAM: Okay. So we'll add Sue's  
11 name to that. And I will be in touch with you guys  
12 next week to move on that.

13 Item 14, ACMUI planned a teleconference to  
14 discuss 10 CFR part 37 rulemaking and safety culture  
15 on Monday, December 13th, 2010 from 1:00 p.m. to 3:00  
16 p.m. Eastern time. The backup time and date are  
17 Wednesday, December 15th, 2010 from 11:00 a.m. to 1:00  
18 p.m. Eastern time. Sound good?

19 (No response.)

20 MS. COCKERHAM: Okay. That takes care of  
21 the meeting summary. For the next meeting, obviously  
22 the next meeting will really be in December with that  
23 teleconference. For April and May, if you will turn  
24 to tab 23? You should have a calendar in there.

25 ACTING CHAIRMAN THOMADSEN: We got pretty

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1 much feedback about they do what they do without  
2 compromising safety. I think it's pretty hard.

3 Okay. Let's see.

4 MS. COCKERHAM: Tab 23.

5 ACTING CHAIRMAN THOMADSEN: Yes.

6 MS. COCKERHAM: It's good to narrow the  
7 dates out a little bit further. If you want to put  
8 X's on April 13th, 14th, 15th, and then flip to May  
9 and cross out the 23rd, 24th, and 25th?

10 MEMBER GILLEY: Wow. The week of May 9th?  
11 Say that again, Ashley.

12 MS. COCKERHAM: April 13th, 14th, and  
13 15th.

14 MEMBER GILLEY: And the May?

15 MS. COCKERHAM: Twenty-third, 24th, and  
16 25th. So our options are extremely limited. Any  
17 preference for April versus May? We can start there.

18 ACTING CHAIRMAN THOMADSEN: April.

19 MS. COCKERHAM: April? Okay. So April  
20 11th and 12th or 27th and 28th? Any conflicts with  
21 those or preference for earlier/later? One is a  
22 Monday-Tuesday. The other is a Wednesday-Thursday.

23 MEMBER ZANZONICO: Would it be easier for  
24 most people traveling on Sunday or --

25 MEMBER MATTMULLER: Yes.

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1 MS. COCKERHAM: So the Sunday gets the  
2 long travelers a day that is not totally away for the  
3 office? Okay. So April 11th and 12th can be the  
4 first choice. Do you want to take a later --

5 ACTING CHAIRMAN THOMADSEN: Checking the  
6 holidays.

7 MS. COCKERHAM: Are you checking a  
8 calendar? Okay.

9 MEMBER LANGHORST: I'm checking holidays.

10 MS. COCKERHAM: Is it Passover holiday,  
11 Dr. Thomadsen?

12 ACTING CHAIRMAN THOMADSEN: Purim, which I  
13 don't -- oh, here we go. Sunday, the 20th. So that  
14 seems to be April 20th.

15 MS. COCKERHAM: Are you in 2010 or 2011?

16 ACTING CHAIRMAN THOMADSEN: '11.

17 MEMBER GUIBERTEAU: Easter is the 24th.

18 MS. COCKERHAM: Yes. That's on --

19 ACTING CHAIRMAN THOMADSEN: We're in 2011.  
20 Oh, March. Okay. So that's a completely wrong month.

21 MS. COCKERHAM: Okay.

22 ACTING CHAIRMAN THOMADSEN: So yes.  
23 That's fine. Yes.

24 MS. COCKERHAM: For an alternate date, do  
25 you want to stick with the April or do you guys want

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1 to pick a date in May as the alternate date?

2 MEMBER ZANZONICO: There's really not much  
3 in April.

4 MEMBER GILLEY: How about May 9th and 10th  
5 as an alternate date?

6 MS. COCKERHAM: Okay. May 9th and 10th?  
7 Conflicts there?

8 (No response.)

9 MS. COCKERHAM: All right. So those will  
10 be our backup dates. So first choice, April 11th and  
11 12th, which is a Monday-Tuesday. Backup date May 9th  
12 and 10th, which is also a Monday-Tuesday. Okay? That  
13 takes care of that.

14 Next item on my list is financial  
15 disclosure forms. I have them back from most of you.  
16 If you have not turned it in, if you can get it to me  
17 today, great. If not, I will send you an e-mail with  
18 the address for you to mail it to our Office of  
19 General Counsel. And if you could get those in next  
20 week, that would be greatly appreciated.

21 All right. The next one is time and  
22 attendance. If you want to complete your form, I have  
23 blank forms here if you want to complete it and give  
24 it back to me, go ahead. If not, you can turn it in  
25 tomorrow. You will need to send an e-mail to Shayla

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1 tomorrow morning or tomorrow I guess as soon as you  
2 get home or know your hours. Let her know. But if  
3 you fill out the hard copy here, we won't really need  
4 an e-mail. I will give her this information today.  
5 So I will pass these around. You all have to complete  
6 one.

7 And then the next thing is you will be  
8 getting an e-mail with a form. I've drawn a blank  
9 right now.

10 ACTING CHAIRMAN THOMADSEN: Sixty-four?

11 MS. COCKERHAM: Sixty-four.

12 ACTING CHAIRMAN THOMADSEN: Sixty-four.

13 MS. COCKERHAM: Sixty-four. You're right,  
14 yes. And it will be your travel voucher form. So you  
15 will need to complete those to claim expenses for this  
16 meeting. And you will probably get that e-mail next  
17 week. You will have a week or so to get that done and  
18 send the information.

19 You are going to mail everything back to  
20 Sophie. And she will double check it and then submit  
21 it so you can get all of your money back. So that  
22 will be coming next week.

23 And the last thing I have is to take off  
24 your name tags and set them on the table.

25 ACTING CHAIRMAN THOMADSEN: One question,

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1 one quick question, for you.

2 MS. COCKERHAM: Yes?

3 ACTING CHAIRMAN THOMADSEN: At this time  
4 of day, is it getter to take a cab or the Metro to --

5 MR. LEWIS: Which airport?

6 ACTING CHAIRMAN THOMADSEN: What's that?

7 MR. LEWIS: Which airport?

8 ACTING CHAIRMAN THOMADSEN: National.

9 MR. LEWIS: Metro. Well, thank you,  
10 everybody. This has been a very good meeting.

11 (Whereupon, the foregoing matter was  
12 concluded at 4:40 p.m.)

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