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NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

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TELECONFERENCE

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WEDNESDAY,

JANUARY 6, 2016

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The meeting was convened by teleconference at 2:00 p.m., Philip Alderson, M.D., ACMUI Chairman, presiding.

MEMBERS PRESENT:

PHILIP O. ALDERSON, M.D., Chairman

FRANCIS M. COSTELLO, Agreement State Representative

VASKEN DILSIZIAN, M.D., Nuclear Cardiologist

RONALD D. ENNIS, M.D., Radiation Oncologist

STEVEN R. MATTMULLER, Nuclear Pharmacist

MICHAEL O'HARA, Ph.D., FDA Representative

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

JOHN J. SUH, M.D., Radiation Oncologist

LAURA M. WEIL, Patients' Rights Advocate

PAT B. ZANZONICO, Ph.D., Vice-Chairman

Non-Voting: DARLENE F. METTER, M.D.

Non-Voting: ZOUBIR OUHIB

NRC STAFF PRESENT:

PAMELA HENDERSON, Deputy Director, Division of Material Safety, State, Tribal and Rulemaking Programs

DOUGLAS BOLLOCK, ACMUI Designated Federal Officer

SOPHIE HOLIDAY, ACMUI Alternate Designated Federal Officer and ACMUI Coordinator

MARYANN ABOGUNDE, NMSS/MSTR/MSEB

NEELAM BHALLA, NMSS/MSTR/MSEB

JENNIFER BISHOP, R-III/DNMS/MLB

JACKIE COOK, R-IV/DNMS/NMSB-B

SAID DAIBES, Ph.D., NMSS/MSTR/MSEB

ANTHONY DELAMOTTE, NMSS/MSTR/MSEB

SARA FORSTER, R-III/DNMS/MLB

MICHAEL FULLER, NMSS/MSTR/MSEB

FARRAH GASKINS, R-I/DNMS/MB

VINCENT HOLAHAN, Ph.D., NMSS/MSTR

ESTHER R. HOUSEMAN, OGC/GCLR/RMR

DONNA-BETH HOWE, Ph.D., NMSS/MSTR/MSEB

ERIN KENNEDY, R-III/DNMS/MLB

JAN NGUYEN, R-I/DNMS/MB

PATTY PELKE, R-III/DNMS/MLB

GRETCHE RIVERA-CAPELLA, NMSS/MSTR/MSEB

LIZETTE ROLDAN-OTERO, NMSS/MSTR/ASPB

VERED SCHAFFER, R-III/DNMS/MLB

ALEXA SIERACKI, NMSS/DSFM/LTSF

TOYE SIMMONS, R-III/DNMS/MLB

KATHERINE TAPP, Ph.D., NMSS/MSTR/MSEB

TORRE TAYLOR, NMSS/MSTR/MSEB

ROBERTO TORRES, R-IV/DNMS/NMSB-B

LESTER TRIPP, R-I/DNMS/MB

DUNCAN WHITE, NMSS/MSTR/ASPB

ALSO PRESENT:

ROBERT DANSEREAU, New York State Department of Health

MICHAEL DE LA GUARDIA, Cook Children's Health Care System

SUSAN ELLIOTT, Arkansas Department of Health

SANDRA GABRIEL, *unaffiliated*

MICHAEL GUASTELLA, Council on Radionuclides and

Radiopharmaceuticals

ANGIE D. HALL, Arkansas Department of Health

YUNGMI KIM, Spectrum Pharmaceutical

CAITLIN KUBLER, Society of Nuclear Medicine and Molecular Imaging

KAREN LANGLEY, University of Utah

RALPH LEITO, St. Joseph Hospital

SAMUEL LEVERITT, Cardinal Health

GARY LUNGER, Bayer

STEVE MACK, Arkansas Department of Health

MICHAEL MILLER, Spectrum Pharmaceuticals, Inc.

MICHAEL PETERS, American College of Radiology

JOSEPHINE PICCONE, *unaffiliated*

AMY SCHOPPMAN, Webster Chamberlain & Bean LLP

MICHAEL SHEETZ, University of Pittsburgh

DAVID STEPHENS, Arkansas Department of Health

BRUCE THOMADSEN, University of Wisconsin

JARED THOMPSON, Arkansas Department of Health

CINDY TOMLINSON, American Society of Radiation Oncology

MICHAEL WELLING, Virginia Department of Health

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P R O C E E D I N G S

2:07 p.m.

CHAIRMAN ALDERSON: Welcome to the conference call. Today we're here to discuss the Draft Final Rule and the comments of the ACMUI Subcommittee that reviewed the Draft Final Rule.

At this time, I think we'll take the roll call. Is that correct?

MR. BOLLOCK: Yes. This is Doug Bollock. I have some opening comments as the Designated Federal Officer I'll go through and the roll call will be part of that.

CHAIRMAN ALDERSON: Good. Mr. Bollock, go ahead.

MR. BOLLOCK: Thank you, Dr. Alderson. As the Designated Federal Officer for this meeting, I'm pleased to welcome you to this public meeting of the Advisory Committee on the Medical Use of Isotopes.

My name is Doug Bollock. I'm the Branch Chief of the Medical Safety and Events Assessment Branch. I have been designated as the federal officer for this Advisory Committee in accordance with 10 CFR Part 7.11. Present today as the alternate Designated

Federal Officer is Sophie Holiday, our ACMUI Coordinator.

This is an announced meeting of the Committee. It's being held in accordance with the rules and regulations of the Federal Advisory Committee Act and the Nuclear Regulatory Commission. This meeting is being transcribed by NRC, and may also be transcribed or recorded by others. The meeting was announced in the October 14th, 2015 edition of the Federal Register Volume 80, pages 61850-61851.

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 issues that we'll discuss today. I also recognize there may be minority or dissenting opinions. If you have such opinions, please allow them to be read into the record.

At this point, I'll perform a roll call

of the ACMUI Members participating today. Dr. Philip Alderson.

CHAIRMAN ALDERSON: Here.

MR. BOLLOCK: Thank you. Dr. Pat Zanzonico.

VICE CHAIRMAN ZANZONICO: Here.

MR. BOLLOCK: Thank you. Mr. Frank Costello.

MEMBER COSTELLO: Here.

MR. BOLLOCK: Thank you, Frank.

MEMBER COSTELLO: I was already on mute.

MR. BOLLOCK: Dr. Vasken Dilsizian.

MEMBER DILSIZIAN: Here.

MR. BOLLOCK: Thank you. Dr. Ronald Ennis. I believe he's not going to be able to make it today. Dr. Sue Langhorst.

MEMBER LANGHORST: Here.

MR. BOLLOCK: Thank you. Mr. Steve Mattmuller.

MEMBER MATTMULLER: Here.

MR. BOLLOCK: Thank you. Dr. Michael O'Hara.

MEMBER O'HARA: Here.

MR. BOLLOCK: Thank you. Dr. Christopher

Palestro.

MEMBER PALESTRO: Here.

MR. BOLLOCK: Thank you. Dr. John Suh.

MEMBER SUH: Here.

MR. BOLLOCK: Thank you. And Ms. Laura Weil.

MEMBER WEIL: Here.

MR. BOLLOCK: Thank you. All right. I've confirmed that we have at least seven Members and a quorum. On the phone we also have Dr. Darlene Metter and Mr. Zoubir Ouhib. Dr. Darlene Metter has been selected as the ACMUI Diagnostic Radiologist; Mr. Zoubir Ouhib has been selected as the ACMUI Therapy Medical Physicist. Both Dr. Metter and Mr. Ouhib are pending security clearance but may participate in the meeting; however, they both do not have voting rights.

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

DR. DAIBES: Said Daibes.

MR. FULLER: Michael Fuller.

DR. HOWE: Dr. Donna-Beth Howe.

MS. BHALLA: Neelam Bhalla.

MS. ABOGUNDE: Maryann Abogunde.

MR. BOLLOCK: Thank you. All right. Now we'll go to NRC Headquarters employees that are on the phone.

MS. TAYLOR: Torre Taylor.

MS. HOLIDAY: Sophie Holiday.

MR. BOLLOCK: Thank you. Next we have the NRC Regional offices. Do we have anyone on the call from Region I?

(No response)

MR. BOLLOCK: Hearing none, do we have anyone on the call from Region III?

(No response)

MR. BOLLOCK: Okay, moving on. Anyone on the call from Region IV?

(No response)

MR. BOLLOCK: All right, moving on. Members of the public who notified Ms. Holiday that they would be participating in the teleconference will be captured in the transcript. Those of you who did not provide prior notification please contact Ms. Holiday at sophie.holiday@nrc.gov. That's S-O-P-H-I-E.H-O-L-I-D-A-Y@NRC.gov, or call her at phone number (404)997-4691.

We have a bridge line available and that phone number is 1-888-864-0940. The pass code to access the bridge line is 7452745 followed by the # sign. This meeting is also using the gotowebinar application to view presentation handouts real-time. You can access this by going to www.gotowebinar.com and searching for Meeting ID 123-282-291.

The purpose of this meeting is to discuss the ACMUI's Subcommittee's report on the ACMUI review and comments to the Draft Final Rule for Title 10 Code of Federal Regulations, Part 35, Medical Use of Byproduct Material.

Individuals who would like to ask a question or make a comment regarding a specific issue the Committee has discussed should request permission to be recognized by the ACMUI Chairperson, Dr. Philip Alderson. Dr. Alderson, at his option, may entertain comments or questions from members of the public who are participating with us today. Comments and questions are usually addressed by the Committee near the end of the meeting after the Committee has fully discussed the topic. I would also like to add that handouts and agenda for this meeting are available on the NRC's public website.

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 will ask everyone to exercise extreme care to insure that background noise is kept to a minimum as any stray background sounds can be very disruptive on conference calls this large.

Before turning it over to Dr. Alderson, I'd also like to inform the Committee that Mike Fuller of the NRC Staff is prepared to provide you with the NRC Rulemaking Working Group's perspective on the various recommendations as you deliberate these today, so he'll be able to address those, as needed.

And upon the completion of the ACMUI's portion of this meeting, Dr. Alderson will turn the meeting back over to the NRC. We have one question that we would like the public to allow them for public comment on that issue. Thank you. And back to you, Dr. Alderson.

CHAIRMAN ALDERSON: Thank you, Mr. Bollock. Good.

So, to lead this discussion, Pat Zanzonico who chaired this Committee, would you like to take over at this point and we'll follow you through the summary, and the Committee's work, and then the Committee's comments.

VICE CHAIRMAN ZANZONICO: Okay, thank you very much, Dr. Alderson. And I'd just like to begin by acknowledging my fellow Subcommittee Members who really did an outstanding job as you hopefully can tell from length and more importantly, the rigor of our review. It really was a very thoughtful, time-consuming review, and hopefully it's received in that spirit.

My fellow Subcommittee Members were Frank Costello, Ron Ennis, Sue Langhorst, Steve Mattmuller, and Laura Weil. And what I propose to do is to simply step through the Executive Summary, and as indicated in the first paragraph of that summary some additional background material and historical and other details are included in subsequent numbered sections of our report.

So to begin, our Subcommittee originally had reviewed and commented and submitted a report to the NRC on a previous version of Part 35, the so

called Proposed Rule, and the NRC Staff subsequently responded to that report. So, this Draft Final Rule which we currently reviewed and which is the subject of today's teleconference incorporates revisions made in response to our original Subcommittee report, as well as comments submitted by professional societies and other stakeholders. So our recommendations on the major elements of the current Draft Final Rule follows. And again, further comments and background material and so forth are provided in the accompanied numbered sections in the square brackets.

So to begin, the Subcommittee endorses that component of the current proposed rule redefining medical events in permanent implant brachytherapy in terms of activity that is source strength rather than radiation dose. And just to comment further, this was one of the most difficult and I would say contentious issues in the Draft Final Rule; but, again, the overall recommendation of the Subcommittee is to adopt the activity-based definition of a medical event in permanent implant brachy.

Secondly, the Subcommittee endorses but

with serious reservations designating the current proposed rule defining medical events in permanent implant brachytherapy as Compatibility Category C. Again, however, with the activity-based medical event metrics defined as an essential program element rather than as Compatibility Category B, which was our Subcommittee's original recommendation.

Our understanding of the distinction between Compatibility Categories B and C is that a Compatibility Category B would basically require all Agreement States to conform exactly to the NRC rule, in this case the NRC definition of medical events in permanent implant brachy; whereas, Compatibility Category C would allow what appears to be considerable latitude on the part of the Agreement States in supplementing or expanding that activity-based definition of medical event. And Dr. Ronald Ennis, who unfortunately can't join us because of a medical or a patient issue, was fairly strident on this point, and it was his feeling that since an increasing number of radiation oncologists practice in multiple jurisdictions, meaning across state lines, that it really was in the interest of practitioners, as well as patients to have as uniform

a definition of medical events in permanent implant brachytherapy as possible, which was the -- our rationale originally for recommending Category B rather than C. However, we understand from NRC's Staff that in regulatory parlance really Compatibility Category B is reserved for those rules which have transboundary implications and not simply to assure uniformity. So given that regulatory constraint, we do recommend Compatibility Category C, but with the reservations I already have voiced.

Moving on to the next point, the Subcommittee recommends changing the language for a Wrong-location medical event in permanent implant brachy from the current proposed language which I'll read as follows: "Sealed sources implanted directly into a location where the radiation from the sources will not contribute dose to the treatment site as defined in the Written Directive." We recommend changing that language to "sealed sources implanted directly into a location discontiguous from the treatment site as defined in the Written Directive." And it may seem like simply a matter of semantics but we really think the change in language has important implications in the sense that with the original

definition, a gamma or x-ray emitting source virtually anywhere in the body will contribute some non-zero dose to the treatment site. So in a rigorous physics sense, not contributing dose to the treatment site is really not achievable. But more importantly, we understood from Dr. Ennis and others that the practitioners, the physicians often will implant seeds outside what might be considered the conventional or nominal clinical tumor volume in order to achieve by design an optimum dose distribution within the target volume, and this may include implanting seeds, as I said, outside the nominal clinical tumor volume, but it could be construed by an inspector, for example, as being a misadministration since there would be seeds, as I say, outside this tumor volume. And we think the word "discontiguous" is really appropriate in this context. It was suggested by Dr. Ennis because it does convey the notion of a seed being placed by design in a anatomical location well away from the clinical tumor volume. So a location can be contiguous and implanted by design, but yet outside the nominal clinical tumor volume, but yet not discontiguous. And that would capture the notion of

seeds being implanted outside the nominal tumor volume by design to deliver the optimum dose distribution. So, I think the word "discontiguous" is very appropriate then in this context.

Moving on to the next point. The Subcommittee recommends revising the passage in lines 4182 to 4186 on page 167 of the Draft Final Rule as follows, thereby eliminating the dose-based criteria for a medical event related to a leaking source. Again, the intent of this change in language was to try to eliminate all MEs and permanent implant brachy based on dose-based criteria which the Subcommittee felt, as well as a number of stakeholders, commenters felt was impractical for a number of sites. So the suggested revised language is simply, "An administration that includes the wrong radionuclide, the wrong individual human research subject, a leaking sealed source, or a sealed source or sources implanted into a location discontiguous from the treatment sites as defined in the Written Directive." So again, the recommendation of this, or this specific recommendation of the Subcommittee with respect to a leaking source ME was specifically designed to eliminate any dose-based criteria for an

ME related to a leaking source.

Moving on to our next recommendation, the Subcommittee endorses the elimination of the preceptor statement requirement for Board Certified individuals, for AUs and other authorized professionals. So in other words, if such an individual is appropriately Board Certified there would no longer be any need for a preceptor statement. That's already in the new rule, or the Draft Final Rule, and the Subcommittee endorses that change.

Moving on to the next point, with respect to the amended requirements for a preceptor attestation for an individual seeking regulatory authorization as an AU or other authorized professional, the Subcommittee also endorses changing the language for the preceptor attestation from "The individual has achieved a level of competency to function independently for the authorization," to "the individual independently fulfilled the radiation safety-related duties associated with that authorization." So again, this is with respect to professionals seeking authorization through the alternate pathway rather

than through the Board certification pathway. So such individuals would require a preceptor attestation. And what the Subcommittee is endorsing is a change from the preceptor having to make a subjective judgment on competency to simply an objective statement that the individual has fulfilled the radiation-related training and experience in the course of their training program.

The next point, the Subcommittee recommends that the date of recognition by the NRC of a certifying board should not impact individuals seeking to be named as an authorized user or other authorized professionals. And, as you know, that is not exactly what is stated in the Draft Final Rule in which a specific date of recognition of a Board by the NRC is required. The Subcommittee is recommending that there should be no such date of recognition requirement of a Board for any Board Certified individual.

The next point is regarding breakthrough of the parent radionuclide in radionuclide generated systems. And the Subcommittee recommends that the NRC adopt the parent breakthrough limits for radioisotopes generated specified in the relevant

FDA-approved package insert. And Steve Mattmuller led the way on this particular point.

So among the reasons for this recommendation is that at the moment there are only two generator systems currently in routine practice and specified in NRC regulations, the molybdenum-99/technetium-99m generator, and the rubidium generator. And it would seem to simplify everyone's life, including the NRC, that once new generators become available and are used in clinical practice, like a germanium-68/gallium-68 generator the most expeditious way of regulating these would be to simply, for users to comply with the FDA-approved package inserts, including the parent breakthrough limits. The NRC, as we understand it, prefers to evaluate and draft regulations on a generator by generator basis rather than to simply adhere to the corresponding FDA parent breakthrough limits.

Moving on to the next point, the Subcommittee does not endorse the new requirement in the Draft Final Rule of reporting requirements for end-users to report out of tolerance parent breakthrough both to the NRC and to the manufacturer and vendor. Rather, the Subcommittee is recommending

that users be required to report out of tolerance solutions only to the vendor and that a requirement can be imposed on the vendor or manufacturer or distributor to report to the NRC.

This would not only reduce the reporting burden on end-users; perhaps more importantly, the Subcommittee feels that this is a more effective way of collecting, collating, and so forth reports of out of tolerance parent breakthrough than having users report both to the NRC and to the vendor, because the users, among other things, are very, very highly motivated to report very quickly to vendors that they have an out of tolerance generator in terms of parent breakthrough because they can't use the eluent for a patient, and they need to get a replacement generator or some other remedy very, very quickly, so this would be a self-driven very effective means of collating such out of tolerance elutions, that is reporting to the vendor and then having the vendor who would collect these from multiple users as they occur to the NRC.

The next point, the Subcommittee endorses allowing Associate Radiation Safety Officers, or ARSOs to be named on a medical license.

Moving to the next point, the Subcommittee recommends that the designation of a Board Certified AU or other authorized professional as an RSO or as an ARSO requires that their Board certification includes the designation RSO eligible. Not all Board certifications of the respective Board certified professionals will have that designation, many will, but not all. And again, the Subcommittee is recommending that only Board certified individuals with such a designation on their certification should be allowed to fill the role of an RSO or ARSO.

Moving to the next point, the Subcommittee does not endorse establishing a separate category of AUs for parenteral administration of alpha-emitting radiopharmaceuticals distinct from that for gamma and beta-emitting radiopharmaceuticals, so the Subcommittee recommends rewording the appropriate section of the Draft Final Rule simply as parenteral administration of any radioactive drug for which a Written Directive is required.

Again, it's the position of the Subcommittee which we know is different from that of the NRC, that Authorized Users who are qualified to

administer gamma and beta-emitting radiopharmaceuticals under a Written Directive have all of the training and experience to also do so for alpha-emitting radiopharmaceuticals. And Dr. Langhorst provided a table of current and under development therapeutic radionuclides, including a number of alpha-emitting radionuclides showing that all such radionuclides administer, already administer beta and/or gamma rays so that the same detection and radiation protection measurements and so forth that can be done for beta and gamma-emitters only can also be applied to these alpha-emitting radionuclides.

A technical point, moving on to the next point, the Subcommittee endorses the elimination of the requirement to submit copies of NRC Form 313 or a letter containing the information required by that form when applying for a license, an amendment, or renewal.

And our final recommendation, the Subcommittee recommends changing the medical events language in lines 5531 to 5532 on page 232 of the Draft Final Rule from, "A licensee shall report as a medical event any administration requiring a Written

Directive except for an event that results from patient intervention." Change that language back to the language originally in the Draft Final Rule, "A licensee shall report any event except for an event that results from patient intervention." In other words, to eliminate the "any administration requiring a Written Directive" qualifier.

So that summarizes our recommendations on the major elements of the Draft Final Rule. And as I said, additional comments, background, historical notes, so forth and so on are provided subsequently in our report in the sections identified with each of those bulleted recommendations. So that concludes my final -- my summary presentation of our report.

CHAIRMAN ALDERSON: Yes. Dr. Zanzonico, thank you very much for a very complete report, and thanks to all the Committee for all the work that led into this lengthy and fine report. So, at this point we will open the discussion to comments from the Subcommittee. Are there any such comments?

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

CHAIRMAN ALDERSON: Yes, Sue. Please, go

ahead.

MEMBER LANGHORST: I wanted to add just a couple of things, and let me start by that last item. And, Dr. Zanzonico, I'm very sorry but I missed that this got changed, and it's exactly opposite of what you've read there. It should be, our recommendation was that that language needs to be what was in the proposed Draft Rule rather than changing it back to the original language at this late date. Does that make sense?

VICE CHAIRMAN ZANZONICO: So, Sue, this is Pat, again. So -- and I apologize for the confusion. Obviously, this is something that should have been caught before now in our many reviews of our report. But is the recommendation that the language should be, "A licensee shall report as a medical event any administration requiring a Written Directive." You want to leave in that qualifier?

MEMBER LANGHORST: Yes, that's correct, because that was what was in the Draft Proposed Rule.

VICE CHAIRMAN ZANZONICO: Understood. Understood. My apologies for that confusion.

MEMBER LANGHORST: That got switched.

VICE CHAIRMAN ZANZONICO: Yes.

MEMBER LANGHORST: That changes the whole discussion on that point, too.

VICE CHAIRMAN ZANZONICO: Yes, yes.

MEMBER LANGHORST: Let me jump back to the beginning again. So on the Compatibility Category C for the permanent implant brachytherapy, I think it's important to include that the reason the Subcommittee recommends going ahead with Compatibility Category C was that this activity-based medical event metrics is defined as an essential program element, which means that Agreement States cannot put in a dose-based criteria. So that does help with consistency across states. So I just wanted to emphasize that point.

Next, I wanted to jump down to where we talk about the Subcommittee recommends that date of recognition by an NRC or by a certifying Board be waived or not -- that there not be a date on that at this point in time. Basically, that comes back to the ACMUI's recommendation that all Board Certified individuals be allowed to be grandfathered at this point in time. They, obviously, have to have updated training in the type of medical use that they're trying to become an Authorized User.

Now, as an alternative that I suggest for NRC Staff, I had asked whether the NUREG-1556 Volume 9 update would be available for us to look at at the same time that we were looking at the Draft Final Rule, and it's not yet, so I certainly appreciate that. But it would have been nice to have that included to review, too. But if that NUREG could discuss how you deal with Board Certified individuals seeking AU status, if their Board certification is before October, I can't remember the date now. And I reference the licensing guidance for Gamma Knife Perfexion has a way to deal with those types of individuals, so I propose that as an alternative for the NRC Staff to consider.

I want to now jump to the Subcommittee recommends the designation of Board Certified individuals to be RSOs and inclusion of RSO eligible designation. I was confused in reading the Draft Final Rule because that RSO eligibility was not mentioned, and I was concerned that that would be seen as making that designation irrelevant. So I recommended that that be noted someplace so that if a person is Board Certified and has that RSO eligible designation on their certification, that means -

- that's a very good indicator they could be an RSO. Otherwise, they have to go through training with an RSO, and it's not just that they are an Authorized User or an Authorized Nuclear Pharmacist. They do have to have some RSO training.

I'm going to skip down to the next item that talks about the elimination of the requirement to submit copies of the NRC 313 form and so on. Again, this was something I found confusing because it sounded like you didn't have to send in that form at all. So I just would suggest that NRC might consider saying duplicate copies. And believe me, I appreciate not having to send in an extra copy of a 300 some page broad scope license application.

And then as I noted that last bullet item, we just have it switched from what we had originally discussed, so those were my comments, and I appreciate you listening.

CHAIRMAN ALDERSON: Dr. Zanzonico, do you wish to reply to any of those comments?

VICE CHAIRMAN ZANZONICO: No, I think -- well, first of all, I apologize again for the confusion on the last point and appreciate Dr. Langhorst pointing out the correction. But beyond

that, I think Dr. Langhorst has fleshed out with some important background some of our thinking on a number of these points. And at least some of that material is included in the subsequent sections on these respective points, but I have nothing to disagree with what Dr. Langhorst just said.

CHAIRMAN ALDERSON: Dr. Langhorst, then. I'd like to ask you to go again through what you said about RSO eligible designation because I thought you were headed in one direction, and then I heard you going in another direction. Would you just restate that issue, please?

MEMBER LANGHORST: Okay. There are certain Board Certifications, for instance, I believe Medical Physics Board Certification. They can have some additional training and additional testing to then also have not only their medical physics certification, but have it state on their certificate that they are RSO eligible.

CHAIRMAN ALDERSON: Yes.

MEMBER LANGHORST: And my thought was is, I was concerned that with that not even being stated anywhere in the discussion of this point that I was questioning whether NRC was making that RSO eligible

designation irrelevant. And I don't think they meant that, and so I was suggesting that that be mentioned.

CHAIRMAN ALDERSON: Okay.

MEMBER LANGHORST: So that people know they have to have some additional training to be an RSO. It's not good enough just to be a Board Certified Authorized User.

CHAIRMAN ALDERSON: Yes. I very much agree with your point on that, and just didn't understand that when you said it before. Does anyone else from the Subcommittee have a comment on this issue?

(No response)

CHAIRMAN ALDERSON: Hearing none, all right. Then, Dr. Langhorst, do you have other comments?

MEMBER LANGHORST: No, I -- those were the points that I wanted to raise, and I'm glad to answer any questions that people have as we go through the discussion.

CHAIRMAN ALDERSON: Good, all right. So, I asked just a moment ago about such questions or comments. Before I open the floor to other Members of the Subcommittee, does anyone else have a question for Dr. Langhorst about one of her statements?

(No response)

CHAIRMAN ALDERSON: Hearing none, we'll open the floor to other Members of the Subcommittee who would like to comment on Dr. Zanzonico's report.

MEMBER COSTELLO: Yes, this is Frank Costello.

CHAIRMAN ALDERSON: Okay, Mr. Costello. Frank, please go ahead.

MEMBER COSTELLO: Yes. I mean, Sue correctly said that the Subcommittee thought it important that the -- for Compatibility C that they emphasize that the activity-based requirement be an essential program element, but that was pointed out that is already included in the Subcommittee's Executive Summary in the second bullet, it mentions that this be defined as an essential element. So, while I agree with Sue, I think that we've already done that. That's all.

CHAIRMAN ALDERSON: Very good. That's your only comment?

MEMBER COSTELLO: Yes.

CHAIRMAN ALDERSON: Very good. Do other Members of the Subcommittee have comments?

MEMBER ENNIS: It's Ron Ennis here.

CHAIRMAN ALDERSON: Yes. Oh, hello, Ron. We thought you might not be on the call. Thank you.

MEMBER ENNIS: Yes. So, I mostly just want to let you know I have been on the call since the point where Pat was describing our language for seeds discontiguous from the target.

CHAIRMAN ALDERSON: All right.

MEMBER ENNIS: I think he did an excellent presentation of it, so I don't actually have anything to add to his presentation of our points. But I am on the call, and happy to discuss if people have questions about our thinking on those topics.

CHAIRMAN ALDERSON: Very good. So, while you've made that statement, does any one of the Subcommittee Members have a question or would they like Ron to extend the thinking on that topic?

(No response)

CHAIR ALDERSON: Hearing no comments, we'll go back to the general Subcommittee again. Other Members of the Subcommittee who would like to comment on the discussion?

MEMBER MATTMULLER: Yes, this is Steve Mattmuller.

CHAIRMAN ALDERSON: Yes, Steve.

MEMBER MATTMULLER: Just a brief comment on page 16 of the report at the very bottom on page 133. It states, "The Subcommittee does not support the proposed change in wording from commits to satisfies." And I believe we have those two words mixed up, it should be -- the existing wordage is satisfy, and the proposed language is to change it to commits, and we believe it should stay as satisfy.

CHAIRMAN ALDERSON: All right. Dr. Zanzonico, do you want to comment on that?

VICE CHAIRMAN ZANZONICO: No, I apologize again for that error that crept into the report, but beyond that, no, I have no further comment.

CHAIRMAN ALDERSON: Okay. Anyone else wish to comment on that?

(No response)

CHAIRMAN ALDERSON: Okay. Hearing none, I'll assume that the Subcommittee agrees with that recommended change. Other Members of the Subcommittee now who would like to comment on any parts of the report?

(No response)

CHAIRMAN ALDERSON: Hearing no comments, are there Members of the ACMUI who are not Members

of the Subcommittee who would like to comment on the report, ask questions? The floor is open.

DR. METTER: This is Darlene Metter.

CHAIRMAN ALDERSON: Yes, Dr. Metter, please.

DR. METTER: So my question is about the Board eligibility statement, and giving Authorized User status for Board Certified physicians. And I believe if you recall, the American Board of Radiology changed their training requirements for Authorized User, I believe in 2005. Is that correct, Phil?

CHAIRMAN ALDERSON: Yes, that's about right.

DR. METTER: So I think from that time on we might have to put a timeline for radiologists because prior to that, the training was not within the program requirements for radiology.

CHAIRMAN ALDERSON: Yes. I very much agree with your comments on that in that regard, and it was with respect to the ABR experience that I actually raised a similar question in the dialogue that occurred verbally and on line prior to this meeting. Would anyone else wish to comment on that issue on

Board eligibility in any way?

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

CHAIRMAN ALDERSON: Yes.

MEMBER LANGHORST: The problem I have is when I have Board Certified senior-level physicians who were Board Certified prior to those dates, how do I get them to become an Authorized User for a given type without them having to start from scratch so to speak, and get all retrained in a new program? That's what I'm talking about that maybe NRC can provide some guidance in their guidance document about how maybe on an individual basis NRC or Agreement States can review those types of individuals and their most current up to date training on that specific type of medical use, how to get them authorized.

CHAIRMAN ALDERSON: Yes, good comment. I think that in a sense you and Dr. Metter are focusing on the same issue, on different aspects of the same issue. And it is true that if they weren't certified by a particular date then you'd have to have some other criteria. You are also correct, I believe, if I heard correctly that if there is no date

requirement of any kind then all the people would be eligible even though they may or may not have established a certain learning level. So this is an issue that we probably should revisit at another time that we probably will not be able to resolve here today. Further comments on this issue?

(Off microphone comment)

CHAIRMAN ALDERSON: If someone is commenting there, I can't -- some in the background. That was - did other people hear that? There was a faint voice in the background, we're asking for other comments from Members of the ACMUI.

MEMBER ENNIS: This is Ron Ennis.

CHAIRMAN ALDERSON: Yes, Ron.

MEMBER ENNIS: So maybe I hadn't really quite appreciated this. So if I'm now understanding saying from 2005 on eliminates this concern about diagnostic radiologists who did not have the training that would raise to the level of Authorized User.

CHAIRMAN ALDERSON: That's what Dr. Metter is indicating, yes.

MEMBER ENNIS: Okay, that is an important point then. And maybe we do need to reconsider, or at least I would be interested in reconsidering the

Subcommittee's position that the date should be eliminated completely unless we have another mechanism for making sure that diagnostic radiologists trained before that time are truly educated and have the proper training and experience to become Authorized Users.

CHAIRMAN ALDERSON: Good, yes. So you would vote for reconsideration -

MEMBER ENNIS: Yes.

CHAIRMAN ALDERSON: -- of this at some greater detail.

MEMBER ENNIS: Yes.

CHAIRMAN ALDERSON: That would also be my position. Other comments on this particular issue?

MEMBER LANGHORST: Dr. Alderson, this is Sue Langhorst again.

CHAIRMAN ALDERSON: Yes.

MEMBER LANGHORST: The Health Physics certification, that Board was approved with -- I don't believe there was any changes needed to be made, so people like me who were Board Certified prior, if I had not been named as an RSO on a license, I wouldn't be able to be named as an RSO on a license, or maybe even not for a new type of medical use. So

it's very confusing, and for those of us who didn't have to change our Board Certification requirements to meet the NRC's certifying Board criteria, it's a frustrating situation.

CHAIRMAN ALDERSON: Well, further evidence it seems to me that we do want to consider this issue further and we've got both the issue of Authorized User status, which is specifically what the ABR worked on, and the RSO status for physicists, so I -- hearing no comments to the contrary, I think that we will move away from this issue for today and say that we will have to as a Committee of the ACMUI consider this further.

VICE CHAIRMAN ZANZONICO: This is Pat. I'd just like to -- and I understand the need to move on from this, but I really echo Dr. Langhorst's earlier comment in that if there is a specific date in the regulations, then that's a black and white reg that would seem one cannot deviate from. Yes, there are going to be some Boards, as Sue pointed out, where that date is irrelevant, and other Boards where a particular date may be relevant.

CHAIRMAN ALDERSON: Yes.

VICE CHAIRMAN ZANZONICO: And so I think

I would endorse Sue's idea, therefore, that that be handled in guidance space rather than regulation so that specific dates could be eliminated from the reg because that sort of then is an ironclad rule, it's a regulation, and addressed better in guidance. So that's just an additional comment I wanted to make on that topic.

CHAIRMAN ALDERSON: Very good, yes. I think that because of the way that this discussion could continue, for example, talking about well, perhaps we should adjust for Boards that have a date listed in their criteria, and those that do not. But I think we will probably need to extend. All of these comments are very relevant and helpful, and we need to extend this discussion at a future time.

Are there any other Members of the ACMUI who would like to comment about any part of the current presentation? Are there any further comments? I'll ask B

MEMBER PALESTRO: Phil, this is Chris Palestro.

CHAIRMAN ALDERSON: Yes, Chris.

MEMBER PALESTRO: Yes. I have a question for Pat to try to get some clarification. The

Subcommittee does not endorse the new requirement that licensees report to the NRC as well to the manufacturer/vendor generator elutions with out of tolerance parent breakthrough and so forth. What's the rationale for that, Pat? I'm not quite clear.

VICE CHAIRMAN ZANZONICO: The rationale basically is several fold. One is that -- and Steve perhaps can follow-up because he was a mover on this topic within the Subcommittee. But one is, obviously, to reduce the reporting requirements on the user, the end-user, but also the fact that the manufacturers and distributors who have a very intimate relationship with their end-users, with their customers, really are in a better position to accurately and expeditiously capture information on parent breakthrough, out of tolerance parent breakthrough, and that that would be a more effective conduit for collating information, rather than the information going from the end-user to the NRC. So, Steve, do you have any further comments you'd like to add on that point?

MEMBER MATTMULLER: I think you pretty well sum it up. The NRC is interested in getting information on breakthrough issues in generators, and

we feel that find a way that -- for the most accurate information and for the most expeditious information is for that information and report to come from the manufacturer to the NRC. As they've got it proposed now, there will be as we say 38 different routes because of NRC States and 37 Agreement States pathways for the information to make its way to the NRC. So it just makes far, far more sense for the manufactures because they're going to get this information anyway, to collate the information, and for them to send it to the NRC in a timely manner. So, thank you.

CHAIRMAN ALDERSON: Further comments on this issue?

MEMBER LANGHORST: Yes, this is Sue Langhorst.

CHAIRMAN ALDERSON: Okay, Sue, go right ahead.

MEMBER LANGHORST: Dr. Palestro, in addition to notifying the NRC and that -- within seven calendar days, within 30 days the licensee has to provide NRC with a written report on this incident. So if you've got -- let's say we have a bad batch of generators that go out to several different

licensees, well, you've got several written reports having to go to the NRC or to Agreement States and again work their way up, which if it's focused at the manufacturer's level, that licensee calls the manufacturer right away because they don't have a generator they can use right now, and they need one that they can use. And that report and written report which is more extensive as to why there was breakthrough on these generators going from the manufacturer to the NRC, or to Agreement States. And that's a much quicker, much more effective way of reporting this. And it does relieve licensees of having to write these written reports if they're having to notify the NRC. Thank you.

CHAIRMAN ALDERSON: Further comments on this clarification of the dual reporting requirement now being only to the manufacturers?

MEMBER PALESTRO: That answers my question. Thank you.

CHAIRMAN ALDERSON: Thank you. Thank you, Dr. Palestro. Other comments from other Members of the ACMUI?

OPERATOR: You do have one person queued up on the phone if you'd like to take that.

CHAIRMAN ALDERSON: If there are no other comments from Members of the ACMUI, I'd be happy to take a comment from a member of the public on the phone.

MEMBER MATTMULLER: Dr. Alderson, this is Steve Mattmuller; if I could just add one more comment to the past discussion in regards to generator reporting. This -- what we're proposing is also consistent with what's actually happening now with rubidium generators in that those users of rubidium generators report on a daily basis to the manufacturer already, whether it's good or bad. They're reporting their breakthrough results on every elution. So, Braaco already has this information, so if and when there's a problem, they're ready to go and would be able to put together a report very quickly and accurately for the NRC.

CHAIRMAN ALDERSON: Well, that's a good context, Mr. Mattmuller. Thank you. So we'll now go to the phone. Would the caller please identify themselves?

MR. FULLER: Excuse me, Dr. Alderson. Before we go to comments from members of the public.

CHAIRMAN ALDERSON: Yes.

MR. FULLER: This is Mike Fuller with the NRC Staff, and I would like to get clarification on a couple of things before we proceed.

CHAIRMAN ALDERSON: Absolutely. Go right ahead, Mr. Fuller.

MR. FULLER: Okay. Well, first of all, in your Subcommittee report you have a number of bulleted items, and I heard I think Dr. Langhorst, or perhaps Dr. Zanzonico say these are the Subcommittee recommendations. And then there's also things that we haven't seen today or talked about today that you refer to as a general comments. So my question is -- and, of course, we're going to -- everything that we receive after we have the deliberation, and after the Full Committee votes, everything we receive we are going to, obviously, review, and consider, and respond to. So my question is, you have whole nother list of things that you refer to as general comments, and I want to know if those are also recommendations that we should review and respond to, or if that's just background information?

VICE CHAIRMAN ZANZONICO: This is Pat. Mike, it's -- this is -- the general comments are

basically background material. In other words, there are no actual recommendations in the general comments that do not also appear among the bulleted points. We may reiterate those in the related general comments, but there are not specific recommendations or specific different or additional recommendations among those general comments. Those are basically background material, historical background, expanding on the thinking of the Subcommittee and so forth, but there are no additional or different recommendations among the general comments.

MR. FULLER: Okay. Thank you very much for that clarification.

My other question has to do with the conversation we had, and I think a different recommendation, although I'm not sure, that we just discussed having to do with the date of certification for certain Board Certifications. So one of the things that makes it difficult for us as we try to follow this discussion, it is not sure unless we receive something subsequent that captures these conclusions or these agreed to, voted on recommendations it's going to be difficult for us to understand what the recommendation is. For instance,

I heard Dr. Langhorst say that in addition to this recommendation, you know, that she recommends that the Staff consider including in guidance and so forth. It's very, very important to us that any recommendations that we receive today are actually in writing and it's clear that they were endorsed by the Full ACMUI, or else we are unable to take action on them. So I'm just cautioning everyone to please be clear that when you finally vote on something that everybody knows what you're voting on, and it's very clear to everyone exactly what the recommendations are. Because, for instance, recommending to the Staff that we include something in guidance, that's a little bit -- it's a difficult thing for us to deal with based upon a verbal recommendation, so it's just a caution.

VICE CHAIRMAN ZANZONICO: Mike, this is Pat again. Would it be possible, and this sounds more like a procedural issue but an important one. But would it be possible to vote on the report with the exception that we would table for the moment or for the time being the issue of the date of recognition of the Board? In other words, could we vote on all parts of the report excepting that item?

MR. FULLER: Yes, you could say as a motion that you are, you know -- someone make the motion that, for instance, all recommendations except for A, and B, and C, you know, be endorsed or what have you, or put forth. And then it would be clear to us. So, yes, you could do that, and that would be helpful if that's what you felt like you wanted to do.

CHAIRMAN ALDERSON: So I think that given the discussions we've had, I think Dr. Zanzonico has come up with a very good way to handle the lack of clarify Mr. Fuller discusses. Dr. Zanzonico, would you like to make a motion?

MR. FULLER: Well, wait a minute B

VICE CHAIRMAN ZANZONICO: I don't think we're up to that point yet.

CHAIRMAN ALDERSON: All right.

MR. FULLER: One other final thing to make clear is, if we receive -- we're going to move out and work hard to address all the recommendations that we hear today, and we're going to be working extremely hard to meet the deadline that has been established for getting the Draft Final Rule to the Commission for their vote. So, if you're going to

withhold a recommendation for further comment, and consideration, and deliberation, and so forth, I also would like to caution the ACMUI that there may not be an opportunity in this rulemaking to address those things, so just be aware that this is not an open-ended process. We have very, very specific milestones that we really need to make. We can address whatever the ACMUI provides us, absolutely.

CHAIRMAN ALDERSON: Well, one way to potentially move this forward, not necessarily to its conclusion, would be to actually consider a motion such as the one Dr. Zanzonico made to approve the remainder of the report with the exception of this item. Get that off the table, and then come back and decide among us if we would like to really hash out this item right here today on the call, or if we would like to put it off in some way knowing the risks that are involved. Would that be acceptable?

MR. FULLER: Absolutely. And then I have two other things that I'm prepared to discuss, but only if the ACMUI is interested. The topic of wrong treatment site and the term discontiguous versus what we have come up with in the Draft Final Rule. That is something that was discussed extensively amongst

the Rulemaking Working Group, and so I'm happy to provide you those perspectives. And also, the question about adopting the FDA package insert issues related to generator parent breakthrough issues, I'm also prepared to provide you with the Staff's perspective on that, as well, if you're interested.

CHAIRMAN ALDERSON: Yes, I believe it would be useful for the ACMUI to hear your perspectives on those important issues.

MR. FULLER: Okay. So with regards to the term discontiguous, the Working Group not only in this particular -- I say the Working Group, the Rulemaking Working Group which includes several different offices within the NRC and also Agreement State folks really considered that very term as well as another term that was considered, which was not adjacent to, and we understand that also back in a previous Rulemaking Working Group effort many years ago when this very same rule was being worked upon before it went in another direction, as we all are familiar with with regards to reproposals and so forth, that a different Working Group worked on those terms and had a lot of difficulty coming up with an understanding of what these terms would mean. And,

also, all agreed with I think the intent of where the Subcommittee was trying to go which was to add clarity. So we are very, very interested in making sure that inspectors do not confuse terms and require or expect of licensees things that were not intended in the rule. So for that reason, we wanted to get to what is the important, or what we believe to be the important aspect of this idea or concept of wrong treatment site. That's why we came up with the criteria, if you will, that the dose from a source that was directly implanted is clear to everyone was mistakenly placed at some place, in a place that is distance from the treatment site. So we heard the conversation about how some Authorized Users intentionally implant sources or seeds, you know, on the margins or outside of the actual tumor site and so forth, and that's why we're so very, very careful to say that Authorized Users define what their treatment site is. So in that case, the treatment site would include those sources.

So what we're trying to get at is a situation where it is clear that a source that was mistakenly directly implanted somewhere other than the treatment site or adjacent to or near, or

contiguous to the treatment site would be clear to inspectors, as well as everyone that this is a mistake. So, one of the things that we discussed amongst the Working Group was if you were an inspector and you saw something in reviewing records or cases and so forth that looked like it was outside of the intended -- by some significant amount outside the intended treatment site, then it would be incumbent upon that inspector, and this is something we will cover in training and guidance, it would be incumbent on the inspector then to ask the physicist hey, what's the story on this seed over here? And then allow the physicist to explain whether or not -- or the Authorized User whether or not that source was implanted and they believe it somehow contributes to the therapeutic dose. So that was our thinking behind it. Again, I'm not trying to say don't give us that recommendation because we'll be happy to take it up again, but I wanted to provide you with our thinking. It was not that we did not consider that, we considered it at great lengths.

With regards to the generator breakthrough and the recommendation that we follow the FDA package inserts for parent breakthrough

limits and so forth, that -- just for your information, that is a recommendation that would -- that is outside the scope of this current rulemaking, and if we actually -- well, we're happy to accept that recommendation and we'll work on it, and we'll write a response to it, but if we agree that we need to change that and we agree with that recommendation, it would require us to re-notice the rule. In other words, we would have to go back out and re-propose this rule -- I'm sorry, republish this rule for further public comment and public involvement. So it's just a matter -- it's just for your awareness and for whatever you deem appropriate as you continue to deliberate. And I'd be happy to answer any questions anybody has, but that's really all the points I wanted to make before you continue.

CHAIR ALDERSON: Yes, all right. So I B thank you for those comments, Mr. Fuller. And I would like to -- my reception of that is that it is clear that the NRC Working Group isn't happy with discontiguous. I want to ask Dr. Zanzonico as the representative and the Chair of the Subcommittee if he believes that we can pursue this discussion at this point, or if discontiguous should, in fact,

remain the recommend -- the advice and recommendation of the Subcommittee?

VICE CHAIRMAN ZANZONICO: I think this -- you know, since it's an issue of language, I think it's an issue we can address now. And I would like to defer, though, to Dr. Ennis. He was the author of that word, which I thought was a very good one, and is closest clinically to where this issue will arise. So, Dr. Ennis, what is your feeling on this?

MEMBER ENNIS: So first, I certainly want to thank Mike and the NRC Staff for all the work on this rule, and certainly I'm quite pleased with how it's developed in the big picture over all this time, so that at the outset. And I do think that everyone on this call who's been working on this rather recently is trying to find words to say the very same thing. So I do not feel like there is some kind of underlying disagreement, if you will, between what Mike just said and what his Committee has been wrestling with, and what our Subcommittee is trying to wrestle with. And I guess the concern that I have is once it's written and then it's out there, then people who are not involved in the conversations are ultimately going to interpret the language, and I'm

trying to find the language that will be as clear as possible and interpreted as accurately as possible to convey what we're trying to convey, which essentially is a seed that's really far away that obviously was not placed where it was supposed to be, is a problem, and is a medical event, but a seed that is part of the therapy is okay. But finding words to express that clearly for a regulator and an Authorized User who don't even speak quite the same language is a challenge.

I think that saying any dose which is the language now is problematic because I can envision the regulators saying well, it is contributing, or an Authorized User saying it's 10 centimeters away and it's the wrong breast but it is contributing a little bit of dose, so it's not a medical event. But I think that that would obviously be disingenuous, but hard to say that that's a problem based on the language. To throw in the word therapeutic dose, which is what Mike had just said is something that we talked about I think in our Subcommittee, and certainly crossed my mind, might be a little better, but it's also a little ambiguous because what does therapeutic exactly mean? Is 100 centigray

therapeutic? Well, a little. Is, you know, 100 centigray? Well, more. Right? And that's the problem here, so I think I remain feeling that word like discontiguous, meaning that the seeds are in an organ or something completely separate from the area of the implant and, therefore, couldn't really be placed there by the AU with the intention of actually contributing to the treatment is a good word for capturing that. And I do still feel, at least in my opinion, that it's superior to using dose or even therapeutic dose.

CHAIRMAN ALDERSON: Thank you for those comments, Dr. Ennis. Having just listened to this discussion, I want to ask about a phrase that occurred to me that all of you, Mr. Fuller and the NRC Group and our people probably have all thought about before and already discarded, but just let me throw it out there. What if it were something about a source that was outside of or beyond the intended treatment area? And that's very plain English, and I'm sure that an inspector would understand what that meant. How do people respond to that phrase?

MEMBER ENNIS: So let me describe clinical situation, and then see how you react to that. So

let's say I have a tumor along the psoas muscle in the retro peritoneum and I am implanting some seeds along that, and I decide that I need to put some seeds into the muscle but only a little part of the muscle. So how is that treatment site then defined? If it's defined by the seeds that I put in then we never have a medical event because the seeds define the treatment volume. If the treatment site is the tumor bed plus a couple of centimeters or something like that, then that is potentially a definition, but it becomes very ambiguous when another organ is partially implanted and partially not implanted.

CHAIRMAN ALDERSON: Right. And that was the reason -- the word that's in the phrase that I threw at you was intended and it would -- the question would then be if the radiation oncologist decided that a seed needed to be, I'll use your word, discontiguous because there was a treatment issue that was discontiguous and the seeds were thus properly placed at a somewhat minimally distant site for treatment purposes, that would be fine. On the other hand, if he or she were trying to implant the seeds along this facial plane that you described in the thigh, and a couple of seeds got away and they

wound up in the patella, that would not be an intended treatment site, and that would have to be a medical event.

MEMBER ENNIS: Right, so let me try again. I hear what you're saying and, you know, it's a fine line. But the way the treatment site term is used as I understand it means that area I'm trying to treat. We are now all understanding that doesn't necessarily mean an organ, it could mean an additional area around that organ.

CHAIRMAN ALDERSON: Right.

MEMBER ENNIS: And we call that, you know, CTV or planning target volume, things like that. But my point is that we often in radiation oncology are going to purposely put sources beyond the treatment site in order that the treatment site itself gets the full dose, or even more than the full, you know, some high dose or something like that, so one needs to put seeds outside of the actual treatment site and adequately treat the treatment site.

CHAIRMAN ALDERSON: Right.

MEMBER ENNIS: So now we're talking about coming up with another name for there's the treatment site, and then there's some other thing. And that's

creating a whole new verbiage that no one in radiation oncology or in the inspector/regulator space uses. And I don't know that we, you know -- that that's doable.

CHAIRMAN ALDERSON: Right. So the problem that tripped me up there in your case was how you define treatment area, but that's exactly what I was trying to convey by the phrase B

MEMBER ENNIS: Right.

CHAIRMAN ALDERSON: -- that I put up. So it would help to turn it around to say the area that needs to be treated, well, that would be fine, too. But if treatment area is above it -- but in any case, I have made my attempt to, you know, bring some new wording forward that might allow us to resolve this issue at this time, as Dr. Zanzonico suggested. So I will step back for a moment and let other people comment on this or other approaches to see if we can move to a resolution.

MR. OUHIB: This is Zoubir.

CHAIRMAN ALDERSON: Yes.

MR. OUHIB: I do have a comment actually going back to Mike's example, and certainly the case that you were just talking about. I think in the

language we need something in there that specifically states that excluding migrating seeds, because -- and it's a little bit tricky because, you know, when you say directly implanted. So it could very well be that the Authorized User was implanting the seeds directly into the target. Now that seed is about two centimeters away from the intended target, and now all of a sudden we have an issue. Well, how do you actually document what was directly implanted, what was -- what did migrate, and so on and so forth? So I think there's still some confusion in there.

MEMBER ENNIS: Could I speak?

CHAIRMAN ALDERSON: Please.

MEMBER ENNIS: Yes. So, I mean, this has been discussed quite a bit, Zoubir. And I think the language is used specifically for this purpose, and to avoid -- and to eliminate this concern is that it was directly implanted. If you're asking well, later on when a scan comes back and seed is seen many centimeters away, how would a regulator know? I guess that would be maybe something that Frank could speak to. I would assume that the thing -- there would be a conversation, did you directly implant, you know, or read him an operative note to see how the -- you

know, where the seed was directly implanted. But I believe the language is meant to be clear that it's only if it's directly implanted to specifically exclude the concern you have about, you know, migrating seeds.

MEMBER COSTELLO: This is Frank. Can I make a comment?

CHAIRMAN ALDERSON: Yes, Frank, please.

MEMBER COSTELLO: Yes. I think you could trust the Agreement State inspectors to approach this with some sense of reasonableness. I'm very supportive of the language discontiguous because another word we use where we often -- it's not hard to understand. And the question is if we would ask the physician or we ask the services well, what happened here, and that's what we would rely on. I don't think you'll really find inspectors, you know, instead of reading CT scans and looking for seeds, they rely on what they're being told by the licensee. I think the language really has to be clear to the medical practitioners. I'd worry less about how the inspectors interpret it, to make sure that it's clear for medical practitioners what it means so they know what to report. I think if it's clear to

practitioners as to what to report, then I think we've got good language. That's all.

CHAIRMAN ALDERSON: Good, thank you. Further comments on this? If there are no further comments and we have not agreed on different language, I think we're back to the point about whether the ACMUI wishes to make the word "discontiguous" part of its advice or recommendation, or whether it does not. I'd like to refer that to Pat Zanzonico to potentially make some motion or take an action here.

VICE CHAIRMAN ZANZONICO: I think -- it strikes me that the issue is elimination of the reference to a dose, to a radiation dose. There's some ambiguity there in terms of what sources are contributing what dose and are those doses therapeutically significant or not? And, you know, as the science changes and so forth, that could be a moving target. And I think introducing the concept of dose into the definition of an ME inherently has some ambiguity. I think Ron's suggested word of discontiguous is a good one, but frankly, I'm less concerned with sort of the word that describes the geographic distribution of the seeds than eliminating

the concept of dose as part of the definition of an ME. You know, I think discontiguous is as good as any. I'm sure there are equally good alternate words or phrases that can be used, but I think as long as we've eliminated the dependence of the ME definition on dose, anything that conveys the notion of a geographic distribution of seeds that is clearly to any reasonable observer beyond what was intended and beyond which could be justified by the AU or the AMP, I think is fine. So again, I'm not necessarily endorsing the word "discontiguous," just as long as we eliminate the dependence of the definition of ME on dose. Given that, as I say, I think discontiguous is as good a word as any.

CHAIRMAN ALDERSON: All right. So I hear you speaking in favor of making discontiguous part of the recommendation rather than trying to search for new wording. I do think that that is the issue before us at this particular time. Are there further comments from the Committee before we tell Mr. Fuller how we'd like to rule on this?

(No response)

CHAIRMAN ALDERSON: Hearing none, Pat, would you like to just make a simple motion in this

regard?

VICE CHAIRMAN ZANZONICO: Well, I would make a motion to adopt the ACMUI's -- the recommendation regarding the language for a wrong location medical event in permanent implant brachytherapy.

CHAIRMAN ALDERSON: Thank you.

VICE CHAIRMAN ZANZONICO: Namely, sealed sources implanted directly into a location discontiguous from the treatment site as defined in the Written Directive.

CHAIRMAN ALDERSON: Yes, fine, thank you. Now if I recall correctly, since this is a Subcommittee we don't need a second, so that particular motion is out there. I would like to hear any comments or discussion from all of -- any Member of the ACMUI who would wish to do so.

MEMBER LANGHORST: This is Sue Langhorst.

CHAIR ALDERSON: Yes, Sue.

MEMBER LANGHORST: I fully support the effort of removing dose from this language because that's what we worked so hard to get out of. So I agree with the use of discontiguous and removing any reference to dose.

CHAIRMAN ALDERSON: All right. So your comment is in favor of the motion that's on the floor at this time. Yes, thank you. Any other comments?

MEMBER SUH: Phil, this is John Suh.

CHAIR ALDERSON: John Suh, please.

MEMBER SUH: Yes. I also favor the use of the word "discontiguous." I think it conveys what we are trying to define as being a medical event. And I also strongly endorse eliminating dose definition as a proxy for medical event. So I think the word "discontiguous" is as good a word as any, and it relays what the -- you know, how you see clearly outside the intended treatment area is.

CHAIRMAN ALDERSON: Yes, so Dr. Suh also supports using discontiguous. Other comments from the ACMUI?

(No response)

MEMBER COSTELLO: Hearing none, I think we will take a vote on this issue. All those that are in favor of the retention of the word "discontiguous" and the continued support of the removal of dose from the definition say aye.

(Chorus of ayes)

CHAIRMAN ALDERSON: Those opposed? Any

abstentions?

(No response)

CHAIRMAN ALDERSON: Well, that passes unanimously, Mr. Fuller, so you have your advice on that one.

MEMBER ENNIS: Dr. Alderson?

CHAIRMAN ALDERSON: Yes?

MEMBER ENNIS: Could I just ask Mike one question?

CHAIRMAN ALDERSON: Certainly.

MEMBER ENNIS: Mike, to address Zoubir's concern about traveling seeds not directly implanted, is there a way -- and again, I'm a little unfamiliar with all the regulatory documents that go along with these types of things, so I'm relatively new, in guidance or something like that where NRC Staff could spell out that direct implantation, you know, is specifically meant to exclude as an ME an event where, you know, a seed got into the vasculature and traveled further away?

MR. FULLER: Yes, Dr. Ennis. In fact, I think I can do you one better. In the Draft Final Rule language we already have an exception for migrating seeds, so by definition a migrated seed is

not a wrong treatment site. So we already have that covered.

MEMBER ENNIS: Excellent. And I apologize, I probably read that but didn't remember it. Don't think I didn't read it.

MR. FULLER: That's okay. We do this all the time. I know you have other things.

CHAIRMAN ALDERSON: All right. Well, thanks everybody. I think we have our discussion and our vote on discontiguous. And the second issue that Mr. Fuller raised was this issue with respect to generator breakthrough, that this is outside the scope of this current rulemaking. If the ACMUI makes the recommendation that it has written, then the NRC would republish for further public comment. Again, giving the Chairman the prerogative, I'm going to go back to Pat and ask him to comment on this issue.

VICE CHAIRMAN ZANZONICO: Well, you know, at the risk of sounding dense, Mike, can you just reiterate, you know, can you crystalize for us once again the -- why the current recommendation is beyond the scope of the current rulemaking? I'm not quite understanding why that's the case.

MR. FULLER: Yes, I'll be happy to. So

first of all, a little bit about the process. It is -- we are happy to receive the recommendation. Okay? Then what we will do with that is we'll take that back, because we're going to reconvene the Working Group and go over all of these recommendations, so we will look at that. And if everyone agrees that it's outside the scope, and I'll get to that in just a minute, then we will respond that it's outside the scope, in which case we would not have to re-notice the rule for public comment.

Now again, not to prejudge, but I believe as a member of that Working Group that -- I think it's pretty clear to me that this is outside the scope of this current rulemaking. There were no changes on the breakthrough issue -- I'm sorry. The idea of having to require our licensees to follow FDA package inserts is contrary to another part of the rule which specifically says that, and for good reason, that NRC licensees are not required to follow all of the provisions of FDA-approved package inserts because again, it's the whole practice of medicine thing. So, it would require us to open that section of the rule, as well. So, that's one of the reasons why it's outside the scope.

The other thing is that it's really not -- while we are asking folks to report breakthrough, what constitutes breakthrough is not -- has not been opened in this current rulemaking. It only has to do with reporting breakthrough which is a different section of the regulations.

CHAIRMAN ALDERSON: Does that answer your questions, Dr. Zanzonico?

VICE CHAIRMAN ZANZONICO: So if I understand correctly, the reason why it's outside the scope of the current rulemaking is that if a reg were put on the books to follow the FDA recommendation, that would be some sort of intrusion on medical or pharmacy practice?

MR. FULLER: It could be, but the point is it's directly contrary to another section of the rule which says NRC licensees are not required to follow the FDA package inserts.

VICE CHAIRMAN ZANZONICO: Understood. It strikes me that it's a bit of a matter of semantics in the sense that, you know, it could -- there could be companion recommendation to change that language, as well. And I thought we actually had addressed that in the general comments on this point. Well, maybe

that was when I reiterated in the general comments your previous response on this point.

MR. FULLER: And that's the point I'm trying to make. Any changes in the Draft Final Rule that were not changed in the proposed rule that was published for public comment would have to be sent back out for an additional public comment period. And then we would review those comments, and then those would come back to the ACMUI for their review and -- so you see, this is -- again, we're happy to receive your comments. I do not want to discourage that, but I want you to know that we're -- anything that's outside the scope of the current rule that the Working Group might agree needs to be pursued would have to be re-noticed for additional public comment period, and then we start the process over again.

VICE CHAIRMAN ZANZONICO: Well, not again. Mike, we really -- we're all cognizant on the Subcommittee in drafting this report of the practical implications of what we were recommending on the timeline and this issue of having to reissue the rule and so forth and so on. And no one wants to prolong this process any longer than necessary, and I'm sure you all feel the same on the NRC. It's been going on

a long, long time. So really we're very aware of that, and very sensitive to that.

Having said that, we felt collectively that our obligation was to make a good faith recommendation on what we felt were the best way to go forward in finalizing this rule. So my feeling is, if there's not a conceptual issue countering our recommendation, I would think we should let our recommendation stand as is, and let the chips fall where they may. You know, and I don't say that cavalierly, and ignoring the practical implications of that, but I think we really are obligated to make our best good faith recommendation on these points, and not do otherwise for the sake of expediency.

MR. FULLER: Dr. Zanzonico, this is Mike, and I want to make sure that everybody understands. We are absolutely in alignment on that point. We are happy to receive any and all recommendations from the Advisory Committee on the Medical Uses of Isotopes, and we will be happy to review them in good faith and respond to them, you know, and like you said, and let the chips fall where they may. You're right, it is not -- the time frame and the schedule is not the most important thing here. I was simply trying to

point out what the potential consequences or impacts might be. But yes, we are happy to receive whatever you provide us, and we are very, very appreciative of all of your recommendations and comments.

VICE CHAIRMAN ZANZONICO: Understood.

CHAIRMAN ALDERSON: So for all of us listening in to this, Dr. Zanzonico has just -- as the Chair of the Subcommittee has just made the recommendation that we stay with the FDA language as it is currently cited in the recommendations, and Mr. Fuller has said that the Working Group would be happy to receive such a recommendation. Does anyone on the ACMUI have comments they would like to make on this issue?

MEMBER ENNIS: I do.

CHAIRMAN ALDERSON: Identify, please. I didn't hear who it was.

MEMBER ENNIS: Ron.

CHAIRMAN ALDERSON: Yes, Ron.

MEMBER ENNIS: Yes. For Mike, just so -- I think I understand, but just to be clear. Are you saying that if it ends up going down that pathway, the entire rule would have to be republished or just we're talking about the one section of the discussion

but the rest could go forward?

MR. FULLER: No, the rest could not go forward.

MEMBER ENNIS: Okay. So could I make another comment then?

CHAIRMAN ALDERSON: Yes, please. Go ahead.

MEMBER ENNIS: I'd like to hear then from Steve, in particular, about how important this issue is because while giving ideally our perfect recommendations, I do believe that we need to sometimes accept some imperfections to move things along. And it horrifies me, frankly, to think that we might at the 11th hour and 59th minute throw a monkeywrench into this proposed rule process for who knows how long. So I'd be reticent to support something that might do that unless I could be, you know, convinced that it's really important.

CHAIRMAN ALDERSON: Yes, go ahead, Steve.

MEMBER MATTMULLER: I'd like to keep the language as is because I think it's important that we're trying to move the NRC in the direction of good regulation, because I really think if this phrase was in the regulations it would make for much more effective regulation for the NRC. However, I think

Mike touched on an issue with regards to the scope of the rulemaking. And the initial scope in regards to the technetium generator I believe was scope of testing frequency, not necessarily the testing results, so I have a pretty strong hunch that even if we leave our language as is, the rulemaking group will say we like this idea, too, we'd like to incorporate it, but it's outside the scope of the rulemaking. So, hence, it's not going to work. And I would be okay with that because I agree with your previous comment, I do not want this proposed regulation to be delayed at all. I guess I would like a comment from Mike, if -- the chances are of this -- of our proposed language being deemed outside the scope?

MR. FULLER: Well, I think -- I can't really speak for the Working Group at this point, Mr. Mattmuller. I would just have to repeat what I said before. We will happily receive whatever recommendations we receive. Then we will come together as a Working Group, and that Working Group includes, like I said, folks from our Office of General Counsel, people from -- folks from the Agreement States, others, as well as the Program

Office, the Medical Team folks, and we will look, and we'll have to make a determination about whether or not it's in the B within the scope. I suspect that it's not, and then we'll have to decide whether or not it's in the best interest of everything to re-notice the rule and send it back out again, or whether we should send it along -- send the rule along the path that's been charted along with maybe a note to the Commission that this something that they could do. So I don't want to try to prevent -- it's not a dead issue at this point, but I would not want to predict today exactly what might come, but I think we could all assume that the appropriate considerations will be addressed looking at the big picture. I hope that helps, but that's probably about all I can say at this point.

CHAIRMAN ALDERSON: So to reiterate the issue as I have heard it, because there are other items in rules that already exist indicating that to follow the FDA in blanket is contrary to other general rules. I agree with the concept that this is likely to run afoul of the Working Group, and we just heard what will happen if that happens. It could either of two ways, but we run a risk that the entire

rulemaking would be rolled through another cycle. So, I do believe that we now have to make a decision as to whether we would wish to keep this language in the recommendation, or whether we would remove this language in the interest of the rest of the recommendation.

VICE CHAIRMAN ZANZONICO: Dr. Alderson?

CHAIRMAN ALDERSON: Yes, Dr. Zanzonico.

VICE CHAIRMAN ZANZONICO: This is Pat Zanzonico.

CHAIRMAN ALDERSON: Yes.

VICE CHAIRMAN ZANZONICO: Could I suggest -- I mean, Steve was the driver on this point, not surprisingly, Mr. Mattmuller was the driver on this point. And if I understood from the last comment, he voiced some flexibility on the point. So if we eliminated this as a recommendation, but included it in our general comments, not as a recommendation, but for future consideration by the NRC that they consider compliance or conformity with FDA regulations on parent breakthrough, we would have made that point on the record, but not in the form of a recommendation. So the NRC would not have to respond to it in the current rulemaking cycle, and

it would not require re-noticing the rule; yet, we would have made that point on the record in other than a recommendation form. Would the Members of the Subcommittee, in particular Mr. Mattmuller, deem that acceptable?

MEMBER MATTMULLER: Yes, I would.

MEMBER LANGHORST: This is Sue Langhorst. I wouldn't. I think our recommendations are our recommendations, and the NRC can choose to accept them or not accept them. So I don't think it'll be addressed unless we have it as a recommendation.

MEMBER ENNIS: This is Ron. I would support the change you just suggested, Pat.

CHAIRMAN ALDERSON: Others?

MEMBER COSTELLO: This is Frank. Can I ask Mike a question?

CHAIRMAN ALDERSON: Yes.

MEMBER COSTELLO: Okay. I'm still troubled understanding this within the scope, without the scope, and the Working Group. If the Working Group were to decide that this was within the scope and they like the idea, could they just adopt it without re-noticing it?

MR. FULLER: Theoretically yes, Frank;

however, that's not like -- that can't happen because it's clearly outside the scope.

MEMBER COSTELLO: Okay. If the Working Group decides it's outside the scope and they think it's a bad idea, can they just reject it out of hand?

MR. FULLER: Yes.

MEMBER COSTELLO: Okay. So the problem becomes if the Working Group thinks it's outside the scope, but they think it's a good idea. Is that the -- is that how we would wind up having to re-notice it?

MR. FULLER: Yes, that's the most immediate path.

MEMBER COSTELLO: That they think it's outside the scope but it's a good idea.

MR. FULLER: And we would have to propose in the Draft Final Rule to the Commission that it go out and I believe it would be re-noticed. I've got my -- we have an attorney sitting here right next to me. In other words, would that be a decision that the Staff could make to re-notice the rule, or would the Commission have to vote to re-notice the rule?

MS. HOUSEMAN: I have -

MEMBER COSTELLO: Okay, so it would not

have to go to the Commission, the Staff could decide to re-notice -- counsel would have to at least consult with the Commission. Correct?

(Off microphone comment)

MEMBER COSTELLO: Okay.

MS. HOUSEMAN: So you would probably want to give the Commission a head's up before you even start going down that route -

MEMBER COSTELLO: Right.

MS. HOUSEMAN: -- a proposed rule to go out for comment, because if it's outside the scope then that is a proposed rule.

MEMBER COSTELLO: Okay. Could it go up to the Commission with the ACMUI recommendation as it is, but with the Staff not accepting it, and then the Commission either accepts it or they don't accept it?

MR. FULLER: Yes, and that's exactly what we did on the proposed rule with regard to compatibility. That's exactly what the Commission did.

MEMBER COSTELLO: Okay. So that the Commission -- so if we went that path, we would still make -- get a recommendation in there and the Commission would decide, and they would not have to

go out for comment any more.

MS. HOUSEMAN: No, that's not the case. The Administrative Procedure Act is going to require notice and comment on that proposed rule regardless of what the Commission's position is on whether it should be adopted, regardless of the Staff's position, because if it's something that the public has not received notice of and an opportunity to comment on, then you can't just go out and adopt it.

MEMBER COSTELLO: Okay. In that case, I would be in favor of withdrawing the recommendation.

MS. HOLIDAY: Esther, can you identify yourself for the court reporter?

MS. HOUSEMAN: Yes, this is Esther Houseman with OGC.

MS. HOLIDAY: Thanks.

MEMBER COSTELLO: I regret it, but I don't want to delay the rule any more.

CHAIRMAN ALDERSON: So we seem to have Members of the ACMUI who believe that they could go with a compromise and withdraw, and others who said they would not. So I'm going to ask for other comments, and then I'm going to try to bring you to a vote on this because this is a pretty important

question and has sort of the whole rule floating out here in limbo at the moment. Further comments on this issue?

MEMBER MATTMULLER: This is Steve Mattmuller, again. I'm in favor of Pat's suggestion of moving it to a general comment. Primarily -- I mean, a lot of my impetus for pushing in this direction was to have the NRC to have relevant regulations that reflect accurate practice or current practices in nuclear medicine and nuclear pharmacy. Even if they don't adopt our language those contemporary compliant practices are going to continue. It's just that the NRC regulations will still be a little bit out of touch. So from a safety perspective, life will still be safe in nuclear medicine, so I'm -- you know, with the possibility of delaying this whole process just one more month is just so unpalatable, I really don't even want to give or create a chance for that to happen. So it's somewhat reluctant, as you know I've been passionate about this, but I would agree with Pat's recommendation.

CHAIRMAN ALDERSON: And, Frank, will you accept moving it to a general comment?

MEMBER COSTELLO: Absolutely.

CHAIRMAN ALDERSON: Mike Fuller, if this is moved to a general comment, does this remove the problem?

MR. FULLER: Yes, I believe so. Again, as long -- and this is something we were going to say in a moment. If you move it to the general comments, please make it clear in the final written report that we receive that general comments are not recommendations of the ACMUI, and then that would be fine.

The other thing to keep in mind is once you're on the record whether it be in general comments or recommendations and so forth, we will capture that for consideration for future rulemaking. So either way you go, it will be captured, and if not in this rulemaking, in a future rulemaking.

CHAIRMAN ALDERSON: So, Pat Zanzonico, are you willing to put your motion out there again? I think we're -

VICE CHAIRMAN ZANZONICO: Yes. So the motion is to remove as a recommendation that the NRC adopt the parent breakthrough limits for radioisotope generators specified in the relevant FDA-approved

package inserts, remove that as a recommendation and include a comment to that effect, but not as a recommendation, in the general comments. That is the motion.

CHAIRMAN ALDERSON: Okay, further discussion before we decide to vote on this?

(No response)

CHAIRMAN ALDERSON: Hearing none, all those in favor?

(Chorus of ayes)

CHAIRMAN ALDERSON: Opposed?

MEMBER LANGHORST: Nay.

CHAIRMAN ALDERSON: That's one vote nay, and that means that the ayes have it, so this recommendation passes, and it will go to the general comments section. And there will be a clear notification in the whole document that things that are in the general comments are not recommendations. So that took care of those two points.

The one point that we still have pending before us that we haven't resolved because we got off onto these two points when it was being discussed was this issue of Board certification, and the fact that a number of commenters suggested that that issue

needed further discussion, and wasn't ready to be included. So, Mr. Fuller, if that issue were withdrawn at this time, would that cause any problem with the approval of the rule, the recommendations?

MEMBER LANGHORST: Dr. Alderson?

CHAIRMAN ALDERSON: Yes.

MEMBER LANGHORST: This is Sue Langhorst.

CHAIRMAN ALDERSON: Yes, Sue.

MEMBER LANGHORST: I did send a slight rewrite to Pat, Dr. Zanzonico and to Ms. Holiday on that point, but I think that could be something that is put in general comments also, because it mainly recommends that NRC consider providing guidance on these individuals who are Board Certified before NRC recognition on ways they can become authorized.

CHAIRMAN ALDERSON: All right. And are you making that as a motion we should consider?

MEMBER LANGHORST: I'm making that as a motion. I don't know if you want to look at that language, or you want me to read the language?

CHAIRMAN ALDERSON: I think you should read the language to us, please.

MEMBER LANGHORST: And, Pat, I don't know if you've had a chance to look at it.

VICE CHAIRMAN ZANZONICO: I'm looking at it now, Sue.

MEMBER LANGHORST: If you're okay with that, I'll go ahead and read it.

VICE CHAIRMAN ZANZONICO: Yes, please do.

MEMBER LANGHORST: All right. Let me bring that back up. So I wrote, "The ACMUI previously recommended the date of the certifying Board not impact individuals seeking to be an Authorized individual." That was the 2013 number 8 ACMUI recommendation. This recommendation was not accepted for inclusion in the Draft Proposed Rule and the Draft Final Rule. The Subcommittee recommends that NRC Staff consider providing guidance in the NUREG-1556, Volume 9 update to licensees on the ways individuals with these Board Certifications prior to NRC Board recognition may seek authorization.

CHAIRMAN ALDERSON: Sue, I think that's nicely done. I think that much of the beginning of that is what would usually come under one of the clauses as a ''Whereas''. It's like a background statement, and the actual idea is to -- for the NRC to consider guidance on this issue. Do you agree with that?

MEMBER LANGHORST: Yes, but I thought it was important that we have made that recommendation before and it was not accepted by NRC Staff, so I just wanted that to be clear and in general comments that's background information.

CHAIRMAN ALDERSON: Yes.

MEMBER LANGHORST: So you want a whereas in front of it?

CHAIRMAN ALDERSON: Well, that's the way these things are often worded. It's background, for background, you could say for background if you don't like whereas. This, and this, and this happened in the past; therefore, we at this time would, you know, suggest that the NRC consider guidance, and then you put your other words in with it.

MEMBER LANGHORST: Well, since it's not a recommendation I can work with Pat on what that wording is.

VICE CHAIRMAN ZANZONICO: But, Sue, if I understood the latter part of the statement which I think is really excellent is in the form of a recommendation. And I think it merits being included in the recommendations. Whether we include those first two sentences in the bulleted point or in the

general comments, you know, is debatable, but I think including the last sentence as an actual recommendation is worthwhile.

MEMBER LANGHORST: Okay.

MR. FULLER: Just for clarification, this is Mike Fuller. We're fine with that, as well.

CHAIRMAN ALDERSON: And, Mike, does this particular item as a recommendation, does that threaten the entire document as the previous issue did?

MR. FULLER: No, because you're recommending that we develop the guidance and we will take that and do it. I mean, our -- in other words, the recommendation to develop guidance and so that will not be considered as a recommended change to the Draft Final Rule language, and it will be handled accordingly.

CHAIRMAN ALDERSON: Okay. All right. So I think in interest of coming to a conclusion here we should try one more time to agree on the sort of language this is going to be, and then we should vote on that. So, Pat, do you want to take a shot at it?

VICE CHAIRMAN ZANZONICO: Yes. And I would just parrot the last sentence in what Sue just read.

"The Subcommittee recommends that NRC Staff consider providing guidance in the NUREG update for licensees on the ways individuals with Board Certifications prior to NRC's Board Recognition date may seek authorization." And that would replace the recommendation in the Executive Summary that read, "The Subcommittee recommends the date of recognition by the NRC of a Certifying Board should not impact individuals," so forth and so on.

CHAIR ALDERSON: Yes.

VICE CHAIRMAN ZANZONICO: That the last sentence in Sue's writeup replaces that recommendation.

CHAIRMAN ALDERSON: Sue, will you accept that?

MEMBER LANGHORST: Yes.

CHAIRMAN ALDERSON: Other comments from Members of the ACMUI?

(No response)

CHAIRMAN ALDERSON: Hearing none, let's vote. All those in favor of accepting this approach say aye.

(Chorus of ayes)

CHAIRMAN ALDERSON: Opposed? Abstentions?

(No response)

CHAIRMAN ALDERSON: Hearing none, that is what will happen. Thank you very much. I believe that those were the issues that we had pending. Back to Mr. Fuller now, are there other comments from the NRC Staff relating to other issues in the document?

MR. FULLER: No, not related to any of the other issues. And I will remind you, Dr. Alderson, I think early on in this teleconference there was a comment, or a member of the public that wanted to make a comment.

CHAIRMAN ALDERSON: Yes. In fact, that's where I intend to go now given that the ACMUI and the Staff have made their comments. So I would now like to go back to members of the public who might be on phone lines, particularly the member who was -- who has so patiently waited if they're still on the line before, so would that member please identify themselves and make their comment?

OPERATOR: And just a reminder, hit *1 and record your name if you would like to make a comment or ask a question. We have Ralph Leito queued up. Go ahead, Ralph, your line is open.

MR. LEITO: Thank you. I wanted to support

the Committee's recommendation regarding eliminating date of recognition by the NRC of Certifying Boards, but I had a specific question and maybe recommendation regarding the item regarding -- dealing with the breakthrough limits.

My question is to Mr. Fuller. Mike, is the issue the fact that the recommendation specifies the FDA-approved package insert? That's what it sounded like it dealt with.

MR. FULLER: Yes, that's part of it, Mr. Leito, but I think based upon the recommendations that we have now received, I think it might be somewhat B

MR. LEITO: Well, if they take this out of a recommendation and just a comment, does that mean this would remove any type of reporting requirement?

MR. FULLER: No, the reporting requirement is still there.

MR. LEITO: But it would -- the criteria for reporting would be removed. Correct?

(Off microphone comment)

MR. FULLER: Yes, the criteria is what is currently in the rule. That has not changed, and it

was not proposed to be changed. That's why B

MR. LEITO: Well, the limits -- I mean, the limit -- the criteria for reporting is the action level order limits. Correct?

MR. FULLER: Correct.

MR. LEITO: So you're saying it has to be reported but you're not going to specify what is the criteria for reporting.

MR. FULLER: No, it's already in the rule. It has not been proposed to be changed; therefore, it stays as is in the current rule, the one that's on the streets today.

MR. LEITO: But there's not a specified limit say for the -- for other generators that would come along.

MR. FULLER: Correct. Those would be -- we would have to develop customized licensing guidance for that.

MR. LEITO: I guess my question would -- could I pose a question to Mr. Mattmuller regarding this?

CHAIRMAN ALDERSON: Please do.

MR. LEITO: Steve, would -- if they remove the recommendation referencing the inserts and said

something like manufacturer's recommendation or if there's limits specified say in the U.S. Pharmacopeia wouldn't that be appropriate?

MEMBER MATTMULLER: In my mind yes, it would be appropriate, but I think in reference to comments that Mr. Fuller has made previously in regards to the scope of the rulemaking, that it was initially pointed in the direction of frequency of testing, especially for the -- or only for the technetium-99m generator, that it never addressed the actionable limit. And then for our recommendation tends to point or push them towards what the actual action limit should be especially for the rubidium generator, and then that would also include any future generator that would come along and would allow them to regulate on a very timely basis. So while I'm still emotionally in favor of our recommendation, given the big picture of trying to keep this moving along, I'm willing to make it a general comment.

MR. LEITO: I can understand not wanting to have to wait another 10 years.

One of the -- I have a question regarding the -- it's on page 3 of your recommend -- I think

it's the last bulleted recommendation where you said that -- this is I guess addressed to probably Sue Langhorst and Pat, that the wording got reversed on your recommendation. Does that mean your first quote there is supposed to be reversed with the other one, and that the recommendation is, "A licensee shall report any event from patient intervention." Is that what you're recommending, or the quote above it?

VICE CHAIRMAN ZANZONICO: No. And, Sue, correct me if I'm wrong because I don't want to make a second mistake. What we're recommending is the first quote, "A licensee shall report as a medical event any administration requiring a Written Directive." So it's less inclusive than the second quote, and it's that first quoted statement that we're recommending.

MR. LEITO: So that would mean if it -- if an administration not requiring a Written Directive B let me rephrase it. Only medical events requiring a Written Directive have to be reported. Is that correct?

MEMBER LANGHORST: Dr. Alderson, may I speak? This is Sue Langhorst.

CHAIRMAN ALDERSON: Please go ahead, Sue.

MEMBER LANGHORST: Okay. Ralph, my point here is the same point that Mr. Fuller was making, is that the words in the Draft Final Rule should not revert back to the previous rule because they did not include that wording in the Draft Proposed Rule. The Draft Proposed Rule, the wording is that first one, and so what I took issue with is that NRC proposed a Draft Rule that had the wording, "A licensee shall report as a medical event any administration requiring a Written Directive," and so on. They should not at this late date change it back to what the current rule says without public comment on that, because proposed this change. I don't think anybody commented on it, and they shouldn't then revert back to what they had before. So that was what I was concerned about.

MR. LEITO: Okay, because I -- if I'm interpreting this first statement which you're recommending that they should keep, if I had a diagnostic administration, intended to be a diagnostic administration and they ended up giving a dose that exceeded the dose level reporting for a medical event, I wouldn't have to report it because it didn't require a medical directive.

MEMBER LANGHORST: A Written Directive, and that is what was proposed in the Draft Rule. So if you look at that document of the Draft Final Rule, it's on page 232, and it's about -- near the top. NRC has written there what their proposing to change from what they printed in the Draft Proposed Rule. And I think that change was significant enough that that requires public comment again. So that's why we were not supportive of NRC returning to the current language that's in the current regulations but what they published in the Draft Proposed Rule.

MR. LEITO: Okay. I understand your point now. I just find it interesting that there's categories of medical events that would not probably have to be reported now.

MEMBER LANGHORST: That's correct.

CHAIRMAN ALDERSON: Other comments?

MR. LEITO: Thank you.

CHAIRMAN ALDERSON: Other comments? Further questions, Mr. Leito?

MR. LEITO: Appreciate the opportunity to ask questions and get some clarification.

CHAIRMAN ALDERSON: Thank you. Are there other members of the public who would like to make a

comment?

MS. KIM: Yes, hi. Can you hear me?

CHAIRMAN ALDERSON: We can hear you. Please identify yourself.

MS. KIM: Yes. My name is Yungmi Kim, and I'm with Spectrum Pharmaceuticals. I wanted to thank you and appreciate the review of the ACMUI and the NRC Staff on the training and experience requirements for beta-emitters, but are disappointed that the Draft Final Rule does not include a change to the 700-hour training requirements to allow the hematologists and oncologists to become Authorized Users.

Spectrum and other stakeholders request that the NRC lower the 700-hour requirements to 80 hours similar to sodium iodine I-131. We would like to urge the Commission to wait to finalize this rule until the following -- following the March 17th-18th ACMUI meeting on the appropriate level of training and experience for these therapeutic radiopharmaceuticals. Thank you.

CHAIRMAN ALDERSON: Comments? It is my impression that in fact we are going to discuss that issue at the March meeting of the group.

MS. KIM: Okay, thanks.

CHAIRMAN ALDERSON: Other comments from the ACMUI to Dr. Kim?

(No response)

CHAIRMAN ALDERSON: Hearing none, are there other members of the public who would like to comment?

MR. GUASTELLA: Dr. Alderson, can you hear me?

CHAIRMAN ALDERSON: I can hear you. Identify yourself, please.

MR. GUASTELLA: This is Michael Guastella, and I'm the Executive Director of the Council on Radionuclides and Radiopharmaceutical. And I'd just like to briefly reiterate and reinforce what Yungmi just commented on. CORAR is also disappointed that the Draft Rule did not include a change in the 700 hours. There have been a number of stakeholders that have requested that the NRC lower the 700-hour requirement to something approaching the requirement for I-131. I believe that's approximately 80 hours. And we would also -- CORAR would also urge the Commission to wait to finalize the Final Rule, consider the report following the March 17th-18th

ACMUI meeting on the appropriate level of training and education, or experience, excuse me, for these therapeutic radiopharmaceuticals to what we believe will help improve access to these important drugs. Thank you very much.

CHAIRMAN ALDERSON: Yes, thank you. Given the late hour here, I'm going to ask for -- if there's one more public comment. This would be the last public comment. Is there another person on the line who wishes to speak?

OPERATOR: We actually have no further people from the public.

CHAIRMAN ALDERSON: No further members of the public. Then I believe we are at the point in this discussion where the NRC would like to make some comments to us, so I think this is back to the NRC.

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

CHAIRMAN ALDERSON: Yes, Sue.

MEMBER LANGHORST: Don't we need to vote on the whole report?

CHAIRMAN ALDERSON: You're quite right. I'm sorry, that's a mistake on my part.

MEMBER LANGHORST: Okay, just being there

for you.

CHAIRMAN ALDERSON: Well, thank you, a couple of St. Louisans staying together on this issue. Okay, you're right. So having completed the discussion and listened to the public comments we are now ready to vote on the recommendations as amended in this discussion. All those in favor?

(Chorus of ayes)

CHAIRMAN ALDERSON: Are there any opposed? Are there any abstentions?

(No response)

CHAIRMAN ALDERSON: Hearing none, then the recommendations as amended are approved.

Now I believe that we are ready to turn this discussion back to Mr. Bollock and the NRC who have something they'd like to go over with us.

MR. BOLLOCK: Thank you, Dr. Alderson. And yes, another objective of today's public teleconference was to hear from the public any views on the NRC's policy on Cumulative Regulatory Effects or commonly referred to as CRE. We are interested specifically in hearing from members of the public any views on whether or not the proposed 180-day implementation period is adequate. We received a few

comments on this issue when we published the Proposed Rule, and this is another opportunity for members of the public to express their views on whether or not 180 days is an adequate amount of time to implement the new rules once they are published, or after they are published.

CHAIRMAN ALDERSON: So, Mr. Bollock, are you suggesting that you would like the members of the public on the call at this time to comment on that issue?

MR. BOLLOCK: If there are any members of the public on the call at this time who would wish to provide us with their comments, we are prepared to receive them, yes.

CHAIRMAN ALDERSON: Are there any such comments to be made? Are there any members of the public still on the call?

OPERATOR: Showing nobody queuing up at this time.

CHAIRMAN ALDERSON: Nobody queuing up. Mr. Bollock, it seems that there are no more members of the public on the call.

MR. BOLLOCK: Thank you.

CHAIRMAN ALDERSON: So I think we cannot

pursue this particular issue with the public at this time.

MR. BOLLOCK: No, we just wanted to open it up for their comments if they had any.

CHAIRMAN ALDERSON: Okay, so there were no comments to be made. Are there other items of business to be brought before this conference call?

MR. BOLLOCK: No.

MEMBER COSTELLO: Yes, this is Frank.

CHAIRMAN ALDERSON: Yes, Frank.

MEMBER COSTELLO: I should have spoken up earlier. The two members of the public suggested that the rule not be published in final until the -- after the March 17th and 18th meeting of the ACMUI to discuss the recommendations of our Subcommittee on necessary training for alpha-emitters. I think that's a reasonable request that we have the Subcommittee, and I don't know what the purpose of the Subcommittee would be if the rule is already gone and they can't do anything about it, so I would think if we waited, you know, for like I guess two months I guess it would be for the Subcommittee to report, I think we'd be doing the public a service by doing that. End of my comments.

CHAIRMAN ALDERSON: Yes, it has fairly major implications.

MEMBER COSTELLO: Mike, could you speak to that?

CHAIRMAN ALDERSON: Mike Fuller, would you comment on the effect of that if that were to be done?

MR. BOLLOCK: Actually Mike or I could speak on this, but basically the reason we don't want to do that is because what we have now in the regulatory relief that the current rule would give will be out this year with, you know, after your recommendations and comments are vetted and reviewed by the Working Group and we send that up to the Commission, and they vote. It can go out within month of March. Withholding the rule until after the March ACMUI spring meeting would not -- it would delay the rule not just a few months to then put it up to the Commission, but anything that comes out of that would have to be then proposed because it's outside the scope of this rule. To be proposed, goes through public comment, come back as a final, go through comment again, be reviewed by you, be reviewed by the Agreement States, and would be delayed two years. So

based on what we have now which we're months away and it's been fully vetted for the past few years we would be putting that on hold for one new thing.

MEMBER COSTELLO: This is Frank. Then in that case, I withdraw my comment. Thank you.

CHAIRMAN ALDERSON: Thank you, Frank. I think that's the right thing to do. And I don't think we need to discuss -- he has withdrawn the comment so we don't need to comment further on the fact that he does not have a comment to make at this time.

Are there any other items of new business to come before the Committee or the ACMUI today?

(No response)

CHAIRMAN ALDERSON: Hearing none, is there a motion to adjourn?

MEMBER ZANZONICO: Motion to adjourn.

CHAIRMAN ALDERSON: Sure. And I don't think we need a second. All those in favor?

(Chorus of ayes)

CHAIRMAN ALDERSON: Thank you everyone for a lengthy excellent, to the ACMUI, to the NRC, excellent conference call today, and hopefully now we'll be able to move forward with this important business of rulemaking.

Thank you, everyone, and I believe that ends the calls.

(Whereupon, the proceedings went off the record at 4:21 p.m.)

JOSEPH J. HECK
3RD DISTRICT, NEVADA

COMMITTEE ON
ARMED SERVICES

EDUCATION AND
THE WORKFORCE COMMITTEE

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January 5, 2016

Ms. Sophie Holiday
Advisory Committee on the Medical Use of Isotopes
Subcommittee on Training and Experience for Alpha and Beta Emitters
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Dear Subcommittee Members:

As you are aware, the Nuclear Regulatory Commission (NRC) regulates the medical use of radiolabeled products to treat cancer and other life threatening diseases. The NRC's regulations require that a physician treating patients with a therapeutic radiopharmaceutical must be licensed as an "Authorized User." My office has heard from patient advocates and physicians about the shortage of Authorized Users and the barriers to patient access to these life-saving cancer treatments such as Zevalin, a beta-emitter treatment for patients with non-Hodgkin's lymphoma.

The NRC's proposed rule on the "Medical Use of Byproduct Material—Medical Event Definitions, Training and Experience, and Clarifying Amendments" (RIN: 3150-AI63 [NRC-2008-0175]) intended to address related issues, including shortages of authorized users, the classification of radiopharmaceuticals and associated work experience requirements. In its rulemaking, the NRC specifically requested comments on whether its regulations "*discourage licensees from using certain therapy options or otherwise adversely impact clinical practice, and if so, how.*" On March 2, 2015, I offered my comments as a physician and as someone trained in the Medical Effects of Ionizing Radiation by the Armed Forces Radiobiology Research Institute. However, on December 29, 2015, the NRC released its draft final rule, which failed to include any changes to the training and experience requirements for authorized users of therapeutic radiopharmaceuticals.

I write today to restate my concerns with the burdensome Authorized User requirements and to request ACMUI work to establish a more equitable training requirement for physicians wishing to administer therapeutic radiopharmaceuticals, in order to ensure patient access to these drugs.

The NRC's current regulatory framework requires that most hematologists and oncologists who want to become Authorized Users must complete 700 hours of training and experience, including a minimum of 200 hours of classroom / laboratory training in radionuclide handling techniques. This training requirement has created a shortage of Authorized Users able to administer therapeutic radiopharmaceuticals, particularly in the community oncology setting. Outside of major academic medical centers, patients sometimes have to travel great distances in order to

find Authorized Users able to administer these products. For patients living in rural areas, especially elderly patients with mobility difficulties, these barriers can be insurmountable. The regulations have the effect of limiting the treatment options available to these cancer patients.

The Spring 2016 ACMUI Meeting on March 17th presents another opportunity for the NRC to address the current shortage of Authorized Users able to administer these anti-cancer therapies. By creating a training requirement commensurate with the precautions necessary to administer these products, the NRC can ensure that products are handled safely and appropriately, while ensuring all patients can access these treatment options. I understand that there is precedent in the NRC regulations for reduced training and experience requirements for products that pose minimal safety and handling risks prior to and after administration. For example, the regulations require only 80 hours of classroom and laboratory training in order to administer oral sodium iodide I-131.

As the Committee reviews the subcommittee report on Authorized User training and experience hour requirements for alpha- and beta- emitters, I strongly urge the you to seriously consider the information provided regarding the shortage of Authorized Users able to administer alpha- and beta-emitting products, and to make a recommendation to the NRC that reduces the training and experience requirements to a level appropriate for these lower risk products. This will increase access to critical, life-saving therapies without exposing patients or providers to any significant risk.

I appreciate your consideration and look forward to being updated as the process moves forward.

Sincerely,

Joe Heck, D.O.
MEMBER OF CONGRESS

cc: The Honorable Fred Upton, Chairman, House Committee on Energy and Commerce