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NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL

USES OF ISOTOPES

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TELECONFERENCE

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WEDNESDAY

JANUARY 5, 2011

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

MEMBERS PRESENT:

LEON S. MALMUD, M.D., Chairman

BRUCE R. THOMADSEN, Ph.D., Vice Chairman

DARRELL R. FISHER, Ph.D., Member

DEBBIE B. GILLEY, Member

MILTON J. GUIBERTEAU, M.D., Member

SUSAN M. LANGHORST, Ph.D., Member

STEVEN R. MATTMULLER, Member

CHRISTOPHER J. PELESTRO, M.D., Member

JOHN H. SUH, M.D., Member

ORHAN H. SULEIMAN, Ph.D., Member

MEMBERS PRESENT: (continued)

WILLIAM A. VAN DECKER, M.D., Member

JAMES S. WELSH, M.D., Member

PAT B. ZANZONICO, Ph.D., Member

NRC STAFF PRESENT:

MARYANN ABOGUNDE

MICHELLE ALBERT

VALERIE BARNES

HECTOR BERMUDEZ

JUNE CAI

SUSAN CHIDAKEL

ASHLEY COCKERHAM, ACMUI Coordinator

JACKIE COOK

SAID DAIBES

JAMES FIRTH

SARA FORSTER

MICHAEL FULLER, Designated Federal Official

SANDY GABRIEL

SOPHIE HOLIDAY

DONNA BETH HOWE

JAMES LUEHMAN, Deputy Division Director

GRETCHEN RIVERA-CAPELLA

SHIRLEY XU

RONALD ZELAC

ALSO PRESENT:

SUE BUNNING, Society of Nuclear Medicine

CHARLES BURNS, New York State Department of Health

ROBERT E. DANSEREAU, New York State Department of Health

KEITH DINGER, Government Liaison, Health Physics Society

LYNNE FAIROBENT, American Association of Physicists in Medicine

THOMAS HUSTON, Department of Veterans Affairs

SYLVIA MARTIN, State of Oregon

JANETTE MERRILL, Society of Nuclear Medicine

MARY MOORE, Philadelphia Veterans Affairs Medical Center

DENNIS O'DOWD, New Hampshire Department of Health and Human Services

MIKE PETERS, American College of Radiology

GLORIA ROMANELLI, American College of Radiology

GEORGE SEGALL, Society of Nuclear Medicine

MICHAEL SHEETZ, University of Pittsburgh

SASHA SIMPSON, ML Strategies

CINDY TOMLINSON, American Society for Radiation Oncology

GARY A. WILLIAMS, Veterans Health Administration

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P R O C E E D I N G S

Time: 1:04 p.m.

MR. FULLER: This is Mike Fuller. I am the alternate Designated Federal Official -- Officer, I should say -- for this meeting. So we will go ahead and get started.

Actually, was that you typing, by any chance? Someone is typing. I will get to that in just a moment.

We will go ahead and get started. As I said, as the alternate Designated Federal Officer for this meeting, I am pleased to welcome you to this teleconference meeting of the ACMUI.

My name is Michael Fuller, and I am the Team Leader for the Medical Radiation Safety Team, and I have been designated as the alternate Federal Officer for the 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 December 21, 2010 edition of the Federal Register.

The function of the committee is to

advise the staff on issues and questions that arise on the medical use of byproduct material. 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 will be discussed today, but I also recognize that there may be minority of 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 members participating today. Dr. Leon Malmud.

CHAIRMAN MALMUD: Here.

MR. FULLER: Dr. Bruce Thomadsen.

VICE CHAIRMAN THOMADSEN: Here.

MR. FULLER: Dr. Darrell Fisher.

MEMBER FISHER: Here.

MR. FULLER: Ms. Debbie Gilley.

MEMBER GILLEY: Here.

MR. FULLER: Dr. Mickey Guiberteau.

Dr. Sue Langhorst.

MEMBER LANGHORST: Here.

MR. FULLER: Mr. Steve Mattmuller.

MEMBER MATTMULLER: Here.

MR. FULLER: Dr. Christopher Palestro.

MEMBER PALESTRO: Here.

MR. FULLER: Dr. John Suh.

MEMBER SUH: Here.

MR. FULLER: Dr. Orhan Suleiman.

MEMBER SULEIMAN: Here.

MR. FULLER: Dr. William Van Decker.

Dr. James Welsh.

MEMBER WELSH: Here.

MR. FULLER: And Dr. Pat Zanzonico.

MEMBER ZANZONICO: Here.

MR. FULLER: Okay, I will note that we have a quorum, and we have at this point only two members who are not in attendance.

I would 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 nuclear medicine physicians, respectively.

I will not introduce the NRC staff members who are present here at NRC headquarters. Again, my name is Mike Fuller. I have with me Mr.

James Luehman. I also have June Cai, Dr. Ronald Zelac, Susan Chidakel, Shirley Xu, Ed Lohr, Dr. Donna Beth Howe, and --

MS. ALBERT: Michelle Albert.

MR. FULLER: Michelle Albert, and then also we have some NRC Headquarters employees on the phone. Could those individuals please identify themselves at this time?

DR. DAIBES: Said Daibes.

MR. FULLER: Okay, Dr. Daibes. Any other NRC Headquarters?

DR. BARNES: Valerie Barnes.

MS. RIVERA-CAPELLA: Gretchen Rivera-Capella.

MS. COCKERHAM: This is Ashley Cockerham.

MR. FULLER: I'm sorry, Ashley. Who was the other person?

MR. BERMUDEZ: Hector.

MS. COCKERHAM: We will go to the Regions.

MR. FULLER: Yes, we will get to the Regions in a moment.

MS. HOLIDAY: Hey, Mike, this is Sophie.

MR. FULLER: Okay, Sophie. There was one other person prior to Gretchen. Can you repeat your name again?

MS. COCKERHAM: Mike, I think that was Valerie Barnes or Michelle Albert.

MR. FULLER: Valerie Barnes. That is who it was. Thank you.

MS. COCKERHAM: You are welcome.

MR. FULLER: Okay, next we will go to the Regions. Who do we have on the call from Region I?

DR. GABRIEL: Sandy Gabriel.

MR. BERMUDEZ: Hector Bermudez.

MR. FULLER: Anyone else from Region I? Okay, we will go to Region III. Who do we have on the call from Region III?

MS. FORSTER: Hi. This is Sara Forster.

MR. FULLER: Anyone else from Region III? Now NRC Region IV?

MS. COOK: Jackie Cook.

MR. FULLER: All right. The next thing I will do is identify the members of the public who notified us that they would be participating in the teleconference. So when I call your name,

please indicate if you are on the call.

Keith Brown, University of Pennsylvania? Sue Bunning, Society of Nuclear Medicine?

MS. BUNNING: Here.

MR. FULLER: Charles Burns, New York State Department of Health?

MR. BURNS: Here.

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

MR. DANSEREAU: Present.

MR. FULLER: Keith Dinger, Health Physics Society?

MR. DINGER: Here.

MR. FULLER: Lynne Fairobent, American Association of Physicists in Medicine?

MS. FAIROBENT: Here.

MR. FULLER: Dr. Thomas Huston, Department of Veterans Affairs?

DR. HUSTON: Here.

MR. FULLER: Jackie Kavanaugh, Nordian? Sylvia Martin, Oregon?

MS. MARTIN: Here.

MR. FULLER: Andrew Mauer, Nuclear Energy Institute? Janette Merrill, Society of

Nuclear Medicine?

MS. MERRILL: Here.

MR. FULLER: Mary Moore, Philadelphia Veterans Affairs Medical Center?

MS. MOORE: Here.

MR. FULLER: Mike Peters, American College of Radiology?

MR. PETERS: Here.

MR. FULLER: Gloria Romanelli, American College of Radiology?

MS. ROMANELLI: Here.

MR. FULLER: Dr. George Segall, Society of Nuclear Medicine?

DR. SEGALL: here.

MR. FULLER: Michael Sheetz, University of Pittsburgh?

MR. SHEETZ: Here.

MR. FULLER: Sasha Simpson, ML Strategies?

MS. SIMPSON: Here.

MR. FULLER: Cindy Tomlinson, American Society for Radiation Oncology?

MS. TOMLINSON: Here.

MR. FULLER: Gary Williams, Veterans Health Administration.

MR. WILLIAMS: Here.

MR. FULLER: And Stanley Wilson, Emory University?

Okay, is there anyone else on the call that I did not recognize?

MR. O'DOWD: A member from the public, Dennis O'Dowd, representing New Hampshire Department of Health and Human Services.

MR. FULLER: Okay, anyone else?

MEMBER VAN DECKER: This is Bill Van Decker. I just want to let you know I got on.

MR. FULLER: Oh, okay. All right. Did Dr. Guiberteau join us, by any chance? Okay.

All right. At this time, I will ask that everyone on the call who is not speaking to please place their phones on mute. If you do not have the capability to mute your phone, please press 6 to utilize the conference line mute and unmute functions. I would ask everyone to exercise extreme care to ensure that background noise is kept to minimum. Any stray background sounds can be very disruptive on a conference call 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.

With that, at this point I would like to turn the meeting over to Dr. Malmud.

CHAIRMAN MALMUD: Thank you, and welcome to all of you, and a Happy New Year to everyone. We have rather a full agenda today and a limited amount of time in which to accomplish the discussion. So if I may, we will begin promptly with the first item on the agenda.

Now that is listed as the ACMUI Reporting Structure. However, we also had a new item added that appear on your email today, which is the Patient Release issue. So if we can, we will begin with that issue. Sue, do you wish to comment on that?

MEMBER LANGHORST: Yes, I will be glad to. This is Sue Langhorst.

We received comments on the ACMUI patient release report, and we will have a handout to the comments and our draft response, which Chairman Malmud and I -- We appreciate the additional insights that we were given on the comments and reasoning behind the original

rulemaking for the patient release.

Nevertheless, it is clear to ACMUI that NRC established per patient release limits. In that handout we provide you that conclusion. I won't read through those, but this is what the regulated community has to go by, a new rulemaking.

So I believe that we need a vote from the Committee, Chairman Malmud, that whether the ACMUI -- that the NRC believes the patient release criteria should be changed from a per release criteria, annual criteria, this change would require new rulemaking, as was noted in the regulatory issue summary.

CHAIRMAN MALMUD: Thank you. If I understand your intent, it is that we, the ACMUI, currently believe that it is per release, not per year, and that in order to change it to per year, which we do not endorse, it would require a rulemaking change. Is that correct?

MEMBER LANGHORST: Yes, that is correct, and that would be the motion I would put forward.

CHAIRMAN MALMUD: Is there a second to that motion, please?

MEMBER GILLEY: Second. Debbie Gilley.

CHAIRMAN MALMUD: Thank you. It has been seconded by Debbie Gilley. Is there further discussion of this motion?

MS. CHIDAKEL: Well, I am Susan Chidakel. I am the OGC Senior Attorney that was involved in this matter, and I just want to tell you, I want to thank you for your input.

I do want to tell you that we have looked at the statements that you have cited and read in the context of what was being discussed when the rule was finalized, and we do not believe that they support your view.

We have found no basis in reviewing the information you have provided or in re-reviewing the entire regulatory history to change our position that this was not intended to be a per release, release. Our position, as we said, was the rule is, obviously -- It doesn't address it. The regulatory language itself doesn't say anything.

We do agree that we need a rulemaking to clarify the intent, but we don't agree with you as to your saying that the intent was that it was

a per release basis rather than per year.

CHAIRMAN MALMUD: Thank you for your comment. Do we have other comments in response to counsel's comment?

MEMBER WELSH: This is Dr. Welsh here.

CHAIRMAN MALMUD: Dr. Welsh.

MEMBER WELSH: I suppose the big question at hand is not whether the wording really supports per year versus per event at this point, but what we would advise NRC to really have in clear language. From my understanding, what the ACMUI is advocating is that we seek per event rather than per year, and the next question is do we really need to have a rulemaking to make it clear to all that it should be per event or is NRC going to insist or recommend that it be per year, and we still need a rulemaking for that? That is the question at hand, from my understanding.

CHAIRMAN MALMUD: Thank you, Dr. Welsh. I believe that that question should be addressed to Susan Chidakel. Am I correct, Susan?

MS. CHIDAKEL: I would like you to please repeat the question, if you don't mind.

CHAIRMAN MALMUD: If I may interpret Dr. Welsh's question, it is as follows. The ACMUI

believes that it should be on a per release -- that is, per event basis -- not an annual basis, based upon our understanding of what has been promulgated in the past.

Therefore, the question is do we need to recommend that there be a change in rulemaking in order to achieve agreement that it should be per release or can the accumulated wisdom of the NRC staff interpret this in a way which will allow us to continue practicing on a per release basis?

MS. CHIDAKEL: Our answer is that we think you need a rulemaking.

CHAIRMAN MALMUD: Then that would require that the ACMUI recommend to NRC that there be a change in rulemaking. Dr. Welsh, does that answer your question?

MEMBER WELSH: It does. Thank you.

CHAIRMAN MALMUD: Now if I may, having discussed this with members of the Committee, our concerns are as follows. Number one, there is no methodology currently available to add up the per release events between and among institutions for individual patients, number one.

Number two, there is concern that, if the interpretation of NRC is that it must be per

year, and without the ability of the physician to accumulate the data or to assure the data, will there be penalties for treating patients who might exceed the per year limit on the basis of being treated per event until this issue is clarified; because this really interferes with the current practice of medicine?

That is a question to counsel.

MS. CHIDAKEL: That isn't actually a question. What you have done is you have stated your concern.

CHAIRMAN MALMUD: It is a concern. I am always willing to have an expert in the law clarify an issue for us.

MS. CHIDAKEL: Well, I think your issues are perfectly valid, and I think they are things that you can raise if you want to propose the rule, a rule change.

CHAIRMAN MALMUD: All right.

MS. CHIDAKEL: As far as the second question about penalties and so forth, that is an enforcement issue, and I can't really address that. We are talking about a rule change. I am not prepared to address enforcement issues, I am afraid.

CHAIRMAN MALMUD: Who would be addressing the issue of enforcement in the interim?

MS. CHIDAKEL: I leave that to the staff.

CHAIRMAN MALMUD: Is there someone from staff who wishes to comment? It seems to me -- and I speak as the Chairman, having heard the input from the members of the committee -- that the Committee is almost unanimously, with one exception, supportive of this being continued to be practice on a per release basis, not a per year basis. However, now that the issue has come before NRC for clarification and there is no ambiguity, according to counsel from NRC, there would be concern in the medical community that, in the event that a patient does receive more than the annual limit by virtue of the current per release practice, that there not be a prosecutorial effort made against physicians who, number one, have no ability to add up these doses which may be given by different institutions and, number two, who have been practicing this way until now anyway.

MR. LUEHMAN: Dr. Malmud, this is Jim

Luehman. I think that -- I think, going back to the October 20, 2010 Commission meeting when I testified to the Commission, I told them that I think -- I thought that this issue needed to be clarified, because as Susan stated, right now the regulatory language doesn't say either. It just -- You know, you have to really rely on the history to look at the language and make the determination.

Given that, I think that -- At least, I personally then and I am of that same mind now, think that this does need to be clarified in the regulations. But what I would say in the interim is, while the staff has a position, and we feel it is a strongly supported position, the fact is that from an enforcement standpoint, since the regulation right now is silent on whether it is per episode or per year, I think it is very unlikely that there is going to be any enforcement action taken until this is clarified; because the staff would have a burden to show that there was a violation of the regulation, and with the language as it presently is, that is probably not something that we would pursue.

Having said that, I do think that your

concerns -- that you and the Committee and the medical community have some concerns, and that takes me full circle back to, at least personally, I support what the Committee is suggesting, that we need to get into a -- we need to do a rulemaking and clarify the language one way or the other, because that is the only way that is going to fix this problem once and for all.

MEMBER LANGHORST: Mr. Chairman, this is Sue Langhorst again. Let me speak as a licensee who would not have the access to the full rulemaking history documents that NRC staff would have.

In the statement that NRC put in the final rulemaking, they said NRC is establishing a dose limit of 5 millisieverts total effective dose equivalent to an individual from exposure to the release patient for each patient release.

To me, there is no doubt that the current regulations are per release and, if the NRC intended it to be per year, that is not what is stated in their final rulemaking. So if NRC wants to move from per release to per year, that is where rulemaking needs to occur, but as you stated, Mr. Chairman, the ACMUI's majority feels

that it should remain as a per release limit. Thank you.

CHAIRMAN MALMUD: Thank you.

MS. CHIDAKEL: If I may speak, this is Susan Chidakel again. As I said before, we have looked at all of the statements that you have presented. As a lawyer, I have looked at them from a legal standpoint in the context in which these statements were made.

You have to look at the entire context and from looking at the context in which these statements were made very carefully and looking at all of the supplementary information, as I said, we have not changed our position.

Again, the regulations do not clarify it, but the regulatory history indicates that the intent was that it should be an annual limit.

CHAIRMAN MALMUD: Thank you. We have heard both positions, the position of the majority of the ACMUI Subcommittee and the position of NRC counsel. We recognize that there is a difference.

Therefore, in order to move forward, there is a motion from ACMUI -- I believe, from Sue Langhorst -- which would indicate that the ACMUI recommends that the interpretation be on a

per release basis, and that pending clarification of this or rulemaking, that it be allowed to continue as a per release basis so that practitioners need not fear prosecution in the care of their patients.

MEMBER SULEIMAN: Dr. Malmud, this is Dr. Suleiman.

CHAIRMAN MALMUD: Yes, Dr. Suleiman?

MEMBER SULEIMAN: I have a question that would affect how I would feel about this. The per limit -- per event limit is realistic. It is practical, and is really what should be adhered with how the ACMUI has felt. However, the overriding question: Is there or isn't there an annual limit; and if, in fact, there is an annual limit that happens to be the same as the per event limit, the annual limit preempts the per release limit, but in this case it doesn't matter. It is limited to one.

So is there or isn't there an annual limit? The regulation doesn't say that. 35.75 doesn't say that, but the guidance kind of implies that, but I kind of find it upsetting that guidance which should be clarifying, in this case has actually confused the community.

So there either needs to be better guidance or rulemaking where the annual limit does not coincide with the per event limit, because we are not dealing with occupational dose values here. We are dealing with very low amounts of radiation, and to spend this amount of time on something that is essentially very safe has not been fair to the community and has caused a lot of confusion.

CHAIRMAN MALMUD: Thank you, Dr. Suleiman. Does anyone care to comment?

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

CHAIRMAN MALMUD: Yes.

MEMBER LANGHORST: Let me clarify my motion. My motion is that ACMUI agrees, if NRC believes the patient release criteria should be changed from a per release criteria to an annual criteria, this change would require new rulemaking, as was noted in Regulatory Issue Summary 2008-07.

CHAIRMAN MALMUD: Thank you. That is your motion. It has been seconded, has it not?

MEMBER GILLEY: Yes. Debbie Gilley seconded it.

CHAIRMAN MALMUD: Thank you. Is there any further discussion of this motion? Hearing no further discussion, may I ask those voting members of the Committee to say Aye if you agree.

Are there any negative votes? Are there any abstentions?

MEMBER SULEIMAN: I abstain.

CHAIRMAN MALMUD: Dr. Suleiman abstains. Otherwise, it is a unanimous vote.

So we believe that, in having taken this vote that we have placed the issue before NRC staff for resolution and, in the meantime, would plead for understanding on the part of NRC with regard to physicians treating patients according to the manner in which they have been with regard to this issue.

If we may, we will move on to the next item on the agenda, unless there is any further discussion of this. Are there any comments from members of the public? If not, thank you very much, and thank you, Sue Langhorst, for your effort, and thank you, Sue Chidakel, for your input. We hope that we will be able to get clarification for all parties involved so that patients and members of the public can both be

safely treated and be safely cared for.

The next item on the agenda is the ACMUI Reporting Structure. Who wishes to comment on this? Did I go mute or no one wishes to comment? Shall I?

MEMBER THOMADSEN: Dr. Malmud, this is Bruce Thomadsen. I will just say that I had thought that this was about the document that we had been dealing with, with our interactions with the NRC as a committee, but it was clarified that this is not about that. It is about who we report to. So I will, just with that clarification, give it over to -- I am not involved in that one.

MS. COCKERHAM: Dr. Malmud, this is Ashley.

CHAIRMAN MALMUD: Yes, Ashley, I was just about to call on you.

MS. COCKERHAM: Okay. So to preface this, the Commission last year directed staff to provide options or to provide recommendations on how the ACMUI should report within the agency. Currently, the ACMUI reports to Rob Lewis as the Division Director in FSME.

So we are just looking for feedback from the Committee. I am drafting the paper that

we will provide to the Commission, and talking about the options that we have, we could continue to report -- or the ACMUI could continue to report to the Division Director or there is the option of them reporting directly to the Commission, which would, obviously, require some changes.

So we are looking into those options and looking for feedback from the Committee and basically whatever input the Committee provides today -- I will use these transcripts and this information to provide that directly to the Commission in my paper.

CHAIRMAN MALMUD: Thank you, Ashley. If I may, I should fill the entire Committee in on my more recent experience. I have met individually with the Commissioners, those who were able to meet with me on a day that I went back to Washington after having not been able to attend the last meeting that you all attended.

I expressed to them the concerns of the ACMUI with regard to the reporting mechanism. It was my impression from discussion with staff as well as with the Commissioners that reporting directly to them versus reporting in the current manner through Rob Lewis would not necessarily

shorten the time frame required to process issues. That is number one.

Number two, I was reassured and, in fact, experienced the availability of the individual Commissioners to us. Whenever I need to call upon them, I could arrange a meeting with one or with several of them, assuming their availability on the same day.

So that is an important issue, because we have not always availed ourselves of that opportunity, and the opportunity is both available to us and, in this case, I took advantage of it.

The frequency that our Committee meets is such that issues are not resolved -- I'm sorry, was someone saying? When the issues are not resolved, it takes a number of months before the next committee meeting is physically together. That, I don't think, would change.

There are two issues related to the reporting. One is the need for the Committee to feel that the issues that we discuss are, in fact, transmitted to the Commissioners without being filtered in some fashion.

I was astonished, quite frankly, at how knowledgeable each of the individual

Commissioners was with regard to issues that we have discussed. Considering the breadth of their portfolios, I was pleasantly surprised that they were as knowledgeable about what we are doing and what we have done as they are. They also seemed quite genuine in their expression of availability.

Now the next issue was staffing. We clearly feel that we need more staffing, because the way in which we function is as a committee, when we have staff availability to us, but our work is really done by subcommittees. For example, this most recent issue was dealt with by Sue Langhorst, and issues in the past have been dealt with by other Subcommittee chairs, whether it is the Vice Chair of the Committee or Dr. Welsh or others.

In those areas, we could use some additional staffing, and I transmitted that with the additional message that we have never had -- Although we have very good support from NRC, we certainly are enjoying the strongest support we have ever had with Ashley working directly with us.

So it was not by way of complaint, but by way of need, in that we feel we need a little

more staff support, which may mean that we want to ask for some more staff support for Ashley. The other option of reporting directly would mean establishing a staffing level which, I think, given the current budget concerns in Washington, would probably not be addressed. However, if the committee feels very strongly about it, we could present it, though I wouldn't be optimistic about it, and I say that just from reading the newspapers.

So I was very satisfied with both the willingness and the knowledge of the Commissioners regarding the issues that we are dealing with, and also with their genuine appreciation of the effort that the members of the Committee put forth.

Now having -- Are there members of the Committee who wish to express some opinions regarding this issue?

MEMBER ZANZONICO: This is Pat Zanzonico. Can I -- Ashley, can you just clarify again, frankly, what the issue is at hand? Based on what Bruce said, I presume we are not considering FSME Policy and Procedure 2-5 at this time, but a separate issue specifically dealing with the route of reporting.

MS. COCKERHAM: Yes. Okay, so last year -- I am pulling up the SRM right now. Last year on July 21st the Commission -- Once the Commission has a public meeting, typically they send staff a Staff Requirements Memorandum, and that is staff's marching orders. That is what we need to do following that meeting.

So following that meeting, on July 21, 2010, there was an SRM from the Commission, and it had two pieces. The first piece was that staff should develop internal guidance for all major medical policy. That is the Policy and the Procedure that you guys have been talking about at past meetings, and we have feedback from ACMUI on that, and that piece is moving up the chain. So that is one part of the SRM.

The second part of the SRM says that staff should work on a Commission paper outlining possible improved mechanisms for providing the Commission with the ACMUI's feedback regarding medical issues, including the pros and cons of restructuring the ACMUI such that it reports to the Commission.

So this paper will also include an implementation plan that would be used to affect

such a restructuring, should the Commission decide to move forward.

So I am working on that Commission paper, and in that Commission paper I need to be able to provide ACMUI's input or feedback on what this structure looks like or how the current structure is working, possible improved mechanisms for the current structure or if the Committee wants changes. Basically any feedback you have I am going to include that in my paper. Does that help clarify?

CHAIRMAN MALMUD: Yes, thank you, Ashley. I'm sorry, who was speaking next?

MR. LUEHMAN: Sorry, Dr. Malmud. This is Jim Luehman. Just to clarify what Ashley -- to extend on what Ashley said, one option for the Committee to consider is that the update of the procedure, the first SRM item that Ashley spoke about, the Committee could find that with that enhanced procedure that that has gone a long way to addressing many of the concerns that you said about the Commissioners getting the Committee's opinions in an unfiltered manner.

Therefore, you could find that the present structure with the enhanced procedure

addresses your issues, or you could say -- So that is one option.

The Commission said -- asked the staff in the second item to say, but even looking beyond that, even if the staff enhances the way the Commission is informed of the ACMUI's issues and views on issues, does the committee or does the staff -- What would the options be, if you go a step beyond that and actually do a reorganization or re-reporting -- change the reporting structure so that not only do we enhance the procedures, but we change the structure.

So I think that what I am trying to say to the committee is you have a number of options. You could look at the procedure and say that the procedure addresses your concerns. You could say, well, the procedure doesn't quite get there, because we still have these staffing issues that you addressed, but we don't think -- you addressed, but we don't think the reorganization necessarily addresses those. So, therefore, we don't favor the reorganization, but we do favor some additional staffing, or you could say, yeah, we favor reporting to the Commission.

I guess what I would say about that,

just sort of previewing where I think Ashley is going with the paper, we think that the most logical place that -- way that that could be accomplished would be the Committee would then, if that was the recommendation and the recommendation was accepted by the Commission, it would most likely be a structure where the ACMUI would be supported by part of the structure that presently supports the ACRS.

You are aware of the structure for the Advisory Committee on Reactor Safety. They have a staff director who has staff that supports the ACRS, and then the committee itself reports directly to the Commission.

If that structure -- If similar structure was going to be recommended for the ACMUI, what we as the staff envision is that that Executive Director that supports the ACRS would then have some number of staff under his or her purview to support the ACMUI directly, but that that structure would take advantage of the existing resources such as in the administrative area that already support the ACRS, so that we wouldn't have to duplicate those to support the ACMUI, if they were going to report to the

Commission.

So you have a whole -- I think that what I am trying to say is there is a whole number of variations that you can go from, from requesting additional staff support to additional staff support plus a streamlined or updated procedure, to completely changing the reporting requirement to have the Committee report to the Commission.

There's pros and cons to all of those, but we are trying to get -- Ashley is trying to get, I think, a sense of sort of where the Committee as a whole would be in sort of that spectrum of options, so we can accurately reflect that in the Commission paper.

CHAIRMAN MALMUD: Thank you for that perspective. I would like to hear from several members of the ACMUI, if we may, regarding their current feelings.

The move to ask for status similar to that of the ACRS dates back a number of years, and those who were the strongest proponents of it are no longer members of the ACMUI. They rotated off, and I wonder if the current members would care to comment on their feelings at the moment.

MEMBER WELSH: Dr. Malmud. Dr. Welsh.

CHAIRMAN MALMUD: Dr. Welsh.

MEMBER WELSH: I have a question perhaps, to start off the discussion. That is: Has anybody from ACMUI, specifically you, Dr. Malmud, as our Chair, been in touch with anybody from the ACRS to get insight from them about their feelings about the reporting scheme they experience, and compare and contrast that with the ACMUI reporting scheme to see if there are any advantages or disadvantages that we could be aware of?

CHAIRMAN MALMUD: The answer to your question is I have not approached a member of the ACRS. I have asked staff at NRC for their informal opinions with regard to the issues that concerned ACMUI members, and they are timeliness of response and also explanations for rejections of ACMUI recommendations.

We are, obviously, pleased with the feedback regarding recommendations that are accepted. There is some dismay among members of the Committee with regard to recommendations that are not accepted with what is perceived to be inadequate explanation of why the recommendations

were not accepted, and also a timely telling of why they were not accepted. But if the committee wishes to, I could get the names of some of the members of the ACRS and ask them what they feel.

My impression from speaking to staff was that we would really not achieve one goal, which was to have faster turnaround, because that is really based upon the frequency with which we meet. But there is consensus, I believe, among ACMUI members that we do need some additional staff support for some of the yeoman work that is being done by our subcommittees.

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

CHAIRMAN MALMUD: Yes, Sue?

MEMBER LANGHORST: There's many of us who are new to the Committee, and I still kind of count myself as that, because it has been a little over a year since I have been appointed to the Committee. So I don't have a strong view one way or another, and really don't fully understand all that maybe what Ashley is putting into this paper.

So I don't have good sense one way or the other, and probably will talk to some of my predecessors to ask their opinions of what the

issues were then and how they perceive issues at this point in time.

So I can't say one way or another, and so, Ashley, I apologize. I can't give you a good consensus from -- I mean, I just don't know the issue well enough.

CHAIRMAN MALMUD: I appreciate your position, and I understand it. As one of the more senior members of the Committee in terms of my tenure with the Committee, I think that I have seen a great change in the actions of the Committee, the interaction with staff, and I think that we are functioning at a different level than we did some years ago, and there is greater satisfaction on the part of ACMUI members with respect to the interaction.

I believe the same thing is true of staff at NRC. So that some of the issues that we are discussing were of significant concern to former members of the Committee and, since they are not here, they cannot express their concern, but all I can say is that I don't feel the intensity of those concerns, and I didn't then. I thought some of the issues were not regulatory. They were a matter of style of communication.

So that is why I am asking current members if they really feel that they want to change something which, from my perspective -- and I have no personal investment in this, but from my perspective is functioning better now than it did four or five, six years ago.

MEMBER ZANZONICO: This is Pat Zanzonico. I would have to reiterate. At the risk of sounding dense, I am not entirely sure what the issues we are currently considering are, but having said that, I again -- As a new member of the Committee, I haven't gotten a sense at all that there is an inefficient or censored or however one would like to characterize it pathway of communication from the Committee to the Commissioners or other officials at the NRC.

So perhaps, as you are alluding to, Dr. Malmud, things have improved to the point where something that may have been a problem of style or otherwise in the past has largely been resolved.

CHAIRMAN MALMUD: Thank you. Are there any --

MEMBER THOMADSEN: Dr. Malmud, Bruce Thomadsen.

CHAIRMAN MALMUD: Yes, Bruce?

MEMBER THOMADSEN: From discussions with some of the previous members of this Committee and descriptions of how things were, both interacting with the staff at the time and with the Commissioners, I think the situation has changed remarkably.

I don't personally see this as a big issue at this time. As the Commission changes with time, it may again be. As the staff with whom we work changes, it again may be. I would assume that this Committee could bring up the issue at that time.

CHAIRMAN MALMUD: Thank you, Dr. Thomadsen, and that is my feeling and, in addition to that, you know, I am based in Philadelphia. If there is an issue which is hot and burning, I am more than willing to hop on the train and make an appointment to see one or several of the Commissioners directly, express our concerns, and then take the train back again. It is not a major issue for me, and I am willing -- more than willing to do that. However, I will not always be the Chair, and in addition, Ashley will not always be our main point person.

Therefore, the concern may arise again in the future. I don't think it exists at the moment, but I don't want to make that decision since I am the one who, in a sense, engaged in the self-congratulation.

MEMBER SULEIMAN: Dr. Malmud, this is Orhan Suleiman.

CHAIRMAN MALMUD: Yes, Dr. Suleiman?

MEMBER SULEIMAN: I have always sensed I think the Committee is operating pretty well right now. There is a history going way back where the committee -- and there was quite a bit of tension between, among a number of individuals, and I think Ashley really needs to be commended, because I think she has improved the communication and the effectiveness to a large degree, and I don't know whether her superiors are actually aware of this, but I think she has contributed in a major way.

Having said that, I find both the NRC at times and the Advisory Committee at times, not really sure of what they are asking each other for. I think sometimes the charges are not clarified to the Committee, and I think sometimes the Committee goes off on a slight tangent.

So I don't know whether new protocols need to be addressed or whatever, but I think that, clearly, a little bit more clarification in what the committee is being asked to do would help, and sometimes the rules of how the Committee should operate. If, in fact, we are in violation of something, we need to be aware of that rather than go ahead and expending a lot of effort and then finding out that we went into an area that we really didn't need to.

Aside from that, I think the -- I would give everybody a passing grade, but I think there needs to be -- There is more room for improvement in terms of clarification of what we need to do and how we go about it.

CHAIRMAN MALMUD: Thank you, Dr. Suleiman. You are also one of the more senior members of the committee in terms of tenure, and I appreciate your opinion.

MEMBER SULEIMAN: Don't let me -- I am sorry for interrupting, but also under your leadership -- I really don't want to take that for granted. I think you help the committee tremendously as well. I don't want to omit that.

CHAIRMAN MALMUD: Well, thank you. We

have had really, I think, superior interaction with staff members of NRC, and I am appreciative of their efforts which has made things easy for me and, of course, we have had -- Both the current members of the Committee and the previous members of the Committee, the intellect and the experience of all of you is extraordinary, and the public is well served by this Committee's intellect and knowledge, and I think NRC is well served, as we are well served by NRC.

Now having accomplished the congratulations, I would ask the Committee whether they feel that we should go through the process of requesting a status similar to the ACRS or whether we should maintain the current structure, asking for some additional staff.

MEMBER WELSH: Dr. Malmud, I am Dr. Welsh. I would like to --

CHAIRMAN MALMUD: Yes, Dr. Welsh.

MEMBER WELSH: -- ask one additional question here before we proceed. As a semi-senior for the ACMUI, I, too, have witnessed some dramatic improvement in the past few years, and therefore, the question in my mind might be one of the old adages; should we attempt to fix something

that is not broken anymore.

I can appreciate and understand the previous members' concern, but I generally agree with you that maybe some of those concerns have already been addressed and rectified.

Having said that, I am aware of the former Advisory Committee on Nuclear Waste and Material, and they have merged with the -- They are now part of the ACRS, leaving -- just correct me if I am wrong -- only two Advisory Committees, us, the ACMUI, and the ACRS, and there seems to be a little bit of a -- There is a disconnect in the fact that one Advisory Committee has a different reporting scheme than the other Advisory Committee.

Would it help NRC in any form or fashion if all Advisory committees, if there are only two now -- would it be better to have the uniform reporting status for all Advisory Committees? So this is a question, I suppose, for NRC staff.

CHAIRMAN MALMUD: Well, we can ask Ashley to inquire of more senior NRC staff if they are looking for a change, and then get that feedback to us.

MR. LUEHMAN: Dr. Malmud, this is Jim Luehman. I just -- I will attempt to answer that right now. A couple of things.

One is, you know, I know that the new members are at somewhat of a disadvantage, but basically -- and I don't want to oversimplify this, but the way the ACRS operates is they meet about -- formally, about once a month, and that is their meeting frequency, and they have a lot of subcommittees in the interim, and for each issue that they review, what they do -- and this is the way that they get formal visibility with the commission -- is they issue a formal letter to the Commission on their position on significant licensing action or approval of a reactor design or whatever it is that they are looking at, and the staff is required to formally respond to that letter.

That is really the methodology that they -- that is, by regulation and by statute, is that that is how they get -- that their views are directly transmitted to the Commission.

There is -- Obviously, it gives the ACRS direct access to the Commission, but I would say that that comes with a cost to the Committee.

Their structure is -- they are very structured in the way -- in the regularity of their meetings. They have definite deadlines for the production of these letters.

So they are on pretty tight schedules as they review those things. Given the make-up of that committee, that there are many emeritus and retired individuals, not all the full ACRS but many, they are able to do a lot of their work in that regard.

All I would offer is that, if the ACMUI, being for the most part practicing physicians, I would say that such a structure may not be the best, given that it is a little bit less flexible. But that is for your consideration.

As far as your question about what the staff recommends or sees, our view is, again, we think that you should -- We think that the structure can be significantly enhanced by the Policy and Procedure that has been discussed, that if that is done right and lays out clear guidance as to how the staff is going to engage the ACMUI and what the staff's responsibility for transmitting the ACMUI's views to the Commission

and when that has to be done, in what circumstances, we think -- this is just my personal opinion, and I think many of the staff -- that that will address much of your concern that you brought up where you said that you are happy when they adopt ACMUI positions. You are somewhat a little bit disappointed or dismayed or, in fact, uninformed as to when or why certain positions weren't adopted that the ACMUI recommends, that you don't always get that feedback when there is not adoption.

Again, we think that the procedure -- updating the Policy and Procedure and making those feedback loops clear would probably be the best option, but the Commission asks -- again, in Part 2 of the SRM, as I said, they ask for an exploration of all the options.

The other one would be a more formal reporting. Now as to Dr. Welsh's concern or comment about there being two committees and would it make sense for both Committees to report along the same chain, I think that the staff's view on that is that the ACRS affects -- The Policies and Procedures that they deal with reach across a number of -- many offices at the NRC, now that

they include the ACNW. It includes the Office of Nuclear Reactor Regulations, the Office of New Reactors, the Office of Nuclear Materials Safety and Safeguards, as well as a portion of our office here in FSME.

The issues that they deal with span all of those offices, and that is why I think the Commission level reporting exists there. For the ACMUI, while the very important issues that you deal with, they only report in -- There is only one office that has regulatory responsibility for the medical issues, and that is the office -- this office.

I think that is originally why, and I think it is my view, personal view, why I think that a more tailored reporting for the ACMUI was originally structured, and again my personal view why it is still apropos today. But again, that is just my opinion and why I think that it makes sense that, if it stays this way, if the Committee felt strongly that they would want to be part of the larger structure, then that is fine, too. That can be considered.

MS. COCKERHAM: Dr. Malmud, this is Ashley.

CHAIRMAN MALMUD: Yes, Ashley?

MS. COCKERHAM: Just to add one thing to what Jim said as well, as far as structuring of ACRS versus ACMUI, just a little bit of history.

ACRS is mandated by law. It is something that Congress came up with. They said there will be an ACRS, and they will advise the NRC. Then the way the ACMUI came about, it goes all the way back to the Manhattan Project, but long story short, the Commission, not Congress, created ACMUI to advise staff.

So just -- It is not like we just magically came up with this and said, oh, we are going to have two different reporting structures. It goes way, way back from how they were created from the very beginning, and ACMUI is not mandated by a law, but they are created by the Commission. So we operate at the level that we do. I don't know if that helps.

CHAIRMAN MALMUD: Yes, it does. It is historical perspective on it.

MS. COCKERHAM: Yes.

CHAIRMAN MALMUD: Are there other comments?

MEMBER GILLEY: Dr. Malmud, this is

Debbie Gilley. Can I just ask Ashley a question? If the ACMUI were to report directly to the Commission, would that require statutory changes or is that something that the Commission can do internally?

MS. COCKERHAM: The Commission would be able to do that internally.

MEMBER GILLEY: Thank you.

CHAIRMAN MALMUD: I will comment by saying that I am more than willing to take the time and meet with members -- with the Commissioners at the request of the Committee, and they have expressed a willingness to meet with me, and it needn't be on a restricted basis. It can be on the basis of need.

So having been in administration for a while, I am always concerned about unintended consequences and, therefore, my own inclination would be to keep the reporting lines as they are with the enhancements that were discussed earlier.

MEMBER WELSH: Dr. Malmud.

CHAIRMAN MALMUD: Yes, Dr. Welsh.

MEMBER WELSH: Dr. Welsh again. Given what I have just heard in response to my comments and questions, I think that I as a member of the

ACMUI feel very fortunate that we don't have the horrible circumstances that the ACRS is subjected to. So perhaps I would just like to count my blessings and, for all it is worth, I think that maybe it is best to keep things the way they are and not try to fix them if they are not broken anymore.

CHAIRMAN MALMUD: Will that be a motion from you?

MEMBER WELSH: I can phrase it in the form of a motion, which is: I propose that we maintain the status quo in terms of our ACMUI reporting scheme.

CHAIRMAN MALMUD: With the enhancements that were suggested?

MEMBER WELSH: Thank you.

CHAIRMAN MALMUD: Is there a second to Dr. Welsh's motion?

MEMBER ZANZONICO: Seconded by Zanzonico.

CHAIRMAN MALMUD: Thank you. Any further discussion?

MEMBER VAN DECKER: Dr. Malmud, this is Bill Van Decker.

CHAIRMAN MALMUD: Yes, Bill?

MEMBER VAN DECKER: Recognizing that I am probably one of the now senior members of this group -- that scares me -- let me just make a couple of comments, and you personally probably recognize my inability to really recognize regulatory structure or internal structures at all usually in life. So I don't know what models work, but I would point out that one of the issues that, I think, has been very helpful in the last few years is that the Commission has met personally with ACMUI once a year, and actually had an open forum that actually sometimes has even included other stakeholders.

I would point out that there was a period of time where that did not occur, and I think that that actually is a very, very useful process for making everyone feel comfortable, that there has been some personal discourse for the filtering issue, whatever people may believe, and I think that we should really believe that that should happen every year.

I think that the staff has done an incredibly good job, and I have been very pleased with their give and take and their knowledge base and helping ACMUI work right now.

My last comment would, obviously, be that the biggest sticking point to this situation is usually when very, very personal rulemaking is going on, because that intensifies pressure of Part 35, patient release and that type of stuff where people really want their views heard, and things kind of are really clear-cut in their mind.

The role of any committee is, obviously, to hear and to be heard. So the "to hear" piece is each of us has a constituency, and a good portion of what we do is hearing things from the other side and transmitting to the constituency and getting feedback. That is kind of like work-arounds and operational stuff, not much big deal there. That needs to happen and happen smoothly.

The other piece is, obviously, being heard, and being heard in a manner that seems to carry the weight that we have, the concerns for our constituencies. So sometimes in the rulemaking process and the structure that we may find out how well the communication is going and how satisfied people are.

Having said that, there is no reason in my mind to expect that, you know, as some of

this stuff starts to come to fruition in the next year or two, that we won't have anything but fairly transparent and clear-cut back and forth and that type of stuff. But I do think when it becomes very clear rulemaking stuff that the concerns heighten, and the communication, obviously, needs to be fairly clear. But I do thank the Commissioners themselves for meeting with us on a yearly basis over the last couple of years, and I think that that is very, very helpful, and I think that the model itself depends on the good faith of everybody involved and what they are trying to accomplish, and I think that that is the most important thing.

So I am personally comfortable where we currently are, but I think that some enhancements and making sure that some things are happening, especially in the rulemaking process for discussions of decisions and especially a yearly personal meeting to express the body language and concerns is important.

CHAIRMAN MALMUD: Thank you, Dr. Van Decker. Any other comments or discussion? There is a motion which has been seconded.

MEMBER LANGHORST: Mr. Chairman, this

is Sue Langhorst.

CHAIRMAN MALMUD: Yes, Sue?

MEMBER LANGHORST: I still feel at a real disadvantage on this, and if we do vote on this today, I would have to vote no, because I just -- I would like the draft of the report that Ashley is putting together so I can have a more full understanding personally.

CHAIRMAN MALMUD: So would you like to table the motion or are you objecting to the motion?

MEMBER LANGHORST: Well, I think we need some time, especially given that we didn't even know what this item covered. I think it would be nice to table the motion and have some time to review what Ashley is putting together.

CHAIRMAN MALMUD: Thank you.

MEMBER GUIBERTEAU: Chairman Malmud, hi, this is Mickey Guiberteau. I have joined the call sometime ago, but I was waiting for a chance to speak.

I would support tabling this motion for the reasons that Sue said, and although I have heard most of the conversation, it was not clear to me that on this call that this would be

something that we would be putting on the table, either to reject or to put forward as a model.

So I think further discussion among the Committee would be a good thing, further thought and, as you have suggested, perhaps some further consultation with the Commissioners.

CHAIRMAN MALMUD: All right. Thank you, Dr. Guiberteau. There have been two recommendations for tabling this. It could be brought up at our spring meeting, at which time I would ask if Ashley could have her comments prepared. Would that be a reasonable time limit, Ashley?

MS. COCKERHAM: Yes. Did you say before the next phone call?

CHAIRMAN MALMUD: The next meeting.

MS. COCKERHAM: Yes.

CHAIRMAN MALMUD: Which is in April, I believe.

MS. COCKERHAM: Oh, actually, my paper is due to the Commission before.

CHAIRMAN MALMUD: It would be even before that? That is even better.

MS. COCKERHAM: Yes, and actually, this is why we set up the January 12th

teleconference, and there is one topic on the agenda, and it is the ACMUI reporting structure. I actually need feedback from the Committee for sure before the end of this month, because my paper is due to the Commission April 1st, and I will not be here for that next meeting anyway.

CHAIRMAN MALMUD: So then we will have this discussion on January 12th, if we table it today. Is that correct?

MS. COCKERHAM; Yes.

CHAIRMAN MALMUD: All right. Is that acceptable to those who made the motion?

MEMBER WELSH: This is Dr. Welsh, and I agree fully with what Dr. Langhorst has brought up, that perhaps it would be wise to table this until this presentation concludes before we proceed.

CHAIRMAN MALMUD: Thank you. If the Committee is in agreement, we will table it for the Committee phone meeting January 12th. Is that acceptable? Any opposed to it? Sounds like it is acceptable. Okay, thank you.

We now move on to the next item on the agenda, which is the rulemaking and implementation guidance for physical protection of byproduct

material. Who is going to tackle that for us?

MEMBER GILLEY: This is Debbie Gilley. I kind of started the ball rolling. Sue Langhorst and Darrell Fisher also serve on our Subcommittee.

We took a high level approach to coming up with comments over the overall regulations, just detailed comments, and they were provided for you in a draft report for your review.

The recommendations from the report from the Subcommittee: Encourage NRC to implement the existing orders into regulations and not to enhance them, and also to begin looking at developing strategic rulemaking that can be based on risk informed.

I will answer questions to the report, if you have had a chance to read it.

CHAIRMAN MALMUD: Has anyone not had a chance to read it?

MEMBER GILLEY: I would ask also that Dr. Fisher and Dr. Langhorst please weigh in on this. It has been a real tight timeline for us.

CHAIRMAN MALMUD: Thank you. Do we have additional comments from either Dr. Fisher or Dr. Langhorst?

MEMBER FISHER: Yes. Dr. Malmud, this is Darrell Fisher. I have got a little laryngitis. So I hope you can bear with me.

The Subcommittee supports the general concepts that this proposed Part 37 works toward, but in many cases a lot of new requirements have been added that are not currently part of the orders to which licensees must comply; and in a lot of cases, the extra burden of complying with the new requirements may be so burdensome to the licensee that it will have two distinct impacts on the practice of medicine.

The first distinct impact would be to greatly increase the cost of providing certain services that require use of Category I and Category II materials.

The second ultimate impact of these new regulations appears to be such that, with the requirements for safety and security being so burdensome, that medicine will abandon the use of these procedures outright, and that they will not be available to benefit patients.

So we believe that there is a -- that a reasonable balance between availability of Category I and Category II sources for patient

therapy and research and counterbalanced with a need for safety and security, but that excessive requirements for safety and security would neither make these sources safer nor make them available to patients who need them.

So I would agree with what Debbie Gilley has summarized, that there is a reasonable balance that can be achieved, that can be successful in securing these materials so that they are not available for illegal activities.

CHAIRMAN MALMUD: Thank you.

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

CHAIRMAN MALMUD: Yes, Sue?

MEMBER LANGHORST: The Subcommittee -- we also agree that we understand that the need to implement, to develop and implement the increased controls, license orders necessitated the structure of a one-size-fits-all model, but we are concerned that perpetuation of this one-size-fits-all model into the regulations with added requirements is not in line with how NRC develops their performance based risk enhanced regulations.

So we feel that there was much upheaval for licensees, and speaking as a medical

licensee, a lot of upheaval in my office, when we implemented the increased controls, license orders, and added the FBI fingerprint/background check, and we currently have those in line.

I think a lot of licensees are doing well in that, and have enhanced security for these sources. So I think this is an opportunity to move from orders to regulatory space, as I call it, or to codify these current requirements, and then work in a very strategic manner on what is going to be effective security enhancements.

One of the things that I personally would like to see is that there be more performance base in between what you do for determining individuals' trustworthiness or reliability versus what the actual situation is for a given source, either by what isotope it is, what form it is in, what device it is in.

So I would like that performance based opportunity to be able to let up a little bit on the trustworthiness and reliability requirements, if you have really strong physical protection.

Thank you very much.

CHAIRMAN MALMUD: Thank you. For those of you who might wonder what Sue was

referring to, page 4 of her document -- her Subcommittee's document -- lists the ACMUI recommendation, and she was referring in the second part of this discussion to the second bullet point, which had to do with working with developing a strategic rulemaking.

You have all had a chance to review the document from the Subcommittee. This is now a meeting of the actual Committee itself and, therefore, the Subcommittee report would be considered a motion to the Committee. Is that fair, Debbie?

MEMBER GILLEY: Yes, sir.

CHAIRMAN MALMUD: So this is a motion to the Committee. Is there a second to this motion?

MEMBER SUH: I second the motion.

CHAIRMAN MALMUD: Who seconded?

MEMBER SUH: It is John Suh.

CHAIRMAN MALMUD: Thank you. Further discussion?

MEMBER ZANZONICO: This is Pat Zanzonico. Just for my personal clarification, based on my reading of the proposed rulemaking and the Subcommittee report, I gather that perhaps the

two issues that are the most onerous are the background check issue and the requirement of licensees to interact with local law enforcement, which do strike me as the most problematic components in practice of the proposed rulemaking.

Is that basically -- Am I reading the Subcommittee report correctly in kind of inferring that from the report?

CHAIRMAN MALMUD: This is Malmud. I read it similarly, but not exactly. So, therefore, I would ask the Chair of the Subcommittee, Debbie Gilley, to comment. My interpretation was that there are two major issues. One was the cost involved, and the other one was, because of the cost and the regulatory delays and requirements, that some of the services may be made unavailable to patients as a result of the expense and time commitment.

Was that a summary between the two of us, Debbie?

MEMBER GILLEY: That is correct. It is really on two different levels. We took a high road or a big universal approach, and the cost of doing business with the additional requirements is definitely at a higher level.

The individual activities that Dr. Zanzonico brought to attention of the Committee are just areas where we are demonstrating that cost and that implementation and, most importantly, licensees remaining compliant with the requirements are problematic.

CHAIRMAN MALMUD: Thank you.

MEMBER ZANZONICO: I will just say thank you.

CHAIRMAN MALMUD: So I think the problems are well summarized on page 4 of the document that the Subcommittee presented, and the recommendations are well summarized. The problems are well summarized in the first three pages.

This has been presented as a motion with a second. Any other comments? It is a very thoughtful and detailed document which represents a lot of effort, for which we are appreciative to members of the Subcommittee.

All in favor? Any opposed? Any abstentions? It passes with unanimity.

MEMBER GILLEY: Thank you.

CHAIRMAN MALMUD: Thank you. Thank you, Debbie Gilley, Sue Langhorst and Dr. Fisher.

If we may, we will move on to the next

item on the agenda, which is the impacts of the Draft Safety culture Policy Statement for Medical Licensees. Who would like to tackle that one?

MEMBER THOMADSEN: I think I am probably the one who should probably --

CHAIRMAN MALMUD: Bruce?

MEMBER THOMADSEN: -- address that.

Yes. I was the one who raised most of the issues with that when it came before the ACMUI before. Since that time, there was a second version of the Policy Statement which was sent to the ACMUI with two clarifications, which apparently had meant to be in the Statement that was sent out but got cut somehow.

One was pointing out that the traits are not complete, that there are other traits that would be important, and the other is that the traits were not intended to be enforceable, which basically addressed most of the points that I had, worrying about this Statement.

On the 24th there is a meeting in Washington to discuss the Safety Culture Policy Statement. I am going to be representing the ACMUI at that meeting, and to that end, I would like to tell the Committee what I am planning on

saying, and seeing how it strikes the rest of the Committee.

I will start by saying I now think that the Policy Statement is, in general, a good statement, a good policy, and as explained but not necessarily in the policy, I am not as worried as I was about how it might be used in enforcement. But with your permission, I will tell the five points that I plan on making at that meeting.

CHAIRMAN MALMUD: Please do.

MEMBER THOMADSEN: And, please, if you have comments about any of them or how they are being stated, please let me know as we go.

The first is, while good, the list traits are not exhaustive. There are many other traits organizations with safety cultures that are not included. The policy statement does recognize this.

Two: Also while the traits are good, an organization need not exhibit the traits to be safe. For example, an organization without trust or respect can, and likely would, establish procedures with layers of redundancy, possibly automatic, to prevent errors, since the leaders would not have trust that the workers would

execute their jobs correctly.

Three: Safety is easiest and most natural in organizations that exhibit such traits and that is why publishing them would be a good educational enterprise.

Four: A positive safety culture is in the nature of an organization and cannot be forced upon an organization. While practices can be imposed, forcing practices that appear as traits in a good safety culture likely will not have the same effects as if the organization developed them naturally, and can be counterproductive if it uses resources that could be devoted to actual safety practices.

Five: Given point four, the statement in the policy, these traits are not necessarily inspectable and were not developed for that purpose, should be remembered into the future.

That is the -- That is pretty much the sum and substance of what I will be saying at the meeting.

CHAIRMAN MALMUD: Thank you. Dr. Thomadsen is inviting comments from members of the Committee or others who wish to comment on his five points. Hearing none, may I ask you a

question, Bruce?

MEMBER THOMADSEN: Please.

CHAIRMAN MALMUD: Having recently experienced surgery, I was still awake when they had a "time out," at which time a list of details was checked, including the name of the patient, date of birth of the patient, the site of the surgery, and the specific procedure, etcetera, etcetera.

This was not something which came from within the world of surgery but really was imposed, if you will, by a higher authority, both centrally and within the institution, and it is very effective.

Is that compatible with your item number four?

MEMBER THOMADSEN: It actually is, in that I would like to have -- I would like to see more data on your point that it is very effective. Statistically, it has not been shown to be very effective. The number of wrong side surgeries -- and this is in a study that came out two years ago -- had not changed since before those “time outs” were instigated.

Why that was the case, the authors of

the article didn't have a clue, but it is not clear that that was so effective, and in part it may not be so effective, because it may be something, a trait, which is forced upon hospitals and may not be performed very sincerely.

CHAIRMAN MALMUD: All right. So that my observation, which is based upon a sample of one, may not hold, although I do know that at our own institution I probably would have been alerted had we had an incorrect limb operated on or something like that.

MEMBER THOMADSEN: Yes, right, and in your institution, which may be, I would assume, an organization that has a good faith culture, adoption of such measures might not be forced, but when offered a "something" that appears like it may be useful, may be adopted quite willingly and with rigor and sincerity.

CHAIRMAN MALMUD: Okay. I am laughing, because I am thinking back to my experience when the surgeon stopped everything and said time out. It reminded me of, when my daughter was younger, behavior in the preschool where they had a time out if something was going wrong, and everyone did stop, and everyone did

fulfill a checklist of requirements before they went on with the procedure, and I was, I guess, a little amused by it, but also impressed that people of such stature in terms of anesthesia, nursing and, of course, the surgeons were doing this.

All right. Well, in that case, I am perfectly agreeable with what you have pointed out. Anyone else have a comment?

MEMBER ZANZONICO: This is Pat Zanzonico. I also just wanted to pursue that point for all of you. I mean, it is kind of akin to a statement that, you know, morality can't be legislated, and the issue is then, is it a futile exercise? If an organization or whatever doesn't have a rigorous or any safety culture, is it futile to enumerate traits to kind of codify a safety culture in the way it is being proposed, etcetera, etcetera?

I am kind of agreeing with Dr. Malmud, I guess, in that sort of forcing some organizations like some people to do certain things for their good and the greater good is worthwhile and serves the greater good, and isn't that somewhat counter to your point four?

MEMBER THOMADSEN: No, and do not confuse trying to impose a safety culture with safety practices. They are entirely different, and let's assume for the moment that time outs actually do serve some function.

Imposing that particular behavior could be useful, just as requiring what big tests of radiation sources can be useful, even if that wouldn't be something that the culture of the nation wanted to do.

You don't have to change their culture to change that behavior, and in this case the point to be made is, if there are safety behaviors that have to be in place that are not -- and those would not be traits but things that have to be done -- enforcing that upon the licensees can be very useful and productive. You don't have to change their attitude toward it, which would be their culture.

If you look at the list, the list isn't of behaviors so much as attitudes. You can force an organization to be open to people raising concerns. How they deal with those concerns is quite another matter.

It is like the suggestion box in the

cartoons with the bottom cut open. You can be open to suggestions being submitted, but that doesn't mean you are open to the ideas.

You can't force something like that, but you can force whatever behaviors you think are necessary for safety.

MEMBER ZANZONICO: Understood.

CHAIRMAN MALMUD: I am not a philosophy expert and, therefore, I am treading in dangerous ground for myself, but the imposition of rules carried over a period of time can alter a culture, can it not?

MEMBER THOMADSEN: Absolutely.

CHAIRMAN MALMUD: And that is what we are seeking. That is what you are seeking.

MEMBER THOMADSEN: That is what I would be seeking.

CHAIRMAN MALMUD: Yes. That is what we are hoping for.

MEMBER THOMADSEN: Right.

CHAIRMAN MALMUD: In the same manner, we have seen the transition to hand washing before touching a patient and upon leaving the patient's room. We have known for over 100 years that that was necessary, but now we are imposing it, and it

is being carried out, and it is second nature to us now. So that the imposition of a rule has made it part of our culture.

MEMBER THOMADSEN: That is correct.

MEMBER FISHER: And, Mr. Chairman, this is Darrell Fisher. I would like to take the position as a member of the Committee that the Statement of Policy is really quite well written, very carefully drafted, and very sensitive to comments that have been received from the public, and I think that those who have developed this statement really need to be congratulated.

As a Committee, I think we should consider endorsing this wholeheartedly so that it can go forth to the Commission with our positive recommendation.

CHAIRMAN MALMUD: Thank you. Will that be the second to the motion?

MEMBER FISHER: Yes.

CHAIRMAN MALMUD: The motion coming from the Subcommittee?

MEMBER THOMADSEN: What is the Subcommittee?

CHAIRMAN MALMUD: I thought that was--

MEMBER THOMADSEN: I don't think that

there was a Subcommittee working.

CHAIRMAN MALMUD: Oh, it was a subcommittee of one. Thank you, Dr. Thomadsen.

MEMBER FISHER: This is Fisher again.

CHAIRMAN MALMUD: We will accept this as Dr. Thomadsen's recommendation, seconded, and open for further discussion, if any.

MEMBER THOMADSEN: I think that I would be delighted to take this motion as another bullet point to put into the presentation. Actually, I would put it as the first bullet point, saying all those things that Dr. Fisher said, and would ask him to send me an email with the exact wording that he just said, along with just noting the concerns that the Committee has about the Policy Statement.

CHAIRMAN MALMUD: All right. This is Malmud again. I want, first of all, to thank you, Bruce, for the effort, and I will present this to the Committee as the motion, which has been seconded, to be added on. Any further discussion?

All in favor? Any opposed? Any abstention?

MEMBER GILLEY: Debbie Gilley, abstaining.

CHAIRMAN MALMUD: Debbie Gilley abstains. All right. Any further comment? If not, it carries, with one abstention.

MEMBER THOMADSEN: Mr. Chairman, can I ask, just in case it may be something we should include in the presentation, what Ms. Gilley's hesitation is, why she is abstaining? Is there something I should include in the message we send?

CHAIRMAN MALMUD: Debbie that is a question to you from Dr. Thomadsen.

MEMBER GILLEY: Well, I come from the regulatory side of the house, and the Policy Statement is not enforceable in regulatory world, and I don't know how we can have consistent safety culture requirements across agreement states and NRC without it either being in regulations or we won't be able to enforce it, if it is just a policy statement.

CHAIRMAN MALMUD: Thank you for clarifying that. Dr. Thomadsen?

MEMBER THOMADSEN: I am not sure exactly how to put that in and whether it -- Is that sentiment common for the Committee? Should that be included in the report?

CHAIRMAN MALMUD: Dr. Thomadsen is

asking a question of members of the Committee.

MEMBER THOMADSEN: Yes.

CHAIRMAN MALMUD: Any members have a comment?

MEMBER ZANZONICO: This is Pat Zanzonico. I am certainly sympathetic to Debbie's position, but my overall feeling is that not every pronouncement from a regulator such as the NRC need be an enforceable regulation to have some value among the entities being regulated, and I think this is one example of that.

So I understand and sympathize with the issue, but I think this statement as a nonenforceable statement has value potentially for users.

MEMBER SULEIMAN: Chairman Malmud, this is Dr. Suleiman.

CHAIRMAN MALMUD: Yes, Dr. Suleiman?

MEMBER SULEIMAN: I sort of agree with Pat. I think trying to establish an attitude of culture -- we do it all the time in FDA for a variety of things. It is not necessarily enforceable. In fact, it is good that it is not enforceable. It is just an attitude where people pay attention more to safety than other things.

You see that a lot in the airline community, for example. So I have no trouble supporting this.

CHAIRMAN MALMUD: Thank you. Any other comments?

MEMBER GUIBERTEAU: Yes. This is Mickey Guiberteau. I just wanted to ask Debbie, what is -- In terms of the inability to regulate the elements of this policy, instead, is there not a mechanism by which the states or by which the organization of agreement states may endorse or actually adopt this policy for states and use it in the way that we have discussed in terms of changing attitude and culture?

MEMBER GILLEY: Yes. That is not the issue. The issue is it is a policy statement that has no enforceability to it. It will be interpreted by every agreement state, at NRC, at their whim, which leaves the licensee somewhat not knowing when they have a safety culture and when they do not have a safety culture.

In other words, there is not clear guidance provided for you to know when you have a safety culture.

MEMBER GUIBERTEAU: Well, would you

propose that some guidance be developed along with this policy or is that -- Is there a mechanism for that?

MEMBER GILLEY: I don't know. You know, I live in the world of regulation. Policy statements -- you know, if they had -- implied that medical communities already had a safety culture that is completely above the small subset of nuclear medicine and therapy that might be going on in their institution. We hope that that is the way it is.

So in some respect, this is additional safety culture policy to an organization that should already have the best safety culture out there, because they are dealing with human beings in a medical environment.

CHAIRMAN MALMUD: This is Malmud. I'm sorry, who was --

MEMBER VAN DECKER: Oh, I'm sorry, Dr. Malmud. This is Bill Van Decker.

CHAIRMAN MALMUD: Yes, Bill?

MEMBER VAN DECKER: Let me ask Ms. Gilley a question. The additional part of this discussion a few weeks or a month ago, whatever, seemed to imply to me that there may be a second

step in this process that somebody described as, quote, "implementation safety characteristics" which to me implied that there may be a movement toward regulatory space with some pieces of this as it got fleshed out.

I assume that Debbie would be willing to be giving us her vote and her opinion on that stuff as it develops down the line.

MEMBER GILLEY: If that were the direction that it was going, but right now it is on the table as a policy statement, and I assume that if the policy statement works as is, there will be no reason to go the next step as far as implementation for regulatory noncompliant issues.

MEMBER VAN DECKER: It comes under the heading of be careful what you ask for in life.

MEMBER GILLEY: You know, I kind of sit on this committee and look at what we can, as the agreement states, regulate, and this one is a hard one, because I think we are going to see safety culture be interpreted across the board in many different directions.

Then I look at what the licensees can -- we can truly expect them to be able to respond to and become compliant of, and in this particular

case, it is a policy statement that is somewhat nebulous.

MR. FIRTH: This is James Firth on the NRC staff, if I could add a little bit, please.

CHAIRMAN MALMUD: Please do.

MR. FIRTH: The Committee has received the draft Federal Register notice that is going to be going to the Commission. There is also a Commission paper that is going to convey that up to the Commission, and there we do talk about some of the next steps that we are taking.

The way we have been looking at the policy statement and what would come afterward is that we don't want the policy statement to go out and that there be no further effort on education or increasing awareness. Otherwise, we would lose the value of the policy statement.

So we would be looking at continuing to increase awareness among medical as well as non-medical licensees. The policy statement includes common terminology which includes definition in the traits that have been discussed.

As we were developing that framework, we were also looking at there may be more industry specific terminology which might include certain

examples of good practices that might then be developed and included as something that would be available to licensees, whether it is in guidance or whatever.

So there is common terminology in this policy statement, trying to reach across the board, but we are planning on taking steps to look at what we might do for the different applications of nuclear material, and that might get a little bit to some of Debbie's concerns in terms of that the policy statement may be a little bit on the general side, and something else later might be useful.

CHAIRMAN MALMUD: Thank you. Is that helpful, Debbie?

MEMBER GILLEY: That is all right, but I am still abstaining.

CHAIRMAN MALMUD: Thank you. All right. So the motion carries with one abstention, and I think it expresses the concern of all of us, including Debbie Gilley, with regard to the nature of a safety culture and the ultimate goal of achieving greater patient safety and safety to the public. That is a concern of all of us.

The issue is not concern for it, but

the best way in which to achieve it.

Are there any other items that members of the Committee or the public wish to bring before the Committee at this moment? Hearing none, I would ask Ashley; are there any business items that you wish to bring before us at this time?

MS. COCKERHAM: No. We already have the January 12th meeting scheduled for 1:00 p.m. to follow up on the ACMUI reporting structure. So I will try to provide some information to the committee as soon as possible.

CHAIRMAN MALMUD: Thank you.

MS. COCKERHAM: They can discuss it next week.

CHAIRMAN MALMUD: Thank you. I thank the members of the committee, the members of the NRC staff and members of the public for having joined us, and we will meet again on January 12th. Thank you all.

MR. FULLER: This is Mike Fuller. As the alternate Designated Federal Officer for this meeting, I would also like to thank everyone who participated in the ACMUI for their service, and at this point in time I would like to adjourn the

meeting.

CHAIRMAN MALMUD: Thank you. The meeting is adjourned.

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

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