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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE

MEDICAL USES OF ISOTOPES

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TELECONFERENCE

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MONDAY,

DECEMBER 13, 2010

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The meeting was convened, at 1:00 p.m. Eastern Standard Time, Leon S. Malmud, M.D., ACMUI Chairman, presiding.

MEMBERS PRESENT:

LEON S. MALMUD, M.D., Chairman

BRUCE THOMADSEN, Ph.D, Vice Chairman

DARRELL FISHER, Ph.D, Member

DEBBIE GILLEY, Member

MILTON GUIBERTEAU, M.D., Member

SUE LANGHORST, Ph.D, Member

STEVE MATTMULLER, Member

CHRISTOPHER PALESTRO, M.D., Member

JOHN SUH, M.D., Member

MEMBERS PRESENT (CONT'D):

ORHAN SULEIMAN, Ph.D., Member

WILLIAM VAN DECKER, M.D., Member

JAMES WELSH, M.D., Member

PAT ZANZONICO, Ph.D, Member

NRC STAFF PRESENT:

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

CHRISTIAN EINBERG, Designated Federal Officer

MICHAEL FULLER, Alternate Designated Federal Officer

NEELAM BHALLA

JAMES BIGGINS

ELVA BOWDEN BERRY

LISA DIMMICK

ASHLEY COCKERHAM, ACMUI Coordinator

JACQUELINE COOK

SAID DAIBES, Ph.D

JAMES FIRTH

CINDY FLANNERY

SARA FORSTER

SOPHIE HOLIDAY

DONNA BETH HOWE, Ph.D

PENNY LANZISERA

ED LOHR

GRETCHEN RIVERA-CAPELLA

NRC STAFF PRESENT (CONT'D):

MARIA SCHWARTZ

DIANE SIERACKI

DAVID SOLORIO

KATIE STREIT

CATHERINE THOMPSON, Ph.D

GLENDA VILLAMAR

DUANE WHITE

RONALD ZELAC, Ph.D

MEMBERS OF THE PUBLIC:

JAMES D. ALBRIGHT, NC Dept. of Environmental and Natural Resources

DAVID J. ALLARD, PA Dept. of Environmental Protection

CHRISTOFER ALSTON, Georgetown University Hospital

MAXWELL AMURAO, Georgetown University Hospital

SUE BUNNING, Society of Nuclear Medicine

ROBERT E. DANSEREAU, NYS Department of Health

WILLIAM DAVIDSON, University of Pennsylvania

DEIRDRE ELDER, University of Colorado Hospital

NANCY FARRINGTON, Iowa Department of Public Health

THOMAS HUSTON, Ph.D, Department of Veterans Affairs

KAREN LANGLEY, University of Utah

ANDREW MAUER, Nuclear Energy Institute

CANDI MCDOWELL, Georgetown University Hospital

HERB MOWER, Lahey

MEMBERS OF THE PUBLIC (CONT'D):

JOSEPH OCH, Geisinger Medical Center

MIKE PETERS, American College of Radiology

MELANIE RASMUSSON, Iowa Department of Public Health

GLORIA ROMANELLI, American College of Radiology

GEORGE SEGALL, M.D., Society of Nuclear Medicine

MICHAEL SHEETZ, University of Pittsburgh

CINDY TOMLINSON, American Society for Therapeutic Radiation and Oncology

RICHARD VETTER, Ph.D, Health Physics Society

MICHELLE WHITE, DMS Health Technologies

JENNA WILKES, Society of Nuclear Medicine

SANDY WOLFF, Sentara

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P R O C E E D I N G S

1:36 p.m.

MR. EINBERG: As the Designated Federal Officer for this meeting, I am pleased to welcome you to this public teleconference of the meeting of the Advisory Committee on the Medical Uses of Isotopes.

My name is Chris Einberg. I am the chief of the radioactive materials safety branch, and I have been designated as the Federal Officer for this Advisory Committee in accordance with 10 CFR part 7.11.

This is an announced meeting of the Committee. It is being held in accordance with the rules and regulations of the Federal Advisory Committee Act, and the Nuclear Regulatory Commission. The meeting was announced in the November 19th, 2010, edition of the Federal Register, Volume 75, Page 70955.

The function of the Committee is to advise the staff on issues and questions that arise from the medical use of byproduct materials. The Committee provides counsel to the staff, but does not determine or direct the actual decisions of the staff or the Commission.

The NRC solicits the views of the

Committee, and values their opinions. I request that whenever possible, we try to reach a consensus on issues that we will discuss today. But I also recognize that there may be, there may be minority or dissenting opinions.

If you have such opinions, please allow them to be read into the record. At this point, I would like to perform a roll call of the ACMUI participating today. Dr. Malmud, ACMUI Chairman, hospital administrator?

CHAIR MALMUD: Here.

MR. EINBERG: Dr. Bruce Thomadsen, Vice-Chairman, therapy medical physicist?

VICE CHAIR THOMADSEN: Here.

MR. EINBERG: Dr. Darrell Fisher, patients' rights advocate?

MEMBER FISHER: Here.

MR. EINBERG: Ms. Debbie Gilley, State Government representative?

MEMBER GILLEY: Here.

MR. EINBERG: Dr. Mickey Guiberteau, diagnostic radiologist?

MEMBER GUIBERTEAU: Here.

MR. EINBERG: Dr. Sue Langhorst, radiation safety officer?

MEMBER LANGHORST: Here.

MR. EINBERG: Mr. Steve Mattmuller, nuclear pharmacist?

MEMBER MATTMULLER: Here.

MR. EINBERG: Dr. Christopher Palestro, nuclear medicine physician?

MEMBER PALESTRO: Here.

MR. EINBERG: Dr. John Suh, radiation oncologist?

MEMBER SUH: Here.

MR. EINBERG: Dr. Orhan Suleiman, FDA representative?

(NO RESPONSE)

MR. EINBERG: Okay. Dr. William Van Decker, nuclear cardiologist?

(NO RESPONSE)

MR. EINBERG: Okay. Dr. James Welsh, radiation oncologist?

MEMBER WELSH: Here.

MR. EINBERG: Dr. Pat Zanzonico, nuclear medicine physicist?

MEMBER ZANZONICO: Here.

MR. EINBERG: Okay. We have a quorum, so we can start, or, proceed. I would also like to note that Dr. Guiberteau and Dr. Palestro do not have voting

privileges at this time, but they will listen and speak on behalf of the diagnostic radiologists, and the nuclear medicine physicians, respectfully.

I would now go around the table here, here at headquarters, and introduce the NRC staff members and, I'm Chris Einberg. I'm the Branch chief of the radioactive materials safety Branch, as I've said earlier.

MS. DIMMICK: Lisa Dimmick, licensing Branch.

MR. LOHR: Ed Lohr, rulemaking.

MR. BIGGINS: James Biggins, Office of general counsel, reactor and materials rulemaking.

MR. LEWIS: I'm Rob Lewis, Director for materials safety and state agreement.

MS. BHALLA: Neelam Bhalla, from rulemaking.

DR. HOWE: Dr. Donna Beth Howe, and I'm in the radioactive materials Branch.

MS. HOLIDAY: Sophie Holiday from the radioactive materials Branch.

MS.RIVERA-CAPELLA: Gretchen Rivera-Capella, radioactive materials safety Branch.

MR. EINBERG: Okay. Well, also, do we have anybody from the NRC headquarters on the phone? I know

we have Ashley Cockerham, do we have anybody else?

DR. DAIBES: Yes, Said is here, as well. Said Daibes here from headquarters.

MR. EINBERG: Okay.

DR. ZELAC: Also, Dr. Ron Zelac, medical radiation safety team.

MR. EINBERG: Okay, thank you.

MS. COCKERHAM: Guys, this is just confirming I'm on the line. This is Ashley.

MR. EINBERG: Thank you.

MS. FLANNERY: Cindy Flannery, FSME.

MR. EINBERG: Thank you. Anybody else from headquarters? Okay. Nobody else from headquarters. Now, I'd like to go to Region 1. Can Region 1 identify who is participating, please?

MS. LANZISERA: Penny Lanzisera, from Region 1.

MR. EINBERG: Penny, are you there by yourself, or, anybody else with you?

MS. VILLAMAR: I am. This is Glenda. I just signed in.

MR. EINBERG: Okay. Thanks, Glenda. Okay, I'd like to go to Region 3 now. Region 3, do we have any, anybody on the line?

MS. STREIT: This is Katie Streit with

Region 3.

MR. EINBERG: Okay. Anybody else from Region 3? Okay. Let's go to Region 4 now. Who's on the line from Region 4?

MS. COOK: Jackie Cook from Region 4.

MR. EINBERG: Thank you. Okay. Next, we, we will identify members of the public who notified us that they will be participating with the teleconference. When I call your name, please answer. Let me go through that list. James Albright?

MR. ALBRIGHT: I'm here, thank you very much.

MR. EINBERG: Very good, thank you. And Dave Allard, Pennsylvania Department of Environmental Protection?

MR. Allard: Yes, I'm here.

MR. EINBERG: Okay, thank you. Chris-- Christofer Alston, Georgetown University hospital?

MR. Alston: Here.

MR. EINBERG: Okay, and Maxwell Amurao, Georgetown University hospital as well?

MR. AMURAO: Yes.

MR. EINBERG: Sue Bunning, from SNM?

MS. BUNNING: I'm here.

MR. EINBERG: Randy Dahlin, Iowa Department

of Public Health?

(NO RESPONSE)

MR. EINBERG: Robert Dansereau, New York State Department of Health?

MR. DANSEREAU: I'm here.

MR. EINBERG: William Davidson, University of Pennsylvania?

MR. DAVIDSON: Here.

MR. EINBERG: Deirdre Elder, University of Colorado Hospital?

MS. ELDER: Here.

MR. EINBERG: Nancy Farrington, Iowa Department of Public Health?

MS. FARRINGTON: Here.

MR. EINBERG: Dr. Michael Hagan, Department of Veteran's Affairs?

(NO RESPONSE)

MR. EINBERG: Dr. Thomas Huston, Department of Veteran's Affairs?

DR. HUSTON: Here.

MR. EINBERG: Karen Langley, University of Utah?

MS. LANGLEY: Here.

MR. EINBERG: Dr. Edward Maher, HPS?

(NO RESPONSE)

MR. EINBERG: Andrew Mauer, NEI?

MR. MAUER: Here.

MR. EINBERG: Candi McDowell, Georgetown University Hospital?

MS. MCDOWELL: Here.

MR. EINBERG: Janette Merrill, Society of Nuclear Medicine?

(NO RESPONSE)

MR. EINBERG: Janette Merrill, Society of Nuclear Medicine?

(NO RESPONSE)

MR. EINBERG: Herb Mower, Lahey?

MR. MOWER: Here.

MR. EINBERG: Joseph Och--Och?

MR. OCH: Here.

MR. EINBERG: Was that a yes, here?

MR. OCH: Here.

MR. EINBERG: Yes, okay. Melanie Rasmusson?

MS. RASMUSSON: Here.

MR. EINBERG: Dr. George Segall?

DR. SEGALL: Here.

MR. EINBERG: Michael Sheetz?

MR. SHEETZ: Here.

MR. EINBERG: David Switzer? Minneapolis

Radiation Oncology?

(NO RESPONSE)

MR. EINBERG: Cindy Tomlinson?

MS. TOMLINSON: Here.

MR. EINBERG: Dr. Richard Vetter?

DR. VETTER: Here.

MR. EINBERG: Gerald A. White?

(NO RESPONSE)

MR. EINBERG: Michelle White?

MS. WHITE: Here.

MR. EINBERG: Jenna Wilkes?

MS. WILKES: Here.

MR. EINBERG: And, Sandy Wolff.

MS. WOLFF: I am here.

MR. EINBERG: Very good. We have another person who joined us also. Can you please identify yourself?

MS. BOWDEN BERRY: I'm Elva Bowden Berry, and I'm from OGC.

MR. EINBERG: Okay, thank you.

MS. ROMANELLI: Gloria Romanelli with ACR, as well.

MR. EINBERG: Okay. Thank you. Is there anybody else who we didn't call?

MEMBER SULEIMAN: Yes, Orhan Suleiman, I'm

with the ACMUI and FDA Center for drugs.

MR. EINBERG: Okay, thanks for joining us, Orhan. This is, double check--do we have Dr. Van Decker on the line? We do not. At this time, I ask that everyone on the call who is not speaking to place their phones on mute or pause. If you do not have the capability to mute your phone, press star-6 to utilize the conference line mute and unmute functions.

I would ask everyone to exercise extreme care to ensure that the background noise is kept to a minimum as any strange background sounds can be very disruptive on conference calls this large.

Following a discussion of each agenda item, the ACMUI chairperson, Dr. Leon Malmud, at his option, may entertain comments or questions from members of the public who are participating with us today.

And, at this point, I'd like to turn the meeting over to Rob Lewis. He has a few opening statements before he turns it over to Dr. Malmud.

MR. LEWIS: Thank you, Chris. Thank you everyone for participating. I will keep this very short. There's four topics on today's agenda. Our first is trying to improve our interactions with the Committee between the Committee and the NRC staff,

something we always need to focus on.

Also, we have an extended discussion on patient release issues. Our Part 37 Rulemaking, which is our new regulation to have security requirements for sources of radioactive materials. And last we have a discussion on, ongoing discussion on our safety culture policy statement.

Those are four issues for which we are very eager to collect the Committee's views so we can move those forward within NRC. So, so I won't speak much longer. I just wanted to mention, since it is a phone call, please be mindful to identify yourself when you speak. It's a little more difficult to manage especially for the transcriber than the, typical meeting.

And also, one management change here of note. Since the Committee last met, Cindy Carpenter, who is the Deputy Office Director under Charlie Miller, has gone to do a special project for another, for the EDO within the agency, the Executive Director of Operations, and that project is focused on reducing the NRC's overhead and budget space.

So, she'll be gone doing that for at least six months. It's an agency wide project, and back filling for her during that time is Mr. Scott Moore,

who many of you may remember came from NMSS. His current full time job is the Deputy Director for NRC's Office of International Programs, but at least for the next six months, he'll be the Deputy Office Director here in FSME.

So, with that, I will turn the meeting over to Dr. Malmud. And, and thank you very much.

CHAIR MALMUD: Thank you, Rob. This is Leon Malmud. I was introduced, first item on the agenda is that of the NRC interactions with staff for major medical policy. In plain English, it really is an opportunity to express our thoughts about how we, the ACMUI, interact with NRC.

In the past, there were some very constructive comments made regarding ways of improving that interaction, and currently, the, some of the problems that existed then have been resolved. However, this is an opportunity for those of us currently on the Committee to express our feelings and make recommendations regarding ways in which the communication can be improved.

So, rather than introducing it myself, I would invite any Member of the Committee to open the discussion, if he or she wishes to. If not, I'll open the discussion.

VICE CHAIR THOMADSEN: I think that--this is Bruce Thomadsen. I had been involved with coordinating some work on the official policy that would guide the relation between the Committee and the NRC staff.

The members of the Committee have looked at the policy and have commented, I believe, that all of the communication about this have been made available and there has been a document that incorporates all of the comments from the Committee that we would propose sending to the NRC staff on formalizing the arrangement.

CHAIR MALMUD: Malmud again. Thank you, Bruce. That document was emailed, I believe, to all the members of the Committee. Is there anyone on the Committee who has not received it?

(NO RESPONSE)

CHAIR MALMUD: Hearing no response, I assume that everyone has received it. I would like to therefore follow up on Bruce's comments and the email with the following. I, I have met, following the last meeting, I, which I could not remain at due to a short term illness, I had the opportunity to meet with the Commissioners.

I met with three and one staff person. I

would make the following comments. Number one, the Commissioners are very well informed about what we're discussing within ACMUI. I was quite frankly surprised that they were as knowledgeable as they are, considering the breadth of their portfolios.

But, they are well informed. They also appreciate the work that the ACMUI does, and feel that if we are concerned about getting the message that we wish to get to them, delivered, more promptly and perhaps more effectively, that they are, they remain available for direct meetings with me as the Chairman or any subsequent Chairmen in order to effect that.

The, the issues that I raised with them were several. The first, of course, was that the ACMUI has felt that when we make a recommendation, and it isn't adopted, that we would appreciate knowing why it wasn't adopted and hearing about it in a timely fashion.

A lot of effort goes into our recommendations. They are often discussed over the period of a year or more at our biannual meetings and therefore there is a sensitivity with respect to whether or not the advice is accepted. Clearly, we do not assume the responsibility for the final decision, the Commissioners do.

But we would like to know why recommendations that were not accepted were rejected. We are satisfied, I believe I spoke on behalf of the Committee, that we are satisfied in knowing why, when the Committee, when the Commissioners choose to accept a recommendation from us. It's the ones where we differ that we seem to have a need for more feedback.

That was one issue. The other issues that were raised had to do with the staffing of the ACMUI and the feelings of some of the Committee members that we might be better off reporting in a more direct line than, as the Committee, we are. I discussed this with each of the Commissioners, and they are interested in hearing more about it from us.

I think that there are some realities which I brought up to them and which they did not deny existed, and that is that it would be more costly, certainly, to staff up in the way another body does. And, it would be more costly for us to have fixed conference rooms dedicated just for us, which was one of the requests which had come from some of the Committee members, who I believe have subsequently rotated off of the Committee.

And therefore, in this, in the current budget mood of the entire country, adding expenses is

probably not something that would finally be approved, but they were not negative about hearing our concerns. The turnaround time if we used a method similar to the ACRS, would not be improved.

I, I--perhaps I shouldn't use the term improved. It would not be very different from the turnaround time now, and that has to do with the frequency with which we meet, as well as the need to go through staff. So, that, I'm not certain that the concerns about turnaround time would be met by changing us to a reporting mechanism similar to ACRS.

I did say, and I think I spoke for all of us, I, I did say very strongly that we do feel that the ACMUI needs more staff, that it's been my pattern, since I've been Chair, to delegate most discussions to subcommittees, and these subcommittees do extraordinary amounts of work with most of the work being done by the members of the ACMUI, with the need for more support staff.

Currently, our support person, at least, the person we look to for our support, is Ashley, who seems to be omnipresent and an extraordinary individual who is, who handles perhaps more work than we've ever asked any other person in her position to handle, and she does it.

But it's quite clear to us that the subcommittees need some more staff support in producing their documents, particularly, I said that this might be addressed by even having someone to assist with email communications, since we don't have that now.

The--those were the major issues. The, the feelings of the Commissioners are very supportive of us, they are very appreciated of the work that we do, and I would ask for comments from members of the Committee at this point.

So, I discussed the ACMUI recommendations, and our concern about hearing back when they're not accepted. I discussed the turnaround time, the support staff, and the concern that at least one or two of the previous members of the Committee had that our recommendations were quote, filtered, end quote, before reaching the Commissioners.

I must tell you that from my initial conversation which each of them--with each of them, I did not have the feeling that anything has been filtered. They seemed extraordinarily well informed. I am therefore inviting comments from members of the ACMUI.

DR. ZANZONICO: Well, this is Pat

Zanzonico. I was glad to hear, Dr. Malmud, about your opportunity for direct communications with the, with the Commissioners and the only suggestion I had, and I think I had communicated this previously over the draft document is if that could be incorporated formally into that document, that, that a mechanism exists or is available for direct communication between the ACMUI, whether it's through the Chair or otherwise, with the Commissioners. That kind of formal inclusion of that variability doesn't seem to be incorporated into the draft of the policy.

CHAIR MALMUD: Thank you. We certainly could include that, if you wish. We do have the opportunity now, already, for a, I think they call it a drop in, and I've been invited to do a drop in again whenever we feel a sense of urgency about something. From my perspective, I, I'm hesitant to drop in on a Commissioner with something that the ACMUI itself has not reached some sort of a consensus about.

I don't believe that we will, that the members of the ACMUI in total, because of the diversity of the Committee and our own parochial view of things- though we all agree about our mission- that we'll ever be necessarily unanimous in anything. But I am hesitant to bring to the Commissioners something

that we haven't fully discussed.

However, if we've fully discussed it, it's quite clear to me that I, I would, I would be comfortable bringing it to them and they would be, they would be receptive to one or several of the Commissioners giving us audience. I would ask a member of the NRC staff if my interpretation of my meetings was, is pretty correct or not.

MS. BHALLA: Yes. Dr. Malmud, this is Neelam Bhalla from NRC.

CHAIR MALMUD: Yes.

MS. BHALLA: The, what happened was, back in July when Commission had a meeting, a briefing on the ME Rule, as part of that, that meeting, the Commission directed the staff--the Commission directed the staff to prepare internal staff guidance, actually a procedure whereby we would convey to the Commission ACMUI's views including dissenting views on major, major medical policy issues and rulemaking, including rulemaking.

So, we have the procedure that has been provided, actually provided to all the members is actually the procedure which, which is an attempt to do just that, where we would be, whenever we send something to the Commission, maybe a rulemaking on

other policy issues where we are looking for Commission direction, that we do include ACMUI's views on that, including dissenting views, if any.

So, in October, we have provided the draft guidance and, at that time, the procedure was endorsed by the ACMUI. And as it moved up the chain here, after October, we were asked to put a few clarifications in there, specifically what determines or what makes a major policy issue.

So, in that, we made the change to the document and then we also discussed a little bit about the predecisional nature of the document and how we can make it for ACMUI for potentially make it, you know, a publically available document because there are procedural issues involved.

So, right now, what the Committee, what you have in front, or with you is this revised version of the draft, and we are looking for, for ACMUI to endorse it. This is precisely, you know, the, the procedure that we'll be using, where we would be conveying to the Commission ACMUI's views and how staff is going to, if we took them in, or if we didn't, then what's the reason that we didn't.

CHAIR MALMUD: Thank you. You're correct, of course. The term that I had used in my discussions

with the Commissioners was that we would submit a minority report as well, in those instances in which the Committee was, was not unanimous in it's recommendation, so that those on the Committee who, who had a minority opinion would have the opportunity to have it seen, although it was not the majority vote.

The issue that, that I have on behalf of the ACMUI is this. When we do something in the Subcommittee, it is not official until it's presented to the Committee in a public meeting. And therefore, I am concerned about discussing issues that have not yet been fully discussed at ACMUI in a formal public meeting.

Because, the Subcommittee report, though it's where a good bit of the work is done, is still not officially presented until it’s at a full meeting with the public--in a public forum. But, having said that, the document that was prepared I think covers the, the concerns that I had heard from the members of the Committee.

And what I am asking at this moment is, is there anyone on the Committee who feels that the document does not sufficiently incorporate the concerns that have been discussed? I'm presenting the

question to the members of the Committee.

MEMBER LANGHORST: Dr. Malmud, this is Sue Langhorst.

CHAIR MALMUD: Yes?

MEMBER LANGHORST: I don't have a concern about that but I do have a question on how we bring our opinion that, that we would like to voice on a certain issue that maybe has not been identified or presented to us by the NRC.

And, and I'm thinking, it's very obvious that Part 35 rulemaking comes to us. That just has, you know, little question to it. But, if there are issues that are in Part 20, or for instance, in part--the proposed Part 37 that we're going to be discussing here soon, how do we--how's the best way for us to--to you and the NRC staff that we would like to weigh in on, on certain topics?

CHAIR MALMUD: Thank you for the question. The way that I would approach it, and I'll, I'll ask a parliamentarian or someone from legal to confirm this, would be for any Member of the Committee to bring it before the public meeting of the Committee and request that it be brought before the Commission in some fashion.

At which point, it would have been

expressed publically and the Committee would make comments about it and then we would or would not take it forward according to the wishes of the Committee.

MR. LEWIS: Dr. Malmud, if I could. It's Rob Lewis.

CHAIR MALMUD: Yes, please, Rob.

MR. LEWIS: I would agree 100% with everything that you just said, although I'm certainly not from legal department. But, but I think that also if there's any, any issue that someone feel strongly about, please raise it immediately, especially if it's a safety concern.

Because, we can get working on it, the NRC staff, especially if we don't yet have a full Committee meeting to bring--bring the issue to. Well, we would bring it to the Committee eventually but we shouldn't sit out for six months, for example, on a, on a big issue.

So, we do look for the Committee members to bring those up to us just as we would any other licensee and, and the process is simple. Just email Ashley or, or me or any one of our staff here and we'll get it in the process.

The second thing I would like to raise in that regard, if it's an issue, and I want to reiterate

because there's several members of the, of the Committee that are new. I want to reiterate something that I promised several times, and, and also that Charlie Miller feels very strongly about, and he promised when he had my position, is that if there is ever any issue that the Committee or even some sub-part of the Committee feels that the Commission needs to know about, we have an open door.

We can--you can just write up the issue and send it in, and we have several very vehicles to get that before the Commission for information very quickly. And that--and again, that's an open invitation to do that. As Dr. Malmud said, every issue doesn't need to go to the Commission, so we may certainly want to talk to you a little bit and make sure your feelings are understood, your, your views are understood.

And, and that it's appropriate to go to the Commission at, at a certain time. But at the end of the day, the call would be the Committee members. And, and that also, that promise also goes for any meeting. If, if a, if a Committee Member is going to be in town and, and feels the need to meet with a Commission or a Commissioner, we're very happy to set those up.

NRC staff wouldn't be further involved beyond just setting them up. And the third option that the Committee always has at it's disposal, and that, and this comes up in a couple of instances in the past, is the Committee can, can certainly write a letter to the Commission, the Chairman and the Commission.

And, and that's come up in the past, and that is always a vehicle open. That of course has to happen in, in the letter writing session has to be part of the public ACMUI meeting to follow the FACA requirements. But, but that's very, we're very familiar with that process. The ACRS does that all the time.

So, so if that's ever something that someone wants to pursue, or any particular issue that anybody wants to pursue, that, the right time to interject it, as, as Dr. Malmud said, is during the agenda planning, right before each meeting. But, but certainly don't wait until then if it's a big issue. Thank you.

CHAIR MALMUD: Thank you, Mr. Lewis. Does that address the concern that you've raised?

MEMBER LANGHORST: That helps me greatly, and, and as one of those newer members, that, that

helps me have the process a little bit better in my mind.

CHAIR MALMUD: Thank you. I think that there, there are really two parallel issues. One is, a matter of bringing a subject that's been discussed within the Committee before the Commissioners, and the other one is the recognition on the part of anyone in ACMUI of a potential risk to patients or members of the public that needs to be addressed immediately.

And that should, to NRC staff, immediately. It does not require a process other than bringing it to their attention if it's an issue of either patient or public safety. Or security, for that matter, since we now have other issues to be concerned about.

By the way, I, I neglected to mention that I also expressed our concern to the Commissioners about the issue of fingerprinting and a new security regulations which are going to be costly for institutions. However, these, these issues are governed by Homeland Security and not directly by the NRC.

But I did express the frustration and concerns of the members of the Committee. Is there a motion to approve the document that's been prepared

and distributed to you by email?

VICE CHAIR THOMADSEN: Mr. Chairman, Bruce Thomadsen. I make that motion.

CHAIR MALMUD: Is there a second to Dr. Thomadsen's recommendation?

MEMBER GILLEY: Debbie Gilley. Second.

CHAIR MALMUD: Thank you. Is there further discussion?

MEMBER MATTMULLER: Yes. This is Steve Mattmuller. We're discussing, or, preparing to vote on the document that Bruce edited and circulated?

CHAIR MALMUD: That's correct.

MEMBER MATTMULLER: Okay. Great.

CHAIR MALMUD: Is there further discussion of the document, or the need, or a concern about appending it in any fashion? If not, all in favor?

MEMBER: Aye.

MEMBER: Aye.

MEMBER: Aye.

MEMBER: Aye.

MEMBER: Aye.

MEMBER: Aye.

MEMBER: Aye.

MEMBER: Aye.

MEMBER: Aye.

CHAIR MALMUD: Any opposed?

(NO RESPONSE)

CHAIR MALMUD: Any abstentions?

(NO RESPONSE)

CHAIR MALMUD: It passes unanimously. Thank you. With that, we'll move onto item number two, if that's acceptable. And item number two is the patient release following I-131 therapy for thyroid doses.

MEMBER LANGHORST: I'll take that on. This is Sue Langhorst.

CHAIR MALMUD: Thank you.

MEMBER LANGHORST: First off, I, I do want to say that it is the report, it concerns patient release in general, and not just limited to I-131 therapy. However, that was one instance that we focused upon, so the, it should be patient release report.

CHAIR MALMUD: Thank you.

MEMBER LANGHORST: First off, I want to thank all for the Subcommittee members, especially for their patience, as we did some reworking of the report following our presentation of it at the October meeting and following discussions, great discussions, in, with the Commissioners.

One issue that came up during the October

discussion, which was somewhat surprising to me, was the confusion over whether the current 10 CFR 35.75 criteria was on a per release or per year basis. As a result of that, of that identification and especially the, my understanding that there was confusion over this, we re-reviewed the final rulemaking notice for the current part 35.75 criteria.

And, added much more reference to that in our report. When you read the final rulemaking in that January 29th, 1998 final rulemaking, it is clear that the current 35.75 Rule is on a per release basis. Confusion I think may have come up with the release of the regulatory issue summary 2008/07 that was issued in March of 2008, that said that NRC had met that criteria to be on a per year basis.

And the NRC staff considered, or, or commented at the Commission hearing, that they believed the current Rule was on a per year dose limit. After that discussion and, and Dr. Thomadsen very wisely suggested that we take some of the comments that we heard in October and do some rework on our report, we determined that even in our Subcommittee's opinion at that point in time that there was a 50-50 split in really what the current Rule meant.

And, our Subcommittee came to conclusion that the basis for the per release limit should not be changed from that final rulemaking document notice without further rulemaking and public discussion. We also discussed that we, what our current opinion was, and that the vast majority of us believe that the current 35.75 release criteria should remain as a per release limit.

We did have one dissenting vote in our Subcommittee who felt that an annual--that a dose limit without a time frame was not appropriate, but felt that if any discussion were to happen with a per year dose limit for release criteria that the amount of dose, the dose limit itself, should be discussed and perhaps, increased.

So, that discussion was added, and recommendation added, to the summary item two in the first bullet in that on page two. And on the second section on annual versus per release on pages 13 through 15. Dr. Malmud, I'll ask if you want to discuss this point, or should I go through further changes in the report?

CHAIR MALMUD: Thank you, I'll ask the members of the Committee if they wish to--anyone wishes to comment at this point. If not, we'll move on

to the next item.

MEMBER LANGHORST: Okay.

CHAIR MALMUD: Thank you.

MEMBER LANGHORST: We also, our Subcommittee also had further discussions on patient release to non-private resident locations, like hotels. And added that discussion to that section of the report, which is on page 12. We added a, a paragraph or actually clarified a paragraph and that goes on page 12 from lines 400 to 423.

Now, as we had this discussion, the Subcommittee did have different opinions on how best to address patient release to locations like hotels. You'll see in the report we had one of our Subcommittee members who felt it should not be allowed, another who was questioning whether it should be allowed.

Six of the members felt that it should be allowed and differed only in how licensees should control that release. Is there any other--any questions on that, or shall I continue?

CHAIR MALMUD: The items that you're referring to are on page 12 and lines 400 to approximately 417?

MEMBER LANGHORST: 23. 423. So, let me go

ahead and finish what we have changed. As part of that added discussion, we expanded what was formerly known--called Appendix one, and now is just called the Appendix. We added a realistic dose calculation column to tables 1 and 2.

And expanded that Appendix discussion to hopefully be a more standalone section for people to use in the future. And that Appendix is page, is on page 20 through 24. We, in our past draft report we presented to the Committee in October, we had an Appendix two that was a short summary responding to specific questions that were raised in what we've been calling the Markey report.

The Subcommittee decided to drop that short Appendix from this current report, and discussed developing a separate report with a point by point response to that Markey report. We added a few emphasis items on the negative medical impact of the past 30 millicurie Rule, and that's in several parts of the report.

We strengthened discussion on benefits to family members for patient release, and that is in section exposure to other individuals from patients released from licensee control. That goes from page 3 to 4. There are a few edits throughout the report on

just a little bit different wording.

I'm not sure where that comes from, but it wasn't me. If there's--that's--summary of the changes that we made in the report.

CHAIR MALMUD: Thank you. Are there comments regarding the report or those changes that were made?

MEMBER GUIBERTEAU: This is Mickey Guiberteau. I, I just would like to ask Sue, in terms of the Appendix 2 in response to the Markey letter. I think the, if I understood what you said, that it was a recommendation that this be removed and expanded separately. Is, I mean, what, what was, what was your intent in terms of separating this from the report? Did you think this was not extensive enough, or do you think it served separate emphasis?

MEMBER LANGHORST: There has been a parallel path going on doing, putting together a draft as far as point by point of all issues for the, for the Markey report. Quite frankly, we felt that this report needed to get out, and we weren't sure how quickly we could finish the, the full response to the Markey report, although we feel that the issues that we raise in this current patient release report addresses all of the concerns as far as release

criteria goes. It doesn't necessarily deal with process, NRC process concerns that were raised in the Markey report.

MEMBER GUIBERTEAU: Okay. And, and, and was it also a feeling that this might separate some of the more controversial areas of I-131 as the report has essentially been refocused to address patient release in, in, you know, multi radiopharmaceutical radioisotopic settings?

MEMBER LANGHORST: No, I don't believe that was one of the considerations.

MEMBER GUIBERTEAU: Okay.

MEMBER LANGHORST: I'll ask my Subcommittee members if they thought it was.

VICE CHAIR THOMADSEN: This is, this is Bruce Thomadsen. And I do not believe that was case. I think it was, it was just a matter of space in the report available for a more extensive reply.

MEMBER GUIBERTEAU: Okay. Fair enough. I was just curious.

MEMBER MATTMULLER: Could somebody please repeat the question from Dr. Guiberteau?

CHAIR MALMUD: Dr. Guiberteau, would you please repeat your question?

MEMBER GUIBERTEAU: My, my question was the

motivation for, in, you know, how, how this might be enhanced or actually presented as presenting Appendix two as a separate report, rather than separating these issues from, you know, from the present document.

I presume that meant not leaving the, you know, and I'm sort of clarifying my thought there, is that I presume that this would actually disappear from the report, Appendix two, and be with, with a thought of having a more extensive separate report addressing these, these points. Or, would you keep this Appendix two and just expand on it in another document?

MEMBER LANGHORST: Mickey, the plan was to have a, to, to drop Appendix two from this report and to have a separate report address point by point the Markey report. It would probably highly reference current patient release report.

MEMBER GUIBERTEAU: Okay. I just was unclear when you said just recommended that it be separated, I wasn't sure exactly what that meant as well.

VICE CHAIR THOMADSEN: This is, this is Bruce Thomadsen again. At the last meeting, it was, it was decided by the Committee to have the subgroup that was writing the response to the Markey report include a response to the last letter and have that be a, a

full report.

CHAIR MALMUD: This is Malmud. Thank you, Bruce. Does that mean that the issues relating to the concerns of, of the congressman will not be included in the final recommendation for the advisory Committee?

VICE CHAIR THOMADSEN: Of, of this--the report that you have in front of you, that would be correct. Although, actually, all of the issues that were of concern are addressed in this report, just not in a line by line response, and that's what the other report's going to be.

CHAIR MALMUD: Yes, thank you. I understand that, that means though that the response to the Markey concerns will be delayed in a separate report?

VICE CHAIR THOMADSEN: Yes, that is correct.

CHAIR MALMUD: Thank you. Just wanted to understand that fully.

MEMBER GILLEY: Dr. Malmud, this is Debbie Gilley. I think also that Subcommittee was going to be looking at the October 16th or 17th letter also that comes from Representative Congressman Markey's Office, maybe the 19th of October, and combining those.

VICE CHAIR THOMADSEN: That is correct.

This is Bruce again.

CHAIR MALMUD: So, that--this is Malmud again--so that the, what is considered the Appendix in this report will be deleted and instead submitted as a separate report incorporating with it the responses to the concerns of Chairman Markey, that are more, more recently received.

VICE CHAIR THOMADSEN: The only correction is, that when you say the, the Appendix to this report, that is, what was Appendix two, what is Appendix one is still in the current report.

CHAIR MALMUD: Thank you for that clarification, Dr. Thomadsen.

MEMBER GUIBERTEAU: This is Mickey Guiberteau again. I, I think this is, I understand the plan here. I just want to express a concern, that if we should get a third and a fourth letter during this process, I think we need to be certain that there is some end to, to a specific report, and it not be a never-ending report.

Because, I think there are some issues here that are not only specific but generic that need to be, that are of concerns, I think, to, to more than Congressman Markey, to the public. And I think we should be certain that at some point we do get this

report out and that we not have, you know, a continuing response.

So, I'm not sure how we would do that but I do think that some consideration should be giving--should be given to that, so that we do have a timely response to the most cogent of these, of, of these concerns, with respect to, to the broader interests of the public.

CHAIR MALMUD: Thank you, Dr. Guiberteau, for expressing that concern. May I make the following suggestion? And that is, that we, a vote on approval or not of the current report, including Appendix one, and then we recommend, to, we recommend to the Subcommittee that Appendix two be presented for approval at the next meeting of the AC--the next public meeting of the ACMUI, incorporating in it the concerns of the Committee Chairman, Congressman Markey, and that we call closure on it at that time.

MR. LEWIS: Dr. Malmud, it's Rob Lewis. Could I make a comment?

CHAIR MALMUD: Please do.

MR. LEWIS: Just, that plan would be fine. I would note that the NRC's formal response to Congressman Markey will have been sent long before the next ACMUI meeting. So, I'm sure there will be

subsequent communications on this issue, as Dr. Guiberteau mentioned. But, the, the current letter we have before us, I believe we have to, we've been asked by his Office to respond on a very short time frame.

MR. EINBERG: And, I believe--and this is Chris Einberg--and I believe the plan was to include the ACMUI's report on patient release to the Congressman Markey, as one of the attachments.

VICE CHAIR THOMADSEN: This is, this is Bruce Thomadsen again. Just with a question to Mr. Einberg or Mr. Lewis, do we have a, a schedule that, that we can use for the ACMUI's reply to the Commission that would keep it in line with the, with that goal of getting the, attaching the Appendix to the response?

MR. LEWIS: I don't have his letter before me but, but I do remember it had a, had a please reply to me by a certain date. If anybody on the phone has that letter. But I, we're trying to meet that date, and, and logically, that means this is the only opportunity of ACMUI to provide any input before that date.

MR. EINBERG: And, and--this is Chris Einberg, once again--and, I would just add that the two dates are in the type of congressional letters are

usually very short, on the order of two weeks to a month usually to respond. In this particular case, we did ask for a, an extension from the Congressman's Office, which was granted, and I believe one of the justifications for the extension was that we will be providing this Subcommittee report, or this Committee report, to the congressman's Office.

CHAIR MALMUD: Thank you, this is Malmud again. Perhaps I misunderstood. I thought that additional inquiries were from the Congressman's Office. Were they not?

MR. EINBERG: Yes, we've, we've received numerous inquiries from the Congressman's Office, and it, just as recently as late last week we received an additional letter pertaining to the release of patients that have been treated with radioactive iodine.

CHAIR MALMUD: But, is it my understanding that these letters are not bringing up new issues, but simply expressing continuing concern about the old issue?

MR. EINBERG: That would be a fair characterization.

CHAIR MALMUD: If that's so, would the members of the Committee be agreeable to just leaving

Appendix two in the report and submitting it, since we are facing somewhat of a deadline and we don't intend to change the content, simply the presentation, if I understood the discussion earlier?

VICE CHAIR THOMADSEN: Dr. Malmud, Bruce Thomadsen again.

CHAIR MALMUD: Yes?

VICE CHAIR THOMADSEN: I think that I was the most vocal Member of the Subcommittee to remove the Appendix. My feeling was that it as, it did not really address the issues that were raised, and it did very little to clarify the situation. I thought it was probably less than useful to have the one page response included in the, in the report.

CHAIR MALMUD: Thank you, Dr. Thomadsen. Was yours a, a single objection, or was that, the Member, or did the majority of the members of the Subcommittee feel the same way?

VICE CHAIR THOMADSEN: There was a vote on the, on the exclusion of that, of that Appendix, which obviously carried, and since that's in the, in the document.

MEMBER LANGHORST: This is Sue. Yes, that was--Sue Langhorst--this was a, a, the majority of the Subcommittee decided to remove Appendix two and

discuss about doing a point, point report.

CHAIR MALMUD: Thank you for the clarification. So is, therefore, is there a motion to approve the advisory Committee report from the Subcommittee, for excluding Appendix two, would be the first motion.

VICE CHAIR THOMADSEN: Excuse me, can you clarify what the--

MEMBER LANGHORST: This is--

VICE CHAIR THOMADSEN: --can you clarify what the motion is?

CHAIR MALMUD: For acceptance of the report absent the Appendix two.

VICE CHAIR THOMADSEN: So, the, the motion is to accept the report as presented to the ACMUI?

CHAIR MALMUD: Correct.

VICE CHAIR THOMADSEN: Thank you.

MEMBER ZANZONICO: This is Pat Zanzonico. But, can we get some clarification from the NRC staff? I infer from what was just said, and I may be completely wrong about this, but that there might not be, if it were not included in the Subcommittee's report, the current report, there, there would or would not be another opportunity to submit a detailed response from the ACMUI? Can that be clarified,

please?

CHAIR MALMUD: I'll, I'll try to clarify it if I can. This is Malmud again. If we approve the, the advisory Committee, Subcommittee report, it would go forward. The response of NRC staff to the congressman would also go forward without our having submitted Appendix two.

The recommendation would have been made by the NRC staff to, to the congressman. We would then submit our recommendation after that recommendation had been made.

MEMBER GILLEY: Excuse me, this is Debbie Gilley. I think the report that we have on the table before us now addresses Congressman Markey's concern. It's just not a point by point, item by item rebuttal. I think all of the information in that report is there, and therefore, NRC could reference and include an attachment to that report. Thank you.

CHAIR MALMUD: Thank you--

MEMBER SULEIMAN: This is Orhan Suleiman. I think the Committee was pretty much, had a strong consensus on our response to [sic Congressman] Markey, but I don't think

we agreed on exactly how to present it in a quick way, or whether we needed more time to go into more detail.

So I think we really disagreed more on process and how much detail and justification was warranted.

I think I agree with, with Debbie, I think if someone were to study this report, they're going to get a good sense of exactly where we're coming in on this. To me, personally, I don't think it makes any difference whether we did or didn't include it.

I think the intent is, is obvious. There isn't, for your purposes, Dr. Malmud, there wasn't any major controversy over to accept the level of detail and preparation and more documentation, but I don't think it's changing our conclusions any.

CHAIR MALMUD: No, the sub--I agree, the substance hasn't changed. What I'm trying to find out from the Committee is, given the fact that the congressman is expecting a report from the NRC, we do have a deadline, which we have not established but which is necessary in order to respond to a Member of Congress in a timely fashion.

Therefore, we can either approve the current report with Appendix--with a second Appendix or without it. It seems to me that the members of the Committee are moving forward to approve the report without Appendix two, and if, and then Appendix two will not go forward in a timely fashion.

It will go forward after NRC has already responded to the Member of Congress. Those are the realities. So, we really have a choice, of either approving it with Appendix two or without, agreeing that there's no substantive change, it's only the issue of line by line addressing the concerns.

With that background, the Chair would still seek a motion for approval of this report, with or without Appendix two, from a Member of the Committee.

VICE CHAIR THOMADSEN: Mr. Chairman, a point of question here. If we decide, if we decide today to have another meeting of the ACMUI, a tele, a teleconference, how far ahead, or how far from now would that have to be?

CHAIR MALMUD: Well, of course, public meetings need to be announced in advance. Then, there would be the discussion and, it, we haven't gotten a clear deadline date from NRC staff as to when the congressman expects the report from NRC. But, from my last meeting with the Commissioners, I had the feeling that the deadline was coming close. Does anyone on the NRC staff know when the response was promised to Chairman Markey?

MR. LEWIS: No, sir. We're, we're trying to

find that. We're not at our desks, so.

MR. EINBERG: And, and--this is Chris Einberg--if I'm not mistaken, the due date actually probably passed already, and it's, it's at the highest levels right now being reviewed. And I think the thing was that we were waiting for this report to be finalized, so I don't think there's much time left here before it's going to go out.

MEMBER LANGHORST: Mr. Chairman, this is Sue Langhorst.

CHAIR MALMUD: Yes, Sue?

MEMBER LANGHORST: I believe in, and Mr. Lewis and Mr. Einberg can correct me if I'm wrong, that the NRC did a point by point response to the Markey Report earlier last spring, and I believe Dr. Guiberteau, if, if you could point out if there's any issues other than NRC process that we have not addressed in this Subcommittee report, those should, that should be included.

But, we believe we, we touched on all of the scientific merit of the issues raised by the Markey Report in our current patient release report.

MEMBER GUIBERTEAU: This is Mickey Guiberteau. I would certainly concur with that, and it wasn't my intent to imply that it had not. It is just

that, you know, from a non-subcommittee member point of view, and in fact from a non-voting Committee ACMUI Member, I, I like Appendix two even though I think that, you know, a separate document expanding on this and including some of the other items would be, and, and the latest letter, would be excellent.

I'm just not certain what the advantage is of removing this and, and, and, as, as opposed to just expanding in another, these same issues in another document unless you feel that these might be accepted as, you know, the answers rather than the expanded answers. It, it seems to me that they're concise and very clear.

VICE CHAIR THOMADSEN: Can I, can I address that point? This is Bruce Thomadsen again. And the feeling was, at least, my feeling on that was that they are concise. They are not very persuasive at all, whereas the complete document response was much more persuasive. And that if somebody looks at the Appendix two as it was an earlier version, they would get the feeling that there was not very strong arguments against the points that they're being addressed.

MEMBER GUIBERTEAU: Well, then, then, if, again, I'm a bit confused. Is it your intent to write a, an expanded Appendix or a separate document?

VICE CHAIR THOMADSEN: It would be a separate document, that's what was approved by the Committee at the last meeting. Mr. Mattmuller may be able to tell us what the status of that document is.

MEMBER MATTMULLER: At this point--

CHAIR MALMUD: Is this Mr. Mattmuller?

MEMBER MATTMULLER: I'm sorry, this is Steve Mattmuller.

CHAIR MALMUD: Thank you.

MEMBER MATTMULLER: I mean several drafts of the point by point have been worked on, although additional comments in regards to the most recent letter from October, Congressman Markey have not been included into it.

CHAIR MALMUD: Thank you. May I make the following suggestion? That we approve of the document without Appendix two, and that the Subcommittee continue working on the material in Appendix two into a separate document in anticipation of questions from the Congressman's staff for further clarification, should those questions arise.

MEMBER WELSH: So moved.

MEMBER FISHER: Darrell Fisher, second the motion.

CHAIR MALMUD: It's been moved and

seconded. Any further discussion?

VICE CHAIR THOMADSEN: One more question. I did not, this is Bruce Thomadsen again. I did not get a reply from the NRC staff as far as what the, what delay has to be for notification of another meeting of the ACMUI.

MR. LEWIS: The, the meeting of the ACMUI I believe would require a minimum of 14 days posting and, and the other main schedule driver is availability of everyone that we need to be involved.

VICE CHAIR THOMADSEN: Yes.

MR. LEWIS: So, so that's the, the response to that.

PARTICIPANT: I do think we need to know who was the seconder of that motion. Who made the motion and who seconded it.

MS. HOLIDAY: James Welsh proposed the motion.

CHAIR MALMUD: And it was seconded by?

MEMBER FISHER: Darrell Fisher.

PARTICIPANT: Darrell Fisher?

CHAIR MALMUD: Fisher. Thank you.

MR. LEWIS: If we're in the point of discussion, Dr. Malmud, I did have a question for the Committee.

CHAIR MALMUD: Yes, please.

MR. LEWIS: And, and, I think the Committee, this motion would endorse this report, as I understand, so within the report, are several suggestions or recommendations to NRC and I think we would need maybe, at a, at a future meeting, to have Committee discussion of whether any of those are intended by the Committee as actions for NRC.

Because, I think that the summary statement and recommendation section doesn't always have the recommendations that are in the full text, behind it. For example, the one on hotels, there are, in line 423, there's a comment that we should hold broader community discussions on this topic, but that doesn't appear in the summary statement and recommendations.

So, so if there are actions embodied for the NRC staff, I think we, we should, I would suggest the Committee should have further discussions so we can put them on our action item list that Ashley has, but endorsing this report will give us the basis to send it along with the NRC response, as a separate matter.

MEMBER LANGHORST: This is, this is Sue Langhorst.

CHAIR MALMUD: Yes?

MEMBER LANGHORST: Rob, let me ask you how best to, I mean, we need to specifically say action items, is that right?

MR. LEWIS: Yes.

CHAIR MALMUD: Yes.

MEMBER LANGHORST: Okay, I, and that is my fault, as being a first time Chairman of one of these Subcommittees.

MR. LEWIS: It's not a fault, I think it's still a good report, and there's a lot of good recommendations in there. But, may, maybe a point by point, if you will, when speaking of point by points, to know which ones of these the full Committee says the NRC should take as an action item.

MEMBER LANGHORST: This is Sue. I understand now, thank you.

CHAIR MALMUD: There is a motion which has been seconded. Is there further discussion of the motion?

MEMBER WELSH: This is Jim Welsh.

CHAIR MALMUD: Yes, Jim.

MEMBER WELSH: I'd just like to point out that Dr. Guiberteau's point about this being a potentially, ongoing, never-ending process is well

taken, and that's part of the reason why I make the motion of this, this particular issue, to, to move it along.

As an example, we just discussed last week the difference, the discrepancies, perhaps, between veterinary patients and human patients. And, it opens up a whole new chapter, but if we were to try to stop and address that inconsistency in this report, it would delay it further, and then there could be another letter from a congressman or another issue in a newspaper that would slow us down further and further, so I think that we do have to heed Dr. Guiberteau's advice and, and move, move things along, and we have something that we can move along right now.

CHAIR MALMUD: Thank you for that comment.

MEMBER SULEIMAN: This is Orhan Suleiman. And, and I've been a Member of the Subcommittee and my biggest frustration with the entire process all the way from the NRC Directive of what we need to do to the Committee to the Subcommittee I think our roles haven't been clearly defined.

And, I've been concerned that the Subcommittee has spent an, an awful lot of extra time on a report that could have gone to full Committee for

further discussion. And I too agree that we have a lot of other things to do, and I think our intent is obvious. I'd like to see this closed, and move onto some of the other issues, because I, the Subcommittee charge I think is just a subset of the overall Committee's responsibilities, and I think the other Committee members need to partake in some of the discussion and bring closure to this. We can't afford to really discuss this issue for another year.

CHAIR MALMUD: Thank you, Dr. Suleiman. So you are speaking in favor of approving the motion?

MEMBER SULEIMAN: That's what I would, what--the motion is to include both--

PARTICIPANT: No--

MEMBER SULEIMAN: --Appendix two--

CHAIR MALMUD: No, the motion is to include--exclude Appendix two. And, if I am, if the items which are clarified in Appendix two in kind of a line by line way, require a response, it will have been prepared and readied when those questions arrive.

MEMBER SULEIMAN: Okay. My concern is, frankly, to get this over sooner rather than later. I, I, I agree that if we delay, you know, we're going to, the NRC is going to respond to [sic Congressman] Markey and you'll have this other report and what's to

prevent other questions or other letters to the NRC and, you can continue this for a long time without bringing closure, and--

CHAIR MALMUD: Well--

MEMBER SULEIMAN: --report what--

CHAIR MALMUD: --Dr. Suleiman, I agree with you and with your concern about the time being spent. However, if a Member of Congress and a Committee Chairman remains concerned about the issue, we will continue to receive inquiries and the NRC will be obligated to respond, and we will be asked to comment. So, that, perhaps the way that you're goal could be best achieved is to approve the document with Appendix one, but not Appendix two, and then continue, have the Subcommittee continue on with it's effort to expand Appendix two into a separate document in anticipation of questions which we are rather certain will continue to come in. We serve, we don't, we don't dictate process.

MR. EINBERG: Dr. Malmud, this is Chris Einberg. I, going to say this point is up for discussion. I have a couple things I wanted to bring to your attention. First, email here on my BlackBerry to find out what the due date for the latest letter is.

We have an internal due date of January 3rd for the latest letter from Congressman Markey. So, we'll be working on that. Then, this is the one that deals with the release of pets that have been treated with radioactive iodine.

Secondly, I also have a letter from two members of the public that has to be read into the record, and I will put it in when the appropriate time in your opinion would be, to do that, before the vote or after the vote.

CHAIR MALMUD: If they relate directly to the content of that which we are voting on, it might be in the best interest of the public to have them read before we vote.

MR. EINBERG: Okay, and with your permission, then, I'll go ahead and read that into the record now, then.

CHAIR MALMUD: Please do.

MR. EINBERG: Okay. This letter is dated November--it's actually an email. It's an email dated November 30th, 2010, to the Advisory Committee on Medical Uses of Isotopes, from David Switzer, M.S., and Walter Roberts, M.D. The subject is, written statement regarding patient release following iodine 131 therapy.

Thank you for the opportunity to provide a written statement with regard to patient release following the administration of therapeutic quantities of iodine 131. We have provided services for many years for thyroid cancer patients using iodine 131.

We have observed that a large number of these patients have been young mothers who, if released, would have had to contend with maintaining separation from their children. A few patients have been incontinent. A few patients have been confined to psychiatric institutions, and not compliant with the usual requirements for release, had it been feasible.

Other instances could be enumerated. Under good practice, there are patients who do indeed qualify for release during their post administration period. At the same time, there are many patients whom we may better serve by confinement in minimal care circumstances.

Certainly, many studies have been undertaken that confirm the low risk involved for appropriate release of patients and the information generated by these studies should be taken into consideration. The bottom line is, the authorized users with competent medical physics support when needed should be independently determine when and if

it is appropriate to confine a patient and there should be appropriate reimbursement for any and all such instances where confinement is indicated.

Guidance provided by the NRC guide on radionuclide therapy has been very useful in determining length and need of confinement. And that concludes the statement.

CHAIR MALMUD: Thank you for reading that statement to the Committee. Is there a second one?

MR. EINBERG: No. It's, it's signed by both David Switzer and Walter Roberts, MD.

CHAIR MALMUD: Thank you. It's, having heard what you just read, it seems to me that what they're saying is the judgment should be that of the physician who is treating the patient and I think they're also suggesting there should be reimbursement for the inpatient stay.

That seems to be something that's determined by hospital, individual hospital policy and by individual insurers willingness to pay for that. That's my only comment in response to hearing it. Do other members of the Committee have comments regarding the communication from these two professionals?

MEMBER ZANZONICO: This is Pat Zanzonico. I think it's, it sounds perfectly consistent with what

the, the Subcommittee and the Committee are recommending and it's consistent with best practice based on a case by case evaluation there will be some patients who are suitable for releasability and others who are not, and, and this letter seems to simply reinforce that, that position.

CHAIR MALMUD: Thank you. Any other comments from members of the Committee?

MEMBER MATTMULLER: This is Steve Mattmuller. I, I concur with Pat. I mean, that was my take on the letter also, that it's very consistent with, with our report. Thank you.

CHAIR MALMUD: Thank you. Any other comments? If not, may we call the vote? All in favor of the report?

MEMBER: Aye.

MEMBER: Aye.

MEMBER: Aye.

MEMBER: Aye.

MEMBER: Aye.

MEMBER: Aye.

MEMBER: Aye.

MEMBER: Aye.

MEMBER: Aye.

MEMBER: Aye.

CHAIR MALMUD: Any members of the Committee opposed to the report?

(NO RESPONSE)

CHAIR MALMUD: Are there any abstentions?

(NO RESPONSE)

CHAIR MALMUD: Having heard the vote, the vote is unanimous in favor of submitting the report. Thank you. If we may, we'll move onto the next item on the agenda.

MEMBER MATTMULLER: Excuse me, Dr. Malmud, this is Steve Mattmuller.

CHAIR MALMUD: Yes, Steve?

MEMBER MATTMULLER: First, I'd like to thank Sue Langhorst. She did an incredible job in putting this report together, and I daresay she's probably working harder than an NRC Commissioner right now in trying to balance her normal job and the work she did on this report.

So, she did a terrific job. The second question would be, and I suppose this would be to the NRC staff. Since it appears that we are out of time to get an official ACMUI response on a line by line basis to the Markey report, do, what other options do we have, if any?

CHAIR MALMUD: Oh. If I may, may I first

interject that it's my assumption that, that we will continue refining what was Appendix two into more of a line by line response in anticipation of further communications from the Chairman, meaning-- Congressman, because I, I'm not certain that this will be the last that we'll hear of this issue.

And, an enormous amount of work has gone into the document as well as in the refinement in the Appendix and it's, I believe it's a worthwhile item to address in anticipation of further questions. From the rate of correspondence that the NRC has been receiving, I don't think it's going to end with this recommendation.

And, I would second what you've said with respect to thanking Sue Langhorst, but I, I would, as, as Chairman of the ACMUI, wish to thank not only Dr. Langhorst, but Dr. Fisher, Debbie Gilley, Mr. Mattmuller, Dr. Suleiman, Dr. Thomadsen, Dr. Welsh, and Dr. Zanzonico, all of whom have participated in this process.

We are truly appreciative of it. It is, it is a lengthy, complete, and well thought out document. Thank you. May we move on, or does, do you wish to discuss anything relevant to this, and--

MEMBER MATTMULLER: I'm sorry. This is

Steve Mattmuller.

CHAIR MALMUD: Steve.

MEMBER MATTMULLER: I guess this would be to Chris and Rob. Do you concur with Dr. Malmud's analysis, of, that, we can still--I, I guess--one would, maybe I should phrase it this way. When would it be most helpful to you to have the line by line response to the Markey report into the NRC?

CHAIR MALMUD: Is that--you're asking a Member of the NRC that question, am I correct?

MEMBER MATTMULLER: Yes, either Rob, or, or to Chris.

MR. LEWIS: This is--I'm going to, I'm going to dodge the question.

CHAIR MALMUD: I, I think that they have to dodge the question because they haven't been asked for information yet.

MR. LEWIS: Right.

CHAIR MALMUD: What I'm saying, as Chairman of the ACMUI, not a Member of the NRC staff is that I think we should anticipate further questions. That, I'm just saying that from, from the correspondence that's occurred up until now. And, and I think that the Committee has thought it out, Subcommittee, excuse me. The Subcommittee has thought it out in detail, and

it's worth putting that document together in anticipation of what I believe is most certain to be presented to us as further questions.

MR. LEWIS: Yes, and I, and I would agree. This is Rob Lewis. I think that the timeline of getting a, a document, I think we can wait until the next full meeting, is my personal opinion, because it will be very useful as these discussions continue.

It will be a useful tool. The timeline, if, if the Committee were to request or, or expect the NRC would include this document in, in whatever the NRC response to the congressman, I think that the timeline is, is very short, even, even, you know, basically, it would have to be voted on today.

So, so I think that, in a, in a, in a future correspondence with a, with the congressman, we may be able to, to work this in. But in any event it would be a very useful tool for the NRC staff to have in preparing any response to any congressman on, on this issue that keeps coming up. So--

CHAIR MALMUD: Thank you.

MR. LEWIS: Thank you.

CHAIR MALMUD: Does that address your concern?

MEMBER MATTMULLER: Yes. This is Steve.

Yes, it does. Thank you.

CHAIR MALMUD: Thanks again, Steve. If we may, then, we'll move onto the third item on the agenda, which is the rulemaking and implementation guidance for physical protection of byproduct material, that's the 10 CFR part 37.

VICE CHAIR THOMADSEN: Mr.--Mr. Chairman? Mr. Chairman?

CHAIR MALMUD: Essentially, security requirements.

VICE CHAIR THOMADSEN: Mr. Chairman?

CHAIR MALMUD: Dr. Thomadsen?

VICE CHAIR THOMADSEN: Yes. Well, one last thing before we get off that. If, if we would be able to get the, the ACMUI, to get on a call at the end of December, that would give us time for a, a notice of the meeting and it could give some time for the NRC staff to include our recommendations to, in their response. Would you like to, to see if the ACMUI could make such a call? Could attend?

MS. COCKERHAM: Dr. Thomadsen, this is Ashley. Just to kind of give you an idea on time lines, it takes three days to publish something in the Federal register, and it has to be published 15 days before the meeting. So if it was published today the

meeting could be on December 29th at the very earliest. And it does take time, you know, at least a day or so, to coordinate when the Committee's available, what time, draft the notice, get that through the paperwork process.

VICE CHAIR THOMADSEN: Okay, so that's in addition to the, to the time that we were given earlier, as far as how much lead time we need?

MS. COCKERHAM: Yes.

VICE CHAIR THOMADSEN: Okay. I retract that.

CHAIR MALMUD: Thank you. And, and we will therefore move onto the next item on the agenda, which is 10 CFR part 37, which is the security requirements. Who's going to lead off on that discussion?

DEBBIE GILLEY: This is Debbie Gilley, and I brought this up for the Commissioner's briefing in October on behalf of the ACMUI. And we're very busy with patient release criteria and this kept getting pushed further back and further back.

And so, when I spoke at the Commissioner's briefing, I always spoke on items that may be of interest to the medical community from the Part 35--37 security proposed regulations. I have a, a, started a report. I've had help from Sue Langhorst and Darrell

Fisher to help start the process.

Part 37 is a rather expansive piece of regulation out there, and based on the comments that were made at the Commissioners briefing, the report is at a, a higher level, maybe, not as detailed as the patient release criteria report is, and it really focuses on the security regulations and the impact they may have on the access to medical care.

In the briefing that was done, there were four topics that were discussed, that was the expansion of the background checks that would be required with the regulations over the orders. The expansion of security requirements based on possession limits versus the exact activity that was on hand, and then the third one was the coordination with law enforcement and how much regulatory oversight a licensee might have in getting compliance with local law enforcement.

The report is in, still in a draft stage. I would appreciate it if I could get a little feedback from the ACMUI Committee if there are, this is the route they wish to go, and then I'll be glad to send the draft report out.

The recommendations of this report, it's not very long. It's only four pages long, is that

ACMUI would be interested in having the orders that are currently enforced be codified into Rule and not expanded, and that any additional requirements from the proposed regulations would have an accumulative, negative impact on the access to medical care, basically because of cost.

And that licensees have stepped up to the plate on these orders and have expended already lots of limited resources to meet the compliance of the orders. And the other component was the National Source Tracking and the licenses--the licensees activities with that.

And, considering that most of the medical community only has to deal with annual inventory, because only the sources that of, that are of, are the major sources of concern are cobalt 60 and gamma stereotactic units and blood irradiators, then maybe they should be allowed to have the most efficient licensee notification process and maybe not necessarily the notification process of choice by NRC. I would like feedback of any of you that have had or read those proposed regulations or other things that need to be included in that report.

CHAIR MALMUD: I thank you for the request. Is there any feedback at this time from a

member of the ACMUI?

MEMBER LANGHORST: Mr. Chairman, this is Sue Langhorst.

Debbie has tried her best to get our attention, and bless her heart, we've had a few other things on our plate with the patient release report. But with regard to NRC's justification of the new proposed Part 37, they give very good explanation of why it's not ideal to have this kind of regulatory authority reside in license orders. And I am fully supportive of the move to regulatory space, as I call it, of those requirements that are in license orders. But there's not been a good justification of why there is the expansion of requirements being proposed here.

One of the issues that I did not fully grasp until I went to -- I think it was the September 20th workshop at Headquarters, NRC Headquarters, was that this rule expands this security requirement to licensees who have not had to address it in the past.

If a licensee has radioactive material possession limits that are in excess of the quantities of concern, even though they don't have that excess in one space, they will still have to be able to develop an authorization program and do background checks, as Debbie was explaining. And that is a license that may

not even realize that they will be coming under this rule as it's being discussed.

The idea of licensees doing credit checks on all individuals who request unescorted access is quite a substantial requirement. And it is not clear why or what that gains for licensee in being able to evaluate security issues.

I understand if people are under a financial pressure that may lead to being coerced to do something. But if a licensee has to do all these various credit checks, it may negatively impact their security program because of the resources they're having to apply to areas of personal information that licensees don't get into at all.

Debbie has made clear to several of us that this is a big impact to the Agreement States that may not be able to even do credit checks or evaluate these things on a reviewing officer.

So, there's a lot to take in with this proposed rule that it is just yet another upheaval to us licensees with these types of materials that impact our security program just once more. And it is a big effort in a medical environment to keep much needed medical devices that come under this rule. Thank you.

CHAIR MALMUD: Thank you.

Are there other members of the Committee who wish to comment about this issue? No one?

MEMBER GILLEY: Dr. Malmud, would you take any comments from the public? I know there are several medical institutions RSOs that are on the call?

CHAIR MALMUD: We are always inviting comments from the public. Are there comments from members of the public?

All right. If there's anyone on this call who is a member of the public wish to make a comment with regard to this issue?

MS. LANGLEY: This is Karen Langley from the University of Utah. And I would second what was just said.

CHAIR MALMUD: Thank you. You're seconding the concern about the cost of doing credit checks on individuals seeking authorized user status for radioactive material?

MS. LANGLEY: That is correct. It creates quite an additional burden.

CHAIR MALMUD: Thank you. Are there other members of the public who wish to comment?

MR. OCH: This is Joe Och from Geisinger.

CHAIR MALMUD: Yes.

MR. OCH: I second what has just been said considering that a credit check, well you just said that, about an authorized user. I don't think this same level of scrutiny applies to people that are actually going to be doing surgery or medicine.

We'll allow them into the OR with no problem. I think we can allow them access here.

CHAIR MALMUD: Thank you for that comment.

Other comments from members of the public?

MR. ALLARD: Mr. Chairman, this is Dave Allard, Pennsylvania. We're going to be submitting some formal comments. But on the credit check aspect, I would think you know in these economic times it's probably fairly common for people to have bad credit. That doesn't really apply to whether their trustworthy and reliable. So, I'd just take that under consideration. Thank you.

CHAIR MALMUD: Thank you for the comment.

MEMBER LANGHORST: Mr. Chairman, this is Sue Langhorst again.

CHAIR MALMUD: Yes, Sue?

MEMBER LANGHORST: I've had just a little opportunity to look at the transcript from the cesium chloride workshop that occurred at the beginning of November. And I would just encourage the other ACMUI

members to maybe take a look at that at some of the public discussions that's going on with regard to even Part 37. Thank you.

CHAIR MALMUD: May I ask you what conclusions you drew from your experience?

MEMBER LANGHORST: I can't say that I've drawn any conclusions yet, because I've only just looked at them briefly and have not had time to study them. I don't know if any of our members of the Committee went to that workshop in November

CHAIR MALMUD: Are there any other members of the Committee who attended that workshop.

MR. LEWIS: Dr. Malmud, it's Rob Lewis.

I don't believe any ACMUI members were there. But I could offer a point of view. I was there.

CHAIR MALMUD: Please do.

MR. LEWIS: We had two medical licensees there, there were several but two gave presentations in some of the sessions. And I believe a gentleman from Harvard and a gentleman from the Mayo Clinic in Jacksonville, Florida.

And many of the same issues that we have just heard were raised, particularly credit checks was a big issue. But I will say that those people also

made some positive comments about some of the things in Part 37. In particular the new requirement to have a security plan. In their case, at least, that's something that they have anyway, so they don't see that as an additional burden to do even though the increased controls orders did not require a security plan in writing.

Other aspects of the regulation. The possession limits, I think that it was the -- the possession limits were always the key factor, not what was actually possessed. At least the way the NRC did the increased control orders. We issued them to anybody who had a possession limit who could possess that material, whether they possessed it or not. And the question in the orders was whether you needed to implement. And all people were ordered based on possession, and only a subset of those had to implement based on actual possession.

And I think it is true there is some different language in the new rule, although I think the rule was never that different. That possession limit defines certain things to do, but actual possession defines many more things to do.

And the transcript for the cesium chloride workshop is available on the NRC website. If you just

go to -- and I think click key issues and cesium chloride, you'll find the transcript. There's a page dedicated to the cesium chloride policy statement.

The other aspect of that meeting, of course, it was very narrowly focused on cesium chloride, but the take home message that we got from the entire workshop was the policy statement on cesium chloride, which is a little different issues than Part 37. Most people think the draft policy statement hit the mark very well.

So, and that's a summary of some of the Part 37 things that were said at the cesium chloride workshop.

When the time is right, I do have a logistical problem to bring up before the Committee about the Part 37 comments. Thank you.

CHAIR MALMUD: Are there any other comments from members of the public or from members of the Committee? I have a question for NRC Staff. Does this item on the agenda require action on our part?

MR. LEWIS: No, I don't believe it does.

CHAIR MALMUD: For information only?

MR. LEWIS: Well --

MEMBER GILLEY: Not exactly. This is Debbie Gilley. I think the NRC wants a report from

ACMUI on Part 37, am I correct?

MR. LEWIS: I don't recall that we've asked for a report on Part 37. But the Committee, of course, is very welcome to submit public comments. And that was my logistical problem. Maybe the time is right now, Mr. Chairman.

CHAIR MALMUD: The time is now. Please present your logical problem or the logistical problem has already been presented.

MR. LEWIS: Yes. I think the comment period for this rule, which has already been extended post January 18th, and I think that if the Committee as a group were looking to submit a public comment letter on the rule, this may be the last opportunity today to do something. But if the Committee as individual Committee members were to submit comments, of course, then that issue is solved. But we do have a January 18th deadline for comments, public comments, on this proposed rule.

CHAIR MALMUD: If I may, I'll ask a question then. Who bears the economic expense of doing the credit check on an individual at a particular institution? Is this going to be borne by a federal agency or by the mother institution?

MR. LEWIS: Yes, the licensee.

CHAIR MALMUD: The licensee? So this is an additional expense for the licensee?

MR. LEWIS: Yes.

MEMBER LANGHORST: Mr. Chairman, this is Sue Langhorst.

CHAIR MALMUD: Yes, Sue?

MEMBER LANGHORST: We have estimated that we currently for our need-to-know access, people spend about $1100 per person on the current review under increased controls and about $1200 per person on unescorted access.

We estimate because of the time involved in the discussions with individuals about credit reports and other background checks that those costs will about double per person. And so effectively diminish the number of people that we will have who can have access to these much needed research instruments and medical equipment.

CHAIR MALMUD: Those are the kinds of data that I was hoping you would present. And how many individuals currently would you have to document?

MEMBER LANGHORST: We believe of the order of around a couple of hundred.

CHAIR MALMUD: So if it were several hundred and it's about another $200,000, give or take,

from what you said, it's a substantial expense?

MEMBER LANGHORST: As with any research university, medical use university, we have people coming and going all the time. And so it is we estimate about a 100 or so that go through both those different levels in any one year. And the new regulations will require us to redo background checks every ten years, although that should be a little easier because people will have tended to stay here for ten years and have fewer local law enforcement checks required on them.

CHAIR MALMUD: So for your institution it would be about $200,000 per year?

MEMBER LANGHORST: At least.

CHAIR MALMUD: And one could extrapolate that to other larger research institutions as well.

So the answer to the question from NRC Staff is that the ACMUI Committee members and the public is concerned about the expense entailed in meeting these requirements. It's essentially a mandate without funding. Does that answer your question, Rob?

MR. LEWIS: Yes.

MR. EINBERG: Chris Einberg once again.

CHAIR MALMUD: Yes.

MR. EINBERG: If the Committee wanted to

make a formal comment or discuss this further and to solidify the Committee's view on this, there may be an opportunity to have another teleconference in the January time frame. As we had discussed about a week ago, we discussed having a teleconference to discuss the reporting structure of the Committee.

CHAIR MALMUD: Yes.

MR. EINBERG: And this could be an opportunity to use that same teleconference in the January time frame to solidify the ACMUI views on this and to formally submit something to the NRC.

CHAIR MALMUD: So your suggestion is that our teleconference in January we discuss two issues thus far. One is the ACMUI reporting mechanism versus the ACRS reporting mechanism, that's item 1. And number two is the concern about members of the public and the Committee members themselves regarding the unfunded mandate for a census of doing credit checks on individual who will be handling radioactive material?

MR. EINBERG: Yes, that is correct. However, you would need to have something that the ACMUI would be voting on. So, one of your members would need to put together some type of document that you'd be voting on and endorsing.

MEMBER GILLEY: Dr. Malmud, Debbie Gilley. There is a draft document that's circulating around a Subcommittee. It's just we did not have time to finalize it as a Subcommittee report to bring it before the Committee today.

CHAIR MALMUD: Thank you, Debbie. I don't believe I've seen it. Am I correct that I have not? It's not been sent to me yet?

MEMBER GILLEY: No, sir.

CHAIR MALMUD: So that might be a good basis for discussion. May I ask a question of a member of the public? Dr. Vetter, are you still with us from the Mayo Clinic?

DR. VETTER: I am still with you, but I represent the Health Physics Society.

CHAIR MALMUD: Oh, okay. Do you have any concerns about this additional mandate with regard to credit checks?

DR. VETTER: The Health Physics Society has not taken a position on that particular issue.

CHAIR MALMUD: Thank you. Have you any other comments?

DR. VETTER: The only other comment I would make is that the Health Physics Society would be in favor of expanding security to include Category 3

sources, but they would not be in favor expanding increased controls.

CHAIR MALMUD: Could you elaborate on that, please?

DR. VETTER: Well the increased controls are those regulations that require the credit checks, fingerprinting and so forth. And they are currently required for Category 1 and 2 sources.

CHAIR MALMUD: Yes.

DR. VETTER: But the Health Physics Society would not be in favor or expanding increased controls to include Category 3, but they do believe that increased security would be appropriate for Category 3.

CHAIR MALMUD: Thank you. Has the Society sent anything by mail yet to the NRC regarding their position?

DR. VETTER: They have not, but they do plan to submit comments by the January 18 deadline.

CHAIR MALMUD: Thank you. My inquires are intended to invite you to do so.

DR. VETTER: Thank you for the opportunity to share our comments.

DR. VETTER: Thank you.

MEMBER FISHER: Dr. Malmud?

CHAIR MALMUD: Yes.

MEMBER FISHER: Darrell Fisher.

CHAIR MALMUD: Yes.

MEMBER FISHER: I think of more concern in terms of cost may be the proposed requirements under subpart (b) access authorization program, which would require a background investigation on persons having access to these Category 1 and Category 2 sources.

My understanding is that a full background investigation could be much more expensive than a security -- then a credit check.

MEMBER GILLEY: That is actually kind of correct. There are nine items that are required for the background check. The credit report is just one of those.

CHAIR MALMUD: This is Malmud. I have a question for Debbie Gilley. When you approximated 1100 dollars for one item and 1200 dollars for another, I rounded it off to 2000 dollars. Didn't that include the background, the 2000 dollars?

MEMBER GILLEY: Dr. Langhorst is the one who provided you those numbers based on her institution.

CHAIR MALMUD: Excuse me. Then I'll address my question to Sue Langhorst.

MEMBER LANGHORST: Yes. That includes credit checks, background checks and so on, and the time it takes to gather all those from every state or foreign nation that the person has resided in.

CHAIR MALMUD: Thank you. Thank you. So the number that I rounded off very approximately to 2000 dollars did include the background check. It really boils down to, other into the intrusion into one's privacy, it boils down to an expense which is not minimal in a large institution. Would that cover the spirit of your concern?

MEMBER LANGHORST: Yes, that's correct. And also, this is not the only security requirement that is being imposed on us. There are select agents, chemical security and so on. And anytime that the Federal Government adds these things if they can coordinate the effort so that there is a combination that if you could pass with one, you could pass with the other, that would also be helpful. But that's not currently being looked at by all these different federal agencies adding these security requirements.

CHAIR MALMUD: Yes, I have to agree with you. But, hopefully, these things will be coordinated at some time in the future.

Well, all right. Then we will have a

Committee meeting in January to discuss this item as well. And if that document could be presented to the members of the Committee in advance, the draft of the document, we'll have something to work with before the Committee actually meets in January. And I thank you for that.

MR. EINBERG: Dr. Malmud, could we ask Ashley to coordinate the dates for this next teleconference?

CHAIR MALMUD: Yes, of course.

MR. EINBERG: Ashley, would you be so kind?

MS. COCKERHAM: I'm sorry. I'm just making sure it's before January 18th.

MR. EINBERG: Okay. Did you want to do that right now while you have all the Committee members on the line?

MS. COCKERHAM: I think it may be easier if I pick like three different days, three different times. I don't know, unless everyone has their calendars right now, we can do it.

MR. EINBERG: However you normally do, it Ashley.

MS. COCKERHAM: For teleconference I would typically send out options in an email and ask for a

response within a couple of days as to everyone's availability to pick the date that works best for everyone.

MR. EINBERG: Okay. That's fine with me if it's fine with Dr. Malmud.

CHAIR MALMUD: Yes, it's fine with me. The best days would be probably be Wednesday afternoons. If not, we could try a Monday again, but obviously not the 3rd.

MS. COCKERHAM: Okay. Monday morning option.

CHAIR MALMUD: Afternoons I think are -- my experience has been that afternoons are better for most members of the Committee.

MS. COCKERHAM: Okay. And we do have people on the West Coast, so I know it's still morning for them.

CHAIR MALMUD: All right. We'll look forward to hearing from you about that.

MS. COCKERHAM: Okay.

CHAIR MALMUD: And if we may, we'll move on to the next item.

MEMBER GILLEY: Thank you.

CHAIR MALMUD: Thank you. The next is just the impact of the draft safety culture statement for

medical licensees. And who is going to lead off on that?

MS. SCHWARTZ: That is Maria Schwartz. I'm with the Office of Enforcement. I'm here with Kitty Thompson and Dave Solorio from the Office of Enforcement as well.

CHAIR MALMUD: Okay.

MS. SCHWARTZ: I don't know what you would like us to do. Whether you'd like us to do a little presentation of what we've done since we last met with you.

CHAIR MALMUD: Yes, please.

MS. SCHWARTZ: Okay. Well, all right. Let me do that then. What we're looking for today is a motion in support of the revised draft safety Statement of Policy. And since we last met with you we have made a few revisions to the Statement of Policy, two of which were made in response to suggestions or comments that you made at our last meeting. So, specifically I'd like to go over those.

First, we added language indicating that the Commission is aware that the Statement of Policy is applicable to a diverse group of organizations and that the Commission will take that what various organizations have already done during implementation

so that there will be awareness that some organizations have already expended significant time and resources.

And then the second thing we added was a ninth trait questioning attitude. And we did that to address concerns about complacency.

Then based on other comments from the September 17th Federal Register notice, we added additional language regarding the use of rewards as a means for encouraging certain behaviors. We wanted to make sure that people looking at that concept of rewards would recognize that some monetary incentives or other reward programs can work against making a safe decision.

So, the seven items that I guess we would like to highlight in the final draft Statement of Policy is that:

First, the Statement of Policy adopts the definition and traits that were developed at the February 10, 2010 workshop, which have gotten consensus from stakeholders during our outreach. And that includes the preamble and addressing security since the term security has not been included in the definition or the traits.

The second thing is that the Statement of

Policy itself includes the traits, whereas the draft Statement of Policy did not. The draft statement had a lot more description and it was more down into almost implementation space. The traits that we have now which were the ones that were developed at the 2010 workshop are very high level, and they are very just descriptive of the sorts of things that people should be considering when they are developing their own implementation strategies.

The third thing to notice that implementation is not directly addressed in the policy statement. It just provides our overarching Statement of Policy.

Then as I mentioned, it recognizes the diversity of the various organizations.

And then in our September 17th Federal Register notice we discussed the differences between a regulation and a policy statement and why the Commission at this time believes that moving forward with a Statement of Policy is the more appropriate way to engage stakeholders. And since we are now moving forward with a Statement of Policy I think that indicates why that we are going in that path.

We also added vendors and suppliers, safety related components. They've been included in

the Statement of Policy.

And finally, as I mentioned, we added the ninth trait, questioning attitude to address complacency.

So that's kind of a brief overview of where we are since the last time we spoke.

CHAIR MALMUD: Thank you. And are we asked to take any action on this?

MS. SCHWARTZ: We're asking you to endorse, I guess to do a motion in support of the Statement of Policy.

CHAIR MALMUD: Do I hear such a motion?

MEMBER ZANZONICO: This is Pat Zanzonico. I had a couple of issues with the draft SOP. And, you know as far as I can tell it at no point did I see any consideration of those issues. So, I'd like to re-raise them if I may.

CHAIR MALMUD: Please do.

MEMBER ZANZONICO: Okay. The first issue was I didn't see any mention of redundancy. And it seemed that in any safety culture, and again this may be getting a bit down into the weeds in terms of implementation, but I think it would be important that in an SOP to at least mention redundancy as a general approach or a general feature of safety culture.

I had originally submitted that comment in September -- or October, rather, after having seen the September draft. And I still maintain that's a note worthy feature of a safety culture as included among the traits.

And the second issue, which I think at least needs to be acknowledged, I'm not even sure how it should be addressed, but at least acknowledged is the issue in terms of safety culture of an organization like a hospital in which in some instances there may be a conflict between safety at the admission of the entity, of the licensee. And by that I mean an instance, where for example a post-therapy patient has some acute event and needs some acute hands-on medical care.

Now in an instance like that safety, frankly, is taking a backseat to delivering the appropriate medical care. And I know that this document -- or I shouldn't say I know. It appears that this safety culture document widely grew out of the power industry. But it was going to be applied across all licensees.

And again, I don't know in what form, but there should be some acknowledgement that there are issues operated to things such as cost, and so forth

and so on, where safety may in effect in conflict with other appropriate features and so forth and practices of the licensee. Again, I submitted that comment as well. So those are my two comments:

(1) Number one that redundancy should be incorporated into the traits of a safety culture, and;

(2) Some acknowledgement that in the medical setting staff's safety may in effect be in conflict with other issues.

So those are my comments.

MS. SCHWARTZ: Okay. And Dr. Zanzonico, I think that you sort of hit the nail on the head when you talked about the redundancy in terms of it being something that we would be really considering and each Program Office would be looking at during implementation.

I think that comes under and probably in that mind-mapping exercise that we had at the February workshop, things like that did come up because of course with power reactors redundancy is a big issue. But one of the traits that we developed or the workshop panelists developed, was work processes in which the process of planning and controlling work activities is implemented so that safety is maintained. And I would believe that that redundancy

would be one of the things that would be considered under that trait.

I mean, the traits that we have now are very high level, and so they really have a lot of different pieces underneath them that would be part of the implementation piece of this. And it would be done during that implementation phase.

As far as the other discussion, I don't know if James Firth is on the line and he could pick that up. Because we have talked about that before with the patient safety versus use of materials. And my understanding would be that we wouldn't be discounting the fact that the patient had undergone some kind of treatment that involved nuclear materials, but that the patient's safety, of course, is the primary thing that a doctor is considering. But they shouldn't be in direct conflict. It would be very unusual that that would happen.

MR. FIRTH: Yes, this is James Firth. We have received a number of comments in terms of how the medical community addresses patient safety versus other forms of safety. And I guess as a separate example, the National Transportation Safety Board has looked at the safety of its personnel when they're going out to get to airplane crashes. That they

mandated that their personnel should not be driving while on the cell phones because it's important that they get to the site safely as well as being able to get there and to look at the safety of the people that might be involved in the accident.

So, safety is not one-dimensional. So, in say a hospital setting there's aspects in terms of the safety of the patient, safety of the medical personnel that just couldn't be somewhat -- it's multi-dimensional. So things are going to be having to be looked at.

And it's not in terms of: (a) culture of the organization. If the organization is rational about how it's making its decision and how people are acting, then that's still okay. If people are grossly negligent in terms of recklessly trying to do things that they're not asking those questions as they're acting, that might be a little bit more of a concern.

But I guess, Dr. Zanzonico, in terms of your question we did not specifically get into the details of that interplay in the Statement of Policy. We've kept it at a very general level.

It looks like it would be something that as we get into things here within what we would do in

terms of medical licensees, whether it's infections or guidance, or what have you, that would be something that FSME would develop further and in more detail then.

CHAIR MALMUD: This is Malmud, if I may, Dr. Zanzonico made a very important point, though, and that is that a good safety programs includes redundancy. And I believe that the word "redundancy" is not used in the document, is it?

MS. SCHWARTZ: No, it's not.

CHAIR MALMUD: Would the document not be improved by the use of that word since we use redundancy in patients who are being prepped for surgery and so on. It's routine. I use redundancy in treating a patient with radioiodine, everything is double checked even though it's obvious that it isn't necessary. But nevertheless, checking it off and documenting it makes a mistake less likely. It's like a “time-out” before surgery.

So I think Dr. Zanzonico's recommendation is one that might be worthwhile incorporating.

MS. SCHWARTZ: And I don't discount that at all. Because I believe redundancy, as you mentioned for yourself and probably for any number of our licensees and certificate holders, is a really

important consideration.

The checklist that you mentioned also are ways of making sure that you've not only looked at it, but you've gone back and checked that you've looked at it. And that kind of redundancy as a surgical patient myself I can really appreciate some of the things that I've seen in operating rooms that ensure that everybody is on the same page of music before you start an operation.

But this is something that we really will be addressing at the implementation stage. And each type of organization or licensee will have different needs and different ways of addressing redundancy. And what we were doing under this work practices and procedures would be to ensure that people are starting to consider those very sorts of things as they are thinking about ways that they want to implement a safety culture or have started probably, probably and have started implementing a safety culture. So that's why it's not called out specifically in this higher level overarching safety policy statement.

CHAIR MALMUD: I see. But you anticipate that it will be?

MS. SCHWARTZ: Absolutely.

CHAIR MALMUD: Thank you. Does that

address your concern, Dr.Zanzonico?

MEMBER ZANZONICO: This is Pat Zanzonico. Well, I think there's so much that we'll agree to disagree. I think it would be worthwhile to have redundancy explicitly incorporated into a general document or general SOP such as this. But certainly if subsequent documents that go out of this were included, I could live with that. But, again, we can agree to disagree. I would still recommend including it explicitly in this document, but if for other reasons that was decided not to be done, I could live with that.

MS. SCHWARTZ: One of the things that we've called to the Commission's attention is the fact that many of the comments that we've received from stakeholders indicate that there's a real desire to continue working with the Commission as implementation proceeds so that there'll be various workshops, like we had the workshop in February, where people will get together from various organizations and look at what they really need to do to ensure that this safety culture is implemented in their own organization most effectively. And this is where that will be coming up.

MR. FIRTH: This is Jim Firth. If I could,

I guess, a couple of things. One is that the way the Statement of Policy is written it indicates that there may be some other examples of safety culture traits that were not listed in the Statement of Policy. I just wanted to mention that.

If the Committee is interested in either going on record of having redundancy included in the Statement of Policy or specifically included in other things that we would consider later, you may want to consider a motion to do that for the record. Because the next step is pretty much for the proposed Statement of Policy to be provided to the Commission for their approval. And they may be making some changes as well. So any recommendations that you have could influence a Commission decision as well as what that might do for the FSME implementation.

CHAIR MALMUD: Thank you. With that, would you care to make a motion Dr. Zanzonico?

PARTICIPANT: Can I ask something?

MEMBER ZANZONICO: Yes, I'd be happy to. So I would move that the trait or characteristic of redundancy be explicitly incorporated into any SOP and/or related document on safety culture.

CHAIR MALMUD: That's a motion. Is there a second to the motion?

MEMBER WELSH: I second it.

CHAIR MALMUD: Who seconded it, please.

MEMBER WELSH: Jim Welsh.

CHAIR MALMUD: Oh, thank you, Dr. Welsh. Now, is there any discussion of the motion?

VICE CHAIR THOMADSEN: Yes, this is Bruce Thomadsen.

CHAIR MALMUD: Yes.

MEMBER THOMADSEN: And I'd like to speak against that. Redundancy is great, we use it a lot. But it's one tool out of a huge toolbox. It's not the essential tool. There's a lot of other tools that could do a stellar thing.

I don't think it's appropriate to single out that one tool in this high level document.

CHAIR MALMUD: Thank you, Dr. Thomadsen. Other comments regarding this?

MR. SOLORIO: Dave Solorio from the NRC Staff.

CHAIR MALMUD: Yes.

MR. SOLORIO: I just wanted to add to a prior discussion before Dr. Thomadsen. I hope I pronounced his correctly.

The higher level traits that we have right now were really developed by a large group of

individuals from varying backgrounds. So what we have here is some terminology that, hopefully, the reactor community, the materials community, the medical materials community, the medical industrial community could agree on at a high level. And that once they got to the point of actually trying to implement these higher level traits, each entity organization, you know each area for instance medical materials, would then take those high level traits and put them in language that means a lot more sense to the medical community, and the industrial materials folks would do the same, and the reactor folks would do the same.

So, that's what we were trying to speak to as far as implementation. And if in fact the medical community believed that diversity was important, then they would build it into their programs under the general area of work practices. And that's kind of how the high level language came about.

Just wanted to add that. Thank you.

CHAIR MALMUD: Thank you. Other comments?

MEMBER ZANZONICO: This is Pat Zanzonico again. Your comments are very well taken, and actually the emphasis on the higher level language in this document, in fact I'm going beginning to appreciate it, it's a bit of legalese to me. But I understand

the intent.

My concern is, for example, if you look through the traits of a safety culture, and this is not a rhetorical question: Which of those would happen might imply or lead to redundancy, in lack of a better term, lower level language in an implementation document?

PARTICIPANT: The work processes in which the process of planning and controlling activities is implemented, where the safety is maintained. Also when you think about it, you could even put it under problem identification and resolution where you look at a situation and realize that adding a layer that addresses a redundancy is something that needs to be done in order to more effectively address a situation.

I think there's various ways. Even question attitude, which was added, when you're looking at all the various process you might say in this case we need to add another layer that addresses redundancy. But again, this is something whereas this progresses in implementation phase, each of the organization's entities that's involved would determine how to carve that out most effectively for their own organization. Because redundancy for a nuclear power plant is going to be different than

redundancy for an individual in a hospital.

CHAIR MALMUD: Thank you. So it sounds as if you've anticipated these things.

Dr. Zanzonico, would you like to leave your motion on the table, table it or withdraw it?

MEMBER ZANZONICO: I think I'm convinced. I think I will withdraw it and based on the last series of comments.

I mean, of course I think it's still an essential component of a safety program. But perhaps given the language and so forth in this current draft SOP it's better left for a subsequent implementation document. So, on that basis I would withdraw it.

CHAIR MALMUD: Thank you. And I might add that your mere raising of the subject documents it in perpetuity. So you should feel reassured by that as well.

Yes? Who is speaking, please?

MEMBER VAN DECKER: This is Bill Van Decker. How are you?

CHAIR MALMUD: Dr Van Decker. Fine, thank you.

MEMBER VAN DECKER: Can I ask a question of our presenters here? Because my small mind is still trying to grapple with some of this.

You know, and my perspective obviously, Statement of Policy is something like from "Pirates of the Caribbean," it's kind of kind guidelines. And I think that we certainly would not argue with the philosophical goodness of some of the things that are laid out here, and we'd like to say we're reaching for those types of philosophically good traits.

But I guess my question becomes the more pragmatic from North Jersey, you know coming out of the Enforcement Section here. Do we see citations coming out because somebody didn't follow trait 6, or somebody didn't follow trait 4? Do we see this implementation phase being the devil is in the details and that there will be specific markers of implementation for these traits that then become part of regulatory guidance or even regulatory space? I'm just trying to get a feel for it down the line. This should be something that I think we would all support philosophically and all would hope to believe we're doing?

MS. SCHWARTZ: Well, the devil is in the details in the sense that at the implementation phase each one of our organizations and the entities that are involved will have to figure out what is the approach that they should be taking. And that will

require a lot of brainstorming and a lot of further thought.

The NRC is trying very hard at this point, the Commission is specifically trying very hard to make sure that we're focusing on a safety first approach to the way that activities are conducted. And this policy statement is a way to do that without getting into regulation.

Right now they really want to engage stakeholders into a thought process. Our mission as an agency is to provide for adequate protection of the public health and safety. When an entity has a safety first focus, they can ask a lot more of themselves as the regulated -- I mean you're responsible for safety. We're responsible for providing for adequate safety. You're responsible for safely using your materials.

And whenever you engage in any activity, of course you're going to be focusing on safety. But we're not using this as a check list to go into enforcement space. We're using this as an opportunity for people to consider sort of a way of looking at the spirit of the law, so to speak. Instead of when you're faced with choices that you consider the safe use above anything else.

And production is a big deal. I mean, we

live in a society that is very focused on money. So, you know this is a way of saying we want a regulated community to really consider the important aspects and the impacts a safety culture can have on it.

MR. FIRTH: This is James Firth. I could add that, I mean if you look at the safety culture traits, a lot of these are embedded either implicitly or explicitly in the existing regulations. So going forward, what I think you can foresee is that similar to what we we're doing today, which is the violations are based on the requirements that are in place, is what would happen.

If, in the course of doing that, the root cause is indicating that there's weaknesses in an area that's important to safety culture, that might be an element of discussion between NRC and the licensee, for example. It's not that we would be fighting against weaknesses in the trait, but to help the licensee to perform better there would be that discussion, or if something does not rise to the level of a violation, if certain things are seen by inspectors, they might use some of the language in the policy statement that might help the licensee identify things earlier so that they might make corrections before something more significant might have happened

later.

So, a lot of it is in terms of communication, trying to address things early before violations. But it's not necessarily in terms of -- it's at an informal level because the licensee are responsible for their own activities in terms of what they're doing for safety culture.

MEMBER VAN DECKER: Thank you.

CHAIR MALMUD: Dr. Van Decker, does that address your concern?

MEMBER VAN DECKER: Well, I believe it is adequate. There's an explanation of where we're heading, and I appreciate it.

CHAIR MALMUD: Thank you. Now may I ask what is sought of the Committee today with respect to the issue of this? An endorsement?

MS. SCHWARTZ: Yes. Some kind of a motion in support of the revised draft of the Statement of Policy.

CHAIR MALMUD: Is there anyone who wishes to make that motion?

MEMBER LANGHORST: This is Sue Langhorst. I so move.

CHAIR MALMUD: Is there a second to the motion?

MEMBER ZANZONICO: Yes. This is Pat Zanzonico. I'll second it.

CHAIR MALMUD: Thank you. The motion has been made and seconded. Any further discussion?

VICE CHAIR THOMADSEN: Mr. Chairman?

CHAIR MALMUD: Yes.

VICE CHAIR THOMADSEN: It's Bruce Thomadsen.

CHAIR MALMUD: Yes.

VICE CHAIR THOMADSEN: And this morning I sent out my comments on this draft. It's the third draft that I have commented on.

And just as preparation, I would like to point out, as I did in those comments, that I have taught the Patient Safety Course at University of Wisconsin for over a decade. As part of that course I teach about safety cultures, I teach about the tools, I teach the importance of all these aspects in patient safety.

Looking at the document and being asked to support it, is like having your son come to you and start out by saying "Dad, don't you agree that bonding time is good in principle?" And, of course, expecting if you agree, to go on with enforcement of how that might look.

It's very hard to really make an endorsement of a policy statement like this without knowing what it's going to look like in the end. And it's quite clear that that isn't known yet.

It's sort of like going to war without an exit strategy or just starting out for a vacation getting into the car and driving and deciding later where you'll go.

That being said, I think there are problems with the policy statement, many which I have pointed out in the document with almost each of the traits that are listed. But I think the big problem is trying to assess whether or not this is a reasonable policy without having any idea where its headed.

I think we would be remiss to the medical community to endorse these statements and not know how they're going to be used in evaluation of programs, possibly against people despite the vague assurances that we've been given at this meeting.

I realize that this is like trying to stop a freight train at the moment. That it's on the way, it's not going to be stopped. But I think that we at least do not have to let it go by without comment.

CHAIR MALMUD: Well, thank you. That's

exactly what we're being asked for.

VICE CHAIR THOMADSEN: I realize. I'm speaking against the motion, obviously.

CHAIR MALMUD: Thank you. Are there any other comments for or against the motion? I think we've now heard two which I would interpret as being at least of concern if not, frankly, against the motion. Dr. Van Decker's as well as yours, Dr. Thomadsen with the same concern, and that is how will this be enforced and will the end result of this be enough anxiety to actually diminish the availability of services.

MR. FIRTH: This is James Firth. If I could say something either in favor or against the motion. But that is that if there are other concerns that the Committee may have that you might want to do a separate motion, that might clarify that, we'd be interested in terms of getting a feel for any of the other issues that you'd like to raise.

MEMBER LANGHORST: Mr. Chairman, this is Sue Langhorst.

CHAIR MALMUD: Yes, Sue?

MEMBER LANGHORST: I'm glad that Bruce made his motion and his comments. And I while making the motion, was hoping that that would then bring in

that discussion.

I, too, am concerned about how this will ultimately be used. I think they're very clear. NRC has been very clear in their statement that the policy statements cannot be considered binding upon or enforceable against NRC or Agreement State licensees and certificate holders. And I hope that guidance that gets developed from this we can at least have some initial look at that to make sure that that is how policy statements continue to go. Thank you.

CHAIR MALMUD: It isn't clear to me whether you were speaking in favor of or against the motion.

MEMBER LANGHORST: I like the idea of bringing the ideas that this policy statement brings. But I agree with Dr. Thomadsen that I am concerned of how it will be used. And so I made the motion so that we could get to this discussion point.

I would say that if we want to have a separate motion of our concern about how ultimately the policy will be used, I would be in favor of supporting the current policy as it stands, but with that concern that we've voiced here about how it will be used.

MEMBER SULEIMAN: This is Orhan. How was

the motion exactly worded again?

CHAIR MALMUD: Will the individual who made the motion please clarify his or her statement?

MEMBER LANGHORST: This is Sue Langhorst.

I believe I made the motion in support of the policy. And so I am just also voicing that I have the same concern that Bruce does, how it will be used. And so I am -- I can amend my motion that we support it but we are concerned of ultimately how it will be used against licensees.

CHAIR MALMUD: That's an amendment to a motion.

MEMBER LANGHORST: This is Sue Langhorst. That's correct.

CHAIR MALMUD: Who seconded the motion?

MEMBER ZANZONICO: Pat Zanzonico.

CHAIR MALMUD: Are you willing to second the amended motion?

MEMBER ZANZONICO: Yes.

CHAIR MALMUD: So the new motion has been moved and seconded that there is approval but concern for the manner in which it will be effected and interpreted. Is that a fair statement.

MEMBER LANGHORST: This is Sue Langhorst. I'll agree to that.

CHAIR MALMUD: Any further discussion of this amended motion?

VICE CHAIR THOMADSEN: Yes. Mr. Chairman.

CHAIR MALMUD: Dr. Thomadsen.

VICE CHAIR THOMADSEN: If we were voting on that, then I would say I also have issues with the statement itself. While the principles themselves are very nice traits, if they are being used in any way, and this is separate from how its being enforced, to push organizations to try to look like this, like what's shown, it's going to have quite negative results. It can sap resources from safety applications that may not appear to follow these traits.

Also, you have the problem that with trying to look like the organization has these traits, they may sublimate their actual trait. You would have situations, for example, where somebody is trying to look like they are addressing concerns that are raised and set up some sort of sham mechanism by doing that but not change what the administration of that organization feels should be done.

As a matter of fact, in my response I go through several of the traits and show that they really aren't what we would want to be evaluating an

organization on.

In the end, what's going to make a difference is the organization's behavior; whether they actually are acting in a safe manner or not. And then the staff who had looked at this a lot says you can't really change the culture. What we can change is their behavior and they can be forced to behave in a safety manner by the regulation. They may not be able to be forced to have an attitude that we would like to see, but that becomes irrelevant.

As such, I don't think that you can separate the value of this statement as a matter of policy from how it's going to be enforced. And just as a matter of policy, it's probably bad as far as a way to go.

As a matter of education, it may be good. But then it wouldn't be coming out as a policy statement.

CHAIR MALMUD: Therefore?

VICE CHAIR THOMADSEN: I'm speaking against the revised motion.

MEMBER ZANZONICO: This is Pat Zanzonico. Can I direct a question to Dr. Thomadsen?

CHAIR MALMUD: Yes, please do.

MEMBER ZANZONICO: Bruce, so are you

opposed to an SOP in general on safety culture or just the specifics of how its formulated in the current draft?

VICE CHAIR THOMADSEN: I guess the question comes down to what you mean by SOP. This a policy statement. I don't know what an SOP is in the NRC.

CHAIR MALMUD: Are you seeking a definition of a SOP from the NRC?

VICE CHAIR THOMADSEN: Or from Dr. Zanzonico.

MEMBER ZANZONICO: No. I'm not volunteering to give a definition. But I would like to hear one from the NRC.

CHAIR MALMUD: Anyone on the NRC Staff have a definition of the NRC's SOP?

MR. FIRTH: Yes. This is James Firth. Basically the Statement of Policy allows the Commission to either direct things internally in terms of what the NRC Staff is going to be doing, but it also allows its a vehicle for the Commission to express its views on something, issues that are germane to the Commission's activities at large.

So this one is a Statement of Policy. Unlike the medical use policy statement that provides

a very clear outline in terms of how the Commission was going to be proceeding with regulating the medical use of isotopes. This policy statement is more along the lines of expressing an expectation that does not have that similar framework as the medical use policy statement.

So it's expressing an expectation. It's not setting anything specifically in line for specific implementation.

The discussion on implementation generally arises from the Commission's interest in general of having the NRC increase the attention that it pays to safety culture. So, anything that we would do on the material side to increase the attention to say either among the NRC Staff or with licensee or certificate holders, we would want to be consistent with this policy statements. But that increased attention could happen with or without the policy statement. The policy statement is expressing its expectation on what the Commission would like to see licensees and certificate holders, and vendors and suppliers of safety-related equipment to do.

VICE CHAIR THOMADSEN: In that case an answer to Dr. Zanzonico, I do feel that you can't separate support for the policy from support for how

it's going to be used, which we don't know yet. And that is as I call in my response, the ominous last sentence of this, the Commission will take this into consideration as the Statement of Policy is implemented, which we have no idea where that's going.

Do keep in mind the old Quality Management Program that was implemented by NRC years ago. It did not have the expected results. I have the feeling that something like this may not have the effected results either.

MEMBER SULEIMAN: This is Orhan. Wouldn't this sort of send a sense of support for the policy. The policy is not a regulation, it's not even a guidance. It's just a general statement as to what our thinking is.

So lacking any specifics, I appreciate Dr. Thomadsen's concerns, but I'm wondering if the NRC would get more specific, would we have a chance to comment on that if it deviated from this?

CHAIR MALMUD: That's a question from Dr. Suleiman to a member of the NRC Staff.

MS. SCHWARTZ: And I think that's absolutely correct.

MR. FIRTH: This is James Firth.

If I could clarify. The policy statement

is going up to the Commission for their consideration. And if they say they want it to be more specific, depending on the direction that they give us would determination whether or what degree of public involvement there would be. So sometimes policy statements could be rewritten at the Commission level and then issued. But if it comes back to the staff, presumably, there would be another opportunity. But we have to see how things would develop.

MS. SCHWARTZ: That's the response time.

CHAIR MALMUD: So, if I can summarize. It sounds as if the members of the ACMUI are strongly supportive of a safety culture policy for medical licensees. However are concerned regarding the manner in which these will be regulated and enforced because excessive penalties or enforcement may result in a limitation of access to these technologies by patients. Is that a fair summary of what we've heard.

MEMBER LANGHORST: This is Sue Langhorst. I think that's good.

VICE CHAIR THOMADSEN: This is Bruce. I still don't think it's quite captured. I think the policy statement may result in detrimental effects to patient safety as a result of trying to at least look like you're adopting the traits.

MR. SOLORIO: This is Dave Solorio from the NRC Staff. I would just like to add one thing to speak to this concern. We expect all individuals and organizations performing regulated activities to take the necessary steps to promote a positive safety culture by fostering these traits as they apply to their organizational environment.

We already recognize the diversity of the organizations out there and acknowledge that some organization have already spent significant time and resources in development of positive safety culture. So, we would take this into consideration as the Statement of Policy is implemented.

So, to speak to the concern about the medical community trying to adopt all these nine traits and then hurting themselves, the goal here would be as we're working through the implementation we try to take advantage of what the medical community is already doing. They may not have to implement all nine traits for their environment. It's going to be a very collaborative effort between the NRC and the medical community to come out to a place where there is an implementation expectation for the medical community on the policy statement.

Thank you.

CHAIR MALMUD: Thank you. Any further discussion of this motion?

MEMBER MATTMULLER: Dr. Malmud, this is Steve Mattmuller?

CHAIR MALMUD: Yes, Steve?

MEMBER MATTMULLER: My concerns in regards to all this is that from the medical licensee's perspective, and I suppose this is mostly directly to the NRC Staff, is that our safety culture right now is being driven by the Joint Commission. And despite our current employment by the NRC and even with Orhan in the room, we pay the most attention to the Joint Commission when it comes to safety culture issues.

And so my concern would be that something developed by the NRC does not conflict or hinder, or work against what the Joint Commission has already been quite successful in establishing in medical licenses.

Thank you.

CHAIR MALMUD: Thank you. Your concern, therefore is there might be conflict between NRC policy and Joint Commission policy.

MEMBER MATTMULLER: Right. Right. I mean, it's somewhat addressed in the policy, and I don't have the exact words in front of me because I can't

talk in my phone and read my screen at the same time. But the previous speaker from the NRC mentioned that individual or specific organizations will have the flexibility to tailor the safety culture to their environment. And what I'm trying to emphasize is that the medical community already has developed a pretty good safety culture by way of influence from the Joint Commission.

MR. FIRTH: This is James Firth. If I could add a little bit of elaborating information.

Part of the effort with the policy statement was to develop some common terminology relating to safety culture. And in the public workshops that we held to come up with the definition and the traits in February of this year, we included a number of the Joint Commission on the stakeholder panel that developed the language.

so, the intent is not to develop anything that would conflict with other organizations, but would to have what NRC would like to comport with or be consistent with what others are doing. So, the intent is not to be creating a new structure, but that the essence and principles behind it are there.

And I guess with medical licensees as well as others who do have some variability in terms of how

well the organizations are functioning and whether there are problems are not.

CHAIR MALMUD: Thank you. Other comments?

MEMBER GUIBERTEAU: This is Mickey Guiberteau.

I think that comment begs the question did the representative from the TJC on the panel feel that there was any conflict of interest or express that? I mean, he may have felt that. But did he express that?

MR. FIRTH: Yes. This is James Firth. When the decision on coming up with the language of the definition as well as the specific lists of traits, and this was does not include questioning attitude per se, the basis for consensus was whether each of the organizations or individuals felt that they could live with it for their constituencies. And everyone affirmed that was the case.

He did not mention any problems or inconsistencies or areas of concern with what we had.

MS. SCHWARTZ: And, in fact, there was some discussion about the do no harm, and that all of this was wrapped into the final sort of alignment on the definition that was developed as not conflicting with any of the-- it wasn't perhaps what each would

have liked if they'd individually written it, but it was one that everybody could live with because it was broad enough to encompass what all the organizations had in mind.

CHAIR MALMUD: Thank you.

MR. SOLORIO: This is Dave Solorio again. I wanted to just add that I found out today that one of your members, I believe, is going to be a speaker at the training or meeting we're having on the 24th January. Maybe it's Donald. I don't remember.

MS. SCHWARTZ: It's Dr. Thomadsen.

MR. SOLORIO: It's Dr. Thomadsen. So you have a firsthand opportunity also to express these concerns to the Commission.

CHAIR MALMUD: This is Malmud again. As Chair of the Committee, we do want to make a statement, I'm sure, that we wish to always support the safety culture for medical licensee. I don't think we wanted to appear that we're opposed to the concept. At the same time we want to communicate our concern regarding the issues that Dr. Thomadsen has raised, and that have been echoed by others.

So the question is what kind of a statement can we make that indicates both of those issues? And is that statement contained in our

current motion?

VICE CHAIR THOMADSEN: Mr. Chairman.

CHAIR MALMUD: Yes, sir.

VICE CHAIR THOMADSEN: Bruce Thomadsen again. I think that you summarized quite well what the motion might say. It's not what we have on the table right now. But we could say that the ACMUI strongly supports medicine following cultures of safety. And that the traits in general do not stand out as contradictory to this. Or you could even be stronger about that. But the Committee has concerns for the policy statement as it is written and how it may be used in the future.

CHAIR MALMUD: Thank you. I'll try to make it briefer statement, if I may.

The members of the ACMUI strongly supports a safety culture policy for medical licensees. Period. It remains concerned about the policy not conflict with the access to care or existing standards care as they are applied in various disciplines.

How's that?

VICE CHAIR THOMADSEN: Well, I don't think that quite captured it at all, but--

CHAIR MALMUD: Okay. Well if you don't think it captured it at all, it's not good. Let's see

if we can do something that will capture your concern.

I mean, the Committee's clearly in favor of a safety culture policy statement for medical licensees.

VICE CHAIR THOMADSEN: I don't know. That's what we were voting on, but we haven't voted yet so we don't know that that's the case.

CHAIR MALMUD: Well, I haven't heard anyone object to that part of it.

VICE CHAIR THOMADSEN: Oh, I'd object to that.

CHAIR MALMUD: I think what we're concerned about is -- well you raised, which is a valid concern. And how do we put the two together, that's my question.

MEMBER LANGHORST: Mr. Chairman, this is Sue Langhorst.

If it's helpful, I can withdraw my motion.

CHAIR MALMUD: Well, what I'm trying to do is to address Dr. Thomadsen's concerns because they're real. We've experienced circumstances in the past where the Commission's felt that regulations were intrusive and obstructive, and not necessarily in the best interest of the patient. And --

VICE CHAIR THOMADSEN: Dr. Malmud?

CHAIR MALMUD: Yes, Dr. Thomadsen?

VICE CHAIR THOMADSEN: Let me try again then. The motion could be that the Committee supports a culture of safety in medicine, but short of understanding how a policy statement would be used, the Committee cannot support the current policy statement.

CHAIR MALMUD: That's one way of phrasing it.

MEMBER GUIBERTEAU: This is Mickey Guiberteau. Is there a time constraint for this endorsement?

CHAIR MALMUD: You have to ask NRC Staff that question. Is there a time constraint?

MS. SCHWARTZ: Well, we're planning to send this up to the Commission the 20th of this month. So, originally we had like a March date, but the Commission moved that up to January. So we have had to respond accordingly.

MR. FIRTH: This is Jim Firth. I guess I would also add that the Commission meeting is scheduled for the 24th of January. And it does sound as if there is going to be another teleconference that's going to be in the first part of January. So that might provide another opportunity for the

Committee to revisit if they need to and of they wanted something to inform, say, a Commission briefing even if it's something that we would not be able to incorporate in what would go up to the Commission.

MEMBER GUIBERTEAU: This is Mickey Guiberteau. I think given the concerns that we all have in how this expression of support with some reservations might be expressed, I think perhaps we should work on this and do this in our January phone call.

I realize it wouldn't be the ideal endorsement, presuming that's what it is, in terms of timing. But I think it would be best if we express it so that we cover exactly what we're talking about.

CHAIR MALMUD: That's a recommendation from Dr. Guiberteau. Is there a second to that recommendation?

MEMBER GILLEY: I second it. I second it. Debbie Gilley.

CHAIR MALMUD: Any further discussion? All in favor?

ALL: Aye.

CHAIR MALMUD: Any opposed?

(No response.)

CHAIR MALMUD: Any abstentions? If not,

the decision to defer it until January is unanimous.

And that completes the business of this official meeting.

Are there any comments from the public that we have not had an opportunity to entertain as yet? If not, I will --

MR. EINBERG: Mr. Malmud, a quick one.

CHAIR MALMUD: Excuse me.

MR. EINBERG: Mr. Malmud, can we take about two minutes to see if there's anyone else on the line who didn't identify themselves? If so, could they identify themselves now?

CHAIR MALMUD: Is there anyone who joined the Committee meeting who wishes to be identified for the record.

MR. PETERS: This is Mike Peters from the American College of Radiology.

CHAIR MALMUD: Thank you.

MEMBER VAN DECKER: And Bill Van Decker a couple of minutes late.

CHAIR MALMUD: Thank you.

MS. SIERACKI: Diane Sieracki, NRC.

CHAIR MALMUD: Thank you.

MS. FORESTER: And Sara Forester, Division of Nuclear Materials Safety, Region III.

CHAIR MALMUD: Thank you.

MS. COCKERHAM: Dr. Malmud, this is Ashley. I just wanted to let you know I'm going to send an email to the Committee for potential dates for the next teleconference.

CHAIR MALMUD: Thank you.

MS. COCKERHAM: I'm looking at January 5th, 10th, 12th and 17th. So if everyone could respond to that email, I would appreciate it.

CHAIR MALMUD: 5th, 10th, 12th and 17th are our choices.

MS. COCKERHAM: Yes. From 1:00 to 3:00 p.m.

CHAIR MALMUD: I think we're still here. Is there a motion for adjournment?

PARTICIPANT: Yes, a motion.

CHAIR MALMUD: All right. There is a motion for adjournment. I would like to thank you all for a lengthy meeting, but a very productive one. And one in which we've heard a variety of opinions, all of which are valuable. And we look forward to our next meeting.

Wishing you all a happy holiday season and a happy and healthy New Year.

(Whereupon, at 3:57 p.m. the

Teleconference was adjourned.)