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NUCLEAR REGULATORY COMMISSION

Title: Advisory Committee on the Medical Uses of Isotopes

Docket Number: (n/a)

Location: Rockville, Maryland

Date: Thursday, May 7, 2009

Work Order No.: NRC-2797 Pages 1-323

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NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

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THURSDAY, MAY 7, 2009

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The meeting was convened in the auditorium of Two White Flint North, 11545 Rockville Pike, Rockville, Maryland, at 8:00 a.m., Leon S. Malmud, M.D., ACMUI Chairman, presiding.

MEMBERS PRESENT:

LEON S. MALMUD, M.D.	Chairman
DOUGLAS F. EGGLI, M.D.	Member
DARRELL FISHER, PhD	Member
DEBBIE GILLEY	Member
MILTON GUIBERTEAU, M.D.	Representative
RALPH P. LIETO	Member
STEVE MATTMULLER	Member
SUBIR NAG, M.D.	Member
ORHAN SULEIMAN, PhD	Member
BRUCE THOMADSEN, PhD	Member
WILLIAM VAN DECKER, M.D.	Member
RICHARD J. VETTER, PhD	Vice Chairman
JAMES S. WELSH, M.D.	Member

NRC STAFF PRESENT:

ROB LEWIS	Director, MSSA
CHRIS EINBERG	Branch Chief, RMSB
CINDY FLANNERY	
STEVEN BAGGETT	
NEELAM BHALLA	
ASHLEY COCKERHAM	
DONALD COOL, PhD	
LEIRA CUADRADO	
CASSANDRA FRAZIER	
SANDY GABRIEL	
DONNA-BETH HOWE, PhD	
DORIS LEWIS	
ED LOHR	
PATRICIA PELKE	
GRETCHEN RIVERA-CAPELLA	
MARK SCHAFFER	
MARK THAGGARD	
GLENDA VILLAMAR	
DARREL WIEDEMAN	
DUANE WHITE	
RON ZELAC, PhD	

MEMBERS OF THE PUBLIC PRESENT:

GARY BECKER, ABR (PHONE)

KEVIN CROWLEY, NAS

MEMBERS OF THE PUBLIC PRESENT CONT.

MELISSA CACIA, AACE (PHONE)

ROBERT DANSEREAU, NY (PHONE)

WILLIAM DAVIDSON, U OF PENN (PHONE)

RICHARD EATON, MITA

LYNNE FAIROBENT, AAPM

BONNIE HAMILTON, MDS NORDION

KAREN LANGLEY, UT (PHONE)

MATTHEW MAURO, SIR

KATRINA MILLER, AACE (PHONE)

MIKE PETERS, ACR

DOUG PFEIFFER, AAPM

GLORIA ROMANELLI, ACR

JOE RODGERS, THERAGENICS (PHONE)

RIAD SALEM, SIR

REED SELWYN, UNIF. SVCS. UNIV. OF HLTH. SCI.

BRIAN STAINKEN, SIR

STEPHEN THOMAS (PHONE)

KEN THURSTON, SIRTEX

CINDY TOMLINSON, SNM (PHONE)

ANN WARBICK CERONE, MDS NORDION

EMILY WILSON, ASTRO

JENNIFER YOUNG, AACE (PHONE)

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P-R-O-C-E-E-D-I-N-G-S

8:00 a.m.

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

My name is Chris Einberg. I'm the Chief of the Radioactive Material Safety Branch and I have been designated as the Federal Officer for this Advisory Committee, in accordance with 10 CFR, Part 7.11.

Present today as the Alternate Designated Federal Officer is Cindy Flannery, Team Leader for the Medical Radiation Safety Team.

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

The meeting was announced in the April 2, 2009 edition of the Federal Register, Volume 74, page 15313.

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

As part of the preparation for this meeting, I have reviewed the agenda for members and interests based on the very general nature of the discussions that we are going to have today and tomorrow.

During this meeting, the Committee will discuss the National Council on Radiation Protection and Measurements Report 160, ionizing radiation exposure of the population of the United States.

Three members of the Committee were identified as contributing to certain sections of this report. The identified contributors are Dr. Bruce Thomadsen, Ms. Debbie Gilley and Dr. Orhan Suleiman.

These individuals can provide factual information and answer questions on these sections of the report that they worked on. However, they should

not make any recommendations to the Committee or staff on these specific sections.

Additionally, these members may advise the Committee or staff on those sections of the report which they had no involvement.

I have not identified any additional items that would pose a conflict. Therefore, I see no need for an individual member or -- of the Committee to recuse themselves from the Committee's decision making activities, other than those just discussed.

However, if during the course of our business, you determine that you have a conflict, please state it for the record and recuse yourself from that particular aspect of the discussion.

At this point, I would like to introduce the individuals seated at the table today. Dr. Leon Malmud, Chairman, Health Care Administrator; Dr. Richard Vetter, Vice Chairman, Radiation Safety Officer; Dr. Subir Nag, Radiation Oncologist; Mr. Ralph Lieto, Nuclear Medicine Physicist; Dr. Douglas -- can you hear us? Pause just for a moment.

(Off the record comments.)

MR. EINBERG: I'll continue. Dr. Douglas Eggli, Nuclear Medicine Physician; Dr. Orhan Suleiman, FDA Representative; Dr. William Van Decker, Nuclear

Cardiologist; Dr. James Welsh, Radiation Oncologist; Dr. Darrell Fisher, Patient Advocate; Dr. Bruce Thomadsen, Medical Physicist, Therapy; Mr. Steve Mattmuller, Nuclear Pharmacist; Ms. Debbie Gilley, State Government Representative.

I would like to mention that Dr. Milton Guiberteau is representing the Diagnostic Radiologist. Dr. Guiberteau does not have voting privileges, but he will listen and speak on behalf of the diagnostic radiologist. I would like to thank Dr. Guiberteau for acting in this capacity.

Dr. Leon Malmud, ACMUI Chairperson, will conduct today's meeting. Following a discussion of each agenda item, the Chair, at his option, may entertain the comments or questions from the members of the public who are participating with us today.

Regretfully, as Dr. Malmud pointed out, Rob Lewis will not be joining us until after lunch today, and so, I have a few opening remarks to add to the comments that I just made.

The pre-publication copy of the NCRP Report 160, that was just provided to you for your review, it's anticipated that that final copy will be published this month.

Rob also previously provided updates on

the National Source Tracking System. The system is now up and running, and licensees are required to report category one and two material, transfers to the system.

Regarding the status of hiring for the three positions on the Committee, the RSO, the Radiation Safety Officer selection is currently with management for final approval. A recommendation for the nuclear medicine physicist position is being sent to management and the radiation oncologist call for nominations closed on April 21st. Nominees will be reviewed in the next few months.

Also, we wanted to note that there have been changes to the agenda, to accommodate some of the speakers who need to attend the funeral of an NRC staff member on Friday. So, that's why we have rearranged it a little bit.

So, with that, I'll turn over to Dr. Malmud.

CHAIRMAN MALMUD: Thank you, Mr. Einberg. We'll move directly on to the item of old business, for which Ashley Cockerham will make the presentation.

MS. COCKERHAM: All right, I have two, actually. I have two charts that I'm going to pass around. One is from 2007, the next one is from 2008.

We're going to go through the 2008 recommendations first, and they are displayed up on the screen. Gretchen, if you could scroll down to them.

Okay. So, everyone has a copy. We're going to start with 2008. This is item number two. It says, "NRC staff should pursue rulemaking to allow more than RSO on a medical use license with the indication of one RSO as the individual in charge," and this is scheduled as a part of the next Part 35 rulemaking, which will begin later this year. So, that item should be accepted.

Item number five, "NRC staff should incorporate the subcommittee's recommendations for the Gamma Knife Elekta Perfexion in future rulemaking." This is in the user need memo for the 2009 rulemaking and this is something that's moving from guidance space to regulations. So, I know that's always been a concern of the Committee's. This will be the first item to do that.

Item number nine, "NRC staff should revise the AO criteria to read, `a medical event that results in one, death or two, a significant impact on patient health that would result in permanent functional damage or a significant adverse health effect that would not have been expected from the treatment

regiment, as determined by an NRC Agreement State designated consultant position."

This item is still pending and the last time we talked to you, we said that AO revisions would be sent to research in early 2009. We have submitted this request to research.

I do know that both -- the two reactor offices also have pending commission action items that may require them to revise their AO criteria as well, and so, research is waiting to see if NRR, NRO and FSME, which is our office, will have changes, and they would like to make all of those changes at once.

There's a working group within research that will be meeting this summer, and they will make that determination then. So, we should have another update at the next meeting.

So, item number 14, "ACMUI should form a subcommittee for the permanent implant brachytherapy rulemaking." The subcommittee's charge is to meet within the next two weeks to prepare ACMUI's comments on the proposed rulemaking.

The subcommittee includes Dr. Nag as the Chair, Mr. Lieto, Dr. Thomadsen, Dr. Vetter and Dr. Welsh. There is no NRC action on this, and the subcommittee did provide their final report in

November 2008.

DR. NAG: Ashley?

MS. COCKERHAM: Yes.

DR. NAG: Can I ask you a question? What do you mean by no NRC action? This is something that's still ongoing, and I know that the NRC is still in the middle of this passing. What do you mean by no NRC action?

MS. COCKERHAM: The recommendation pertains just to the creation of the subcommittee, there's nothing that NRC needs to do.

You created the subcommittee, you reported and so, when I received the report for the subcommittee, I close out your subcommittee. The recommendations related to that, do come later.

Okay, so, we're going to move to item 15, "NRC staff should provide a status update on the technical basis for the Rittenour or AAPM petition at the October 2008 ACMUI meeting."

We did provide this status update at the October meeting on the 28th. So, that item is now closed.

Item 18, "NRC staff agreed to consider incorporating the subcommittee's recommendations from the August 1, 2008 fingerprinting subcommittee report

and the NRC's questions and answers, with regards to fingerprinting and criminal history records, records checks or use another appropriate method of communication to transmit the information to licensees."

The medical team has passed along the ACMUI's recommendations to the working group, and we will let you know what action they take.

Item 19, "NRC staff should accept the six recommendations of the current implant brachytherapy subcommittee report with one modification."

Recommendation six should be modified to read, "When a written directive is required, administrations without a prior written directive are to be reported as regulatory violations and may or may not constitute a medical event."

This item is pending, and ACMUI's recommendations are being considered and acted upon with other comments on the proposed rule by the Part 35 revision working group.

This is --

MS. GILLEY: Debbie Gilley. Is this the 2009 rulemaking activity or later?

MS. COCKERHAM: This is -- I will ask Ron Zelac, but this is the rulemaking that already

started, not the 2009 rulemaking that will start.

This was one that they had already started and then, we stopped it to do a direct final rule and some other rulemakings, but it was already in the process and had already gone out for public comment. Cindy, is that correct? The permanent --

MS. FLANNERY: Yes, that's correct.

MS. COCKERHAM: Okay, so, this rulemaking had already started. Okay, so, we're on to item 20. "The ACMUI endorsed the permanent implant brachytherapy subcommittee report." There was no NRC action on this, so, the item was closed.

Item 21, "The ACMUI formed a subcommittee to draft a set of proposed qualifications, that interventional radiologists must satisfy to become Authorized Users for yttrium-90 (Y-90) microspheres." The subcommittee includes Dr. Bruce Thomadsen as the Chair, Dr. Douglas Eggli, Dr. Subir Nag, Dr. James Welsh and Mr. Steve Mattmuller.

There is no NRC action, and I have left this item open until the subcommittee reports back to the NRC, and this is an item on the agenda for today.

Item 22, "ACMUI encouraged NRC staff to begin the rulemaking process, to move the medical use of Y-90 microspheres from 10 CFR 35.1000 to another

section of the regulations, so that the training and experience requirements for Authorized Users can be vetted through the public review process, instead of residing in guidance space.

This item was partially accepted. We do intend, as we have done with the Gamma Knife Perfexion, to move Y-90 microspheres from guidance to regulations. However, we made two revisions in 2007, two revisions in 2008 and there's a possibility that we'll make another revision in 2009.

So, we would look to put this in the next rulemaking, and when I say next, I don't mean the 2009 rulemaking that will start next, but when that 2009 rulemaking closes, we would look to put Y-90 microspheres into rulemaking space.

MR. EINBERG: Ashley, before you proceed, Dr. Malmud, with your permission, Dr. Miller is here, and he'd like to make a few statements and remarks.

CHAIRMAN MALMUD: By all means, thank you.

MR. EINBERG: Okay, Dr. Miller.

DR. MILLER: Good morning. Thanks for letting me crash in on your agenda. Today's the day that is one of those days that's kind of melancholy for me because some of the members are here for the last time and I wanted to take a few minutes to come

down and present them a certificate of appreciation for their service.

So, with your indulgence, Dr. Malmud, I'll do that.

CHAIRMAN MALMUD: Thank you.

DR. MILLER: What I'd like to do, is to bring them up, just read a little bit for the benefit of everyone, some of the highlights of their service while they've been on the Committee.

First, I'd like to acknowledge Ralph Lieto. Ralph's a nuclear medicine physicist. He's been on ACMUI since 2001. He's chaired the medical radioactive material event subcommittee. He's been a consultant to the NRC staff on the review of training and experience of medical physicists, and he's served on numerous subcommittees, which include the iodine-131 therapy incidents review subcommittee, Part 35 training and experience and the medical event revision. Ralph.

Dr. Subir Nag. Dr. Nag is a radiation oncologist and he's been with ACMUI since 2000. He's aided the NRC by reviewing and commenting on rulemaking and guidance documents for brachytherapy. He's served on numerous ACMUI subcommittees, including Part 35 training and experience, new modalities,

medical radioactive material events subcommittee, permanent brachytherapy subcommittee, Perfexion Gamma Knife subcommittee. Dr. Nag.

Dr. Richard Vetter, the first Radiation Safety Officer representative on ACMUI. So, we think that that's been a great addition, with regard to that specialty.

He's been a Radiation Safety Officer representative since 2000, the Vice Chair of ACMUI since 2006 and he's served on numerous subcommittees, including Part 35 training and experience, new modalities, subcommittee on sodium iodide-131 incidents, dose evaluation subcommittee, fingerprinting quarters, working group, fingerprinting subcommittee, medical physicist subcommittee. Dr. Vetter.

Just maybe a couple other words. I think the service that each of your provide to the Committee is extremely valuable. I'd like to thank each of you because I think the nature of the Committee and the challenges that are before you and the challenging of the staff and each other in areas is very healthy for the regulatory process.

So, again, thank you very much for your service and I wish you well in the rest of your

careers. Thank you.

CHAIRMAN MALMUD: Thank you, Dr. Miller. As Chairman of the Committee, I'm certain that I speak for the current members of the Committee, as well as those members of the Committee who rotated off prior to your leaving the Committee, in expressing our thanks for you collegiality, your wisdom, your advice and it's been extraordinarily productive and helpful to all of us, to learn from you and to gather your advice and then use it in a constructive fashion on behalf of the mission of the ACMUI.

So, it's as the Chair for the Committee that I also wish to second the thanks of Dr. Miller on behalf of all of us who have enjoyed working with you as colleagues.

CHAIRMAN MALMUD: Thank you, Dr. Miller, and we'll return to the agenda with Ashley.

MS. COCKERHAM: All right, I believe we're still on the 2008 recommendations. We're going to turn to page two and start with item number 23.

Item 23 reads, "The ACMUI strongly encourages NRC to continue supporting the exportation of highly enriched uranium materials for Moly-99 targets used by international producers and provide all possible help towards the development of U.S.

producers of moly-99."

In response to this, NRC has acknowledged this recommendation and adds that, "NRC's role in the exporting of highly enriched uranium for the production of medical isotopes is to issue export licenses to the U.S. Department of Energy."

In 2008, NRC's Office of International Programs issued DOE a license to export HEU target materials to Atomic Energy of Canada for medical isotope production in 2009 and as far as the second item, to provide all possible help towards the development of producers, NRC does not have a role in promoting a domestic supply of moly-99.

NRC's role is to provide stable regulatory basis -- provide a stable regulatory basis for evaluating any application and regulating any domestic supplier.

In fiscal year 2009, NRC received two letters of intent from Babcock & Wilcox and the University of Missouri, to develop domestic molybdenum-99 production facilities in the U.S.

The Office of Federal and State Materials and Environmental Program staff will work with NRC's Office of Reactor Regulation to review and resolve policy issues associated with the new licensing

request.

Item number 24, "ACMUI formed a subcommittee to develop a solution that satisfies both the training needs of residency program and the NRC requirements for achieving Authorized User status, using board certification pathway. The subcommittee should create a recommendation to be discussed at a future teleconference prior to the spring 2008 ACMUI meeting."

The subcommittee includes Dr. Douglas Eggli as the Chair, Dr. Subir Nag, Dr. William Van Decker and Dr. Milton Guiberteau, as the technical consultant.

There is no NRC action this, and the item is still open, and we will be discussing this on Friday.

Item number 25, "NRC staff should revise 10 CFR 30.35(b) to allow licensees to exceed the limits short term, for example, 60 days, during source exchange." This item is accepted, and it was included in the user need memo for the 2009 rulemaking.

For item number 26 -- actually, for items 26, 27, 28, 29 and 30, all of these are to be included. The items are accepted, and they are included in the user need memo, which means they'll be

looked at in the 2009 rulemaking. So, I'm just going to read the recommendations.

"NRC staff should revise 10 CFR 35.40 to clarify that the Authorized User should sign and date the pre-implantation and post-implantation portions of the written directive for all modalities with two-part written directives."

Item 27, "NRC staff should revise 10 CFR 35.40, to clarify that an Authorized User, not the Authorized User, should sign and date both the pre-implantation and post-implantation portions of the written directive for all modalities with two-part written directives," and there is a note that this allows for one AU to sign the pre-implantation portion of the written directive and another AU to sign the post-implantation portion of the written directive.

Item 28, "NRC staff should revise 10 CFR 35.65 to clarify it does not apply to sources for the medical use. However, NRC staff should not require licensees to list the transmission sources as line items on their license."

"NRC staff should also revise 10 CFR 35.590 to permit the use of transmission sources under 10 CFR 35.500 by Authorized Users meeting the training and experience requirements of 10 CFR 35.590 or

35.290."

Item 29, "NRC staff should revise 10 CFR 35.204(b) to require a licensee that uses moly-99/tech-99m generators of preparation of tech-99m radiopharmaceuticals to measure the moly-99 concentration after the receipt of a generator to demonstrate compliance with not administering to humans more that .15 microcuries of moly-99 per milli-curie of tech-99m."

Number 30, "NRC staff should require licensees to report to NRC, events in which licensees measure moly-breakthrough that exceeds the regulatory limits."

Number 31, "NRC staff should pursue a change to allow grandfathered AU's to be supervisors and preceptors," and this item is accepted and is being addressed in the current rulemaking.

Number 32, "The ACMUI medical nuclear materials event subcommittee should review events and provide analysis to the full committee annually in the spring, instead of the fall." There's no NRC action on this, and it is an item on this spring agenda.

Item 33, "ACMUI believes that 10 CFR 35.491 provides adequate training and experience for the use of NeoVista's EpiRad 90 device, if the

training under 10 CFR 35.491 is accompanied by appropriate device specific training."

This item is accepted. The guidance was revised recently and was sent out on the medical list server on May 5th. So, this item is now closed.

Item 35, "NRC staff should notify ACMUI when the NRC Office of General Counsel makes a determination on the regulations regarding grandfathered Authorized Users as supervisor and preceptors for the purposes of training and experience." This was completed. We provided the response on January 9th.

At this time, NRC -- item number 36, "At this time, NRC should continue its policy of not requiring infiltrations of diagnostic dosages to be reported as medical events." There is no action on this, since this is our current policy, and this item was closed.

Item 37, "As recommended at the October ACMUI meeting, NRC staff should revise the guidance to allow individuals qualified under 10 CFR 35.491 with device specific training to be Authorized Users for the NeoVista EpiRad device."

This authorization only applies for the use of the device under the current standard protocol

used in clinical trials. Furthermore, any off-label use of the device should require the Authorized User to meet the current guidance which states Authorized Users must meet the T&E requirements of 10 CFR 35.490 or 35.690.

ACMUI added that there should be no physical presence requirement for individuals qualified under 10 CFR 35.490 or 35.690. This item was accepted. The guidance was revised and was sent out on the medical list server on May 5th.

CHAIRMAN MALMUD: Thank you. Are there questions? Debbie Gilley?

MS. GILLEY: Yes, item number 31, which was the grandfathering AUs to be supervisors and preceptors, I thought you all were going to do a direct final rule for that activity.

MS. COCKERHAM: Ron, I would ask you, are we doing the direct final rule on that right now?

MR. ZELAC: Yes, we are.

MS. GILLEY: Thank you.

CHAIRMAN MALMUD: Dr. Nag?

DR. NAG: Item number 33 and 37, is 37 going to be an explanation on top of the 33, because 33, on its own, can be misleading. It says 491 bringing in experience for the EpiRad 90 device, but

then it's only true if it's accompanied by 37, not as it stands alone.

CHAIRMAN MALMUD: Is that a question?

DR. NAG: Yes, I mean, the 33 will make sense only if it is accompanied by 37. But 33 on its own can be misleading, because 33 on its own looks like if you have 491, you can use the EpiRad 90 device. That's true, only if you are doing under protocol.

Your 33 and 37 should be linked somehow, and not be a stand-alone.

CHAIRMAN MALMUD: Thank you, Dr. Nag. I'll ask Dr. Howe to comment on that.

DR. HOWE: Dr. Nag, if we -- we just published new guidance for the NeoVista and if you look at the guidance, you're required to have -- meet the same kind of hours and topics in 491, but everyone that's an Authorized User needs the specific NeoVista training.

So, they are linked together. They are not independent. So, we used 37, where you have both 491 and NeoVista specific training.

MS. COCKERHAM: Dr. Nag, I think this will clarify. If you look at the dates of when these recommendations were made, the Committee was moving

towards what you're seeing in 37.

I think that 33 was a step towards that. That's where the Committee started in October and we realized we needed more information and we held a teleconference in December. We discussed it more thoroughly and then 37 was the final recommendation we got out of it.

So, when Cindy revised the guidance, she was looking at both, but obviously, at 37, with 33. Does that help?

DR. NAG: Yes.

MS. COCKERHAM: Okay.

CHAIRMAN MALMUD: Thank you.

MS. COCKERHAM: All right. Now, we're going to switch over to the 2007 recommendations. For item number one, "NRC staff should issue an information notice which describes errors previously made and provides examples of best practices with regards to units of Air Kerma Strength (AKS) versus apparent activity in milli-curies for brachytherapy sources."

"The IN should be done in collaboration with the American Association of Physicists and Medicine and coordinated with the Agreement States."

This recommendation was accepted and we're

still working to incorporate comments and get a final draft.

Item number two, "NRC staff should remove the attestation requirement for board certified individuals and rewrite the attestation requirement for individuals seeking authorization under the alternate pathway. The rewritten attestation should not include the word 'competency', but should instead read, `has met the training and experience requirements'."

This item is accepted, and it is included in the User Need Memo for the 2009 rulemaking. Additionally, I have here the paper that went to the Commission providing these recommendations and the Commission came back and said, "Yes, please pursue this." So, if anyone wants to see a copy of the actual recommendations and the Commission instructions they sent back, I have it here.

For item number three, "NRC staff should revise the regulations so that board certified individuals who are certified prior to the effective date of recognition were certified by previously recognized boards listed at subpart J of the previous editions of Part 35 are grandfathered."

This item is pending. We will need to

develop a technical basis, and the decision of whether or not to pursue a technical basis has not yet been determined. Ron Zelac is working on this now. We sent letters to the boards, and Ron is working to incorporate those comments, to determine if a technical basis is justified.

For item number six, "NRC staff should add the words `or equivalent', so it is clear that information included in the letter is the same as that which would have been submitted in NRC Form 313A." This item is accepted and is in the User Need Memo for the 2009 rulemaking.

Item number seven, "NRC staff should revise 10 CFR 35.50(c)2) to include Authorized Users, Authorized Medical physicists or Authorized Nuclear Pharmacists identified on any license or permit that authorizes similar types of use of byproduct material."

Additionally, the authorized, Authorized Medical Physicist or Authorized Nuclear Pharmacist must have experience with the radiation safety aspects of similar types of use of byproduct material for which the individual is seeking Radiation Safety Officer authorization.

This item is accepted and is in the User

Need Memofor the 2009 rulemaking.

Item number eight, "NRC staff should remove the attestation requirement from 10 CFR 35.50(d) for Authorized Users, Authorized Medical Physicists and Authorized Nuclear Pharmacists seeking Radiation Safety Officer status. If the AU, AMP or -- or ANP seeking RSO status will have responsibilities for similar types of uses, for which the individuals authorized."

This item is accepted and it's in the User Need Memo for the 2009 rulemaking.

Item 10, "NRC staff should allow more than one RSO on a license with the designation of one RSO as the individual in charge. NRC should create a Regulatory Issue Summary (RIS) to inform the regulated community of NRC's interpretation. The RIS should be sent to ACMUI and the Agreement States for review and comment."

This draft RIS was sent to ACMUI in September of last year, and it is scheduled as part of the next Part 35 rulemaking to begin this year.

Item 16, "NRC staff should revise the current guidance to conclude that the surgical removal of the sentinel lymph node is an independent procedure and should not be regulated by NRC."

This item was accepted. The guidance was revised and this item was closed -- I'm sorry, the IN was sent out in January of this year.

Number 25, "NRC staff should revise the current regulations to include Canadian trained individuals who have passed the American Board of Nuclear Medicine certification exam."

This item is accepted and it's in the User Need Memo for the 2009 rulemaking.

For item 30, "The Elekta Perfexion should be regulated under 10 CFR 35.1000 until 10 CFR 35.600 is modified to be performance based, which would allow the Perfexion to be regulated under 35.600."

This item is accepted and it's in the User Need Memo for the 2009 rulemaking.

Item 31, "NRC staff should require experienced RSO's and AMP's to receive additional training if the individual is seeking authorization or responsibility for new uses." This item is accepted and it's in the User Need Memo for the 2009 rulemaking.

Item 32, "NRC staff should not require experienced RSO's to attain written attestation to become authorized or have responsibility for new uses." This item is accepted and it is in the User

Need Memo for the 2009 rulemaking.

Item 34, "NRC staff should modify 10 CFR 35.491(b)(2) to specify superficial ophthalmic treatments. Additionally, NRC staff should change the title of 10 CFR 35.491 to specify superficial ophthalmic treatments."

This item is accepted and it's in the User Need Memo for the 2009 rulemaking.

Item 35, "NRC staff should not revise 10 CFR 35.491 to include training and experience for the new intra-ocular device. Instead, NRC staff should regulate the new intra-ocular device under 10 CFR 35.490."

This item is partially accepted. Staff expects to include in future rulemaking.

Item number 36, "NRC staff should not require medical licensees regulated under 10 CFR 35.400, 500 or 600, as applicable, to only use the sealed source and devices for the principle use as approved in the Sealed Source and Device Registry."

This item is accepted in the User Need Memo for the 2009 rulemaking.

Item 37, "NRC staff should revise 10 CFR 35.290 to allow physicians to receive training and experience in the elution of generators and

preparation of kits under the supervision of an Authorized Nuclear Pharmacist."

This item is accepted and is in the User Need Memofor the 2009 rulemaking. Any questions?

CHAIRMAN MALMUD: Thank you. Are there any questions?

MS. COCKERHAM: I think overall, we're making progress. We have many, many items that have been on the back0-burner since 2007, but they are moving into rulemaking and we are starting the rulemaking, which is good news.

CHAIRMAN MALMUD: Thank you very much.

MS. GILLEY: I have a question.

CHAIRMAN MALMUD: There is a question. Debbie Gilley?

MS. GILLEY: The IN from June 2007, concerning Air Kerma Strength vs. apparent activity. Two years? We've had quite a few medical events.

MS. COCKERHAM: It's being drafted.

MS. GILLEY: Thank you.

CHAIRMAN MALMUD: Any other questions? If not, thank you for a very thorough presentation, and we'll move on to Ms. Burgess, who is going to present item number three, which is medical event reporting to the International Nuclear Event Scale.

MS. BURGESS: Hi, I'm Michelle Burgess. I am one of the regional coordinators in Chris's branch and I wanted to use this as an opportunity, this meeting, as an opportunity to bring an issue to your attention.

About three years ago, France forwarded a proposal to the IAEA, to start including medical events in INES, and that's the international database that collects the high end events.

At this point, all of the medical events are excluded from that, and France would like to start including them in there.

INES is the database that's primary function is a communication tool to the public. The NMED database, which a lot of you are familiar with, is a tool that we use here nationally, to collect all of our events. We to trending on it. It's sharing amongst more regulators than a public-type information tool.

But the gist of the IAEA database is a public communication tool. So, there's a little bit of a different approach to and are some sensitivities that might be there.

In your binders, there is the background information from the last meeting that we had, to

discuss the proposal to IAEA and some background information on INES, as well as the summary of the scale that France is proposing that we use for medical events.

I've given that information to you. We're not going to -- I wasn't going to go through it today in detail, because our primary purpose here is to make you aware of this proposal and to begin soliciting some feedback from you guys.

We see this as somewhat different than some of the other issues that we've addressed with INES. Most of the other proposals for changing the scale or including events haven't had quite the sensitivity that we've had with the medical industry and we would -- one of our primary goals is not just alignment of the scale with the agency position and our goals here, but this has that extra component of making sure that we understand the impact and the effect from the medical industry, because of the publicity of the events that are going on here. For most of the other licensees, there isn't that same sensitivity.

I'm not sure if we have -- have had a lot of chance to look through the presentation materials and if you guys have any specific feedback

for me here, now, or if this is a thing that we need to stage out for you providing some input to us at a further -- at a future date, because of the timing for the next meeting, they want to have that in November.

We're looking to see if we can any input that you may have for us, any thoughts or feedback or insights, by the end of June, so that we can incorporate anything we have in any response, in preparation for that November meeting.

Was there any specific input that you had now for us?

CHAIRMAN MALMUD: Does any member of the committee any comments? Yes, Dr. Vetter?

VICE CHAIRMAN VETTER: More of a question. Is the intent to actually add medical events to the database or is it -- or is the intent to use the INES scale to measure the significance of medical events?

MS. BURGESS: To add them to the database. To create a scale and the scale that we have from France now, is not quite in alignment with the IN -- the current INES scale, with respect to relative significance.

It's one of the things we'd like to hear back from you on. We have to set the scale. That's one step of it. But then the end point is an intent

to actually include all of these events in INES, which would then put them out there in that public communication tool.

That's one of the reasons that we think it's important to make sure we have the scale set correctly. Right now, the scale is set in the French proposal -- is off-set from the INES scale, where it's going to put an apparently higher significance level for any kind of event.

For example, a death call by a medical event is going to look like it has more significance than the death calls by any other kind of event and there are some proponents in the international arena that think that that's appropriate, and other thinks that we need to kind of base line it, so that we're not calling medical events out as somehow more egregious than any other kind of radiation exposure, for example.

So, it's two parts. It's to set that scale and then eventually, to be able to include those in INES.

CHAIRMAN MALMUD: Dr. Nag?

DR. NAG: On the INES scale, that would -- that calls for people where any regulation exposure would face the accidental -- not normal. Whereas, in

a medical implant, you as using radiation to treat and therefore, those scales are much higher and when ever you're trying to reach one side on medical event on INES scale, you have to keep that in mind, that the medical event or medical therapy, you are giving the therapy to that patient that would be quite -- there would be some amount of radiation exposure already expected on that patient.

So, for other devices, yes, you can use the INES scale, but for the patient himself or herself, the amount of radiation that you're giving them might be quite high, you know. That has to be kept in mind when ever you're trying to match the two scales.

MS. BURGESS: And that's correct, and one of the things that we're doing is the idea of -- what would be included in there would be things defined as a medical event, which also -- which already tries to take that into consideration because it has to be an unexpected dose in the -- to a wrong area or higher than expected to the correct area.

So, we try to take that into consideration in that aspect. But there is also the idea that some of the effects, you may get a measurable effect from another radiation event that is totally unexpected.

But when you're dealing with a medical event, sometimes some of those results -- the unwanted, but expected results, is that a matter of, it would happened anyway, or is that a matter of, it happened because there was a medical event?

Those are some of the issues that we're trying to bring forward, raise those, the points that we need we need to make sure that we cover, if we're going to include these, that even in the definition, how we define the event or what we're going to put in the threshold that we use for events, that we make sure we take all those things into consideration, that we're not giving the wrong message to the public, with respect to the significance of the medical events.

CHAIRMAN MALMUD: Dr. Van Decker?

DR. VAN DECKER: Yes, I just want to raise some concerns in the process here, that this gets done with a lot of thought.

I think that we're all very cognizant, as you're trying to gently point out, that there is emotional overlay to medical events, who is the adjudicator of what's a medical events, whether there was real harm done or not.

We know we deal with this all the time in the definition of what's a medical event and public

disclosure and Congressional disclosure and everything else.

I think this discussion would probably have been a little bit more helpful to some degree, if could bring like concrete examples of what we think are -- or what really -- real life events would have fit into this scaling system, who would have adjudicated it in the scaling system and how it would really play out, as far as where it's going, where the information is going.

I think we're all for transparency and we want to see good be done, but I think that I'm a little bit nervous, without seeing some concrete pieces to this, as to exactly how this is going to play out, and I think that since the process is moving along quickly until November, somebody along the way has to think about each of those different stops.

MS. BURGESS: And that's one thing that we're doing. In the meetings, we've started some preliminary checks against, here is real events, here is the scale. Where would they fall out?

November is not when they're going to put it into place. November is simply the next meeting where the working group needs to come together and bring all of the issues and start discussing where we

need to go, the things we need to resolve.

So, the timing is just for getting all the information together, to get to that next step for discussion, and we do have examples that we've started to work through. The purpose of bringing it to this meeting today was to start dialog with ACMUI, to see if you wanted to engage in this and then, we can move forward through Ashley, to figure out what the best mechanism is, to continue the discussions that we start today.

But this was to raise the issue to your attention and get it started, but I'm looking forward to whatever interactions we can have between now and November.

CHAIRMAN MALMUD: I think Dr. Suleiman has a question and Mr. Mattmuller, then Dr. Vetter.

DR. SULEIMAN: I don't care much for conceptual concepts, but this is nice in this case. I think you have to be very, very careful. I think other people expressed that. We're talking about patients, you know, the dose that's being delivered to them, whether it's a therapeutic, whether it's a diagnostic.

You're talking about the occupational workers. You're talking about the public, and how you

blend them into a broader scheme that the IAEA has developed that may cover things that are clearly outside the purview and trying to lump them in there, strictly based on some technical radiation metrics, could be, if not clearly planned out and thought out ahead of time, could be problematic.

I think we had some of that issue earlier with defining the border of a tumor, you know, where practice of medicine is not very, very black and white and there's a lot of grey in there and that grey is allowable., and so, you don't want that to trigger a number.

I know with FDA, you know, we have a very -- we require -- we ask, we beg people to report information. The intent is to identify if there's a recurrent emerging problem associated with a certain technology, with a certain drug and so on.

So, we classify it -- things as either adverse events, which could be nothing more than a slight rash on the skin to serious adverse events, which basically has the term `life threatening' and that still is pretty broad.

But the intent, and I think your intent is to identify emerging problems with a certain product that all users are doing wrong or maybe a certain, you

know, source that is having a problem. I think that's really what the mechanism is intended to identify.

So, I think how you parse that off from the very beginning would be critical. If we get blended in with everything else, you're going to have problems down-stream.

CHAIRMAN MALMUD: Thank you, Dr. Suleiman. I believe that you were next, Steve.

MR. MATTMULLER: My one concern with reporting this and using it as a tool for the public is that there's -- it's just a number of incidents. There is not -- I didn't see any temporary expression, medical cases, having a denominator, so they could get a feel for the rate of how often this happens, because if it's one event with the total number of say, a Gamma Knife exam or a procedure versus a much more -- you know, one event there is much more significant than one event, say, with a therapy for the item at issue.

So, I think it would very important to make at attempt, at least, to estimate the total number of procedures that that event derived from, which I realize is a huge issue, but I think it's important to the public to see that because I think it takes much imagination for them to see one event this

year and next year, there's two in there and they say, "Oh my gosh, the medical community is out of control," because there's 100 percent increase in events, and without the other information, I'm afraid our media might make those conclusions.

MS. BURGESS: And I have that down here as a note with an asterisk to see if there's a way to address the denominator issue at large because in INES, there is no denominator addressed for anything.

If somebody does output from the data, then you'd try to put the denominator in. For example, NMED, we do the same thing here. There is no denominator in NMED, but then when we do the annual report that comes out of NMED, there is where we try to apply the denominator.

So, it's a difficult subject in any of these data collection systems, to figure out what that denominator is and any information that you might be able to offer us, ACMUI might be able to offer us, with respect to denominators or where we can get that information, we're always open to that.

We've gone to different sources when we do our annual reports that we do out of NMED. So, we're always looking for a better, more up to date, more accurate source or two sources to compare, so that we

can have some sort of range and validation.

But I'll put that down as a general issue, not just for medical, but for everything and I will make sure that it's clear that part of our concern is that it's not just the data that's going in, but making sure that we understand how any trending or analysis will be characterized. That was raised on this side of the room as well.

We need to make sure that denominator is in there. That's part of any trending. So, I have there here as well.

CHAIRMAN MALMUD: I believe that Dr. Vetter was next.

VICE CHAIRMAN VETTER: Many hospitals and clinics are accredited by The Joint Commission and they have a term called sentinel event that describes various bad things that can happen and have to be reported, investigated and so forth, and I just wanted to point out that as you proceed forward here in defining what these events are and where they fit on the scale, it might be good to be sure you're not -- that any of these definitions are not inconsistent with The Joint Commission's definitions of sentinel events.

CHAIRMAN MALMUD: I believe --

MS. BURGESS: You said that's a Joint Commission?

VICE CHAIRMAN VETTER: The Joint Commission.

CHAIRMAN MALMUD: That's JCAHO.

VICE CHAIRMAN VETTER: No, I'm sorry.

CHAIRMAN MALMUD: Just The JC? Started out as JCIH and then became JCAHO and now they're JC?

VICE CHAIRMAN VETTER: Yes, now, they're TJC.

MR. MATTMULLER: Now, they're The Joint Commission, TJC.

CHAIRMAN MALMUD: What's in a name?

VICE CHAIRMAN VETTER: The is capitalized. They probably learned that from The Ohio State University.

MS. BURGESS: And the point you raise ties into a lot of what we're trying to do, as far as definitions. Right now, the definitions that are in the French proposal, are not very clear.

Significant effect or less significant effect, that's not helping us. We wanted one, to make sure that the rankings are clear, so that everybody is ranking things the same way.

If the whole purpose of INES is to give a

relative significance, we want to know -- we want to make sure everything is pretty fairly being consistently characterized and the other piece is with this interaction with the industry, is the impact on it, but also trying to use things that are understandable by the community, that fit in with -- or at any rate, aren't inconsistent with the definitions that already exist, since there's so many out there already, in the medical arena versus others.

VICE CHAIRMAN VETTER: Just as one example, probably the most specific example that's pertinent to this discussion is a skin dose that exceeds 15 Gray (Gy) is a sentinel event, period, and the hospital must investigate that as a sentinel event.

CHAIRMAN MALMUD: I believe the Chris had a statement.

MR. EINBERG: Yes, Michelle, I guess what you're seeking right now, and let me know if I'm wrong, you're seeking the recommendation as to what the threshold for a medical event should be, to report it to the INES and also, you're seeking what the definition for a medical event that's reportable to INES should be, is that correct?

MS. BURGESS: We're looking for several things here, open dialog to start and then to build

upon. We're not going to accomplish everything today.

So, opening some dialog, getting some thoughts and then either here or working with Ashley to figure out a way we can continue to work.

The content that we're looking for is any input on the definition of what events should be included in here versus not included, making sure that we're consistent with the medical community, the words and the definitions that are used there, looking for any feedback that you can give us, with respect to should we try to engage with industry itself?

We want to measure -- we want to know that what we're going to do here isn't going to have some adverse effect and the medical community is going to have difficulties or sensitivities in what we're trying to do here.

If we could accomplish that here, that's fine, but if not, and you recommend that somehow, we reach out to the medical community itself, any input that you can have that way, with how to do that, the timing for doing it, how best to accomplish it, so that we -- if we're going to put it out there, we put it back out with our best foot, so that we can engage productively with them, as opposed to triggering sensitivities and it becoming an upsetting situation.

All of this is -- again, we're just trying to pull as much as we can together in preparation for that November meeting.

The U.S.'s position at this point is to move forward slowly, so, we're well aware of what we do because the problem with one of these databases is, once you get it started, it's hard to stop.

So, we want to make sure all the pieces are in place before we start and that we're fully aware of where we're going and the impacts that we're going to have.

CHAIRMAN MALMUD: Dr. Suleiman?

DR. SULEIMAN: One more clarification. Looking at the schema, it appears this is more accident or major failure type of reporting. It's not necessarily what happens during routine practice of medicine.

MS. BURGESS: Correct, it would be --

DR. SULEIMAN: So, maybe it would be good to steer clear of that and just allow catastrophic elements to --

MS. BURGESS: To drive it.

DR. SULEIMAN: Yes, to drive it.

MS. BURGESS: Yes, the minimum threshold that we would have here would be reportable events,

events that are reportable to the NRC, because that would be the sub-set that we would pool from and for the most part, it should be immediately reportable events, not the 30 days reportable, but anything -- most of the medical ones trigger to the tie-in's anyway.

So, that's what we're looking for as a minimum threshold. For IAEA though, for other events, we don't send everything that gets sent to us. There's a higher threshold. It's sort of like where we do the AO's, there's that higher level. It's a higher level that we send to INES as well.

So, we would be looking for, is there a way of those things that are immediately reportable, to cut some other threshold in there, to say these are the things that we're going to communicate to INES and it's the things that are going to be out that -- that the public has a right to know about. It's that communication tool, the same way we're putting out for other events.

CHAIRMAN MALMUD: Dr. Eggli?

DR. EGGLI: Who do you propose will actually do the categorization of the severity? Will that be done at NRC before it's -- before it's submitted? Are you expecting the end-user to

categorize, because looking for uniformity, even if you say the scale is one to five, plus the zero, that's six categories and expecting the end-user to have any kind of uniformity in that kind of a rating system is very difficult.

I think Orhan referred to a two grade system at FDA, so that you would assume you would need a very small group of experienced folk to assign the category before that information would be submitted forward, to try to maintain some form of uniformity and grading.

MS. BURGESS: The grading is done here at the NRC, the same way that we do for the IN - - all the rest of the INES events that are already going in.

There is a guidance document that's put out, but then it's staff here in our branch here, we would be doing it and then it's double checked some individuals that are down in our incident response branch, NSIR-- the operations side of that and then it gets submitted over.

So, it's done here by a small group, so you do have that consistency.

CHAIRMAN MALMUD: Mr. Lieto?

MR. LIETO: I have a few questions, actually, a follow up to Dr. Eggli's question. I

think there's a real concern with the fact one, that this is going to be a public reporting and then you want this immediate -- you know, as soon as it's reported by the licensee or where ever the event occurs, to get transferred into this international reporting mechanism, and I think there needs to be -- I guess to use medical terminology, a time-out where you really investigate this one, to determine is it a medical event that needs to go into this international reporting mechanism.

And I guess I have a question, and I don't know if you have an answer for this now, but is, what is the purpose of this immediate reporting of these medical events in one country, into an international mechanism and I'm still a little confused as to, you know, what's going to be the value of that?

I could see if there was some type of a process of being sure that this is an actual medical event. What is the lesson learned? In other words, some follow up investigation, because right now, medical events have to be reported within 24 hours of discovery, and I would really hate to see that being sort of escalated and then it's, "Oh, nevermind," you know, after a month later.

Another point that I'd like to make is

that these would be only radioactive material events. The international, shall I say practice of radiation medicine, if you will, encompasses all uses, which basically are the machines, and that's where you're -- where I'm going to say your largest use of radiation occurs and maybe events are likely to be reported.

I'm assuming, this is just my personal opinion, I'm assuming that because this is largely coming out and driven by the French, it's a follow up to the events that occurred in their country, I think a year or two ago, where they had just a major issue with improper, I think, calibrations of the machines and so forth, and I can understand that process.

But there is no mechanism in the United States where there is reporting of medical events into a national database regarding machines, and so, I think that's a major discrepancy between what you're going to be trying to compare on an international scale versus what's happening in this country.

So, I think that's an issue that needs to be addressed before we, shall we say, join this.

Also, looking at your information, I think that if this is going to be an internationally reporting mechanism, I think you need to include more of the international community.

I notice that there's no representatives from Canada or the UK on this, at least in the descriptions that I read, and I think that you really need to, as you go forward -- and this warrants -- you want buy-in by, I think the United States. I think that you need to be sure that there is going to be a buy-in by other countries, and this isn't just sort of a U.S/French type thing.

So, that was another point I wanted to make and again, you know, I think how are the differences in the practice of medicine in from one country to another, going to be incorporated into this reporting mechanism?

MS. BURGESS: To hit your point, the concern about the immediately -- immediate release to the public, the timing for that would be the same as the timing that we have for release of reportable events to the NRC's website. I think there's a three day hold on it.

A five day hold on it. So, it -- the timing for what would be no sooner than that. We would have to arrange -- although the reporting for INES right now, for other types of events, is 48 hours. We would need to tie that timing to, at the minimum, at least not -- before we would be putting it

out on a public website.

But I have the note here with, do we want to have an even longer wait, because of the fact that we're dealing with patients and medical issues, to make sure that we're not a potential event, but we really are certain that this is an event and we have our facts straight.

Your second point was about needing more -- why do you need international reporting? The whole concept with INES for reporting all types of events is participating in this national effort to ensure that the public as a whole, not just the U.S., but across the board, are aware of the types of things that are happening. It's the disclosure, the transparency part. So that's what's been driving the whole thing for all of INES, including this proposal to include medical events. They're just trying to roll a subset of events that have always been excluded into the general rule.

On the other radioactive only versus machines, you're right. And that is one of the issues we're trying to address. The NRC can easily address the radioactive material part.

On the table is one of the questions. And you're bringing one that we have raised ourselves,

what about all the machine events? And that's going to be something we're going to have to tackle.

We're going to have to figure out, what do we do? If that's the intent and we're supposed to be including those events in here, there is no easy mechanism, like there is to pull it out of NRC's events. And so we have to figure out how to address that. And we don't have an answer that. So we'll need to work through that.

And your last one about the international representation, the people who were at this particular working group were just those entities, those representatives from the member states, IAEA, that could participate.

There's a larger putting a contacts group that anything this working group comes up with goes to that larger group and all the member states, where all their representatives vote on it.

So there is larger participation. This isn't just France and the U.S. and the couple of countries that happened to be there. It is a larger group. Unfortunately, the working group couldn't draw the people together.

I know I am running out of my time.

CHAIRMAN MALMUD: No, you're not.

Actually, is there another question for you from Dr. Thomadsen?

MEMBER THOMADSEN: Further on that last point, there is a large European database for radiation --

MS. BURGESS: Machines?

MEMBER THOMADSEN: -- medical events, for Rosis. Do you know, are they in discussion with this group, this IM permit?

MS. BURGESS: I don't know. I haven't heard that name brought up. Will you tell me that name one more time?

MEMBER THOMADSEN: R-o-s-i-s.

MS. BURGESS: Okay. Is that materials only or machine?

MEMBER THOMADSEN: It's medical radiation.

MS. BURGESS: So it's everything. Okay. I'll double check of that, but that would be one thing that we would make sure we would need to bring into this as far as the mechanism and agree to discuss it.

I mean, I know they wanted to talk with the World Health Organization to bring it under discussion. It happened the same way we're engaging with you to engage with them to get the perspective that we might not be seeing from the regulators and

just looking at it from an event point of view but bringing these extra things in it that we're not aware of.

MEMBER THOMADSEN: That is not in regulatory space. That is in medical space.

MS. BURGESS: No. But that's what I mean. These things that we're not aware of that can help bring those pieces to us that might change where we want to go or improve where we're going.

CHAIRMAN MALMUD: Dr. Guiberteau?

MEMBER GUIBERTEAU: I would like to focus a comment on your comments regarding whether or not to consult and/or interface with the medical community and if so, how to do that.

I would hope that you move beyond the first and are focusing on how to do that. I believe not only with respect to acceptance of this in the future, but in many cases, it is the medical organizations and the physicians who will have to explain these things to their patients.

And I would implore you to use what we already have in place in the United States. And that is numerous medical representative organizations who deal with these issues because I think, as Ralph said, the practice of medicine does have different

sensitivities in the United States than it may have in other countries. And so I think it would be exceedingly important to get this on the right footing to begin with.

MS. BURGESS: Do you think that as an active participation in development or for awareness and information?

MEMBER GUIBERTEAU: Well, I think either or both. I do think the broader spectrum of input you can get at this stage would be great guidance in terms of any trends that you see and concerns from the medical community.

Participation might be a little more difficult because obviously these things are perhaps better done in smaller groups. But some participation would likely be a good thing.

CHAIRMAN MALMUD: Thank you, Dr. Guiberteau. I believe that Debbie Gilley had her hand up next.

MEMBER GILLEY: Just a clarification. There are states out there that do also monitor medical events with machines and do keep registries of that, just as we do with radioactive materials. Thank you.

CHAIRMAN MALMUD: Thank you.

And Dr. Van Decker?

MEMBER VAN DECKER: I was just going to ask a question. Beyond the international public transparency of this, do you see an additive regulatory advantage to this? Because most registries are done not just to let people know what is going on in the community but also some sense for rulemaking or regulation in the future. Where do we see the regulatory advantage of this for U.S.?

MS. BURGESS: The IAEA standpoint on this is it's from their viewpoint only a public communication tool. That said, I do see a regulatory benefit for those member states that want to use it.

I, for example, go in. I am one of the events coordinators. I go in. And I do watch the events that are on there to see if there are any lessons I can learn from those materials events that are being posted on the site that we can then drop in. In fact, I dropped them, was dropping them in, and Duane is dropping them in now, into NMED so that we can see them with the lessons learned concept.

Is it something only here? Is it something that happened there that we can learn from their event before it happens here for the device failures or a new mode of failure?

Somebody did something wrong and it's not been seen, that mode, here before. So yes, I do see that regulatory benefit for those member states that want to go out and use it.

CHAIRMAN MALMUD: Thank you.

Dr. Suleiman?

MEMBER SULEIMAN: I am confused when you say "machine events." FDA requires industry to report to us all problems with their equipment analysis, causing radiation-related issues with mechanical problems or whatever.

Then, of course, we're cast with the problem of trying to differentiate whether it was, in fact, a machine problem or it was a user problem using the equipment inappropriately. But that's required.

And I know that NRC is aware of this. Donna-Beth Howe I know is aware of this. This has been going on for decades.

MS. BURGESS: Right. There is reporting. I don't think FDA has the kind of centralized repository that we have like for NMED. And so far we have never had the opportunity, the need to tap into that concept with respect to drawing that information together to report to IAEA at any rate.

Since NRC's mission doesn't include that,

we haven't spent the resources to find out if anybody is taking that data, doing anything with it, doing the trending or the analysis that we're doing in the materials events. So it's one thing that we're starting to look into in all of these data points.

Donna-Beth has some points for us that we can use to go in and see what is happening as we try to answer that question. Do we send the machine events over? And if we do, where do we get that data? Who puts it together? Where can we pull the source? And how do you get it over there?

And then right now we're trying to make sure that the definitions, the international community is trying to make sure that the definitions, fit, not just for materials events but for machine events as well, that the scale fits everything.

And we're also looking at the difference between therapeutic and diagnostic. There are some that think it ought to be limited to the therapeutic only because there is where you get your more significant issues.

But there are some that are curious whether or not there is a way or a need to put the therapeutic in there as well.

CHAIRMAN MALMUD: Dr. Thomadsen?

MEMBER THOMADSEN: Not wanting to put words into --

THE REPORTER: Could you speak into the microphone, please?

MEMBER THOMADSEN: Not meaning to put words into Ms. Gilley's mouth, I think when she said "machine event," she just meant events using accelerators, as opposed to radioactive materials, not implying that there was a problem with the machine that would be reported to the FDA.

MEMBER GILLEY: It could be both. We haven't found the FDA reporting requirements to be significant as far as us communicating with our licensees or registrants with linear accelerators. Your reporting requirements are much more delayed than our reporting requirements for a medical event.

MEMBER SULEIMAN: Well, most of the accelerator events I would suspect would fall under a user issue, rather than equipment problems.

CHAIRMAN MALMUD: Mr. Lieto?

MS. BURGESS: For this database, we're looking for human error issues as well as device failure issues because the modes of failure, of human failure, sometimes can be something we can learn from as well.

MEMBER SULEIMAN: I mean, manufacturers are required by law to report to us. So I know that information is collected. But, as I said, radiation is just one subset of many.

CHAIRMAN MALMUD: Mr. Lieto?

MEMBER LIETO: Yes. Just one final I guess maybe suggestion for improvement is that if you are going to be using the NMED reporting mechanism as the principal route and having chaired the committee that has reviewed these and reports to this group, I think there need to be some real improvements in what the reporting mechanism is in format because if you're going to learn anything from this by reporting it on an initial level, there needs to be I think much more details of the event than currently are provided by those reports.

And I am sure as you go forward, there is going to be some type of established standard reporting format, as opposed to every country just kind of like taking their piece and throwing it into this international mechanism.

But I think there needs to be some improvement there in order to follow up with what Dr. Van Decker said, that if you're going to learn anything from reporting in this, you need to be sure

you're getting the information that is going to provide you a mechanism to find where those areas of source or problems occur.

MS. BURGESS: To characterize it correctly, to make sure there is sufficient detail in there to characterize what went wrong and where it might have been able to be either mitigate it or avoid it.

MR. LIETO: Right.

MS. BURGESS: Okay.

CHAIRMAN MALMUD: If I may summarize, therefore, it sounds as if the Committee feels that the exercise of investigating this opportunity is worthwhile, number one; number two, that our databases are not coordinated perhaps in the same fashion in which European or French method is coordinated or in a way in which they are seeking the data.

In addition, in the United States, there are certain cultural differences in the way that we deal with these issues and the way that we investigate these issues and upon whom we rely for our database.

So that perhaps the advice that you mentioned earlier that we go slowly is good advice, not in the sense of creating friction but in the sense of collecting appropriate data so that we understand

what we are doing ourselves before we share the data with an international body that might interpret the data in a way that we had not intended or in a way that is not in the best interest of the public, which is essentially our concern.

Does that summarize that which has been said thus far?

(No response.)

CHAIRMAN MALMUD: I assume the silence is agreement and, therefore, you have our opinion at the moment. So that we should pursue this, but our first goal should be to refine our own database and understand how we achieve it and whether or not we are prepared to evaluate it in a fashion in which it has been suggested that we do this.

MS. BURGESS: And as far as further communications, work that through --

CHAIRMAN MALMUD: We welcome further communication on a regular basis from your efforts. We are intensely interested in it. It would affect the practice of medicine, which is our concern, not as members of the ACMUI but in our professional lives and, therefore, are very concerned about the risk of unintended consequences coming from an intellectual effort, which may not have a sound database at the

moment.

MS. BURGESS: I greatly appreciate all of the input here. I have been taking notes throughout. Some of them are echoing things that we brought up in our committee, which is reassuring me because at least we were on track for a good bit of it. We're having apparently some of the same thoughts that you guys were. But there are a lot of details that you have added to this.

So I thank you very much for the immediate input and will work with Ashley to continue this dialogue. And hopefully we'll be in a better place for November and what we want to tell IAEA then.

CHAIRMAN MALMUD: Thank you.

From the discourse that just occurred, it's obvious to me that the Committee is very interested in what you are doing. And if we can be of any assistance in the future, we are here and ready to do so.

MS. BURGESS: Thank you.

CHAIRMAN MALMUD: Thank you.

CHAIRMAN MALMUD: We will, therefore, move on to the next item on the agenda, which is Dr. Thomadsen, who will be discussing training and experience, T&E, a subcommittee report on

interventional radiologists as Authorized Users for yttrium-90 microspheres.

MEMBER THOMADSEN: I have some slides to know where we are on this.

MS. COCKERHAM: This is Ashley. If you are looking for slides, they were provided today. So we don't have any hard copies.

MEMBER THOMADSEN: Right. I apologize for that, but maybe people will pay attention to the screen.

The goal of the subcommittee was to develop training and experience requirements for interventional radiologists, who become Authorized Users for radiolabeled microspheres.

In general, for whatever medical use, the Authorized Users have three sections, two or three depending what they are, as far as requirements, training in basic radiological sciences, the training specific to the modality sort of, and experience under supervision.

The basic radiological science was fairly standard between all of the modalities. I won't put the list up. The duration is different for the different uses. Ophthalmic applicators was between 24 and 80 hours of these didactic trainings. And they go

up for different types of modalities depending on how complicated they may be as far as the radiological sciences.

The subcommittee took a vote on this. There was sort of consensus around 80 hours. It was not uniform. There were some who felt that it was too much, some who felt it was too little. But there seemed to be a number of hours that people could agree on.

Here are the topics. And the list, as I said, is very standard across the board. The 80 hours is towards the low side. It's higher than the ophthalmic applicators but at the bottom of everything else.

And we get the specific modality trainings. And I have lists here of what is specified for some of the similar types of therapies. Here is I-131, greater than 33 millicuries.

And you have experience in -- and then there is the lowercase Roman numerals: ordering, receiving, and packing, performing quality control, calculating measuring safety, preparing patients, using administrative controls to prevent medical events, using procedures to contain spilled byproduct material, and administering doses to patients.

One through 5 are sort of under the misconception that the Authorized User would ever do those things. Number 6 is actually the part here that they have to have experience administering doses to patients or human research subjects and include three cases.

Manual brachytherapy, 500 hours work experience ordering, receiving, et cetera, checking survey meters, preparing implants. C is certainly relevant -- it's not clear that most Authorized Users do that, as opposed to their staff -- maintaining/running inventories, using administrative controls, et cetera, using emergency procedures.

And this is the third part of the training and experience that I had on that second slide. Manual brachytherapy, as opposed to the I-131 therapies, has the additional requirement to have three years supervised clinical experience in radiation oncology.

Ophthalmic applicators, you need the supervised training, of course. I, examining each individual to be treated, calculation of the dose to be administered, administration of the dose, and follow-up and review of each individual case history.

This list actually deals with stuff that

the Authorized User has to do. I and IV deal with the practice of the individual, but it's not dictating medical practice. It's just dictating what sort of experience the person has to have in order to do this, just like requiring a medical license would be.

Dose rate brachytherapy, we have similar lists of items that the Authorized User has to be trained in: 500 hours work experience, including those things it does not have a list of practice things, but it does have a three-year requirement in that potential third part of the training and experience.

The subcommittee at this point had a little problem. Here is one proposed list of training that the Authorized Users for microspheres should have. Taken as a hybrid from some of the other lists, you'll see a lot of the same things there. The suggestion does not have anything like a three-year residency following it as a third part to this proposal.

In discussion of the proposed training, there was concern by one of the people looking at the list that the red were comments that we should change some of the wording there, "performing quality control procedures and instruments." That's fine.

Number 3 was commented as vague and dealing with practice of medicine. Three was examining each individual patient to be treated. And down in number 7, some words again. That's not a big problem.

In number 8, we have the follow-up and review of each individual treatment case treatment, where another individual had some similar comments in number 3, that this dealt with the practice of medicine and should be stricken. And number 5 also was practice of medicine and should be stricken.

So one of the questions that's coming up and I wish to discuss with the whole ACMUI right now so that we can get past the training and experience is whether or not these do dictate medical practice or if they do just relate to the medical training and experience of the Authorized Users for this procedure.

So what I would like to do, Mr. Chairman, is that this is the report of the subcommittee that we have not come to a consensus on this. I would like to discuss with the whole Committee proposed specific training and experience for the interventional radiologists.

CHAIRMAN MALMUD: Thank you.

You are opening this for discussion now?

MEMBER THOMADSEN: If I may.

CHAIRMAN MALMUD: Thank you.

Dr. Eggli?

MEMBER EGGLI: In response to Dr. Thomadsen's comment, I think that the -- what is it? -- 3 and 8 are sort of practice of medicine, but when you look at the issue of risk, they're sort of more interference in the practice of medicine as the risk gets greater.

On every therapy I do in part 390, I do a focused examination of the patient. And, likewise, I don't think you will find a single interventional radiologist who doesn't do extensive follow-up on their interventional patients. I don't see that as imposing a good to the practitioner to do those things because I think they're part of our practice anyway.

CHAIRMAN MALMUD: Thank you.

Dr. Nag?

MEMBER NAG: I agree wholeheartedly that 3 and 8 are not really the practice of medicine. They are necessary to effectively treat this patient. And if you are going to give them Authorized User status, they necessarily have to evaluate. Otherwise you are giving X number of millicuries without knowing why you are giving that number of millicuries. So you

graduate to medicine.

So 3 and 8 are necessary to be in there. If it's under 390 or 490 by 3 years experience, we don't have 3 years experience here. So we hare not giving medicine, but we are making sure that the individual who is becoming an Authorized User might have the training to be able to use it properly.

CHAIRMAN MALMUD: Thank you.

Dr. Welsh?

MEMBER WELSH: I would concur that item 3, examination of the patient, and 8, follow-up and review of each individual case, is imperative as a component of this treatment modality for an Authorized User.

It, of course, is medically related and relevant, but it is also very essential for the radiation safety aspects. There are nuances about radiation safety in medicine that are sometimes under-appreciated, specifically regarding the organ to be irradiated and the isotope that is being used.

For example, the radiation of the sclera, which is very, very radiation-resistant, might not require the same degree of intensive understanding and training that somebody who is going to treat the retina would have to experience.

For example, in this particular case, I'm talking about that there might be a difference in the level of training and expectations for somebody who is using an ophthalmic applicator versus the NeoVista.

Similarly for thyroid treatments with iodine-131, the risk of injury to this person and the organ that is being targeted is very different from injury to the liver or to the lung, which possibly could be a fatal event.

And, therefore, there are differences in training and expectations between thyroid treatment with I-131 and Y-90 microsphere therapy of the liver. These radiation safety aspects are often under-appreciated and are really involved with radiation safety as well as medicine.

Therefore, items 3 and 5 are truly relevant to this group here when we talk about radiation safety, although they superficially could be more medical-related, rather than safety-related. They are truly safety-related.

CHAIRMAN MALMUD: Thank you. Dr. Welsh.

Are there other comments? Dr. Guiberteau?

MEMBER GUIBERTEAU: As a diagnostic radiologist representative, I don't think there is any real issue with either of these because it is the

standard of practice for interventional radiologists for all of their procedures, a pre-qualification examination of the patients in a follow-up for expected or unexpected complications. I mean, this is really the standard of practice.

Second of all, I would just like to remind those of you here that interventional radiologists are also board-certified diagnostic radiologists, many of whom are qualified to get if they have not already Authorized User status in 290, 392, and many in 394.

So there is experience in their diagnostic radiology training that they get. So that they do have experience with unsealed radioisotopic sources.

CHAIRMAN MALMUD: Thank you.

I believe we have a comment form a member of the public.

DR. STAINKEN: Thank you very much.

CHAIRMAN MALMUD: Introduce yourself.

DR. STAINKEN: Certainly. My name is Brian Stainken. I'm here as a representative of the Society of International Radiology. I serve the society as its president currently. We represent 4,300 interventional radiologists practicing across the country.

With regard to the specific issues, we

agree wholeheartedly. We strongly emphasize and endorse that all of our members should see patients prior to treatment and follow the patients longitudinally for the treatment that they provide that's also endorsed by the American College of Radiology as a resolution ten years ago.

CHAIRMAN MALMUD: Thank you.

Dr. Van Decker?

MEMBER VAN DECKER: Yes. You know, it would be different if it said that this category should be applied only to the following types of patients or it made specific clinical scenarios here. That would certainly be interfering with medicine.

But the question I guess I wanted to put on the table just to raise a ball of wax is it says, "each patient to be treated," and it doesn't really give a number, which right now I guess is a guidance space to some degree.

You know, I have no horse in this race, but I was just wondering what the thoughts of that were as far as keeping things in guidance and to dah dah dah dah and where we thought that was going because iodine is not necessarily the same.

CHAIRMAN MALMUD: Thank you.

Dr. Thomadsen?

MEMBER THOMADSEN: May I address that?

CHAIRMAN MALMUD: Please.

MEMBER THOMADSEN: In the third part of this, there is a requirement to participate in three cases for the type of microsphere that is being used. This list doesn't give a number of cases for that because it is training in the follow-up and review of teach individual's case; that is, making sure people know for these types of cases how they should be reviewed and followed up. So that's why there's no number of cases listed for that.

CHAIRMAN MALMUD: Thank you.

And I believe that Dr. Suleiman was next.

MEMBER SULEIMAN: I want to remind people that the indications for which the microsphere products were approved by FDA were for humanitarian use for non-resectable hepatocarcinoma.

And I wanted to be very clear that when you hear the term "dose" here, it doesn't mean anything near the level of precision or accuracy when you're dealing with external beam or brachytherapy.

There have been some interesting investigations, but you probably cannot accurately estimate to within an order of magnitude what the actual dose is being delivered.

A certain amount of radioactivity is administered. And so you don't have the benefit yet. It's something to be developed of scientifically determining how much activity has been delivered to the tumor.

So be careful about comparing this specific application to a lot of other traditional therapeutic applications.

CHAIRMAN MALMUD: Thank you.

I think there is another comment from a member of the public.

DR. STAINKEN: Thank you. Brian Stainken again.

With regard to that, I appreciate what you are saying. I think that a lot of the competency with regard to these therapies relates to the knowledge and skill and catheter placement, catheterization, and microcatheterization in the label, which also certainly influences the dose delivered on the per cc basis.

In terms of determining a threshold number of cases for the purpose of experience, I would support the three-case observation threshold with the experience of getting through residency and fellowship and interventional radiologists, which addresses the

catheterization experience. And most programs also experience observing Y-90 procedures.

CHAIRMAN MALMUD: Thank you.

It sounds as if, Dr. Thomadsen, that there is unanimity of agreement with regard to the eight items on the slide entitled "Proposed Specific Modality Training."

MEMBER THOMADSEN: Excellent. We have one more order of business here, then. If I go backward through here, high dose rate brachytherapy requires 500 hours of those items; that is, in addition to the three years supervised training. Actually, it's concurrent with.

Ophthalmic applicator does not really specify the duration of the training for those four items. Manual brachytherapy has the 3-year residency and the 500-hour again requirement for those items. I-131 treatments greater than 33 millicuries does not specify the number of hours.

So the next and the last question that I think we need to address is for the eight items, do we feel we need to put a time for the training on these items or not?

In argument against a time, all except possibly 3 and 8 would be included during the

residency for a radiologist in their training. And, as a result, the residents would receive all of these trainings normally. The argument for putting a thumb limit on these is for completeness, just so that we specify that.

I would entertain suggestions from the Committee.

CHAIRMAN MALMUD: Dr. Eggli?

MEMBER EGGLI: I think as a general pattern, when a training requirement is specific and limited to a single application, the time required has been less than when you can broadly practice in a category. I'll take the areas that I'm familiar with, which are the part 300 uses.

If I am going to treat broadly and my training requirement comes under 390 and I have to have 200 hours and training but if I have a narrow focus, such as the radioiodine training -- and I actually think that both 392 and 394 do require 80 hours of training -- then a lesser number of hours is required.

Part of the reason for putting the hours in there I think is to support the alternate pathway for people who don't always achieve board certification but, yet, qualify as Authorized Users.

And I think given the pattern that we have seen over many applications, that it is reasonable to have the 80-hour T&E requirement for this application as well.

And, as you have already mentioned, Dr. Thomadsen, that 80 hours is typically covered in most training programs because ABR requires that the trainees meet requirements currently, at least for 392, which does have an 80-hour requirement in it, so we don't produce a hardship for the diagnostic radiologist requiring 80 hours of basic education in radiologic sciences. But we do set a recommendation for the individuals, who would train via an alternate pathway.

So I agree with you that it is important to set a limit. And, again, I would use the pattern that has been used for regulation in this arena. When you train broadly, you have a greater requirement than when you train specifically. And I would support an 80-hour training requirement for this application.

CHAIRMAN MALMUD: Thank you, Dr. Eggli.

Dr. Welsh?

MEMBER WELSH: I was one of the individuals who did support an hour, number of hours, in this particular proposal. And this is why I

brought up my points earlier about radiation safety being organ-specific. And there are some nuances that are sometimes or not infrequently overlooked.

And with iodine-131 therapy as an example, the potential risks associated with this type of treatment are such that perhaps 80 hours is sufficient. But when you are talking about treatment to the liver, to the lung, other treatments that might have potentially fatal consequences if not administered properly, I do think that it is very prudent to have a set number of hours as a minimum level of training. And that's why I would propose in favor of having hours stated.

CHAIRMAN MALMUD: Dr. Nag?

MEMBER NAG: Dr. Thomadsen, I thought in your second or third slide, it had shown you had already said that the members of the subcommittee had agreed on 80 hours. So why is the number of hours coming up again if the subcommittee members had agreed on 80 hours?

MEMBER THOMADSEN: These are again the three areas of training. The first is basic radiological sciences. That's mostly didactic training. And that is where we have the 80 hours for this curricula.

The next is specific for the modality. And that's where we have these lists of these types of training, which would be didactic and laboratory, which we have not set the hours for yet. The 80 hours was for the basic radiological sciences.

We now have the specific modality treatment that we have not set hours for. The subcommittee did not either. We were divided on that issue.

CHAIRMAN MALMUD: Thank you.

Does that answer your question, Dr. Nag?

MEMBER NAG: Yes.

CHAIRMAN MALMUD: I think we have a member of the public, then Dr. Eggli.

MR. STAINKEN: Thank you very much. Brian Stainken for SIR.

As far as modality-specific training, I would submit to the Committee that the critical training relates to the understanding of catheterization, the technical experience, and microcatheterization, understanding of the flow dynamics, particularly in the liver collateral circulation particle flow and distribution, and a fairly sophisticated understanding of the dynamics of the bed in which one is working.

This is gained through both a diagnostic residency and certification there as well as the fellowship in interventional radiology and the second step of certificate-added qualification after a year of fellowship. Those aspects, unlike a radioisotope that might be orally, are critical to the effective performance of the procedure.

Thank you.

CHAIRMAN MALMUD: Thank you.

Dr. Eggli?

MEMBER EGGLI: I think I have to do it in hoops. I was supporting the general 80 hours, not an additional 80 hours, of modality-specific training.

When I treat a patient with radioactive iodine who has lung metastases, I can cause pulmonary fibrosis and kill the patient. If I treat a patient with limited bone marrow reserve with radioactive iodine, I can kill the bone marrow and subsequently kill the patient.

The patient complaint that I have had most commonly that caused patients to refuse further treatment is the management of the possible risk of zero stoma.

So I would argue that there are both life-threatening and disabling consequences of

treatments that fall in the part 300 range that I think are of similar magnitude to the microsphere treatment of the liver.

So I will say I misunderstood the question. I would not support any additional modality-specific training. I think that the risks of this treatment are quite comparable to a part 394 treatment. And I would not support any additional training requirement beyond the 80 hours of basic radiologic science.

CHAIRMAN MALMUD: Thank you for clarifying your position, Dr. Eggli.

Dr. Howe?

DR. HOWE: I wanted to kind of expand upon something Dr. Eggli said earlier and also to clarify. When NRC revised 35-300 area and added 396, 396 can't really be equated to 392 or 394. Three ninety-two and 394 were meant primarily for endocrinologists that were treating a single organ. And so those 80 hours pretty much stand alone.

If you look at 396, that was an expansion upon an ability for a group that already had three years of residency training or three years of clinical experience in 400 uses or 600 uses.

So the radiation safety basis for the 396

people is much more extensive than for the 392 and 394 for a reason. And that's why we accepted 80 hours with the 396 people, because they had much more extensive radiation safety patient training.

CHAIRMAN MALMUD: Thank you, Dr. Howe.

Dr. Thomadsen? Are the questions that you raised resolved in your mind with respect to the Committee's opinion?

MEMBER THOMADSEN: No. Before we get out of here for the break, I think we need to have a time set on this. As far as a lot of the radiation safety problems with this, the modality is a multidisciplinary treatment, where there is either a medical physicist or a radiation oncologist present.

So addressing many of the radiation safety problems would probably fall to those people. And the interventional radiologists, who may not have as much experience with preventing spills and addressing contamination due to the spills, would have the backup of people who are trained and certified in that, those types of issues.

So I would suggest that the duration here of 80 hours would also be sufficient. And I would put that forth as a proposal for this list of training.

CHAIRMAN MALMUD: You are proposing that

80 hours would be sufficient for the use of yttrium microspheres in the liver?

MEMBER THOMADSEN: For the interventional radiologists in this listing. That's assuming that they have gone through a residency. We could specify that in the part 3, like this, the interventional radiologist, who is applying for Authorized User status for the microspheres has completed a three-year residency in radiology. We could do that also.

CHAIRMAN MALMUD: Other comments? Dr. Stainken?

MR. STAINKEN: I believe I was after Dr. Guiberteau, but I would be glad to proceed if you choose. Several quick comments.

The radiology residency is four years after a one-year clinical internship. Subsequent to that, interventional radiologists complete a one-year fellowship, all of which go through the American Board of Radiology certification process.

The issue specific to Y-90, we believe that are unique aspects to the arterial delivery of these radioisotopes. Technically it's performed in a fairly well-controlled sterile environment, with a sterile operator being the interventional radiologist.

We believe in many centers across the

country, teams have been formed with IRs, radiation safety, radiation oncology, which are working well. And we endorse that. Likewise, there were teams that had been formed with nuclear medicine and radiation safety and interventional radiology.

What we are seeing in the community, however, is that there appears to be a greater need for these procedures than capacity to form these sorts of teams can provide for.

What we're seeing is upwards of 170,000 new patients a year presenting with colorectal liver-dominant disease and hepatocellular carcinoma, the majority of which are unresectable, and can potentially profit personally from this sort of treatment.

We see this as an access issue. We believe that the combination of residency training, fellowship training, observed experience, and a focused course specific to the delivery of Y-90 will provide a pool of safe operators and give more patients access to this important therapy.

Thank you.

CHAIRMAN MALMUD: Thank you for your comments. I have only observed two of these procedures and don't pretend to be an expert in them.

Clearly, the skill of the interventional radiologist is an essential component to delivering the microspheres. And that skill resides from my observation only with the interventional radiologist. There's no one else on the team who has the ability to provide that service.

With respect to the radiation issues, however, the interventional radiologist is not the individual who traditionally, at least in our environment -- and I admit to very limited experience with this -- has the routine ability to identify the dose to be administered and who has the experience in handling the radioactive material. There is always some other person there, whether that is a physicist, a nuclear physician, or a radiation oncologist.

Would you agree or is my perception from my limited experience not valid?

MR. STAINKEN: Well, certainly from the perspective of the regulations as they currently stand, that would be accurate because that is a requirement of the regulations that the Authorized User be present.

As an interventional radiologist Authorized User personally, I can speak to those issues. I think that it is an issue of focused

competency.

I think that this therapy, in particular, has been addressed earlier, the whole issue of dosimetry, how the dose is delivered, flow dynamics in the area of the presence or absence of collaterals in terms of determining target or this is off-target delivery are critical. It's a lot of expertise, a lot of unique and unusual perhaps expertise that's required toward accurate dosimetry.

We are certainly moving into a phase where it also may be driven to some degree by the type of histology or in the nature of the tumor in terms of how dosimetries performed.

I would submit to you that what is required is focus and expertise. I believe that that can be obtained through a team of radiation oncology in IR with radiation safety nuclear medicine, IR with radiation safety as well, as IR plus radiation safety presence as long as that IR is sufficiently expert.

What we are proposing is a process to document and validate that, in point of fact, they can meet that standard.

CHAIRMAN MALMUD: I'm not sure that I understand. And you'll pardon my confusion.

To me it is axiomatic that the key person

here is the interventional radiologist. Now, who calculates the dose? That's my question. Are you suggesting that a interventional radiologist himself or herself be the individual who does the initial calculation of what percentage of the liver is involved and the dose to be administered, not under the current regulation but under the theory that in order to provide this therapy to the latest number of patients possible, that the interventional radiologist have this responsibility? Is that what --

MR. STAINKEN: In centers where the interventional radiologist is the Authorized User, the expectation would be that the interventional radiologist will perform the dose calculation and sign off on the prescription.

In institutions where the Authorized User is someone other than the interventional radiologist, that responsibility would go to that individual.

CHAIRMAN MALMUD: Well, in a situation in which the interventional radiologist is an Authorized User, that interventional radiologist would be sole a practitioner who is doing the catheterization and also calculating the shunting, if you will, calculating the dose to the liver without any other necessary skills from radiation oncology or physics or nuclear

medicine?

MR. STAINKEN: That's correct. And that's currently my practice. And, actually, other people around the country are interventional radiologists, Authorized Users.

CHAIRMAN MALMUD: I just want to make sure that the Committee understands what the proposal is.

Dr. Suleiman?

MEMBER SULEIMAN: All right. With a little prodding from Dr. Eggli, this is an area that when I started to look into it, I was very surprised. Dosimetry in the classical sense is not conducted here.

The imaging is done to make sure that there is no contraindication that most of the particles are going to the liver. The distribution in the liver is not uniform or homogenous.

They're not calculating dose per for the target organ. These are refractory patients, humanitarian use label. It is not dosimetry at all in the classical sense.

Maybe somewhere down the line people will image, determine the volume of the tumor, somehow deliver an accurate within maybe 100 or 200 percent absorbed dose. It's not being done here. This is not

X-ray beam therapy, external beam therapy, or brachytherapy.

So the skill here is in the delivery of the radioactivity to the patient and hopefully that it's going primarily to the liver and not getting sidetracked through the vascular system elsewhere.

CHAIRMAN MALMUD: If I may, Dr. Suleiman, but the issue is not hopefully because there has to be someone with the skill -- and that could be the interventional radiologist if the interventional radiologist has a skill to make certain that the shunting is not excessive because then the injected material will not go solely to the liver.

MEMBER SULEIMAN: Oh, absolutely. I agree with that.

CHAIRMAN MALMUD: So it is an issue of concern about delivery of radiation to a portion of the body that was not intended to receive it? That's the issue. I agree that it's not an issue of dosimetry in the classical sense. I just want the Committee to understand it. That's all I'm trying to do.

Dr. Eggli?

MEMBER EGGLI: But that estimate of the shunting to other critical organs is really done by a

fairly standard nuclear medicine procedure with regions of interest and percent activity shunted.

And regardless of whether or not the interventional radiologist is the AU, odds are some nuc med doc or radiologist with a region of interest program in standard clinical nuclear medicine software will contribute that part of the determination as typically MAA has shut down the catheter and the distribution as a percent of activity in the field of view in the lung or in the stomach is reported.

And, again, the other second thing is we don't prescribe a dose. We prescribe an activity to be administered. And to me the key thing is knowing when to turn off the pump because you are seeing reflux of activity outside of that distribution.

And I think that the interventional radiologist is well-qualified to do these things with the proper software support. I see the interventional radiologist as well-qualified to determine the percent of activity administered that resides outside the liver in either the lung or the stomach.

CHAIRMAN MALMUD: Thank you.

I am not sure that I heard you say that he is or is not qualified to determine.

MEMBER EGGLI: Is well-qualified.

CHAIRMAN MALMUD: Well-qualified. Good. Okay. Thank you.

Dr. Nag?

MEMBER NAG: Thank you. At one point Dr. Suleiman's statement about users, but there is only one TheraSphere. What it says here, it is FDA-approved for use for the past uses for colon cancer. So that does seek clarification.

I think in our previous ACMUI meetings, we have already, the ACMUI had already, solved the problem. We have said that interventional radiologists could be Authorized Users.

I think the only work at hand now is what are the additional qualification and additional experience that are needed by an interventional radiologist to become qualified as an AU.

So we have already agreed that we are the best person to know where to place the catheter, how to place the catheter. All of that has already been solved. Therefore, I don't see a need to discuss whether interventional can be Authorized User or not. We have already voted on that, and we had said yes.

So the additional thing that they need to know is how to help make how many millicuries to be placed in, who are the proper candidates to be done

because if you are not having a nuclear medicine person or a radiation oncology person involved, they need to do that. You just have to add those persons in.

So I think we have only a limited amount of work left to solve this problem.

CHAIRMAN MALMUD: Exactly. Now, from the prior meetings of the ACMUI, did we not agree that three cases would be sufficient, the experience of three cases would be sufficient?

MEMBER NAG: Yes.

CHAIRMAN MALMUD: So that if the interventional radiologist is the Authorized User and has experience with three cases supervised, he or she is now qualified to do this procedure in his or her institution.

MEMBER NAG: Right. And having these 80 hours, we have agreed on 80 hours also, right?

MEMBER THOMADSEN: The 80 hours at the basic radiological sciences. We have not agreed on, first, whether we want to place a number of hours on this list or just use this list as a check sheet of what things they have to have had. And if we want a number of hours, how many hours would be covered by it.

CHAIRMAN MALMUD: That's why I asked my question. I wanted the Committee to understand what we are discussing so that when the Committee makes a recommendation, it will be on the basis of your summary.

Dr. Guiberteau?

MEMBER GUIBERTEAU: I think it might be informative to learn or be reminded by one of our interventional radiologists what sort of training is provided since this was originally coming to us as a device, what sort of training for interventional radiologists is provided by the manufacturer.

CHAIRMAN MALMUD: Thank you, Dr. Guiberteau. We have actually had that review at prior meetings.

MEMBER GUIBERTEAU: I understand. I know we are --

CHAIRMAN MALMUD: You are reminded of it?

MEMBER GUIBERTEAU: Well, I think just in terms of -- we're talking about three cases, but I think it wouldn't be a bad idea to have at least two minutes to hear again so that the Committee can be reminded that there is some additional training involved because we have heard about reflux through the catheters, et cetera.

But these were major concerns because these are the things that lead to what you have been talking about. And that is the appearance of Y-90 microspheres in places where it was not intended to be.

CHAIRMAN MALMUD: I am happy to have it reviewed. Though the Committee has already approved it, I am happy to have it reviewed for historical purposes. Who would care to review that?

MR. SALEM: I guess I can do that.

CHAIRMAN MALMUD: Please introduce yourself again.

MR. SALEM: Riad Salem, interventional radiologist.

So just to go over what we had discussed last time for the training, there are two manufacturers of the microspheres: Sirtex Medical and MDS Nordion.

Sirtex Medical provides on-site support and proctoring by physicians that are Authorized Users for three infusions. And I think Dr. Malmud mentioned that he was -- that's the treatment that he underwent for MDS Nordion and TheraSpheres. They actually put on a course that actually we administer at Northwestern for all sites that are starting. And I

believe Mr. Lieto and Dr. Thomadsen, in fact, have been to that course.

So there are two different mechanisms. And, in fact, the Committee has reviewed them last time and has approved that either mechanism is appropriate.

CHAIRMAN MALMUD: Thank you.

Dr. Guiberteau, is that sufficient for your suggestion?

MEMBER GUIBERTEAU: Yes, it is.

CHAIRMAN MALMUD: Thank you.

Dr. Welsh?

MEMBER WELSH: Well, I have a question that may be relevant to this matter at hand. And the question is, during diagnostic radiology residency training, do all of the residents receive the 80 hours that we're talking about here?

The question, of course, is relevant because if they do, that would mean they aren't qualified to do SIR-Spheres and TheraSpheres because of their residency training and not necessarily have to have additional hours and training during their interventional radiology fellowship.

I might have some comments and questions about that depending on your answer. Can anybody

answer that question?

CHAIRMAN MALMUD: Dr. Guiberteau?

MEMBER GUIBERTEAU: Under the current residency programs, our residents in diagnostic radiology, which would include budding interventional radiologists, does include 80 hours. That 80 hours falls under 392 at the moment -- we are in the process of requesting an expansion of that -- plus 700 hours of training and experience under 390.

MEMBER WELSH: Thank you.

If I may continue with that?

CHAIRMAN MALMUD: Please do.

MEMBER WELSH: So then I would ask this Committee as well as our interventional radiologists who are in the public audience today if we are all in agreement that the 80 hours that are obtained during diagnostic radiology training are truly sufficient for microsphere brachytherapy.

I can tell you in my opinion additional training specifically in radiation safety, radiation biology, and the medical aspects of this particular procedure may be appropriate.

But I just raised the question because the question I had about the number of hours doing radiology training.

CHAIRMAN MALMUD: Dr. Eggli?

MEMBER EGGLI: I would agree with one of the three issues that Dr. Welsh raises on the specific radiation safety of handling microspheres for therapy. But that's provided in the additional training that one has to receive to become certified.

Again, I think anyone who has met the threshold and, again, as ABR goes back and I believe upgrades for 394, then I believe that they have had sufficient radiation biology for this purpose, again given the very primitive state of dosimetry that Dr. Suleiman has already described.

So I would agree that any end user needs specific training in the handling of particulate unsealed source, which is effectively at, behaves as therapeutic agents. But that is provided in the specific training that's required.

CHAIRMAN MALMUD: Thank you, Dr. Eggli.

Dr. Nag?

MEMBER NAG: I would like to make sure that we do not leave any unintended consequence. We are now dispensing how and in terms of interventional radiologists who could become an Authorized User. So we are starting with the assumption based on assumptions that these are going to be for diagnostic

radiologists who have then also undergone interventional training because they have already had quite a lot of training in radiation.

What I do not want to happen is that sometimes the way it is written, that portion is missed. And someone from a different specialty, maybe medicine or someone, a medical oncologist, for example, can say, "Well, I'm only going to do this 80 hours." And they are not fully qualified because they would not have had many of the other general radiology training.

Dr. Thomadsen, could you make sure that we do not create a report like that?

MEMBER THOMADSEN: After we finish with the discussion of the eight, we will terminate with discussion of a similar requirement to this specifying that they have completed three years supervised clinical experience in diagnostic radiology with particular emphasis on interventional.

MEMBER NAG: Yes. I think that will help to put that in.

CHAIRMAN MALMUD: Thank you, Dr. Nag.

Dr. Thomadsen? The ball is back in your court, Dr. Thomadsen. What are you seeking from the Committee at this point?

MEMBER THOMADSEN: Well, I would hear Mr. Lieto's comments since he has I think been waiting.

CHAIRMAN MALMUD: Oh, I am sorry. I didn't see you raise your hand, Ralph.

MEMBER LIETO: Just regarding the list here, I had just a question on clarification. It's not really clear to me where the specific training requirements for dose calibrators or devices used to measure dosages is in that list. And I am wondering if we should maybe add a specific line item to that effect. That was one question.

And just a comment regarding the training. I think we need to be careful because if we're looking at using the diagnostic radiology residency training as documentation of adequate training and experience, we need to be careful because there is also a requirement that when they apply to become an Authorized User, that has been completed within a seven-year period.

So if you have somebody doing a residency and completing their training and they don't apply for this Authorized User application until beyond that time period, they're still going to have to go through this 80-hour requirement again anyhow.

CHAIRMAN MALMUD: Thank you, Mr. Lieto.

Dr. Guiberteau?

MEMBER GUIBERTEAU: Well, I want to point out several things in terms of the diagnostic radiology certification process. There is a portion of the examination dedicated only to radiation biology that must be passed by all of the diagnostic radiologists.

I think in section 392, which is also part of the certification process, there are a number of items here, in fact, many items, that overlap with the 390 and with the items up here, including calculating, measuring, and safely preparing patient and human research subject dosages.

And in this case, as we have pointed out, the administered activity is the most important aspect of this therapy. So that this training is what is included in the current process.

CHAIRMAN MALMUD: Thank you, Dr. Guiberteau.

So, if I may, Dr. Thomadsen, it seems to me that what the Committee is saying is that we recognize that an interventional radiologist is, first of all, a radiologist who has received the requisite number of hours of training, that the interventional radiologist, in addition, has the skills of the

interventional radiologist which are necessary, essential for the performance of the actual delivery of the material into the blood vessel and that if the interventional radiologist is an Authorized User, that that individual is the captain of the ship for this procedure and assumes the responsibility for the procedure having been done correctly, whether or not the interventional radiologist has working with him a radiation oncologist, a nuclear physician, or a radiation physicist. Is that a fair summary of what the Committee has said?

MEMBER GUIBERTEAU: Yes.

CHAIRMAN MALMUD: Hearing no comment --

MEMBER NAG: Yes.

CHAIRMAN MALMUD: Oh. Dr. Nag?

MEMBER NAG: I would agree with your comments except for one part, which is that even when a radiation oncologist, like me, is involved, I still have a radiation physicist who is helping in many of the calculations. So I would not be very open to excluding a radiation physicist from that group.

CHAIRMAN MALMUD: Well, I would ask you a question, then. Do your requirements in providing radiation oncology require that you have a radiation physicist backing you up or may you practice without

the physicist if you wish?

MEMBER NAG: We basically supervise the physicists, but I need detailed calculations through the physicists. And I think, Dr. Thomadsen, if you would like to make some comment? We depend for many of our calculations on our physicist.

CHAIRMAN MALMUD: Dr. Eggli?

MEMBER EGGLI: I think generally that's true. But, again, to come back to Dr. Suleiman's point, there are no detailed calculations occurring in this procedure.

CHAIRMAN MALMUD: We agree. We agree. My question to Dr. Nag was of a different nature. And that is that in order for you to provide radiation oncology, is it a requirement in writing that you must have a physicist participate in the case with you.

MEMBER NAG: In many of the subparts; for example, in HDR brachytherapy, you use an Authorized User and a physicist, too. There is at least a subpart of radiation oncology where we need the critical calculations.

CHAIRMAN MALMUD: The reason I am asking the question is that if that applies to radiation oncology, then there would be a logical extension for that to apply here with regard to radiation safety.

But if it's not a requirement, then you as the captain of your ship in providing radiation oncology can provide a therapeutic program without the participation of the physicist if you choose to do the calculations yourself.

MEMBER THOMADSEN: Can I? Just a point of order.

CHAIRMAN MALMUD: Dr. Thomadsen?

MEMBER THOMADSEN: I don't think that this is really germane to this discussion.

CHAIRMAN MALMUD: Okay.

MEMBER THOMADSEN: We're only talking about whether the interventional radiologist can serve the function of the Authorized User. And it's not dealing with anything different about how the procedure is being done.

CHAIRMAN MALMUD: Of course, you're correct, but the purpose of my question was to avoid putting into a regulation or a standard of practice something that would constrain the interventional radiologist from performing the procedure in an institution that is not a large institution that doesn't have a large staff in order to provide the service to the patient.

Not all of us are large university

hospitals or very large institutions. And the incidence of the potential application of this therapy we have heard might be as great as 170,000 cases a year.

I doubt that they are all going to get it, get that therapy, but the point is that that is the incidence of the disease, metastases to the liver.

DR. STAINKEN: That's correct.

CHAIRMAN MALMUD: So I am just trying to make sure that all of us understand what we are voting for and about. Now, what is the question remaining on the table?

MEMBER THOMADSEN: Mr. Lieto still has a --

MEMBER LIETO: No. I was just going to answer the Chairman's question in that my understanding is that what we're voting on is the training and experience requirements to authorize IRs to function independently as Authorized Users without necessarily the presence of medical physics, radiation oncology, or nuclear medicine involvement.

CHAIRMAN MALMUD: And we know that they have the 80-hour requirement because they are board-certified and they received it in the course of their residency. So now that we know that they have

that 80 hours and we also know that from our previous discussions we are requiring participation in three cases or attendance of that course depending upon the product, the question is, do we want to require anything more by virtue of number of hours? Isn't that your question on the table?

MEMBER THOMADSEN: I will make a motion right now --

CHAIRMAN MALMUD: Please do.

MEMBER THOMADSEN: -- that the training and experience for interventional radiologists would include: one, the list that we have already used; two, is this list with the addition of another Roman numeral dealing with the operation and quality management or operation of dose calibrators without specification of hours; and a third part specifying completion of three years supervised clinical experience in radiology with particular concentration in interventional radiology.

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

MEMBER NAG: I will second to the motion. I was going to make a similar motion anyway. So I will second it.

CHAIRMAN MALMUD: Thank you.

Discussion of the motion? Dr. Eggli?

MEMBER EGGLI: My only concern is the question of the dose calibration because it is very difficult with the standard dose calibrator to calibrate a Y-90 dose. And typically you rely on the statement of activity provided by the provider of the dose, who has better capability of measuring the actual activity. And then you apply an NEK correction, which may be necessary based on time of administration.

So I'm not sure that we need a specific statement about calibrating doses in a dose calibrator because, again, betas are notoriously difficult to calibrate in a dose calibrator.

CHAIRMAN MALMUD: Thank you, Dr. Eggli, for reminding us of that. You're correct, of course.

Dr. Howe?

DR. HOWE: I was just asking for a clarification. In the discussion ACMUI is having right now, the proposal that Dr. Thomadsen has put up does not require board certification. And when you are discussing it, you keep saying that because they have board certification, we know they have this. But that is not in the criteria.

CHAIRMAN MALMUD: Thank you for bringing

that to our attention. Dr. Thomadsen, did your recommendation include board certification?

MEMBER THOMADSEN: Well, it did not because I was mostly thinking of this as how we can specify for the alternate way. And I take that as almost a friendly amendment that we should specify board certification as we normally would, however we normally would do that nowadays for these people.

But that would be covered by the three years supervised clinical experience.

CHAIRMAN MALMUD: Are you suggesting that the three years of supervised clinical experience would be instead of board certification?

MEMBER THOMADSEN: As the alternate pathway.

CHAIRMAN MALMUD: So either board certification and/or three years of supervised clinical experience?

MEMBER THOMADSEN: Yes.

CHAIRMAN MALMUD: Is that acceptable? Can we have a discussion? Mr. Lieto first.

MEMBER LIETO: Well, I would ask our visitors in terms of becoming an interventional radiologist, are there interventional radiologists who are not board-certified?

CHAIRMAN MALMUD: Please?

MEMBER LIETO: I would be real reluctant to have such an alternate pathway required.

CHAIRMAN MALMUD: Okay. Let's get the question answered.

MR. MAURO: Thank you, Mr. Chairman. My name is Matt Mauro. I am actually chairman of the Interventional Radiology Commission and one of the Board of Chancellors of the American College of Radiology.

My answer is that currently everyone who is practicing this level of therapy are subspecialty trained and board-certified interventional radiologists. And from our perspective, we will support the notion of requiring board certification. And, in addition, we support Dr. Thomadsen's notion of requiring added training in interventional radiology for this type of experience.

CHAIRMAN MALMUD: Therefore, there is enthusiastic support from the representation of interventional radiologists that board certification be included in diagnostic radiology.

Dr. Eggli?

MEMBER EGGLI: This may be a regulatory question. I realize that most regulations have

definitions up front, but maybe as a portion of the credentialing for this, we could describe the qualification, the base qualifications, of what it is to be an interventional radiologist.

CHAIRMAN MALMUD: I can't answer that without asking an interventional radiologist to comment. Dr. Thomadsen, do you want to say something?

MEMBER THOMADSEN: Yes. Just to question, a legal question, is there a problem with that with restraint of trade? I mean, I think the reason why there are alternative pathways is to avoid that problem. I don't think this is any different from anything else.

CHAIRMAN MALMUD: Dr. Howe?

DR. HOWE: I don't know if I can answer that, but I will tell you that we call the alternate pathway the alternate pathway. The alternate pathway historically has been the primary pathway because it was the first pathway. And then board certifications came later.

I think NRC might have difficulty figuring out what interventional radiology boards because there may be more, there may be more groups that want -- if you put criteria in there, there may be more groups that want to come under that that you may not have

considered. You just have to be very careful. And that's probably something that OGC has to answer.

CHAIRMAN MALMUD: Then would your motion be amended acceptably if it said either satisfying the alternate pathway for radiologists or a board certification in radiology plus the training in interventional radiology? Would that be acceptable?

MEMBER THOMADSEN: Almost, with the wording that I had used before, with the supervised training in radiology plus a -- I think it was a concentrated training in interventional. Then it would be acceptable.

I think the task of the subcommittee was essentially to define the alternate pathway, what would be the acceptable training and experience other than just saying board-certified radiologist?

CHAIRMAN MALMUD: Dr. Eggli?

MEMBER EGGLI: What if you were to take this statement and add to that "which includes at least one year of training in interventional radiology"?

MEMBER THOMADSEN: I would like that myself if that would be acceptable. I would consider that a very friendly amendment.

CHAIRMAN MALMUD: May I ask the

interventional radiologist who was our guest today to comment on that?

MR. SALEM: We would enthusiastically support that.

CHAIRMAN MALMUD: It has enthusiastic support of interventional radiology. May we move on with the motion then? Another comment? Steve?

MEMBER MATTMULLER: Yes. Another friendly amendment. I'm not sure whether it belongs on this page or the previous page. I know we have discussed this in past discussions, and I haven't seen it quite yet, the requirement that -- I'm trying not to say interventional radiologist, IR, but the individual would also complete specific training from the specific manufacturer of the product that they are going to use.

MEMBER THOMADSEN: That's already --

MEMBER MATTMULLER: Is that?

MEMBER THOMADSEN: Yes.

MEMBER NAG: I think it's in there.

CHAIRMAN MALMUD: We've done that previously.

MEMBER THOMADSEN: That's not in here. That's already in the requirement for performing the procedures. They cannot perform the procedure without

specific training for participation in three cases. That's outside of this scope. It's already in authorization to do the procedure.

Whether you are an interventional radiologist Authorized User or radiation oncology Authorized User, that requirement stays.

CHAIRMAN MALMUD: Thank you.

Ashley, you had your hand up.

MS. COCKERHAM: Actually, I just would like you to come back to me before you vote so I can clarify exactly what I have written down is going to be your actual recommendation.

CHAIRMAN MALMUD: We will do that before we vote.

MS. COCKERHAM: Thank you.

CHAIRMAN MALMUD: We have two more comments, I believe. Dr. Van Decker?

MEMBER VAN DECKER: The dumb guy from north Jersey still needs a clarification, I guess. So this magic three patients, that's then going to be in guidance for the procedure? And does it need to be in rulemaking space that will be considered a requirement of any of the people being involved in the procedure?

Is that the way we envision this? What space does that sit in? This is going to go in some

category of point whatever, right? And so the question is, where does this other requirement go? How does it get linked?

CHAIRMAN MALMUD: The space experts are here. Dr. Howe? Dr. Zelac?

MEMBER SULEIMAN: If you will recall, when we first started on microspheres, it was only specifically the radiation oncologists that were the Authorized Users, acceptable Authorized Users. And it was easy in the guidance to indicate who those persons were because we have a category in the regulations already under 490.

So simply saying under 490 or 690, I think it says, the person could be an Authorized User, then subsequently be considered nuclear medicine physicians. And who from that group could have appropriately also be considered as an Authorized User? And, again, it was easy to do because it was simply a reference to 390.

Here for interventional radiologists, however, we have a difficulty because there is no section in the regulations who can easily be referenced by a number when stating who the Authorized User should be.

So that's why we're getting more specific

here as to exactly what the qualifications should be for an individual whom I'll call the interventional radiologist to be named as the Authorized User.

DR. HOWE: Dr. Malmud, also to clarify in space, microspheres are in 35-1000. So the requirements for using the microspheres are currently posted on the Web site and can be revised in a much easier manner than if they were in the regulations.

And, as Ashley said earlier today, we are still seeing evolution of the microsphere use. So we are not putting it into rulemaking space until the one after the 2009. We're hoping it's stabilized by then. So it's in 1000 space.

CHAIRMAN MALMUD: Thank you.

Does that answer your question, Dr. Van Decker?

MEMBER VAN DECKER: Yes and no. It answers my question that the 3 is in 1000 space right now, which is what I would have assumed. And then when it comes out, then it would have to go in here somewhere I would assume.

DR. HOWE: And the decision of where it goes hasn't even been started to be made.

CHAIRMAN MALMUD: Thank you, Dr. Howe.

Dr. Nag?

MEMBER NAG: Two friendly amendments. One would be taking it out of calibration and putting it as someone should have experience and training in the three calculations, instead of calibrator, since calibrator is probably not appropriate or not needed in this case.

And the second amendment would be that we put the three cases -- we bring the training here because for diagnostic radiologists, they do not have three cases or they do not have the space, like we do for 490, 690, or 390. So that's the three cases through the training requirements right here.

MEMBER THOMADSEN: I don't consider either of those friendly. The last, I think since we have not put three cases in anywhere for the radiation oncologists or the nuclear medicine physicians, I don't think this is the appropriate place to put this at this given time.

And if it moves out of part 1000 and we will have to do that for the others, other Authorized Users, that would be the time to figure out where we're going to be putting them. So I would rather wait and be consistent with all the Authorized Users for this procedure at that time.

As far as this calibrator, I disagree

heartily with Dr. Eggli as far as the appropriateness of a dose calibrator. I think you do have to know what you are doing if there are peculiarities with dealing with the beta emitter. That's why the training in the dose calibrator is so important.

It is also important to check the radionuclide's activity when you receive it. There have been cases where it has not been correct.

CHAIRMAN MALMUD: Dr. Eggli, do you wish to respond?

MEMBER EGGLI: I understand Dr. Thomadsen's point. And I don't disagree with it. However, currently I guess, then, requiring the use of a dose calibrator to measure this dose on the site is currently not in regulation.

I realize it's in the revisions proposed for radioactive iodine, but I don't believe there is a current requirement to actually measure a dose on site that has been precalibrated by a supplier. Am I wrong on that?

CHAIRMAN MALMUD: Dr. Howe?

DR. HOWE: The microspheres are currently considered as manual brachytherapy. And so I believe in the guidance you're supposed to be following the criteria in the 35-1000 series. And there you have to

either calibrate it or use the manufacturers' numbers.

MEMBER EGGLI: But that's either/or.

CHAIRMAN MALMUD: That's either/or. Thank you, Dr. Howe.

So Dr. Thomadsen would prefer that the motion stand as it is if that is acceptable to you.

MEMBER NAG: I am okay with that.

CHAIRMAN MALMUD: Thank you.

Any more comments before we move on the motion? Dr. Suleiman?

MEMBER SULEIMAN: Yes. I would first like to get clarification myself. I am confused about what is exactly on the table. I also want to share my feelings just for the record.

As a scientist, when I first got involved with some of these radiotherapeutics, I was basically in shock at the lack of dosimetry. But then I started to realize that these are competing not only with radiation therapy procedures. They're also competing with conventional oncology drugs.

And when FDA approves a product, we pretty much defer to the medical community and the practice of medicine and the self-standardization and certification and qualification. So we really don't get into that level of detail. Maybe sometimes we

should, but we don't.

And something that still burns in my ear from one of our physicians because we have all sorts of specialists back at the agency and I was arguing with them about the dosimetry and they said, "We have to get these products out because if we make them so restrictive, they may never see the daylight."

And these are not necessarily competing with radiation therapy. They're competing with chemotherapy drugs. And there are some inherent advantages.

So I am wondering, are we, speaking on the Nuclear Regulatory Commission, the ACMUI, so muddling this? Are we going to handicap the users to such a degree?

And I really defer to the medical doctors on the Committee for their opinions on this. But can the profession self-regulate itself sufficiently or does everything have to be specified within 10 CFR?

So I am just laying it out there. I think you are going to need a lawyer to figure out what you are supposed to do. And is this going to so inhibit the adoption of some of these therapies that they just won't be used? They'll defer to the alternative chemotherapy drugs or some other alternative.

CHAIRMAN MALMUD: Well, thank you for bringing that concern to us. That was my concern in trying to allow the interventional radiologists to perform this technique because it's the interventional radiologist's skill, the catheterization that is lacking in all the other specialties.

So if we don't encumber him or her with unnecessarily regulation, we can move forward. And it seemed to me that Dr. Thomadsen's subcommittee's recommendations fulfilled that need to get the therapy to the patient in the hands of a highly recognized, highly trained group of individuals, meaning the interventional radiologists in this case.

So if we may with the motion on the table vote for it, recognizing your concern, our concerns, I think we could achieve some guidance for the use of the therapy.

Dr. Nag?

MEMBER NAG: I would appreciate Ms. Cockerham and with the Committee, Dr. Thomadsen, review what the motion is after all the amendments have been made to everyone? Because we made some amendments after the initial statement.

CHAIRMAN MALMUD: Thank you.

I will ask Dr. Thomadsen to do that since

it's his motion.

MEMBER THOMADSEN: I would be happy to, and I never thought I would say this. But Mr. Lieto is very shy and has not made himself obvious as he wants to make comments today. But it looks like he has one more comment before we summarize.

MEMBER LIETO: Well, I just wanted to clarify the three-case training and experience. It is my assumption that this here is in addition to the three-case training and experience that must be a part of this training and experience to become an Authorized User because it's ubiquitous whether you're a rad onc or a nuc med or an IR. Is that correct?

MEMBER THOMADSEN: That is correct, yes.

MR. LIETO: Okay.

MEMBER THOMADSEN: The proposal on the table, are we ready over there?

MS. COCKERHAM: Yes.

MEMBER THOMADSEN: And please correct me if you have something I don't have.

MS. COCKERHAM: I am going to type it twice.

MEMBER THOMADSEN: Training and experience for interventional radiologists desiring Authorized User status for radioactive microspheres would include

80 hours training in this list.

I won't read the list because you can capture it from the slides and training that includes these eight items plus a ninth item, which would be the operation and quality management for dose calibrators and --

MS. COCKERHAM: Can you repeat that part at the end?

MEMBER THOMADSEN: Yes. The operation of and the quality management for dose calibrators and has completed three years of supervised clinical experience in radiology and one year in interventional radiology. Has that captured the amendments that you guys made?

CHAIRMAN MALMUD: Yes, I believe that it does.

MEMBER THOMADSEN: I think that's it.

CHAIRMAN MALMUD: We'll move the motion. All in favor?

(Chorus of "Ayes.")

CHAIRMAN MALMUD: Any opposed?

(No response.)

CHAIRMAN MALMUD: Any abstentions?

(No response.)

CHAIRMAN MALMUD: Let the record show that

the motion moved unanimously.

First of all, thank you, Dr. Thomadsen, for a yeoman's job. And congratulations.

(Applause.)

CHAIRMAN MALMUD: May we take a break now? Thank you. No more than 15 minutes.

(Whereupon, the foregoing matter went off the record at 11:00 a.m. and resumed at 11:21 a.m.)

CHAIRMAN MALMUD: Dr. Howe will make the next presentation, which is the topic of potential changes to 10 CFR Part 35. Dr. Howe?

DR. HOWE: Thank you, Dr. Malmud. I really only have two issues that I am going to be presenting today. The first one is that, as we have been implementing Part 35, we have looked at 390.

Yes, Ashley?

MS. COCKERHAM: Can everyone turn to Tab 12 in their binders to find these slides?

DR. HOWE: Yes. I was going to give this presentation tomorrow, and we changed it to today. So -- okay?

MS. COCKERHAM: Tab 12.

DR. HOWE: And as we looked at 35.390, and the clinical experience, we looked more carefully at the definition of what we had for Category 3, and it

says it is parenteral administrations of any beta emitter or photon-emitting radionuclide with a photon energy less than 150 keV.

And as we looked at the reading that we had, and of course it is one that requires a Written Directive, we realized that you don't have -- as we implemented the NARM rule, we are starting to see alpha emitters. And the question is: where did the alpha emitters go?

And we found out that there are very few -- there are no pure alpha emitters. They have a beta associated with them, or they have a gamma associated with them. And, therefore, they don't go into Category 4; they come into this Category 3.

So we took a more extensive look and we said, "Do we have anything that fits into Category 4?" Because originally we did the reading, that -- we thought that was going to pick up the alphas if we ever got them, and that they would be anything other than what was in 3.

And the conclusion we came to is there is nothing in Category 4. And we are looking, and we are saying, "Well, that is not really what we intended to do." And so now that we have alphas and we have now radionuclides that are being used therapeutically for

their alpha component, even though they may have incidental betas or gammas.

So what we are proposing is that we revise 35.390(G)(3) and (G)(4), so that 3 becomes the betas and the low energy emission photons, and that is your primary -- that is the component of the radionuclide that you are really using on a therapeutic basis.

And then, for 4, that it is requiring a written directive for any radionuclide that is being used, because of its alpha particle emission. So what we changed is the words "because of its beta emission or low photon emission."

So we are looking now at different radionuclides fitting into Category 3 because they have a radioactive modality as -- because of their alpha emission and their photon emission is what is being used. And then, in 4 we want to put the alphas that are being used primarily for the alpha emissions.

So that is our recommended way of solving the problem that everything was going into 3, and we weren't really distinguishing between differences of experience that you needed.

CHAIRMAN MALMUD: Thank you, Dr. Howe. Are you looking for comments from the Committee?

DR. HOWE: I certainly am looking for

whether you agree with the issue and our potential resolution.

CHAIRMAN MALMUD: Perhaps one of our physicists has a comment. Mr. Lieto?

MEMBER LIETO: I guess if you are looking for agreement or disagreement, I disagree. My recollection is to the contrary, that when we proposed this rule, number 4 was intended to capture anything other than what was up there. And I guess I would ask you, what would ever go into 4 if it wouldn't be an alpha emitter, or a combination alpha/beta emitter?

DR. HOWE: The way 3 is written nothing ever goes into 4. And the intent -- and I believe you are right, we were thinking that the intent was that it would go -- the alphas would go into 4. But the way the rule is written, because it says "any beta," not that it is being used for its beta, but if there is any beta associated in the radionuclide, it automatically fits into 3.

So we are changing the focus in 3 and 4 to what component of the radioactive decay scheme is being used.

MEMBER LIETO: Well, I --

DR. HOWE: Yes, keep going.

MEMBER LIETO: Then, what I would suggest

is that you delete 4 and just put -- and add "beta emission, low photon emission, or alpha emission," and just make it -- and just add that one -- those two words on to that, and just delete 4 all together, if there is never going to be anything to go into it.

DR. HOWE: We managed to separate them, because we believe that with the three clinical cases that there is a difference in using the alphas for radionuclide therapy, but you mainly have -- may want different experience than just using P-32 or I-125.

MEMBER LIETO: Well, it was my impression that for number 3 -- would be something like samarium-153, which is both a beta and a gamma emitter. And that would fall into number 3, which is a combination of the two. I think by -- again, my suggestion of just adding "or alpha emission" would -- into number 3 would cover anything or any combination of the three emissions.

CHAIRMAN MALMUD: So Mr. Lieto is suggesting that 3 and 4 be combined, because the wording is essentially the same for the first two lines, and just add "alpha particle" under 3. But that doesn't separate the two, as you are suggesting. Are you opposed to their separation, Ralph?

MEMBER LIETO: I just am thinking that

this would be more flexible in terms of any future radionuclides that might come down the pike, because something that is both a gamma and an alpha emitter, I mean, would that then have to have a number 5?

I think, again, just -- my suggestion of having the "or beta or low photon or alpha" would be -- would cover any combinations and be more flexible and not have to revisit this rule again.

CHAIRMAN MALMUD: Are there other comments? I think somebody had his hand up. Dr. Vetter?

VICE CHAIRMAN VETTER: Well, I think what Dr. Howe -- I think Dr. Howe's point, one that I picked up on anyway, was the issue of, when do you need to have another three patients as part of your training? And alpha therapy would certainly be quite different from beta/gamma therapy, and that would be the reason for separating it out, so that when a new monoclonal antibody with alpha emitter attached to it is developed and needs to be marketed, you wouldn't be able to use the training under number 3 -- that is, the three patients, satisfy the three-patient rule -- under 3. You would have to have a new three patients for that alpha particle if you have -- if the alpha is under 4. That is the way I understood your comment.

DR. HOWE: And that is --

CHAIRMAN MALMUD: Was that your point?

DR. HOWE: That is our point.

CHAIRMAN MALMUD: That was Dr. Howe's point. Dr. Suleiman?

MEMBER SULEIMAN: I tend to lean toward Ralph's concepts more so, because I think by trying to differentiate between the actual -- we are thinking physics here -- alpha, beta, gamma, whatever -- most of the emissions give off -- most of the decay schema give off everything. It is just that some are more predominant than others.

So I don't know -- most any decay has some very low energy gammas coming off of it, and the alpha and the beta are more particulate. They are more local. They have more in common than you may appreciate. I think the key thing is the ultimate indication for which the drug has been developed.

And so by trying to segregate, that is going to dictate how it is used more so than the radiation safety aspects. I think alpha and beta therapeutics are probably going to behave similarly and be treated similarly than a gamma emitter.

So I think you are going to fall into this problem of trying to micro-define the different types

of emissions.

CHAIRMAN MALMUD: Dr. Thomadsen?

MEMBER THOMADSEN: Well, I would tend to disagree with that. I think the alphas themselves make a big difference. And I don't think that we want to be using -- or that there are applications where we are using a radionuclide that has incidental alpha emissions other than maybe two or three parts per million, or something where it is very low, because the biological effect of those alphas are very high.

And I can see why they should fit in a separate category from the others, although I think you do raise a very good point. And I think that the -- some of the radioimmune drugs are very different from just labeled molecules that aren't mediated in the same way, and they might form their own category.

CHAIRMAN MALMUD: Dr. Thomadsen, can you clarify for me, please, are you in favor of Dr. Howe's motion or Mr. Lieto's recommendation?

MEMBER THOMADSEN: I am in favor of Dr. Howe's recommendation. I am suggesting it may not go far enough in dividing classifications. But at the moment, just narrowly looking at the proposal, I would support the proposal.

CHAIRMAN MALMUD: Thank you. Dr. Fisher?

MEMBER FISHER: Darrell Fisher. I support the potential changes that Dr. Howe has presented. I think I like this because of the -- it recognizes the functionality of the isotope, rather than just its emissions, radiation emission quality.

There will be drugs in the future that are cocktails of both alphas and betas and gammas, and this recognizes the therapeutic benefit of the alpha emitter.

CHAIRMAN MALMUD: Thank you. Dr. Nag was next.

MEMBER NAG: Yes. I would support separating the alpha with -- the penetration is not the same. Alpha has very limited penetration. It was more in line with the beta. Plus, the effects at the molecular level are much higher. So I would favor the separation. You know, I would go along with Dr. Howe.

CHAIRMAN MALMUD: And Dr. Welsh?

MEMBER WELSH: So I generally support the concept of the separation. However, with the new wording, two points. One is, do we mean to say "low energy" rather than "low photon emission"? Maybe that is just semantics. But the more important question is: where would something that is primarily being used because of its Auger electron emission now fall?

With the old wording, it would fall into 3. With the new wording, it becomes a question.

CHAIRMAN MALMUD: I will address that question to Dr. Howe. The question relates to something that is an Auger electron.

DR. HOWE: Ron, would you like to jump in here?

DR. ZELAC: The Auger electron clearly is not going to fall into category 4 as alpha. I think it belongs in 3, but the wording I think in 3 needs to be polished a bit before it would be proposed.

MEMBER WELSH: That was my point. Maybe we should add another line there.

CHAIRMAN MALMUD: A line to which? I am sorry.

MEMBER WELSH: To 3, as it is currently written. "That is being used because of its beta emission or low photon energy emission or Auger electron emission."

CHAIRMAN MALMUD: So Dr. Welsh is suggesting that the line of subparagraph 3 have "and/or Auger electron emission," and that 4 remain as it is. Is that what your suggestion is?

MEMBER WELSH: Yes.

CHAIRMAN MALMUD: All right. Is that

acceptable to you, Dr. Howe?

DR. HOWE: That certainly is acceptable, because what you are saying is it is being used because of that.

CHAIRMAN MALMUD: We will accept Dr. Welsh's recommendation as the second.

Any more discussion of this motion? Dr. Suleiman?

MEMBER SULEIMAN: I still disagree. Each drug is going to be based on its characteristics. And the physician that is using it is going to know that if it is an alpha emitter it is going to be prescribed for a certain indication. If it is a beta emitter, whatever. I think you should look at it from the radiation safety profile.

And if you look into your decay scheme, which I have had the misfortune of having to do lately, you get lots of -- go back to physics. You know, these things are not pure emitters. They all give off all sorts of other emissions. So I think by trying to come up with specific definitions for all of these things, you are going to cause more problems downstream.

CHAIRMAN MALMUD: I will ask a question if I may. Would it be acceptable to both parties if

paragraph 3 read that, "The parenteral administration requiring a written directive for any radionuclide that is being used primarily because of its beta emission or low photon emission and/or Auger," and that number 4 be written, "That is primarily being used because of its alpha particle." Would that be acceptable?

MEMBER SULEIMAN: Not to me.

CHAIRMAN MALMUD: Not to Dr. Suleiman. How about to Dr. Fisher?

MEMBER SULEIMAN: Just combine them.

MEMBER FISHER: Yes, that would be acceptable I think.

CHAIRMAN MALMUD: And Dr. Welsh?

MEMBER WELSH: I was going to ask a separate question.

CHAIRMAN MALMUD: Okay. Dr. Thomadsen?

MEMBER THOMADSEN: Yes.

CHAIRMAN MALMUD: It is acceptable to him.

MEMBER THOMADSEN: With the correction of --

CHAIRMAN MALMUD: Yes.

MEMBER THOMADSEN: -- low energy photon emissions.

CHAIRMAN MALMUD: Right. Dr. Howe, is

that acceptable?

DR. HOWE: That is acceptable to us.

CHAIRMAN MALMUD: Primarily --

DR. HOWE: Yes.

CHAIRMAN MALMUD: Now, Dr. Welsh did have a question.

MEMBER WELSH: My question is for Dr. Howe. I understand Dr. Suleiman's points, but, Dr. Howe, you said you wanted to have separate category number 4 for alpha. Can you please explain why you feel that way, and why it should not be lumped into 3, as some of us have suggested?

DR. HOWE: Well, we think as the radiopharmaceuticals that are being developed with the accelerator produce materials that now have -- are being used primarily for the alpha. Because you have a different factor of four in their ability to kill cells, there are a lot of different things that you are going to want to know about in order to make the right judgment on why you are using it.

And we believe that judgment is different for alphas than it would be for the existing pharmaceuticals we have now, like P-32 and samarium and the other ones that are being used, and I-125.

MEMBER WELSH: My question -- my followup

question might be that, isn't that for a medical decision that --

DR. HOWE: But we are distinguishing based on what your primary radiation function is. And we do for therapy address radiation safety, the patient for therapy. And so we are saying that we think you need to know more about how an alpha is measured, how it functions, how you are using it, than you might for something else. So we are basing it on its radiation properties.

CHAIRMAN MALMUD: Mr. Lieto?

MEMBER LIETO: Based on what you just said, Dr. Howe, then you should have different requirements for P-32 colloidal chromate phosphate, different requirement for P-32 phosphate, and then something else for Y-90, because they are all different beta emitters, have all entirely different clinical applications and uses.

And I think the distinction was intended to be made originally, because 1 and 2, which aren't shown here, are oral administrations, and these are parenteral administrations. And that was I think the difference in the separation originally for the classifications for the different uses of radionuclides.

CHAIRMAN MALMUD: Dr. Eggli?

MEMBER EGGLI: Yes. There are sort of two questions here. One is the scientific question, which I have heard debated, and the next one is, what is the practical impact for end users? The reality is, I think as a new therapeutic comes out, the chance that the vendor will let you have that without some specific vendor training, because they don't want someone to mess up shortly after a product's introduction, is pretty remote.

So whether you tell me I have -- you know, that I am covered or I am not covered by my prior training, odds are the vendor is not going to let me have it without specific training. We even see that in diagnostic radiopharmaceuticals, you know, and I can't see a new class of therapeutics coming out, regardless of the regulation, without the vendor requiring vendor-specific training.

So I think the impact on the regulated community would be small. The scientific discussion is a legitimate one, but I think the impact doesn't matter, because you are going to be required by the vendor to train.

CHAIRMAN MALMUD: Thank you.

We have a motion, Dr. Howe's motion,

seconded by Dr. Welsh I believe. Further discussion? Dr. Thomadsen.

MEMBER THOMADSEN: Yes. A question to Mr. Lieto. I am very sympathetic with the points you were just making, and they were similar to the points -- Dr. Suleiman's points that I also was sympathetic with, that in addition to the physical differences between the emissions, probably a greater difference in their use as far as their application to humans, is the vehicle.

Do you have a suggestion for what should happen to this part? And should you maybe -- are you recommending getting rid of the four parts all together, and just making some general statement as far as training relevant to the nature of the emission and the carrier?

MEMBER LIETO: I guess I am trying to look at a less prescriptive regulation. I mean, I recognize their concern about the alpha emitters. Okay? But I think I would rather have a regulation that is less prescriptive, more flexible. I mean, can you say that somebody who has been doing beta emitter radiotherapy for years, a new alpha emitter comes along, and their training and experience is not appropriate?

I mean, just as Dr. Eggli said, you are going to get the clinical training for that specific modality anyhow. But is the radiation safety training and background that you have done already, say for -- if you had training and experience in just beta emitters, now going to have to be duplicated because you haven't used an alpha emitter before?

MEMBER THOMADSEN: It is only the three cases, not the training.

MEMBER LIETO: Well --

CHAIRMAN MALMUD: I am sorry. I didn't hear the last comment.

MEMBER THOMADSEN: It is only the three cases we are talking about, not the -- all of the other training.

CHAIRMAN MALMUD: Thank you.

Was there another comment? Dr. Welsh?

MEMBER WELSH: Maybe a quick comment is that for somebody who has had seven hundred hours of residency training and experience, 200 hours of classroom training, do you really need three cases for learning how to use an alpha emitter, if you have done hundreds or thousands of beta emitters over your career? It is a question of -- it is a rhetorical question, but I think that this concept of three cases

might need to be revisited.

CHAIRMAN MALMUD: Dr. Suleiman?

MEMBER SULEIMAN: I think it would have to be for the specific product. I think if -- even betas have different energies. So one radio-labeled beta emitter may not perform the same way as another radio-labeled beta emitter. But they probably have more similarities with an alpha emitter.

I think you should look at the safety profile back again. How is it being delivered? Is it a generator? Is it pre-packaged? And how is it going to be handled from that point to when it is administered to the patient? And then, when it is administered to the patient, again -- I assume we are dealing with therapeutics here, but you administer to the patient after that.

You are not going to worry about the range of the beta or the alpha or whatever. That has already been thought out ahead of time. That is why you are using that specific radio-labeled drug. So trying to define a regulation that is going to kind of second-guess that after the fact, the physician is going to make the choice of the appropriate radio-labeled drug based on its characteristics, be it radiation, be it anything else, be it that it is

labeled to a monoclonal or it is being physically, you know, stopped by the liver.

That decision has already been factored in. And so if it is a therapeutic where you are dealing with large quantities, and whether it is a gamma emitter or a particulate emitter, it is going to have a very different radiation safety profile, and you are going to handle it based on two or three general classifications.

You are micro-regulating here in terms of trying to define alphas and betas and gammas and Auger electrons, and we can think of some other emissions in there, too. I think ultimately the product has been approved based on evidence-based science. It works or it doesn't work. And that has all been factored in during the trial.

So I think trying to micro-regulate based on different energies -- you might as well, if you are going to go with the alpha definition, you might as well define "beta" by energy range and get more specific. I mean, you either take that argument to its full degree or back off and keep it simpler.

CHAIRMAN MALMUD: I think Mr. Lieto was next.

MEMBER LIETO: I just wanted to follow up

on a question that Dr. Welsh posed. Has this come from, like, the Agreement States? Has this been an inquiry from the Agreement States? Or are you guys kind of like looking into your crystal ball and trying to predict what might be coming down the pipe and cut it off at the pass?

CHAIRMAN MALMUD: Your question is addressed to Dr. Howe.

MEMBER LIETO: Yes, I am sorry.

DR. HOWE: Yes. I think we are looking at it. It hasn't come from the Agreement States. It has come from thinking about the new radionuclides that we have now, thinking that this is where they were going to go, and then reading the regulation carefully and realizing that they, as currently written, don't go there. And that is where we had expected them to be.

CHAIRMAN MALMUD: Okay. Dr. Thomadsen?

MEMBER THOMADSEN: Well, I actually, after having spoken towards the motion, will speak against it.

(Laughter.)

And suggest that there either be a subcommittee of ACMUI established to work with Dr. Howe to look at what might be the most effective and efficacious way of addressing the problem and

potential problem, although I can't make that motion now because we have a motion on the floor.

CHAIRMAN MALMUD: Dr. Eggli?

MEMBER EGGLI: As a Part 300 practitioner, and just to sort of -- I would like to sort of talk a little bit about how I think about Part 300 therapies. In general I think, is the radiation gamma or not? I think, is the thing I am administering soluble or not? And then, how do I administer it? Intravenous, intra-arterial, orally, intracavitary, or intra-articularly? And all of those things are important in a therapy.

The reason I spoke before that it probably -- that 3 or 4 probably doesn't matter is because, again, I still think within a new -- with a new agent you are going to get vendor training. But, truthfully, I am not sure how an alpha particle, other than its range and tissue and its appropriateness for some therapies, versus a beta particle, will change my thinking on, you know, is it radiation gamma or not? Is the physical form soluble or not? And how do I administer it?

Those are the things I think about when I do a Part 300 therapy. And I would ask that since Jim does Part 300 therapies, I would ask if he thinks

differently about the therapeutic agents.

MEMBER WELSH: I would say I agree 100 percent with your thinking, which is why I asked Dr. Howe the question initially about why he would want to have category 4 with alpha being separated from the others, when clinically we think of unsealed isotope therapy just as Dr. Eggli has outlined.

So, in my mind, I am still not fully clear why the alpha is being treated separately, other than the idea that this is a new category of agents that may have widespread applications in the next couple of years. So, therefore, for the time being, if NRC still feels that it is appropriate to take alpha out as a separate category, I would say that I agree with 3 and 4.

But, conceptually, I think that ultimately we will just have category 3, as Ralph Lieto has stated, and some day just add, "In addition to beta emission, low energy photon emission, Auger electron, and alpha emission." Instead of having category 4 separate. But for the time being, I guess the idea is that alpha is going to want to be separated, but I agree 100 percent with the clinical thinking of Dr. Eggli.

CHAIRMAN MALMUD: Mr. Lieto?

MEMBER LIETO: I would like to suggest that -- I don't know if there is a proposal on the floor already, but I would like to suggest that this be tabled, because there is not any urgency to it. I think we are trying to solve a problem that doesn't exist yet.

I think there are additional questions being raised, because if you look at this it says -- you know, was it A, B -- 1, 2, 3, and 4. One and 2 address oral, 3 and 4 address parenteral. Are there other ways to administer radionuclides that may not be listed here, in terms of the clinical --

CHAIRMAN MALMUD: How are you defining "parenteral"? Does that cover all of the categories of intravenous, intra-arterial, intracavitary, interstitial, and intra-articular? Are those all broadly covered under the term "parenteral"?

DR. HOWE: That was our concept. The original one was the oral I-131, and then you went into parenteral.

MEMBER LIETO: To me, the treatment implications of those five routes are very different. And it is interesting that you would separate "oral" off when an intracavitary treatment or an interstitial treatment or an intra-articular treatment are very

different than an intravenous or an intra-arterial treatment.

DR. HOWE: I believe the oral was separated out, because it is not just oral, it is oral I-131. And that treatment can be done by physicians that don't necessarily need all of the training and experience for 300.

MEMBER LIETO: I can buy that.

CHAIRMAN MALMUD: So we have a motion on the floor, which is Dr. Howe's motion with the addition under paragraph 3 of Auger electron, and paragraph 4 in the initial motion stands as it is. Is that the motion? No.

MEMBER WELSH: And the inclusion of the word "primarily."

CHAIRMAN MALMUD: Right, and the word "primarily."

MEMBER LIETO: And low energy. Did you get that? Low energy photons.

CHAIRMAN MALMUD: Low energy? Inserted where?

MEMBER LIETO: Between "low" and "photon."

DR. HOWE: I think there is --

MEMBER LIETO: As opposed to "low photo emission," which would mean few. Unless that is the

intent.

DR. HOWE: I think it is a typo, because I think that is in the regs right now as low energy. Ashley is looking.

CHAIRMAN MALMUD: Then, that should be "low energy emissions."

DR. HOWE: Yes.

CHAIRMAN MALMUD: Low energy photon. The word "energy" is missing.

MEMBER LIETO: It says "photon-emitting radionuclide with a photon energy less than 150 keV."

CHAIRMAN MALMUD: Yes. So it is "low energy" in the regulation currently.

DR. HOWE: It is what -- it is "low energy," yes.

CHAIRMAN MALMUD: Okay. So we have those three corrections to the motion, which were moved and seconded. Should we call the motion?

All in favor? Would you keep your hands up, please? Three, four, five.

Opposed? Three opposed, four opposed. Five-four. Motion carries.

DR. HOWE: Thank you.

The next topic is --

CHAIRMAN MALMUD: Excuse me.

MEMBER WELSH: Dr. Thomadsen had proposed that we create a working group to get back with you. Dr. Thomadsen, would you like to expound on that or discuss it any further?

MEMBER THOMADSEN: It seems that the Committee has made a decision on this. So there is not much point to that.

CHAIRMAN MALMUD: Well, Ashley has her hand up. Has the Committee made a decision?

MS. COCKERHAM: I am not sure if the Committee has -- no. I have five votes in favor, four opposed. That is nine. I need 11 votes.

MEMBER EGGLI: We have got an abstention here.

MS. COCKERHAM: Two abstentions?

CHAIRMAN MALMUD: Two abstentions.

MS. COCKERHAM: Thank you.

CHAIRMAN MALMUD: Drs. Eggli and Van Decker.

DR. HOWE: Now, I want to remind you that if you have agreed that we could go put this into our user need memo, you will see this again. This is not the last time you will see it, and there are still other barriers it has to get over in order to get into rulemaking. So -- okay?

Can I move on to the next issue?

CHAIRMAN MALMUD: Please do.

DR. HOWE: Okay. We actually had a question come in on this one, and the question was whether an Authorized User for 400 uses, and then we extended it to 600 uses, could get their 500 hours of supervised work experience at some place other than a medical institution, in a private practice, a limited clinic, where you did not meet the criteria of being a medical institution.

And I believe the criteria for being a medical institution is that you practice two or more specialties. It doesn't say, "Did you practice two or more radiation specialties?" It just says, "Did you have two or more specialties?"

So part of the concept is that medical practice has changed over the ages, and now we do have more procedures being done at stand-alone units, and especially like for manual brachytherapy, but it may also apply to those 600 uses of remote afterloaders, teletherapy, or gamma stereotactic. And so the question is whether we would want to change from medical institution to something else.

Keep in mind that both of the requirements in 490 and 690 do require three years of radiation

oncology, radiation training. And in that part, you probably would get a diversity of exposure. So the question we have, because we don't really have a -- that proposal is whether a stand-alone clinic would be an appropriate place to receive the 500 hours of training.

CHAIRMAN MALMUD: Well, it looks as if Dr. Nag wants to be the first one to tackle this issue.

MEMBER NAG: Thank you. Whether we bring in a given, you know, university medical institution, or part of that is given in a non-medical institution, really should not matter. It is still training. So if the less than -- or part of the time with a smaller entity, that is still included in the training.

And, you know, even for board certification, the training at whatever level is all included. I have no problem of the training being in any institution, not necessarily in a non-institution.

DR. HOWE: Okay. Just let me clarify. When we say "medical institution," we don't necessarily -- certainly a university medical institution meets the criteria, but there are also smaller entities that meet the institution, smaller hospitals. Actually, some multiple group practices with two or more specialties could also meet the

definition of "medical institution."

So I just wanted to clarify we are not talking about the difference between a university medical institution and some other place. Just to make it clear.

CHAIRMAN MALMUD: Dr. Howe, does "other institution" include those that are not reviewed by the JC?

DR. HOWE: Yes.

CHAIRMAN MALMUD: Well, I certainly have feelings about it, but I will let the other members of the Committee speak first. You realize that this is almost anti-Flexnerian. Flexner was the man who reviewed American medical institutions in the second decade of this 20th century and found that people were getting certified as physicians by simply paying a subscription to a doctor and then getting certified, and they had no training.

And he recommended the closure of a number of American medical schools based upon the fact that there was not adequate supervision of the training of medical students. His impact was felt immediately and led to the closure of a number of American medical schools, the conversion of others into first-quality schools.

We do need supervision, and allowing for supervision to occur without oversight by anybody other than an individual can lead to -- can lead to, would not lead to in most circumstances, but can lead to, in a minority of circumstances, inadequate supervision without any oversight.

So it concerns me, but that is just a -- I am just speaking as a citizen. It concerns me. And it is almost anti-Flexnerian in its aura.

So I will allow my colleagues to comment on this. Dr. Eggli?

MEMBER EGGLI: One is a question. The way this is written, I assume that no one could vouch for training for a modality that they weren't authorized. For instance, say, 400 practitioners certainly shouldn't be able to vouch for 600 training. And then, secondly, I am inclined to agree with Dr. Malmud generically when training programs aren't answerable to some authority that maintains and validates the quality of that training.

There is a tendency toward crawling under rather than jumping over the bar, and I think that I have no problem with free-standing clinics being able to provide training, but it needs to be in a framework where the quality of that training is validated by

some validating authority.

CHAIRMAN MALMUD: Dr. Suleiman.

MEMBER SULEIMAN: Just a quick clarification, because we deal with this in a vague way ourselves. How do you actually define "medical institution"?

MS. FLANNERY: I can read it for you. It is in 35.2. "Medical institution" means an organization in which more than one medical discipline is practiced."

MEMBER SULEIMAN: Period.

MS. FLANNERY: Period.

MEMBER SULEIMAN: Okay. Interesting.

DR. HOWE: Very open.

CHAIRMAN MALMUD: Dr. Nag?

MEMBER NAG: I can see a problem. For example, some radiation oncologists, as part of their board certification, have to spend a short time in getting experience in a modality -- for example, high dose radiation brachytherapy.

So that their primary institution has good training in everything else, but had only limited HDR experience, so they are sent out to a clinic that does nothing but HDR brachytherapy. And if you are going to discount that part of their experience, this

individual, although he is now board certified, would have a problem meeting that requirement.

DR. HOWE: Dr. Nag, there is still a requirement for a three-year residency program, and there is no restriction in the three-year residency program as to where the training is obtained in that residency program.

So if the residency program has an arrangement with other facilities to pick up that training, that is under the three-year residency part.

MEMBER NAG: Under what circumstance do you think someone would get board certified, would have training but have training only in a private practice institution? I fail to see how that would be --

DR. HOWE: We are not necessarily talking about the board certification process, because in the board certification process you successfully complete three years of residency -- I am looking at 490 -- three years of residency program and radiation oncology that is approved by the Residency Review Committee. And then, you pass the examination.

What we are looking at is the alternate pathway where you have 200 hours of classroom laboratory training, you have 500 hours of work

experience in these things, and then you also have completed three years of supervised clinical experience in radiation oncology under an Authorized User who meets the requirements of 35.490 as part of a formal training program approved by the Residency Review Committee. So the 500 hours is outside of that three-year residency.

MEMBER NAG: So if someone has not had enough experience and is more experienced in, let's say, HDR brachytherapy, and went outside that to have extra experience, I think that -- you know, that is -- that should be counted and be used. Otherwise, this person would have no way of getting Authorized User qualification for that subspecialty. I mean, this person would already have three years of training in a broad specialty, and is going outside that to get extra training in a subspecialty.

DR. HOWE: Now, the 500 hours is -- if you look at 35.490 is specific to the basic radiation safety issues -- ordering, receiving, unpacking, checking survey meters, preparing, implanting, and removing brachytherapy sources, maintaining running inventories, and using administrative controls, and then using emergency procedures. And they are all under the supervision of someone that meets -- that is

already an Authorized User for 35.490.

But this is -- so this is not your three years of clinical residency, but it is more focused on the radiation safety.

CHAIRMAN MALMUD: Dr. Zelac?

DR. ZELAC: And because it is focused on radiation safety, I believe that that was the reason for having it at a medical institution, as defined, meaning there was more than one discipline being practiced, so that the breadth that one would receive during this 500 hours would be sufficient, and not focused on one particular type of usage, to cover the subjects that Dr. Howe just enumerated.

CHAIRMAN MALMUD: Thank you. Mr. Lieto?

MEMBER LIETO: I am very sympathetic to what Dr. Zelac just pointed out, but what we are looking at is a specific use training, which is manual brachytherapy. So I guess the question would be --

DR. HOWE: We raised the question also for 35.690.

MEMBER LIETO: Well --

DR. HOWE: So you may want to address just one of them, or you may want to address both of them.

MEMBER LIETO: Well, okay. I guess the question would go to both modalities. The question

is, if someone wants to get just manual brachytherapy or teletherapy training in authorized use, is it a requirement that they have to be in a medical institution? And if they weren't, would they still end up getting inadequate training and experience?

CHAIRMAN MALMUD: That is the question you are raising.

MEMBER LIETO: That is the question I have.

CHAIRMAN MALMUD: Yes. And that is the question we are discussing. We agree the question is good. Do you have any feelings about it?

MEMBER LIETO: Well, I would feel that, yes, they could. I mean, if a physician wishing to become just -- becoming an Authorized User, say, in manual brachytherapy, could he get the appropriate training and experience in a free-standing clinic that specializes in that modality? I think, yes, he could.

CHAIRMAN MALMUD: Thank you.

Dr. Nag?

MEMBER NAG: There have been regulations made that they may not have had the broad training, but that portion of it would be met by the three years' training in radiation oncology, because it is not a stand-alone. They must also have had three

years of training in radiation oncology, and that would give them the broad basis, and, you know, this is only for the -- specifically for that -- either 690 or the 490 use.

CHAIRMAN MALMUD: Dr. Vetter?

DR. HOWE: I think Debbie Gilley has been over here --

(Laughter.)

CHAIRMAN MALMUD: I am sorry, Debbie. My head was turned. Debbie Gilley was next. All right.

MS. GILLEY: Debbie Gilley. I would just add a little clarification on this. Manual brachytherapy happens in outpatient surgical centers. They are one use. All they have is a license to do seed implants. This is a group that if you do any of your training, your 500 hours, at an outpatient surgical center, currently it cannot count towards those 500 hours with the way this is written.

Thank you.

CHAIRMAN MALMUD: Dr. Vetter?

VICE CHAIRMAN VETTER: So I guess I -- I am not sure if I was going to make a comment or ask a question. I just want to be sure that we are talking about one modality here, the 500 hours is for a single modality, not for --

DR. HOWE: No. The 500 hours is to get authorization under -- and it ends up that the regulations are identically worded for 490 and for 690. So if you are looking at 490, the 500 hours would cover anything that would be under -- when you got the authorization, you would have the authorization for anything under 490, and the same would hold for the 690.

CHAIRMAN MALMUD: Dr. Thomadsen?

MEMBER THOMADSEN: A question for --

DR. HOWE: Can you please speak into the microphone?

MEMBER THOMADSEN: I am sorry, a question. For those stand-alone centers that do implants, they would be practicing radiation oncology, and, assumably, anesthesiology, would they not? So would they not qualify as a medical institution?

DR. HOWE: I know our license reviewers have essentially taken a pretty broad view of this. Are you practicing more than one specialty? And in most cases they come out with yes, but they are not -- so they are not -- the definition doesn't limit it to more than one specialty we regulate. It just says "more than one specialty."

MS. GILLEY: My interpretation is it is

more than one specialty we regulate. If they did diagnostic nuclear medicine and seed implants, then they would be classified as a medical institution. We didn't look at it at the broader scope -- broader scope as if they do anesthesiology or orthopedic and seeds, then it would be multi-specialty.

MEMBER WELSH: "Medical discipline" doesn't seem to be defined in Section 2.

MS. GILLEY: So it opens itself up for interpretation.

DR. HOWE: That is correct.

MEMBER WELSH: So it would have to be clarified.

CHAIRMAN MALMUD: May I ask Debbie a question?

MS. GILLEY: Sure.

CHAIRMAN MALMUD: So in Texas it is okay to get the training.

MS. GILLEY: Florida.

CHAIRMAN MALMUD: In Florida, sorry. In Florida, it is okay to get the training in a free-standing clinic?

MS. GILLEY: Not at this state. We only allow the training to be done at medical institutions, and it has been a problem in our state with people

meeting the 500-hour requirement, both for HDR, gamma knife, and for low dose permanent implants. We are looking at changing that within the state of Florida to allow the 500 hours to also be included as part of those facilities that only have one discipline.

Most of our gamma knives we -- our gamma knives, only two are associated with a broad scope medical. There are other -- the remaining ones are privately owned gamma knives. HDR devices, over half of them are in clinics, and then maybe the other half are in a medical institution.

CHAIRMAN MALMUD: So that in the state of Florida you don't have enough gamma knives to train all of the potential users.

MS. GILLEY: Not affiliated with our definition of a medical institution.

DR. HOWE: Debbie, isn't your definition of a medical institution the same definition as our definition of "medical institution"? It is a compatibility E.

MS. GILLEY: No.

DR. HOWE: Definitions?

MS. GILLEY: A medical institution is a compatibility D, I believe, for that particular one. And ours is --

DR. HOWE: Some definitions are --

MS. GILLEY: -- of what our state of Florida defines as a medical institution under the Medical Quality Assurance Act.

DR. HOWE: So what you are looking at is to loosen up on your definition of "medical institution"?

MS. GILLEY: Yes. For the purposes of meeting the 500 hours of training requirement, to allow them to get it at more than medical institution locations, since the nature of health care has moved somewhat away from the hospital-based to a more clinic or outpatient-related facility.

DR. HOWE: If I understand your position, you are essentially moving to where some of our licensed reviewers are looking, and they say two medical specialties. They don't restrict it to medical specialties we regulate. And then, you may go one step further and just say, "Okay. Only one medical specialty there," and that is brachytherapy.

MS. GILLEY: Well --

DR. HOWE: Or gamma knife.

MS. GILLEY: -- one medical radiation-related specialty there. It is the termination -- the definition of "medical specialty" that is also at

issue in how we interpret it versus how NRC interprets it.

DR. HOWE: And that is --

MS. GILLEY: I suggest that there are 35 other states that have their own interpretation of this, too, not just Florida.

CHAIRMAN MALMUD: Dr. Suleiman?

MEMBER SULEIMAN: A quick question. How do you differentiate between a free-standing clinic and an outpatient clinic that is associated with an institution, but they are physically the same type of structure?

DR. HOWE: We would do it by license. In other words, if they are free-standing and had their own license, then they are not part of an outpatient that is associated with the hospital.

MEMBER SULEIMAN: But the two physical structures could have the same exact environment.

MS. GILLEY: But it also depends on who owns it. It becomes a legal entity issue that we are dealing with. I have broad scope medical facilities that have 14 different locations. They are all under one licensing authority because of their corporate structure. I have affiliates of other medical institutions that have a stand-alone license.

CHAIRMAN MALMUD: I am still not clear on this. Let me give you a concrete example, maybe a little absurd, but a concrete example. If I were a physician entrepreneur who controlled a particular technique in a private office, and recognized that I could augment my income by charging other physicians to rotate with me and get the training required, without any oversight of any educational institution or board or licensure organization, I could do that under the proposal. Is that correct?

DR. HOWE: I think under our broad -- or original broad interpretation of "medical institution" you may be able to do that now. The criteria we would look at is whether you had an Authorized User that was doing the supervision that was the required Authorized User and was actually supervising the right topics.

CHAIRMAN MALMUD: Does the Authorized User at the private for-profit institution have to be -- he or she be monitored by anyone in his supervision of the trainees?

MS. GILLEY: Not as we do with medical institutions and radiation safety committees that would approve a preceptor activity.

CHAIRMAN MALMUD: By anyone? Would anyone be monitoring the effort put forth in training

individuals? Anyone other than the Authorized User himself or herself?

DR. HOWE: I think for that one you have to look at what we have accepted under supervision in Part 35, and we have accepted a very broad description of "supervision." So it is only in a few special cases where we require the physical presence that you would have someone that would be physically there supervising by requirement.

Now, so that is the only answer I can give you.

MS. GILLEY: May I suggest that the definition of "medical specialty" includes anesthesiologists and seed implants. We already have that going on.

CHAIRMAN MALMUD: I didn't gather -- I didn't understand the last thing you said.

MS. GILLEY: I suggest that if we are looking at the definition of a medical institution being more than one medical specialty, that we may already have that particular activity going on.

CHAIRMAN MALMUD: With more than one specialty.

MS. GILLEY: If you look at the medical specialty being something other than the two that we

would regulate -- or more than one medical specialty that we regulate, as NRC regulates.

DR. HOWE: And, Debbie, do you have in your definitions of medical specialty -- is something that you regulate? You have narrowly defined it?

MS. GILLEY: Ours is you have to have more than one radioactive material activity going on. And we also require you to offer 24-hour services, and a lot of other things, because we have to use the state of Florida's definition of what a medical institution is.

DR. HOWE: Okay.

CHAIRMAN MALMUD: Excuse me. That wasn't my concern. My concern was not the issue of medical institution. In training medical students or residents, we are required to have any rotation that they go through monitored for the quality of the education that they are receiving, either by the LCME or by the Residency Review Board.

We can't send a resident to a private doctor's office because he has a piece of equipment that we don't have without supervision, without his being a member of our faculty, and use that as training experience for one of our residents. And it seems to me that those rules make sense, because we do

have to protect the public from people who are not really trained.

And we know from history that there is a temptation, not amongst the majority of physicians but certainly among a very small minority, to augment income by "training," but not delivering the training.

There has to be some monitoring of the educational process, and this proposal, as I interpret it -- and I may be misinterpreting it -- would allow for an individual to provide training with our approval without oversight. That concerns me.

DR. HOWE: I believe your interpretation is correct. We --

CHAIRMAN MALMUD: That concerns me.

DR. HOWE: We still have the requirement for three years of residency, and the three years of residency does have the more -- I don't want to use the word "institution," because then it could be confusing. But you have oversight from groups that are saying the residency program is adequate, not the NRC, but you have already residency review groups, but this is the 500 hours, and that is separate.

CHAIRMAN MALMUD: Please, Dr. Welsh.

MEMBER WELSH: It is not uncommon for a medical institution, as defined here, which has a

residency training program in radiation oncology and came to provide the board certification requirement and the 500 hours, it is not unusual for those institutions to not provide the full breadth of brachytherapy experiences.

Therefore, they occasionally will have their residents go to an institution which may not meet the definition of "medical institution" as here defined. It may be a facility that does only brachytherapy, but why not tap into the resource and allow the residents to get that training? And, therefore, meet the 500 hours of work experience.

To answer Dr. Malmud's point, these individuals who the residents are training with are typically adjunct faculty, they are always Authorized Users, and they happen to have a great deal of expertise in a specific area of specialization. And this I think is a very good solution to the problem of institutions -- medical institutions who do not have the full breadth of brachytherapy experience to allow the individual to get that 500 hours of required work experience.

So I am in agreement with the expanded definition here.

CHAIRMAN MALMUD: If I may, you just

included adjunct facility as part of the requirement.

MEMBER WELSH: Yes.

CHAIRMAN MALMUD: And our adjunct faculty must meet certain standards to be adjunct faculty. This does not address -- this motion does not address faculty appointments or any oversight at all.

DR. HOWE: And I think that what we are looking for is for you to separate out the residency aspects of it, because we only cover the residency aspects where I think -- you know, I don't know in every case, but I am assuming in the residency aspect, if you don't have the modalities, there is an agreement between whoever offers the residency and this other location.

So they come under the umbrella of the group offering the residency, and we would consider them to be part of this institutional training under the residency program. But this is separate from that, unless you are saying it is part of that.

CHAIRMAN MALMUD: Dr. Nag?

MEMBER NAG: Yes. I would support expanding the private practice limits. And the reason I submit is that the specialty clinics who do, let's say, only seed implants or only HDR, are even more specialized. They do a higher volume. If anything,

they will probably provide a higher degree of training than other institutions which only does it part-time. It may be an institution, but they do a smaller volume.

And the safety of the public would be safeguarded, because these individuals would also have to qualify and have done a residency training anyway. So the broad experience would have been qualified, and they are going to a center of excellence where they can learn some of this specific training. I would support it.

CHAIRMAN MALMUD: The concern that I have is as follows. When we approved, for example, three cases to get approved for the microspheres or the course, we recognized, whether we said it explicitly or not, that the manufacturer was at risk for not assuring that this process was a real process, because the manufacturer has the deep pocket, if there is to be an adverse event on the part of the trainee at his own institution, and then proof that he wasn't really trained.

I don't see that protection built into this motion. This is a motion which says it is up to an individual who owns a piece of equipment. Yes, we know that 99.5 percent of the time it will all go

according to the way that we propose. There is no oversight.

Everything that we do in education requires not only the teaching but the documentation that the teaching really occurred with some oversight bodies, someone monitoring it. I don't see the monitor here, and it may be my deficiency in not seeing it.

Dr. Eggli?

MEMBER EGGLI: Let me paint a generic situation that describes what Dr. Malmud is talking about. Again, this would be I think a rare situation. But I am a radiation -- I am a radiation worker physician who has been in practice for many years. I now take a new job at a practice where a modality is practiced that I have never been trained in.

My partner really wants me to share the call responsibility. My partner is trained in that. So my partner just writes a preceptor for -- statement for me, even though I have really never had a whole lot of training. Who guarantees in a situation like that that the training is actually occurring and is quality training?

And that is whether it be, you know, a 390, a 490, a 690, type of use, because if you change

this, you allow that. And maybe you allow it anyway right now.

DR. HOWE: I would suggest that that does occur even in medical institutions, from my inspection.

MEMBER EGGLI: I understand that it does occur.

MEMBER NAG: Again, whether a medical institution or non-medical institution, the same thing would occur. That is number 1. Number 2, in private practice, the liability even more on that private -- if the partner is sued, he is also involved in that lawsuit. So for his own protection, he will make sure that he has been properly trained before allowing his partner to take care, because in private practice the liability is even higher.

DR. HOWE: I will say that probably 20, 30 years ago we did not allow a private practice physician to train someone else just for Dr. Eggli's reasons. We felt that the -- the NRC felt that the pressure to say this person had the training was too great to really give them the training. But we have moved on from there.

CHAIRMAN MALMUD: If I may digress, that is 20 or 30 years out of date. The NRC has moved on.

Dr. Guiberteau?

MEMBER GUIBERTEAU: I just have a comment that the word "private practice," having just been on a task force for the American College of Radiology, trying to determine what that means, is that actually it is an economic determination. The Mayo Clinic is a private practice of physicians. So many institutions under this definition, many clinics, are also private practices.

I think that is a very difficult word to define, and I suggest that whatever happens here that we do not use that one. There is solo practice, there is community practice. There are non-academic practices, but private practice is an all-encompassing term.

CHAIRMAN MALMUD: Thank you. I believe the term that Dr. Howe used was "stand-alone clinic."

DR. HOWE: Well, I used "clinic" or "private practice," meaning I guess in our mind, since we are not involved with the definition of it the way he is, is it is essentially a very narrow practice. They do one thing. They may have one person; they may have two people. But there are not a whole bunch of people there.

MEMBER NAG: Then, we call it a single

specialty practice.

CHAIRMAN MALMUD: Mr. Lieto?

MEMBER LIETO: I don't think we need to even go here. I am looking at this b1, the 500 hours in b1. It says you have to complete that, and then it says "and." And then, there is two, "has completed three years of supervised clinical experience," dah, dah, dah, dah, dah, dah, dah. "This experience can be obtained concurrently" -- no, "as part of a formal training program approved by a Residency Review Committee."

So I don't see how they are going to get -- if 1 and 2 are linked, 2 requires that you are part of a three years' supervised residency program. You have got to be at a medical institution. So I think that Part b1 is already going to have to occur at an institution regardless. Otherwise, you -- I mean, because you are not going to have a residency program approved at something that is not a medical institution.

Is my logic making sense here? I just don't think we -- I don't think we even need to change this.

DR. HOWE: Your logic is not there, because what you are doing is you have b1, and it is a

structured educational program. It doesn't say where it is. And then, b2 -- well, and part of that goes into your 500 hours. Then, you get to the next one, and the next one stands alone. You have to have all of them, but the next one stands alone.

The next one does not -- the residency program is the residency program, and it has nothing to do with the medical institution out there. It could have something to do, but it doesn't have to.

You have to meet the requirements of b1 and b2. You have to meet the requirements of b1 and b2. b1(ii), is the one that says it is at a medical institution, and specifically says that. b2 doesn't say that, because there is an assumption that if you are in a -- as part of a formal training program approved by a Residency Review Committee, there is no issue here as to whether you are at a medical institution or not. There is that oversight doctor I was looking for.

CHAIRMAN MALMUD: Dr. Eggli?

MEMBER EGGLI: I think I have to agree with Ralph on this, because Part b1 is connected to Part b2 by an "and" not an "or." So --

DR. HOWE: Which means you have to have the -- you have to meet the criteria in b1, and you

have to meet the criteria in b2. That does not say the medical institution -- that the residency program is where you get the D(ii). The D(ii) doesn't have to be in the residency program. That is just at a medical institution.

You don't go back up. You say, okay, I have got to meet the training and experience requirements, the formal training and experience and work experience requirements of b1. Then, you go to b2, and you say, I have got to have three years of residency program. You have got to do both of those things. But it doesn't take the residency program up into b1.

Ralph, do you want to jump in?

MEMBER LIETO: I would agree with Dr. Eggli. It fits in linked by an "and." They both have to occur. And they are under -- and they are both under the 500 -- has completed a structured program.

CHAIRMAN MALMUD: Dr. Zelac?

DR. ZELAC: I have been wanting to say this for a while, and this seems to be the appropriate place. I don't understand why there is an issue here with regard to either the 490 requirements or the 690 requirements, because both of those, for these alternate pathways, require a three-year residency in

radiation oncology.

And it is inconceivable to me that an individual going through a three-year residency program in radiation oncology would not cover -- include in that three months covering these specific topics in each of 490 or 690.

DR. HOWE: It could be, but it doesn't have to be.

DR. ZELAC: It could be, but it doesn't -- well, I am not so sure about that. I think it really depends on what the requirements of the residency program are. And I can't imagine in either case that the residency program wouldn't include these subjects.

CHAIRMAN MALMUD: Dr. Welsh?

MEMBER WELSH: Perhaps I could bring up a specific example to illustrate one area that I think might be of concern. I was trained at the Johns Hopkins Hospital. The residency program was considered an outstanding program in general, but we did not have any prostate brachytherapy at all.

So, to me, it seems like it would be a deficiency in residency training to allow our residents to graduate without any experience in prostate brachytherapy. And, therefore, since the institution does not perform or did not perform

prostate brachytherapy in the '90s, it would be a great idea to allow the residents to get training in this modality at a clinic or private practice, which is exactly what the residents wound up doing.

But I guess because of the definition it couldn't count towards the 500 hours, which seems a little bit absurd. Therefore, I think that the training at the clinic, or private practice, as herein defined, should be considered part of the 500 hours of work experience, because the residents going there were being trained under Authorized Users with years and years of experience, and who happen to be adjunct faculty and were approved by the residency program in general.

Therefore, I like this proposal.

CHAIRMAN MALMUD: Dr. Nag?

MEMBER NAG: I would like to add to Dr. Welsh's argument that they really do not even need to be adjunct faculty. You could have a, you know, world-famous brachytherapist next to you and that person may not be an adjunct faculty of Johns Hopkins, but would be very well qualified to provide that practical training.

So even adjunct faculty are not needed, as long as that person is an Authorized User and is

prepared to sign that they have, you know, provided that training, because when that private practitioner signs that, you know, "I have provided that training," he carries certain obligations with him or her.

CHAIRMAN MALMUD: So it would appear from the discussion that the Committee feels that the training, as part of a residency, even though it is not in the NRC-reviewed component of the residency, if it is in association with the residency, is acceptable.

DR. HOWE: It doesn't even have to be part of the residency in our regulations. It can be outside of the residency.

CHAIRMAN MALMUD: This would change the regulation?

DR. HOWE: No. Our regulation does not have it inside the residency. It is not required to be inside the residency. It can be outside.

CHAIRMAN MALMUD: So, then, we are okay with approving this. So we will take this as a motion? With --

DR. HOWE: I can't make a motion.

CHAIRMAN MALMUD: No. We still have to make a motion.

MS. GILLEY: I can make the motion.

CHAIRMAN MALMUD: Please do. Debbie?

MS. GILLEY: I make the motion that we accept the proposed changes to 10 CFR 35.490 as described.

CHAIRMAN MALMUD: Is there a second to the motion?

MEMBER NAG: I would like to offer a friendly amendment.

MS. GILLEY: Sure.

MEMBER NAG: Instead of having the words "private practice" there, that be taken out, at a medical institution or --

MS. GILLEY: Clinic?

MEMBER NAG: -- or private clinic. But not private practice, because most practices now, even if they are multiple specialty, are private practice.

MS. GILLEY: Friendly amendment accepted.

DR. HOWE: Debbie, does your amendment include 690? You just said 490.

MS. GILLEY: Oh. We will do both 490 and 690, two birds with one stone. Yes.

CHAIRMAN MALMUD: It has been amended to include 490, 690, drop the term "private practice," just say "medical institution or clinic."

MEMBER FISHER: Second.

CHAIRMAN MALMUD: And, Dr. Fisher, you were seconding it as well?

MEMBER FISHER: Yes.

CHAIRMAN MALMUD: All in favor? Any opposed? Any abstentions? Mr. Lieto abstains. All of us voted for it.

DR. HOWE: Thank you.

CHAIRMAN MALMUD: Thank you, Dr. Howe.

Now, we are running a little behind in our agenda, so what we are going to do now is, if it is okay with you, take the lunch break, come back promptly. Let's see what time we should come back. Any suggestions? 1:15?

All right. We will come back at 1:15, and then there will be some slight adjustments in the agenda in order to accommodate some of our speakers whose times are limited. Is that okay, Chris?

MR. EINBERG: That is fine.

CHAIRMAN MALMUD: 1:15 return. Thank you, all.

(Whereupon, at 12:38 p.m., the proceedings in the foregoing matter went off the record for a lunch break.)

A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N

(1:28 p.m.)

CHAIRMAN MALMUD: There is a change in the program for this afternoon. Patricia Pelke has offered to give the next presentation, because our other speaker has been held up.

So as soon as the substitute is ready, we will begin. But I gather that that is going to take a few minutes to get ready.

MS. PELKE: Oh, no. I think we are all set up.

Ron, did you have some comments before we get started?

DR. ZELAC: No. If you just want to get started, that is fine for us.

CHAIRMAN MALMUD: In that case, I will introduce our next speaker, who is Patricia Pelke, the Chief of the Materials Licensing Branch for Region III. I am familiar with Region III.

MS. PELKE: First of all, I would just like to clarify that I will not be the speaker. Sandy Frazier actually, one of the inspectors, is going to be doing the presentation this afternoon.

Sandy, if you are ready.

MS. FRAZIER: Yes.

MS. PELKE: Just another last minute. We also had another co-presenter, Darrell Wiedeman, who is frantically back at the hotel picking up his baggage. And he is en route to leave later on this afternoon, but he should be back momentarily.

CHAIRMAN MALMUD: So our speaker will be Cassandra Frazier, Senior Health Physicist for Region III. Welcome.

MS. FRAZIER: Thank you. Good afternoon. I am going to try to -- attempt to work this.

I am going to have a presentation on the Department of Veterans Affairs Medical Center and the multiple medical events involving the prostate brachytherapy treatments.

Go to the first slide.

We thought before we start with the specific details that we would talk a little bit about the Master Materials License. The VA Philadelphia, which is the facility that had the medical events, is under a Master Materials License. So I am going to give you just a little bit of background.

The Department of Veterans Affairs, the DVA, they hold a Master Materials License. And a Master Materials License is a license that is issued to a federal facility, organization, and it authorizes

the use of material at multiple sites.

The DVA has a National Radiation Safety Committee, and that Committee has the responsibility to provide oversight of the implementation of the Master Materials License.

Just to give you an idea of the National Radiation Safety Committee, it has several members on the Committee, and it is made up of different areas, including research. It includes the medical field, it includes the radiation safety area. And that Committee has delegated the authority to actually manage the radiation safety program to its National Health Physics Program, and we call that the NHPP.

The NHPP, they are responsible for issuing licensing permits to the individual VA facilities. They also have the authority to conduct inspections. They perform event followup. They investigate incidents. They also process allegations. And they do enforcement.

As you can tell, the MML is a unique license of ours in that they remain an NRC licensee, but they also have the authority to perform certain functions and activities as regulators. So that makes them very unique.

And the VA Philadelphia, they are a

permittee that is issued under the Department of Veterans Affairs' Master Materials License.

I wanted to give you an idea of how VA Philadelphia's brachytherapy prostate program is set up. They maintain -- retain the services of consulting radiation oncology physicians, and they also have the medical physicists and the dosimetrists. They are all contractors.

And the rest of the program, the health physics staff, as well as the nursing staff, is part of the VA. And their consulting services include -- they do the pre-treatment planning, they do the implant preparations, they do implant treatments, and they do the post-treatment planning.

And what we find is that a lot of the VAs are set up this way, in that most of the brachytherapy program is set up by contractors.

Now, I will start with the sequence of events. The VA Philadelphia, they initiated their brachytherapy program, and they implanted their first patient on February 25, 2002.

On February 3, 2003, as well as October 3, 2005, they had two adverse events involving their prostate brachytherapy program, and both of the events involved seeds being mistakenly implanted into the

patient's bladder instead of into the prostate.

In the first case from February 2003 -- we are going to provide some details on both of these two cases. As Patty said earlier, Darrell Wiedeman will be coming in, and he is going to actually provide the specific details on these two procedures.

So what I am going to do is I am going to keep going, and when Darrell comes in he can come up and do his talk on that.

I am going to skip down to May of 2008. The National Health Physics Program notified NRC on May 16, 2008, of a possible medical event involving a patient that received a dose to the prostate that was less than 80 percent of the prescribed dose. Once --

MS. PELKE: Darrell is here now.

MS. FRAZIER: Oh.

MS. PELKE: That way we can maintain our order of presentation.

MS. FRAZIER: Okay. Darrell will come up, and he will speak on the February 2008 and October -- I mean, sorry, 2003 and October 2003 events.

MR. WIEDEMAN: Back in October 2005, during a seed implant, 45 out of 90 seeds were implanted mistakenly into the patient's bladder. At that time, a urologist was able to take a cystoscope

and remove the seeds from the bladder. And the physician, he revised the written directive.

So, therefore, it was determined that this did not meet the criteria for a medical event.

Then, later on, in 2005 -- I am sorry, this happened also in 2003, and then also in 2005.

The sequence of events in May of 2008, NHPP initiated an onsite reactive inspection in response to reported medical events. Based on the number of discovered medical events, in June of 2008 they suspended the prostate brachytherapy program.

The program, when it was suspended, NHPP expanded the scope of their inspection and review and looked at an additional 19 prostate implants. And the NHPP reported four additional possible medical events, and, again, expanded -- on 6/11 of '08, they reported four to five possible medical events.

Out of the 92 medical events, 57 were considered underdoses of less than 80 percent of the prescribed dose. An additional 35 were considered overdoses to organs or tissues that were unintended. Out of the 35, there were 25 of them that met the current AO criteria.

Can we go to -- let's see. It is not working.

Once again, we have the 92 medical events. Fifty-seven were due to low doses, and 35 to higher than what was expected.

Here is a case that we looked in Minneapolis VA. The prescribed dose was 144 Gray, and the dose that they actually administered was 148. You can see that the seeds are pretty well distributed throughout the prostate.

Now, for those that are unfamiliar with this particular computer program, this came from the VariSeed program. This is essentially a sagittal slice. You can look at the little man over here on the far left, and that shows you the orientation. Head is to your left, and the rectum would be to the right.

They used the color isodose curves, and, once again, you will see 140 Gray. And that was the prescribed dose. And, as you can see, the prostate is pretty well distributed around 140.

Here is Cincinnati VA, and you can see that the seeds are pretty well distributed throughout the entire prostate. This was considered an acceptable and a very good implant.

Now we go over to the Philadelphia VA. Prescribed dose was 160 Gray. But the dose that was

administered was actually 43 Gray.

Now, an interesting thing about this was that for about a one-year time period they were unable to do post implants, because the CTs would not talk to the VariSeed program. There was an interface problem. But that didn't stop them from doing the implants.

So, basically, for about a year, a lot of their patients they didn't even know what the actual dose was. And as you can see, there are quite a few seeds on the outside of the prostate. Here is one where they just about missed the prostate completely.

In this case, 160 Gray was prescribed. However, only 24 Gray was administered. The physician that did this particular implant, once again, he felt that the 24 Gray was clinically acceptable.

And, once again, we don't prescribe what the dose is for the patient. That is a medical decision. And if he felt that 24 Gray was satisfactory, that is the way it was.

Okay. Anything else, Sandy?

(No response.)

Any questions? Yes, sir.

MEMBER NAG: Yes. There will be plenty of questions, and I will just go one by one. What was the numerator? You have said there are 92 medical

implants. Out of how many total that were examined? And how many total implants were there at the VA?

MR. WIEDEMAN: One hundred fourteen treatments.

MEMBER NAG: Okay. So out of 114, 92 were medical events. That is about 80 percent or so. Now, out of these 92, how many were medical events because of something like this, where half the seeds are outside the prostate?

MR. WIEDEMAN: 57.

MEMBER NAG: Versus how many were medical events, because they just met the criteria of medical event as it was defined in 2005/2006? Because I am sure you realize that the ACMUI -- and we have documentation that many of the criteria for medical events that were there are not really appropriate to define medical event for permanent brachytherapy.

So that separation is very, very important. Otherwise, you create fear in the public.

MR. WIEDEMAN: There are -- 57 of those implants were considered underdoses. One of them was considered 20 percent above the prescribed dose. The other --

MEMBER NAG: My question is different. How many were underdosed because of something like

this, where most, if not all, of the seeds were outside the prostate versus how many of those 57 were underdosed? Because when you implant the prostate, the prostate can expand. It depends on how you -- on the contour, and you may get 72 percent, and that is still an underdosing but not necessarily an underdose based on the current definition that we are recommending.

So there are two different -- one is something like you show it here, which is an obvious underdose. And the other would be all or most of the seeds are put -- or have been placed within the prostate volume, but because the prostate has expanded in between, the final dose after one month -- a CT done after one month, and during that time the prostate has either grown bigger or smaller.

And, therefore, when you finally do the dosimetry, you find the number is now 72 percent of what you expect. And that difference is something that is very, very important, at least to me, because I am going to make a comment about the two differences.

MS. FRAZIER: Dr. Nag, let me make sure I understand. Are you saying that maybe if they were recontoured that a number would have been different?

MEMBER NAG: No. What I am saying is that even if you do a proper medical implant of a prostate, and an implant -- you had thought you needed 30 millicuries, you give 145 Gray. Even if you execute it properly, there will be certain cases where it will not meet the dose criteria.

We recognized that in 2003 we had -- the ACMUI had said that it is not appropriate. There was a subcommittee meeting to come up with new ways to examine prostate -- oh, not prostate, permanent brachytherapy. We came up with those recommendations.

We know very well that the prostate, especially prostate, for any permanent brachytherapy, you cannot really examine it those ways. You have to examine it based on the activity that has been prescribed. Was it the activity that had ended up in the treatment area? And that is all the discussion that has been going on in the last two or three years.

I know you have been reacting by going -- by what is on the criteria in the books, but I want to make that differentiation, because what is happening is that you may have five cases where the seed is completely outside the prostate. That is a bad medical practice.

And another 20 or 30 where the seed

already implanted itself, but it also, for various reasons, like prostate shrinking or prostate expanding, and so forth, it became a medical implant based on the criteria that are in the books.

So that differentiation is very important to make the differentiation for the public. I mean, from a purely medical -- based on what we have in the book, you may be correct. But then, if you go and examine the entire county based on the method that you have done on this book, you are going to find about maybe 20 percent or so that will not meet the criteria.

And so of the 100,000 of them that have been done in the country that became a permanent implant, you are going to have 20,000 cases which will meet the current definition of "medical implant." And that is the reason why we changed the definition of "medical implant" from being a dose-based to being activity-based or source-based.

MR. WIEDEMAN: Dr. Nag, I think I understand your question. It is a good question. I will say this is not the only view that looks like this. There are several that I have seen. I can't tell you there was 45 out of the 57. Maybe the region knows that.

What we are asking the regional inspection team to do is verify compliance with the current regulation, though.

MEMBER NAG: Sure. I understand.

MR. WIEDEMAN: We have an action from the results of this study, which we have actually delayed the "medical events" definition rule to make sure that the things that we learn from this inspection are factored into that rule and how we ultimately redefine "medical events."

MEMBER NAG: Right. Are you going to see -- you are going to have 20,000 medical events at least in the country, if you examine everyone.

MR. WIEDEMAN: We have --

MEMBER NAG: If you use the same rule that you are applying now.

MR. WIEDEMAN: We have done a lot of inspections of brachytherapy, and we don't see a lot of inspections that have results like we saw at the VA.

MS. PELKE: If I can just carry on to Rob's comment, and also, Dr. Nag, your comments. We are assessing these treatments in accordance with current rules and current requirements. So we were looking at the plus or minus 80 percent of the D-90.

We did determine that we could go with D-90, and there was a consensus, and we have documentation that that was an appropriate measure for prescribed dose.

What we had here -- and we had to make an assessment based on what we saw at this particular VA facility in Philadelphia, and assess, well, could this possibly -- could we have the situation at other VA permittees that were doing prostate brachytherapy?

And so we went out and did an extended condition inspection. That inspection activity is still open, but what we have found at the other facilities conducting permanent prostate brachytherapy is dramatically different than what was going on at VA Philadelphia.

There were some situations or some scenarios that aren't necessarily unique to a Veterans' Affairs hospital. They employ contractors they -- going on good faith that the contractors that they had retained were experts in the field, they believe.

And we have not only seen this at the VA, but we have seen this at other medical institutions that have actually had medical events identified with the modalities that were practiced by that contracted group, is that when a contractor comes on board, and

they are experts in the field, that there is some assumption that they are experts, they should be running the shop, and that we should be getting, you know, a high standard of care. And that is not necessarily so.

So we do believe, once we have wrapped up all of our inspection activities, and we have completed the extent of condition, that we will hopefully be coming out with some type of generic communication, just on the contracted services, and reminding licensees of their responsibility going forward.

And I will say that the events and the treatments that were done at Philadelphia, there are -- you know, there were two precursor events, in 2002 and 2005. And as a result of those precursor events, there was a concern by the physician about putting seeds into the bladder. And as a result of that, the physician, in their technique, tended to back off, but without any quantitative measurement of how far they were backing off. And as a result of that, you see an example of the quality of the implants.

And then, they also had an extenuating circumstance in that the treatment planning system they were using, the VariSeed, they had done some

upgrades on security. And as a result of some of the upgrades that they did, they had experienced problems with transmission of the images they were using of the prostate into the VariSeed treatment planning system.

They had been working on resolving those issues, but in the meantime approximately one year went by where they continued to treat patients. That kind of never crossed their mind, that maybe we should suspend the program until we get this treatment planning system up and running, and our images or input, so we are getting accurate results. They didn't do that.

So, you know, there is a number of issues relative to some of the decisionmaking. And we did have a team there. We didn't have necessarily an Authorized Medical Physicist, because that is not required, as you know, for permanent prostate brachytherapy. But we certainly had medical physicists involved, as well as qualified Authorized Users.

So, really, I think that there is a benefit coming out of this in that, you know, the timing is right. We have proposed rulemaking on the table. We are going to be able to better inform that process, so that we will get a rule moving forward

that includes all of the parameters that we may want to consider moving forward. But right now we are still with a dose-based requirement.

MEMBER NAG: May I -- I agree with all of the points you made. What I am trying to say is that you will probably make this a better report if you did write those two kinds of medical implants separately, one where there was a definite case where the seeds are either well below or well above the prostate versus what you have done at -- you have two different kinds of problems, one a problem with a definite seed outside the prostate, and that is called a medical event, and I agree wholeheartedly with that.

But, at the same time, you have quite a few -- I don't know how many -- that have opened up a full medical event, just because it meets the definition of "medical event," although from a -- if you are using activity-based it would not be called a medical event. And if you lump the two together, you are going to create a fear throughout the community, because people are going to say, "I am doing the right thing. I have put all my seeds into the prostate," but it is still called a medical implant, because you are going by dose-based.

If you separate the two issues, you will

be more believable, because then you are going to hear, "Well, out of the 92, 80 or 60 were really medical events, because seeds were outside the prostate." But my -- although in part the definition of "medical implant" is the -- you know, if you are applying the new definition, it will not be.

I am just asking you to separate those two separately.

MS. PELKE: And, Dr. Nag, I will -- I can let you know that part of the charter for the inspection activity was not to compare the results of the implants that we assessed at Philadelphia against proposed language in a rule. And we also understand that that rulemaking language will be changing as we move forward, so we assessed those under a current set of criteria.

Now, I would also like to offer that certainly 92 identified medical events out of just maybe less than 120 treatments totally performed between 2002 and 2008 as a regulatory agency is very troubling to us.

So of course we wanted to get a better assessment on, you know, do we have certain circumstances at one facility that were precursors to this? And to not use this as an example of where we

want to go in regulatory space going forward.

MEMBER NAG: It may be possible that one or two of the practitioners were bad practitioners or they didn't know how to use the ultrasound.

And then, you got quite a few that were really bad implants, and the others may be reasonably good brachytherapists, but because of the definition got caught in the net, and I want you to -- if you don't, you are going to make everyone afraid to do any permanent brachytherapy because of fear they might do it wrong, but yet it may be called, you know, misadministration.

MS. PELKE: And I will offer that those that were identified as underdoses, we are not talking at 79 percent of what was delivered, or close to 80 percent. We are talking about percentages dramatically lower than that.

CHAIRMAN MALMUD: I think that Dr. Fisher has a question.

MEMBER FISHER: This is an interesting case. Obviously, the problem is, as you show on the slide, incorrect placement of seeds. Was this transrectal-guided ultrasound-administered seed implant?

MR. WIEDEMAN: Yes.

MEMBER FISHER: Have you identified what the root cause is of the incorrect placement of seeds over a series of patients? You have listed corrective actions that include going back and reviewing the treatment planning relationship. But what was going on that the seeds were consistently placed incorrectly? What was the root cause of that?

MR. WIEDEMAN: Well, one of the things that we noticed was that the physician that was primarily involved in the brachytherapy program, he consistently did this. They didn't use fluoroscopy during seed placement. He refused to use fluoroscopy, said he didn't need it.

And also, their computer program, they couldn't do a final treatment plan, so, therefore, they weren't sure of where the seeds were once they implanted them into a patient.

We also have a situation where we had a medical physicist, Authorized Medical Physicist, back in 2002 realize that, in his words, the placement of seeds were not appropriate. And he had talked to the Authorized User about it, and I asked, "Well, what did the Authorized User do about it?" and he said, "He just said he would try to improve his technique."

And so they realized -- the physicist

realized back in 2002 that there was a problem, and then just recently, in 2007, another physicist said the same thing, that he felt that the seeds were improperly implanted. And he was concerned about it, but unfortunately he didn't take it to the licensee and discuss it with them. He discussed it with people across the street, the university hospital.

And the one thing -- we found that there was poor management oversight, or there was none, of the contractors. The training, when we interviewed various different people, they indicated they have never been trained on the definition of a medical event, who to report a medical event to if they did discover one, and the typical things that you would expect a medical physicist to know. But in this case they claimed that they were not very knowledgeable about that.

And then, we found that the contractors, both the physicist and the physician contractors, no one was looking over their work. The radiation safety staff, they did quarterly audits, but their audits didn't pick up any of these problems. So we also have another problem.

CHAIRMAN MALMUD: Mr. Lieto, you had a

question?

MEMBER LIETO: Two questions. Is it correct that they use the standard to bring the patient back after so many weeks and do some type of an image to evaluate seed location and migration, after edema settles out and so forth? Are you saying that they did not bring any of these patients back at some time period afterward and do, say, a CT imaging or whatever the standard might be?

MR. WIEDEMAN: They brought the patient back in 30 days, and they did a CT. But the CT, at that time, couldn't -- they couldn't interface it with the VariSeed program.

MEMBER NAG: If I may clarify. That means that they did the CT, but they did not do the dosimetry. So they did the CT, but they never looked at it. In fact, if you do the CT, you don't even do a dosimetry, you just look at the CT and you see both of the seeds are outside the prostate, even without any dosimetry you would know that it is a mistake or an error.

So not having the dosimetry or the VariSeed program working is really not an excuse, because if you can see half of your seeds are outside, there is no way you will meet the definition anyway.

MS. PELKE: I might offer that the Authorized User stood by all of these implants and believed in some cases if you intended to give 160 Gray and you only delivered 23 Gray that you were still delivering some dose to the treatment site.

So there was -- I mean, that is a practice of medicine issue, and -- but I will tell you that we were confounded by some of the information that we obtained.

CHAIRMAN MALMUD: Are there questions? Dr. Welsh?

MEMBER WELSH: You mentioned that fluoroscopy was not used intra-operatively. And I am not so sure that fluoroscopy really is essential or is necessary for this type of procedure. But it seems from the two examples that you did provide the seeds were grossly outside the prostate volume suggesting that the clinician was not fluent with prostate anatomy on ultrasound. That is what I would guess is the root cause of this particular problem.

But that raises the question about these images here. Who contoured the prostate on these CT images? And do we have confidence that those seeds are not truly within the prostate? And that that volume of prostate is accurate?

MR. WIEDEMAN: The prostate was contoured by a combination of two people. One was the Authorized User, and the other was a urologist.

MS. FRAZIER: Well, let me just explain. What they did is they had an independent organization come in. They had an independent radiation oncologist, expert in the field, and they had an independent medical physicist. And so they did a new CT on every single patient, and they had that independent radiation oncologist recontour the prostate, and then they had the dose calculations completed by the medical physicist.

So they had outside independent experts come in. And after they had that done, then they made the call of medical event or not.

MR. WIEDEMAN: I might add that this particular VariSeed picture, it was taken over a year, year and a half later after they finished the implant.

MEMBER NAG: May I offer up an impression? One is that if you are taking a CT one year later, the prostate shrinks remarkably, so you have to take that into account. I am not saying it totally negates your report, but you have to take that into account. Number 1.

Number 2, I have investigated quite a

number of medical events in prostate brachytherapy. The most common reason I have found is misidentification of the prostate on ultrasound, because -- usually because of inadequate training on ultrasound, whether it is by the urologist or whether it is by the radiation oncologist. Urologists are good at surgery. Radiation oncologists are good at developing radiation. Some of them may not have had training -- either the urologist or the radiation oncologist may not have training in the ultrasound.

So that is the major reason I have found for these medical events. The other thing is that when you are contouring the prostate independently, even though it is kind of like an independent third person doing it, there is a huge variation on how someone contours the prostate post-implant.

Several years ago, in fact, in 2002, we did have a study between the top radiation oncologists in the field. We got together at one of the meetings. We took I believe eight different post-prostate contours, and we -- each of us identified the prostate independently. And I do have the result with me. It is very interesting, I think you will find.

For a patient in whom the prostate -- 145 Gray was prescribed, because of the way each of us

contoured the prostate, the dose that finally turned out between -- was between 91 Gray and 260 Gray. There was that much of variation.

On the same prostate, if you do the same -- you can tell there is a standard deviation of 15. Okay? The other one, which is the volume, that we point to it, it would be between 41 to 63 ccs with a standard deviation of 5.5.

So this would not even take into account different planting -- whether you are implanting prostate, so all of that, you know, would have to be taken into account. These are all of the reasons why I am requesting that you apply the -- on something like this, it would be a medical event, it would be a medical event no matter how you define it. But some of the others may have been caught in the net.

CHAIRMAN MALMUD: Dr. Welsh.

MEMBER WELSH: If I might make a quick comment to what Dr. Nag was saying. That appears to be a gross medical event, if the red is truly correctly contoured and it doesn't extend two or three centimeters inferiorly to where it ends up there. And that is the question that I think does remain on the table.

MR. LEWIS: We have -- this is information

that the VA has produced, not the NRC staff. At this point in time, we have issued our inspection report, and we will be looking for VA to respond to it.

MEMBER NAG: I think here not only -- you don't even have to contour the prostate. The bladder itself, the prostate is always immediately below interior and posterior to the bladder. You know, that -- the bladder itself is a very good -- I always like to have a contrast in the Foley balloon, because even if you make a mistake with the ultrasound, a second backup would be a fluoroscopy image with a Foley balloon in the bladder.

And if your needles are way below that, or way above that, you know no matter what you see on the ultrasound there is a mistake. So very often I tell the new practitioner, even though you do have the ultrasound, for the first few patients to be very on the learning curve, take a fluoro just to make sure you are not making a gross mistake. You know, I think a fluoro is still helpful, at least for the beginners.

CHAIRMAN MALMUD: Dr. Suleiman.

MEMBER SULEIMAN: I want to just clarify a couple of points. You had said that other sites had been inspected, and this -- these sites clearly were out of the normal range of what you were seeing. So

there is that standard for comparison in terms of inspections.

MR. WIEDEMAN: The degree of medical events was not as significant as Philadelphia. We found sort of a generic problem, such as Jackson, Mississippi. They also had problems with their computer interface. We also found the same problem out in Reno. But, once again, there were no medical events associated with the Reno, but there was a couple down in Jackson.

MEMBER SULEIMAN: Now, the other thing, you had mentioned that in one case they had delivered 80 percent lower dose, and they decided that that was just normal uncertainty in the practice of medicine, so they were not distressed by the fact that they had given a much much lower dose?

MR. WIEDEMAN: Correct.

MEMBER SULEIMAN: That was due to placement or calculation of the seeds?

MS. PELKE: Placement.

MR. WIEDEMAN: Placement, yes.

MS. PELKE: Exactly. That is the clinician, the physician, the Authorized User made that call.

MEMBER SULEIMAN: And that picture was

taken one year after the implant?

MR. WIEDEMAN: Approximately a year later.

MEMBER SULEIMAN: Obviously, I think for some of the reasons Dr. Nag raised -- I mean, it raises questions. It raises questions.

Thank you.

CHAIRMAN MALMUD: We have a member of the public who wishes to say something.

MS. FAIROBENT: Yes. Lynne Fairobent of AAPM. I just had a question about the comment you made regarding a follow-up by a medical physicist being there or not being there. Under Part 400, an AMP is not required. So could you clarify what you were saying about the reference to an Authorized Medical Physicist? It is only required under Part 600 for NRC.

MS. PELKE: That is correct, and that was how I was qualifying my remarks. They had medical physicists involved, and in this case they were Authorized Medical Physicists, which I was trying to qualify indicative of meeting training and experience requirements under Part 35. But I recognize that for 35.400 modalities, the Authorized Medical Physicist is not required for those treatments. Does that clarify things?

MS. FAIROBENT: That clarifies it. But that was not the impression I was getting --

MS. PELKE: Oh, I am sorry.

MS. FAIROBENT: -- listening to what you were saying in tying an AMP to Part 400.

MS. PELKE: Right, right. Thank you for that. Thank you.

CHAIRMAN MALMUD: Mr. Lieto?

MEMBER LIETO: Yes. I had another question or two. I guess I am trying to understand these causes here. There is indicated a lack of safety culture. Was this from top down, in other words from the national -- was it this NRSC on down? Was it the health physics service? Was it just in the RSO on the site? Because I think it is kind of important, because I think it gets to a lot of I think the causes of this action.

MS. PELKE: Shall I?

MR. WIEDEMAN: The RSO, according to what she told me, they claim that they hired the experts. They got the best that money could buy from the local university. So, therefore, they didn't really require a lot of training or oversight, because they were the experts. And there was a lot of little problems that they ran into that were taken to the Radiation Safety

Committee. The Committee did nothing about it. Sometimes they didn't even discuss it, but yet it was on the agenda.

And so, all in all, the safety culture just wasn't there, starting with the RSO, their staff.

Yes, Ralph?

MEMBER LIETO: Just a followup question on this. In the National Health Physics Program, do they have board certified medical physicists as a part of the group? Or are they certified HPs?

MS. PELKE: Well, they certainly have a diverse experience group that works within the VA organization. And they have a -- I am not sure if he is certified or not, but he is a specialist in prostate brachytherapy, so he certainly is involved.

But I think that what probably impressed me more than anything as a result of these inspection activities is how much expertise within the VA organization itself, and other permittees, relative to prostate brachytherapy, and physics -- physicists involved. Excuse me.

They certainly have the experts within their own organization to set standards and threshold and expectations for performance going forward. And as far as the safety culture, I would like to qualify

that somewhat more in that, you know, we had indications that during initial treatments back in 2002, the physicists involved with the Authorized User had some questions about the quality of the implants, mentioned it to the Authorized User, but didn't take it any further within the organization.

And that happened periodically, and it appears that there was not an environment that fostered, look, if you bring an issue up and you are dismissed or you believe that it hasn't been appropriately characterized and followed up on, that you shouldn't stop there, that you should take it further up the organization. So that was missing there.

But as far as NHPP, because they actually responded to this initially back in May, and then in June, and when they responded back in May they took a look at an index case where seeds of different activity were ordered, and what was the root cause there. That was really a different track than really where this got us.

But as a result of their reactive inspection activity, they asked the permittee, "Hey, go back and look at the last 10 you have done." And based on that assessment, they were identifying

medical events that they hadn't been -- that hadn't been identified in the past, so then NHPP said, "Well, expand the scope a little bit further."

And as they uncovered more and more problems, a decision was made by the permittee, that being VA Philadelphia management, to suspend the program, and that was suspended last June, early June, and is still suspended.

MEMBER LIETO: So your assessment, then, I gather is that the NHPP has the expertise to do sort of a top-down type of an audit of the various facilities and programs.

MS. PELKE: Yes.

MEMBER LIETO: Okay.

CHAIRMAN MALMUD: Any other questions? Dr. Suleiman?

MEMBER SULEIMAN: I see several areas to focus on. Number 1, did they image properly? Did they place the seeds properly? Or did they rely on software too much? Today's culture is I think people think software will do everything automatically. And, I mean, I have had a lot of therapy colleagues tell me, "It is frustrating. I can't -- I am completely dependent on the software." But, still, there are things they can do to verify that it is working.

Probably the thing that bothers me the most is the consulting physicist had identified some problems earlier on, and somehow that -- aside from making a comment and assuming that somebody is going to grab it and follow up with it, was there -- were they aware that there was a chain of command, or there was -- if they had a concern, who did they report that to? And why didn't it get to where it was supposed to?

You said it should have gone up the chain of command. Were they aware that they had that responsibility? And who is it they should have contacted to bring that point home?

MS. FRAZIER: Well, I think part of the issue is that, if you look at their corrective action, they are providing training to their staff as part of their corrective action. And I think just -- part of that is that the staff did not receive training in order to know that they were -- they had to bring these issues up.

And normally they would bring the issues up to the radiation safety staff, or, if they didn't get an answer there, they should be told to go higher than the radiation safety staff. But normally they would bring it up to the radiation safety staff.

MS. PELKE: Also, I will offer -- in this case, there was no internal peer review on brachytherapy, and that was at this institution one of the most highest risk activities they did, yet they had not instituted any form of peer review, which is outside of the norm.

They did do peer review for external being, but they didn't do it for prostate brachytherapy.

I am trying to stay with my train of thought, so -- as far as the reporting, no, there was not a -- there was not a management presence there on the part of the permittee, VA Philadelphia. As we stated earlier, they believe that they hired experts, and that they were running the program in an expert fashion.

So there were -- and there were audits being done. I don't know that the audits were necessarily -- by the permittee, VA Philadelphia. I don't know that these audits didn't reveal any of these problems, so there is a question about the training that was being provided by the radiation safety staff on the audit, the purpose of the audit, and what to look at for the audit, as you are looking at that.

MEMBER SULEIMAN: But there were some early warning indicators, obviously, that they just -- it is great in retrospective analysis, but it didn't help any.

MS. PELKE: Correct. Yes.

CHAIRMAN MALMUD: Debbie Gilley.

MS. GILLEY: Yes. In response to your lack of safety culture, did you take a look at other modalities such as HDR, LDR, or teletherapy as potential issues?

MS. FRAZIER: Well, we did look at the Nuclear Medicine Department, and what we found --

MS. PELKE: Well, first of all, I just want to preface this that prostate brachytherapy was the limit as far as therapeutic applications at this facility. So they did no teletherapy, no HDR, no gamma knife. Yes, that would have been a concern.

MR. WIEDEMAN: But we went back and looked at the nuclear medicine to --

MS. PELKE: And we also looked at the nuclear medicine program.

CHAIRMAN MALMUD: And did you find a culture of safety with regard to radiation handling in nuclear medicine?

MR. WIEDEMAN: In nuclear medicine, it was

a completely different program. In that case, every one of the technologists and the staff down there knew exactly what a medical event was, could quote it word for word, and they knew exactly who to report it to.

CHAIRMAN MALMUD: An entirely different culture.

MS. PELKE: Right, right.

CHAIRMAN MALMUD: Dr. Fisher?

MEMBER FISHER: Fisher. I looked at the list of causes of medical events. I am surprised one is missing, and that would be no post-implant verification of seed implant, which I would consider a cause.

Did you look at the prior experience of the implant physician?

MS. PELKE: This physician had received training back in --

MR. WIEDEMAN: 2002.

MS. PELKE: -- yes, 2002, and -- but from the time the physician had received training to the time they started the implant program, there was some delay. And there was no -- there was no effort on the part of the physician to maybe proctor or observe or be involved with some implants before they decided to go and proceed and treat their first patient. so, and

that was a decision that was made by the Authorized User.

MEMBER WELSH: So, therefore, there would be lack of experience by the physician doing the surgical implants.

MS. PELKE: Well, the physician met our training -- at the time met the training and experience requirements.

MEMBER WELSH: Was the surgeon a contractor or a VA employee?

MS. PELKE: Contractor.

MEMBER WELSH: Okay.

CHAIRMAN MALMUD: Dr. Nag.

MEMBER NAG: Now, you are focusing mainly on the Philadelphia, but you added the other VAs as well. The contractor was -- he was a contractor, not a VA employee, right?

MS. PELKE: Well, within the VA organization there is a number of different scenarios. You can -- they fully contract some services, or they may have a physician that is partial contract, partially funded FTE. So, and there is different variations of that throughout the organization.

MEMBER NAG: The question I have is: does this contractor provide service elsewhere, either on

an outpatient or in a hospital or --

MS. PELKE: Yes.

MEMBER NAG: And, if so, have those implants been checked, even though you are concerned only with the VA? Those or any other additional medical events?

MS. PELKE: Yes. We were concerned about affiliate institutions that the Authorized User may practice at. We did inform the affiliate institution, which is an Agreement State licensee, of the circumstances. The Agreement State also had a representative onsite at Philadelphia when we exited during our special inspection that was last fall. So we attempted to inform all of the organizations necessary to -- relative to where the Authorized User had privileges.

MEMBER NAG: That didn't answer my question. My specific question was: have the other implants done by this Authorized User, or this group of Authorized Users, at other sites been inspected? And, if so, have they caught additional medical implants? Not that they were informed or not, but have they been inspected?

MS. PELKE: They will be going out, it is my understanding, in early June for an inspection at

that facility. Also, it is our understanding that the affiliate institution primarily treats external beam for prostate brachytherapy. They do few implants.

CHAIRMAN MALMUD: Does that answer your question? This is a very disturbing discussion, as you can gather from the questions being raised. Clearly, there are two issues. One is the medical issue, and the competence of the physician who engaged in this practice. And the second one is the radiation issues. The two are related, obviously.

Our concern is the radiation issue, which is an outgrowth of the practice of the physician. Do we agree so far, Dr. Nag?

Now, the concerns that are being raised are, number 1, how could this happen in an institution which is, number 1, inspected by the JC, and should meet the practice standards of the JC? Which is a medical issue, not for us.

And the second one is, with respect to the radiation concerns, which are ours. One can understand that if the physicist was not able to communicate the physicist's concern about what was going on directly to the physician in charge, because the physician in charge either did not know what he was doing or didn't want to hear any complaints, is

there not in the management system or structure that we have in the NRC some route for that physicist to go when the physicist needs silence or a stonewall with regard to his or her observations?

So let's put aside the medical issue for a moment. What should the -- well, let's say this happened today in another institution. The physicist recognizes a problem is occurring, tells the attending physician. The attending physician stonewalls the physicist. What should that physicist be doing next?

MS. PELKE: The physicist could pick up the phone and call the NRC with their concerns.

CHAIRMAN MALMUD: Did that physicist not know that?

MS. PELKE: I --

CHAIRMAN MALMUD: Was that a trained physicist?

MR. WIEDEMAN: As a minimum, the physicist should have gone to the Radiation Safety Officer. That was her job, to look into these issues.

CHAIRMAN MALMUD: The Radiation Safety Officer of the VA or of the --

MR. WIEDEMAN: The VA.

CHAIRMAN MALMUD: -- mother institution? Of the VA. Was it possible that the physician was the

chief -- was the chairman of the committee of the RSO? Who knows? I don't know.

MR. WIEDEMAN: They are in some sense. "Well, you know, I couldn't do anything, because no one ever told me we had a problem." And I hired the very finest, so you can buy that these were the experts. So I assumed that they were doing it the right way.

CHAIRMAN MALMUD: What would we do if that happened again today at another institution? After all, that is our role, which is --

MR. WIEDEMAN: Same thing.

CHAIRMAN MALMUD: -- to say -- what would we do?

MS. PELKE: Well, I can -- as a result of our followup inspection activities, we typically go out and do risk-informed inspections. We don't -- you know, we are going out and looking at a slice of time. And if there have been medical events at an institution in the past, we would evaluate those in the program when we go out during a routine.

Beyond that, you might be doing a sampling. So as a result of this information, we are informing our inspection process to be more intuitive in that program, to ask more questions, and to pull

more strings than maybe we have done in the past. And we are going to share that with the Agreement States as well as the other regions. But that is something that we are going forward with, forward-looking.

CHAIRMAN MALMUD: If today a patient were treated at another institution with a prescription for 94, and received only 20 percent of those, would that not be an automatic alert to the NRC, if it inspected that institution? And whether the order was rewritten or not, it doesn't make sense that 20 percent of the dose is acceptable.

MS. PELKE: I would agree that 20 percent of the dose is not acceptable. If there --

CHAIRMAN MALMUD: But do the physicists and the radiation oncologists agree? Dr. Vetter?

VICE CHAIRMAN VETTER: The problem in that example you just cited is that, first of all, the radiation oncologist needs to notify someone that only 20 percent of the seeds are in the prostate. And if he or she fails to do that, no one will know.

CHAIRMAN MALMUD: Not even the physicist.

MEMBER NAG: Because you can draw a circle wherever you want. Even though I see the prostate there, I draw my circle, you know, who is going to know? I mean, I would know, but who else is going to

know that --

CHAIRMAN MALMUD: So if I am a patient going in for a treatment of prostate cancer, I have a choice of multiple therapies, the therapy that I choose is seed implantation, I think we have confidence in the system, as it is described today, is close to zero.

MEMBER NAG: Well, but the same if you are doing with external beam. If I brought the external beam, my prostate field would be the bladder, and I pick the bladder, let me know. So, I mean, that is not a question of prostate or seed implant. It is a question of the integrity of the condition.

CHAIRMAN MALMUD: But in this case -- I agree about that. But in this case, the physicist became aware of it and says that the physicist -- you reported to us that the physicist was concerned, expressed concern, and it ended there. Is that a correct interpretation of what you described?

MS. PELKE: Yes.

CHAIRMAN MALMUD: Now, when that happens, there should be a route for the physicist to bypass with protection. I mean, otherwise, if the physicist knows he will be fired for reporting something that the attending didn't want him or her to, then we --

there needs to be something in -- to protect this person with regard to the chilling effect. But what is the routine?

MR. LEWIS: Dr. Nag, can I offer to help respond to this?

CHAIRMAN MALMUD: Yes.

MR. LEWIS: I am sorry. Not Dr. Nag, Dr. Malmud. In our regulations, if a licensee is following our regulations, which is one of the things we inspect at each inspection, in Part 19 of our regulations, which apply to all licensees, not just medical, it requires the licensees to post notices to the workers of how to raise a concern. It is on the NRC Form 3.

It also requires licensees, in the next part of Part 19, to give training to workers. Part of that training should be how to raise an issue. So all of those things should have happened, according to the regulations. In this case, we had a licensee who was not following the regulations in terms of training. That is one of the findings. So there was a breakdown there.

It is one of the things we inspect in all of our inspections, and all of the Agreement States also inspect similarly. Because this was a Master

Materials License, we had kind of a mini-NRC within the VA that was doing that function. And that is one of the things we are looking at is how they were doing that job.

CHAIRMAN MALMUD: So in this particular case, because it was a VA with a master license, it was not handled the way it would have been handled in another department?

MR. LEWIS: Well, that may be a contributing issue, but I think that is not to say an NRC licensee could also not be following the regs, but presumably our inspection program is designed to capture that.

CHAIRMAN MALMUD: Dr. Vetter?

VICE CHAIRMAN VETTER: Yes, just to reflect on your expression of the lack of confidence in prostate brachytherapy in this country. I think what we are looking at here is an extremely unusual case. I think in most -- in nearly all hospital systems, you have a very good working relationship between the Radiation Safety Officer, the physicist, and radiation oncologist. And the physicist and radiation oncologist are working side by side, so everyone really does know what is going on.

CHAIRMAN MALMUD: What we are learning is

that some departments use CT for localization. Some that do not have CTs available are using ultrasound still?

MEMBER NAG: No, no, no.

CHAIRMAN MALMUD: Ultrasound is --

MEMBER NAG: The implantation is done, in most center, under ultrasound guidance. But the dose implant, whether it is the same day a few hours later, same day one hour later, or same -- or a month later, it is done under CT to confirm and do the dosimetry of where the seed went. The needle localization and the driving force is the ultrasound, but the analysis is done later under CT.

CHAIRMAN MALMUD: When you say that most institutions do the seed placement under ultrasound, what does the minority do? Is that --

MEMBER NAG: The minority can do the seed implantation under MRI. I know some institutions are doing it under MRI. Some institutions are doing it under CT. So, but the reason why we don't do it under CT is because that would take a longer time, putting each needle, doing a CT, putting each needle, doing a CT. But I have done it under CT in a patient who we couldn't do an ultrasound. So, but that is the minority.

Only very few institutions in the whole country have an MRI, and an MRI is much more accurate in defining a prostate volume than CT or ultrasound, you know, but then there are only I think one or two MRI-based institutions in the whole country. So most of them do it under ultrasound guidance.

CHAIRMAN MALMUD: So they are done under ultrasound. The CT is used only to determine the post-therapy location of the seeds.

MEMBER NAG: Right.

CHAIRMAN MALMUD: Is that what all institutions use, the CT?

MEMBER NAG: No. Again, if you have an MRI, and you can do it -- you can do the dosimetry under MRI or CT. Most of them doing it are doing it under CT, because that is most widely available, even though there is ultrasound-based dosimetry.

MEMBER FISHER: Yes. The problem with ultrasound dosimetry is finding the seeds. You often cannot see particular seeds under the ultrasound.

The problem in doing dosimetry with the MR is the axial position of the seeds becomes very uncertain, because they cast shadows well outside of the slice that they occur.

CHAIRMAN MALMUD: Dr. Welsh?

MEMBER WELSH: Just one comment in this discussion. We are talking about well over 99 percent of practitioners use ultrasound in the operating room, and over 99 percent are using CT for post-implant dosimetry. So when we talk about the small minority, it is a very small minority.

CHAIRMAN MALMUD: What about the therapy planning, what did they use?

MEMBER WELSH: It is the post-implant CT.

CHAIRMAN MALMUD: No. Aren't there three basic, therapy planning --

MEMBER WELSH: Yes.

CHAIRMAN MALMUD: -- therapy planning, then the implantation, then the post therapy?

MEMBER WELSH: Yes. That is using the ultrasound.

MEMBER NAG: Ultrasound.

CHAIRMAN MALMUD: Ultrasound for the planning as well?

MEMBER WELSH: With the planning and the CT for the dosimetry.

CHAIRMAN MALMUD: And did they have all of these techniques available to them when they were doing this at that institution?

MS. PELKE: They did not have MRI. They

used --

CHAIRMAN MALMUD: Not MRI. CT and ultrasound.

MS. PELKE: Yes.

CHAIRMAN MALMUD: But I thought I heard somewhere in the story that the CT was not available.

MS. PELKE: No. The CTs were available, but the problem was the treatment planning system they used to determine dose, VariSeed was the product that they used. They had an information transfer problem where they could not import CT images into their treatment planning system, and, therefore, they were doing no dose determinations at the completion of the implants for approximately a year.

CHAIRMAN MALMUD: Is that acceptable in the world of radiation oncology?

MEMBER NAG: It is not acceptable, but the CT would have picked up that the seeds were in the wrong place. It would not have given you the exact dose, but if you know that half of your seeds are outside the prostate, it would have picked up that it is in the wrong implant, regardless of what the dosimetry showed.

So they were not able to perform the dosimetry, the exact dose distribution. But the CT

would have shown where the seeds were in relation to the prostate.

CHAIRMAN MALMUD: So I thank you for the educational process. Now my question is: what do we, as the ACMUI, do to reassure the public that this will not happen again? Isn't that our responsibility, to advise the NRC, so that this will not happen again? What do you suggest that we do?

MEMBER NAG: Before that, you had mentioned that you had two concerns, one with the medical and one with the radiation. I have a third concern, and the third concern is that while we have found some gross errors, like these where the seeds are outside, unfortunately the method by which we went by, you know, following the previous rules, we also caught a few or many that are probably not a real medical event, but met the definition. And, therefore, it is creating a lot of fear in the community, in the medical community, and how do we also take care of that fear?

CHAIRMAN MALMUD: I understood that concern, because you expressed that early on in the comments, and that there may be some cases which really were not medical events from a medical perspective, though they may have been -- appeared to

be from the radiation perspective.

But putting those aside, I am still trying to focus on a problem having been brought to out attention, we being the ACMUI, not a governing board for radiation oncology. What should our role be in helping to prevent this from recurring ever again in any institution?

And I think Dr. Suleiman was next, then Mr. Lieto.

MEMBER SULEIMAN: Okay. I think the first step in solving any problem is defining it. I am not sure we have clearly defined why this happened. When it was brought to the attention of the Authorized User, why he or she didn't do what they should have done.

The same thing with the physicist who verified that there were some questions. Who did they go to? Why didn't they, you know, follow up on it? So I think probably I am answering part of the question. You have got to give some avenues or paths for reporting to some authorities where something is going to get done.

CHAIRMAN MALMUD: Well, it has been explained to us that this is an ongoing investigation. It is not completed, am I correct?

MS. PELKE: That is correct.

CHAIRMAN MALMUD: So we have to let them move ahead with what they are doing. I believe this information was transmitted to us because some members of this Committee were concerned that we were not being kept posted on what was going on at the Philadelphia VA. So we have to let those who are responsible move ahead with it.

But, clearly, it is going to be our role not to establish practice standards for the American Board of Radiation Oncology, but for us to help prevent this from happening again, to the extent that it is a radiation safety issue.

Dr. Nag?

MEMBER NAG: Yes. I feel the rules are in place. For example, whenever you are doing any form of radiation therapy, whether it is external beam or implant, there is a rule that you are supposed to have peer review. So if I do an implant and I -- you know, I want to fool people, like they are way outside the prostate, in the peer review process, when one of my other colleagues looks at that, they will find that that is not the prostate.

The system is in place, but, like any other thing, how do you prevent the test? If someone

wilfully wants to disobey the rules that are in place, you know, that is a problem. And definitely -- you know, that rule is already in place. The other problem about the rules is most -- I mean, this would be primarily to do the calculations.

But if an M.D., the person who is employing him, tells him, "Well, this is the seed. This is the prostate. You don't worry -- this is -- I am supposed to draw my outline of the prostate. Here is" -- some of them at least will have a difficult time saying, "I override your medical knowledge." I say, "This is the prostate. What you are saying is wrong. I am going to report you to the NRC." Some of them may, but some of them won't. It is a very hard thing to do.

CHAIRMAN MALMUD: I understand all of that, and I understand your comment that the rules are in place. But, clearly, with the rules in place, this has occurred. How do we assure the public that this will not happen again? It may require a change in the rules. I don't know whether that change will come from the American Board, or whether it needs to come from us. But, clearly, the rules being in place have not prevented this from occurring.

Mr. Lieto?

MEMBER LIETO: I have two questions. One is a general in terms of this master medical license, and I don't know if it is headquarters staff or region staff that can answer this best. But the master medical license that the Department of Veterans Affairs has, are the only ones with a master medical license? Or is it just government entities like Department of the Army and whoever? And are there any master medical licenses that are not government entities?

MS. FRAZIER: Well, it is a Master Materials License, and they are just for federal organizations. And we do have two other federal organizations that have a Master Materials License, the Department of Navy and the Department of Air Force. And the Department of Air Force is handled out of the Region IV office, and the Department of Navy is out of the Region I office. Now, they have been Master Materials Licensed for quite some time.

MEMBER LIETO: My follow-up question, then, from the medical side is you have a list of corrective actions being implemented or intended to be implemented regarding this specific incident. Is this being taken up also by all of the VAs? Is it something that is just being applied to the

Philadelphia VA?

I think it might go maybe to the question that Dr. Malmud has in terms of restoring -- or I shouldn't say restoring, but assuring confidence regarding not only the VA system but other licensees that -- where the Master Materials License may have a medical component.

MS. PELKE: Well, certainly, the corrective actions that were outlined in the presentation were specific to the events that occurred at Philadelphia. But the VA, as a regulating organization, is using that information to inform the rest of their permittees. And they are looking at options available to them in the future as far as how they want to proceed with permanent prostate brachytherapy as they move forward.

If they have -- they had 13 permittees. They have approximately I would say probably between 112 to 115 permittees that they cover under their master material license. Of those, 13 were authorized to conduct permanent prostate brachytherapy. And for some of those institutions, they didn't have very active programs, and others were very, very active. So they are considering possibly going to centers of excellence.

We also had a concern in that if you are familiar with the VA organization, they are affiliated with large teaching institutions. And they provide a variety of medical care to our veterans, so initially -- and as we move forward, we are very, very concerned with the impact these events have had on patient care.

Some programs voluntarily suspended their treatment, and our next question was, well, where are those patients being treated? Has that imposed a hardship to the VA organization? But they have adapted and continue to treat patients successfully at other institutions?

CHAIRMAN MALMUD: I think Dr. Thomadsen was next.

MEMBER THOMADSEN: I have a question and a comment. First, you said of the physician that performed these that he stood by the doses and the implants. He does not acknowledge that there was any problem with these implants? Was that the case?

MR. WIEDEMAN: No. According to him, it was clinically acceptable. As a matter of fact, his exact words are, "43 Gray is better than zero Gray."

MEMBER THOMADSEN: But he is giving almost that much dose to everybody else in the OR.

(Laughter.)

Obviously, that is not doing them much good.

The comment is to Dr. Malmud, and that I don't think we are in a position to assure the public everything is fine or to make a statement about that, to make recommendations for what to do. It would be firing off half-cocked from the hip at the wrong targets. I think that we should wait until we have data. And even when we have data, I am not sure that we will have the information to do what you want to do.

CHAIRMAN MALMUD: I agree with you. We are waiting for the investigation, at which point we will do something. But if it is in our purview, we will do something or make some recommendation, but not yet.

But clearly, I mean, I am not easily shaken in terms of medical competence, having practiced for as long as I have and seen as much as I have. But this is a very anxiety-provoking story.

Dr. Welsh?

MEMBER WELSH: So this -- I can see this discussion could go on for hours. It is very important. There is a lot of relevant issues that need to be contemplated and discussed. But as far as

the important question at hand, which is, is there any advice that we can provide to prevent this from ever happening again? I think that we have suggested something about Part 19, about making sure that physicists are aware that there are avenues to go through, including the RSO, and to the NRC if necessary.

But I might propose something here that may not be the -- within the purview of the NRC and this Committee. But it is mindboggling to me that a physician could say that a dose of 40 Gray, 24 Gray, is acceptable, and then look at these implants and not realize that this is gross incompetence.

And in every facility that I have ever practiced or seen, there is some form of active peer review going on, so that if something like this was presented to me I would say that that is obviously a suboptimal implant, and I would never want to see that again in any physician that I am associated with as a partner.

Therefore, perhaps to prevent something like this from ever happening again, there should be an insistence, or at least a recommendation, that X percentage of brachytherapy procedures undergo peer review by another qualified Authorized User who is

familiar with the procedure, because I can tell you I would not agree with the physician who says that 24 Gray is better than zero. I would not agree with somebody that is showing an attitude with dosimetry rounds and saying that he stands by that.

He would come under heated criticism, and I think that maybe we could make a recommendation that peer review is part of the standard of care for this.

CHAIRMAN MALMUD: Dr. Eggli first, and then Dr. --

MEMBER EGGLI: I would like endorse what Dr. Welsh just said. I would make it a little broader and say that every brachytherapy program should be required to have a quality management component, which includes peer review. I would like to, though, ask one yes or no question that is -- is it acceptable medically not to do post-implant dosimetry?

MR. WIEDEMAN: Not in 2009.

MEMBER EGGLI: And then, that could be a second part of the specification for brachytherapy is that if you are going to do brachytherapy you must do some form of post-implant dosimetry.

MEMBER NAG: I can address that. The ABS has the recommendation that what -- from the paper in 1999. I was the lead author on that. And it does

state you need peer review, you need post-implant dosimetry.

The other thing is there I am seeing the list of corrective actions that you have in here, and the recommendation that the ACMUI needs to make is that these are the same recommendations we would have made. We can reinforce these. You know, all of those are already written here.

MEMBER WELSH: Yes. If I might expand on that.

CHAIRMAN MALMUD: Dr. Welsh? Oh, Debbie, I am sorry.

MS. GILLEY: Want me to go ahead now? Excuse me. One of the things that I think would be a good recommendation, and it has always struck me as being ironic, that we don't require an Authorized Medical Physicist for participation in brachytherapy, low dose or permanent brachytherapy. We do require them in HDR and gamma knives, but we don't require them in these activities.

I have no reason why, but as you can see, if the medical physicists had been a key player as required by regulations, maybe they would have taken this another step and another initiative. And from my conversation here, it appears that the radiation

oncologists do depend on that medical physicist to provide them some expertise in doing this treatment planning.

CHAIRMAN MALMUD: I think Dr. Nag wants to address your point.

MEMBER NAG: Yes. I don't necessarily agree with you. The medical physicists are definitely required in the planning process. So they are involved in how many millicuries need to be ordered, and so forth. They are involved in the post-planning process, but they are usually -- in some institutions, I have seen they do have a medical physicist there. But they are not required in the placement of the -- placement of the application. That is a medical decision.

So, and having a medical physicist there would not necessarily have brought this. So I agree with you that the reason why we have an Authorized Medical Physicist for the HDR is that the treatment occurs instantaneous, that you have no time to get a consultation of a medical physicist later on. So that is why we have both for HDR, because the dose rate is so rapid.

But for a no dose rate implant where we place the applicator, and, you know, you have an

X-ray, and then you can decide how many millicuries you want to put, there are both sides of the story. Some places have a medical physicist in there, and then at others they don't.

CHAIRMAN MALMUD: Dr. Thomadsen?

MEMBER THOMADSEN: I would just take issue that there is a difference there. With the high dose rate it is all instantaneous. With a prostate implant, it is all instantaneous. You put the seeds in, and they are there.

MS. GILLEY: But it is radiation. I mean, it is -- you know, the method or the length of time it takes, it is still the necessity of having good quality assurance up front.

MEMBER THOMADSEN: It is a creative dose.

CHAIRMAN MALMUD: May I ask a question? What is the standard of practice in Canada and in Europe with regard to brachytherapy, and the presence and participation of physicists? Does anybody know the answer to the question?

MEMBER NAG: In patients, I have observed -- I mean, I haven't observed every center, but I have observed some centers in Europe, some centers in Canada. It is both ways. There are some centers where the position is quite comfortable. They want to

know how many millicuries they need to put. The placement of the applicator is on their own. In other centers, they do have a medical physicist there.

CHAIRMAN MALMUD: So it is not a requirement.

MEMBER NAG: It is not a requirement any place.

CHAIRMAN MALMUD: Thank you. Somebody else want to make a comment? Who was next? Dr. Suleiman?

MEMBER SULEIMAN: Okay. If the standard of practice doesn't address it, and this may be a case where sometimes you get into the discussion about voluntary standards, the problem with voluntary standards is they are voluntary. And so maybe this post-therapy validation can be made a regulatory requirement. I mean, that is what was mentioned earlier.

MEMBER WELSH: So if --

CHAIRMAN MALMUD: Dr. Welsh?

MEMBER WELSH: Perhaps we could frame this in the form of a motion, that the ACMUI recommends that for programs that wish to participate in brachytherapy that there be some form of peer review required, and I would recommend that we -- for

prostate brachytherapy that we use the published American Brachytherapy Society recommendations, and that that would be a minimum standard for brachytherapy programs in the United States.

CHAIRMAN MALMUD: Comments regarding Dr. Welsh's recommendation? Dr. Zelac?

DR. ZELAC: For those that have a recollection of what the NRC's medical policy statement includes, it does indicate in one of the four points that there will not be interference with medical judgment except to the point where it involves patient safety. And then, clearly, I think that we are at that point when we are having this discussion.

Now, there is already a section in the regulations under the 400 series called Safety Precautions. And a recommendation for an additional rule, as Dr. Welsh has suggested, could probably very easily fit in as another subsection of that existing safety precautions recommendations.

CHAIRMAN MALMUD: Thank you, Dr. Zelac.

Dr. Howe:

DR. HOWE: I think we would have a very difficult time putting into regulations a standard of care that was based on somebody else's procedures, and how would we enforce it, and how would we inspect

against it. But you could require an Authorized Medical Physicist.

You don't have to require them to be physically present, but you could require the manual brachytherapy programs to have an Authorized Medical Physicist, and you could specify what his duties are in the pre-implantation part, in the post-implantation part.

So I think regulatory-wise you could do that. I am not sure for NRC purposes whether you could impose a standard of care that is based on medical care.

CHAIRMAN MALMUD: Who was next? Dr. Welsh?

MEMBER WELSH: If I might comment on that. I think that I agree that it makes a lot of sense, but I think that there might not be a substitute for physician input in terms of the peer review. For example, in this particular example on the screen, a physician would be expected to have the training and knowledge to say that that prostate is not implanted with the seeds.

Not all physicists -- many of them will, but not all physicists will know prostate anatomy sufficiently on CT or ultrasound to really comment on

the physician's quality of implant. I think only another physician who is familiar with the procedure and fluent with CT and ultrasound imaging would be able to really provide appropriate peer review in this context.

CHAIRMAN MALMUD: Dr. Eggli?

MEMBER EGGLI: I don't think that requiring a quality management program, including peer review, constitutes infringement on the practice of medicine, because each licensee could design their own quality management program. I mean, we do that with our administrations of radioactive iodine.

We have a quality management program that we design and implement internally, but I don't think that it is an infringement on practice to require one, nor as a patient safety issue do I think it would be an infringement on practice to require documentation of post-implant dosimetry. That is a radiation safety issue that I don't believe interferes with medical practice.

So I think that I -- although I wholeheartedly agree that NRC should not be in the business of regulating practice, but I don't see either of these suggestions as interfering with the practice of medicine, but they are very much patient

safety oriented. I don't think the Joint Commission would have any difficulty imposing that kind of requirement on us.

CHAIRMAN MALMUD: Dr. Nag?

MEMBER NAG: I think adding extra regulation is not going to solve the problem, because quality management programs already have been built into that. The problem here was that the person was not following that quality management program. So the problem we have to address is how to enforce the QMP that was already there, so we don't have to reinvent --

MEMBER EGGLI: Forgive me for speaking out of turn, but I am not sure that there is any evidence that the VA medical center in Philadelphia had an established quality management program that reviewed the brachytherapy -- the use of brachytherapy or did any peer review.

MS. PELKE: That is correct. They did no peer reviews.

MEMBER NAG: But you were supposed to have --

MEMBER EGGLI: I know, but -- no. By regulation, brachytherapy does not require a quality management program. NRC cannot go out and inspect

against that requirement and say, "Show me the documentation that you have a quality management program."

Now, admittedly, NRC can't go and inspect how the quality management program operates on a professional level, but they can at least say, "Show me the documents which describe the quality management program." And right now, in regulation, they can't do that for brachytherapy.

MEMBER NAG: I would like for the NRC official there -- whenever we -- whenever I have gotten a brachytherapy program, we have a QMP that we had to develop as part of the licensing. So they don't need the QMP to start the program.

DR. HOWE: Let me respond to that. Back in probably 1992, 1994, we implemented a quality management program. And that was to ensure that the administration was in accordance with the written directive.

In 2002, we took the main "quality management program" away. There is still a program, and it is in 35.41. It says that you must have written procedures that provide high confidence that the administration is in accordance with the written directive. It is performance-based. We don't

specifically say what has to be in that procedure other than a very few things.

Now, it may be that the ACMUI believes that there is something else that needs to be specifically in there, and that could be in regulations. But we do have a program. It is not called a quality management program anymore, but it is in 35.41.

CHAIRMAN MALMUD: Thank you.

Mr. Lieto?

MEMBER LIETO: Well, Donna-Beth stole my thunder, but the written directive, what we call written directive assurance program, has been there in the regulations. I think maybe rather than going into regulatory space, maybe it might be something that can be done quicker and also have flexibility in the future, is to say what we consider to be components of that written directive assurance program for, say, brachytherapy.

I am sure most places already have it for your iodine therapies, your dual verifications, all of these other types of things that go into place, but maybe have something that might be specific to a brachytherapy program. Maybe there should be something also for gamma knives, and so forth and so

on. But maybe just do it in guidance space as a regulatory -- in the NUREG amendment, or revision if you will, rather than try to do it through rulemaking, which could take years.

CHAIRMAN MALMUD: Thank you.

Well, you have certainly presented a very stimulating topic to us. Oh, Dr. Thomadsen.

MEMBER THOMADSEN: I think you have a motion on the floor.

CHAIRMAN MALMUD: And what is the motion?

MEMBER THOMADSEN: Well, you don't quite, because I don't think it was ever seconded.

CHAIRMAN MALMUD: The motion was?

MEMBER THOMADSEN: Jim?

CHAIRMAN MALMUD: Dr. Welsh?

MEMBER WELSH: ACMUI advises, as a means of preventing this from happening in the future, that peer review or some form of formalized quality assurance program be mandated in any brachytherapy program.

CHAIRMAN MALMUD: Is there a second to the motion?

MEMBER SULEIMAN: Second.

CHAIRMAN MALMUD: Any further discussion of the motion? Dr. Thomadsen?

MEMBER THOMADSEN: Yes. I would suggest postponing this and trying to establish a more coherent, comprehensive, and consistent recommendation looking at at least the three standards that are out there and seeing what accepted standards of care would be and making a single proposal that might encompass something that would cover all of the places of risk that we would identify.

CHAIRMAN MALMUD: Dr. Vetter?

VICE CHAIRMAN VETTER: I support Dr. Thomadsen's suggestion. I think we also need to provide an opportunity for stakeholder input. I do really like the idea of peer review, but I have -- sitting around this table, I really have no idea how it would affect so many practices.

CHAIRMAN MALMUD: Dr. Nag?

MEMBER NAG: Yes. I would support delaying any decision at the moment, because we already have many of the rules in position. We have to learn how to apply and enforce the rules rather than making up a new rule.

CHAIRMAN MALMUD: Dr. Suleiman?

MEMBER SULEIMAN: I sort of agree to wait, because I have an aversion toward adopting some sort of general peer review process. I think it would be

more important to identify what the critical requirements would need to be, and address it maybe from a regulatory point of view. And that would be the linchpin that would hold it together.

But just requiring some sort of general peer review process or document is going to require another major effort, and somewhere in there there is something -- the critical things. Let the practice of medicine address most of the deficiencies, but some of the issues here may -- the safety issues specifically could conceivably boil down to one or two very specific recommendations. I think that would make the process a little bit simpler and more ready -- easily enforceable.

CHAIRMAN MALMUD: Dr. Welsh, would you like to table your motion, or move it forward?

MEMBER WELSH: I would. I would like to say that perhaps it is wise to wait until we have a bit more information and discuss it again in the future. The numbers are alarming to me. Ninety-two medical events makes me wish to move faster rather than slower.

Therefore, when you asked the question about, how can we prevent this from happening again, I put forth this motion. But I am comfortable with

tabling it and bringing it to the surface again. But 92 medical events is 92 medical events.

CHAIRMAN MALMUD: So Dr. Welsh is recommending that his motion be tabled. Is that acceptable?

MEMBER NAG: It means that motion has been tabled. I would like to make a separate motion. I would like to make a recommendation to the investigative authority at the VA -- and I am not sure who -- which body that is, whether it is the NRC or the master licensee, or whatever -- that when they are investigating and going into further details on this series of medical events, that they try to separate the errors of placement versus errors that are due to the difference in the definition of what a medical event is.

I don't know if that is -- if that was -- otherwise, what will happen is that you are going to hear 92 -- the number 92 medical events out of 114, and there may be quite a few of these that were really not medically events, but because of the definition of 20 percent would maybe -- if all of the seeds are still in the prostate, but because of the swelling of the prostate or having done it one year later, and so forth, they became medical events.

MR. LEWIS: From the NRC staff's point of view, before that motion is seconded, if it is, that might be a motion that is kind of outside of the roles and responsibility of the Committee perhaps, because a recommendation by the Committee to a particular licensee would be very awkward.

If the Committee wanted to make a recommendation to the NRC staff to consider such thing, that might be appropriate.

MEMBER NAG: Okay. It may be -- that is why I said I did not who -- whether it is the NRC staff, or whomever, but someone needs to differentiate the two. And if you want -- I have done a lot of these. If you want my assistance, I am willing to volunteer some of my time, if needed.

CHAIRMAN MALMUD: Thank you.

May I ask another question, which is kind of -- crosses two different subjects? Isn't the VA in Philadelphia a teaching affiliate of the University of Pennsylvania?

MS. PELKE: Yes, that is correct.

CHAIRMAN MALMUD: And did Penn's residents in radiation oncology rotate through the VA for their experience in prostate treatment?

MR. WIEDEMAN: For external treatment.

CHAIRMAN MALMUD: Only external, not implants. Thank you.

Thank you very much. Does that complete your presentation?

MS. PELKE: Yes, it does. Thank you.

CHAIRMAN MALMUD: Oh, I am sorry. Mr. Lieto?

MEMBER LIETO: Just one quick question. When do you expect to complete your investigation report? Or is that an unfair question?

MS. PELKE: No, it is a fair question. It is difficult to project, because we have a number of activities that are ongoing. But we are hoping to wrap things up by the fall. That may not be as soon as a number of people would like, but we have a number of matters that we are still considering.

And also, in closing, I would still like to remind everybody that we had 92 medical events reported. That was as of, I would say, the early part of October. And to date none of those have been retracted, so I -- and that is based on the criteria that is currently in the rules, in Part 35, for reporting medical events.

MEMBER NAG: Thank you for that information.

CHAIRMAN MALMUD: I think I would be remiss in not telling you that the Committee is very supportive of your investigation of this, and we appreciate -- you know, it is a very unpleasant ordeal, but we appreciate your effort, because our concerns are the same as yours, which is the health and safety of the public and those who work in radiation.

MS. PELKE: Thank you.

CHAIRMAN MALMUD: Thank you.

Now, is the next presenter here? Kevin Crowley?

Do you want to take a break for five minutes, or do you want to move on? Okay. We will take a break for no more than 10 minutes.

(Whereupon, the proceedings in the foregoing matter went off the record at 3:11 p.m. and went back on the record at 3:32 p.m.)

CHAIRMAN MALMUD: We have juggled the schedule today, and Dr. Crowley has accommodated to it, and we appreciate that.

So we will move back to agenda item number seven, and if you will turn to Tab 7. No? CR-7.

MS. COCKERHAM: Six.

CHAIRMAN MALMUD: Excuse me. There we

are. The woman says no handout.

MS. COCKERHAM: Tab 6.

CHAIRMAN MALMUD: Thank you.

MS. COCKERHAM: I have handouts for everyone on these.

CHAIRMAN MALMUD: Do you want to pass them out now?

MS. COCKERHAM: Two pages or three pages.

CHAIRMAN MALMUD: Two pages? Thank you. And we will then get started.

MR. CROWLEY: Are you ready for me to begin?

CHAIRMAN MALMUD: We are ready. Yes, thank you very much.

MR. CROWLEY: Well, thank you very much for the invitation. I am sorry I'm late. I got hung up on the Metro when they closed one of the Metro stations.

What I'd like to do is talk to you today about a study that we finished in January of this year called "Medical Isotope Production Without Highly Enriched Uranium."

I was the study director for that study. So I have a fairly in depth understanding of what's in the report, and hopefully I'll be able to answer your

questions.

When you get my handout, you're going to see that I've got 26 pages of fairly detailed information. I do not intend to read all of that to you. I've put this together to make it self-contained, and what I hope to do in the next 15 to 20 minutes is to go through this and just highlight some things.

And I guess I'm responsible for making sure that I check the slides here.

So here is the outline of my presentation. I'm assuming that you're not all experts in medical isotope production. So I will provide a little background. Then I'll talk about the study charge, the study plan, and I'll spend most of my time talking about the results.

This is just for your information, some organization information. We are the National Academies, and as I think you know, that's both an honorary organization and working arm. We're a private, nonprofit organization. We were created by the government to provide advice to the government, and Congress, as you will see, Congress came to us in this case and asked us to do this study.

All right. so let me give you a couple of

slides of background. The request for this study came to us from Congress in the Energy Policy Act of 2005. It was sponsored by the Department of Energy, and Congress, I think, was trying to strike a balance between two national interests when they asked us to do the study. The first one was insuring the availability of reasonably priced medical isotopes. Congress had been told by industry that if they were forced to convert medical isotope production from highly enriched uranium -- and I'll tell you what that is in a second -- that it would be very expensive.

And the medical societies were concerned about supply reliability if, in fact, the companies were forced to convert. On the other hand, we have a national policy top minimize the civilian use of uranium that has been enriched in Uranium-235, and highly enriched uranium is uranium that's been enriched in Uranium-235 to greater than or equal to 20 percent.

The HEU, and I'm going to use the word "HEU" for highly enriched uranium, that is used to produce medical isotopes is almost entirely 93 percent. That's weapon grade HEU, and there's a concern that that HEU could be diverted for use in improvising devices.

All right. Well, the isotope of primary concern here is Molybdenum-99, which as you know decays to produce Technetium-99m, which is used in medical isotope treatments. Both of those isotopes have very short half-lives shown there, 66 hours for Moly and six ours for Tech. So they require a very sufficient supply chain and any disruption can have a great impact on medical practice.

The primary method of production of this isotope is by taking targets made of highly enriched uranium, irradiating them in research and test reactors. Around the world we use between 40 and 50 kilograms of HEU every year. Most of that HEU is U.S. origin. The quantity of concern of HEU by the IAEA is 25 kilograms, and the quantity of concern is a concern for using material to make improvised nuclear devices.

This agency, the Nuclear Regulatory Commission, actually regulates quantities greater than five kilograms of HUE, comes under tighter regulatory control by this agency. Again, the concern is this material can be used to produce improvised nuclear devices.

The other point I want to make on this slide is that not only are we using 40 to 50 kilograms annually of HEU, but the waste for medical isotope

production is also HEU; that during the irradiation of the targets in the reactor, only about three percent of the Uranium-235 is consumed. So you go in with about 93 percent HUE; you come out with about 90 percent HEU. It's still weapon grade.

There are hundreds of kilograms of that material sitting in solid and liquid form around the world. Now, it's protected, but nevertheless, there is a very large inventory of this material out in civilian commerce.

The other point to make from this slide is that between 95 and 98 percent of the world's supply of Moly-99 is made using HEU, and it's made by there are four organizations, one in Belgium, one in Canada, one in South Africa, and one in the Netherlands.

And the next slide is a schematic showing you where these organizations are and what the primary supply chains are. There are some secondary supply chains that aren't shown.

A couple of points to make from the slide. The United States market shown in the upper right accounts for about half of moly use. The rest of the world uses about half.

Almost all of the moly used in the United States is produced by two producers, MDS Nordion in

Canada and Covidien, Mallinckrodt Covidien. They actually produce it in the Netherlands, but they also have a manufacturing facility here in the United States for making technetium generators.

The other two producers are IRE in Belgium and NTP in South Africa. You can see that MDS Nordion produces about 60 percent of the medical isotopes used in the U.S., and Covidien makes about 40 percent.

The left column shows the reactors that are used to produce these isotopes. The world's supply of isotopes is produced in about five reactors, one in Canada, three in Europe, and one in South Africa. All of these reactors are 40 to about 52 years old. They are, for the most part, past their useful lifetimes, and as you practicing physicians know, there's a supply reliability problem, and that problem is primarily because of these aging reactors. And I'll have a little more to say about that later in the talk.

Break this up a little bit with some pictures. I'm assuming that you're not all familiar with how this material is produced. So I've got four pictures here that illustrate some important points. The picture in the upper left-hand corner is an HEU target. So a target is basically typically a flat

plate. It's a uranium-aluminum alloy clad in an aluminum cladding. The targets are typically about 15 centimeters long and a few centimeters wide, and several of those targets would be placed into a reactor, and they would be irradiated for about five days.

In the upper right-hand corner is a picture into the core of the research reactor at the University of Missouri, and some of you may know that the University of Missouri is trying to actually start Moly-99 production, but these reactors are relatively small. They're much, much smaller than a power reactor. They typically sit in pools, and you can see them from the surface as you can see down here in the picture.

The targets are either put into the core of the reactor or they're put into the reflector region around the core, and they are put in remotely, and they're removed remotely, and again, they're irradiated for about five days.

The picture in the lower left corner shows a processing facility. This particular facility is in Argentina. Once the targets come out of the reactor, they are very radioactive. They can't be handled. They have to be processed remotely, and so they're

processed in these heavily shielded facilities called hot cells, and these can have several feet of concrete, and the windows can be many inches to feet of leaded glass.

And the apparatus in the hot cell, which is shown in the lower right corner, is actually very simple. It can sit on this table top, and the targets are basically dissolved, and they are chemically processed, and the Moly-99 is absorbed onto an aluminum column. All of that happens within the hot cell.

So this process, two components of this process are very expensive. The hot cells are very expensive, and the reactors are very expensive. Hot cells, tens of millions of dollars to build; reactors, hundreds of millions of dollars to build.

All right. Well, let me now turn quickly to the study charge. We had a five-part study charge. Four of the charges were given by Congress. One of the charges we negotiated with the sponsor.

Charge number one, we were asked to assess the feasibility of procuring supplies of medical isotopes from sources that don't use highly enriched uranium, and Congress had a three-part feasibility test. You can read the first two parts. The third

part, which is the third bullet, is really key, and that is is the average anticipated total cost increase from production of medical isotopes without HEU less than ten percent.

So Congress is asking if we forced producers to switch to, say, low enriched uranium or some other way of making medical isotopes, would the resultant cost increase be less than ten percent?

Congress did not specify the point in the supply chain or the time scale for the feasibility determination. So that was one of the things that we had to determine for ourselves.

Okay. Charge two was the current projected demand and supply for medical isotopes in domestic use.

The third charge is really not relevant to this, the interest of this group. So I'll skip over it.

The fourth charge is the potential cost differential of the medical isotope production in reactors at target processing facilities, if the products are derived from systems that don't involve fuels or targets that use HEU. So we actually had to do a cost calculation, and I will explain how we did that a little later.

And then the fifth charge, which is the charge that we negotiated with the sponsors, was to identify additional steps that could be taken by DOE and medical isotope producers to improve feasibility of conversion and to identify any reliability of supply issues that could arise as a result of such conversions.

All right. Well, as we do for most of our studies, we put together a committee of experts. We had a committee of 14 experts. One of the points I want to make here is that two of those experts were nuclear medicine physicians. We understood that the implications of this study were quite significant for medical practice, and we wanted to make sure that we have medical experts on the committee both to keep the committee honest and also to provide a very important medical perspective.

This was more than just a paper study. We did extensive fact finding. We visited all of the major medical isotope facilities except South Africa. They wouldn't cooperate with us.

In addition, we visited medical isotope production facilities in Argentina and Australia. Those two are significant because they're not producing medical isotopes with low enriched uranium,

and, in fact, Argentina produces only for its own market, but Australia actually has plans to become a global producer. So we wanted to understand exactly what their plans were.

Also, before our report came out, it received extensive peer review. We had 14 committee members and 14 peer reviewers. So the report got a good vetting.

And here is the committee membership. The medical physicians were Steve Larson from Memorial Sloan-Kettering. He was the Vice Chair, and Dick Rieba from Med Star, Georgetown Hospital.

All right. Now, let me just turn to the results. So with respect to the second charge on projected demand and availability, I need to give you a definition, and that definition is six-day Curies rates. Moly-99 is sold in terms of six-day Curies, and six-day Curie is the number of Curies remaining six days after the shipment leaves the producer's facility. So remember it has a 66 hour half-life, which is about two and three-quarters days. So, you know, it is decaying away even while they are transporting the targets to the processing facility. They're processing the targets. They're shipping it out.

By the time they ship it from their loading docket to the technetium generator producer it may have undergone one or maybe even one and a half half-lives. So you don't have very long to work with this stuff.

So the global supply of Moly-99 in 2006 was about 12,000 six-day Curies per week. As I said before, the U.S. market uses about half of that 5,000 to 6,000 six-day Curies per week. There hasn't been much of a change in the supply since 2006, and as I said earlier, the great majority of this isotope is produced using HEU targets.

In terms of demand, we look both at estimates that had been made by others, and then the committee made its own estimates based on information available to it, and we heard estimates of demand growth for Moly-99 in the range of three to ten percent. The committee thought that the demand growth, particularly in the U.S., would be lower than that, zero to five percent with most likely three to five percent.

The committee thought that the demand would continue to rise as the U.S. population ages, and also they thought that because of the current practices favoring the clinical use of Tech-99

radiopharmaceuticals, that they probably wouldn't be displaced, at least in the foreseeable future by other modalities, and there's actually a fairly extensive discussion in the report about other modalities and the pros and cons of those relative to Tech-99 system.

All right. With respect to the feasibility of conversion to LEU, if you remember, we were asked to assess the cost of conversion, and what we decided to do was to look at cost at three points in the supply change: the cost for producing Moly-99, the cost of the technetium generator, and the cost of a Tech-99 dose. So we basically hit the entire supply chain by considering those three points.

And then in addition to evaluating cost, we also looked at other potential impediments to conversion, technical regulatory timing and impacts on supply reliability, and there's a separate chapter in the report on all of those.

We also looked at the experience of the large scale producers. These are those four global producers that I told you about before, and the regional producers like Australia and Argentina.

So remember I told you that Congress gave us three tests for feasibility, and I'd like to run through those now fairly quickly. Test one was have

targets been developed and demonstrated; have LEU targets been developed and demonstrated for use in targeting processing facilities that produce medical isotopes to serve U.S. needs.

The short answer is, no, neither MDS Nordion nor Mallinckrodt are producing moly with LEU targets. However, LEU targets have been developed, and they have been demonstrated. They're being used in Argentina and Australia. We don't see any technical barriers to their use by producers that currently supply the U.S. market, and we believe that at least three of the four current large-scale producers -- and this would be MDS, Nordion, Mallinckrodt, and IRE -- could convert to LEU based production within their current facilities. They have extra hot cells, although some modification to the process equipment might be required, and the conversion will take several years.

All right. The second feasibility test: are sufficient quantities of medical isotopes available for LEU targets and fuel to meet U.S. needs?

The short answer again, not at present. No technical reasons it couldn't be done, and no demonstrated evidence that the large-scale producers were taking any steps to convert.

And with respect to that last point, there's a good reason that the large-scale producers aren't taking any steps. There's really no business reason for them to do so. They have their systems in place. They've optimized their systems. It will cost money and it will take time to convert, and in the business perspective there's really no reason to do that.

All right. Test three is the average anticipated total cost increase from production of medical isotopes, less than ten percent, and basically what we did here was a present value calculation. We said let's assume that prices increase by exactly ten percent for producing moly for buying the cost of a technetium generator and the cost of a dose, and then we amortized that over the life of a facility, and we look at its present value and then we ask are the present value revenues sufficient to convert, and we concluded that conversion is feasible with a ten percent cost increase if conversion was carried out at producers' existing facilities.

It might also be feasible even if extensive modification or new construction is required, and that a ten percent increase would have a negligible, a bout a .1 percent impact on costs of

typical U.S. medical isotope procedures,a dn the numbers are described in detail in the report.

All right. If you remember, the last charge asked us to recommend steps to DOE and producers for improving their feasibility, and I want to run through these slides very quickly. I've got several slides, and I just want to make a couple of points.

Our advice to Moly-99 producers is basically, look, conversion isn't going to happen until you make a commitment to make it happen. So we recommended that the producers announce a commitment and a best effort scheduled conversion, and we also recommended that they work with the industry organizations and the scientific and medical societies for marshalling, coordinating and supporting conversion.

To the Department of Energy, we also made several recommendations, and I want to just focus on a couple here. It was clear from our data gathering that the medical isotope producers do not have all of the necessary in-house technical R&D that they need to actually convert, whereas a lot of that necessary R&D expertise lies within the national laboratories.

So we recommended that DOE make the

expertise of the national laboratories available to producers and that they examine options to share R&D costs with the producers.

To Congress we said, you know, if DOE is going to share R&D costs, you've got to appropriate the money. So from government cost sharing, and we also recommended that they consider -- and we didn't say do this. We said consider doing this -- condition supply of U.S. origin HEU, and I didn't mention this earlier, but almost the entire world supply of medical isotopes is made with U.S. origin HEU. South Africa uses its own HEU. The rest of it is U.S. origin HEU.

We recommended that Congress consider conditioning supply of U.S. origin HEU for medical isotope production. There was the Schumer amendment in the 1992 Energy Policy Act, actually conditioned the supply of U.S. origin HEU on producers' progress in converting to LEU, and the Schumer amendment was vitiated by the 2005 Energy Policy Act, and we said, Congress, consider reinstating that with a phaseout period, perhaps a seven to ten-year phaseout period.

We also suggested that they consider prohibiting the export of HEU for medical isotope production to new reactors. There are two new reactors under construction in Europe. They will come

on line starting in, I guess, 2015 to 2018. They will both come on line. They will probably replace the reactors that are being used now to produce medical isotopes, and we said, you know, one of the things you could do is make it clear early on that you are not going to export HEU for medical isotope production in those new reactors. It's a clear signal to the producers that they need to convert.

Okay. One other suggestion we made to Congress was that Congress could consider a temporary financial incentives for production or purchase of LEU-based Moly-99. For example, they could provide technetium generated producers with a tax credit if they had purchased LEU based 99. So that's kind of a market pull for LEU based medical isotope production, and we made a recommendation to the Food and Drug Administration that it work with industry and DOE's technical experts to insure that there's a common understanding of LEU based processes and requirements from FDA requirements.

One of the things we heard from the producers was that they thought that FDA approval was a substantial barrier to conversion from HEU based production to LEU based production. The committee did not see the barrier, but the committee thought that by

getting FDA in through the door early to talk with industry, perhaps that could smooth the way for conversion.

And I know Orhan actually briefed our committee, and he may have something to say about that during the Q&A period.

All right. Well, let me just finish up with a couple of slides on reliability of Moly-99 supply. As I mentioned earlier, the supply of Moly-99 to the U.S. is very fragile. Actually during the course of this two-year study, we had substantial outages at reactors, unplanned outages that created a real shortage, a global shortage situation.

And this reliability problem is primarily a problem with aging reactors, as I've said before. All of these reactors are older than 40 years. They are nearing the ends of their lifetimes, and they are now encountering unanticipated maintenance issues that are forcing them to shut down, in some cases for extended periods of time.

The committee thought that supply reliability was likely to become a serious problem in the early part of the next decade without newer or refurbished reactors, and it will take five to ten years for substantial new sources of supply to come

onto the market.

AECL in Canada had hoped to start up two new isotope producing reactors in the 2003-2005 time frame, the Maple reactors. They have never been able to get them to run properly, and in October of last year they pulled the plug on the reactors.

So right now, MDS Nordion is relying on a 52 year old reactor whose license expires in 2011 to produce 40 percent of the world's supply and 60 percent of the U.S. supply of medical isotopes.

The other point that the committee made was that this reliability of supply issue is not a conversion issue. When you talk about conversion, you're talking about really changing the targets that you're using and altering the processes in your hot cells to recover the moly. The reactors stay the same. So conversion would not have an effect on reliability of supply unless, of course, you did the conversion very, very poorly.

The other thing that the committee pointed out was that government assistance might be required to improve supply reliability because all of these reactors that are being used to produce medical isotopes are government built reactors, and they are funded by the government. So it's very hard to get

the private sector to spend hundreds of millions of dollars to build one of these reactors. The government is probably going to have to stay involved at least on the reactor side.

All right. So let me end there. I mentioned that the report was issued in January of 2009, and if you don't have a copy and you're interested in it, you can download it at the URL shown there, and the report will be issued in final form before the end of this month.

Thank you very much.

CHAIRMAN MALMUD: Thank you.

Questions or comments?

Dr. Nag.

DR. NAG: You mentioned that the U.S. is using up about 50 percent of the world's HEU produced molybdenum and using more of the HEU. If that's the case, why hasn't the U.S. been using HEU in the ordinary act rather than importing it? Is it a question of cost or what?

And the second part is why are we now trying to use any new and why not just try to use HEU in the reactor here.

MR. CROWLEY: Well, we have not produced medical isotopes domestically since 1998. The

Cintichem was producing those isotopes in a reactor in New York. It shut down, and then DOE looked at the possibility of using some of its reactors to produce medical isotopes. They did a feasibility study. The looked at the cost. The medical isotope producers looked at that and said, "We're not interested. It's too expensive."

Research and test reactors in this country have been shutting down over the past ten or 20 years because a lot of them are very old, and until University of Missouri stepped up and said, you know, "We're interested in doing this," there was not really a viable alternative.

In addition, there's another company, Babcock & Wilcox that is proposing to build what is called a solution reactor, which basically doesn't have fuel, but it's a solution that has LEU dissolved in it, and they would run that and then separate out the Moly-99.

So we now have two viable proposals on the table for producing medical isotopes in this country. As to why we don't do this with HEU, it's because the government has made a policy decision to eliminate civilian use of HEU.

DR. NAG: And why is that? Why that

policy?

MR. CROWLEY: It's because HEU can be used to make improvised nuclear devices and used in terrorist attacks against the country.

CHAIRMAN MALMUD: Other questions? Dr. Van Decker.

DR. VAN DECKER: I thought your summary and your report was great, and we appreciate --

MR. CROWLEY: Thank you.

DR. VAN DECKER: -- the efforts of everybody because I think everyone around the table realizes that the supply is unreliable, and we have major problems here.

You know, in addition to reporting some public-private ventures here for intellect, which I think it's going to take, and I'm interested in your outlook on how that's going to happen with overseas reactors for some of the switch-over which is not within the country, and the other part of this is not just the cost of the R&D and getting these things running, but it's the pass-through cost on each dose that eventually comes down the line in the current environment of health care reform and costs. You know, ten, 20 percent on the cost of each individual dose for a patient study, especially in a diagnostic

realm where, you know, it's not a small number is a big deal, and so, you know, that needs to be thought about as we try to do all of this as to how we can really make this happen.

MR. CROWLEY: Let me take your first comment first and just respond to that. In terms of the fact that most of the world's supply is made in these foreign reactors, as you may have noticed from the slide that I showed toward the beginning of my talk, this is really a global industry, and it's a global supply chain, and there's a lot of global interest in having redundancy.

So it's good, the fact that there are a number of foreign reactors that make this stuff. Al;so, one of the things that we learned during the study is that the irradiation of these targets is a very important revenue producer for these reactors. These reactors are multi-purpose reactors, and one of their more important missions, besides medical isotope production, is research, materials research, academic research.

And particularly for the academic research, people don't come to the table with big bags of money to support the reactor. So the work on medical isotope production really helps to support the

continued operation of these reactors.

CHAIRMAN MALMUD: Thank you.

Dr. Welsh.

DR. WELSH: Thank you, Dr. Crowley.

If you could explain to me or answer the question about whether or not when cost effectiveness was being analyzed if they took into consideration the full big picture matter, meaning a reactor might not turn a profit by selling medical isotopes, but the cost to the nation as a whole by reducing production of HEU and the concomitant shipping costs and security costs, as well as having that material shipped back over international borders, makes me wonder if it would be actually cost effective to produce the isotopes here, despite the initial superficial belief that it's just not cost effective.

So has cost effectiveness been looked at from a global perspective?

MR. CROWLEY: When we embarked on this study, our initial approach for estimating cost was to do a bottoms-up roll-up, to do exactly what you said: look at every part of the production process, look at what does it cost for the HEU, what does it cost to transport the HEU, what are the security costs; compare that to LEU; go all the way down the supply

line.

And what we realized very quickly was that was not possible to do because people didn't know what these things cost.

Basically these reactors were about four decades ago. They were funded by the government. The money that the medical isotope producers paid to irradiate their targets do not cover the costs of running those reactors. So the government is subsidizing this process.

This is a very unusual public-private partnership where you have the government paying for the upstream end of medical isotope production and you have private enterprise that is then from the target on forward taking that material and selling it and making a profit.

The companies are subsidized by the government to do that, and I think at least as long as we continue to rely on these large, multi-purpose reactors that will continue.

DR. WELSH: If I might ask a follow-up question, under steps to improve feasibility, Step 2, Department of Energy, the last bullet item there says maintain consistent pricing for LEU versus HEU on a common U-235 mass basis.

But shouldn't LEU be far more affordable? Why consistent? Why not wait for the obvious?

MR. CROWLEY: Well, right now, unfortunately when we did the study what we learned was it was cheaper for countries to buy HEU than it was LEU. So LEU was more expensive than HEU. You're absolutely right. It should be less expensive, but it is not. It's more expensive, and we're saying at least make it, you know, the same cost on a per mass basis.

As it turns out, the cost of the material is only about ten percent of the cost of producing the medical isotope, but you know, it sends the wrong market signal.

CHAIRMAN MALMUD: Dr. Fisher.

DR. FISHER: Mr. Chairman, with your permission I have maybe four questions that will be fairly quick.

And with no disrespect for the National Academies, you're aware of a number of criticisms of this report by either groups or companies involved in Moly-99 production that disagree with the basic assumptions, the data that you used.

MR. CROWLEY: Yeah, why don't you --

DR. FISHER: I'm coming to that.

MR. CROWLEY: Okay.

DR. FISHER: And your final conclusions.

First of all, I noted that the committee membership did not include representatives from the producers of Moly-99 who are most intimately associated with the costs of doing business and the technical obstacles involved --

MR. CROWLEY: That's correct.

DR. FISHER: -- not only in upgrading reactors, but in making conversions to an alternate target form and in some cases fuel form.

MR. CROWLEY: It would have been a conflict of interest for them to be involved on the committee.

DR. FISHER: And to involve that expertise.

MR. CROWLEY: Yes. We did involve the expertise by seeking briefings from them and by visiting their facilities.

DR. FISHER: And you're aware that these producers have criticized the report for the reasons I mentioned?

MR. CROWLEY: I'm aware of some of the criticisms, but you might want to say exactly what they are for the benefit of the rest of the group.

DR. FISHER: Secondly, you speak of a government policy against using HEU, but you did not acknowledge that our unstated policy is to use HEU for other purposes, in particular, the operation of our naval submarine fleet.

So I think the Committee should be aware that this is a largely political policy rather than a well established federal policy, and we're all subject to the politics of those members of Congress who have various political leanings.

MR. CROWLEY: I want to correct what you just said because I disagree. What I said was that there is a national policy to minimize the civilian use of HEU. Naval reactors is military use of HEU.

DR. FISHER: I understand.

MR. CROWLEY: Okay.

DR. FISHER: I'd like you to maybe address, and maybe the final report will do that, but the --

MR. CROWLEY: What you see now is the final report.

DR. FISHER: The Society of Nuclear Medicine, as you know, issued a press statement strongly criticizing the assumptions based on flood data. Would you address that criticism?

MR. CROWLEY: Well, I'll tell you what I know about it. One of the criticisms from the Society for Nuclear Medicine was that they thought that we underestimated the cost of the technetium generator. Is that what you're referring to?

DR. FISHER: That's one of the criticisms.

MR. CROWLEY: Okay. What is the other criticism or the others?

DR. FISHER: Well, the assumptions involved in the cost of Moly-99 production using oil enriched targets.

MR. CROWLEY: The cost of production using low enriched targets?

DR. FISHER: Let me not go into the details of -- I'm aware of --

MR. CROWLEY: Let me respond to your first one, Darrell. One of the criticisms of the Society for Nuclear Medicine was that they thought that the price that we quoted for a technetium generator, a 10 Curie technetium generator, we said that in 2006 the price of that was 1,900 U.S. dollars, and they said that's too low, and what they didn't realize was that actually if we had used the higher price, it would have made conversion look even more feasible because what you're doing is you're taking the cost of the

technetium generator, you're adding ten percent, you're amortizing; you're multiplying that by the number of technetium generators that are sold every year. You're amortizing that over some period of time, and then you're calculating the present value.

So what we were trying to do was to be conservative. We used what we thought was the lowest reasonable cost for a technetium generator so that we wouldn't be accused of cooking the books. If we had used the higher cost for the technetium generated, the numbers would have come out better. It would have been more feasible. So that was an indication where I think perhaps the society didn't read the report very carefully.

So for the cost of producing medical isotopes using LEU, we did not provide a cost estimate in the report. What we did was we estimated the amount of revenue that would be available to a moly producer if they raised their prices by ten percent. We looked at their facility. So the next present value of that revenue, and I should tell you that revenue is hundreds of millions of dollars, and then we looked at what are the producer's facilities now. Could they convert within their existing facility. They have extra hot cells, and it's just a matter of

doing the R&D, and you're changing the processing equipment in the hot cells. You're looking perhaps at few tens of millions of dollars. That's a no brainer if you've got hundreds of millions of dollars of revenue.

The other thing that we did was we looked for information from the two producers that are now making Moly-99 from LEU. What does it cost them to produce moly from LEU compared to what it cost them to produce from HEU. The only data point we were able to find was Argentina.

Argentina converted in 2005, and they did a study where they looked at what did it cost them to produce moly net present value, HEU 2002 to 2005 and then 2005 to 2007, and the cost difference was on the order of five percent. It was a five percent increase, and that increase came about -- the only reason for that increase was because of the way they made their targets it was more labor intensive.

So it wasn't really a matter of the process costing any more. It was just that they changed the way they made their targets, and it was more labor intensive.

DR. FISHER: Finally, Mr. Chairman, one last question.

Speaking directly to the Argentinean experience, Dr. Von Saal DeVilliers of NESCA South Africa at a meeting I attended earlier this year made the comment that that cost of production, that small scale does not scale linearly to a full commercial scale operation, which would be far more expensive and cost prohibitive, and what he said was that although technologically feasible to produce Moly-99 using low enriched uranium, it is not commercially feasible on a large scale, and I quote, "without substantial federal subsidy."

And he wasn't talking ten percent. He was talking multiples of the cost of presently producing Moly-99. Now, I'd like to --

MR. CROWLEY: Let me respond to that.

DR. FISHER: -- say that those are not my words.

MR. CROWLEY: Because --

DR. FISHER: I'm not finished.

Those are not my words. Those are the words of a recognized world expert in the topic who I'm not sure was consulted in the production of --

MR. CROWLEY: You're right. He wasn't consulted. The South Africans would not cooperate with us. We asked for their cooperation, and they did

not cooperate.

With respect to your first assertion that it would be more expensive to scale up, actually scaling up reduces costs because you get economies of scale that you don't have in a small scale operation like you do in Argentina. One of the reasons that they spend more to produce their targets is because they're a small scale producer, and it's a very labor intensive process.

If you go to larger production, you have opportunities to automate that you don't have with lower scale production. During the course of the study we heard over and over again from the other large scale producers it is more expensive to produce this stuff with LEU, and we asked, all right, show us your cost calculations. And it was pretty clear they hadn't done any.

These are assertions that as far as we could tell had no technical support or they weren't willing to share the technical support with us.

CHAIRMAN MALMUD: That completes your questions. Dr. Welsh.

DR. WELSH: Maybe a quick related question, and maybe you don't know the answer, but I'm wondering why AEC Canada decided to ditch the Maple.

Does anybody know?

MR. CROWLEY: Well, the problem with the Maple was that it had what is called a positive coefficient of reactivity, which was not a design feature of the reactor. What it means is that as you increase the power, the reactor becomes more reactive rather than less reactive. So it becomes harder to control.

And because it was not a design feature of the reactor and because they didn't understand the origin of that, the regulator said, "Look. You can't run this thing at full power. They put a lot of effort into understanding the problem. They consulted with a couple of national labs and with a company in Argentina,a nd I think they just decided that it was just going to cost too much to fix the reactor.

It was also clear to the committee toward the end of the study that the Canadians may not be interested in staying in the business, not MDS Nordion but AECL may not be interested in staying in the business.

CHAIRMAN MALMUD: Thank you very much.

Steve.

MR. MATTMULLER: I have a few questions also. You talk about the useful life of a reactor,

and I'm curious because I am concerned of the canadian reactor. It's the oldest and the biggest supplier that we have, but given current good maintenance, I mean, does anyone really know what the life of the reactor is or is it specific to that individual reactor?

MR. CROWLEY: It's reactor specific. If the reactor is well designed, you can basically replace almost everything, and in fact, that's one of the nice features about the University of Missouri research reactor. Just about everything can be replaced, including the tank, and that means that the reactor can run for a long time.

In the case of some of the other reactors, the problems that you're having are, for example, aluminum corrosion. Some of the pipes are corroding particularly where they come in contact with the concrete. There is a chemical reaction there. Some of those pipes are encased in the concrete, which means if you have a leak, it's really hard to get at it, and that is, in fact, what happened with the HFR reactor later last year. They were shut down for several months because of a corrosion problem.

With respect to the NRU reactor, we were never able to get in depth information about what

would be required to continue operating that reactor for a long period of time. We were told by the Canadian government that they thought it would cost hundreds of millions of dollars, and they confirmed that in a subsequent conversation, to get the reactor re-licensed for another five years beyond 2011.

We don't know whether or not putting in hundreds of millions of dollars would mean that, you know, it could run for another 20 or 30 years. We just do not have that information.

One of the concerns about refurbishing the reactor, that reactor sits in a tank, and that tank was last replaced 30 years ago, and the last time they replaced that tank the reactor was shut down for two years. So I think the issue with NRU is the government seems willing to put the money into it to maintain it at least for another five years, but the question is can they do that without shutting down the reactor for an extended period of time.

If they can't, there's a real supply reliability issue here because for the rest of the world capacity is not sufficient to produce. All of these reactors have to shut down. Every month they've got to shut down for a week or two for maintenance. So you'll have shortages if NRU goes down for extended

periods of time.

I think it's fair to say that the Canadian government lat this point doesn't know. I think that's what they're looking at now, is trying to figure out what is it going to take to get this thing re-licensed, and they're working with the regulator on that.

MR. MATTMULLER: In regards to Australia, the new moly process is up and working now?

MR. CROWLEY: That's correct, yes.

MR. MATTMULLER: And do you know, do you have an update on what they're thinking about for their mega moly process and how much that would cost them to get that up and running?

MR. CROWLEY: I have that information. It's proprietary. I can't share it. What I can tell you is that if they decide to go to mega moly, it will be expensive. In other words, there will be substantial upgrades. It will take several years to make those upgrades, and at the end they would be able to supply a good portion of the current world supply of Moly-99.

The other thing I can tell you is that they are looking at the U.S. market as a potential, you know, new market for them.

MR. MATTMULLER: You also mentioned two new European reactors under construction. From the report I saw where the French are rebuilding one or building a new one.

MR. CROWLEY: The Jules Horowitz, yes.

MR. MATTMULLER: And then what was the second one?

MR. CROWLEY: The second reactor actually right now it's a paper reactor. It's called the Pallas reactor, P-a-l-l-a-s, and it's planned to be a replacement to the HFR reactor at the Petten site. They have not yet decided where it will be built, but they are thinking that it will probably be the Petten site.

In January of this year, they received design proposals from three companies, and I think they are now having a discussion with the European Commission about funding, and I think they hope to go forward and have something on line by 2018, 2017.

CHAIRMAN MALMUD: Thank you very much.

MR. MATTMULLER: I'm sorry.

CHAIRMAN MALMUD: Another question?

MR. MATTMULLER: Yes, I'm sorry. I actually did download the report and read it. You might have noticed that.

I guess just to summarize quickly, I think the most important statement you made in your report is the last statement in your preface in that in essence the cost difference is really inconsequential, and if I can go off the record for ten seconds, I just came back from an APA training meeting with a lot of pharmacists, and they would gladly pay a lot more than ten percent for a technetium generator if they could get it.

MR. CROWLEY: That's what we heard, too, yes.

MR. MATTMULLER: But reliability is our whole issue, and I hope in any further conversations you have with Congress in regards to this issue that that's the number one priority, is increased reliability, and we'll deal with costs later.

MR. CROWLEY: When we briefed Congress, we made it very clear that we thought reliability was very important, and I can also tell you the other thing that we heard from a lot of the users of medical isotopes is, "Ten percent? You've got to be kidding. Why are we worried about ten percent."

MR. MATTMULLER: Thank you.

CHAIRMAN MALMUD: Dr. Welsh?

DR. WELSH: Thank you.

Well, I fully appreciate and understand the sensitivities surrounding the issue of national security, and I think the Schumer amendment is a reasonable step, provided we have some backup plan if those who do produce methyl isotopes do not wish to convert over from HEU to LEU because although national security is certainly an issue, this Committee is concerned with medical use of isotopes, and we might not have jobs if the Schumer amendment is put back on the table and nobody wants to switch over.

So is there a backup plan? Obviously the solution is to produce the isotopes in this country and use LEU, but what if that's not in the near future?

MR. CROWLEY: Well, actually, there are several efforts underway in addition to the two that I spoke about with the Missouri University reactor and the Babcock & Wilcox reactor. Triumph in Canada now is examining the feasibility of producing these isotopes using photofission, using accelerators and photofission. We know it can be done. It's just a question of can you produce the quantities and what is the cost of doing that. You know, you might have to build a lot of accelerators to get that done.

More generally though to answer your

question, I think, you know, this Committee was not asked is this the right national policy. Congress said, "Look. This is our policy. we want to phase out civilian use."

On the other hand, they made it very clear to us we don't want to do anything that is going to impact patient care, and this debate is going to play out in the halls of Congress.

DR. WELSH: And if you could make a comment on the non-moly isotope issues. Anything that we should be aware of from the proposed conversion from HEU to LEU in terms of availability and reliability of the sources for non --

MR. CROWLEY: You mean like iodine? Yeah. Actually, you know, Congress asked us to look at medical isotopes, and initially we had gone in with the idea that we would look at all of them, and we very quickly convinced ourselves that, you know what? If you look after moly, you've looked after all the others because the others just come along as a byproduct, and as long as you're making moly using fission, you'll make the others. If you switch to LEU, you'll make the others in the same proportion that you make moly just as you do with HEU. It doesn't matter whether it's HEU or LEU.

As it turns out, a lot of the producers don't even recover those other isotopes. They are just so cheaply available from some other sources. So they're byproducts, never get recovered, never get sold.

CHAIRMAN MALMUD: Thank you very much.

DR. HOWE: Dr. Malmud, can I ask a question?

CHAIRMAN MALMUD: Oh, another question. Dr. Howe.

DR. HOWE: Yes, I also read the report from beginning to end, and there's one point I'd like to get clarification on. In the report you considered a world producer to be 1,000 six-day Curies, and you talked about Australia becoming a world producer, the implication being that they would get up to the 1,000 six-day Curies. Are you saying today that you think Australia will produce way in excess of 1,000 six-day Curies?

Because to really be a major producer, you've got to be up on the level of Petten and NRU.

MR. CROWLEY: From a capacity point of view, Australia is capable of being a major producer. They've got a very nice reactor, brand new reactor and refurbished hot cells. They could really ramp up

production if they wanted to.

Somebody mentioned mini moly. Mini moly will just about bring them up to that threshold. They will be just slightly below the threshold. Mega moly, if they decide to implement it, which would require not really reactor upgrades, but some other facility upgrades, would take them well over that 1,000 Curies per week.

DR. HOWE: So it appears as if you have a real example of the cost of going from low production to higher production, and have you factored that in?

MR. CROWLEY: Well, you know, none of the producers would tell us what their costs were, and so we had to sort of figure that out indirectly, and one of the ways we were able to do that was to look at the processes, look at the costs at some points in the processes and then make some extrapolations.

Now, I'm giving you my own personal opinion here because it didn't appear in the report. I think probably the Australians are at or below ten percent in terms of the difference in cost.

But one of the other points I would make is if you look at cost for Moly-99 across the world, as far as we can tell they vary by about plus or minus 40 percent. This is a market item, and they mark it

up to get whatever they can get for it.

So when Australia shut down for two years to convert to LEU, they were buying from the South Africans and they were spending a lot more than what we quoted in the report as the cost of Moly-99 production.

CHAIRMAN MALMUD: Dr. Suleiman.

DR. SULEIMAN: I want clarification. When you say ten percent increase in cost or 40 percent, that's just for the radionuclide itself. Radiolabeled drugs have a drug component. You're not factoring that in at all, and the drug component is far, far, far more expensive, constitutes a much larger proportion.

So the cost would not be an increase of ten percent for the entire drug. It would only be ten percent for the radionuclidic portion of the radiolabeled drug.

MR. CROWLEY: Well, that's absolutely right, and in the report we give two example of common cardio procedure and common bone scanning procedure. We looked at the Medicare reimbursement rates were like $250, and we said all right. If you take the cost of Moly-99 and you increase it by ten percent, what does it do to the cost of that procedure?

Well, it increased the cost of that procedure by about one-tenth of one percent. And then we said, well, what if you increase the cost of the dose of moly or dose of Tech-99 by ten percent. What does it do to that cost of procedure?

It increases the cost of that procedure by about four-tenths of a percent. So you can really raise the cost of Moly-99 and not have a huge impact on it, assuming that you pass those costs down and don't add anything on top of them. You just pass them down and it doesn't really have an impact on the end cost of the procedures.

CHAIRMAN MALMUD: Dr. Welch.

DR. WELSH: If I might ask Dr. Suleiman a question, does it make any difference in the net cost of the drug production, the radiopharmaceutical production if the isotope is coming from overseas, Belgium, Africa, South Africa, Australia, Canada versus coming from Missouri? Is there any expectation that the price could be a net reduction?

DR. SULEIMAN: Well, I'm not an economist. So I assert I have no expertise in this area other than my own interest. Clearly, we get it from Canada now, but I would think I don't know how much damage it would be, but I don't anticipate any major difference

there. I think coming from Australia could be -- I mean, there's a longer time period, but I guess the NRC would have the export-import licenses to get them into the country.

MR. CROWLEY: They basically put this stuff on commercial aircraft and fly it in. MDS Nordion uses its own charter aircraft to go from Canada to the U.S., but again, understand that companies will charge what the market will bear, and so even if Missouri can produce the isotope more cheaply, it may slightly try to undercut to establish market share, but you know, if people are willing to pay, they're going to charge.

CHAIRMAN MALMUD: Dr. Nag.

DR. NAG: Yes. I think the cost is not the major issue here. I think the major issue is the strategic importance of being self-sufficient. For example, if other countries for one reason decide to stop the exportation of the moly to this country, you know, I think, the Congress is trying to find ways not to have to import for strategic reasons.

CHAIRMAN MALMUD: Steve.

MR. MATTMULLER: I'm sorry. One more, the last one. This is in regards to the Petten reactor that had the major shutdown that caused the latest

problem, is from what I've read and heard that it was due to a pipe encased in concrete that was generating a source of bubbles that had everyone concerned.

MR. CROWLEY: Corrosion products, yes.

MR. MATTMULLER: And so at this point they haven't fixed that.

MR. CROWLEY: They have fixed it.

MR. MATTMULLER: They have fixed the corroded pipe?

MR. CROWLEY: Yes.

MR. MATTMULLER: Okay.

MR. CROWLEY: We have a couple of reactor experts on our committee, and this is not Petten's view, but our committee experts' view was when reactors start having this problem, that's a real indication that you're facing end of life issues.

CHAIRMAN MALMUD: Does that complete the discussion? Dr. Suleiman.

DR. SULEIMAN: So my perception, so at least when I explain it to other people, the Australians really have come up with the newest and theoretically have the capacity to help alleviate the problem. However, right now with the four or five existing ones we're really very, very vulnerable because none of them plan to shut down intentionally,

but unintentional shutdowns are unanticipated.

MR. CROWLEY: That's right, yes.

DR. SULEIMAN: So until others step up to the plate.

MR. CROWLEY: Well, in this country there are two that might step up, would be Murr and Babcock & Wilcox, and it will take them a minimum of five years to step up. So keep your fingers crossed.

CHAIRMAN MALMUD: If I may, I believe that the issue started in 1979 when TMI went. The public turned away from investing in nuclear energy. The icing on the cake came when the Russians allowed Chernobyl to occur, which made the whole world very suspicious of nuclear power.

We will have ample supply of isotopes when our nation decides that it will use nuclear power for generating electricity and when one of the byproducts will be isotopes. But that also means it has to overcome a major political question, which is not in my backyard. You're not going to put a reactor in my backyard, and I don't want the nuclear waste in my backyard.

So until the public is convinced that the risks of nuclear power are less than the risks of entering another war to maintain its supply of fossil

fuels, the problem won't be solved. It's 30 years since TMI, and the issue is moving toward a resolution. If I live long enough I'll see us reenter the world of nuclear power. We'll buy our technology back from the Japanese who are using it well. The French are producing what, 90 percent of their electricity from nuclear power, and we're sitting here on our hands because we had an accident in 1979 that killed no one.

The mining of coal and the drilling of oil destroys many more lives. However, we have a public which is not educable. We have a public which is partly illiterate. We have high school kids coming out with fifth grade education. So until we correct a few of those problems, which it appears the present administration is interested in curing but I don't know if it has the ability to do it, but if they do, we'll all be fine. We'll all have all of the isotopes that we need.

Until then all that we say means very little, and you are correct. It's a matter of cost, and what's needed is for someone to invest. Usually it's the private sector, but the private sector won't invest not because of the cost of the investment but because of the risk and the liability of investing.

So it's the government that has to do it. When the government does it, then somebody will come in and live off of the investment that the government has made. It's an economic issue. It's not a medical issue.

Unfortunately, we are the ones at the end of the pipeline who suffer the medical consequences of it, and that's not us. Actually it's the patients. So that we wish our politicians well in dealing with the public and helping to educate the public with regard to the uses of nuclear energy for the good as well as for defense, and until then we are prisoners of this system.

PARTICIPANT: Is that a motion, Mr. Chairman?

CHAIRMAN MALMUD: All that we say, it means absolutely nothing.

DR. WELSH: I second the motion.

(Laughter.)

CHAIRMAN MALMUD: But it's good to be able to talk. It makes us all feel better.

Dr. Welsh.

DR. WELSH: Just a quick editorial here.

(Laughter.)

DR. WELSH: The present economic crisis

has changed the public attitude and the politics surrounding this to the point where I am actually hearing for the first time in many years people and towns and locations in general who are saying, "I used to say not in my backyard, but if I could get a job there, by all means."

CHAIRMAN MALMUD: Maybe so. I hope that you're correct, but we'll give it a few more years. The price of oil had to go back up again, and when that happens we will hopefully have a nuclear power industry again, and we will enjoy the byproducts of that nuclear power industry.

Until then, no one in his right mind would put any of his own money into doing this because it's too risky. The profit can be made once the product is on line because then the marketplace will take over, but I took advantage of my position as Chairman just to ventilate. But it's 30 years. It's 30 years. No one has lost his life in any of this in the United States, and yet the public still seems very frightened of nuclear energy.

DR. EGGLI: It's in my backyard. I look at it every day.

CHAIRMAN MALMUD: Yes, you do. You do. You live right near TMI. So if I may, having had the

last -- may I have the last word here or do you want to discussion some more? We'll move on to the next topic.

Dr. Nag wants to have the last word.

DR. NAG: I do have -- it's very interesting about what you said. However, we are the advisory committee for the medical use of isotopes, and therefore, rather than just throwing up our hands and saying, well, there's nothing we can do, why not make a recommendation, whether the politicians will deal with it or not; make a recommendation that from the Medical Use of Isotope Committee this is what we feel?

They may not hear it.

CHAIRMAN MALMUD: We did.

DR. NAG: But we can do it as a formal recommendation and put it in our minutes.

CHAIRMAN MALMUD: We already did that. We did that in one of the items that was very eloquently summed up for us a little bit earlier.

MS. COCKERHAM: Item 6.

CHAIRMAN MALMUD: We expressed our concern, haven't we?

MS. COCKERHAM: Item 6.

CHAIRMAN MALMUD: Item 6. We already did

it.

DR. WELSH: We'll do it every meeting until --

(Laughter.)

DR. NAG: Do it every meeting until they hear us.

CHAIRMAN MALMUD: Fine. We ought to make that a five minute agenda item for each succeeding meeting, but we'll limit it to five minutes because you don't want to hear me talk, and we'll be able to present it. Because it's the only way anything will ever happen. It's not under our control.

It's as much under our control as fingerprint for using an irradiator under our control.

(Laughter.)

CHAIRMAN MALMUD: Dr. Vetter will attest to that.

There are some things we simply can't control, but we can remind our elected officials via the Commission that it is an issue of great concern to the public.

May we move on? Thank you very much.

MR. CROWLEY: Thank you.

(Applause.)

CHAIRMAN MALMUD: What's the next item on

the agenda? We juggled our agenda.

MR. EINBERG: It will be the status of the current and future 10 CFR Part 35 Rulemaking.

MS. BHALLA: Good afternoon, Dr. Malmud and the respected members of ACMUI. It has been a long day for you all, and after this very stimulating discussion, I'm just going to make a very short and just provide you the status of the Part 35 rulemakings. As you all know, Part 35 relates to the medical uses of isotopes.

This is by Ed Lohr also, and Ed is not here. He had to leave for some things, but anyway, we are both from the Division of Intergovernmental Liaison and Rulemaking, and I'm going to give you just a quick update.

Right now there are three Part 35 related rulemakings. The one that's in the proposed rules state is the medical event definition rulemaking. Then we have a direct final rule, and I'll go over a little bit about what a direct final rule is as opposed to our proposed rule and final rule process. And then we have plans to do another rulemaking on Part 35 related issues.

With regard to the medical event definition, it's a proposed rule, and the provisions

of the rule are to change most of the medical event criteria from dose based to activity based for Part 1 and brachy implants, and this rulemaking is also going to make some clarifications related to the written directives which are needed for Part 1 and brachy implants.

And also one of the provisions is to add medical event criteria for failure to prepare for written directive when one is required.

The proposed rule was publishes in the Federal Register in August of last year. As you know, proposed rules really solicit comments from all the stakeholders, and it's pretty much for 75 days, and the comment period ended in November.

And right now the staff is working on resolution of those public comments, and after the resolution, the package will move to, you know, the Commission as some point.

And a kind of schedule right now is that we hope to have that published by August, but then as we discussed earlier, the VA events were all discussed in an earlier presentation, and that may delay the publishing of this final rule because, as you know, the VA events did involve medical events, and the question is a little bit that without, in fact, this

rulemaking, do we need to -- may we rate a little bit more on that or move forward.

So, therefore, the schedule is somewhat dependent on that, but hopefully we'll complete it by August or so.

Now, once we get a final rule that we are working on, that rule clarifies the Part 35.57. There is the -- actually Part 35.57 itself has to do with grandfathering of the authorize user's medical physicist, RSOs and so on, but the way the rest of Part 35 is written, it seems like it needs a clarification that the individuals who are grandfathered, that they are able to do the preceptor statements for those people who want to come now and get these authorizations.

So the technical basis for this rulemaking was accepted in January. For those of you, this is a little bit of our internal mechanisms, so to speak. When we get a request for rulemaking, we also now ask for a very good technical basis because sometimes we start a rulemaking and in the middle realize that there's not enough technical basis, and so therefore, now we are quite particular with that. and this was accepted in January.

And this particular rulemaking has been a

very high priority on our list of things to do, and right now we are working on the rule language so that this clarification can be made.

Just a little bit about what is our direct final rule. Frankly, before I came to Rulemaking, although I was in NRC for many years, I myself didn't know the difference between some of these things: what is a direct final rule; what's a proposed rule; what's a rulemaking plan, and so on?

So here just for, you know, everyone's knowledge, we have put a slide up, "What Is a Direct Final Rule?" So a direct final rule, we pretty much make use of this process, where we are not expecting a lot of comments, it's noncontroversial in nature, and sometimes it's minor in nature.

What we do at that time -- and this is a bit of mechanics -- that we prepare both our proposal and a final rule, and it goes to the Federal Register together.

And when we publish it, we again open it for comments so that the Administrative Procedure Act is met with. So folks have an opportunity to make a comment, and if there are no significant comments, then the rule becomes -- we give an effective date pretty much 75 days, and those are the things. Our

folks from ODC, they keep us on the right track.

So in this rule we are pretty much not expecting any adverse comments. So it should become effective if things go the way we are planning. It should be good to go November 2009.

Now, if we do get some adverse comments, then we'll have to pull this final rule version back, and then it follows the proposed rule, final rule process, and that really means we need to resolve each and every comment that has come.

What really is an adverse significant comment, and that is, again, we follow OGC, the Office of General Counsel, to decide on what the comment is and do we need to follow up on that, and if that happens, then it's going to throw us behind, and hopefully we'll do it by next year.

Then a little bit about what's the next 35 rulemaking going to be. We have a user need memo. This is, again, a little bit of our internal process when a division or an office comes to ask for rulemaking. It's done through that memo, and there have been a lot of amendments which are needed, and they pretty much have come from, as you all know, in 2002, Part 35 was revised in total, and also then the T&D rule was revised and went in effect in 2005.

So in the implementation process, the staff and stakeholders, they have brought to our attention that amendments are needed at several sections of Part 35. So we propose to handle those, and then there is going to be also consideration of Rittenouer petition, which was resolved last year, but it needs more information, and the plans are going to include that.

Also, there is the plan to include the preceptor attestation requirements, and that the Commission has approved, and I gave the SECY number in there for if there is any further interest to know exactly what's in the SRM we can provide it for you.

So these are the plans. They are all to be included in the next rulemaking. When do we plan to do it? Hopefully the technical basis development is somewhat going on right now. We hope to start it more fully in summer, and then also we pretty much must finish one rulemaking for a particular part. Then we start the next one. So, therefore, as soon as the Part 35 medical event rulemaking is out the door, we start work on this one, which would mean pretty much for all of this year, and then we will complete the proposed rule by fall of next year, and then the final year, the year after.

So those are the kinds of plans to do our rulemakings.

CHAIRMAN MALMUD: Are there any questions?

If not, we thank you for the least controversial presentation.

(Applause.)

CHAIRMAN MALMUD: The clarity speaks for itself. Thank you.

The next item on the agenda, I think this will be the closing minutes of this meeting. We will regroup tomorrow at 8:00 a.m. and pick up on the program and also catch up on the Commission briefing, which is a closed session, but we will begin at eight o'clock with the open session.

Any questions?

MR. LIETO: Go ahead. You may answer my question.

MS. COCKERHAM: No, go ahead.

MR. LIETO: Well, I'm just curious what is going to be the timing of the closed session because I would think members of the public would want to know sine they're going to be invited out.

MS. COCKERHAM: I'm expecting that it would be at the end of the day because the morning session cannot be changed due to a funeral that many

staff members will be attending tomorrow. So we need to keep on schedule in the morning, and I don't see us closing the session in the middle of the afternoon and then opening back up.

CHAIRMAN MALMUD: No, I announced that we would have the open session beginning at eight.

MS. COCKERHAM: Yes.

CHAIRMAN MALMUD: Yes.

MS. COCKERHAM: So we'll do the closed session at the end of the day.

CHAIRMAN MALMUD: Any other questions about that?

So we thank you for a very productive day, and we'll see you tomorrow morning at 8:00 a.m.

Another announcement, Ashley?

MS. COCKERHAM: This is Ashley. I have two things.

First of all, here are your time sheets. If you can guesstimate your time, it's eight hours today and eight hours tomorrow. There's no question about that. Saturday if you can guesstimate how long it will take for you to get home on Saturday, fill this out, sign it, and give it back to me and I'll make sure that it gets to Shayla. So I'm going to pass these around.

The second one is for the luncheon tomorrow.

(Whereupon, at 4:52 p.m., the meeting was adjourned, to reconvene at 8:00 a.m., Friday, May 8, 2009.)