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NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

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OPEN MEETING

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THURSDAY,

October 21, 2010

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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

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

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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

NRC STAFF PRESENT (CONT'D)

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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.

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

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

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

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

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

Cesium has a long half life, 30.2 years,

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

close to the present time.

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

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

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

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

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

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

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

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

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

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

Think back to my earlier slides. It has

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

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

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

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

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

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

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

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

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

areas.

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

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

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

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

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

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

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

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

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

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

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

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

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

cesium chloride.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

to test for it.

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

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

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

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

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

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

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

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

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

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

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

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

Dr. Zanzonico?

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

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

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

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

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

ACTING CHAIRMAN THOMADSEN: Dr. Suleiman.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

ACTING CHAIRMAN THOMADSEN: Thank you very

much, Dr. Fisher. Ms. Gilley?

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

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

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

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

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

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

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

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

ACTING CHAIRMAN THOMADSEN: Okay. Dr. Welsh?

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

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

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

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

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

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

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

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

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

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

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

ACTING CHAIRMAN THOMADSEN: Dr. Langhorst?

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

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

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

MEMBER LANGHORST: Okay.

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

MEMBER LANGHORST: Okay. Thank you.

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

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

I'm giving an update on the Part 37

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

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

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

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

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

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

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

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

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

MS. COCKERHAM: I think so.

ACTING CHAIRMAN THOMADSEN: Sounds like it.

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

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

MEMBER GILLEY: Do I have the floor?

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

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

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

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

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

Dr. Fisher?

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

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

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

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

(Whereupon, the proceedings went off the

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

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

MEMBER LANGHORST: Thank you very much.

20. PATIENT RELEASE SUBCOMMITTEE REPORT

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

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

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

ACTING CHAIRMAN THOMADSEN: Please.

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

the current international recommendations.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

And they say, "No.

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

So let's discuss this a little bit. One

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

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

My Subcommittee members have nothing to add?

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

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

MEMBER SULEIMAN: I can now or later.

MEMBER LANGHORST: Go ahead.

MEMBER SULEIMAN: I think the low as

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

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

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

ACTING CHAIRMAN THOMADSEN: Pat? Dr. Zanzonico?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

ACTING CHAIRMAN THOMADSEN: Thank you very much.

Dr. Fisher?

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

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

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

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

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

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

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

to the patients themselves but to society generally.

ACTING CHAIRMAN THOMADSEN: Thank you.

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

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

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

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

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

And does anyone else want to add to that?

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

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

MEMBER LANGHORST: Okay.

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

MEMBER LANGHORST: Thank you.

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

criteria.

MEMBER ZANZONICO: Can I just --

ACTING CHAIRMAN THOMADSEN: Yes, Dr. Zanzonico?

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

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

So it just makes sense logically and

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

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

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

ACTING CHAIRMAN THOMADSEN: Thank you.

Mr. Mattmuller?

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

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

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

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

ACTING CHAIRMAN THOMADSEN: Thank you.

Dr. Suleiman?

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

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

So for somebody to go backward and talk

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

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

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

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

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

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

ACTING CHAIRMAN THOMADSEN: Okay. Mr. Lewis?

MR. LEWIS: It was a reaction to that.

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

ACTING CHAIRMAN THOMADSEN: Dr. Welsh?

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

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

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

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

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

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

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

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

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

ACTING CHAIRMAN THOMADSEN: Now Mr. Lewis.

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

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

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

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

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

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

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

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

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

MS. COCKERHAM: Yes.

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

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

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

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

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

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

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

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

MEMBER GILLEY: Thank you. Not yet.

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

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

ACTING CHAIRMAN THOMADSEN: Dr. Suleiman?

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

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

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

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

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

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

or whatever. So --

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

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

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

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

I mean, it doesn't make any difference in

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

it.

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

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

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

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

ACTING CHAIRMAN THOMADSEN: Thank you very much.

MR. CRANE: Thank you.

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

ACTING CHAIRMAN THOMADSEN: Dr. Zanzonico?

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

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

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

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

ACTING CHAIRMAN THOMADSEN: Thank you.

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

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

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

ACTING CHAIRMAN THOMADSEN: Okay.

MEMBER LANGHORST: Can I have the next slide?

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

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

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

MEMBER FISHER: What is the next slide?

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

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

ACTING CHAIRMAN THOMADSEN: Dr. Zanzonico?

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

In other words, a practitioner doesn't

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

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

ACTING CHAIRMAN THOMADSEN: Thank you.

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

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

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

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

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

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

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

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

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

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

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

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

ACTING CHAIRMAN THOMADSEN: Thank you, Dr. Welsh.

Yes, Dr. Palestro?

MEMBER PALESTRO: I have a question. I

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

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

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

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

ACTING CHAIRMAN THOMADSEN: Thank you.

Do you want to reply or --

MEMBER WELSH: I could reply that those

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

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

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

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

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

since 1996.

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

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

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

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

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

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

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

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

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

anew in a comprehensive way.

Thank you.

ACTING CHAIRMAN THOMADSEN: Thank you.

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

ACTING CHAIRMAN THOMADSEN: Did you also use IAEA?

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

ACTING CHAIRMAN THOMADSEN: Dr. Zanzonico?

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

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

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

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

ACTING CHAIRMAN THOMADSEN: Thank you.

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

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

ACTING CHAIRMAN THOMADSEN: Dr. Guiberteau?

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

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

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

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

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

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

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

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

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

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

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

ACTING CHAIRMAN THOMADSEN: Mr. Lewis?

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

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

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

I think a model set of instructions if you

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

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

ACTING CHAIRMAN THOMADSEN: Thank you.

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

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

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

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

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

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

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

ACTING CHAIRMAN THOMADSEN: Thank you.

Dr. Welsh?

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

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

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

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

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

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

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

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

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

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

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

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

ACTING CHAIRMAN THOMADSEN: Dr. Guiberteau?

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

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

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

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

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

ACTING CHAIRMAN THOMADSEN: Thank you.

Dr. Suleiman?

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

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

communication on what to do.

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

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

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

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

ACTING CHAIRMAN THOMADSEN: Thank you.

MEMBER LANGHORST: I provided each of you

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

MEMBER GILLEY: C-o-m.

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

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

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

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

ACTING CHAIRMAN THOMADSEN: And thank you

for the books --

MEMBER LANGHORST: You're very welcome.

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

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

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

MEMBER LANGHORST: Sorry.

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

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

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

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

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

MEMBER LANGHORST: No.

ACTING CHAIRMAN THOMADSEN: -- to deal with.

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

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

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

ACTING CHAIRMAN THOMADSEN: Yes, we have.

Thank you very much.

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

(Laughter.)

MEMBER LANGHORST: Insert foot in mouth.

ACTING CHAIRMAN THOMADSEN: Dr. Fisher?

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

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

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

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

Thanks.

ACTING CHAIRMAN THOMADSEN: Thank you.

Dr. Guiberteau?

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

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

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

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

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

Thank you.

ACTING CHAIRMAN THOMADSEN: Thank you very much.

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

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

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

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

ACTING CHAIRMAN THOMADSEN: Yes.

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

ACTING CHAIRMAN THOMADSEN: Very good.

Is that amenable to the rest of the Committee?

(No response.)

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

MEMBER LANGHORST: Thank you.

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

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

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

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

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

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

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

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

unanimous.

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

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

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

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

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

That is I assume agreeable with the Chair.

MEMBER LANGHORST: Absolutely.

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

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

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

MEMBER FISHER: Preference against Thursdays.

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

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

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

MEMBER GILLEY: Tuesday or Wednesday.

MS. COCKERHAM: Tuesday or Wednesday?

ACTING CHAIRMAN THOMADSEN: Wednesday.

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

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

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

MEMBER FISHER: Sure.

MS. COCKERHAM: Okay.

ACTING CHAIRMAN THOMADSEN: 11:00 o'clock?

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

(No response.)

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

MEMBER SULEIMAN: I have a conflict that afternoon.

MS. COCKERHAM: Okay.

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

MS. COCKERHAM: Okay.

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

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

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

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

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

MS. COCKERHAM: Tuesday is fine with you?

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

MEMBER SULEIMAN: The 15th works for me.

MS. COCKERHAM: Sue, is --

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

MEMBER FISHER: How about December 13th?

MS. COCKERHAM: That's a possibility.

MEMBER LANGHORST: December 13th is great for me.

ACTING CHAIRMAN THOMADSEN: That works for me.

MEMBER SULEIMAN: I'm okay with that.

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

MEMBER ZANZONICO: At what time?

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

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

(Laughter.)

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

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

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

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

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

MEMBER GILLEY: What time is --

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

ACTING CHAIRMAN THOMADSEN: Eastern?

MEMBER SUH: Easter.

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

1:00 to 3:00.

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

ACTING CHAIRMAN THOMADSEN: Yes.

MS. COCKERHAM: Okay.

ACTING CHAIRMAN THOMADSEN: What was the backup?

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

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

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

MS. HOLIDAY: Twenty-three.

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

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

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

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

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

ACTING CHAIRMAN THOMADSEN: Very fine.

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

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

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

21. MEDICAL RELATED EVENTS

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

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

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

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

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

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

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

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

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

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

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

then --

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

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

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

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

ship it back.

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

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

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

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

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

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

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

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

In 35.400, we had 25 medical events. As

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

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

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

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

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

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

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

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

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

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

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

that were identified.

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

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

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

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

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

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

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

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

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

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

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

We had three medical events with a traditional gamma knife.

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

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

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

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

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

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

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

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

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

see that there were problems with immobilizing the patient.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

than it's supposed to be.

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

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

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

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

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

the NMED database? Is that what you mean?

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

MEMBER LANGHORST: Okay.

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

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

ACTING CHAIRMAN THOMADSEN: Dr. Welsh?

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

ACTING CHAIRMAN THOMADSEN: The TheraSpheres?

MEMBER WELSH: Was it SirSphere or TheraSpheres?

ACTING CHAIRMAN THOMADSEN: TheraSpheres.

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

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

thinking about. It was the other.

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

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

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

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

MEMBER WELSH: Dr. Zanzonico may have an answer.

MEMBER ZANZONICO: It's unlikely that

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

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

ACTING CHAIRMAN THOMADSEN: Comments? Yes, Dr. Suh?

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

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

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

ACTING CHAIRMAN THOMADSEN: Ms. Cockerham?

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

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

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

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

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

MS. COCKERHAM: Yes.

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

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

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

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

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

ACTING CHAIRMAN THOMADSEN: Dr. Fisher?

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

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

event?

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

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

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

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

DR. HOWE: Yes.

MEMBER FISHER: Thanks.

ACTING CHAIRMAN THOMADSEN: Other comments from the Committee?

(No response.)

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

MEMBER WELSH: Yes.

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

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

ACTING CHAIRMAN THOMADSEN: Very fine. Thank you again.

DR. HOWE: Yes, sir.

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

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

DR. BUTLER: Thank you.

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

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

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

DR. BUTLER: Thank you.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

targeting October of 2011.

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

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

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

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

What have we heard thus far? Well, we

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

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

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

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

future slide.

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

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

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

Commission briefing yesterday.

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

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

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

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

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

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

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

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

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

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

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

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

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

And, with that, I will ask for any

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

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

ACTING CHAIRMAN THOMADSEN: Thank you very much.

Dr. Van Decker?

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

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

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

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

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

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

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

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

MEMBER VAN DECKER: That is definitely true in cardiology.

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

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

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

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

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

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

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

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

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

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

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

MEMBER GILLEY: You already have them with investigational levels.

MR. LEWIS: Yes.

MEMBER GILLEY: It's a constraint.

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

ACTING CHAIRMAN THOMADSEN: Dr. Suleiman?

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

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

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

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

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

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

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

ACTING CHAIRMAN THOMADSEN: Thank you.

Dr. Fisher?

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

DR. BUTLER: Yes.

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

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

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

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

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

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

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

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

DR. BUTLER: Yes.

ACTING CHAIRMAN THOMADSEN: Dr. Langhorst?

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

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

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

DR. BUTLER: Approval from NRC.

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

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

MEMBER LANGHORST: Okay.

DR. BUTLER: We haven't decided yet.

MEMBER LANGHORST: Right, right.

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

MEMBER LANGHORST: Okay.

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

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

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

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

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

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

MEMBER LANGHORST: Okay.

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

MEMBER LANGHORST: Got you.

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

DR. BUTLER: Right.

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

DR. BUTLER: Right.

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

MEMBER LANGHORST: Can I just --

ACTING CHAIRMAN THOMADSEN: A follow-up?

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

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

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

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

MEMBER LANGHORST: Right.

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

MEMBER LANGHORST: Okay.

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

materials versus having a greater percentage of the medical --

MEMBER LANGHORST: Okay.

ACTING CHAIRMAN THOMADSEN: Dr. Zanzonico?

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

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

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

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

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

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

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

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

DR. BUTLER: Not exclusively.

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

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

MR. LEWIS: Hiroshima survivors was the big one.

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

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

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

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

ACTING CHAIRMAN THOMADSEN: Dr. Welsh?

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

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

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

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

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

ACTING CHAIRMAN THOMADSEN: Dr. Suleiman?

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

MR. LEWIS: Except for one industry.

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

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

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

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

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

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

those come from BEIR IV.

DR. BUTLER: IV.

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

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

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

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

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

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

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

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

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

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

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

ACTING CHAIRMAN THOMADSEN: Any other

comments from the Committee?

(No response.)

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

DR. BUTLER: Thank you.

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

23. SAFETY CULTURE POLICY STATEMENT

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

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

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

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

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

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

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

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

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

safety culture policy statement.

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

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

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

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

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

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

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

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

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

And when the February workshop met, the panelists aligned around a different definition of safety culture and different traits. And the definition that they aligned around and the traits did not include the word "security." And they did this deliberately.

So, first of all, we wanted to find out whether this was something that resonated stronger with the regulated community or whether we should continue to use the draft definition and draft traits that we had already published.

As it turns out, in our outreach activities, there has been a lot of support and in the comments that we received on the draft policy, a lot of support for the February workshop definition and traits. And so we wanted to look at how we could best accomplish what we wanted to accomplish, which is to make sure that we stress the importance of security and at the same time to recognize the concerns that our stakeholders were having with putting the term

"security" in the definition and in the traits.

Most of the individuals that commented on taking security out of the definition and the traits did so because they felt that, first, safety culture is an over-arching concept. It includes safety, and it includes security. And by calling out security specifically, it might not confuse nuclear power plant operators, but it would probably be confusing to a lot of other stakeholders. And so it was not a useful way to approach things.

We still had to recognize the fact that security is an important part of what the NRC does. It's one of our pillars. It is important for us to ensure that when people are looking at how they are addressing safety culture, they recognize the interface of safety and security.

So what we did in the revised draft was to ensure that we would continue a robust discussion of the importance of security; the importance of considering the interface of safety and security; and then, though it was not in the definition and the traits that we adopted, which were from the February workshop, we did add a preamble to the traits and indicated that although security is not specifically called out in the traits, it is important to remember

that the importance of considering both safety and security issues commensurate with their significance as an underlying principle of the statement of policy.

The next thing that we looked at which was of great concern to people was implementation. And that is probably the biggest issues that people have, and it is understandable. Now, of course, this is the policy statement. It's at high level.

If you look at it in tiers, you have your definition, which is your highest tier. The second tier would be your traits, which describe in a very generic sort of way what we believe are included in a positive safety culture.

And then you have the next layer, which is the implementation layer. And, of course, that is where the rubber meets the road. And that is where people have to spend resources. And that is where they have to decide how they need to incorporate this policy statement into what they're doing.

So implementation is very important, but, as I said, since this is a policy statement at this point, we haven't gotten to that third tier.

We intend to continue having the same kind of dialogue with stakeholders as we get to that level, but first, of course, the Commission has to look at

what we have done with the policy statement and determine that they want to improve it. And then they have to also come back to the staff and tell us what they would like to see us do with it. And before anybody can do anything, we have to get that direction.

So the program offices will then look at what the Commission tells them they would like to see happen. And then they will need to work with their stakeholders to see how that works.

We want to continue this dialogue. We have found that the outreach that we have had has really paid off in a big way. People really want to talk about this with us. We feel it has been very open and transparent all throughout the process. And we want to continue that approach as we go into the implementation phase.

We do recognize, even at this stage, that it is going to be very different for a gauge user, who may not have even known, even if they use their materials safely, what safety culture is; whereas, nuclear power plants are testing pilots and to see how some of the traits that they think are important in a positive safety culture lay out.

So it will be very different for the

various stakeholders. And that is addressed in the revised statement, in the revised policy discussion, but it isn't actually included in the actual statement of policy because, as I said, as a third tier, that will be the next phase. And that is really where the most work is going to go.

I mean, this is a lot of work getting here. It's been two years because we have wanted to have stakeholder input. But, actually, when we proceed with implementation, that's where there will be the greatest amount of effort.

The third thing was about, as I mentioned, you know, using a policy statement to enforce something. And when we went back in this revised -- in the FR, we revised the policy statement, we did explain the difference between a policy statement, that it is not enforceable, that it is not a matter of compatibilities, that it reflects an area that is of extreme importance to the Commission over which they have jurisdiction, but it is not like a regulation where they can enforce it and they can use it in that manner.

And after we did that, actually, the comments that have come in have reflected the fact that people now are more aware of what we are doing

and why we are doing it. And they have for the most part still continued to say that they think that a policy statement is the right way to go.

Now, there are a few people that still believe that it has to be a regulation because that is the only way they can dedicate resources, but a predominant view is that this is a policy statement, this is the right way to go, and we should continue to do it that way.

The final thing that was a really big difference is that the Commission asked us to consider whether we should incorporate vendors and suppliers of safety-related components. And I guess most people responded that they thought that was a very good idea.

Why would you isolate this entity and say that they shouldn't be subject to considering the importance of safety culture in their activities? I mean, of course, the problem is that a lot of these are entities that are not under NRC's jurisdiction, but in the agreement states, although we have this strong relationship, they also have a different kind of an approach to this.

And we're not telling them they have to do it. We're trying to I guess lead by trying to develop this together. And so there will be no reason why you

would not want to include vendors and suppliers. But there will be implementation issues that will be very difficult that will have to be worked out in that implementation phase.

So that is pretty much how things have evolved. And before we go to brief the Commission on January 24th, there are other things that we will have to do. We have to evaluate the comments that have come in.

And there actually have been really some meaty comments that have come in this time. Before they were sort of general comments. These have gotten really much more to it. To me that indicates that people are really getting into this and they really want to make sure that we understand that as we are getting to this point of getting to a final policy statement, we understand where they are coming from and what is important to them. So I think that is going to be a very important part of this.

We are making presentations to you. And we are making a presentation at the ACRS because we are hoping to seek your endorsement on this. And then we are developing a SECY paper right now, which will contain the FRM, will have the policy statement. And that will be going to the Commission around January

18th.

And so that is pretty much where this is. It is still ongoing, but it is getting to the point where we are getting down to the final nitty-gritty we are going to be sending up to the Commission.

ACTING CHAIRMAN THOMADSEN: Thank you very much.

Comments from the Committee, questions? Dr. Zanzonico?

MEMBER ZANZONICO: I had sent in some written comments to the Committee.

ACTING CHAIRMAN THOMADSEN: Yes.

MEMBER ZANZONICO: So I will just express them here. One trait I thought would be useful to include explicitly is redundancy. I mean, I think that most people would agree that is a component of a safety program in any operation, checks, double checks, et cetera. And I think the value of including that explicitly as a trait is that, even though you said this is not a regulation, you did allude to the fact that regulations give you some leverage in your home institutions, where you have to expend funds to comply. And redundancy is just such a case.

I mean, if you buy an additional piece of equipment in the nuclear medicine setting, if you need

to buy a dose calibrator close to where you are going to do the injections and not just in a radiopharmacy, so that someone can now recheck an administered activity, I think having that trait explicitly included would be helpful in that regard. And I think that it is legitimately part of a safety culture.

The other comment I had with regard to the definition, where you allude to safety I think over other competing goals of the organization. And I think somehow that needs to be couched to allow for those competing goals that are safety.

I mean, the extreme example would be a firefighter. The last thing that is safe is to run into a burning building. But their goal is to safe life and property by running into a burning building.

There is not nearly as dramatic examples in a health care setting, but potentially there are. The demonstration or the example I cited was someone gets radionuclide therapy and they have some acute event and they require emergency surgery. Well, you're not going to not do the emergency surgery because the surgeon and the surgical staff are going to get a relatively large radiation dose from the procedure.

So I think somehow that should be

reflected, you know, in the unlikely event that someone would say, "Well, but the NRC says, you know, we should have a prevailing safety culture," et cetera, et cetera. So maybe you could be competing non-safety goals of an organization.

So those are my comments.

MS. SCHWARTZ: Thank you.

ACTING CHAIRMAN THOMADSEN: Thank you.

Dr. Fisher?

MEMBER FISHER: I think it's a good thing that the NRC has put this in as policy, rather than regulation, because the question I always have is, how do you measure it? What are quantitative measures of a safety policy? How do you know that one organization has it and another organization doesn't? And are there any definable quantities that help us better understand this concept?

MS. SCHWARTZ: Of course, that's a part of the reason that we developed the traits, because they are indicators. But I agree with you that, at this point at least, we haven't developed into a connotative.

I mean, one of the traits that we concluded was a environment where people trust each other. That would be very difficult to measure,

although if you walk into an environment where you know people don't trust each other, it becomes very obvious very quickly.

But if you were an inspector, you were doing that, how would you write that down? So I agree with this.

ACTING CHAIRMAN THOMADSEN: Dr. Guiberteau?

MEMBER GUIBERTEAU: I just have a question that sort of intrigued me in the Federal Register. And that was you listed the traits and then you sort of focused for a moment on what I guess I would call an anti-trait. And that was addressing the issue of complacency.

And it seemed to be, although it wasn't raised to any significant level, it seemed to appear a few times and seemed to be bothersome to those of you involved in this. And I'm just wondering how since that is a huge issue, sort of the elephant in the room, because if you're doing well, what else do you need to do? So I'm just wondering.

I think you asked the question, should this be addressed? Personally I think it does in some way, but I am just wondering how you are dealing with that.

MS. SCHWARTZ: I think that that was raised when the staff itself especially was reviewing literature. And a lot of the literature reviews point to complacency as a real problem because when you are doing really well, it is so easy to say, you know, "Why mess things up? We're going great. We have great reviews. Everybody loves us."

I think that one of the ways that may address this is by adding a ninth trait, called questioning attitude, which we feel would then address because if you have a questioning attitude, it sort of combats the idea that everything is going great, so never ask any more questions.

I agree with you that it is sort of the flip of the other traits. So it was added as a thought because we do feel some kind of complacency needs to be addressed somehow in the policy.

MEMBER GUIBERTEAU: I guess I am casting my comment that I think it needs to be addressed.

MS. THOMPSON: Public comments?

ACTING CHAIRMAN THOMADSEN: Dr. Mattmuller?

MEMBER MATTMULLER: I did attend remotely the February workshop. And I caution to you, ma'am, that be careful what you ask for because this is a

difficult process. With the time delay, it makes it very hard to actually participate in their time.

MS. SCHWARTZ: Do you mean the September one when you were --

MEMBER MATTMULLER: No. The February.

MS. SCHWARTZ: Oh, okay. Because you're in a different time zone.

MEMBER MATTMULLER: Yes. Or she's thinking ahead or -- I'm sorry. Not a safety culture but a different workshop.

I know that in the February workshop, there was a representative from the Joint Commission. And from a medical perspective, this was heavily represented by -- the Joint Commission I know has worked on this issue diligently over many, many years, 20 years or so. I can remember some of the first attempts. And so I think they have really got it down pretty good for health care facilities.

So I guess my only question would be for you is not to design something that mucks up their efforts because I think we are in pretty good shape. And it was my impression from everything I have read and participate in that it's the nuclear power plants that need a little bit more help and guidance, which I would agree with.

But in terms of health care, medical care, in terms of safety culture, I think we are in pretty good shape.

MS. SCHWARTZ: I mean, I think that that is a good point. We don't want to be mucking up what other people have already started. We wouldn't even want to muck up what we have been starting internally because we have been working very hard towards a safety culture internally as well.

And I think that any organization that started to focus on it and started to work towards it, we certainly don't want to impede those efforts because they are important and they come from the organization itself. So they do reflect what that organization really holds dear.

Luckily, as you said, there was a representative from the Joint Commission. So the definition that we developed did take -- you know, there was an alignment of all of -- and there was given and take on the part of all of the members.

And it was very impressive to me. I had never seen -- I mean, INPO, which had developed these principles, was willing to stand back and say, "You know what? If this is what the group really thinks is important, you know that is what resonates with them,

then we need to step back and look at that."

I was very impressed with that. There was no ego involved. And it was a really amazing process. And so in that spirit, going forward, we still want to keep that in mind.

ACTING CHAIRMAN THOMADSEN: Any other comments? Yes?

MR. LEWIS: NRC, the staff?

MR. FIRTH: If I could add something? James Firth, NRC staff.

We did get three comments from ACMUI members. So we appreciate those. We just wanted to come in here with a copy of the revised draft policy statement. As Kitty and Maria mentioned earlier, once we get to a final, draft final, policy statement, we will be providing it to both of the advisory committees in terms of the ACRS and ACMUI.

We wanted to meet here in this meeting because of the way the timing is working, that by the time that is complete, we are not, the Committee is not, going to be meeting, but I understand there is a chance the Committee may be either meeting by teleconference or might otherwise be able to look at the draft final policy statement.

So we would be interested in either

comments or an endorsement on the policy statement.

ACTING CHAIRMAN THOMADSEN: And we certainly can, yes.

Further comments? Yes?

MEMBER ZANZONICO: So do you ultimately want a formal endorsement from the Committee?

MS. SCHWARTZ: That would be very nice.

ACTING CHAIRMAN THOMADSEN: Ms. Cockerham?

MS. COCKERHAM: To kind of address that, what I talked to James Firth and people within our office about was adding this to that December teleconference that we have already planned so that you have some time to look at the draft that they have provided us so far.

And I think the timing works out about the time that this is going to ACRS. You guys could be looking at this in very early December and they could still meet their January deadline. So you will have more time to look over this and review it. And we would expect that you can endorse it at the December teleconference if that --

MEMBER ZANZONICO: If we get it in time.

MS. COCKERHAM: Well, yes. It's out.

ACTING CHAIRMAN THOMADSEN: Is it? I thought you were coming up with another draft.

MS. SCHWARTZ: Well, there is going to be a final.

MS. COCKERHAM: There will be a final, but you have the draft already.

MS. SCHWARTZ: If you have the revised, that's the --

MS. COCKERHAM: Which is what you commented on. I had comments from three of the members.

MEMBER LANGHORST: It's in our book?

MS. COCKERHAM: It's not in your book.

ACTING CHAIRMAN THOMADSEN: No. We got it electronically.

MS. COCKERHAM: Yes. It was sent electronically.

MS. THOMPSON: We have additional copies if anybody --

MS. COCKERHAM: Sure. Yes. Pass those around.

MR. LEWIS: I guess just for Dr. Zanzonico's comment about endorsement, you know, we would certainly love to have endorsement, but what we're asking, I think we can only ask for the Committee to do is advise us on any policy or technical implications you see for the medical

industry.

ACTING CHAIRMAN THOMADSEN: Thank you very much.

MS. SCHWARTZ: Thank you.

ACTING CHAIRMAN THOMADSEN: And, Ashley, you're up.

24. ADMINISTRATIVE CLOSING

MS. COCKERHAM: What is coming around right now are the recommendations that you made at this meeting. So we'll go over all of those as soon as everybody has a copy.

And while you are waiting for that, I know most of you have met Sophie Holiday. And she is going to be more involved in ACMUI stuff and is definitely going to be helping. So if you see e-mails from her, consider them from me. I'll probably be on cc.

MEMBER LANGHORST: I don't know. Those are big shoes.

MS. COCKERHAM: So we'll be working together a lot in the next few months to handle all of the Committee activities. Chris, could you grab those copies so they don't stop? And there should be one for you as well. And there should be several for the public.

Okay. So if everybody has one, we will

start with item number 9. And it was ACMUI endorses the Permanent Implant Brachytherapy Subcommittee report with the caveat that this is an interim report that may be revised in the future to consider additional input, such as that received from stakeholders at public workshops.

I don't think that is verbatim what you said during the meeting, but does that capture what you wanted? Yes? I'm seeing nods. Okay. Then we'll use that as the recommendation.

For item 10, ACMUI endorses the draft version of FSME policy and procedures 2-5, revision 0 presented at the meeting. Any issues there?

(No response.)

MS. COCKERHAM: Okay. Move on to item 11. Dr. Thomadsen created a subcommittee to prepare a document --

ACTING CHAIRMAN THOMADSEN: I'm sorry?

MEMBER GILLEY: No. Go ahead. I'm going to just say something when you get through.

MS. COCKERHAM: Okay. Dr. Thomadsen created a subcommittee to prepare a document to guide the December discussion on 10 CFR part 35. That should actually read part 37.

Is that what your comment is? Okay. I'm

with you. Can you hand me that pen right next to you?

MEMBER GUIBERTEAU: You won't take that on, too?

(Laughter.)

MS. COCKERHAM: No thank you. Okay. So part 35 will read part 37.

MEMBER GILLEY: That would be a full-time job.

MS. COCKERHAM: All right. So that will be 37. So Debbie is the chair. Sue Langhorst and Darrell Fisher will also be helping out with that document.

ACMUI will incorporate -- this is item 12. ACMUI will incorporate the comments made during the meeting to revise the Patient Release Subcommittee report. The Committee will vote to finalize the report via e-mail and will resubmit it to NRC in the near future. All right.

Next slide on number 13. You may have to correct me on this one, but I think that Steve Mattmuller and Bruce Thomadsen offered to provide support to respond to the letter dated October 20th, 2010 to Chairman Jaczko from Congressman Markey regarding patient release.

MEMBER MATTMULLER: We were able to

recruit another eager volunteer, --

MS. COCKERHAM: Okay.

MEMBER MATTMULLER: -- Susan Langhorst.

MS. COCKERHAM: Sue, you are in on that, too?

MEMBER LANGHORST: Yes.

MS. COCKERHAM: Are you waving the white flag?

MEMBER MATTMULLER: I did say eager.

MS. COCKERHAM: Okay. So we'll add Sue's name to that. And I will be in touch with you guys next week to move on that.

Item 14, ACMUI planned a teleconference to discuss 10 CFR part 37 rulemaking and safety culture on Monday, December 13th, 2010 from 1:00 p.m. to 3:00 p.m. Eastern time. The backup time and date are Wednesday, December 15th, 2010 from 11:00 a.m. to 1:00 p.m. Eastern time. Sound good?

(No response.)

MS. COCKERHAM: Okay. That takes care of the meeting summary. For the next meeting, obviously the next meeting will really be in December with that teleconference. For April and May, if you will turn to tab 23? You should have a calendar in there.

ACTING CHAIRMAN THOMADSEN: We got pretty

much feedback about they do what they do without compromising safety. I think it's pretty hard.

Okay. Let's see.

MS. COCKERHAM: Tab 23.

ACTING CHAIRMAN THOMADSEN: Yes.

MS. COCKERHAM: It's good to narrow the dates out a little bit further. If you want to put X's on April 13th, 14th, 15th, and then flip to May and cross out the 23rd, 24th, and 25th?

MEMBER GILLEY: Wow. The week of May 9th? Say that again, Ashley.

MS. COCKERHAM: April 13th, 14th, and 15th.

MEMBER GILLEY: And the May?

MS. COCKERHAM: Twenty-third, 24th, and 25th. So our options are extremely limited. Any preference for April versus May? We can start there.

ACTING CHAIRMAN THOMADSEN: April.

MS. COCKERHAM: April? Okay. So April 11th and 12th or 27th and 28th? Any conflicts with those or preference for earlier/later? One is a Monday-Tuesday. The other is a Wednesday-Thursday.

MEMBER ZANZONICO: Would it be easier for most people traveling on Sunday or --

MEMBER MATTMULLER: Yes.

MS. COCKERHAM: So the Sunday gets the long travelers a day that is not totally away for the office? Okay. So April 11th and 12th can be the first choice. Do you want to take a later --

ACTING CHAIRMAN THOMADSEN: Checking the holidays.

MS. COCKERHAM: Are you checking a calendar? Okay.

MEMBER LANGHORST: I'm checking holidays.

MS. COCKERHAM: Is it Passover holiday, Dr. Thomadsen?

ACTING CHAIRMAN THOMADSEN: Purim, which I don't -- oh, here we go. Sunday, the 20th. So that seems to be April 20th.

MS. COCKERHAM: Are you in 2010 or 2011?

ACTING CHAIRMAN THOMADSEN: '11.

MEMBER GUIBERTEAU: Easter is the 24th.

MS. COCKERHAM: Yes. That's on --

ACTING CHAIRMAN THOMADSEN: We're in 2011. Oh, March. Okay. So that's a completely wrong month.

MS. COCKERHAM: Okay.

ACTING CHAIRMAN THOMADSEN: So yes. That's fine. Yes.

MS. COCKERHAM: For an alternate date, do you want to stick with the April or do you guys want

to pick a date in May as the alternate date?

MEMBER ZANZONICO: There's really not much in April.

MEMBER GILLEY: How about May 9th and 10th as an alternate date?

MS. COCKERHAM: Okay. May 9th and 10th? Conflicts there?

(No response.)

MS. COCKERHAM: All right. So those will be our backup dates. So first choice, April 11th and 12th, which is a Monday-Tuesday. Backup date May 9th and 10th, which is also a Monday-Tuesday. Okay? That takes care of that.

Next item on my list is financial disclosure forms. I have them back from most of you. If you have not turned it in, if you can get it to me today, great. If not, I will send you an e-mail with the address for you to mail it to our Office of General Counsel. And if you could get those in next week, that would be greatly appreciated.

All right. The next one is time and attendance. If you want to complete your form, I have blank forms here if you want to complete it and give it back to me, go ahead. If not, you can turn it in tomorrow. You will need to send an e-mail to Shayla

tomorrow morning or tomorrow I guess as soon as you get home or know your hours. Let her know. But if you fill out the hard copy here, we won't really need an e-mail. I will give her this information today. So I will pass these around. You all have to complete one.

And then the next thing is you will be getting an e-mail with a form. I've drawn a blank right now.

ACTING CHAIRMAN THOMADSEN: Sixty-four?

MS. COCKERHAM: Sixty-four.

ACTING CHAIRMAN THOMADSEN: Sixty-four.

MS. COCKERHAM: Sixty-four. You're right, yes. And it will be your travel voucher form. So you will need to complete those to claim expenses for this meeting. And you will probably get that e-mail next week. You will have a week or so to get that done and send the information.

You are going to mail everything back to Sophie. And she will double check it and then submit it so you can get all of your money back. So that will be coming next week.

And the last thing I have is to take off your name tags and set them on the table.

ACTING CHAIRMAN THOMADSEN: One question,

one quick question, for you.

MS. COCKERHAM: Yes?

ACTING CHAIRMAN THOMADSEN: At this time of day, is it getter to take a cab or the Metro to --

MR. LEWIS: Which airport?

ACTING CHAIRMAN THOMADSEN: What's that?

MR. LEWIS: Which airport?

ACTING CHAIRMAN THOMADSEN: National.

MR. LEWIS: Metro. Well, thank you, everybody. This has been a very good meeting.

(Whereupon, the foregoing matter was concluded at 4:40 p.m.)