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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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TUESDAY, MARCH 5th, 2013

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The meeting was convened via teleconference at 2:00 p.m., Leon S. Malmud, M.D., ACMUI Chairman, presiding.

MEMBERS PRESENT:

LEON S. MALMUD, M.D., Chairman

BRUCE THOMADSEN, Ph.D., Vice Chairman

DARICE G. BAILEY, Agreement State Representative

MILTON GUIBERTEAU, M.D., Diagnostic Radiologist

SUSAN LANGHORST, Ph.D., Radiation Safety Officer

STEVEN MATTMULLER, Nuclear Pharmacist

CHRISTOPHER J. PALESTRO, M.D., Nuclear Medicine Physician

ORHAN SULEIMAN, Ph.D., FDA Representative

WILLIAM VAN DECKER, M.D., Nuclear Cardiologist

LAURA WEIL, Patients' Rights Advocate

JAMES WELSH, M.D., Radiation Oncologist

PAT ZANZONICO, Ph.D., Nuclear Medicine Physicist

ACMUI MEMBERS NOT PRESENT:

JOHN SUH, M.D., Radiation Oncologist

NRC HEADQUARTERS STAFF PRESENT:

PAMELA HENDERSON, Deputy Director, Division of Materials Safety and State Agreements

CHRIS EINBERG, Designated Federal Officer

ASHLEY COCKERHAM, Alternate Designate Federal Officer, ACMUI Coordinator

SOPHIE HOLIDAY, Alternate ACMUI Coordinator

NEELAM BHALLA, FSME/DILR/RPMB

SUSAN CHIDAKEL, OGC/GCLR/RMR

SAID DAIBES, Ph.D., FSME/DMSSA/RMSB

JAMES DANNA, FSME/DILR/RB-B

TREMAINE DONNELL, OIS/IRSD/ISB/ICT

SANDRA GABRIEL, Ph.D., FSME/DMSSA/RMSB

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

ED LOHR, FSME/DILR/RPMB

DEBBIE PISKURA, FSME/DMSSA/RMSB

GRETCHEN RIVERA-CAPELLA, FSME/DMSSA/RMSB

SANDRA TALLEY, FSME/DWMEP

RONALD ZELAC, Ph.D., FSME/DMSSA/RMSB

NRC REGIONAL STAFF PRESENT:

MARYANN ABOGUNDE, R-I

HECTOR BERMUDEZ, R-II

COLLEEN CASEY, R-III

JACKIE COOK, R-IV

SARA FORSTER, R-III

MICHELLE HAMMOND, R-IV

PENNY LANZISERA, R-I

DENNIS O'DOWD, R-III

BRYAN PARKER, R-III

PATTY PELKE, R-III

MICHELLE SIMMONS, R-IV

JACK WHITTEN, R-IV

PUBLIC PARTICIPANTS PRESENT:

SUE BUNNING, Society of Nuclear Medicine and Molecular Imaging

WILLIAM DAVIDSON, University of Pennsylvania

DAWN EDGERTON, Council for Certification in Cardiovascular Imaging

LYNNE FAIROBENT, AAPM

THOMAS HUSTON, Department of Veterans Affairs, National Health Physics Program

KAREN LANGLEY, University of Utah

RALPH LIETO, St. Joseph Mercy Hospital

ANDREW McKINLEY, American Society of Nuclear Cardiology

RICHARD PEARLSTEEN, New Jersey Department of Environmental Protection

MIKE PETERS, American College of Radiology

JOE RODGERS, Theragenics Corporation

GLORIA ROMANELLI, American College of Radiology

KAREN SHEEHAN, Fox Chase Cancer Center

MICHAEL SHEETZ, University of Pittsburgh

MICHAEL STEPHENS, Florida Bureau of Radiation Control

CINDY TOMLINSON, American Society for Radiation Oncology

CONTENTS

P R O C E E D I N G S

2:03:02 p.m.

MR. EINBERG: Okay, we'll get started. As the Designated Federal Officer for this meeting I am pleased to welcome you to this public meeting of the Advisory Committee on Medical Uses of Isotopes.

Before I continue, is the court reporter on the line?

COURT REPORTER: Yes, I am. Could you please tell me who is speaking?

MR. EINBERG: This is Chris Einberg. I'll start once again.

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

My name is Chris Einberg. I am the Chief of the Radioactive Material Safety Branch, and I've been designated as the federal officer for this Advisory Committee in accordance with 10 CFR Part 7.11.

Present today as the alternate Designated Federal Officer is Ashley Cockerham, who is the coordinator for the Committee.

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 February 1st, 2013 edition of the Federal Register, Volume 78, page 7465.

The function of the Committee is to advise the staff on issues and questions that arise in 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'd request that whenever possible we try to reach a consensus on the procedures that we will discuss today, but I also recognize there may be a minority or dissenting opinion. 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 S. Malmud, the ACMUI Chairman.

CHAIRMAN MALMUD: Here.

MR. EINBERG: Dr. Bruce Thomadsen, Vice Chairman, Therapy Medical Physicist.

VICE CHAIRMAN THOMADSEN: Here.

MR. EINBERG: Ms. Darice Bailey, State Government Representative.

MEMBER BAILEY: 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.

Dr. Orhan Suleiman, FDA Representative.

MEMBER SULEIMAN: Here.

MR. EINBERG: Dr. William Van Decker, Nuclear Cardiologist.

Laura Weil, Patients' Rights Advocate.

MEMBER WEIL: Here.

MR. EINBERG: Dr. James Welsh, Radiation Oncologist.

MEMBER WELSH: Here.

MR. EINBERG: Dr. Pat Zanzonico, Nuclear

Medicine Physicist.

MEMBER ZANZONICO: Yes.

MR. EINBERG: Okay, we have a quorum. We have at least seven members.

I now ask the NRC Staff Members who are present today to identify themselves. We'll start with the people in the room here.

MS. CHIDAKEL: Susan Chidakel, Senior Attorney, Office of General Counsel.

MS. HENDERSON: Pam Henderson, FSME.

MS. HOLIDAY: Sophie Holiday, FSME.

DR. DAIBES: Said Daibes, FSME.

MS. RIVERA-CAPELLA: Gretchen Rivera-Capella with FSME.

MS. PISKURA: Debbie Piskura, FSME.

MS. BHALLA: Neelam Bhalla, FSME.

MR. LOHR: Ed Lohr, FSME.

MS. TALLEY: Sandra Talley, FSME.

MR. EINBERG: Okay. Now I'd like to go to Region I.

MS. LANZISERA: We have Penny Lanzisera and MaryAnn Abogunde.

MR. EINBERG: Thank you.

MR. BERMUDEZ: And Hector Bermudez.

MR. EINBERG: Okay, thank you. Region III?

MS. PELKE: Patty Pelke.

MS. CASEY: Colleen Casey.

MS. FORSTER: Sara Forster.

MR. PARKER: Bryan Parker.

MR. O'DOWD: Dennis O'Dowd.

MR. EINBERG: Okay, thank you. And Region IV.

MR. WHITTEN: Jack Whitten.

MS. HAMMOND: Michelle Hammond.

MS. SIMMONS: Michelle Simmons.

MR. EINBERG: Okay. And now anybody else from Headquarters who is calling in remotely?

DR. HOWE: Donna-Beth Howe.

DR. GABRIEL: Sandy Gabriel.

DR. ZELAC: Ron Zelac.

MS. COCKERHAM: Ashley Cockerham.

MR. EINBERG: Okay. And we also have Jim Danna on the phone. We have the bridge line available and that phone number is 888-864-0940. The pass code to access the bridge line is 35793#.

I now ask the members of the public who are present to identify themselves.

MS. FAIROBENT: Lynne Fairobent, AAPM.

MR. EINBERG: Okay.

MS. TOMLINSON: Cindy Tomlinson, ASTRO.

MS. BUNNING: Sue Bunning, SNMMI.

MR. HUSTON: Tom Huston, Department of Veterans Affairs.

MS. ROMANELLI: Gloria Romanelli, ACR.

MR. PETERS: Mike Peters, American College of Radiology.

MR. STEPHENS: Mike Stephens, Florida.

MS. LANGLEY: Karen Langley, University of Utah.

MR. McKINLEY: Andrew McKinley with ASNC.

MS. EDGERTON: Dawn Edgerton, CBNC/CCCVI.

MR. EINBERG: Okay.

MR. SHEETZ: Mike Sheetz, University of Pittsburgh.

MR. RODGERS: Joe Rodgers, Theragenics Corporation.

MR. EINBERG: Okay, we're going to proceed then.

This is a Category I public meeting. This is an open public observatory meeting that is non-participatory. Members of the public may listen to the meeting. The draft proposed expanded Part 35 rule is considered pre-decisional and has not been transmitted to the NRC Commission for a vote. The rule is anticipated to be sent to the Commission in the later

summer of 2013.

After Commission approval, the rule will be published in the Federal Register and members of the public will be given a 90-day comment period pending Commission approval versus the typical 75-day comment period.

While this meeting is a meeting of the ACMUI, NRC Staff is available to answer questions from the ACMUI members.

At this point, I would like to turn the meeting over to Dr. Malmud.

CHAIRMAN MALMUD: Thank you. At this point, as Chairman I will turn the Committee over to the Committee Chairman, the Subcommittee Chairman, Dr. Zanzonico, who has an extensive report for us. Dr. Zanzonico.

MEMBER ZANZONICO: Yes. Thank you, Dr. Malmud. Hello, everyone.

I'm Pat Zanzonico from Memorial Sloane-Kettering Cancer Center in New York City, and I had the pleasure of serving as the chairperson of the ACMUI Subcommittee on the proposed rule.

Our report has been made publicly available through the NRC, and presumably members of the public as well as of the NRC and, of course, members of the

ACMUI have had an opportunity to look at it. So, I think I will just summarize some of the major points and then we can move on to a discussion.

I should point out that to expedite our review, the review of the Subcommittee, we inserted line numbers into the proposed rule, and many of our comments reference both the page and line numbers, especially with respect to specific comments. And we divided our report into two major sections, general comments which basically deal with major regulatory issues in a general way, significant specific comments, again referenced by line and page numbers, and minor specific comments, really editorial comments likewise referenced by page and line number.

And the real key component of our report, of course, are the general comments. And we had seven such areas that we identified in the draft -- in the proposed rule upon which we commented. And I'd also like to thank all my fellow members of the Subcommittee for their time, effort, and due diligence. I mean, everyone really put in a lot of time, and effort, and thought into submitting comments and reviewing the proposed rule. And in advance of this meeting there was a lot of give and take, very collegial, but give and take, nonetheless, among the members of the Subcommittee.

So, just to go through the general comments. The first issue, and I think really the most contentious, for lack of a better term, was the proposed definition of a medical event for permanent implant brachytherapy. And the key features of the new proposed definition which was based on the recommendations of a Subcommittee of the ACMUI, and subsequently endorsed by the entire Committee, basically expresses or defines a medical event in permanent implant brachytherapy largely in terms of source strength in the proposed rule rather than in terms of radiation absorbed dose. And I think that's the key distinction.

Now, it was pointed out by at least one member of our Subcommittee, and we included a sort of historical review of the -- or the evolution of the ME definition in the regulatory literature. And at least one member of the Subcommittee pointed out that really the proposed rule for an ME for permanent implant brachytherapy is actually not fundamentally different in our opinion from the existing definition. So, in that it allows a definition of an ME in terms of source strength or activity rather than dose, or in addition to dose.

So, one suggestion was made that until the proposed rule is finalized and adopted it might be

prudent to include activity-based MEs until that rule is adopted, because it is, in fact -- such a definition is, in fact, consistent with the existing regulation, the regulatory language in our opinion.

Another issue that was raised by the Subcommittee was concern about the complexity or perceived complexity of the proposed ME definition for permanent implant brachytherapy. And this was specifically related to the provision in which an ME -- one of -- or two of the criteria for an ME in permanent implant brachytherapy was a dose to five contiguous cubic centimeters of normal tissue whether it was within the treatment site or outside of the treatment site. So, additional criteria in the new ME definition would mean that if the dose to such a five cubic centimeter contiguous volume of normal tissue exceeded the prescribed absorbed dose to the target by more than 20 percent, that would meet the criteria for a medical event.

So, there was some concern that that might be onerously complex in the field for both users and regulators for inspection. So, one suggestion was made that the NRC solicit from stakeholders some feedback on whether the complexity or perceived complexity of the ME definition in that respect might discourage

practitioners from using permanent implant brachytherapy, you know, simply to avoid that complexity. Apparently, in supplemental information Section 4D, there's a provision for soliciting such feedback from stakeholders.

Another concern with respect to the ME definition was the compatibility category assigned to the proposed ME definition for permanent implant brachytherapy. And the current designation is as Compatibility Category C, which to our understanding allows Agreement States to retain the dose-based criteria for definition of an ME. And it was explained very eloquently in the proposed rule the rationale for moving from a dose-based to an activity-based criteria; the most important consideration being that the dose-based criteria seemed not to be sensitively and specifically capturing clinically significant medical events, and even certain, for lack of a better term, bookkeeping issues which really had little to no clinical impact were being designated or defined as MEs.

So, it seemed that if the designation of Compatibility Category C were allowed to stand, that that confusion or lack of sensitivity and specificity for clinically significant ME's would be perpetuated, so our Subcommittee recommended that this new definition

of MEs for permanent implant brachytherapy be designated as Compatibility Category B.

We also, thanks to Dr. Welsh, identified a literature reference, a specific reference in support of the five cubic centimeter of contiguous normal tissue criteria for an ME, and we included that reference which is from a working group. We included that reference in our comments.

So, I believe those summarize our major concerns with and comments on the proposed definition for an ME for permanent implant brachytherapy. So, I presume we're going to hold discussion until I've gone through the synopsis of the report. Is that correct, Dr. Malmud?

CHAIRMAN MALMUD: That would be the most efficient way to handle it, I believe.

MEMBER ZANZONICO: Agreed, agreed.

Okay. So, in that case then I'll just move on to the second issue we addressed in our report which was the training and experience requirements for authorized users, medical physicists, radiation safety officers, and nuclear pharmacists. And our Subcommittee, and I think the entire ACMUI is unanimously enthusiastic about eliminating the preceptor statement requirement for Board certified individuals. That was just kind of

an endorsement of that point that we wanted to emphasize.

A second point had to do with the requirement for authorized users on the elution of generators. It appeared that there was -- it's not an additional, an explicit requirement for T&E, for training and experience on elution of generators. And we felt that that training and experience was adequately -- the requirement for that training and experience was adequately covered in the existing training and experience requirements, and that it was unnecessary, and redundant, and so forth to include a separate training and experience requirement on that particular item. As I say, it was felt that the training and experience requirements overall for authorized users implicitly included that particular item; in other words, elution of generators.

The other point we had with respect to training and experience requirements had to do with the language that preceptor attestations would use, and we really felt that it was more than a matter of semantics. For example, on page 19 in Section 4B there was language stating that a preceptor should attest that a authorized user, RSO, et cetera, satisfactorily completed the necessary training and experience requirements, and has achieved the level of competency sufficient to function

independently in the position for which authorization is sought. And we felt that as worded such an attestation really puts an untenable burden on preceptors in that it requires them to make a subjective judgment as to the professional competency of an individual. And what we felt was actually being sought, and what was more appropriate was somewhat amended language; namely, has satisfactorily fulfilled the training and experience requirements consistent with achieving a level of competency sufficient to function independently in the position for which authorization is sought.

And, again, the distinction is subtle, but we think not insignificant between the proposed and this new language in that it eliminates the burden on the preceptor to make a subjective judgment as to professional competency or not. Rather, it simply asks the preceptor to attest that the person seeking authorization had satisfied residency and other requirements of a training program. And we think that's a significant in language. And if you read our report you saw that we -- that that sort of language and the suggested change was made at multiple points throughout the proposed rule and throughout our comments.

The final point we had with respect to training and experience requirements was -- had to do

with certain elements of Section 35.390. And lines 1503 to 1508 in that section states that the current regulation include a broad category for parenteral administration of any other radionuclide. This broad category would be removed as any new parenteral administration of radionuclides not listed in this paragraph would be regulated under 35.1000.

"This approach would allow the NRC to review each new proposed radionuclide for parenteral administration and determine the appropriate training and experience for its use."

And the reservations we have about that is that it appears it would require each new radiopharmaceutical -- that the training and experience requirements for each new radiopharmaceutical that might be introduced. For example, as we recently saw the radium-223 dichloride issue. And our feeling was that an authorized user who has demonstrated acceptable training, and experience, and so forth for any one category of radiopharmaceuticals such as gamma and beta emitters has demonstrated adequate training and experience for all radiopharmaceuticals, that in terms of radiation physics, radiation safety, radiation biology, and clinical applications, all of these radiopharmaceuticals are much more alike than they are

different. And it would just seem to be unnecessarily burdensome and so forth to allow the possibility of radiopharmaceutical by radiopharmaceutical review of credential as new radiopharmaceuticals are introduced. And it sounds like, or at least we infer from the language as proposed that that might be the case.

So, that concludes our comments on the training and experience provisions of the proposed rule.

The next issue is extending grandfathering to certain certified individuals. And this is -- has come to be known as the Ritenour petition. And the ACMUI had previously recommended that all board-certified individuals, individuals certified by Boards recognized, professional Boards recognized by the NRC should be grandfathered, and that should be independent of the date of the recognition of the Board by the NRC.

You know, the ACMUI has argued that the most appropriate group of individuals to judge the professional qualifications of a practitioner are that practitioner's professional peers, namely, the Boards. And that certainly we understand the NRC has a regulatory obligation to review Boards themselves and to decide which Boards are or not acceptable. But we felt that an arbitrary date and time was not reasonable, that once a Board has been recognized and regardless of the date

of board-certification of an individual, or the date of recognition of that Board by the NRC, that that board-certification should be de facto evidence for the NRC of that individual's qualifications, professional qualifications.

There was a second point that was raised by our Subcommittee in terms of certain terminology the NRC has used and is using. And terms such as type of use, modality, and category should be explicitly defined in Section 35.2 definitions so that the regulatory meaning of these three terms, in particular, be understood.

And, again, a third point, but it's really related to the first point I made, as well, was the --with respect to the Ritenour petition was the impact of the date of recognition of a certifying Board by the NRC. And just to reiterate, the ACMUI has recommended and still recommends that the date of recognition should not impact individuals seeking to be named as an authorized user or other practitioner. Once the Board has been recognized, the date of its recognition is really irrelevant in our opinion.

The next general item we addressed and included in the proposed rule is measuring molybdenum contamination for each elution of a molybdenum

technetium generator and reporting a failed breakthrough test; that is, a breakthrough test in which the molybdenum concentration was out of tolerance.

And it was pointed out, of course, that currently there are two generator systems in routine use in nuclear medicine; of course, the molybdenum-99, technetium-99 generator system, and the strontium-82, or strontium-89, rubidium-89 generator systems for cardiac studies. And as has been pointed out, there are other generator systems like gallium/germanium generator systems that are on the horizon, so we raised the issue of whether these newer generator systems should be included in the proposed rule, or should it somehow be generalized to include all current and future generator systems.

The other issue had to do with the NRC regulation in terms of breakthrough, generator breakthrough as it relates to FDA labeling requirements. And at least one of our Subcommittee members felt very strongly that a better way overall of regulating generator breakthrough testing would be to simply defer to the FDA labeling requirements. The FDA will, of course, promulgate labeling requirements for every generator system as it becomes a marketed product, so if the NRC were to defer to the FDA labeling requirements

on this point, then it would automatically take care of the NRC regulation for these newer generators as they're introduced into clinical use without the need for a revision of existing rules, and all of the time, and effort, and review that that entails, as well.

The NRC argued in the proposed rule and made a number of arguments as to why it felt that was not an optimum way to go, but without going into it on a point by point basis, in our report we address the NRC's arguments on this point; namely, the NRC's rationale as to why their own regulation rather than FDA labeling requirements would be more appropriate. And our conclusion was that we really -- we meaning the Subcommittee did not find those arguments compelling, and really felt that deferring to the FDA labeling requirements would ultimately be a more effective and more expeditious way of dealing with this issue.

And, you know, there was also concern about the reporting requirement itself. In the proposed rule, the NRC is basically requiring that licensees submit to at least two notifications, one to the NRC and one to the vendor or manufacturer within 24 hours of the finding of an out-of-tolerance elution result. And our Subcommittee felt that was really -- that was somewhat excessive, that if the licensee simply reported the

out-of-tolerance elution results to the vendor, and then required the vendor to report to the NRC, that that would be sufficient. And that's standard practice, so would not introduce any additional regulatory burden on licensees.

We also thought it might be useful to increase that reporting requirement interval from four hours to 48 or even 72 hours because there might be instances in which a licensee on a weekend or some such thing as that where they're really short-staffed might encounter such a result, and it would really be much more convenient and less intrusive if there were a somewhat longer reporting time interval introduced.

There was also -- in light of the recent experience of the strontium-rubidium generator issue recently as to whether the reporting rule -- the proposed reporting rule is really effective and what additional provisions might or might not be introduced to create a more effective rule that would avoid the use of out-of-tolerance elutions in terms of tear and breakthrough, and thereby avoid these really major disruptions of practice such as we experienced with the rubidium generators. So, some of those points are detailed, as well, in our report.

And just as we did in the case of the

permanent implant brachytherapy issue, we suggested that the NRC solicit comments pursuant to Supplementary Information Section 4D from stakeholders on whether the proposed reporting requirements might discourage licensees from using generators.

The next item, the next significant item we addressed as allowing Radiation Safety Officers -- Associate Radiation Safety Officers, ARSOs, to be named on a medical license, and our Subcommittee strongly endorsed that recommendation. We had some specific comments in the specific comment section on that point.

The next significant issue was simply the -- had to do with the plain language requirement. That's Section 9. And we felt that as well written and as well organized as the proposed rule was, that it perhaps could be shortened and improved further by eliminating some redundancies and consolidating some related sections, and thereby eliminating some identical or nearly identical verbiage that appears multiple times throughout the draft rule.

Perhaps even more importantly, we felt that a more detailed Executive Summary-styled section summarizing maybe in the format of a bullet list the key changes introduced in the proposed rule might be helpful, and that would replace the current very general

one-paragraph summary in the proposed rule.

We had several other minor general comments. These are detailed in our report. And then beyond that, there were a number, as I said, of what we characterized as significant specific comments, and a number of minor or editorial specific comments. But I think -- I certainly don't think it's useful to go through those, so I think I'll stop at this point and leave it up to Dr. Malmud if he thinks it appropriate to open the report for discussion.

CHAIRMAN MALMUD: Thank you, Dr. Zanzonico. That's rather a thorough review of all the material that we've been reviewing via email. And I'd like to first thank you and the members of the Committee for an enormous amount of work that you've done on behalf of these issues.

With that may we, Pat, begin with the first item; if you would just remind us of the first item, we'll take them in order.

MEMBER ZANZONICO: Yes.

CHAIRMAN MALMUD: By the way, I very much appreciate your having numbered the lines on each of the pages so that we could follow them coherently during this discussion.

MEMBER ZANZONICO: I'm glad you found that helpful. I think it would have been intractable

otherwise.

So, the first item has to do with the proposed definition for medical event in permanent implant brachytherapy.

CHAIRMAN MALMUD: Are there comments for Dr. Zanzonico and members of the Committee?

MEMBER WELSH: Well, this is Jim Welsh, if I might start.

CHAIRMAN MALMUD: Please do, Jim.

MEMBER WELSH: I appreciate that this is a very complicated issue, and we've gone through years of discussion, if not lively active debate on this topic, and the complicated nature of this is underscored by the lack of consensus presently even in a tiny Subcommittee. However, I would state that in the opinion of most present and past practitioners of permanent implant brachytherapy, that the Permanent Implant Brachytherapy Subcommittee statement is considered acceptable and appropriate; and, therefore, we would not -- at least I would not advocate any kind of significant changes at this point. And particular reference to the historical background that Dr. Zanzonico has alluded to, I would point out that in that context, activity or dose might have been considered acceptable or appropriate. The --

(Buzzer sound.)

MEMBER WELSH: -- is that dose is absolutely not appropriate when we are talking about medical event definition for the target or what we call the treatment site.

Having said that, we would not feel that dose was entirely inappropriate for medical event definition if we are excluding treatment site, but focusing rather on adjacent or internal normal structures, and therein we have encountered some controversy and lack of consensus.

The 5cc volume was considered necessary or at least appropriate to come up with some -- it was considered appropriate to come up with some volume so that we're not just talking about a dose without a specific volume or a volume without a specific dose. The two are interrelated; otherwise, it doesn't make a whole lot of sense, and is impractical.

We understand that the 5cc criteria might not be optimal, and it is probably not ideal for prostate as a specific example, but because we have used all forms of permanent implant brachytherapy together in this categorization in this medical event definition, we had to come up with something, and 5ccs seems to be acceptable for most of them. It would probably never cause much

difficulty for prostate. And, in specific, we are talking about the refill dose which the volume to the urethra -- the volume of the urethra within the prostate is often not even 5ccs, so by that criteria we might never have a medical event in prostate permanent implant brachytherapy that has been triggered because of excessive dose to an internal structure; but that for other types of permanent implant brachytherapy, it would be inappropriate to have something smaller than 5ccs.

So, we felt that sticking with the original definition that was proposed by the Permanent Implant Brachytherapy Subcommittee that we would have an appropriate and acceptable definition that is not too complex, and would not cause practitioners to avoid pursuing this appropriate form of therapy for their patients.

And when compared to the current, and what I think is an inappropriate medical event definition for permanent implant brachytherapy, this new definition, even with the perceived complexity, is going to be in practice far less complicated, and far less likely to cause avoidance of brachytherapy than the present situation.

Additionally, if we use post-implant dosimetry as has been recommended but not mandated, it's

not going to be too difficult to implement from a practical perspective. So, I don't think that we would be causing practitioners to eschew permanent implant brachytherapy with this new proposed medical event definition.

Finally, as far as Compatibility C, I, for one, would argue that the states should not be allowed to continue to use the inappropriate medical event definition based on dose to the target or treatment site; and, therefore, Compatibility Category B would be most appropriate. So, those are my comments on your points that were brought up, Dr. Zanzonico.

CHAIRMAN MALMUD: Pat, do you have any comments about Dr. Welsh's comments?

MEMBER ZANZONICO: Well, in our discussions among the members of the Subcommittee, you know, I was in agreement with the sentiments he expressed. I thought the -- as he said, in attempting to base an ME definition in part on an excessive dose to normal tissue, one has to specify some volume because, as we know with seed implants or with any focal sources you can get an almost arbitrarily high dose to an infinitesimally small volume of tissue or points in the immediate vicinity of a source which has no clinical meaning, so I think it's critical that some meaningful volume -- that that ME definition

based on -- or criteria for ME based on normal tissue dose have some volume. And, frankly, I defer to others who are far more knowledgeable about this than I, permanent implant brachytherapy, like Dr. Welsh, like Dr. Thomadsen. But I think if those practitioners in that field feel that it's a practical implementable criterion along with the source strength-based criterion, then I'm all in favor of it. And I certainly agree with Dr. Welsh that it's far better than the current dose-based criteria for a permanent implant brachytherapy ME.

The one concern I have is actually on behalf of the regulators, and is that a practically inspect-able criterion for a medical event. So, I would ask either Dr. Welsh, or Dr. Thomadsen, or whomever, if they might comment on that point, the inspect-ability of the excessive dose to 5 cubic centimeters of contiguous normal tissue, is that a practically inspect-able criterion?

VICE CHAIRMAN THOMADSEN: This is Bruce Thomadsen. I think it's a fairly easily achieved inspection criteria.

CHAIRMAN MALMUD: Other comments from other members of the Committee? Is there agreement among the members of the Subcommittee that this is so? Could we

have a voice vote about it on the phone? Are all the members of the Committee in agreement?

(Chorus of ayes.)

CHAIRMAN MALMUD: Are there any abstentions or nays?

MEMBER SULEIMAN: That's for this specific -- this is Orhan Suleiman. That's for this specific part of the report?

CHAIRMAN MALMUD: Yes, we're taking them one part at a time, Orhan. Thank you for clarifying that. So, is there agreement on this item among all the members of the Subcommittee? If so, does the Subcommittee wish to make that recommendation to the Committee?

MEMBER ZANZONICO: Yes. So, I think just to verbalize, or try to make it as explicit as possible what we're recommending, we are recommending that adoption of the proposed definition of a medical event for permanent implant brachytherapy, that's the first point. And I think it's a multi-part vote we're taking, so that would be the part of the vote.

I guess I should ask members of the Subcommittee or the ACMUI overall, do we want to formally recommend to the NRC that they solicit feedback from stakeholders as to whether this definition would or would not discourage use of permanent implant brachytherapy,

or do we feel that that's not -- that's now a non-issue?

MEMBER LANGHORST: Dr. Malmud, this is Sue Langhorst. May I speak?

CHAIRMAN MALMUD: Yes, Dr. Langhorst.

MEMBER LANGHORST: Thank you. Just one way that it might be easier to go through this is, what are the recommendations that we have in our written report right now, and maybe go through them one by one as far as this section goes. For instance, on Item A at the very last sentence we say, "The ACMUI recommends NRC Staff allow use of total source strength as a substitute for total dose for determining medical events for permanent implant brachytherapy until the Part 35 rulemaking is complete."

Maybe if we go step by step on this, if the Committee agrees with those recommendations.

CHAIRMAN MALMUD: Thank you. That's a constructive suggestion.

MEMBER ZANZONICO: Agreed.

CHAIRMAN MALMUD: Let's move forward with it.

MR. EINBERG: Dr. Malmud, Chris Einberg here. If I may suggest, also, every time the ACMUI has a recommendation, if the NRC could -- if you could provide the opportunity for the NRC staff to either

comment on that before you guys vote that would be helpful, as well.

CHAIRMAN MALMUD: Thank you. And are there comments from the NRC staff before this item is voted upon?

MR. EINBERG: Yes, there is; Ms. Neelam Bhalla.

MS. BHALLA: Yes. Good afternoon, Dr. Malmud and the Committee members.

CHAIRMAN MALMUD: Good afternoon.

MS. BHALLA: With regard to Item 1A, the staff feels that this is not part of the --

CHAIRMAN MALMUD: Can you speak up, please? I can't hear you.

MS. BHALLA: Okay. The staff feels that Item 1A is a historical discussion of the ME rule which has been discussed a lot by the ACMUI to the point that, you know, we had done a revised proposed rule, et cetera. So, at this point, especially the last paragraph where it says, "The ACMUI recommends to allow the source strength to be used," this is part of the ongoing issue with the rule, part of the proposed rule. Therefore, when we are going to be presenting your report to the Commission and also our staff responses, we are going to mention that this 1A is not part of the proposed rule,

rather than what the issue is.

MR. EINBERG: Ms. Bhalla, this is Chris Einberg once again. I think that's a useful comment; however, I believe if the ACMUI would like to make that recommendation, you can state in the rulemaking that this is outside the scope of the rule. This, however, may be useful to the staff as we consider our enforcement policy, so it is a useful comment. So, I would just state that if the ACMUI still would like to make that recommendation, we'll certainly entertain that recommendation.

MEMBER ZANZONICO: This is Pat Zanzonico. I think it would be useful to include that recommendation even if it were ultimately determined to be outside the scope of not only the proposed rule but the ACMUI's review of the proposed rule because, if nothing else, it would reinforce the unanimous preference for an activity-based ME criteria as opposed to the existing dose-based criteria. So, I think it would be a useful recommendation to have on the record, nonetheless.

CHAIRMAN MALMUD: Thank you, Dr. Zanzonico. And I think that the members of the Subcommittee and members of the Committee agree with you. Someone said something but they were far away from the speaker and it didn't come through. Can you repeat what you said?

MS. HOLIDAY: Dr. Malmud, this is Sophie. I just wanted to make a quick announcement for all parties that are on the teleconference call.

CHAIRMAN MALMUD: Yes?

MS. HOLIDAY: For all members of the public and for participants who are on the ACMUI or who are staff members that are participating, if you are not speaking at the time, if you would please mute your phone. If your phone does not have that capability you can press *6 and that will mute it for you.

Also, while this has already been happening so far, for members that are speaking please state your name so that we can get on the record for the court reporter.

CHAIRMAN MALMUD: Thank you, Sophie.

MS. HOLIDAY: Thank you.

MEMBER WELSH: This is Dr. Welsh.

CHAIRMAN MALMUD: Yes, Dr. Welsh?

MEMBER WELSH: I apologize to Dr. Zanzonico. He was asking a specific question, and my name came up, and there was a technical failure, and I missed a minute or two of the conversation. If there was anything that I was specifically asked to address, I'm back here again, but I apologize for being out of touch for the past two minutes.

CHAIRMAN MALMUD: Thank you. I'm not aware that you were asked to address anything specifically except with regard to your agreement or disagreement with the rest of the Committee -- Subcommittee's recommendation.

MEMBER GUIBERTEAU: Dr. Malmud?

CHAIRMAN MALMUD: Yes. Who is this, please?

MEMBER GUIBERTEAU: This is Mickey Guiberteau.

CHAIRMAN MALMUD: Yes, Dr. Guiberteau.

MEMBER GUIBERTEAU: Could I -- I can't find a document that has been sent to me that actually gives the members of the Subcommittee. And I can't remember who they might be, but in this discussion, I was not a member of the Subcommittee. It would be helpful for me to know from the -- in that context which speakers are speaking from inside the Committee; that is, they had the benefit of the discussions, and those who may be, you know -- who may have differences with the opinions of the Subcommittee. So, if we could have that information, I think it would be helpful to me and perhaps to those members of the public and others who are listening to this call.

CHAIRMAN MALMUD: Thank you. Would you like that emailed to you, the list of the Subcommittee, as

opposed to --

MEMBER GUIBERTEAU: That would be fine for me, if that's the way we're doing it.

CHAIRMAN MALMUD: Find it. Sophie, is it possible to do that now during the conference call?

MS. HOLIDAY: Would it more beneficial if I go ahead and announce who those Subcommittee members were on the phone?

CHAIRMAN MALMUD: All right. If the interested parties have pencils handy you can write down these names.

MS. HOLIDAY: Sure, and it will also be included in the transcript on the record.

CHAIRMAN MALMUD: Yes.

MS. HOLIDAY: So, the Subcommittee Chairperson was Dr. Pat Zanzonico. Additional members include Dr. Susan Langhorst, Mr. Steve Mattmuller, Ms. Laura Weil, Dr. Bruce Thomadsen, and Dr. James Welsh.

MEMBER GUIBERTEAU: Thank you very much.

MS. HOLIDAY: You're welcome.

CHAIRMAN MALMUD: All right. I believe that we had a statement that there was agreement amongst the members of the Subcommittee with regard to Dr. Zanzonico's recommendation, and it was unanimous. So, we hope that the Minutes will reflect that.

Can we move on to the next item, Dr. Zanzonico?

MEMBER ZANZONICO: Yes. So, this -- in terms of an actionable item, that would be Item C in Section 1; and that is whether to recommend to the NRC -- this is Pat Zanzonico, by the way. Whether we recommend to the NRC that it solicits feedback from stakeholders on whether the proposed ME definition for permanent implant brachytherapy would discourage licensees from using this form of therapy. The alternative is whether we feel now that that would not be the case. I inferred from some of Dr. Welsh's comments that that was his feeling at the moment. So, to put a point on it, should we offer this recommendation or not to the NRC on soliciting feedback?

MS. HOLIDAY: Dr. Zanzonico and Dr. Malmud, this is Sophie, if I could interject real quick. I believe the initial recommendation on the table was for the recommendation that was in 1A, so we wanted just a little bit of clarification. I heard that Dr. Malmud said that the Subcommittee had --

(Paper shuffled.)

MS. HOLIDAY: I do not believe that recommendation was put before the full Committee.

CHAIRMAN MALMUD: You are correct, Sophie.

The Subcommittee unanimously approved it. We can now put it before the full Committee whose members I believe represent a quorum on this phone, on this teleconference. So, therefore, we will put the same motion before the full Committee. Are any -- all in favor?

(Chorus of ayes.)

CHAIRMAN MALMUD: Any opposed? Any abstentions?

(No response.)

CHAIRMAN MALMUD: So, the motion carries unanimously.

MS. HOLIDAY: Thank you.

CHAIRMAN MALMUD: Thank you, Sophie, for the clarification. Dr. Zanzonico, you're on again.

MEMBER ZANZONICO: Okay. So, the point I was addressing was Point C, and whether or not we should make a formal recommendation to solicit input as to the impact of the proposed ME definition. So, again, I was specifically addressing my comments to Dr. Welsh and Dr. Thomadsen and, of course, whoever else would care to offer an opinion on the Subcommittee or Committee. But what is the feeling at this point on that possible recommendation?

VICE CHAIRMAN THOMADSEN: This is Bruce Thomadsen, and having been at a stakeholders' meeting

on this issue in the past, I think we've heard from stakeholders on their preferences. We could do that. I don't think we'll gain much information that we don't already have.

MEMBER WELSH: This is Jim Welsh here. I concur with what Bruce has just said. In my introductory statement, I pointed out that we've been debating and discussing this for several years now, and it's apparent that we're never going to get something that is 100 percent perfect. But I believe that what we have currently on the table is as close as we're going to get, and although I have no major objection to additional input from stakeholders and societies, I agree with Bruce, that I doubt very much that we're going to have any major changes or alternatives that are being proposed seriously. And, therefore, my concern is one of efficiency.

If this process would in any way slow things down, I would not be in favor of it. If it would be time-neutral I have no objections to it, but I don't personally see what would be gained from it.

MEMBER ZANZONICO: Okay. This is Pat Zanzonico. So, my perception then is that we can forego that recommendation unless there's any other comment by members of the Subcommittee or the ACMUI. I would

suggest that we just forego that item all together then.

MEMBER LANGHORST: Pat, this is Sue Langhorst. May I speak?

MEMBER ZANZONICO: Please.

MEMBER LANGHORST: Okay. I do not share Jim's opinion that this would -- I think we should keep this recommendation. And if we don't keep this recommendation, I would hope that stakeholders will comment on it in their comments on the proposed rule when it is published. So, I think it's not a bad idea to propose this question be asked of stakeholders, but I am not opposed to it being dropped out of this recommendation.

MEMBER ZANZONICO: Dr. Malmud, could we then -- unless there is any further comments, can we then move to a vote? And if we follow the model we did on the previous point, we'll have a vote of the Subcommittee followed by a vote of the whole ACMUI?

CHAIRMAN MALMUD: Yes. Are all the members of the -- we'll first poll the Subcommittee members. All in favor?

(Chorus of ayes.)

MS. BHALLA: Dr. Malmud.

CHAIRMAN MALMUD: Yes?

MS. BHALLA: Yes, this is Neelam Bhalla from

NRC.

CHAIRMAN MALMUD: Yes.

MS. BHALLA: We here discussed also this question and staff thinks that this question, even if we want to keep it perhaps could be phrased in a different way, and we could ask the licensees if the proposed new definition has the clarity, and if it meets the requirements of the working physicians, because when the SRM was issued on this subject, the Commission was very clear on -- to us, to the Staff that it should be -- it should not impede on the practicing physicians; and, yet, it should protect the interest of the patients. And, therefore, we brought this -- the proposed rule is pretty much based on what the ACMUI's recommendations were. So, we could perhaps ask the question in our proposed rule is it -- is the definition clear enough rather than saying about this, you know, if it's going to discourage licensees from using this therapy option.

CHAIRMAN MALMUD: Are you suggesting different wording?

MS. BHALLA: Yes.

CHAIRMAN MALMUD: Do you have the specific wording that you would like to suggest?

MS. BHALLA: We could propose something. Actually, we could say doctors, if you must keep

something -- in the Statements of Consideration, if you have seen we do ask in general questions about how this rulemaking is going to impact. We do ask general questions, so either we can just leave this right here and because we have the other questions in general, so we could just leave it there, or for the ME definition we could ask -- the language could be, is this revised definition clear enough or -- I didn't bring the right words, the exact words, but something to that effect, rather than it's going to impact the practice.

CHAIRMAN MALMUD: So, the staff would prefer to see wording other than it's -- the current wording which suggests that it might impact practice. Is that correct?

MS. BHALLA: That is correct.

CHAIRMAN MALMUD: All right. Dr. Zanzonico, do you have a suggestion?

MEMBER ZANZONICO: Yes. How about -- so we can say should the NRC -- the recommendation or the vote would be on the following. Should the NRC solicit stakeholder feedback on whether the proposed ME definition for permanent implant brachytherapy is sufficiently clear in language to not adversely effect clinical practice.

CHAIRMAN MALMUD: Thank you. Does that meet

the spirit of the request? That's to NRC staff, the question.

MS. BHALLA: We believe we should not bring in the concept of the -- what was that word again?

MEMBER ZANZONICO: Well, is the proposed ME definition sufficiently clear in language to not adversely impact clinical practice?

MS. BHALLA: We just want to discuss that here for a second.

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

CHAIRMAN MALMUD: Yes, Dr. Langhorst.

MEMBER LANGHORST: I would like to say that I think the intent here is just to pose a question of the impact of this change, and I think the NRC staff does not, necessarily, have to follow the exact language of a recommendation here, but to ask that type of question, as Neelam was describing to see how this change in medical event definition impacts the practitioners.

MEMBER ZANZONICO: This is Pat Zanzonico. I think Dr. Langhorst's point is very well taken. I think we can leave it to the NRC to formulate the exact language of the inquiry but, basically, some feedback should be solicited on the possible clinical impact of the proposed ME definition. But I would feel comfortable leaving it

to the NRC to devise the exact language.

One other -- if I may, one other point I'd like to raise, and I think it was a point that Dr. Welsh introduced, and it's a very good one. I presume that this solicitation of information would basically be part of in a sense that general public review of the proposed rule so that it should not slow things down. In other words, it would be done in parallel with soliciting other comments, and so forth, rather than in series, so it should not slow things down, which I think is something we all want to avoid. Is that everyone's sense, as well?

CHAIRMAN MALMUD: I suspect that it is, Dr. Zanzonico. I don't think anyone would -- well, I shouldn't speak for the rest of the Committee, but I don't believe any of the members of the Committee would object to what you just said. Am I correct in that? I hear no dissension from members of the Committee, so we fully agree with you.

MEMBER WELSH: This is Dr. Welsh, if I might just add a quick comment.

CHAIRMAN MALMUD: Dr. Zelac?

MEMBER WELSH: Welsh.

CHAIRMAN MALMUD: Oh, Dr. Welsh.

MEMBER WELSH: I suppose I would acquiesce and agree to go along with having this solicitation of

input from stakeholders, but I would remind the Committee as a whole that this is essentially the ASTRO definition with a couple of minor modifications. So, although we're not going to have complete unanimity from the entire stakeholder population, this is essentially a society, specifically ASTRO, the ASTRO proposed definition that has been published and discussed repeatedly at the NRC, the various stakeholder meetings, and within the ACMUI and other venues.

So, I suppose my point is that although I'm not opposed to seeking additional stakeholder input at this point, to me, I think it's a moot point because we're basically using the ASTRO definition. And my major concern is that if there is any possibility that this is going to slow things down, my vote would be in favor of not allowing anything that could slow things down, to move on.

CHAIRMAN MALMUD: Thank you, Dr. Welsh.

VICE CHAIRMAN THOMADSEN: And this is Bruce Thomadsen. I will just point out that one of the other major stakeholders was the American Brachytherapy Society, also agreed that they like the ASTRO definition.

CHAIRMAN MALMUD: Thank you, Dr. Thomadsen. May we move on? So, we're entrusting the final wording to the NRC, and the Committee is supportive of that.

So, Dr. Zanzonico, we're on to the next item.

MS. BHALLA: Well, Dr. Malmud.

CHAIRMAN MALMUD: Yes?

MS. BHALLA: Yes, this is Neelam Bhalla again. We just -- staff would like to just re-emphasize that we are soliciting -- first of all, a proposed rule is soliciting public -- the whole idea of a proposed rule is to solicit comments from public which would mean licensees. And we have already included in our -- under Section 4 under Discussion, we start with what actions is the NRC taking, and then we are specifically bringing to the public's attention where the changes would be. And, therefore, this particular question to put it like that, if it's going to impact the practice, is not appropriate, so we just want to make that notation here, that the question is already asking the public. And, therefore, we should not be asking a specific question in terms of exactly, you know, how it's going to impact the practice.

CHAIRMAN MALMUD: Thank you. Dr. Zanzonico?

MEMBER ZANZONICO: Again, I have no objection to leaving it to the NRC Staff to -- in however they typically formulate solicitations for feedback. And it's understood that just requesting public comment is, in effect, accomplishing the same thing. So, I have

no objection if the NRC feels it's necessary to eliminate the specific language, that there'll still be opportunity for stakeholders to offer whatever comments they may have without specifically soliciting comments on impact on clinical practice.

CHAIRMAN MALMUD: Thank you, Dr. Zanzonico.

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

CHAIRMAN MALMUD: Yes, Dr. Langhorst.

MEMBER LANGHORST: Are we keeping C, or are we not keeping C?

CHAIRMAN MALMUD: Dr. Zanzonico?

MEMBER ZANZONICO: Good question, Sue. I would suggest that -- well, I would suggest this, let's vote explicitly on retaining Point C as currently worded. And I think the further discussion may be moot once we have a vote, but I would suggest we vote on retaining the language as it's currently presented in the report.

MEMBER LANGHORST: This is Sue Langhorst. And I would amend that with recognition that NRC may utilize the language that they think is appropriate for gaining this type of information from its stakeholders.

MEMBER ZANZONICO: So, can -- with Dr. Langhorst's amendment, can I then ask for a vote of the members of the Subcommittee?

CHAIRMAN MALMUD: Yes, Dr. Zanzonico. Do the members of the Subcommittee approve?

MEMBER LANGHORST: I approve.

CHAIRMAN MALMUD: Any disapproval or abstentions? You have unanimity again. Now, should we take it to the whole Committee, Dr. Zanzonico?

MEMBER ZANZONICO: Yes, please.

CHAIRMAN MALMUD: Now members of the entire Committee that have voting privileges, is there anyone opposed to this motion which has been approved by the Subcommittee? Are there any abstentions? I will assume, therefore, that all the other votes are positive. Once again you have unanimity, Dr. Zanzonico.

MEMBER ZANZONICO: Very good, thank you.

So, the next item, this would be Item 1D. And I think this is very explicit, and that is that the Subcommittee recommends that the proposed rule for redefining MEs in permanent implant brachytherapy be designated as Compatibility Category B rather than C.

CHAIRMAN MALMUD: Thank you. That's a motion from the Subcommittee?

MEMBER ZANZONICO: Correct.

CHAIRMAN MALMUD: And the Subcommittee members have approved that thus far.

MEMBER ZANZONICO: Well, we can have a vote.

CHAIRMAN MALMUD: Okay. All in favor -- these are members of the Subcommittee. All in favor?

(Chorus of ayes.)

CHAIRMAN MALMUD: Any opposed? Any abstentions?

(No response.)

CHAIRMAN MALMUD: There's unanimity. May we take that now to the whole Committee? All in favor?

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

CHAIRMAN MALMUD: Dr. Langhorst?

MEMBER LANGHORST: Yes, you may want to ask the staff for their opinion on this before it goes to the whole Committee.

CHAIRMAN MALMUD: Thank you for reminding me, Dr. Langhorst. The opinion of the staff?

MR. EINBERG: Yes. This is Chris Einberg. We don't have anybody from the Agreement States Program here, so we have no comment at this point.

CHAIRMAN MALMUD: Thank you, Chris. Members of the Committee as a whole, any objections? Any abstentions?

(No response.)

CHAIRMAN MALMUD: Hearing none, it's unanimous again. Thank you, and we'll move on to the

next item. Dr. Zanzonico.

MEMBER ZANZONICO: Yes. So, this would -- and I think this is -- I can't imagine this would be contentious, Item 1E. And the recommendation would be to replace the phrasing in the literature or to the literature in terms of support for the 5 cubic centimeter of contiguous normal tissue provision of the ME definition, to replace the "literature" phrasing with the specific references cited, that's Nag, et al 2004. So, can the Subcommittee -- would the members of the Subcommittee vote on approving that revision?

CHAIRMAN MALMUD: All the members of the Subcommittee who approve please say aye.

(Chorus of ayes.)

CHAIRMAN MALMUD: Any opposed? Any abstentions?

(No response.)

CHAIRMAN MALMUD: You've achieved unanimity again, Dr. Zanzonico. If we may, any comments from NRC Staff?

MS. BHALLA: Yes, this is Neelam Bhalla. We just want to thank the Committee, the Subcommittee on this.

CHAIRMAN MALMUD: Thank you, Ms. Bhalla. Now take it to the entire Committee. All in favor?

(Chorus of ayes.)

CHAIRMAN MALMUD: Any objections? Any abstentions?

(No response.)

CHAIRMAN MALMUD: Once again unanimity. Thank you, Dr. Zanzonico. Next item?

MEMBER ZANZONICO: Okay. So, now we're to Item 2, and this is on the training and experience issue. And the first actionable item is 2B. And the basic recommendation is to eliminate the explicit requirement for supervised work experience on the elution of generators with the understanding that -- not that that's not an important consideration, but that it's adequately covered by the other more general training and experience requirements. We just are recommending, in other words, not to separate out this one particular item.

CHAIRMAN MALMUD: All right. Is there discussion of this from other members of your Subcommittee?

MEMBER LANGHORST: This is Sue Langhorst, just a real minor thing, Pat. On those line numbers they should --

MEMBER ZANZONICO: Yes.

MEMBER LANGHORST: -- be 1447 and 1448.

MEMBER ZANZONICO: Correct. Thank you, Sue.

MEMBER LANGHORST: Okay, thank you.

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

CHAIRMAN MALMUD: Yes, Steve?

MEMBER MATTMULLER: I'm -- maybe I'm asking for help from the NRC Staff. I'm not sure, because as I read the proposed reg, it was really more as far as in regards to generator training, was that it could be provided by an authorized nuclear pharmacist, or an ANP. And I think the Subcommittee now has gone an additional step of trying to create a special category that only if the licensee has a generator should then that authorized user have this specialized training, which is where I think it's gone. And at this point, I'm not sure I agree with that. Especially from a perspective that even though the vast majority of sites do have generators, a lot of those same sites still get bulk technetium in the afternoon for evening emergency procedures using such kits as MAA and/or Ultra Tag. So, I mean, personally I believe it's important that the authorized user get this type of training. Thank you.

CHAIRMAN MALMUD: Thank you. Any comments with regard to Steve Mattmuller's comments?

MEMBER SULEIMAN: This is Orhan Suleiman.

CHAIRMAN MALMUD: Dr. Suleiman.

MEMBER SULEIMAN: I'm more concerned with -- I sort of agree with the Subcommittee in that we don't want to burden authorized users who may not be using the generator with that sort of training. However, I'm more concerned with the flip side of that, that people who actually use generators, based on our observations over the last few years when we've had problems in the field, apparently don't understand how generators work. And there have been some safety issues because of that, so I don't know if it comes here, but I sympathize with the need not to burden people who don't use the generators with learning how to use them, but we'll discuss this latter issue when we get further on into the Subcommittee report.

CHAIRMAN MALMUD: Thank you for your comments, Dr. Suleiman.

MEMBER GUIBERTEAU: Dr. Malmud.

CHAIRMAN MALMUD: Yes?

MEMBER GUIBERTEAU: This is Mickey Guiberteau.

CHAIRMAN MALMUD: Yes, Dr. Guiberteau.

MEMBER GUIBERTEAU: You know, I think this is a -- as I have read in a number of emails and articles, this is -- the issue of generators has morphed from a

rather simple device to one, you know, a concept that's become very complex. It is exceedingly large and growing burden on residencies in nuclear medicine, as well as diagnostic radiology, nuclear radiology, and now even cardiology with intimate contact and experience with generators that will likely never be used by the AUs practicing clinical medicine.

I think this is a very important issue, and I also think to Orhan's point that while we may be training and getting experience for everyone, that experience might be somewhat -- terms of bolstering confidence in AUs, might be a little bit unrealistic simply because in real practice it might give us the false sense that people have intimate contact with all sorts of generators when they really don't when they go in practice. So, I mean, I think -- I agree with the Subcommittee. I think that this doesn't -- I agree that this part of the proposed rule is really too much of a burden and likely doesn't accomplish what we would like it to accomplish.

CHAIRMAN MALMUD: Thank you for your comment, Dr. Guiberteau. Dr. Suleiman, do you wish to comment on that?

MEMBER SULEIMAN: I sort of concur with what he said. So, on this part of the Subcommittee report,

I also agree. Why burden an authorized user with operating a generator when that individual may not operate the generator, and it may lead to a false sense of knowing how to operate it.

CHAIRMAN MALMUD: All right, thank you.

MEMBER PALESTRO: Dr. Malmud, Chris Palestro. May I speak?

CHAIRMAN MALMUD: Yes, please.

MEMBER PALESTRO: Okay. I certainly agree with the Subcommittee's comment. I think the number of sites that use generators are few to begin with nowadays, and probably decreasing; that to insist that every AU receive work experience in a generator is probably impractical, and not very useful. And I would think that it would be more appropriate for those AUs who are using generators to receive generator-specific training for the type of generator that they use.

CHAIRMAN MALMUD: Thank you for that comment. I suspect a number of us agree with you. Dr. Zanzonico?

MEMBER VAN DECKER: Can I add one other thought, one other voice? This is Bill Van Decker.

CHAIRMAN MALMUD: Yes, Dr. Van Decker.

MEMBER VAN DECKER: You know, I think that I would agree with the concepts of some of my other

colleagues here. I think that, obviously, what is a generator and how does a generator work is a general topic that everyone needs to know as part of the AU training experience. It would indeed be true that, you know, if you're going to be using a generator you should be pretty well versed in what that generator is, recognizing that there may be newer generator systems coming on line in the future. I think the only thing for us to keep in the back of our minds is -- and I think Dr. Suleiman pointed this out as we get further on, what does that generator-specific training look like, when one adds a modality to one's practice, is it really just the learning of the generator, which I think it should be rather than just the Radiation Safety principles of a generator which is general knowledge in the AU category. And, certainly, we have models for adding modalities and a variety of other regs especially in Radiation Onc-type realm, but I just think it's something for us to keep in mind as we move forward.

CHAIRMAN MALMUD: Thank you for that comment. Dr. Zanzonico, we're back to you.

MEMBER ZANZONICO: Yes. So, I think the recommendation then becomes --

MS. BHALLA: Excuse me, Dr. Malmud.

MEMBER ZANZONICO: Yes?

MS. BHALLA: This is Neelam Bhalla, and I just wanted to say that we -- when we started this rulemaking it was based on what are called these user need memos. It's the need that the implementing division or Program office has to revise these regulations. And in that the need was expressed that this training could be provided. It's in the existing regs, and the training could be provided by authorized nuclear pharmacists along with the other of the authorized users. So, as you know, the rule is due to the Commission very soon. And, therefore, this will be changing the scope of the rulemaking. And, therefore, we just wanted you to know that the request was only to allow the nuclear pharmacists to be able to give this training. So, therefore, the rule is being amended to do that, and we may not be able to at this point go over if AU need that training, of it's possible for them, because that's like starting an issue. And at this point, it's -- not be able to entertain it.

MEMBER ZANZONICO: This is Pat Zanzonico. So, if I can understand the intent of this passage in the proposed rule is not to require, necessarily, supervised work experience on generator elution and so forth, but if such training -- if such supervised work experience is provided, it could be provided by an

authorized nuclear pharmacist, as well as an authorized user. Is that correct?

MS. BHALLA: Yes. What is correct is that it's in the existing training requirement, so the fact that should they be trained in that aspect, that was not on the table, but it was who could provide that training. So, the reg says -- we are amending the regs that this training can be provided by the authorized pharmacists, because they have as much know-how in this system as anybody else. So, no, we are not changing the current training requirement per se, but only who can actually give that training.

MEMBER ZANZONICO: Okay, understood. So, I would -- this is Pat Zanzonico again. I think given that, I would concede that I misunderstood what was being proposed. And in that case, I would suggest withdrawing this recommendation.

MEMBER LANGHORST: Pat, this is Sue Langhorst. I disagree with you. I would -- the questions are there. It's not really any recommendation other than questions as to why this is necessary. And I think based on some of the comments of our colleagues and on the Committee, it's a fair question to ask, and I would recommend that it stay in here.

MEMBER ZANZONICO: Sue, in that -- this is

Pat Zanzonico again. In that case, certainly we can leave our report as is with comments and questions, some actionable items, some non-actionable items. Would you feel comfortable just leaving this particular item as is without couching it in the form of a formal recommendation?

MEMBER LANGHORST: Yes, I would. There is no real recommendation here of ACMUI. It's just raising those questions, and proposing an alternative of how NRC Staff could handle this type of thing in the future.

MEMBER ZANZONICO: Understood.

MEMBER GUIBERTEAU: Pat.

MEMBER ZANZONICO: Yes?

MEMBER GUIBERTEAU: This is Mickey Guiberteau, may I offer a comment?

MEMBER ZANZONICO: Please.

MEMBER GUIBERTEAU: You know, I -- putting aside for a moment whether or not AUs in 298 need generator on-hands experience, if it is going to be continued to be required, which is what I understood is preferred, it is very important that authorized pharmacists be able to provide this, because in many institutions the only place they're able to get it is by sending their residents to a commercial pharmacy where a pharmacist, a nuclear pharmacist is the person

providing the training. And in the past that has been somewhat questioned since in most of the rule you have to have someone providing that training who is actually performing -- an AU in the same areas, clinical areas of the rule. So, I don't want to let --I would prefer that not be lost in this because if we're keeping the training requirement the same, it would be very helpful to know who we can go to, to whom we may go to get this training.

MEMBER ZANZONICO: Understood. My understanding is that the proposed rules would allow nuclear pharmacists to provide the training, and at the same time I think in retaining the language in Item 2B, as Sue suggests, isn't contrary to that.

MEMBER GUIBERTEAU: All right.

CHAIRMAN MALMUD: Therefore, I understand that we will leave it in, recognizing that it will not be acted upon, but it will certainly convey the spirit of the ACMUI and the Subcommittee to whoever reads it.

MEMBER ZANZONICO: Pat Zanzonico. That would be my suggestion and my understanding, as well.

CHAIRMAN MALMUD: Thank you. And do we have approval of the members of the Subcommittee for this? Any objections or abstentions? If not, are there any objections or abstentions from the Committee having

heard the comments of NRC staff already?

(No response.)

CHAIRMAN MALMUD: Hearing none I assume that it's, therefore, approved unanimously.

MR. EINBERG: Dr. Malmud, Chris Einberg here.

CHAIRMAN MALMUD: Yes, Chris.

MR. EINBERG: Does the Committee want to endorse the current language right now also, that the NRC Staff has proposed in the rule to allow the nuclear pharmacist to do the training?

CHAIRMAN MALMUD: Yes, that was -- I believe that was what Dr. Zanzonico was proposing. Am I correct, Pat?

MEMBER ZANZONICO: Well, actually, I was not thinking of this as a -- we're not calling an actionable item, in other words, a votable item at all. But I think that's not unreasonable. So, yes, we could have a vote on the language, and it's in lines 1447 to 1448 on page 48 that says, "ANPs have the T&E to provide the supervised work experience for AUs on the elution of generators." Again, as was pointed out, it's simply allowing ANPs, it's authorizing ANPs to provide that training.

CHAIRMAN MALMUD: All members of the Subcommittee in favor, please say aye.

(Chorus of ayes.)

CHAIRMAN MALMUD: Any opposed? Any abstentions?

(No response.)

CHAIRMAN MALMUD: All right. That's the motion of the Subcommittee. Does NRC staff wish to make a comment before we take it to the whole Committee?

MS. BHALLA: No, we are fine, thank you.

CHAIRMAN MALMUD: Thank you. The entire Committee, we'll consider this a motion from the members of the Subcommittee. All in favor?

(Chorus of ayes.)

CHAIRMAN MALMUD: Any objections? Any abstentions?

(No response.)

CHAIRMAN MALMUD: Hearing neither objections nor abstentions, it passes unanimously. Thank you. We'll move on to the next item.

MEMBER ZANZONICO: So the next item is Item 2-C. We're still on training and experience. And it's a proposed change in language. And the language, and this appears at multiple points in the proposed rule.

The current language in the proposed rule is that preceptors would attest that trainees or candidates have satisfactorily fulfilled the training

and experience requirements consistent with achieving, I'm sorry.

What the proposed rule said, have satisfactorily completed the necessary training and experience requirements, and has achieved a level of competency sufficient to function independently in the position for which the authorization is sought. That's the current language.

The language being proposed, the alternative language being proposed is, "Has satisfactorily fulfilled the training and experience requirements consistent with achieving a level of competency sufficient to function independently in the position for which the authorization is sought."

So again, the distinction is the preceptor attesting that the candidate has achieved a level of competency. The alternate language being proposed is simply asking the preceptor to attest that the candidate has completed training and experience consistent with achieving that competency. So what we're voting on is replacing that current language with the alternative language.

MS. BHALLA: Yes, Dr. Malmud?

CHAIRMAN MALMUD: Yes.

MS. BHALLA: The staff wants to speak on

this a little bit.

CHAIRMAN MALMUD: Please do.

MS. BHALLA: And Susan Chidakel from NRC is going to. Because I think it's somewhat misunderstood.

MS. CHIDAKEL: Hi. Thank you for letting me interject here. I think you have misread the language. The language that you're talking about, you've taken out of our summary of what we're changing.

And what the language that you're talking about, it says the attestation must state that the individual has satisfactorily completed. That's the language that's in the rule now.

We're proposing to take that language out completely and change that whole thing, and take out the reference to competence.

If you look at the actual rule text, for example if you look at Page 98 or 99 for actual rule text that's in the rule itself, you'll see that competence language is not in there.

So I think you've misunderstood what we were doing here. We weren't trying to tell you what we were going to try to change to put in something about competence. We were summarizing the state of affairs right now.

MEMBER ZANZONICO: In that case, this is Pat Zanzonico, in that case then I didn't misunderstand.

MS. CHIDAKEL: You did not misunderstand?

MEMBER ZANZONICO: No, I did, based on what you're just telling me now. It was my understanding, clearly mistaken, that this was the language in the new language.

MS. CHIDAKEL: No. Take a look, for example, at Page 99. If you look at B-2, you'll see a sample of what -- this is for the authorized nuclear pharmacist. You'll see a sample of what the preceptor is going to be attesting to now, in the new proposed rule, just as an example.

And you can look at several sections. You can see the same thing on Page 98, with regard to the authorized medical physicist. I just picked out a couple at random.

MEMBER ZANZONICO: I don't know if you have the line numbers. Is it possible you can identify the line numbers?

MS. CHIDAKEL: On Page 98 it starts on, B starts on 2899. And then it's on 2900, it says too, have obtained written attestation. Do you see that there?

MEMBER ZANZONICO: Right.

MS. CHIDAKEL: Okay. Then just keep reading

on down.

MEMBER ZANZONICO: Okay.

(Off the record comments)

MS. BHALLA: 2901.

MS. CHIDAKEL: I'm sorry?

MS. BHALLA: 2901.

MS. CHIDAKEL: Did I get the wrong line? Here it is, right. Thank you, Neelam, 2901, "Is able to independently fulfill the radiation safety related duties as an authorized medical physicist for each type of therapeutic medical unit for which the individual," et cetera, et cetera, et cetera.

And you see there's nothing in here about competence. And even more clearly, if you flip the page to Page 99, and look at line 2927 --

MEMBER ZANZONICO: Yes.

MS. CHIDAKEL: Two, "Has obtained written attestation signed by the preceptor authorized nuclear pharmacist, the individual has satisfactorily completed the requirements in B-1, and us able to independently fulfill the radiation safety related duties of an authorized nuclear pharmacist." There's nothing in here about competency anymore.

MEMBER ZANZONICO: Understood.

CHAIRMAN MALMUD: This is Malmud, that's

wonderful. Because we've struggled with that term for a long time, and very much appreciate the wording that's now in the document.

MEMBER ZANZONICO: That is why, this is Pat Zanzonico, I acknowledge my misunderstanding. And on that basis, am happy to withdraw consideration of this recommendation.

CHAIRMAN MALMUD: Thank you.

MEMBER ZANZONICO: Although having said that, I think it emphasizes the need for a more explicit executive summary type statement.

CHAIRMAN MALMUD: This is Malmud, were you referring to something specific?

MEMBER ZANZONICO: No, again, it was just, I felt I read the document carefully, and this other language appeared so frequently that it was difficult to not infer that this might be the --

(Telephone interference)

CHAIRMAN MALMUD: Shall we move on? Pat?

MEMBER ZANZONICO: Yes, I think we can move on. So I think Item 2-C is now moot, in that the language referring to attestation of competency actually does not appear in the proposed rule.

CHAIRMAN MALMUD: Thank you. That's an enormous accomplishment. Because we've been struggling

with this, NRC's been struggling with this with us, for a long time. And that alone is quite an accomplishment.

MEMBER ZANZONICO: Yes, agreed.

CHAIRMAN MALMUD: And we thank the NRC staff as well the wisdom of the ACMUI members. All right, then we move on.

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

CHAIRMAN MALMUD: Yes, Doctor Langhorst.

MEMBER LANGHORST: I think maybe we should just vote to make sure that we are taking that out.

CHAIRMAN MALMUD: All right. Is that a motion, Doctor Langhorst?

MEMBER LANGHORST: Yes, it is.

CHAIRMAN MALMUD: Is it seconded?

MEMBER MATTMULLER: It's Steve Mattmuller. Yes, second.

CHAIRMAN MALMUD: Thank you. Any further discussion of the item?

MEMBER GUIBERTEAU: Doctor Malmud?

CHAIRMAN MALMUD: Yes, who is this?

MEMBER GUIBERTEAU: This is Mickey Guiberteau. I'm sorry, I just got back --

CHAIRMAN MALMUD: Yes, Mr. Guiberteau.

MEMBER GUIBERTEAU: -- back on the call.

I hear that we're taking this out. I just wanted to make certain that the sub-committee is, the word competency, as has been said, has always been an issue.

But the statement that was read from the rule, and the statement that is here proposed is a bit different in that the proposed rule really indicates that there should be an attestation that the trainee has fulfilled the T&E requirements, and is able to function independently in the position for the authorization.

So there is still a judgment involved, as opposed to the language here, which simply says that the training has been fulfilled, and that training is consistent with achieving a level, an ability.

So I realize it's small, but there may be some who feel like making any sort of judgment regarding a trainee, as to how they may perform in practice, is not acceptable. And I just want to point that out before you eliminate this.

CHAIRMAN MALMUD: If you take a look at Page 99, lines 2927 through 2930, are those lines acceptable to you, Doctor Guiberteau?

MEMBER GUIBERTEAU: They're acceptable to me. And to be honest, I think they're fine. But I'm just pointing out that there is a difference that what

is read, and I don't have that in front of me unfortunately. I'm not in a location where --

CHAIRMAN MALMUD: Oh, I'll read it to you if I may.

MEMBER GUIBERTEAU: All right, right.

CHAIRMAN MALMUD: "Has obtained written attestation, signed by a preceptor authorized, in this case nuclear pharmacist, that the individual has satisfactorily completed the requirements in Paragraph D-1 of this section, and is able to independently fulfill the radiation safety related duties as an authorized nuclear pharmacist."

MEMBER GUIBERTEAU: Right. Personally, I have no issue with it. I'm only pointing out that there is a judgment as to whether a person is able to do the job, as opposed to what the statement that the sub-committee has written, which said that the training has been achieved, and that training is consistent with an ability, but doesn't require a judgment.

And I'm just saying that in the past there was the issue of judging competency. In this case, it's judging an ability. And if we're fine with that, then I personally am fine with that.

But I do know that there have been some objections to a judgment of any sort on the part of future

performance by a trainee by some of the authorized users who provide these statements. So I just want to make sure that everyone is clear on that before we move on.

CHAIRMAN MALMUD: Yes, I understand your concern, Doctor Guiberteau. Are there others who wish to comment about this?

MEMBER ZANZONICO: This is Pat Zanzonico. I think the point is well taken. And the intent in my suggested language was to eliminate entirely the judgment call.

So if we amended this language, made a recommendation to amend this language, say in Line 2929 and elsewhere, and change "and is able to independently fulfill," change that, consistent with being able to independently fulfill, or consistent with the ability to independently fulfill, et cetera. That would seem to eliminate any judgment call.

MEMBER GUIBERTEAU: Dr. Malmud?

CHAIRMAN MALMUD: Yes.

MEMBER GUIBERTEAU: This is Mickey Guiberteau.

CHAIRMAN MALMUD: Yes.

MEMBER GUIBERTEAU: I think that language that has been proposed, quite frankly, is excellent, by the sub-committee. And I think it would be acceptable

to a broader group of authorized users who are serving as preceptors. And so I would support that.

CHAIRMAN MALMUD: You would support the current language, Doctor Guiberteau?

MEMBER GUIBERTEAU: No. Although I personally don't have any issue with the proposed rule, I do think that the language proposed by the sub-committee is preferable to a wider spectrum of authorized users acting as preceptors for trainings. And so personally I would support the language proposed by the sub-committee, as an ACMUI member.

CHAIRMAN MALMUD: All right. So we have a comment from Doctor Guiberteau, a member of the ACMUI, that the other language is preferable to that which is in Line 2828 and 2829, specifically 2929. Dr. Zanzonico?

MEMBER ZANZONICO: Well, let me just reiterate then what that language is. The language would be, "Has satisfactorily fulfilled the training and experience requirements consistent with achieving a level of competency sufficient to function independently in the position for which authorization is sought."

And the key distinction in that language is the preceptor is simply attesting to achieving training and experience consistent with. So there's no

judgment call at all.

I think that's preferable. I think the language which most decisively eliminates the judgment call on the part of the preceptor is preferred.

CHAIRMAN MALMUD: You have re-entered the word competency, though.

MEMBER ZANZONICO: Well, good point. Yes.

MEMBER GUIBERTEAU: This is Mickey Guiberteau. I think the word competency is also a loaded term that many authorized users acting as preceptors are uncomfortable with.

I totally agree with their position. I do think that the language that the sub-committee has proposed, that if we use the language that you had amended that language to a moment ago, by using ability as consistent with achieving an ability to act, is preferable to competency.

MEMBER ZANZONICO: Right, I agree, I agree.

MEMBER LANGHORST: Doctor Malmud, this is Sue Langhorst.

CHAIRMAN MALMUD: Doctor Langhorst, yes.

MEMBER LANGHORST: Based on this discussion, I will remove my motion to remove this paragraph, I guess.

CHAIRMAN MALMUD: You want to remove the paragraph beginning on Line 2927, which relates to the

nuclear pharmacists?

MEMBER LANGHORST: I'm sorry, no. We're talking about this paragraph 2-C, where I had made motion to remove that paragraph. And so I was wanting to remove my motion because it sounds like we want to keep the paragraph and modify the language.

MEMBER ZANZONICO: Can I offer the re-revised language, based on Doctor Guiberteau's comment?

CHAIRMAN MALMUD: Please do, Doctor Zanzonico.

MEMBER ZANZONICO: Okay. It would be, "Has satisfactorily fulfilled the training and experience requirements consistent with being able to independently function in the position for which authorization is sought."

CHAIRMAN MALMUD: Is that a motion, Doctor Zanzonico?

MEMBER ZANZONICO: Yes, let's call it a motion.

CHAIRMAN MALMUD: Do you want to put that before your sub-committee?

MEMBER ZANZONICO: Yes. So let me re-read that. The motion would be to use the language, "Has satisfactorily fulfilled the training and experience

requirements consistent with being able to independently function in the position for which authorization is sought."

MEMBER GUIBERTEAU: I like it.

MEMBER LANGHORST: This is Sue Langhorst. I like it too. But I think we need to clarify that there's more changes needed in that paragraph to get rid of the confusion of what you thought was the language.

MEMBER ZANZONICO: Agreed. No, I agree. I would revise our report. This was a draft report, the sub-committee draft report. I will revise it at a number of points, including clarifying my confusion on what I thought was being proposed versus what actually is being proposed.

VICE CHAIRMAN THOMADSEN: Pat, this is Bruce Thomadsen. Could you please repeat the current motion?

MEMBER ZANZONICO: Okay. The current motion would be to replace, in the proposed rule, to replace language that states a candidate is able to independently fulfill the radiation safety related duties for which authorization is being sought -- again, whether it's a nuclear pharmacist, authorized user, et cetera -- to change that language, "Is able to independently fulfill the radiation safety related duties," to "Has satisfactorily fulfilled the training and experience

requirements consistent with the ability to independently function in the position for which authorization is sought."

VICE CHAIRMAN THOMADSEN: Thank you.

MS. BHALLA: Doctor Malmud?

CHAIRMAN MALMUD: Yes, I was just about to ask you for NRC staff's opinion about this.

MS. BHALLA: Yes. At the ACMUI meeting held in April of 2011, we discussed this very issue about the specific language. So the language that we have here is the one that was approved, or recommended by the ACMUI at that time.

And we just believe that there isn't a whole lot of different words being proposed now. So just wanted to say that what we have right now is what was approved by the ACMUI back in April of 2011.

CHAIRMAN MALMUD: Yes, this is Malmud. I have the same recollection as you do. You have the advantage as well of having the minutes of that meeting. And we struggled with it at that time.

And we had hoped that the NRC would be willing to accept terminology that eliminated the word consistent. And we achieved that in the wording that you have in the current document.

I truly don't see much difference in what

Doctor Zanzonico is proposing, and in what's on paper. Because if the concern is that someone may be sued for the actions of his or her trainee some years later, I don't see a difference between the wording that was proposed and the wording that's in here.

But this is just one man's opinion. And the wording of consistent with being able to independently, and being able to independently function, isn't much of a difference to me.

When we train people, we recognize that not only will they be learning a lot more when they're out in the field than they learned during the training program because of the advances that are occurring constantly, but that some of the things that they were trained with, that are not used frequently, are forgotten or need to be re-trained.

So I think that the wording that's been achieved in the current document represents that which we worked for, for a period of several years, at least.

However, if the committee feels that there's an improvement to be made with this, then obviously we'll recognize it. Excuse me. I don't see the difference between the two.

MEMBER WELSH: Dr. Malmud?

CHAIRMAN MALMUD: Yes, I hear two voices.

MEMBER WELSH: Jim Welsh here, if I might.

CHAIRMAN MALMUD: Doctor Welsh.

MEMBER WELSH: If I recall correctly, please correct me if not accurate, it was not the word consistent, but the word competence that was most offensive.

CHAIRMAN MALMUD: You're correct, you're correct. It was the word competence. That was my slip. It was the word competence.

MEMBER WELSH: The current iteration, although the words may not be exact, seems to be in the correct spirit.

CHAIRMAN MALMUD: Yes.

MEMBER WELSH: It just is a matter of word-smithing to make sure that we don't have the word competence, which leaves us liable as preceptors, or even the board as an organization, to say that this person is qualified and is competent because he passed the boards. That omission of the word competence is what we are seeking today.

CHAIRMAN MALMUD: Yes, you are correct. I mis-spoke in this last statement. I earlier said it was the word competence that was the issue of conflict, and it was the issue of conflict. It appears to be resolved, but I think someone else wanted to make a comment as

well.

MEMBER PALESTRO: Yes, Chris Palestro.

CHAIRMAN MALMUD: Yes, Doctor Palestro.

MEMBER PALESTRO: I have to agree with you, Leon, in reading the two sections. I couldn't really appreciate a difference. One may sound more palatable than the other, or less intimidating. But I'm just not sure that there's significant difference between the two.

MEMBER ZANZONICO: This is Pat Zanzoniko. Given this discussion, I think the language using the word consistent is preferable. Having said that, I have no strong objection whatsoever to the language as it's, the new language, currently in the proposed rule.

And I would have no hesitation about asking the sub-committee, and then the full committee, for a vote on the language as it appears in the, the new language as it appears in the proposed rule.

CHAIRMAN MALMUD: So is that proposal to your committee that the current language as printed in the document, without change, is acceptable?

MEMBER ZANZONICO: Yes. That would be asking for a vote on that recommendation.

CHAIRMAN MALMUD: Does the rest of the sub-committee agree with Doctor Zanzonico?

MEMBER PALESTRO: Yes.

MEMBER LANGHORST: Yes.

CHAIRMAN MALMUD: Any objections to it? Any abstentions? So you have unanimity once again, Doctor Zanzonico. Now we'll present that to the entire committee and ask for their approval of the wording as it's printed in the current document, an example of which is on Lines 2927 through 2930, for approval.

Anyone object? Does anyone abstain? Hearing neither objection nor abstentions, we will declare it unanimous. I must tell you that I have to congratulate you, Doctor Zanzonico, and members of the committee.

Because you've achieved something we've been struggling with for three, if not four, years. Thank you very much. We will move on to the next numbered item if we may.

MEMBER ZANZONICO: Yes. And this was Item 2-D. And the issue, as I tried to state it initially, seemed to be that the proposed rule was parsing, for lack of a better term, authorization to use different types of radionuclides and radiopharmaceuticals that is more restrictive than what's in the current rule.

Again, in Lines 1503 to 1508 it states, "The current regulations include a broad category for

parental administration of any other radionuclide." This fourth category would be removed as any new parental administration of radionuclides not listed in this paragraph would be regulated under 35-1000.

This approach would allow the NRC to review each new proposed radionuclide for parental administration and determine the appropriate P&E for its use.

Now, the NRC staff will correct me if I misunderstood. But my inference is that this new proposed rule would allow the NRC the latitude to review each new radiopharmaceutical, or radionuclide, on a case by case basis, which just seems far more onerous, potentially, than the current rule, which at least has broad categories of types of radionuclides. So again, I think the sub-committee feels that the different classes of radionuclides and radiopharmaceuticals, in terms of clinical applications, radiation safety, radiation biology, are far more similar than they are different, and that a radionuclide by radionuclide, or radiopharmaceutical by radiopharmaceutical authorization is really excessive and unnecessary.

And so we feel that practitioners who have the requisite training in engineering, and experience, rather, to safely and effectively utilize any one, any

class of diagnostic and therapeutic radionuclides have the training and experience to utilize all of them.

CHAIRMAN MALMUD: That's been the assumption until now, that if we're competent to use a class of radiopharmaceuticals, or radionuclides, that we are able to handle others as they come.

MEMBER ZANZONICO: Right. If I could ask the NRC staff, am I misunderstanding the meaning of the language, of the relevant language in the proposed rule?

CHAIRMAN MALMUD: That's a question from Doctor Zanzonico to NRC staff.

Dr. Howe, are you on the line?

DR. HOWE: Yes, I am.

CHAIRMAN MALMUD: Would you like to comment?

DR. HOWE: Okay. The intent was to break the radiopharmaceuticals into basic categories, either oral I-131 or --

COURT REPORTER: Excuse me, this is the court reporter? Who is speaking, please?

DR. HOWE: This is Doctor Howe.

COURT REPORTER: What is your first name?

DR. HOWE: Donna-Beth.

COURT REPORTER: Thank you.

DR. HOWE: So the idea was to break it into major groups, so that one group would be the oral

administration of I-131. And there would be two groups of that, either less than 33 millicuries or greater than 33 millicuries.

Then the next category was for all radiopharmaceuticals that are used primarily for their photon or electron emissions.

So each time you got a new radionuclide, you would look and see what it was being primarily used for. So you would not be making a judgment on every individual new radiopharmaceutical or radionuclide, as longs as it fit into the category. And the fourth category was that it was being used primarily for its alpha emissions. And so if something is primarily used for its alpha emissions, it would go into the fourth category.

Now, if there were some other type of radionuclide that's not used primarily for its electron, photon, or alpha, then that would go into the statement of consideration we're talking about, that we would review independently.

So that was the intent. So the intent is not to look at each individual radionuclide and make regulations for it, but just to see if it fits into one of those four categories.

And only if it didn't fit into one of those

four categories, would we be making an independent evaluation. Does that help clarify things?

MEMBER ZANZONICO: It does, thanks. Another question though. So for example, would an authorized user be authorized to use the individual classes of radiopharmaceuticals?

So for example, they could be authorized to use I-131 photon emitted, beta emitted, but conceivably not alpha emitters.

DR. HOWE: That's correct. If they did not have clinical experience with the alpha emitters, then they would need the clinical experience with an alpha emitter. And then that would be added to their category.

MEMBER ZANZONICO: That's where I think my objection would lie. If an authorized user had the necessary training and experience to use, for example, I-131, or a beta emitter therapeutically, that should suffice to allow them to use the alpha emitters therapeutically, whether or not they had specific experience with an alpha emitter.

This is the issue that arose, of course, in connection with the radium dichloride. And so I understand it's not radionuclide by radionuclide, or radiopharmaceutical by radiopharmaceutical, but it is type of emitter by type of emitter authorization.

And my personal feeling is that that's excessive. I don't know what the feelings of other members of the ACMUI may be.

VICE CHAIRMAN THOMADSEN: This is Bruce Thomadsen. And as I recall, our discussion at the ACMUI meeting that was, indeed, the consensus of the group.

MEMBER ZANZONICO: Yes. That's my recollection as well. Thank you for confirming that. So I think our --

MEMBER LANGHORST: Pat?

MEMBER ZANZONICO: Yes.

MEMBER LANGHORST: This is Sue Langhorst. May I speak?

MEMBER ZANZONICO: Please.

MEMBER LANGHORST: One of the confusing factors of adding a parental alpha emitter, there'll be a lot of licensees who don't have that approval to use that type of radiopharmaceutical.

So it basically negates being able to get training and experience under 390. And if NRC insists on having all these separate sub-categories, I would recommend that the 390 be done away with, and you keep only the 392, 394, 396, and then add a 398, I guess, for the alpha emitters.

Because it gets so confusing as to who's

been trained on what. And I agree with Pat. If you know how to administer parental radiopharmaceuticals, alpha versus beta has very little difference.

And I don't agree with having the separate Item D in that category for alpha emitters. It makes no sense to me. Thank you.

MEMBER ZANZONICO: Thank you.

CHAIRMAN MALMUD:So, Pat, what do you recommend at this point?

MEMBER ZANZONICO: Let me see if I can formulate this in terms of a votable recommendation.

MEMBER SULEIMAN: Well, this is Orhan Suleiman. Can I say something?

MEMBER ZANZONICO: Please.

MEMBER SULEIMAN: As I recall, I disagreed with the majority at that meeting, because the chemical form of the radio-labeled drug may cause it to behave very differently.

And where the radioactivity winds up may cause it to behave very differently. And so whether this is an NRC regulatory requirement, or this is just prudent practice of medicine where the physician has the appropriate privileges to do something, I really have a bad case for lumping everything into simple categories.

Because as we're starting to see, the more

complicated procedures you have, not only with all sorts of complex therapies, when you start to get into the potential armamentarium for radio-labeled drugs, I don't think you can micro-regulate.

But at the same time, I don't think exempting and allowing everybody in the group to have the authority to use all sorts of different radio-labeled drugs is good.

Take it away from the Research Institute. Take it away from the Memorial Sloan Kettering, or any of the other places where most of you work. And go out into the hinterland where you've got some users who never show up at these meetings, who really just want to practice medicine, and they're authorized to use a certain class of radioactive drugs.

And along comes something that's very similar. And you're going to allow them the authority to start using it when they may, in fact, not have the necessary training. So that's my thinking.

How do you protect against that? I'd like to hear from our physician members. How would you ensure that a physician, a nuclear medicine doctor, or a therapy physician at some community hospital who's authorized to use one of these other products, gets something new, and how do you assure that he's got the appropriate

training?

MEMBER LANGHORST: Sue Langhorst. I know I'm not a physician, but can I take a shot?

CHAIRMAN MALMUD: Please do, Doctor Langhorst.

MEMBER LANGHORST: Thank you. Orhan, there's a difference between training and experience requirements to become an authorized user and then the license to use certain radioactive materials, and the specific training that a licensee and their authorized users need to have in order to utilize a new radiopharmaceutical.

So I think what we're talking about here is what is the base training and experience an authorized user needs to have in order to work with the normal radiopharmaceuticals, and then have enough depth of knowledge that then they can apply with additional vendor training on new radiopharmaceuticals, the specific procedures that have to be in place, both radiation safety and patient safety-wise, in order to administer these new forms of radiopharmaceuticals.

MEMBER SULEIMAN: Orhan Suleiman. Well, if that's how it plays out, that's great. But how do you ensure that these individuals will exercise the proper, and again, the proper professional judgment to say I

really need training to use this modality.

MEMBER ZANZONICO: And this is Pat Zanzonico. Your point is well taken. But my feeling is that parsing radiopharmaceuticals by the type of emission doesn't address that issue.

There's always going to be an issue of practitioner competency with any new radiopharmaceutical, or in medical oncology any new drug, or in surgery a new surgical procedure.

But in the context of clinical use of radioactive materials, my point, as I said, is that parsing authorization based on type of emission still doesn't address that.

You can have very diverse beta emitters, or beta emitting radiopharmaceuticals for therapy, and an AU can be as competent, or incompetent, in using these very different beta emitting radiopharmaceuticals, as using a beta emitter versus an alpha emitter.

So it's not that the issue of a learning curve and competency in using different agents is not a real one. It's that parsing them according to radiation emissions doesn't address that issue. It's an artificial regulatory manipulation that really doesn't serve any purpose.

MEMBER MATTMULLER: Dr. Malmud, this is Steve

Mattmuller, if I may.

CHAIRMAN MALMUD: Yes, Steve.

MEMBER MATTMULLER: First of all, I'd like to agree with Orhan one important point, that I certainly agree that the radiopharmaceutical chemical composition is a far more challenging aspect for physicians getting experience with these therapeutic radiopharmaceuticals, in that the I-131 antibody affects are, Tositumomab is far more challenging to use safely in a patient then, say, a single dose of even radium-226 alpha radon.

The type of radioactive emission is really inconsequential. It's the type of radiopharmaceutical that can present a much greater challenge to being used safely.

That said, I think we have to realize the limitations of the NRC's regulatory reach, in that they can only regulate per type of radioactive emission, whether we want to go with what they suggested in separating them out, or keeping them all together, as Pat had suggested and Sue had suggested. And I would agree with that concept also.

And then just to address Orhan's other concern, actually the FDA, in the introduction of new complex radiopharmaceuticals, it does have a training program for a new user to go through, and prepare to do

the calculations necessary for planning the treatment.

And these calculations all have to be reviewed and approved before they can attain an independent status of using it (telephonic interference). So there is some training in place for the more complex radiopharmaceuticals right now. Thank you.

CHAIRMAN MALMUD: Thank you. We're back to the issue, Dr. Zanzonico.

MEMBER ZANZONICO: Well, again, I don't think there's disagreement that new or additional training for new and potentially different and more complex radiopharmaceuticals is appropriate.

I think where the sub-committee and the ACMUI disagree with the NRC is that basing the training and experience requirements on radiation emissions doesn't address that, and really doesn't serve the public or patients.

So unless there was additional comments from the sub-committee or the ACMUI, or the NRC staff, I would offer the following recommendation for a vote, first by the sub-committee, then the committee as a whole.

And that is, and it's basically the last sentence of Item 2-D, namely "Pracitioners who have the requisite training and experience to safely and

effectively utilize any emitter diagnostically, and/or therapeutically, have the training and experience to utilize all of them. And authorization should not be emission specific."

So what I'm asking for then, is approval by the sub-committee, and then the committee as a whole, to submit that recommendation to the NRC.

CHAIRMAN MALMUD: So you're putting the motion before the sub-committee.

MEMBER ZANZONICO: Correct.

CHAIRMAN MALMUD: And you're going to poll the sub-committee. All right, polling the sub-committee, all in favor of this motion --

MEMBER WEIL: Dr. Malmud, this is --

CHAIRMAN MALMUD: Who's speaking please?

MEMBER WEIL: This is Laura Weil.

CHAIRMAN MALMUD: Yes?

MEMBER WEIL: Before we actually vote, could I ask NRC staff to respond to Doctor Zanzonico's last comment, and justify why they feel it might be inadequate?

CHAIRMAN MALMUD: Certainly you can ask. NRC staff, who wishes to respond? Doctor Howe?

DR. HOWE: Getting off mute. When we look at the radiation safety issues that are associated with different radionuclides, we believe that the radiation

safety that's involved with photons, and then with beta particles, or with alpha, are very different.

With radium-223 we were able to look at how you measured it. And you measured it basically using the photons. And so there wasn't a difference as to how you could detect contamination, how you could measure what you believe to be the activity of things.

You could use the same equipment that you were using automatically already. But we do believe that there's a difference in how beta particles interact, and that since most nuclear medicine positions are primarily photon, that there is a need for additional training for some of these new emitters coming down. So that's our basic reasoning. Thank you.

CHAIRMAN MALMUD: Does that answer your question?

MEMBER WEIL: It does. It does and I have to say that I agree with NRC staff on this.

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

CHAIRMAN MALMUD: Yes, Dr. Langhorst.

MEMBER LANGHORST: I would like to get a clarification from Dr. Zanzonico. Pat, are you saying that the NRC should do away with the different levels of I-131 therapy and diagnostics?

MEMBER ZANZONICO: No, Sue. Because I think that there is a fundamental distinction between whether one is using radioactivity diagnostically or therapeutically.

If one is using it therapeutically, the authorized user has a responsibility to medically manage a patient who may suffer acute or deterministic effects as a result, and has to have the training and experience to do that properly.

If one is strictly using them diagnostically, those classes of effects are inapplicable. So I mean I think there is a fundamental distinction between, or among, or between therapeutic and diagnostic applications and therefore in relation to administered activities.

But I think all authorized users, and who use radioactivity clinically, have training and experience in radiation physics, in radiation detection and instrumentation and so forth. And understand the capabilities and limitations of different instruments in detecting different types of radiations and so forth.

So it's not to say that there aren't valid distinctions and valid reasons for different types of required training and experience among different applications of radiopharmaceuticals or radioactivity

clinically, but that basing that distinction strictly on admissions is not a valid one.

MEMBER LANGHORST: Okay, this is Sue Langhorst again. I think the first part of 390 is I-131 sodium iodide less then 33 millicuries. And please for give me for that old unit.

The other one is I-131 sodium iodide greater then that. And I think those two, first one tends more towards diagnostic use. Second one is definitely therapy.

I think what you're proposing, Pat, and please forgive me for trying to put words in your mouth, but I think is that the parenteral-administration, as opposed to those first which are oral, the parenteral you're saying don't have two separate categories for that, have it be one category that includes all the photon betas and alpha emitters?

MEMBER ZANZONICO: Yes, that's basically correct.

MEMBER LANGHORST: Okay, I agree with that. Thank you.

CHAIRMAN MALMUD: Just a minor correction. The lower doses of I-131 below grade are also therapeutic therefore hyperthyroidism versus the ones that are 100 millicuries or more which tend, or 50 millicuries or more which tend to be for thyroid cancer. Or for thyroid

cancer.

MEMBER LANGHORST: Thanks for correcting me Dr. Malmud, this is --

CHAIRMAN MALMUD: Okay, I'm sorry. But you are also correct in that there are lower doses of I-131 in the order of 3 millicuries, which is still used in remote locations were I-123 is not available for diagnostic purposes. You are correct in that.

At any rate, getting back to the subject. So Dr. Zanzonico, the ball is in your court.

MEMBER ZANZONICO: Well I would still, I mean I appreciate the comments and the rationale offered by the NRC staff, but I'm unconvinced at this point and would still offer my recommendation for a vote. And I can repeat it if you like?

CHAIRMAN MALMUD: Please repeat it.

MEMBER ZANZONICO: Okay. The recommendation would be, or the vote would be to recommend to the NRC the following:

"Practitioners who direct the training and experience to safely and effectively utilize any radiopharmaceutical, diagnostically and therapeutically, have the training and experience to utilize all of them and authorization therefore should not be emission specific."

CHAIRMAN MALMUD: That is the motion.

VICE CHAIRMAN THOMADSEN: Okay, this is Bruce Thomadsen. If I could propose an amendment? Instead of all of them, any of them.

MEMBER ZANZONICO: Okay, agreed.

CHAIRMAN MALMUD: Any other amendments to this motion which is being put before the subcommittee?

MEMBER LANGHORST: Well we have, this is Sue Langhorst, so we have a chance to ask more questions?

CHAIRMAN MALMUD: Absolutely.

MEMBER LANGHORST: Can I now?

CHAIRMAN MALMUD: Yes you may.

MEMBER LANGHORST: Pat, I believe what you're proposing here encompasses all of 190, 290 and 390? And so I don't think I can agree with this.

And that's why I was trying to clarifying, you're only talking 390 and are you only talking C and D items or do you mean NRC should do away with 190, 290 and 390?

MEMBER ZANZONICO: I have to confess to you, I'm just not as familiar off the top of my head with the Sections of the Regs as you are. The gist of what I'm trying to propose, and perhaps you can formulate it in a much better way, but the gist of what I'm trying to propose is eliminating the language, or the sections in

the proposed rule, which would require separate training and experience based on type of emission, of radiation emission.

MEMBER LANGHORST: And this is Sue Langhorst again. So you mean between the beta emitting therapy radiopharmaceuticals, beta and proton emitting versus alpha emitting? Is that the --

MEMBER ZANZONICO: Correct.

MEMBER LANGHORST: Okay, so I would agree with your point if that's what you're limiting it to. But the wording you're using is all and any.

MEMBER ZANZONICO: Yes, understood. So --

MEMBER LANGHORST: I would recommend that the motion might be that ACMUI recommends that alpha emitter, parenteral-administered alpha emitting radiopharmaceuticals not be separately called out for training and experience, that instead the training and experience should be limited to parenteral-administration of radiopharmaceuticals?

MS. BHALLA: Dr. Malmud?

CHAIRMAN MALMUD: Yes.

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

CHAIRMAN MALMUD: Yes.

MS. BHALLA: So for clarification, I think

it's important to then defer to Section 35-C-96, because that's the section that pertains to the parenteral-administration of radiopharmaceuticals.

So that would eliminate any confusion about going back to 190, 290, et cetera because those sections are not included in the -- again I'll talk about the user need memo where the request came that right now we have, under the 35-C-96, categorization of certain beta emitters and then gammas up to a certain energy.

But there was no, I think that question came up, what about alpha emitters? So the staff expressed a need to create a separate category for that modality and that's why this was open. So when you make your report, please refer to Section 35-C-96 because that's what's open to amendment.

CHAIRMAN MALMUD: Thank you for that.

DR. HOWE: Dr. Malmud?

CHAIRMAN MALMUD: Yes.

DR. HOWE: Dr. Malmud, this is Dr. Howe. Actually 390 and 396 are both open because 396 pertains only to the radiation oncologist, where 390 applies to the nuclear medicine physicians.

CHAIRMAN MALMUD: Thank you for clarifying that, Dr. Howe.

MEMBER LANGHORST: This is Sue Langhorst.

Dr. Howe, I disagree with that. 390 refers to any physician that meets that requirement, be they radiation oncologist or nuclear medicine.

My radiation oncologists are approved under the 390, so I don't think you can clarify it in that simplistic of terms.

DR. HOWE: Well the, this is Dr. Howe again. The original intent for 396 was to allow radiation oncologists that have authorized users status as radiation oncologist, to use parenteral treatment without having to go through the 200 hours and the other requirements in 390.

Now I understand some of the board certifications are covering both now, but if you look carefully at 396, the criteria for using 396 is that your are either recognized under 35-400, which is brachytherapy, or in 360, which is the remote afterloader, the teletheraphy and the gamma stereotactics. So there is a distinction there, although it's getting a little fuzzier.

MEMBER LANGHORST: This is Sue Langhorst. My point is, is that radiation oncologist also practice under 300. I mean not just that one section, but all of 390.

MEMBER WELSH: This is Jim Welsh. I fully

agree with what Dr. Langhorst has just said. It's part of the board requirements now.

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

CHAIRMAN MALMUD: Yes, Dr. Langhorst.

MEMBER LANGHORST: I would like to suggest that maybe the subcommittee work on the wording for this section a little bit in this week between our teleconferences and bring forward some new language on it?

MEMBER ZANZONICO: This is Pat Zanzonico. I agree completely. I think we're in agreement on the sense of what we want to express, but it will require some additional discussion to formulate it properly.

CHAIRMAN MALMUD: Okay, that's a decision which the subcommittee chair can deal with. Dr. Zanzonico?

MEMBER ZANZONICO: Absolutely. And so we would just defer this item, Item 2D to our offline discussion and then pick it up again at our next teleconference.

CHAIRMAN MALMUD: Or the next meeting.

MEMBER ZANZONICO: Or the next meeting.

CHAIRMAN MALMUD: Thank you. Is that acceptable to the staff?

MS. BHALLA: Dr. Malmud?

CHAIRMAN MALMUD: Yes.

MS. BHALLA: We would really appreciate it if it's done at the next teleconference which is scheduled for next week, I suppose, to meet our schedule for the rule to be taken to the commission.

CHAIRMAN MALMUD: Thank you. Can that date be met Dr. Zanzonico?

MEMBER ZANZONICO: Absolutely.

CHAIRMAN MALMUD: Okay, you're wish is subcommittee's command. Thank you. Dr. Zanzonico?

MEMBER ZANZONICO: Before continuing, the question I have is, what the schedule is in terms of the next teleconference?

I'm wondering at this point, since we're approaching the end of the allotted time for today's teleconference, if it might be more logical and more productive to resume our discussion, first with this last point and then go on to Item 3 and the remaining items at that time as opposed to beginning a discussion of these additional items at this point?

CHAIRMAN MALMUD: I think that's a constructive suggestion. The Committee maybe facing fatigue since we're approaching three hours. Is that acceptable to the members of the NRC staff as well as

to our Committee members?

MS. BHALLA: Dr. Malmud, this is Neelam Bhalla. Very quickly I wanted to bring one clarification so that when we meet next time maybe the subcommittee can take a look at that before we meet?

CHAIRMAN MALMUD: You want to --

MS. BHALLA: And that should not --

CHAIRMAN MALMUD: I beg your pardon?

MS. BHALLA: I said that should not take long, it's one clarification I want to make and so that when we meet next time subcommittee would have had time to look at that.

CHAIRMAN MALMUD: All right, Dr. Zanzonico, is that okay?

MEMBER ZANZONICO: Absolutely, no please.

CHAIRMAN MALMUD: Go ahead then.

MS. HOLIDAY: I just wanted to interject really quick, this is Sophie. I believe you asked for what our schedule is like and so we do have a backup teleconference scheduled for next week on the 12th at the same time, from 2:00 to 5:00 p.m.

The ACMUI was given the draft, the proposed draft FRN December 21st. So our 90-day deadline to receive your comments in the form of a final report would be March 21st.

So if at all possible, we would like to resolve all comments and have approval or a consensus on that subcommittee report by the end of next meeting?

MEMBER ZANZONICO: Ms. Sophie, that's our intent, absolutely.

MS. HOLIDAY: Great, thank you.

CHAIRMAN MALMUD: We shall endeavor to do so Sophie.

MS. HOLIDAY: Thank you, Dr. Malmud.

CHAIRMAN MALMUD: Dr. Zanzonico and Bhalla?

MEMBER ZANZONICO: Well I just wanted to hear this comment related to Item 3A?

CHAIRMAN MALMUD: Yes.

DR. BHALLA: Yes. So in Item 3A, which is about extending grandfathering to certain certified individuals, which is the Ritenour Petition.

I would just bring the, it seems like when you read this paragraph, especially the last line it says, wouldn't they already be named on our license? This is with regard to those qualified individuals.

It seems like it's a question and I just wanted to make the clarification that the whole of the Ritenour Petition was based on the fact that there were certain individuals. Namely, the petitioner said, the RSOs and the physicists who were not named on the

licensed, because 35-57 starts with these individuals who were certified on an NRC license.

So the petition came, we said that well there were people who were qualified but they were not named on a license and therefore here NRC, do something about it for these individuals. So I just wanted to do that clarification right now, that the entire petition is based on the fact these people were not licensed, were not named on a license and therefore they got kind of left behind or they were not grandfathered.

So with that clarification, maybe the subcommittee would rethink as to why the importance laws of that particular date be October 2005. Because that's when the old Subpart J went away and these people who were not named on a license, now they needed to, or right now they need to meet the new requirement.

And therefore what we want to or how we want to correct that, is to bring back all those rules. And you would have seen that in the proposal. We literally brought the old rules back into the Regs.

We didn't want to refer them to, that go back to 2002 or to 2005 and go look at all the rules. So I just wanted to bring that to the attention of the subcommittee that the date is important and that, yes indeed, these people were not listed on the license.

CHAIRMAN MALMUD: Thank you and --

MEMBER ZANZONICO: Thank you.

CHAIRMAN MALMUD: -- what's the proposed resolution to the issue?

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

CHAIRMAN MALMUD: Yes Dr. Langhorst.

MEMBER LANGHORST: Neelam, thank you very much for your clarification on that because I don't think that the language in the draft proposed rule right now makes that clear. And that's what we were trying to get across in this point.

And so we will be a little more, Pat, if you allow me to say this, we'll be a little more careful in pointing out where we think that is not made clear in the draft proposed rule that you have before us.

MEMBER ZANZONICO: Absolutely.

MS. BHALLA: And this is Neelam again. And we appreciate that and we would make that clarification that these were the people who were not named on the license.

CHAIRMAN MALMUD: Thank you.

MEMBER ZANZONICO: That's helpful, I think it will, that this will expedite the discussion of this item on the next teleconference.

MS. BHALLA: Correct.

CHAIRMAN MALMUD: Thank you.

MS. BHALLA: Thanks.

CHAIRMAN MALMUD: It's about 5:05 now in eastern standard time. So unless there's objection, we will call an end to the meeting today, pick it up at the next session which is on the March the 12th at 2:00 to 5:00 p.m.

Hopefully complete all the (telephonic interference) that time so that we could meet the deadline, which is March 21st. Is that agreeable with everyone?

MEMBER ZANZONICO: Yes.

CHAIRMAN MALMUD: Is there anything of any urgency that anyone feels must be brought today up at this time?

MS. HOLIDAY: Dr. Malmud, this is Sophie.

CHAIRMAN MALMUD: Yes, Sophie.

MS. HOLIDAY: I would like to make the announcement for members of the public, if you wish to participate, or if wish to call in to listen to teleconference meetings on next Tuesday, please send me an email and I will provide you with the bridgeline information, it would be different from the one that was used today.

CHAIRMAN MALMUD: Thank you. And I know that we'll receive an email from you with regard to the members' bridgeline?

MS. HOLIDAY: Yes, sir.

CHAIRMAN MALMUD: Thank you. Any other issues to be brought up today? If not I want to thank everyone for participating in this call today, particular Dr. Zanzonico and the members of the subcommittee who've done an extraordinary amount of work since we last spoke.

I've been following all the progress and discussion via the emails. And I want to thank you all again and we'll look forward to meeting again next week.

MEMBER ZANZONICO: Very good, thank you.

CHAIRMAN MALMUD: Thank you all.

MEMBER ZANZONICO: Bye, bye then.

CHAIRMAN MALMUD: Is there comment from NRC staff?

MR. EINBERG: This is Chris Einberg. On behalf of the NRC staff we want to thank the ACMUI and the subcommittee for all this very hard work. I know it's been quite a bit to review and so we greatly appreciate all your input.

CHAIRMAN MALMUD: Thank you all.

MEMBER ZANZONICO: Okay, thank you bye, bye.

CHAIRMAN MALMUD: Bye.

MEMBER LANGHORST: Bye.

(Whereupon, the hearing in the above-mentioned matter was adjourned at 4:53 p.m.)