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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

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TELECONFERENCE

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TUESDAY, MARCH 12, 2013

The meeting convened telephonically at 2:00 p.m. Eastern Daylight Time, Leon S. Malmud, M.D., ACMUI Chairman, presiding.

MEMBERS PRESENT:

LEON S. MALMUD, M.D., Chairman

BRUCE THOMADSEN, Ph.D., Vice Chair

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

JOHN SUH, M.D., Radiation Oncologist

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

NRC STAFF PRESENT:

BRIAN McDERMOTT, Director, Division of Materials Safety and State Agreements

CHRISTIAN 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

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

ED LOHR, FSME/DILR/RPMB

DEBBIE PISKURA, FSME/DMSSA/RMSB

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

NRC REGIONAL STAFF PRESENT:

JACKIE COOK, Region IV

ROBIN ELLIOTT, Region I

SARA FORSTER, Region III

DENNIS O'DOWD, Region III

LESTER TRIPP, Region I

MEMBERS OF THE PUBLIC PRESENT:

KEITH BROWN, University of Pennsylvania

SUE BUNNING, Society of Nuclear Medicine and Molecular Imaging

DAWN EDGERTON, Council for Certification in Cardiovascular Imaging

LYNNE FAIROBENT, AAPM

KAREN LANGLEY, University of Utah

RALPH LIETO, St. Joseph Mercy Hospital

ANDREW McKINLEY, American Society of Nuclear Cardiology

MICHAEL PETERS, American College of Radiology

MICHAEL STEPHENS, Florida Bureau of Radiation Control

CINDY TOMLINSON, American Society for Radiation Oncology

MICHAEL WELLING, Virginia Department of Health

GARY E. WILLIAMS, Department of Veteran Affairs, National Health Physics Program

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P R O C E E D I N G S

2:01:51 p.m.

CHAIRMAN MALMUD: Hello, everyone. This is Leon Malmud, and this is a continuation of our ACMUI teleconference which began last week, and we will continue it today. However, I would like to first introduce the member of the NRC Staff who will greet us all, Chris.

MR. EINBERG: Okay, very good. Good morning, or good afternoon.

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 Chief of the Radioactive Materials Safety Branch, and I have been designated as the federal officer for this Advisory Committee in accordance with 10 CFR Part 7.11. Present today is the alternate Designated Federal Officer, Ashley Cockerham, coordinator for the Committee.

This is an announced meeting of the Committee. It is being held in accordance with rules and regulations of the Federal Advisory Committee Act and the Nuclear Regulatory Commission.

This meeting is being transcribed by the

NRC, and it may also be transcribed or recorded by others.

The meeting was announced in the February 1st, 2012 edition of the Federal Register, Volume 78, page 7465, and is a continuation of teleconference meeting that was held on last Tuesday, March 5th, 2013.

The function of the Committee is to advise the Staff on issues and questions that arise on the medical use of byproduct material. The Committee provides counsel to the Staff but does not determine or direct the actual decisions of the Staff or the Commission. The NRC solicits the views of the Committee and values their opinions.

I request that whenever possible we try to reach a consensus on the procedural issues that we will discuss today, but I also recognize there may be a minority or dissenting opinions. If you have such opinions please allow them to be read into the record.

At this point I would like to perform a roll call of the ACMUI Members participating today. Dr. Leon S. Malmud, the ACMUI Chairman.

CHAIRMAN MALMUD: Here.

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

VICE CHAIR 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.

MEMBER SUH: Here.

MR. EINBERG: Dr. Orhan Suleiman, FDA Representative.

MEMBER SULEIMAN: Here.

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

Ms. Laura Weil, Patient's Rights Advocate.

MEMBER WEIL: Here.

MR. EINBERG: Dr. Jim Welsh, Radiation Oncologist. Dr. Welsh, are you on the line?

No, moving on. Dr. Pat Zanzonico, Nuclear Medicine Physicist.

MEMBER ZANZONICO: Yes.

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

I now ask the NRC Staff members who are present to identify themselves.

MS. HOLIDAY: Sophie Holiday, FSME.

MR. WHITE: Duncan White. I'm the Branch Chief for the Agreement State Program Branch in FSME.

DR. HOWE: Donna-Beth Howe, FSME.

MS. BHALLA: Neelam Bhalla, FSME.

MS. CHIDAKEL: Susan Chidakel, OGC.

MR. EINBERG: Okay. For the people that are on the line from Headquarters can you please identify yourselves.

DR. ZELAC: Ronald ZELAC, FSME.

MR. EINBERG: Could you repeat that for the court reporter?

DR. ZELAC: Ronald ZELAC, FSME.

MR. EINBERG: Thank you.

MS. PISKURA: Debbie Piskura, FSME.

MS. COCKERHAM: Ashley Cockerham, FSME.

MR. EINBERG: Okay. We were just joined by Ed Lohr also here in Headquarters. Now, I'd like to go to the regions. Region I, who do we have on the line?

MS. ELLIOTT: Robin Elliott, Region I, DNMS.

MR. TRIPP: Lester Tripp, DNMS.

MR. EINBERG: Anybody else from Region I? Okay, now I'd like to go to Region III. Is there anybody on the line?

MS. FORSTER: Sara Forster.

MR. EINBERG: Okay. Can you please repeat that?

MS. FORSTER: Sara Forster.

MR. O'DOWD: Dennis O'Dowd.

MR. EINBERG: Okay, Region IV now, who's on the line? Anybody from Region IV? Okay.

Next I'd like to identify members of the public who notified us that they would be participating on the teleconference. When I call your name please answer that you're present. Keith Brown, University of Pennsylvania.

MR. BROWN: Here.

MR. EINBERG: Sue Bunning, Society of Nuclear Medicine and Molecular Imaging.

MS. BUNNING: Here.

MR. EINBERG: William Davidson, University of Pennsylvania. Casey Deitrich, CQ Transcriptions. Dawn Edgerton, Council for Certification in Cardiovascular Imaging.

MS. EDGERTON: Here.

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

MS. FAIROBENT: Here.

MR. EINBERG: Norman LaFrance, Jubilant Draxlmage, Incorporated. Karen Langley, University of Utah.

MS. LANGLEY: Present.

MR. EINBERG: Ralph Lieto, St. Joseph Mercy Hospital.

MR. LIETO: Present.

MR. EINBERG: Magali Lurquin, Jubilant Draxlmage. Andy McKinley, American Society of Nuclear Cardiology.

MR. McKINLEY: Here.

MR. EINBERG: Tamara Mills, Jubilant Draxlmage. Mike Peters, American College of Radiology.

MR. PETERS: Here.

MR. EINBERG: Joe Rodgers, Paragenics Corporation. Gloria Romanelli, American College of

Radiology. Michael Sheetz, University of Pittsburgh. Michael Stephens, Florida Bureau of Radiation Control.

MR. STEPHENS: Here.

MR. EINBERG: Cindy Tomlinson, American Society for Radiation Oncology.

MS. TOMLINSON: Here.

MR. EINBERG: Michael Welling, Virginia Department of Health.

MR. WELLING: Here.

MR. EINBERG: Gary Williams, Department of Veterans Affairs, National Health Physics Program.

MR. WILLIAMS: Here.

MR. EINBERG: Okay, thank you. Is there anyone else on the call that I did not call?

MR. McDERMOTT: Yes, this is Brian McDermott, Director of the Division of Material Safety and State Agreements in FSME.

MEMBER WELSH: James Welsh with the ACMUI.

MR. EINBERG: Okay. Thank you, Jim.

As you know, we have a bridge line available for this call, and that phone number is (888)864-0940. The pass code to access the bridge line is 34081#.

At this time, I ask that everyone on the call who is not speaking to place their phones on mute.

If you do not have the capability to mute your phone, please press *6 to utilize the conference line mute and unmute functions. I would ask everyone to exercise extreme care to insure that the background noise is kept to a minimum as any background sounds can be very disruptive on a conference call this large.

This is a Category I public meeting. This is an open public observatory meeting, but 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 late 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.

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

CHAIRMAN MALMUD: Thank you, Chris. If I may, we have one item to present prior to the agenda and that is a comment from Duncan White who will brief us on an issue that was raised by members of the

Committee and which he will address for us. Please, Duncan White.

MR. WHITE: Thank you, Dr. Malmud. Again, my name is Duncan White. I am the Branch Chief for the Agreement State Program Branch.

My Branch has -- one of its primary responsibilities is to review all Agreement State regulations for compatibility, and we do this for all 37 Agreement States. And as part of that process, we look at a wide range of regulations including the medical ones and make determinations if the States' regulations are compatible with NRC regulations.

In addition to that, as part of the NRC rulemaking process, I serve as a co-chair to what's called Standing Committee on Compatibility. When draft rules are made available for comment, as you know, they are provided to the states, and also at that time our Committee also takes a look at it with the objective to insure that the proposed rule and the compatibility determinations made in that proposed rule are consistent with the Agency's Policy Statement on adequacy and compatibility. We also look to ensure that it's consistent with other rules and regulations that are already in existence out there.

This group has been in place for about four

years now, and we've looked at a number of different rules, hopefully to ensure that there's a consistent application of the Policy Statement.

Again, as with any proposed rule, the Committee had an opportunity to look at the proposed rule that you're all looking at right now. We met yesterday. We discussed the draft rule yesterday with all five members of the Committee, also Neelam Bhalla who was the Project Manager for that, and Ed Lohr participated in that discussion.

One of the things that we did focus on was the specific question that is in the proposed rule to ask about is the Compatibility Category for the Section 35.3045 Report and Notification of a Medical Event. Again, the draft FRN will ask, and again this will be out for public comment, get people's view on the compatibility with Category B, or Compatibility Category C. And I think as written in the proposed rule right now it provides a balanced view of why maybe you think it would be a B, or you think it would be Category C.

The Committee did discuss this at length and unanimously indicated back to -- and we'll be writing this in the memo. We unanimously agreed that we felt it should be Compatibility Category C. And the

reason we came to that conclusion is for a couple of different reasons.

For some -- for a section of the regulations to be Compatibility Category B it has to have significant trans-boundary implications. And for Compatibility Category C it has to be -- the requirements for that, is has to -- that the absence of the compatibility designation, if it's Compatibility Category C it cannot create a gap, duplication, or anything like that in the national program.

And after our discussions with that, we felt it did not meet the definition of significant trans-boundary implications, and certainly it did qualify as Compatibility Category C.

Again, one of the things the group did point out and did discuss at length is that -- made it very clear, if the final rule, for example, is Category C, the states would still be required to report the source strength criteria to the NRC. They would be required to do so. That is considered part of the essential objective of that rule, and the states must report that.

Under Category C they would have the option of requiring their licensees to report the dose-base criteria in addition to that, but they would still be

required, like NRC licensees are required to report the source strength of the activity-based quantity. They could also do this additional one.

The other reason is that the important aspect of the Policy Statement is to insure that there's flexibility given to the states to adhere to local conditions and local requirements. There are -- we are aware of some states that do collect information on medical events, misadministrations. They call them different things with regard to collecting additional information for their -- for individual states.

Some states have specific legal requirements that they must meet. There's a state law that they must adhere to, and that's why they collect the information.

We had a similar situation in the past where we had a different rule where, again, the NRC changed the regulation, specifically changed the compatibility requirements from Category C to Category B, and the states -- it caused a great deal of conflict with the states because the states had existing programs in place. And when you go to Category B, you basically require the states to have the identical, exactly the same, and I mean identical, I mean word for word exactly the same requirements. And there were states that had

existing programs for -- it involved registration of general license devices. And some states took -- some states eventually decided to petition the NRC, and eventually that was -- about eight or nine years later, it was returned to Category C.

Again, the Commission recognized that the states need that flexibility for the local situation the states were in. And, again, it wasn't a one-size fits all.

So, for this reason the Compatibility Committee decided with regard to this particular rule, again, we recognize it's a matter of compatibility. They need to have -- they still need to adhere to the new requirements which would be activity-based. They could still have the option of requiring their licensees to report the dose, but they still must require to have the activity information reported to us. And like any medical event, some of this information must be reported to the -- a medical event must be reported to the Headquarters Operations Center and tracked in the national database. They are required to report this activity-based requirement, again, if the rule is put into place and finalized, as such. They would still be required to do that.

Again, that's what Compatibility Category

C would mean. Again, if it was C, they may ask for the dose-base, and that's their prerogative to do so. And they need to ask for additional information. Again, that's their prerogative to do so.

If it was a B, again, they would not be able to collect any other information, and that may put them in conflict with their state laws, and their state requirements. So, again, this was the basis for the Committee's decision to endorse the Compatibility Category C with regard to this.

Again, our recommendations will be forwarded to Neelam Bhalla, and they will be part of the Commission paper that will go up as well as I understand the ACMUI's views, too, on that.

So, with that are there any questions for me?

CHAIRMAN MALMUD: This is Dr. Malmud. Are there any questions?

MEMBER ZANZONICO: This is Pat Zanzonico. I have a question, if I may.

CHAIRMAN MALMUD: Please do.

MEMBER ZANZONICO: I gather in the past rule on medical events for permanent implant brachy one of the criteria was a dose differing from the prescribed dose that would have resulted in an effective dose of

5 rem, a normal organ dose of 50 rem, et cetera, et cetera.

If this were Compatibility C would the states have the option, the Agreement States have the option, for example, of retaining those dose-based criteria?

MR. WHITE: Yes, they could. Again, they could do that. Again, what the requirement was for Category C is to meet the essential objectives of the rule. And, again, the essential objectives of the rule is to report events that have -- that meet the definition from a dose -- activity-based perspective. If they choose to do additional stuff, they may use to choose that 5 rem.

MEMBER ZANZONICO: I don't mean to speak either for the Subcommittee or the ACMUI as a whole, and actually I think I may have misspoken in the written draft report when I said that there was unanimity with respect to Cat B versus Cat C recommendation. But my concern, if that's the case, is that the -- to me, the point of the revised criteria for MEs was to accurately, to sensitively and specifically capture clinically significant medical events in permanent implant brachy. And with a Cat C specification, if these additional dose criteria can still be -- can still remain in

effect, it seems to be undermining that key objective of sensitively and specifically capturing clinically significant events.

I think the ACMUI Subcommittee on criteria for permanent implant brachy medical events went through a lot of time and effort to craft a set of criteria that met that objective. And if States can individually superimpose additional criteria, it just seems to undermine that entire objective. And I think that's the underlying rationale of the majority of the ACMUI in recommending a Cat B specification for this -- for the ME definition.

MEMBER WELSH: This is Dr. Welsh, if I might contribute.

CHAIRMAN MALMUD: Please do.

MEMBER WELSH: Yes, I would agree with what Dr. Zanzonico has just stated, that Compatibility C wherein States are still allowed to impose what the Subcommittee feels were inappropriate criteria for medical events would seriously undermine many years of very intensive hard work that has been done to communicate to the NRC at the very highest levels the inappropriateness of the previous definitions. And the key point regarding the inappropriateness of the previous definitions was the use of dose as criteria.

And, therefore, it just does not seem to make sense that what has been almost conclusively and unanimously felt to be an inappropriate medical event definition, i.e., use of dose as a criteria, should really not be permitted anymore because that does go back to the use of clinically irrelevant or clinically inappropriate definitions for medical events. And we would not have gained a whole lot after all this time and effort if the states were to continue to use dose inappropriately as Compatibility C might enable.

VICE CHAIR THOMADSEN: Dr. Malmud.

CHAIRMAN MALMUD: Yes.

VICE CHAIR THOMADSEN: This is Bruce Thomadsen, if I may comment.

CHAIRMAN MALMUD: Please do.

VICE CHAIR THOMADSEN: One other -- one reason that making this a Category C would be a problem is that it's very likely to set up two tiers of quality in medicine, and the states that may keep the dose-based medical events criteria, practitioners who would practice defensively might indeed compromise what they do to definitely avoid the medical events even though that also may compromise their ability to treat the patients, as well, compared with States that have abandoned that.

This also would make training very difficult on a national level, and much of the training for brachytherapy is nationally run, in which case there would have to be two completely different sets of training to make sure that the practitioners would know what their medical events categories would be, and how to defensively practice not to violate those from State to State. And in a national training course, this would add difficulty.

We heard during the stakeholders' meetings of the problems that the current definition has caused in the disciplines, and having part of the country maintain the previous problematic definition, and part of the country not, is certainly going to add confusion in the field. And that cannot be good for patient care.

CHAIRMAN MALMUD: Thank you. Are there responses to that comment from Dr. Thomadsen?

MR. WHITE: Again, from our -- this is Duncan White. With regard to the comments, again, our focus was really looking at, you know, is there a -- for Category B is there specific trans-boundary. And, again, we weigh that in terms of a national program. We do recognize that the states are still going to have to require them to provide that information. And from a practical standpoint, again, I think a lot of States

would go over to what the NRC would have. Some would have -- I would honestly say would probably have -- may have a two-tier system. That's very possible, and I can't deny that would not happen. Again, it's hard to predict with 37 Agreement States exactly what path all of them would take.

But, again, one thing we focused on is, you know, health and safety aspect of the rule. Again, we don't -- that's what we really focused on. And, again, we came to the conclusion that, again, it would be better served as Category C in that respect. Again, we're very sensitive to the fact that States may have to meet other, again, requirements. Again, it's not --I certainly appreciate the comments about this should be clinically significant, two-tier system. I certainly appreciate that, and those are very good points. Again, what we are very sensitive to is that there is other -- we recognize other statutory requirements in the States that they must meet, so that was part of our basis for the recommendation.

I'm also -- I think it's -- in fact, it's a question that's in there, and public input on that I think will be very good, and very, very helpful just to hear -- get a full airing of this discussion. I think that would be very, very good.

VICE CHAIR THOMADSEN: This is Bruce Thomadsen. May I ask another question of the --

CHAIRMAN MALMUD: Yes, Dr. Thomadsen.

VICE CHAIR THOMADSEN: Are there any other parts of the Part 35 change that may require a state to change its State regulations, its laws?

CHAIRMAN MALMUD: That's a question for anyone on the conference call.

MEMBER BAILEY: That would be very -- this is Darice Bailey, the Agreement States' Rep. That would be very difficult say not knowing all the State laws. An example of what Duncan mentioned regarding State laws that doesn't relate to this at all is Texas has a law that we have licensed medical physicists and that supposedly is a problem with NRC, but it's a law, it's not a rule. So, we have to live with that law. So, there may be similar type situations that make these very difficult. I cannot answer regarding 35 right now in any particular State.

CHAIRMAN MALMUD: Thank you. Are there other comments?

MR. WHITE: Dr. Malmud, this is Duncan White. I'd like to make one more comment about the previous question.

CHAIRMAN MALMUD: Yes.

MR. WHITE: I know there's another State that, for example, requires -- does not allow reporting of specific information about the location of a particular medical event, details about that. Again, it's a State law, so when we do get the reports from this particular state, there's no hospital listed. The entries are not listed because, again, State law prohibits the department there from providing that information.

Again, it's not directly -- it's tangentially related to this rule but, again, it's another example of individual state requirements out there that do -- that they have to adhere to. And, again, we can't ask the states to break their own laws, basically, to do that.

And to answer the question, again, I don't have a specific knowledge of any other areas of regulation that may be in conflict with those state laws. I don't know of anything specifically but, again, we do what we do. Periodically, we do run into some periodically.

CHAIRMAN MALMUD: Thank you. Further comments or discussion?

MEMBER ZANZONICO: This is Pat Zanzonico. I understand and empathize with the requirement of the

NRC not to promulgate rules and regulations that might violate state laws, but isn't that always a possibility? It would seem to make the Cat B Category specification moot because it would seem that any rule promulgated by the NRC conceivably might be counter to a given State's law, so how can -- in any instance, the NRB is sure that that's not the case, unless it's based on a state-by-state review of each and every rule and its compatibility or lack of incompatibility with state laws. And if that's not done it seems to make the Cat B specification almost irrelevant.

CHAIRMAN MALMUD: Dr. Zanzonico's comment is quite insightful. Is there a comment from NRC Staff? The implication is that if any State has a law that it would dictate to NRC what NRC can do and, in fact, could affect the regulations in all the states.

MR. WHITE: This is Duncan White, again. There have been occasions where the NRC Commission has approved rules and regulations which may run counter to existing state laws or state regulations, and they are required -- they will be required to change them. That has happened in the past. Again, the Commission once it votes and approves the final rule with the final Compatibility determination, that's the final determination and we go forward from that. And, again,

pending a petition or some other mechanism to change the rules, the states are to find a way to comply with the Compatibility Category. And if that means changing law, that means changing law.

CHAIRMAN MALMUD: Thank you for clarifying that for us. Other comments? If not, may we move on having covered the subject that Duncan White presented to us?

MR. WHITE: Thank you, Dr. Malmud, for the opportunity talk to the Committee.

CHAIRMAN MALMUD: You're welcome. Thank you for helping to clarify the issue. The issue is not resolved but it is clarified, and we appreciate the clarification.

MEMBER ZANZONICO: Dr. Malmud, this is Pat Zanzonico again. I know there was a sort of a preamble so to speak to the actual teleconference, but would it be appropriate at this point to either have a vote or re-vote on the recommendation with regard to Cat B versus Cat C as it currently appears in our draft report?

CHAIRMAN MALMUD: If someone wishes to make the motion, we can move on it for a vote.

MEMBER ZANZONICO: Well, if I may, I would like to make the motion so that we can move past this

issue on to the subsequent issues.

CHAIRMAN MALMUD: The Chair welcomes your making such a motion.

VICE CHAIR THOMADSEN: And this Bruce Thomadsen. I will second that.

CHAIRMAN MALMUD: There has been a motion moved and seconded. Is the motion clear to those who are on the conference call?

MEMBER LANGHORST: Dr. Malmud, this is Sue Langhorst. No, I don't know what the motion is.

CHAIRMAN MALMUD: Thank you, Dr. Langhorst. We will ask to have the motion repeated.

MEMBER ZANZONICO: This is Pat Zanzonico. I can read it. And the motion is that the ACMUI recommends that the draft rule redefining medical events in permanent implant brachytherapy be designated as Compatibility Category B.

MEMBER LANGHORST: Thank you. This is Sue Langhorst. It's clear now.

CHAIRMAN MALMUD: Thank you, Dr. Zanzonico and Dr. Langhorst. Other -- is there anyone else who requires clarification of the motion? If not, is there a discussion of the motion?

(No response.)

CHAIRMAN MALMUD: Hearing no further

discussion, all those in favor please say aye.

(Chorus of ayes.)

CHAIRMAN MALMUD: Are there any opposed?

MEMBER BAILEY: Yes.

CHAIRMAN MALMUD: Dr. Langhorst, is that you?

MEMBER BAILEY: Darice Bailey.

CHAIRMAN MALMUD: Oh, thank you.

MEMBER BAILEY: Thank you.

CHAIRMAN MALMUD: One opposed. Any abstentions?

MEMBER GUIBERTEAU: Yes, this is Mickey Guiberteau. I abstain.

CHAIRMAN MALMUD: And Dr. Guiberteau abstains; otherwise, the motion carries. So, the motion carries with one abstention and one negative vote. Both from Texas, I assume.

MEMBER GUIBERTEAU: I guess that's right.

CHAIRMAN MALMUD: You truly are the Lone Star State. Thank you, and thank you, again, Duncan White, for your presentation.

That being the case, we'll move on to the agenda, and the agenda belongs to a very hardworking Chairman of the Subcommittee, Dr. Zanzonico.

MEMBER ZANZONICO: Okay, thank you very

much. And I also have to acknowledge all of the time and effort of my fellow Subcommittee members, and other members of the ACMUI. There's been a lot of give and take, and really a lot of thoughtful discussion and exchanges among the members of the Subcommittee and the ACMUI as a whole. And I think we can all be proud of our effort.

We had covered from our draft report, and since last week's teleconference a second draft has been generated based on the teleconference, and based on subsequent exchanges. And the in-progress as I call it second draft was circulated to all the members of the ACMUI and earlier today to the NRC. And we had basically addressed up to this point the first three items in our draft report, the medical event definition for permanent implant brachytherapy, the training and experience requirements for Authorized Users and other authorized professionals, and the extending grandfathering to certain certified individuals per the Ritenour petition.

So, those three issues, as I say, had been addressed and we had votes on the motions and so forth. Unless anyone has a need or desire to revisit those issues, I would move on to the next item in our draft, Item 4, which has to do with measuring molybdenum

contamination in generators. But before I do that, is there any further comment or discussion of any of the first three items?

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

CHAIRMAN MALMUD: Yes, Dr. Langhorst.

MEMBER LANGHORST: I think, Pat, that we were finishing up Item 2D and hadn't gotten to 3 yet.

MEMBER ZANZONICO: Is that correct? Okay, I guess I was too optimistic.

MEMBER LANGHORST: Sorry about that.

MEMBER ZANZONICO: No, thank you for correcting me. And you are right, you are correct. And I should have recollected that from our most recent emails. So, let me return then to Item 2D.

This has to do with the training and experience requirements for different classes of radionuclides or radiopharmaceuticals based on their radiation emissions. And in the proposed rule, it's proposed to include a category for alpha-emitting radiopharmaceuticals as well as beta gamma emitters. And my feeling and the feeling of others, though not necessarily everyone on the Subcommittee as well as the ACMUI was that that was not necessary or desirable, specifically that an Authorized User who has the

requisite training and experience to use beta and gamma emitters therapeutically already has the appropriate training and experience to use alpha emitters, as well. And there was no significant difference in these different kinds of decay properties to warrant this kind of parsing of authorization.

And then there was some -- there's been continued discussion by email among the members of the Subcommittee and the ACMUI, but one analogy that came to mind as I was discussing with some of my fellow Subcommittee members was in the field of medical oncology where medical oncologists are -- many medical oncologists are sub-boarded as I understand in that specialty, and in that case a medical oncologist can and likely would use a wide variety of anti-cancer drugs which have very, very different mechanisms of action, very different organ toxicities and so forth; yet, being qualified to perform chemotherapy-based treatment of cancer, they have the necessary training and experience to do that across all anti-cancer agents. And I think that's actually a fair analogy, a good analogy to using say alpha emitters therapeutically versus gamma beta emitters therapeutically versus auger electron emitters therapeutically. That's not to say they might not need additional training on a specific

radiopharmaceutical but yet they have the basic body of knowledge to be able to integrate a new radiopharmaceutical regardless of its decay properties into their practice, into their management of patients; just as a medical oncologist might require additional training with a new anti-cancer agent, but yet they have the basic underlying training and experience to safely and effectively incorporate that into their practice.

So, on that basis among other considerations I personally -- my personal recommendation would be that this introduction of a new category of Authorized User, in effect, based on alpha emission is really unnecessary, unwarranted, and so forth. And with that, I would open this point up for discussion by the members of the Committee.

CHAIRMAN MALMUD: Thank you, Dr. Zanzonico.

MEMBER WEIL: This is Laura Weil. Can I make a comment related to Dr. Zanzonico's statement?

CHAIRMAN MALMUD: Certainly.

MEMBER WEIL: So, if a purpose of regulation is public protection, I think we can all agree that that is the case. At present it might be sensible to include radium-223 since that's the case in point we're after here with a larger group of radionuclides for

licensing purposes. But I'm posing the possibility that future use of not yet identified alpha-emitting radiopharmaceuticals with characteristics that are very different from radium-223, those other alpha emitters might need different equipment skills and knowledge. And alpha emitters are different enough, they have different radio biology, they have different contamination concerns. They need to be managed differently enough to, I believe, require different authorizations.

And I'm not sure that I agree with Dr. Zanzonico's analogy between chemotherapeutic agents, in general, and radionuclides because there's a difference in worker and public exposure to chemotherapeutic agents than there is to radionuclides in the instances of mishaps, spills, or other kinds of errors, if you will. So, I'm not buying the idea that we should go ahead and just lump everything together into one kind of authorization. I think that for protection and safety purposes, it makes sense to have different categories of emitters.

VICE CHAIR THOMADSEN: Dr. Malmud.

CHAIRMAN MALMUD: Yes, Dr. Thomadsen.

VICE CHAIR THOMADSEN: May I comment on that?

CHAIRMAN MALMUD: Please do.

VICE CHAIR THOMADSEN: If we look at possible alpha emitters we really do not see any isotopes that are going to behave very differently than the radium-223. They just do not exist as possibilities for radiotherapy treatment.

As we look at the current isotopes that are being used in their clinical forms, we see that biologically the colloidal P-32 is very different than intravascular P-32 for polycythemia vera. They just are biologically completely different animals.

If we look at the betas from the P-32 and compare them with the betas from any OJ emitter, biologically they're incredibly different. Their relative biological effectiveness are incredibly different also. As we look at the radioimmune carriers in which we would put any of these radio isotopes and compare their biology with the IVP-32, it's incredibly different.

All the time we're looking at these radiopharmaceuticals, each one is very different and unique in its own right. That's why it exists. That is part of what learning in the residency how to adapt to these types of differences is very important in the training, but looking at the potential for the alpha

emitters that much difference is no greater than the difference between all the existing radionuclides.

CHAIRMAN MALMUD: Thank you, Dr. Thomadsen. Ms. Weil, does that reassure you at all?

MEMBER WEIL: Reassuring is perhaps not the right word. Perhaps I might say then that categorization by class of emitter is less than perfect, but I'm having difficulty with the blanket licensure for all Authorized Users.

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

CHAIRMAN MALMUD: Yes, Dr. Suleiman.

MEMBER SULEIMAN: Okay. Laura, don't feel bad because I've always been conflicted about this. You have to understand that there are two different regulatory authorities or professional groups of responsibility. One is the handling of the radioactive materials, so the general feeling, and I sort of tend more to that, is that as long as the practitioner, the Authorized User understands the radiation safety aspects and knows how to handle these, in terms of the worker, in terms of good practice, it ought to be sufficient. So, I also don't really see a big difference in terms of the different particulates or photons; though, clearly, clearly how these behave in the body,

how their -- the actual chemical, the radio label chemical may behave very different chemically biologically, but in terms of outside the body, that should be more than adequately covered by appropriate vendor training.

Now, getting away from the radiation safety aspect, you've got the whole medical issue. These are specialists, these are physicians trained with this specific drug, for this specific treatment, and that really comes under the medical authority to practice medicine. And we have to trust that the medical community is insuring that these procedures are being used properly, so I -- the NRC can't really cover all of those other issues. Those come under just the ethnical practice of this radio labeled therapy. So, although conflicted because you're always going to have examples of all sorts of things, I think sometimes simplifying, continuing to generate more and more subcategories to me in the bigger picture continues to cause confusion. So, I would be supportive of the proposal.

MEMBER WELSH: This is Dr. Welsh, Jim Welsh, if I might comment, also?

CHAIRMAN MALMUD: Yes, Dr. Welsh.

MEMBER WELSH: So, what I've heard from

Laura, a statement that alpha emitters might have very different biology from auger electron emitters or beta emitters, and this is true. There could be differences in the radio biology. There is no doubt about it. There could be differences in clinical uses or clinical outcomes, as Bruce Thomadsen has pointed out with the P-32 colloidal versus intravenous for different applications. Same radio isotope, very, very different clinical outcome because of a slight difference in the chemical formulation, colloidal versus -- for example. And Dr. Zanzonico has pointed out an analogy with chemotherapy that initially I wasn't so sure about it, but I am board certified as a neural oncologist and do prescribe chemotherapy. And the more I thought about his statement the more apropos I think his assertion is.

Therefore, although there are some differences in biology and differences clinically for different isotopes and different chemical formulations of the same isotope, the overall radiation safety aspects are similar, and the overall radiation safety aspects, which is the question at hand if I understand from Laura are similar enough that the overall training and experience that an Authorized User has received for one should suffice for all, even though we

understand that there are subtle differences in the clinical outcomes and clinical applications, and subtle differences in the biology, sometimes they're not so subtle. But the radiation safety aspects for handling and administering these are while maybe not identical, they are similar enough that the training and education is sufficient.

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

CHAIRMAN MALMUD: Yes, Dr. Langhorst.

MEMBER LANGHORST: I want to remind the Committee that the question at hand has only to do with the work experience that is required. The fact that we're suggesting not splitting between beta gamma, and alpha doesn't mean that an Authorized User physician would not get trained in both. That is going to be much more prevalent as we get more of these alpha-emitting radiopharmaceuticals in use.

So, it is the parenteral administration and that work experience that we're saying let's not add to the confusion of saying okay, you've got three cases of alpha and three cases of beta gamma. If you have three of any combination of those, that is work experience in determining a parenteral administration. And with all the additional training that these

Authorized Users get, that covers the full breadth, as Pat was talking about in regard to medical oncology and chemotherapy.

So, Laura, I wanted to assure you they still get training in all of this, and may get work experience, but we're saying don't split it that fine into those two different categories that then I as a radiation safety officer have to tally up who's got what parenteral administrations, and if they're already an Authorized User do they have to go back and get it? And it just -- that's, I think, an unnecessary bookkeeping requirement that splitting them would impose upon us. Thank you.

CHAIRMAN MALMUD: Thank you. Laura, has the issue been clarified for you to your satisfaction with regard to your concern?

MEMBER WEIL: I certainly am grateful for the clarification of other members of the Committee's comments, but I'm concerned that staff seemed to have a very different perspective about this. And given that there's very little input from Staff in this process, I am -- I don't feel that I'm hearing both sides of the argument.

MEMBER GUIBERTEAU: Dr. Malmud, this is Mickey Guiberteau. May I --

CHAIRMAN MALMUD: Yes. Dr. Guiberteau.

MEMBER GUIBERTEAU: You know, I feel very comfortable, Laura, with the consensus that appears to be developing in terms of the safe handling and administration across a broad spectrum of alpha emitting radio isotopes that there really is little in the way of safety differential in terms of the patient.

One of the things that we're -- from the point of view from which you come in terms of safety for the patient and the consumer, there is also the concern of access to care which we always try to balance with any sort of safety regulation. And the opposite of this would be to divide these into two different categories with different bars, and with different work experience required which most of us feel is unnecessary, which does have the potential for creating a differential in access to care which is also unsafe in many circumstances in terms of denying patients or delaying patients in terms of reaching a therapy that may be better for them.

So, there is a balance here. I do understand your concerns, but I think in terms of access to care and in terms of the radiation safety uniformity pretty much between alpha emitters and gamma emitters

as we know them, that this -- the way this has been stated by the Committee makes a lot of sense.

CHAIRMAN MALMUD: Thank you for your comment, Dr. Guiberteau. Laura, any response?

MEMBER WEIL: I have -- yes, the access issue is something that I have thought about it, and it's -- Mickey, you're right. It's an extremely important aspect to this whole question. I'm willing to stop objecting to this; whether I'll agree to it or not, I really haven't decided.

CHAIRMAN MALMUD: All right, thank you. Further discussion of this issue? If not, I'll turn it back to Dr. Zanzonico.

MEMBER ZANZONICO: Well, thank you all again for some very thoughtful comments, and special thanks to Laura for her thoughts on this.

I really don't have any -- personally any further comments to add other than to reinforce what both Dr. Langhorst and Dr. Guiberteau said; namely, that not including a work experience requirement does not at all mean there will not be additional training. Even when new diagnostic radiopharmaceuticals are introduced or new imaging modalities are introduced, there's often additional -- extensive additional training for the practitioners. And that will certainly

be the case for alpha emitting therapy or any other form of radionuclide therapy.

And the other key point to consider is one of access. And I -- as Dr. Guiberteau was speaking, I think of the case of some of the radionuclide-based bone palliation agents which really, I think, are very effective, very convenient for the patient, et cetera, et cetera; yet, there seems to be some disconnect between the physicians who care for these patients, typically medical oncologists and the nuclear medicine physicians so that these very effective, safe, convenient therapies don't seem to be used nearly as extensively as they could be or should be. And, again, that's at least in part to training and experience requirements. There are other issues, economic and otherwise involved, but I think the issue of wide access to effective and safe therapy is one we need to consider, as well.

Having said all that, I would like to move -- to make a motion that we can vote on that is in our draft report. And I'll read the motion.

The ACMUI recommends that the work experience for parenteral administrations under Sections 35.390 (b)(1)(2)(g), and 35.396 not be separated between parenteral administrations of a beta

gamma emitting radiopharmaceutical versus an alpha emitting radiopharmaceutical as proposed in the proposed rule. So, I would make a motion that we vote on that recommendation.

CHAIRMAN MALMUD: Thank you, Dr. Zanzonico. That is a motion. Is there a second to the motion?

MEMBER GUIBERTEAU: Second.

CHAIRMAN MALMUD: Who seconded, please?

MEMBER GUIBERTEAU: Mickey Guiberteau.

CHAIRMAN MALMUD: Thank you, Dr. Guiberteau. The motion has been moved and seconded. Is there further discussion?

(No response.)

CHAIRMAN MALMUD: Hearing none, all in favor of the motion?

(Chorus of ayes.)

CHAIRMAN MALMUD: Any opposed? Any abstentions?

MEMBER WEIL: Yes, this is Laura Weil. I will abstain.

CHAIRMAN MALMUD: Thank you. So, the motion passes with one abstention. Thank you, Dr. Zanzonico.

MEMBER ZANZONICO: Okay, thank you.

So, lest I skip over another item, and I thank Dr. Langhorst for keeping us on track, the next

item would then be Agenda Item 3. What I would like to do is read the motion as it appears in our draft report and then solicit comments. There may or may not be, so let me read the recommendation.

The ACMUI has recommended and still recommends that the date of recognition of a certifying board should not impact individuals seeking to be named as an Authorized User, Authorized Radiation Safety Officer, Authorized Medical Physicist, or Authorized Nuclear Pharmacist through the certification pathway. So, the essence of that recommendation is that the date of recognition does not -- is irrelevant, in effect. This is in relation to the Ritenour petition and certain other issues, but that's the crux of the recommendation.

I don't know if there's -- if anyone has comments to offer, but I would ask if there are any comments that folks come forward with them.

CHAIRMAN MALMUD: Are there any comments?

MS. BHALLA: Yes. Dr. Malmud, this is Neelam Bhalla. May I speak on this?

CHAIRMAN MALMUD: Absolutely. Thank you.

MS. BHALLA: Yes, the entire Ritenour petition is based on grandfathering an individual. And right now under 35.57 in the regs it starts that any individual who's identified on a license, and that

identification goes back to 2005 time frame, that person need not comply with the training and experience requirements of the current regulations. So, therefore, that date is very important because after that date, after the 2005 revision the boards had to meet certain requirements to meet with the new training and experience requirements.

So, therefore, when the petition came, Ritenour's petition came, the petition was that there were individuals who met the old Subpart J requirements in terms of for the medical physicists and for the RSOs, but they didn't have an opportunity to be named on a specific license for a whole lot of different reasons.

So, when NRC reviewed the petition, agreed with the petitioner that yes, the way the rule got written it did compromise some of those people who were boarded, who met our Subpart J requirements, but just because they were not named on a license as of that date they now had to meet the new requirements.

So, therefore, when we have now amended this rule to take care of all those individuals and to recognize their board certifications as of the old Subpart J, we need to leave that date. It's very important. Otherwise, if there is no date, then the people who are meeting the new boards, they're already

-- they would be -- they would not need this -- they would not fall into the old Subpart J. So, therefore, the 2005 date is crucial, and we would keep it.

MR. LOHR: And I have a clarification question, and I believe this is what's being discussed.

CHAIRMAN MALMUD: Identify yourself.

MR. LOHR: I'm sorry, this is Ed Lohr. I believe what's being identified is the individuals who are boarded after 2005, but before the NRC has recognized that board. I believe the comment was made that all boards regardless of when should be recognized. And the Ritenour petition did not address that, as Neelam has been saying. It addressed those prior to 2005 when the NRC was recognizing those boards. But there is a so called gap, if you will, between the time from 2005 until the boards were recognized under the new process. And I believe that's what has been brought up by Dr. Zanzonico, but I didn't want to put words in his mouth. I just want to make sure that's what he's talking about.

MEMBER ZANZONICO: This is Pat Zanzonico. That's basically it. There does seem to be a gap here that's problematic, or potentially problematic.

CHAIRMAN MALMUD: Dr. Zanzonico, is that what you were addressing?

MEMBER ZANZONICO: Yes.

CHAIRMAN MALMUD: Thank you.

MEMBER ZANZONICO: This is Pat Zanzonico again. I guess my question is, and I apologize for being dense on this point. I still don't quite understand what the problem would be with the ACMUI recommendation as I verbalized it. In other words, making the date of recognition of a board by the NRC irrelevant. I don't -- I still don't quite understand what regulatory issue that would introduce.

CHAIRMAN MALMUD: Neelam, could you address that?

MS. BHALLA: Sure. What we are amending is 35.57 in the regs; 35.57 starts with people who are ----- okay. It starts with an individual identified as a Radiation Safety Officer, teletherapy physicist and so on, and then they need not comply with the training requirement. So, there's a very specific date in there. And legally that's the part we are amending. We are amending 35.57 and we cannot in there go back to -- we can only go back to 2005, and maybe Susan, our legal person, can explain that better.

MS. CHIDAKEL: Let me try to explain what we're tried to do here. Okay? The date 2005 --

CHAIRMAN MALMUD: Excuse me, this is Dr.

Malmud. Would you please identify yourself for the Committee.

MS. CHIDAKEL: I'm sorry. This is Susan Chidakel from the Office of General Counsel.

CHAIRMAN MALMUD: Thank you.

MS. CHIDAKEL: And I don't think that -- I think there's a disconnect in what you're seeing in this rule. I don't think your concern is in the -- what's in the rule is not going to -- your concern doesn't connect with this.

What we're trying to, as Neelam said, okay, we had a new rule in 2005 in which Subpart J expired. This impacted people who had been certified by the boards listed under Subpart J.

What we're trying to do is say all those people who were recognized by boards before the new rule came into effect, whether or not they're listed in a license, they're now -- their certification is good. They're now -- you know, they don't need any more education, or any more recertification, or anything of that sort.

The reason the date is in there is because in 2005, those boards were no longer recognized, so we want to make clear that after 2005, you know, these new individuals coming in are going to have to have

certification by the boards that are now being recognized under the new rule. Am I making sense? Am I making this clear to you? So, it's not impacting -- I guess I don't see the problem. I read your recommendation several dates that the date of recognition should not impact individuals seeking to be named. I don't see where the date of recognition of a board has anything to do with what we're doing here in this new rule. We don't say anything about the date of recognition of a board.

What we're saying is, we're saying any boards that were in existence that have certified people as of the date that Subpart J expired, these people are now recognized, you know, the same as anybody else whether or not they're on a license. So, I don't quite understand the gist of your concern, and I'm wondering if I have alleviated your concern in any way, or made this more clear.

CHAIRMAN MALMUD: I think you have clarified it. What do other members of the Committee feel?

MEMBER ZANZONICO: This is Pat Zanzonico. I think you've clarified it, as well. My concern -- and, again, I think you clarified it, was that individuals who might have been board certified -- whose board may

-- who may be certified by a board which was recognized after this date somehow fell through the cracks. But you're assuring me that's not the case.

MS. CHIDAKEL: No. The whole idea is to -- using 2005 is the point where the new rule came into effect and we had boards now that had to come in for certification. Donna-Beth, did you want to add something?

DR. HOWE: Yes, this is Dr. Howe. When we changed the rule in 2005, all the boards had to come in to be recognized. And there were new criteria for them to be recognized. Not all of the boards met the new criteria on the date that the rule came into effect and many boards -- I won't say many, but a number of boards had to change their program so they could comply with the new criteria for recognizing the board. And that may have taken a year, two years, or longer, so there are boards that were continuing to issue certificates but they did not meet the NRC requirements 2005 until the date that they're recognized on our website, which was -- an individual date was negotiated for each board.

So, in some cases for the nuclear pharmacy board, it's totally moot. We recognize the nuclear pharmacy board from almost day one. There was no gap.

For other boards like nuclear medicine they had diplomates that didn't receive training under Authorized Users, and our regulation said we could only recognize those that had training under Authorized Users, so there became a distinction between different board certifications whether they were in the U.S., or outside of the U.S. So, we have specific certificates that are recognized because the process that goes with those certificates are recognized by NRC.

MS. CHIDAKEL: But the point is that even if the -- you know, no matter what happened with the boards and whether they were recognized in 2005 or not, if individuals were certified by those boards before 2005, they can continue to practice. They don't need additional education. This is what we're trying to do. We're trying to -- that's what we're trying to fix.

This issue that Donna-Beth is raising, that was a board problem, but if an individual had been recognized when the new rule came into effect, they're good.

MEMBER ZANZONICO: This is Pat Zanzonico. That still raises an issue because after the date of expiration of Subpart J, if an individual was certified by a board after that date but that board was not recognized until subsequently because its training and

experience requirements were deemed inadequate by the NRC, what happens to that individual who was board certified after the expiration date of Subpart J, but before the recognition of that board by the NRC?

DR. HOWE: There's not a clear -- this is Dr. Howe. There's not a clear answer to that, because in some cases the boards recognized that they had maybe one or two years in which their board certificates were not recognized, and they went back. But they believed that their candidates did meet the criteria. It's just their processes didn't state exactly what we needed, so they went back and picked up the few individuals that weren't Authorized Users. Mainly, this is for the medical board, and picked up the Authorized Users that weren't listed yet, and had a process where they could reissue a certificate that had the boards we were looking for in them so that we could recognize them back to an earlier date. And that's specified in our website.

There are a number of other boards that did not do that, and did not want to go back, so they are recognized from a specific date forward. I think the Health Physics Board is an example where they're recognized at a certain date that's not 2005 because they did not want to go back and verify the training

and experience met our criteria even though their criteria was much broader than ours. Individual members could meet our criteria, but the board itself didn't until a certain date.

MR. LOHR: This is Ed Lohr again. I believe to answer the question a little more bluntly is those people in the gap are still required to come through alternate pathways, and we do not at the NRC recognize that board certification.

MEMBER ZANZONICO: I guess -- I mean, that really puts a point on it, and I think really is the essence or the motivation for this rationale. I mean, frankly, that strikes me as not right. You know, an individual met training and experience requirements for professional board certification, and a board that was recognized by the NRC. And they're effectively being told that, you know, because of an accident in time of when they were certified, that their certification is not acceptable.

Practices change, training and experience requirements change, and so forth. It seems unfair to those individuals to penalize them on that basis when they had met the prevailing training and experience requirements at the time they were certified.

DR. HOWE: Dr. Zanzonico, this is Dr. Howe.

For the most part what you're saying is true, but you cannot make that assumption across the board, because we did have a number of boards that were nowhere near meeting the recognition criteria. And they had to totally restructure. They weren't necessarily giving examinations to test people, they didn't have criteria for people to be board certified that came anywhere close to what was being recognized afterwards, so there is no clear cut date that you can say everybody is covered, because we did have a few boards that just were totally inadequate in criteria.

MS. BHALLA: Dr. Malmud, this is Neelam Bhalla. May I speak?

CHAIRMAN MALMUD: Please do.

MS. BHALLA: Yes. So, for the purposes of this rulemaking, the NRC Staff when we resolved this petition, Ritenour's petition, we have -- we are obligated to -- we are under, I suppose, as a condition of that petition resolution, that we need to amend our regulation in 35.57. And that relates to strictly people who got boarded under the old Subpart J; so, therefore, so far as the Ritenour petition goes and amending 35.57, according to that, that's what we have done. And anything beyond about this added issue about -- this is beyond the scope of the Ritenour petition.

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

CHAIRMAN MALMUD: Yes, Dr. Langhorst.

MEMBER LANGHORST: I think the Committee voiced its opinion in September and probably a couple of different times that we don't think that people who are board certified just by the fact of their having been certified a year after this October 2005, and their board wasn't through, it just does not seem fair that a person who was board certified right before that date can meet this criteria, but the person just a year after potentially could not meet that criteria that is in 35.57.

As the Part 35 rules have changed, Section 35.57 has gotten more and more complex. And let me tell you, as an RSO it confuses me to no end, so I think we all are in agreement that we would like to kind of start with a clean slate so that board certified individuals have an opportunity to practice their profession, and I -- from a personal point of view, I hope that NRC takes this opportunity to try to simplify 35.57 as much as possible, because it's just near impossible to understand. So, thank you very much.

CHAIRMAN MALMUD: Thank you. This issue has come up repetitively, and I think we all understand

why the interpretation was given to it by the NRC, but I think the vast majority of us don't agree with it. Is that a fair statement?

(Chorus of yeses.)

CHAIRMAN MALMUD: So, we are asking the NRC to recognize that we do not feel that the solution that was arrived at, though logical, is practical, and we are concerned that it will interfere with the practice of the specialties involved. And, therefore, we would encourage the NRC to attempt to resolve this for us in some regulatory fashion that would not exclude people from practicing who we feel by virtue of their training are qualified despite the fact that their boards may not have responded to the NRC's repeated requests to meet those standards at that time; that this is a deficiency in documentation rather than a deficiency that's been demonstrated to be in practice. It's a deficiency in documentation, and perhaps some exception can be worked out so this can be resolved, because we're concerned about the availability of these people to practice their specialties on behalf of patient care.

MEMBER ZANZONICO: Dr. Malmud, this is Pat Zanzonico. I would just like to append your statement with the fact that we concede this is a separate but perhaps related issue from the Ritenour petition and

is outside the scope of the NRC's response to that petition, but we think it warrants some remediation, nonetheless.

CHAIRMAN MALMUD: Thank you, and that's what we're requesting of the NRC Staff and its legal consultants. We're seeking a practical solution to a practical problem that will affect some practitioners in a way which we feel is not in the best interest of the end product which is patient care. May we move on, because we're not going to resolve that particular element of this discussion this conference call.

MEMBER ZANZONICO: Understood. I guess my question is, and this is really for members of the ACMUI, should we -- do we feel we want to vote and include -- vote on and include this recommendation in our report or not in light of the NRC staff's explanations and clarifications?

CHAIRMAN MALMUD: Well, I think that the --from the voices that I heard on the phone, the vast majority agrees with your position, Dr. Zanzonico.

MEMBER ZANZONICO: Okay.

CHAIRMAN MALMUD: And I think that the -- we recognize the nature of why the decision -- recommendation was made by the NRC. They are driven by the law, and the law must be adhered to. At the same

time, it's an impractical solution given the fact that there's a cutoff date which had to do with the law, but would interfere with individuals who are competent to do what they had been doing, but whose boards for a variety of reasons which are difficult to understand, did not meet the NRC request for documentation at that time. So, all we can say is that we favor a generous solution to the existing problem. It's not a larger problem as 11 million undocumented aliens and, therefore, we feel that solution might be able to be worked out given some effort, additional effort by the NRC staff and legal department in working with perhaps even the Commissioners themselves to resolve a very practical issue which doesn't affect an enormous number of people, but could cause some individuals some embarrassment. And, therefore, you can put your motion forward, Dr. Zanzonico.

MEMBER ZANZONICO: Okay. Then I'll make the motion that we adopt the following recommendation; that is, that the date of recognition of a recognized -- the date of recognition of a certifying board should not impact individuals being named as authorized professionals, AUs, Authorized RSOs, et cetera, so that is the motion.

CHAIRMAN MALMUD: That is the motion. Is

there a second to that motion? I don't hear a second.

VICE CHAIR THOMADSEN: This is Bruce Thomadsen.

CHAIRMAN MALMUD: Dr. Thomadsen. You seconded it?

VICE CHAIR THOMADSEN: Yes.

CHAIRMAN MALMUD: Thank you. Is there further discussion?

(No response.)

CHAIRMAN MALMUD: We recognize that we are making a recommendation as a consulting body, and that it may -- a portion of it may be not approved, but we want the spirit of the recommendation to be clearly transmitted to the interested parties in the best interest of maintaining the ability of individuals to practice on behalf of the public. So, all in favor of the motion?

(Chorus of ayes.)

CHAIRMAN MALMUD: Any opposed? I hear no opposition. Any abstentions?

(No response.)

CHAIRMAN MALMUD: So, the motion is passed unanimously which should assist in addressing the importance of the issue including that element of it to the bodies that we consult for within the NRC.

Dr. Zanzonico, any other items?

MEMBER ZANZONICO: Yes, there are. So, we want to move on to Item 4 in our report, and this has to do with the measuring moly breakthrough, and reporting of failed breakthrough tests. And to expedite matters on this point, there -- I think we are all in agreement, we on the ACMUI are all in agreement with the provisions of the proposed rule requiring testing of moly breakthrough on every elution of a moly-tech generator rather than after only the first elution.

There are two contentious issues, though, which have arisen in the course of our last teleconference and subsequent emails. The first of these is related to the reporting of out-of-tolerance breakthrough results.

The proposed NRC rule, as I understand it, is requiring a reporting to the -- by the user, by the licensee requiring reporting of out-of-tolerance elution results, breakthrough results to the NRC, and to the manufacturer.

The two options are reporting the results only to the manufacturer and leaving it to the manufacturer to report these results to the NRC. And the second option would be to recommend the proposed NRC rule requiring dual reporting. That's the first

issue.

The second issue is related to generators not included in the covered proposed rule, and there was concern among the ACMUI members that -- about generators that might be introduced in the near future like germanium/gallium generators and what to do with those in terms of breakthrough testing. And one possibility would be to the -- for the NRC to generalize its rule to address future generator systems, and the alternative would be that the NRC by regulation adopt the FDA label instructions, the package insert for generator QC procedures. And the rationale for that latter approach would be that it would not require revision of NRC rules as each new generator system is introduced.

So, those are the two issues. And I guess we should take them one at a time; the first one being reporting of out-of-tolerance results. If there's any discussion or comment on reporting requirements to both the NRC and the manufacturer versus the manufacturer only. So, at this point I would solicit comments from the Committee on that point.

MEMBER VAN DECKER: Dr. Malmud.

CHAIRMAN MALMUD: Yes, thank you.

MEMBER VAN DECKER: This is Bill Van Decker.

Can I speak to that first?

CHAIRMAN MALMUD: Yes, Dr. Van Decker.

MEMBER VAN DECKER: I think that the Subcommittee did a fairly thoughtful go-around on your first draft here. I would say I would tend to personally agree with that draft. I don't think that anyone disagrees with the fact that generators are important items in the process of delivering dose to a patient, and we have to have a great QMP program for each generator, and a good QC program, but we also have to recognize that breakthrough unto itself is not a medical event, although it certainly can lead to the opportunity to have one, and is something that's going to take some investigation and some look into things before it really gets settled out.

In a busy clinical world where people are trying to give access to care at the same time, you know, a call to a manufacturer who's helping in the piece of the troubleshooting, and then he's kind of mandated to take that to the NRC in a more streamlined manner than licensee having to make multiple reports in multiple places with multiple time lines, just adds a lot of complexity to the overall situation.

I don't think we all disagree with the concept of everyone in the current era with current

histories and everything else wants to be as sure as possible. And I think the practicing community wants that to be true, as well, but we think that reporting to -- or I think a lot of people feel that reporting to a manufacturer as an initial step, and at least at that point having made sure that you've done your QC, your QMP correctly, and do some troubleshooting from there is a very reasonable process indicator for where you need to be, and not a medical event unto itself. And that would kind of be my concept of this, and I'm happy to hear from others.

CHAIRMAN MALMUD: Dr. Van Decker is seeking other opinions.

MEMBER PALESTRO: Dr. Malmud.

CHAIRMAN MALMUD: Yes, sir.

MEMBER PALESTRO: Chris Palestro. I disagree a bit with Dr. Van Decker. I don't have any experience with rubidium generator but certainly have had 30 years of experience with the molybdenum-technetium generator because that's all we've ever used. We don't use the unit doses. And I have to -- cannot recall a single incident of molybdenum breakthrough in any of the generators that we use at the various locations that I've been over the course of my career. So, while the reporting may be a bit

cumbersome and time consuming, it's something that I think happens so infrequently that that shouldn't be governing whether or not we want dual reporting.

My concern with the manufacturer, quite frankly, is I'm not a big fan of manufacturers. They have other items on their agenda, and I think that dual reporting is better than going through the manufacturer.

MEMBER SULEIMAN: Dr. Malmud, Orhan Suleiman.

CHAIRMAN MALMUD: Yes, I was just about to thank him for his opinion. And, Dr. Suleiman, your opinion is welcome.

MEMBER SULEIMAN: Okay. This is basically from real life experience. Breakthrough does not occur very often, but it does occur, and there was a case a few years ago where a user was getting breakthrough and reporting it to the manufacturer. And this kept on going on, and the generator -- he was getting a generator replaced. Eventually he got fed up because he -- this was a recurring problem and it was something he hadn't experienced before. So, he reported it to the NRC, who shared that information with us.

It took a while for the investigation to follow but there was a manufacturing issue underlying

the problem. It doesn't happen often, but in terms of trends if you get maybe a bad batch of molybdenum or a bad batch of the column, the chemical that makes the column, you may start to see breakthrough across multiple sites, and everyone will say well, it's just one thing, I'm not going to bother. But if there's -- it's sort of an early warning thing. And I don't think anybody I've spoken to thinks that it would be burdensome to just -- I wouldn't expect that the NRC reporting requirement would be massive in terms of paperwork, but that's sort of saying, you know, we picked up the moly. And it's also a system of checks and balances.

When you rely solely on the manufacturer and a lot of manufacturers are good, and professional, and we learn a lot from their expertise, but there's also always the temptation of conflict of interest. So, they may want to solve the problem before they -- you know, let's take care of this. This is not a really serious problem. And by the time they come to the conclusion that maybe it is a more serious problem, it may have proliferated. So, I think it's a very prudent and simple requirement.

CHAIRMAN MALMUD: Thank you, Dr. Suleiman. We've heard from two members of the Committee both of

whom are supportive of the dual reporting line, both the manufacturer and the NRC. Are there any voices in support of that, as well, or who oppose that?

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

CHAIRMAN MALMUD: Yes, Steve.

MEMBER MATTMULLER: And I do have a few comments in regards to this. I believe the justification for the proposed reporting requirements have misidentified past incidents as radiation safety incidents but, in fact, they are a product quality issue.

The breakthrough test in question is a radiopharmaceutical product quality control test. The testing procedure is clear. The licensee is to perform the measurement for breakthrough before the product is used. If the product passes the measurement, then it may be used for patients. If the product fails the measurement then it may not be used for patients.

The discussion within the proposed rule misses this fact, I think, from past incidents; that is, when pharmacists found breakthrough limits that were exceeded in their technetium-99m elutions, they discarded the elution, patients were not injected. If a product fails this measurement it's a product quality

issue that is best solved by the licensee contacting the manufacturer.

If a licensee has a generator that fails breakthrough testing they are, in essence, out of business. If they want to return to business, they have to call the manufacturer because only the manufacturer can supply a replacement generator for the defective generator. And believe me, this is a strong incentive for a licensee to contact a manufacturer.

For well over a decade it's been standard practice for any licensee who uses a generator to also use the computer system such as biodose or NMIS, or their own in-house system such as ones developed by Triad and Cardinal.

An important component of these computer systems is the calculations that are automatically performed for moly-99 breakthrough testing. As one assays the technetium-99m and the moly content of an elution, this information is entered into the program and it automatically calculates the ratio of technetium to moly.

If it passes, it's good to go. If it doesn't pass, it can't be used for making -- for kits or for being used to dispense for doses. In fact, some pharmacies now are even going one step further and

they're printing the moly-99 content on the individual technetium-99m unit dose labels.

The same steps apply to the strontium-82, rubidium-82 generator except that instead of an in-house computer system the assay results of the elution are now entered into an online system monitored by Bracco. If an elution with substandard product quality is disposed of and not administered to patients, how would the NRC ever see a report of a radiation safety issue in a patient?

In other words, if a licensee is following the regulations and performing a breakthrough test, the NRC will only see reports regarding product qualities or issue regarding product quality.

So, I would say the NRC responsibility is patient safety. The best way to insure patient safety is that a safe product is being used. The best response from the NRC should be to do the breakthrough testing according to FDA product labeling.

I'd also like to make a few additional comments on the rationale listed in the proposed regulations as justifications for the new reporting requirements. One of the first --

CHAIRMAN MALMUD: Steve?

MEMBER MATTMULLER: Yes?

CHAIRMAN MALMUD: I just want to interrupt you for a moment, and that is, therefore, you are arguing against the dual reporting line.

MEMBER MATTMULLER: Yes, I am.

CHAIRMAN MALMUD: Thank you. I just wanted to clarify that. Now, please go ahead.

MEMBER MATTMULLER: Not a problem. The first justification was that the FDA may not investigate each reported incident and may take a considerable amount of time in investigating the cause of reported failures. This is probably an accurate description of past FDA actions, but without knowing the specifics of each event, this is probably an entire appropriate action by the FDA.

According to FDA current good manufacturing practices, if a manufacturer gets a product complaint, there are several standard operating procedures in place that they must follow. One of these standard operating procedures is that the manufacturer will start an investigation as to the cause of the problem, and the result of the investigation and any proposed modifications to the manufacturing process, and any validation studies of these modifications will all be available for FDA review.

Even though the FDA may not have its

inspectors in the manufacturer's facility at the time, in a very big way an inspection is being conducted in a manner approved by the FDA. Think of these standard operating procedures as representative of its in-house FDA office within the manufacturing site in that these SOPs, or standard operating procedures are all FDA approved and they direct the actions of the manufacturer in these and all other situations.

I'll skip to the third and come back to the second. The third statement was, additionally, some incidents of failed generators may not be reported to the FDA because certain manufacturers are not in the United States. And the generators are distributed by vendors who are not required to report to the FDA.

Whether or not a company's headquarters or its manufacturing site is inside or outside of the United States is misleading. If a product is used in the United States, it will have FDA approval. Its application for this drug, its standard operating procedures, its manufacturing site will all be reviewed, inspected, and approved by the FDA before the product comes to market.

If a licensee's generator is not performing well and that licensee can't use it for their patients, they will contact the manufacturer, as only

the manufacturer can send them a replacement generator.

There was also a statement about how the generators are distributed by vendors who are not required to report to the FDA. I'm not clear to the intent of this because to my knowledge the vast majority of generators are sold direct to the licensee by the manufacturer; 95 percent of all technetium generators are sold direct to commercial nuclear pharmacies. The other 5 percent are sold direct to large medical institutions such as Massachusetts General or Sloan-Kettering. All the rubidium-82 generators are sold direct by Bracco.

If there is a unique example of a vendor distributing a generator that would represent a very small percentage of all generators, it would be doubtful this small number could justify a regulatory action. Plus, in a sense it doesn't matter. A failed generator is a failed generator. Even if a vendor is involved, the licensee is out of business. If a vendor is contacted by the licensee that they have a failed generator, the vendor has to contact the manufacturer to arrange for a replacement generator for the licensee.

In regards to the second statement, the NRC believes that requiring each incident of a failed generator to be reported would provide the NRC the

opportunity to evaluate and take prompt action, as needed.

Again, these are not radiation safety issues; these are drug quality issues, clearly in the realm and expertise of the FDA. The generator's manufacturer radioactive materials license is for the safe use of radioactive material within their manufacturing facility. This license is concerned with items such as radiation exposure to the employees, proper security of the radioactive material, and proper disposal of radioactive waste. These are all areas of the NRC's expertise and regulatory charge.

A manufacturer's radioactive material license, though, from the NRC should not be used as a pathway to investigate a manufacturer's manufacturing procedures. These procedures are clearly the expertise of the FDA.

To allow the NRC a pathway to investigate manufacturer's procedures would be akin to allowing the FDA to investigate operating procedures at a nuclear power plant. It would be inappropriate.

But even if these reports are allowed, any subsequent investigation by the NRC will have a very unequal effect on the various generator manufacturers. One has to remember that the NRC's regulations are

enforced by 37 Agreement States in the U.S. And just as the NRC really does not have the appropriate staff, such as a chemical engineer or a radiochemist with FDA manufacturing experience, neither do the respective Agreement State Radiation Protection Programs.

As a reminder, the Covidien manufacturing sites in St. Louis, Missouri, the Lantheus manufacturing sites in Boston, Massachusetts, and one of the manufacturing sites for the Bracco rubidium generator is in Ottawa, Canada.

There are a couple of scenarios to consider for this. The first one would be breakthrough is found in a licensee in Missouri from a Covidien generator that was manufactured in Missouri. The licensee sends a report to the NRC. If the NRC decides an inspection is needed, they can inspect right away.

In scenario two, breakthrough to be found by a licensee in Ohio from a Lantheus generator that was manufactured in Massachusetts. The licensee sends a report to the Ohio Bureau of Radiation Protection. The Ohio Bureau sends a report to the NRC. If the NRC decides an inspection is needed, they have to suggest this to the Massachusetts Radiation Control Program. Does the Massachusetts program have to act? And, if so, to what extent? So, as demonstrated in the recent

rubidium-82 generator incident, the NRC only had an advisory role as the manufacturing site was in New Jersey.

And the third scenario, breakthrough is found by a licensee from a Bracco generator that was manufactured in Canada. The licensee sends the report to the NRC. If the NRC decides an inspection is needed, they can't because they have no authority in Canada.

Actually, the third justification listed regarding manufacturers outside of the U.S. is not a problem for the FDA, but it is a problem for the NRC. And can an agency legally promulgate a regulation when they know that any subsequent regulatory action will be unequally applied? So, clearly the NRC should leave the manufacturer of radiopharmaceuticals to the FDA.

In all three examples above, the FDA can inspect the manufacturing facilities regardless of state or international borders. There should not be any additional reporting requirement.

This is the same recommendation from the participants in the two workshops held by the NRC on this proposed regulation. The NRC should continue to emphasize adherence and expect the 35.204 but there should be no additional reporting requirements. Thank you.

CHAIRMAN MALMUD: Thank you, Steve. Any further comments? We've now heard both sides, those in favor of dual reporting, and those in favor of reporting only to the FDA. Any further discussion?

(No response.)

CHAIRMAN MALMUD: Pat.

MEMBER ZANZONICO: Yes, shall we make a motion?

CHAIRMAN MALMUD: Please do.

MEMBER ZANZONICO: Then the motion I would propose, even though it's not explicitly included in our draft report but I think it's worth making is -- the motion would be that the ACMUI endorses the provision in the proposed rule for reporting of out-of-tolerance moly breakthrough results to the NRC. So, that would be an up or down vote, that the ACMUI either endorses or does not endorse that provision.

MEMBER MATTMULLER: Dr. Malmud, this is Steve Mattmuller again. Pat, could you read that a little bit slow --

MEMBER ZANZONICO: Yes.

MEMBER MATTMULLER: Technetium generators but all generators.

MEMBER ZANZONICO: Certainly, we can vote on that point, and I understand the rationale. So, the

-- we're voting on a motion to recommend reporting of out-of-tolerance breakthrough results, generator breakthrough results to the NRC. So, again, it's and up or down vote, we're recommending reporting of such results to the NRC, or recommend -- or not reporting such results to the NRC.

CHAIRMAN MALMUD: But, Dr. Zanzonico, your motion is that it be reported.

MEMBER ZANZONICO: Correct.

CHAIRMAN MALMUD: That is an up or down vote.

MEMBER ZANZONICO: Correct. Correct, that's the motion.

CHAIRMAN MALMUD: Is there a second to that motion?

MEMBER WEIL: This is Laura Weil, I'll second.

CHAIRMAN MALMUD: Laura Weil seconds the motion. So, the motion has been moved and seconded that the breakthrough be reported to the NRC.

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

CHAIRMAN MALMUD: Yes, Dr. Langhorst.

MEMBER LANGHORST: I'd like that motion clarified that notification to NRC, you're talking

about the licensee who is using the generator.

MEMBER ZANZONICO: Correct. Correct. This is a reporting requirement for the licensee.

MEMBER LANGHORST: Thank you.

CHAIRMAN MALMUD: Thank you for that clarification, Dr. Langhorst and Dr. Zanzonico. So, the motion is that the licensee report this to the NRC. All in favor of the motion?

(Chorus of ayes.)

CHAIRMAN MALMUD: Any opposed to the motion?

(Chorus of ayes.)

CHAIRMAN MALMUD: We'll have to take a vote then, and we'll have to do this by each individual identifying himself or herself. So, those in favor of the motion are, number one, Dr. Zanzonico.

MEMBER ZANZONICO: In favor, yes.

CHAIRMAN MALMUD: Number two, who seconded the motion?

MEMBER WEIL: Laura Weil.

CHAIRMAN MALMUD: Laura Weil, number two. Number three in favor?

MEMBER PALESTRO: Chris Palestro.

CHAIRMAN MALMUD: Dr. Palestro. Number four?

MEMBER SULEIMAN: Orhan Suleiman.

CHAIRMAN MALMUD: Dr. Suleiman. Number five?

VICE CHAIR THOMADSEN: Bruce Thomadsen.

CHAIRMAN MALMUD: Dr. Thomadsen. Six? Is there a sixth?

(No response.)

CHAIRMAN MALMUD: I do not hear a sixth. Those opposed to the motion? Number one? Steve?

MEMBER MATTMULLER: Steve, yes.

CHAIRMAN MALMUD: Number two?

MEMBER LANGHORST: This is Sue Langhorst. I'm opposed.

CHAIRMAN MALMUD: Dr. Langhorst. Number three?

MEMBER BAILEY: Darice Bailey.

CHAIRMAN MALMUD: Thank you. Number four?

MEMBER VAN DECKER: Van Decker.

CHAIRMAN MALMUD: Dr. Van Decker. Number five?

MEMBER WELSH: Jim Welsh.

CHAIRMAN MALMUD: Dr. Welsh. Six?

MEMBER SUH: John Suh.

CHAIRMAN MALMUD: Dr. Suh. Seven?

MEMBER GUIBERTEAU: Mickey Guiberteau.

CHAIRMAN MALMUD: Dr. Guiberteau. Eight? So, the motion fails by a vote of 7-5. The Chair has not voted. Thank you.

Now, Dr. Zanzonico, you have another motion, do you not?

MEMBER ZANZONICO: Yes, well another issue I think that warrants discussion on the generator issue. And it's not unrelated. And this has to do with future generators. And the issue is whether the ACMUI should recommend that the NRC adopt FDA label instructions for QC procedures for radioisotope generators.

The first -- one alternative would be no, that the NRC promulgates its own required QC procedures. And, obviously, the other alternative would be that yes, the NRC adopt the FDA label instructions. And, again, the advantage of the latter to my way of viewing is that as new generators become marketed products there will be built-in QC procedures as part of the package insert. So, it wouldn't require a revised rulemaking by the NRC to incorporate these new generators into its regulatory oversight, the scope of its regulatory oversight. So, that is an issue open for discussion, and I would invite comments from the Committee.

CHAIRMAN MALMUD: Thank you, Dr. Zanzonico. Are there comments?

MEMBER BAILEY: Yes, this is Darice Bailey.

CHAIRMAN MALMUD: Yes.

MEMBER BAILEY: I would like to clarify from a regulatory standpoint whether you're saying that NRC should, or the Agreement States, whatever, should adopt FDA's label or if through rule or license conditions require the licensee -- that the licensee follows the package insert, which is different things.

MEMBER ZANZONICO: Yes. This is Pat Zanzonico. I would -- it's a subtle but I understand important distinction, and to my way of thinking, I would personally recommend the latter.

MEMBER BAILEY: I would, too.

MEMBER ZANZONICO: Yes.

CHAIRMAN MALMUD: Thank you for clarifying that. Other comments?

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

CHAIRMAN MALMUD: Dr. Suleiman.

MEMBER SULEIMAN: I want to clarify that it's not accepting an FDA approved label. This is the manufacturer's operating instructions. This whole thing is put together by the manufacturer, though we eventually approve it, so it's not like our version versus theirs. And a point of distinction, though I

don't know different people interpret it differently, I think what we were focusing on was the breakthrough limit as specified in the label. Obviously, how they do breakthrough is important and should be following the manufacturer's instructions.

A third point is that recently, for example, the strontium-rubidium generator, the manufacturer decided to lower the breakthrough limit, so the NRC through rulemaking has etched in the regulations a limit that the company has now changed. So, this would give the NRC a little bit more flexibility in that they could say, you know, the limit is what the label specifies, so if you get a new generator where maybe the impurities are even less, they want to change the limit, you get a different type of generator, you have a completely different, you know, specified amount of radionuclide per breakthrough. That would all be taken care of very easily, and that way it would also allow for making changes in manufacturing.

CHAIRMAN MALMUD: Thank you, Dr. Suleiman. So, you're speaking in favor of the NRC asking that the manufacturer's label, which is eventually approved by the FDA, be the guideline.

MEMBER SULEIMAN: Be the regulation.

CHAIRMAN MALMUD: Be the regulation. Did

I interpret that correctly?

MEMBER SULEIMAN: And, in fact, they've always done that with the label, but then manufacturers may change the requirement, and the NRC is stuck holding a regulation that's outdated that then has to go through rulemaking to change.

CHAIRMAN MALMUD: When the manufacturer changes the label doesn't that require FDA approval?

MEMBER SULEIMAN: Oh, yes. Oh, yes. In other words, for a manufacturer to change the label they file what is known as a supplement.

CHAIRMAN MALMUD: Yes.

MEMBER SULEIMAN: And they say we want to make these changes. You know, we've learned some new things, we want to -- for a multitude of reasons. And when the new label comes out it basically replaces the old label.

CHAIRMAN MALMUD: Yes, I understand. So, that really simplifies it for the end user by having one standard to adhere to.

MEMBER SULEIMAN: That's how I see it.

CHAIRMAN MALMUD: Thank you.

MEMBER GUIBERTEAU: Dr. Malmud, this is Mickey Guiberteau. Could I ask a question, please?

CHAIRMAN MALMUD: Of course, Dr.

Guiberteau.

MEMBER GUIBERTEAU: This is sort of a curious circumstance, but in terms of the FDA labeling and requirements for a generator, as well as putting some limits on the -- approving the limits of the manufacturer on the moly breakthrough, let's say in the instance of a molybdenum-99, technetium-99 generator. If -- what are the implications for off-label use in the sense of medical necessity if there is not an absolute limit within say the NRC regulations?

And just by way of example, if I were to elute a generator and I had exceeded the 0.15 microcuries per millicurie, but felt that I had an emergency procedure that needed to be performed, and I used this anyway. Would that be something that would be defensible?

MEMBER SULEIMAN: I think that would -- Dr. Malmud, Orhan Suleiman again. I think that's a perfect example of justified practice of medicine issue. You know, you may have an emergency. This may be the only generator available, this may be the only test that would give you relevant efficacious information, and you exercise your authority as a practitioner of medicine. And I would not see any problem with that at all. Our oncologists, I talk to them all the time,

and I said so you can change your dose? I said, you know, in terms of chemo or whatever or change the protocols, he says oh, yes, that's -- we can do that under our practice of medicine. So, even though we have an official protocol that's approved as part of the label, physicians -- and I'm going to defer to the other physicians on the panel, oncologists, my understanding is that's done often, you know, if you feel that something may improve for a specific patient. So, the answer to your question is it would be justified.

MEMBER GUIBERTEAU: And do you see that as a difference in culture between say such a regulation of an absolute limit in the NRC as opposed to one made by the manufacturer under FDA labeling?

MEMBER SULEIMAN: What the -- this is – I, you mean, we sometimes to get policy have to go through all sorts of reviews and whatever. This is clearly my interpretation of our policy, but if I think somebody is circumventing the regulations and saying I'm doing this under practice of medicine, but clearly doesn't want to comply with the safety aspects of it, at that point I believe they assume -- they do assume the liability themselves. And as long as everything works out okay, it's acceptable.

Most of the manufacturers when they

develop a medical product they're working hand and hand with the user community, with the physicians. So, it's not a them or us thing. I think everybody is trying to get a product out that's going to be safe, that's easy to use, and there are some safety standards in place. So, your example was pretty easy, you know, but sometimes when people really border on negligence, you know, do they want to invoke -- often they'll blame some other person or some -- you know, they were confused with the instructions, or they'll blame one of the intermediary health professionals. But I don't think -- I don't see where somebody would go against what the manufacturer is recommending.

MEMBER GUIBERTEAU: Thank you. I just wanted to clarify that in my own mind.

MEMBER SULEIMAN: Did I confuse or --

CHAIRMAN MALMUD: No, I think you clarified it, at least you clarified it for me, Dr. Suleiman.

MEMBER SULEIMAN: Thank you.

MEMBER GUIBERTEAU: And me, also.

CHAIRMAN MALMUD: Other comments?

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

CHAIRMAN MALMUD: Yes, Dr. Van Decker.

MEMBER VAN DECKER: I think I would echo

some of the comments of some of the people that have spoken prior. I think that we all want to look at generators as a non-generic set of issues here because there may be more down the line, and we want them all handled in a similar level playing field kind of situation. So, I think that that's a good idea.

I think the concept of not having very, very specific numbers in rulemaking space is also a wonderful concept because we know, and we're watching even now how long it takes rulemaking to get readjusted. So, I think we want to make sure we give ourselves the leeway as the science evolves and as we see how things play out.

I have to admit that I'm hopeful that the FDA labeling concept works, or possibly not knowing the fine points of the legality of some of this it makes me a little nervous because, you know, physicians always talking about on-label and off-label, and how quickly does that change, and what's the update. You know, I think I had spoken to a few people about the possibility of, you know, can we do some of this in appendix space rather than just use FDA label or just change numbers, or use -- or make it somewhat clear that the FDA's labeling concept here applies only to the breakthrough component of the eluate per se. So, I don't know the

real answers to that, but if people who know more than me believe that this fulfills the reality of being flexible, allowing for us to move the science forward, and to make changes we need to, then I trust people in that regard.

CHAIRMAN MALMUD: Thank you, Dr. Van Decker.

DR. HOWE: Dr. Malmud, this is Dr. Howe. May I speak?

CHAIRMAN MALMUD: Yes, Dr. Howe.

DR. HOWE: This is kind of historical, but in about 1994 we went through a very long, prolonged rulemaking that was referred to as the Practice of Pharmacy in Medicine Rule. And in that rule, we were told by the medical community that we could not hold licensees to package inserts in the preparation of radiopharmaceuticals or the elution of generators, nor could we hold licensees to use of materials as described in the package insert. And we were told that we were enforcing FDA requirements when FDA was not enforcing those requirements, and recognize there was more flexibility. And as a result of that rulemaking, we removed all requirements for our licensees to follow FDA package insert. We specifically added a section in Part 35, 35.7 that says nothing in this part released

the licensee from comply with the applicable FDA, other federal and state requirements governing radioactive drugs or devices.

But we did not say, and in 2002 they tried to go to plain language and say you're required to follow the FDA requirements. And we very carefully went back and said no, we cannot do that. We just can only say that you're not relieved of following them. So, to try to in rulemaking put NRC following an FDA package insert and enforcing an FDA package insert would be taking us back to pre-1994 situations in which the medical and the pharmacy community said we were doing the wrong thing. Thank you.

MEMBER MATTMULLER: Dr. Malmud, this is Steve Mattmuller, if I could reply to that, please.

CHAIRMAN MALMUD: Yes, Steve.

MEMBER MATTMULLER: Part of the issues that were raised back then were that -- were, for example, indications of when what specific test a radiopharmaceutical could be used for. And if it wasn't in the package insert, then a licensee was in non-compliance if they used it for a different indication; and/or in regards to preparing a kit according to the manufacturer's instructions, Orhan touched on it, to sometimes change product information

is a costly experience for the manufacturer, so even though they know the field is say, for example, putting 400 millicuries of technetium into a sulfur colloid kit versus the product label of 200, they know people are doing quality control testing and it's a safe product, but they're not going to go through the time and expense to revise the product labeling to say yes, you can now add 400 millicuries of pertechnetate to a sulfur colloid kit.

In this discussion, I think it would be important to say that the measurement for the radionuclidic impurity levels shall be in accordance with the generator's FDA's product labeling section, as Bracco calls it, their Eluate Testing Protocol. So, what we'd be recommending is that just to follow that aspect in the product labeling; that is, the Eluate Testing Protocol, not the complete -- we're not putting out a blanket statement for the whole product or package insert, just that specific section on testing for radionuclidic impurities in the package insert for that specific generator.

And I'd also like to make a -- it's been touched on. This is a current problem now with rubidium generator in that there are more restrictive testing requirements in the product labeling, but NRC

regulations aren't even addressing it in this revision. And it could be another seven to ten years before they do accept it with the current strategy that the NRC uses for this type of enforcement.

And I think that's all I have for right now. Thank you.

CHAIRMAN MALMUD: Thank you, Steve. So, I want to thank Dr. Howe for her historical perspective on this, but I'm not certain about the concise point that you're making, Steve. Could you just clarify it?

MEMBER MATTMULLER: Well, I think her concern for going back -- let me put it this way. If we're careful in how we word our recommendation or how the regulation is worded in that testing is only to the specific part in the package insert in regards to eluate testing, and not to the whole package insert as far as indications, or as far as product preparation, then I think we're in sound territory.

CHAIRMAN MALMUD: Thank you. Dr. Howe, do you wish to respond to that?

DR. HOWE: I'm not sure it's that clear, because I know that prior to 1994 when people were testing materials for purity, they weren't using the purity tests that were in the USP. And if they change -- if the manufacturer or the commercial nuclear

pharmacy changes how it measures the breakthrough in any way from the package insert we would be in a position where we would have to enforce an FDA accepted package insert when FDA may not. And we can't go back there.

CHAIRMAN MALMUD: Thank you. Dr. Zanzonico?

MEMBER ZANZONICO: Well, it seems like a regulatory dilemma but, again, the ACMUI is an advisory body, and I think we should make what we feel is the most appropriate recommendation. And, of course, leave it to the regulator, the NRC, to either accept and implement it, or not. But at least our position would be on the record for the benefit of the Commission. So, I think we should move forward with a vote on the recommendation unless there's further discussion.

MEMBER SULEIMAN: This is Orhan Suleiman again.

CHAIRMAN MALMUD: Yes, Dr. Suleiman.

MEMBER SULEIMAN: Okay. A point of clarification, the way I interpret it. We were basically referring to the breakthrough limit in the label. I don't think we were implying that the NRC adopt the entire label, which then could be subject to all sorts of different interpretations. I think here we're talking about the quantitative limit as specified in the label.

CHAIRMAN MALMUD: Ah-hah. Dr. Zanzonico, is that in agreement with your recommendation?

MEMBER ZANZONICO: It is now. I think that's an important clarification, and I think our recommendation should reflect that point.

CHAIRMAN MALMUD: That would be a limitation to the breakthrough level in the label. Who seconded your motion, Dr. Zanzonico?

MEMBER ZANZONICO: Well, I don't think I actually made the formal motion, but I'll be happy to do so.

CHAIRMAN MALMUD: All right.

MEMBER ZANZONICO: So, it'll be a bit on the fly, but the motion is the following. The NRC -- I'm sorry, the ACMUI recommends that the NRC adopt the FDA package -- the FDA approved package insert for breakthrough limits for radio isotope generators.

CHAIRMAN MALMUD: Thank you, that's a concise recommendation. Is there a second to it?

MEMBER MATTMULLER: I'll second it. Steve Mattmuller.

CHAIRMAN MALMUD: Thank you, Steve. May I ask Dr. Howe if she thinks that this might fly?

DR. HOWE: I --

CHAIRMAN MALMUD: You don't want to -- I'm

sorry, I didn't hear you.

DR. HOWE: Oh, Neelam will speak.

CHAIRMAN MALMUD: Thank you.

MS. BHALLA: Yes, this is Neelam Bhalla. And we believe this for -- as a rule writer we have been always guided that in our rules we should state the limits, what the regulations are directly in our regs so that a licensee is not referred to or not sent somewhere else. And this is referred to as incorporation by reference.

For example, in the Part 20 about public protection or radiation exposure to the members of the public, many of the things are based on the ICRP or the NCRP recommendations, so we don't say in our regs go to ICRP-100 and look at whatever those numbers are, and that's what our regulation is.

So, in this particular case I'm not really sure if we are treading onto that wrinkle where we are sending the licensee somewhere else. So, I'll be a little bit reluctant on -- and I just wanted you to know about that, that we -- generally, we like to put whatever the regs are, whatever numbers are right in our regs.

CHAIRMAN MALMUD: Thank you for that clarification. I wanted to -- the purpose of my asking

for it was to have it expressed so that the Committee members will understand the issue. I heard another voice?

VICE CHAIR THOMADSEN: That is Bruce Thomadsen. May I comment?

CHAIRMAN MALMUD: Please, Dr. Thomadsen.

VICE CHAIR THOMADSEN: I very much appreciate the NRC trying to keep everything in the one document, and I think as a user it is very convenient to do so. The problem that's trying to be addressed here is the ossification of the recommendations even as situations change, and the recommendations get out of date and actually may become dangerous.

The question of sending the user somewhere else and having them look these things up is not as big of a problem here as it would be if you were referring to an ICRP report to which many people may not have ready access. But if you're dealing with a generator, it's assumed that you also do have their package insert, and you would have the recommendations that go with the package insert right there before you.

MEMBER BAILEY: Dr. Malmud, this is Darice Bailey. May I speak?

CHAIRMAN MALMUD: Yes, but first, Dr. Thomadsen's point is well made. Okay. You're on.

MEMBER BAILEY: I want to add to his point, NRC in their transportation rules referenced Title 49 extensively and it's really difficult to look them up. So, it is done in NRC rule territory to reference other numbers.

MS. CHIDAKEL: Excuse me. This is Susan Chidakel. I have been sitting here listening to this discussion, and I haven't participated because, to be honest, I don't know the answer. But I do want to tell you that there are legal issues here that are being raised that may have a definite answer. It's more than just expressing an opinion whether this fits within here, or fits within there, whether this is like our DOT regs, or whether this is like the IAEA regs, or whatever it is. We have certain legal standards.

I, personally, do not know what they are off the top of my head, but I just want to warn you, you know, opinion doesn't matter here. This is something that may be dictated by what the legal standards are. I just want to caution you on that. You can make a recommendation that I can go back and research this out, or discuss this with my management and find out that this is not legally permissible.

CHAIRMAN MALMUD: Thanks.

MS. CHIDAKEL: It may be. I don't know.

CHAIRMAN MALMUD: Thank you, Counselor Chidakel. That's why I raised the issue the way that I did, because I wanted the Committee members to understand that our recommendation might not be accepted. We don't --

MEMBER VAN DECKER: Dr. Malmud.

CHAIRMAN MALMUD: I'm sorry, who's speaking?

MEMBER VAN DECKER: This is Bill Van Decker.

CHAIRMAN MALMUD: Yes, I just wanted to finish my sentence, which is that that's why I raised the issue so that there would be an understanding among the Committee members that this may or may not fly. Thank you. Dr. Van Decker.

MEMBER VAN DECKER: Yes. I think that, you know, we're not going to solve the exact wording here today. But I think that, you know, the thing that has come across everyone who has spoken is that we're looking for something not written in stone in rulemaking space that doesn't allow us dexterity to change with the times; that if we go with something along the concept of FDA labeling, we're really talking about only the breakthrough piece and not the rest of the clinical piece of this. And, you know, whether that is some other way to describe what we're trying to refer to, or whether

that's some way to create some appendix with exact numbers that fulfill the spirit of what's FDA labeling in that regard, I think that most of us would probably be flexible with that, but we would kind of prefer to see, you know, some good be done for long-term stuff. And, I guess, the real proof of the pudding will be when we all see the exact wording that tries to get us to where we're all trying to go.

CHAIRMAN MALMUD: Yes, thank you. And that's what we're hoping that our learned counsel might be able to tackle on our behalf.

MEMBER SULEIMAN: Dr. Malmud.

CHAIRMAN MALMUD: Yes, Dr. Suleiman.

MEMBER SULEIMAN: Yes. I, too -- at FDA we've been told at times by our lawyers don't adopt by reference. That's for general safety rules, that's for like public protection or whatever when you're dealing with certain types of standards.

These are very product-specific so you're not going to be hunting for a different -- you should have your user manual, or your label, or your instructions right there. It's no different than saying you should tune up your car, but then you decide, and you say all the parts have to be tested, have to be 3,000 rpm at this setting. Well, it's going to vary

by car, so in this case each generator, you know, has the manufacturer's specified limit, so I think it's quite prescriptive. And that way you're not stuck with using a limit that may have changed.

CHAIRMAN MALMUD: Thank you. We do have a motion before us. It's been moved and seconded.

MEMBER MATTMULLER: I'm sorry, could I make one more comment?

CHAIRMAN MALMUD: Yes. Who's --

MEMBER MATTMULLER: I'm sorry, Steve Mattmuller.

CHAIRMAN MALMUD: Thank you, Steve.

MEMBER MATTMULLER: One other advantage this strategy would have is that for a long time the vast majority of moly-99 used in the U.S. came from two reactors, and their HEU uranium came from one supplier, the U.S. Government. We're now in a transition phase moving to low-enriched uranium coming from different -- a far greater web of reactors all using LEU, all using our own target design, and these new target designs all have new target processing procedures.

And in addition to reactors producing moly, we have new linear accelerator manufacturers trying to come on line, so there could be a whole new

wrinkle to rating the quota of contamination in our generators. And this will be identified and handled by the FDA, but it's going to be -- and then any subsequent would be in their package insert, which by the way does come with each generator when you receive it.

So, the way I look at this, if the NRC is saying patient safety, radiation safety, I think it's incumbent upon them to find a way to do it this way, because to me it's unconscionable to think that if a new generator gets approved, it could take seven to ten years in the typical process for it to ever make it into an NRC reg. Thank you.

CHAIRMAN MALMUD: Thank you.

DR. HOWE: Dr. Malmud, this is Dr. Howe.

CHAIRMAN MALMUD: Yes, Dr. Howe.

DR. HOWE: There's another process, that if we get a new generator that is significantly different from what we have seen in the past; in other words, the moly breakthrough has to have different values, we can move things into 35.1000 and handle those in a matter of a few months, so one should not think that we need to get everything into rulemaking in order to handle new products. And that's what the purpose of 35.1000 is. Thank you.

CHAIRMAN MALMUD: Thank you for clarifying that. So, if we may we'll move on with Dr. Zanzonico's motion. All in favor?

(Chorus of ayes.)

CHAIRMAN MALMUD: Any opposed? Any abstentions?

(No response.)

CHAIRMAN MALMUD: The motion carries unanimously. Thank you. Next item, Dr. Zanzonico.

MEMBER ZANZONICO: Okay. I think some of the remaining items will move quickly, at least I hope that's the case.

So, this moves us on to item 5, allowing Associate Radiation Safety Officers, ARSOs, to be named on a medical license. And the draft recommendation in our report is that the ACMUI recommends that addition of ARSOs and temporary RSOs be included in exemptions in the same manner as AUs, ANPs, Authorized Nuclear Pharmacists, and Authorized Medical Physicists. So, the crux of this recommendation is to endorse the inclusion of ARSOs being named on medical licenses.

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

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

CHAIRMAN MALMUD: Thank you. Is there discussion of the motion?

MEMBER LANGHORST: Dr. Malmud, this is Sue again. I'd like to clarify that again.

CHAIRMAN MALMUD: Please do.

MEMBER LANGHORST: As you can see in the draft report, these are exemptions for the Type A Broad Scope licensees, and the crux of the request is that just like Authorized Users, Authorized Medical Physicists, Authorized Nuclear Pharmacists are named by the Radiation Safety Committee of those Type A Broad Scope licensees, we'd like to be able to have that same flexibility for ARSOs and clarify it for temporary RSOs, also. Thank you.

CHAIRMAN MALMUD: Thank you. Further discussion?

(No response.)

CHAIRMAN MALMUD: All in favor of the motion?

(Chorus of ayes.)

CHAIRMAN MALMUD: Any opposed? Any abstentions?

(No response.)

CHAIRMAN MALMUD: The motion carries unanimously. Dr. Zanzonico, you're on a run. You want

to take --

MEMBER ZANZONICO: Yes, we're on a roll. Yes, the next item -- this is Item 6, and it has to do with -- and it really is a very minor point, and I'm not even going to make a motion, but just an editorial suggestion.

As I was reading through the proposed rule, and as with all regulations it's tough sweating. I thought it might be helpful to -- that it could be shortened, and I think improved by eliminating redundant passages that appear throughout the document, and perhaps replacing the very brief, very general abstract with an Executive Summary styled section that summarizes perhaps in a bullet format the key changes. I think that would be welcomed by the user community to present these changes up front and in a very explicit format rather than dispersed, or in addition to being dispersed through the body of the proposed rule. So, that's just a suggestion. I don't think it necessitates a motion or a vote by the ACMUI unless anyone objects.

CHAIRMAN MALMUD: I'm certain that no one objects.

MS. BHALLA: Dr. Malmud.

CHAIRMAN MALMUD: Neelam.

MS. BHALLA: Yes, this is Neelam. I just

wanted to say I wholeheartedly agree that it becomes a very long document, and it sounds and looks very repetitious. But this is a Federal Register Notice of the proposed regulations. We are bound by our procedures whereby we need to follow section by section what we are changing and why we are changing. So, although 100, 200, 300 and so on, they are pretty much similar, but because of these stipulations we need to follow that process.

And, also, about the -- it's very well said, but the -- you know, we could do bullet form, but again we are bound by our own writing style. And, therefore, we hear you but that's a way we are supposed to do it.

CHAIRMAN MALMUD: Thank you, Neelam. We understand that, and that's why I suspect Dr. Zanzonico made a recommendation for those of you who actually draft these to do what you do best. Dr. Zanzonico.

MEMBER ZANZONICO: Okay. Well, we're really down the home stretch. There was a seventh item, that was just additional general comments. And really the most notable of these, in effect, has been eliminated, and that had to do with the separate training and experience requirements for beta gamma versus alpha emitters. We really addressed that in our previous

discussion and the previous item. And I thank Dr. Langhorst for correctly pointing out that Item 7B really is no longer necessary based on our earlier actions, so that's been eliminated.

Other than that, there are minor comments in Item 7B that I don't think warrant or necessitate discussion. So, I think we really have hit all the conceptual points.

I should point out that we had and have a subsequent section in the -- in our draft report on --that I called Specific Comment Significant. Some of these -- a number of these based on clarifications from the -- based on our previous teleconference and clarifications provided by the NRC Staff, as well as by emails among the ACMUI members, a number of these have been eliminated. These have been indicated by strikethrough text.

And the other point I'd like to make is that these Significant Specific Comments really don't introduce anything new, but just reference specific passages relevant to the general items that have already been discussed to make sure that they're consistent, the language is consistent in our opinion.

So, again I don't think, unless anyone on the Committee feels otherwise, that they warrant

additional discussion. Basically, these Significant Comments are made to insure compatibility between what we were recommending among our general items that we discussed at length already and the related specific passages in the proposed rule.

CHAIRMAN MALMUD: Thank you. And these are the items that are listed on pages 8 through the end of the document.

MEMBER ZANZONICO: Eight through eleven.

CHAIRMAN MALMUD: Yes.

MEMBER ZANZONICO: Then -- so, again, I'll -- you know, I don't want to suppress discussion if there is any.

CHAIRMAN MALMUD: Is there any discussion of these?

(No response.)

CHAIRMAN MALMUD: I hear none, so you haven't suppressed anything. Move on.

MEMBER ZANZONICO: All right. Then the last bit of -- the last item is Specific Comments Minor, and these are just purely editorial, and they're just suggested. These have no scientific or technical substance to them. They're just a product of my own compulsion, so there's absolutely no need for any discussion of whether a comma should be a semicolon

or a colon. And that's really the balance of the report.

I will generate a third draft based on our teleconference today and any subsequent feedback I get from the Committee members. But I think we're very near a final draft for submission --

MS. BHALLA: Dr. Malmud, may I speak?

CHAIRMAN MALMUD: Yes, Neelam.

MS. BHALLA: About the Minor Comments, I know you -- there are some very good suggestions, for example, hyphenate the words et cetera. And, again, I just want to say that we get bound by our -- it's called the Administrative folks. They are the ones who actually make our regulations get published in the Federal Register. So, therefore, there are certain requirements. I wish we had indicated for this review that not be so concerned with these kind of edits because ultimately it's there between the NRC's writing style, and the publishing document style and so on, so we do get a lot of those restrictions. And, therefore -- but, nonetheless, we would take a look into these, all of these because, you know, considering it's a very large document, I'm sure, you know, we have perhaps missed on even maybe sentences here and there. So, it's great to have this, but I just want you all to know that we do get bound by other restrictions.

CHAIRMAN MALMUD: I can assure you that the members of the ACMUI recognize that, and that this document is a reflection of the diligence with which this Subcommittee and its members have gone through the document, and recognize that some of these recommendations will not be considered appropriate using the verbiage the NRC uses, but they are still recommendations in the best interest of clarification. And we do appreciate both your effort on this, which is enormous, as well as that of counsel, particularly Counsel Chidakel who works -- we're sure works on these things behind the scenes, as well. So, we do appreciate that, but we did want you to know and the members of the Subcommittee wanted you to know what we thought might be perhaps optimal wording, if it's acceptable.

MS. CHIDAKEL: Thank you, Dr. Malmud. This is Susan Chidakel. I very much appreciate your praising me that way.

I also would like to mention that we decided we were going to only be giving you substantive and major things at this point, and we realized when we gave you this draft, and I realized when we gave you this draft that we have a lot of changes that we're still making to the actual language, so that it's not just that we are bound by certain restrictions with

regard to your minor comments, but some of those things may go away just through editing and through fine comb toothing, whatever.

MS. BHALLA: Yes.

MS. CHIDAKEL: Anyway, fine combing with fine tooth. And I've already noted to Neelam, you know, some of the things that are going to need to be changed as far as the editorial mix, so I just wanted to add that in.

CHAIRMAN MALMUD: Thank you. And the Committee also appreciates what has been a positive change, and you give us feedback when things are not acceptable so that we understand why some of the recommendations of the ACMUI were not acceptable because that helps justify the amount of effort that the Committee members put into this, even when it's not accept -- even when it's not finalized. So, we do thank you.

Dr. Zanzonico, you have taken us right through this document.

MEMBER ZANZONICO: Yes, we have.

CHAIRMAN MALMUD: And it looks like it's a grand slam. And we still have a minute or two, but I think we have to ask Chris who's the official representative who opened the meeting if he has any

comments at this point, or his delegate.

MR. EINBERG: Yes. Thank you, Dr. Malmud, Chris Einberg. Once again, I wanted to thank the ACMUI and the NRC Staff here, as well, for all the hard effort that everybody's put into this document and to this proposed rule.

We went through all the comments here, substantial changes were made or the recommendations where changed here so the next step is for Dr. Zanzonico or the ACMUI to finalize the report, and then send it to the NRC Staff.

We cannot go through another review of this because that would be deliberations, and outside of FACA, or if we do so, of if there's a strong feeling to do so, we would have to have another public teleconference to have deliberations in the public space. So, I encourage you to make those revisions and get them back to us, and we look forward to receiving those and trying to address the comments. And Ms. Holiday here has something she would like to add, as well.

CHAIRMAN MALMUD: Thank you, Chris.

MS. HOLIDAY: I just wanted to add that at this time, as Chris mentioned, we have to get the finalized report from you, so you actually have to vote

on finalizing the report pending these -- the incorporation of these revisions and recommendations, and since this is the only meeting time to do it, I guess this would be the time now that the full Committee would need to vote to approve the Subcommittee report to include those revisions as mentioned during this teleconference to finalize the report now.

CHAIRMAN MALMUD: Thank you. Would the Chairman please make that as a recommendation?

MEMBER ZANZONICO: I guess that's me.

CHAIRMAN MALMUD: You're the Chairman of the Subcommittee.

MEMBER ZANZONICO: Yes. So, I make a motion that the Subcommittee approve our report pending incorporation of all suggested or all approved revisions.

CHAIRMAN MALMUD: Is there a second to the motion?

MEMBER GUIBERTEAU: Mickey Guiberteau, I second this.

CHAIRMAN MALMUD: Thank you, Dr. Guiberteau. Any further discussion of this report with all the recommendations made in these six hours of conferences that we've had?

MEMBER LANGHORST: Dr. Malmud, this is Sue

Langhorst.

CHAIRMAN MALMUD: Dr. Langhorst.

MEMBER LANGHORST: I'd just like to clarify that that motion is for the full Committee and not just the Subcommittee?

CHAIRMAN MALMUD: That's correct.

MEMBER LANGHORST: Yes, thank you.

CHAIRMAN MALMUD: The motion is coming from the Chair of the Subcommittee to the entire Committee. That is its purpose.

MEMBER LANGHORST: Thank you.

CHAIRMAN MALMUD: Thank you for clarifying that for anyone who might not have understood that. Appreciate it. So, all in favor?

(Chorus of ayes.)

CHAIRMAN MALMUD: Are there any opposed? We hear no opposed. Are there any abstentions?

(No response.)

CHAIRMAN MALMUD: We hear none, so the Committee passes this unanimously, that's the ACMUI passes this recommendation of the Subcommittee unanimously, and we thank the Subcommittee and each of its members for an enormous amount of effort. We spent six hours in discussing this but that's a fraction of what the members of that Committee spent on drafting

and crafting this document, so we're very appreciative of it.

Now, let's see. Chris and Sophie, any other comments from NRC?

MR. EINBERG: Nothing from this end. I believe that when you're ready to adjourn, you can adjourn.

MEMBER ZANZONICO: Can I just ask one point of clarification. At this point what is our submission deadline for actually submitting the final report to the NRC?

MS. HOLIDAY: I can receive that report no later than March 28th.

MEMBER ZANZONICO: Okay, that's fine.

CHAIRMAN MALMUD: Very good, thank you. And we're going to be meeting in April, are we not, Sophie?

MS. HOLIDAY: Yes, sir, April 15th and 16th here at headquarters.

CHAIRMAN MALMUD: And each of the members of the Committee by now should have had his or her transportation and room arrangements solidified.

MS. HOLIDAY: Ideally.

CHAIRMAN MALMUD: Ideally. If any member of the Committee who intends to attend the meeting has not done so, I would suggest at this point that you

contact Sophie who might be help you to expedite the arrangements. Is that fair, Sophie?

MS. HOLIDAY: Yes, sir.

CHAIRMAN MALMUD: Thank you. I think everyone's arrangements are completed, but I just want to make sure in case one of you has not yet done so.

And with that, I'd like to thank everyone who participated in these discussions for their efforts and their wisdom in trying to achieve a final document which, hopefully, will result in an efficient operation all in the interest of optimal patient care. So, thank you all. We look forward to seeing you in April, and hearing -- and the NRC receiving the draft document by March 28th.

MS. HOLIDAY: Final document.

CHAIRMAN MALMUD: Final document. Thank you very much.

MS. HOLIDAY: Yes, sir.

MR. EINBERG: Okay. Thank you very much.

CHAIRMAN MALMUD: Thank you.

MR. EINBERG: Goodbye, everyone.

CHAIRMAN MALMUD: The meeting is adjourned. Thank you.

(Whereupon, the proceedings went off the record at 4:45:18 p.m.)